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THE DESIGN AND CADAVERIC ASSESSMENT OF A NEW ARTIFICIAL FIRST METATARSOPHALANGEAL JOINT REPLACEMENT FOR THE GREAT TOE

By

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in partial fulfilment of the requirements for the degree of
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DECLARATION

I, Craig Nevin, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being or is to be submitted for another degree in this or any other University.

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ABSTRACT

The great toe is the part of the foot that most often requires surgical intervention. The first metatarsophalangeal joint (FMTPJ) is the most prominent joint of the great toe. Primary causes of FMTPJ failure are rheumatoid arthritis, osteoarthrosis and joint degeneration secondary to deformities such as hallux valgus, hallux rigidus or the trauma of previous surgery. FMTPJ prostheses are used to restore a measure of motion, correct deformities and relieve pain. FMTPJ replacement is most often indicated for elderly and less active patients but is contra-indicated for young, rheumatoid and active patients.

The most common types of FMTPJ prostheses are made from silicone elastomer. Although these have been in use since the 1960's, there are many problems associated with these and all other types of FMTPJ prostheses. For example, recent research has shown that silicone elastomer metatarsophalangeal arthroplasties may cause severe, chronic silicone granulomatous disease. Also, previous studies of the pressure distribution under normal feet, and pathological feet before and after surgery, can be used to show that FMTPJ prostheses fail to restore normal weight-bearing. In this regard, FMTPJ arthroplasties perform little better than amputation.

The reasons for the poor biomechanical performance of FMTPJ arthroplasty are not well documented. Existing theoretical models of FMTPJ function cannot be used to explain why almost all surgery of the first ray causes weight bearing to transfer to the lateral side of the foot. A new hypothesis of FMTPJ function was therefore formulated. It is known that the motions of the FMTPJ are linked to motions of the other bones of the foot and ankle because the strong fibrous tissues of the plantar aponeurosis connect the hallux to the calcaneus. However, it is hypothesised that the particular orientation of the bones at the final stages of the stance phase is crucial to the weight-bearing functions of the FMTPJ. A specification for a new prosthesis was therefore developed in accordance with the biomechanical principles contained in the hypothesis.

Various potential designs of prosthesis were investigated, but a ball-and-socket configuration was selected because it appeared to allow the motions necessary to restore normal loading in the foot. Three slightly different prototype ball-and-socket FMTPJ prostheses were designed and manufactured. These prototypes were inserted into cadavers; which allowed the range of motion of the prototype prostheses to be assessed in relation to the constraints imposed by the strong fibrous attachments in the foot. Some of the rudimentary surgical techniques and the instruments required to insert and align the prostheses were developed. The various design features that had been incorporated in the different prototypes were assessed in terms of their relevance to ultimate performance of the arthroplasty.

In order to verify the biomechanical design principles, cadaveric FMTP joints were tested for range of motion before and after inserting the prostheses. The results were compared to the range of motions obtained from a dry bone specimen, and to the most successful FMTPJ design to date—a double-stem silicone elastomer prosthesis. Finally, the results from all the tests were compared and discussed in relation to the original hypothesis about the function of the great toe.

The results obtained from the new prosthesis were sufficiently encouraging to be able to recommended that the prototype be manufactured for further clinical trials. The new prosthesis was found to simulate the conditions that are necessary to re-establish normal weight-bearing patterns in the foot; such as an elevated centre of rotation for the proximal end of the first metatarsal bone, tension in the plantar aponeurosis, mobile bones in the arch, and weight-bearing by the first metatarsal. Previous prostheses used in FMTPJ arthroplasty are believed to be inadequate in that they do not restore at least one of these conditions, which ultimately lead to implant failure. Within the limits of cadaver trials, the new design has demonstrated that it has the potential to succeed.

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LIST OF ABBREVIATIONS

ABH	Abductor Hallucis muscle
ADH	Adductor Hallucis muscle
EDL	Extensor Digitorum Longus muscle
EHB	Extensor Hallucis Brevis muscle
EHL	Extensor Hallucis Longus muscle
EMG	Electromyocardiogram
FDA	Flexor Digitorum Assessorius muscle
FDL	Flexor Digitorum Longus muscle
FHB	Flexor Hallucis Brevis muscle
FHL	Flexor Hallucis Longus muscle
FMT	First metatarsal bone
FMTP	First metatarsophalangeal
FMTPJ	First metatarsophalangeal joint
HDPE	High density polyethylene
MT	Metatarsal bone
MT-base	Metatarsal base; the proximal end of first metatarsal bone
MT-head	Metatarsal head; the distal end of first metatarsal bone
PL	Peroneus Longus muscle
RMS	Root mean square average
TA	Tibialis Anterior muscle
TP	Tibialis Posterior muscle
UHMWPE	Ultra high molecular-weight polyethylene

GLOSSARY

antagonist:	muscle that nominally moves a joint in the opposite direction.
anterior:	in the front of the body.
arthrodesis:	bony fusion replacing a joint.
arthroplasty:	surgically reconstructed joint.
bending moment:	balanced bending force that tends to compress one side of an object while tensioning the opposite side.
bunion:	excess bony growth on medial side of the metatarsal head.
cadaver:	preserved human body.
callosities:	abnormally thick accumulation of soft tissue.
chamfered:	sharp corners that have been smoothed off.
coefficient of friction:	measure of slipperiness.
cortex:	the thick outer wall of a bone.
crista:	the raised central reinforcing rim of a helmet.
cyclic fatigue:	process where microscopic cracks are enlarged due to tearing at the end as they are repeatedly forced open and closed.
dacron:	a strong surgical fibre used for sutures.
distal:	the portion furthermost from the trunk of the body.
dorsal, dorsi-, dorso-:	the top of the foot.
dorsiflexion:	movement that bends a joint towards the knuckles.
electromyography:	electrical measurement of muscle activity.
eversion:	movement at ankle that turns the plantar aspect of the foot away from the opposite foot.
extension:	movement that straightens a joint.
flexion:	movement that brings the parts of a joint closer together.
force plate:	device that measures forces when it is walked or stood upon.
follow up study:	study where a patient's progress is monitored long after convalescence is complete.

grommet:	washer around a shaft at a flexible joint.
hallux limitus:	limited mobility in the great toe.
hallux rigidus:	immobile great toe—usually due to chronic articular fusion.
hallux valgus:	deformity where the great toe points towards the lesser toes.
hemi-arthroplasty:	procedure which replaces only one side of the joint.
hyper-:	more than is usual.
***in vitro*:**	in the laboratory (literally, in glass).
***in vivo*:**	inside a living body.
lateral:	part furthest to the side away from the body's mid-line.
lateral rotation:	movement that rotates the anterior aspect of a body part towards the lateral side.
locus:	route of movement.
Mayo Procedure:	resection of the first metatarsal head.
medial:	towards the middle trunk—in the foot towards the second toe.
medial rotation:	movement that rotates the anterior aspect of a body part towards the middle axis of the trunk.
medullary canal:	the area within the cortex of the shaft of a long bone.
osteophytes:	abnormal spiky bone formations.
pedobarograph:	from the roots *pedo-* foot, *baro-* pressure, *graph-* display.
periosteum:	the outer membrane of a bone.
piezoelectric:	material that converts pressure directly into electrical charge.
plantar:	underside of the foot.
posterior:	towards the rear of the body.
principle stresses:	the highest and lowest stresses at a particular location.
pronate:	movement where the foot twists away from the fifth toe.
prosthesis:	an artificial device replacing a part of the body.
proximal:	portion closest to the center of the body.

ray:	the group of structures which comprise an individual toe.
resection:	surgical cutting away.
revision:	repeat of a surgical procedure – due to unsatisfactory outcome
sagittal plane:	a plane that corresponds to a side-on profile view of the body
second moment:	a measure of bending stiffness (inertia).
self-reducing:	clicking back into place without assistance.
semi-constrained:	when physical contact between components partially prevents movement in one or other direction.
shearing stress:	a side-ways force acting across any plane not perpendicular to the directions of the principle stresses.
static force analysis:	mathematical technique that assumes that the forces that accelerate components are small enough to be disregarded.
strain gauge:	electrical device for measuring elastic distortions.
stress:	force per unit area.
sublux:	dislocate so that the component articulate in the wrong groove
supinate:	movement where the foot twists towards the fifth toe.
synovia:	fluid found inside normal joint capsules.
toe-off:	point in the gait cycle where the great toe leaves the ground.
torque:	a turning or twisting force.
trabeculae:	highly organised fine fibres of bone within the cortex.
transverse plane:	a horizontal plane that provides a cross-sectional view of the trunk of the body when it is standing upright.
tuberosity:	a normal bony protrusion.
wedge osteotomy:	surgical procedure where a wedge is cut from a bone; used to alter the alignment of the remaining bone fragments
windlass:	a mechanical winch.

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CHAPTER 1
INTRODUCTION

The great toe is the part of the foot that most often requires surgical intervention (Cracchiolo 1981). The first metatarsophalangeal joint (FMTPJ) is the most prominent joint in the forefoot. The primary causes of FMTPJ failure are rheumatoid arthritis, osteoarthrosis, and joint degeneration secondary to deformities such as hallux valgus, hallux rigidus or the trauma of previous surgery. The expectations of a joint replacement are that it will restore motion to the joint, correct any deformity, and relieve the pain. Nevertheless, prosthesis usage in the great toe is fraught with difficulties; such as the reoccurrence of the deformity, restrictions of motion, joint-shortening, implant wear, breakage, loosening, dislocation, and unfavourable bone tissue reaction.

FMTPJ prostheses were initially used to replace either one or both of the joint surfaces, without success. Encouraged by the successful replacement of finger joints with double-stem silicone elastomer hinges, surgeons applied this technique directly to the great toe. Despite attempts at improving the design, a modification of the original finger implant remains the most widely reported prosthesis in use today. Although certain subjective post-operative studies reveal that up to 90% of patients are apparently satisfied with silicone toe implants (Shankar et al 1991) the expectations of FMTPJ prosthetic arthroplasty are not borne out by objective experimental measurements. A review of the literature reveals that the patterns of weight distribution under feet with silicone implants (Beverley et al 1985) are found to be almost identical to weight bearing patterns of feet (Mann 1988) in which the great toe has been amputated. This exposes the fact that although current surgical techniques may afford pain and cosmetic relief, they cannot claim to produce functional improvements.

Not surprisingly, a study by Granberry et al (1991) found that there is no statistical correlation between patient acceptance and the rate of implant failure. Johnson (1989) even suggests that at his tertiary referral centre more implants are removed because of pain than are inserted. Even supporters of silicone arthroplasty (Kampner 1992) admit that the technique is contra-indicated in deformed rheumatoid, young and/or active patients.

The problem is not confined to FMTPJ prostheses; any surgery affecting the FMTPJ appears to completely disrupt the normal weight-bearing under the foot. No plausible explanation for this phenomenon could be found in the literature. Therefore it was felt that a new hypothesis of FMTPJ function had to be developed in order to explain the successes and failures of existing implants. It is believed that without such an explanation the progress of FMTPJ arthroplasty would remain problematic.

In this regard, the motions of the FMTPJ could be envisaged in two ways: either as the hallux flexing and extending at the end of the foot, or as the hallux fixed on the floor while the foot moved around it. It was proposed that the latter motion is crucial to the orientation of the lower limb during gait and for balance. To test this hypothesis, an experiment was performed on dry bones to measure the motions of the metatarsal bone as it moved around the stationary phalanx. The findings of this preliminary experiment were, in part, used to specify a new prosthesis. All available engineering solutions were considered and the one that satisfied most of the design criteria was selected. Three slightly different prototype prostheses were then designed and manufactured.

The prototypes were inserted into cadavers so that the surgical technique could be refined; this also revealed a need for specialised surgical instruments to insert the prostheses. The range of motion of the joint was measured inside and outside the cadavers and contrasted with the results obtained from the preliminary experiment on dry bones. In light of these results, a new model of the mechanics of the reconstructed joint was formulated in which the successes and failures of the existing range of prostheses could be explained and the potential performance of the new prosthesis assessed.

The starting point of this research was the realisation that the biomechanical performance of existing FMTPJ prostheses is little better than that which can be achieved by amputation. The mandate for this research was therefore to design a prosthesis that addressed these deficiencies. The process was deemed to be complete when further developments involving living patients could be considered practical enough to be ethically justified. In the process it was necessary to derive and verify the criteria whereby the prosthesis could be judged, build a prototype, and assess some rudimentary surgical techniques on cadavers. It was felt that the determination of wear and fatigue strength, which are normally associated with design testing, did not fall within the ambit of this research, being more appropriate in the product development stage.

It should be borne in mind that the design and testing of a prosthesis is an iterative process. For example, although the design process begins with a critical examination of the limitations of existing prosthesis, the process does not necessarily end with the first prototype, or even for that matter with the initial production model. In this situation, a single problem description/ methodology/ results/ discussion/ conclusion framework has obvious limitations since the problem itself needs to be critically re-assessed after each design decision is made. Allowance therefore needs to be made for some preliminary experimentation, theoretical analysis and discussion of the nature of the joint articulation, which due to the extensive scope of the research could not always be rigorously explored. This should not be seen as a methodology flaw, but as an essential part of an all inclusive iterative design process; the prime objective of which was the design of a successful FMTPJ prosthesis.

CHAPTER 2
LITERATURE REVIEW AND RELEVANT BACKGROUND

2.1 ANATOMY

2.1.1 FUNCTIONAL ANATOMY

The First Metatarsophalangeal Joint (FMTPJ) is formed by the synovial articulation between the head of the first metatarsal bone and the proximal phalanx. The joint also includes two sesamoid bones which are firmly attached to the base of the phalanx via a thick cartilaginous plantar plate. Importantly, the tissues that constitute the FMTPJ also constitute the anterior buttress of the arch of the foot [Figure 1].

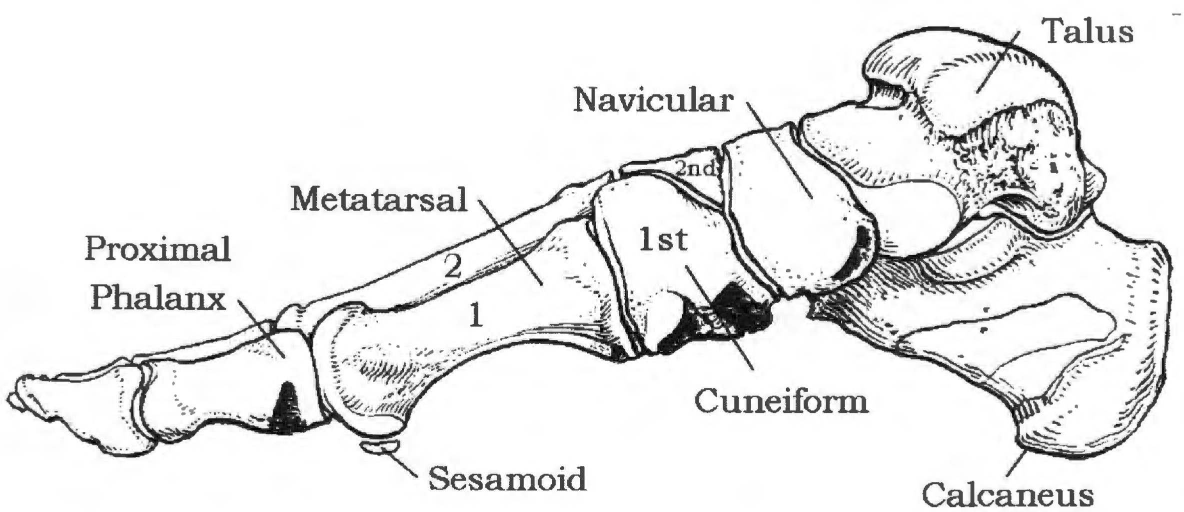


Fig. 1. Bony arch of the foot—medial aspect (adapted from Williams et al 1980).

The joint is variously described in the literature as a ball and socket, an ellipsoid, and even as condylar joint. The range of motion is about 45° flexion to 90° extension. However, due to the attachments of various fibrous structures, the achievable range of motion during standing is considerably less. The plantar aponeurosis—a strong band of fibres that connects the skin of the toes to the calcaneus—makes the FMTPJ an indispensible part of the foot.

2.1.2 BONES

The first metatarsal bone (MT) is the shortest of the five metatarsals; its proximal end articulates with the first cuneiform bone. The other major bone of the joint is the proximal phalanx; a short bone with a very thick basal cortex. The metatarsal's shaft is long and straight; but the phalanx's shaft tapers markedly from the bone's base towards its distal end. The Sesamoids are small bones which are embedded in each of the two tendons of flexor hallucis brevis at a fixed distance from the proximal phalanx. They articulate in grooves beneath the metatarsal head (MT-head). The sesamoids and the cartilaginous fibres inserting onto them form two-thirds of the total surface articulating with the MT-head.

Wyss et al (1989) conducted a study of 129 feet with FMTPJ pathologies with the object of gathering quantitative data for a new FMTPJ implant; 112 of the feet belonged to females. The dimensions of the bones in the foot were taken from lateral and dorsi-plantar radiographs. The data was found to be useful for the dimensional specifications of the protoype prostheses [Appendix A].

Ruch and Banks (1986a) recognised the existence of three different profiles of the MT-head–round, oblong and with a central ridge [Figure 2]. However, these shapes appear to occur naturally on the anterior, dorsal and plantar portions of the articulating surfaces of the MT-head respectively.

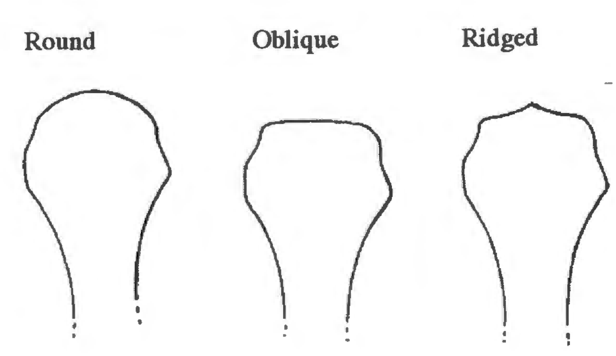


Fig. 2. Common shapes of first metatarsal head (Ruch and Banks 1986a).

Stokes et al (1979a) measured the lateral profile of 5 amputed metatarsal specimens [Appendix A]. They found that the lateral two-dimensional profile of the MT-head could be described by two arcs of different radii, one for the dorsal portion and one for the plantar portion [Figure 3]. The dosal arc (r_1) was on average about two millimetres smaller than the plantar arc (r_2). Also the line at which the arcs intersected was found to lie at an average angle (ρ) of 46° dorsal to the long axis of the metatarsal.

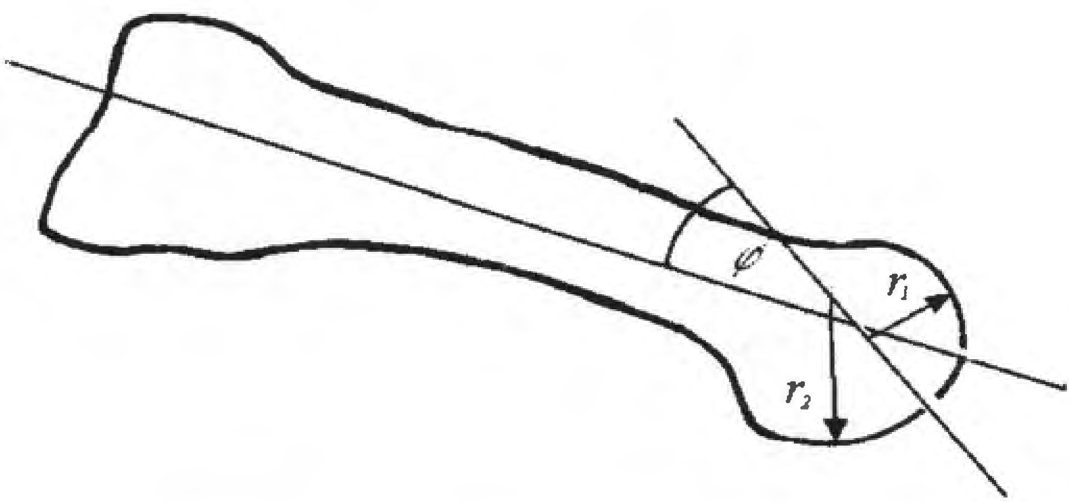


Fig. 3. Lateral profile of first metatarsal head (Stokes et al 1979a).

The orientation of the trabeculae throughout the bones in the arch of the foot can be seen in Figure 4. The points to note are the high density of trabeculae in the MT-head that intersect at about 45°, while there is a sparsity of trabeculae within the shaft.

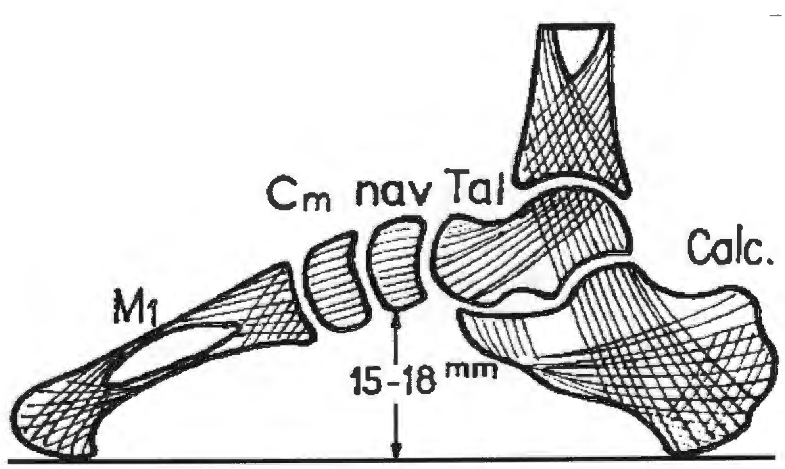


Fig. 4. Trabeculae bone orientation in the arch of foot (adapted from Kapandji 1987).

2.1.3 LIGAMENTS AND FIBROUS FASCIA

The collateral ligaments of all the metatarsophalangeal joints are described by Williams et al (1980) as rounded chords arising from the dorsal tubercles on the metatarsal head, inserting into the sides of the proximal phalanx. However, unlike these authors, Leventen (1991) identifies the ligaments of the FMTPJ as two anterior sesamoid ligaments—which attach the sesamoids to the plantar MT-head—and a short thick intersesamoidal ligament [Figure 5]. These are all strong ligaments which are hidden beneath the MT-head, preventing hyperextension and joint dislocation. A deep transverse ligament span the gap between the capsules of the first and second metatarsal heads, preventing the toes from splaying apart. The absence of a corresponding ligament on the medial side of the foot means the phalanx can and sometimes does rotate towards and under the other toes of the same foot—a chronic condition called hallux valgus.

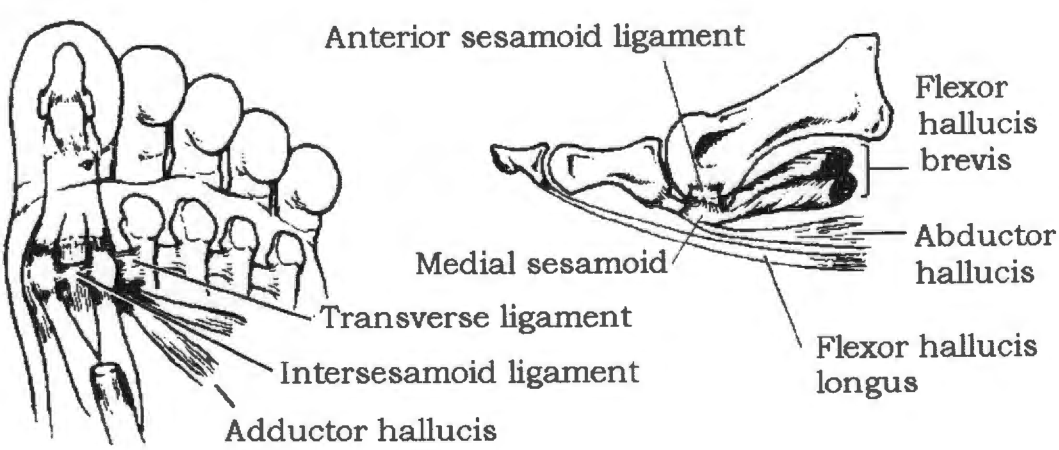


Fig. 5. The sesamoid ligaments and other plantar attachments (adapted from Leventen 1991).

The plantar aponeurosis is a wide band of fascia stretching between the calcaneal tuberosity and the plantar aspects of all the proximal phalanges, consisting of distinct slips to each toe. These are connected by various transverse bands of fascia and the transverse ligaments beneath the MT-heads. In the forefoot, an intricate 3-dimensional lattice of fibres connects the skin to the aponeurosis and the periosteum (Bojsen-Møller 1979). This fibrous network stiffens the skin when the toes are dorsiflexed. Hicks (1954) observed that the fleshy cushions beneath the MT-heads seem to function as powerful cables that link the aponeurosis to the phalanges in addition to their more obvious role of soft fatty pads that distribute the pressure beneath the MT-heads.

However, the synovial capsule of the FMTPJ contains little inherent strength (Hicks 1955). The capsule arises from the periosteum of the MT-shaft, is continuous with the sesamoid bones and inserts into the basal rim of the proximal phalanx. MacConaill (1967) explained that the articulating surfaces of all bones are in fact histologically continuous with the capsule, forming an enclosed space containing a synovial fluid.

The toe is supplied by the digital plantar nerves and the digital plantar arteries. Both of these run in bundles inferiomedial and inferiolateral to the phalanges. For this reason the FMTPJ is best exposed through a dorsomedial incision one centimetre medial to the tendon of Extensor Hallucis Longus (EHL). A more direct dorsal incision encounters the extensor attachments, and does not facilitate bone resection (Vanore et al, 1986).

2.1.4 MUSCLES

There are no direct muscle attachments between the two main articulating bones of the joint. In fact, there are no muscle attachments at all to the distal half of the metatarsal. However, a substantial group of muscles does insert into the plantar base of the proximal phalanx and the sesamoids; these include the two heads of Flexor Hallucis Brevis (FHB), Abductor Hallucis (ABH) and the transverse and oblique heads of Adductor Hallucis (ADH). The convergence of so many tendons onto the sesamoid complex means that the insertions are practically indistinguishable from each other.

Three tendons cross the FMTPJ; Extensor Hallucis Longus (EHL) and Extensor Hallucis Brevis (EHB) both lie superior to the joint; Flexor Hallucis Longus (FHL) courses beneath the joint passing between the sesamoids. The muscles are normally positioned so that they can move the phalanx in any direction within the limits imposed by the ligaments [Figure 6].

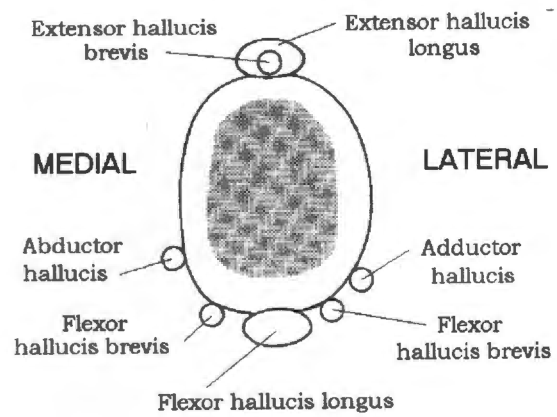


Fig. 6. Normal tendon positions at the FMTPJ (Sammarco 1980).

Most literature sources list the muscles as arch supporting structures. However, Basmajian (1984) showed in EMG studies, that the intrinsic muscles of the foot are only involved in postural adjustments of the arch and during peak periods of foot activity—they do not provide support for the arch under normal static loading conditions. However, there are a number of muscles which have origins in the lower leg which are believed to be involved in the dynamic functions of the FMTPJ because they bow-string around the ankle before inserting into metatarsal or crossing the FMTPJ [see Appendix B]. Three insert into the proximal end of the metatarsal; of these two have multiple insertions onto other tarsal bones, Tibialis Anterior (TA) attaches superiorly, Tibialis Posterior (TP) inferiorly. Peroneus Longus (PL) inserts exclusively into the inferior to the proximal end of the MT and runs diagonally medial to lateral under the foot. A minor muscle, the First Dorsal Interosseous, span the intermetatarsal space

The biomechanical significance of some of these anatomical structures in the foot is described in Section 2.3. Since much of the relevant experimental data in the literature involves comparing normal and pathological gait; it is therefore necessary to describe some pathologies of the hallux and the surgical procedures used to correct deformities before describing the normal biomechanics of the FMTPJ

2.2 ARTHROPLASTIES OF THE FMTPJ

2.2.1 SURGICAL BACKGROUND

The primary causes of FMTPJ failure are rheumatoid arthritis, osteoarthrosis, hallux rigidus, degeneration secondary to trauma (including previous surgery) and deformities such as hallux valgus. The deformities of the first ray which most often require treatment, according to Ruch and Merrill (1986), are hallux valgus and hallux rigidus or limitus. The goals of implant surgery are currently limited to pain relief, restoration of joint motion, reduction of the angular deformities and the maintenance of the correction over time. There are four main options available to the surgeon:-

Arthrodesis [Figure 7a] or fusion of the joint eliminates pain, corrects the deformity and stabilises the hallux, but sacrifices motion. Arthrodesis is the procedure which causes the least complications in young or active patients although the limitation of motion is often a cause of dissatisfaction.

Resection arthroplasty [Figure 7b] involves excision of one or both of the bone surfaces, creating a space between the bones. The Keller Procedure—first described in 1908—excises the proximal phalanx, while a Mayo Procedure resects the metatarsal head. The usual postoperative course is that the joint becomes unstable, the hallux retracts, motion is restricted and the pain returns.

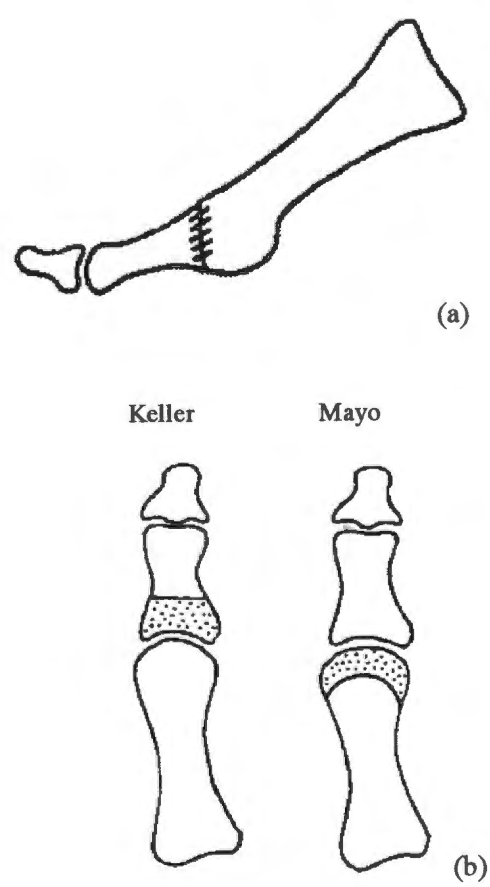


Fig. 7. FMTPJ arthroplasties
(a) arthrodesis
(b) resection.

Interpositional arthroplasty [Figure 8a] involves the interposition of a soft tissue flap or other artificial material on either side of the joint, usually in the form of a cup or a cap. Interposition is often used to fill the space created during a resection arthroplasty.

Replacement arthroplasty [Figure 8b] involves articular reconstruction of either one or both joint surfaces. The components are usually made from rigid material, cemented or pressed into the intramedullary canals. The shapes of the articulating surfaces can either be exact replicas of the bone i.e. "anatomical", or they may be of a known mathematical shape.

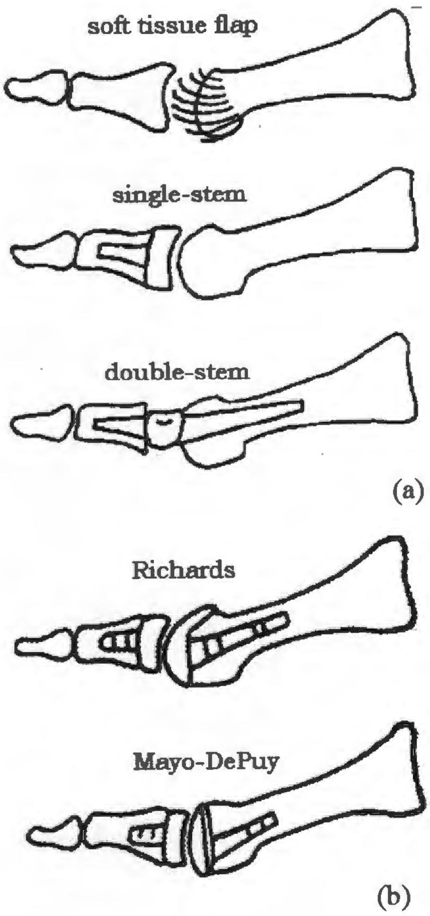
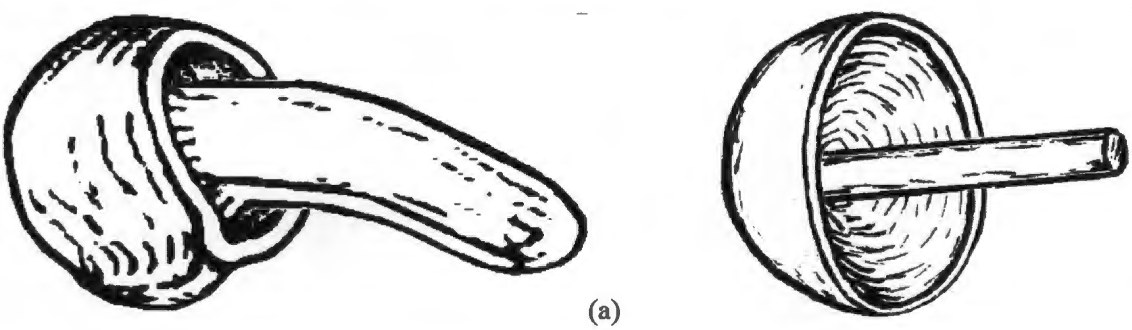


Fig. 8. Prosthetic FMTPJ arthroplasties (a) interposition (b) replacement.

2.2.2 PROSTHETIC DEVICES

(a) METATARSAL HEAD REPLACEMENTS

Vanore et al (1986) provide a good overview of the history of FMTPJ arthroplasty. The earliest prostheses were made from ivory, glass, gold, acrylic and stainless steel, resulting in breakages and bone resorption around the implants. In 1952 Swanson attempted to replace the metatarsal-head with a non-cemented metal prosthesis [Figure 9a] which had an anatomic intramedullary stem. It failed due to bone resorption, loosening of the implant and gross instability. Ten years later Seeburger revived the procedure using a metal cap with a thin locating peg [Figure 9b], but experienced similar failures, even though the prostheses are markedly different in design.

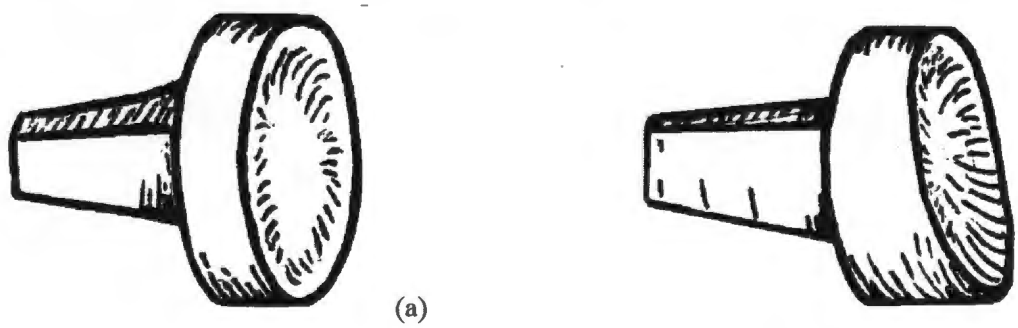


(a) (b)

Fig. 9. Metatarsal head replacements (a) Swanson anatomical design (b) Seeburger cap.

(b) SILICONE ELASTOMER PHALANGEAL REPLACEMENTS

In 1965 Swanson produced an almost identical silicone version of his earlier metal anatomic metatarsal-head design [Figure 9a] but quickly abandoned it, preferring to concentrate on the phalangeal side of the joint. In a major development he introduced the single-stem silicone elastomer 'Great Toe Prosthesis' which soon became popular [Figure 10a]—the single stem inserted into the base of the phalanx. Later, Weil introduced various modifications [Figure 10b] such as angling the cuff to accommodate the natural valgus angle of the phalanx and reinforcing the silicone with a dacron mesh.



(a) (b)

Fig. 10. Prostheses replacing the proximal phalanx joint surface (a) Swanson phalangeal 'Great Toe' prosthesis. (b) Weil modification with an angled cuff.

Swanson (1972) followed-up on 73 silicone phalangeal 'Great Toe' prostheses inserted over the previous 4 year period—the procedure was described as an augmented Keller resection of the phalangeal base with the capsular flap being sutured back onto the metatarsal head. The result reportedly provided complete pain relief, with no implant fracture, dislocation nor rejection. There was no bone resorption on the phalangeal side—as opposed to his earlier designs. The average range of motion was 60° extension to 5° flexion, which is the most extension reportedly achieved by any FMTPJ prosthesis.

Swanson et al (1979) again reviewed 165 feet operated on between 1968 and 1978. The indications for surgery were rheumatoid arthritis (57%) hallux rigidus (30%) and other pathological conditions (13%). The range of extension achieved was considered 'good' at 50°. No breakages were reported. The 'Great Toe' phalangeal prosthesis was recommended for hallux rigidus; but a new double-stemmed silicone hinge was already being preferred for rheumatoid arthritis. However, despite the favourable report, it is felt that these results are selectively described, giving a false impression of the rate of success. For example, 24 feet (15%) were revisions of the same procedure. One can only ask if the original 'failures' were included in the sample? Also, from the statistics provided, the hallux valgus angle consistently reflects only a 50% improvement postoperatively and valgus deformities began to occur where none had existed before.

A poor long-term result for these single stem prostheses were soon predicted by various authors:

- Gudmundsson and Róbertsson (1980) in which 29 cases were reviewed 4 to 6 years postoperatively. Although largely pain free, they found a high incidence of reactive bone changes, and implant breakages in 5 cases (17%).
- Sethu et al (1980) followed-up 77 silicone phalangeal prostheses for a period of between 12 and 92 months. They reported that in the long run, it had not proved

satisfactory for hallux valgus, as the deformity had partially reoccurred in all cases, with a 28% reoccurrence of bunions and callosities.

- Brewood and Griffiths (1985) reported 8 breakages (73%) out of the 11 prostheses in their follow up of prostheses which had been inserted for longer than 4 years.

Verhaar et al (1989) reported disturbing inflammatory responses in 59 prostheses after a mean period of 59 months:-

- Cysts were noticed in 34 of the proximal phalanges (58%), and in 40 of the metatarsal heads (71%). Histological examination revealed a foreign-body giant-cell reaction to silicone wear particles, which was destructive to the bone architecture.
- Osteolysis was noted around the stem in 34 feet (58%), with 18 cases (31%) showing considerable bone resorption. There was a considerable decrease in the length of the toe, averaging 3,4mm. Half of this shortening was in the implant itself, with the remainder due to resorption of the phalanx.
- Bone spurs were present around 24 implants (41%). The implants themselves showed progressive wear with time, resulting in severe damage.

Recently, Rahman and Fagg (1993) drew attention to the incidence of silicone granulomatous disease subsequent to silicone phalangeal-arthroplasty. Their findings were based on radiographic evidence in 56 out of 78 feet, and histological specimens. They recommended that the procedure be abandoned because of both the extent and progressive severity of the disease.

Summing up in retrospect, Vanore et al (1986) observed that the initial reported successes of the silicone phalangeal prosthesis resulted in its over-utilisation. Serious problems manifested themselves after a few years of use. Nevertheless, rather than to discard silicone prostheses altogether, the trend was to convert to the newer double-stem variety.

(c) DOUBLE-STEM SILICONE ELASTOMER HINGES

In 1977 Swanson modified his double-stem finger implant for use in the toe [Figure 11a]. This implant continues to be widely used almost 20 years after its introduction (Ruch and Cain 1986). Only recently was the design modified by the addition of titanium grommets to reduce abrasion damage at the base of the stems (Corigan and Kanat 1989).

In 1982, Sutter Biomedical Company introduced two alternative varieties of double-stem elastomer prostheses, both with solid "V-shaped" collars:-

The LaPorta version had either a built-in 15° dorsi-flexion or a straight stem, either with or without a 10° valgus angle [Figure 11b].

The Lawrence version of the design incorporated a stem with built-in 15° dorsiflexion angle, with the size of the plantar collars reduced to allow for the preservation of the aponeurotic insertion [Figure 11c].

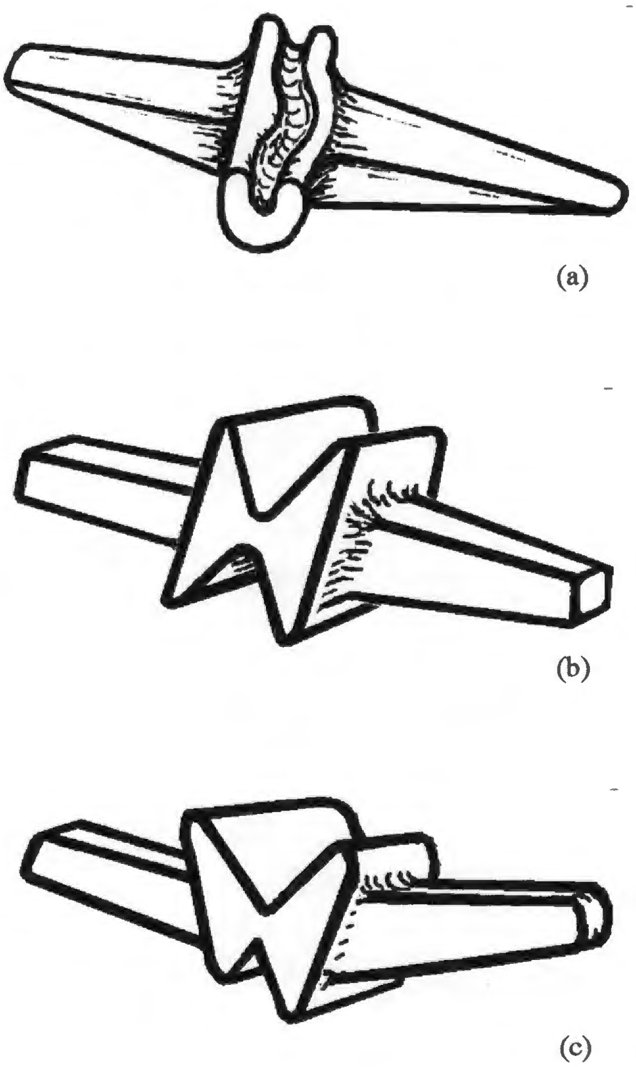


Fig. 11. Double-stem silicone-hinge prostheses. (a) Swanson (b) LaPorta (c) Lawrence.

Cracchiolo and Swanson (1981) reviewed 159 feet which had had double-stem silicone hinges inserted 6 to 18 months previously. Complications were reportedly minimal, with pain relief being achieved in all cases. Dacron-reinforced prostheses were also used, but were considered unsatisfactory due to breakages. Although the authors do not appear to distinguish between the different Swanson and Sutter designs, the use of a few dacron reinforced prostheses suggests the latter.

Grace (1984) reviewed 150 double-stem implants; he abandoned phalangeal prostheses due to complications and found dacron-coated stems unsatisfactory. In regard to double-stem prostheses, 94% of patients felt their condition had improved. Average flexion was 18° and extension 20°. The average valgus angle improved from 36° to 14°, but the postoperative correction decreased with time by an unspecified amount.

McAuliffe and Helal (1986) reported on the results of the Sgarlato double-stem ball-shaped silicone spacer inserted into 142 great toes [Figure 12]. 94% of patients were satisfied with pain relief and appearance, 91% were pleased with the movement obtained, but shoe wear was only more comfortable in 44% of cases, while only 18% could wear narrower shoes. Sesamoid alignment was only improved in 40% of patients, with no improvement in the intermetatarsal angle—it should be noted that the intermetatarsal angle is considered the most reliable indicator of a valgus deformity (Ruch and Banks (1986a), Wyss et al (1989), Scott et al (1991)). The occurrence of complications was 23%. Although pain relief was achieved, the overall

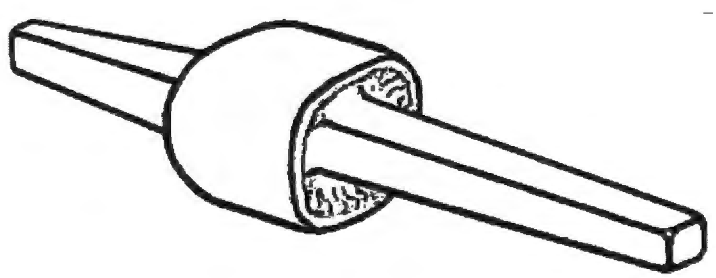


Fig. 12. Sgarlato double-stem ball-shaped silicone spacer.

results were not considered as good as for the Swanson implant, but no reasons were given for this conclusion—on the face of it they appear much the same.

Laird (1990) reviewed 228 double-stem silicone hinges inserted over a period of 8 years (average 4 years); 82% for hallux valgus and 18% for hallux rigidus. Post-operatively 83% had minimal pain, 14% had pain when standing for long periods, and 8% had continual discomfort or severe pain with movement. 88% had an excellent cosmetic result.

Shankar et al (1991) review 106 silicone hinges after a period of 1 to 5 years. The researchers devised separate criteria for subjective and objective evaluations, claiming that nearly 90% of patients had excellent or satisfactory results. However, under their scoring system hallux amputations—viz. Mann et al (1988)—achieve excellent subjective ratings, and an implants which have totally disintegrated, which commonly occurs with phalangeal prostheses—viz. Verhaar (1991)—achieve excellent objective ratings!

In a more pragmatic study, Granberry et al (1991) followed up 90 Sutter silicone hinges after an average of 3 years (range 2 to 5 years):

- Although subjective results were satisfactory, the procedure was eventually discontinued due to a high incidence of implant breakages—it was found that the longer the implant had been inserted, the more likely it was to break. They projected that half of the implants were likely to seriously deform or break within 4 years.

- Callosities were present in 69% of the cases. Post-operative shortening of the ray was, on average, found to be 8,5mm in cases with callosities, but only 2,5mm in those without. The average shortening was 3mm after two years, but increased to 11mm after five—mostly due to bone resorption and implant subsidence.

- Osteophytes had formed around the implant in 53% of the toes; in 23% their radiographic outlines appeared to touch or overlap.

- Range of motion was 35° when the implants weres intact, but increased to 51° when they failed. Rather significantly, patients with radiographically intact implants exerted less weight beneath the phalanges than those with fractured implants.

Kampner (1992) criticised the above report on the grounds that with proper patient selection many of the problems could be avoided. In reply, Granberry et al (1992) conceded that the results could be improved if young, rheumatoid, active, and deformed patients were excluded from silicone arthroplasty. However, this is precisely the population that seeks the benefits most. Bearing these criticisms of silicone elastomer prostheses in mind it is worth examining the performance record of some more traditional rigid implant materials.

(d) METAL-ON-POLYMER PROSTHESES

The concept of precisely replacing both articulating surfaces with congruent surfaces manufactured from materials with low coefficients of friction has been used in many designs. Three such designs utilise a stainless steel metatarsal component articulating with a polyethylene phalangeal component, all cemented in place with acrylic bone cement. As far as is known, these designs were only used in a limited number of trials:

In 1975 Richards Manufacturing produced a metatarsal component with a long stem and a large dorsal articulating surface. It had a central crista-like ridge which slid in a groove in the HDPE component [Figure 13]. The design is referred to as semi-constrained presumably because of the small ridge. The performance of the Richards prosthesis can only be assessed through a case study reported in the literature as there are no follow up studies available. The prosthesis was inserted into a 33-year-old woman who had had some unknown previous FMTPJ surgery. The phalanx promptly dislocated medially, and could not be held in place by 'bandaging or any other jury-rigging' (Johnson 1989).

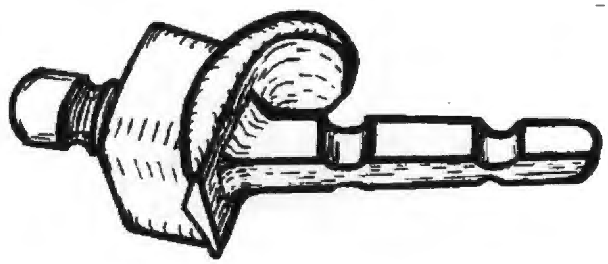


Fig. 13. Richard's prosthesis.

The Mayo-DePuy design featured a small, smooth, convex, short stem metatarsal component sliding freely on an polyethylene phalangeal component [Figure 14]. Following up on 25 patients for five years, Johnson (1989) found that, although it did afford pain relief in some cases, the Mayo-DePuy design performed no better than resection arthroplasty.

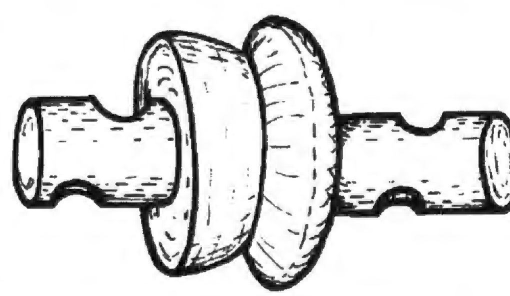


Fig. 14. Mayo-DePuy prosthesis.

Merkle and Sculco (1989) reported on a design which featured an anatomically-shaped stemless titanium metatarsal component—with an extended plantar range for the sesamoids—which articulated with a modular polyethylene phalangeal component [Figure 15]. A feature of this design was that the soft tissues were not released, joint laxity being adjusted by selecting one of a

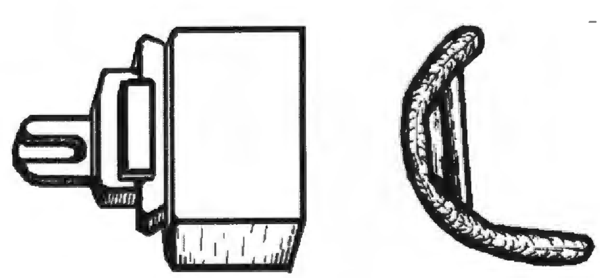


Fig. 15. Merkle and Sculco's prosthesis.

few alternative thicknesses of phalangeal component.

9 patients fitted with this anatomical semi-constrained titanium-polyethylene design were followed-up for an average period of 21 months. A disturbingly high rate of loosening (54%) was found, although all patients had relief from pain. Hallux valgus reoccurred in 3 of the 4 cases treated for the condition despite the semi-constrained feature. Range of motion was 'very good', averaging 45° active, and 58° passive dorsiflexion. Two patients, however, ended up with an extension contracture. One patient preferred the opposite foot, on which a Keller resection had been performed. They concluded that their device failed due to poor fixation, and recommended that an arthrodesis, silastic or resection arthroplasty technique be used instead.

In searching for explanations for the failures, Gerbert and Dobbs (1986) suggest the performance of the 'two-component' systems is compromised by the need to achieve stability and control abnormal forces. They claim that the soft tissues, which are necessary to achieve stability, need to be released if excessive pronatory forces are to be controlled. However, Johnson (1989) emphasised that almost any implant will remain in place if sufficient soft tissue is resected, but criticised this approach as being an expensive two stage Keller Procedure—one stage to resect the tissues and insert the prosthesis, the other stage to remove the prosthesis when it fails.

(e) OTHER PROSTHESES

In the pioneering days, finger joint prostheses were often used in the toe due to the absence of suitable toe prostheses:-

Wenger and Walley (1978) described the use of a variety of means to fill the dead space created by a resection arthroplasty. The average follow up period was two years:-

- In four cases the authors carved a custom made spacer from a solid block of silicone elastomer, and in five cases they used a silicone phalangeal prosthesis. Although satisfactory results were obtained in both cases, there was no stabilising effect.

- In 78 cases, Swanson double-stem silicone finger prostheses were inserted. The results were the same whether the prostheses were inserted as in the hand or with the notch "upside down". The overall short-term assessment was considerable pain relief in 98% of patients, with a good or excellent objective assessment in 79% of hallux valgus and 86% of hallux rigidus patients (Wenger and Walley 1978).

- Three Calnan-Nicolle finger prosthesis consisting of a stainless steel hinge encased in polypropylene [Figure 16] were used, but one fractured and had to be removed.

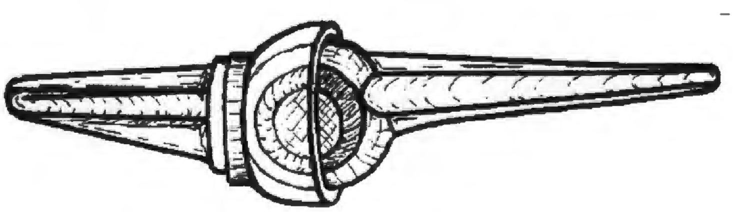


Fig. 16. Calnan-Nicolle finger prosthesis

August et al (1984) reviewed the use of a De La Caffinière ball and socket trapezio-metacarpal prosthesis inserted in the thumb [Figure 17]. The performance of this prosthesis is reviewed here because it is believed that its cemented stem fixation in the small bones of the hand may have some parallels in the small bones of the foot. The prosthesis comprises a long cobalt-chromium metacarpal component with a long-stem, flange and head, and a polyethylene cup.

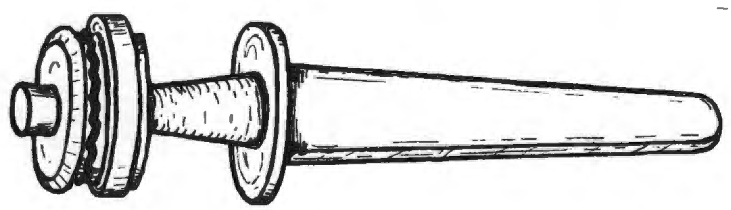


Fig. 17. De La Caffinière thumb prosthesis.

21 patients were examined an average of 15 months post-operatively. Due to cup loosening, 24% needed revision, another 24% had loose cups and a further 19% had radiolucent lines around the cup. Five of sixteen cups had rotated between 20° and 40° within their bony socket, but on the other side of the joint the cemented metatarsal stems showed little radiographic signs of loosening. One ball had been forcibly dislocated and the cup had filled with fibrous tissue. Despite the serious problems, all but one patient were pleased with the result.

2.3 BIOMECHANICS

2.3.1 FIRST METATARSOPHALANGEAL JOINT

Hicks (1954) compared the mechanics of living feet with cadaver specimens. He noted that when the FMTPJ is extended:

- The arch appears to rise.
- The foot supinates.
- The tibia rotates laterally.
- The plantar aponeurosis becomes taught.

By attaching radiographic markers to the aponeurosis, Hicks determined that the head of the metatarsal acts as the drum of a windlass [Figure 18]. When the phalanges are extended, the aponeurosis winds around the drum, shortening the distance between the calcaneus and the toes by about 1 cm. Because the structures are linked the arch rises; i.e. the metatarsal elevates relative to the cuneiform, and the cuneiform elevates relative to the navicular.

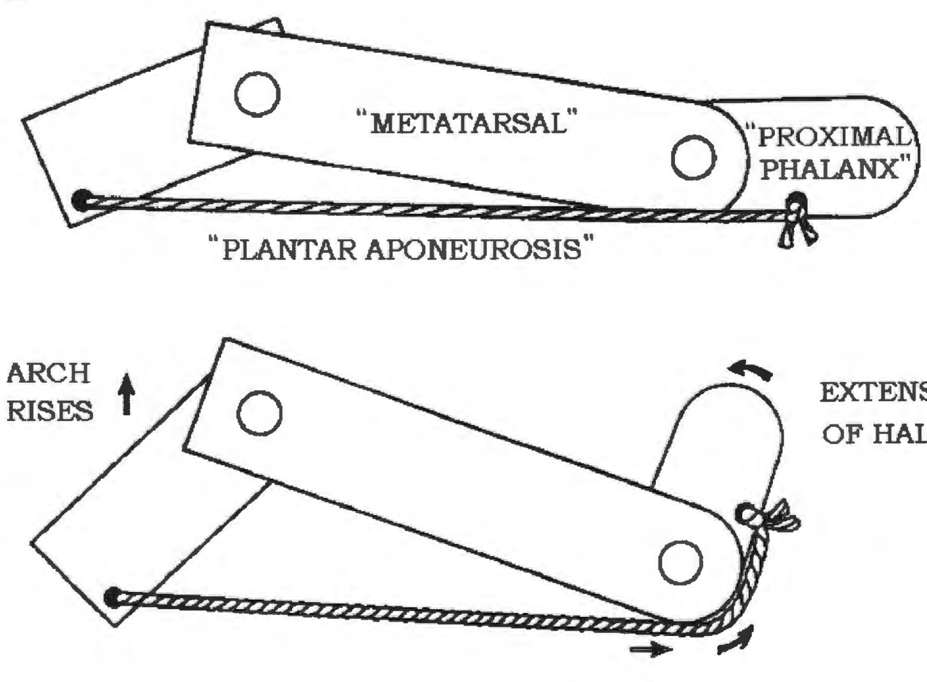
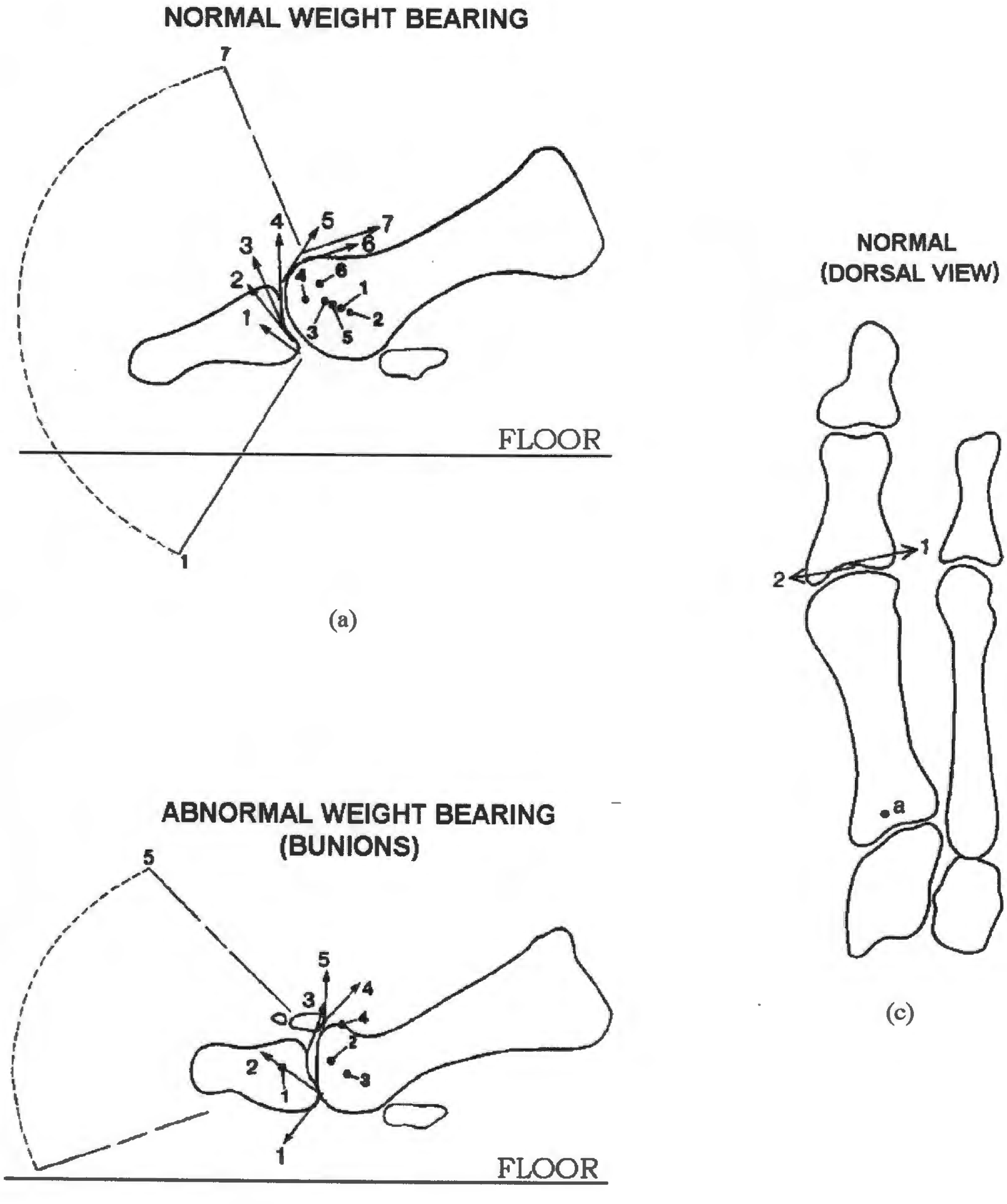


Fig. 18. The principle of the windlass mechanism in the great toe (Sammarco 1980).

These effects are independent of muscle action, as they can be induced in both the living and the dead. Hicks also noted that if the joint is extended, there is always an irresistible downward motion of the metatarsal head relative to the posterior part of the foot. In a previous paper, Hicks (1953) had shown that supination of the foot always accompanies hyper-extension of the toes. This effect occurs in all the toes, but is more pronounced in the first ray. All these effects cease when the plantar aponeurosis is divided.

Importantly, while bearing weight on the forefoot, the range of toe extension that can be achieved by muscle activity alone is small. The greater the load, the less the range of active extension—active extension is that movement that can be induced by voluntary muscle activity. The maximum range of active extension is 50° to 60°, which reduces to only a few degrees under full body weight. It should be noted that the maximum range of passive extension is about 90°, i.e. 30° to 40° more than can be achieved by active extension alone. The reduced range of motion is ascribed to the aponeurosis tension 'unwinding' the windlass, forcing the phalanges onto the ground.

In regard to the independent motions of the bones of the FMTPJ, Sammarco (1980) provided vector diagrams of the instant centres of rotation of the Proximal Phalanx about the MT-head in a normal foot and in a foot with bunions [Figure 19]. Unfortunately, he does not name the source or describe the method used to obtain the data. It will be noted, in the sagital plane of a normal joint [Figure 19a] that the centre of rotation of the phalanx alters position as the joint flexes and extends. Although the centre of rotation of the phalanx appears to move anteriorly in regular increments as the phalanx is progressively extended, closer inspection reveals that the change in the center of rotation is not incremental. The normal center "oscillates" back and forth along a line as the phalanx is extended. In the joint with bunions [Figure 19b] the motion is less predictable. In the transverse plane [Figure 19c] the center of rotation of the phalanx coincides with the proximal end of the metatarsal.



(a)

(b)

(c)

Fig. 19. Instant centre of motion of the proximal phalanx of FMTPJ (Sammarco 1980)

(a) normal joint (b) joint with bunions (c) normal joint (dorsal view).

2.3.2 WEIGHT DISTRIBUTION UNDER THE FOOT

The load pattern generated under the foot when walking or standing provides information on the distribution of forces within the foot itself. This information is required for the design of an implant, but it also allows objective assessment of the efficiency, or otherwise, of various surgical procedures.

Stokes et al (1979b) examined the forces under the hallux valgus foot before and after surgery. Measurements were made using a force plate comprising a series of parallel 12mm beams. The subjects walked on the plate with the beams parallel to the direction of walking, and then again with the beams rotated through 90°. Discrete values were obtained by aligning the two results via ink impressions of each step.

Pre- and postoperative measurements of peak toe load were made of patients undergoing surgery to correct for hallux valgus. The results of Keller's operation, MT-shaft wedge osteotomy, silastic phalangeal prostheses were compared to healthy feet:-

- In healthy feet, no correlation could be found between peak forces, their position and physical characteristics such age, sex, weight, skeletal measurements etc.
- Keller's operation, wedge osteotomy and phalangeal prostheses not only failed to restore normal loading but actually increased the abnormalities seen postoperatively, with the load shifting laterally in 75% of the cases. (This load shift is a recurrent theme in all load bearing studies). The authors found the load shift difficult to explain, but attribute it to a shortening of the first metatarsal compared to the second.

Hutton and Dhanendran (1979) used a more accurate force plate consisting of 128 15mm x 15mm tiles mounted on strain gauged steel loops to study the load pattern under 144 normal feet. They established a consistent pattern of load transfer in the foot while walking. The centre of pressure starts near the heel at heel strike, progresses anteriorly until it reaches the vicinity of the third metatarsal, then veers sharply medially, ending somewhere between the first and second toe at toe off.

In a separate component of their research they compared the sizes of the metatarsal bones, estimating that the first metatarsal was four times stronger than the second. This surprised them because they calculated that the bending moment in the first metatarsal was only twice the bending moment in the second metatarsal. They could not explain this. In regard to the age of the subjects, they found that the load borne by the great toe began to decrease after the age of 30.

Dhanendran et al (1980) using the same 128 segment force plate, compared pre- and postoperative load patterns under hallux valgus feet treated with a Keller operation—a postoperative reduction in the load under the hallux was observed.

Beverly et al (1985) used the 128 segment force plate to measure the distribution of load under 33 feet which had had silicone hinge prostheses inserted, comparing them with the patients' opposite normal feet:

> They found that under feet with prostheses the peak load rose by 65% under the second and third metatarsal heads, while it dropped by 43% and 23% under the hallux and the first metatarsal head respectively. At least one third of patients complained of some discomfort under the second and third metatarsal heads. They also noted that even careful maintenance of toe length and preservation of the flexor tendons and sesamoid articulation during the surgery failed to restore normal weight bearing. The centre of pressure line of both feet of one patient is illustrated in Figure 20.

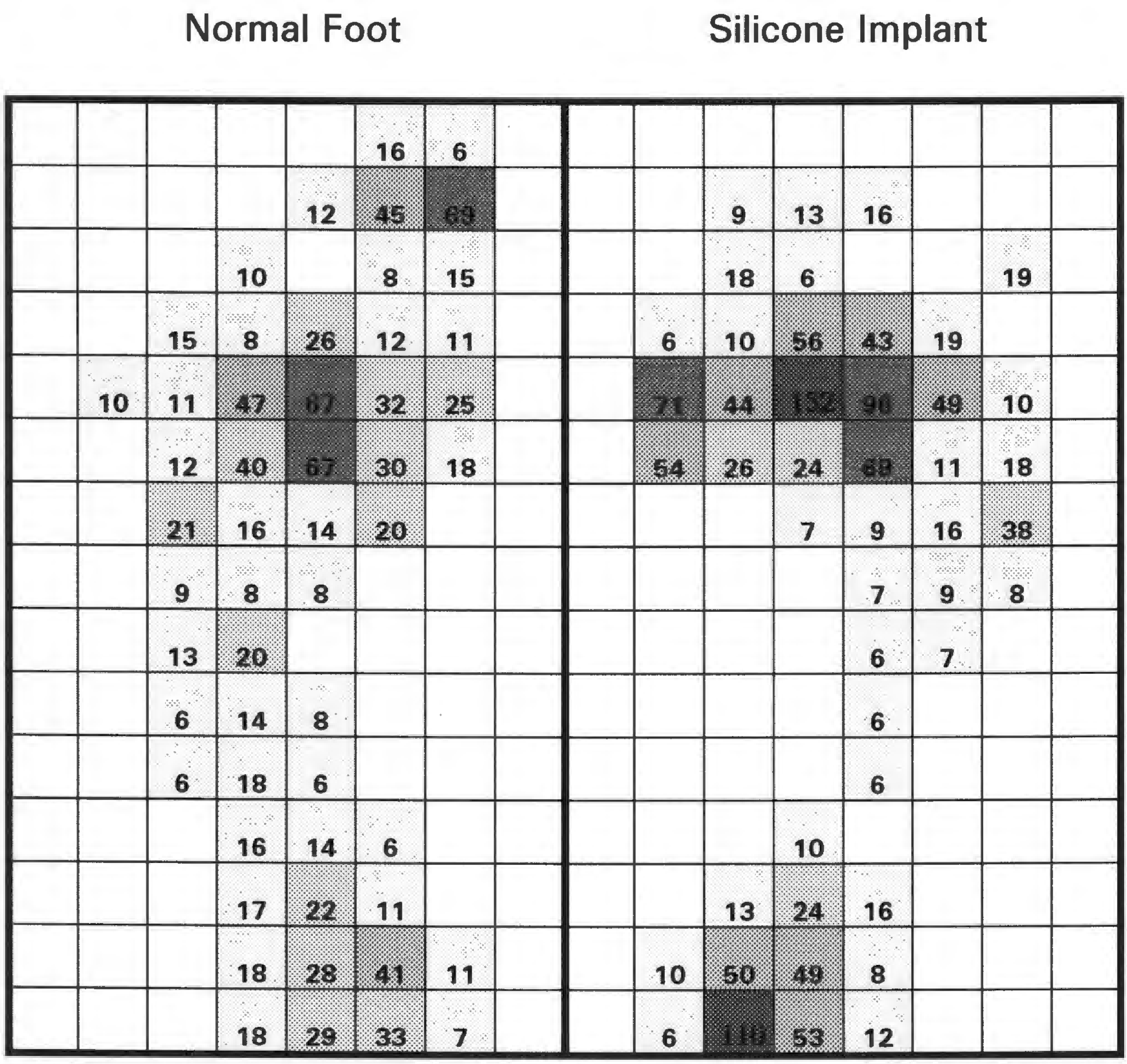


Fig. 20. Peak weight bearing pressures (in Newtons) measured under foot during gait, comparing the normal foot of a patient with the opposite foot that has a silicone-hinge prosthesis (adapted from Beverly et al 1985).

Mann et al (1988) used a piezoelectric force plate to monitor the load under patients who had had their great toe surgically removed for re-implantation in the hand. Unlike Beverly et al (1985) no effort had been made to restore the functions of the joint by reattaching the intrinsic muscles, stabilizing the sesamoids or reattaching the plantar aponeurosis. Ten patients were examined, ranging in age from 15 to 34 years. The course of the center of pressure in feet with and without the great toe is illustrated in

Figure 21. This can be compared to the pressure pattern under a foot [Figure 20] on the previous page in which a silicone prosthesis has been inserted; the two patterns are almost identical. In both the case of the amputee's foot and the foot with a silicone prosthesis, the centre of pressure remains beneath the third metatarsal head for a longer period of the stride than in the normal foot. Not surprisingly, the site of increased pressure often coincides with the site of callosities in pathologically deformed feet.

Fig. 21. Periodic progression of centre of pressure beneath both feet of a hallux amputee (a) normal foot (b) foot with amputated hallux (Mann et al 1988).

The amputees' shoes all showed a decrease in wear under the first metatarsal head. There was increased wear under the lesser metatarsals and along the lateral border of the foot. Due to a loss of function, one amputee had had to give up his job as a construction worker as he could no longer balance on girders. This is the only indication in the literature that one of the great toe's functions is to maintain balance.

In regard to the shape of the arch, lateral weight-bearing radiographs showed that the sesamoids had on average migrated 11mm proximal (range 6,7mm–21,3mm). Following surgery, both ends of the entire first metatarsal dropped relative to the second metatarsal, with the proximal end dropping more than the distal end. The navicular dropped in 8 cases, the cuboid dropped in 6 cases but in all cases less than the navicular. Also, the density of the bone in the metatarsal of the amputated hallux had decreased sufficiently to be readily apparent in the radiographs presented, symptomatic of reduced bone stress.

Hughes et al (1990) used a pedobarograph (which utilises reflected light to form a proportional image of the pressure under the foot) to investigate the role of the toes in walking; 160 normal subjects were studied. Amongst their findings was the fact that no correlation could be found between the peak pressure under the toes and/or under the metatarsal heads, and the relative length of the great toe when compared to the second toe.

Granberry et al (1991) presented two bilateral pedobarograph images of a patient who had received a Sutter double-stem silicone hinge implant in one foot; one image is of normal stance and the other of stance on the fore-foot. Although these images are for standing and not walking as examined in the other studies, the results are similar in that little or no pressure is exerted under the phalanges of the hallux.

2.3.3 FORCES AT THE FIRST METATARSOPHALANGEAL JOINT

The magnitude and direction of the forces acting at the joint need to be quantified in order to specify the strength of any new implant. In vivo measurements are difficult in a weight-bearing foot, a theoretical force analysis is therefore essential. Experimental data from force plates studies is utilised to quantify the internal joint reaction forces.

Stokes et al (1979a) developed a model of the static forces acting at the FMTPJ. The vector analysis is presented in Appendix C. Dimensions were derived from a combination of lateral radiographs, photographs of cadaver metatarsals, cinematography and estimates from photographs of markers on the skin. Ground reaction forces were obtained using a segmented force plate by combining the results of two footprints, the one measured by rotating the plate through 90°. Simplifying assumptions include those required to justify a static force analysis approach. Overall accuracy is estimated at ±50% due to the uncertainty of the resolution of the rather primitive force plate used. The mean peak FMTPJ reaction force in six subjects was calculated at 79,9%.

Hutton and Dhanendran (1981) used the same analysis as Stokes et al (1979a) but used ground reaction forces obtained from the 128 cell force plate instead of by the ink impression method, claiming an improvement in accuracy. Even so, their mean peak force of 86,8% of body weight calculated from a sample of 69 patients were similar Stokes et al's 79,9%. They measured the forces under each toe, detecting a lateral shift of loading in 'older' patients and those with hallux valgus. Their results also failed to confirm the existence of a transverse arch in the fore-foot.

Wyss et al (1990) analysed the joint reaction forces in ten elderly patients between the ages of 64 and 73 years. Their vector force analysis appears to differ from that of Stokes et al (1979a) in that the sesamoid reaction force is not considered vertical

[Appendix C]. The mean maximum joint reaction force was found to be 35% of body weight, with a range of 10% to 90%. The loading pattern was found to vary little between individuals; the net resultant force was found to act within 0°–10° of the long axis of the metatarsal in 8 of the 10 cases.

In a second comparative study of 11 young female (average age 27 years) the mean maximum FMTPJ reaction force was found to be 53% of body-weight . These values are considerably less than those of Stokes et al (1979a). The difference may be due to variations in the static analyses used, but because the effect of the intrinsic muscles have been ignored, the former considered their results as lower bound values. Wyss et al (1990) subjects' were also studied wearing shoes; it is claimed that shoes increased the load on the sesamoids, although this does not appear to be a valid conclusion judging from the wide distribution within the data presented.

2.3.4 FOOT AND ANKLE INVOLVEMENT WITH FMTPJ FUNCTION

Both Hicks (1954) and Kapandji (1987) describe the link between extension of the great toe and supination of the foot. This effect relies on the shape of the bony joints and the alignment of the soft tissues and muscles that manipulate them. Because the plantar aponeurosis ties the calcaneus to the proximal phalanx of the great toe, the motions of calcaneus need to be examined.

Morris (1977) described the relative motions of the lower leg with reference to the joints of the foot. In particular, the talocalcaneus (subtalar) joint is so shaped that internal rotation of the leg causes supination of the calcaneus, while external rotation of the leg causes pronation. The rotation of the leg is then multiplied at the ankle joint. Rather than absorbing the internal rotation of the tibia, as one might expect, the ankle joint exaggerates this rotation during the initial period of ankle dorsiflexion. The consequences of this ankle motion in relation to the function of the great toe was not explored anywhere in the literature. Biomechanical studies of walking (Kairento 1981; Salanthé 1986; Whittle 1991) treat the toe as a terminal rocker, i.e. as a pivot or hinge.

In the midfoot, Sammarco (1980) explains that when the talonavicular and calcaneocuboidal joint axes are parallel, the midfoot is able to flex and extend with ease in relation to the hind foot. However, when the heel is inverted, i.e. with the arch elevated, or the foot supinated, the axes become divergent in relation to one another, locking the joints in the midfoot region. According to Morris (1977), this locking mechanism goes into effect when a force of 36 kg (i.e. 350 N) is exceeded.

There is certain indirect evidence in the literature which is believed to be important in determining the relationship between foot movements and FMTPJ function. Firstly, Ruch and Banks (1986a) found that callosities formed under the lesser MTs following a Lapidus Procedure (i.e. a fusion of the first metatarso-cuneiform joint). Lastly, Ruch and Banks (1986b) reported that regardless of the fixation device employed, there is a tendency for the distal segment of the first metatarsal bone to become elevated following early weight-bearing after any proximal osteotomy procedure used to correct the intermetatarsal angle for hallux valgus. The relevance of these observations will be made apparent in the discussion section of this thesis.

2.4 ENGINEERING DESIGN

2.4.1 DESIGN CRITERIA

Neale (1967) provided the minimum requirements that need to be taken into account when designing a joint replacement:

- The pattern of movement,
- The pattern of loading that is to be applied,
- The performance (durability) of the joint,
- The effect of the biological environment on the prosthesis and vice versa.

The success of a surgical procedure can be judged on a number of criteria. A patient usually expects a cosmetic improvement of deformities, pain relief and restoration of normal motion. The surgeon is most often satisfied if the procedure is technically feasible, simple to perform, relieves the symptoms, and results in few complications that require further treatment (Johnson 1989). From an engineering perspective, the design criteria presented by Elloy et al (1976) were considered adequate to ensure all relevant issues are addressed. The engineering criteria are:-

(1) Appropriate articulation
(2) Good stability
(3) Adequate strength
(4) Good fixation
(5) Correct choice of materials
(6) Low friction forces
(7) Acceptable wear rate
(8) Good salvage potential
(9) Fail safe feature

(10) Standardisation

(11) Sterilisation

(12) Cost effectiveness

(13) Surgical instrumentation

2.4.2 POSSIBLE ENGINEERING SOLUTIONS

Neale (1967) categorised all weight-bearing joints into one of only four possible types:

- Roller bearings, such as ball or needle bearings.
- Plain surface contact bearings.
- Plain bearing surfaces separated by a lubricant.
- Flexible members connecting the components.

He observed that all successful artificial prostheses were either of the plain surface contact bearing type or flexible members. Roller bearings are the most efficient bearing used in everyday engineering practice, but cannot be used in the human body because of the dangers of entrapping tissues between the moving parts. When replacing a joint, it seems simple enough to reproduce natural shapes of the articulating surfaces in rigid materials with a low coefficient of friction. However, because natural joints differ between individuals, a simplified model of the articulation is often used instead.

Lubricated bearings in the body equate to sealed units which are isolated from the body's fluid environment; all healthy synovial joints fall into this category. Attempts at making an artificial capsule, such as enclosing the artificial joint with a flexible sleeve, or inserting a pre-sealed bearing containing a lubricant have never proved successful in the past. Charnley (1967) found from personal experience that it was improbable that a flexible silicone elastomer sleeve could be designed that would survive longer than a bearing that was designed to withstand continual exposure to the body's fluid environment. He also emphasised that, due to various reasons, it is impossible to insert a factory-sealed lubricated bearing under normal operating theatre conditions. In particular, the surgeon can only expose one side of the joint at a time. He therefore has to finish inserting the prosthesis into one bone before inserting it into the other side. This requires that the joint space be opened by retracting or releasing the soft tissues.

MacConaill (1967) asserted that the natural articulating surfaces are histologically continuous with the synovial capsule, i.e. the natural joint a fully enclosed unit. When a surgeon inserts new artificial articulating surfaces they soon become encapsulated in fibrous tissues. Charnley (1967) provided photographic evidence of post mortem hip specimens that show that this new fibrous capsule forms so tightly around the hip prosthesis that it keeps the components in contact and prevents them from dislocating without any support from the muscles. A negative effect of the new fibre capsule was that the fibres tug at the components as they articulate, increasing the stresses at the bone interface over and above the frictional effects present—this restrains the motion and contributes to component loosening.

2.4.3 DESIGN AND TESTING OF FMTPJ PROSTHESES

The design rationale and the testing of two prostheses—the Swanson silicone prosthesis and the Charnley artificial hip—are believed to be relevant to this work; the first because it is widely used, and the latter because it is arguably the most successful prosthesis of any type used so far. It is noticeable that these designers used different approaches:

Swanson (1972) claimed that the design rationale behind the double-stem silicone hinge was simply to modify the existing successful metacarpophalangeal implant for the hand for use in the toe; unscientific but reasonably successful. As for the testing of the silicone prosthesis, Swanson (1979) tested the tear resistance of the silicone material by flexing the prosthesis 325 million times at 4,3 Hz without serious damage. However the apparatus used did not simulate compressive forces, the rotation about the long axis nor the variation in the centre of rotation of the joint during extension, all of which are present in the human foot. This test procedure may have justified the strength of the material, but it completely disregarded the biomechanics of the FMTPJ. Other would-be-designers (Wyss et al 1989) claim that improvements could be made if the biomechanics are considered. However, they do not appear to appreciate that the FMTPJ is part of a linkage running from the knee to the phalanges, preferring to concentrate their efforts on precise replication of the joint surfaces.

Charnley attributes the success of his hip prosthesis to two primary factors: Firstly he reserves the term 'artificial joint' for one in which both surfaces are replaced. Secondly he considered rigid fixation for both components to be essential; even minute micromotions of the components result in pain and rapid loosening of the component, therefore he preferred to cement the components in place. He also considered the non-reactivity of bone cement with the bone as a positive aspect of fixation, because it reduced reactive bone changes.

Charnley (1967) also emphasised the folly of relying purely on laboratory experiments for joint performance information, preferring to base his design on the results of practical surgical experience backed-up by fundamental scientific principles. He found that laboratory experiments to determine the coefficient of friction were unreliable because *in vivo* conditions differ considerably, and sometimes unpredictably from *in vitro* conditions. For example he found that in some joints, 'pasty' films developed between teflon components, which altered their low friction properties. Also, theoretical force analyses could not always explain why the wear pattern sometimes deviated as much as 25° from the direction perceived to be "mathematically correct"—even when the original radiographs were used to calculate the vectors.

With regard to the design of ball-and-socket joints, he found that acetabular sockets with thin walls would rotate at the bone-socket interface. This phenomenon is also seen in the De La Caffinière ball and socket trapezio-metacarpal prosthesis (August et al, 1984) where socket rotation was the prime cause of failure. Charnley found from the results of surgical trials, that by progressively decreasing the diameter of the ball (and hence increasing the thickness of the socket) the frictional torque was reduced until the socket no longer rotated at the bony interface. His view was the smaller the ball the better; his preference was for a 22,25mm diameter head in a 50mm acetabular socket.

Based on the experience of wear in teflon sockets, Charnley et al (1969) determined that the rate of volumetric wear (V) in plastic sockets was related to the diameter of the head (d) by an equation of the form

$$\dot{V} = kd$$

where k is a constant value which is dependent on the properties of the materials. The lifespan of the socket can be determined as the time taken for the prosthetic head to penetrate the socket wall. The rate penetration of a 22,25mm head into a polyethylene socket was determined by Charnley and Halley (1975) averaging 0,15mm per year.

The rate of wear was found vary considerably between individuals; the activity level of the patients increased the wear rate, whereas the mass of the patients did not appear to be a significant factor.

The rigid materials most often used in joint design are stainless steel alloys, and cobalt-chrome alloys, articulating on UHMWPE or high density polyethylene (HDPE) usually cemented in place with acrylic bone cement. Polymers cannot articulate directly on bone because they become felted (Charnley 1967) while silicone elastomer disintegrates if used in this manner (Verhaar 1989). Alternatives to metal and polymers were sought, for example ceramics, but again with little success (Saha 1989). Historically, many other materials have been proposed for joint design, but few if any of these have been successful.

The problems of rigid fixation can be avoided by using soft silicone elastomer components which can be inserted by bending and squeezing them into the intramedullary cavities, but their maximum range of motion is limited to about 60° (Neale 1967). A benefit of silicone elastomer is that it is more flexible than the bone, which as a result does not resorb due to stress shielding—a condition associated with stiff implant materials. However, the bone does resorb due to the reduction of compressive stresses, and jagged bone edges can scour the soft surface, initiating fatigue crack growth and causing minute, highly reactive debris (Verhaar 1989; Corigan and Kanat 1989; Rahman and Fagg 1993). The literature was therefore reviewed with the aim of identifying suitable alternatives to silicone elastomer, either in existence or under development, but no suitable bio-inert material could be found (McMillin 1989, Tencer 1989).

CHAPTER 3
JOINT ARTICULATION

3.1 AIMS OF PRELIMINARY EXPERIMENTATION

Elloy's first criterion of joint design is to determine an 'appropriate articulation'. A preliminary experiment was therefore conducted with the aim of identifying what articulation is appropriate for the FMTPJ. As a starting point, the centre of motion of the FMTPJ has been described by Sammarco (1980), but there are a number of problems arising from his results. Firstly, the centre of motion of the FMTPJ fluctuates as the phalanx is flexed and extended; i.e. there is no obvious mechanical axis of rotation. A lack of a centre of rotation implies that the joint is not a simple mechanical hinge. Secondly, the phalanx is shown to be depressing into the floor; but this motion is clearly not possible. In order to clarify these fundamental inconsistencies, it was necessary to:-

(1) Measure the motion of the FMTPJ as a motion of the metatarsal bone about a stationary phalanx, representing the situation arising during the load bearing stance phase of gait.

(2) Determine which are the most significant variables, parameters or indicators that need to be measured when evaluating the motions of a FMTPJ prosthesis.

The predicament was how to eliminate the ground as a variable parameter of the joint motion. It was felt that if the phalanx was used as the reference for joint motion, the normal joint articulation would not result in the metatarsal depressing into the ground. The difficulty was that the metatarsal is part of the foot, which in turn is part of the body's skeleton. This makes it is practically impossible to keep the hallux stationary and physically rotate the entire body about the toe. A novel experimental technique was therefore developed which would allow the hallux to be flexed and extended, but would measure the motion of the metatarsal relative to the hallux.

3.2 METHOD AND MATERIALS

To make the experiment repeatable, two matching dry bones were selected to act as a master for moulding. The bones were encased in a white liquid catalysed silicone rubber (Dow Corning QR-4487) which was selected for its ability to preserve the original shape of the bones without shrinking. The cavities were filled with a hard black casting resin (Araldite SV416) which was also selected for its properties that allowed the resin to replicate the original shapes of the bones [Figure 22].

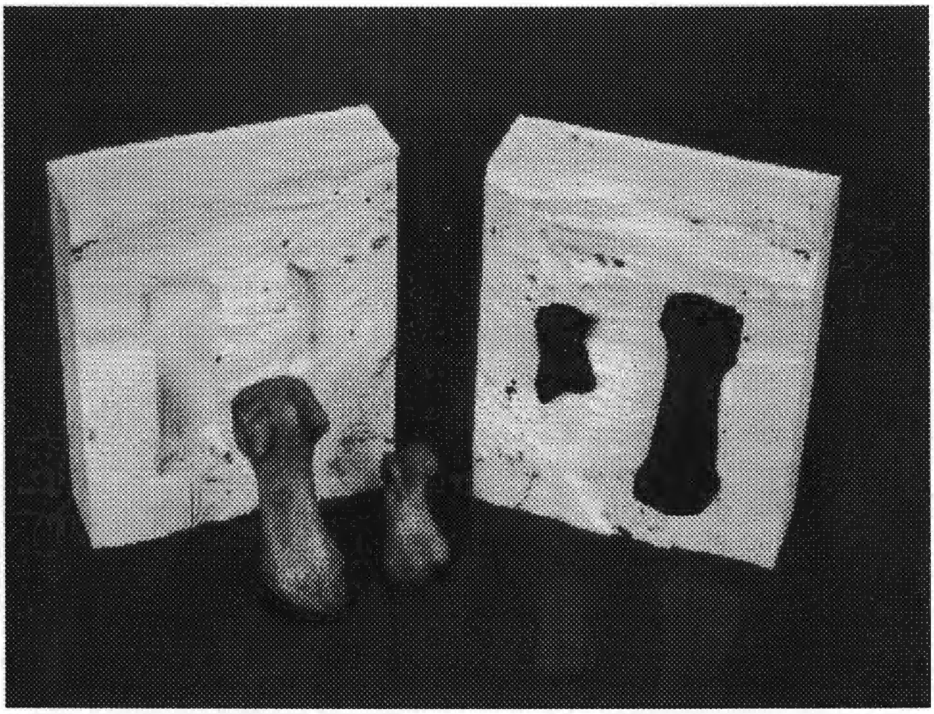


Fig. 22. Dry bones, moulds and castings used during preliminary investigation of joint motion.

Bone castings were used in preference to the bones themselves because it was envisaged that the surgical technique for inserting the prosthesis would be developed on the castings. Since the type of prosthesis had yet to be decided, it was necessary to have a duplicate of the articulating surfaces available; in case they were needed for controls in any comparative testing involving anatomical resurfacing prostheses.

To measure the motions of the metatarsal, a phalanx bone was bolted a few centimeters above a transparent measurement grid via a C-shaped bracket [Figure 23]; the matching metatarsal was similarly bolted above a larger opaque base-board. The transparent base to which the phalanx was fixed was designed to slide freely on top of the opaque baseboard. The bone castings were brought into alignment by adjusting the height of their mounting brackets. The bones were set up with their sagittal plane parallel to the base-boards and the transverse plane perpendicular to the boards. In the transverse plane the bones were set up with a 5° valgus angle between the axes of the phalanx and the metatarsal – this angle was selected because, when rotated in flexion, the oval base of the phalanx had a similar clearance on both the medial and lateral sides of the intersesamoid ridge beneath the MT-head.

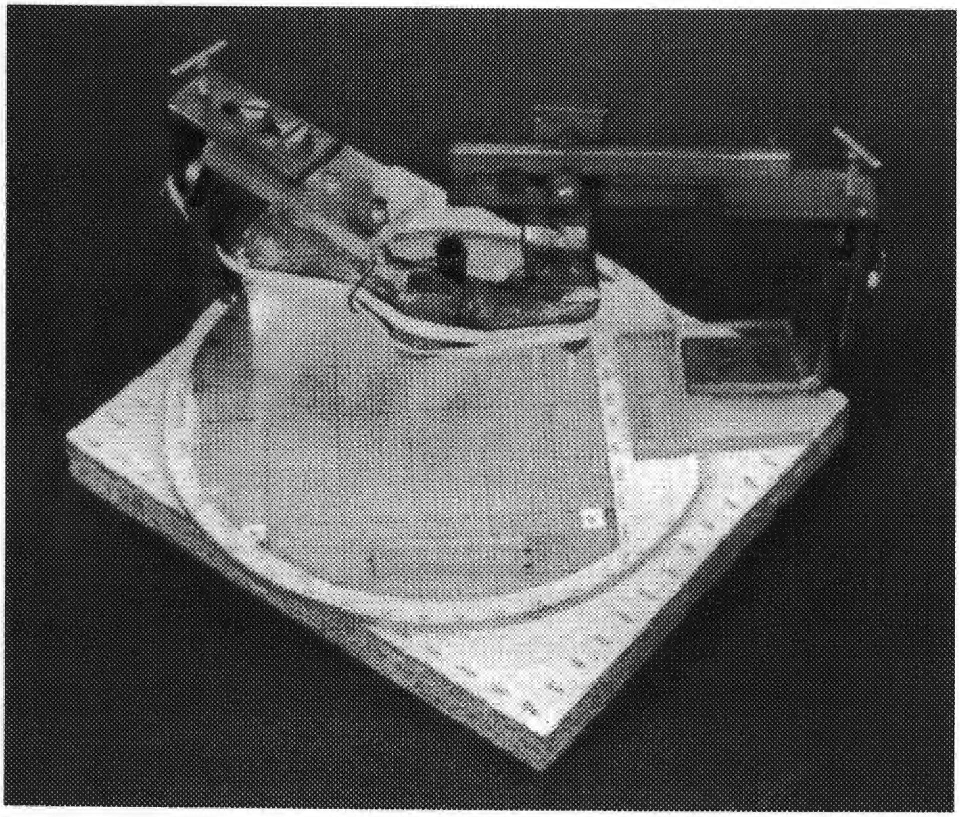


Fig. 23. Apparatus for measuring motions of a dry metatarsal bone relative to the phalanx.

The bone castings were held in opposition by two strands of elastic tape, which were tied to the vertical metatarsal bracket. The one end of each tape was routed inferior to the metatarsal then around the distal saddle-shaped phalangeal head; the other end was routed superior to the metatarsal, the ends meeting up at an eye-ring buckle superior to the joint. This configuration was selected so that the strands ran in the sesamoid grooves, mimicking the line of action of the two heads of FHB and the plantar aponeurosis. The tape was held in position at the metatarsal shaft—both superiorly and inferiorly—by a loosely fixated wire loop.

Passive muscle tension was simulated by locating a plastic clip on the tape—superior to the phalanx and distal to the metatarsal—so that mechanical interference between the clip and the wire loop caused the tape to behave as if it were a long tendon; i.e. when the joint was flexed, the elastic became taught superiorly, simulating the resistance of EHL; when the joint was extended, the elastic tape tightened inferiorly, replicating the tension in FHL and the plantar aponeurosis. The elastic chords were tensioned manually; tension being regulated by pulling the four free ends through an eye-buckle.

Two perpendiculars were projected down from two specific points of interest on the metatarsal bone. The first point was chosen to coincide with the palpable high-point of the arch, and the second point chosen to coincide with the position beneath the MT-head at which the tendons of FHB last make contact with the metatarsal [see Figure 24]. The first location was chosen so that the arch-raising effect could be examined; the latter to investigate the correlation between the motions of the metatarsal head and the rotation of the drum of a windlass. The outline profile of metatarsal bone was projected perpendicularly down onto the opaque baseboard surface, and the outline of the phalanx projected onto the transparent phalangeal grid. The transparent grid was then rested on the opaque baseboard, and the bones brought into contact and aligned via adjustable setting within their mounting brackets.

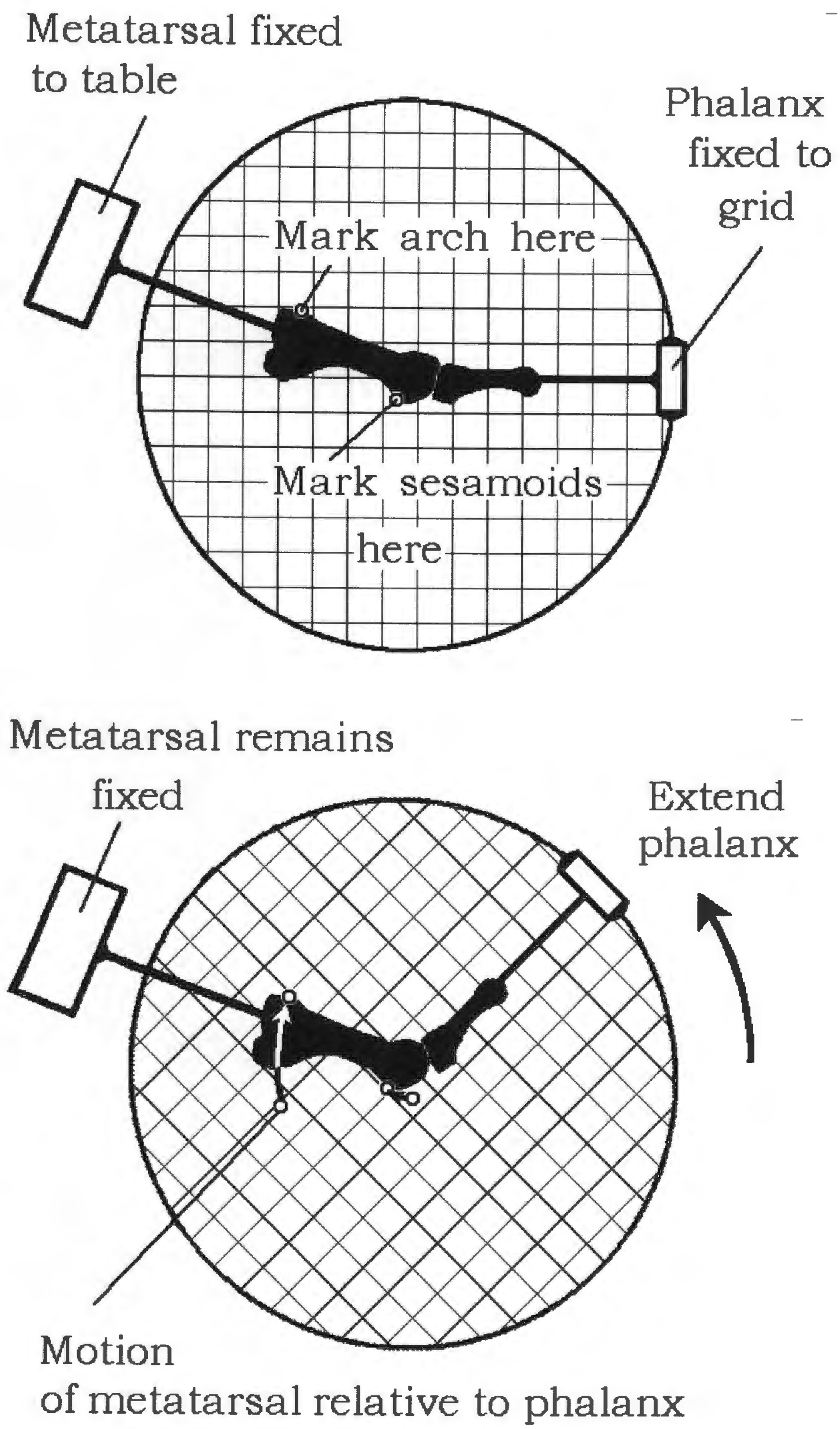


Fig 24. The technique of measuring the relative motion of two bones with the aid of a transparent reference grid.

3.3 PRELIMINARY RESULTS AND FINDINGS

The experiment consisted of rotating the two bones and their attached reference grids through their full range of motion. Readings were made at regular intervals by recording—on the phalangeal grid—the co-ordinates of the proximal (superior arch) and distal (inferior sesamoid) positions of the metatarsal. This created a trace of the locus of the metatarsal motion in relation to the phalangeal axis, which is duplicated in Figure 25.

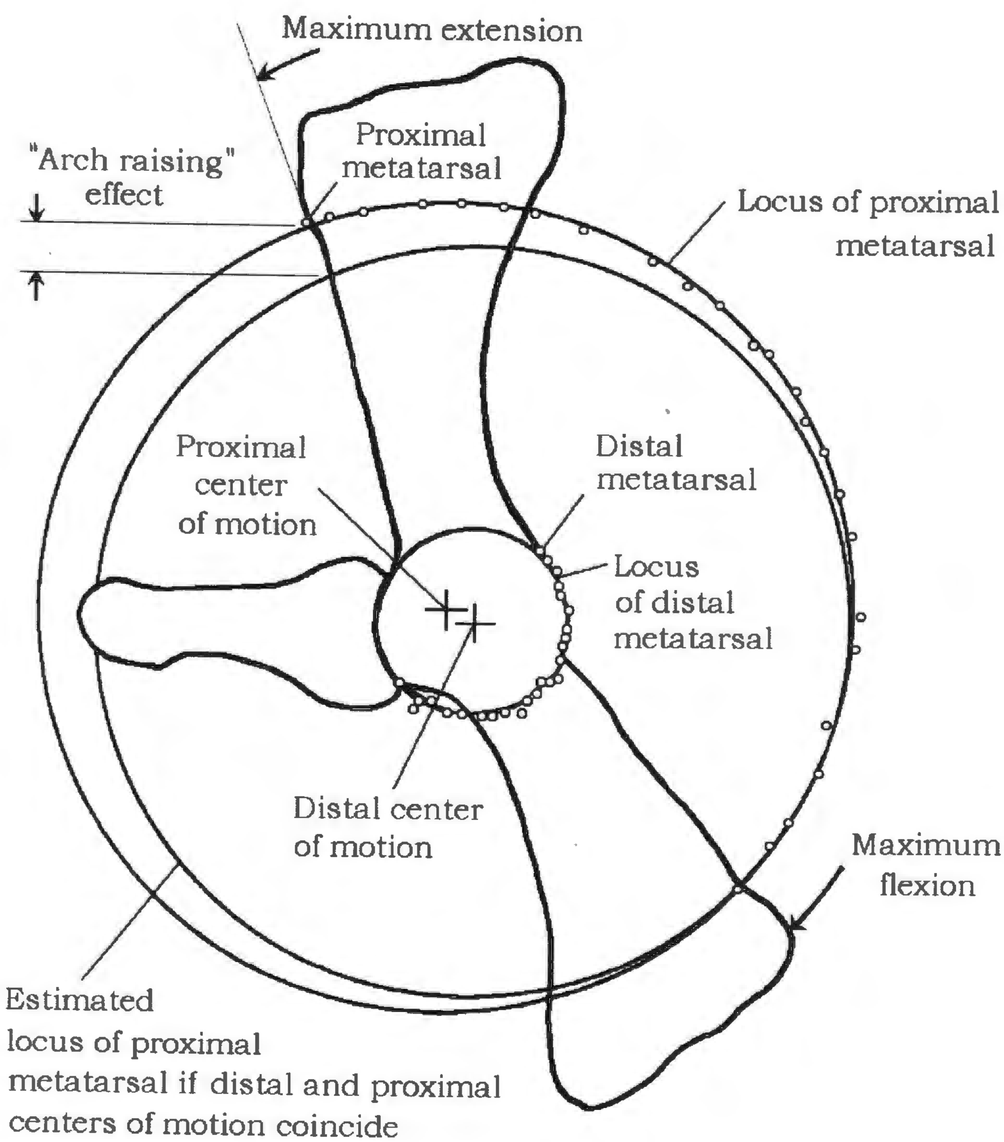


Fig. 25. Motion of dry metatarsal bone about the phalanx.

From the result of the preliminary experiment, it can be seen how both ends of the metatarsal—the arch and the inferior point of the sesamoid ridge—each scribe an arc when the joint is flexed and extended in the sagittal plane. The centre of rotation of the MT-head was found to coincide with the centre of curvature of the base of the phalanx, which is not unexpected since the MT-head glides on the phalanx. However, the proximal end of the metatarsal has its own distinct centre of rotation, which is not concentric with that of the MT-head, but is displaced superior and distal to it.

The effect of having separate centers of motion for each end of the metatarsal can be emphasised by drawing another arc around the "center of motion of the phalanx about the metatarsal head". When this is done at a radius corresponding to the position of the proximal metatarsal, it can be seen how—in full extension—the position of the proximal metatarsal (i.e. the arch) is elevated in relation to the phalanx. Perhaps the most significant finding was how little the locus of motion of the proximal and distal metatarsal deviate from their respective arcs; the worst fit of the radius in a single experiment was only 0,9mm; the RMS value of all the residuals of the radius length calculated at each data point was only 0,1mm. This is despite the fact that the metatarsal appears to rise a total of about 7mm at full extended position. This effect can only occur if there are gliding motions at the articulating surfaces. The practical implications are that the motion of either one of the extremities of the MT, but not both, can be reproduced by a prosthesis rotating about a single fixed point.

A limitation of experiments on dry bones related to the simulation of the soft tissues. Tension in the simulated tendons needed to be maintained at an approximately constant level for the entire range of travel, because this is how natural tendons behave. If the tension rose above a specific value the tape would stretch, thin, and slip through the eye-buckle until the tension returned to a lesser magnitude. As the joint was extended or flexed, the buckle migrated along the tape due to this slippage. Therefore the results of tests on the same or different bones were not compared directly with each other because it was not possible to determine to what extent the discrepancies between tests reflect the variations in the simulated 'soft tissue tension' rather than the anatomy of the bones.

Under such circumstances a statistical significant sample of results could not be guaranteed, therefore no attempt was made to measure *n* number of bones. Also, it is superfluous to model the unknown parameters outside the human body without a detailed anatomical knowledge of the mechanics of the soft tissues. The experimentation on dry bones was therefore curtailed because it was believed to be insufficiently controlled to be able to reliably predict the behaviour of the FMTPJ within the human body. The number of unknown parameters was also too large to enable a reasonable determination of the exact centre of motion of the FMTPJ outside of a fully functional human body without being side-tracked from the prime objective of designing a prosthesis. However, due to the importance of these parameters, a sizeable portion of this thesis was redirected towards developing a theoretical understanding of the systemic role the FMTPJ plays in lower limb mechanics. Precisely how this theory of FMTPJ function impacts on prosthesis design is discussed in Chapter 7.

The influence of the anatomical constraints was even more apparent when an attempt was made to determine center of rotation of the metatarsal bone in the transverse plane. The apparatus had been designed so that the dry bone specimens could be rotated through 90° and measurements made of movements in any plane. However, the apparatus could only measure the motions of the bones in one plane at a time; measurements in the transverse plane were simply not feasible because there was no indication as to what the constraints on the motion were because the precise centre of rotation of the FMTPJ is dependent on the angle between the phalangeal and metatarsal axes. Another important variable is the angular rotation of the metatarsal around its long axis. None of these can be determined by merely looking at the bones or conducting a careful inspection of the anatomy. Also, there is no published data that could be utilised for this purpose.

The structure of the FMTPJ is believed to be unique to bipedal humans (Williams et al 1980) therefore animal trials were neither feasible nor appropriate. Experiments on cadavers were considered a better way of investigating the phenomenon of metatarsal motion within the human body because the number of unknowns could be reduced by using the natural attachments already in place. Motion tests in cadavers were also considered appropriate because the key motion under investigation—viz. the motion of the metatarsal in relation to the phalanx and the plantar aponeurosis—had be shown to be present in cadavers (Hicks 1954).

3.4 CONSEQUENCES FOR DESIGN

In summary it may be said that the prime objectives of the preliminary experiment had been achieved. Firstly, in regard to the testing of the prosthesis, the variables that need to be measured during the cadaver trials had been identified. These were the extent to which the motion of the proximal metatarsal approximates a circular path, and the location of the center of this motion relative to the center of rotation of the MT-head. Secondly, the innovative experimental method that was used had been demonstrated to be an effective way of determining the motion of the FMTPJ.

The preliminary findings also provided useful insights into the possible behaviour of the FMTPJ, which were used to arrive at a definition of an appropriate articulation. This definition was used in the specification for the new prototype prosthesis. The following criteria and premises were used to clarify what may be considered an 'appropriate articulation' for a prototype FMTPJ prosthesis:

(1) The motion of the FMTPJ is best considered as a rotation of the metatarsal around a stationery phalanx.

(2) The metatarsal motion can be resolved into rotations of its proximal and distal extremities. Each extremity scribes an arc, although their centres of motion differ.

(3) The rotation of the proximal metatarsal—i.e. the high-point of the arch—is considered the most important motion to preserve because the shape of the foot is influenced by the position and orientation of the proximal metatarsal.

(4) Aponeurotic tension needs to be maintained or restored in order to preserve the systemic functions of the great toe in the broader context of the foot and ankle.

(5) The crucial time-period is during the final portion of the stance phase of gait when the toes are in extension, the arch is raised and the metatarsals are bearing weight.

CHAPTER 4
PROTOTYPE DESIGN

4.1 MECHANICAL DESIGN REQUIREMENTS

The design requirements include the range of motion of the prosthesis and the peak forces it must be designed to withstand. From the literature, it is possible to quantify the maximum force in the FMTPJ as follows:-

(1) 90% of body weight – for the most active individual (Wyss et al 1990).
80% of body weight – for the average active population (Stokes et al 1979a)
53% of body weight – for the average active female population.
35% of body weight – for the average elderly female population.
10% of body weight – for the least active individual.

(2) The range of motion of the replaced joint should be between 45° flexion to 90° extension, with an ability to simultaneously supinate and pronate about 30°.

4.2 POSSIBLE SOLUTIONS

The range of existing solutions has been reviewed in Chapter 2. From the solutions already attempted, it is discernible that:-

- A simple bone resection is preferable to anatomical resurfacing of the joint; if only one side of the joint is to be replaced, it is preferable to replace the phalanx surface.
- Prostheses that replace the metatarsal head fail due to rapid loosening.
- Silicone single-stem phalangeal prostheses can be used as interpositional spacers to augment a bone resection, but these prostheses tend to disintegrate over time.
- Silicone double-stem prostheses fail to restore normal load bearing, and only partially correct the alignment of the hallux.

In searching for better solutions, the concept of flexible prostheses for finger and toe joints has proved successful in the past; therefore as a starting point it is worth exploring alternative uses of flexible materials to produce a new FMTPJ prosthesis. Although the flexibility of elastomer allows it to adapt to the minor shifts in the centre of rotation of the joint without imposing much strain on the bony fixation, the very same flexibility means it cannot support compressive forces, and hence cannot replicate normal joint functions. The range of motion is also of concern, because the maximum excursion of any flexible member is only about 60° whereas 145° of movement is the normal.

To achieve the desired range of movement, it was proposed that the prosthesis consist of a flexible elastomer ring with two intramedullary stems [Figure 26a]. Unfortunately a review of the properties of a wide range of biomaterials revealed no suitably strong bio-inert material that could bear the required load without the ring pinching closed—the prosthesis would have to be so stiff that it would not be capable of bending. Also, silicone elastomer is too soft and its debris too reactive. Therefore the idea of a spring-steel hinge was considered [Figure 26b], but was rejected because such a design cannot duplicate all of the three-dimensional motions of the hallux that are required.

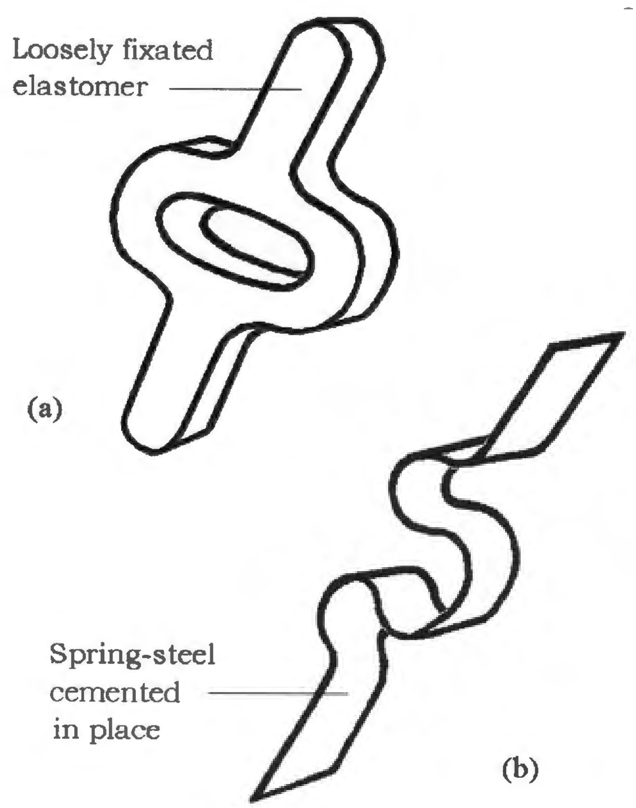


Fig. 26. Preliminary design concepts
(a) flexible ring (b) spring-steel hinge.

A third proposal was explored whereby the ring was replaced by a flexible loop rotating in the manner of a rolling track [Figure 27a]. Such tracks can support large vertical loads while facilitating horizontal motion. Unfortunately, to achieve the required flexibility, the track itself needs to be supported. This requires either a set of solid rollers—the idea of which has already been rejected—or some form of hydraulic support such as a strong flexible ball or sac filled with a liquid or gel [Figure 27b]. However, because there is no solid contact between the bones, the soft flexible material would still need to transfer the full compressive load. A sac is likely to burst, split or tear, or the fluids escape due to the porosity of the silicone membrane. Therefore the idea of replacing the supporting rollers with a solid sliding contact was investigated [Figure 27c] but was rejected because the resulting design became too complex.

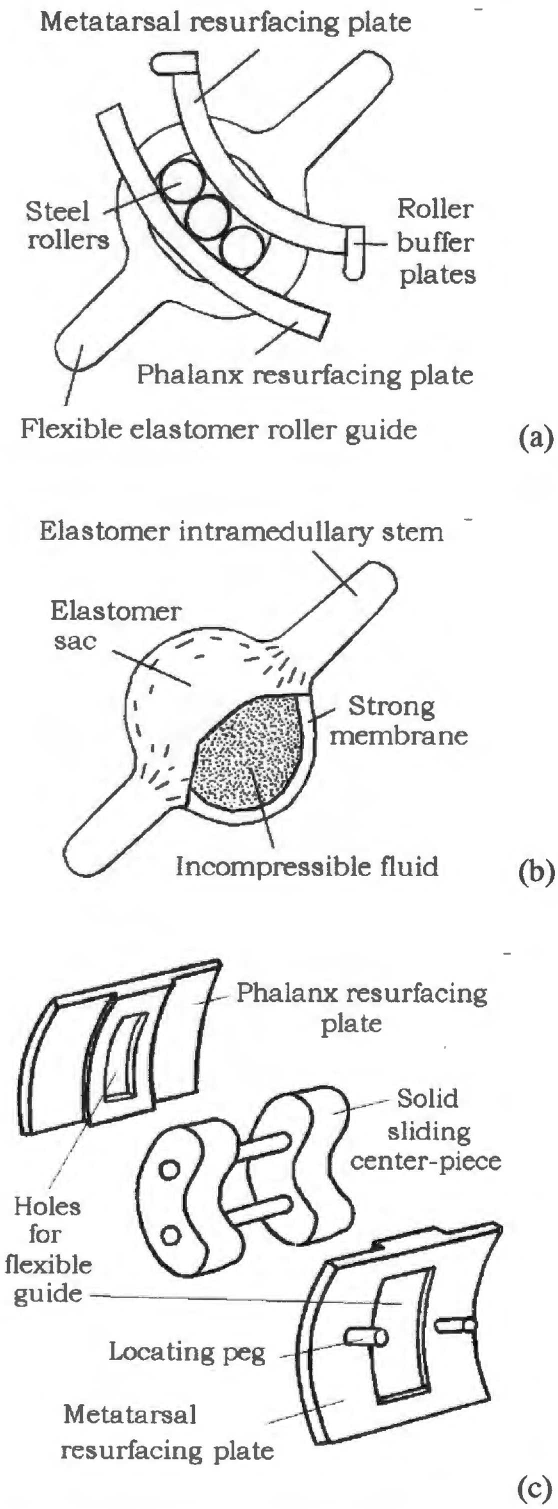


Fig. 27. Multi-component design concepts.
(a) rolling track (b) fluid-filled sac
(c) solid sliding contact.

4.3 BEST SOLUTION – BALL AND SOCKET

The inability of any flexible prostheses to resist compression without deforming, the excessive complexity of multi-component prostheses, and the proven failures of anatomical resurfacing prostheses prohibit their use. The only other perceived alternative is to use a congruent joint capable of flexion, extension, abduction, adduction and axial rotation, namely a ball-and-socket joint.

4.3.1 ADVANTAGES OF A BALL AND SOCKET

On the face of it, anatomical resurfacing prostheses are the logical choice, but all such designed have failed. Of the 'unnatural' alternatives, a flat plain bearing can only accommodate axial rotation; a cylindrical bearing can accommodate either flexion-extension or abduction-adduction motions, but not axial rotation; only a ball-and-socket prosthesis can accommodate all of these motions. Any other shape of artificial surface has different curvatures in different planes. Firstly, there is no reason why an artificial shape should perform better than anatomical prostheses. Secondly, one surface will always impinge on the other when the joint is rotated; resulting in localised wear, which will eventually alter the shape of the surface. Claims by Wyss et al (1989) that the lack of anatomical precision of the articulating surfaces is the main cause of FMTPJ prosthesis failure, must therefore be viewed with some degree of scepticism.

Unlike the other solutions, a ball-and-socket prosthesis has the advantage that it can rotate in any direction and still bear load. It is however dependant on the soft tissues for stability and alignment. It is worth noting that in a normal FMTPJ it is the soft tissues and not the bones that constrain the motion. Existing partially or semi-constrained prostheses have never proved their worth; therefore there is no substantial reason for including ridges or grooves on the articulating surfaces on the prototype prosthesis.

The insertion of an artificial ball-and-socket joint into the hallux will, however, result in some changes in the configuration of the bony articulation. Unlike in the hip, where the socket is inserted into a bony cavity that provides physical support all around, there is no such bony support in the hallux; the FMTPJ socket would have to reside in the soft tissue sling enveloping the metatarsal head. Also, the socket would need to be fixed to the phalanx—this would be similar to resecting the MT-head and fusing it to the phalanx [Figure 28] creating a rigid structure where there used to be a joint. The site of the articulation will shift proximally. The question must arise whether the space normally occupied by the MT-head can be occupied by a rigid structure that moves with the phalanx.

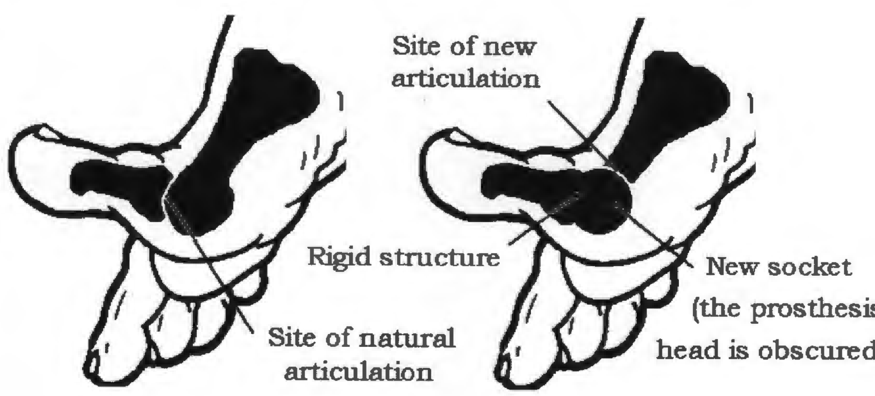


Fig. 28. Changes in the mechanical elements of a FMTPJ brought about by a ball-and-socket arthroplasty.

A close inspection of the motions of the hallux, however, soon reveals that the MT-head could quite easily be considered to be part of the mobile part of the hallux rather than as part of the remainder of the foot. This is due to the fact that there is little significant gross displacement of the position of the MT-head beneath the skin as the hallux is flexed and extended. Functionally, Hicks (1954) showed that extension of the hallux depresses the first MT-head, which then cannot be forced back into line with the MT-heads of the lesser toes until the hallux is flexed, i.e. the MT-head functions as though it is part of the phalanx. So from a cosmetic, structural and functional perspective, the first MT-head may be treated as a rigid extension of the proximal phalanx.

4.3.2 DESCRIPTION OF MAIN COMPONENTS

Having decided to develop the ball-and-socket prototype, the basic specifications, such as the materials to be used and the gross size and shape of the prosthesis, need to be established before the final details can be evaluated by examining the design constraints. The nomenclature used to describe a ball-and-socket configuration is given in Figure 29.

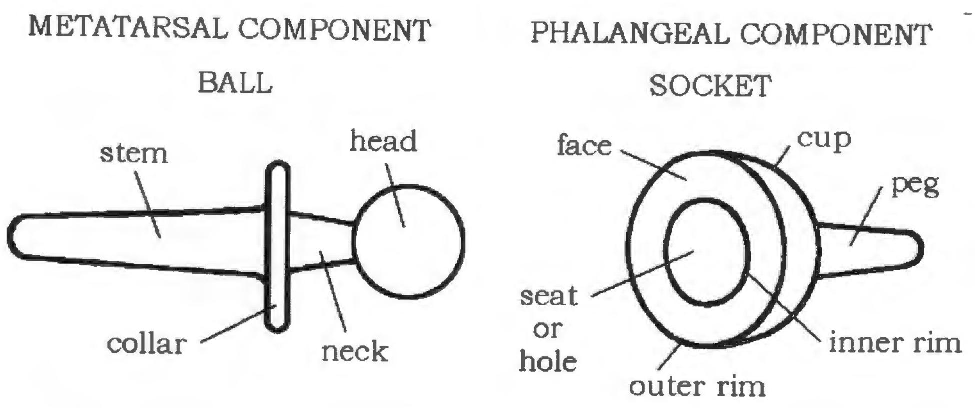


Fig. 29. Nomenclature for identifying the parts of a ball-and-socket prosthesis.

The four main parts of the MT-component are the head, neck, collar and stem. The position and length of the stem are constrained by the length and internal diameter of the medullary canal. The position of the centre of the head is determined by the centre of rotation of the proximal metatarsal. The shape of the prosthesis neck must be considered together with the size and shape of the face of the cup; for example the thicker the neck the less is the range of motion. The use of a collar at the interface with the resected bone is optional, but it greatly facilitates locating and positioning the prosthesis. The extent of the collar is constrained by the outer diameter of the metatarsal shaft. As is standard practice, sharp corners were avoided in order to reduce the stress concentrations at the junctions between the collar, neck and stem.

The role of the phalangeal component is to accurately locate the head of its counterpart. The main constraint is space because considerable tolerance is required to enable the neck of the MT-component to sweep through the full range of motion. For this reason the whole of the MT-head needs to be resected. Resection of the base of the phalanx is unnecessary because its natural shape allows it to accommodate a spherical cup with minimal preparation of its basal surface.

The cup needs to be orientated so as to permit 90° extension and 45° flexion by the MT-component, i.e. the cup should be inclined dorsally and face superiorly. The cup may also face laterally to accommodate the natural 0°–10° angle between the long axes of the phalanx and metatarsal bones. However, these angles of insertion are relatively small compared to the 145° flexion-extension angle. If the cup was built with a lateral inclination to the peg, different components would be required for left and right great toes. For standardisation purposes a single design that can be used in either foot is preferable.

Due to space constraints, the cup needs to be the same size and shape as the resected MT-head. The most prominent feature on the MT-head is the inferior crista-like ridge that separates the two sesamoids. The prosthetic socket—that has a built in ridge—would be need to be rigidly attached to the phalanx; therefore the sesamoids will no longer articulate with the metatarsal. This results in a fundamental change in the orientation of the soft tissues of the prosthetic joint compared to the soft tissues of natural joint because the ridge that separates the sesamoids is now in line with the pull of the muscles.

4.3.3 MATERIALS OF CONSTRUCTION

The mechanical principle of a ball-and-socket is largely independent of the materials used. For this reason the materials were selected for factors such as proven strength, durability, wear characteristics, mechanical and biological compatibility, ease of manufacture, availability and cost.

With contact bearings it is best to have one relatively soft surface articulating on a harder surface, the latter having a high quality surface finish. The socket is always made of the softer material because this configuration produces the least wear. The materials that could be used for such prostheses when manufactured are ultra high molecular weight polyethylene (UHMWPE) for the socket, and stainless steel alloy or cobalt-chrome alloy for the head. Due to the lack of manufacturing facilities to produce Co-Cr alloy, its cost and the fact that the strength and the wear characteristics of the prototype prosthesis were not being tested, stainless steel was selected for the MT-component, while standard industrial grade high density polyethylene was selected for the socket.

It is possible for the phalangeal component, including the peg and the cup, to be machined from a single sheet of polyethylene—but for the prototype, the peg and cup were manufactured separately and secured by either press fitting a stud on the peg into a hole in the cup wall, or with small diameter screws if the cup wall was thick enough to secure the thread. Metal backing for the cup was considered a possibility in active patients because the cup is not supported by bone. Besides being stronger than pure polyethylene, a metal backing might also limit distortion due to plastic flow or material creep. On the other hand, although a pure polyethylene socket may be expedient from a cost perspective, it might prove unwise from a structural point of view. Both metal-backed and pure polyethylene types of socket were therefore considered as potential alternatives for the eventual prototype prosthesis specification.

4.4 DESIGN CONSTRAINTS

The prosthesis is constrained by size, shape, and material properties. The head diameter is directly related to the bearing pressure on the head, frictional torque, rate of wear, range of motion and possible component dislocation. A compromise between these factors is necessary, therefore design parameters such as the head size, the cup shape and the shape of the intramedullary peg and stem need to be optimised in relation to each other. Maximum and minimum values were determined for each parameter, then conflicting requirements were then assessed using durability and functional integrity as the key criteria.

A direct comparison between a hip ball-and-socket and a hallux ball-and-socket was considered the best means of sizing the components because similar materials are being used for both the FMTPJ and hip prostheses. This procedure is in fact the one recommended by Weightman (1977) when designing prostheses for joints that enjoy less attention than the hip. Since there have been few successful developments in FMTPJ design after that date, this advice remains as valid today as it was in 1977.

4.4.1 JOINT FORCES

The forces acting on the joint govern almost all design decisions. These forces can be analysed in a number of ways, viz. either as those acting on the two mechanical elements (i.e. the prosthesis components fixed into their respective bones) or as the forces at the prosthesis/bone interface; or as the forces transferred directly through the contact of the prosthetic components. The forces that act on the mechanical elements of the prosthesis [the white force-vectors in Figure 30] are similar to the forces in a normal FMTPJ. The forces acting at the prosthesis bone interface have complex relations and are difficult to predict from theory alone. The forces at the interface of the prosthesis components [black vectors in Figure 30] can be resolved into a compressive joint reaction force (J) a frictional shear force at the prosthesis head (H), and a tensile force due to stretch in the capsule's fibres (C).

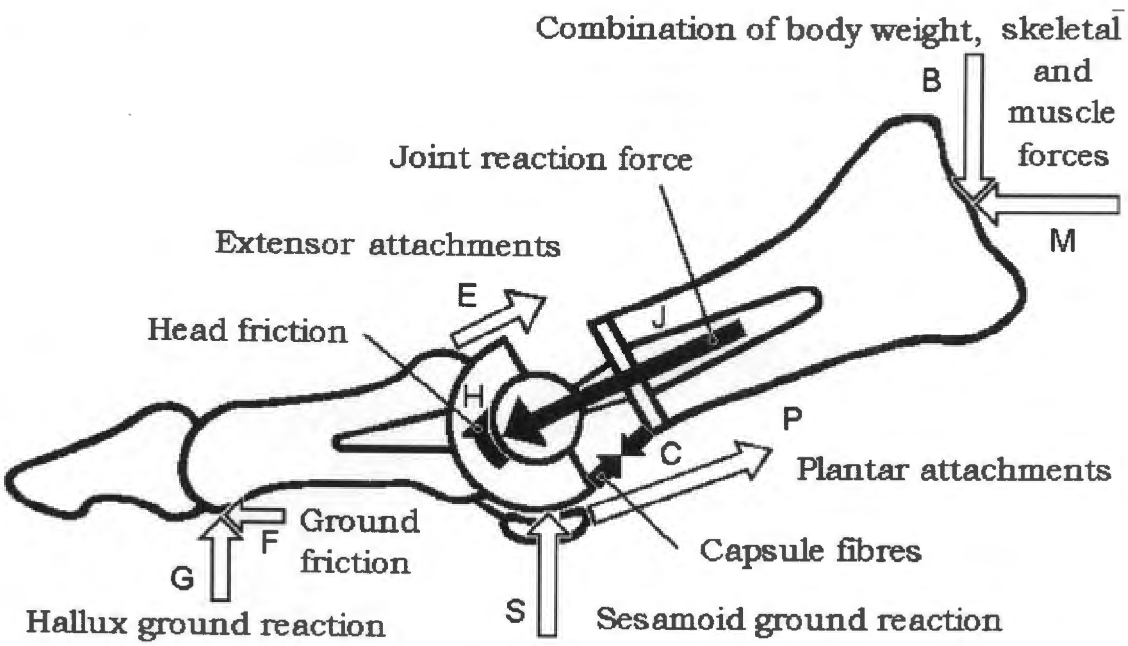


Fig. 30. Forces in a FMTPJ ball-and-socket prosthesis.

As a first approximation, the first metatarsal can be treated as a two-force member; i.e. because the muscles attach exclusively to the proximal portion of the MT-bone, the resultant compressive force (J) within the metatarsal will be directed along its long axis. The direction of this compressive force has confirmed by the static force analysis study of Wyss et al (1990). The tensile forces across the joint are carried by the plantar attachments (P) and the extensor insertions (E). The contribution of the extensors during passive extension is small; and since they act as antagonists to the plantar attachments, the effects may be combined. The flexibility of the plantar plate attachment to the phalanx ensures that the forces in the soft tissues of the sesamoid complex are tensile. The forces in the rigid mechanical elements are therefore always compressive, which minimises the effects of bending moments within the metatarsal and phalanx shafts.

In a normal static force analysis, it is usual to ignore friction forces. The coefficient of friction in a synovial joint is small; therefore this assumption is valid. However, in a replaced joint the head-friction (H) needs to be taken into account in the force polygon. Ground friction (F) is needed to balance the effects of the body and muscle forces (B/M) forces, at the "push-off" phase of gait; but again, these can be combined with force P. Another force active in the replaced joint is the stretch in the new reformed fibrous capsule (C); Charnley (1967) implicated such fibre tension as a cause of cup loosening in the hip. However its direction and effect are similar to that of force P, therefore their effects may be combined. The vertical ground reactions at the tip of the hallux (G) and under the MT-head (S) must equal the load under the hallux measured, for example, in a force plate study. The ratio of these forces can only be determined from data obtained from force-plate studies on feet with ball-and socket prosthesis has been inserted. Currently such data does not exist; therefore the force polygon [Figure 31] cannot be drawn to scale; but it appears to be approximately similar to the force polygon derived for normal joints (Stokes et al 1979a; Wyss et al 1990) [see Appendix C]. The data from the published studies was therefore used unaltered to size the implant.

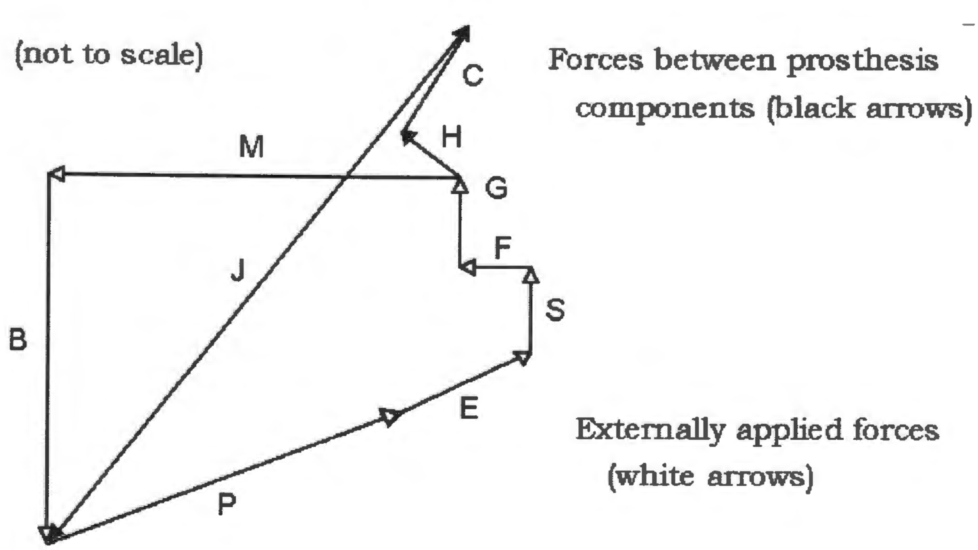


Fig. 31. Force polygon in a FMTPJ ball-and-socket prosthesis.

4.4.2 BEARING PRESSURE

The maximum sustainable bearing pressure that can safely exist between the metal prosthesis-head and the cup is governed by the material properties of the metal and polymer. The maximum bearing pressure governs the minimum size of the prosthesis head. There are however, considerable variations in the forces exerted by various individuals, as well as differences in their mass and physical size. The concept of body-weight is therefore used in force calculations because it normalises the forces within the body against the body-weight of each individual. This smoothes the variations considerably, because it may be presumed that a person's bone size and strength are appropriate for their weight. If optimal stressing of bone stock is assumed, the stress level in the bones may be approximately constant across a range of individuals. Therefore body-weight is justifiably treated as a constant throughout the equations that follow, even though the actual forces may vary.

Charnley determined the optimum head size to prevent hip cup rotation was 22,25 mm. A conservative high average load in the hip is estimated by Crowninshield et al (1978) to be 3,6 x body weight. This data was used to estimate the prosthesis bearing area in the hip:-

$$\begin{aligned}\text{Hip Bearing Area} &= \text{Head diameter}^2 \times \pi/4\\ &= 22{,}25^2 \times \pi/4\\ &= 389 \text{ mm}^2\end{aligned}$$

Dividing 3,6 times body-weight by the bearing area, gives a mathematical constant for the acceptable bearing pressure on the polyethylene cup in the hip:-

$$\begin{aligned}\text{Maximum bearing pressure in polyethylene} &= \text{Load} \div \text{Bearing Area}\\ &= 3{,}6 \times \text{body-weight} \div 389 \text{ mm}^2\\ &= 9{,}25 \times 10^{-3} \text{ body-weight/mm}^2\end{aligned}$$

In the hallux, Stokes calculates the average peak FMTPJ load as 79,9% of body-weight, which allows the bearing area of: polyethylene in the FMTPJ to be calculated:-

$$\begin{aligned} \text{Bearing area in the hallux} &= \text{Load / Acceptable bearing pressure} \\ &= 0{,}799 / 9{,}25 \times 10^{-3} \\ &= 86 \text{ mm}^2 \end{aligned}$$

This leads to an estimate of the diameter of the prosthetic head required for the toe:-

$$\begin{aligned} \text{Prosthetic head diameter} &= \sqrt{\text{Area} \times 4/\pi} \\ &= \sqrt{86 \times 4/\pi} \\ &= 10{,}5 \text{ mm} \end{aligned}$$

A more conservative estimate of the mean maximum FMTPJ force in a young active female population is 0,53 x body-weight, Wyss et al (1990). The mean maximum force in an elderly population is 0,35 x body-weight. The maximum force calculated in any individual in the literature is 0,9 x body-weight. Substituting these values into the above equations, minimum diameters can be determined for the various activity levels as follows:

Maximum activity (90% of body weight)	11,1 mm
Mean active population (80% of body weight)	10,5 mm
Mean active female (53% of body weight)	8,5 mm
Mean elderly population (35% of body weight)	6,9 mm

As can be seen, an acceptable prosthesis head size is anything between 7–12 mm, depending on the patient. In order to standardise on a head size, a range of six representative head sizes was selected for further investigation, namely 7, 8, 9, 10, 11 and 12 millimetres.

4.4.3 FICTIONAL TORQUE

The friction at the prosthesis head is an important constraint because it limits the shear forces that can be transmitted through the socket/bone interface. This in turn limits the force that can be supported at the distal tip of the hallux; and provides an ultimate limit for the shear and bending stresses that can develop within the phalanx-socket structural element [Figure 32].

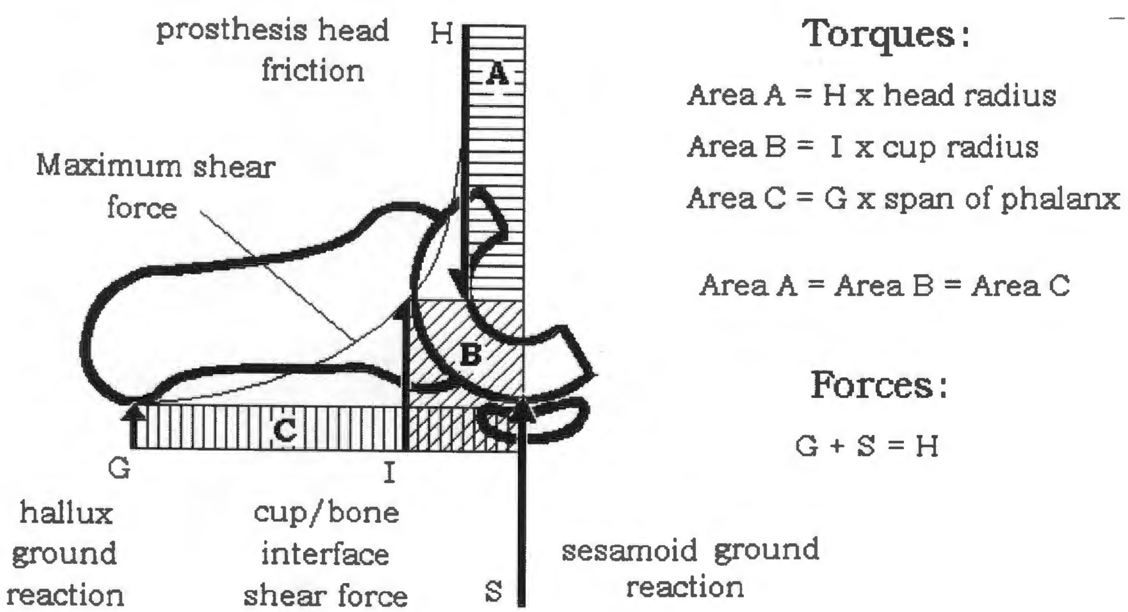


Fig. 32. Frictional torque in a FMTPJ prosthesis and it's effect on shear forces in the hallux.

When the head exceeded a certain diameter, the magnitude of the frictional torque reaches a point where the cup rotates within its bony bed. This results in rapid loosening of the implant. With a ball-and-socket design, a low friction arthroplasty is considered essential because if hallux is loaded distally by the patient standing on the tips of the toes, the joint must rotate at the head/cup interface rather than at the phalanx-bone cement-socket interfaces. Most importantly, the resulting two-point loading on the proximal phalanx establishes the basis for the theoretical analysis of the experimental results and the discussion of FMTPJ function that is to follow in Chapter 7.

If the head radius is kept small, and the cup wall is made thick enough the head should always slip in the cup before the critical torque is exceeded at the bone interface. The joint moves until the forces at the distal hallux and under the sesamoids are balanced.

The ratio of the head diameter to the cup outer diameter regulates the maximum shear stress that can be applied to the phalanx cement/prosthesis bond. The outer diameter of the cup is determined by the anatomy and, within very tight limits, cannot be increased– the only parameter that can be adjusted is the ratio of the head diameter to the cup diameter. Since the minimum head diameter is fixed by the acceptable bearing pressure, the optimal head size lies somewhere between these limits.

The maximum and minimum sizes of the cup was determined by reference to an anthropometric study of 129 bones (Wyss et al 1989). The mean length of a series of 129 metatarsal bones was found to be 61,96 mm ± 4,5 mm standard deviation; the specimen used as the mould master had a length of 66 mm. Assuming that a normal statistical distribution may be used to describe the range of bone sizes in the patient population, it can be shown that the castings would be bigger than 73% of the bones in the anthropometric study. In other words, about 75% of patients would need a prosthesis that was the same size or smaller than a prosthesis that would suit the bone casting model, and about 25% would need to be bigger.

The anthropometric study reveals the width of the MT-head to be 20,48 mm ± 2,21 mm standard deviation. The articulating area on the head of the bone used in the trials was 22 mm and the head was measured 25 mm at it widest point. Therefore, in order to specify a standard range of cup sizes, the maximum cup size was set at 24 mm for the largest expected bone, with lesser sizes of 22 mm, 20 mm and 18 mm being required to complete the range of cup sizes.

In a low-friction 22,25mm Charnley hip prosthesis the ratio of the head to cup diameter is 22:50 or **0,44**. As a first approximation, this provides an estimate as to which cup diameters can be used with which head sizes if the minimum requirements for a low friction arthroplasty *in vivo* are to be met. Table 1 compares a range of head and cup sizes for the FMTPJ—with acceptable ratios in bold:

Head diameter	Cup diameter			
	18mm	20mm	22mm	24mm
7 mm	**0,39**	**0,35**	**0,31**	**0,29**
8 mm	**0,44**	**0,40**	**0,36**	**0,33**
9 mm	0,50	**0,45**	**0,41**	**0,38**
10 mm	0,56	0,50	**0,45**	**0,42**
11 mm	0,61	0,55	0,50	**0,46**
12 mm	0,67	0,60	0,55	0,50

Table 1. Ratios of FMTPJ head and cup diameters—minimised to improve the frictional torque properties of the articulation.

For example the maximum head size that could be used in a 20 mm cup is 9 mm in diameter, but a 10 mm head could safely be used in a 22 mm cup. It should be noted that because conditions in the hip and hallux differ, these ratio's can only be used to estimate relative head and cup diameters. However, the frictional torque is an important criterion, particularly since cup loosening was found to be the prime cause of failure in the De La Caffinière trapezo-metacarpal thumb arthroplasty, which was a ball-and-socket design inserted into small bones. On the positive side, the effects of the cup peg have not been included in the calculations. This would introduce a factor of safety to the fixation, although it is best to avoid placing undue stress on the peg fixation as this will certainly aggravate the already significant problem of component loosening.

4.4.4 WEAR

A major consideration in designing a joint is wear. Not only do wear particles cause undesirable inflammatory responses, but the centre of rotation, may shift to a point where the joint no longer functions correctly. Charnley et al (1969) noted that in the hip; the volume (V) of wear particles produced is related to the diameter of the head (d) by a linear constant (k) by the equation:

$$V = k.d \qquad (1)$$

where k is a property of the materials used. This general wear equation is held to be independent of the materials used. Because the wear invariably occurs in a cylindrical tunnel that has the same diameter as the head (Charnley et al 1969), the volume of wear particles can also be expressed in the form:

$$V = A.l \qquad (2)$$

where A is the area of the head and l is the depth of penetration. Substituting equation (1) into equation (2) an expanding the area A, allows the constant k to be expressed in terms of the head diameter (d):

$$k.d = A.l$$

$$k.d = \pi.d^2.l / 4$$

$$k = \pi.d.l / 4 \qquad (3)$$

In the hip, a 22,25 mm head wears through the polyethylene cup at an average of about 0,15 mm per year (Charnley and Halley 1975). Substituting these values into equation (3) the wear constant for polyethylene becomes:

$$k = 2,6 \qquad (4)$$

By rearranging equation (2) the linear wear rate per unit time (L) for any diameter head becomes:

$$L = \frac{k.d}{A} \qquad (5)$$

The expected rate of wear for the various head sizes can now be calculated [Table 2].

Head diameter (mm)	Volume wear-rate (mm^3/year)	Cross-sectional Area (mm^2)	Penetration rate L
6	15,7	28,3	**0,556 mm/year**
7	18,3	38,5	**0,477 mm/year**
8	21,0	50,3	**0,417 mm/year**
9	23,6	63,6	**0,371 mm/year**
10	26,2	78,5	**0,334 mm/year**
11	28,8	95,0	**0,304 mm/year**
12	31,5	113,1	**0,278 mm/year**
13	34,1	132,7	**0,257 mm/year**
14	36,7	153,9	**0,238 mm/year**

Table 2. Average expected rate of penetration of various FMTPJ head sizes into ultra high molecular weight polyethylene.

The wall thickness of the cup limits the depth of penetration. It is therefore possible to estimate when the head will penetrate the cup wall. The wall thickness (W) is related to the outer diameter of the cup (D) and the inner diameter of the cup (d) by the equation

$$W = \tfrac{1}{2}(D - d) \qquad (6)$$

If t is the time it takes for the head to penetrate the wall, and L is the annual wear rate then

$$W = t.L \qquad (7)$$

which can be rearranged to

$$t = \frac{D - d}{2L} \qquad (8)$$

This gives an estimate of the expected life of the cup for any combination of head and cup sizes. Substitution of the appropriate values allows the expected life of the cup to be determined [Table 3]. The optimum cup life occurs when the head diameter is half the cup diameter; however by increasing the cup diameter a longer cup life is possible.

Head size (mm)	Average time prosthesis for head to penetrate cup wall			
	18 mm cup	20 mm cup	22 mm cup	24 mm cup
6	10,8 years	12,6 years	14,4 years	16,2 years
7	11,5 years	13,6 years	15,7 years	17,8 years
8	12 years	14,4 years	16,8 years	19,2 years
9	**12,1 years**	14,8 years	17,5 years	20,2 years
10	12 years	**15 years**	18 years	21 years
11	11,5 years	14,8 years	**18,1 years**	21,4 years
12	10,8 years	14,4 years	18 years	**23,4 years**
13	9,7 years	13,6 years	17,5 years	21,4 years
14	8,4 years	12,6 years	16,8 years	21 years

Table 3. Estimated average time for FMTPJ prosthesis head to wear through cup wall.

The penetration of a head can be considered excessive if the head is smaller than 7mm or bigger than 12mm. The penetration of a 8 mm head is more satisfactory, but its long term prospects are poor. The difference in performance of a 10 mm head and a 12 mm head is less pronounced. Considering that the assumption of a linear volumetric wear rate is based on an equation that is extrapolated beyond the range of the original data; these values should only be seen as accurate within an order of magnitude.

4.4.5 STEM AND PEG FIXATION

Implant fixation is one of the most important considerations that influence the longevity of artificial joint replacements Biological fixation or bone ingrowth is sometimes used as an alternative to the more common and traditional cemented fixation. However, the long-term results of this method are not always promising. The difficulties of manufacturing such implants effectively prohibited their consideration for a prototype, but the warnings by Charnley (1967) that the non-reactivity of bone cement with the bone is, in fact, a desirable quality, was heeded. Cemented implants are also more adaptable as they can be inserted into a wider range of bone sizes and shapes. The MT and phalangeal cortices are relatively thin, which makes non-cemented fixation in the hallux a delicate procedure, and one that is best avoided.

The position, size and shape of the phalangeal intramedullary peg and MT stem are constrained by the shapes of the bones. After reaming the canal and providing for a cement layer, there is little practical choice as to the cross-sectional size of the stem. The MT-stem needs to have a square cross-section so that it can resist the supination-pronation torque's acting around its long axis. The corners need to be chamfered to reduce the stress concentrations in the cement mantle. However, if the stem cross-section is made too round, the prosthesis may not be able to transfer the supination and pronation torque's between the prosthesis and the bone without rotating within the cement mantle. The stem also needs to taper proximally towards its tail to assist in compressing the bone cement during insertion.

The phalangeal peg was designed with a triangular cross-section tapering to a distal point. This was done because the 3-D profile of the medullary canal of the phalanx is roughly triangular. The added strength at the peg/cup juncture was also considered a desirable feature to prevent fracture at this critical location. However, with repeated cyclic loading, a tapered peg might work itself loose and migrate proximally out of the cement mantle. Therefore the peg was designed in the shape of an inverted "T-section" instead of triangular. Not all of the surfaces of a "T-section" are tapered, which encourages a rigid fixation because the peg would be keyed into the cement [Figure 33].

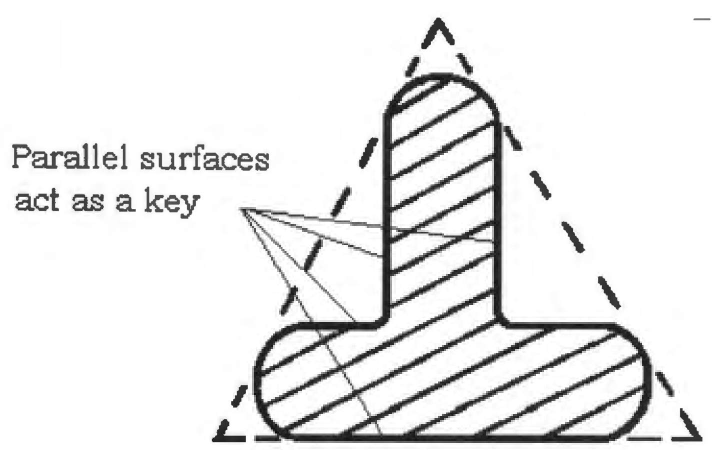


Fig. 33. Cross-section of socket peg.

Notches that have been machined into the sides of the stem and peg are common features of the existing range of cemented FMTPJ prostheses; it is likely that these notches were introduced to help prevent the stems from migrating out of the cement mantle. However, the prototypes under development here were designed without notches, primarily because of the "T" shaped peg design made them unnecessary, and they may complicate any arthroplasty revision procedure in the relatively thin and delicate bones.

4.4.6 RANGE OF MOTION

The design features which physically determine the range of motion of the prosthesis are the relative shapes of the neck and the cup face. From an engineering point of view it is wise to ensure a compressive axial force across the whole cross-sectional area of the metatarsal, so that cyclic fatigue cracks can be avoided. To achieve this, the centre of the head must fall within the cone formed by projecting the neck forward.

However there is a limit on the maximum size of the neck because neck size is one of the factors that constrains the range of motion. The critical area of concern is the region between the neck and the cup face that is adjacent to the head. Another constraint on the range of motion, is the possibility of the components dislocating. There are various ways a prosthesis may dislocate [Figure 34].

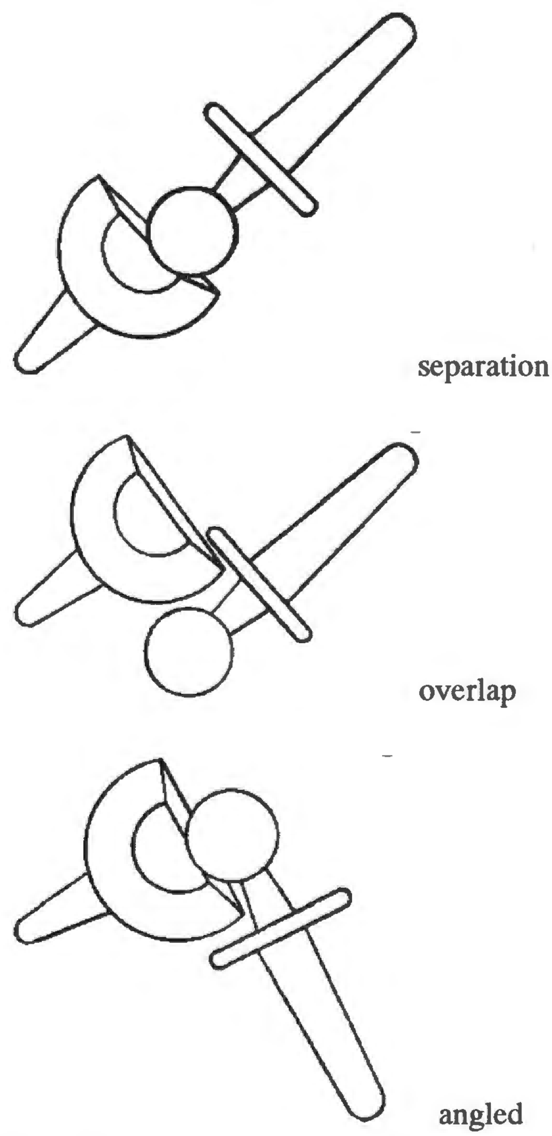


Fig. 34. Modes of dislocation in ball-and-socket prostheses.

Design features which influence joint dislocations are the size of the head, the articulation of the neck with the cup wall, and the configuration of the collar.

The probability and effect of dislocations can be reduced by either:-

Deepening the cup by raising the inner rim or cutting back the outer rim.

Broadening the seat by angling the face or raising the outer rim.

Providing a collar to prevent the components from slipping past each other.

Shaping the collar or shaping the outer rim to prevent angular dislocation.

Any dislocation must involve a proximal displacement of the head. This can be countered by either recessing the head deeper into the cup, or by raising the inner rim of the wall relative to the outer rim. Component separation occurs when the bones are pulled apart, but is more likely to occur when the head is levered out of its seat in hyper-extension or hyper-flexion. However, component separation is considered unlikely, firstly because FMTP joint-space shortening invariably occurs after resection arthroplasties, and secondly because Charnley (1967) found that the strength of the reformed fibrous capsule was more than adequate to prevent the separation of even small diameter heads in the hip. Considering that there is a very high proportion of fibrous structures in the hallux; a strong fibrous capsule will develop around the FMTPJ prosthesis, and the components should not separate unless they are levered apart.

As to the size of the head, the bigger it is, the further it needs to move before it can vacate the cup; but the bigger the head the more the encapsulating fibres stretch when the joint articulates In the hip this is seen as undesirable, because the fibres tug at the cup causing it to rotate within its bony bed. However, the role of the hallux is different from that of the hip. In the hallux, tension in the aponeurotic fibres naturally raises the MT-head, therefore stretching of the fibres in extension may actually be an advantage. However, this must be balanced against increasing the stresses at the socket/bone cement interface. The relative influence of these factors can only be assessed through *in vivo* experience.

Angular or lateral dislocation is seen as a greatest danger because the neck must sooner or later impinge on the cup in hyper-extension, resulting in the head being levered out of its seat. The mechanics of this type of dislocation are such that when the stem is subjected to an axial reducing force while the head is out of the cup, the components will move together until the collar contacts the cup. At this point, the head dislocates laterally as the collar literally rolls around the outer spherical surface of the cup. Since the possibility of the neck impinging on the cup's outer-rim cannot be excluded, the cup/neck and cup/collar interfaces need to be designed to prevent the stem subluxing.

By machining flats on the outer sphere [Figure 35] the rim becomes concave rather than convex at the point of contact with the neck–hence the stem does not roll laterally under compression. Sufficient space exists for a flat to be machined on the superior, lateral and medial surfaces of the cup, but not inferiorly because of the ridge. Unfortunately cutting away material from the cup sides undermines the strength of the cup wall, which is bound to reduce the life-span of the socket.

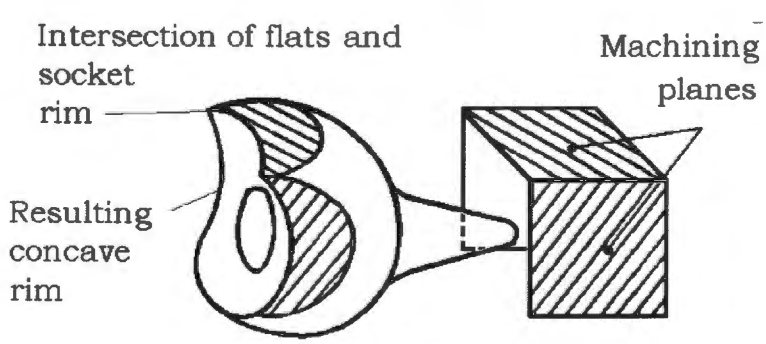


Fig. 35. Flats machined on cup sides to contain dislocations of the neck.

A disadvantage of flat cup sides is that problems may develop when the stem is positioned over the high point created by the intersection of the flats and the cup rim. Acute dislocation is most likely to occur in hyper-flexion. For example if the patient trips or stumbles, there is a possibility that the MT-component might relocate laterally on the wrong flat, rotating the hallux through 45° very similar to pathological hallux valgus. It is therefore believed to be preferable to maintain the spherical shape of the cup rim and to concentrate on the design the collar to prevent dislocation.

Angular dislocation is really synonymous with closing the space between the collar and the cup on one side, while opening it on the other. Therefore angular dislocations can be contained if the gap between the collar and cup can be kept open. This can be achieved by the curving the collar into a "pincer" shape. Solid contact between the cup and collar will keep the head directly above the seat, so that when the joint is reduced the head will slip back into the cup rather than slipping off to the side.

An advantage of a collar becomes apparent at the limits of flexion and extension, i.e. when the stem is parallel to the face of the cup. With no collar, there is little to constrain the components in an axial direction. However, with a collar overhanging the cup, dislocation is prevented by physical interference of the components. The disadvantage of the collar is related to wear. If the collar is fitted with too close a tolerance to the outer cup wall, wear of the seat will gradually displace the stem axially until the collar edge contacts the face of the cup. To prevent this, the neck of the stem must be made longer–chamfering the outer rim also helps. Importantly the former involves resecting about 5 mm more bone from the metatarsal than might normally be considered necessary at the time of surgery.

To maximise the range of motion the neck should rest flush against the cup face at in both the fully extended and fully flexed positions. This was not found to be a constraining factor for either the 10, 11 or 12 mm head. However, it was found that the cup wall needs to be chamfered on the inner rim to prevent impingement if the head size is 8 mm or smaller; a 9 mm head may impinge once wear has deepened the seat.

4.4.7 SOFT TISSUE REATTACHMENT

Due to the space constraints the proximal attachments of the capsule and the ligaments may need to be sacrificed; i.e. provision might need to be made for the reattachment of certain soft tissue fibres. The experience of Charnley (1967) was that a strong fibrous joint-capsule reforms around the components in the hip, that it prevents the dislocation of the components; because of this no artificial attachments may be necessary.

Swanson (1972) recommended the drilling of a small hole in the phalanx to reattach the capsular flap after inserting a silicone prosthesis. Unfortunately with a ball-and-socket design the FMTPJ capsule would need to be released proximally, necessitating that it be reattached to the MT-shaft. This is practically impossible because the bulk of bone stock has been resected. Holes were therefore drilled in the prototype collar to evaluate the possibility of attaching the capsular flap to the prosthesis itself if necessary [Figure 36].

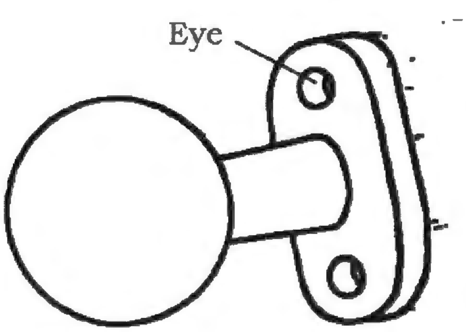


Fig. 36. Eyes in the collar for the reattachment of the capsule.

Eyes were also machined into the medial and lateral sides of the prosthesis cup so that new fibres could grow through the loops, or the old capsule could be sutured in place to assist recuperation [Figure 37].

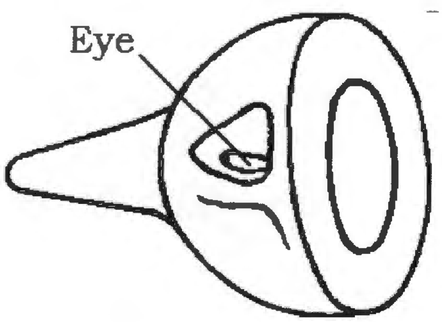


Fig. 37. Eyes in the cup wall for the reattachment of the ligaments.

4.5 PROTOTYPE SPECIFICATION

Having assessed various combinations of head and cup sizes; the best configuration can be determined for each specific constraint. The optimum head sizes for the various configurations of cup sizes are summarised in Table 4. The constraints are listed in order of importance, with the acceptable range of head sizes given in parentheses.

DESIGN CONSTRAINTS	OPTIMUM HEAD DIAMETERS REQUIRED TO SUIT STANDARD CUP SIZES			
	18 mm cups	20 mm cups	22 mm cups	24 mm cups
1. Wear–durability	9 mm (±1 mm)	10 mm (±1 mm)	11 mm (±1 mm)	12 mm (±1 mm)
2. Frictional torque	8 mm (or smaller)	9 mm (or smaller)	10 mm (or smaller)	11 mm (or smaller)
3. Bearing pressure (max.)	11 mm (9-11 mm)	11 mm (9-11 mm)	11 mm (9-11 mm)	11 mm (9-11 mm)
4. Range of motion	10 mm (or larger)	10 mm (or larger)	10 mm (or larger)	10 mm (or larger)
Optimum Solution:	**9 mm** (9-10 mm)	**10 mm** (10-11 mm)	**11 mm** (10-11 mm)	**12 mm** (11-12 mm)
Standard head size	**9 mm**	**11 mm**	**11 mm**	**11 mm**

Table 4. Summary of suitable FMTPJ head dimensions for various cup sizes.

The prototype head sizes were specified at the maximum and minimum limits, because this was most likely to expose any design flaws. Therefore an 8 mm head was specified for the smallest MT-component, and a 12 mm head for each of the other two prototypes.

Three different designs of socket, and three designs of metatarsal components were manufactured in order to test the viability of various features [Table 5].

PROTOTYPE:	DESIGN 1	DESIGN 2	DESIGN 3
Head size	12 mm	8 mm	12 mm
Cup size	24 mm	20 mm	22 mm
Socket backing	none	none	metal
Cup face	flat	dished	flat
Sesamoid ridge	no	yes	yes
Dislocation constraint	"pincher" collar	3 flat cup sides & flat oval collar	outer rim chamfer & "pincher" collar
Capsule reattachment	none	none	collar eyes & cup eyes
MT-stem shape	5 mm rectangular stem tapers to 3mm	5 mm rectangular stem tapers to 3mm	5 mm rectangular stem tapers to 3mm
Socket peg shape	Large tapered T	Short tapered T	Tapered triangular

Table 5. Prototype specifications.

The particular combinations of features and head sizes included in the different prototypes were selected to suit the capacities of the available machine tools and other manufacturing facilities. All the MT-components were made from stainless steel and the sockets from high density polyethylene. For the prototypes only, the polyethylene cups and the pegs were manufactured separately. Due to the wall thickness of the smallest cup, the peg was fixed to the cup with brass screws for maximum bond strength; the larger peg was manufactured with a stud on the end that was pressed into a locating hole in the 24mm cup. The metal backing cup was machined out of a single piece of metal. The cup was located by pressing a small polyethylene stud into a recess in the back of the metal casing. Scale drawings of the prosthesis are given in Figure 38.

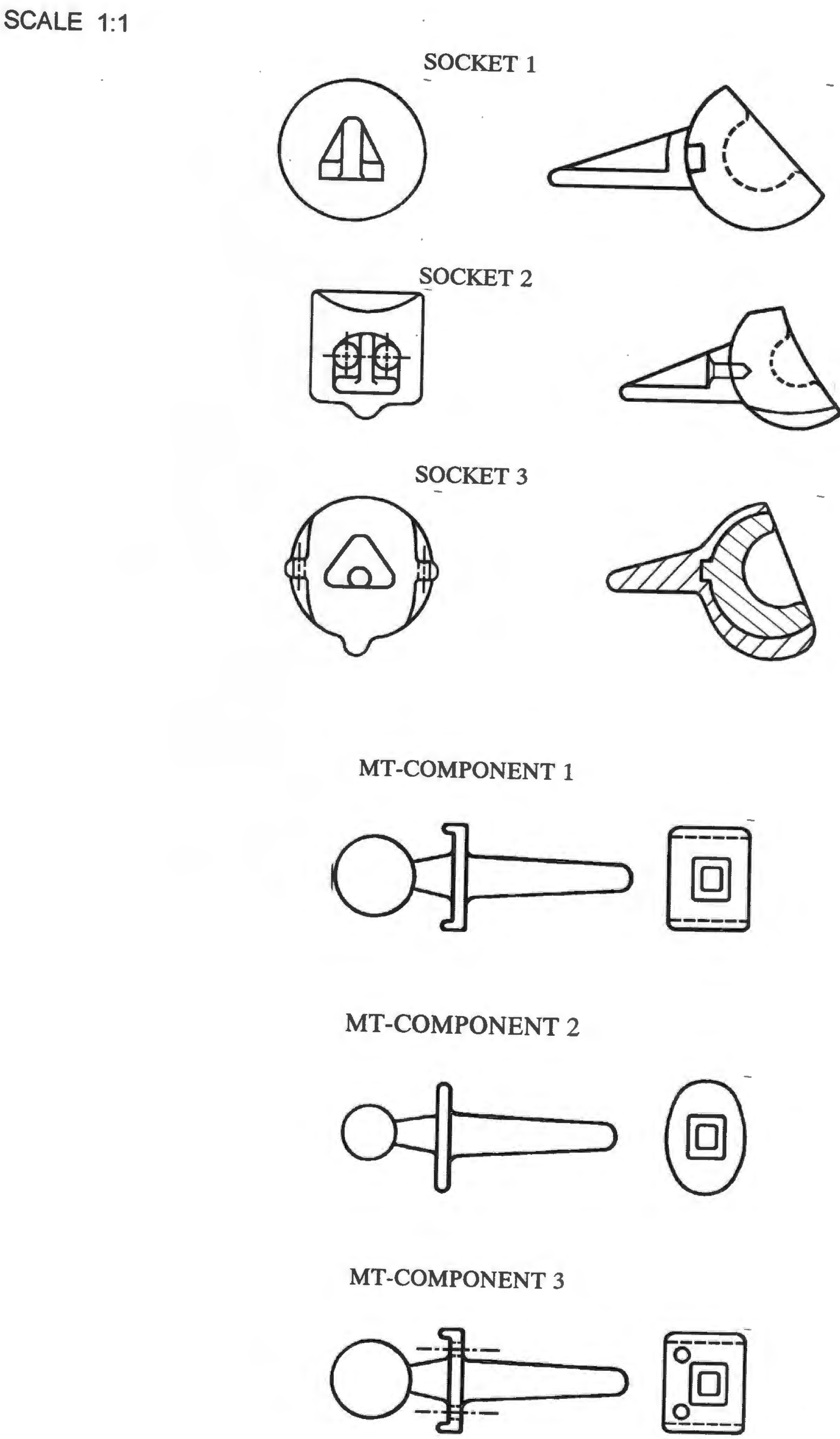


Fig. 38. Full scale drawings of prototype FMTPJ prostheses.

CHAPTER 5
CADAVER TESTS AND RESULTS

5.1 AIMS

The objective of testing the prototype prostheses in cadavers was to determine whether a ball and socket is an appropriate articulation for the FMTPJ. Firstly, it was necessary to determine whether the motion of a cadaver specimen conforms to the pattern of motion of the metatarsal predicted from the dry bone specimens. Secondly, it was necessary to determine whether the prototype prosthesis restores the normal pattern of motion of the joint in a cadaver. Finally the pattern of the motion was compared to that produced by a Swanson double-stem prosthesis to establish whether or not the new design was an improvement over existing implants.

To achieve these objectives, the following data was collected:

(1) pre-insertion pattern of motion of a cadaver's FMTPJ.

(2) post-insertion pattern of motion of the same cadaver's FMTPJ after inserting a prototype ball-and-socket prosthesis into the joint.

(3) post-insertion pattern of motion of the FMTPJ after inserting a Swanson flexible silicone hinge prosthesis into a joint amputated from the cadaver.

Besides using the cadavers for FMTPJ motion tests, the cadavers simultaneously served as material for the development of the surgical procedure and instruments necessary to insert a ball-and-socket prosthesis, the results of which are presented in Chapter 6. A variety of feet with different deformities were used with the objective of gaining as broad an insight as possible into the difficulties likely to be encountered by the surgeon. The preferred approach was to address potential problem areas rather than seeking statistical repeatability on one or two issues. This multi-faceted approach was in part necessary because of the broad scope of the design, build and test mandate; the under-researched nature of the biomechanics of the FMTPJ; the limited number of cadavers available for the experiments and the fact that the cadaver tissues were fixed in different postures.

5.2 METHOD AND MATERIALS

5.2.1 CADAVERS

Five feet from four cadavers were used for the testing. One cadaver was a female with a minor hallux valgus deformity in one foot, the opposite foot being of normal appearance—both of these feet were used. The other cadavers were a female without any foot deformity; and two others, a male and female, both with hallux rigidus and callosities under the lesser metatarsal heads The last cadaver was used to develop the surgical technique, but no motion tests were performed on it because the weak cadaveric bone fractured badly.

5.2.2 APPARATUS

The apparatus for measuring the motion of the cadaver FMTPJ was in principle similar to the apparatus that was used to measure the articulations of the dry bones [Section 3.2]. However, certain modifications were made to accommodate a cadaver foot:-

- The apparatus was mounted on adjustable legs that could tilt the base up to 45°.
- Shaped stainless-steel plates were used to clamp the wet bones onto the mountings.
- The phalanx was clamped to a shaft that was connected to a universal joint, which permitted the proximal phalanx to rotate in any plane, or around any axis.

The phalanx was clamped in such a manner that the long axis of the phalanx coincided with the center of the universal joint. The phalanx's rotations were measured by attaching pointers to the axles of the universal joint; rotations of the phalanx in the lateral plane were converted directly to two-dimensional displacements of the transparent reference grid by allowing the pointers to trace across scales fixed perpendicular to the axles. Vertical motion relative to the baseboard was absorbed by mounting the universal joint in a rectangular channel so that it could slide up and down without altering its co-ordinates relative to the measurement plane [Figure 39].

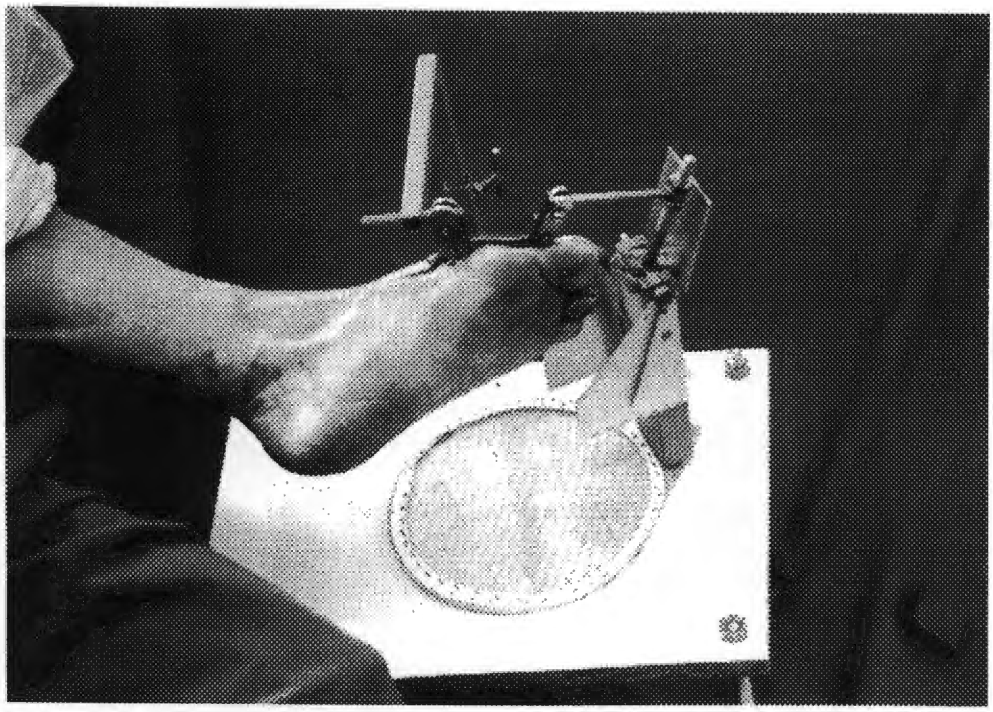


Fig. 39. Cadaver FMTPJ motion-test apparatus.

5.2.3 TEST PROCEDURE

The cadavers were placed supine with the lower leg, supported at the calf, protruding over the table edge [Figure 39]. The abdomen of the cadaver was then tilted so that the metatarsal was roughly horizontal. The measurement apparatus was arranged on another table placed beneath the protruding leg. A 10 cm incision was made medially through the skin of the foot superficial to the joint. The soft tissues were carefully retracted from the shafts of the metatarsal and phalangeal bones, taking care to preserve as many of the fibrous attachments as possible. The stainless-steel clamps were inserted through the incision and clamped around the shafts of the bones. The inclination of the baseboard of the measurement apparatus was adjusted to conform to the alignment of the long axis of the metatarsal. The clamps, which were already in position on the MT-bone, were positioned on the MT-bracket and the locking screws tightened so as to rigidly fix the MT-bone to the apparatus base.

Two perpendiculars were projected from separate positions on the metatarsal by using two right-angle set-squares—placed edge-on to each other and the baseboard—and abutting them against the skin of the hallux. The positions of the peak of the arch and the proximal intersesamoid ridge were physically marked on the baseboard as in section 3.2. However, due to the thickness of the mass of skin over the sesamoid complex, the exact co-ordinates of the sesamoids could only be estimated to within ±5mm of the actual location of the sesamoid ridge.

The transparent grid was placed flush on top of the markers, and the phalanx clamped to the free-floating bracket. The cadaver's phalanx was then manipulated so the transparent reference grid moved in unison with the bone. The co-ordinates of the metatarsal were recorded as their markings appeared beneath the transparent phalangeal reference grid. These positions were later plotted graphically so that the motion of both ends of the metatarsal could be visualised with respect to the phalanx. The arc scribed by the locus of the markers was compared to the equation of a circle by using an iteration algorithm, which was used to determine the best fit center and radius [see Appendix D].

Each test consisted of first extending the joint to the maximum limit permitted by the cadaveric tissues, then flexing it to its limit. The apparatus was reset to the neutral position after both the flexion and extension movements; enabling any hysteresis in the apparatus to be noted. The test was repeated twice, making a total of three tests per joint configuration. An appropriate prosthesis was inserted and three more range-of-motion tests were conducted. The data from each test was recorded along with the apparatus settings. Appendix E contains an example of the data recorded for one test. In total 34 tests were successfully completed on four feet—15 inside cadavers and 19 on specimens amputated from them. 10 of the tests conducted in the cadavers were to establish their normal range of motion, 2 were on a ball-and-socket prototype inserted into a hallux valgus joint and 3 were to establish the motions after a Keller resection. Bone fractures prevented more tests being performed on the prototype prostheses, which meant that some joints had to be amputated and tested outside the cadavers [Figure 40]. Amputated joints were used only if a prosthesis could not be inserted; either because the bones had been irreversibly damaged during the previous test, or in the case of the Swanson prosthesis, when it proved completely incapable of withstanding the normal forces in the cadaveric joint. Of the amputated joints, 12 tests involved Swanson prostheses, 4 prototype prostheses, and 3 tests were on a joint with an intact capsule but without any other attachments. Six tests of the tests that were planned for prototype prostheses in the cadavers produced no data due to the bone fractures. The full test programme is given in Appendix F.

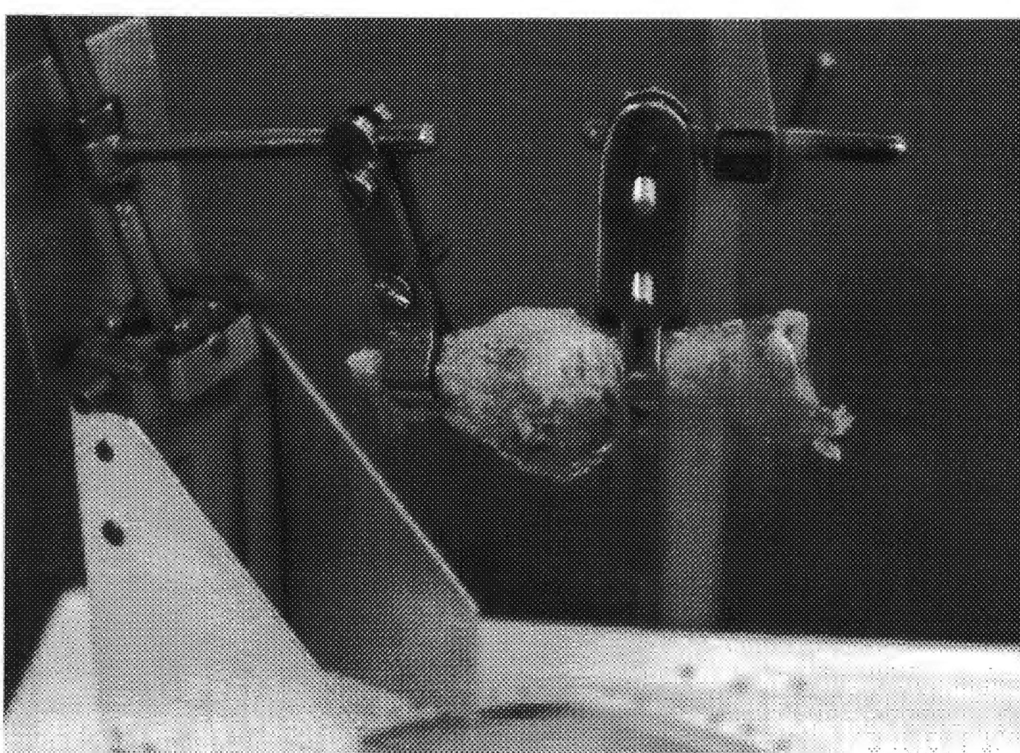


Fig. 40. Amputated joint in motion-test apparatus.

5.3 RESULTS

5.3.1 METATARSAL MOTIONS

The locus of the superior portion of the metatarsal and the locus of the inferior metatarsal head were plotted in the lateral plane [Figures 41–43]. The results are all individual tests were compared to enable any characteristic trends to be identified. Firstly, the pattern of motion for a normal joint was established. Figure 41 compares the motions of three normal cadaveric joints and a hallux valgus joint with a prototype ball-and-socket prosthesis. A characteristic of these results is that the centers of rotation of the different ends of the MT are widely separated (i.e. about 30–40 mm apart), with the center of rotation of the proximal end lying superior to the phalangeal axis.

Figure 42 shows how the motion differs, depending on whether the joint is measured inside the cadaver or as an amputated joint. All the test results in Figure 42 are from the same cadaver using identical apparatus settings for each test. The objective of this series of tests was to establish how the cadaveric attachments affect the motions of a joint. By using the same joint surfaces for all the tests, the differences in the motion that did occur can only be ascribed to the various attachments rather than the shapes of the bones.

It can be seen that there is little difference in the motions of the new prototype prosthesis, a Swanson prosthesis or the intact capsule when measured outside the cadaver. However, there is a large difference between the results depending on whether they were made inside or outside the cadaver. The main difference between the motions of the joint with and without its cadaveric attachments, is the separation of the centers of rotation of the proximal and distal ends of the metatarsal. Another difference is that the motion of the sesamoid reference point in a cadaver produces a cluster of data points at the MT-head rather than the more circular locus seen in all the amputated joints.

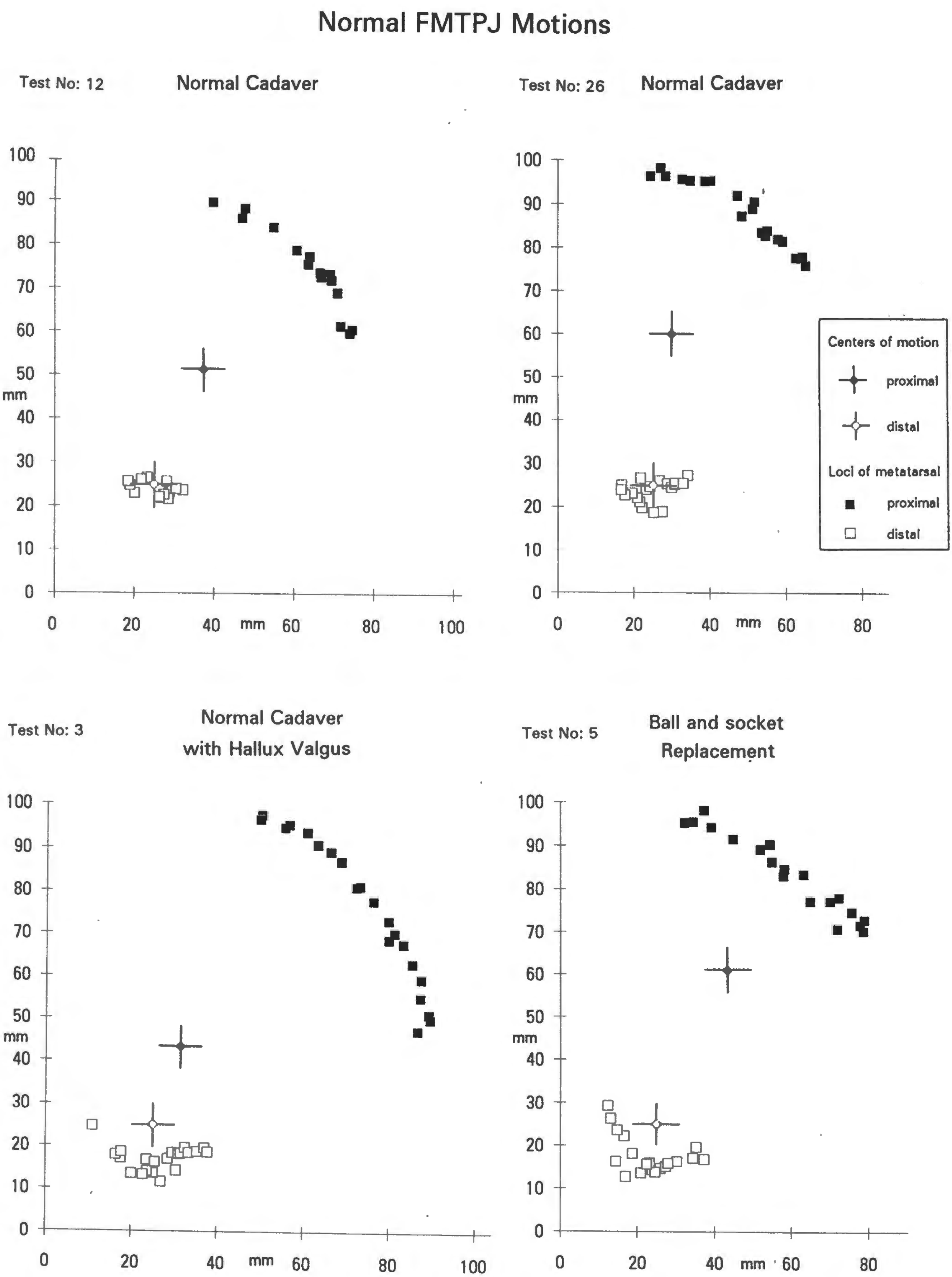


Fig. 41. Motions of the first metatarsal in normal cadavers.

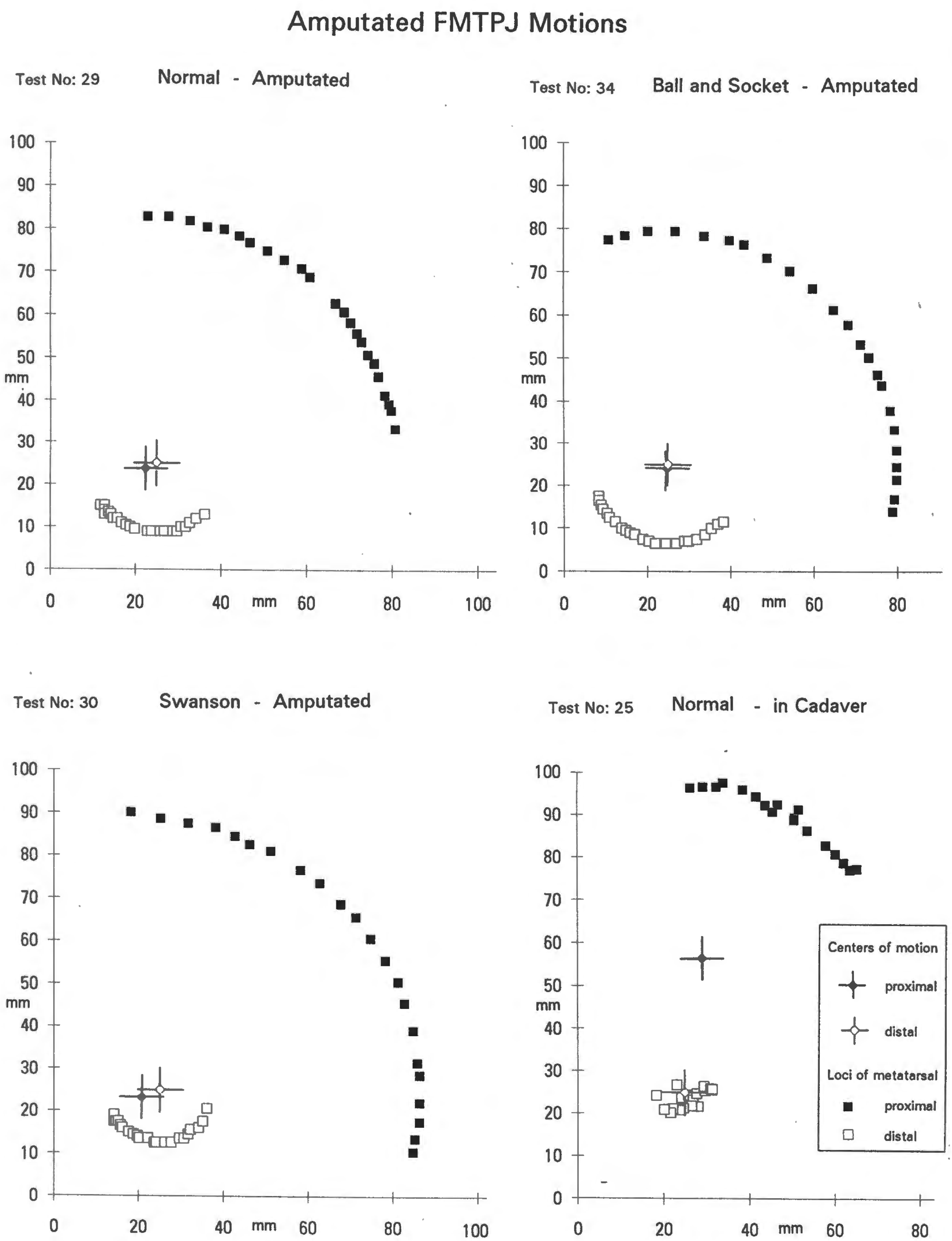


Fig. 42. Motions of different prostheses compared to the motions of the same joint with and without the plantar cadaveric attachments.

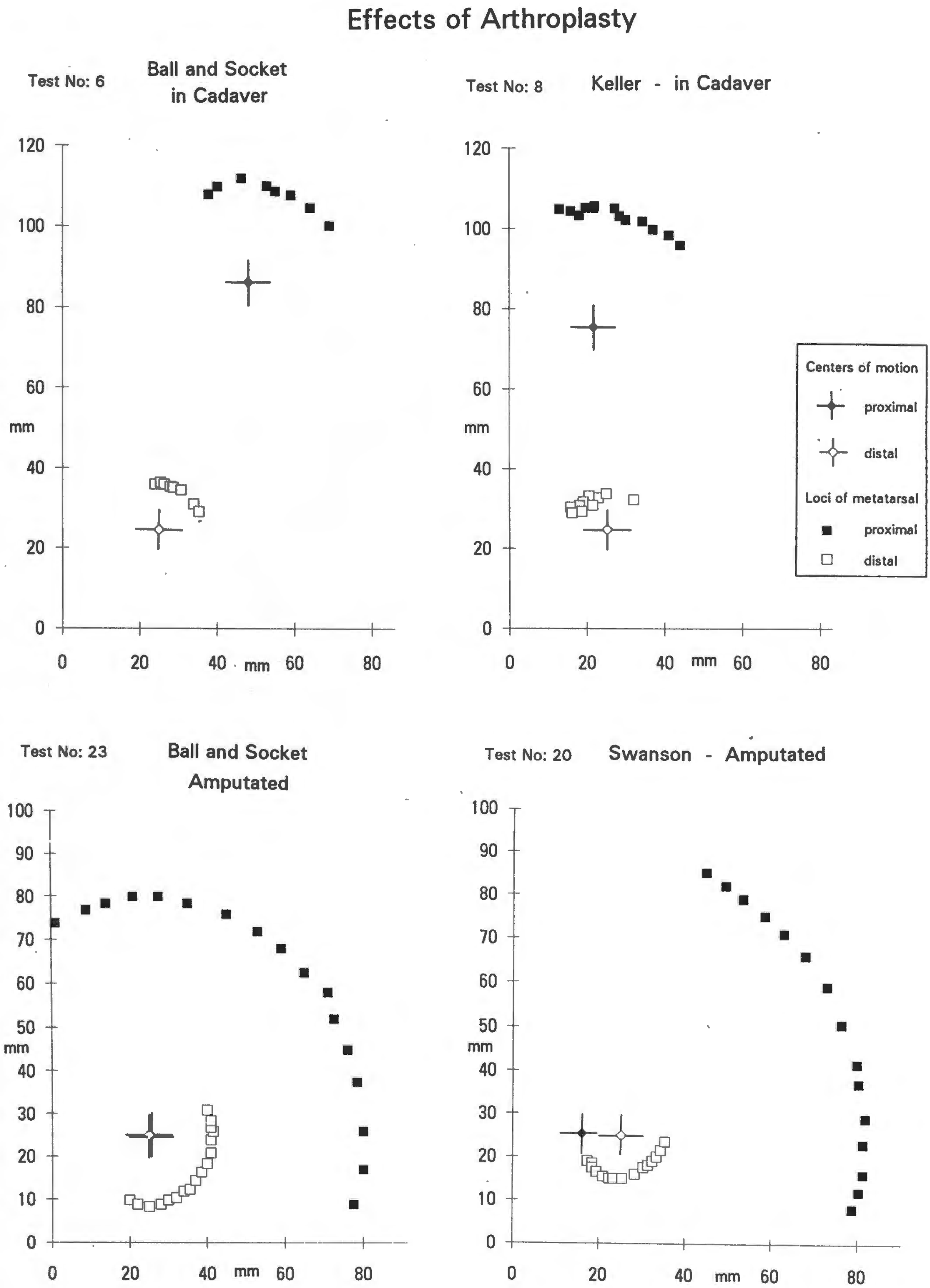


Fig. 43. Metatarsal motions after Swanson, Keller and prototype ball-and-socket arthroplasties.

Figure 43 compares the effects of various arthroplasties: Figure 43a shows the motions produced by a ball-and-socket prototype in the hallux valgus joint. This can be compared to the motions that occur after a Keller procedure [Figure 43b] or after the cadaver soft tissue attachments have been removed [Figure 43c] or with a Swanson prosthesis [Figure 43d]. Certain observations can be made:

Firstly, the results of the ball-and-socket prototype and Keller procedure are similar in that the center of proximal rotation is superior to the phalangeal axis, and that the distal locus is superior to the center of rotation of the phalanx. The positioning of the distal locus of motion superior to its center of rotation is, however, due to the assumptions of the algorithm that the motion is circular. The fact that the locus has a reverse curvature is a result of the MT-head being depressed as the hallux was extended. The unusually wide separation of the centers of rotation (i.e. 50–65 mm) is due to reverse curvature of the motion; as the curvature of the locus approaches a straight line, the center of motion cannot be defined, which causes a mathematical discontinuity at that point.

The motions of the other two prostheses were measured in amputated joints. A characteristic of the Swanson prosthesis is that the center of rotation of the proximal end is displaced towards the distal tip of the hallux [Figure 43c], which was discovered to be a characteristic seemingly peculiar to that type of prosthesis. Finally, the center motion of the ball and socket coincided with that of the ball when the motion was confined to one plane [Figure 43d].

The results of individual tests are presented to highlight the difference between the motions of the MT when tested under different conditions. Where more than one test was done on the same joint, the median position of center of rotation is presented. However, the results from all the tests are combined in Figure 44 overleaf (the loci of the motions have been omitted). The displacements of the proximal centers of rotation of all the arches were compared relative to the center of rotation of the MT-heads. By using the center of rotation of the metatarsal head from each test as the fixed origin of motion, the centers of rotation of all the arches can be compared on the same reference axes [Figure 44].

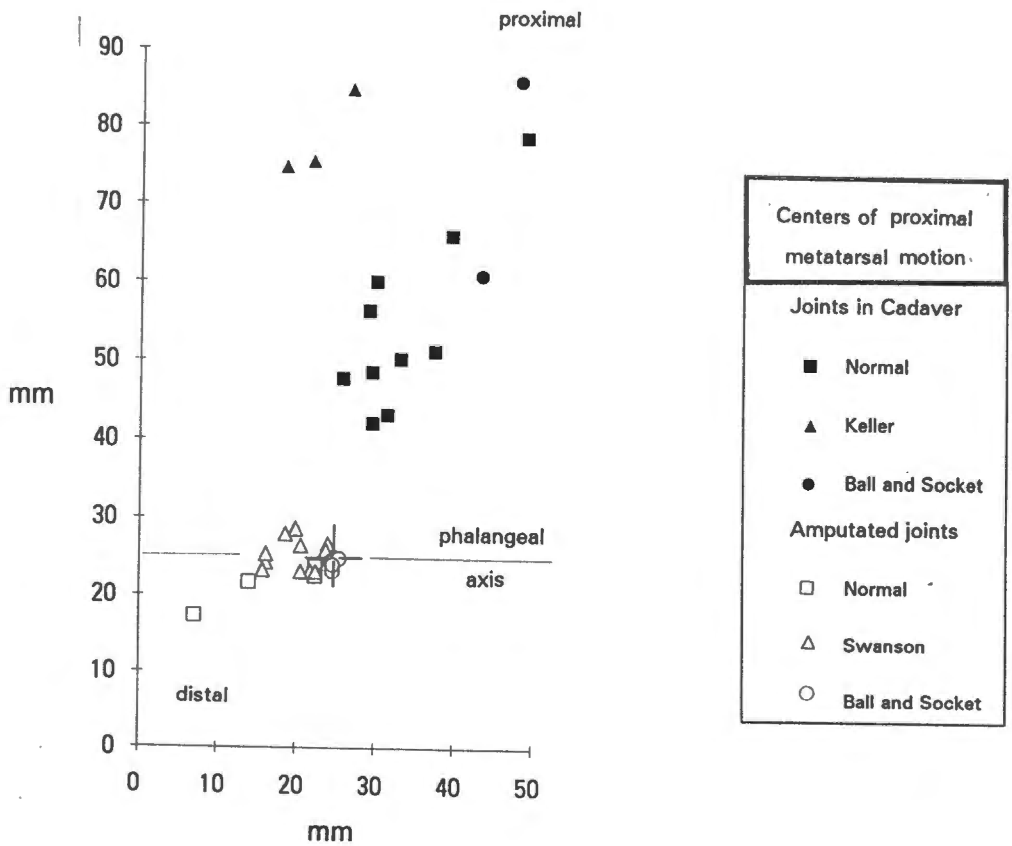


Fig. 44. Relative centers of rotation of the superior portion of the arch of the foot compared to the centers of rotation of the FMTPJ joint.

On close inspection of the combined results [Figure 44] it can be observed that the center of motion of the arch can be seen to occur in a number of different locations in the foot. The location appears to vary according to the conditions under which the measurements were made. For example, the natural cadaveric joints (the black markers in Figure 44) all exhibit an elevated center of rotation for the arch. Normal joints all have a proximal center of rotation that is to be found superior to the MT-axis at the resting position. The Keller joint lies directly superior to the center of the MT-head; and the ball-and-socket prosthesis on the same axis as the natural joint but more proximal to the ankle. The centers of rotation of the arch of amputated joints (the white markers in Figure 44) all lie near to the phalangeal axis; those of the Swanson prostheses are grouped together about 1 cm distal to the center of the FMTPJ; those of the ball-and-socket prototypes coincide with the center of the joint; and those of the amputated FMTPJ lie a few millimetres distal to the center of the FMTPJ.

5.3.2 RELIABILITY AND REPEATABILITY

The primary limitations of using cadavers as research material was related to the poor mechanical properties of the preserved tissue. This meant that experiments could not be repeated because damage to the tissue attachments was irreversible. There were other limitations, for example besides the natural anatomical variations differences between the cadavers, each cadaver was also fixed in a different posture. The apparatus settings therefore had be altered to suit the cadavers and not vice versa. This was not a trivial issue because it meant that the alignment of the apparatus and the bones could not be duplicated in consecutive tests, and hence a degree of experimental control had to be forfeited.

The number of confounding variables was, however, reduced by carrying out a range of different tests on the same joint. For example the joint was first tested in its natural state inside the cadaver, then a prosthesis was inserted and the tests repeated on the same cadaver. This method minimised the effects of natural variations in anatomy between subjects. However, considerable variability in the raw data was expected due to fact that the bones had to be set-up differently for each cadaver. Trigonometric correction factors were therefore necessary to calibrate the movements of the bones with the movements of the measurement scales [see Appendix G].

The aims of the experiment required that the measurement be passive in nature; i.e. it was essential that the apparatus measure the natural motions of the joint without providing fixed constraints for the motion. Therefore the phalanx was minimally constrained; i.e. the phalanx was attached to a reference grid that was constrained only in the sagittal plane. The combined effect of the variations in the set up positions, the anatomy, and the single constraint to motion, dictated that there was no common physical reference point or bony landmark that could be used to orientate the bones. Hence a direct statistical comparison of one set of results with another was not possible.

The reliability of the results therefore had to be checked by analysing the errors between consecutive data points. For example, gross errors were detected by comparing the distance between the ends of the metatarsal readings at each sampling locality and the length of the hypotenuse between the original data co-ordinates [see Appendix G]. A continuous plot of the readings was made to check for step-like offsets in the data. The magnitude and direction of these variations were then compared to the apparatus calibration readings, and to the direction of the force that was being applied at the time. In this way, error in the data could be accounted for. Comparisons between each and every consecutive pair of readings was the only way of checking the validity of the results given the indeterminate nature of the problem. In total 559 pairs of readings were taken, but only 17 data points (3%) were discarded as being potentially unreliable, most of which were believed to be due to distortions in the photographic transparency used as the measurement scale.

The data was processed by an algorithm that calculated the center and radius of the motion [Appendix D]. Raw data, calibrated data, and data transformed to take into account hysteresis in the clamping arrangement, was used to generate a set of results for each test. The results from all of these methods were compared to determine the extent of the influence of the various variables. It was found that the calibrated data reduced the spread seen in the raw data; however, the data that had been transformed to take into account hyteresis in the clamps was found to be no more concordant that the calibrated data. This was believed to be due to the poor resolution of the parameters (±2 mm) that had to be used to estimate the unaccounted errors compared to the properly graduated scales that had been specifically designed to calibrate small (±0,1 mm) displacements in the apparatus. The calibrated data was therefore used for presenting the results.

In summary the magnitude of the errors and uncertainties were not found to influence either the findings or the conclusions of the experiment in any significant way. The fact that the data was found to insensitive to potentially significant variations in the apparatus alignment, provides reason to believe that the results are a consistent accurate reflection of the motions of the hallux despite the fact that direct comparisons between cadavers was not possible. The results show that there are distinct centers of motion for opposite ends of the metatarsal in a cadaveric joint and a cadaveric joint replaced with ball-and-socket prototype. This distinction, however, disappeared when the joints were amputated.

CHAPTER 6
SURGICAL ASSESSMENT

The assessment of the new prosthesis was approached from a number of perspectives. Aspects related to surgery are discussed in this chapter; the biomechanical performance to the arthroplasty is discussed in chapter 7. From the surgical perspective, the prosthesis was assessed in terms of the feasibility of the procedure, the difficulties likely to be encountered by the surgeon, and any special precautions that need to be taken into account due to the nature and severity of some of the deformities.

6.1 SURGICAL TECHNIQUE AND INSTRUMENTATION

The joint motion tests required that the plantar and dorsal fibrous attachments to the skin be preserved. Therefore the toe was approached through a direct medial incision sufficiently long to expose 3 cm of the MT- and phalangeal shafts. This approach was preferred to the usual dorsomedial incision in the foot because of the need to expose the bone shafts in a manner that least disrupted the fibrous connective tissues in the skin.

After testing the motion of the "intact" joint, a dorsal flap was made to expose the joint capsule. The capsule was released medially and the metatarsal head resected. Distally, a pilot hole was drilled into the tough base of the phalanx. The hole was enlarged by reaming the cortex with a conical burr. Care had to be exercised because the pointed tools could easily slip a centimeter into the phalanx's medullary canal and puncture the relatively thin cortex in the shaft, especially since the phalanx was being reamed to accept a triangular stem-shape.

Two instruments were designed to help the surgeon insert the prosthesis [Figure 45–46]. The one clipped on the neck of the MT-component, and the other clipped over the face of socket. Their handles were designed to be in line with the respective pegs and stems.

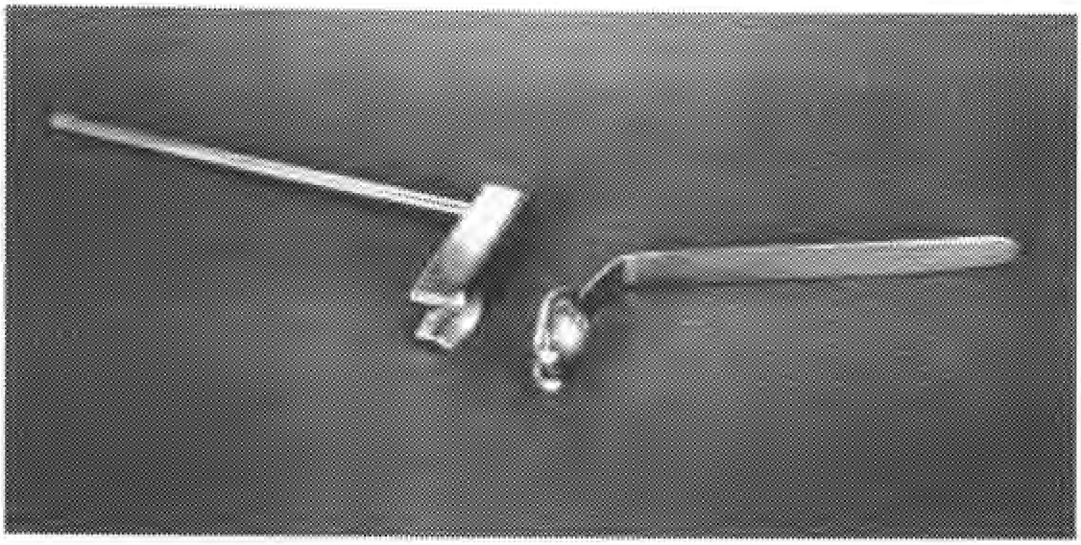


Fig. 45. Surgical instruments designed to insert the prototype prostheses.

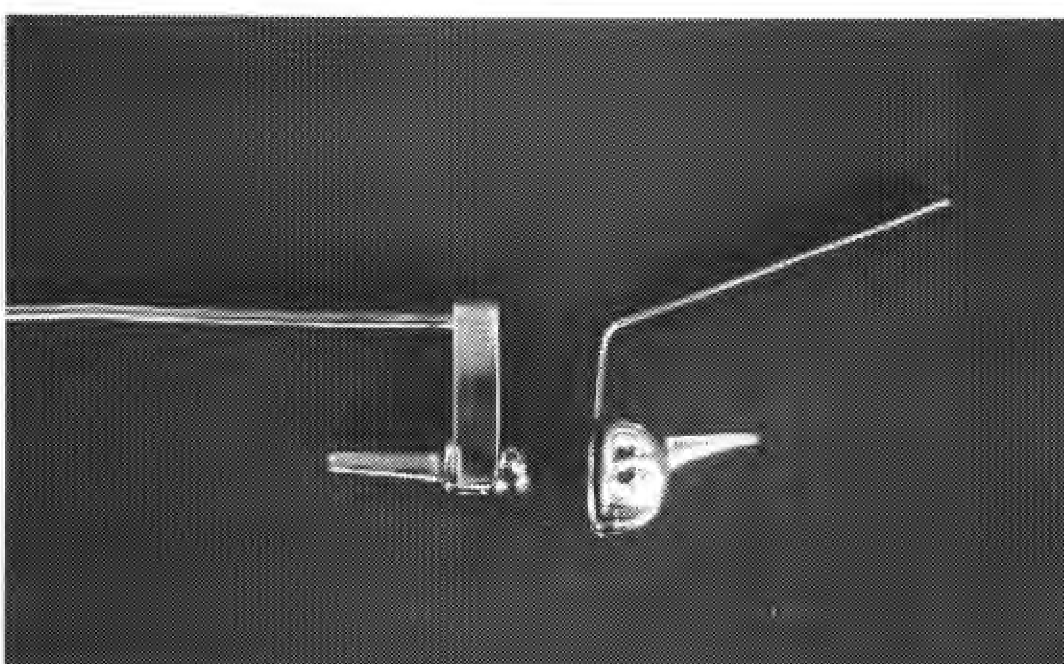


Fig. 46. Surgical instruments with metal-backed prosthesis in place.

Once the bone cement had been inserted, it was essential that the prosthesis could be speedily and accurately aligned and held in place while the bone cement cured. In practice the instruments were found to be essential for the speedy handling, insertion and alignment of the components. The long handles provided a good grip and the extra leverage permitted the surgeon to exercise a surprisingly fine control over the alignment.

A difficulty with combining the motion tests and surgical assessment was that in many cases the phalanx fractured due to the extraordinary pressure the clamps exerted on the bone. Clamping pressure needed to be maintained in order to prevent the clamps from slipping on the bone. Variables and a limited supply of cadavers dictated that a compromise had to be accepted between clamping pressure, bone damage, and the accuracy and repeatability of the measurements. Many of the cadaveric bones fractured; therefore a senior orthopaedic surgeon was called in to assess the viability of the surgical procedure by attempting to insert a prototype prosthesis into a cadaver [Figure 47].

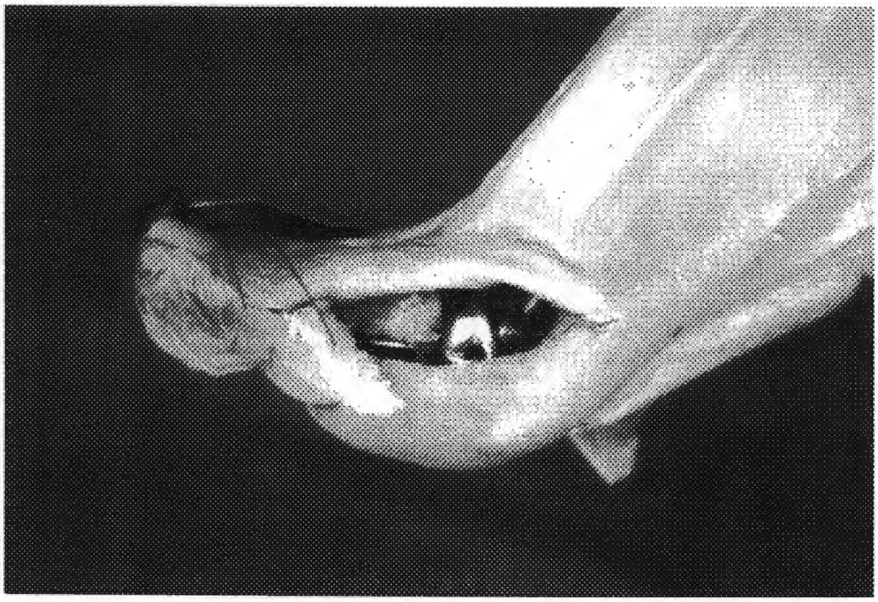


Fig. 47. Prototype prosthesis inserted into cadaver to evaluate the surgical technique.

The joint was not subjected to motion testing prior to the surgical assessment so as to avoid unnecessary damage to the bone. Despite the precautions, and despite the surgeon working diligently, the cadaver's phalanx fractured at its shaft. The senior surgeon's assessment was that the cadaver was far to stiff to allow adequate access to the joint. Surgical procedures and techniques that worked well in living patients apparently failed to achieve the same results in the cadaver. The main difficulty was in retracting the tissues and manipulating the bones due to the cadaver's thick leather-like skin. Difficulties arising from inadequate exposure to the joint are not new; as Charnley (1967) has previously pointed out, it is absolutely essential that both sides of the joint are accessible to the surgeon before he can be expected to perform effectively. Access in this case was restricted due to the lack of suppleness in the cadaver tissues.

Significantly, in the cadaver specimens without deformities, the bones did not break as readily under clamping pressure as did the cadaveric bones of deformed feet. The impression was gained that the bones in deformed feet were weaker, although no strength measurements were performed. It is possible that reduced load bearing under the pathological hallux, which has been demonstrated in numerous force-plate studies, may result in bone stock loss in the bony shafts due to chronic reductions in the pre-operative stress level. Bone stock loss may therefore be a contra-indication for ball-and-socket FMTPJ arthroplasties.

The viability of the procedure is dependant on the strength of the bone-fixation, which judging from the cadaver tests was extremely fragile. Due to its importance, some practical evidence was required that could confirm that conditions in living patients indeed differ from those in cadavers. A comparison was therefore made between the stem sizes of Swanson's double-stem prostheses—that are routinely inserted into living patients—and the size of the prototype stem and peg [Figure 48].

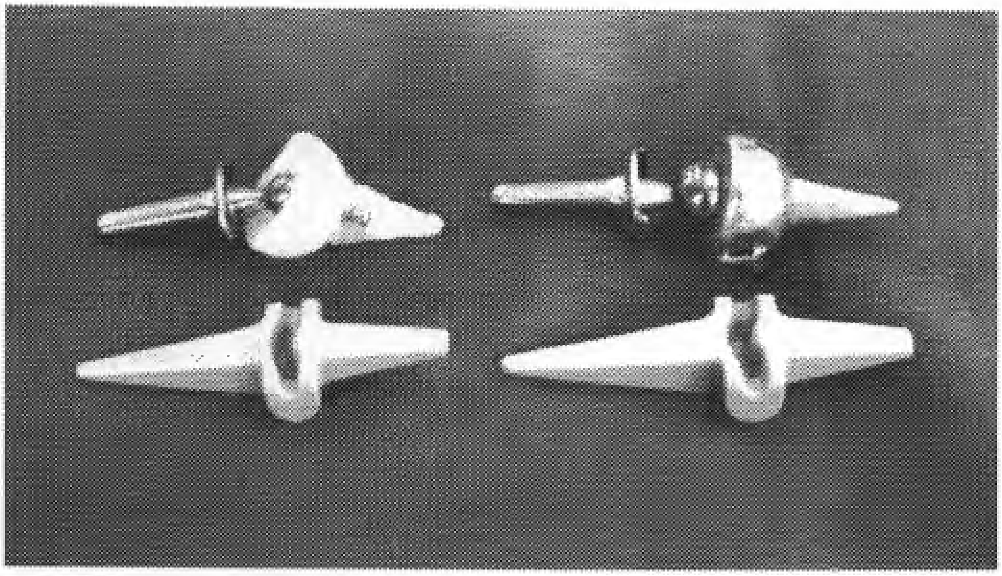


Fig. 48. Comparison between the sizes of the stem and peg of the prototype ball-and-socket prostheses and the stems of Swanson's No. 4 and No. 6 prostheses.

As can be seen in the photograph, the stems of Swanson's No. 4 and No. 6 prostheses require approximately the same size of hole to be reamed into the phalanx as the new prosthesis does, even if allowance is made for the cement mantle. It was therefore concluded that the bone breakage's encountered in this study might well be restricted to cadavers, but trials in living patients will be needed to confirm this assessment.

6.2 HALLUX ABNORMALITIES

Currently the majority of silicone elastomer FMTPJ prostheses are inserted into patients with hallux valgus or hallux rigidus deformities. The procedure is usually contra-indicated for patients with severe forefoot deformities that require a total forefoot reconstruction. The expectations of the new prototype prosthesis are that it will be able to correct a broader range of pathologies. Trial insertions were therefore conducted on a variety of cadavers with different pathologies in order to identify as many potential problems as possible that could be related to each specific deformity.

6.2.1 NORMAL FOOT

Two normal feet were selected to act as experimental controls. The motions of the normal joint were first tested in the cadaver. A prosthesis was then inserted and the test repeated. In one case the joint was amputated, taking care to keep the capsule intact. The motions of this joint were then tested free of any other attachments.

There were interesting differences in the anatomy of the two 'normal' joints selected. When the 'better' of the two normal joints was exposed, it was discovered that access to the medial side of the MT-head was restricted by the tendon of Abductor Hallucis (ABH). It should be noted that the 'ideal' position for this muscle's insertion into the phalanx is around the medial side of the MT-head, which effectively prevents the joint from adducting due to it's lever action. It is significant that in none of the 'problem' feet was this muscle aligned to prevent a hallux valgus deformity from occurring. Basmajian (1984) noted from dissections, that in 43% of feet the insertion of ABH was such that the muscle acted as a flexor of the toe rather than as an abductor; to act as an abductor the insertion needs to pass on the medial side of the MT-head. In these trials, exposure of the medial side of normal and hallux rigidus joints were restricted by the presence of the ABH insertion. In pathological valgus joints, this insertion was invariably found to be inferior to the joint, and therefore did not restrict access to the joint.

Another abnormality (encountered in Cadaver A's normal joint) was the presence of tiny bones in the joint capsule. Sammarco (1980) in depicting the motions of a foot with bunions, showed that these bones were present in at least one of his subjects [Figure 19, p25]. In Cadaver A, perhaps surprisingly, the tiny bones were only present in the cadaver's better foot, not in the opposite foot that had a hallux valgus deformity. In other words, the presence of these small bones alone does not appear to necessarily predict joint malfunction.

6.2.2 HALLUX VALGUS

Hallux valgus is the predominant deformity of the great toe corrected by prostheses; therefore a prototype prosthesis was inserted into the cadaver that had such a deformity. After the routine measurement of the joint's range of motion, the 8 mm head component was inserted into the metatarsal; and cup with the cut away flanks was inserted into the phalanx. The first difficulty encountered was that by approaching from the lateral aspect, the component stems could not be centred in the bones, nor could they be aligned with each other—their axes forming an unwanted "V" in the dorsal view. When the arthroplasty was extended, the prosthesis displaced medially.

To correct this misalignment the socket was removed and reinserted. However, the problem reoccurred. When the prosthesis was removed from the cadaver for the second time, it was noticed that—prior to rigor mortis setting in—the phalanx had rotated through 45° around its long axis, i.e. the medial sesamoid had subluxed into the lateral groove beneath the MT-head, with the lateral sesamoid articulating on the lateral side of the MT-head [Figure 49]. This soft tissue misalignment is typical in cases of severe hallux valgus.

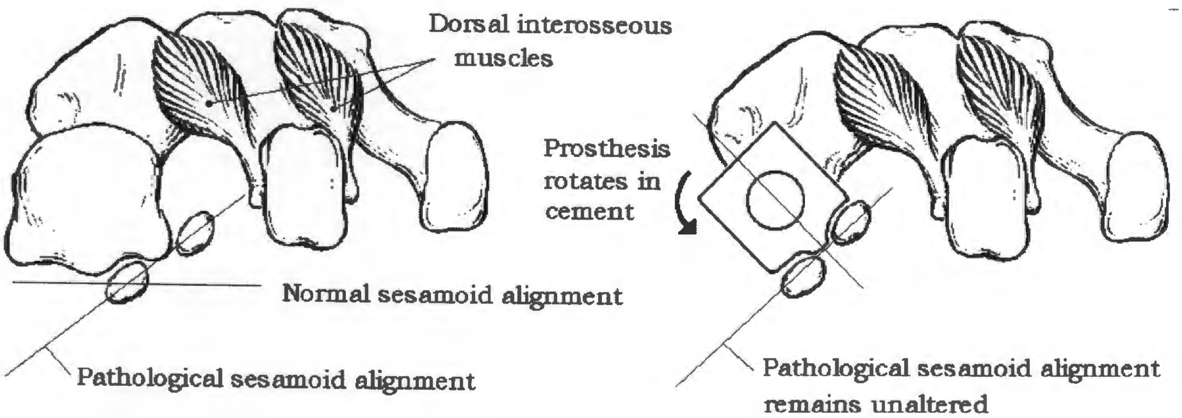


Fig. 49. Pathological misalignment of soft tissues in the case of hallux valgus.

It was found that the misalignment was not due to carelessness, but rather due to the fact that the inferior ridge on the cup was spontaneously aligning itself with the existing pathological off-set in the sesamoid apparatus. Freshly mixed bone cement is pliable, and hence it cannot prevent this undesirable axial rotation of the socket when the joint is reduced.

Initially this alignment problem was thought to be due to the lack of specialised instruments to insert the prosthesis—new instruments were therefore designed. Surgical instruments were needed that could hold the prosthesis in proper alignment until the cement had cured. The extended handles on the instruments allow the surgeon to hold the prosthesis correctly so that the soft tissues can be aligned on the prosthesis, and not vice versa.

6.2.3 HALLUX RIGIDUS

A cadaver that had a fixed extension contracture of all the toes was selected as the second subject. The toes were all fused at 90° extension (hallux rigidus) and there was a single massive callosity beneath all the metatarsal heads. It was felt that if alive the subject would benefit from the restoration of the proper weight-bearing mechanics of the great toe so that the size of the callosities could be reduced. Large callosities are often associated with hallux rigidus and other severe forefoot deformities.

An "L" shaped incision was made in the skin so that the clamps could be inserted onto the bone shafts. However no joint motion was possible because the phalanx base had become chronically fused to the MT-head. The phalanx's base was therefore excised from the MT-head, drilled and shaped to accept a prototype prosthesis. The largest 24 mm cup was selected for this cadaver. However, the socket peg proved too big for the phalangeal cortex; after a few flexion movements of the replaced joint, the wedged-shaped peg split the phalangeal base into a number of fragments. The shattered basal fragments of the phalanx were removed from the joint space—in effect performing a Keller resection. The apparatus was then coupled-up to the resected phalanx shaft, and three range-of-motion tests were performed on the joint simulating the performance of a Keller arthroplasty.

The lesson learnt from this was that prototype pegs can not be too large. The prosthesis stems had been deliberately designed on the large size to investigate the possibility of non-cemented press-fitting fixation. The triangular stem-shape contributed to the failure as the stem acted as a wedge, simply splitting the bone apart. Once it was realised that non-cemented fixation would be problematic, the pegs of all the prototypes were machined down 2 mm all around to accommodate a cement mantle.

Swanson (1979) recommends that—in order to preserve the weight-bearing function of the metatarsal—the majority of bone be resected from the base of the phalanx rather than from the metatarsal head. In a normal joint this appears to be completely impractical because the base of the phalanx is such a solid block of bone that resist most any attempt at resection. However, in the case of hallux rigidus, the base of the phalanx is often fused to the MT-head; it cases like this it is almost inevitable that the phalanx will fracture at the shaft, making a Keller resection of the base the wise alternative. This is perhaps why historically, the single stem silicone prosthesis was often used in preference to the double-stem design when treating hallux rigidus; even though both types were available. Also the fact that the base of the phalanx—and hence all the plantar attachments—are fused to the MT-head may explain why joint contracture has been found, on average, not as significant a problem in hallux rigidus as it is with other types of deformity (Stokes et al 1979b).

6.2.4 AMPUTATED JOINTS

Due to the limited capacity to insert a prosthesis without damaging the cadaveric bones, some of the FMTP joints were removed intact by performing an amputation at the cuneiform-metatarsal joint. The apparatus settings were locked in place after the first recording the range of motion inside the cadaver. This ensured that the results obtained outside the cadaver, without the plantar aponeurosis, could be compared directly to the results obtained inside the cadaver. Inserting a prosthesis into an amputated specimen allowed the intrinsic ligaments to be evaluated independently of all the other attachments.

The amount of bone that needs to be resected from the metatarsal varies according to the type of prosthesis that is to be inserted. The relative amounts of bone resected during this process can be compared in Figure 50.

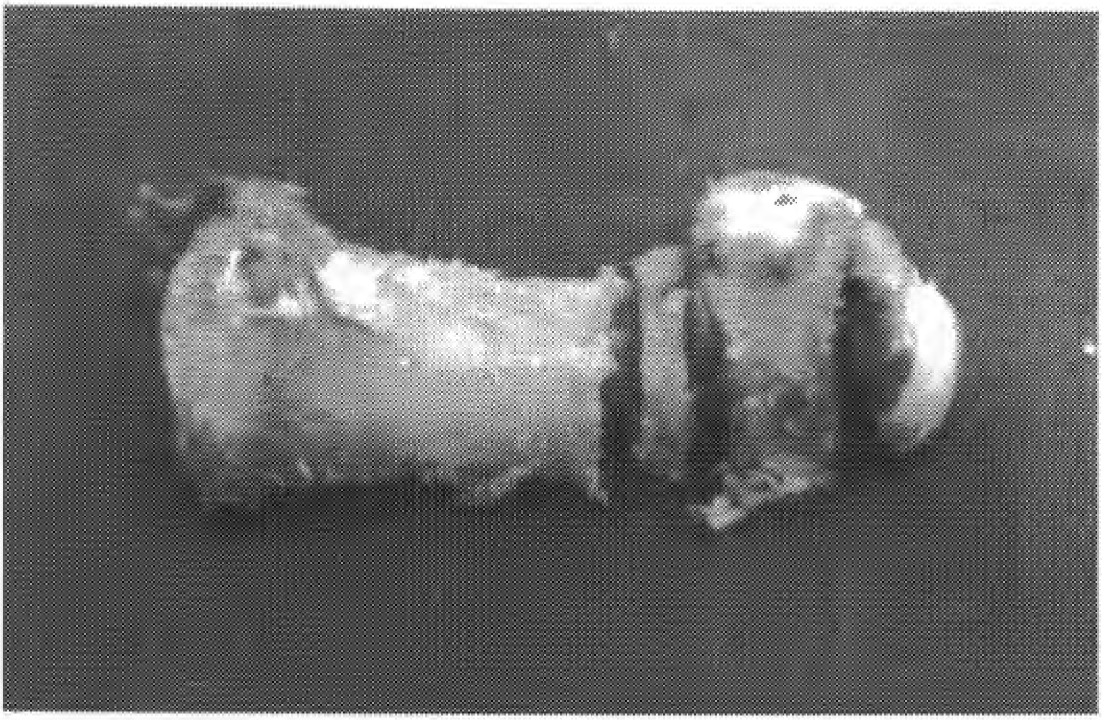


Fig. 50. Quantity of bone resected from the metatarsal at various osteotomy sites. From left to right: (1) plantar ligaments sacrificed, (2) plantar ligaments preserved, (3) minimum resection for a Swanson double-stem elastomer prosthesis.

Of the various arthroplasties examined, a Swanson prosthesis requires the least resection. However, when a ball-and-socket prototype was inserted in the space vacated by a Swanson prosthesis, the plantar ligaments prevented the joint extending. Additional bone therefore needs to resected from the metatarsal head and shaft. An exploratory osteotomy for the MT-component was made immediately distal to origins of the metatarsal's ligaments so as to preserve their attachments. However if the plantar ligaments are not resected the ball-and-socket arthroplasty joint cannot extend much beyond about 10°, if at all [Figure 51].

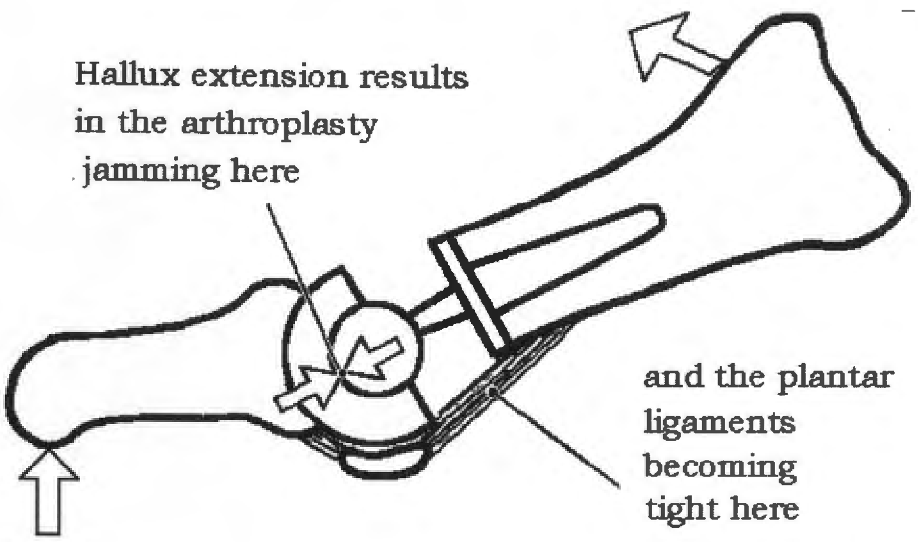


Fig. 51. Constraint of joint motion by the plantar ligaments in an amputated FMTPJ due to insufficient bone resection during a ball-and-socket arthroplasty.

To achieve a mobile joint, either the base of the phalanx or the distal part of the metatarsal—to which the collateral ligaments where attached—had to be resected. The resection of the FMTPJ's ligaments may be seen as a drastic measure because they maintain the integrity of the toe; if they are resected the options for revision are limited. However, if a ball-and-socket prosthesis is to be used, it is mandatory that they be resected. The biomechanical effects of resecting the ligaments are examined in more detail in Section 7.3.1.

CHAPTER 7
DISCUSSION

The experiments that measured the motion of the FMTPJ were based on the premise that the motions of the FMTPJ could be better understood if the joint motion was viewed as a rotation of the metatarsal about the proximal phalanx. The experiments allowed two principle observations. Firstly, there was a difference between the motion of the metatarsal when it was measured inside a cadaver with all its attachments in place—and the motion of the same metatarsal when it was freed from its attachments. Secondly, inside a cadaver, the proximal end of the metatarsal has a different center of motion from that of its distal end.

The new information obtained from the experiments needed to be reconciled with the existing body of knowledge, so that the validity of the numerous assumptions that had been made during the design process could be assessed. The cause and effect relationships that existed between the anatomy of the FMTPJ and its functions was examined using a theoretical approach because very few of the variables that may affect the outcome of the arthroplasty could be tested experimentally in research of this length.

The experimental results, in conjunction with the theory, were used to explain why current arthroplasty techniques fail to restore normal weight-bearing under the hallux. Independent observations from a variety of sources have been included to provide additional support for the design principles that suggested that a ball-and-socket configuration was the best means of restoring proper FMTPJ function. The performance of the new prototype is then discussed in terms of the specific design features that were included in the prototypes; projections are made as to the likely performance of the prototype *in vivo*; and finally, the potential patient population is defined in terms of the biomechanical model.

7.1. METATARSAL MOTIONS – CAUSES AND EFFECTS

The primary finding of the experiments was that motion of the metatarsal within the cadaver was different to the motion of the same metatarsal that had been freed of its extrinsic attachments. The causes of this variation needed to be identified in order to analyse the practical performance of the various arthroplasty techniques. Firstly a theoretical approach, which relied in the existing body of published information, was used to identify the causes of the variations in the metatarsal motion. The resulting practical consequences of failing to preserve proper control over the movements of the metatarsal were explored, and compared to the known performance of various arthroplasty techniques. The findings support the argument that a ball-and-socket arthroplasty is the technique most capable of restoring proper FMTPJ function.

7.1.1 SHAPE OF THE JOINT SURFACES

It is normal for the articulating surfaces of any natural joint not to be a perfect match (MacConaill 1967). The bones of any joint, including the FMTPJ, need to make at least two or three points of solid contact, spread over a finite area. The sagittal profile of the MT-head has been described by two intersecting arcs (Stokes 1979b). There is however, a medio-lateral separation of these arcs, which creates three distinct "tracks" upon which the base of the phalanx can travel [see Figure 52]. The base of the proximal phalanx is ovoid; therefore even though supination/pronation motions may alter the precise points of contact, the contact will invariably occur in the general areas marked 1, 2 and 3.

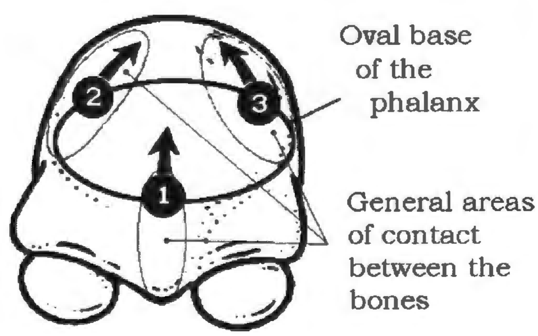


Fig. 52. Bony contact zones in FMTPJ.

In flexion bony (cartilage) contact occurs on the centre of the sesamoid ridge (1) However, as the joint is extended, the intersesamoid ridge recedes in prominence until bony contact occurs medially (2) and laterally (3) on the phalanx base.

It is known that these principle bearing areas have different centers of curvature, represented by the radii r_1 and r_2 in Figure 53. If it is assumed that the joint is extended through a finite angle $\emptyset$ at position (1) the superior contact points (2 & 3) – represented in the side-view by point (2) – will glide a similar distance (x) along the metatarsal surface. However, due to the tighter radius r_2, contact point (2) will rotate at a faster rate ($\emptyset+d\emptyset$) than the contact at position (1).

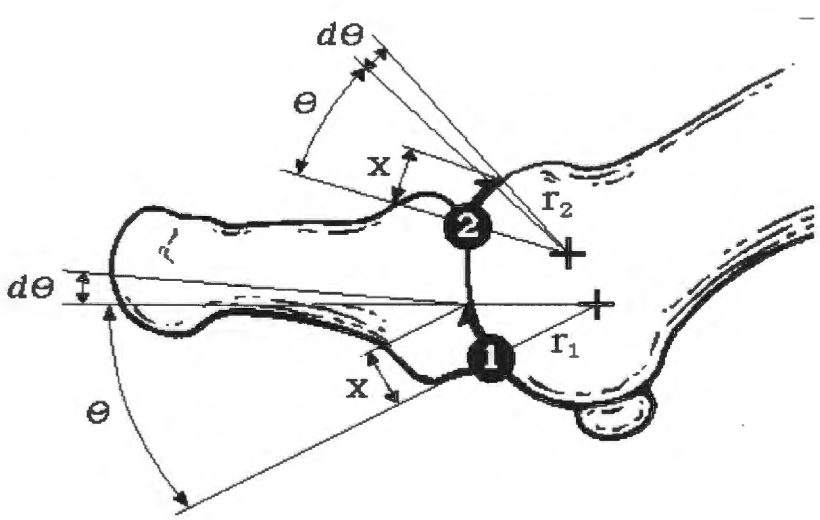


Fig. 53. Angular displacement of MT bone.

The $d\emptyset$ reflects an acceleration in the phalanx-metatarsal angle. However, the angle ($\emptyset+d\emptyset$) is larger than the nominal angle of extension ($\emptyset$). Therefore, the phalanx base must slip inferiorly on the metatarsal in order to maintain the nominal extension angle; which inevitably results in a continual series of relatively minor adjustments to the equilibrium position of the MT-head. The phalanx will slip on the metatarsal whenever the angle $d\emptyset$ exceeds the coefficient of friction, resulting in a "jerky" motion.

These to-and-fro fluctuations in the motion of the phalanx are believed to account for the fluctuations in the center of motion of the phalanx that are apparent in Sammarco's results (1980). Also, the downward-slip of the phalanx that is necessary to maintain a constant angle $\emptyset$ on the MT would manifest as a relative raising of the MT-head by the plantar aponeurosis, particularly if the phalanx cannot move into the ground. This is in accordance with the observation of Hicks (1954) that hallux extension raises the arch.

Tension in the plantar aponeurosis is believed to determine the bone alignment because if there was no tension to maintain contact at (1), the joint space would open-up by $d\emptyset$ [Figure 54]. There would then also only be one center of motion for the entire metatarsal, which would be the center of r_2.

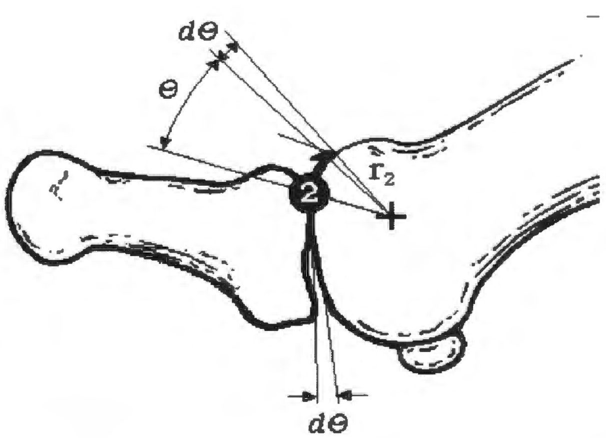


Fig. 54. MT-head movements without the constraint of plantar aponeurosis tension.

The results of the experiments showed that if the plantar attachments were released, there was only one center of motion for the metatarsal. This supports the observation by Hicks (1954) that dividing the plantar aponeurosis eliminates the arch raising effect. The findings of the experiments are therefore consistent with previous research. However, the experiments provide additional information that can be used to extrapolate the motion of the FMTPJ proximally rather than distally. Significantly, this enables one to predict how the other bones in the foot move in relation to the FMTPJ, which was not possible before.

7.1.2 PASSIVE MOTIONS OF THE FMTPJ

Hicks (1954) noticed that the FMTPJ is a passive mechanism; i.e. the muscles do not control all of its movements. This is an important concept, because if some of the FMTPJ functions do not involve the muscles, the muscles may not be in a position to 'compensate' for any deficiency that may arise from FMTPJ failure; particularly if the joint fails during the extended passive range of hallux movement.

The energy needed to drive the FMTPJ mechanism and accelerate the metatarsal towards the phalanx as a person walks on firm flat ground, must be provided by either stored muscle energy or by another source of potential energy, such as that released by lowering of the person's mass. The principle of conservation of energy dictates that the raising of any object such as the human body, requires a certain amount of work to be done against gravity. When the fore-foot is on firm flat ground, any increase in the body's potential energy must involve muscle-energy or some other form of stored mechanical-energy such as a spring. Although theoretically possible, the existence of efficient biological 'springs' has yet to be proved; therefore they have been disregarded.

The 'raising' of the arch implies an upward motion relative to a reference datum. However, due to the windlass effect, the raising of the arch is also associated with a lessening in the horizontal toe/heel separation. A finite amount of energy must therefore be supplied in line with the direction of shortening. Now, if this energy was supplied by a muscle, such as FHB, the synchronous action required would slacken the plantar aponeurosis and render it redundant for the purpose of raising the arch. There is also compelling electromyographic evidence (Basmajian 1984) that shows that no muscle activity is involved in supporting the static arch. Therefore the plantar aponeurosis must at times be assumed to function independently of muscle action – this basic contention is supported by the fact that the arch raising effect operates even in the dead.

Because the arch can be raised independently of muscle action, and because muscle action is necessary to raise the body's centre of gravity, it follows that the plantar aponeurosis does not function as a mechanism for raising the body's centre of gravity. It is therefore safe to presume that even if the plantar aponeurosis is capable of raising the arch without the assistance of muscles, it cannot do so if this also involves raising the body's centre of mass. The difficulty of simultaneously raising the arch and the body's mass, is borne out by the fact that attempts to passively extend the toe during weight bearing cause pain. This pain is believed to be a result of the body structures being forced to attempt the impossible.

However, normal gait is pain-free. It is therefore necessary to examine how the foot functions during the later stages of the stance phase of gait; particularly when the fore-foot is bearing weight and the plantar aponeurosis is being progressively tensioned by the extended hallux. This stage of gait coincides with the passive range of FMTPJ extension when no muscle energy is apparently needed to raise the arch. It is worth noting that in this posture, the heel must be off the ground; therefore there is space for the heel, ankle, knee and leg to drop sufficiently to release some of the person's gravitational potential energy, which can then be utilised to drive the windlass mechanism. This is not the case when the foot is squarely on the ground.

Another point to note is that while the hallux is being extended, frictional torque in the ball-and-socket joint will result in the proximal phalanx being forced towards the ground until it comes to rest on, or approximately parallel with the ground. The axis of the shaft of the proximal phalanx may, therefore, be used as a reference datum for analysing the relative motions between the bones of the FMTPJ and the motions of the remainder of the human body during this specific period of the gait cycle.

7.1.3 MUSCLE CONTROL OF THE ARCH

In order to verify that the FMTPJ is primarily a passive mechanism, it is necessary to examine the muscles insertions that act directly on the bones of the mid-arch [Figure 55].

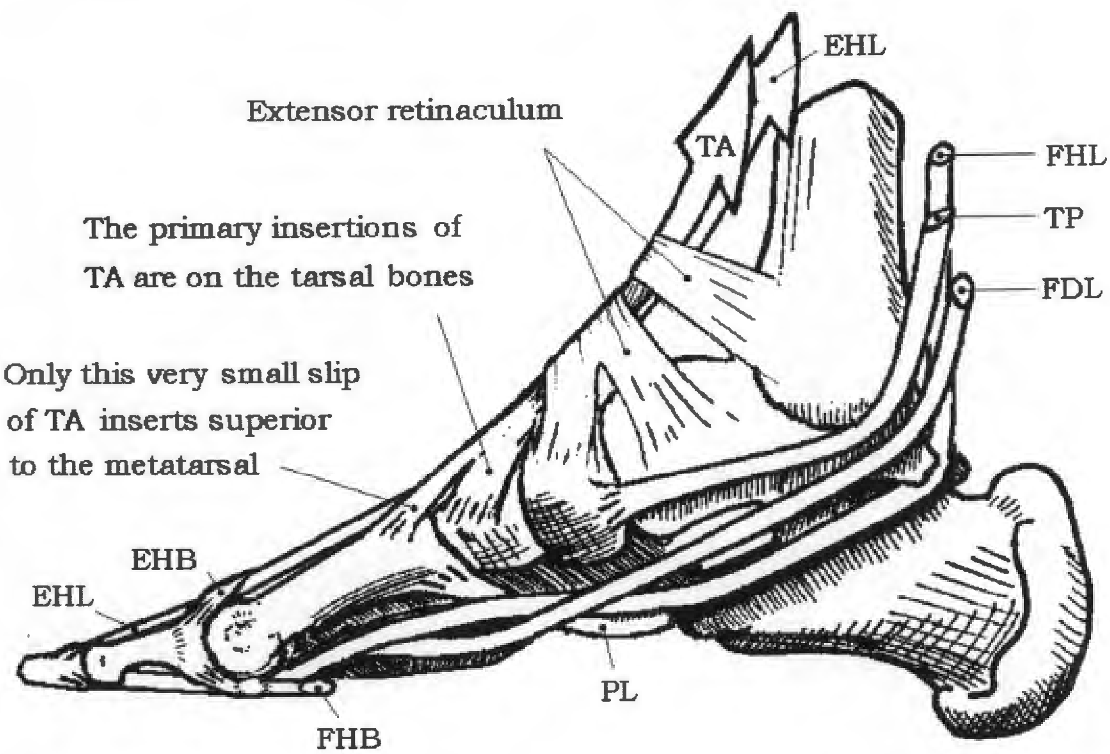


Fig. 55. Muscles tendons inserting into the hallux.

The vast majority of the tendons insertions are inferior to the proximal MT. The significant observation is that due to the multiple insertions of their tendons, the muscles that actually insert into the metatarsal, for example TA, TP and PL, are not in a position to raise the MT independently of the other tarsal bones. The muscles that pass superior to the bones such as the extensors EHL and TA, also pass inferior to the extensor retinaculum that is attached to the tarsal bones. From the positions of the tendons, it is clear that neither the extensors nor the muscles passing posterior to the ankle are capable of raising the proximal end of the metatarsal without first raising the other bones of the foot.

In general, muscles are usually described as moving their insertions towards the origins. However, to use an analogy in the case of the great toe, this would be similar to pulling oneself up by one's own boot-laces. If a horizontal gravitational potential-energy reference datum is applied to the motion, the converse action must occur; i.e. muscle contraction must pull the bones of the upper body down towards the hallux. It is therefore distinctly probable that if the first metatarsal bone is to be raised, this must be achieved by the passive bone/ligament/fascia components of the FMTPJ in association with the plantar aponeurosis rather than by the muscles that pass inferior to the ankle or the extensor retinaculum.

Another important observation made by Hicks (1954) is that once the FMT is raised, it cannot then be 'depressed'; apparently no amount of effort can restore the MT-head into alignment with the other MT-heads. This in effect converts the mobile bones of the arch into a rigid weight-bearing structure that will support almost any physiological load. When the hallux is extended, the muscles that connect the leg to various parts of the foot are stretched around the ankle bones like a taught bow-string, ready to propel the bones of the mid-foot and heel up and forward when they contract [refer to Appendix B for Kapandji's analysis of the muscle control of the arch]. When the muscles do contract they cannot pull the metatarsal inferiorly – therefore the muscles must raise the tarsal bones on the elevated MT, the latter serving as a secure foundation for weight bearing.

If arch raising can be induced independent of muscle action, it becomes apparent that the raising of the first metatarsal portion of the arch by the FMTPJ – prior to muscle activity – may be a unique characteristic of the joint's function that may need to be preserved by a prosthesis.

7.1.4 REFERENCE AXES FOR METATARSAL MOTIONS

Although the function of the hallux may vary with the posture of the lower limb, the position of the hallux when the foot is off the ground is of little immediate significance for the prosthesis designer. The motions of concern are those where the fore-foot is on the ground bearing weight. The difficulty is that the behaviour of the FMTPJ can only practically be determined by moving the hallux around the foot and not vice versa; a predicament that has led to a number of apparent contradictions in the presentation of the results by previous authors. It is necessary to ensure that observations of Hicks (1954) and Sammarco (1980) are consistent with the results of the latest experiments because the observations of Hicks in particular were central to the development of the theory of FMTPJ function, and were used to establish the design principles.

For example, Sammarco (1980) determined the centre of rotation of the FMTPJ as a movement of the phalanx about the MT-head. His depiction of the motion is suspect because the phalanx motion is extrapolated into the floor. Clearly such a motion is impossible with the foot on the ground. A similar contradictory situation arises from the observations made by Hicks (1954). On one hand he observed that extension of the FMTPJ 'raises' the arch, while on the other hand he observed that passive extension of the great toe caused an irresistible 'downward' displacement of the MT. Since the MT is a part of the arch, the stated directions of the MT motion are contradictory.

A reason for using a transparent reference grid, was to measure the motions of the metatarsal with reference to the proximal phalangeal axis. Using this technique, it is possible to use the phalangeal axis to describe the extension/flexion movements that occur within the foot; thereby removing the contradiction from the observations. It also allows the motions of the hallux to be examined in the broader context of the mechanics of the lower limb. Since the windlass effect direct involves the calcaneus in functions of the FMTPJ, it is necessary to define the motions of the hallux in relation to the hind-foot. A number of different reference axes may be used for this purpose [Figure 56]. The MT-head/heel axis (1) is usually the most convenient because it is the easiest the measure without radiographic images. Significantly, the MT-head/heel axis (1) and the hallux/heel (2) axes coincide when the foot is squarely on the ground, but they diverge when the heel is raised. The fact that they diverge during ankle dorsiflexion is a recognised fact because during gait analysis the fifth MT-head, rather than the first MT-head, is often considered a better landmark to use as an indicator of ankle flexion.

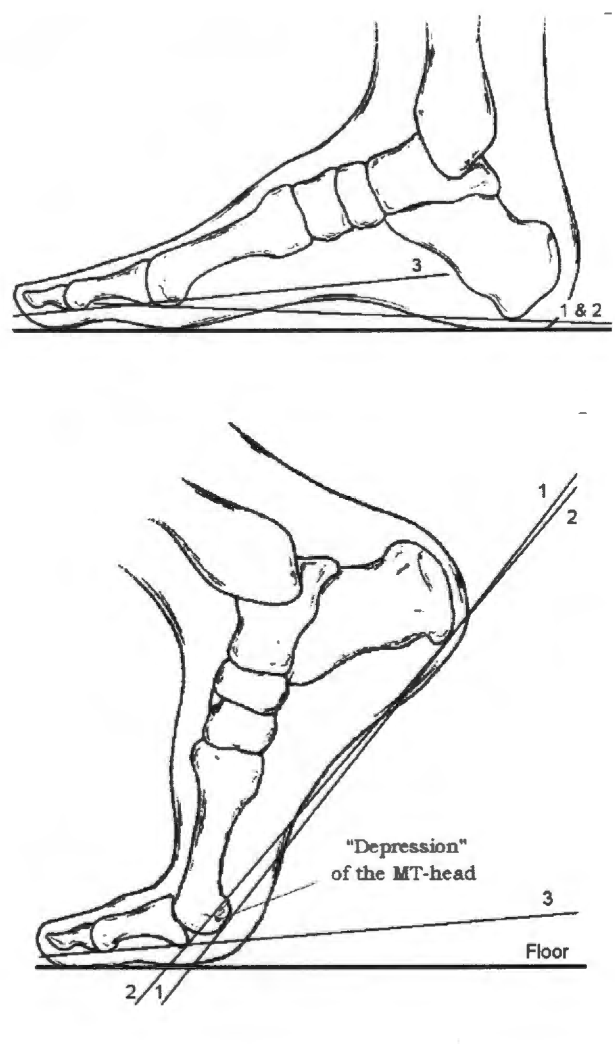


Fig. 56. Reference axes used to define the motions of the hallux.

At the time that the hallux is extended the hallux is on the ground and hence the MT cannot move down any further. Conversely it has been argued that the metatarsal cannot move up against body weight if the hallux is being passively extended. It will be noticed in Figure 56 that raising of the heel prior to toe-off causes the MT-head to cross the hallux/heel axis (2), which in terms of the hallux/heel axis appears to become "depressed". However, when the hallux axis (3) or the floor is used as a reference line, it can be seen that extension of the hallux does not result in the "depression" of the MT-head. This contradiction is eliminated by the correct choice of reference axes.

Similarly, for the purposes of defining the potential energy of the body, it is convenient to refer to ground level rather than the phalangeal axis as the fixed axis of reference for all movements. However, the assumption can be made that the phalangeal axis is parallel, or nearly parallel, with the ground throughout the majority of the crucial fore-foot stance when both ends of the phalanx are being passively forced onto the ground by the body's mass. Such an assumption can be justified as follows:

For a start, the low frictional torque design of the prosthesis ensures that the first ray will always dorsiflex under load; hence the proximal phalanx needs to be supported both proximally and distally. For this to occur, the distal tip of the hallux must always be on the ground. The proximal end of the phalanx can, however, be raised if there is enough tension in the fibrous plantar attachments to raise the first metatarsal head off the floor. If this occurs the relative position of the bones is not altered if the phalangeal axis was used as the reference. The phalangeal axis may therefore also be used as the potential energy reference line instead of the ground provided the hallux is on the ground.

However, even if phalanx is not on the ground—or if the precise angle between the ground and the proximal phalanx is not known, or alters, due to the pliability of the fatty pads and skin beneath the toe—the difference may be considered small when compared to the angle between the proximal center and distal centers of rotation that was measured experimentally. Significantly, it can be shown that any error introduced by the alignment of the apparatus used to measure the joint motion can be resolved into a single angular displacement of the phalangeal-ground angle [see Appendix G]. This means that the angle between the ground and phalanx can be included in the measurements without changing the linear separation of the centers of motion of the opposite ends of the MT. In other words the separation (but not necessarily its angle to the ground) is a quantifiable parameter that is neither an artefact of the experimental method employed, nor is it an artefact of the reference axes used to define the motion of the FMTPJ.

7.2 FUNCTIONS OF THE FMTPJ

It has already been discussed how metatarsal motion can be related to the posture of the arch. This section is used to describe how the complex movements of the FMTPJ effect weight-bearing in normal and pathological feet. The FMTPJ, in association with the plantar aponeurosis, is ideally positioned to exercise control over weight distribution under the foot. Briefly, it will be described how weight can be transferred between the heel and the fore-foot via the plantar aponeurosis; and transferred laterally between the hallux and fifth toe by raising the arch and supinating the foot. The long-term consequences of disrupting or repairing this mechanism are also discussed.

7.2.1 WEIGHT DISTRIBUTION UNDER THE FOOT

A study of hallux amputees' shoes show a distinct shift of load to the lateral side of the foot away from the affected hallux. Surprisingly, the weight-bearing patterns of nearly all feet that have undergone surgery of the FMTPJ—for whatever reason—exhibit a peak pressure pattern that is almost identical to that of great toe amputees. For example Keller resection, single-stem and double-stem silicone arthroplasty, and anatomical resurfacing all increase the pressure under the third MT-head; there is also an increase in the duration of this pressure, and a lateral load shift. Furthermore, the development of callosities beneath the lesser MT-heads is reason to believe that the same loading conditions are inevitably associated with deformities such as hallux valgus and hallux rigidus and for procedures such as distal and proximal arthrodeses of the first MT.

In searching for an explanation for the concentration of load beneath the second MT-head, gait analysis and anthropometric studies in a normal foot (Hughes et al 1990) have failed to establish a correlation between the relative lengths of the first and second metatarsal bones and the proportion of load borne between them. This is surprising when one looks at the bone structure of the foot. The second metatarsal is the longest metatarsal; therefore it is ideally situated to bear most of the load at toe-off when the metatarsals are inclined perpendicular to the ground. Based on this evidence, even under normal circumstances one might presume that callosities would develop under the second metatarsal. However, callosities do not develop in normal feet; which points to the existence of a mechanism that effectively lengthens the first ray so that the hallux and the second ray can share the load and reduce the peak forces experienced at any one point.

As has been previously explained, when the hallux is extended, the MT-head depresses in such a manner that this movement cannot be reversed by any amount of upward pressure from below. These two conditions—viz. the apparent 'downward' motion of the MT-head and its ability to resist any 'upward' force—can compensate for any deficiency in the length of the first ray and allow the medial side of the fore-foot to bear weight. The fact that maximum weight is borne by the hallux during the last portion of the stance phase of gait—when the effects of a short first ray would presumably be at their worst—confirms that weight bearing occurs simultaneously with hallux extension.

The apparent 'downward' motion of the MT-head has been shown—through theoretical analysis—to be due to the reference axes used. In fact the metatarsal is raised relative to the ground by tension in the plantar aponeurosis, which effectively increase in length of the first ray. This makes it possible for hallux to support the forces under the fore-foot at toe-off. But this effect is inextricably associated with arch raising and foot supination (Hicks 1954). Arch raising and supination have in their turn been linked to lower limb rotations (Morris 1977). Even though the various sub-components of such mechanisms have been documented in the literature, the potential link between motions of the hallux and motions of the lower limb up to the knee has apparently not been recognised. For the purposes of determining the loading conditions on a FMTPJ prosthesis, it is necessary to explore the possible consequences of the existence of such a link.

7.2.2 FOOT SUPINATION

The link between hallux extension, arch raising, foot supination and load bearing could not be confirmed experimentally in the cadavers because of the limitations of the 2-dimensional analysis used in the experiments. It was therefore necessary, once again, to refer to the literature in order to construct a theoretical model of this mechanism.

In the normal foot, supination of the foot causes an external rotation of the tibia, which is multiplied by the ankle joints (Morris 1977). The multiplication of the rotation leads one to believe that a rotation of the tibia is a desirable feature of limb mechanics. Arguing this viewpoint further, the leg rotation that is induced by raising the arch must be absorbed either at the knee or ankle—but because the rotation is multiplied at the ankle it must be absorbed at the knee. Incidentally, the rotation of the tibia can be absorbed at the knee because the knee has a rotational 'screw-home' mechanism that limits the range of knee extension when the tibia is externally rotated on the femur.

Briefly delving deeper into the rather complex mechanics of the foot, it should be noted that when the foot is supinated the calcaneus moves under the talus, rotating the talar head. The axis of the talonavicular joint is then no longer parallel to the axis of the calcaneocuboid joint—with these two axes parallel, the mid-foot is able to flex and extend in relation to the hind foot. However, when the heel is inverted with the arch elevated, these axes become divergent in relation to one another, locking the transverse tarsal joint—which prevents supination-pronation motions in the mid-foot. This mid-foot locking mechanism goes into effect when there is a force of approximately 350 N (36 kg) in the arch (Morris 1977). Practically this means that the fore-foot has to be bearing about 50% of the body's mass before this effect will manifest. Note that normal forces in the foot arches of 'active' populations range between 50%–90% of body-weight, and those in less active populations fall within the 10%–35% range (Wyss et al 1990).

In a normal limb, the foot is supinated as a natural consequence of FMTPJ function at the end of the stance phase of gait. This is speculated to have two important consequences. Firstly, due to the extension of the hallux at this time, the tibia will be externally rotated precisely when the knees are passing each other during gait, which prevents them from fouling each other. Secondly, due to the external rotation of the tibia, the knee cannot hyper-extend when the leg straightens to push-off; i.e. it is prevented from "bending the wrong way" under load, which is particularly important if walking and running over uncertain terrain. In this regard, the angle of the hallux may act as a passive sensing device that automatically compensates for irregularities in the ground. Perhaps more importantly for the prosthesis recipient, the loss of this function may seriously affect a person's ability to balance, particular in the elderly whom are often susceptible to falls.

It should be noted that these effects are dependant on the arch being raised. If the arch is not raised, normal extension of the knee results in an internal rotation of the tibia, and the knee screw-home mechanism induces pronation in the foot. However, pronation is prevented if the foot is supinated before the knee is fully extended because, with the foot supinated, the hallux is extended, and the FMT-head withstands all attempts to force it into line with the other MT-heads. With the arch raised by the windlass effect, the tibia cannot rotate internally; however, this does not affect the relative motions between the tibia and femur. The femur therefore rotates externally if the arch is raised. If the arch is not raised the tibia rotates internally, inducing pronation in the foot.

Pronation forces are believed by many to be a predisposing factor in hallux valgus during the stance phase of gait (Ruch and Merrill 1986). It has been argued that pronation occurs only if the FMTPJ cannot raise the arch. The fact that hallux valgus deformities regularly reoccur after arthroplasty, even where none had existed before (Swanson et al 1979) may indicate that current arthroplasty techniques may not only fail to restore the arch raising effect of the FMTPJ, but they may actually reinforce many of the negative biomechanical conditions that eventually lead to hallux valgus and bunions.

7.2.3 CONSEQUENCES OF FMTPJ FAILURE

The preceding speculative analysis of joint function is important because it serves to highlight the consequences of FMTPJ failure that extend beyond the initial painful symptoms and cosmetic concerns of the patient. Currently one of the aims of surgery is to restore a measure of joint motion. However, "joint motion"—as defined by simple joint flexion-extension motions—does not necessarily produce the separate centers of rotation that may be observed from the experiments to occur in normal cadaveric feet. However, one must also question whether the results obtained in cadavers apply to the living. Again this issue needs to be addressed theoretically.

Theoretically, it can be argued that without the arch being raised there is less rigidity in the limb; without which the push-off force must be reduced, with a limited push-off force there is little loading of the arch; with little load in the arch, the tarsal bones in the mid-foot are not locked, therefore they can supinate and pronate. If supination occurs at this point, the second MT acts as the load-bearing fulcrum for lateral rotation of the foot, and there is an associated increase in the lateral loading of the foot. These effects are apparent in almost all weight-distribution studies that have been conducted on numerous normal and pathological feet.

The primary experimental finding of this research was that in a normal cadaver each extremity of the FMT bone possesses its own center of motion. This is believed to be the vital indicator of proper FMTPJ function, because if the centers of motion of both ends of the MT happen to coincide, it is not possible for the:-

(1) arch to rise,

(2) the foot to supinate,

(3) the first ray to bear load, or

(4) the foot to stiffen at toe-off.

It can be argued that in a normal FMTPJ these conditions prevent lateral foot loading during toe off, pronatory forces during straight-legged stance, increased pressure under the second metatarsal head and excessive pronatory forces at the FMTPJ respectively.

From a biomechanical perspective, four basic conditions need to be met before an appropriate articulation can be justifiably claimed to exist. These are:-

(1) an elevated centre of rotation for the proximal MT

(2) aponeurotic tension

(3) a mobile bony arch

(4) weight-bearing by the FMT bone.

It is believed the known performance of FMTPJ arthroplasties can be predicted from the presence or absence of these conditions. This will be discussed in the next section. However, the evidence presented so far highlights the possible consequences of disrupting FMTPJ function. At this stage of the discussion, it is sufficient to be aware of the possible need to duplicate the precise motion of the proximal first MT-bone while retaining the proper spatial relations between anatomical structures within the foot that connect the hallux to the calcaneus. Even though the proof of much of what has been discussed is clearly beyond the scope of this thesis, there are compelling indications to claim that the results of the cadaveric experiments do indeed justify the design principles that led to the specification of a ball-and-socket prosthesis for the FMTPJ.

7.2.4 EFFECTS OF ARTHROPLASTIES

The ideal outcome of this research would be to predict how the experimental findings, which were based on experiments with dry bones and cadavers, can be projected to living patients. Evidence that supports or contradicts the theory of metatarsal motion in living patients is therefore discussed here. Most of this "evidence" is in the form of the published observations and personal experiences of surgeons involved with FMTPJ arthroplasty development, or in follow up studies of various procedures in the living—more precise data is difficult to obtain without having implemented specific controls before and during dedicated clinical trials.

The first issue that needs to be addressed is if the "accelerated" rotational displacement of the first metatarsal measured in the cadavers also occurs in living patients. In this regard, there is some independent evidence of a direct link between the elevation of the distal segment and load-bearing following an osteotomy of the proximal MT because Ruch and Banks (1986b) emphasised that precautions need to be taken to prevent early weight-bearing from causing the distal segment of the MT from becoming elevated [Figure 57].

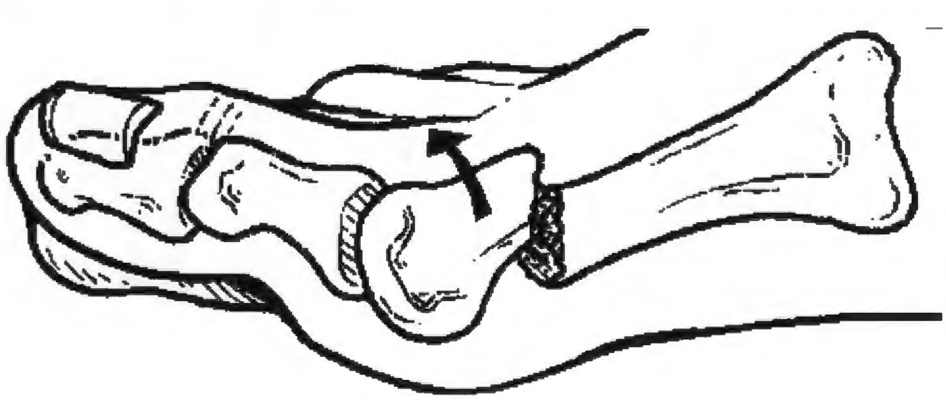


Fig. 57. Elevation of the distal MT-segment following premature weight-bearing after an osteotomy of the first metatarsal.

Bone fusion is apparently delayed if the joint is subjected to premature load bearing; therefore they recommend an extended recuperation period to strengthen the fusion of the MT-shaft. This tends to support the experimental findings both in terms of the forceful (i.e. accelerated) elevation of the MT, the direction of the force, and its intimate association with load-bearing because there are no muscles attached to the elevated segment that can raise it.

More evidence of the importance of FMTPJ function within the living foot is provided by the results of a fusion of the first metatarsal-cuneiform joint (Ruch 1986b). Firstly, it is known that callosities form under the lesser MT-heads following this procedure, which is apparently caused by the lateral shift in fore-foot loading that appears to be symptomatic of all FMTPJ failures. Callosities are believed to develop because, by fusing the first metatarso-cuneiform joint, the very reason for the existence of the complex arch-raising mechanism of the FMTPJ is compromised; i.e. even though the sesamoid articulation mechanism of the FMTPJ may be fully functional, arch raising cannot occur because the previously mobile bones at the top of the arch are fused.

The resulting lateral load-shift after fusion of the arch emphasises the dynamic character of FMTPJ function as opposed to, for example, the static load-bearing character of the second metatarsal. This dynamic character of the FMTPJ and its associated structures again highlights the unique importance of toe-off phase of gait where the reference axes of movement diverge under load bearing. All of these dynamic effects are believed to be necessary conditions for proper FMTPJ function.

However, the primary cause of FMTPJ failure is believed to be the release of tension in the plantar aponeurosis. The aponeurosis need only be shortened by about one centimetre to render it inoperative (Hicks 1954). Mann (1988) found that the sesamoids migrated between 7 and 23 mm proximally after amputation of the phalanx; therefore joint contracture is a crucial parameter in assessing an arthroplasty's performance. The follow-up reports of prostheses in the literature reveal that joint contracture is a common complication after Keller's procedure, and for silicone arthroplasties for all indications except, oddly enough, hallux rigidus (Stokes et al 1979b). Implant subsidence is another cause of joint shortening, which is seen to occur in both silicone and anatomical FMTPJ arthroplasties (Johnson 1989; Granberry et al 1991)—bone tends to resorb if there is a chronic decrease in the bone stress levels.

Although the importance of tension in the plantar aponeurosis has been recognised, Beverly et al (1985) found that re-attaching the sesamoid complex after a MT-head resection did not restore normal loading. Merkle and Sculco (1989) attempted to take up the slack in their anatomically shaped joint by inserting a custom made spacer into the joint space, but this approach failed. The latter case is a particularly interesting one as it appears to meet the necessary requirements for successful FMTPJ arthroplasty, viz. aponeurotic tension and a natural bone shape, yet the prosthesis became loose; one patient even preferred the Keller resection on her opposite foot.

The critical question must be asked, why does an anatomical resurfacing prosthesis such as Merkle and Sculco's not succeed, particularly when tension in the plantar aponeurosis is ostensibly restored? It is believed that this particular failure might be explained by the restriction of motion imposed by the fibrous encapsulation of the prosthesis's components. The mass of fibres that reform around the MT-head is believed to bind the MT to the plantar aponeurosis and other tissues, and in so doing, disrupts the smooth gliding motions that occur in the synovial capsule. This prevents the MT from elevating because it changes the center of motion of the MT-bone by altering the force equilibrium conditions at the joint surface. Anatomically shaped prostheses that become encapsulated probably fail due to rapid loosening of the MT-component because the fibres increase the strain on the cement fixation when the bones are forced to articulate—Charnley (1967) noted a similar effect in the hip was a major cause of socket loosening. The effect encapsulation has on an anatomically resurfaced FMTPJ is compared with that of a ball-and socket prosthesis in Section 7.3.1.

It is interesting to examine why the plantar load pattern under feet with implants does not differ much between naturally deformed and surgically corrected feet, for example why the load pattern under hallux valgus foot is similar to the post-operative condition of silicone implants (Stokes 1979b). It is believed that this can be ascribed to the fibula sesamoid articulating on the lateral side of the MT-head—which nullifies the windlass effect. Also with this misalignment of the soft tissues, the arch is not raised as much as the intermetatarsal space is widened—this is believed to be significant because a wide intermetatarsal angle is the most reliable indicator of hallux valgus deformity.

The reason that a Keller resection is reasonably successful is believed to be because the MT-head can move anteriorly in the space created by the basal resection of the phalanx. In the contradictory case of hallux rigidus; the phalangeal bone fragment that was attached to the plantar plate might well fuse onto the MT-head, either through a chronic pathological bony fusion or via a tight fibre capsule. The resulting rigid arch structure can also be used to explain why callosities are common symptoms of hallux rigidus, even though, on average, joint shortening is a less common complication than it is with hallux valgus.

Swanson's prostheses, which are widely used, warrant special mention. This particular prosthesis was tested by first recording the normal range of motion of a cadaveric joint, then inserting the silicone elastomer prosthesis and testing the motion of the joint again. As expected, the silicone prosthesis simply collapsed under the pressure exerted by the cadaver's plantar attachment. Since the cadaver tissues could not be released without jeopardising the aims of the experiment, i.e. keeping the plantar attachments fully functional, no motion tests were possible within the cadaver. Gerbert and Dodds (1986) encountered similar difficulties with tissue release when they inserted silicone hinged-prostheses into living patients. The photographic evidence that they provide, illustrates the difficulties they encountered with prosthesis compression. Their photographs reveal to what extent the soft tissues of the FMTPJ have to be released at the time of insertion to prevent the prosthesis from compressing when the joint was extended.

In joints amputated from the cadavers, the compressibility of the prosthesis was tested by replacing the plantar aponeurosis with artificial ligaments, the tension in which could be altered. However, no change in the pattern of motion due to variations in the ligament forces across the joint could be demonstrated – provided that the forces were kept beneath the distortion threshold of the silicone elastomer. From the photographic evidence provided by Gerbert and Dodds (1986) the distortion threshold was judged to be similar to the point where a surgeon would consider releasing the soft tissues. Above the threshold no tests could be conducted because the prosthesis seemed capable of a large variety of bends, twists and distortions that effectively prevented any form of controlled experimental procedure from being conducted on the joint motion.

'Soft tissue release' is recommended by most surgeons in the literature when referring to a successful outcome. For example, during a Keller resection, adequate release is gauged by the surgeon opening a semi-permanent gap the size of his finger-tip between the bones. However, this 'soft tissue release' is believed to be practically indistinguishable from 'total release' of aponeurotic tension. Silicone arthroplasty has been technically defined as an augmented resection utilising an interpositional spacer (Vanore et al 1986); soft tissue release therefore appears obligatory to ensure the silicone prosthesis can be inserted at all – but in the process it effectively removes any prospect of restoring normal joint function.

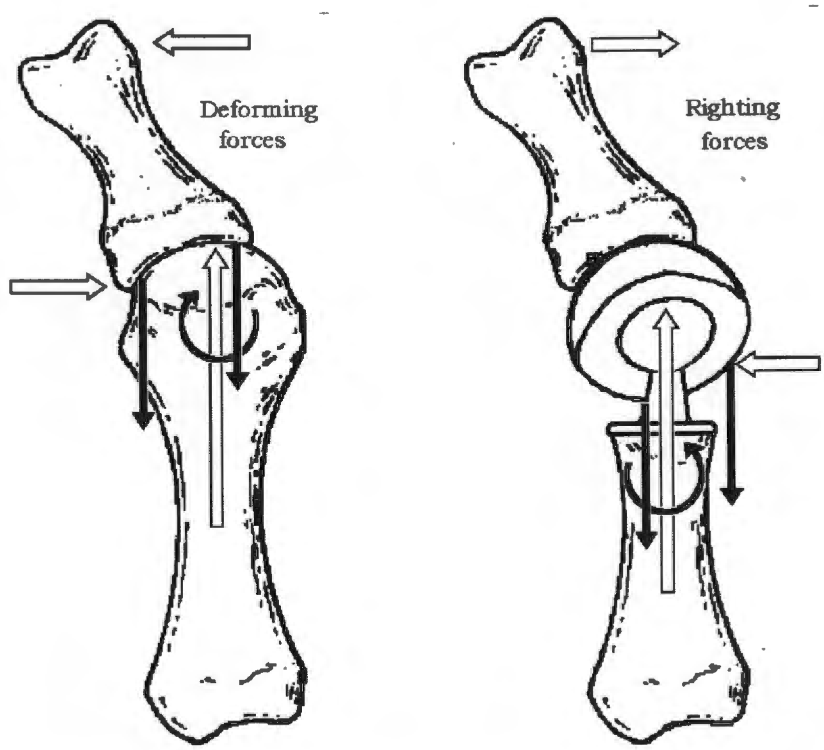
7.3 ASSESSMENT OF PROTOTYPE DESIGN FEATURES

The first criterion of a good design is an appropriate articulation; this has already been discussed at length. The second criterion is that the prosthesis must have good stability, which will be discussed next, followed by an assessment of the degree to which the various design features that were included in the three prototypes meet the remaining criteria. Finally, the types of patient that may benefit from arthroplasty are defined in terms of the biomechanical model. The discussion is brought to a conclusion by attempting to predict the performance of the new prosthesis *in vivo*, and weigh up the potential benefits and risks to the patient.

7.3.1 STABILITY AND ALIGNMENT

A ball-and-socket configuration was the preferred solution, even though such a design requires the resection of the joint's ligaments and a large portion of the metatarsal bone. For this reason, it is necessary to assess whether the replaced joint will be stable without its ligaments. The cadavers were not entirely suitable research material in this regard because the tissues were stiff and could not be surgically corrected. Although the joints were tested outside the cadavers, their potential behaviour *in vivo* could not be predicted because the apparatus settings constrained all movement to a single plane. Artificial ligaments were of little value because the positions, lengths and relative tensions of these could not be accurately estimated because of the complex nature of the FMTPJ motion.

Firstly it needs to be said that the normal FMTPJ is potentially unstable because the phalangeal attachments insert distally to the centre of rotation. This instability is aggravated if there is no muscle or ligament insertions into the hallux from the medial side of the foot. For example, a valgus rotation of the hallux shifts the proximal phalanx across the MT-head, increasing the lever arm of the soft tissue attachments that insert into the base of the proximal phalanx—this inevitably result in the proximal phalanx being pulled across the metatarsal surface. A situation of unwanted positive feedback exists; i.e. as the deformity increases, so to do the deforming forces [Figure 58].



(a) (b)

Fig. 58. Self-aligning properties of a ball-and-socket prosthesis.

A ball-and-socket design is believed to be inherently more stable than all existing prostheses because the sesamoid grooves have been transferred to the other side of the joint hence the plantar attachments act proximal to metal-head through which the compressive joint reaction forces pass. Whenever the ball-and-socket prosthesis is displaced in valgus, the lever arm of the plantar aponeurosis pulls on the medial side of the ball [Figure 58b]. The tendency is therefore for the tensile forces to invariably straighten the hallux when the ball-and-socket prosthesis is out of alignment.

Experimentally, this effect was demonstrated in the cadaver with hallux valgus. When the hallux was extended or flexed, the intersesamoid ridge on the prototype cup was pulled into line with the plantar attachments; whereas in the very same natural joint, prior to the arthroplasty, the hallux was pulled out of line by the same movements. Although both the valgus and inversion angle of the hallux were routinely measured in the experiments, the findings could not be presented as statistically conclusive due to the limited sample size and the lack of control that could be exercised over the soft tissue alignment in the rigid cadaver. [The prosthesis was only successfully inserted into two cadavers because of cadaveric bone fractures; and only correctly aligned in one due to the problems with tissue stiffness]. However this finding is consistent with the outcome of the long-stem Richard's prosthesis, which was known on least one occasion to have fail after an irreducible dislocation.

The prototype design relies on the fact that a fibrous capsule will form around the components and prevent them from dislocating. Obviously a capsule was not going to form in the cadavers, but it is predicted encapsulation will occur *in vivo*. Charnley's experience with the hip reveals that stability in that joint is primarily maintained by a strong tight fibrous capsule reforming around the ball, preventing dislocation. The same will predictably occur in the hallux due to the high proportion of fibrous tissue in the fore-foot region.

Precisely how the plantar aponeurosis will behave *in vivo* in the presence of new fibrous tissue remains unclear. The mechanics of the replaced joint must be different from the normal joint. When the replaced FMTPJ is extended, the fibres might well stretch in an arc between plantar side of the cup rim, the MT-collar and the calcaneus. Despite the fact that the prosthesis-head cannot rise in the socket, the calcaneus will still be pulled anteriorly because the distance between the socket rim and the collar increases when the replaced joint extends. Like the drawn string of a bow, extension of the replaced joint should pull the cup and the calcaneus closer together—remembering that about 1 cm of shortening is all that is needed for the windlass effect to cause the arch to rise. Figure 59 compares the distribution of fibres in an anatomical resurfaced arthroplasty and a ball-and-socket prosthesis.

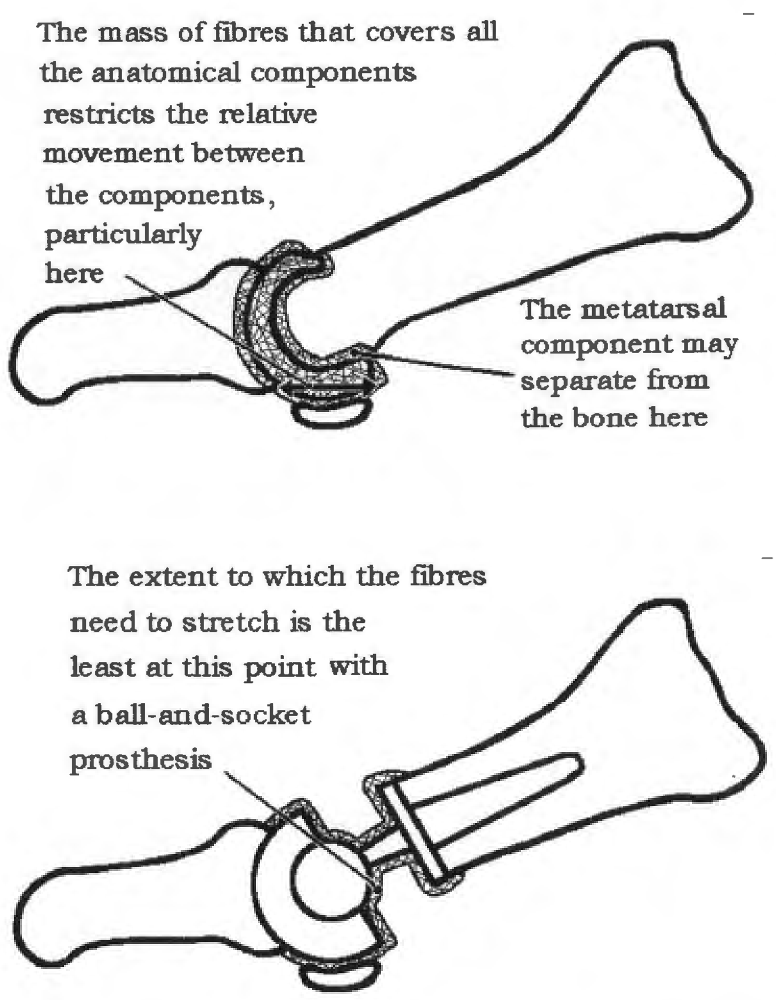


Fig. 59. Envisaged effect of fibrous encapsulation on two types of replaced FMTPJ.

The characteristic two centers of motion were indeed found to be present in the two prototype prostheses that was inserted in the cadavers, but again due to bone fractures a significant sample could not be obtained to be able to make any conclusive statements, although the results seemed promising.

The primary cause of dislocation in the replaced joint is likely to be soft tissue misalignment, particularly since proper instruments have been designed to correctly align the prosthesis with the bone. However, the poor state of the preserved tissue did not permit a proper assessment of the facilities needed to correct the alignment of the soft tissues *in vivo*. The eyes on the sides of the prosthesis were originally believed to be necessary to align the soft tissues with the cup. However, this function demanded the development of special tools to align the cup with the bone while the bone cement was still pliable. It was found that if acute dislocation did occur, the joint would be so badly aligned that it would need immediate revision. In this case, the use of the collar to prevent the components from slipping past each other was found to be the best solution. The potentially serious effect of chronic deformities developing due to scar tissue and fibrous contractions, could not be predicted from the available information.

The intersesamoid ridge on the cup is an important feature because it directs the line of action of the strong phalangeal-sesamoid attachments. Because of the importance of soft tissue alignment is suggested that the eyes in the cup wall be retained, even though it might only be necessary for the surgeon to suture the sesamoid attachments in position if the patient has serious deformities. In the longer term, there may be a need for soft tissue to grow through the eyes to anchor the plantar attachments to the prosthesis and thus prevent them from subluxing or stretching.

7.3.2 STRENGTH OF FIXATION

The quantity and orientation of the fibres around the replaced joint will determine the direction of the joint reaction forces. Considering the properties of cadaver bone, and the fact that the strength and flexibility of the reformed capsule are not known, it was believed that any theoretical or experimental stress analysis of the fixation at this stage of the design process might have produced misleading results. It is perhaps necessary to justify this point with an example from the literature review: Swanson (1972) proved *in vitro* that a silicone prosthesis could be flexed so many times that it would allow a patient to walk around the planet earth about 15 times without serious damage—yet *in vivo* its use is contra-indicated in active patients.

The fixation of the components to the bone is a major concern on both sides of the joint. On the MT side the trabeculae within the MT-medullary canal give a good indication of the direction of the principle stresses in the bone at any particular point. The trabeculae in the distal MT-head are structured in the form of a diamond lattice. Any prosthesis stem inserted in this region will be orientated so that it bisects the angle between the trabeculae, i.e. the prosthesis-bone interface will lie on the plane of the maximum shearing stress—arguably the worst orientation for the prosthesis-bone fixation. Also the fibrous tissue growth around implants, particularly with the two-component bone-resurfacing variety, is believed to alter the loading pattern considerably. A combination of the poor bone/prosthesis stress matching and the additional force vectors that are introduced when the reformed capsule is stretched, may explain why MT-head prostheses with non-cemented short stems fail due to poor fixation and gross instability.

However, neither the trabeculae orientation nor their density is constant along the length the metatarsal. In the mid-section of the shaft the trabeculae are tangent to the cortex, which makes this an ideal location for the prosthesis stem. The Richard's prosthesis is the only type of existing design that has a stem that is sufficiently long to be cemented into the mid-shaft region. In one case, this prosthesis apparently failed due to a non-reducible dislocation. Similarly in the hand, the fixation of the long stem of the De La Caffinière thumb prosthesis appears secure—the prosthesis failed due to cup rotation. The long MT-stem is therefore considered a positive feature in the FMTPJ.

The stems and pegs of various existing FMTPJ prostheses have large notches in them, which key the components into the cement. Notches were not included in the prototypes because it was necessary to remove the prototype to examine the thickness of the cement mantle. However, some form of key may be needed to ensure a permanent rigid fixation. On the phalangeal side of the joint, the T-shaped peg had parallel surfaces that provide better security against torque than a notch, and its second moment of inertia improves its bending strength/weight ratio. Notches may be more useful on the MT-stem, because even though they create stress risers; fractures in the thick metal stem are believed to be unlikely because of the relative thin cross-section of the metatarsal's cortical bone.

7.3.3 FRICTION AND WEAR

The prosthesis was designed according to the principle of low frictional torque between the head and the cup, which dictated that the head size be minimised compared to the cup wall thickness. However, in the hallux, the wear rate places equally significant, but contradictory constraints on the head size. The wear rate and frictional torque were both calculated by extrapolating data from the hip; even though there are distinct differences in the biomechanics of the hip and hallux.

Compared to the hip socket, the average projected wear rate in the FMTPJ is rather poor (0,3 mm/year vs 0,15 mm/year). This difference is compounded because the wall thickness is much less in the hallux. On the other hand, the loading pattern is less demanding in the hallux, peaking only before toe-off. On the positive side, wear in the hip does not alter the joint forces; but in the hallux, prosthesis wear may alter the loading pattern—the more the wear the less the load.

Unfortunately, the wear rate in hips has been shown to be more dependent on the activity level of the patients rather than on variations in their weight (Charnley et al 1969). This means that a less arduous loading regime might not necessarily reduce the wear rate in the hallux. This is because the mechanisms of wear, for example scouring, pitting or flaking, can vary according to the bulk of material present and the distance travelled by the surfaces rather than simply on the bearing pressure. However, the data from the hip should not be discarded as unreliable simply because it predicts an extraordinarily higher wear rate in the hallux than is currently experienced in the hip, despite the smaller size of the prosthesis.

Not all the effects of prosthesis wear need be detrimental because as the prosthesis wears, the MT-length decreases. This may be beneficial to the survival of the FMTPJ prosthesis because it may reduce the load borne by the prosthesis. On the other hand, wear might well undermine the biomechanical improvements brought about by the new design. The situation is even less clear when one considers that, unlike in the hip, a limited amount of joint stiffness may actually assist the plantar aponeurosis in raising the arch and stiffening the foot.

As a wear pattern becomes established, the prosthesis neck still needs to be long enough so as not to interfere with the articulation. The larger the head, the greater is the range of motion. The gap between the head and the collar also needs to be sufficient (about 2 cm) to prevent a direct fibrous linkage forming between the collar and the cup. This is believed to be vitally important because it is precisely this fibrous encapsulation around the close-fitting components of an anatomical prosthesis that is suspected of causing them to fail. The conflicting constraints of wear and frictional torque can only really be resolved *in vivo*, but since wear penetration is a serious concern, it was preferred to err towards a larger head size, for example a 11 mm is preferred to the smaller 9 or 10 mm head.

7.3.4 STANDARDISATION AND COST EFFECTIVENESS

The prosthesis is a simple geometric design that can be manufactured with standard machine tools. A single head size (11 mm) may be used as standard, but at least four different cup sizes may be needed (18 mm, 20 mm, 22 mm, 24 mm). It is preferable though, that a smaller head size (9 mm) be used with the smallest socket because of the wear. The prosthesis can be used in either hallux, because of it's symmetrical design.

The precise specifications of the metal and polymer to be used, and details such as the qualities of the surface finish have not been specified here, but they should be of the highest quality so as to reduce the effects of wear. It should be noted that the ball-and-socket principle developed in this research is largely independent of the materials used in its construction, therefore when new hard-wearing materials become available they could be used for the prosthesis without significantly altering its design. However, new material development is a field all of its own, and it was considered better not to confuse the issue of designing a FMTPJ replacement with developments in new materials.

The cost effectiveness of the prosthesis has not been explored. This is intimately linked to the number of prostheses that are to be manufactured. This depends on which pathological conditions the prosthesis can correct. The opportunities are many because the FMTPJ is the joint in the foot that most often requires surgical intervention, and current surgical techniques all appear to have limited success. A major difficulty is likely to be one of perception; the functions of the hallux are obscure and therefore easy to dismiss as being of secondary concern. Additional research is therefore required to conclusively link the functions of the hallux to the functions of the limb.

7.3.5 SAFETY AND REVISION

The most pressing need for any prosthesis is that it can be inserted in the first place. Almost any prosthesis will stay in place for a few years if sufficient soft tissue is released (Johnson 1989). However soft tissue release is tantamount to removing all function from the joint, possibly to the extent making the prosthesis redundant. In order to restore function, unlike existing designs, a ball-and-socket configuration demands that a large portion of the MT bone be resected. The question must arise as to whether such a risk is justified, particularly because most patients seem to be satisfied with the pain relief afforded by existing procedures, and to some degree by the cosmetic improvements possible with silicone rubber prostheses.

Unfortunately surgery is always traumatic, which appears to inevitably result in the disruption of FMTPJ function. This might explain why any even "successful" surgery of the FMTPJ produces weight distribution patterns that are almost indistinguishable from the results of amputation. Excessive pronatory forces are often listed as a primary predisposing factor in hallux valgus. Both surgery and current prostheses fail to correct this imbalance; in fact they appear to aggravate it by removing the joints supination functions.

The restoration of the foots ability to supinate to counter excessive pronation, is therefore desirable, not only to restore function, but to reduce abnormal loading on the prosthesis itself. One unexpected 'beneficial' side-effect of most if not all current FMTPJ surgery is that it appears to completely disrupt the weight bearing function of the joint. This ensures that the prosthesis cannot be exposed to the excessive biomechanical demands placed on the normal joint. Pain is relieved by keeping the damaged bone surfaces apart; and a double-stem prosthesis may partially influence the alignment of the hallux. Nevertheless in the final analysis, it is the silicone prosthesis's inherent incapacity to bear weight that completely excludes its use in active patients.

Under these circumstances it is not surprising that it is the Swanson silicone prosthesis that functions best—because it is so flexible that it is completely incapable of raising the arch in the first place. For the Swanson prosthesis to be inserted at all requires adequate soft tissue release. If excessive pronatory "forces" are apparent during insertion, the surgeon will release the soft tissues. The prosthesis thus avoids the extreme stresses and torque's present at the toe-off phase of gait. However, its "success" (as Granberry et al 1990, pointed out) is solely based on limiting its application to the undemanding client that has had a chronic loss of joint function that will not be suddenly missed if function is not restored, making pain relief and cosmetic appearance the sole criteria for replacing the joint. It is perhaps ironic that the Swanson double-stem is the most successful design to date precisely because it does not restore function rather than succeeding in restoring function. For the optimist this may be seen as the ultimate in conservative treatment; but the end result is that the silicone prosthesis still performs no better than amputation.

This unusual situation possibly accounts for the fact that prostheses that only offer marginal improvements invariably perform worse than expected, and worse than the Swanson silicone prosthesis that offers few biomechanical benefits. With the hallux, there appear to be no half-measures, either a prosthesis restores full function or it does not. It is important to bear this in mind when considering the need for large amount of bone resection required to insert a ball-and-socket prosthesis—a step that was not taken without due consideration of the consequences of failure and subsequent need for revision.

If one design criterion cannot be met, perhaps the best one to avoid is the need for revision. Normally such an approach is often a desperate one, which should be condemned outright in the interests of patient safety. However, the FMTPJ does not appear to tolerate failure very well. It is only after careful consideration of the role of the FMTPJ that such a measure is even suggested. It appears that the very nature of the FMTPJ function leaves little margin for error. In such circumstances, and only in such circumstances, should the need for revision be relegated in importance—after all the prosthesis should be design to succeed, rather than being designed to fail just in case it needs to be revised. The new prosthesis appears to offer the prospect of complete rehabilitation, if perhaps of a limited duration due to the poor projected wear rate.

7.3.6 CLASSIFICATION OF PATIENTS

Currently many potential patients are excluded from the benefits afforded by prosthetic arthroplasty; therefore it is necessary to identify why this is so. More precisely, it is necessary to define the patients in terms of biomechanical characteristics rather than as merely "young", "active", or "rheumatic deformed". FMTPJ prostheses are currently contra-indicated for these patients.

The fact that FMTPJ arthroplasty is contra-indicated for active persons is believed to be related to the physical phenomenon that causes the joints of the mid-foot to lock under a combination of supination and load-bearing. Locking the mid-foot joints effects the FMTPJ because, while the arch is elevated and the foot is bearing weight, supination-pronation motions occur primarily at the metatarsophalangeal joints. When the foot is inactive and unloaded, the joints in the mid-foot are unlocked and the supination-pronation motions occur in the mid-foot away from the FMTPJ. However, active patients are more likely to engage in activities such as running which demand more extensive fore-foot involvement. Without the arch being raised, supination must occur at the FMTPJ, which is detrimental to any prosthesis that is not designed to withstand a combination of weight-bearing and rotation forces simultaneously.

As for the elderly patients, the plantar aponeurosis has shown to deteriorate after the age of 30 years (Hicks 1954; Hutton 1981). Load bearing may be compromised by the reduced strength of the plantar aponeurosis in later life. It should be noted that "active" patients need not necessarily have a functional FMTPJ, but failure to preserve the functions of the FMTPJ will be particularly detrimental to active patients. Therefore silicone prostheses might well work in "elderly active" patients because the definition of active is no doubt relative to age. Elderly sedentary patients may benefit from silicone arthroplasty that addresses the pain and cosmetic concerns of such individuals but these narrowly defined "benefits" cannot be extended to young active patients that need the full range of biomechanical functions be restored. If the proper function of the FMTPJ is not restored, strenuous activity will increase the physical demands made on the prosthesis, without any benefit accruing to the patient. This is over and above the natural increase in demands made due to the variations in activity levels alone. The truth is that a silicone prosthesis might only function well in an "elderly sedentary" patient that place few demands on her feet. As Johnson (1989) observed, "(current) surgery will not make it possible for the patient to enter the local '10-km' race".

The selection of patients for future trials needs to be done with care. Due to the large amount of bone that needs to be resected it is suggested that patients be selected from those who currently have no recourse to corrective surgery, or those who need revisions of previous surgery. For example, a potential candidate would be one with a failed bony fusion following an osteotomy of the distal shaft. Other candidates would be patients that have had distal MT-head osteotomies, a procedure that is routinely performed during total fore-foot reconstructions. Neither of these categories of patient are suited for silicone prostheses. Offering such patients a chance for rehabilitation in experimental trials, might offset the initial risk that the ball-and-socket prototype might encounter difficulties with bone necrosis, fixation difficulties and the effect of fibrous encapsulation—aspects that cannot be resolved in cadaver trials.

The patients who stand to benefit most from biomechanical characteristics of the new prosthesis are the young and active. However, the high projected wear rate may count against them in the long term at least until data pertaining specifically to the hallux can be accumulated from clinical trials.

It is convenient to note here that although the plantar aponeurosis connects to all the toes, the windlass effect is chiefly applicable to the first ray. This is because the lesser MT-heads are much smaller and they do not have sesamoid bones to increase the mechanical advantage of the plantar aponeurotic attachments to the proximal phalanx. Also the smaller toes each have three phalanges as opposed to the two of the great toe. The combined effect of these differences means that tension in the plantar attachments tends to claw the small toes; i.e. the small toes are raised by arching (clawing) instead of the foot arch itself being raised. Hence a FMTPJ prosthesis cannot be used in the lesser toes.

The design and testing of a new prosthesis inevitably raises as many questions as it answers. Hopefully the exercise of designing a new FMTPJ prosthesis has shed some light not only on the answers, but may also go some way to answering future questions that it may be raised. Since design is an iterative process, this research can therefore be considered to have achieved its objectives—a practical prosthesis has been designed that has a reasonable chance of succeeding in restoring the biomechanical function to the great toe in living patients.

CHAPTER 8
CONCLUSIONS & RECOMMENDATIONS

8.1 CONCLUSIONS

1. Motions of the FMTPJ were measured as a motion of the metatarsal bone relative to the axis of the proximal phalanx. Using this method in cadavers, each end of the first metatarsal bone was found to possess its own distinct center of motion. The center of motion of the distal end of the metatarsal is located near the center of the metatarsal head; the center of motion of the proximal end of the metatarsal is located at a distance of about half the length of the metatarsal proximal and superior to the metatarsal head.

2. The two centers of motion for the opposite ends of the metatarsal were found to be dependant on the natural fibrous attachments within the cadaver because the FMTPJ exhibited a single center of motion when the motions of the FMTPJ were was measured in amputated specimens.

3. The locus of movement of the proximal metatarsal in the sagittal plane was circular.

4. The design of a new FMTPJ prosthesis relied on adhering to the following principles:

   - the replaced joint had to be capable of bearing a normal amount of weight.
   - the circular locus of motion of the proximal metatarsal had to be maintained.
   - the joint had to be free to supinate and pronate at any angle of flexion or extension.
   - the correct tension in the plantar aponeurosis had to be maintained.

5. The only design alternative that could meet these requirements was identified as a ball-and-socket configuration.

6. Essential features of the metal metatarsal head component were:

   - cobalt-chrome or stainless steel prosthesis head.
   - a head diameter of between 9–11mm.
   - a long stem inserting into the metatarsal's intramedullary canal.
   - a collar, shaped to limit component dislocation.

7. Essential features of the polymer cup were:

   - ultra high molecular weight polyethylene cup.
   - an outer cup diameter of between 18–24mm.
   - a short "T-shaped" triangular intramedullary peg that inserted into the phalanx.
   - anatomically shaped intersesamoid ridge built into the plantar side of the cup.

8. Special surgical instruments were found to be essential for the handling and alignment of the new prosthesis. Care had to be exercised to ensure that the prosthesis was correctly aligned with the bones rather than the soft tissues. Soft tissue release cannot be advocated, but it is essential that the ligaments of the joint be resected. At least 3,0 cm of bone needs to be resected from the metatarsal head to allow sufficient space for the prosthesis to articulate. The components must be cemented in place because the bone cortices are too thin to allow for a press-fitting biological fixation.

9. Cadavers were considered adequate experimental material despite the fact that many difficulties were encountered. The motion tests achieved good results, but the insertion of the prototype prostheses proved problematic due to the stiffness of the preserved tissue. The invasive nature of the measurements and uncertain condition of the cadaveric bone both contributed to bone damage, which prevented a statistically significant number of prototype prostheses from being inserted in the cadavers.

10. The prime advantage of the new design is that it is designed to restore the biomechanical functions of the joint, not merely the movements of the hallux. The new prosthesis has the potential to be inserted into a wider range of patients than is currently possible given the biomechanical limitations of elastomer prostheses. In particular, patients that currently have little recourse to corrective procedures, such as those that suffer from pathological and surgically induced deformities of the metatarsal head, may benefit from the new prosthesis.

11. Potential limitations of the new design are that projections of the wear rate in the hip conservatively predict that prosthesis life may on average be limited to between 15–25 years. However, the design is largely independent of the materials used and the development of newer hard-wearing materials may be able to extend its life-span.

8.2 RECOMMENDATIONS

1. The prototype prosthesis appears to offer distinct advantages over existing arthroplasty techniques. It is therefore recommended that the prosthesis be manufactured in limited quantities for clinical trials.

2. Further research is necessary before the procedure can be considered safe. It is therefore recommended that the surgical technique required to insert the prosthesis be reviewed and developed further by orthopaedic surgeons.

3. The findings indicate that there are structures unique to the FMTPJ that determine the center of rotation of the metatarsal bone. These are believed to be part of a mechanism that controls a wide variety of leg movements without the intervention of the muscles. It is therefore recommended that research be conducted into the detailed anatomical structure of the joints of the lower limb as a linked mechanical chain stretching from the great toe to the knee.

4. It is possible that the FMTPJ directly controls of the center of weight-bearing during all types of bipedal stance or locomotion. Since this aspect of gait analysis has been neglected in the past, it is recommended that the role of the FMTPJ in maintaining bipedal balance be investigated.

5. The FMTPJ mechanism could be analysed in terms of a work-energy paradigm. The combination of energy and stride length suggest that these effects might be related to the efficiency of walking and running. Research should therefore be focused on the effects FMTPJ motion has on stride length and energy expenditure during walking and running so that the mechanical limitations of athletes and invalids can be defined.

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APPENDICES

APPENDIX A

BONE DIMENSIONS

Bone Dimensions	Mean Value	Standard Deviation
Metatarsal length:	61,92 mm	4,49 mm
Shaft width (lateral view):	20,48 mm	2,21 mm
(dorsal view):	20,92 mm	2,03 mm
Phalanx width (lateral view):	19,08 mm	1,68 mm
(dorsal view):	17,36 mm	1,72 mm
Sesamoids	No data published	

Table A-1. Dimensions of the FMTPJ bones of a sample of 129 feet (Wyss et al 1989).

Metatarsal No.	r_1 (mm)	r_2 (mm)	x (mm)	ϕ (degrees)
1	11	10	-2	104
2	13	9	4	36
3	10	8	2	15
4	12	8	4	36
5	10	7	3	40

Table A-2. Dimensions of a sample of five metatarsal heads (Stokes et al 1979a).

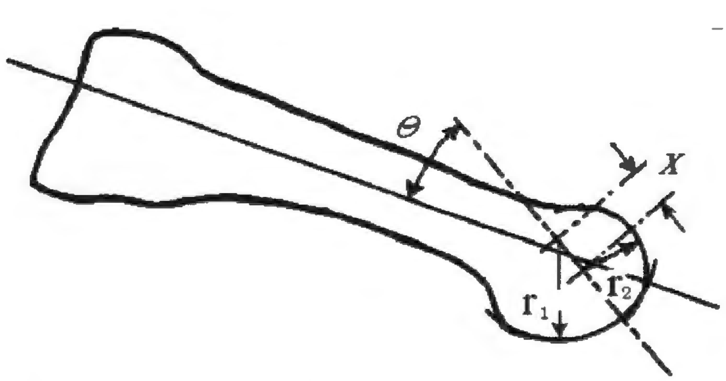

Fig. A-1. The four variables used to define the profile of the MT-head (Stokes et al 1979a).

APPENDIX B

MUSCLES CONTROL OF THE MEDIAL ARCH OF THE FOOT

The muscles of the foot can alter the shape of the arch. In Figure B-1 it should be noticed how the end points of the arch move relative to the ground and whether the shape of the arch A-C is raised or flattened by the muscles. Another important effect is how FHL orientates the calcaneus by the bow-stringing of its tendon around the sustentaculum tali—a small overhanging bony protuberance on the calcaneus. FHL is also involved with anterior/posterior movements of the talus relative to the calcaneus.

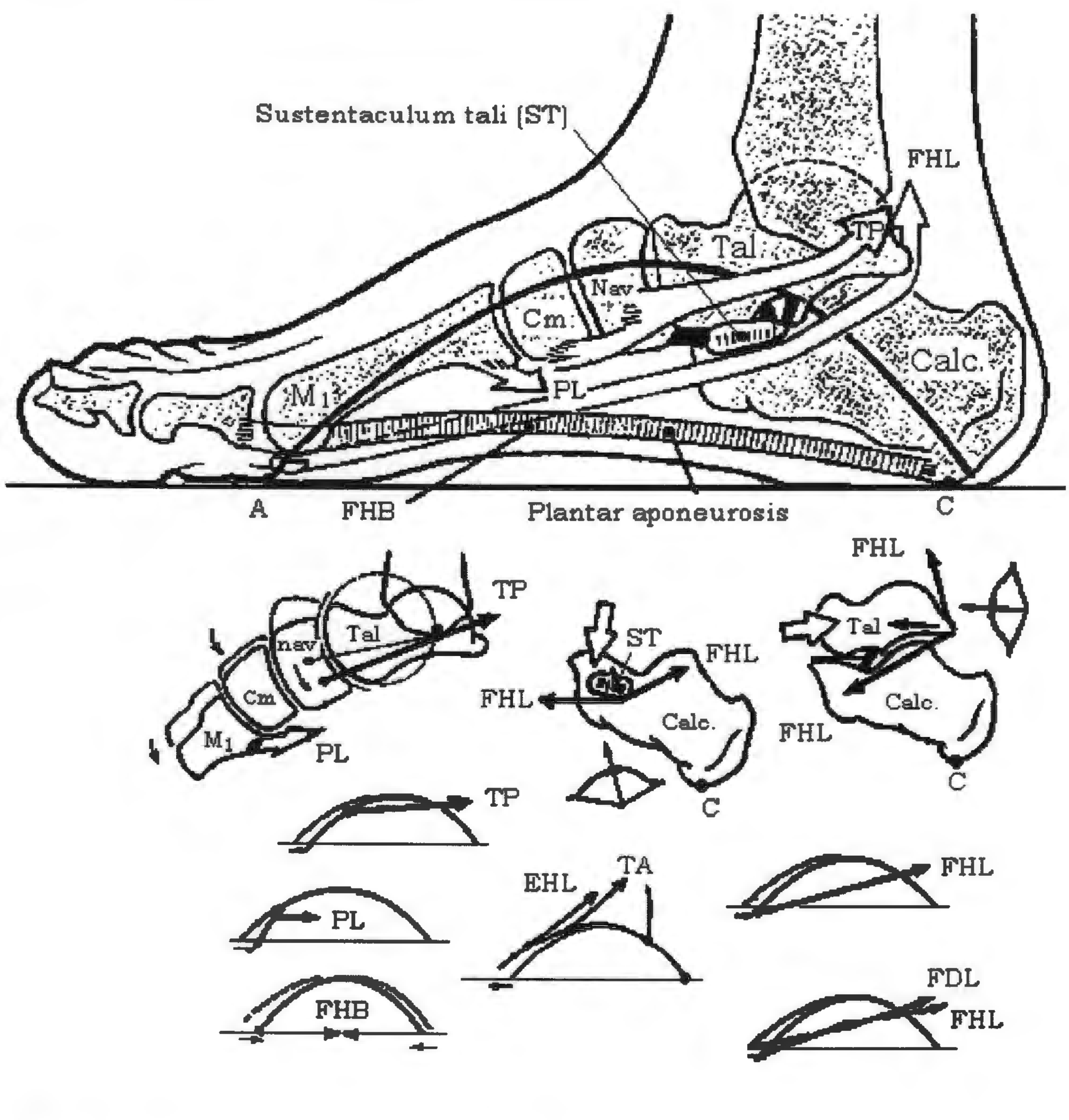

Fig. B-1. Muscle force vectors and their effect on the shape of the arch of the foot and the relative displacement of the bones. (Adapted from Kapandji (1987)).

APPENDIX C

ANALYSES OF FORCES IN A NORMAL FMTPJ

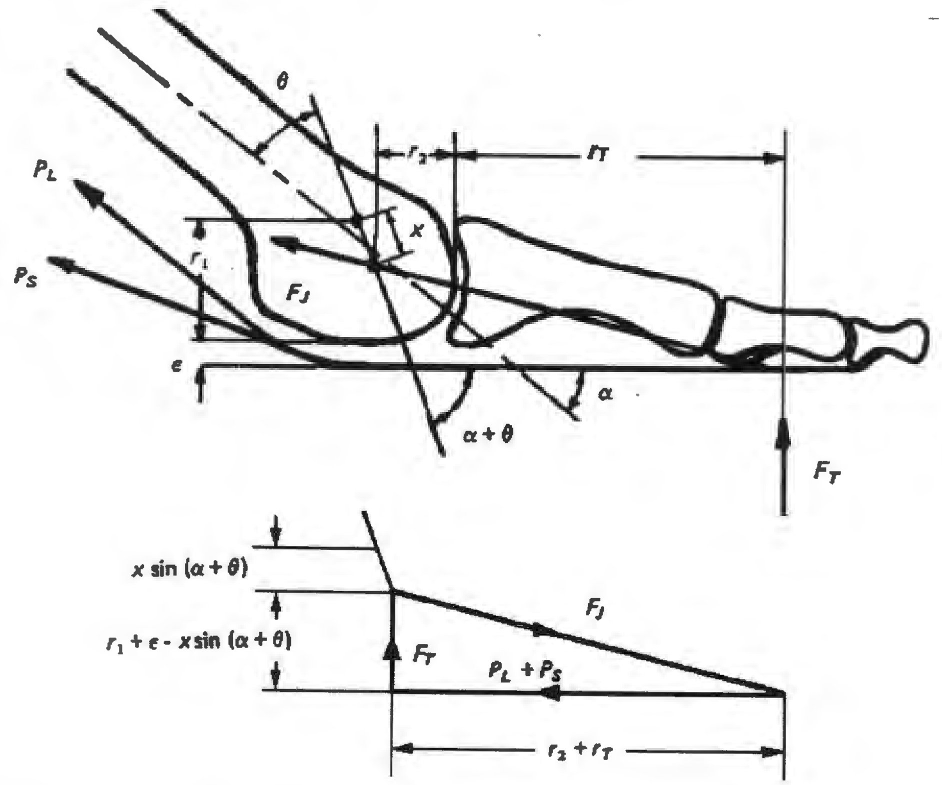

Fig. C-1. Vectors used to determine the forces acting on the FMTPJ during walking. (Stokes et al (1979a).

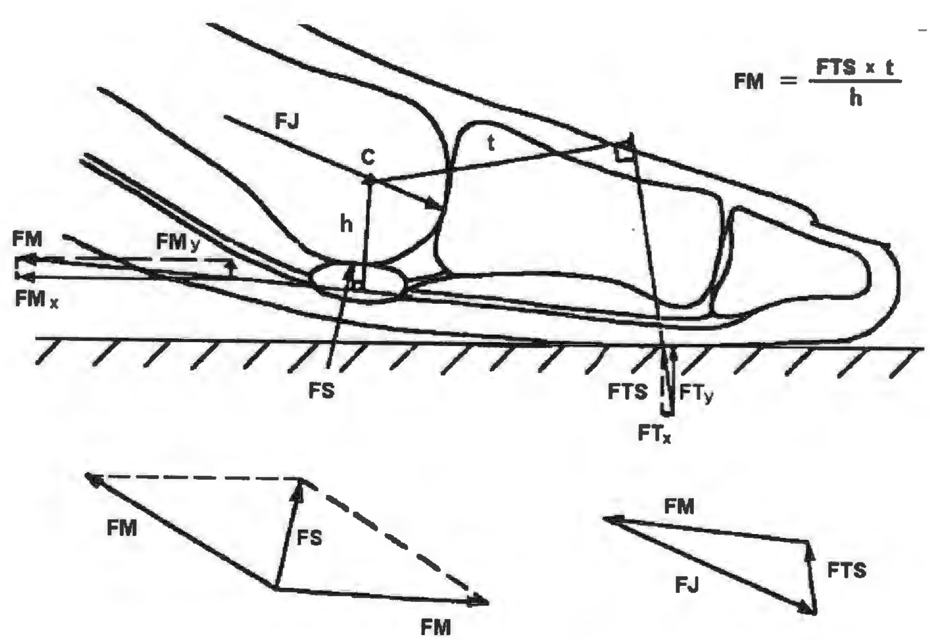

Fig. C-2. Biomechanical model of the FMTPJ in the sagittal plane. (Wyss et al 1990).

APPENDIX D

DATA PROCESSING ALGORITHM

The following algorithm was used to test the validity of whether the locus of the metatarsal was circular in the sagittal plane. According to Adams (1976) it is semi-rigorous determination of the co-ordinates of the center and radius of a circle made from observations of XY co-ordinates of points on the circumference [Figure D-1].

The equation of a circle of Radius R, center at x_0,y_0 is:-

$$(x - x_0)^2 + (y - y_0)^2 = R^2$$

Expanding:-

$$x^2 - 2x_0x + x_0^2 + y^2 - 2y_0y + y_0^2 = R^2 \qquad (1)$$

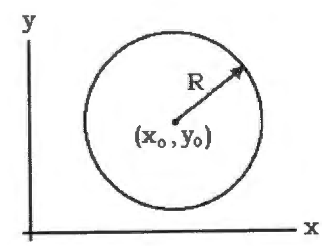

Fig. D-1. Circle coordinates

Now say that from 3 suitably sited points on the circumference of the circle we calculate the approximate center co-ordinates and the approximate radius x_a,y_a and R_a.

Now let:-

$$x_a + \Delta x = x_0$$
$$y_a + \Delta y = y_0$$
$$R_a + \Delta R = R$$

Then we can write (1) as:-

$$x^2 - 2(x_a + \Delta x)x + (x_a + \Delta x)^2 + y^2 - 2(y_a + \Delta y)y + (y_a + \Delta y)^2 = (R_a + \Delta R)^2$$

whence expanding:

$$x^2 - 2x_ax - 2\Delta x.x + x_a^2 + 2x_a\Delta x + (\Delta x)^2 + y^2 - 2y_ay - 2\Delta y.y + y_a^2 + 2y_a\Delta y + (\Delta y)^2$$
$$= R_a^2 + 2R_a\Delta R + (\Delta R)^2 \qquad (2)$$

If we now take out a join between the approximate values of the circle center x_a,y_a and any point x,y on the circumference of the circle we get:-

$(x_a - x)^2 + (y_a - y)^2 = D^2$ say.

Expanding:-

$$x_a^2 - 2x_a x + x^2 + y_a^2 - 2y_a y + y^2 = D^2 \qquad (3)$$

Equation (2) MINUS equation (3) gives:-

$$- 2x\Delta x + 2x_a.\Delta x + (\Delta x)^2 - 2y.\Delta y + 2y_a\Delta y + (\Delta y)^2 = R_a^2 + 2R_a.\Delta R + (\Delta R)^2 - D^2$$

But Δx, Δy and ΔR are small therefore $(\Delta x)^2$ etc. are of second order of smallness therefore we may write:-

$$2(x_a - x)\Delta x + 2(y_a + y).\Delta y - 2R_a.\Delta R = R_a^2 D^2$$

Therefore

$$(x_a - x)\Delta x + (y_a - y)\Delta y - R_a.\Delta R + (R_a^2 - D^2)/2 = d \text{ say.}$$

If we treat this as an observation equation then we can form NORMAL EQUATIONS for *n* observations as follows:-

Δx	Δy	ΔR	$= l$
$[(x_a - x)^2]$	$[(x_a - x)(y_a - y)]$	$- [(x_a - x)(R_a)]$	$[(x_a - x)(d)]$
	$[(y_a - y)^2]$	$- [(y_a\ y)(R_a)]$	$[(y_a - y)(d)]$
		$[(R_a)^2]$	$- [(R_a)(d)]$

Table D-1. Normal Equations for determining the center and radius for a circle by iteration.

The solution is strictly an iterative problem, since an approximate estimate of the center co-ordinates and the radius are made initially. For all practical purposes, a single iteration is adequate. After determination of Δx, Δy and ΔR, the values are applied to x_a, y_a, R_a to obtain x_0, y_0, R_0.

ALGORITHM

```
! This is a TRUE BASIC PROGRAM that determines the best center and radius
! through a set of XY data co-ordinates by iteration.

DECLARE DEF cot, sec, csc, asin, acos, acot, asec, acsc
LIBRARY "\true\minmaxyz.tru"
DIM x(1),y(1),xt(1),yt(1),rr(1),rt(1),dr(1)
DIM a(1,1),l(1,1),at(1,1),b(1,1),c(1,1),d(1,1)

OPEN #1: ! INPUT DATA FILE
   INPUT #1: n          ! n =number of data points
   MAT redim x(n),y(n),xt(n),yt(n),rt(n),dr(n)
   MAT redim a(n,3),l(n,1),at(3,n),b(3,3),c(3,1),d(3,1),rr(n)
   FOR i = 1 to n
      INPUT #1: x(i)
      INPUT #1: y(i)
   NEXT i
CLOSE #1

! CALCULATE CENTER OF GRAVITY OF DATA
   LET totx=0
   LET toty=0
   FOR i = 1 to n
         LET totx=x(i)+totx
         LET toty=y(i)+toty
   NEXT i
   LET mx=totx/n
   LET my=toty/n

! TRANSFORM DATA TO COORDINATES BASED ON CENTER OF GRAVITY
   FOR i= 1 to n
      LET x(i)=x(i)-mx
      LET y(i)=y(i)-my
   NEXT i

!  SET UP COORDINATE MATRIX (ADAMS 1976)
   LET ra=40            ! Initial estimate of radius length
   LET xa=0
   LET ya=0
   DO
   FOR i = 1 to n
      LET a(i,1)=xa-x(i)
      LET a(i,2)=ya-y(i)
      LET a(i,3)=-ra
      LET l(i,1)=(ra^2-((xa-x(i))^2+(ya-y(i))^2))/2
   NEXT i
```

```
   MAT at=trn(a)
   MAT b=at*a
   MAT b=inv(b)
   MAT c=at*l
   MAT d=b*c
   LET x0=xa+d(1,1)
   LET y0=ya+d(2,1)
   LET r0=ra+d(3,1)
   LET xa=x0
   LET ya=y0
   LET ra=r0

! ITERATE
   IF abs(d(1,1))<0.1 and abs(d(2,1))<0.1 and abs(d(3,1))<0.1
     THEN LET ok=1
     ELSE LET ok=0
   END IF
   LOOP until ok=1

   FOR i= 1 to n
      LET x(i)=x(i)-x0
      LET y(i)=y(i)-y0
   NEXT i

! DEVIATION AND VARIANCES
   LET sig=0
   FOR i = 1 to n
      LET rt(i)=sqr(x(i)^2+y(i)^2)
      LET dr(i)=rt(i)-r0
      LET sig=dr(i)^2+sig
   NEXT i
   LET std=sqr(sig/(n*(n-3)))

   LET xc=x0+mx
   LET yc=y0+my

OPEN #2: ! OUTPUT FILE
   FOR i = 1 to n
   PRINT #2: "Radius",r0,"(",xc,",",yc,")",std
   PRINT #2: dr(i)
   NEXT i
CLOSE #2
END
```

APPENDIX E

SAMPLE DATA FOR ONE TEST

Administration Details		Cadaver Details	
Data Sheet N°:	26	Sex:	Female
Cadaver N°:	A	Size:	Small/Medium
Trial N° (Repeat):	3	Foot:	Right
Procedure/ Prosthesis:	None	Condition/ Appearance:	Normal

Metatarsal Coordinates				Apparatus Settings		
Arch		Sesamoids		Valgus offset	Axial offset	Clamp offset
x	y	x	y	V	I	C
58▿	223	86	288	19	12	46
62	220	85	287.5	19	12.5	46
69	217	82.5	286.5	19	14	46
72	216	82	286	18.5	14	45
76	216	81	287	19	14	45
78	216	80	286.5	18	15	45
82.5	215.5	80	286.5	18.5	15.5	45
84	214	77	285	19	16.5	45
86.5	216	78	287	17.5	17	45
62▿	224.5	83	293	17.5	18	45
57	228	85.5	293	20	17.5	45
55	230	87.5	293	21.5	16	44
54	229	87.5	292	18.5	17	44
52	231	89	291	23.5	17	44
50	232.5	89.5	291	25	14	45
47.5	234	92.5	289	25.5	10.5	44
46	233.5	93.5	286.5	26	9.5	44
45.5	234	94	286	26.5	6	44.5
58▿	221	88	285	23	10	44

Notes: All readings in millimetres. ▿ Joint in neutral unloaded position.

Table E-1. Example of the data collected during one FMTPJ motion-test.

APPENDIX F

CADAVERIC TEST PROGRAMME

Data Sheet N°	Cadaver	Foot	Condition/ Appearance	Procedure/ Prosthesis
1 2 3 4	A	left	Hallux valgus	None
5 6	A	left	Hallux valgus	8mm ball 22mm plastic socket
7 8 9	B	left	Hallux rigidus	Keller; performed after phalangeal shaft fractured
No data recorded	B	left	Hallux rigidus	12mm ball 24mm plastic socket
Surgical trial	C	right	Hallux rigidus	12mm ball metal backed socket
10 11 12	D	right	Normal	None
13 14 15	D	right	Amputated wet bones; no soft tissues	Swanson N°2; Artificial ligaments
16 17 18	D	right	Amputated wet bones; no soft tissues	Swanson N°4; Artificial ligaments-minimum tension
19 20 21	D	right	Amputated wet bones; no soft tissues	Swanson N°4; Artificial ligaments-maximum tension
22 23	A	right	Amputated bones; no soft tissues	12mm ball, 22mm metal backed socket
24 25 26	A	right	Normal	None
27 28 29	A	right	Amputated bones; capsule intact	None
30 31 32	A	right	Amputated wet bones; no soft tissues	Swanson N°4
33 34	A	right	Amputate bones; no soft tissues	12mm ball, 22mm metal backed socket

Table F-1. Summary of all tests performed on the cadavers.

APPENDIX G

CALIBRATION

METATARSAL SET-UP

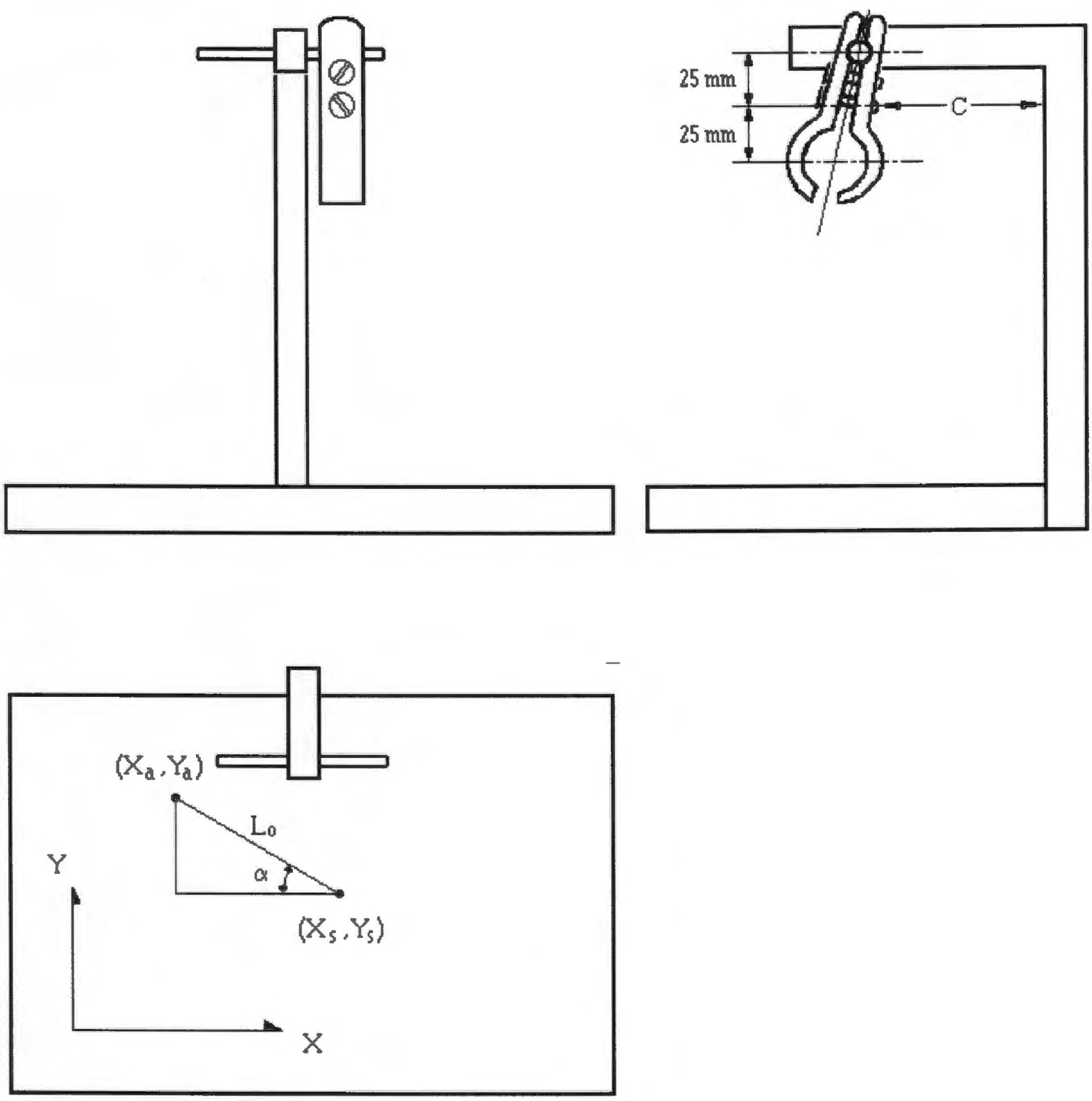

Fig. G-1. Metatarsal set-up for the cadaver trials.

PHALANGEAL SET-UP

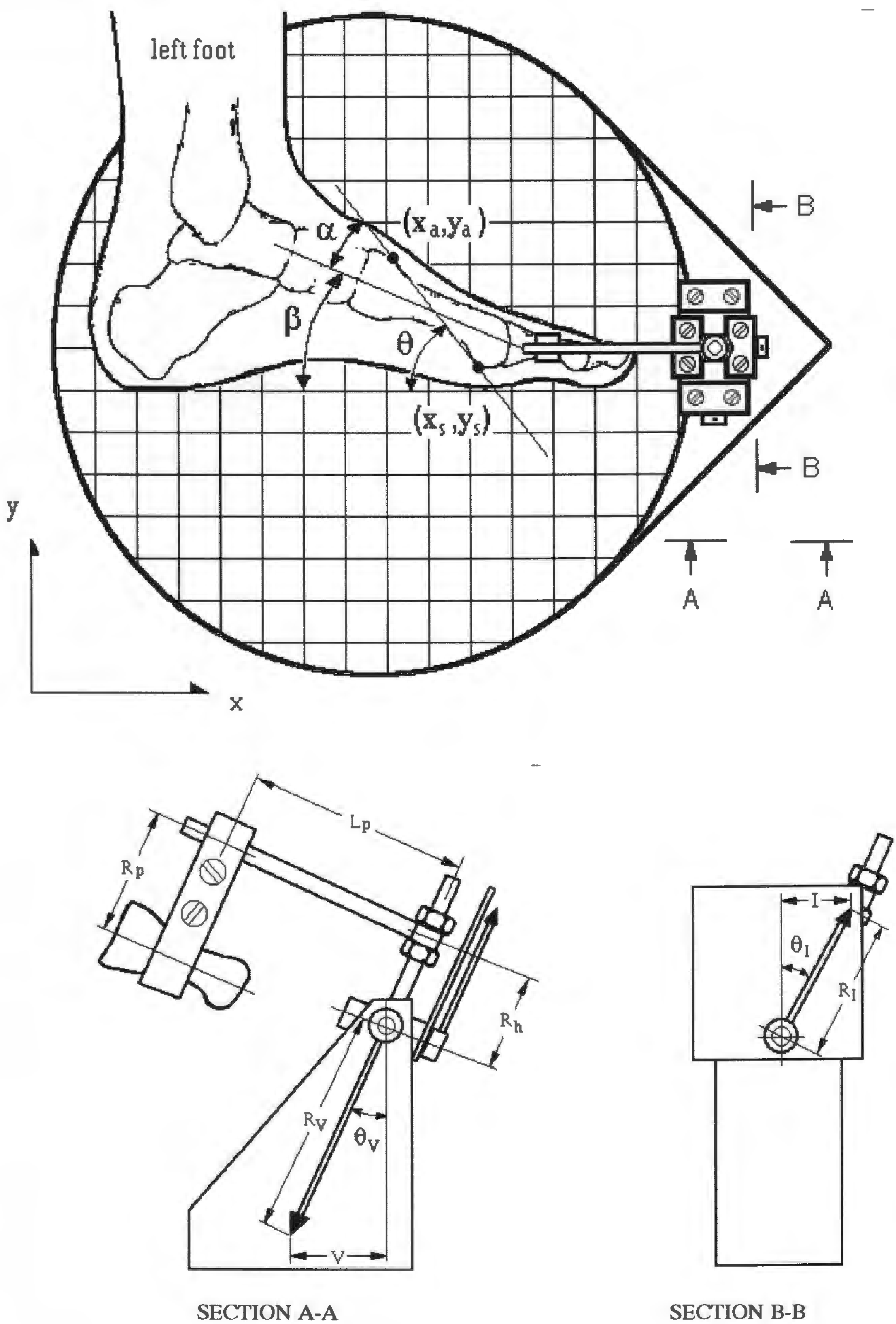

Fig. G-2. Phalanx set-up for the cadaver trials.

SET-UP CONSTANTS

Test No.	METATARSAL CO-ORDINATES				MT-length	Angle to X-axis
	Proximal Arch		Distal Sesamoids			
	X_a (mm)	Y_a (mm)	X_s (mm)	Y_s (mm)	L_0 (mm)	α degrees
1-6	225	340	300	315	79,06	18,4°
7-9	210	335	280	315	72,80	15,9°
10-15	280	345	220	320	65,00	22,6°
16-20	290	350	235	320	62,65	28,6°
21-23	275	350	225	320	58,30	31,0°
24-34	275	350	210	320	71,60	24,8°

Table G-1. The co-ordinates of the first metatarsal as projected down from the suspended cadaver foot onto the opaque baseboard.

PROXIMAL PHALANGEAL SET-UP CONSTANTS		
Constants	Value	Definition
R_p	50 mm	clamp length (between bone and shaft center-lines)
R_V	87 mm	valgus indicator-arm length
R_I	63 mm	internal rotation indicator-arm length
R_h	measured directly	height of phalanx mounting shaft above UV-joint
L_p		distance phalanx clamp and UV-joint along the shaft

Table G-2. Constants needed for the calibration of the phalangeal set-up.

MEASURED VARIABLES

Variable	Description
x_a	X_a in terms of phalanx reference co-ordinates
y_a	Y_a in terms of phalanx reference co-ordinates
x_s	X_s in terms of phalanx reference co-ordinates
y_s	Y_s in terms of phalanx reference co-ordinates
V	displacement of the transverse-plane rotation indicator
I	displacement of the axial rotation indicator
C	displacement of the clamp on the MT-bracket in the Y direction
n	number of experimental observations

Table G-3. Variables that were recorded during the experiment.

DERIVED VARIABLES

Variable	Definition	Description
α	$\tan^{-1}[(Y_a-Y_s)/(X_a-X_s)]$	angle between MT-coords and MT-shaft
$\emptyset$	$\tan^{-1}[(y_a-y_s)/(x_a-x_s)]$	angle between MT-coords and Phalanx shaft
β	$\emptyset - \alpha$	FMTPJ extension angle
$\emptyset_V$	$\sin^{-1}(V/R_V)$	angle of valgus deformity in transverse plane
$\emptyset_I$	$\cos^{-1}(I/R_I)$	angle of internal rotation of phalanx on MT
ΔV	$(\sum V_i) / n - V$	deflection of valgus-indicator
ΔI	$(\sum I_i) / n - I$	deflection of rotation-indicator
ΔC	$(\sum C_i) / n - C$	deflection of MT clamp in Y direction

Table G-4. Experimental variables derived from the measured variables.

CALIBRATION EQUATIONS

x_a	y_a	x_s	y_s
$-\Delta V.L_p(R_p-R_h) / R_v$		$-\Delta V.L_p(R_p-R_h) / R_v$	
	$+\Delta I.L_p(R_p-R_h) / R_I$		$+\Delta I.L_p(R_p-R_h) / R_I$
$+2\Delta C\sin\beta$		$+2\Delta C\sin\beta$	
	$\pm 2\Delta C\cos\beta$		$\pm 2\Delta C\cos\beta$

Note: ± sign determined by inspection [+ if right foot; - if left foot].

Table G-5. Calibration equations that were used to correctly align the MT-co-ordinates on the transparent grid with the proximal phalanx suspended above it.

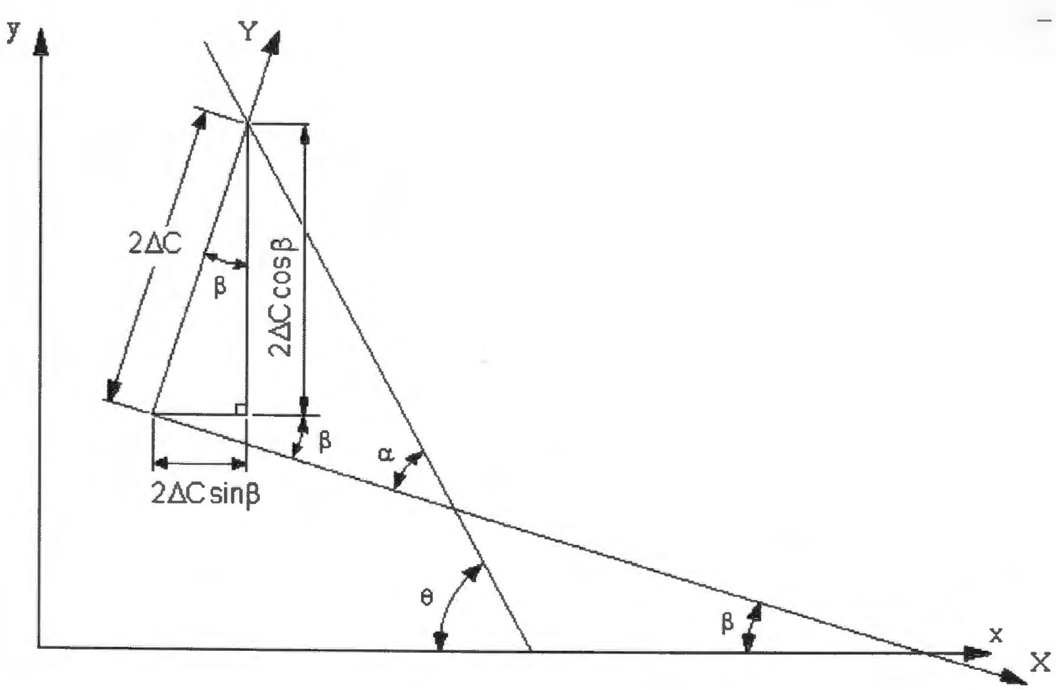

Fig. G-3. Derivation of the metatarsal clamp calibration equations in terms of both phalangeal (x,y) and metatarsal (X,Y) reference co-ordinates.