COMPUTER AIDED DESIGN AND ALIGNMENT OF LIMB SHAPES FOR BELOW KNEE PROSTHESES

by

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ABSTRACT

The use of computer aided design and manufacturing techniques (CAD/CAM) in the prosthetics industry has been a focus of research and development since 1972. Efforts to date have been devoted primarily to prosthetic socket design. A fully integrated CAD/CAM system would include software for the design of the complete limb shape (cosmesis), and thus allow the clinician to reap more fully the benefits of automation in product delivery.

One philosophy for a CAD procedure for below knee (BK) prosthetic limb shape design is that aspects of human limb shape can be standardized and that variations among people can be approximated using mathematical relationships. CAD software was developed whereby the prosthetic limb shape for a BK amputee can be created. Data input consist of selected anthropometric measurements from the contralateral limb, a reference limb shape selected from a computer-based shape library, and measurements of the final prosthesis alignment.

A matrix of five reference limb shapes was created from castings of volunteers. These shapes represent varying degrees of muscularity and adiposity in the adult population. Each was digitized in the form of cylindrical coordinates. Data were stored within the matrix of a computer based reference shape library.

Based on anthropometric measurements from an amputee's contralateral limb, the software selects a reference shape and scales it non-homogeneously to design a unique primary limb shape emulating the contralateral limb.

Taking socket shape, socket-foot alignment, and ankle shape data of the artificial foot, the primary shape is modified by the software to create the final

shape ready for production. The final shape accommodates the socket, conforms to the limb alignment, and merges with the ankle of the artificial foot.

In order to test the CAD procedure, anthropometric measures and socket-foot alignment data were obtained from a single volunteer patient. Using these data, primary and final limb shapes were created. Each was compared numerically in terms of cross-sectional area and shape with data taken from the subject's contralateral limb and conventionally produced prosthesis. Results indicated the CAD process was capable of producing a limb shape with the necessary alignment modifications with an accuracy comparable to that of conventional methods.

DEDICATION

To my beloved Susan,

and to the precious gifts

she has given me.

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1. REVIEW

1.0 Introduction

The field of prosthetics is presently going through a transformation with increased use of computer technology in various facets of the industry. Originally used in research for modelling, data acquisition and analysis, computers have found use more recently in the clinical setting in the form of patient record-keeping and accounting systems.

Another major branch of computer technology, computer aided design and manufacturing (CAD/CAM), has been growing steadily in its application to prosthetics. Orthotics and custom shaped seating are also fields which are now being investigated for potential applications of CAD/CAM. Besides extensive work on using computerized tomography data for CAD/CAM of endoprostheses for the hip, CAD/CAM research has focussed on development of systems specific to the design of lower limb prosthetic sockets for amputees (D.F. Radcliffe, 1986). A small number of prosthetic socket design systems are now commercially available and usage is increasing among the more technologically inclined clinics.

These systems enable the prosthetist to create the socket, but not to complete the production of the prosthesis with a cosmetic limb shape. The present work is aimed at designing a system for the production of the limb shape, so that a complete prosthesis may be produced by automated means.

The first part of the review is an overview of the present artisan techniques used in the design, fitting, and manufacture of below-knee prostheses. The main focus is on the various types of structural configurations and the cosmetic restorations applicable to each.

The second part describes the development and use of computer aided design and manufacture techniques in prosthetics.

The third part reviews documented knowledge of three dimensional shape definition of the human shank. The limited number of investigations on this subject area are discussed.

1.1 Conventional Techniques in Prosthetics

This section of the review looks at some conventional manual techniques used by Canadian prosthetists. Several common approaches are discussed, indicating how labour-intensive these techniques tend to be. Socket casting and design is described first, then alignment and the techniques used to transfer this alignment to the finished prosthesis. Alignment transfer techniques depend on whether the prosthesis is of exoskeletal or endoskeletal design. Cosmesis shape considerations follow and then finally, a brief summary of the assembly time required for the artisan techniques is listed.

1.1.1 Casting and Socket Design

The first step in the creation of a below-knee (trans-tibial) prosthesis, is to take a casting of the residuum. The casting process begins with covering the residuum with an elastic sock and marking the sock with indelible ink to show the locations of useful anthropometric landmarks. Markings are made on the casting of the locations of such structures as the patella and the tibial tubercle (Radcliffe and Foort, 1959, MacCoughlan, 1983). The sock is then covered with a cast made of wetted plaster bandages that are worked into the sock to ensure complete congruence with the residuum. The cast shape is altered, while it is still pliable, so as to clearly define the position and size of the patellar tendon and the femoral condyles. The cast is also impressed in the popliteal region by the prosthetist's hands while the cast is still on the residuum.

Once the cast has solidified, it is removed from the residuum. It is referred to as a "negative" cast. The markings from the sock are automatically transferred to this negative cast because the ink bleeds from the sock to the plaster bandage. The negative cast is filled with plaster of Paris to make a positive cast, and a mandrel is inserted into the plaster for later use as a support for mounting. Again, the markings are transferred as the ink bleeds from the negative cast to the positive cast. The shape of this positive is then altered by removing material with a file in some areas and by adding material in the form of extra plaster in others. The result is a positive of the socket shape. The changes are made in order that the final socket will transmit the forces of ambulation to pressure-tolerant tissue such as muscle, while sparing pressure-intolerant areas such as the head of the fibula where the peroneal nerve passes.

At this point in the process, many prosthetists will create a check socket to test whether the socket shape needs changing before committing themselves to the time-consuming process of laminating a socket.

A check socket is often made using a process known as drape-forming. Here, a sheet of plastic (eg: polypropylene) is warmed in an oven at 200 degrees Centigrade for about 25 minutes until it becomes completely pliable, and then draped over the socket cast. The socket cast is mounted horizontally with the anterior aspect facing upwards. The self-adherent plastic is pinched together along the posterior aspect of the cast and a vacuum is applied to suck it in against the socket so that the shape conforms accurately. This is a quick way to prove or disprove the socket shape.

Ideally, the check socket is made with a clear material which allows the prosthetist to see the distribution of load-bearing or contact areas while the amputee is wearing the socket in a load-bearing state. If it is made with an opaque material, the prosthetist inspects the skin for reddened areas after a few minutes of standing or walking.

Since minor corrections can be made to the final socket, some prosthetists consider the check socket step unnecessary. Many prosthetists are confident enough of their socket cast shape that they proceed directly to the final socket, especially in cases where the amputee's residuum is not problematic.

To begin the process of forming the final socket, the positive cast is covered with a form-fitting layer of liner material: either some type of foam, or leather if the amputee has an allergic reaction to synthetics. The socket is then laminated around the liner, using layers of stockinette as reinforcement for the resin. The stockinette is separated from the liner with a thin film of polyvinyl alcohol (PVA) tailored into a bag; this will prevent the laminate adhering to the liner. A second layer of PVA covers the outside of the stockinette (Foort, 1989). Resin is poured into the space between the PVA bags from the top to soak the stockinette. The work is subjected to a vacuum so that the shape of the laminate conforms to the shape of the liner. The vacuum is maintained until the resin has cured.

In separating the socket from the positive mould, the positive is either destroyed or saved, depending on the prosthetist. In most cases it is possible to heat the socket and blow it off of the positive using a compressed air gun, but there is a risk that some of the desired shape quality is lost. If they are saved, the positives can be used to make extra liners and extra sockets, although storage space is used up quickly in this way.

Researchers at University College London have developed a vacuum forming system for production of prosthetic sockets (Davies, *et al*, 1985). The "Rapidform" machine takes a bell shaped thermoplastic preform, warms it, and then vacuum forms it over a positive mould.

Although there is variability in the style of sockets made by different prosthetists, there is a fundamental design approach used for the majority of trans-tibial amputees (Foort, 1990). The Patellar-Tendon-Bearing (PTB) Socket, developed at the University of California at Berkeley, incorporates several innovations which cause the socket to transfer the forces of ambulation to load-tolerant tissues whilst avoiding intolerant tissues (Radcliffe and Foort, 1961, Foort, 1965).

The name seems to imply that the weight is borne primarily by the patellar tendon. This is not at all accurate: the amputee's weight is not borne exclusively by the patellar tendon, but the patellar bar was the most notable characteristic of this design when it was introduced. Force is also transmitted via the medial and lateral aspects of the tibia.

The PTB socket extends to the middle of the patella and partially covers the femoral condyles. The posterior aspect does not extend as far and it flares outwards, allowing clearance for the hamstring tendons.

Variations on this design include the Patellar-Tendon-Supra-Condylar Suspension (PTS) Socket introduced by Fajal in 1964 (Lyquist, 1970).

Like the PTB socket, the PTS socket bears weight via the load-tolerant areas. The difference is that it extends more proximally: the majority of the femoral condyles are covered. They are gripped by the socket, and this serves as a suspension system for the prosthesis in lieu of corsets and rivets. Variations on, and compromises between these two designs have arisen, such as the supra-patellar-supra-condylar PTB socket, where the patella is also covered.

In order to construct the prosthesis the socket is attached to a mounting block using some kind of glue or filler. An alignment jig complete with pylon is attached to the mounting block, the foot is added, and a rough prosthesis is ready for the amputee to try. The amputee visits the prosthetist to see if the socket is a good fit. If it is not, the prosthetist modifies it by either grinding or stretching the socket (after heating up the area that is to be stretched). The degree of the modification is limited by the fact that the socket material can only be stretched moderately; too much of a stretch, or too much grinding, and the socket must be begun again, possibly right from the casting stage.

1.1.2 Determination of alignment

Prior to the second visit with the amputee, the prosthetist will have set the prosthesis up with a bench alignment following the specifications of Radcliffe and Foort for the Berkeley alignment jig (1959, 1961), or similar guidelines. The choice of technique depends upon the style of alignment jig and the biomechanical properties of the artificial foot being used. Then with the patient standing and walking on it, the prosthesis is dynamically aligned using the bench alignment as a starting point.

Most alignment jigs consist of a multi-degree of freedom mechanism placed between the mounting block and the pylon. They allow anteroposterior and mediolateral tilting, and internal and external rotation of the foot relative to the socket. In addition, they allow anteroposterior and mediolateral adjustment of the foot position.

The goal of the alignment of the below-knee prosthesis is to achieve minimal discomfort with as normal a gait as possible. Alignment depends on several factors. For example, mediolateral positioning of the foot depends largely on the length of the stump. For very short stumps, the foot is placed more laterally to avoid excessive medial-proximal and lateral-distal forces. This adjustment results in an exaggerated lateral sway during walking (Radcliffe and Foort, 1959).

Anteroposterior positioning depends largely on the type of artificial foot used. Certain more recent foot designs, the Seattle foot and the Flex foot, are generally "given more toe" (placed more anteriorly) than the SACH foot, due to their more flexible nature (McGuinnes, 1990).

1.1.3 Alignment transfer: exoskeletal design

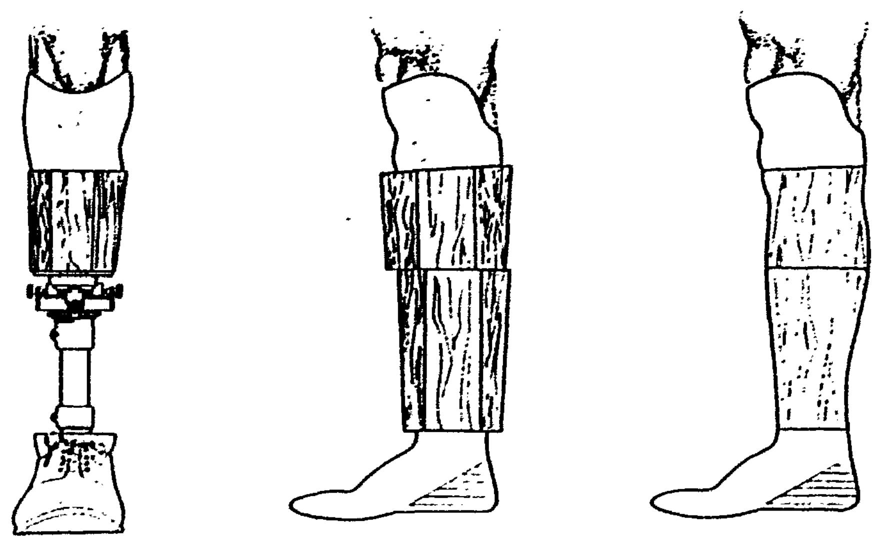
Once a satisfactory dynamic alignment has been obtained, it must be retained while the alignment jig is removed and replaced with the final hard shell structure. To begin, the prosthetist removes the liner from the socket. Then in order that it can be mounted securely, the socket is held in place in a frame with set-screws. Alternatively, the socket is filled with plaster, another mandrel is inserted as a mounting bar, and the plaster is allowed to set.

The prosthesis is then held in a transfer jig, which will maintain the alignment between the socket and the ankle and foot. The foot is removed and the ankle block is bolted into a bracket on the jig. Next, the socket is locked in place. Finally, once the ankle and socket are frozen in space, the alignment pylon can be removed and the exoskeletal cosmesis can be created in one of a few different methods.

Carved wood and laminate

The oldest commonly used method is that of the wooden exoskeletal cosmeses. The prosthetist removes the foot from the aligned prosthesis, and places the prosthesis in a horizontal transfer jig. Using a saw that is held in place by a mitre guide, he or she saws off the tip of the wooden block at the socket end of the alignment device. This frees up the alignment device so that it may be removed and leaves a smooth, flat, perpendicular surface on the wood. The position of the socket is recorded with some stoppers and then the socket end is slid back to allow a fresh block of wood to be bolted into place at the distal end of the jig. This block is then cut with the same saw, in the same position, and the socket end is moved back to touch it. The two pieces of wood are first marked to allow proper reunion afterwards, and the pieces are then removed from the jig. Next, they are glued together with a small amount of glue, lined up using the markings, and held in a vice till the bond sets (**Figure 1.1**).

Figure 1.1 - Manufacture of wooden exoskeletal prostheses



(Adapted from A.B. Wilson, Jr., 1967, with permission)

Once the glue has set, the foot is bolted back on and a rough profile of the shank is sculpted by passing the prosthesis longitudinally through a band saw from several angles. A grinder or a rasp is used to bring the wood down to the desired shape, with allowances for the thickness of laminate which will later be added to the outside. The finish of the wood is smoothed off with sandpaper.

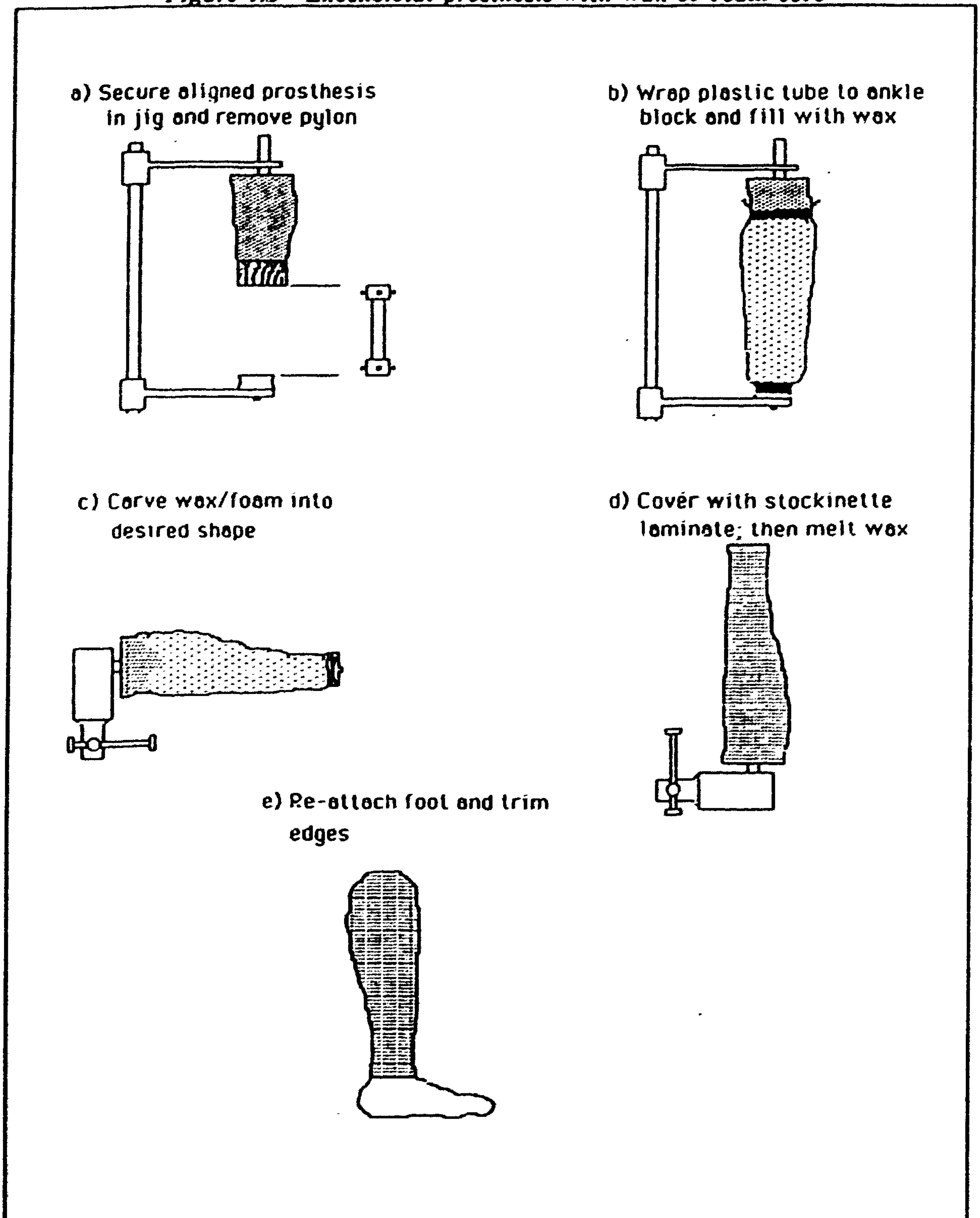
The next step is to separate the pieces of the prosthesis so the inside can be hollowed out. In order to bring the weight of the prosthesis down to a reasonable value, the wood is split into two halves transversely at the glue line and the hole on the inside of each section enlarged until the wall thickness is something of the order of 0.5 cm (1/4 inch). The wood is still very strong at this thickness, but in order to increase toughness and ensure durability, the wood is then reassembled and covered with a laminate made up of a few layers of stockinette soaked under vacuum with resin. The vacuum gives the laminate a smooth finish and a fairly constant thickness.

Laminate over wax or foam

Alternatively, the cosmesis can be made with laminated stockinette over wax or hard foam. This method also results in an exoskeletal cosmesis. In this case, the alignment jig is oriented in the vertical direction. A clear plastic bag is taped to the ankle block so as to create a tall cylindrical container. The tube is then filled with wax or a thermosetting foam, wrapped at the top around the socket brim such that the bottom of the socket is encased within the wax or foam. Once it has set, the result is a solidly aligned prosthesis, held together by the wax or foam (**Figure 1.2**).

The wax or foam is now carved; a rasp is used by the prosthetist to create the desired cosmesis shape. Once it is satisfactory, several layers of stockinette are pulled over the wax or foam and are soaked with resin under a vacuum to make a strong laminated shell. Sometimes the stockinette is further strengthened by adding some fiberglass or carbon fibre before laminating. Again, the prosthetist actually makes the wax or foam shape a bit smaller than the desired size to allow for the thickness of the laminate.

Figure 1.2 - Exoskeletal prosthesis with wax or foam core



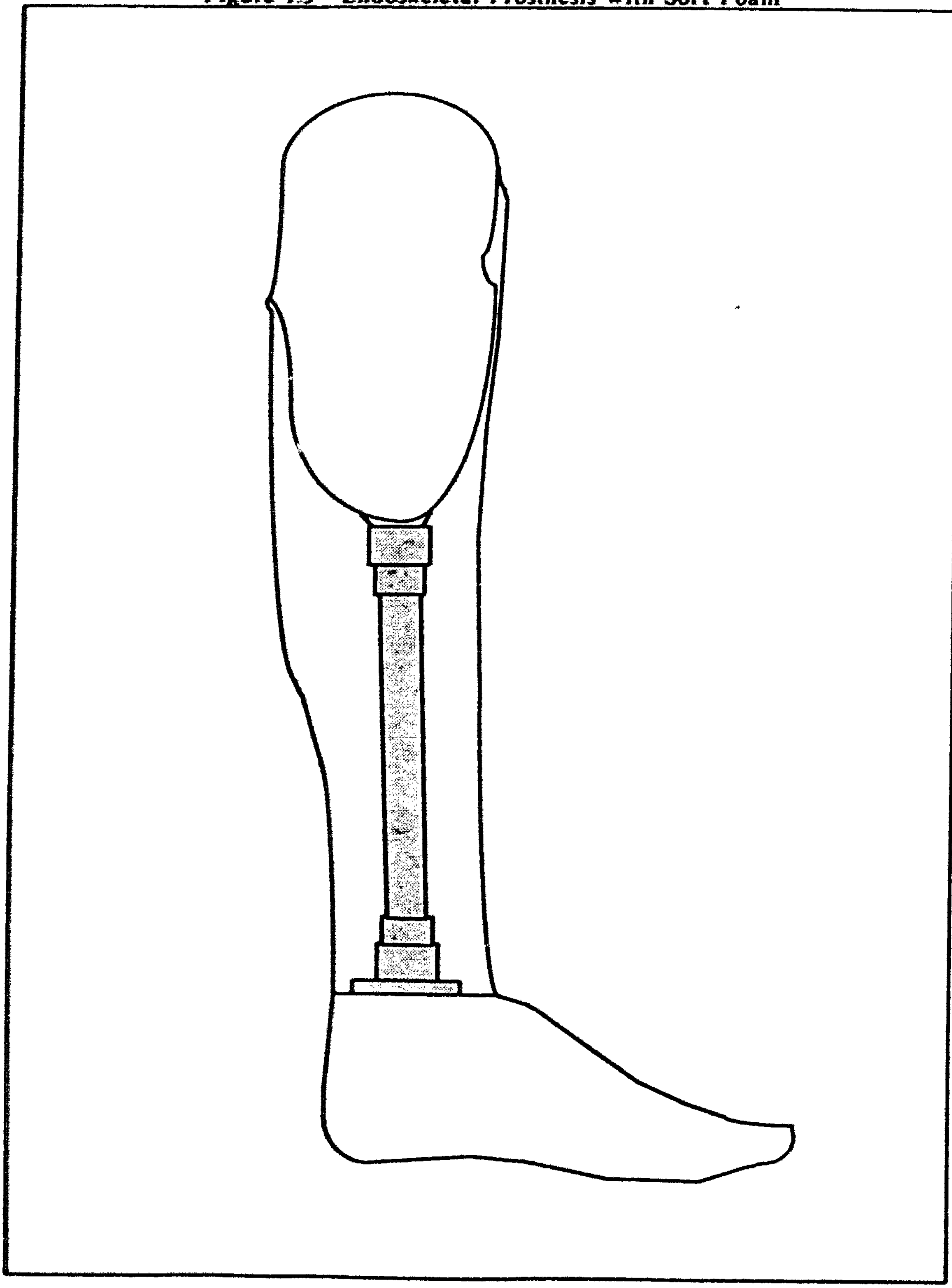
In the case of the wax method, after the laminate has set up completely, the bolt hole in the ankle piece is opened up, and the prosthesis is placed in the oven at a moderate temperature so that the wax can melt and pour out. For this reason the technique is often referred to as the "lost wax" method. If foam is used, it is usually left inside the prosthesis, although it may be removed if a particularly light prosthesis is required.

Finally, the prosthesis is removed from the jig, the edges are shaped and smoothed, and the foot is added.

1.1.4 Alignment transfer: endoskeletal design

Endoskeletal designs, often called "modular", have a number of advantages over the exoskeletal approach to prosthesis structure. The structural components do not have any cosmetic function, which lends to their being mass produced. In this case the alignment device is a simple, lightweight design consisting of a pylon of cylindrical tubing with two adjustable couplings, one proximal and one distal, and remains as the main structural support for the prosthesis (Figure 1.3). Therefore there is no need to transfer the alignment as with exoskeletal designs. The pieces are simply taken off the shelf, assembled aligned for the amputee, and then covered with a cosmesis made of foam or other light material. Probably the greatest advantages is the ability to make adjustments to the alignment at any time after the initial construction of the prosthesis (Hobson, 1972, Van de Veen, 1989). As an example, this is useful for changing the dorsi-plantarflexion angle of the foot for shoes of new heel height.

Figure 1.3 - Endoskeletal Prosthesis with Soft Foam

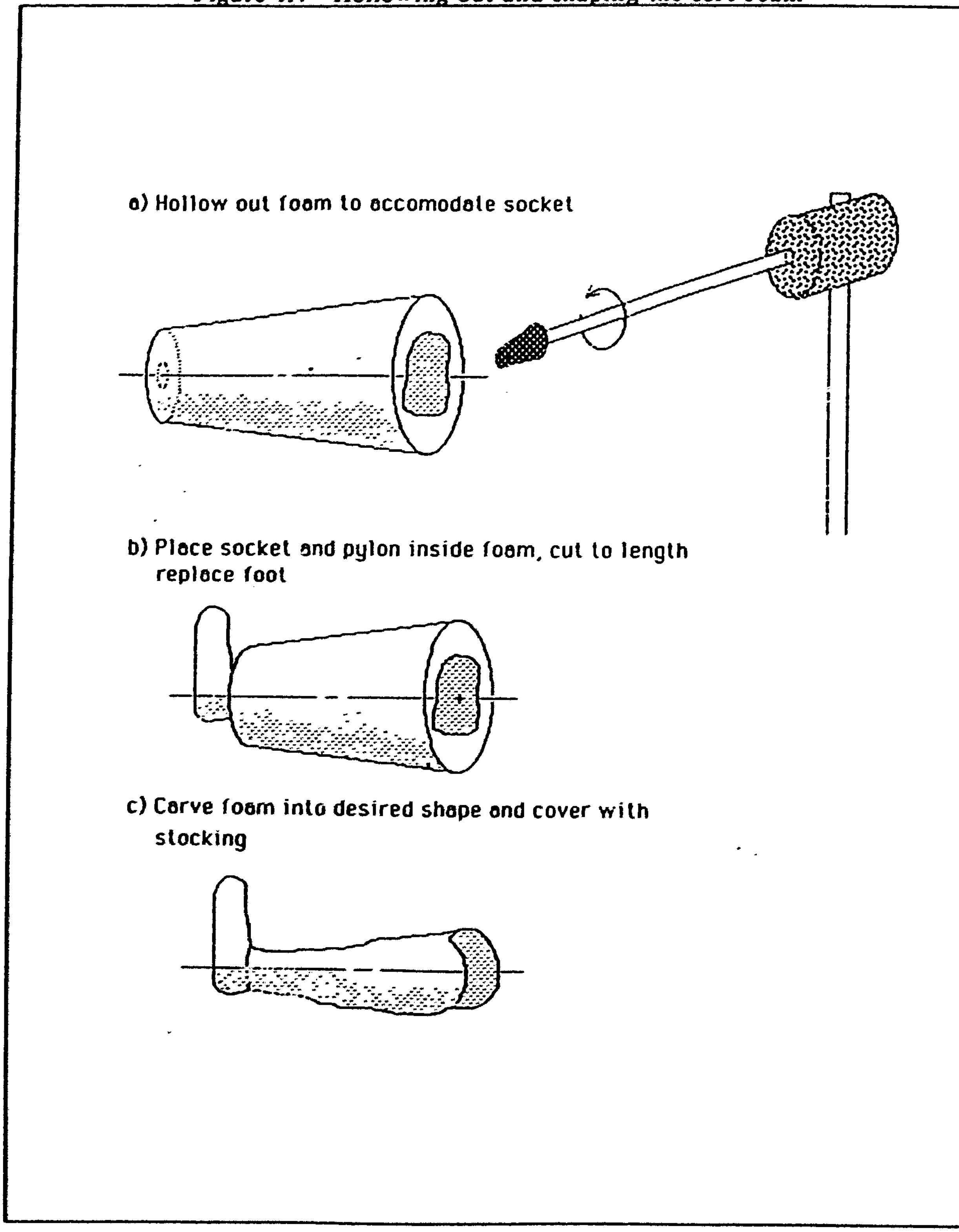


The cosmesis is not required for load-bearing. It is necessary, however, that the cosmesis be tough enough to withstand the wear and tear of daily use. This can be a problem for an active amputee or one who works in industry. Excessive overall weight of below-knee modular design has been a drawback (Van de Veen, 1989), but materials research is progressing so that the modular design approach is being used more and more, especially in Europe.

Cosmetic coverings are most commonly made of lightweight polyethylene or plastizote foam blocks that are carved to suit and then covered with a stocking or painted. The foam comes supplied in ready-to-carve blank shapes, such as a cylinder complete with a hole drilled through the middle to accommodate the pylon of the modular prosthesis system. In order to use these blanks, the first step in the process is to hollow out the inside of the cylinder at the top so that the socket will fit inside the foam snugly (Figure 1.4). Next, the foam is cut to length so that the foot can be re-attached. Finally, the foam is carved to the final shape using a grinder and a buffer.

Other types of cosmeses are used with endoskeletal designs, made from various materials such as open-cell polyurethane (Sauter, 1972). The cosmesis used with the new "Flex-foot" design is generally made with soft foam which is cut to fit on either side of the flat structural pylon, as opposed to fitting around a cylindrical pylon.

Figure 1.4 - Hollowing out and shaping the soft foam



1.1.5 Cosmesis shape considerations

The object of the carving of the cosmesis is to obtain a shape which matches the amputee's contralateral leg. The basic shape of the average human leg is stored in the mind of the prosthetist. Girth measurements from the amputee's contralateral leg and, in some workshops, mediolateral and anteroposterior profile tracings serve to help.

Because of prosthesis alignment, the shape of the cosmesis is often distorted to accommodate protrusions of the socket. Near the ankle, the shape is smoothed into congruence with the artificial foot. Occasionally the alignment couplings of modular constructions protrude if the final alignment leaves them near the limit of their adjustment range. The prosthetist or technician is required to carve an appropriate shape within these constraints. The process is time-consuming and the finished product is, at best a rough approximation.

Often the cosmesis is made slightly smaller than the contralateral limb. This is because experience has shown that the artificial material is perceived to be larger than its living counterpart when the size is matched exactly. This perception is affected somewhat by the materials used to finish the leg. Skin-tone laminate is hard and has a slight shine, while the stocking that is used to cover endoskeletal soft foam cosmeses creates a softer, more realistic finish. However, there is resistance on the part of some men to use the soft foam, not simply because it is less durable, but because it has a stocking on the outside, which is perceived to be unmasculine. Clearly, individual tastes in terms of colouring and texture should be addressed in addition to biomechanical and other technical considerations when selecting the type of prosthesis.

1.1.6 Construction time

Simply put, the artisan nature of this work requires a large amount of time for each unit. Clearly this is a highly labour intensive process which could benefit from automation. Time expenditures for the artisan techniques described above are shown in **Table 1.1**. These values are estimates based on the experience of a Vancouver-area prosthetist.

Dewar and Lord (1985) also described the time required for production of a below knee prosthesis using the conventional techniques that are employed in the United Kingdom. Although the individual task times were different the total time was, coincidentally, twelve and a quarter hours. Although these are estimates, the main point is that the manufacture of limb prostheses is presently still a highly labour-intensive process.

Table 1.1 - Time expenditures for artisan techniques

SOCKET			
Casting (with amputee)	0.5 to	1.0	hr
Modify cast and make socket positive		0.5	hr
Construct liner		0.75	hr
Laminate the socket		0.75	hr
Delays, difficulties	1.0 to	2.0	hrs
ALIGNMENT			
Assemble the prosthesis for alignment		0.5	hr
Align the prosthesis (with amputee) (1 hr X 2 or 3 visits average)		3.0	hrs
Delays, difficulties	1.0 to	2.0	hrs
FINISHING			
Transfer the alignment		0.75	hr
Carve the cosmesis shape		0.75	hr
Laminate cosmesis & finish product		1.75	hrs
Delays, difficulties	1.0 to	2.0	hrs
TOTAL	12.25 to	15.0	hrs

1.2 CAD/CAM in Prosthetics

1.2.1 Introduction

Automated manufacturing techniques have been in use for decades for mass production of large quantities of identical items. More recently the power of the computer has been harnessed to facilitate the design and manufacture of components and systems. This approach has come to be known as computer aided design and manufacture (CAD/CAM).

Prosthetics is an industry where certain components can be considered in terms of mass production, but where others are generally custom built. For example, artificial feet and the alignment couplings of modular systems are typically mass produced and supplied as off-the-shelf items.

The socket and cosmesis on the other hand are structures of complex shape which vary between amputees. Although studies have been made into the development of standard sized stock units for sockets and cosmeses, with encouraging results (PORDU, 1968), their use has not taken hold. Sauter (1972) wrote that the economics of making the necessary moulds, and forming the components precluded their use in all but the larger centres. This was probably a fair assessment given the manufacturing techniques that were available at the time, but the development of computer aided techniques was progressing to the point where the concept could be pursued from a different angle.

Historical Development

After years of work developing shape definition techniques for lower limb prostheses, Foort first envisaged automated shape manipulation techniques in the field in about 1960 (Foort, 1960). He anticipated that although computers were still fairly new and expensive, affordable models would one day be capable of handling the large quantity of numerical data required to define the shapes used in prosthetics.

Foort had observed that the residua of below knee amputees tend to be very similar in size and geometry. In studies done in 1967 at the Prosthetics and Orthotics Research and Development Unit (PORDU) in Winnipeg, Manitoba, it was shown that standard sized prefabricated sockets were adequate for fitting the majority of new BK amputees with instant temporary prostheses (PORDU, 1968). Sockets were used that were incremental in size by 1/8 inch of radius throughout the range covered. Interestingly, out of 19 different standard sockets (left and right), 75 percent of new amputees were fitted successfully with five sizes, and one particular size fit 50 percent.

These ideas formed the basis for continued work by Foort and colleagues at the Medical Engineering Resource Unit in Vancouver. The use of automated procedures has been the focus of research at MERU since 1971 (Foort, 1979 & 1989). These researchers first concentrated on photographic shape sensing, primarily shadow moire techniques. Once the shapes were digitized, they were replicated with an industrial computer-numerically-controlled (CNC) milling machine, using specially designed algorithms to control the machine as it carved the complex shapes (Saunders, Foort and Vickers, 1981).

In the early 1980's, the Vancouver group collaborated on this work with researchers at the West Park Research Centre, University of Toronto and the Bioengineering Centre, University College London (UCL). The work was aimed at developing further the three components required for an automated prosthetics plant.

Each group focussed on a separate part of the shape plant. The group at West Park pursued the automated measurement of shape using laser light streak techniques (Saunders and Fernie, 1984). The group at the MERU embarked on the design of a computerized method for systematically designing and modifying socket shapes (Novicov and Foort, 1982). Finally, since the CNC machine that was in use in Vancouver was more accurate and of heavier design than necessary, the group in London designed a task-specific carving machine ("Masterform") which could replicate the desired shapes to an appropriate degree of accuracy (Crawford *et al*, 1985). An accompanying development was the "Rapidform" process for socket forming. It is through these efforts that CAD/CAM technology was first applied to the field and the term "CASD", for computer aided socket design, was coined.

Although a fully automated shape sensing device was under development, inclusion of the technology into the total system was not feasible at that time, so a standard reference socket shape in conjunction with a small number of simple manual measurements was used for input to the computer.

The MERU-CASD system was designed in a modular fashion so that as time progressed and as the cost, speed and accuracy of shape measurement devices improved to make them more attractive, they could be employed for input. Similarly, the output data could be fed into any manufacturing system that might be developed in the future.

The MERU-CASD system was originally designed around a single standard reference socket shape stored in the computer. This shape was used as a starting point for each socket, and was scaled and adapted to the measurements taken from the amputees stump. The group at UCL decided to use shape data digitized from a plaster wrap cast of the amputee's stump, designing a CASD system which applied a standard rectification map to the measured shape to obtain the socket shape for carving (Dewar *et al*, 1985).

The work at MERU and UCL was aimed primarily at the design of below knee sockets. Meanwhile, researchers in Japan were beginning to work on a CAD/CAM system for the above knee case (Nakajima, 1982). These and other systems are described in **Section 1.2.2**.

Efficacy of CAD/CAM for Prosthetics

The benefits of a computerized system are many. Just as the prosthetist can create an effective socket shape with hands and plaster, the same prosthetist can, after a moderate period of familiarization with the computer, perform this task with computer aided socket design.

CAD/CAM offers potentially great time savings (Dewar and Lord, 1985). It can perform many of the routine modifications necessary to produce the socket shape automatically from the input data. Finer adjustments are all that remain for the prosthetist to complete the task.

There are also the benefits of having the amputee's shape data on diskette. The storage of shapes can be maintained with a minimum of space required. This allows a systematic approach to socket design for the long term. If an amputee returns in need of a new prosthesis because the old one has worn out or has been broken, the same shape can be generated again without delay. If there have been some changes to the shape of the residuum since the last fitting, the new socket can be modified from the original shape data accordingly.

There is great potential for research and educational applications, since shape data used and created by CAD/CAM systems can be analyzed and compared. In the case of new amputees especially, the shape of the residuum changes as it matures with time. The opportunity to document these changes in shape for large numbers of amputees promises to be of great benefit in studies of the treatment and rehabilitation of amputees.

Once the prosthetist has completed the socket shape, the data for the final shape is stored, together with a record of the prosthetist's modifications that went into it. Thus, these can be reviewed and compared quantitatively to show which methods are most successful for particular stump characteristics. Also, the work of senior prosthetists can be assigned to students for review, thus opening doors to instructional applications for CAD/CAM in prosthetics (Fernie *et al* 1984, Fernie, 1986, Spiers, 1989, Boone *et al*, 1989).

In current practice, using artisan methods, amputees living in smaller towns must generally come to an artificial limb clinic in a large population centre for each fitting. This means spending three or more days away from their home and occupation, since it is necessary for the prosthetist to obtain input from the amputee on several occasions before the limb is completed. Any savings in the overall time required is an improvement in this regard.

Once an amputee finds a prosthetist who provides a good fit, he is often reluctant to change. The fact that the shape data are stored on a diskette may potentially give the amputee more security and mobility as CAD/CAM becomes widely used. If either the amputee or the prosthetist moves to a different location, the diskette which contains the shape data for the socket ensures that a subsequent fit by a new prosthetist can be based on the previously acceptable fit.

Computer aided socket design systems as they currently exist may not necessarily produce a better initial fit than conventional methods. The software merely offers a different method which includes considerable benefits to the prosthetist in terms of speed of production and the ability to store the shape in a compact way.

Dewar and Lord (1985) report some variability in the quality of fit in clinical practice, and suggest that while a given CAD/CAM system may not produce a socket of higher quality than a skilled prosthetist:

> "CAD/CAM potentially means that all patients will be fitted with sockets whose initial design has been produced in a precise and repeatable way. The clinician prescribing a limb will know exactly what features it will have and the prosthetist's skill will be employed not in carrying out a set of routine procedures but in modifying the basic design to suit his patient by making changes which are completely controlled and automatically recorded."

Bo Klasson (1985) offered a look into the future from the viewpoint of the prosthetist who will be affected by CAD/CAM. He reviewed the work to date by the research teams in Canada and Great Britain, and noted:

> "Probably the most pressing problem in prosthetics and orthotics research, development and clinical practice is that the fitting procedure is not reproducible..."
>
> "Lack of reproducibility is ... a serious bottleneck in research and development. No prosthesis is better than the fit (the interface between the stump and the prosthesis) irrespective of the sophistication of the rest of the prosthesis. Often when a new prosthetic component is subject to evaluation, it is not possible to isolate the quality of the new component from the quality of the fit."

Referring to the MERU-CASD system, which was the only one in use at that time, he expanded his argument, describing the CASD system as the "new prosthetic component". He suggested that in evaluation studies, the quality of the reference socket shape would likely affect the results more than the quality of the CAD/CAM system per se. No CAD/CAM system for prosthesis shapes can be more effective than the input measurement.

There are more cautious, skeptical projections of the use of CAD/CAM in prosthetics. John Michael (1989) offers a thoughtful critique of the phenomenon.

He predicts that CAD/CAM is coming to the profession whether it is wanted by the prosthetists or not, and that they should therefore embrace it now (without becoming enamoured) in order to infuse their practical experience into the design process and thus ensure the best possible quality of product. He argues that one weakness of existing CAD/CAM systems is that they are only successful for easy-to-fit below knee amputees. Another is the fact that current systems rely upon surface data without regard for the internal structure. Finally he suggests that the creative process should be allowed to run free without unnecessary restrictions or standardizations, beyond some cooperative interchangability between the developers' system modules.

Future Directions

It would be wise indeed to allow the system designers to continue to enhance their designs, improving the quality steadily over the years. Some research groups are looking beneath the surface of the skin with the use of ultrasound or stiffness measurement in combination with surface shape (Childress, 1989, Faulkner and Walsh, 1989, Krouskop *et al*, 1989). The work of these groups will be discussed in greater detail in Section 1.2.2.

Derek Jones (1988) advocates the use of expert system techniques to improve the fitting capabilities of CAD/CAM. His group at the University of Strathclyde have begun a study into this approach (Jones, 1990). Similar work is under way towards an expert system for determination of dynamic alignment (Childress, Rovick and Van Vorhis, 1987).

Overall, as these CAD/CAM systems improve, the quality of fit is expected to exceed that of conventional techniques. This is likely because of the more reproducible adjustments made to the socket shape by a CAD program, and the improved opportunity to quantify and compare efficacy of socket design techniques. It is likely that new insights into prosthesis design will result from the wealth of quantitative data that will be collected as this technology is utilized. With the passing of time, more information will be accumulated about the relationship of the socket to the stump, and more effective CAD/CAM systems will emerge.

1.2.2 CAD/CAM Systems

Canada - University of British Columbia (MERU)

The development of the MERU computer aided socket design system is synonymous with the early development of CAD/CAM techniques in prosthetics described in **Section 1.2.1**. The system evolved steadily, ultimately incorporating a reference shape library of nine BK socket shapes, to account for more patient variability.

Using the MERU-CASD system, the input measurements from the amputee's residuum are obtained manually using calipers and measuring tape (Saunders *et al*, 1985). Anteroposterior and mediolateral breadths are obtained with the calipers, and girths are measured with a measuring tape. An alternative input device, the MERU-CASD BK Area Tool, was developed at the MERU. Its readings are used to approximate the cross-sectional area at several levels along the residuum (Saunders *et al*, 1989).

These simple measurements are keyed into the computer[1] and the MERU-CASD system proceeds quickly to select the most appropriate socket reference shape, then scale and adjust its size appropriately.

The working shape is displayed on the graphics terminal as a sagittal[2] section with selected cross-sections shown. By setting tabs for the longitudinal and angular extents of a desired change, the prosthetist can modify patches of the shape, either relieving regions above load-intolerant tissues or removing material in regions where there is compressible bulky tissue. This is analogous to the removal or addition of plaster, with the exception that the original shape can always be recovered. The MERU-CASD system has several standardized modification options on its menu board. These help the prosthetist to perform the more common modifications by guiding the process.

The socket shape may be displayed on the computer monitor in different ways. The "wireframe" representation traces longitudinal lines along the facing side of the socket shape. The "rendered" representation displays the shape with facets of solid colour, shaded according to how light might be reflected off the shape. The sense of the three dimensional shape is quite effective for the viewer.

In 1985, the MERU reported the first clinical trials of the CASD system (Foort, Spiers, and Bannon, 1985). Results of further clinical studies were reported in 1989 (Saunders *et al*, 1989, Saunders and Bannon, 1989).

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[1] It is also possible to import an arbitrary shape for modification. For example, an amputee's stump or old socket shape might be input to the system from a scanner or digitizer.

[2] Actually, the prosthetist is able to see longitudinal sections from any selected direction, from true sagittal to coronal (full 360 degrees).

The MERU-CASD system has also been adapted to the above-knee (quadrilateral socket) case (Torres-Moreno, 1987), although extensive clinical trials have not been performed. Researchers have also performed pilot work using the MERU-CASD system on applying CAD/CAM to the design of spinal orthoses (Raschke, 1989, Raschke, *et al*, 1990).

The MERU-CASD BK system was released commercially in 1987 by Shape Technologies Inc. under the name "CANFIT".

England - University College London, Roehampton

In 1985, the research group at University College London reported development of their own computer aided design system (Dewar, *et al*, 1985). In order to get closer to the partially loaded stump shapes with which prosthetists are familiar, a purpose-built mechanical digitizer for measuring the internal shape of a wrap cast of the stump was developed. The digitizer records the shape of the inside surface of the cast with a long stylus reaching inside.

The casted shape was thus input to the CASD system and altered in a prescribed way that follows standard prosthetic practice. This process has become known as the rectification map approach since a map, or template, representing standardized rectifications is superimposed upon the data from the amputee's casting.

Carving of the plaster-based blanks into socket moulds is accomplished using the purpose-built "Masterform" machine, carving a helical path using 36 points per slice with an eighth inch pitch. The "Rapidform" machine is then used to vacuum form the completed socket.

Derivatives of the UCL system are being offered for use commercially by two different companies. One version of the UCL system is being marketed worldwide under the name Applied Bioengineering Technology Ltd (ABT). At the same time, another is available as "System Shape" from Shape Products Limited in the United Kingdom. This company has a subsidiary called Adaptive Rehabilitation Technologies (ART) in the United States. Each company offers the system with a choice of mechanical digitizing of wrap cast or laser scanner inputs. Output is sent to a purpose-built carver based on the Masterform design.

Scandinavia - CAPOD System

Another European CAD/CAM system comes from Scandinavia: the Computer-Aided-Prosthetic and Orthotic Design (CAPOD) System (Oberg, 1985, Oberg *et al*, 1989). The system consists of a laser-scanner for limb measurement, a CAD/CAM workstation, and an NC milling machine for carving of the socket mould. Scanning, modification, and machining are all controlled by the CAD/CAM workstation.

Shape input of the sock-covered unloaded residuum is performed by a purpose-built laser video scanner[3]. The optics are encased in a housing that resembles a truncated cone.

The CAPOD carver uses 100 longitudinal passes of the tool to carve the shape rather than a helical tool path as has been used in other systems. The mould is held still as the cutter carves each trace along the length of the mould. More traces are required this way in order to obtain a smooth shape (just 36 points per

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[3] Several laser scanner systems have been developed for scanning unloaded stump shapes (Fernie, 1984, Carrico, 1989, Faulkner, 1989, Oberg, 1989). Each follows basically the same approach: a laser projector and video camera are mounted upon a frame which rotates about the stump shape. The laser projects a line which is aimed inwardly through the axis of rotation. The video camera system is used to detect the contour of the laser line projected obliquely onto the surface.

slice are used for other systems), however this allows the cutter to move faster over flat areas.

Belgium - CEBELOR System

Beginning in 1987, work has proceeded gradually on a Belgian CAD/CAM system for above knee prosthetic sockets (Van Rolleghem, 1989). Data from computed tomography scans are used as input to a GE/CALMA System. The project is still in a development phase.

Germany - Ipos Barlach System

Beginning with the concept of making computer-aided stump models and lower extremity prostheses in 1985, researchers developed a system under the working title "Barlach", named for a sculptor (ipos, 1989). The ipos system consists of a host computer and a purpose-built CNC carver. Input measurements are obtained manually using a measuring stand (if necessary), a set of pre-fabricated brims, and a measuring tape. Currently underway is a project to expand the ipos method to allow 3-D on-screen modifications of the shapes generated by their brim-based system.

Both stump forms and soft covers for endoskeletal prostheses are shaped by the carver. Limb shapes are not currently modified to match the aligned socket and foot orientation, so it is unlikely that the ipos system would be readily used for the exoskeletal case.

Japan - Mitsubishi Research Institute

In the early 1980's, Researchers at the Mitsubishi Research Institute in Tokyo began to develop a CAD/CAM system for above knee sockets (Nakajima, 1982). Initially, linear potentiometer measurements from a plaster wrap cast of the stump were used for input (D.F. Radcliffe, 1986). Later, building on years of study with shadow moire techniques, an automated shadow moire system was used in combination with a mechanical analyzer for biomechanical characteristics of the stump (Nakajima and Suga, 1989).

USA: Chicago - Northwestern University

At the Prosthetics Research Laboratory at Northwestern University in Chicago, Childress and associates are developing several concepts to advance the application of CAD/CAM techniques to prosthetics. As stated in his address to a CAD/CAM course in San Antonio:

> "Rather than mimicking the prosthetist's or orthotist's design protocols, we hope the reasoning behind their design decisions can be interpreted in order to form the foundation of specialized CAE programs in rehabilitation (Childress, 1989)."

The focus at Northwestern University has been on CAD/CAM of below knee sockets (Childress *et al*, 1989). More recently efforts have been applied to the above knee and below elbow cases. The approach is along the lines of studying the mechanical interaction between the body and the device, in this case the prosthesis. Input devices under development include digital image processing of computed tomography (CT) scans, and a prototype mechanical digitizer for shape and stiffness measurement. The stiffness is measured by the amount of tissue deflection seen with the application of a known force. This is referred to as the CASTLESS technique (Castless Acquisition of Surface Topography and Localized Elastic Surface Stiffness). Data treatment is by application of a finite element analysis (FEA) for structural modelling, and this has been used to develop rectification principles for below knee sockets.

For several years an important aspect of this work has been a search for an anatomically-based *a priori* alignment prescription technique (Childress, Rovick and Van Vorhis, 1987). For this purpose a gait analysis laboratory has been assembled.

Analysis centres around direct determination of the limb loading, as opposed to indirect inference from observed gait abnormalities as is done in the clinical setting. Using rigidly defined skeletal axis systems for the tibia, femur, and pelvis, as well as the prosthetic foot, the relationship between alignment and limb loading is being studied.

On the manufacturing side, another study looked at testing of materials used in prosthetics and orthotics, focussing on tensile strength, impact testing, hardness, and wear tests for resistance to abrasion. Direct automated manufacture of a socket has been demonstrated using the Stereolithograph from 3D Systems (see **Section 1.2.3**).

The eventual goal of these projects is to integrate the techniques and information to produce totally complete, ready-to-wear prostheses, not needing any alteration or adjustment to alignment.

USA: Houston - Institute for Rehabilitation and Research

Thomas Krouskop and colleagues in Houston, Texas report development of a system for above-knee sockets (Krouskop *et al*, 1987b, 1989). In order to account for the underlying structure of the residuum, a CAD system was designed which takes measurements of the unloaded limb shape and soft tissue mechanical properties as input. A finite element grid is applied with a loading function tempered with special load constraints to create the socket mould shape.

Shape measurement is via an automated mechanical sensor built specifically for the task. It consists of a rotating base with two stainless steel probes that move horizontally inward towards the limb at each location until touching.

Biomechanical tissue properties are evaluated using an ultrasonic Doppler system (Krouskop *et al*, 1987a), which calculates Young's Modulus for the limb tissue at a few selected sites. Although theoretically an improvement over surface-only measurement, a limitation of this combined measurement is that the Young's Modulus is measured at only four sites. In addition, the values vary through the depth of the tissue, and these are averaged.

USA: San Antonio - University of Texas

Researchers at the Rehabilitation Engineering Lab (REL) at The University of Texas Health Science Center at San Antonio have as a main goal, "the development of a low cost, all plastic prosthesis that can be designed, manufactured, and fitted by field workers anywhere in the world" (Walsh *et al*, 1989). This includes the implementation of advanced techniques using thermoplastic components (see **Section 1.2.3**) and the development of a CAD/CAM socket design system.

Shape scanning for The San Antonio System is performed with an in-house designed laser scanner. The amputee's stump is unloaded, simply covered with a sock and held suspended.

The CAD software is unique, in that it has been set up to run on either a Macintosh II, a Sun workstation, or an IBM/AT. It allows several types of modifications to the shape, although none are performed automatically as with reference socket or a rectification map. At this stage in the development of the project, the shape is converted to ABT/ART format for carving of the mould.

In another project Faulkner and Walsh (1989) have taken a high-tech extreme using computed tomography data to design a below knee socket, citing the virtue of seeing below the skin when considering the topography of the residual limb. Using a CEMAX 1000 for display and manipulation of the CT scan data, the researchers were able to make use of bone shape in designing a below knee socket shape. The process was performed using standard software for the CEMAX 1000, and so the modifications had to be performed one slice at a time.

USA: Seattle - Prosthetics Research Study

In Seattle, Washington, researchers at the Prosthetics Research Study have been involved in an extensive study of the UCL CAD/CAM system. A large part of their work has been aimed at development of prosthetic socket rectification rules, citing the potential benefits of such analysis in prosthetics research and education (Boone *et al*, 1989).

In order to study more closely the concept of rectification mapping, a system was developed to run on Apple Macintosh computers to compare the scanned shapes of stumps and completed sockets (Sidles, *et al*, 1989a). To compare two shapes properly, they must first be aligned according to some criteria. This system uses a least-squares approach applied to nodes of surface data to align the shapes. It is reported that the process is very fast, even with surfaces described by several thousand nodes. Different weightings can be specified by the prosthetist for the nodes in this alignment calculation.

As a natural consequence, the CAD/CAM system developed by these researchers uses the rectification map approach (Sidles, *et al*, 1989b). The system, known as Shape Maker, is reported to be complete and in daily clinical use. The system is commercially available and is marketed by Bio-Logic and Adaptive Rehabilitation Technologies (ART) in North America.

Canada: Vorum Research Corporation

In a joint venture with LIC Orthopaedics of Sweden, Vorum Research Corporation has developed a distinct CAD/CAM system called CANFIT-PLUS™.

CANFIT-PLUS^{TM} is a generic system for the design of prosthetic and orthotic appliances. The system consists of a master system software shell in which a number of application modules can be run. The first application to be developed was orthopaedic shoe last design. Input measurements are taken from a weight bearing imprint of the foot, and either a laser light scan of the foot or manual measurements. A number of orthopaedic shoe lasts are stored in a library; these are scaled according to the input measurements.

The next application developed was prosthetic socket design, using a wrap cast for input. This technique was developed in response to the North American market's need for working directly from stump data. It encourages practitioners to use their preferred casting technique. Prosthetists set up their own individual modification overlays which can be used as "shape modification macros."

The CANFIT-PLUS^{TM} system takes the following inputs: UCL/ABT mechanically digitized wrap cast or a Cyberware laser scan of the stump shape. The system runs on IBM clones, 80386 and 80486 based AT-BUS computers. Carving can be performed on an industrial CNC Machine, the ipos carving machine, or one of the commercial versions of the Masterform carver developed at University College London.

1.2.3 Manufacturing Considerations

Once the prosthetist using the computer aided socket design has completed the desired modifications and wants to proceed to fabrication of the socket, there are generally two steps involved: carving the socket shape positive to serve as a mould and, forming the socket over the mould. The first step is automated and the second may be, depending on the system used. The automated aspects of the process constitute computer aided manufacture (CAM).

Carving of the mould takes place with either an industrial computer-numerically-controlled (CNC) milling machine, or with a purpose-built computer controlled carver such as the Masterform carver.

Before carving takes place, the shape data must be translated into a series of commands which drive the carving machine (Saunders *et al*, 1986). This is accomplished with a post-processor. A post-processor in this case is a computer program which takes the shape data output from the CAD system and creates the code which directs the position of the carving tool. In most cases the post-processor converts the shape data from a layered cylindrical grid into a continuous helical path.

The post-processor should also perform exhaustive interference checking. Each point in the cutter path is checked to ensure that there will be no undercutting, which occurs where there is a large change of radius on the mould relative to the width of the cutter itself[4]. Correction is made by retracting the cutter as far as necessary.

The MERU-CASD system creates a positive mould shape, or one that appears as the original shape. The mould is carved from a cylindrical blank mounted on an aluminum tube. These are placed in the chuck of the rotary table of the CNC machine for carving.

Material for use in carving moulds should possess certain properties. Jarman and Dewar (1985) list that ideally the material should meet the following criteria:

1) have structural integrity for machining and forming

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[4] A three-quarter inch ball-nosed cutter is used with the MERU-CASD System.

2) be easily removed from the formed socket

3) be inexpensive relative to plaster (and recyclable)

4) be easily fabricated into the blank forms

5) be dimensionally stable

To this list, one might add that it be light weight (for shipping by air freight), especially when a centralized fabrication network is being considered.

The carving process in the MERU-CASD system uses polyurethane foam. It has the advantage of being very light weight and easily carved, although in the carving process large amounts of abrasive dust are created, and the mould can be quite difficult to remove from the completed socket.

Jarman and Dewar found that a mixture of microballoons and plaster yielded good results, and an alternative was found using pure maize starch in place of the microballoons[5].

Once the mould is carved, a socket or limb shape can be laminated over it using conventional techniques. Alternatively, a socket can be thermoformed. In this process a thermoplastic cone is held over the mould in an oven equipped with a vacuum system sealed to the open end of the cone. As the thermoplastic material softens, the vacuum sucks it downward onto the mould creating an intimate fit and transference of the desired shape. It is questionable as to whether this process will work well with limb shapes; the material will likely undergo necking in the slender region of the ankle.

Another alternative is outlined by Walsh *et al* (1989). Heat shrinkable thermoplastic materials which have "memory properties" are proposed for use in

[5] The starch must be free of additives (especially borax) which inhibit the setting of the plaster.

socket production. Two methods are to be pursued. The first entails an intermediate step whereby the thermoplastic is moulded into preforms of relatively large diameter. These are then warmed and a vacuum applied as the thermoplastic shrinks down onto the mould. It is reported that the process demands less accurate control of temperature than the "Rapidform" system, and results in consistently good wall thickness. The second method under consideration avoids the intermediate step by blowmoulding the thermoplastic outwards into a bivalved (negative) socket cast shape. These techniques may also have application to the limb shape for exoskeletal prostheses.

It would be even more advantageous for a computer aided manufacturing system to avoid the two step process of mould carving (Davies, 1986). Devices which offer a glimpse into this future are Stereolithography and Laminated Object Manufacturing (Childress, 1989). With these processes, a single device may be used to perform direct fabrication of sockets and prosthetic limb shapes (ie: exoskeletal shells) by automated techniques. Stereolithography uses a computer-controlled laser, optically curing a liquid photopolymer to form solid models. Laminated Object Manufacturing follows a similar approach, using scintering powder instead of liquid photopolymer.

1.3 Shank Shape and Composition

Bannon (1983) digitized the shape of the contralateral shank of a unilateral below-knee amputee. A casting was taken to duplicate the shape of the limb, and then the cast was digitized on the CNC machine at the MERU using 10^{o} increments and 1 inch intervals. The shape was inverted and then carved to produce the shape for a cosmesis. No adjustments were made to the shape to accommodate for the size and shape of the socket material, nor for the distortion due to the alignment of the artificial foot and the socket, but the project demonstrated the feasibility of using the computer to store and replicate cosmetic shapes.

Marshall and Lord (1983) conducted a statistical analysis of profile data that had been obtained from the shanks of 100 men and 200 women. The data consisted simply of anteroposterior and mediolateral silhouettes obtained using a television image fed into a microcomputer. Unfortunately, this provided only four points per cross-section, so the shape of each cross-section could not be well-defined. Marked inhomogeneity was found in the leg shapes and attempts at accommodating the variations with a system of modules was found to be prohibitively complex. They proposed the use of artistic input of typical shapes, using scaling and interpolation as required to create the desired shape.

The U.S. military standards for human engineering design criteria have been derived from the measurements of thousands of service-men and women (U.S. Department of Defense, 1974). These data include calf height, kneecap height, seated knee height, popliteal height, knee-to-knee breadth, calf circumference, and ankle circumference. The data are given with the 5th and 95th percentiles, and can therefore be used to predict the range of shank sizes that might be encountered in clinical practice.

The majority of anthropometric data on the lower leg are concerned with segment lengths, tissue volumes, and subcutaneous fat layer thickness at selected sites. When girths are recorded, it is sometimes the minimal girth on the ankle and more commonly the maximal girth on the shank[6]. Weiss and Clark (1985) used B-mode ultrasound to investigate subcutaneous fat and skeletal muscle thickness in the calf. Haggmark, *et al* (1978) used computed tomography to study cross-sectional areas in the thigh musculature. Tissue shape was not considered in these studies.

Cross-sectional anatomy texts do show elevations and cross-sectional shape corresponding to each elevation, but the shapes are often distorted. They are not *in vivo*, and refer to a single subject only; their purpose is primarily qualitative rather than quantitative in nature.

Rovick and Walker (1986) reported the design of an off-the-shelf knee orthosis using averaging techniques. Plaster wrap casts were taken of the right and left legs of 15 male volunteers. The casts, taken in extension, were cut into 50 equal slices and the shapes were traced on a digitizing tablet for input to a computer. These slice shapes were aligned according to axes defined from boney landmarks and scaled to average length. Considerable variation was found between the fifteen subjects limbs, however the final shape was very realistic.

Five of the volunteers were also casted with the knee at 45 degrees of flexion and at 90 degrees of flexion. Thigh and calf casts of these same legs were taken with the different major muscle groups acting in turn, to investigate the shifts of the tissue volume.

Rovick and Walker reported small shape changes associated with knee flexion and with contraction of the gastrocnemius. The main changes were in the

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[6] In many cases, this maximal girth is found at approximately 70 percent of the distance between the inferior border of the lateral malleolus and the popliteal crease (Weiss and Clark, 1985).

muscle belly. Changes were particularly small just below the knee and along the front of the tibia. Greater variation was seen in the thigh. With muscle contraction, mediolateral width decreases while anteroposterior width increases for quadriceps and hamstrings. Shape changes just above the knee were small.

Cooper (1986) used computed tomography data to create a reference model of the bones of the lower leg, including the distal femur. He investigated various scaling techniques that could be employed to fit the model to the residual bones of human amputees using input of readily measured palpable points. For some of the subjects observed, he found considerable nonhomogeneity of bone shape between the CT scans and the computer generated models. In addition, reference point measurement variability was identified as a primary source of error. For several subjects, the reference model was a good fit without scaling, since it was of average size.

Delp and Delp (1989) used the Polhemus[7] digitizer to digitize the shape of the pelvis and leg bones from a single skeleton. These points are connected in a polygon mesh (roughly 300 polygons per bone) to give a rough model of the bones of the lower limbs, including the pelvis. Using a combination of digitization and scaling and revolving of profiles, they were able to create a very impressive representation of the same surfaces consisting of over 22,000 polygons.

In summary, there are not any published comprehensive databases which describe three dimensional shape of the limbs, nor the shape of underlying structures. This lack of information is largely due to the fact that devices capable

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7 Polhemus™ is a magnetic digitizer with a small (pen-sized) stylus (Polhemus Navigation Sciences, Colchester, Vermont).

of recording the information quickly and without great expense have only recently become available.

1.4 Summary

Although automated design techniques have been applied to prosthetic sockets, there has been little in the way of research into the automated design and alignment of prosthetic limb shapes and its consolidation into total prosthetics manufacturing systems. The ultimate goal of this line of research is to produce a wholly automated lower limb prosthetics design and manufacturing system. The elements of socket design, prosthesis alignment measurement and aligned limb shape design must be integrated into a single system to permit automated manufacture of the complete prosthesis.

2. OBJECTIVES

2.1 Hypothesis

It was hypothesized that a computer aided design system could be developed which would be capable of designing a lower limb shape for a below-knee prosthesis.

2.2 Objectives

In order to test the hypothesis, it was necessary to create a numerical reference shape library and develop computer-aided shape modification procedures. These components would be used to design the unique shape of a below-knee prosthetic cosmesis based on patient input data.

In the course of accomplishing this, the following intermediate objectives had to be realized:

1) Create a computer based library of reference shank shapes which encompass the various characteristics of the normal population in terms of tissue distribution.

2) Verify the cylindrical shape data spacing by using Discrete Fourier Transform (DFT) analysis to determine if the number of points can adequately describe the degree of curvature for shapes that may be encountered.

3) a) Establish suitable anthropometric measurements to be taken from the contralateral limb. b) Develop mathematical relationships and procedures necessary to permit modification of the reference shapes into the desired unique limb shape. These steps permit scaling of the selected reference shape, as well as distorting it to blend smoothly with the contours of the prosthetic socket and foot

as they are aligned in relation to each other. c) Develop a method of acquiring alignment data from the socket and foot, to be provided as input to the system.

4) Determine the accuracy of the shape definition technique in a single trial by comparing the primary limb shape created using the system to the shape of the contralateral limb from which the input measurements were taken.

5) Evaluate the final definitive limb shape in a single trial. This would be achieved by comparing the limb shape created by the CAD system with the limb shape created by standard artisan methods for the same amputee. Each of these shapes would also be compared to the shape of the amputee's contralateral limb from which the input measurements were taken.

6) Undertake a practical test of the CAD procedures by carving a limb shape by automated manufacturing procedures using the output data of the CAD system.

3. CREATION OF THE REFERENCE SHAPE LIBRARY

Use of a computer-based reference shape library relies on the assumption that shape requirements in prosthetics and orthotics can be met by using generic shapes treated with systematic modifications. Further, much of this approach hinges on the assumption that human limb shapes can be categorized in terms of certain well chosen measurements and proportions. These measurements are used to select the most appropriate reference shape from the shape library. The final shape is derived from one of the reference shapes through scaling and local modifications, as required.

The shape of the prosthesis socket has a direct effect on the distribution of pressure on the residuum due to the loads of ambulation. By contrast, the shape of the cosmetic restoration is primarily aesthetic in function, and thus does not require the same degree of accuracy. The basic requirement is a shape, reasonably lifelike in appearance, which fits smoothly around the prosthesis components as they are aligned. Thus, the minimal requirement for an automated system for cosmeses would be a single reference shape. However, it is felt there is sufficient variation in human limb shape that the general population would be better served by a library with a number of distinct shapes.

3.1 Shape Library Structure

The library consists of a five-member family of shank shapes of varying adiposity and musculoskeletal development. Borrowing from the Heath-Carter approach to the somatotyping of human physique (Carter, 1980), two variables were specified for reference shape selection. Regional equivalents for endomorphy and mesomorphy were defined that relied solely on measurements from the lower limbs.

The two variables, RENDO and RMESO, stand for "Regional ENDOmorphy" and "Regional MESOmorphy" respectively. They are derived from standard anthropometric measures (**Equations 3.1 and 3.2**):

$$RENDO = SKF_{ca} / HT_{tib} \quad (3.1)$$

$$RMESO = (G_{ca} - \pi * SKF_{ca}) / HT_{tib} \quad (3.2)$$

Where G_{ca} is the girth, in centimetres, of the calf at its largest level. SKF_{ca} is the medial calf skinfold in centimetres, and HT_{tib} is the tibiali height in centimetres. All measures for the shape library were taken from the left leg. RMESO is equal to "lean" girth, scaled for length.

The selected library shape is subsequently scaled to match the length of the amputee's prosthesis. It is also scaled radially using girth measures at the knee, calf, shank, and ankle. No variable analogous to ectomorphy is used, since this scaling process matches the cosmesis to the measured limb in terms of linearity. Rather, ectomorphy is seen in this case as the lack of both mesomorphy and endomorphy and does not represent an independent variable. Thus, selection of library shapes depends on the degree of regional mesomorphy and endomorphy alone.

By specifying standard anthropometric measures for the library, it was possible to access large banks of data to determine representative values of RENDO and RMESO for the adult Canadian population. To this end, the CANAD Anthropometric Database (Carter, *et al*, 1982) was used to find the cell parameters for the shape library in terms of the means and standard deviations of the variables RENDO and RMESO. The database contains information on 239 men and 206 women between 18 and 35 years of age for which the pertinent measurements had been taken by criterion anthropometrists.

Means and standard deviations for RENDO and RMESO were determined with the SPSSx statistical software package (SPSS Inc, 1986). Although the adult population is known to be skewed somewhat towards the lower end of both muscularity and adiposity (Ward, 1990), a normal distribution was assumed as a reasonable approximation in both terms.

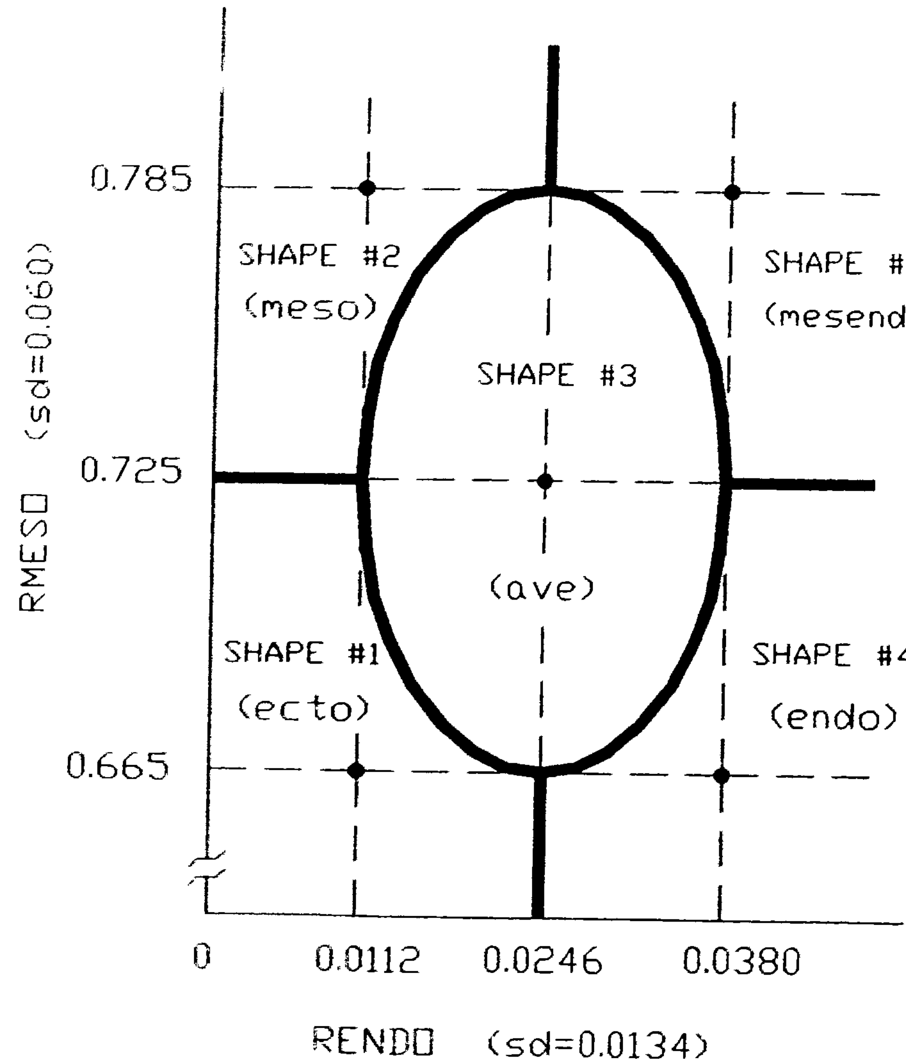
These values were then used as cell parameters for the cosmesis library. The library consists of an 'average' shape with mean values for both RENDO and RMESO, and four shapes divergent by one standard deviation in each direction for both variables. The cell parameters for the five shapes are given in **Table 3.1**:

Table 3.1 - Parameters for the Reference Shape Library

Shape	RENDO	RMESO	Adiposity	Muscularity
#1	0.0112	0.665	1 SD below ave	1 SD below ave
#2	0.0112	0.785	1 SD below ave	1 SD above ave
#3	0.0246	0.725	average	average
#4	0.0380	0.665	1 SD above ave	1 SD below ave
#5	0.0380	0.785	1 SD above ave	1 SD above ave

Based on the two dimensional normal distribution (Tuma, 1970), the boundary of the 'average' shape region was defined as an ellipse with major and minor radii equal to the standard deviations in each variable (**Figure 3.1**). Selection of the appropriate reference shape is performed by comparing the subject variables calculated for the amputee to the library cell parameters.

Figure 3.1 - Elliptical Five Shape Library Matrix



3.2 Recording the Reference Shapes

Adult subjects were found who had RENDO and RMESO values close to the selected values for each of the five reference shapes. One subject was selected for each reference shape. Subjects selected for shapes #1 and #2 were males, while the remaining subjects were females. Each gave written informed consent to have their left leg shape recorded with a plaster bandage wrap cast.

Each subject stood with body weight distributed equally between their legs. Triple thicknesses of plaster bandage were made wet and then applied so as to cover the leg between the levels of the proximal border of the patella and the distal edge of the lateral malleolus. The bandage was applied with longitudinal seams running the length of the cast. The plaster was allowed to set partially, then the cast was carefully opened along the longitudinal seams and eased off of the leg.

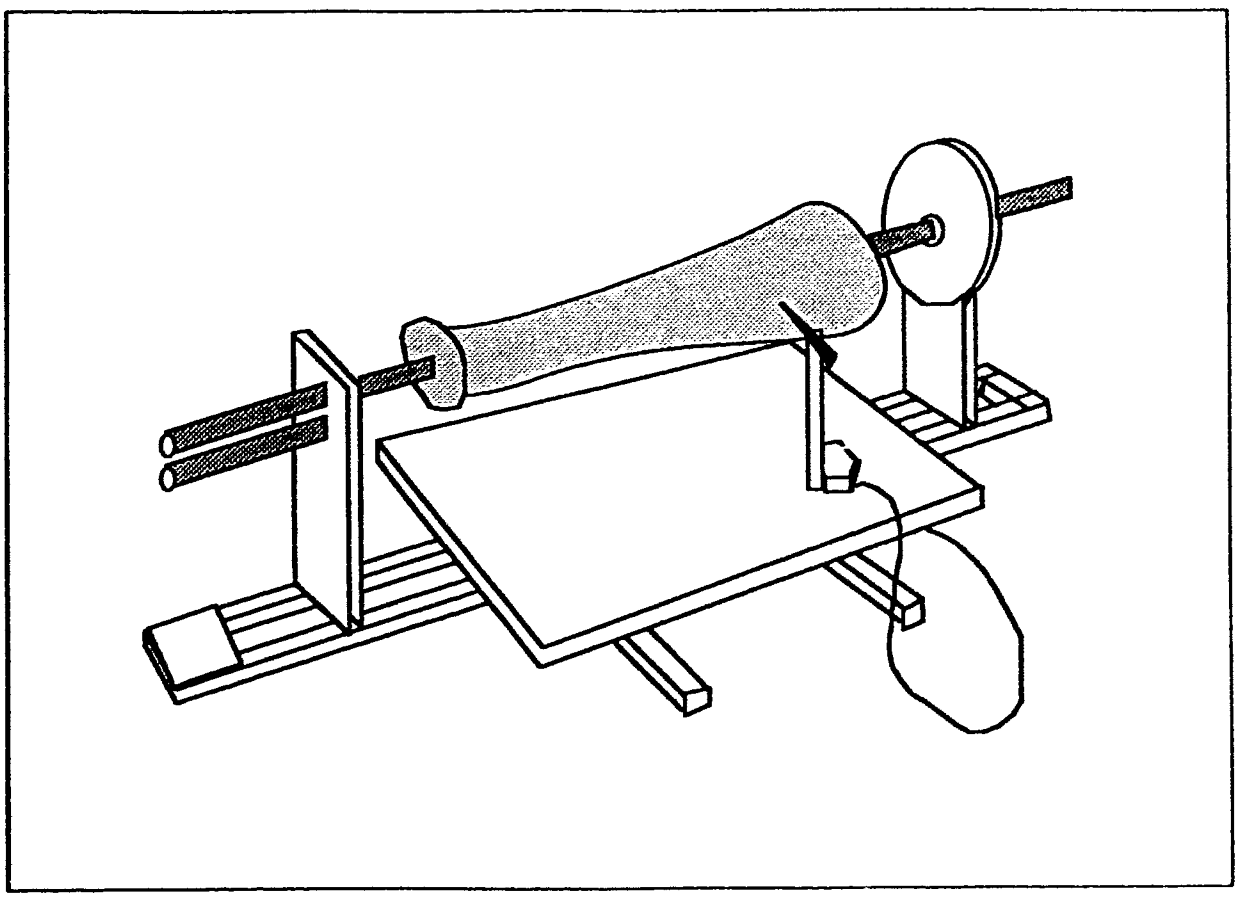
Before the casts set completely the seams were reunited. Strips of plaster bandage were applied to the seams, around each end, and over the ankle hole. Later, the casts were coated with a thin layer of slip (soap) and filled with plaster of Paris to make replicas of the original legs.

The shapes of the plaster of Paris replicas were recorded with an IBM AT personal computer using the MERU Shape Copier (Saunders and Foort, 1986). The Shape Copier consists of a Summagraphics mm1812 digitizing tablet equipped with a rotary table, much like a lathe (Figure 3.2). Accuracy of radial measurements using the MERU Shape Copier was assessed in a previous study (Torres-Moreno, 1987). The results showed a constant error of +0.056 cm and a random error of +/-0.036 cm (based on the standard error of the estimate). The shapes were mounted on the Shape Copier with the central axis passing approximately from the anteroposterior and mediolateral midpoint at the knee joint to the corresponding midpoint at the ankle.

Each shape was recorded with a total of 36 longitudinal traces made at 10 increments. Subject #1 wore a stockinette for the wrap casting, so the radial data in that shape file were corrected for material thickness prior to analysis. When analyzed, the calculated circumferences were generally slightly larger than the tape-measured girths. This discrepancy, likely due to tension in the measuring tape, was small and disregarded since the reference shapes are ultimately scaled radially to match the amputee's measurements.

The numerical representations of the shapes were then scaled by uniform dilation to the arbitrary length of 25.0 centimetres from the knee joint line to the midpoint of the medial malleolus.

Figure 3.2 - The MERU Shape Copier



3.3 Results

The five library shapes are shown in **Figures 3.3 through 3.7**. They are represented in these figures with every second cross section for clarity. The library shapes were compared as to the distribution of tissue bulk along their length. This analysis consisted of comparing the cross-sectional areas at each level along the length. Variation in sectional area (see **Section 6.2** for relevant equation) for all five shapes is represented in **Figure 3.8**.

Figure 3.8 illustrates a characteristic variation in the cross-sectional area along all shapes. Moderate variation in tissue bulk, and in the positions of the minimum and maximum girths, is evident. For example, the level of the largest calf girth for Shape 4 is quite high compared with the other shapes.

Figure 3.3 - Reference Shape #1

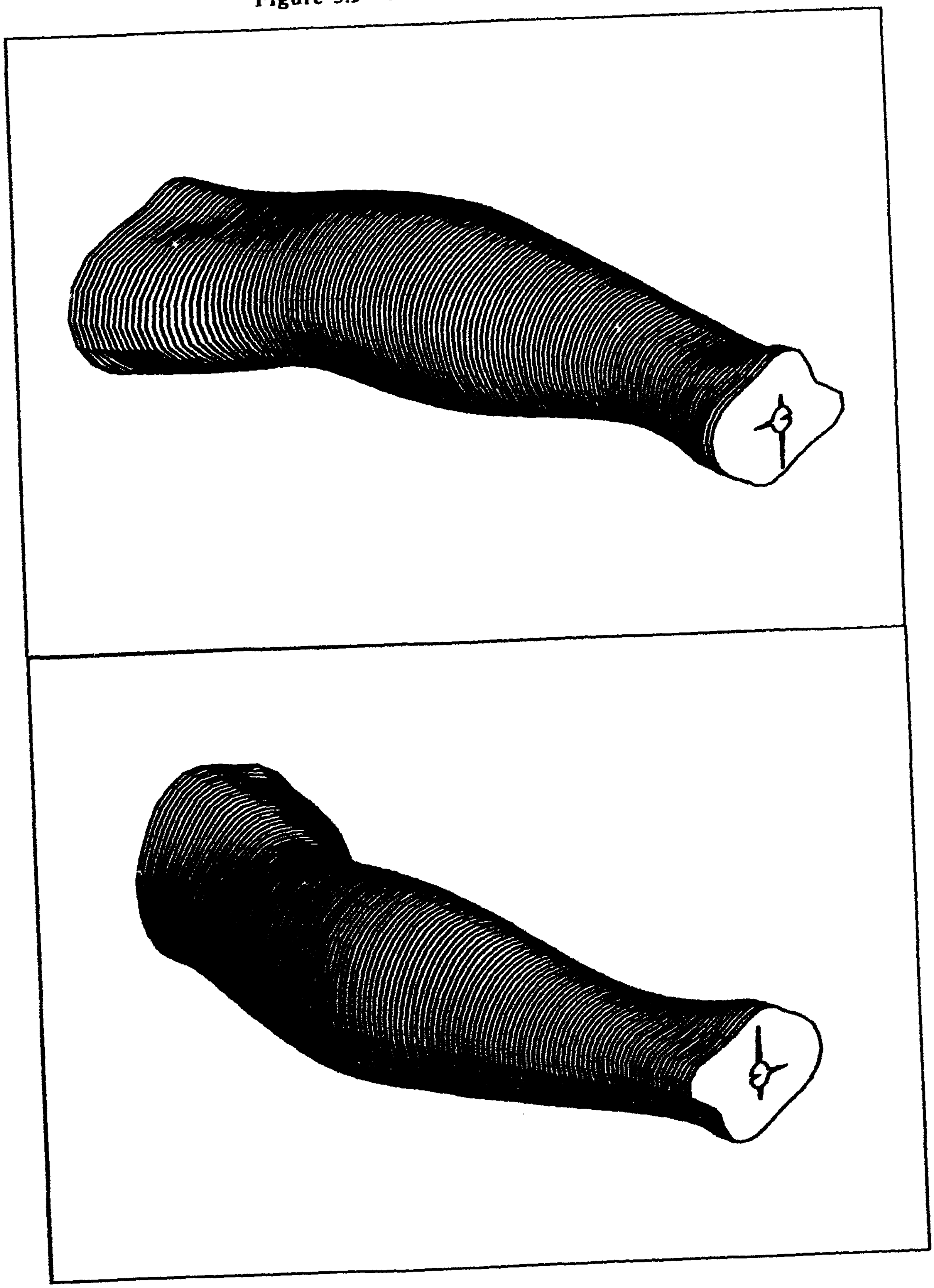


Figure 3.4 - Reference Shape #2

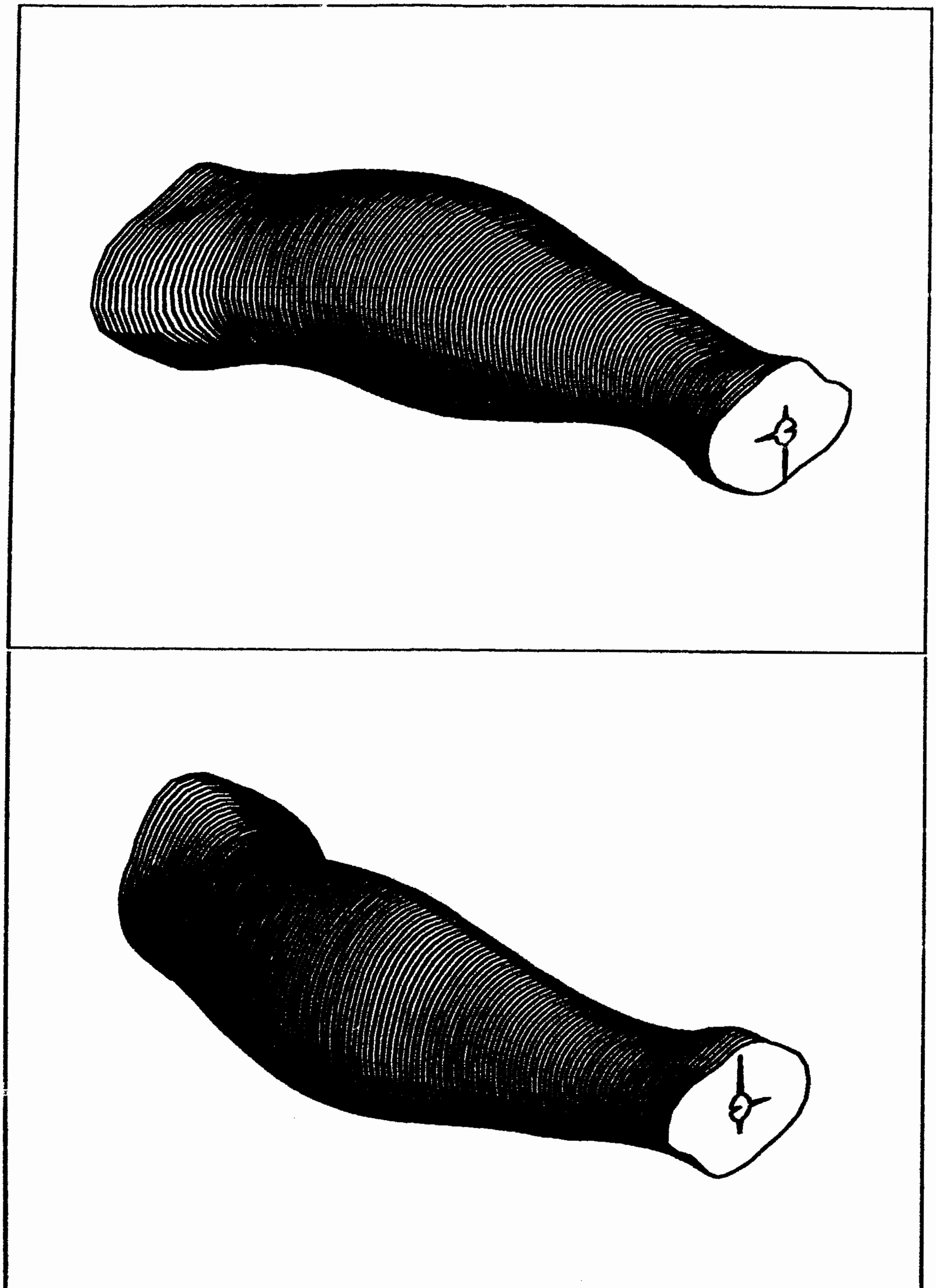


Figure 3.5 - Reference Shape #3

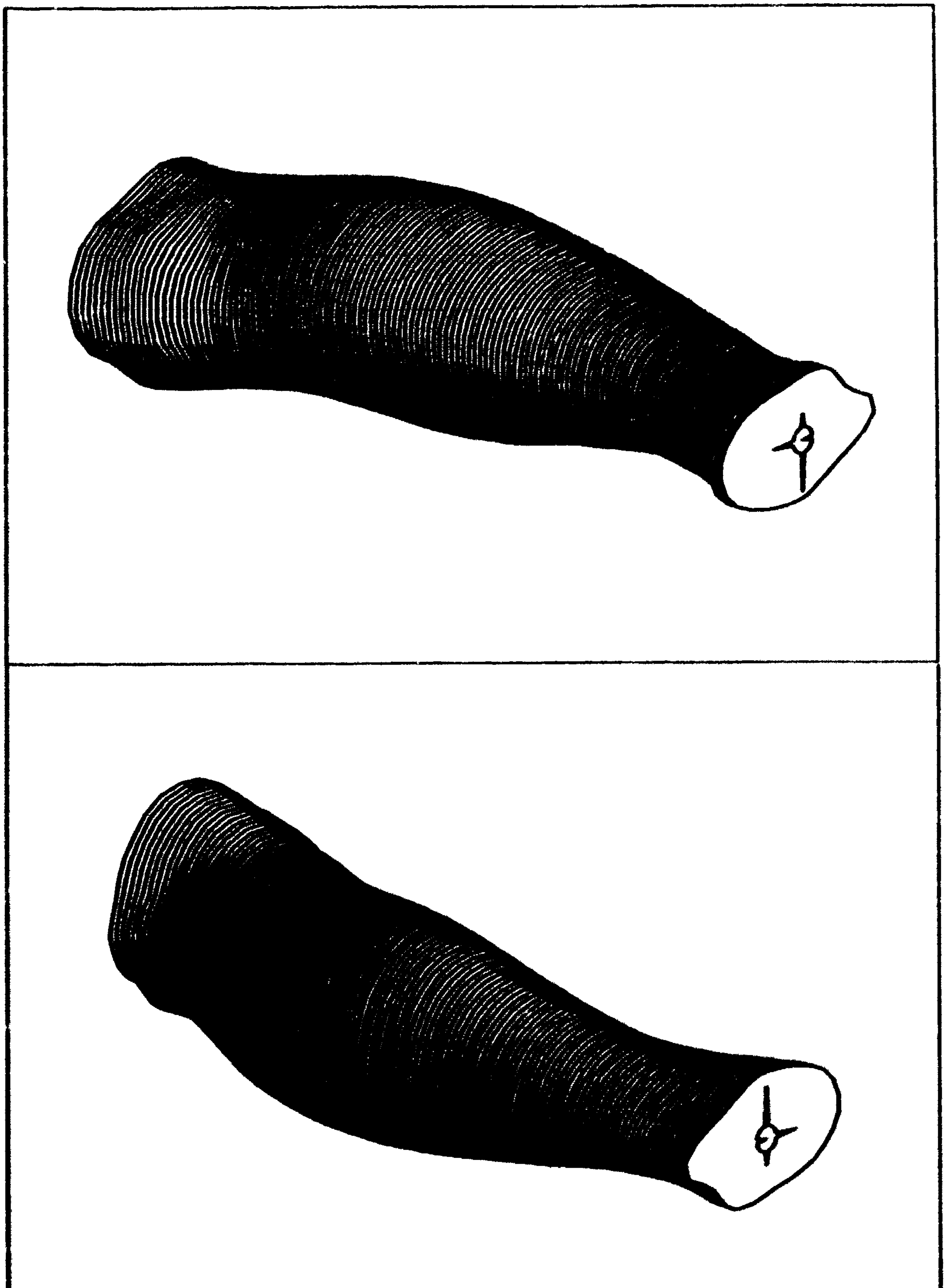


Figure 3.6 - Reference Shape #4

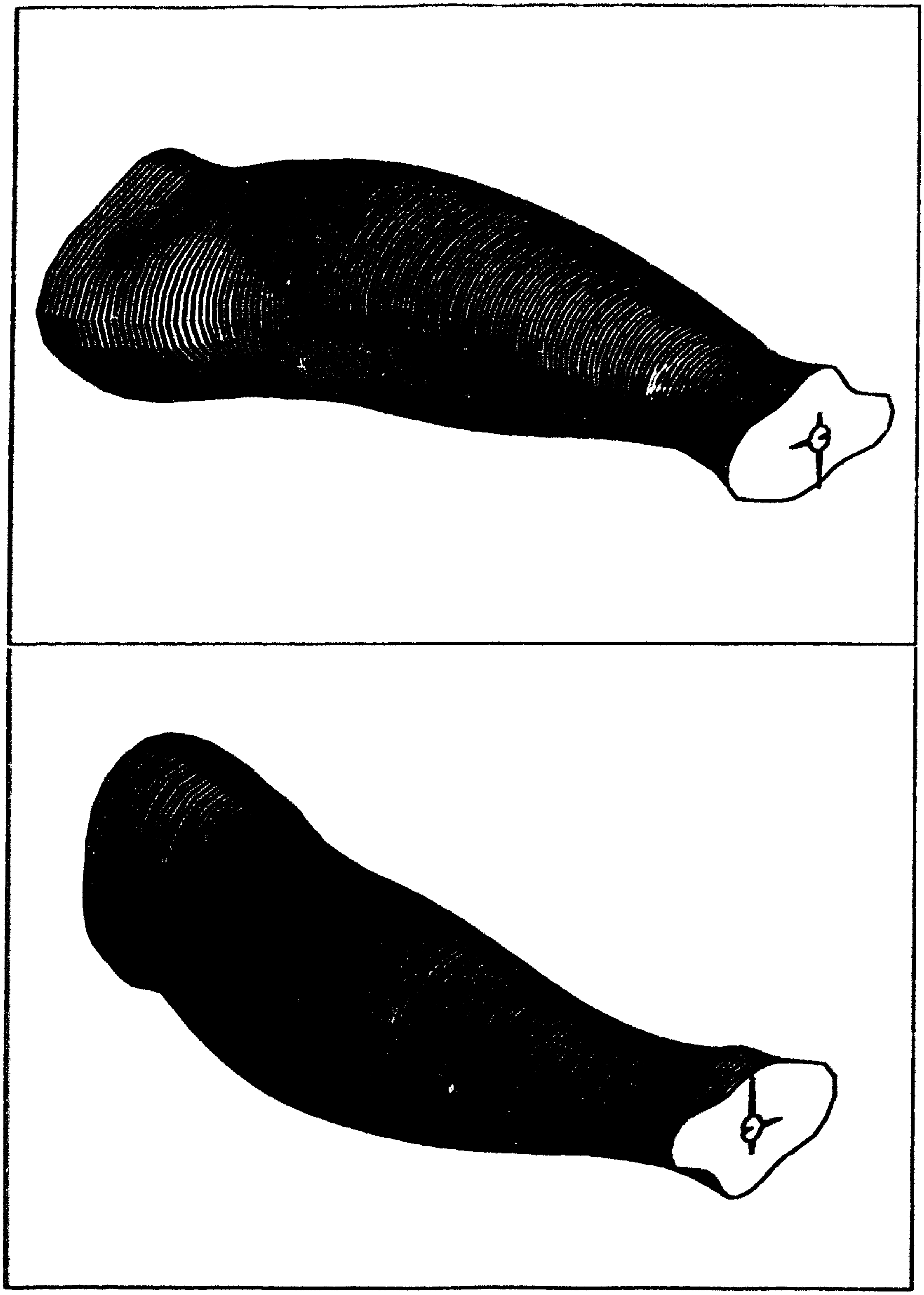


Figure 3.7 - Reference Shape #5

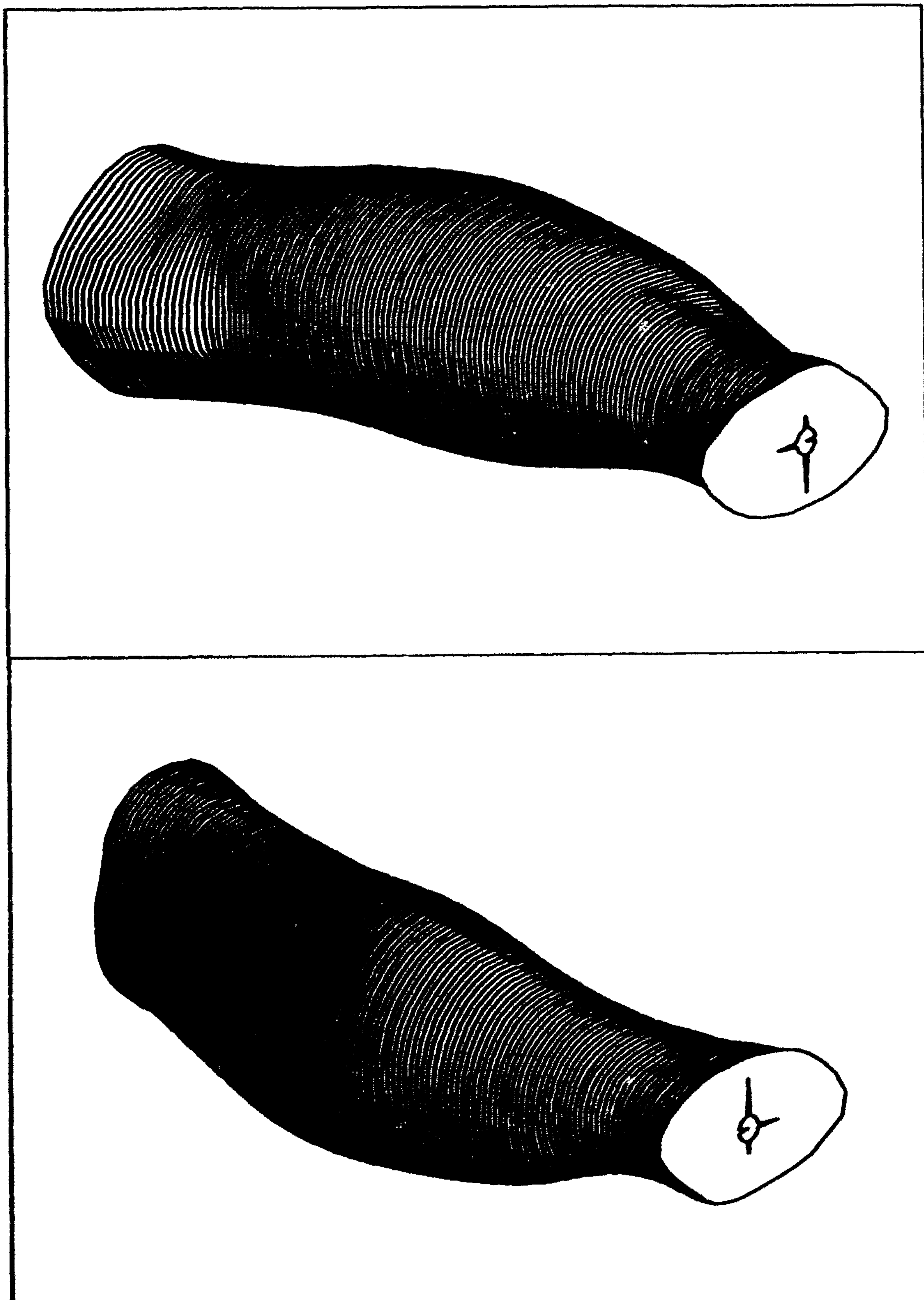


Figure 3.8 - Cross Sectional Areas of the Normalized Reference Shapes

4. VERIFICATION OF DATA STRUCTURE

In order to represent a three dimensional shape using numerical methods, a coordinate system is first selected that is convenient for definition of the surface. A finite number of points on the surface are then recorded in terms of the coordinate system. Despite accurate recordings of the specified points, errors arise in the spaces between.

Intuitively, greater control over this error comes from using more points. Information storage and computer processing time, however, rises with larger amounts of data. Thus, additional points offer diminishing returns and there is a trade-off between accuracy and speed.

Like other computer aided socket design systems, the MERU-CASD system (Version 3.4) describes shapes based on a cylindrical co-ordinate structure defined about a longitudinal axis which is internal to the socket. A cylindrical grid is appropriate, since prosthesis sockets and cosmeses are approximately cylindrical in shape. A cylindrical coordinate system lends itself to manufacture of the mould with an automated milling machine using a spiral milling toolpath.

Shape data for the MERU-CASD system are defined by cross-sectional slices in increments of 0.25 centimetres along the length of the shape. Each slice consists of thirty-six points in 10^{0} increments. This is consistent with other work; for example Rovick and Walker (1986). The choice of increments was primarily based on machining tool diameter; spacing of the points must be small enough to avoid ridges being left behind between the paths of the ball-nosed cutter.

Intuitively, this data structure seems adequate for the purpose of conveying limb shape information. As part of this project, it was considered appropriate to test whether the number of points used in the MERU-CASD system was adequate to describe the shape of a normal human shank.

4.1 Methods

According to digital communication theory, continuous waveforms must be represented by a sampling frequency greater than or equal to the Nyquist frequency for the waveform (Stark and Tuteur, 1979). The Nyquist frequency is equal to twice the highest frequency present in the waveform. If the sampling frequency is lower, aliasing distortion causing high frequency spectral components to appear at lower frequencies.

Ideally, the original waveform consists only of frequencies up to a particular limit. Replication of the waveform can then be exact if sampling frequency is greater than or equal to the Nyquist frequency. However there are often small amplitude components extending into higher frequencies, so some distortion is to be expected. The extent of this can be assessed in terms of cumulative spectral power; the cumulative spectral power of the reconstructed waveform is expressed as a percentage of the total spectral power (**Equation 4.2**).

Power contributed by individual spectral components is in turn calculated by squaring the spectral amplitudes found using a discrete Fourier transform (DFT). A DFT (**Equation 4.1**) is a mathematical technique for analyzing the frequency spectrum (frequency content) of a repetitive wave function, such as sound travelling through the air (Stanley and Peterson, 1978). Here, frequency components X(k) are defined in terms of the original waveform, x(i) (Stark and Tuteur, 1979):

$$X(k) = T/N * \sum_{i=1}^{N} x(i)\, e^{-j2\pi ki/N} \tag{4.1}$$

Where:

$x(i)$ is the original waveform at point, i
$X(k)$ is the frequency component at discrete spectral number, k
N is the total number of points (i) per cycle, and
$j = \sqrt{-1}$

and then,

$$\text{\% Cumulative Power}(m) = \frac{\sum_{k=0}^{m} |X(k)|^2}{\sum_{k=0}^{N/2} |X(k)|^2} \tag{4.2}$$

Where:

$|X(k)|$ is the magnitude of each frequency component,
m is the discrete spectral number under consideration.

A PASCAL language program was written, employing the discrete Fourier transform, for the purpose of testing the validity of the data point spacing used in the MERU-CASD system. Generally, Fourier analysis is used on waveforms that are functions of time. In this project, the algorithm was applied to cylindrical shape data in two ways. First, the radial data of each individual cross-sectional slice were interpreted as a function of angle about that slice. One 360 degree turn about the slice represented a single cycle of this "repeating" function. Second, the radial data of each longitudinal strip were interpreted as a function of position along the strip. To avoid abrupt discontinuities in the radial values, the strips were reflected on themselves, resulting in strips of double length for analysis. This algorithm was applied to individual cross-sections and strips separately.

The data were digitized from a model made from a plaster of Paris replica of the left shank of an adult male. Shape data were recorded with an IBM XT personal computer using the MERU Shape Copier (Saunders and Foort, 1986).

The replica was turned through 360 degrees in 5^{0} increments (72 stops). At each stop, the profile of the shape was recorded on the digitizing tablet using a puck adapted for the purpose. Along the length of each profile, a total of 178 radius values were recorded at 0.25 centimetre intervals. In Figure 4.1, the shape analyzed has been reproduced at 10^{0} intervals for improved clarity in the three dimensional plot.

Although the actual shank shape is continuous, it is only possible to represent it within the computer digitally. Thus, the 72 points per cross-section were used for input to the DFT algorithm. This was assumed to be sufficient to be considered as the standard for the analysis. Spectral power would then be represented in terms of these input data. From 72 points, analysis can show the amplitudes of the first 36 discrete spectral numbers (k). This is in keeping with the task of verifying a 36-point-per-slice data structure, which itself requires that no significant power exists above the 18th discrete spectral number.

Longitudinally, the data had already been resolved to a 0.25 cm spacing in the recording process. The measured shape consisted of 178 data points which were doubled to 356 by reflection to serve as the standard. This did not increase spectral resolution, but controlled against frequency domain artifacts ("leakage") due to endpoint discontinuities which would corrupt the analysis.

4.2 Results

Calculation of cumulative spectral power shows how much information is conserved by the sampling process. Figure 4.2 shows the envelope of maximum and minimum values of cumulative spectral power for each of the 178 cross-sections, expressed as a percentage of the total power for each slice. The DFT analysis showed that the majority of spectral power is transmitted by the constant term and the first three discrete spectral numbers. The spectrum varies along the length of the shape but, in the worst case, 99.98% of the spectral power is transmitted in the first six discrete spectral numbers. Those above the 18th account for less than 0.005% of the spectral power.

The amplitudes of higher discrete spectral numbers diminish asymptotically remaining, in the worst case, below 0.21 millimetres beyond the eleventh. **Figure 4.3** illustrates the envelope of maximum and minimum spectral amplitude values for each of the cross-sections.

Figure 4.1 - Plot of the shank shape that was analyzed

Figure 4.2 - Envelope of Cumulative Spectral Power - Cross Sections

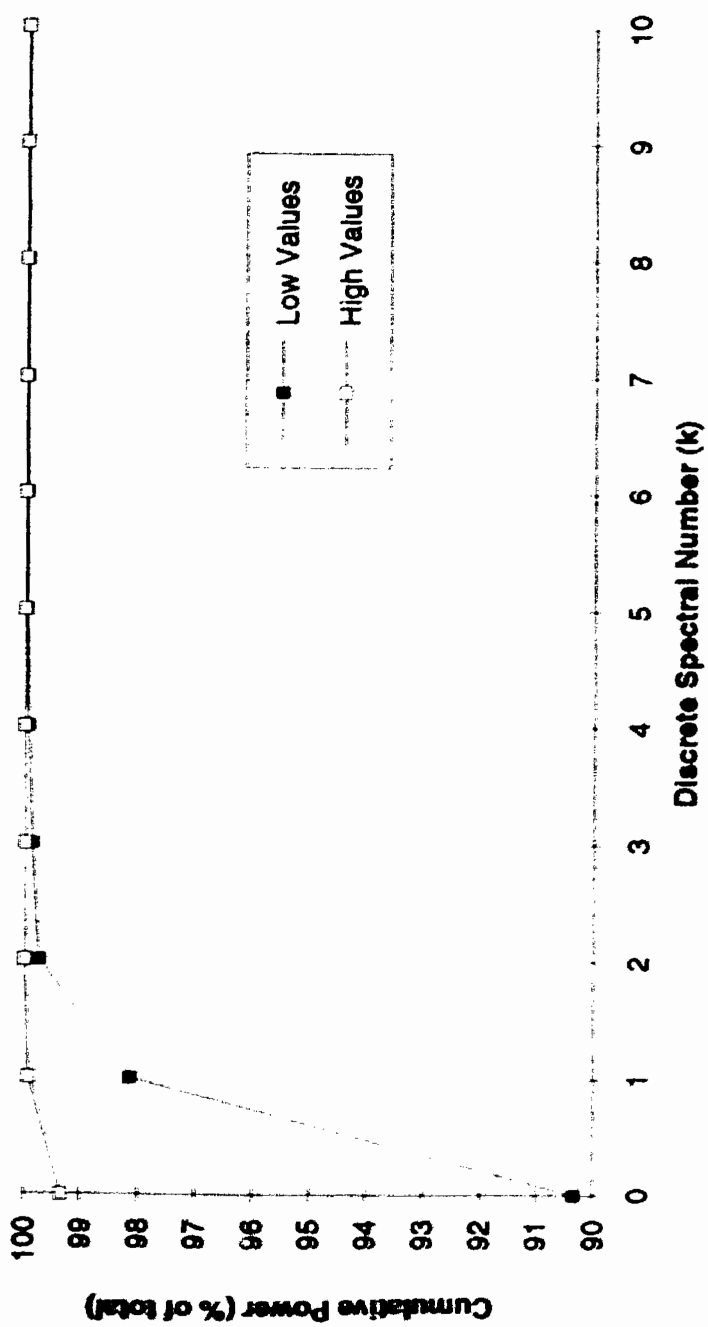
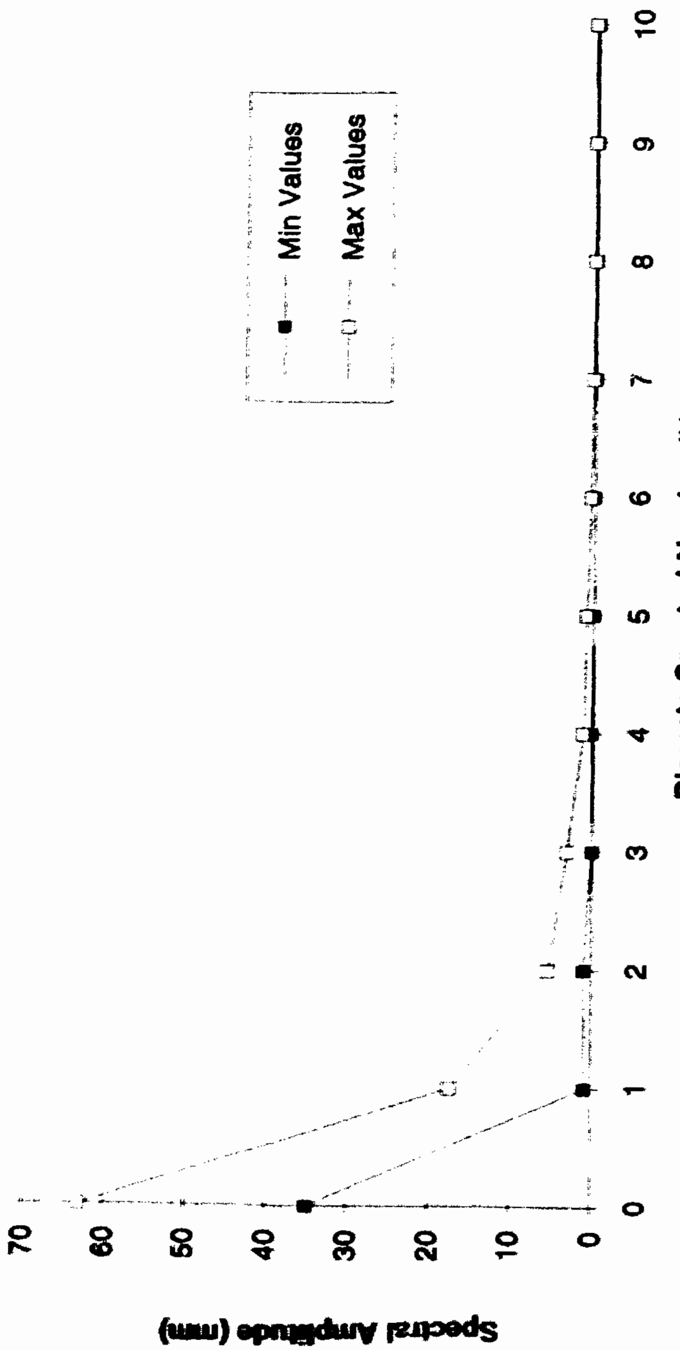


Figure 4.3 - Envelope of Spectral Amplitudes



The contribution from different discrete spectral numbers varies along the shape. The constant term dominates along the entire length, being greatest at the knee. This is an indication of how circular the cross-sections are, as well as how large the leg is at that level. Through the mid-section of the shape, the first discrete spectral number rises in importance, indicating that the shape is more eccentric to the central axis in that region. It is smaller at the knee and ankle since the shape was mounted with the measurement axis located centrally at either end. At the ankle, the second discrete spectral number has its greatest influence. This indicates the elliptical nature of the shape in that region. **Figure 4.4** shows the variation of these amplitude values along the length of the shape.

Analysis of the shape data in the longitudinal direction gave similar results. **Figure 4.5** illustrates the envelope of maximum and minimum values of the cumulative spectral power for each of the slices in the data. Again, the majority of spectral power is transmitted by the constant term and the first four discrete spectral numbers. In the worst case, 99.96% of the spectral power is transmitted by the first six, and those above the 18th account for less than 0.005% of the spectral power.

For discussion of these results, see **Section 7.2**.

Figure 4.4 - Spectral Amplitudes Along Shape

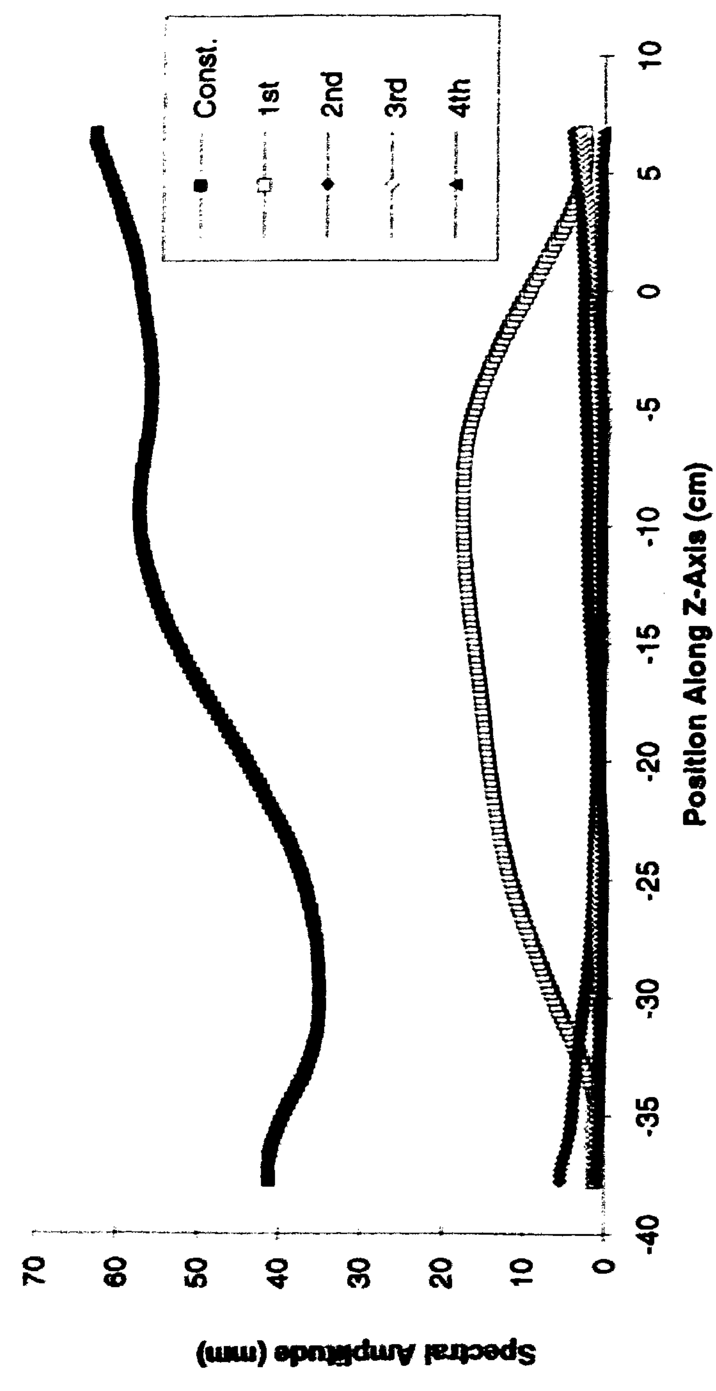
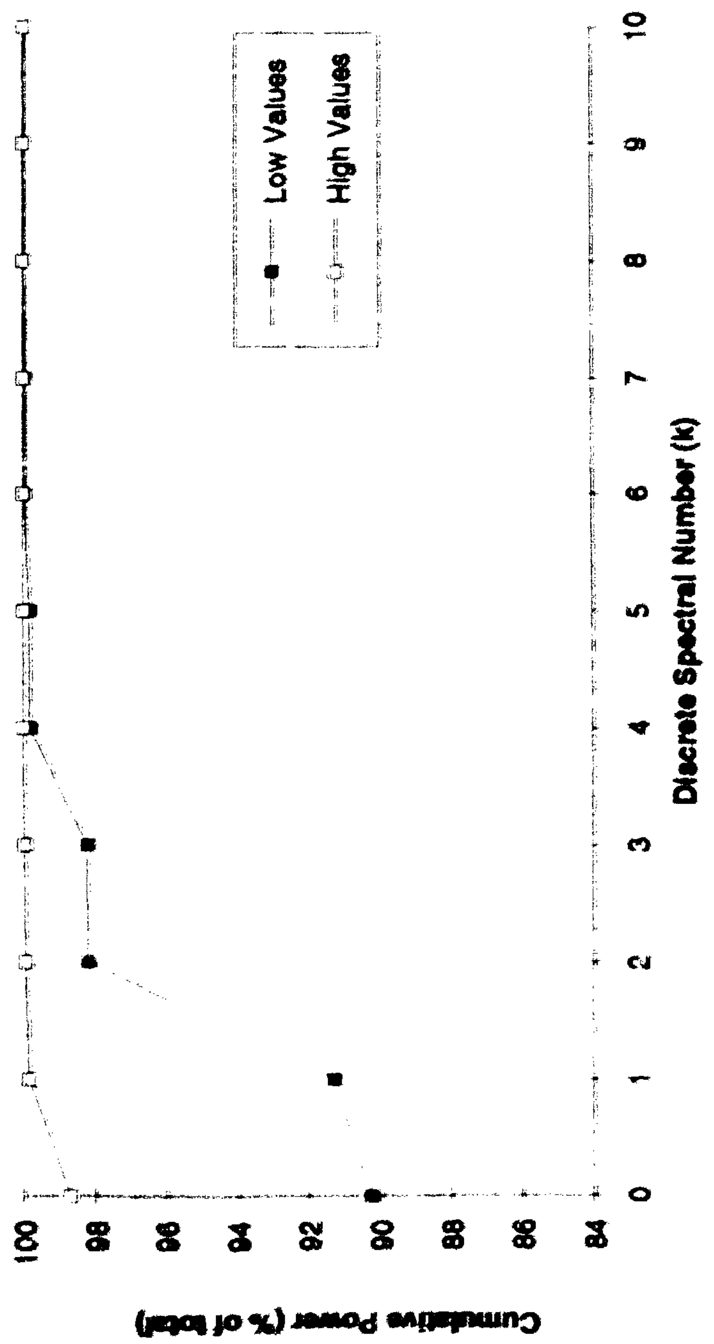


Figure 4.5 - Envelope of Cumulative Spectral Power - Strips



5. PROGRAM DESCRIPTION

The computer aided limb shape design procedures described in this chapter are written in MS-Pascal (Version 4.0). The program runs with MS-DOS on an IBM XT/AT equipped with a math co-processor. Shape data files are stored in cylindrical grid format.

The shape defined for the cosmetic cover emulates the shape of the contralateral limb while satisfying the constraints of fitting over the prosthetic socket and aligning properly with the prosthetic foot.

5.1 Spatial Definition of Aligned Prosthesis

Socket and Foot Shape Input

The combined shape of the aligned prosthesis components (socket and foot) is required so that the cosmesis shape can be modified to accommodate them. The program requires as input the three dimensional shapes of the socket and foot, and their relative spatial orientation.

The amputee's socket shape data file is loaded into the program. This data file describes the inner surface of the socket in terms of socket segmental axes. This file is created either by a computer aided socket design system or by a digitizing utility such as the MERU Shape Copier. Similarly, a shape data file corresponding to the particular make and size of artificial foot used is loaded into the program. This file is created with a digitizing utility program. Each file describes numerically the shape of that segment in cylindrical coordinates about a central vertical axis for that segment.

Upon input to the program, the shape information for each segment is converted from cylindrical to Cartesian coordinates in preparation for manipulation by spatial matrix transformations.

Definition of Segmental Axes

The central vertical axis for the socket shape is defined as passing through the intersections of lines bisecting the AP and ML dimensions at a level 25 millimetres distal to the knee joint line (PTB) and at a level 25 millimetres proximal to the tip of the socket. This technique for axis definition is described by Zahedi, *et al* (1986). A utility program (SHAPREP.EXE) adjusts the socket axis position, in case it does not conform to the definition.

The central vertical axis for the artificial foot is defined as passing through the centre of the hole for the attachment bolt.

In a similar manner as the socket, the central vertical axis for the cosmesis segment is defined as passing through the intersections of lines bisecting the AP and ML dimensions at a level 25 millimetres distal to the knee joint line (PTB) and at the level of the middle of the medial malleolus. The middle of the medial malleolus is the level of the ankle interface with the artificial foot[8].

The vertical axis for each segment is designated as the Z axis, with the positive direction upwards. The origin is defined as the level of the knee joint line (PTB groove) for the socket and cosmesis segments. The foot has a local origin defined at the level of the ankle surface (mid-medial malleolus). The X axis for

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[8] SACH and Seattle™ feet have a horizontal interface at the level of the midpoint of the medial malleolus. Blatchford Endolite™ feet have a low profile curved interface: low enough to be hidden from view by the shoe. The option to carve the extra portion of cosmesis required for this type of foot will need to be added in a future enhancement to the program.

each shape is defined to aim posteriorly from the origin. The Y axis is defined to aim towards the amputee's right side (medially if a left side shape, and laterally if a right side shape).

Alignment Definition and Processing

The software transforms the socket and foot segmental data, according to their final alignment, into cosmesis segmental space. The prosthesis alignment is quantified relative to a global set of axes with a three-dimensional digitizing arm (ACE 5001, Saunders, 1986). It operates with 5 rotational joints; the position of each is determined with optical encoders. With each press of the trigger, the device calculates and records the instantaneous positions of both the stylus tip and the most distal rotational joint (stylus base)[9]. These data are calculated with a microprocessor, and then downloaded to an IBM XT/AT host computer via a utility program (Sabiston, 1990).

For both the socket and foot, the stylus is aimed inward along the local orthogonal X and Y axes. The software uses the resulting three dimensional data to define these local axes of the socket and foot, as they are aligned by the prosthetist, relative to a global axis system.

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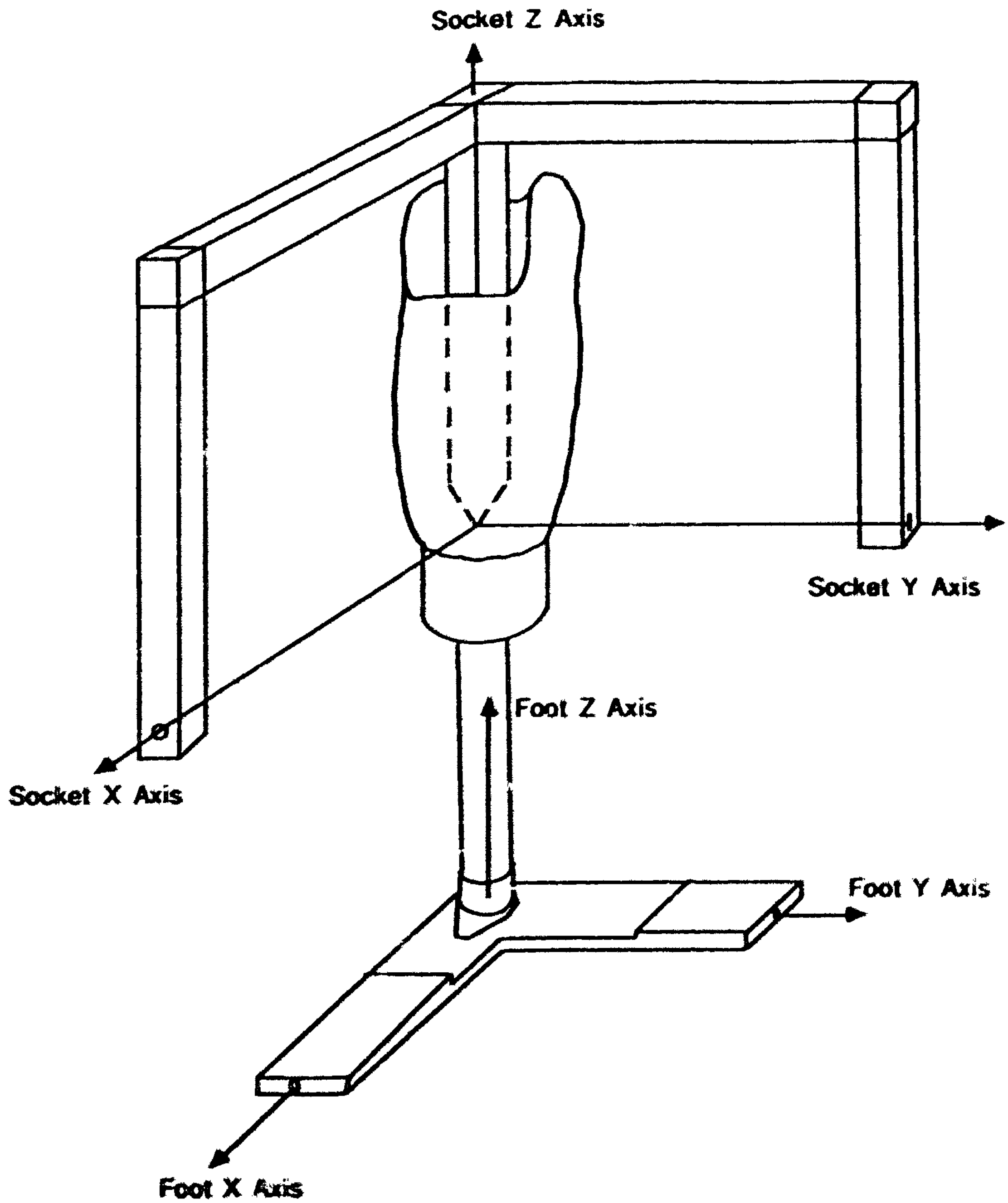
[9] These positions are described in Cartesian coordinates (units: tenths of millimetres) relative to the reference frame of the device.

Figure 5.1 - Alignment Input Jigs



To aid in positioning the stylus, special jigs were fabricated that have holes drilled orthogonally (**Figure 5.1**). These are mounted onto the aligned prosthesis at the distal tip of the socket and the proximal (ankle) surface of the foot. The holes point posteriorly (positive X axis) and laterally (positive Y axis for right side prostheses, negative Y axis for left side prostheses). The recording stylus of the ACE 5001 is placed within each hole on the two jigs to record their orientation in space. The ACE 5001 records the positions of the tip and base of the stylus, so the recorded data consist of two points on each of these axes.

These data points are used to calculate the direction vectors of the X and Y axes and the origins for each segment. Then for each segment the Z axis direction vector is then calculated as the cross-product of the other two.

In the case of the socket, the X and Y axes are recorded at the distal tip of the socket shape. This location is preferable for logistical reasons, but does not coincide with the intended segmental origin. The software therefore calculates unit vectors for the X, Y, and Z axes at the distal end and then redefines the origin to the level of the PTB by moving the origin up along the socket Z axis mathematically. This corrected origin matches the socket shape origin.

The transformation matrix describing the orientation of the socket relative to the foot is calculated from the segmental axes. Each local origin vector and three corresponding Cartesian unit vectors are calculated in terms of global Cartesian space. The four vectors for each shape are grouped into a matrix for that shape. Then the transformation matrix for representing socket data relative to the foot Cartesian space is calculated by multiplying the socket global matrix by the inverse of the foot global matrix.

5.2 Shape Selection and Scaling to Create "Primary" Limb Shape

Pick Reference Shape

Anthropometric data measured from the amputee's contralateral limb are recorded and input to the program (**Figure 5.2**), which calculates values of RENDO and RMESO for the amputee. The software utilizes the cell parameters to determine which region of the reference shape library matrix the amputee's limb shape is located (see **Figure 3.1**). The appropriate reference shape is then selected as input to the program.

Scale Shape

Longitudinal scaling is performed uniformly along the entire length of the reference shape. Rather than scaling according to the length of the contralateral leg, the length of the socket origin vector relative to the foot Cartesian coordinate system is utilized, so that the modified reference shape will mesh most readily with the socket shape. The difference between these techniques will be generally quite small, since the length of the prosthesis is intended to be close in length to the contralateral leg.

Radial scaling is performed with a non-homogeneous scaling factor that varies along the length of the shape according to three key measures from the amputee's contralateral leg. Girth is measured at the knee joint line (j_{kn}), at the level of the maximum girth found on the calf (j_{ca}), and at the level of the minimum girth found on the shank (j_{sh}). These girths are divided by the corresponding girths for the selected library shape to obtain ratios for each level.

Figure 5.2 - Program Inputs

Prosthesis Data Input

Foot data filename:
Socket data filename:
Alignment data filename:
Prosthesis is Left or Right side?:
How thick is the socket liner? (mm):
How thick is each laminate layer? (mm):

Patient Data Input:

Client's name (maximum eight characters):
Client's initials (maximum three):
Client's sex (m/f):
Client's date of birth (maximum eight):
Client's year of amputation (maximum eight):
Today's date (maximum eight characters):
Amputation side ("L" or "R"):

Height of Tibiali Laterali (tibial plateau-cm):
Height of MPT/Medial Tibial Plateau (cm):
Height of maximum girth on calf (cm):
Height of minimum girth on shank (cm):
Height of ankle (mid-medial malleoli - cm):

Girth of leg at knee joint line (cm):
Maximum girth of leg at calf (cm):
Minimum girth of leg at shank (cm):
Medial calf skinfold (cm):

Artificial foot style (SACH,Seattle...):
Foot size(SACH or Seattle foot #):
Memo (maximum 16 characters):

Reference shape record file input data (to calculate scaling factors):

ht_tib_lat,ht_knee,at_calf,ht_shnk,ht_ankl
grth_knee,grth_calf,grth_shnk,skn_calf

Limb Shape Specifications:

Prosthesis shape data filename for storage?>
How many millimetres of downsizing?:
Do you want the proximal end to be completely congruent
with the socket shape (Y/N)?

These ratios are then used to scale the shape as follows, using interpolation functions developed from first principles with cosine functions as a basis for smooth interpolation. These cosine functions begin and end each region with a zero slope, and are used rather than straight line interpolations in order to avoid slope discontinuities at the shank and calf levels.

$$S_j = S_{sh} \qquad j_{an} <= j < j_{sh} \qquad (5.1)$$

$$S_j = S_{sh} + (S_{ca}-S_{sh})*(1-\cos(\pi(j-j_{sh})/(j_{ca}-j_{sh})))/2$$

$$j_{sh} <= j < j_{ca} \qquad (5.2)$$

$$S_j = S_{ca} + (S_{kn}-S_{ca})*(1-\cos(\pi(j-j_{ca})/(j_{kn}-j_{ca})))/2$$

$$j_{ca} <= j < j_{kn} \qquad (5.3)$$

$$S_j = S_{kn} \qquad j_{kn} <= j < j_{max} \qquad (5.4)$$

Where S_j is the radial scaling factor at a given Z-level,

j_{an} and j_{max} represent the distal (ankle) and most proximal cross-sections of the reference shape, and

S_{sh}, S_{ca}, and S_{kn} are the calculated scaling factors at the shank, calf, and knee respectively.

In cases of a right side prosthesis, the data representing each slice are mirrored within this portion of the computer software. This simply entails swapping the order of the 36 radial values as they are listed[10]. This scaled shape is stored to disk as the "Primary" limb shape. It is then modified to accommodate the shape of the aligned foot and socket.

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10 The values for zero and 180° remain the same. The values for 10° and 350°, 20° and 340°, 30° and 330°, etcetera, are swapped.

5.3 Orientation of Limb Shape

This portion of the software orients the aligned socket and foot relative to cosmesis shape coordinates. The socket and foot shape data are first transformed into cosmesis Cartesian space, and then converted into a standard MERU-CASD cylindrical grid.

Transform Shapes to Cosmesis Cartesian Space

The matrices for transforming the foot and socket data into cosmesis Cartesian space are calculated after certain geometric constraints are applied. At the ankle interface (mid-medial malleolus) the AP and ML midpoint of the foot is constrained to coincide with the AP and ML midpoint of the distal end of the primary cosmesis shape. The relative longitudinal (Z) rotation, or toe-out, of the foot relative to the shank is constrained to be zero at this interface (toe-out is therefore taken up between the socket shape and the proximal end of the cosmesis).

Given these constraints, the rotations about the foot X and Y axes are calculated so that the AP and ML midpoints of the cosmesis and socket coincide at a level 25 millimetres distal to the cosmesis origin (Figure 5.3).

The calculated translations and rotations are concatenated into the transformation matrices for moving the foot and socket into cosmesis Cartesian space. Each data point in the foot and socket is then transformed with these matrices.

Convert Shapes to Cosmesis Cylindrical Grid

With the foot and socket shapes represented in terms of cosmesis Cartesian space, the foot and socket data are then converted from Cartesian to cylindrical coordinates (Figure 5.4).

The first step is to interpolate the data into regularly spaced cross sections along the Z axis of the cosmesis Cartesian coordinate system. The data are then interpolated into a regular MERU-CASD cylindrical grid with 10^0 spacing. However this process must be accomplished carefully. When converting to the cylindrical grid, it must be verified that the positional values follow an orderly progression of increasing angle.

The cylindrical data structure requires a single positive non-zero radius value for each angular increment from zero to 350 degrees. No angular value may have more than one radius assigned to it, so if the shape is re-entrant (ie: if it has an overhang), or if the axis is outside the shape at a particular level, the program determines which radii to retain and which must be discarded. The software does this by comparing the angular component of the partially converted points. Overhangs are identified by a reversal in the progression of angular values. Angular progression is enforced by discarding any points showing such a reversal prior to interpolating to the regular angular increment of the cylindrical grid. Missing data points are then assigned default or interpolated values.

5.4 Shape Modifications to Create "Final" Cosmesis

Match Ankle

This procedure is applied to each longitudinal data strip at the distal end of the cosmesis. For each strip, the radius at the ankle interface of the cosmesis is compared to its counterpart on the foot. The difference is applied to the cosmesis as a radial correction to the cosmesis that diminishes quadratically upwardly along the first five centimetres of the shape (Figure 5.5).

Figure 5.3 - Defining transformations to cosmesis space.

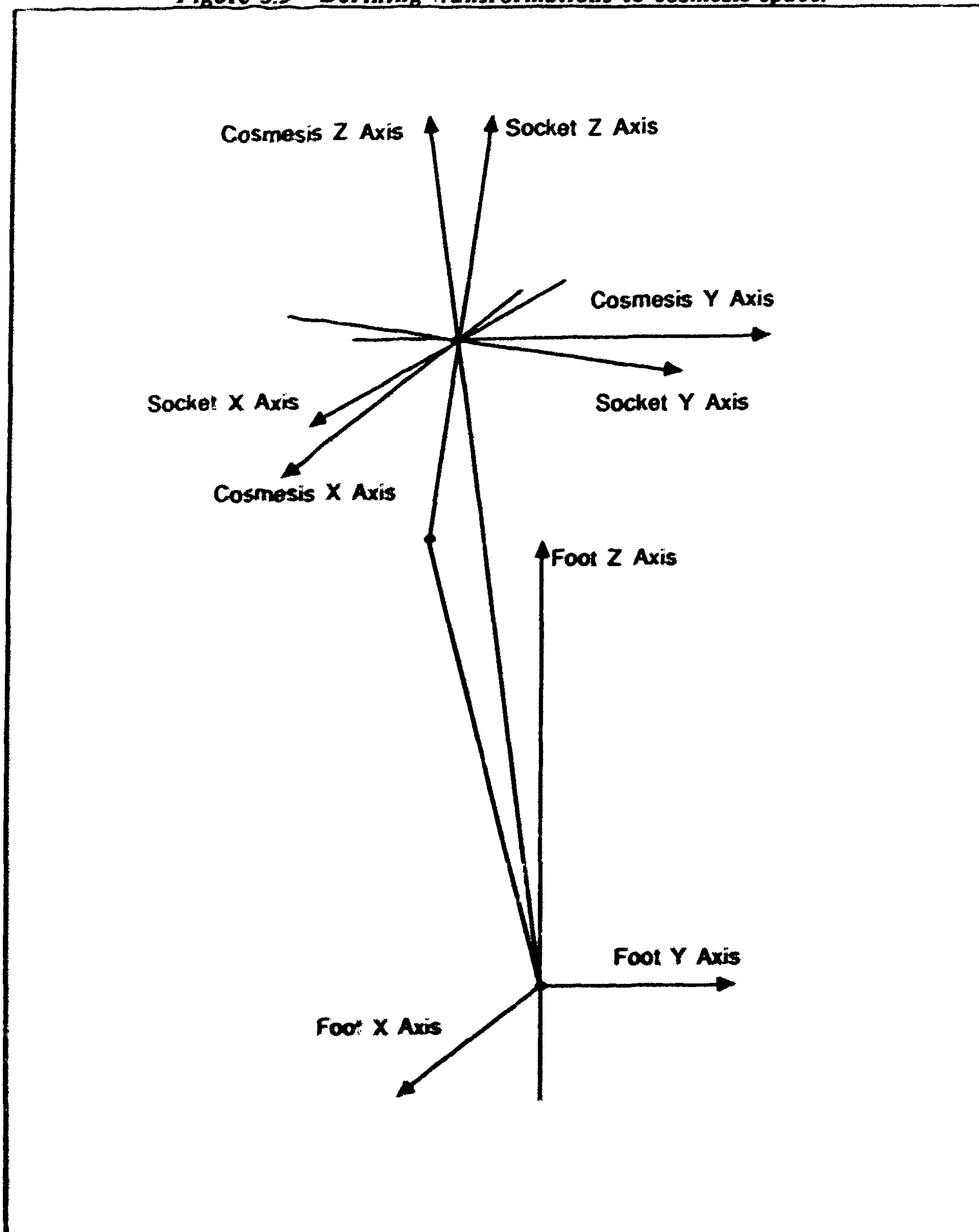
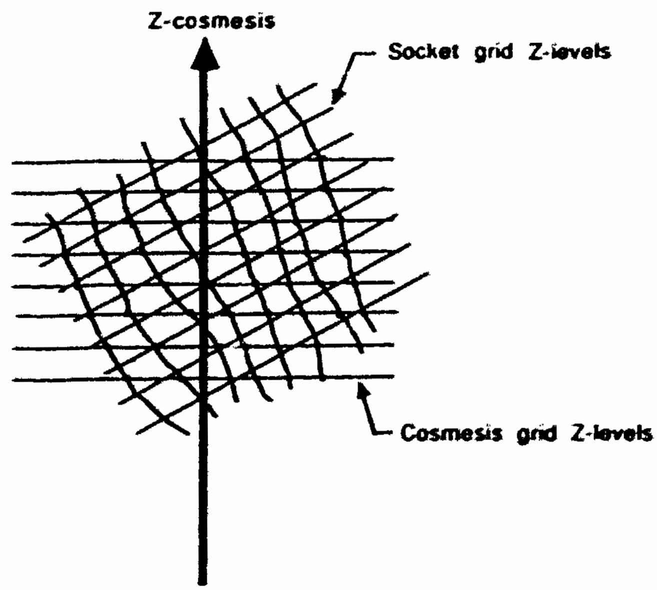
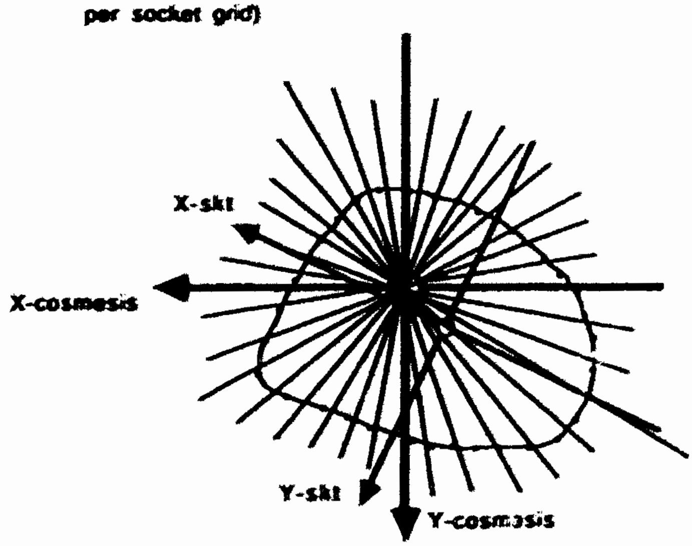


Figure 5.4 - Converting to cosmesis cylindrical grid.



• Intermediate Data Points (longitudinally interpolated to cosmesis grid, yet angular coordinates are still as per socket grid)



To a large extent the variable radial scaling described in Section 5.2, in combination with this quadratic patch, is expected to mimic any edema in the contralateral leg. A slope discontinuity may result at the ankle interface, although this is not entirely unlike the way such tissue hangs over the bony prominences of the ankle, or even the shoes the person is wearing.

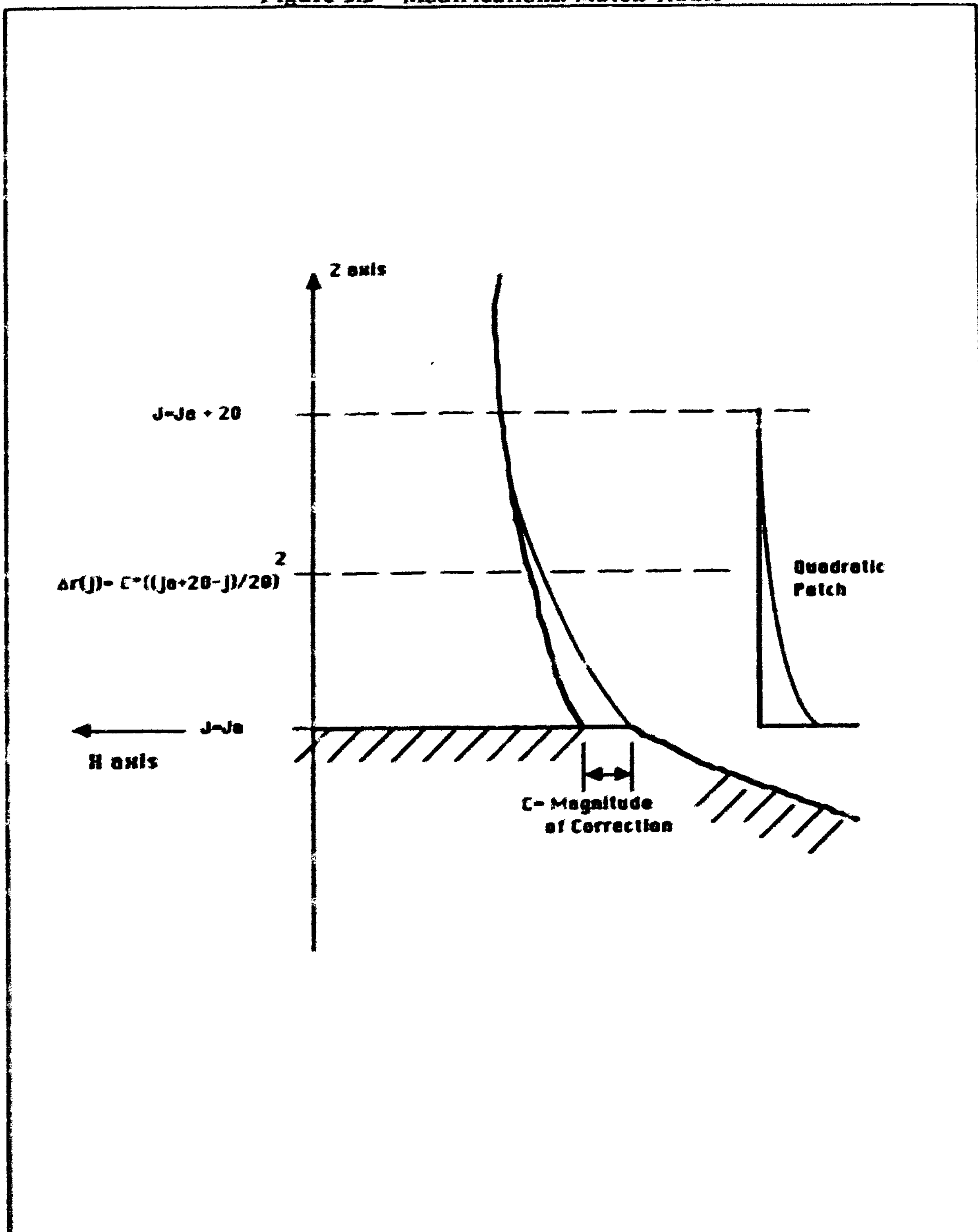
Accommodate Socket

The socket shape data correspond to the inner surface of the socket liner. In order to accommodate the outer shape of the socket within the cosmesis shape the total material thickness must be added to each radius. For this purpose, total material thickness is defined as the sum of a single socket liner thickness added to a double laminate thickness (one thickness for the wall of the socket, and one thickness for the wall of the cosmesis). Values for liner thickness and laminate thickness are adjustable in software.

Cosmesis radial values are compared with radial values for the socket (now described in cosmesis cylindrical coordinates). Cosmesis radii which do not exceed the corresponding socket radii by at least the total material thickness are incremented so that they do.

This modification is performed on longitudinal strips of the shape. As the strip is checked in an upwards direction, the software notes the onset of the socket protruding outside of the cosmesis. After checking ahead a number of levels for the largest discrepancy, a linear patch is applied to the strip backwards over several levels (Figure 5.6).

Figure 5.5 - Modifications: Match Ankle



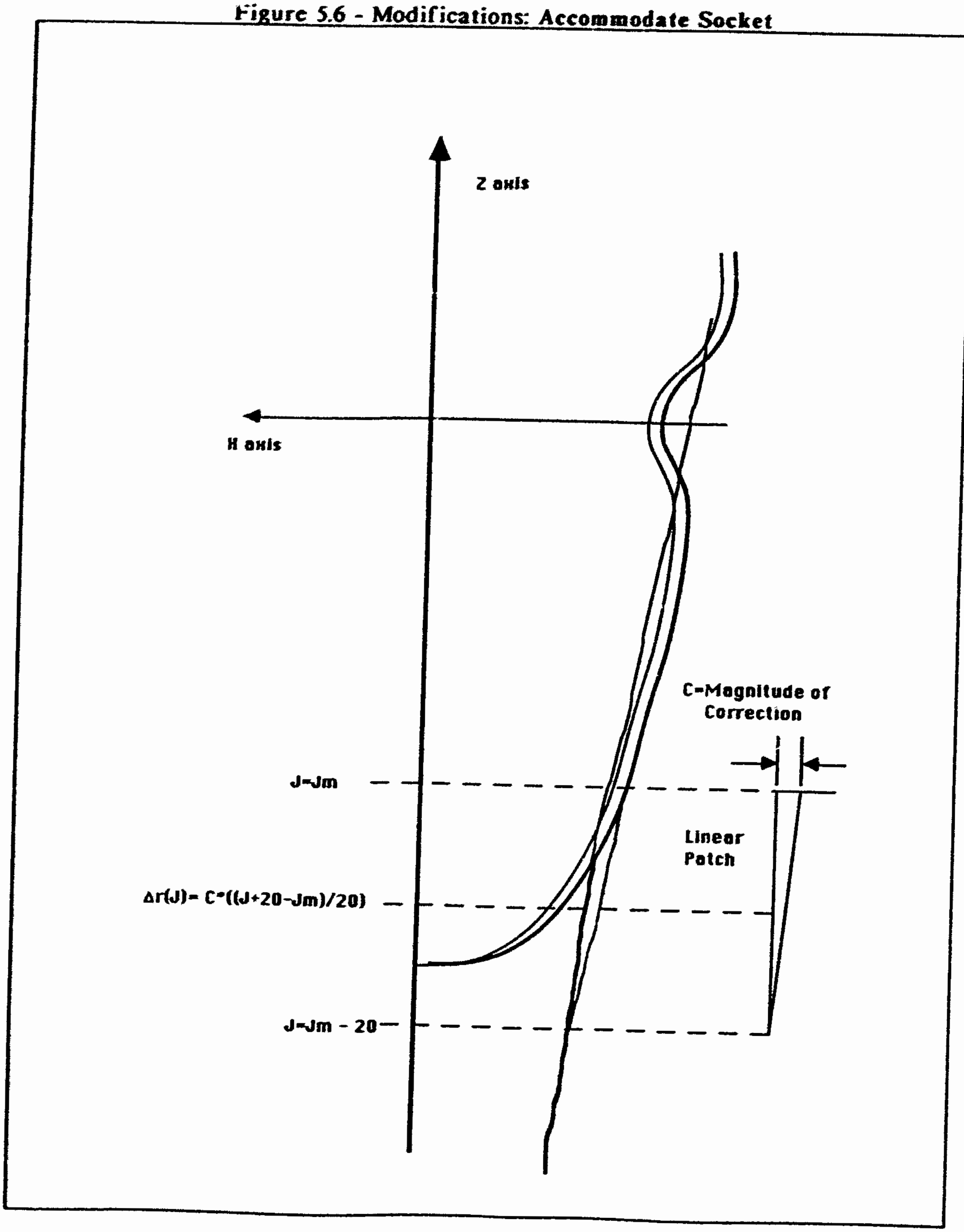
A simulated endoskeletal pylon is located along the Z axis from the foot to the socket. It is set to an arbitrary radius large enough to prevent tool cutter problems if the fully aligned prosthesis shape were carved using a CNC milling machine or socket shape carver. In general, the "Pylon" portion of the shape should not protrude through the **Primary** shape. If it does, the protruding radii are corrected in software.

The void at the rear of the socket above the flare is represented as an approximately flat surface. These radii are of little consequence since the laminate is cut away to make the posterior opening for the socket. The **Accommodate Socket** procedure treats this region in the same way as the rest of the socket, resulting in radial data that are deceivingly large. Again, this is of little consequence as this part of the cosmesis surface will also be cut away in the final preparation of the prosthesis.

Above the knee, the limb shape is made to conform with the socket shape with a snug fit. This prevents a bulky, abrupt border at the proximal end when it is trimmed for use.

This "**Final**" shape is intended to be complete without need for further interactive modifications. If desired, such modifications could be performed easily using the general MERU-CASD program.

Figure 5.6 - Modifications: Accommodate Socket



6. SUBJECT TRIAL

6.1 Trial Protocol

The cooperation of a prosthetist and a client amputee was obtained for a trial of the computer aided cosmesis design system. Informed consent was obtained from the amputee, a Caucasian male in his early forty's. Anthropometric measurements taken from the amputee's natural leg were recorded for input into the computer software.

Shape data files from the subject's completed socket and artificial foot, and the data file describing the spatial orientation of the aligned prosthesis were assembled for input into the program.

Taking these data as input, the software selected one of the reference shapes and scaled it to create the "**Primary**" cosmesis shape. This shape was stored onto the computer disk. Next, this cosmesis shape was modified to conform to the shapes of the socket and the ankle of the artificial foot. This modified shape was also stored onto the computer disk as the "**Final**" cosmesis shape.

A wrap casting was made of the natural leg as described in Section 3.2. This shape was digitized and the numerical data stored on computer disk. Since the subject wore a stockinette for the wrap casting, the radial data were corrected for material thickness prior to analysis. Meanwhile, the prosthetist and his technician completed the prosthesis using artisan techniques to form the cosmesis. Prior to delivery the shape of the completed artisan prosthesis was recorded using the MERU Shape Copier.

As an exercise, the **Final** shape data file was post-processed with a utility program at MERU and the instructions sent to the CNC milling machine. The shape was carved out of foam, demonstrating the potential for automated manufacture of the system output.

6.2 Results

The computer designed shape was acceptable to the prosthetist to the point that he indicated that he would be prepared to use the shape as a mould. Qualitatively, the **Final** cosmesis shape compared well with the natural leg shape, whereas the artisan shape was more cylindrical and lacked some of the characteristic curvatures seen in the natural leg.

The aligned prosthesis shape is shown in **Figure 6.1** to illustrate how the foot and socket are positioned in cosmesis cylindrical coordinates. Note that the shape is made up of the inner surface of the socket, a stylized pylon, and the top portion of the foot.

The **Primary** and **Final** cosmesis shapes were evaluated quantitatively by comparing matched cross sections with the natural leg and the artisan prosthesis. The four shapes considered were numbered as follows:

The amputee's natural leg shape digitized from a plaster casting. Referred to as the "**Natural**" shape (**Figure 6.2**).

The reference shape, selected and scaled by the computer program. Referred to as the "**Primary**" shape (**Figure 6.3**).

The final modified shape created by the computer program. Referred to as the "**Final**" shape (**Figure 6.4**).

The final artisan shape, fabricated by the technician and digitized. Referred to as the "**Artisan**" shape (**Figure 6.5**).

These figures show the shapes with every second slice for clarity.

Figure 6.1 - Aligned Prosthesis Shape

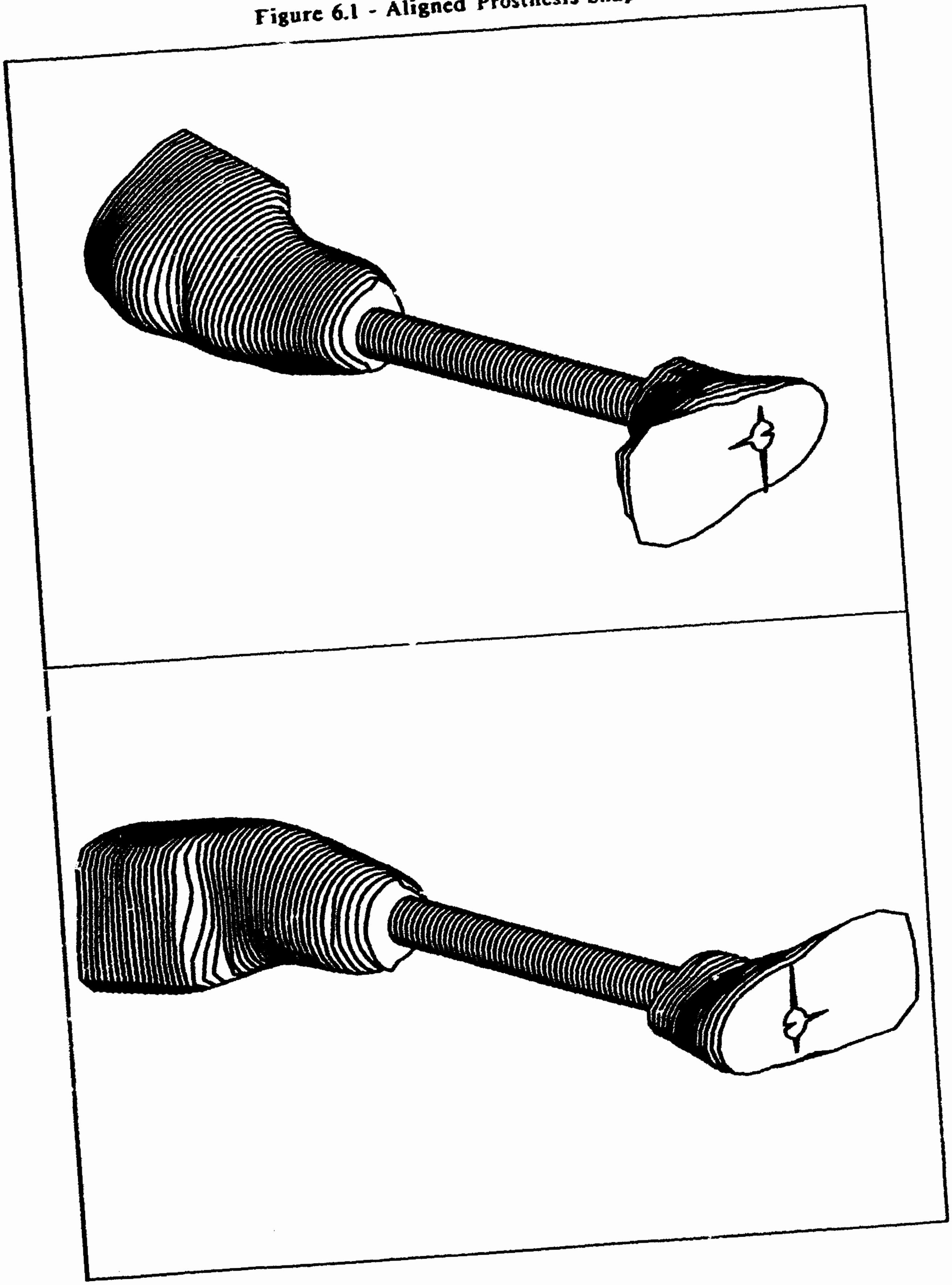


Figure 6.2 - Natural Leg Shape

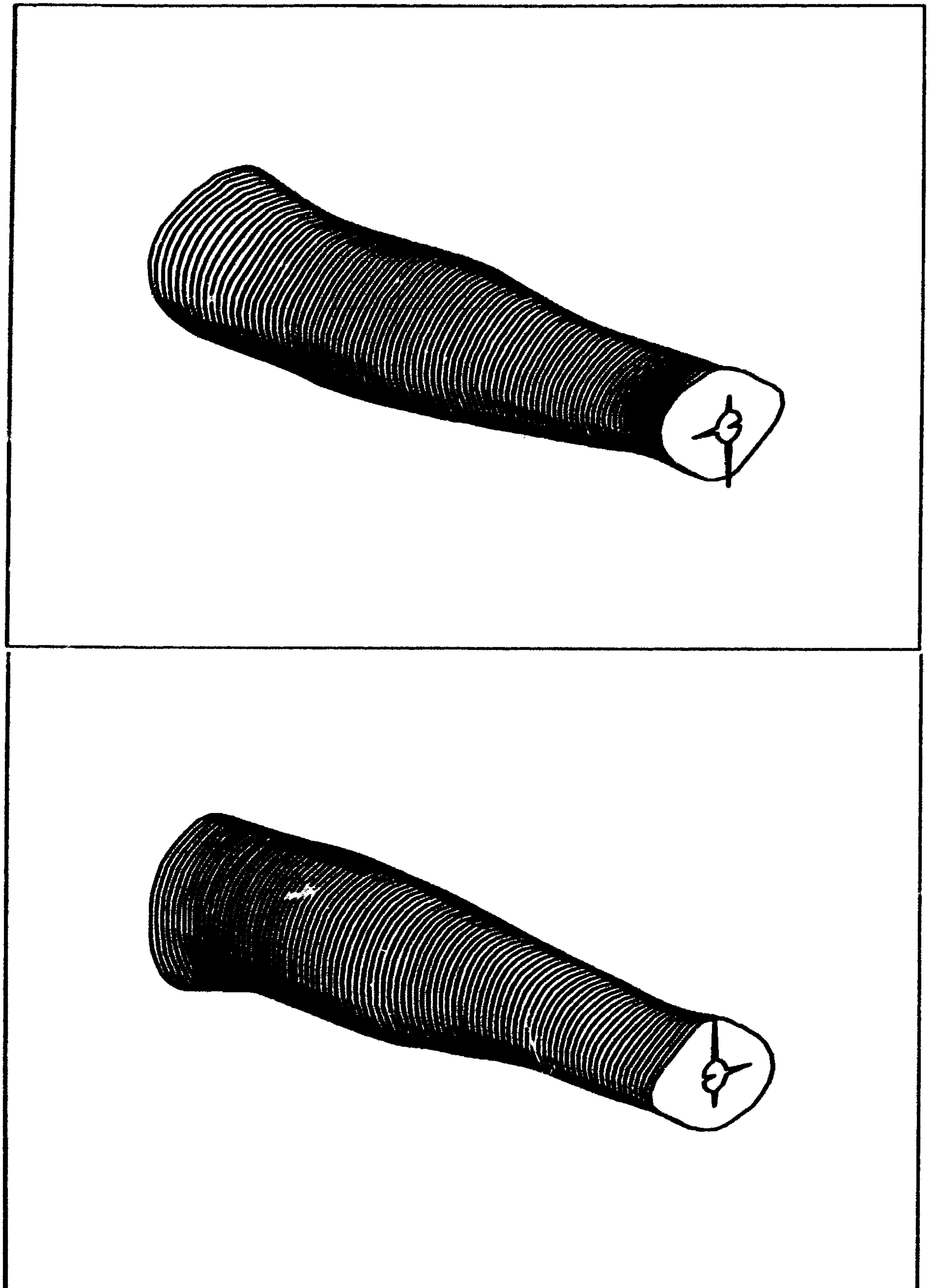


Figure 6.3 - Primary Limb Shape

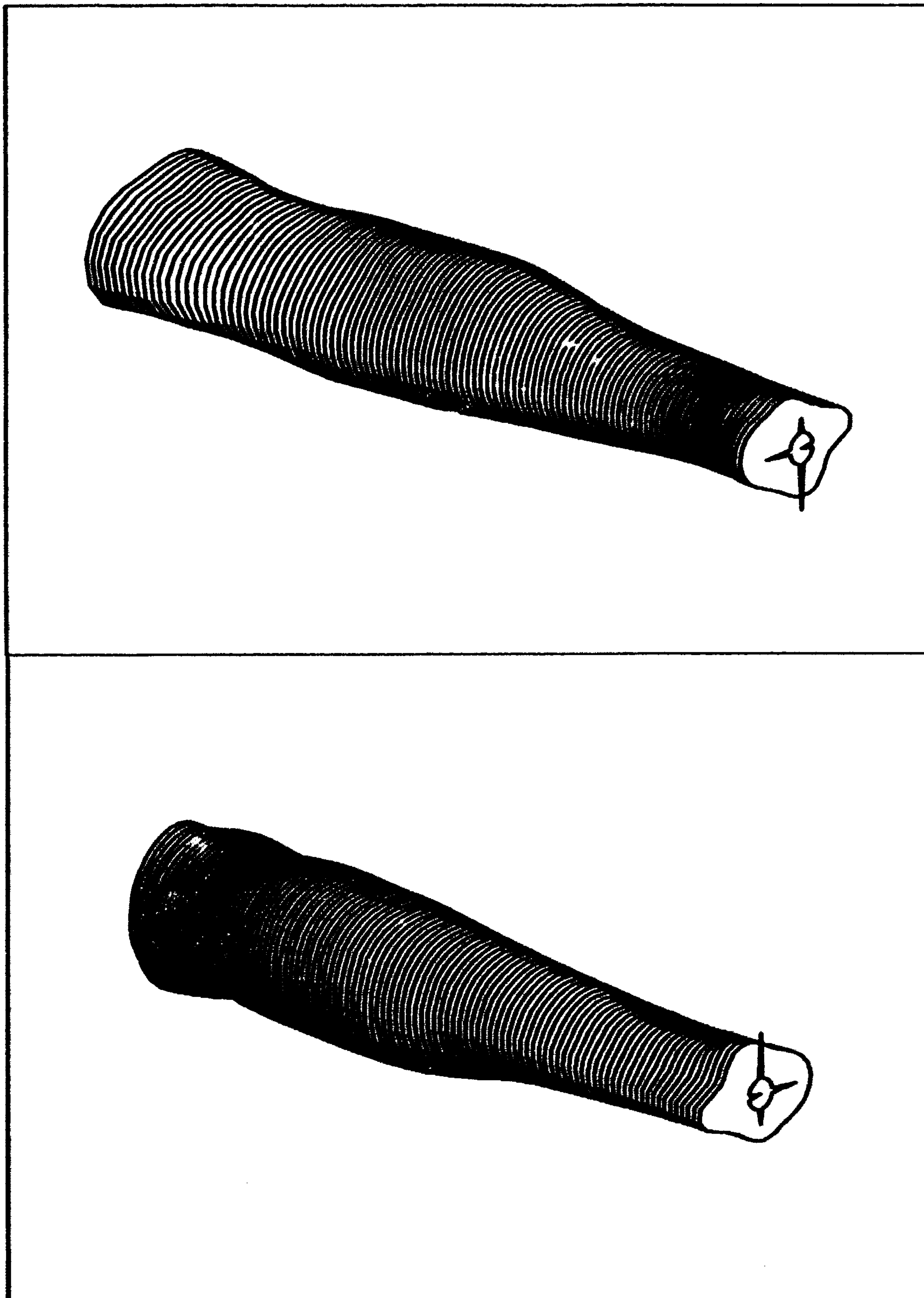


Figure 6.4 - Final Limb Shape

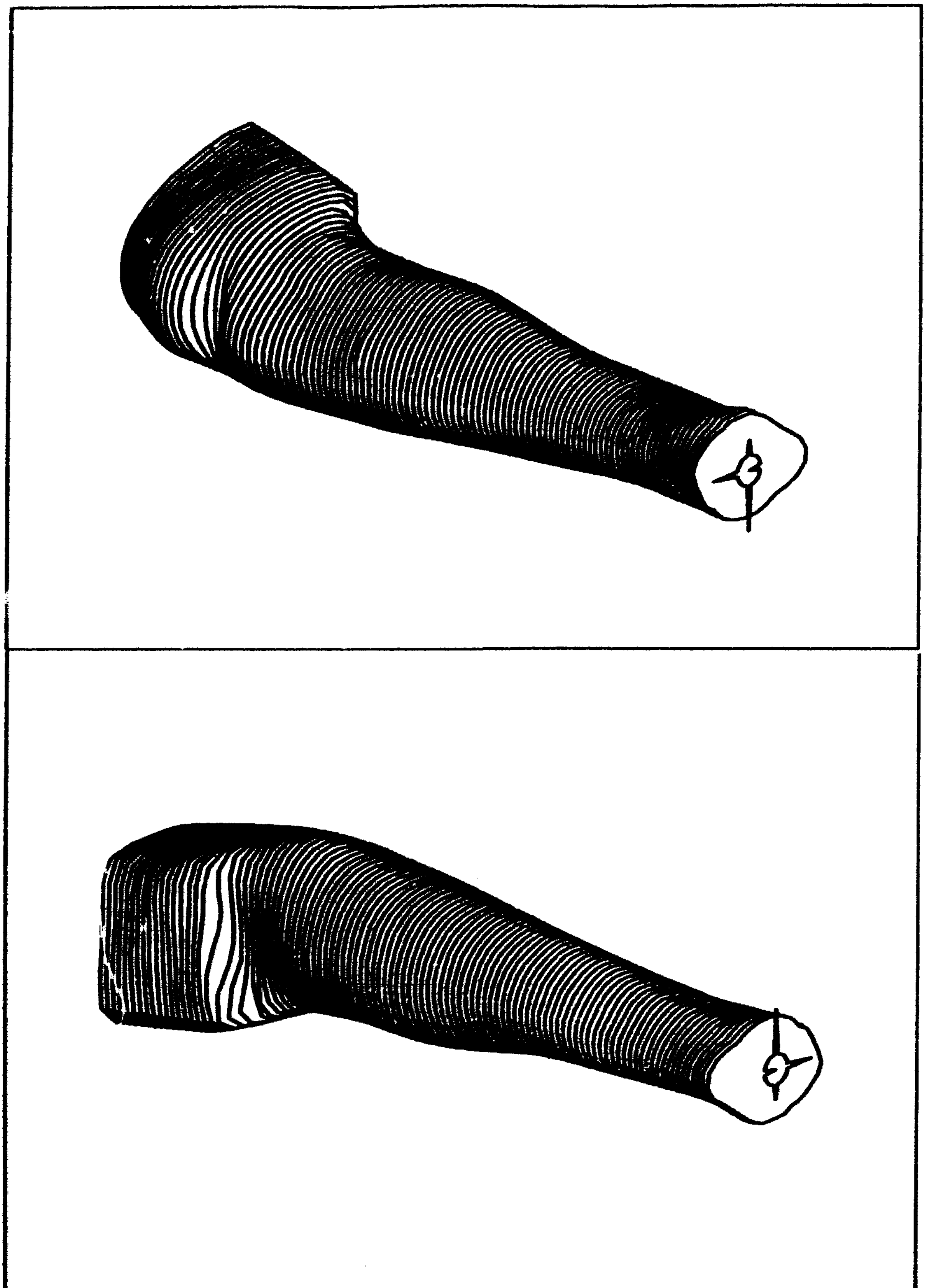
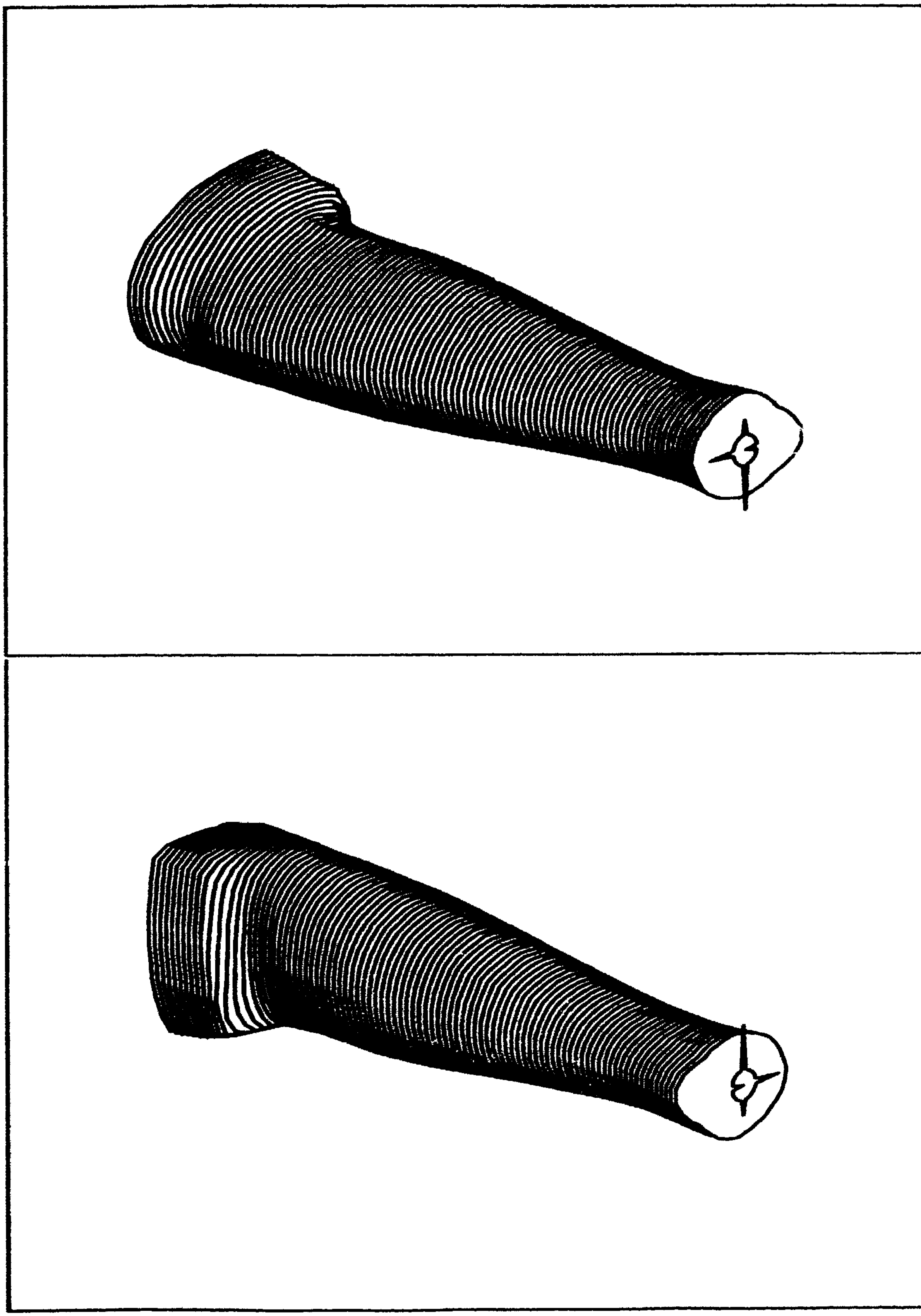


Figure 6.5 - Artisan Limb Shape



Quantitative analysis of the shapes was performed using techniques described by Torres-Moreno (1987). For each independent cross-section slice, the Equivalent Radius (ER) and the Cross-Sectional Area (CSAR) of the four shapes were calculated with the following equations:

$$ER = 1/36 \sum_{i=1}^{36} (r_i)^2 \tag{6.1}$$

$$CSAR = \pi \, ER^2 \tag{6.2}$$

The Equivalent Radius represents the radius of a circle with an area equal to that of the shape being analyzed. Prior to this analysis, each slice was shifted to align the origin with the centroid of the slice.

Figure 6.6 shows the variation of cross-sectional area with distance along the length of each shape. The shapes are aligned with the mid-patellar tendon bar positioned at zero on the abscissa of the chart.

The computer designed limb shapes were compared with the **Natural** leg and the **Artisan** limb shape produced for the patient. Cross-sectional areas of the **Primary** limb shape were 0.91 +/-7.44% larger than corresponding areas on the **Natural** leg over the full length.

The sudden jump in sectional area on the **Final** shape at the level of the knee indicates the rear flare. It is particularly large due to the superfluous addition of material thickness over the posterior aspect of the socket shape (Note that this portion of the shape is removed and discarded to open up the posterior aspect for access).

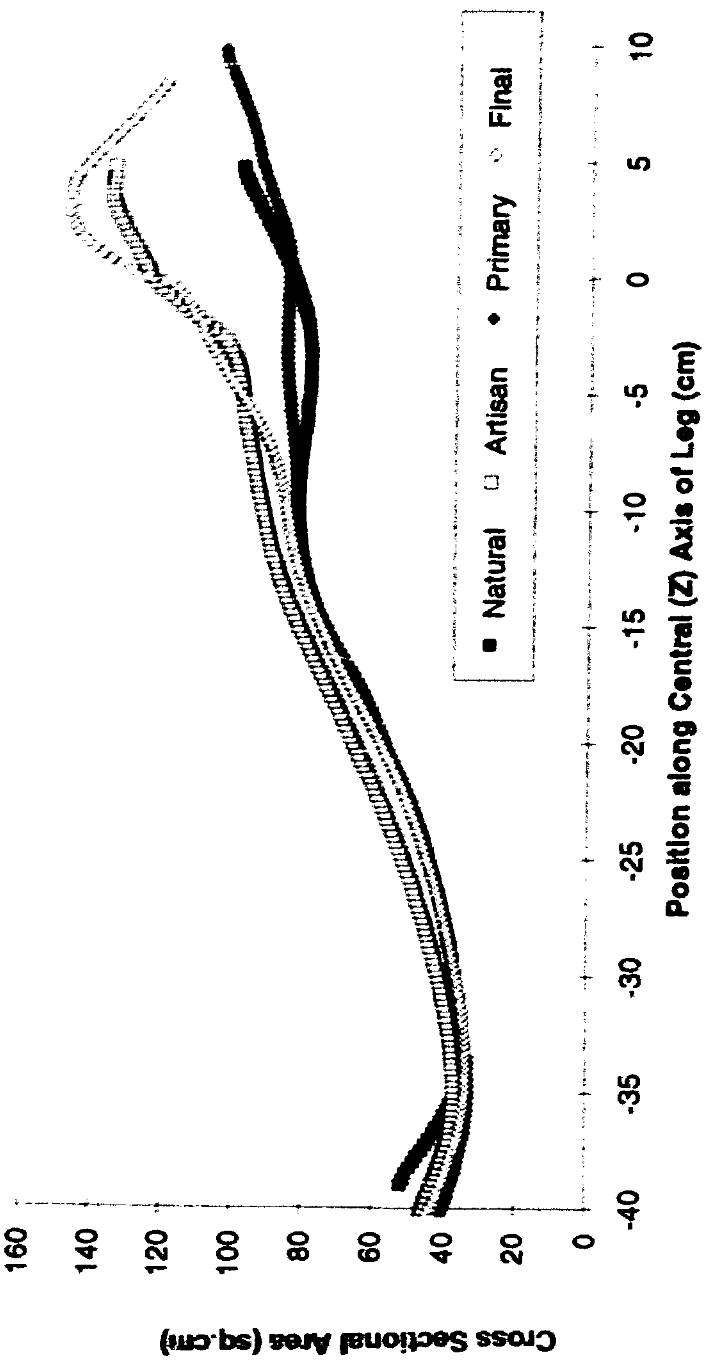
The **Final** computer generated shape is roughly the same size as the **Natural** leg (+0.5 +/-8.3%) between the distal end (Z=-39.0 centimetres) and a point just distal of the rear flare (Z=-5.0 centimetres). No downsizing had been specified for the **Final** shape in this trial.

The figure shows that the **Artisan** limb shape is larger than the **Natural** leg over the same levels, (+10.4 +/-8.9%). This is contrary to the reported trend of downsizing limb shapes in clincial practice for aesthetic reasons.

It can be seen from **Figure 6.6** that the **Primary** cosmesis shape, which was scaled to match the length of the aligned prosthesis, is slightly elongated compared to the natural (contralateral) leg.

The computer generated shapes extend further proximally only because the Shape Copier was limited in its capacity from measuring the full length of the **Artisan** and **Natural** leg shapes.

Figure 6.6 - Cross Sectional Areas of the Clinical Trial Shapes



Although comparison of cross sections of the four shapes provides information on relative mass at each level, and thence longitudinal shapes; these comparisons provide no information on the differences between shapes in the transverse plane. A comparison of cross sectional shapes was achieved by normalizing the areas at each transverse cross section according to their equivalent radii. This procedure allows a comparison of shapes independent of size.

Corresponding cross-sections from pairs of shapes were analyzed by comparing matched radii. Each radius was normalized by dividing it by its sectional ER. RMS error between two shapes is calculated as follows:

$$\mathrm{RMS} = 1/36\sum_{i=1}^{36}(r_{ia}/ER_a - r_{ib}/ER_b)^2 \qquad (6.3)$$

The four shapes were compared in four pairings using **Equation 6.3**.

Comparison 1: **Natural** versus **Primary**

Comparison 2: **Natural** versus **Final**

Comparison 3: **Natural** versus **Artisan**

Comparison 4: **Final** versus **Artisan**

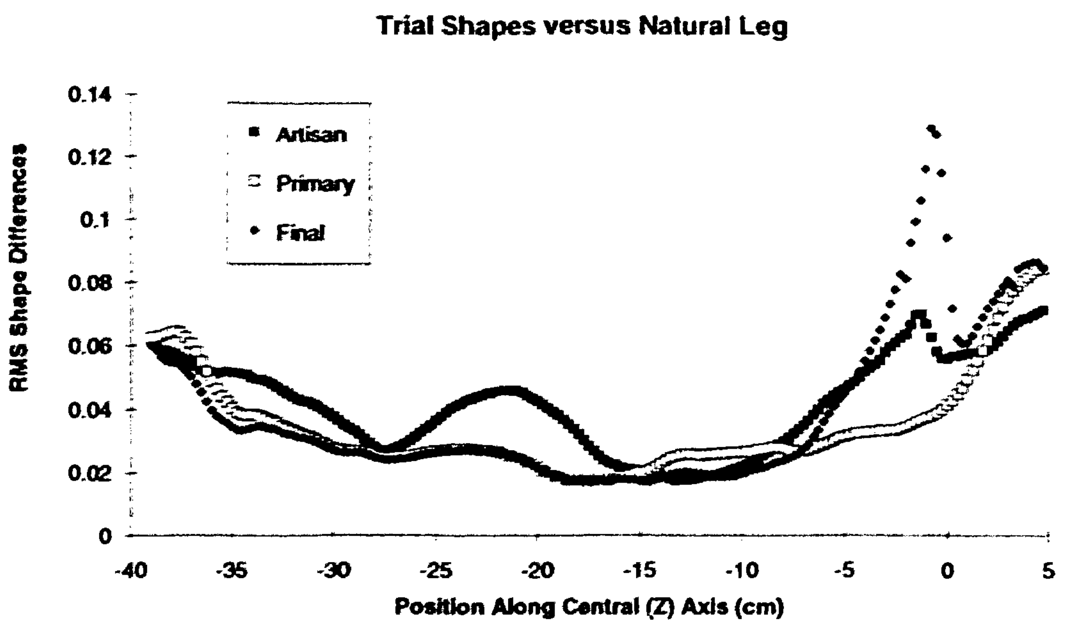
Figure 6.7 illustrates the results of Comparisons 1, 2, 3 and 4. RMS error between the radius values is plotted as a function of Z-level for each of these comparisons. Small RMS differences between the slices in a particular region of the shapes indicate strong resemblance between the shapes in that region.

RMS error values for the **Primary** limb shape compared to the **Natural** leg were 0.034 +/-0.016 over all levels.

RMS error values for the **Final** and **Artisan** limb shapes were summarized along the shapes, between levels Z=-39.0 centimetres and Z=-5.0 centimetres. Cross sections proximal to this level were not included because the **Final** shape included the superfluous thickness on the posterior aspect, mentioned above. This posterior region is not part of the functional shape. RMS values for the Final CAD limb shape were 0.028 +/-0.010, while the values for the Artisan limb shape were 0.036 +/-0.012.

Selected cross-sections from each shape are plotted in Figures 6.8 through 6.11. These are taken at five centimetre intervals along each shape. They are included so that by comparing them visually, they may help to illustrate the origin of the RMS values calculated in the four comparisons.

Figure 6.7 - Shape Resemblance Between Shapes



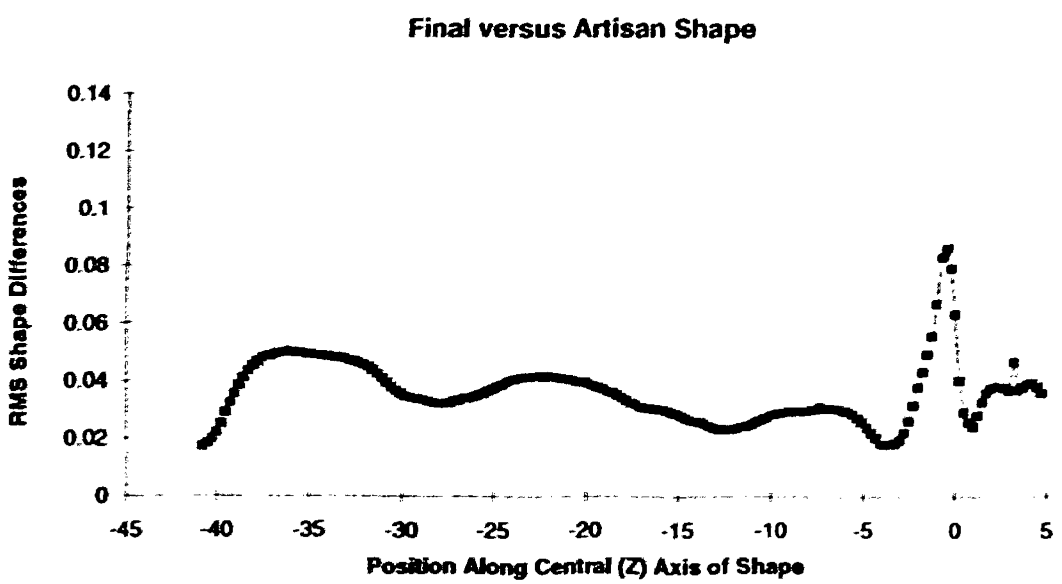
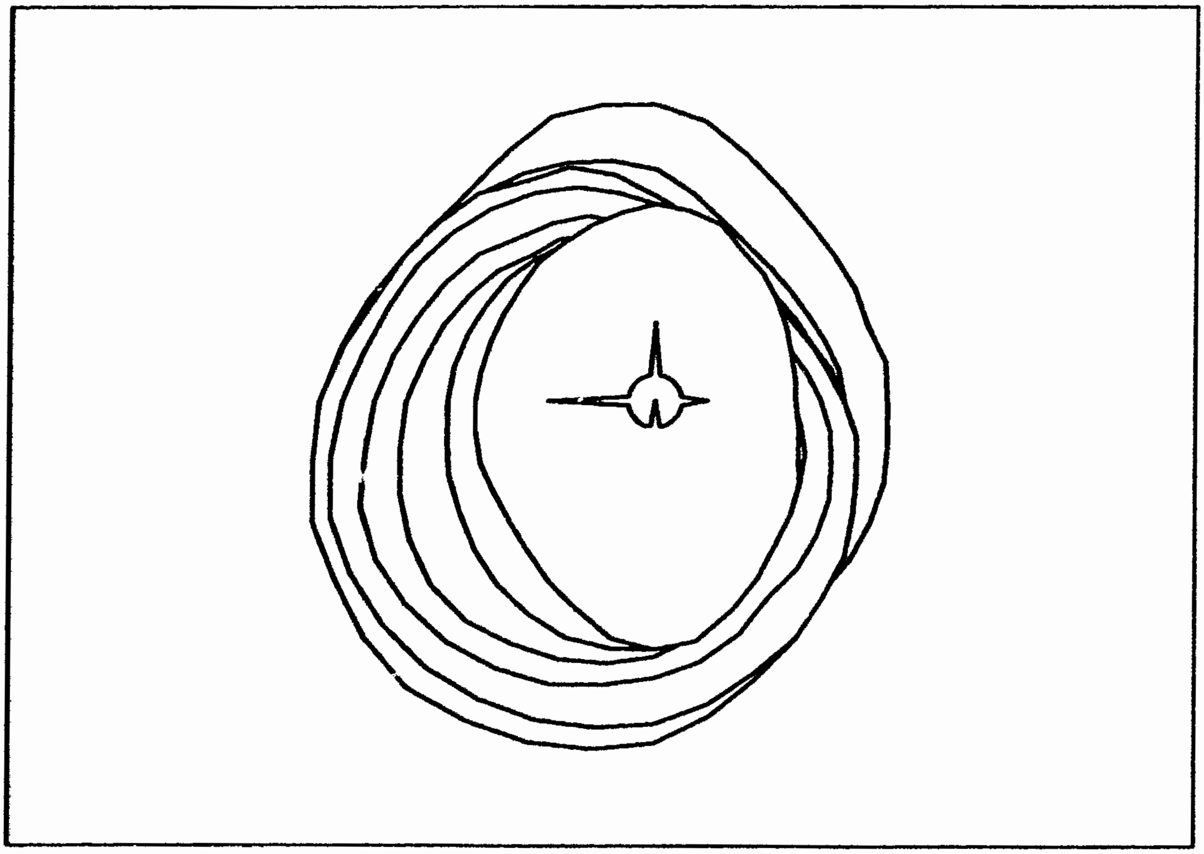
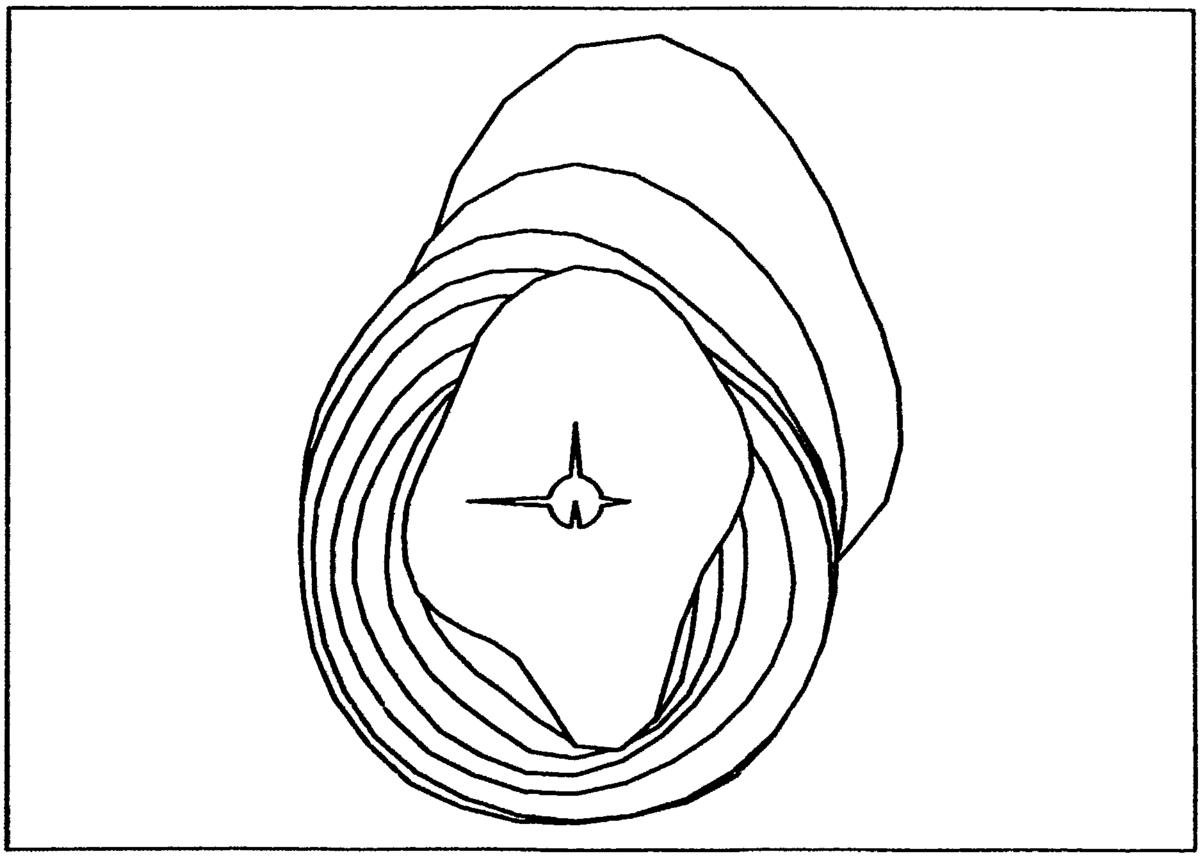


Figure 6.8 - Selected Cross Sections - Natural Leg Shape



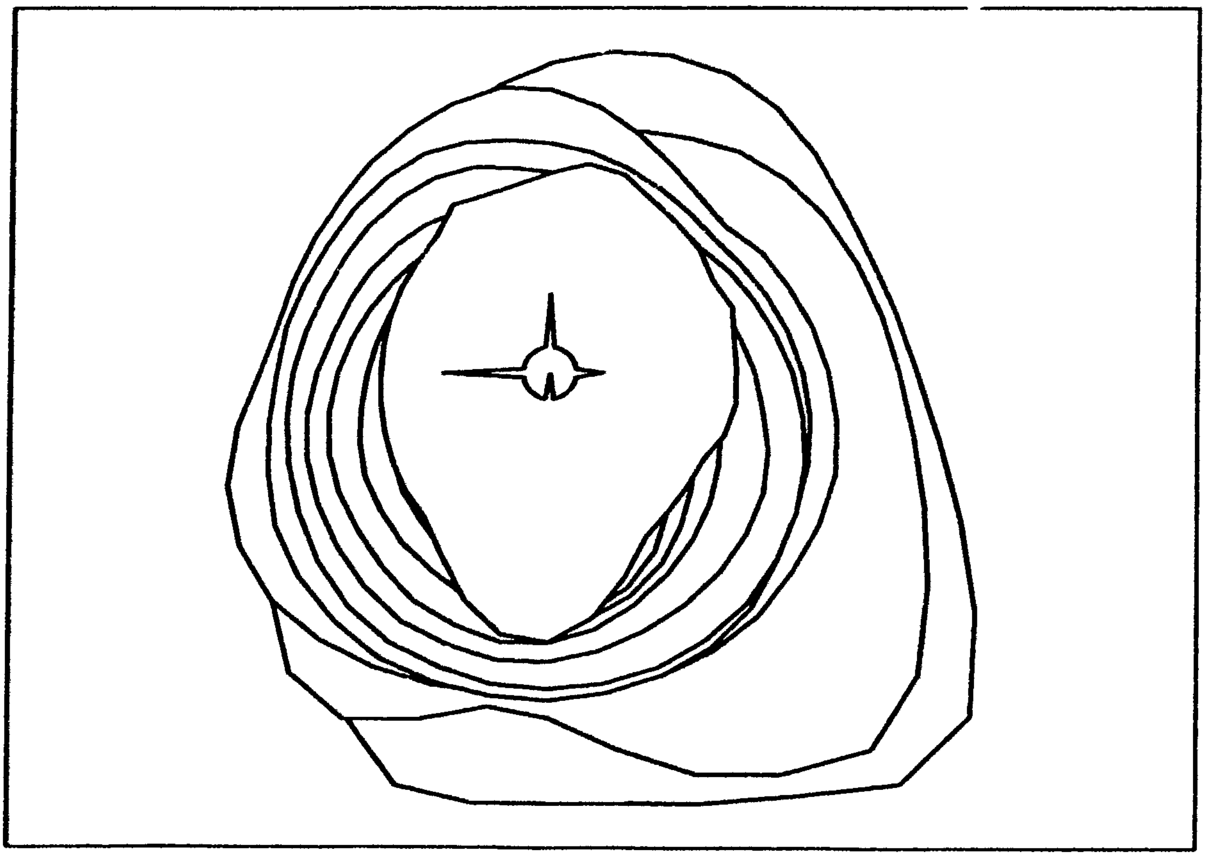
View is Upwards Towards the Knee - 5 cm Increment

Figure 6.9 - Selected Cross Sections - Primary Limb Shape



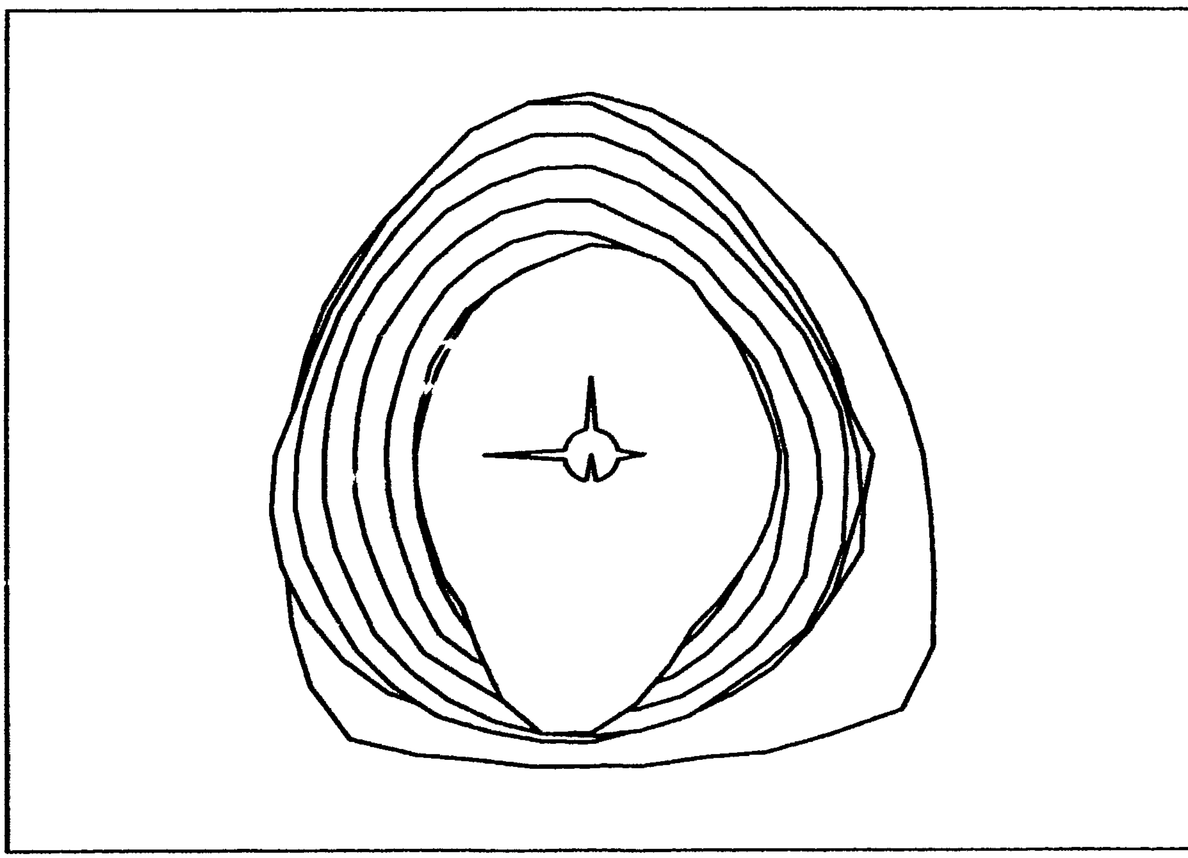
View is Upwards Towards the Knee - 5 cm Increment

Figure 6.10 - Selected Cross Sections - Final Limb Shape



View is Upwards Towards the Knee - 5 cm Increment

Figure 6.11 - Selected Cross Sections - Artisan Limb Shape



View is Upwards Towards the Knee - 5 cm Increment

7. DISCUSSION

7.1 Reference Shape Library

The design of this shape library is based on proportionality and scaling. Certain assumptions allowed straightforward formulation of the library, while satisfying the need for moderate accuracy in the final shape.

A fundamental assumption is that left and right side shapes are basically symmetrical, thus allowing the use of mirror imaging and basing the design of the cosmesis shape on the dimensions of the contralateral leg. Note however that the cosmesis is scaled longitudinally to fit the prosthesis, which may actually differ slightly in length from the natural leg.

The variables RENDO and RMESO are analogous to the concepts of mesomorphy and endomorphy. The distributions of RENDO and RMESO are taken to be approximately normal and the skew existing in the adult population is overlooked. No term analogous to ectomorphy is included since longitudinal and radial scaling are used in matching the degree of linearity of the contralateral leg.

It appears from analysis of the longitudinal variation of sectional areas for the reference shapes that although limb shapes are very similar, there are indeed variations that are not accounted for with the variables RENDO and RMESO.

Although uniformity of proportion is assumed, it is not absolutely the case. For example, the location of the maximum and minimum shank girths are approximately constant. Weiss and Clark (1985) reported that for many, the maximal girth is found at approximately 70 percent of the distance between the inferior border of the lateral malleolus and the popliteal crease. The five reference shapes obtained in the present study demonstrate variability in this aspect of leg shape. Variable radial scaling in the computer software addresses this somewhat by tailoring the selected reference shape to the patient measures.

The population sampled for the CANAD Database is assumed to be representative of the amputee population to be served by this system. No distinction by race, sex or age is addressed by the system in its present form.

Within the scope and purpose of the present study, these assumptions and limitations are justified for the sake of simplicity. Further study may reveal that greater choice is warranted in the design of the shape library and selection procedures or greater detail in anthropometric measures and modification procedures. A possible future development would include separate libraries for people of different sexes and racial backgrounds.

Reference shapes were an appropriate choice for this application, as opposed to digitization of the patient's natural limb, particularly in light of the comparative expense of the two techniques. Digitization of the natural limb would have to be by laser scanner to make it competitive with the speed of a reference shape approach, and very few laser scanners are in clinical use. The effort required to make and digitize a wrap cast for each patient is excessive considering the relative ease of recording a few simple measures and transcribing them into a computer.

7.2 Discrete Fourier Transform (DFT) Analysis

Analysis demonstrated that a cylindrical grid of 36 radii at 10^{0} increments is more than adequate to describe normal lower limb shapes. The use of fewer points in conjunction with mathematical splines is suggested. This analysis technique is a useful tool for establishing the adequacy of a shape-defining data structure, although a technique which was not dependent on the choice of axis would be preferable.

This analysis depends on certain assumptions. First, only one example of shank shape was analyzed, and it is assumed to be representative of the healthy human population. In fact, the shape is from a relatively lean individual. It is arguable that the spectral power distributions of most shank shapes would be weighted even more heavily to the lower discrete spectral numbers (k), since the bony protuberances would be less prevalent on the legs of fatter individuals.

The accuracy of the analysis also rests on the accuracy of the plaster casting process and on the digitization of the shape for input to the computer (see Section 3.2).

As described in Section 4.2, the DFT frequency values depend somewhat on the placement of the central axis of the shape. Locating cross-sections more eccentrically relative to the axis results primarily in a shift in the calculated values of spectral power from the constant term to the first discrete spectral number. The effect on higher frequencies is less noticeable.

In the worst cases, virtually all of the spectral power is transmitted in the first six discrete spectral numbers (see Figure 4.2). This would require just twelve points according to the Nyquist frequency, corresponding to an angular increment of 30^{o} for cross-sectional slices. For longitudinal strips, the increment would be 3.71 cm. These low values suggest that such limb shapes could be defined with generalized equations, reducing the shape storage to an array of coefficients. This could result in enhanced computational speed and more efficient use of the computer's memory. The Discrete Fourier Transform itself could be used in such a representation of shape. At the time of milling, the equations would be used to generate the number of points found empirically to be best for achieving a smooth surface with the tool.

7.3 Computer Program

The number of measurements recorded on the subject measurement form was larger than required for the computer program. It was thought that some may be implemented in future refinements, so they were recorded for that reason. The ultimate goal of this project is to save the prosthetist time, so in clinical use only the essential measurements would be taken.

The reference shape is scaled to mimic the contralateral leg by uniform longitudinal scaling and variable radial scaling keyed to the magnitudes and elevations of the minimum, maximum, and knee girths. This technique relies on the assumption that the maximum and minimum girths may be found at the same proportional elevation for all people. Variable longitudinal scaling may be implemented to deal with shanks of more diverse proportions. This would involve altering the longitudinal scaling factor along the length of the shape so as to fit the elevations of the maximum and minimum girths on the reference shape to the corresponding key elevations recorded from the subject's contralateral leg.

In its present form, the procedure **Accommodate Socket** leaves a horizontal groove across the front of the cosmesis at the site of the patellar tendon bar[11]. This was not corrected, but could be filled in with the interactive modifications of the MERU-CASD system. Future refinements of the limb shape design program will make this an automatic "smart" modification.

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[11] This is simply the socket shape coming through.

The rear flare creates excess sectional area on the proximal posterior aspect of the **Final** shape. This extra bulk shows up in the shape comparisons making the cross-sectional areas for the **Final** computer designed shape appear larger than those of the artisan prosthesis, but it is removed in the process of completing the prosthesis.

7.4 Clinical Trial Discussion

The clinical trial consisted of one subject. This was sufficient to demonstrate the functionality of the computer aided design software. It was not sufficient to prove superiority of the CAD shape over artisan shapes. However, the CAD software performed well in the trial.

The computer generated limb shapes, like the artisan prosthetic limb shape were found to be longer than the casting of the natural leg when measured from the knee joint line to the ankle line (40.75 centimetres for each of the prosthetic leg shapes compared to 39.00 centimetres for the natural leg shape). It is likely that much of this apparent leg length difference is due to erroneous identification of the level of the knee joint line on the plaster cast of the natural leg.

Design and production time was not recorded in this trial. Indeed, the CAD shape was not used in the complete manufacture of a finished prosthesis. It is likely that the computer aided design process would take less time than the artisan design process, assuming the clinic is using the program in conjunction with a computer aided socket design system, and has the necessary equipment in-house. Mould carving could be performed by machine, allowing the prosthetics technician to concentrate on other tasks.

The computer designed limb shapes were compared with the **Natural** leg and the **Artisan** limb shape produced for the patient. The **Primary** limb shape compared well with the **Natural** leg over the full length. Cross-sectional areas were 0.91 +/-7.44% larger and RMS error values were 0.034 +/-0.016.

Qualitatively, the **Final** computer designed shape is satisfactory. It has a more lifelike appearance than the artisan shape; the **Artisan** shape is more cylindrical and lacks the typical varus curvature of the natural leg.

The **Final** shape compared well qualitatively also. Between levels Z=-39.0 centimetres and Z=-5.0 centimetres, cross-sectional areas were only 0.5 +/-8.3% larger than those of the **Natural** leg, while corresponding sections of the **Artisan** shape were 10.4 +/-8.9% larger than those of the **Natural** leg. RMS error values for the **Final** shape were 0.028 +/-0.010, while the values for the **Artisan** limb shape were 0.036 +/-0.012.

Thus, the hypothesis was confirmed by this study. A computer aided design system was demonstrated which designed a lower limb shape for a below knee prosthesis. In this single trial, the accuracy of the **Final** CAD shape was better than that of the **Artisan** limb shape produced for the same patient. While this is encouraging, further trials are necessary before any general claims may be made.

7.5 Accuracy Considerations

Accuracy of the **Final** shape is affected by a number of things. Measurement errors, while relatively small, can introduce variation in the calculated RENDO and RMESO subject values. Skin tension can make accurate measurement of skinfold more difficult.

As the shapes are transformed and converted into cosmesis cylindrical coordinates there are round-off errors due to the interpolations performed. These errors would generally be minor.

Alignment definition was the measurement with the lowest degree of certainty; although it was performed with an automated device, the ACE 5001, the proper position for the socket measurement jig was not easily ascertained nor attained. Thus the definition of the socket axes for this trial was approximate at best. The resulting differences in cosmesis shape would not be of great consequence for an endoskeletal design, since the shape would be carved out of soft foam which could be stretched over the socket to fit. For an exoskeletal design, however, tighter control of this measurement would be essential since the rigid materials used could not generally be made to fit as easily as the soft foams (this will depend upon the particular techniques used).

A source of error specific to the shape analysis and comparisons of this trial is the Shape Copier measurements of the natural leg replica and artisan prosthesis. The magnitude of these errors was discussed in **Section 3.2.**

7.6 Future Work

There is a need for more rigorous clinical evaluation and refinement of the system. A number of potential refinements have been identified.

A more accurate technique for quantifying the final (dynamic) alignment for input to the software is required. A simpler measuring device or technique more readily available than the ACE 5001 will be required. Either a graduated jig or pylon system may suffice; it would not need to be automated. One such device was developed by researchers at Strathclyde University (Zahedi *et al*, 1986). The design of appropriate techniques and devices will be considered in upcoming research projects.

Improvements to the computer software will be made as warranted. For example, a "smart" modification will be included into the software to fill in over the patellar tendon bar. Variable longitudinal scaling may be implemented to deal with shanks of diverse proportions. General systematic shape differences due to factors such as sex and race could be addressed with special shape libraries if warranted. If clinical trials show that oedema is not well enough addressed by the present system, it may be treated with a special modification.

Another consideration to be addressed is how to incorporate atypical marked tibial varus or bowleggedness of the natural limb. One solution would be to have the individual cross-sections displaced systematically, shearing the shape slightly to create greater or lesser amounts of varus.

Extension of this program to design of cosmeses for the above knee case could be fairly straightforward. The below knee spatial transformations would be applied to the thigh and shank portions separately, with paired thigh and shank shape libraries, a foot shape library, and knee shape modules. Alignment measurements would provide relative positions of the thigh compared to the proximal knee module, and for the distal knee module compared to the foot.

The endoskeletal case requires less accuracy in the quantification of alignment. A foam blank could be carved directly and then hollowed out to fit around the modular components. Alternatively, the post-processor might carve a two part (bivalved) negative mould which would then be wrapped around the aligned prosthesis, and the void filled with soft closed-cell foam by reaction-injection moulding.

The exoskeletal case is more demanding in terms of accuracy. One approach would be to produce a bivalved negative mould. The two halves would be wrapped around the prosthesis while held in an alignment transfer jig. Wax or foam would be poured in and allowed to set, and then the bivalve would be removed. Finally, the limb shape would be laminated over as in standard prosthetic practice.

With advances in the systematic prescription of prosthesis alignment, it would be possible to pursue direct forming of the finished socket and cosmetic shells. These would then be bonded together and attached to a foot. If the alignment was not quite satisfactory the prosthetist would specify a change to the socket shape or to the alignment, and another finished prosthesis would be produced.

8. CONCLUSIONS

A computer aided design system was developed which is capable of creating lower limb shapes for below-knee prostheses.

A computer based library of reference shank shapes was assembled for input into the system. These shapes encompass various characteristics of the normal population in terms of tissue distribution.

The cylindrical data grid used by the system to describe shapes was verified by Discrete Fourier Transform (DFT) analysis. It was determined that the number of data points was sufficient to describe the degree of shape curvature that may be encountered.

In designing the computer system, suitable anthropometric measurements were established to be taken from the contralateral limb for input. Mathematical relationships and procedures were developed to permit selection, scaling and modification of the reference shape into the desired unique limb shape. A method of acquiring alignment data from the socket and foot was developed for input to the system. The software scales the selected reference shape and distorts it as required to blend it smoothly with the contours of the prosthetic socket and foot as they are aligned in relation to each other.

In a single clinical trial, the computer designed limb shapes were compared with the **Natural** leg and the **Artisan** limb shape produced for the patient. The **Primary** limb shape compared well with the **Natural** leg over the full length. Cross-sectional areas were 0.91 +/-7.44% larger and RMS error values for the **Primary** limb shape compared to the **Natural** leg were 0.034 +/-0.016.

Between levels Z=-39.0 centimetres and Z=-5.0 centimetres, cross-sectional areas of the **Final** CAD shape were only 0.5 +/-8.3% larger than those of the

Natural leg, while corresponding sections of the **Artisan** shape were 10.4 +/-8.9% larger than those of the **Natural** leg. RMS error values for the **Final** CAD limb shape were 0.028 +/-0.010, while the values for the **Artisan** limb shape were 0.036 +/-0.012. Thus, the computer designed limb shape was more accurate in this trial.

The **Final** limb shape output by the system was subsequently carved by automated means, demonstrating the feasibility of implementing the system for automated manufacture. Before this can be used clinically, certain material and technical details must be addressed.

Potential refinements to the design system were identified. These refinements may improve the aesthetic accuracy and functionality of the design system.

The computer aided design procedures developed in this thesis project permits the further automation of the otherwise time-consuming labour-intensive production of lower limb prostheses.

APPENDIX - GLOSSARY OF TERMS

Bench alignment - As a first step in the iterative process of alignment, the prosthetist configures the prosthesis in a particular way.

Calf Girth - Girth of the lower leg at the level of the largest bulk of the calf. Corrected Calf Girth (CCAG) - Calf girth less the skinfold at the same level. This gives an indication of regional lean mass.

CANFIT - The name by which the original MERU-CASD system, developed at the Medical Engineering Resource Unit, has become commercially available for use in the prosthetics industry.

CANFIT-PLUS™ - The name of a second-generation CAD system developed as a joint venture between LIC Orthopaedics of Sweden and Vorum Research Corporation of Canada.

CASD - Computer Aided Socket Design.

Check Socket - A socket fabricated quickly to determine the effectiveness of the mould prior to dedicating substantial time to the fabrication of the final socket.

Computer-numerically-controlled (CNC) lathes and milling machines are operated automatically by computer programs to perform complex machining tasks quickly and accurately.

Cosmesis - the outer covering of a prosthesis or orthosis, fabricated to give a natural appearance (also: cosmetic restoration or prosthetic limb shape).

Digitizing tablet - A flat rectangular electronic device that can record the absolute position of a digitizing puck as it is slid across the working surface of the tablet. Also known as a digitizer. A digitizing puck consists of a coil of wire and four buttons; it is held in the operator's hand and slid across the surface of the digitizing tablet. Use of the buttons regulate the recording of the positional data.

Dynamic alignment - The final alignment reached by having the amputee stand and walk on the prosthesis, starting with the bench alignment and making small changes as required in an iterative process.

Ectomorphy - Degree of linearity that a person exhibits.

Endomorphy - Degree of adiposity that a person exhibits. Regional Endomorphy (RENDO) - Index of endomorphic characteristics relative to the lower leg.

Endoprosthesis - a prosthesis which is internal to the body (eg: a total hip joint replacement).

Endoskeletal Design - Used to describe a prosthesis where the supporting structure is internal to the normal shape of the limb (NAS, 1971).

Exoskeletal Design - Used to describe a prosthesis where the supporting structure is the outside of or external to the normal shape of the limb (NAS, 1971).

Four Axis - Referring to milling machines, movement of the workpiece relative to the cutting tool is achievable in all three Cartesian directions, as well as rotationally with the axis of rotation usually aligned with one of the Cartesian axes (called a rotary table). The rotary table axis is used as the longitudinal direction of the shapes in the present application.

Lean Body Mass - Fat Free mass plus essential (structural) lipid (Kinemetrix, 1990).

MERU - Medical Engineering Resource Unit. UBC Department of Orthopaedic Surgery, University Hospital-Shaughnessy Site, Vancouver, B.C.

Mesomorphy - Degree of musculo-skeletal development that a person exhibits. Regional Mesomorphy (RMESO) - Index of mesomorphic characteristics relative to the lower leg.

Orthotics - the study and clinical delivery of orthopaedic appliances or apparatuses used to support, align, prevent, or correct deformities or to improve the function of moveable parts of the body (an orthosis) (Dorlands, 1981).

Prosthetics - the study and clinical delivery of artificial substitutes for missing body parts (a prosthesis), such as an arm or a leg, eye or tooth, used for functional or cosmetic reasons, or both (Dorlands, 1981).

Rectification map - a map of adjustments to a shape. Analogous to the addition or removal of plaster from a socket mould.

Reference shape - This term refers to the philosophy underlying the MERU-CASD system: that individual amputees can be well served with the use of one or several standardized reference shapes, scaled to match their particular dimensions. The work reported herein follows this approach for the creation of the cosmetic restoration.

Residuum - the portion that remains of an incomplete limb, also called the stump.

SACH Foot - Solid Ankle Cushioned Heel

Shape Copier - A device designed at the Medical Engineering Resource Unit for recording shapes. The device is used in conjunction with an IBM Personal Computer to record each shape digitally in cylindrical coordinates. The design resembles a rotisserie (spit) held above a digitizing tablet.

Suspension - The means by which a prosthesis is kept from falling off at times when there is distraction force, generally during swing phase. Originally suspension for below knee prostheses consisted of a leather cuff around the thigh.

Tibiali Height (TIHT) - Height off the ground of the tibiali landmark. This is the top of the tibial shelf.

UCL - University College London, London, England.

Working socket - used to describe the shape created by the CASD system from the initial amputee data, prior to any fine-tuning by the prosthetist.

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