

**THREE DIMENSIONAL SHAPE DEFINITION OF ABOVE-KNEE AMPUTEE
SOCKETS FOR COMPUTER AIDED MANUFACTURE**

by

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THREE DIMENSIONAL SHAPE DEFINITION OF ABOVE-KNEE

AMPUTEE SOCKETS FOR COMPUTER AIDED MANUFACTURE

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ABSTRACT

A computer aided socket design procedure (C.A.S.D.) was developed, whereby the unique configuration of an above-knee amputee's socket can be systematically created from selected anthropometric measurements taken from the residuum.

A 3 x 3 x 3 matrix of 27 reference socket shapes was created, having as a common origin a knee disarticulation model. These reference shapes represent the above-knee socket shape characteristics based upon the skeletal structure, tissue mass and residuum length. Each reference shape was digitized to obtain its cylindrical coordinates. Cross-sectional areas and tissue distributions within each shape and between the shapes were analyzed, modified and then stored numerically within the matrix of the computer based reference shape library. Based on this analysis, measurements of the residuum necessary to implement socket size and shape transformation procedures were determined. A simple anthropometer for obtaining these measurements was designed.

Based on the characteristics of a particular residuum, a matrix subset of three reference shapes is selected. The transformation procedures developed, scale the shapes at each cross-sectional level to match the patient's area. With this process, each of the three new shapes accommodate the residuum within its own longitudinal and transverse cross-sectional shape. Appropriate blending of the three new shapes is then determined by tissue mass weighting factors yielding a unique test socket configuration based on the patient's anthropometric data.

A primitive test socket designed by the CASD procedures was manufactured and fitted to an amputee. The amputee was able to load the socket without discomfort. Some shape discrepancies were identified and the shape data were modified by CASD to create a final socket shape.

The final CASD socket shape was manufactured and worn by the amputee during a 35 minutes walking trial. Subjective evaluation was that the socket provided comfort and control comparable to that of the conventional socket, and proved to be acceptable to the amputee.

The CASD socket shapes, were compared numerically in area, shape and volume with data taken from the existing socket, a new socket made by conventional methods, and a topographic model of the residuum. Results indicated that the CASD process compared favorably with conventional methods.

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DEDICATION

To my parents
ELIA and ENRIQUE
for their love,
trust and support.

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CHAPTER 1

INTRODUCTION

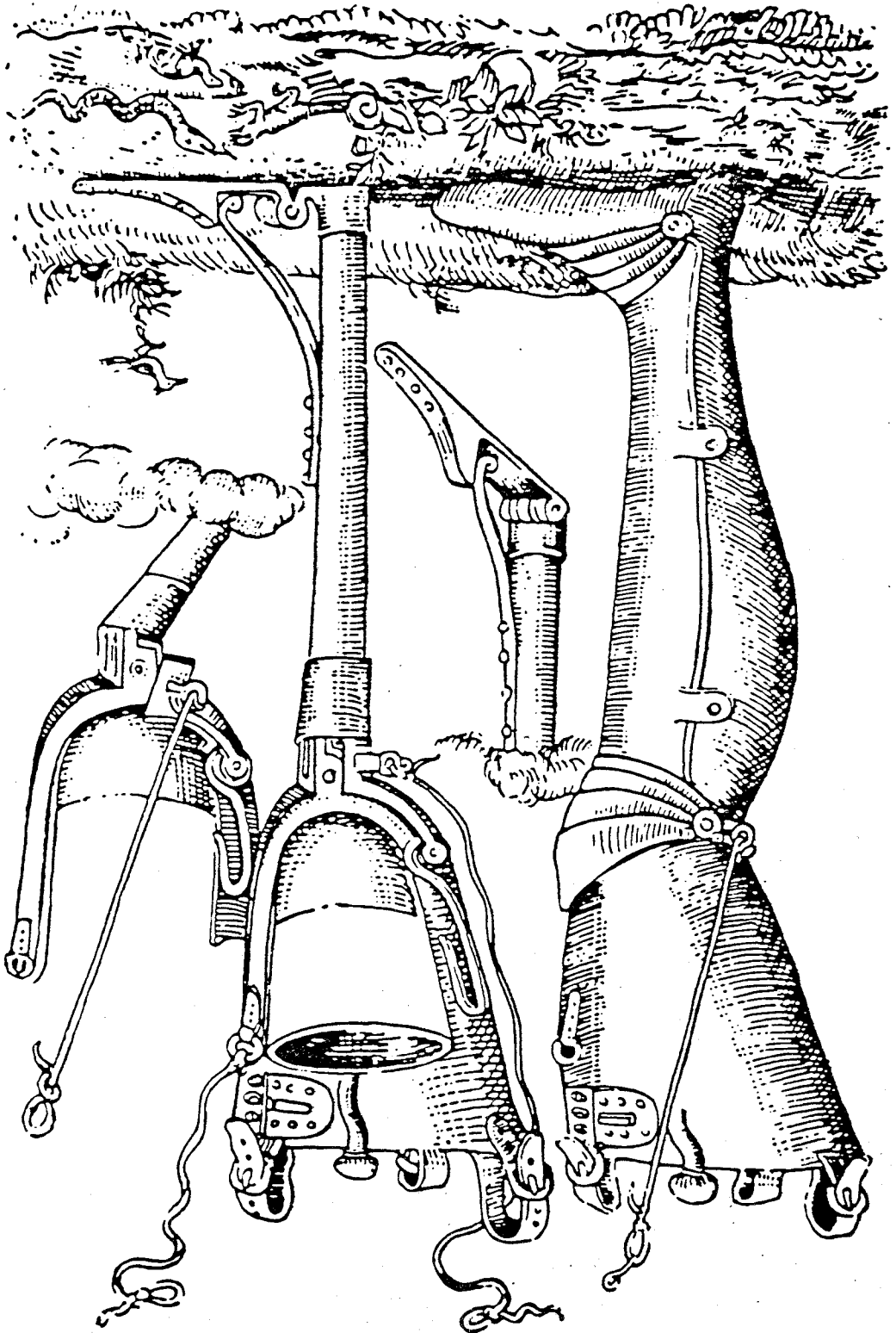
The loss of limbs from such events as crushing injuries and congenital malformations, has been a problem for as long as man has been in existence. In early cultures, persons experiencing the loss of a limb (of whom probably only a few survived) must have compensated for their loss by the use of crude crutches and, in some instances, by the use of improvised peg legs partly fashioned from forked sticks or tree branches. Evidence of this is shown in a mosaic from the Cathedral of Lescar, France, where an amputee is supported at the knee by a wooden pylon. Some authorities place this in the Gallo-Roman Era (Putti).

1.1 Historical Review

The earliest documented record of a prosthesis being used by man was described by the famous Greek historian Herodotus. His classic "History", written about 484 B.C. contains the story of the Persian soldier, Hegesistratus, who, when imprisoned in stocks by the enemy, escaped by cutting off part of his foot, and replaced it later with a wooden version (Bennett, 1967).

In the 15th century, artificial limbs were the work of the armourer. Made of iron, these early prostheses were used by knights to conceal the loss of limbs which had resulted from battle. When Ambroise Pare, a surgeon in the French Army, reintroduced the use of ligatures in 1529 (which were set forth by Hippocrates in the 14 century), a new era for amputation surgery and prostheses began. Armed with an improved technique, surgeons were more willing to employ amputation as a lifesaving measure and, indeed, the rate of survival must have been much higher. Pare's leg for amputation through the thigh (above-knee or trans-femoral) (fig. 1.1) is the first known to employ artificial joints (Bennett, 1967). In 1696, another surgeon Verduin, introduced the first known artificial limb for below-knee amputees which permitted freedom of the knee joint; in concept much like the thigh-corset type of below-knee limb still used by many today.

Figure 1.1: Ambroise Pare's Leg, 1529.



After Pare's above-knee prosthesis which was constructed of heavy metals, the next real advance was the introduction of wood in the 1800's by James Potts of London. Potts' invention was equipped with artificial tendons connecting the knee and the ankle, thereby coordinating toe lift with knee flexion. It came to be known as the "Anglesea leg" (related to the Battle of Waterloo). With some modifications, this leg was introduced into the U.S.A. in 1839, and due to the many refinements made to the original design by American limb fitters, became known as the "American Leg".

The American Civil War produced a large number of amputees and consequently created a great interest in artificial limbs. Many patents on artificial limbs were issued between the time of the Civil War and the turn of the century, but few of the designs seem to have had a lasting impact. With the introduction of chloroform and anaesthetics, surgical procedures were greatly improved, and more functional residuums were produced. Before the Second World War, the residual limb was considered to be a passive structure and surgeons tried to design a conical residuum by allowing the muscles to retract. It was not until after the Second World War with the development of the total contact socket and use of *Myoplasty*¹ for amputations at all levels, that the residual limb was seen as a more dynamic structure providing power and proprioception² to the amputee for successful use of the prosthesis.

The introduction of new devices, materials and technology have materially changed the practice of prosthetics during the last 25 years. However, the best conceived prosthesis remains a poor substitute for an intact human limb.

¹Surgical procedure by which a portion of partly detached muscle is utilized. The level of amputation is usually just above the musculo-tendinous junction of the muscle. The nerves are divided under a light tension, arteries and veins are also divided. The anterolateral group of muscles are sutured under tension to the postero-medial muscles group. Myoplasty also produces a more rounded, smooth surfaced residuum with mobile scars which are easier to fit with a total contact socket, improving residuum control and circulation.

² Feedback to the brain by joint and stretch receptors, muscle spindle and Golgi tendon organs. Also known as deep sensibility.

1.2 Amputation

Amputation may be the result of an accident, or may be necessary as a lifesaving measure to arrest a disease. A small but significant percentage of individuals are born without a limb or limbs, or with defective limbs that require surgery. Conditions for amputation are vascular disease, trauma, tumors, infection, congenital limb deficiency, limb length discrepancy, deformity, paralysis or joint instability (Murdoch, 1984). One of the objectives of amputation is to improve function by substituting an artificial limb for a damaged or defective member.

In some accidents, a part of or all of the limb may be removed; in other cases, the limb may be crushed to such an extent that it is impossible to restore sufficient blood supply for healing. Sometimes, broken bones cannot be made to heal, and amputation is necessary.

In an adult, it is always recommended that the residuum be left as long as possible, nevertheless, the level of amputation is determined by the different circumstances of the disease. In the case of above-knee amputation, the only prosthetic requirement is to leave sufficient space to locate the artificial knee at a similar level to that of the intact limb (measurements "D" and "E" in fig. 1.3). Nevertheless, a knee disarticulation residuum has a great mechanical advantage over the above-knee residuum because it provides a longer lever and an end bearing.

In the case of children, one faces the problem of growth; if during the amputation the distal epiphysis is removed, the final residuum length at maturity may be very short (Aitken, 1963). Whenever possible, it is preferable to preserve the distal epiphysis by disarticulating the knee. In arterio-vascular diseases, the level is determined by the need for adequate blood supply to the tissue for appropriate healing.

Depending on the level of amputation, the muscle attachment is interrupted or relocated (myoplasty), producing changes of the muscle action and the movement pattern of the residual limb. The type and characteristics of the socket will be highly influenced by the level of amputation and rate of the residuum's maturation. The rate of maturation will depend largely on the age, activity level and health of the patient.

Within the different sites of amputation, the lower extremities record the highest frequency, and the above-knee and below-knee amputees represent the majority of those. A survey held in 1964, with 8,416 new cases studied in the United States, gave a distribution of: above-knee 44.1%, below-knee 36.8%, below-elbow 8.6%, above-elbow 3.7% and other levels 6.8% (Glattly, 1964). Due to improvement in medical technology, services and prevention, below-knee amputees gradually are becoming the most common type. With respect to the sex and age of upper and lower limb amputees, data obtained by Statistics Canada in 1980, showed (fig. 1.2) that in 7,123 new cases, males represent 69 % of the cases compared to 31 % who are females. From the global figure, 61.5 % of the cases were patients 55 years old and over.

Before the amputation is performed, it is necessary to consider a series of factors that will determine each individual case. These are the pathology, the anatomy of the proposed level of amputation, the surgical technique proposed concerning effect and tissue management, prosthetic considerations and integrated rehabilitation.

The effect of tissue management in an above-knee amputation determines the level of power and controlled movements that the residuum can transmit to the prosthesis under dynamic conditions³. When myoplasty is not the technique used in the amputation, the hip adductors and extensors are weakened as a result of the loss of their insertion⁴, whereas the flexors and abductors maintain their normal strength tending to cause a flexion-abduction deformity of the residuum. Myoplasty provides a better control of the residuum reducing the muscle power imbalance by reinserting the divided adductors and extensor. Once the femur and muscles are divided, opposing muscle groups (medial-lateral) are sutured to each other⁵ over the end of the bone and anchored to the periosteum (Dererich technique), or sutures are passed through holes drilled in the distal bone (Weiss technique). These muscles are then covered by the other muscle groups (anteroposterior) which are sutured to each other and to the layer below. In these circumstances, the healthy living muscle re-establishes its optimal tension

³Two joints muscles, as the Rectus Femoris and the hamstrings, are transformed into one joint muscles effecting only the thigh.

⁴Adductor Magnus, Gracilis, Biceps Femoris, Semimembranosus and Semitendinosus.

⁵Sutured under slightly more tension than normal to allow elongation during healing.

AMPUTEE DISTRIBUTION BY SEX AND AGE
 CANADIAN STATISTICS, 1980
 7,123 new cases

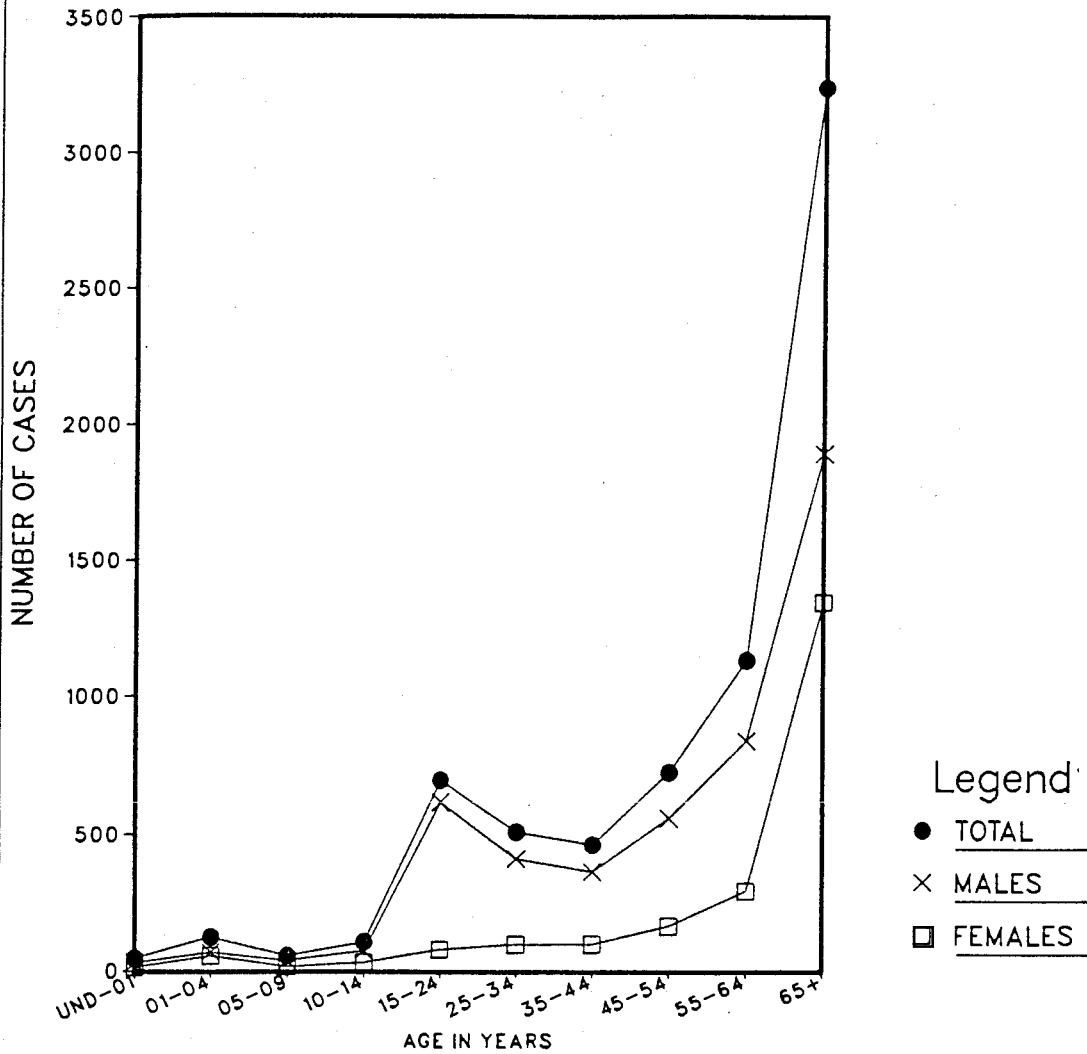


Figure 1.2: Amputee Distribution by Sex and Age. Statistics Canada, Health Division, 1980.

(Fulford, 1970).

1.3 Design and fitting of above-knee prostheses

The positive outcome and usefulness of a prosthesis depends primarily on an appropriate fit⁶ between the residuum and the prosthetic socket. The socket must be capable of transmitting the forces which relate to the support of the body from the residuum to the prosthesis without discomfort for the amputee.

In the normal limb, these forces are transmitted through the bones of the lower limb to the sole of the foot, whereas in the amputated limb, those forces must be transmitted from the residuum to the socket of the prosthesis across the residuum-socket interface. The socket shape should provide stabilization of the residuum to the amputee with an efficient residuum-socket interface in order to transfer his own movements into functional prosthetic movements. The appropriate transmission of control forces that relate to factors such as balance and position during rest and movement, allow the amputee to walk in a manner similar to a normal subject.

Fitting relates to the process by which the socket is modified in area and shape to match particular biomechanical characteristics of the residuum's mass, in order to provide comfort, stabilization and control of the prosthesis. Variations in the pressure tolerance of the tissues, arrangement of the intermuscular septums (tissue tolerance to change), fascia lata and fluid compartments set the limits to which the residuum can be shaped by the socket. This fitting of the socket is achieved by an even distribution of the forces along the entire length of the residuum; the socket should fit tightly, following the contour of the residuum, to reduce to a minimum the movement of the femoral bone within the tissue.

In order to meet this objective, besides the fitting of the socket, an adjustable alignment device is included within the lower limb prosthesis in order to optimize the forces acting on the residuum during walking. This alignment is based on an assessment of the force-couples that the patient experiences while walking, the

⁶If the socket does not fit snugly, the movement within the socket results in loss of control and possible tissue damage.

prosthetist's assessment of the movements performed, and pressure marks on the residuum produced by the socket. With small variations in the mediolateral alignment, pressure is evenly distributed within the socket, avoiding discomfort associated with high loads concentrated in local areas (Redhead, 1979). The residuum's soft tissues will change in shape depending on the position of the limb (with respect to gravity) and the muscle tension.

In addition to the alignment device, an above-knee prosthesis includes a second mechanism, the artificial knee joint (both mechanisms can be seen in fig. 1.3). The artificial knee joint provides two basic functions: a) it ensures that the knee does not collapse during the weight-bearing phase of the walking cycle and, b) simulates in the prosthesis an action similar to that normally provided by quadriceps and hamstring musculature during the swing phase of walking. The swing phase and damping characteristics (acting as an eccentric muscle contraction) are simulated by pneumatic, hydraulic or friction systems.⁷ The amputee's swing phase gait dynamics is influenced by both the mass and mass distribution in the prosthetic shank. Lightweight above-knee prostheses may not perform as well as heavier prostheses which simulate the effects of the human shank (Tsai, 1986).

1.4 Locomotion of an above-knee amputee

In normal bipedal gait, the net energy cost of walking at an average velocity⁸ of 2.5 mph (Bard and Ralston, 1959) is close to 2.5 kcal/min (0.1743 kilowatts) (Peizer, *et al.*, 1970). Walking above or below this average velocity increases the net energy cost per unit distance travelled.

In order to walk with the minimum energy expenditure, it is necessary to keep to a minimum the vertical and lateral displacements and the instantaneous velocity of the body's center of gravity (CG) during walking. The resulting undulated path followed by

⁷ A hydraulic knee (viscous damping) can function over a range of speeds, whereas the constant friction cannot (Tsai, 1986).

⁸ Normal people walk at a well established average velocity of 2.5 mph, which represents the product of the step length and the number of steps taken (distance walked) in a unit of time (Peizer, *et al.*, 1970).

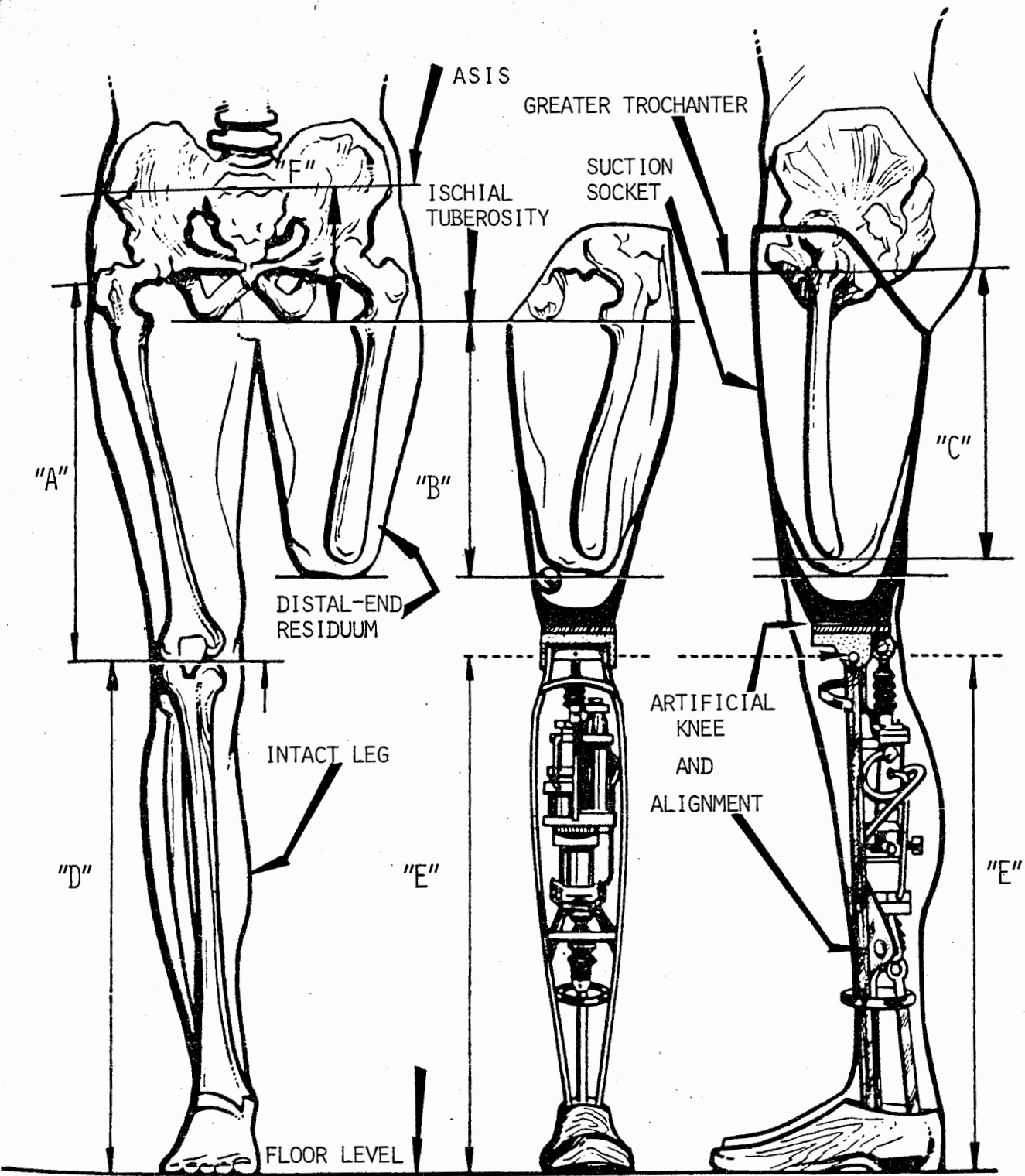


Figure 1.3: The above-knee prosthesis includes an alignment device and an artificial knee joint in order to provide similar function of the artificial limb to a normal limb. Refer to the text for explanation on the measurements shown.

the CG (in the sagittal plane) during normal walking describes a sinusoidal function. At the average velocity of 2.5 mph (with a 30-32 inches per step and 90 to 110 steps per minute), there is a normal vertical and lateral displacement of the CG of 2 inches, and a walking base of 2 to 4 inches.

The normal gait pattern relies upon the coordinated function of the knee and ankle. Absence of these joints results in an increase of the vertical displacement of the CG in the early stance phase. As the residuum becomes progressively shorter (amputation level), the deviation from the midline (walking base) becomes more pronounced. The increased displacement is accompanied by an asymmetrical step length, uneven timing, excessive pelvic sway, torso movement⁹, and increased energy cost to perform the task. It has been shown that the energy requirement for level walking of an above-knee amputee is 100% greater than of the normal person (Fishman, 1962).

Absence of the knee joint and the musculature controlling the knee decreases the ability to distribute forces produced in normal walking (damping effect of the eccentric contraction of the knee extensors). The above-knee amputee compensates by shortening his step and extending the hip joint at heel contact to decrease moments tending to flex the artificial knee. Medial and lateral rotation of the shank produced by hip rotation, during normal walking are absorbed at the residuum-socket interface where they create radial and shear forces on the tissue.

1.5 The above-knee prosthetic socket

The socket, which links the amputee to the prosthesis, has several design features which are a function of the residual limb's tissue properties and the required support and control forces. The forces which are generated during ambulation (radial, shear and axial forces) must be transferred from the prosthetic foot and be distributed over areas of the residual limb (vice versa) which can tolerate repetitive loading, without distorting its biological functions (Saunders, 1985).

⁹The torso may lean over the prosthesis side and thus it enlarges the oscillation.

The shape of the socket which achieves this goal is not usually the negative of the amputee's topographical residuum shape, but rather a distorted shape. The residuum's shape and volume, either unstressed or under proximal stress, needs to be distorted in shape and reduced in volume by shifting it towards the proximal end in order to obtain the approximate shape and volume that the residuum will assume with weight bearing (Barclay, 1970). This socket shape also allows for variation in the density of tissue, variations in the pressure tolerance of the residuum and specific biomechanical requirements related to support and control. Loading of pressure-tolerant tissue, such as muscle, is achieved through a socket volume reduction over these tissue regions, while volume increases are introduced over load-intolerant bony prominences (Barclay, 1970). In order for the amputee to control his prosthesis, the residuum must be-fitted into the socket in such a way that the snug fit ensures enough space for muscle contraction.

With such intimate contact of the socket and the amputee's residuum necessary for biomechanical support, control and comfort, it can be understood that the socket must fit the residuum extremely well in order for the prosthesis to be suitable for prolonged use without either discomfort or tissue damage.

With respect to the above-knee total contact socket (Quadrilateral Socket), part of the body weight (close to 20%) is transmitted by the ischial tuberosity and the gluteus maximus into the socket through the ischeal gluteal shelf¹⁰ but the major support is provided by the four walls (medial, posterior, lateral and anterior walls) of the total contact socket itself (Lyquist, 1970).

Mechanically, the patient is supported upon the relatively incompressible volume of the residuum which is contained within the limits of the socket. The soft tissues of the residuum, which at the macro level are divided in a series of compartments separated by fascial layers and intermuscular septa, behave as an elastic-solid with low

¹⁰Flat horizontal component of the proximal end of the socket. Extends from the adductor longus tendon channel at the anteromedial corner, through the medial and posterior wall, and ends at the posterolateral corner. The rounded contour (rear flare) between the shelf and the posterior or the medial walls of the socket has a radii of curvature of 12 mm in the exterior part. This medial flare has a cylindrical form, whereas in the posterior it is conical. This part of the socket is forced into and under the ischeal tuberosity for proper transmission of forces.

stiffness (Redhead, 1979). With the use of 9 pressure transducers built in different sites over the walls of an above-knee total contact socket, Redhead (1979) was able to quantify pressures acting on the walls (radial pressure) along the residuum-socket interface during static axial compression. With a load of 807 N (82.3 kg) being applied, the average pressure at the ischial gluteal shelf (brim transducer) was 32.2 kN/m^2 (4.6 psi), the wall transducer average was 28.0 kN/m^2 (4 psi)¹¹. The lowest pressures were always recorded on the lateral side of the proximal end of the socket (1 inch below the ischial seat), whereas the highest pressures were recorded at the transducer located on the lateral side of the distal end of the socket at the level of the distal end of the femoral shaft.¹²

To ensure the best possible pressure distribution and correct location of the ischial tuberosity above the ischeal seat (at the posterior wall), the anterior wall is extended proximally beyond the level of the ischial seat until it reaches the inguinal ligament. The proper counterpressure action between these two walls is only achieved when their distance matches the AP (anteroposterior) anatomical dimension of the amputee, measured from the ischial tuberosity to the anterior aspect of the adductor longus tendon.

In order to provide mediolateral stabilization of the pelvis, the lateral wall is shaped along the shaft of the femur and extended proximally to exert firm pressure on the greater trochanter, thus ensuring proper function of the hip abductors (Murdoch, 1977). The critical ML¹³ (mediolateral) dimension is obtained by measuring the anatomical dimension from the greater trochanter to the anterior aspect of the adductor longus tendon.

With respect to the body of the socket, its configuration and the independent slopes of the four walls are determined by the residuum's length and girth, and the location and orientation of the femur. The radii of curvatures that provide a more

¹¹The maximum pressure at the ischial gluteal shelf was 36.6 kN/m^2 .

¹²The location of the femoral axis within the cross-sectional areas determines the different amount of soft tissue cushioning available to distribute the load (Redhead, 1979).

¹³The ML dimension provides the basis for the selection of the brim when the Adjustable-Brim Fitting Procedure is being used (Foort, Berkeley, 1963).

rounded contour at corners and over the top surfaces of the socket (especially at the ischial gluteal shelf) are determined by the comfort of those with fragile skin and sensitive tissue. Therefore, the radii over the edges can be constant at any given region for all the sockets, with the exception of the anterior flare, the inguinal crease and the channel of the rectus femoris, which grow proportionally with the increase in brim size (Foort, 1965).

1.5.1 Socket Types

At present, three different types of prosthetic sockets are being used routinely: open-ended suction; total contact; auxillary suspension. They share general similar configurations, but differences emerge towards their distal ends.

Until the early 60's, the open-ended suction socket had been used increasingly since the First World War. In this design, the fit is intimate between residuum and socket except for the very distal part of the residuum, which extends into an air-sealed chamber once the residuum is completely placed into the socket. This socket produces a positive pressure in the stance phase, but during the swing phase, the pressure is negative¹⁴ creating a suction suspension action maintaining the residuum in position inside the socket.

In recent years, the use of the total contact socket has become more common (Murdoch, 1970); in this design, both the proximal and the distal portion of the socket are in intimate contact with the surface. This distal end of the socket provides some support, but not enough to be termed end bearing. This design relieves the amputee of problems related to oedema and skin stretching over the distal part of the bone caused by the open-ended sockets. Therefore the total contact socket is preferred whenever possible.

Major features of the total contact socket are its provision of increased proprioception, its stimulation of blood supply to the residuum¹⁵ and, due to the lack of

¹⁴The negative pressure required to maintain the socket in its place is close to 1.5 psi, this value is obtain by dividing the weight of the prosthesis by the cross-sectional area of the residuum near the distal end (Radcliffe, 1970).

¹⁵The pressure between the residuum and the socket at the distal end during the stance phase promotes venous return, whereas in the swing phase, when the pressure is

room for the residuum to increase its volume at the distal end, oedema is largely prevented.

1.6 Traditional Plastic Socket Fabrication

The first stage in the traditional plastic socket¹⁶ fabrication procedure (plastic socket, universal type) involves wrapping the residual limb (once the residuum has been measured to obtain the *ML*¹⁷ dimension and fitted with the selected adjustable-brim) with plaster bandage to obtain an impression. The plaster bandage is wrapped around to catch the lower edges of the brim. The plaster impression is then held by hand to distort it into a better, more biomechanically acceptable shape¹⁸.

From this impression, a positive plaster model of the residuum is fabricated. Since this model is largely a replica of the amputee's topographical shape (below the brim area) partly distorted (prosthetist's landmarks), the second stage of production involves altering the model shape. The modification process involves hand sculpting the plaster model using rasps. When the modification phase of the process is complete, the plaster model represents a modified residual limb shape and volume. After the shape has been adjusted, the surface is smoothed off. The last step of the process consists of laminating a socket over the modified shape. The laminate is usually either polyester or acrylic over layers of cotton, nylon, fiberglass or carbonfibers in various combinations. Once the laminated socket has cured, the plaster model is extracted in one piece if possible¹⁹, or

¹⁵(cont'd) reduced, blood flows into the residuum. This blood pump action, is not experienced by the residuum when the amputee is standing or sitting (Lyquist, 1970).

¹⁶There are basically two materials used in the production of sockets: plastic and wood. When using plastic, once the residuum impression is obtained, the model is modified and the socket is made over it. When using wood, a hollow is opened in a piece of wood, the opening is carved until the cavity matches the selected shape. This is done on a trial basis until the appropriate fitting is achieved.

¹⁷Mediolateral dimension, taken from the greater trochanter to the anterior aspect of the adductor longur tendon.

¹⁸The unloaded residuum should be stretched distally when the cast is taken, making the residuum longer and thinner as compared with its shape in the unstressed state. With this, the approximate shape and volume that the residuum assumes when loaded will be obtained (Redhead, 1979).

¹⁹If the the plaster mold is extracted in one piece, or if the residuum's cast is maintained intact, it is possible to store it. This produces a subsequent storage and

shattered in order to free the socket. The result of this process is that very frequently the shape modification information is lost, and hence any future fitting of the same amputee requires the prosthetist to start from first principles (due to its lack of reproducibility) which takes a considerable amount of time. Both the plaster casting and the modification procedure are performed on the basis of individual skills and judgement according to rules, habits or concepts that might change from center to center or from country to country.

A Computer Aided Socket Design "CASD"²⁰ System for below-knee (trans-tibial) amputees has been developed at the Medical Engineering Resource Unit "M.E.R.U.", University of British Columbia at Shaughnessy Hospital. This system is unique in that it represents the first attempt to apply modern production technology to the manufacture of specialized socket shapes required by amputees.

The objective of developing an automated shape management capability is to overcome the shortcomings in artisan production methods without losing the accumulated knowledge and experience of the prosthetists. By relating the details of socket shape modification and production to the computer (CASD System), and by replacing the prosthetist's rasps and plaster socket model with a cursor and a digital socket model²¹ (known as primitive socket shape) displayed on a graphic screen, one is able to quantify the "art" of socket design more readily. The implications of such a quantification are that socket quality can be uniform, an explicit description of the socket fit can be defined, and a digital representation of the socket can be readily stored and transmitted (Saunders, 1985).

¹⁹ (cont'd) retrieval problem.

²⁰ The CASD system is an interactive software package written in PASCAL, operating on an IBM PC/XT microcomputer in conjunction with a Vectrix graphic computer and monitor

²¹ The system utilizes a Reference Shape held in the computer memory, which is scaled differentially to match simple measurements taken from the patient's residuum. These are sufficient to define the shape transformations required to produce the digital socket model known as the Primitive Socket Shape. The basis for the use of the primitive socket shape is the degree of constancy in shape exhibited by sockets for amputees (Foort, 1965).

CHAPTER 2

COMPUTER AIDED SOCKET DESIGN "CASD" SYSTEM

The main objective of orthopedic rehabilitation of lower limb amputees is to restore the function of human locomotion lost through amputation.

Several design features have been incorporated into the below-knee and above-knee prosthesis in order to provide the amputee with a useful device so that normal activities can be restored. While the artificial knee joint (above-knee prosthesis) and correct alignment are essential to a well functioning prosthesis, a well fitted socket is a key part of the system. Its interaction with the amputee's residual limb (residuum-socket interface) will determine the success and usefulness of the prosthesis.

2.1 CASD system for the below-knee amputees

Depending on the anatomy of the residuum, the socket must provide pressures of different magnitudes over different below-knee residuum areas as well as permit uninhibited muscle contractions. In the traditional method, the required shape is developed from a modified replica of the residuum²². In the CAD-CAM system²³, the shape of the replica can be documented by shape sensing (recorded), and translated into the computerized socket design system. The first linkage between amputee's residuum and the CAD-CAM system is the acquisition of the residuum's topographic shape.

There are a number of shape sensing devices designed to obtain a representation of a 3 dimensional object which could be used to define shape for prosthetic purposes (some of these techniques have been used only on an experimental basis); they include ultrasound, T.V scanning, holography, light streaking, stereoscopic photogrammetry (Duncan, 1973), and computer axial tomography. The techniques used for sensing

²²During the wrapping of the residuum, the plaster cast is modified by the prosthetist's hands, therefore the residuum shape itself is not documented.

²³Even though the Computer Aided Design-Computer Aided Manufacture "CAD-CAM" system has been implemented by modern industry for more than three decades, it was not until the early 1970's that advantages of its application to the field of prosthetics and orthotics were recognized.

anatomical shape include silhouetting (boundary trace), rasterstereography (surface curvature maps), static shadow moire (suitable for the assessment of scoliosis) and dynamic shadow moire.²⁴ The objective is to produce contour maps which can then be digitized by hand for data entry into the computer. This is a time consuming process, vulnerable to human error. Accuracy and resolution depend on light source, equipment and methodology used. Another method of measuring the shape of a patient's residuum is a 3 dimensional digitizer which provides the computer with a direct input in a series of points in space related to the residuum's shape. Even though advanced computer techniques have been developed for shape sensing, its use in the prosthetic field has been limited to research work.²⁵

Extensive work has been carried out using surface curvature maps in the diagnosis and measurement of spinal deformity. The maps are used to obtain a qualitative interpretation of the principal curvatures (mean and Gaussian curvatures) in two orthogonal directions (Hierholzer, 1986). When a known parallel grid pattern is projected onto a curved surface from a certain angle and viewed from a different angle, the pattern is distorted by the surface shape. Based on the amount of distortion, the principal curvatures are classified and drawn on a map using special symbols, shades or colours representing the value and sign of the respective curves (Hierholzer, *et al.*, 1981). With the analysis of convex, concave and saddle-shapes, one can easily distinguish between edges, grooves, bulges and humps distinctive for each subject. The distinctive body shapes and overall asymmetry of the pattern produced can later be correlated quantitatively with the skeletal geometry.

The shape sensing technique used is determined by the facility or center using the CASD system, depending on the anatomical data that they consider relevant for the configuration of the biomechanical socket²⁶. In certain research centers, not only the

²⁴The application of Shadow Moire method in human anatomy was used as early as 1970 by Takasaki, Theocaris, Allen, Meadows and Duncan (Duncan, 1973).

²⁵Its use has been limited to research work because it provides topographic rather than biomechanical data.

²⁶Television Scanning obtaining 6000 data point in 600 ms is being used by West Park Research, Toronto; whereas in the Institute for Rehabilitation and Research, Texas Medical Center, researchers designed a computerized device by which a 33 cm above-knee residuum can be characterized by 234 points in 6 min.

shape, but the mechanical properties of the soft tissues of the residuum are evaluated by the use of an ultrasound device (Krouskop, *et al.*,1987). Presently at MERU, the required measurements for shape definition are obtained manually by caliper measurement of anteroposterior and mediolateral breadths, and circumferential dimensions of the residual limb at different sites. These are then used to transform a previously stored reference shape to the dimensions required by the amputee, which are represented in the primitive socket shape.

The computer aided socket design "CASD" system for below-knee amputees developed at MERU, organizes the shape data of the residual limb so that it can be saved, modified, improved and replicated, thereby establishing an objective means for fitting prosthetic sockets.

The "CASD" system software for below-knee amputees (BK) allows systematic visual modification of a primitive socket database using techniques analogous to those employed by prosthetists working with rasps and plaster. During the design stage, ideas can rapidly be drawn, viewed, modified and quantified. When combined with a computer numerically controlled (CNC) milling machine and a vacuum former, a comfortable polypropylene socket can be produced with a process time of less than two hours. In addition, a completely quantified record of each step of the modification process is maintained for further view. The database corresponding to the fully modified socket shape is also recorded.

This shape-management system consists of two general stages, the socket design "CASD" stage, and the socket fabrication "CASM" stage. The latter stage makes use of two automated elements widely used in the industry, the CNC milling machine which carves the male socket mold, and a vacuum former that uses this mold to thermoform a preshaped polypropylene blank from which the socket is produced.

In order to use the CASD system, recording of the below-knee amputee residuum measurements should be available to the computer by means of direct manual recording of input measurements (present technique) or by data from the three dimensional digitizer (future implementation). The system uses these measurements to scale and taper the reference socket database in an attempt to produce a modified socket with

dimensions corresponding to the individual patient. Scaling involves sizing the reference socket shape to fit the patient securely in the knee area. This does not attempt to account for differences in tissue bulk, but rather accommodates differences in underlying skeletal size. Two caliper measurements (anteroposterior (AP) and mediolateral (ML) widths) at the knee joint line on the residuum, are compared to the corresponding measurements from the reference socket shape, and the reference socket shape is scaled accordingly.

Tapering is a modification process designed to compress regions of tissue bulk in the distal portion of the socket without affecting nearby bony areas (Saunders, *et al.*, 1985). This process is required in order to account for differences in tissue bulk between the residuums of different amputees. A facility is then provided whereby the operator can view the automatic tapering and decide if the contours designed by the computer are appropriate. Tapering also serves to adjust the distal region of the reference shape in order to provide an intimate fit to the residuum.

After application of the scale and taper modification to the reference shape database, the resulting modified shape corresponds quite well in size and tissue bulk to the residuum of the amputee from whom the measurements were taken. This shape is referred to as the "primitive socket shape". Subsequent stages in the CASD system allow the operator to apply local patch modifications ²⁷ and further sculpting of the shape to design a total contact socket end (Saunders, 1985).

The "reference socket" was the result of years of experience in fitting techniques and development of prostheses by James Foort (who first expressed interest in CASD as early as 1960). His hypothesis was that the residuums of different below-knee amputees are geometrically similar. For adults, the anteroposterior residuum width at the knee joint varies from 2 3/4 to 3 3/4 inches. The mediolateral width at the same level varies from 3 3/4 to 4 1/2 inches. The length of the tibial remnant, which has a relatively constant cross-sectional area from just below the tibial flares to the distal end of the tibia, ranges from 3 to 9 inches in length. Thus, it seemed quite feasible to fit an amputee with a standard socket that has slight modifications. This fact was confirmed

²⁷The modifications can be quantified by the use of a tape measurement routine that makes quantitative cross-sectional comparisons between diameters and circumferences.

in experiments done at the Prosthetics and Orthotics Research and Development Unit, Winnipeg, Manitoba (1968). It was shown that from a series of 19 standard sockets ranging from 3.5 to 5 inches in the *ML* dimension, 5 sizes were required. By fitting 15 below-knee amputees using the 5 socket set, the median size standard socket was used 50% of the time (fig. 2.1) (Foort, 1984).

Once the scale and taper modification stages are completed, the primitive socket shape is stored in the computer. This shape can be displayed on the graphics terminal as saggital cross-sections with its transverse cross-section displayed adjacently. Modifications can be made (patching stage) to the cross-sections at any level. To make the modification, a cursor on a digitizing tablet is used to trace out the boundaries required for the socket shape. Modifications can be progressively entered for various levels until a desired model is obtained. The region to be patched, is defined by setting tabs and angles on the graphics display and indicating how much relief or compression is desired within that region. Patching is used to provide the selective relief over bony

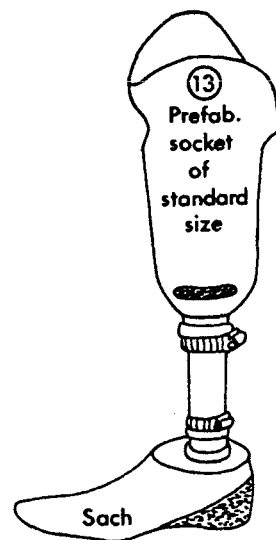
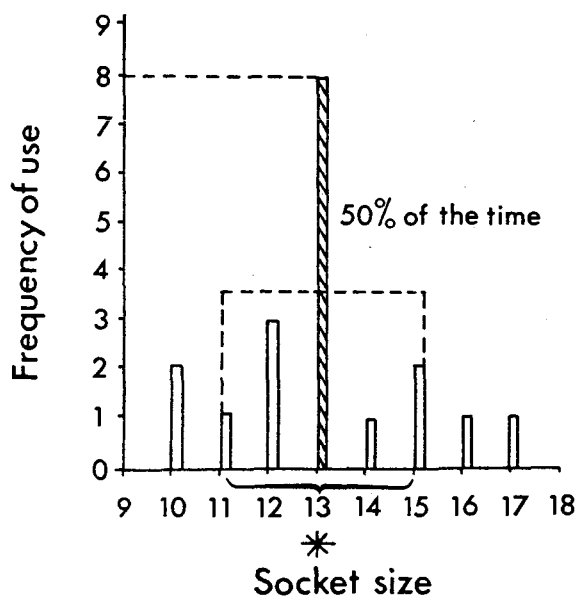


Figure 2.1: Size-frequency of use, below-knee prefabricated standard sockets. (reproduced from Foort, 1984)

prominences and extra "grip" in bulky tissue areas. Patches are applied interactively by the operator as the socket is being viewed, and typically are used to "fine tune" the socket fit. A patch removing material is analogous to a traditional rasp operation, while a relief patch is similar to the addition of small amounts of plaster to a socket cast. The advantage of course is that the underlying shape and the modification are both stored.

Once the socket shape has been designed on the screen, the computer stores the database for that socket. With the amputee's original shape on file, modifications can be added to that shape at each subsequent visit. With this reproducibility capability, the amputee is assured of a progressively better fitting socket and the prosthetist is assured of considerable time saving for repeat fittings. To complete the shape management process, the socket is stored in the computer and the data is translated into a series of commands for a computer numerically controlled (CNC) milling machine, by which a three dimensional mold representing the negative form of the socket is carved from a block of polyurethane foam for further use in the production of the prosthetic socket.²⁸

The advantage that CASD offers to prosthetists is a systematic modification procedure to alter the primitive socket shape. This system allows the prosthetist to keep track of each modification and also makes it possible to review those modifications and quantify them. As all the data has been stored in the system, it is possible to manufacture a duplicate of a socket without recasting the patient's residual limb every time a new prosthesis or prosthetic socket is required. With the conventional procedure, the amount of adjustment possible at the time of manufacture of the socket is limited. If the initial fit is not satisfactory it may be possible to make some changes, for example by putting in pads called liners (to reduce the socket volume) or by grinding the socket wall (to increase the socket volume). But apart from this it is necessary to start the whole procedure again. The CASD system allows the prosthetist to keep track of the residuum's evolution and maturation by quantifying and recording previous sockets and their modifications, enriching the patient's file with useful information for further analysis. This stored information may be used to produce a socket for the same patient at a later date, or for comparing data between patients with similar residuum

²⁸The milling machine carves the polyurethane block by combined movements between a cutter with a vertical displacement, and the axial rotation and axial translation of the block.

characteristics. Besides this important capability, potential advantages of the CASD system include improved comfort for the amputee, reduction of costs, acceleration of prosthesis delivery and a universal quality of the socket and socket fit.

When the CASD system is used, a well fitted socket can be maintained in subsequent fittings through the storage and transmission to different facilities of the socket's data, whereas a change of prosthetist or relocation of the patient could have a dramatic effect on the amputee's comfort when traditional methods are used. Another feature of CASD is that variations which exist between sockets produced by different prosthetists can also be quantified. Statistical information derived from this quantitative data can then be used to specify which design practices are most successful. A systematic approach to handling shape can evolve which can lead to universally high standards of socket fitting, interface comfort, and cosmetic appeal. (Saunders, 1985)

A further development which can be achieved with automated fitting technology is the implementation of central and peripheral CASD facilities. This creates the potential for expanding the system to remote locations or countries where CAD/CAM socket design facilities are not available or the high cost of the CAM equipment makes local production impossible. Centralization of the CASM aspect of the prosthetics service will facilitate the spread of this type of medical services.

The first clinical trials were held at MERU in 1985. Results indicated that it was possible to use CAD/CAM technology to design and manufacture well fitted prosthetic sockets for trans-tibial amputees (MERU, Final Report for Health and Welfare Canada, October 1985). At present, there are four centers undertaking clinical evaluation of the CASD system: West Park Research, Toronto, Canada; Health Science Centre Hospital, Winnipeg, Canada; Strathclyde University, Glasgow, Scotland; and TNO Institute, Delft, Netherlands.

On September 1986, the results of a pilot study conducted at West Park Research involving 10 subjects and 6 prosthetists were reviewed by a panel of experts in the area. The panel recommended that an extended evaluation be carried out involving at least 48 subjects.

Recently (with assistance from MERU, October 1986) the first commercially produced socket to be manufactured by the MERU CASD/CASM system was successfully fitted to an amputee. Following this important accomplishment, 5 below-knee amputees were fitted²⁹ by a local prosthetist within the MERU Industrial Participation Project funded by the Workers Compensation Board of British Columbia.

2.2 CASD system for the above-knee amputees

With the experience and positive results from the development and implementation of the CASD system for below-knee amputees, the extension of the CASD system to include the above-knee amputees was initiated in 1986 at the Medical Engineering Resource Unit "MERU" of the University of British Columbia, with a grant from the Workers Compensation Board of British Columbia.

In common with the geometric similarities presented by below-knee residuums, analysis of the structure of the thigh shows similarities between residuums and between sockets. These similarities are more important than individual differences when related to the socket design (Foort, 1965). Although it is possible to use standardized adjustable components (adjustable-brim at the upper portion of the socket), each socket should be of a size and shape which is tailored to the amputee, adjusted to the physiological changes (shrinking and maturation of the residuum's tissue) and the level of activity (muscle mass) at which the user will function.

Studies at the University of California Berkeley reported at the Manitoba Rehabilitation Hospital Winnipeg (Foort, 1963), show that the distance between the ischial tuberosity and the adductor longus tendon (AP dimension) among adults, measure not less than 2.5 inches (6.35 cm) or more than 4.5 inches (11.43 cm), and that most adults measure from 3 to 3.5 inches. This AP dimension determines the distance between the anterior and posterior walls at the top medial side. With respect to the distance between the adductor longus tendon and the greater trochanter (ML dimension), the studies indicate that the dimension is not less than 4.75 inches (12.065 cm) nor more than 8 inches (20.32 cm), while sockets for most adults measure from 5.5

²⁹All 5 amputees were fitted in two trials or less.

to 6.25 inches between the medial and lateral walls (fig. 2.2). A change of 6% either in the AP or ML dimension at the top of the socket (brim area) is not sufficient to be detected by the amputee (Foort, 1965). The lateral AP dimension differs from the medial AP dimension, from person to person within the same anatomical frame size depending on the muscle mass of the gluteus maximus and the hip flexors. Variations from the basic quadrilateral shape will be directly dependent on the musculature in the anterior and posterior portion of the thigh. Below the brim area, any simple casting technique can be used to define the shape required for the socket.

The above results were obtained at the Biomechanics Laboratory, University of California Medical Centre, San Francisco and were used to design the Adjustable-Brim fitting equipment for the total-contact above-knee socket in 1960. This fitting procedure is actually being used in the design and production of prostheses, and also represents the selected socket structure for the proposed CASD system for above-knee amputees.

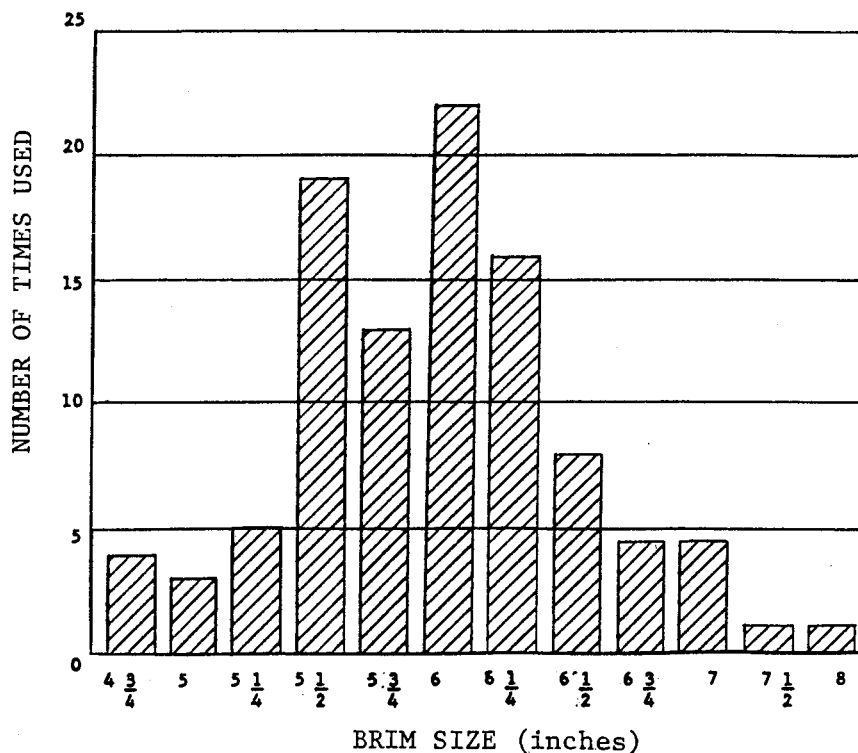


Figure 2.2: A study of one hundred fittings preformed at the University of California, San Francisco during 1960-1961, showed that fittings were accomplished using brims ranging in size from 5.5 to 6.25 inches. (reproduced from Foort, 1965)

Sockets fabricated with the adjustable-brim procedure are made of plastic laminate, and have a quadrilateral shape at the top (fig. 2.3). The shape and volume of the top portion of the socket is determined by the adjustable-brim, whereas the shape and volume of the exposed part of the residuum is determined by the the casting technique, tissue mass and residuum configuration.

2.2.1 Above-knee C.A.S.D. procedures.

Implementation of a CASD system for above-knee amputees will be divided into five interrelated procedures by which the primitive socket shape is structured based on anthropometric measurements taken from the residual limb to be fitted. These procedures are:

1. **PICK**: Based on the patient's anthropometric data, the closest reference shape will be selected from a set of 27.
2. **SCALE**: The reference shape selected, will be scaled down (or up) to match the

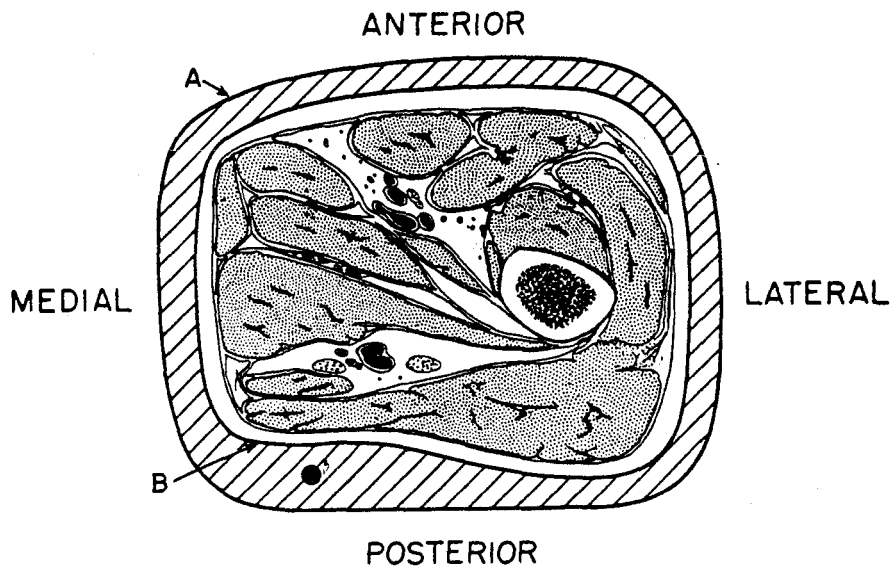


Figure 2.3: Tissue distribution within the quadrilateral socket shape at 2.5 cm below the ischial gluteal shelf (from Radcliffe, 1970).

patient's three skeletal measurements, the trochanter-adductor longus tendon, anteroposterior girth and the thigh length of the contralateral limb.

3. **ADJUST BULK:** Differences in tissue distribution (size and shape) will be adjusted at each level and angular location of the residuum.
4. **END-CAP:** An end-cap will be added to the distal end of the selected reference shape.
5. **ADDUCT FEMUR:** A feature will be included to adduct the lower portion of the socket according to the prosthetist's specification with respect to the femur longitudinal axis position and alignment requirements.

This thesis is concerned with the creation of a computer based reference shape library, and development of shape transformation procedures (*Adjust Bulk*) to adjust library shapes to the unique morphology of the individual residuum, according to simple anthropometric measurements.

CHAPTER 3

OBJECTIVE

The objective of this thesis is to develop a computer aided design procedure whereby the unique shape of an above-knee amputee socket can be created from anthropometric measurements taken from the residuum.

3.1 HYPOTHESIS

It is hypothesised that certain aspects of the above-knee socket shape can be standardised, whereas others must be customised to the individual. By creating a matrix of reference shapes based upon skeletal structure, tissue mass and residuum length, and examining the mathematical relationships between the adjacent elements of the shape matrix, it should be possible to design the unique shape requirements of any individual socket from selected anthropometric measurements of the amputee's residuum.

3.2 Intermediate Objectives

To accomplish the above general objective, the following intermediate procedures were identified:

1. The creation of a 3 x 3 x 3 matrix of reference shapes based on skeletal structures, tissue mass and residuum length. Each reference shape must be created, digitized, analyzed, modified and stored numerically within the matrix of the reference shape library of the computer.
2. Determination of suitable measurement sites of the residuum necessary to implement the *Adjust Bulk* procedure, in which the reference shapes are modified according to dimensions of the patient.
3. Design an anthropometer device to collect the residuum measurement data.
4. Development of mathematical relationships and procedures which permit shape and size transformations between adjacent elements of the shape matrix in accordance with the anthropometric data to create a unique socket data file.

5. Assess the computer aided socket design procedures by constructing "primitive" and "final" test shapes computed from the anthropometric data taken from an amputee and comparing them to: a) the residuum's cast mold; b) a new socket designed by an experienced prosthetist based on the cast mold using conventional technology; c) the actual socket worn by the amputee and produced by conventional technology.

CHAPTER 4

CREATION OF THE REFERENCE SHAPE LIBRARY

4.1 Construction of the Reference Shapes

The socket type selected to be used in the reference shape library was the Quadrilateral Total Contact Socket using the Adjustable-Brim technique,³⁰ which has been used successfully during the past two decades. A set of 27 biomechanical reference shapes, male plaster casts, were produced by James Foort (1986), using traditional techniques. These reference shapes were created in the form of a 3 x 3 x 3 matrix design of brim size, residuum length and girth (fig. 4.1). The reference shape concept is based on studies which established that some surfaces of the top portion of the thigh amputee socket can be constant, and that they change proportionately from size to size, which can be standardized (Foort, 1965).

The first characteristics of the shape matrix is the brim size. The three brim sizes selected were: 5.25 (C), 6 (I) and 7 (E) inches representing the *ML* dimension as the distance from the greater trochanter to the anterior aspect of the adductor longus tendon.³¹ Stump length, defined as the distance from the ischial tuberosity to the distal end of the residuum, constituted the second characteristic of the matrix set, taking reference lengths of: 3 3/8 (S), 7 1/8 (M) and 10 3/8 (L) inches to represent short, moderate (medium) and long residuum. The third characteristic deals with the tissue girth. Three perineal circumferences are included in the matrix as follows: 15 (K), 17 (A) and 19 (F) inches representative of sparse, moderate and bulky residuum tissue. With this 3 x 3 x 3 matrix design (a total of 27 shapes), the set is designed to span the entire combination of brim size, residual length and girth for sockets of the above-knee amputee population.

³⁰This type of socket provides more bearing surfaces which are sacrificed in other types of sockets.

³¹These brim sizes were selected on the basis of a hundred fittings done at the University of California, San Francisco during 1960-1961 which demonstrated that those fittings were accomplished by the use of brims ranging in the *ML* dimension from 5.25 to 7 inches (fig. 2.2), with a central tendency for the 6 inch brim size. These findings were reported in Winnipeg (Foort, 1965).

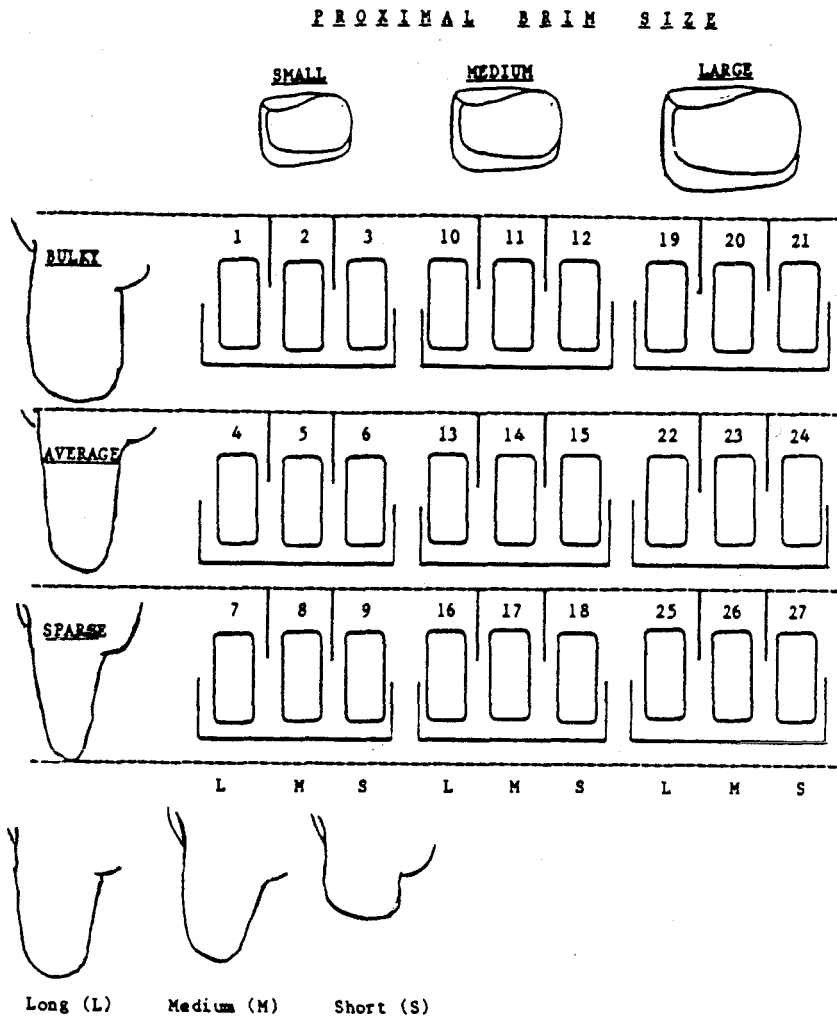


Figure 4.1: Schematic representation of the Reference Shape Matrix, based on the three anatomical characteristics.

The reference shapes (see table 4.1) were all based on the disarticulated knee positive model³² (Foort, 1983) from which the intermediate brim (6 inches), long residuum (10 3/8 inches) and average tissue (17 inches perineal circumference) reference shape # 13ILA (matrix element 232) was created. In order to maintain a fixed relationship between reference shapes, the sequence of production started by digitizing the knee disarticulated model to obtain its cylindrical coordinates. This shape was "amputated" to the long residuum (10 3/8 inches, L) and then carved. From this, the first reference shape cast (13ILA) was manually sculpted, digitized, and carved to yield models from which the adjacent cells of the matrix (fig. 4.1) were manually sculpted (10ILF and 16ILK). Taking again the numerical data of the knee disarticulated model, this was "amputated" to the moderate length (6 inches, M) and carved. From this, reference shape # 14IMA (matrix element 222) was manually sculpted, digitized, and carved to yield the neighboring cells (11IMF and 17IMK). This procedure was repeated for the short residuum (2 inches, S) to produce shape 15ISA from which shapes 12ISF and 18ISK were generated. At the end of this sequence, the first set of 9 reference shape based on the 6 inches *ML* dimension were produced. By repeating this method in the second and third sets (5.25 and 7 inches brim size), the rest of the 27 reference shapes were produced to complete the reference shape library. By this method, the three distinctive characteristics were spread throughout the matrix set.

4.2 Digital Recording of Reference Shapes

By means of a Shape Copier (fig.4.2), the resultant 27 positive male plaster casts (representing the future reference shapes) were digitized. To accomplish this, each plaster cast was mounted on a horizontal jig similar to a lathe, which consisted of a cast holding device, an indexing turntable with notches at 10 degrees increments, an electronic digitizer tablet, and a cursor with an offset probe (Foort, 1986).

³²Model c-6-kd, average adult thigh, with an anatomical dimension of 36.5 cm from the ischial tuberosity to the tibial plateau. This dimension will be referred to in the future as "sd.il" intact length distal on which the longitudinal distal scale procedure will be based.

TABLE 4.1: Reference shape matrix.

REFERENCE SHAPE MATRIX

SHAPE	BRIM	LENGTH	TISSUE	CODE	SB
01	C	L	F	133	1
02	C	M	F	123	2
03	C	S	F	113	3
04	C	L	A	132	1
05	C	M	A	122	2
06	C	S	A	112	3
07	C	L	K	131	1
08	C	M	K	121	2
09	C	S	K	111	3
10	I	L	F	233	4
11	I	M	F	223	5
12	I	S	F	213	6
13	I	L	A	232	4
14	I	M	A	222	5
15	I	S	A	212	6
16	I	L	K	231	4
17	I	M	K	221	5
18	I	S	K	211	6
19	E	L	F	333	7
20	E	M	F	323	8
21	E	S	F	313	9
22	E	L	A	332	7
23	E	M	A	322	8
24	E	S	A	312	9
25	E	L	K	331	7
26	E	M	K	321	8
27	E	S	K	311	9

where: E= Extremo: ML 7 inches (17.8 cm)
 I= Inter: ML 6 " (15.2 cm)
 C= Chico: ML 5 1/4 " (13.3 cm)

L= Long: 10 3/8 " (26.3 cm)
 M= Medium: 7 1/8 " (18.1 cm)
 S= Short: 3 3/8 " (8.6 cm)

F= Fat: 19 " (48.3 cm)
 A= Average: 17 " (43.2 cm)
 K= Skinny: 15 " (38.1 cm)

SB=Subgroup division.

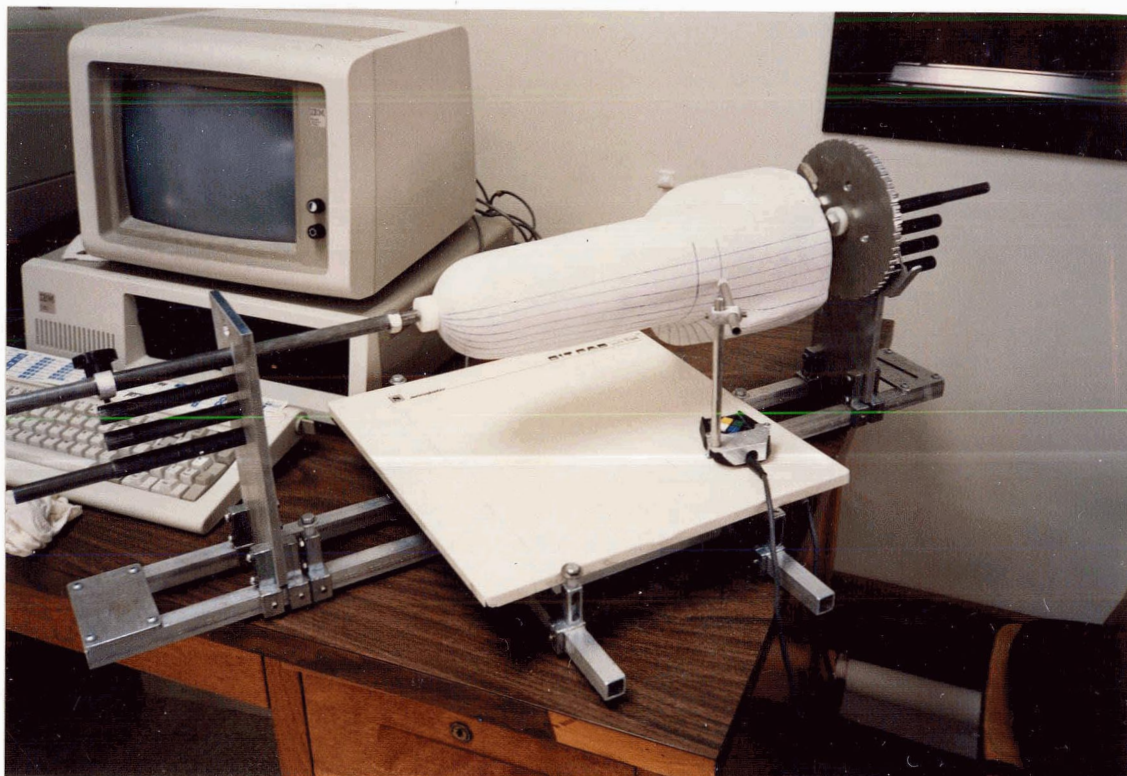


Figure 4.2: The Shape Copier consisted of a cast holding device, an indexing turntable with notches at 10 degrees apart, an electronic digitizer tablet, and a cursor with an offset probe.

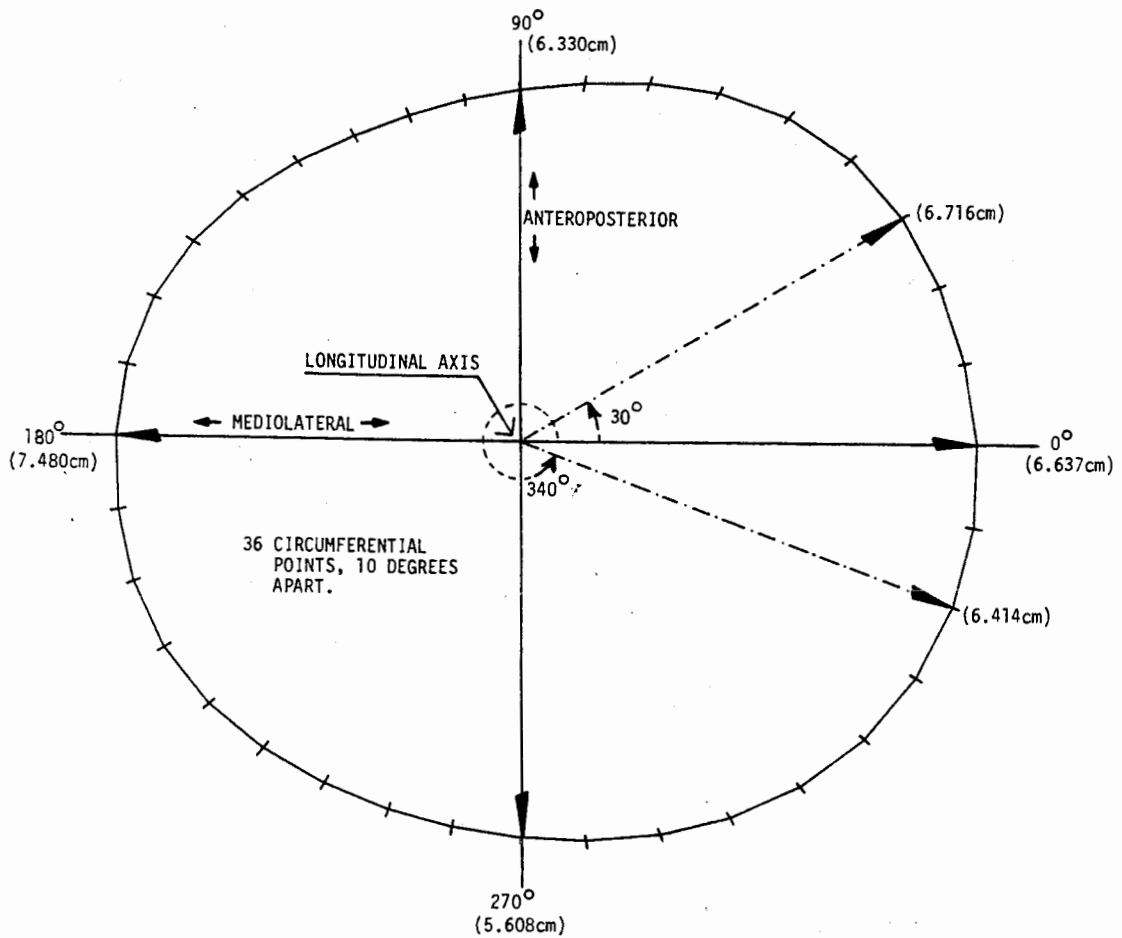


Figure 4.3: Graphic representation of one cross-sectional element, containing 36 radii (some of their values are given in brackets) representing the perpendicular distances from the longitudinal axis to the internal wall of the socket.

To digitize the male shapes, the cast was supported through its longitudinal axis by the rotatable vertical plate at the proximal end, and a guide-pointer at the distal end of the cast. With this apparatus, the cast was rotated 360 degrees in 36 steps of 10 degrees. On each step, a longitudinal trace of the cast shape was acquired by guiding the probe from the distal end to the proximal end of the cast. The software collected data corresponding to the perpendicular radii³³ every 1/8 of an inch along the external wall of the cast.

Once the horizontal trace was completed, the vertical plate was rotated to the next angular step and the operation was repeated until the complete cast had been digitized. At the end of one complete revolution, the numerical data consisted of between 90 and 160 cross-sectional elements (dependent on socket length) each containing 36 radii (fig. 4.3), representing the cylindrical polar coordinates (height, angle and radius) of the particular cast (fig. 4.4). Due to the limited dimensions of the electronic digitizer tablet, some shapes were too long to be digitized in a single file, therefore, those shapes were digitized in two independent data files with an overlapping range of one inch. These files were later integrated to create the final output. The final output file consisted of a two-dimensional array of raw radii (R_i) with one dimension corresponding to known heights (cross-sectional location or slice number) and the other to fixed angles of rotation. This represented a maximum of 5760 and a minimum of 3240 points in the space delimiting each reference shape. These cylindrical coordinates were transformed into CASD system units compatible with both the CASD and CASM software (which was originally developed for the below-knee socket manufacture). With the numerical data obtained from the set of 27 reference shapes, an initial above-knee shape library was created, within which the cylindrical data was available for further analysis.

To assess the accuracy of the digitizing device, an analysis of a known volume was performed. A solid cone was truncated into four sections; each section was connected to its neighbour by a solid cylindrical body of decreasing diameter to match the cone dimension, ranging from 6 to 2 inches in diameter. Similarly, cylinders of matching diameters were attached to either end. This known volume was digitized using the

³³ Radii representing the distance from the longitudinal axis to the external wall of the cast.

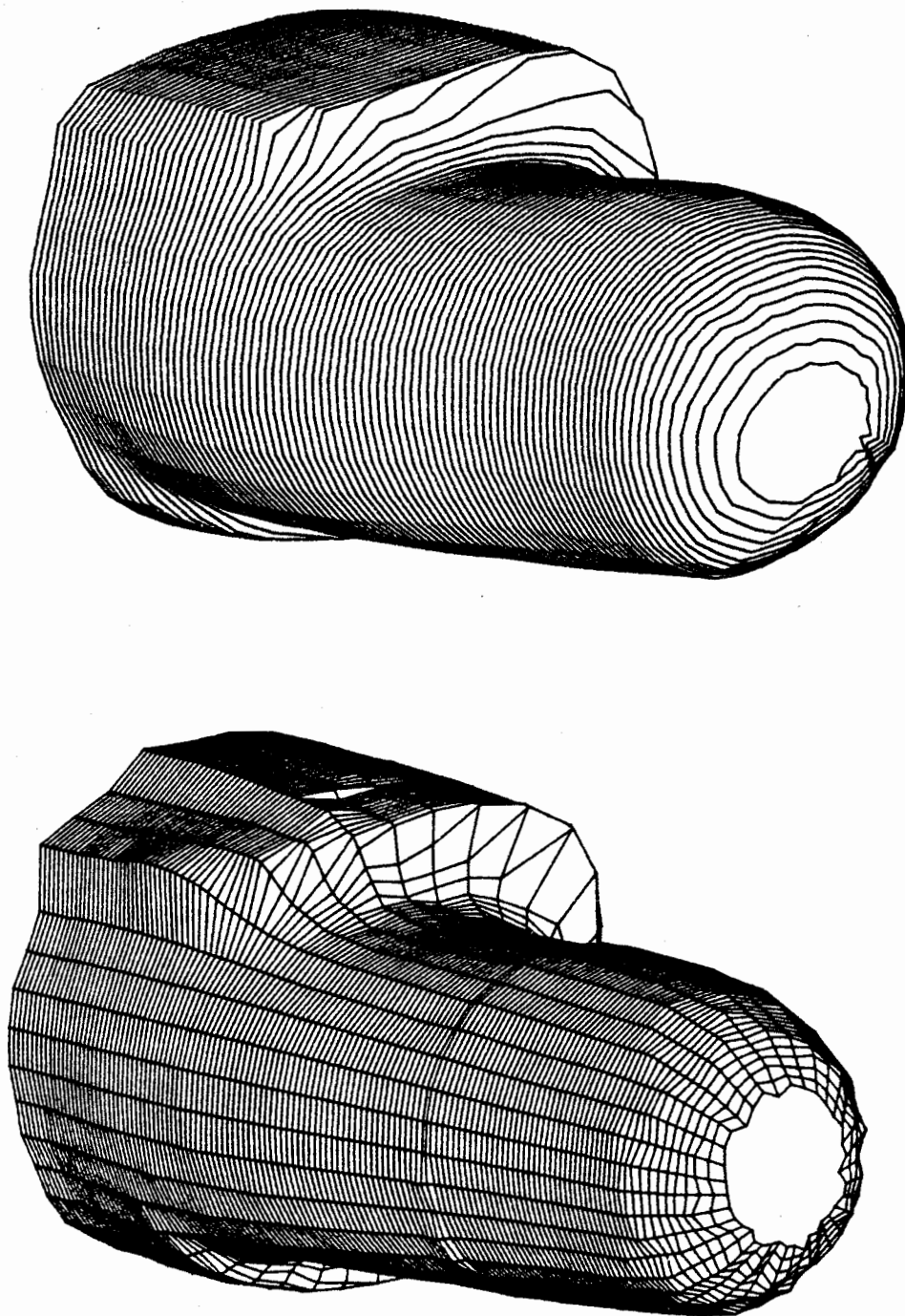


Figure 4.4: Three dimensional representation of the reference shapes # 14IMA code 222 and 19ELF code 333. Lateral and posterior view of a "left" side above-knee socket shape. Its "right" side version can be obtained numerically by producing its mirror image.

Shape Copier device and the same measurement technique employed with the reference shapes. The numerical data acquired by the computer was later analyzed to obtain the Equivalent Radii (**ER**, see next chapter for explanation) (equation 1), the best fitting curve by the "least-square" method, and the Root Mean Square (**RMS**) (equation 2) of the difference between the equivalent radii (**ER**) and raw radii (R_i) for each of the cross-sections of the known volume.

$$ER = \sqrt{\frac{1}{36} \sum_{i=1}^{36} R_i^2} \quad (1)$$

$$RMS = \sqrt{\frac{1}{36} \sum_{i=1}^{36} (ER - R_i)^2} \quad (2)$$

The linear regression line (best fitting curve, $Y = a + bx$) obtained for each of the 61 cross-sections yield that $b = 0.00$ (in each case), and that the mean of the "standard error of the estimate" had a value of 0.036 cm. Taking the " a "³⁴ value (deviation from the **ER**) as the performance radii (R_p) and the real radii as the target (R_t), the "constant error" (CE) (Shutz, 1973) was calculated by:

$$CE = \frac{\sum (R_p - R_t)}{\text{cases}}$$

These results showed that our data had a constant error $CE = +0.056$ cm independent of the distance being measured; and established that the random error of the digitizing device was ± 0.036 cm (based on the standard error of the estimate).

The RMS of each of the cross-sections gave the variability between the raw radii and their respective **ER**. Taking the 61 RMS, the mean and the variance were calculated and yielded $N(0.043, 0.0029)$ cm, ranging from 0.019 to 0.109 cm in the 2196 cases.

³⁴The " a " represents the line's Y-intercept value, and " b " represents the slope of the linear regression line.

CHAPTER 5

TISSUE DISTRIBUTION ANALYSIS

In order to accommodate a particular residual limb configuration in a modified reference shape, adjustments in the brim size and thigh length (*Scale*), residuum tissue distribution (*Adjust Bulk*), and residuum length (*End-Cap*) have to be made. While the adjustments of brim size and thigh length require a linear scaling of the reference shape, adjustment of the tissue distribution requires a nonhomogeneous scaling of the reference shape for both size and shape (Adjust Bulk procedure).

In order to develop an effective procedure for modification of tissue distribution, it was first necessary to acquire information as to how the cross-sections change within the reference shapes and across the reference shape matrix in both area (size) and shape.

To quantify tissue distribution (shape) and size differences along the longitudinal axis of the reference shapes, a series of statistical analyses were performed within each shape and between shapes. In all the analyses, each individual cross-section is represented by an horizontal *slice* representing a certain distance from the ischial gluteal shelf along the longitudinal axis³⁵, and 36 circumferential points (10 degrees apart) given by radii representing the distances from the longitudinal axis to the internal wall of the socket (fig. 4.3). The complete digital description of one cross section is shown in table 5.1.

Appropriate alignment of the cross-sections was ensured through the use of two fixed references: the longitudinal axis, and the zero degree index position (fig. 5.13). These two factors were set in the production phase of the reference shapes, and systemetically located during the initial digitization stage.

³⁵In the example to be given in table 5.1, -3.000 inches represents its location distally from the ischial gluteal shelf.

TABLE 5.1: Digital description of one cross-section.

-3.000

6.637	6.695	6.733	6.716	6.623	6.484
6.362	6.286	6.272	6.330	6.467	6.669
6.908	7.146	7.347	7.484	7.549	7.546
7.480	7.379	7.283	7.186	7.030	6.770
6.432	6.086	5.801	5.608	5.510	5.500
5.578	5.742	5.967	6.208	6.414	6.555

5.1 Independent Cross-sectional Analysis

Taking each cross-section independently (single slice, i level), the Equivalent Radii (ER) (equation 3) and the Cross-Sectional Area ($CSAR$) (equation 4) of all the 27 reference shapes were calculated by the following equations:

$$ER = \sqrt{\frac{1}{36} \sum_{i=1}^{36} R_i^2} \quad (3)$$

$$CSAR = \pi ER^2 \quad (4)$$

The ER represents the radius of a circle with an area equivalent to that of the shape being analyzed. The cross-sectional area was derived by calculating the areas of a series of circular sectors (ACS) (equation 5) with an angle of 10 degrees, and radius R_i :

$$ACS = \frac{\pi (R_i^2)}{36} \quad (5)$$

The sum of the 36 circular sectors represent the Area ($AREA$) (equation 6) of a certain shape:

$$Area = \frac{1}{36} \sum_{i=1}^{36} \pi R_i^2 \quad (6)$$

The Equivalent radius (**ER**) can then be obtained from *equation 6* and yields *equation 3*.

Each independent cross-section was compared with a circle of radius **ER**, and the deviation from that circular shape was calculated by obtaining the Mean Difference (**MD**) (*equation 7*) and the Root Mean Square (**RMS**) (*equation 8*) of the differences between **ER** and the raw radii (R_i) using the following two equations:

$$MD = \frac{1}{36} \sum_{i=1}^{36} (ER - R_i) \quad (7)$$

$$RMS = \sqrt{\frac{1}{36} \sum_{i=1}^{36} (ER - R_i)^2} \quad (8)$$

By plotting the **CSAR** versus the length of the residuum, and across the 27 reference shapes at similar levels (within the same brim size), distribution of tissue volume was obtained (fig. 5.1). By plotting superimposed cross-sections within each socket shape (10 cross-sections evenly spread along the shape as shown in fig. 5.12), the horizontal and vertical orientation of the tissue distribution with respect to the longitudinal axis and the ischial gluteal shelf was determined (fig. 5.13).

To quantify the differences in shape between adjacent cross-sections within each reference shape and between adjacent reference shapes (fat -vs- average and average -vs- skinny), the **RMS** (*equation 9*) of the difference in shape was obtained (fig. 5.2) by using:

$$RMS = \sqrt{\frac{1}{36} \sum_{i=1}^{36} \left(\frac{R_{ia}}{ER_a} - \frac{R_{ib}}{ER_b} \right)^2} \quad (9)$$

The subscript "i" represents a fixed angle of rotation to be analyzed; whereas the subscripts "a" and "b" determine the cross-sectional number (where $b = a-1$)

In order to eliminate the effect of size differences from this comparison of shape, the raw radii (R_{ia} and R_{ib}) were divided by their respective ER to obtain a radial ratio ($R_i \div ER$). This shape analysis was performed between cross-sections in four different formats:

1. Cross-sections of adjacent socket shapes (within each subgroup) at the same longitudinal location (fig. 5.6,7,8).
2. Adjacent cross-sections within the same socket shape (fig. 5.6,7,8).
3. Cross-sections separated by 3 cross-sections within the same socket shape (4 cross-sections apart) (fig. 5.9,10,11).
4. Cross-sections separated by 7 cross-sections within the same socket shape (8 cross-sections apart) (fig. 5.9,10,11).

5.2 Subdivision of the Reference Shape Matrix

It is important to note that, once the first two characteristics (brim size and residuum length) have been used to determine the closest reference shape subset, there are 3 reference shapes that match those specifications (ie. fat, average and skinny). As explained in following sections, the *Adjust Bulk* procedure selects the subset which contains those three reference shapes, scales them first longitudinally (homogeniously) to account for subject size, secondly horizontally (non-homogeniously) to match the required **CSAR** of the residuum, and then interpolates between their shapes at each cross-section level to produce the final cross-sectional shape. For this reason, the reference matrix is divided into 9 subgroups based on the brim size and residuum length. Each subgroup consists of three shapes of different tissue mass: "Fat", "Average" and "Skinny". Hence the matrix set is restructured as shown in table 5.2.

TABLE 5.2: Subgroups of the Reference Matrix.

SUBGROUPS(SG)

BRIM SIZE	RESIDUUM LENGTH		
	10.5 inches	6 inches	2 inches
5.25 inches	SG # 1: 01CLF 04CLA 07CLK	SG # 2: 02CMF 05CMA 08CMK	SG # 3: 03CSF 06CSA 09CSK
6 inches	SG # 4: 10ILF 13ILA 16ILK	SG # 5: 11IMF 14IMA 17IMK	SG # 6: 12ISF 15ISA 18ISK
7 inches	SG # 7: 19ELF 22ELA 25ELK	SG # 8: 20EMF 23EMA 26EMK	SG # 9: 21ESF 24ESA 27ESK

5.3 Refinement of the Reference Matrix

Within the results of the area and shape analysis, a discrepancy appeared within the distal half of the medium and long shapes; a critical area and shape change between adjacent cross-sections emerged. In figures 5.1 and 5.2, these sudden area and shape changes can be observed; refer to figure 4.4 (previous chapter) where in the second reference shape (19ELF) it is possible to observe the effects of the above discrepancies. This was the result of inaccuracy of alignment at the digitization stage where some shapes were collected into two files due to their oversize with respect to the electronic tablet and then merged to form a single shape.

The analyses also revealed some unexpected results: firstly, an overlapping of *CSAR* between some neighbouring shapes (fig. 5.2), secondly, the unmatched position of the rear flare between shapes which reflects longitudinal misalignment and, thirdly, perineal area discrepancies between shapes of similar brim size and tissue bulk, this as a product of the previous area overlapping and the longitudinal mismatch.³⁵ It was also decided at this stage to change the numerical data from the English to the Metric unit

³⁵ Shapes of similar brim size and tissue bulk, were expected to to have similar perineal *CSAR* independent from their length.

ABOVE KNEE REFERENCE SHAPE ANALYSIS CROSS-SECTIONAL AREA -VS- SHAPE LENGTH

BRIM SIZE: 7 INCHES

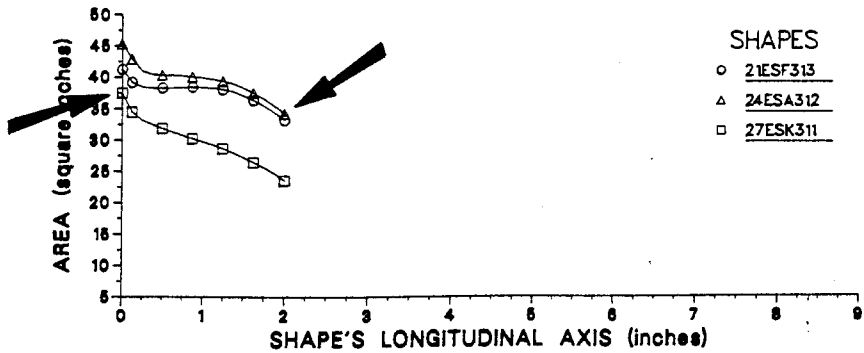
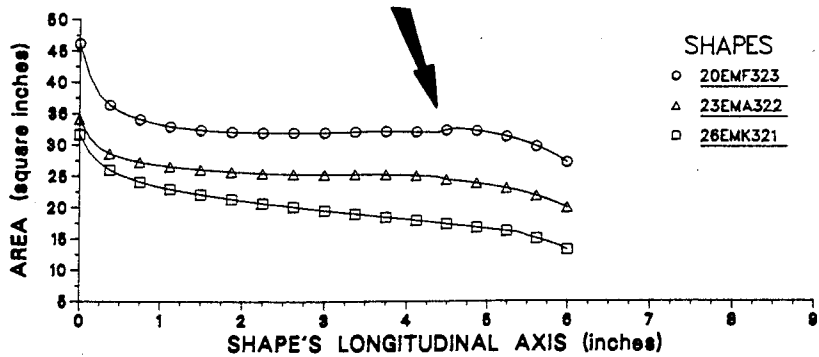
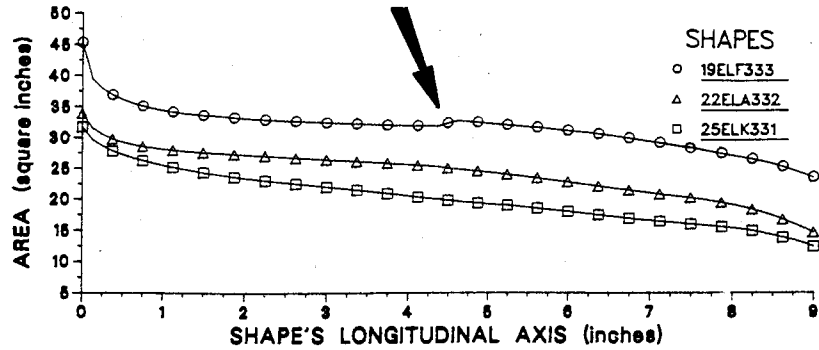


Figure 5.1: Discrepancies in area can be seen (indicated by arrows) in shape 19ELF and 20EMF at 4.5 inches in the longitudinal axis. Shape 24ESA (average tissue) presents a larger cross-sectional area at any given level than shape 21ESF (bulky tissue).

ABOVE KNEE REFERENCE SHAPE ANALYSIS
ROOT MEAN SQUARE OF THE DIFFERENCE BETWEEN SHAPES
SUBGROUP-8, SHAPES: 20EMF f, 23EMA a, 26EMK e

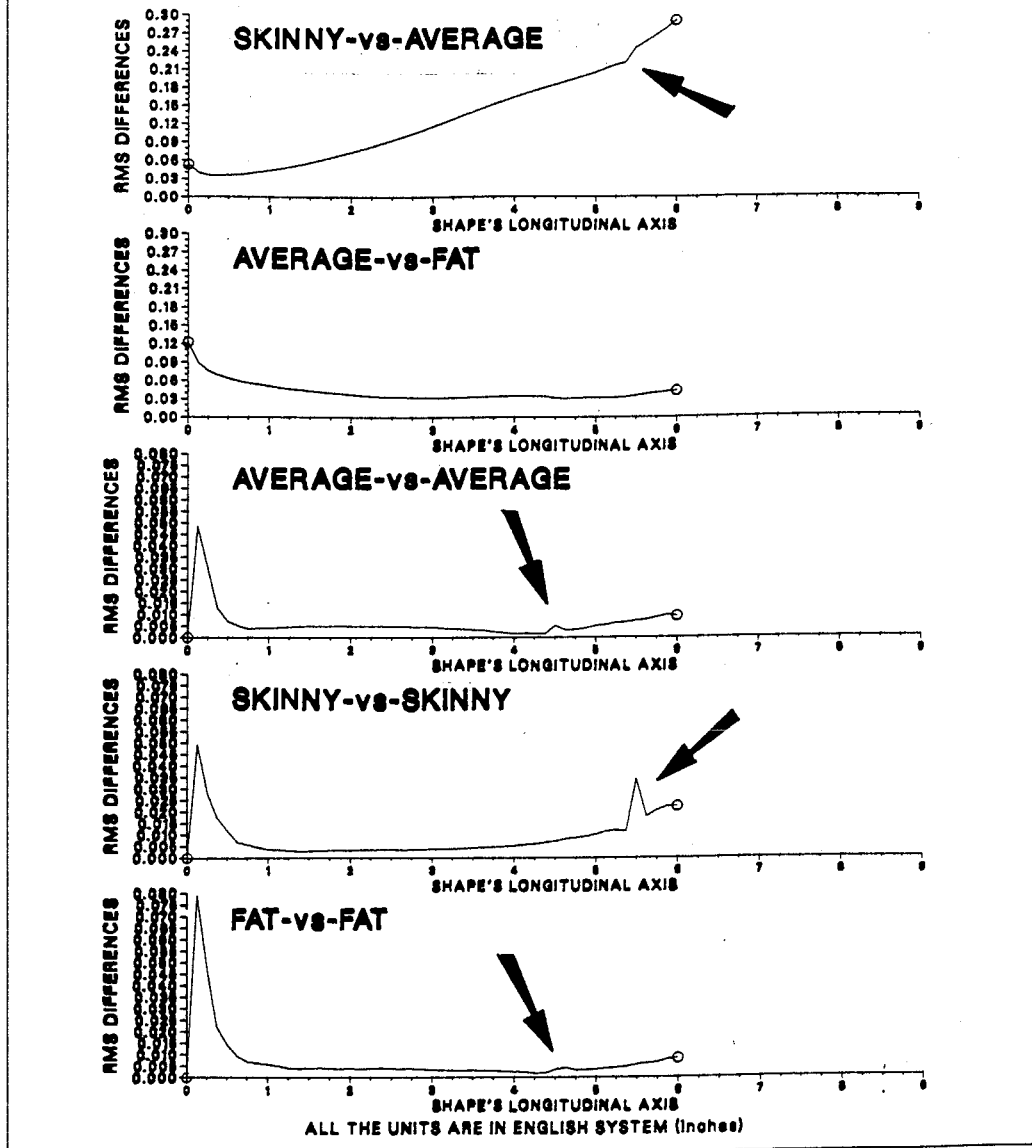


Figure 5.2: The three shapes analyzed show a sudden increment in *RMS* difference where those shape discrepancies occurred within each shape and between the neighboring shapes.

system³⁷ to render the CASD system compatible with international standards.

The reference shapes were realigned longitudinally in order to superimpose the location of the Ischial Gluteal Shelf between all the reference shapes (fig. 5.12) This longitudinal alignment was achieved by medially rotating the reference shape 30 or 40 degrees to locate the maximum *ML* dimension (taken as a reference point), and aligning the ischial gluteal shelf in a fixed point at which the origin (slice 0) was established. Transverse axes were rotated medially 30 or 40 degrees respectively to align them (the zero degree position) perpendicular to the midsagittal plane in order that the brim scaling procedure be representative of the real *ML* dimension parallel to the coronal plane (fig. 5.13).

In addition, the reference shapes were scaled up or down in area so that the perineal *CSAR* became similar between sockets of the same *ML* dimension and of the same tissue mass independent of the residuum's length. The perineal cross-sectional areas were analyzed in order to determine the systematic proportional increments between the three different brim sizes, and the proportional increments between the three different tissue bulks. This analysis indicated that between the three brim sizes, the perineal area of the 5.24 inches *ML* brim size represented 79% of the perineal area of the 6 inch *ML* brim; and the 6 inch *ML* brim size represented 70% of the perineal area of the 7 inch *ML* brim. For any given brim size, even though the *ML* dimension remains the same, the perineal area changes due to differences in tissue bulk between fat, average and skinny socket shapes. With respect to the perineal area proportion between the three tissue bulks, the perineal area of the **Skinny** represented 91% of the area of the **Average** socket, which respectively represented 86% of the area of the **Fat**. This homogeneous area scaling was done by calculating the overall radial scaling factor for each shape by obtaining the square root of the ratio between the required perineal area and the actual perineal area of the shapes. Taking each of the cross-sections within the shape, the original radii were then multiplied by the single radial scaling factor scaling the area without altering the cross-sectional shape or tissue distribution.

³⁷ The original pitch between cross-sections was 1/8 inches; this was shifted to 0.250 cm by linear interpolation.

Scaling of the primitive library shapes was followed by smoothing data around each horizontal cross-section's perimeter, and along the 36 longitudinal strings. The smoothing routine used was the technique known as *Fourth Differences* (Lanczos, 1964). It assumed that the data is sufficiently close together to justify the hypothesis that in a certain finite neighbourhood of points, the second derivative of $f(x)$ does not change significantly (continuity, gradual change in the variable), and adjacent points³⁸ can be joined by a least-squares parabola of the second order (*equation 10*):

$$Y = a + bx + cx^2 \quad (10)$$

To provide smoothing based on the best fit parabola over 5 or 7 points, the following solutions were employed:

$$Y = \frac{-3Y_{-2} + 12Y_{-1} + 17Y_0 + 12Y_{+1} - 3Y_{+2}}{35} \quad (11)$$

$$Y = \frac{-2Y_{-3} + 3Y_{-2} + 6Y_{-1} + 7Y_0 + 6Y_{+1} + 3Y_{+2} - 2Y_{+3}}{21} \quad (12)$$

where:

Y_0 = data point being smoothed.³⁹

Smoothing of the cross-section perimeters (using *equation 11*) was performed from the distal end to the fourth cross-section below the ischial gluteal shelf (slice -4). Proximal to this cross-section, the procedure was limited to the lateral and anterior walls of the proximal end of the socket to prevent unwanted curvatures at their edges. With respect to the longitudinal data strings (*equation 12*), the smoothing routine was performed to the anterior and lateral walls throughout the length with the exception of the 3 proximal and distal cross-sections due to the lack of lateral neighbors. For the other two walls of the socket (medial and posterior walls), the routine was limited to the fourth distal cross-section to slice -12 where the ischial gluteal flare started; this proximal limit was established to prevent unwanted increase of the radii of curvature.

³⁸For circumferential strings, 5 adjacent data points were taken, whereas in the case of the longitudinal strings, 7 points were taken using the same technique.

³⁹The "fourth central difference table" was avoided by replacing it with a "movable strip technique" which yielded *equations 11* and *12*.

5.4 Results

The analysis of the cross-sectional area versus the length of the reference socket shape was divided in three groups according to the respective brim sizes as shown in figures 5.3,4,5. Each brim size group was composed of three subgroups depending on the length of the socket shapes. In each graph, the socket shapes of a single subgroup (three different tissue bulk) are compared. The first 2.5 cm below the ischial gluteal shelf shows similar trends corresponding to the standardized brim structure throughout the reference shape matrix. Outside this range, the rate by which the area decreases depends directly to the tissue mass and the length of the socket. For the distal 1/3 of the sockets, their area changes exponentially.

With respect to the cross-sectional shape analyses within each shape, figures 5.6,7,8 (lower three plots on each figure) show that in the central portion of the sockets there is no significant change in shape except for the proximal 2 cm and distal 4 cm. The change in the proximal portion of the socket results from the effect that the medioposterior flare has upon the cross-sectional shape as the socket reach its proximal end. On the other hand, as the distal end is reached, there is a gradual change in shape but not to the extent seen at the proximal end. These changes in cross-sectional area and shape (tissue distribution) are designed to account for differences in muscle mass at the thigh and the way the residuum was designed during the amputation. This particular shape change at both ends are emphasized when the analysis is performed between cross-sections at 1 and 2 cm apart (fig. 5.9,10,11).

In the upper two graphs of figures 5.6, 7 and 8, the shape analysis was performed between cross-sections of adjacent shapes within a subgroup (fat-vs-average and average-vs-skinny). Three well established trends show that there is a larger degree of shape resemblance between fat and average sockets shapes than between average and skinny socket shapes; in the case of the average and skinny comparisons, shape similarity decreases in a linear fashion as the distance from the ischial gluteal shelf increases; whereas for the fat and average socket shapes, their similarity remains relatively constant along the socket until the distal 5 or 6 cm.

**ABOVE KNEE REFERENCE SHAPE ANALYSIS
CROSS-SECTIONAL AREA -VS- SHAPE LENGTH
BRIM SIZE: 5 1/4 INCHES**

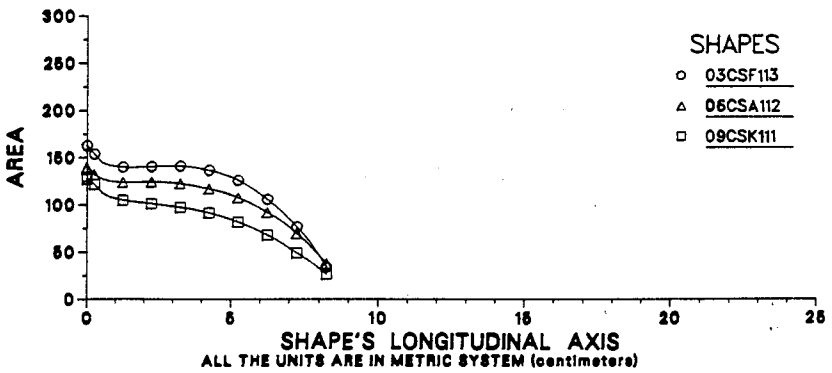
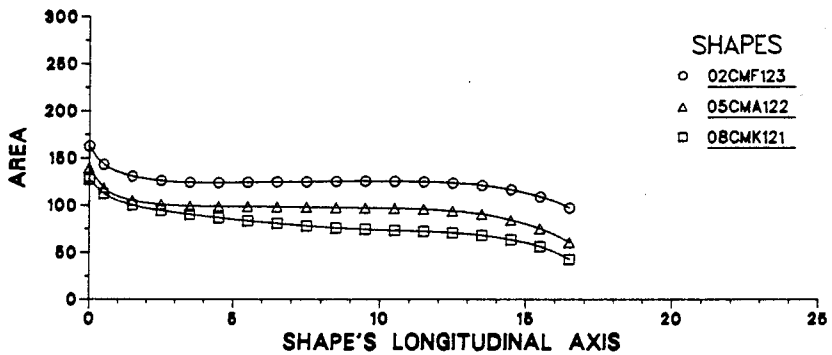
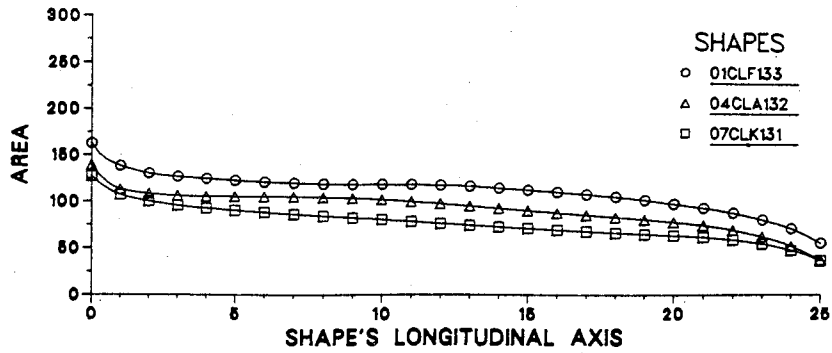


Figure 5.3: Cross-sectional area analysis for shapes with a brim size of 5 1/4 inches ML.

ABOVE KNEE REFERENCE SHAPE ANALYSIS CROSS-SECTIONAL AREA -VS- SHAPE LENGTH

BRIM SIZE: 6 INCHES

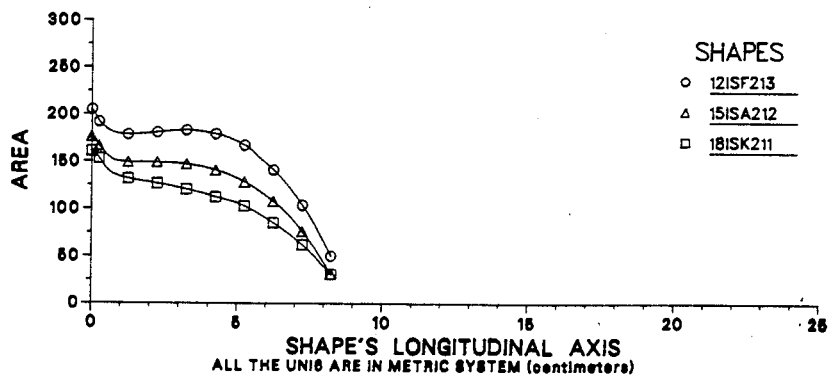
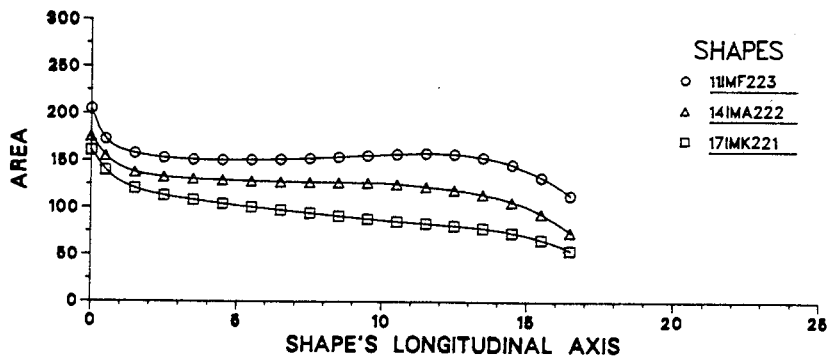
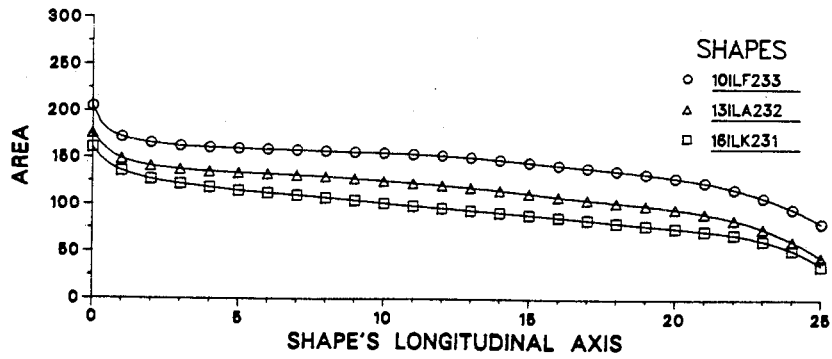


Figure 5.4: Cross-sectional area analysis for shapes with a brim size of 6 inches ML.

**ABOVE KNEE REFERENCE SHAPE ANALYSIS
CROSS-SECTIONAL AREA -VS- SHAPE LENGTH
BRIM SIZE: 7 INCHES**

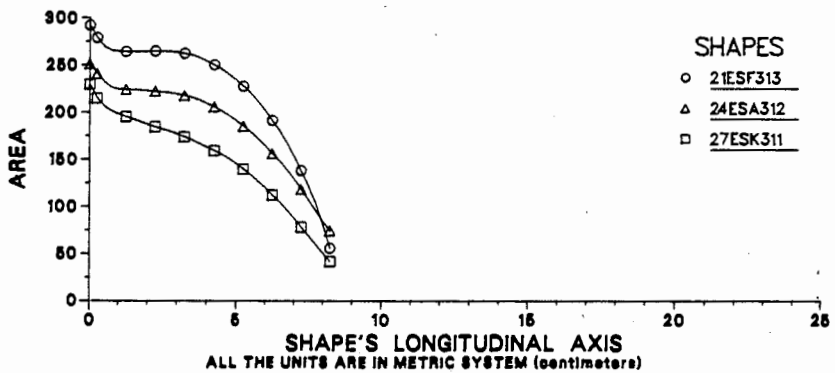
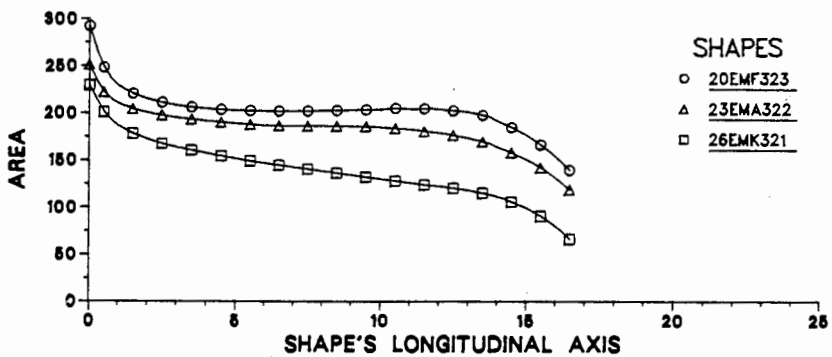
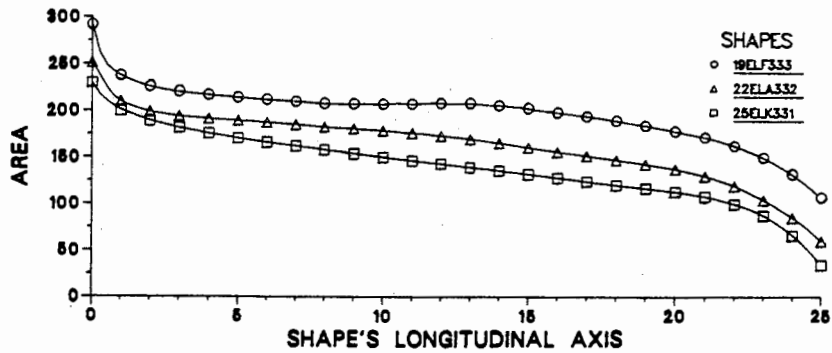


Figure 5.5: Cross-sectional area analysis for shapes with a brim size of 7 inches ML.

ABOVE KNEE REFERENCE SHAPE ANALYSIS
ROOT MEAN SQUARE OF THE DIFFERENCE BETWEEN SHAPES

SUBGROUPS= SG1: 01,04,07, SG4: 10,13,16, SG7: 19,22,25

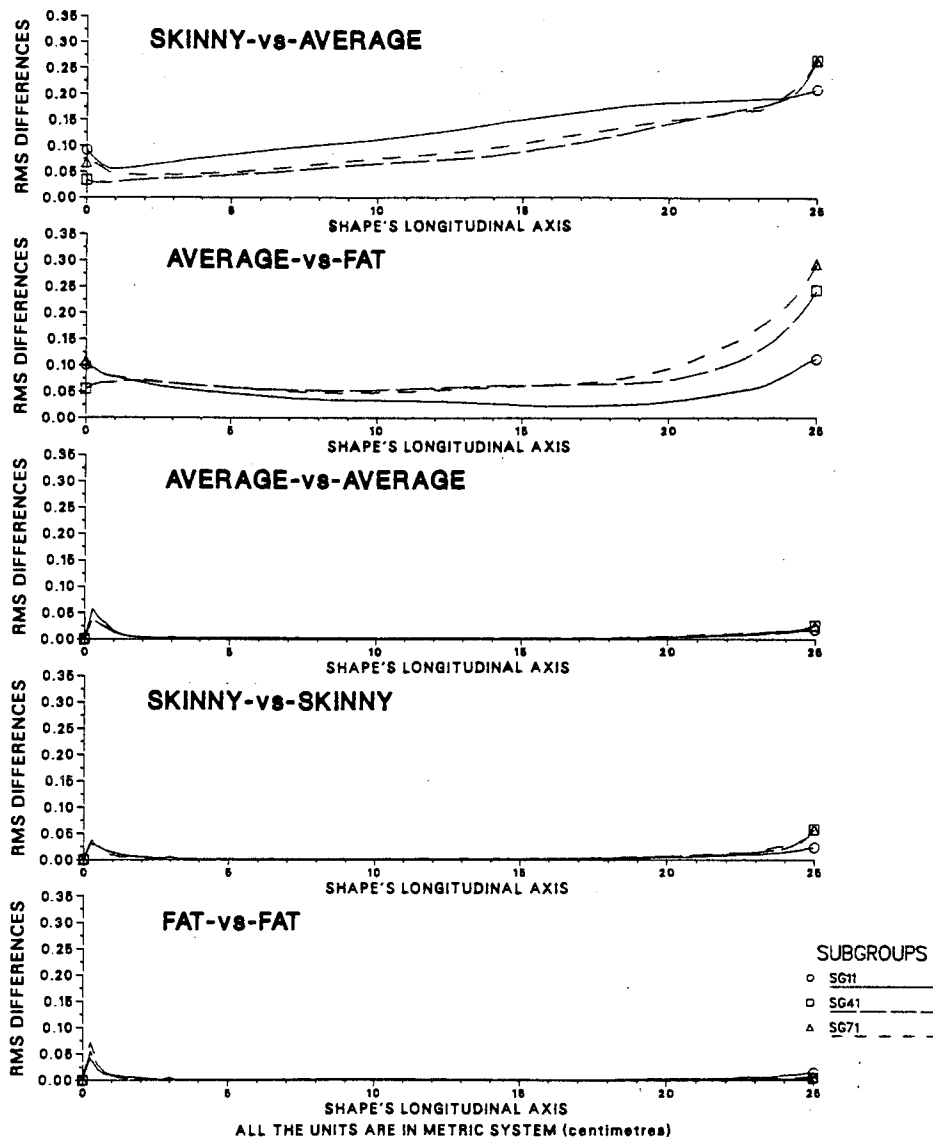


Figure 5.6: Differences in shape of adjacent cross-sections between the socket shapes (top two plots) and within each shape (lower three plots). Subgroups SG1, SG4, SG7.

ABOVE KNEE REFERENCE SHAPE ANALYSIS
ROOT MEAN SQUARE OF THE DIFFERENCE BETWEEN SHAPES

SUBGROUPS= SG2: 02,05,08, SG5: 11,14,17, SG8: 20,23,26

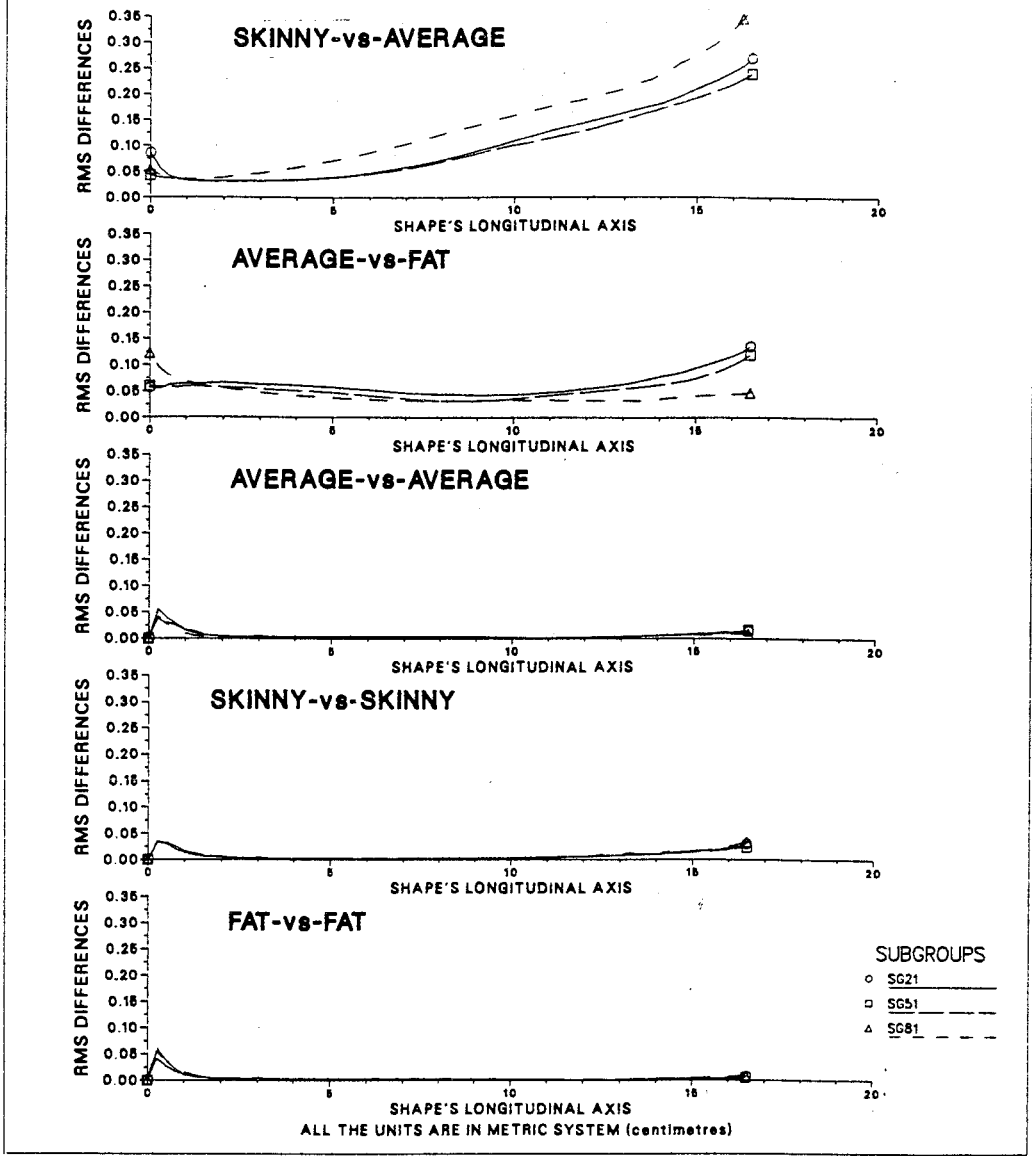


Figure 5.7: Differences in shape of adjacent cross-sections between the socket shapes (top two plots) and within each shape (lower three plots). Subgroups SG2, SG5, SG8.

ABOVE KNEE REFERENCE SHAPE ANALYSIS
ROOT MEAN SQUARE OF THE DIFFERENCE BETWEEN SHAPES

SUBGROUPS= SG3: 03,06,09, SG6: 12,15,18, SG9: 21,24,27

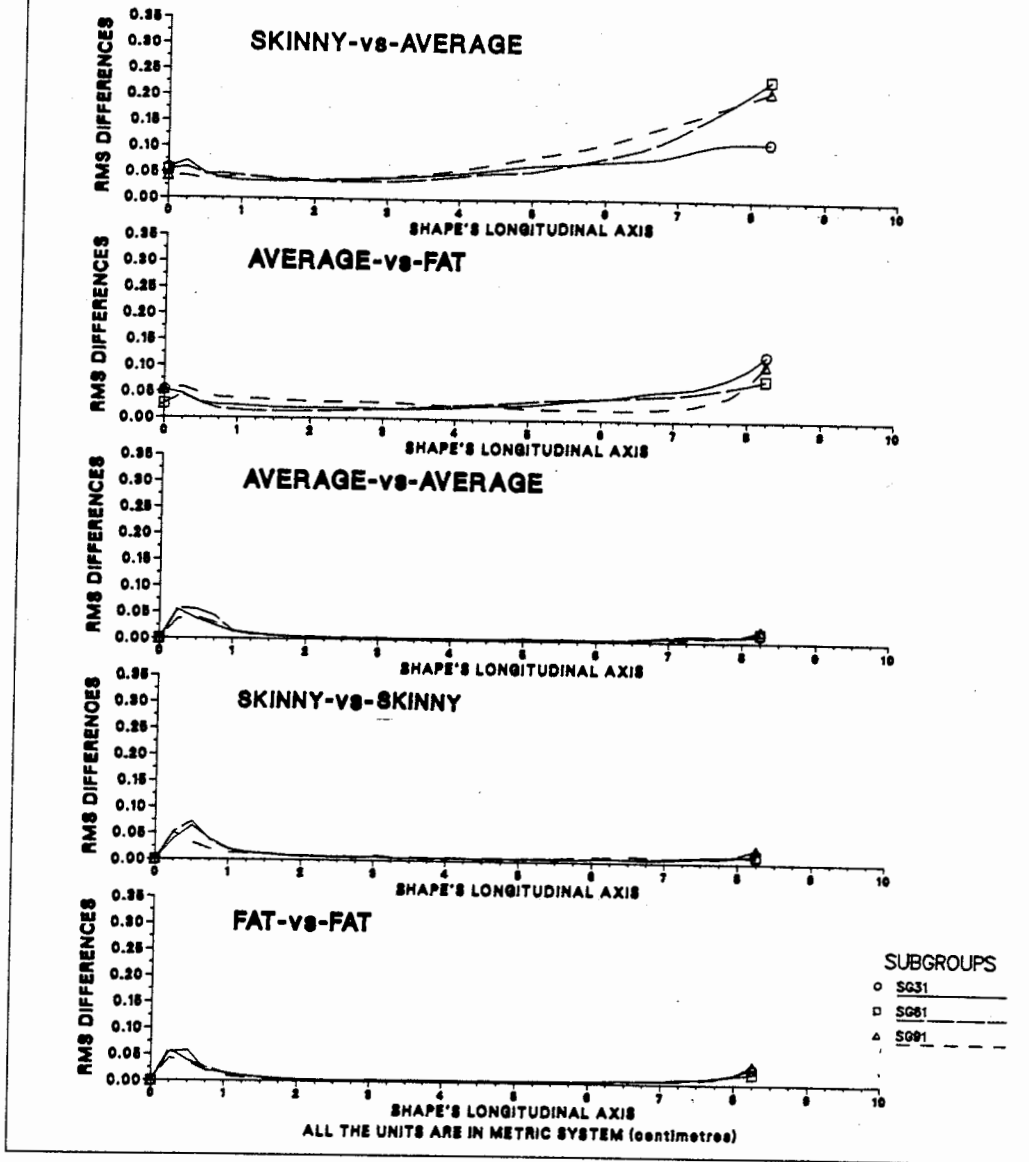


Figure 5.8: Differences in shape of adjacent cross-sections between the socket shapes (top two plots) and within each shape (lower three plots). Subgroups SG3, SG6, SG9.

ABOVE KNEE REFERENCE SHAPE ANALYSIS
ROOT MEAN SQUARE OF THE DIFFERENCE BETWEEN SHAPES

SUBGROUPS= SG1: 01,04,07, SG4: 10,13,16, SG7: 19,22,25
 ANALYSIS AT 4 AND 8 CROSS-SECTIONS APART

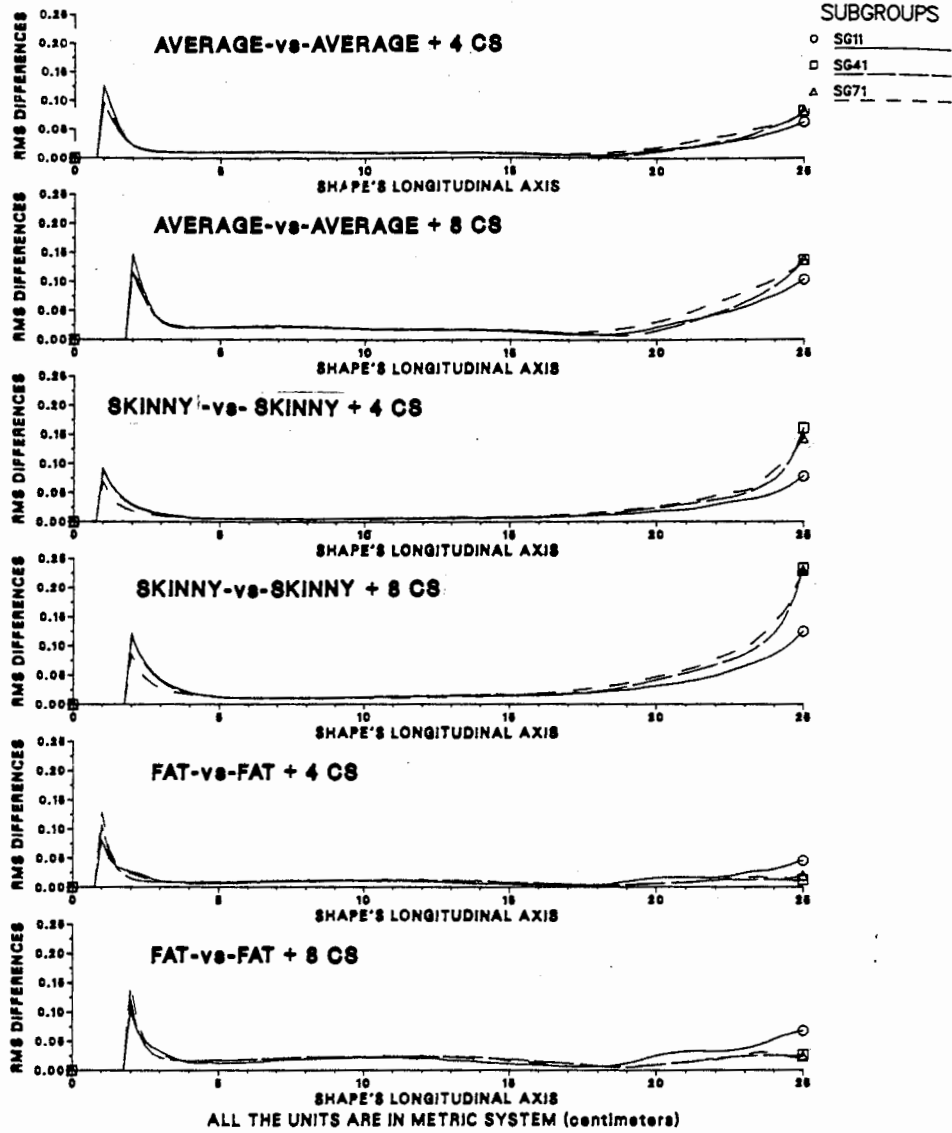


Figure 5.9: Differences in shape between cross-sections separated by 3 and 7 cross-sections within the same socket shape. Subgroups SG1, SG4, SG7.

ABOVE KNEE REFERENCE SHAPE ANALYSIS
ROOT MEAN SQUARE OF THE DIFFERENCE BETWEEN SHAPES

SUBGROUPS= SG2: 02,05,08, SG5: 11,14,17, SG8: 20,23,26
 ANALYSIS AT 4 AND 8 CROSS-SECTIONS APART

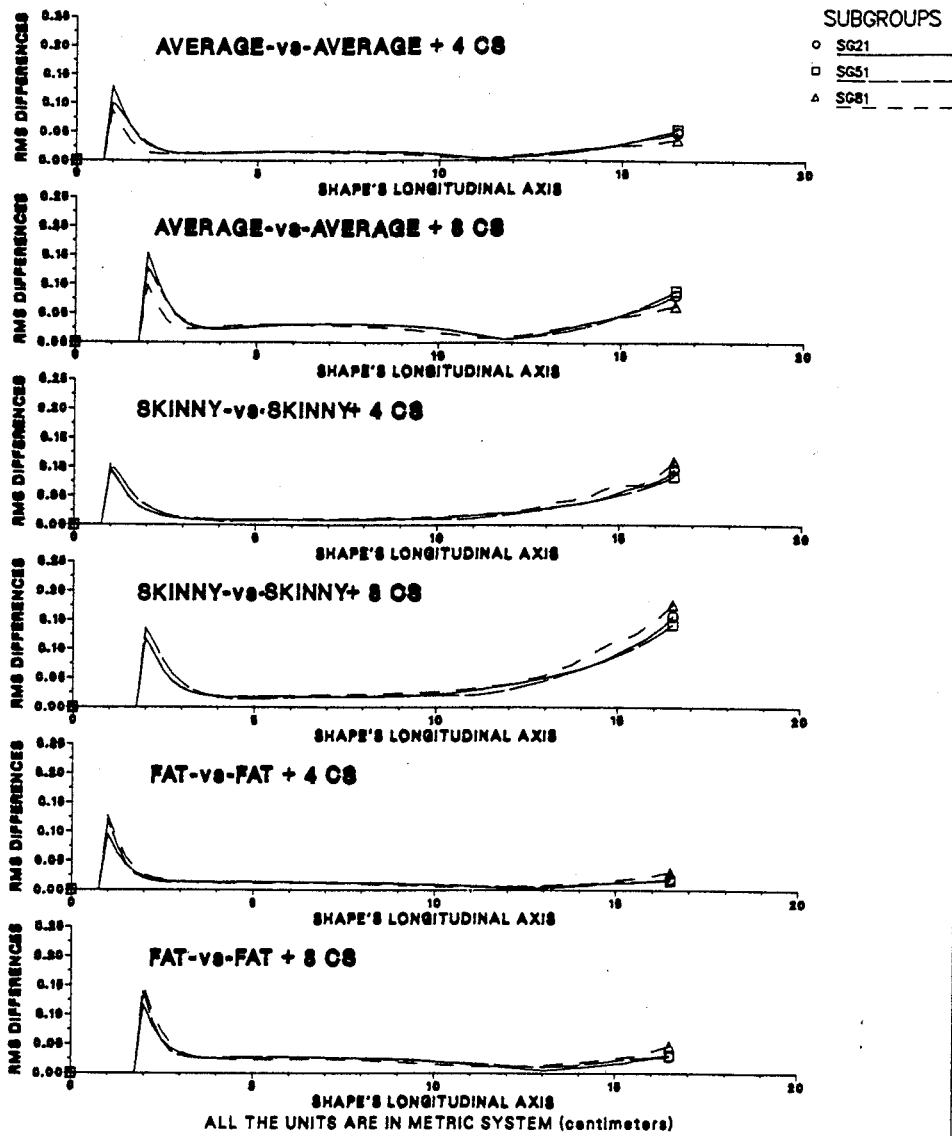


Figure 5.10: Differences in shape between cross-sections separated by 3 and 7 cross-sections within the same socket shape. Subgroups SG2, SG5, SG8.

ABOVE KNEE REFERENCE SHAPE ANALYSIS
ROOT MEAN SQUARE OF THE DIFFERENCE BETWEEN SHAPES

SUBGROUPS= SG3: 03,06,09, SG6: 12,15,18, SG9: 21,24,27

ANALYSIS AT 4 AND 8 CROSS-SECTIONS APART

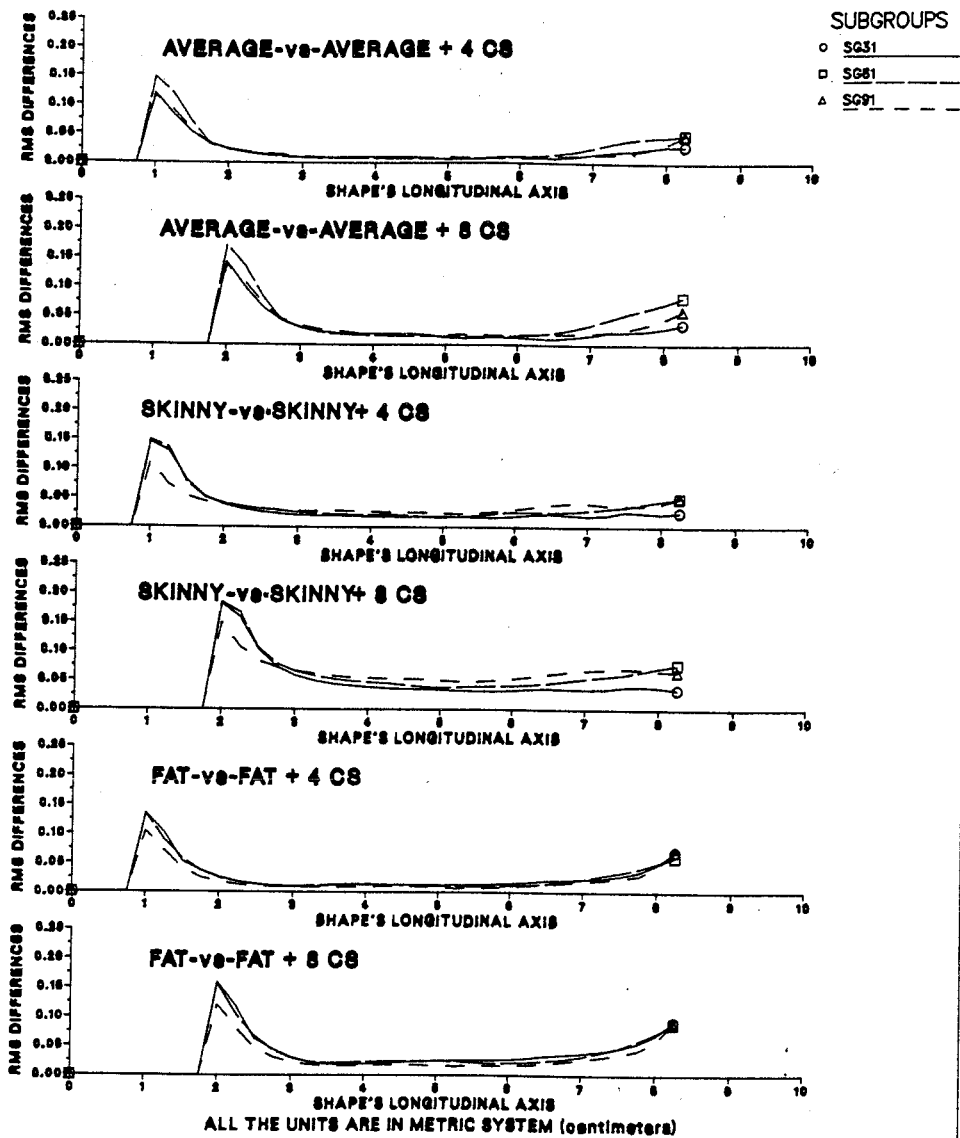


Figure 5.11: Differences in shape between cross-sections separated by 3 and 7 cross-sections within the same socket shape. Subgroups SG3, SG6, SG9.

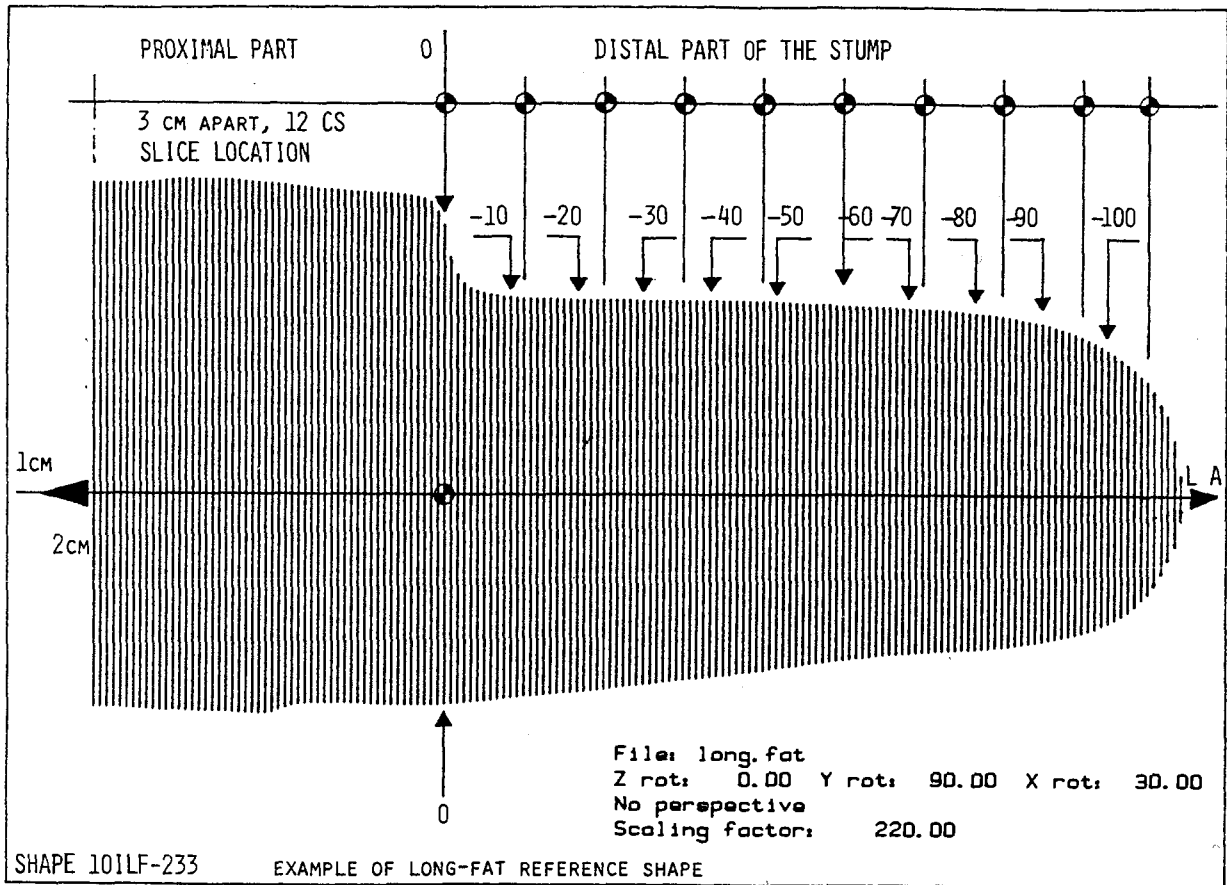


Figure 5.12: Longitudinal slice of the shape 10ILF before the reference shape was rotated 30 degrees in the transverse axis. The series of arrows point out the slice number in the distal portion of the socket, whereas the circles in the upper axis indicates the slices to be collapsed.

SHAPE 19ELF-333

- 12 CROSS-SECTIONS (3 CM) BETWEEN EACH CS SHOWN.

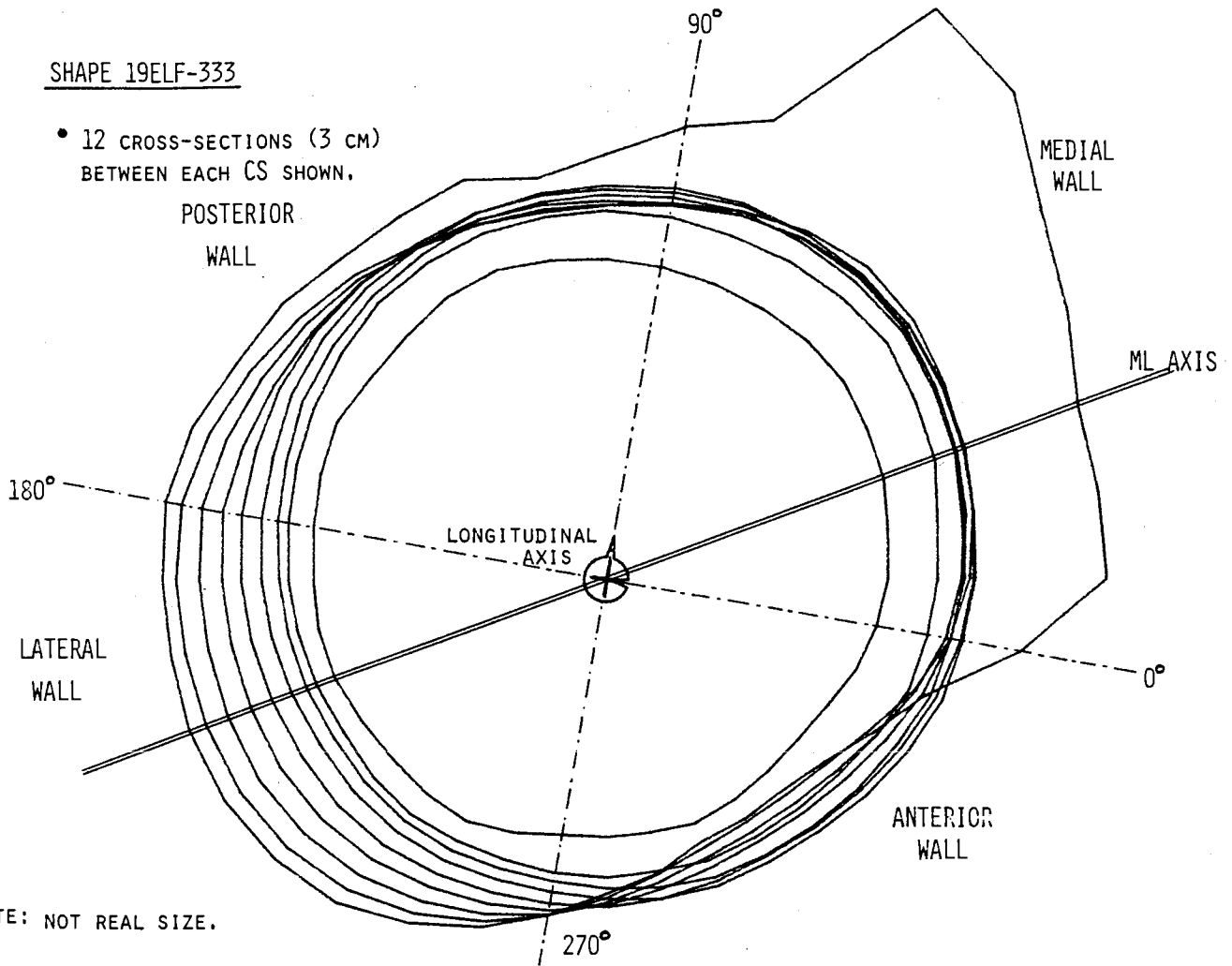
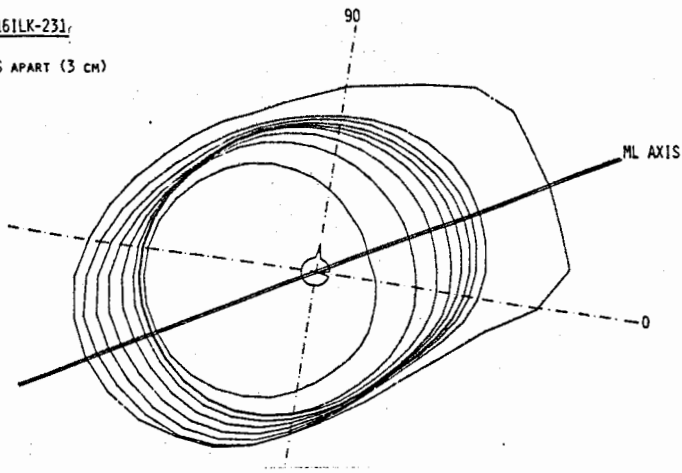
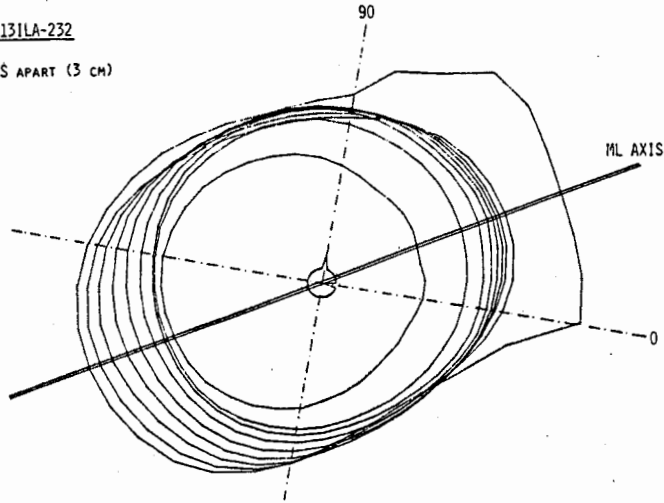


Figure 5.13: Vertical view (transverse plane) through the longitudinal axis of a "Fat" socket shape, showing the relative location of the X and Y axis with respect to the ML axis. Two fixed reference points for the alignment were the longitudinal axis and the zero degree index position.

SHAPE 16ILK-231
• 12 CS APART (3 CM)



SHAPE 13ILA-232
• 12 CS APART (3 CM)



SHAPE 10ILF-233
• 12 CS APART (3CM)

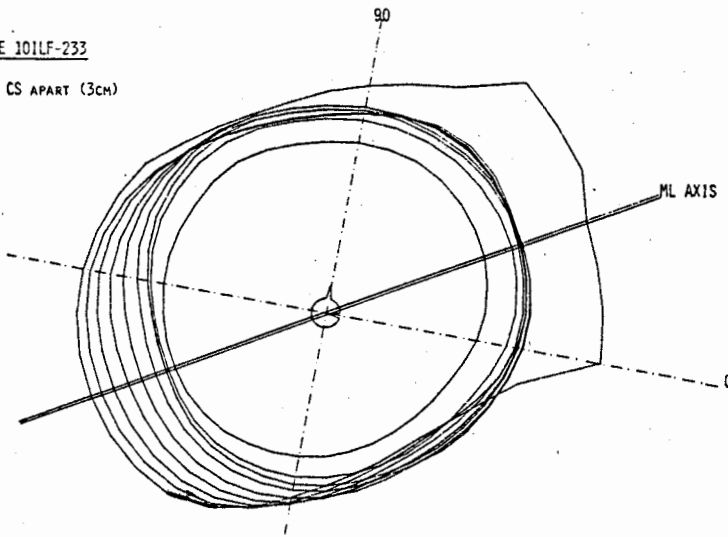


Figure 5.14: Differences in tissue distribution with respect to the longitudinal axis between "Skinny" (16ILK), "Average" (13ILA) and "Fat" (10ILF) socket shape.

Differences in tissue distribution between Fat, Average and Skinny socket shapes of similar length, can be seen in a axial view along the longitudinal axis (fig. 5.14). Each of the three diagrams contains 10 superimposed cross-sections which were taken from their respective socket shapes at similar levels as indicated in figure 5.12. As mentioned earlier, greater resemblance exists between the fat and the average than between average and skinny socket shape. As the muscle mass increases (fat shapes) for any given level, the cross-sectional shape tends toward a more circular shape, rather than elliptic which is the case for the skinny sockets. This may be due to the socket configuration to account for the larger degree of muscle mass change by the anterior (quadriceps) and posterior (hamstrings) muscle groups with respect to the lateral and medial compartments. The bulky sockets maintain a similar tissue location along the walls with the exception of the lateral; the last moves gradually towards the longitudinal axis as the distal end is reached. In the proximal half of the skinny socket, tissue distribution remains constant between anterior and posterior walls. The other two walls (medial and lateral walls) maintain their relative distribution (shape) along the socket as their distance from the ischial gluteal shelf increases. In the average socket, tissue distribution tends towards a circular shape as the distal end is reached.

CHAPTER 6

DETERMINATION OF MEASUREMENTS

The prosthetic socket accommodates the residuum volume within a rigid receptacle having relatively similar volume to the supported residuum, but with differences in shape. The required socket shape will be obtained from the blending of the cross-sectional shapes of the selected subset of reference shapes. This subset was previously scaled according to the anthropometric measures taken from the residuum. These area and shape adjustments are designed to provide appropriate biomechanical force distribution on the residuum for comfort and control of the prosthesis. The pressure difference between the proximal and the distal end of the socket should be minimal; with higher pressures at the proximal end decreasing gradually toward the distal end.

The critical dimensions required for the modification stage must be systematically acquired from the particular amputee to be fitted. Those regions which present similarities of shape and area, such as the central portion of medium and long sockets are not particularly critical to the definition of appropriate socket configuration. Thus less data is required from those sites in order to modify the selected reference shapes. Regions where tissue distribution and cross-sectional areas differ considerably (distal half of the socket and general length of extremely short sockets) are strategic areas of the residuum that should be more carefully defined in order to adjust the specific reference shape to match the patient's anthropometric dimensions.

As previously stated, there are two distinctive groups of musculo-skeletal measurements required for the modification of the reference shape selected: one formed by linear distances taken from the appendicular skeleton (pelvic girdle) for modifications to the proximal portion of the socket (*Scale* procedure); the second, represented by the residuum length and the transverse and longitudinal bulk distribution of the residuum for modifications to the socket in the distal portion (*Adjust Bulk* procedure).

In order to transform the reference shape library to the unique requirements of the patient, it was hypothesised that the most suitable measurements (first group) are:

- * **ML dimension (ML):** Linear distance from the anterior aspect of the Adductor Longus Tendon (near the *Symphysis Pubis*) to the Greater Trochanter.
- * **AP dimension (AP):** Linear distance from the anterior aspect of the Adductor Longus Tendon to the Ischial Tuberosity.
- * **Femur Length (FL):** Linear distance from the Greater Trochanter to the distal end of the residual femur (measurement "C" in fig. 1.3).
- * **Intact Femur Length-A (IFLA):** distance from the Greater Trochanter to the Lateral Condyle of the intact femur (measurement "A" in fig. 1.3).
- * **Intact Femur Length-B (IFLB):** vertical distance from the Ischial Tuberosity to the Lateral Condyle of the intact femur.
- * **Residuum Length (RL):** vertical distance from the Ischial Tuberosity to the end of the residuum.
- * **Pelvic Height (PH):** Vertical distance from the Ischial Tuberosity to the Anterior Superior Iliac Spine (**ASIS**) (measurement "F" in fig. 1.3).

The **Adjust Bulk** procedure requires information from the second group of measurements representing particular characteristics of the residuum:

- * **Perineal Circumference (CIR):** Horizontal circumference of the thigh, taken at the level of the gluteal fold just below the ischial tuberosity. The approximate cross-sectional area derived from this measurement will determine the relative muscle mass of the residuum.
- * **Residuum Length (RL):** vertical distance from the Ischial Tuberosity to the end of the residuum. Due to the relatively different position of the femoral bone with respect to the ischial tuberosity when abducted, this measurement should be taken with the patient standing in the anatomical position (measurement "B" in fig. 1.3).
- * **Cross-sectional Areas (CSAR):** Series of horizontal cross-sectional areas measured along the residuum length depending on the muscle mass, tissue quality and longitudinal residuum shape.

The first group of measurements taken from the amputee will not be altered by the relative position of the residuum with respect to vertical alignment or load state, whereas the second group will change under load with respect to the unload state.

6.1 Acquisition of the cross-sectional areas

As the proximal 2.5 cm (slice -10) below the ischial gluteal shelf and the distal 5 cm of the socket will be modified directly by the **Scale** and by the **End-Cap** procedures of the CASD system respectively, those areas will not be influenced by the cross-sectional areas taken from the *Patient*. The rest of the socket will be scaled depending on the **CSAR** at different sites of the residual limb to be fitted.

To determine the cross-sectional area along the residuum from which the primitive socket shape will be derived, two techniques were employed in two different sessions, one, taking circumferential measurements obtained with the use of a measurement tape (normally practiced in the prosthetic field), the other, by the use of rigid circular rings of fixed area.

6.2 Design of the anthropometer device

Referring to the cross-sectional analysis, values of cross-sectional area obtained from the 27 reference shapes, inside the limits set by the 2.5 cm from the ischial gluteal shelf and the distal 5 cm, ranged from 55 to 225 cm². As seen in figures 5.3 to 5.5, once outside the limits of the posterior flare, the cross-sectional areas reach a plateau and then start to decrease in a constant fashion to the distal third portion of the socket, for the last portion, the area decreases exponentially. Due to the differences in tissue bulk within the 27 reference shapes, the number of cross-sectional areas with a value in the lower 2/3 of this range (from 55 to 190 cm²) occur with higher frequency (see fig. 5.3,4,5). In normal circumstances, cross-sectional areas taken from a patient will display a similar pattern.

Using this information, 15 ring areas were selected (see table 6.1) to be fitted to the residuum and specified by their distance from the ischial tuberosity for the subsequent **Adjust Bulk** adjustment (see section 7.1). The first set (prototype) of 15 circular rings was produced from an injected polypropylene cone. This cone was truncated every centimeter to yield each of the rings. The conical inside wall of each ring was then machined to produce an cylindrical shape of the desired diameter.

TABLE 6.1: *Anthropometric Rings*

CODE	AREA (cm ²)	ER * (cm)
A1	36.3	3.4
B2	56.7	4.3
C3	69.7	4.7
D4	85.3	5.2
E5	98.5	5.6
F6	113.1	6.0
G7	129.5	6.4
H8	145.3	6.8
I9	156.6	7.1
J10	176.7	7.5
K11	186.3	7.7
L12	208.7	8.2
M13	234.0	8.6
N14	243.3	8.8
P15	260.2	9.1

* accurate to ± 0.005 cm

The spacing that is required between the rings, depends on the complexity and longitudinal tissue distribution of the shape being analyzed. In preliminary trials, rings were placed sequentially along the the residuum, extending from 1.2 cm below the gluteal fold to the most distal portion measurable of the residuum.

CHAPTER 7

DEVELOPMENT OF SOCKET MODIFICATION PROCEDURES

The reference matrix consists of 27 reference shapes representing all the possible combinations of the 3 x 3 x 3 matrix design. The majority of the above-knee amputee residuums will require sockets whose configurations are determined within the limits of this matrix. The exact configuration will be obtained by interpolating (or in extreme cases extrapolation beyond the reference matrix) between the dimensions of the adjacent elements within the reference matrix.

7.1 Pick, selection of a single subgroup.

The first step of the CASD system, *Pick*, selects one subgroup of the 27 reference shapes stored in the computer based on anthropometric measurements taken from the residuum. Taking first the *ML* dimension, one of the 3 brim sizes is selected. The second measurement, residuum length (RL), is used to pick one of the three lengths. At this stage, there are three reference shapes that match the two previous dimensions, each having a different tissue mass. All three of these reference shapes are utilized in the *Adjust Bulk* procedure (step 3) in order to compute a unique socket shape dependent on the cross-sectional data of the *Patient*. The third measurement, perineal circumference (CIR), is used to pick one of the three girths. In the *Scale* procedure (step 2), the brim portion of this single reference shape selected (sections "A" and "B" the socket, fig. 7.1) is modified according to the ML and AP dimensions of the *Patient*.

In the particular case of our *Patient* (test trial), the *ML* dimension was 15.2 cm which determined that only groups 4, 5 and 6 were appropriate. The second measurement needed for the selection, the residuum length, was 24.1 cm which yielded group 4 as the matching subgroup. One of these shapes was then selected as the closest match as indicated by the perineal circumference (CIR) of 19.5 compared to 19 inches stipulated for the FAT (shape 10ILF #233 was selected).

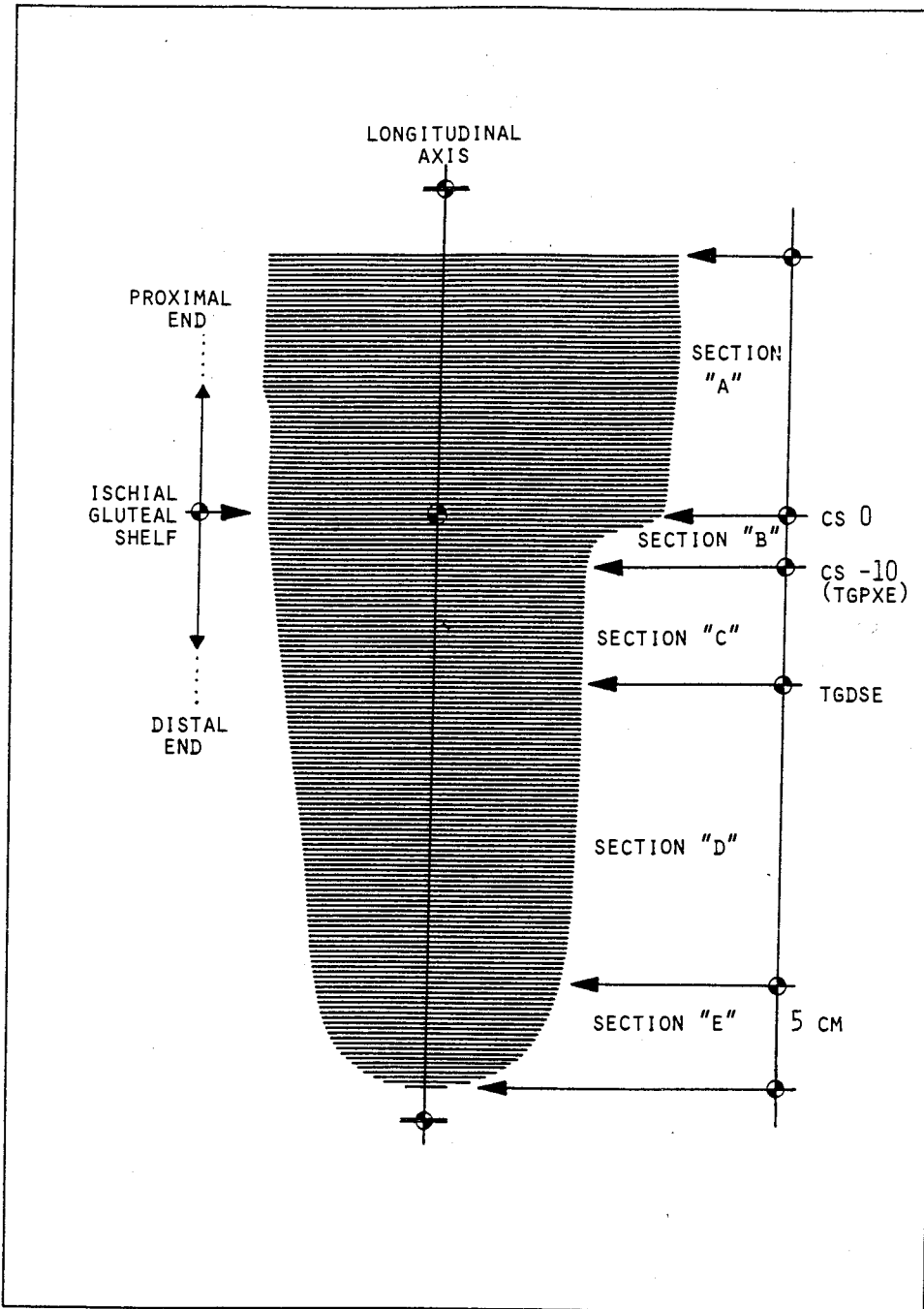


Figure 7.1: Schematic representation of the 5 different sections of the socket depending on the longitudinal and transverse scaling routines to be used.

7.2 Scale, brim and length scaling.

The second step of the CASD system, **Scale**, consists of the scaling of a single reference shape selected (shape 10ILF in the case of our *Patient*) to account for differences in ML and AP dimensions. Scaling is done by calculating the scaling factors ($F1_x$ and $F1_y$) for the X and Y coordinates of the radii at each cross-section. Their values are obtained from the ratios between the *linear ML* dimension and the **AP** dimension of the *Patient* with respect to the corresponding dimensions of the reference shape. In the case of our *Patient* these factors were: $F1_x=1.002632$, $F1_y=0.9046729$ respectively. These factors are rarely the same, therefore, the cartesian components (X,Y) are scaled differently, consequently affecting the previous cross-sectional shape. Not only the shape is modified, but the "resultant radii" from these two components change their orientation with respect to the original structure of 36 radii distributed evenly around the cross-section. In order to bring back the radii to their original structure⁴⁰ without any further shape distortion, the 36 radii are restructured in the original grid by linear interpolation between adjacent radii within the cross-section.

This nonhomogeneous transverse scaling, is followed by two independent longitudinal scaling routines, one to the proximal portion, the second to the distal portion of the socket shape. These routines account proximally for differences in the pelvic height (PH), distally for differences in the Intact Femur Length-B (IFLB) between the *Patient* and the Knee-disarticulation model from which the reference matrix was generated. The longitudinal scaling routines divide the socket into two sections (fig. 7.1) where the spacing between the cross-sections differ from the original 0.25 cm, one from the ischial gluteal shelf to the proximal end, the second, from the ischial gluteal shelf to the distal end.⁴¹

⁴⁰Radial coordinates θ and r (angle and radius), where θ has a value of 10 degrees.

⁴¹In the case of our patient, the new pitch for the proximal end was 0.260 cm whereas for the distal portion the new pitch incremented to 0.309 cm. At the end of the **Adjust Bulk** procedure, the gap between cross-sections are reset to the original 0.250 cm spacing by linear interpolation between adjacent cross-sections.

7.3 Adjust Bulk, scale and blending of the socket shapes.

The third step of the CASD system, *Adjust Bulk* procedure, is used to modified cross-sectional area and shape within the sections of the socket distal to the brim portion. Hence this algorithm is applied only to sections "C", "D" and "E" of the socket (fig. 7.1). The resulting shape is then jointed to the brim portion computed with the *Scale* algorithm.

For each individual case, one subgroup of the reference shapes is selected. The three shapes of the subgroup are scaled (longitudinal and transversely) independently and then, blended together and merged with the brim portion (sections "A" and "B") to produce the primitive socket shape.

The *Adjust Bulk* procedure requires three input packages:

1. Patient data: Residuum length (RL), perineal circumference (CIR) and a series of cross-sectional areas⁴² (CSAR).
2. Numerical data of the three reference shapes of the subgroup selected and their scaling factors ($F1_x$ and $F1_y$) computed by the *Scale* procedure.
3. Brim shape, sections "A" and "B" of the reference socket shape modified by the *Scale* procedure⁴³.

Sections "C", "D" and "E" (fig.7.1) of the three reference socket shapes are scaled at each cross-sectional level to conform to the patient's residuum area. With this process, each of the three scaled shapes will accommodate the residuum but each will have its own unique longitudinal and transverse cross-sections. The blending of these three new shapes, together with the brim portion (sections "A" and "B") will determine the subsequent primitive socket configuration.

⁴²These areas are referred by the location and code of the rings fitted on the residuum, or by horizontal cross-sectional areas taken by any other device.

⁴³These two sections will be merge to the other three sections of the socket obtained from the *Adjust Bulk* procedure to produce the primitive socket shape.

7.3.1 Transition Gap, TG.

It has been learned through experience at M.E.R.U. with the below-knee socket development, that when different parts of the socket are modified by independent techniques, discontinuities may emerge at the joint sites of those parts. In the case of the above knee socket, two distinctive sections of the socket exists which are modified by two independent procedures; one the brim portion (**Scale** procedure), the other, the body of the socket (**Adjust Bulk** procedure). In order to eliminate discontinuities, a transition routine "TG" (Transition Gap, factor F3) was designed to gradually make the transition from the **Scale** to the **Adjust Bulk** procedure. A major difference between these two procedures lies in the transverse section scaling routines. Brim scaling (**Scale** procedure) is performed in *X* and *Y* coordinates independently, based on the *ML* dimension and *AP* dimension ratio between the residuum and the reference shape. When these two scaling factors are different, the coordinates change independently producing radii not evenly distributed around the shape. Therefore, there is a need to reset the radii back to their original regular grid (sections "A", "B" and "C" of the socket shapes). This nonhomogeneous scaling routine also produces changes in the cross-sectional shape, which are not desired outside the limits of the brim. On the other hand, the **Adjust Bulk** is performed by radial scaling rather than cartesian components. This type of scaling shifts the area without a change in the cross-sectional shape (tissue distribution).

In order to provide a smooth transition between the brim **Scale** procedure and the socket **Adjust Bulk** procedure, transition factor F3 (*equations 14, 15, and 21 through 24*) is gradually increased from the value of 0.0 to +1.0 over the extent of the transition gap. The TG starts at the level of the 10th cross-section⁴⁴ (CS -10) below the Ischial Gluteal Shelf, independent of the length or muscle mass of the residuum, and proceeds distally covering 25% of the residuum length.⁴⁵ The distal limit (tgds) and the

⁴⁴The ischial gluteal shelf is referred as cross-section or slice number 0 (coordinate 0.000); all the slices towards the distal end are referred as negative numbers whereas proximally, they are positive. When referring to slice -40 we know that is on the distal portion of the socket; dividing this number by the corresponding pitch (0.250 cm), we obtain its real distance from the **IGS** (-10.000 cm).

⁴⁵Distance from the ischial tuberosity to the distal end of the residuum.

number of slices within the transition gap (gaplevels) are calculated based on the residuum length (RL) and the new pitch between slices. Once the upper (tgp_{xe}) and lower (tgd_{se}) limits of the **TG** are set, the socket is divided into 5 Sections (fig. 7.1) with the following characteristics:

1. Section **A**: Proximal portion of the brim, from the proximal end of the socket to the Ischial Gluteal Shelf (**IGS**, CS 0). Scaled horizontally by the cartesian components scaling routine, vertically by the longitudinal scaling routine (PH).
2. Section **B**: Distal portion of the brim, from the **IGS** (CS 0) to the upper limit of the **TG** (tgp_{xe}, CS -10). Scaled horizontally by the cartesian components scaling routine, vertically by the longitudinal scaling routine (IFLB).
3. Section **C**: Transition gap, **TG** (factor F3), extending from its upper limit (CS -10) to the lower limit (tgd_{se}) of the **TG**. Although the horizontal scaling is preformed independently to X and Y cartesian components along this section of the socket, a gradual transition takes place from the **Scale** procedure to the **Adjust Bulk** procedure.⁴⁶ Scaled vertically by the longitudinal scaling routine (IFLB). The shape blending routine, which starts in this section and proceeds distally, depends on the factor F3 (*equations* 21 through 24).
4. Section **D**: Belly of the socket, embracing from the lower limit of the **TG** to the upper portion of the end-cap. Scaled horizontally by the radial scaling factor (**Adjust Bulk** procedure). Scaled vertically by the longitudinal scaling routine (IFLB). From this point on, the blending of the shapes depends only on the weighting factor ω and not on factor F3 which maintains its value of +1.0.
5. Section **E**: End-cap, which covers the last 5 cm of the distal socket. The horizontal and vertical scaling are performed as in the section "D".

⁴⁶The F1_x and F1_y scaling factors are modified (*equation* 14 and 15) in order to reach the value of the F2 scaling factor which corresponds to the distal end of the **TG**.

7.3.2 Measurement sites.

Each of the cross-sectional areas obtained from the residuum in addition to its perineal circumference are referred as *measurement sites*. Each *measurement site* is composed of the area and its location relative to the ischial tuberosity. The acquisition of those areas can be performed by the use of the anthropometric rings, measurement tape or any other technique. These areas are used to obtain the scale (F2) and weighting factors (ω) for the three shapes of the subgroup. Once these two factors are determined for each *measurement site* (in conjunction with the transition factor, F3), these are transferred to other cross-sections between consecutive *measurement sites* by linear interpolation depending on the number of cross-sections between them. The two transverse scaling routines (sections 7.3.3 and 7.3.4.) and the blending routine (section 7.3.6) make use of these 3 factors (ω , F2, F3) at each slice to perform the necessary cross-sectional adjustment to the area and shape for each of the three reference shapes.

7.3.3 Radial scaling factor, F2.

In the **Scale** procedure (section 7.2), cross-sectional scaling of sections "A" and "B" of the socket is performed using the cartesian X and Y coordinates rather than by radial scaling. Throughout the Transition Gap (section "C"), the the scaling is performed in the same fashion. The two independent scaling factors that modify the X and Y coordinates, are calculated by obtaining the **ML** and **AP** dimension ratios, whereas the radial scaling factor used in sections "D" and "E", is obtained from the square root of the ratio of two cross-sectional areas (*equation 13*). As the scaling routine proceeds distally within the TG, the two independent scaling factors ($F1_x$ and $F1_y$) are modified to become equal⁴⁷ to the radial scaling factor (F2) corresponding to the cross-section at the end of the Transition Gap (tg_{dse}), thus representing a single radial scaling factor. The radial scaling factor (F2) for each slice (cross-section "j") along the shape for each of the three reference shapes is obtained using *equation 13*, where "res" represents residuum and "sh" reference shape:

⁴⁷ At the distal end of the transition gap (tg_{dse}), factors $F1_x$ and $F1_y$ are equal to F2 for that particular cross-section.

$$F2_j = \sqrt{\frac{Area_{res\ j}}{Area_{sh\ j}}} \quad (13)$$

The two independent factors $F1_x$ and $F1_y$ are independent for each of the three shapes, but remain constant along the shape, whereas the radial scaling factor $F2$ changes constantly within the shape. However, within the *TG*, the $F2$ factor used in equations 14 and 15 corresponds to the distal limit of the transition gap (*tgds*). One other factor ($F3$) is included in the equations 14 and 15, this represents the transition factor within the *TG*, ranging from 0 to +1.0, and increasing by linear fashion as the *Scale* procedure is replaced by the *Adjust Bulk* procedure.⁴⁸

The scaling in Section "C" is achieved by implementation of equation 14 and 15 as follows:

$$X_j = [F1_x + F3_j(F2 - F1_x)] * R_{\alpha_j} \cos \alpha \quad (14)$$

$$Y_j = [F1_y + F3_j(F2 - F1_y)] * R_{\alpha_j} \sin \alpha \quad (15)$$

where:

$F2$: Radial scaling factor corresponding to the cross-section at the distal end of the *TG* (*tgds*).

X : Radial component in the X axis (mediolateral).

Y : Radial component in the Y axis (anteroposterior).

$F1_x$: Scaling factor for the X radial component within the brim portion.

$F1_y$: Scaling factor for the Y radial component within the brim portion.

$F3$: Transition Gap, transition factor.

R_j : Radius to be scaled.

α : Angular location of the particular radius within the cross-section.

j : Slice number (within the *TG*, section "C").

⁴⁸The factor $F3$ is obtained by gradual increments starting from 0 and raising its value by the ratio of 1 divided by the number of slices within the *TG*.

7.3.4 Socket Belly Scaling

For this part of the socket (sections "D" and "E"), the scaling routine is simplified to one equation, and the resulting radii maintain their original structure with 36 radii 10 degrees apart. The radial scaling will only depend on factor F2 for all the 36 radii of the particular slice. The new scaled radius is obtained by *equation 16*:

$$R'_{\alpha j} = F2_j R_{\alpha j} \quad (16)$$

7.3.5 Weighting Factor, ω .

Once the three reference shapes have been scaled to match the residuum's cross-sectional areas, each model will have the area required by the residuum but with it's own particular shape. The final primitive socket shape will emerge from the blending of these three particular shapes based on the TG factor (F3) and a shape weighting factor (ω).

In order to determine the shape "weighting" factor for the blending routine, where the three reference shapes are blended to produce the final cross-sectional shape at each slice level, the cross-sectional areas of the original reference shapes are weighted by pairs⁴⁹ with respect to the residuum's cross-sectional area at the same level for each of the *measurement site* (slice number "j" which corresponds to each of the *sites*). Two weighting factors are obtained from *equation 17* and *equation 18* as follow:

$$\omega_{Aj} = \frac{\text{residuum}_j - \text{Fat}_j}{\text{Average}_j - \text{Fat}_j} \quad (17)$$

$$\omega_{Bj} = \frac{\text{residuum}_j - \text{Average}_j}{\text{Skinny}_j - \text{Average}_j} \quad (18)$$

In *equation 17* (or *equation 18* with it's respective variables), if the residuum's cross-sectional area is located between the "fat" or "average" shape respectively, ω_A will

⁴⁹The three reference shapes are divided into two pairs of "large" and "small" areas, Fat-Average (pair A) and Average-Skinny (pair B). With this, four weighting factors for each slice are calculated.

have a value ranging from 0 to +1.0 depending on how close it's area is with respect to the "average" area; the closer it is, the larger the value of ω_A . When ω_A is 0 (*equation 17*), the cross-sectional area of the residuum is exactly the area of the "fat" shape. When ω_A is +1.0, the cross-sectional area of the residuum is exactly the area of the "average". When ω_A its negative, its assumed that the residuum's cross-sectional area is larger than the "fat", whereas if ω_A is $> +1.0$, the residuum's area is smaller than the "average" shape. When ω_A is < 0 , the residuum's cross-sectional area is beyond the "fat". In this case the final slice shape will be congruent to that of the "fat" reference shape but with a larger area. In similar manner, when $\omega_B \geq +1.0$, the residuum's cross-sectional area is equal or beyond the "skinny", in this case the final slice shape will be congruent to that of the "skinny" reference shape of the particular subgroup.

Depending on which single reference shape is selected by the *Pick* procedure (section 7.1) then, for each slice, only one of the weighting factor (ω_A or ω_B) will have a value between 0 and +1.0. This factor will determine three things: the two shapes to be blended (pair A or pair B), the weighting of each shape towards the final cross-sectional shape⁵⁰ (ω_A , ω_B , ω'_A or ω'_B), and the pair of blending *equations* (21, 22, 23 or 24) to be used (section 7.3.6). The weighting factor describes the tendency of the residuum's cross-sectional area to shift between a "pair" of reference shapes, and in fact will indicate if that cross-sectional area shift is towards a "larger" or "smaller" area with respect to the selected reference shape.

Equations 17 and 18 determine the weighting factor (ω) when the single reference shape selected is either the "fat" or the "average", and the residuum's cross-sectional area shifts from the "larger" to the "smaller" area. When the selected reference shape is either the "average" or the "skinny", and the cross-sectional area of the residuum shifts from the "smaller" towards the "larger" area along the socket, the weighting factors are reversed by *equations 19 and 20* as follow:

$$\omega'_{Aj} = 1 - \omega_{Aj} \quad (19)$$

⁵⁰If the "fat" shape is the single reference shape selected: when ω_A is $> +1.0$, then ω_B will be used with *equation 23*. When $\omega_B < 0$, then ω_A is used with *equation 21*.

$$\omega'_{Bj} = 1 - \omega_{Bj} \quad (20)$$

Equations 19 and 20 are not frequently used, due to the cylindrical or conical longitudinal shape of the residuum, which presents, when compared to the reference socket shapes, a reduction rather than an increase in cross-sectional area as you proceed distally.

7.3.6 Blending of the shapes

Within the transition gap exists a second integration, this corresponding to the blending of the three socket shapes to be used within the **Adjust Bulk** procedure. This second integration (mediated by the TG factor F3) represents the gradual introduction of the socket's shape weighting factor (ω) into equations 21 through 24. It is not until the distal end of TG, when F3 reaches its maximum value of +1.0 and no longer affects the weighting factor ω , that the **Scale** procedure is completely replaced by the **Adjust Bulk** procedure. This blending routine is based on equation 21, 22 23 or 24:

$$R'_{ij} = \sqrt{[1 - F3_j \omega_{Aj}] R_{ij}^2 \text{ fat} + F3_j \omega_{Aj} R_{ij}^2 \text{ average}} \quad (21)$$

$$R'_{ij} = \sqrt{[1 - F3_j \omega'_{Aj}] R_{ij}^2 \text{ average} + F3_j \omega'_{Aj} R_{ij}^2 \text{ fat}} \quad (22)$$

$$R'_{ij} = \sqrt{[1 - F3_j \omega_{Bj}] R_{ij}^2 \text{ average} + F3_j \omega_{Bj} R_{ij}^2 \text{ skinny}} \quad (23)$$

$$R'_{ij} = \sqrt{[1 - F3_j \omega'_{Bj}] R_{ij}^2 \text{ skinny} + F3_j \omega'_{Bj} R_{ij}^2 \text{ average}} \quad (24)$$

where:

R_i = Radii of the modified reference shapes.

R'_i = New radii.

F3 = Transition gap, transition factor.

ω_A = Weighting factor for pair "A".

$\omega'_A = 1 - \omega_A$

ω_B = Weighting factor for pair "B".

$\omega'_B = 1 - \omega_B$

j = Cross-sectional or slice number.

When the "fat" shape is selected by the first step of the CASD system, *equations* 21 and 23 are used as indicated by the ω_A and ω_B values.⁵¹ When the selected shape is the "average", then *equations* 22 and 23 are used with ω'_A and ω_B respectively. In the last case, when the "skinny" shape is selected, then only *equation* 24 is used with ω'_B .

7.4 End-Cap, distal end of the socket.

The fourth step of the CASD system, *End-Cap*, adds a preselected end to the distal end of the socket (section "E") to account for different characteristics of the residuum (fig. 7.1). For the purpose of this thesis, and in order to manufacture the prosthetic socket for the fitting trials, a provisional "compress-end" routine was designed to implement the above step. This routine simply sets the proximal end of the *End-cap* (section "E" of the socket) 5 cm shorter than the residuum's length. Then, collapses the cross-sections of the primitive socket shape located distally from the proximal limit. With this, section "E" of the socket (with a length of 5 cm) is composed of x number of cross-sections compressed, but evenly spread along the length of this section, thus shifting the end of the socket to the required location.

Once the shapes have been blended along the socket, and the distal end modified by the "compress-end" routine, the last routine required to define the primitive socket shape is the longitudinal interpolation to reset the cross-sectional spacing to the original pitch of 0.25 cm. This is done by linear interpolation between the radii of adjacent slices.

⁵¹When $\omega_A < 1$ then *equation* 21 is used. When ω_A rises above +1.0, then the scaling routine shifts to *equation* 23 until ω_B turns negative.

7.5 Adduct Femur, femoral alignment.

The last step of the CASD system, **Adduct Femur**, adducts the lower portion of the socket according to the prosthetist's specification with respect to the femur longitudinal axis position and alignment requirements. This last step (yet to be designed), did not form part of the thesis, and thus, will not be discussed here.

CHAPTER 8

ACCURACY OF THE PROCEDURE DESIGNED

To assess the accuracy of the *Adjust Bulk* procedure, an above-knee amputee was measured and fitted with a socket designed by the computer aided socket design procedure developed in this thesis. Anthropometric measurements taken from the amputee, provided the necessary information by which the selected subgroup of reference shapes was adjusted to accommodate particular differences of the residuum's tissue volume. The resultant socket was fitted and compared with two sockets produced by conventional techniques. A volunteer patient was found with the help of prosthetists at the Shaughnessy Hospital Prosthetic Shop.

8.1 Preliminary data acquisition

Measurements were taken from an above-knee amputee (who will be referred to as *Patient*) according to the procedures described in section 6 and also as outlined in this section. The purpose of this first session was to obtain three information packages:

1. Anthropometric measurements from the *Patient* considered necessary for the production of the socket (table 8.1).
2. Topographic representation of the residuum obtained by casting the residuum (shape-1).
3. An impression of the socket currently worn by the *Patient* (shape-3).

From the data obtained in the first session, a new socket shape (shape-2) was produced by the traditional socket fabrication procedure (shape produced by James Foort) to be compared with the shape produced by the CASD system.

The circumferential measurements⁵² (CIR) obtained from the *Patient* (shown in table 8.1) and the plaster impression from the residuum (shape-1, fig. 8.2), were taken by an experienced prosthetist (J. Foort) while the *Patient* was lying down on his left side relieving the residuum from any load but its own. These circumferences were taken

⁵²These measurements were taken before the *Patient* was fitted with the adjustable-brim to take the impression of the residuum.

TABLE 8.1: Patient's Data.

PATIENT'S DATA

Date: March 05, 1987
 Year of amputation: May 1978
 Cause: Train accident
 Transfemoral side: Right

Residuum characteristics:
 Tissue quality: soft
 Maturation: complete
 Shape: tapered

Linear dimensions taken by caliper and measurement tape:
 AP dimension: 3 13/16" (9.7 cm)
 ML dimension: 6" (15.2 cm)
 Rectus femoris-Projected tuberosity: 18.7 cm
 Greater trochanter-Distal femur: 27.9 cm
 Distal femur-Distal residuum: 0
 Greater trochanter-Lateral tibial plateau: 48.3 cm
 Ischial tuberosity-Lateral tibial plateau: 44.4 cm
 Lateral tibial plateau-Lateral maleolus: 44.4 cm
 Rectus femoris-Anterior superior iliac spine: 5.1 cm
 Residuum length: 24.1 cm

Scars: Scar across the distal end of the residuum, reaching 5 inches above on the lateral side, significantly invaginated. Reaching 2 inches on the medial side, but not significant.

Circumference measurements (Trial # 1) taken from the ischial tuberosity to distal end of the residuum at level one inch apart using measurement tape were:

TRIAL # 1		
Location (cm)	Circumference (cm)	Approximate Area (cm ²)
0.0	49.5	195.2
2.5	48.3	185.3
5.1	45.7	166.3
7.6	43.8	152.8
10.2	41.3	135.6
12.7	38.1	115.5
15.2	34.3	93.6
17.8	29.2	67.9
20.3	22.9	41.6

using a measuring tape, placing it in a series of parallel transverse planes (relative to the patient) one inch apart along the longitudinal axis of the nude and unloaded

residuum. The tape was placed softly on the residuum producing no tissue distortion. Based on those circumferences (CIR), and assuming that they represented the perimeter of cross-sectional circular slices, the cross-sectional area (*equation 25*) was calculated.

$$Area = \left(\frac{CIR^2}{4\pi} \right) \quad (25)$$

Beside these measurements, there were 6 extra circumferential measurements taken from the residuum. For this second set of circumferential measurements (Trial # 2), the *Patient* was placed in similar position as for trial # 1, measurements were taken by placing plastic zip locks straps (0.9 cm wide) in parallel planes around the residuum. These plastic straps gave an impression of the effect expected from the use of the anthropometer device to be designed. The cross-sectional areas were calculated using *equation 21* obtaining the results shown in table 8.2 under trial # 2.

8.2 Implementation of the Anthropometric Device

Once the anthropometric device (rings) was produced, acquisition of the cross-sectional areas was repeated (second session, June 10, 1987) in order to assess the feasibility of the device. These new measurements, obtained with the use of the rings, were taken from the residuum under two conditions: first, placing the rings on the nude unloaded residuum (trial # 3, table 8.2), second, taking the measurements when the amputee was wearing a prosthetic sock⁵³ on the residuum loading it radially (trial # 4, table 8.2). These third and fourth sets of cross-sectional measurements were taken by a different investigator who was not experienced in prosthetic fitting (R. Torres-Moreno), and compared with the ones taken 3 months before by an experienced prosthetist.

When the amputee was wearing the sock, the tissue had more consistency and causing soft tissue shifting towards the proximal end. When using the rings with fixed area, measurements were simpler and faster.

During the second session, the *Patient* reported a gain of 15 pounds with respect to his body weight three months before. Due to the fixed area of the rings and different

⁵³Prosthetic sock normally used by amputees to provide cushioning and better fit.

TABLE 8.2: Cross-sectional area acquisition, trials # 2, 3 and 4.

TRIAL # 2

Location (cm)	Area (cm ²)
0.2	181
4.6	165
8.4	142
12.9	113
16.7	80
20.5	59

TRIAL # 3

Location (cm) *	Code	Area (cm ²)
1.7	K11	186.3
6.2	I9	156.6
10.2	G7	129.5
13.2	F6	113.1
14.7	E5	98.5
17.7	C3	69.7

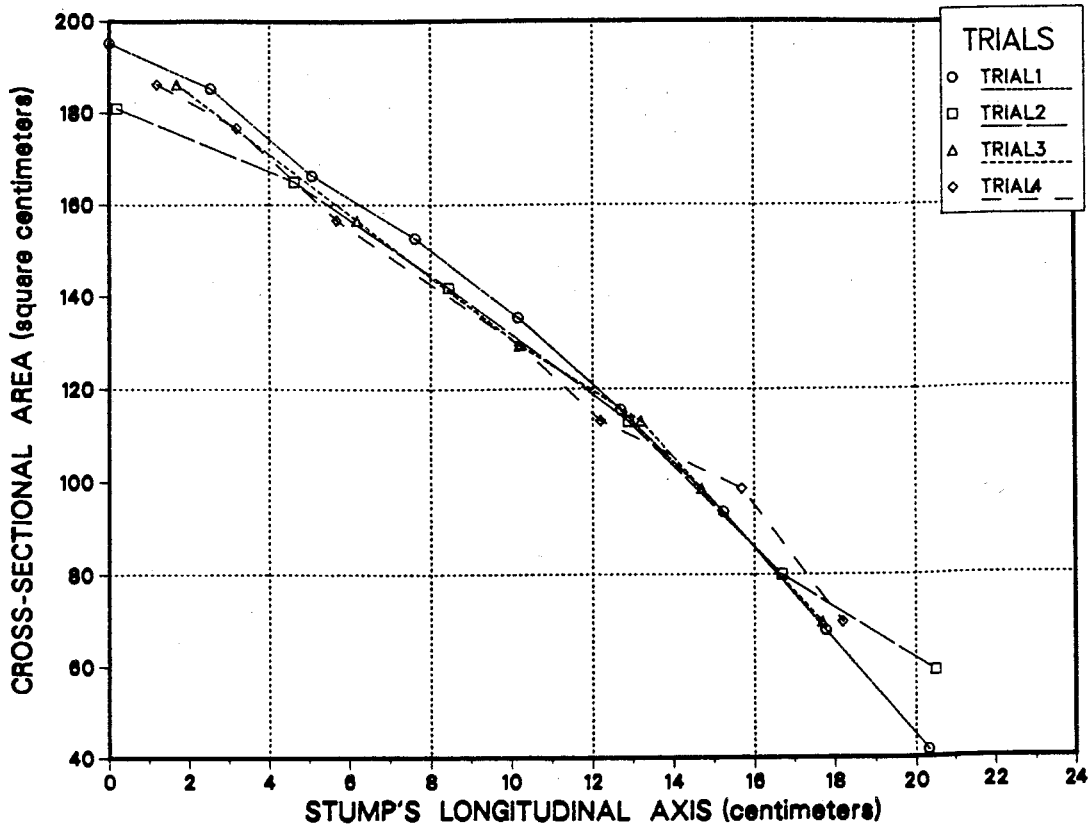
TRIAL # 4

Location (cm) *	Code	Area (cm ²)
1.2	K11	186.3
3.2	J10	176.7
5.7	I9	156.6
10.2	G7	129.5
12.2	F6	113.1
15.7	E5	98.5
18.2	C3	69.7

* accurate to ± 0.05 cm

measuring technique, measurements were taken at different sites for each of the four trials; nevertheless, the measurements were reproducible in both cases. Similar measurements were obtained by the experienced prosthetist 3 months before; despite the change of body weight, the measurements were practically the same for any given level (fig 8.1).

**C.A.S.D. FOR ABOVE-KNEE AMPUTEES
CROSS-SECTIONAL AREAS DATA ACQUISITION**



Note: The set of 28 data points acquired were used to calculate the best fitting nonlinear regression line and the standard error of the estimate ($S_{y,x}$), with the following results:

$$Y = 356.3 - 164.5 e^{0.031(X)}$$

$$S_{y,x} = \pm 0.94$$

Figure 8.1: Cross-sectional area acquisition along the length of the residuum. Data obtained in four trials as specified in section 8.1 and 8.2.

The acquired data was used to calculate the best fit regression line by the method of "least squares"; the variance (V) and the standard error of estimate (SE) for each of the four sets of cross-sectional areas were obtained and yielded results on table 8.3.

8.3 Production of the new Socket Shape

The first group of anthropometric measurements taken from the *Patient* during the first session (Table 8.1), in conjunction with the cross-sectional areas acquired in Trial #4,⁵⁴ were provided as data input to the CASD program. The appropriate subgroup of reference shapes was selected from the reference shape library based on the *Patient ML* dimension (15.2 cm) and the residuum length (24.1 cm) (subgroup # 4). From these three reference shapes of the subgroup (shapes 10ILF, 13ILA and 16ILK), only the closest to the tissue bulk (49.5 cm perineal circumference) was scaled and modified at the top portion of the socket by the *Scale* procedure (shape 10ILF). This routine was performed from the proximal end of the socket shape down to the proximal end of the transition gap (slice -10, refer to fig. 7.1) as described in section 7.2.

The three shapes of the selected subgroup were scaled and modified (blending of the shapes) by the *Adjust Bulk* procedure from the proximal end of the transition gap to the distal end of the socket (fig. 7.1) accordingly to the algorithms described in section 7.3. The end-product of these two procedures was then merged to form the primitive socket shape. The output of the CASD program produced the cylindrical coordinates (r , θ and z) of the 3-dimensional primitive socket shape to be produced and analyzed.

The CASD system programs (originally developed for the below-knee socket design) have the capacity to allow further interactive modifications of the primitive shape by the prosthetist to satisfy his judgement regarding relief of sensitive areas, extra "grip" in bulky tissue areas and data smoothing routines. For the purpose of this thesis, no modifications were applied to the primitive socket shape beside the "data smoothing"

⁵⁴ Set of cross-sectional areas obtained with the use of the rings when the *Patient* worn the wool sock.

TABLE 8.3: Regression lines for cross-sectional area (cm²) acquisition.

$$\begin{aligned} \text{Trial \#1: } Y &= 210.7 - 8.0 (X) \\ V &= 31.8 \\ SE &= 5.6 \\ n &= 9 \end{aligned}$$

$$\begin{aligned} \text{Trial \#2: } Y &= 181.9 - 5.9 (X) \\ V &= 90.5 \\ SE &= 9.5 \\ n &= 6 \end{aligned}$$

$$\begin{aligned} \text{Trial \#3: } Y &= 200.5 - 7.0 (X) \\ V &= 19.2 \\ SE &= 4.4 \\ n &= 6 \end{aligned}$$

$$\begin{aligned} \text{Trial \#4: } Y &= 196.0 - 6.6 (X) \\ V &= 18.0 \\ SE &= 4.2 \\ n &= 7 \end{aligned}$$

where:

Y = cross-sectional area.

X = longitudinal location distal from the ischial tuberosity.

routine⁵⁵ (refer to section 5.2) prior to the socket production. This shape was translated into a series of commands for the computer numerically controlled (CNC) milling machine (see section 2.1) and then carved from a block of polyurethane foam. This 3-dimensional negative socket mould was used to produce a polypropylene prosthetic socket by drape vacuum forming technique. The CNC milling process was carried out at M.E.R.U., and vacuum forming at Shaughnessy Hospital Prosthetic Shop.

A total of five three-dimensional socket shapes (listed below) were created in numerical form within the CASD system. Shapes 1, 2 and 3 (positive plaster models) were digitized, using the same technique as for the reference shapes, to obtain their cylindrical coordinates to be stored by the computer with shapes 4 and 5 for further analysis.

* **Shape-1:** A positive plaster model representing the residuum's topographic shape.

⁵⁵The data smoothing routine employed in the refinement of the Reference Matrix was implemented as an integral part of the CASD system software.

This shape was made by wrapping the residuum with plaster bandage to obtain its impression (refer to section 1.6). The positive plaster model was cast in the cavity formed by the adjustable-brim and the plaster bandage (fig. 8.2).

- * **Shape-2:** A positive plaster model was made⁵⁶ using conventional techniques. Hand sculpting (using rasps and plaster) the positive plaster model of the residuum (shape-1) so that a prosthetic socket could be made over it. These modifications were made by James Foort (prosthetist) (fig. 8.3).
- * **Shape-3:** A positive plaster model cast in the cavity formed by the socket presently worn by the *Patient* (fig. 8.4).
- * **Shape-4:** Cylindrical coordinates of the CASD primitive socket shape obtained from the socket modification procedures (chapter 7). No interactive modifications were applied to this shape prior to carving (fig. 8.5).
- * **Shape-5:** Cylindrical coordinates of the 3-dimensional socket shape obtained as result of the interactive modification of the shape-4 after the first fitting trial (fig. 8.6).

8.4 First fitting trial

On June 19, 1987, the *Patient* was fitted with the primitive socket shape (shape-4). The socket was placed on a jig which was adjusted to the *Patient* height. The *Patient* was asked to remove one of his socks⁵⁷ and to place the residuum inside the socket. The socket was loaded axially as the *Patient* leaned to his amputated side. Through the transparent walls of the socket, it was possible to see a total contact effect in the proximal half of the socket, whereas in the distal half, some of the areas were not providing appropriate support.

The particular position of the femoral bone⁵⁸ with respect to the residuum presented sensitive areas where pressure relief had to be provided. Even though the

⁵⁶This socket shape was not a final socket, it represented just the first attempt, requiring further modification after fitting trial.

⁵⁷The *Patient* worn two wool socks when using his present prosthesis.

⁵⁸The residual musculature was not wrapped around the the bone, and the distal end of the femur protruded from the protective muscle layers.

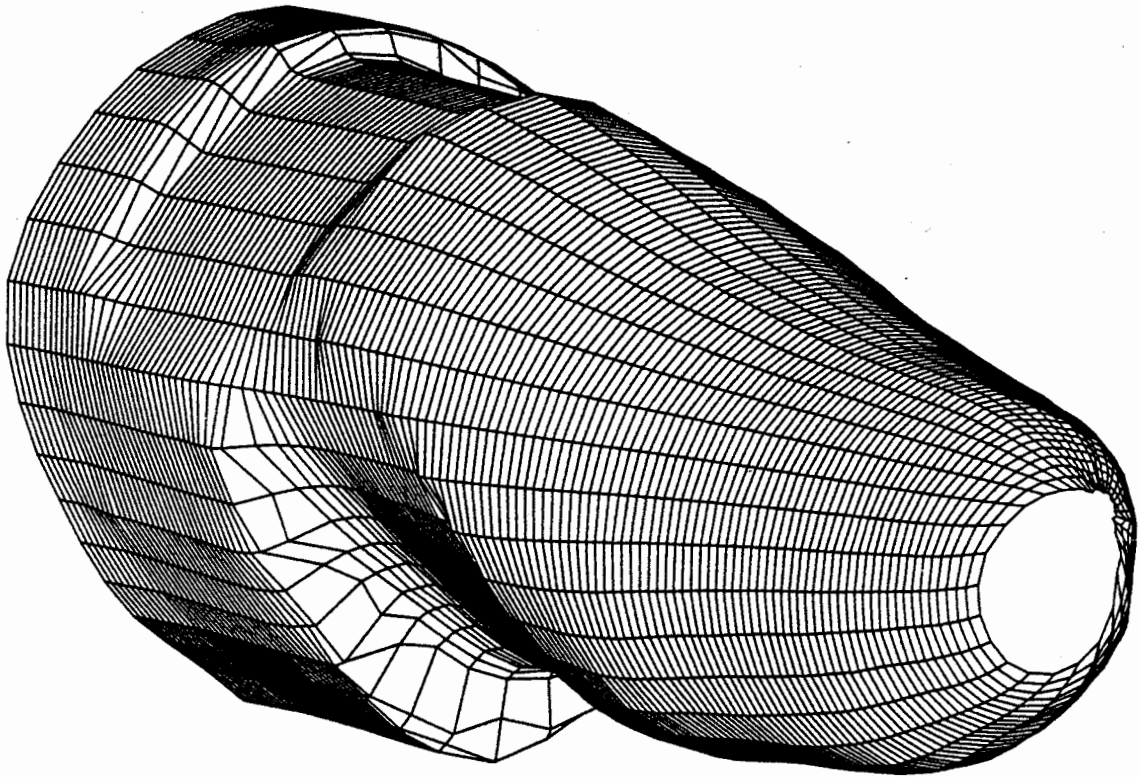


Figure 8.2: Three dimensional representation of *Shape-1*: A positive plaster model of the residuum shape.

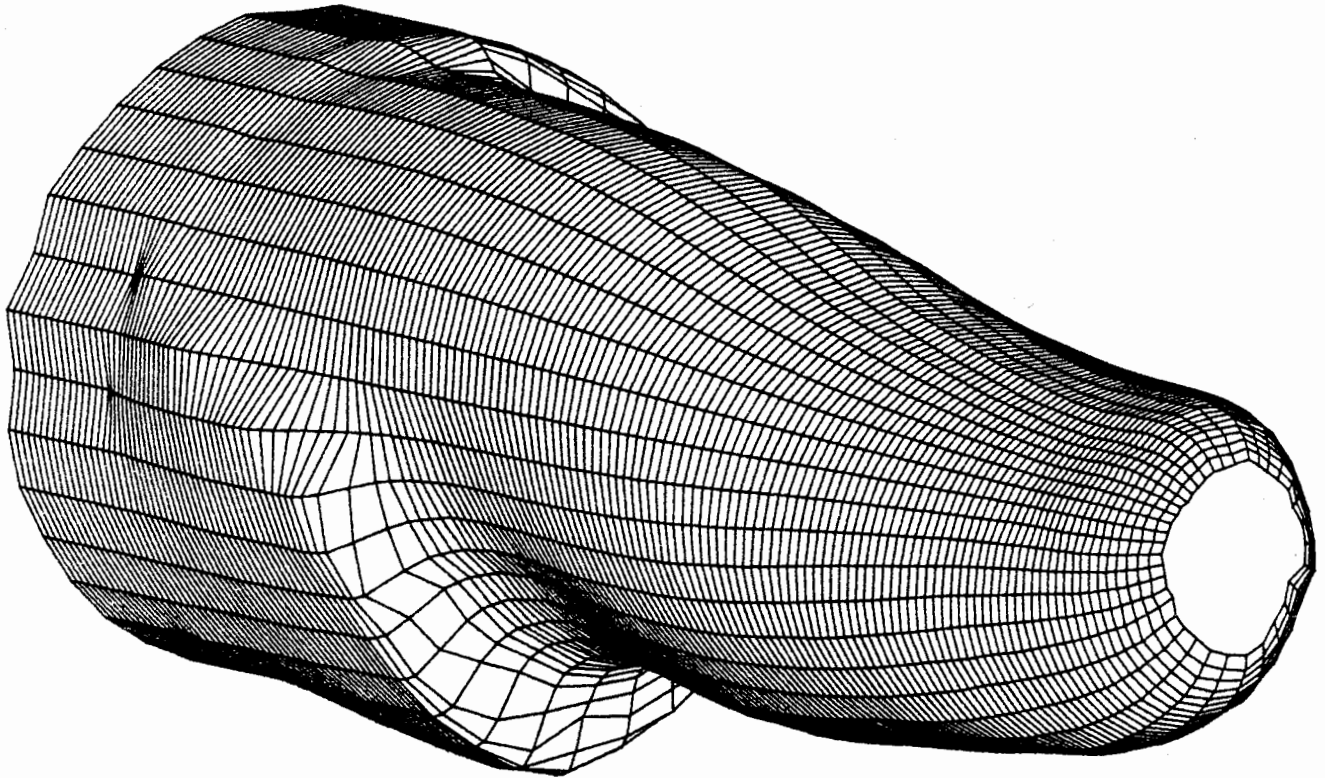


Figure 8.3: Three dimensional representation of *Shape-2*: A positive plaster model of the residuum modified by traditional techniques to provide a socket shape.

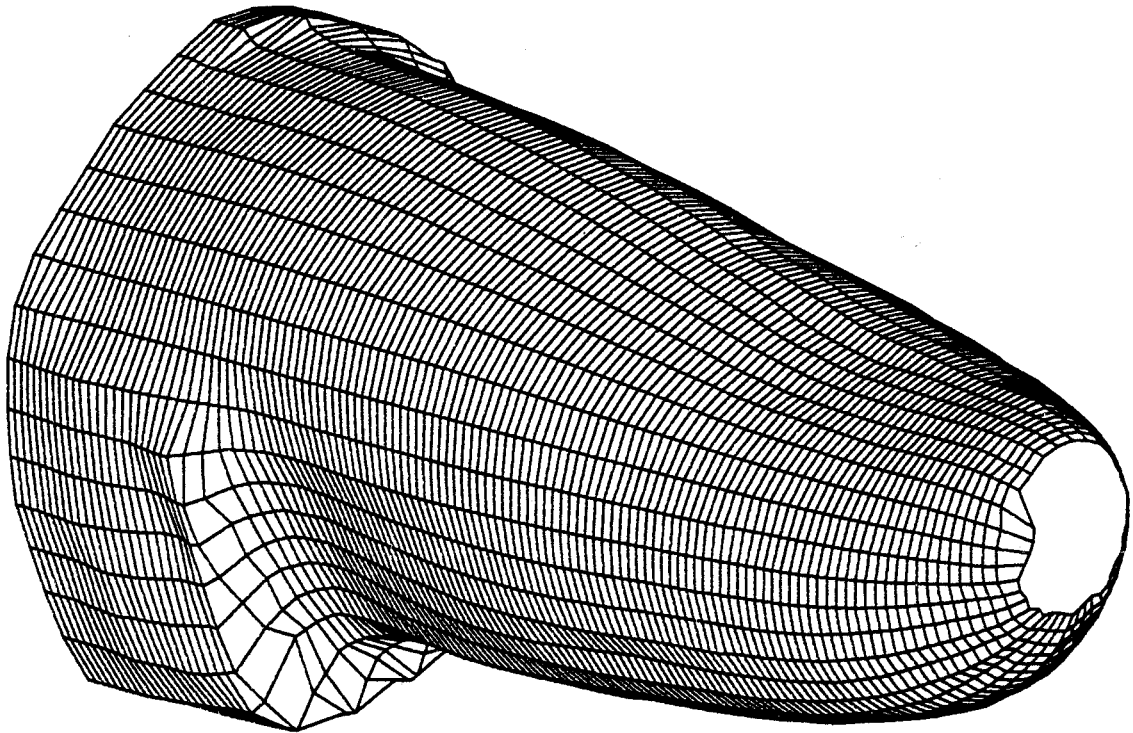


Figure 8.4: Three dimensional representation of *Shape-3*: A positive plaster model of the socket worn by the *Patient*.

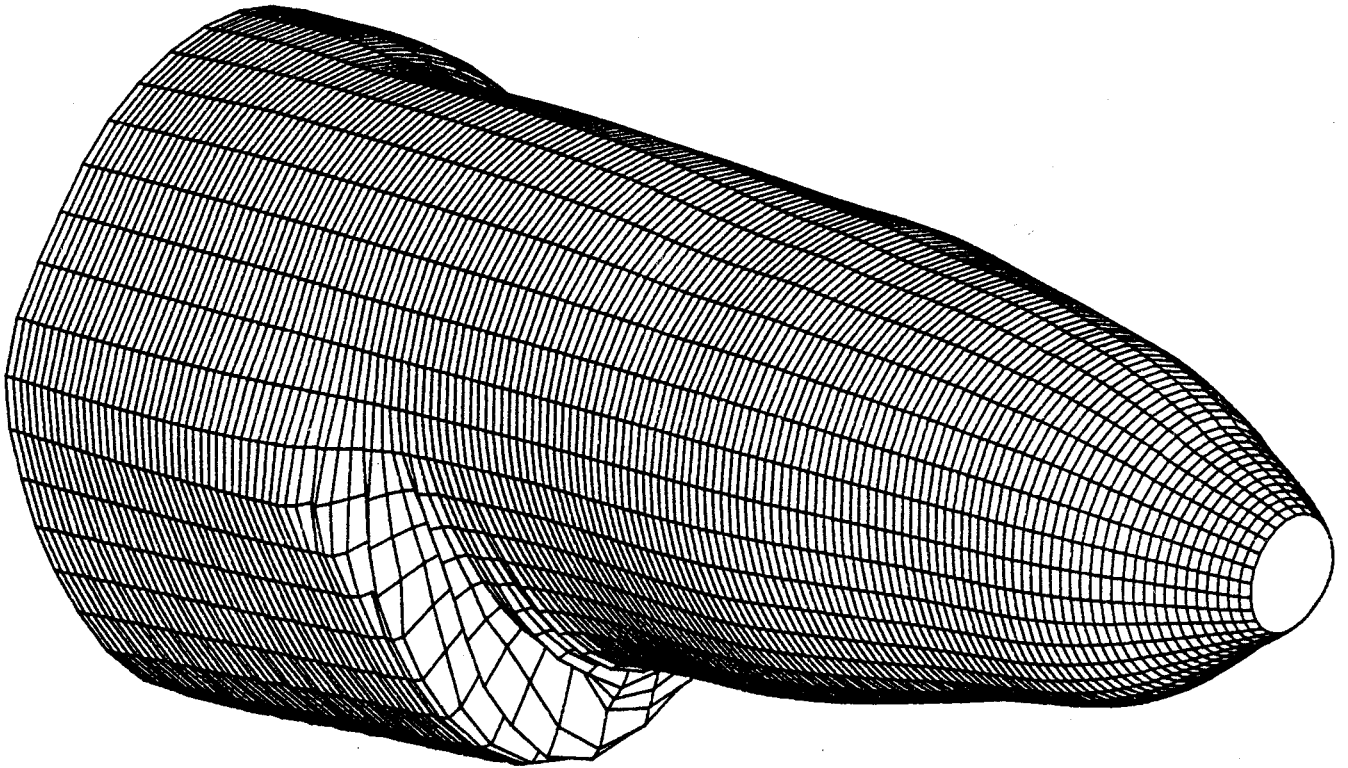


Figure 8.5: Three dimensional representation of the *Shape-4*: The CASD primitive socket shape computer by the socket modification procedures described in chapter 7.

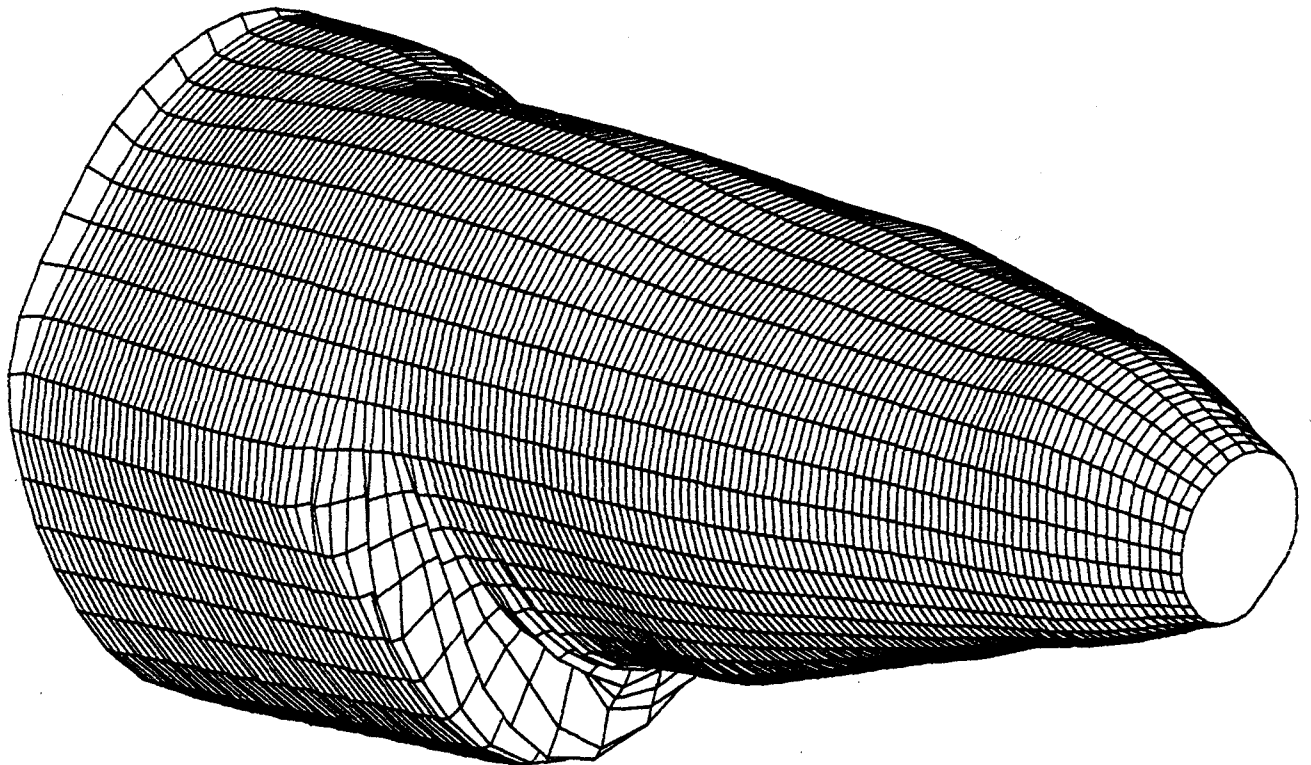


Figure 8.6: Three dimensional representation of the *Shape-5*: The CASD final socket shape produced as a result of interactive modification of Shape-4 within the CASD system after the first fitting trial.

socket had the same length as the unloaded residuum, the residuum when fitted within the socket did not reach the distal end. The reason for this was that the proximal portion of the socket supported the limb, limiting the depth of the fitting. Nevertheless, the fit was comfortable and the resultant pressure profile presented no inconvenience.

To locate and evaluate areas of the socket that did not provide appropriate support, the socket was partially filled with "alginate", then the naked residuum was placed inside the socket to produce a positive pressure inside the cavity. With this, the alginate was displaced from those areas where the fitting was snug, shifting towards sites of lower pressure (second impression of the residuum).

8.5 Production of the final socket shape

Once the second impression of the residuum was obtained, there were 5 specific modifications to be performed by the use of the interactive modifications routine of the CASD on the primitive socket shape (shape-4) in order to provide a better fitting socket. The modifications performed to the primitive socket shape were:

1. Decrease the socket length to reduce the excess volume not providing support at the distal end.
2. Provide relief to the lateral distal end of the socket where the femoral bone had very little soft tissue cushioning.
3. Provide anteromedial compression at the distal end to counteract the lateral relief and provide extra grip.
4. Curve medially the top portion of the lateral wall in order to exert firm pressure on the greater trochanter to provide mediolateral stabilization.
5. Adjust the ischial gluteal shelf in order to provide a horizontal bearing surface. With this adjustment, the appropriate radii of the medioposterior flare would be provided.

The primitive socket shape (shape-4) was then modified to account for the above shape discrepancies in order to create the final socket shape (shape-5). For this purpose, the cylindrical coordinates previously stored in the computer were used as input for the interactive modification routines of the CASD system. It is important to note, that the

last two shape discrepancies (4, 5) of the primitive socket shape emerged as a result of the *Scale* procedure. When the socket shape was scaled longitudinally to account for difference between the patient's femoral length (FL) and pelvis height (PH) with respect to the disarticulated knee model, the scaling routine distorted the curvatures which enlarged their radii of curvature.

8.6 Second fitting trial

The numerical data from the final socket shape (shape-5) was translated into a series of commands for the computer numerically controlled milling machine and carved from a block of polyurethane foam. The foam mould was then used to produce a polypropylene prosthetic socket by drape vacuum forming technique. In order to provide a more realistic evaluation of the performance and fitting of the CASD socket, the final socket was bonded to a prosthetic leg in order to be evaluated in a walking trial.

A walking trial was held at the Medical Engineering Resource Unit located in Shaughnessy Hospital. The artificial limb was adjusted to provide the required height and alignment for the *Patient*. The final CASD socket shape was worn by the *Patient* during a 35 minutes walking trial. The *Patient* stated that the socket provided a snug fit with no sensitive pressure points except for the tip of the femoral bone.

During the trial, adjustments were made to the harness and the alignment device as required for comfort and force transmission of the prosthesis. When the residuum was removed from the socket on completion of the trial, the residuum presented no pressure marks, reflecting a subjective evaluation of the adequate pressure distribution provided by that particular socket shape. The *Patient* expressed interest in a more extensive "home-trial" of the new prosthesis to provide a more accurate evaluation of the new device.

8.7 Comparisons Between Shapes

In order to quantify the differences in cross-sectional area between the five 3-D socket shapes, in addition to obtaining their respective cross-sectional areas (*equation 4*) and ER's (*equation 3*), ten paired comparisons (shape-"a" -vs- shape-"b") were designed:

1. Comp-1: **Shape-1** -vs- **Shape-2**
2. Comp-2: **Shape-1** -vs- **Shape-3**
3. Comp-3: **Shape-1** -vs- **Shape-4**
4. Comp-4: **Shape-1** -vs- **Shape-5**
5. Comp-5: **Shape-2** -vs- **Shape-3**
6. Comp-6: **Shape-2** -vs- **Shape-4**
7. Comp-7: **Shape-2** -vs- **Shape-5**
8. Comp-8: **Shape-4** -vs- **Shape-3**
9. Comp-9: **Shape-4** -vs- **Shape-5**
10. Comp-10: **Shape-5** -vs- **Shape-3**

For comparisons 4 and 9, the Root Mean Square (RMS) (*equation 26*) of the difference between corresponding radii for each of the cross-section were obtained, giving an indication of shape congruency. The RMS analysis for the other 8 comparisons could not be performed due to the differences in the location of the longitudinal axis within the shape. The modified reference shapes, the primitive socket shape (shape-4) and the final socket shape (shape-5) shared similar longitudinal axis alignment, represented by the axial axis of the polyurethane block from which they were produced. This axis location is also shared by the library of 27 reference socket shapes. The first two shapes (shapes-1 and 2) shared similar axial location because one emerged from the other, whereas shape-3, had an independent axial location with respect to the other shapes.

For each of the 10 comparison the difference in **ER** (ERD) (*equation 27*), Absolute Area (AAD) (*equation 28*), and the percentage of area "B" with respect to area "A" (A %) (*equation 29*) were obtained.

$$RMS = \sqrt{\frac{\sum_{i=1}^{36} (R_{ia} - R_{ib})^2}{36}} \quad (26)$$

$$ERD_j = ER_{aj} - ER_{bj} \quad (27)$$

$$AAD_j = Area_{aj} - Area_{bj} \quad (28)$$

$$A \% = \frac{Area_b}{Area_a} \times 100 \quad (29)$$

where:

a: shape-a in the comparison.

b: shape-b in the comparison.

j: corresponding cross-sectional level.

R_{ia} : raw radii of shape-a to be analyzed.

R_{ib} : raw radii of shape-b to be analyzed.

The objective of these comparisons was to obtain an evaluation of the **Adjust Bulk** procedure of the CASD system. To achieve acceptable results, the comparisons 6 and 8 between the socket produced by James Foort (shape-2) and the CASD primitive socket shape (shape-4), and the socket worn by the patient (shape-3) respectively, should produce a relatively small difference in cross-sectional area. Shape-2 produced by J. Foort was a first attempt: Prosthetist considered that, as with shape-4, it would require further modifications after a fitting trial.

A major difficulty in this procedures is to quantify the socket fit and comfort during the fitting trials and, to determine what is "acceptable" in terms of statistical results. To this end, it was assumed that the comparison 5 with respect to the cross-sectional areas between patient's own socket and that made by James Foort was indicative of an acceptable or "expected" range of deviation in fitting. The relative deviation of the of the CASD system primitive socket shape and the other sockets from the primary residuum shape (shape 1) was taken as indicative of the success of the CASD system in "modifying" the primary residuum data to produce a socket shape

adapted to weight bearing and the particular residuum's muscle mass.

8.8 Statistical Results

In figure 8.7, each of the 5 socket shapes is analyzed with respect to their cross-sectional areas. Shape-3 (solid line) is taken as an indicator of an "acceptable" fit with respect to the cross-sectional area and longitudinal tissue distribution along the socket. Differences in area between Shape-1 (circle as a symbol) and shape-3 (solid line) quantifies the appropriate modification of the residuum's cast to reach an acceptable fitting for a socket shape. In the traditional socket fabrication procedure (shape-2), these differences in area and volume have to be made by the prosthetist. Shape-2 (small dotted line, square symbol) represents the socket produce by a qualified prosthetist based on the plaster cast obtained from the *Patient*. The shape-4 (primitive socket shape) (regular dotted line, diamond) shows a close match in areas relative to the socket worn by the *Patient*.

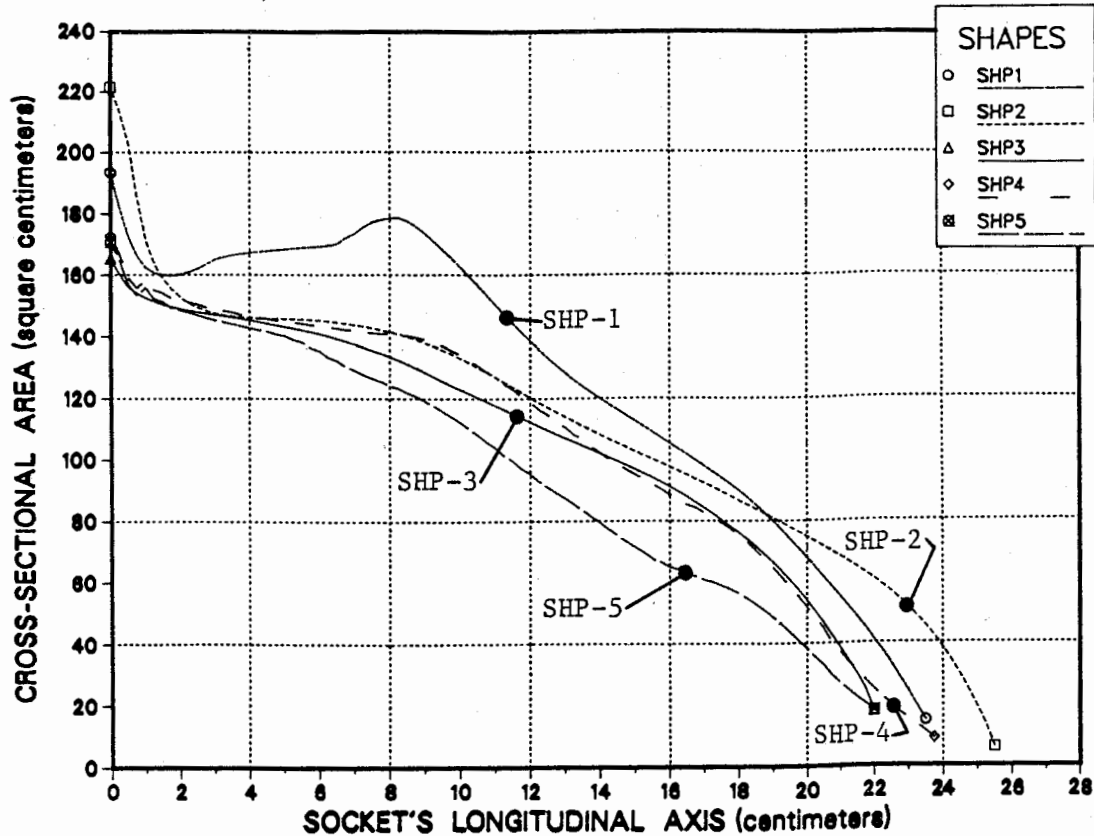
In the first plot in figure 8.8, shapes-2,3,4,5 are compared to shape-1 and expressed in percenatge of area (*equation 29*). The socket shapes show relatively similar areas in the proximal end. Proceeding distally, shape-2 produces excesive pressure relief whereas shape-5 provides a more snug fit in these areas. Similarly, the second plot shows shape-2 to be the largest socket volume, and shape-5 to be the smallest, particularly towards the distal end.

8.9 Differences in tissue orientation between the sockets

Although the five socket shapes do not share similar longitudinal axial alignment, it is possible to appreciate their differences in transverse and longitudinal tissue orientation within the socket (fig. 8.10 through 8.14). Each of these figures represents a view through the longitudinal axis of the socket shape, where 7 cross-sections at uniform location from the ischial tuberosity have been superimposed (refer to fig. 5.12).

The shape-3 (fig. 8.12) shows a quadrilateral shape which is maintained until CS -64 and then gradually shifts towards a circular shape at the distal end; whereas the

C.A.S.D. FOR ABOVE-KNEE AMPUTEES CROSS-SECTIONAL AREAS -VS- SOCKET LENGTH

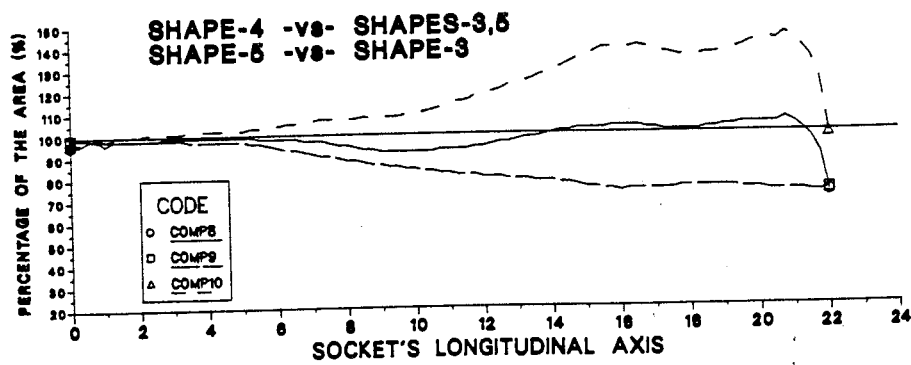
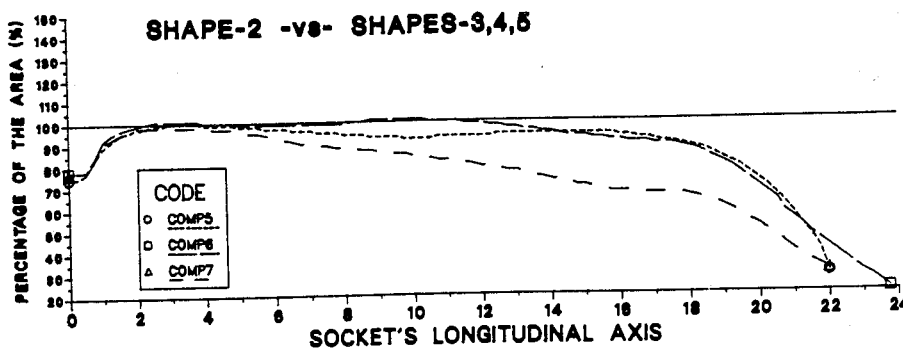
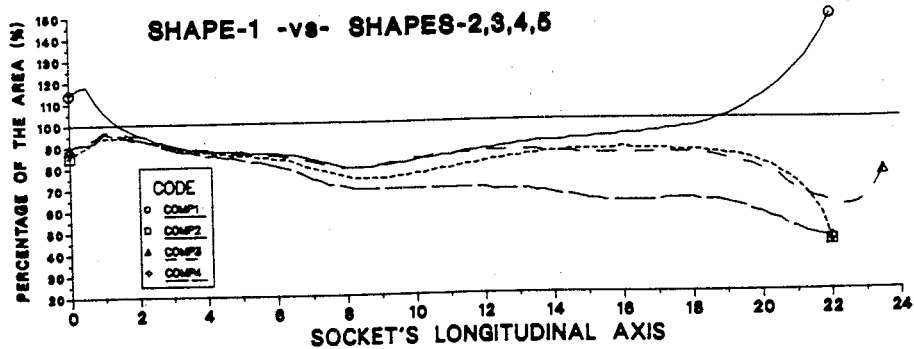


Note: Radial measurements for shapes-1,2 and 3 had two independent errors when digitized, a systematic error of +0.056 cm, and a random error of ± 0.036 cm. The smaller radii at the distal end of the socket, were more sensitive to the two errors than the larger radii located at the proximal end. For the two extremes of the socket (*ei.* radii of 3.5 and 7.8 cm respectively), the systematic error overestimated the area from +3% to +1.5%. All the areas calculated were within $\pm 1.8\%$ and $\pm 1.1\%$ for the smaller and the larger radii respectively. These area tolerances are applicable to figures 8.8 and 8.9 as well.

Shapes-4 and 5 were produced by a CNC milling machine, with an accuracy of ± 0.001 cm for a radius of 7.6 cm.

Figure 8.7: Cross-sectional area comparison between the 5 socket shapes.

C.A.S.D. FOR ABOVE-KNEE AMPUTEES PERCENTAGE OF AREA RESEMBLANCE BETWEEN SOCKETS



ALL THE UNITS ARE IN METRIC SYSTEM (centimetres)

Figure 8.8: Percentage of area resemblance between sockets.

C.A.S.D. FOR ABOVE-KNEE AMPUTEES

ER AND SHAPE RESEMBLANCE BETWEEN SOCKETS

ALL THE UNITS ARE IN METRIC SYSTEM (centimetres)

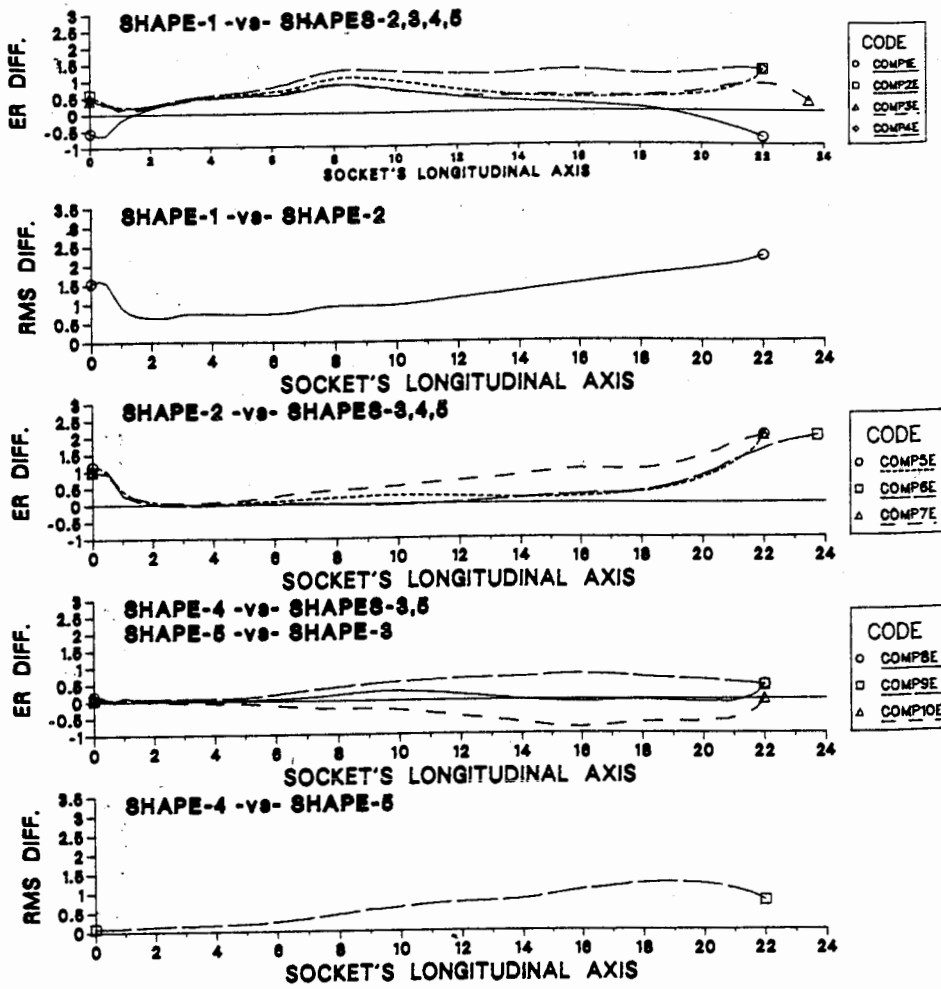


Figure 8.9: ER and shape resemblance between sockets.

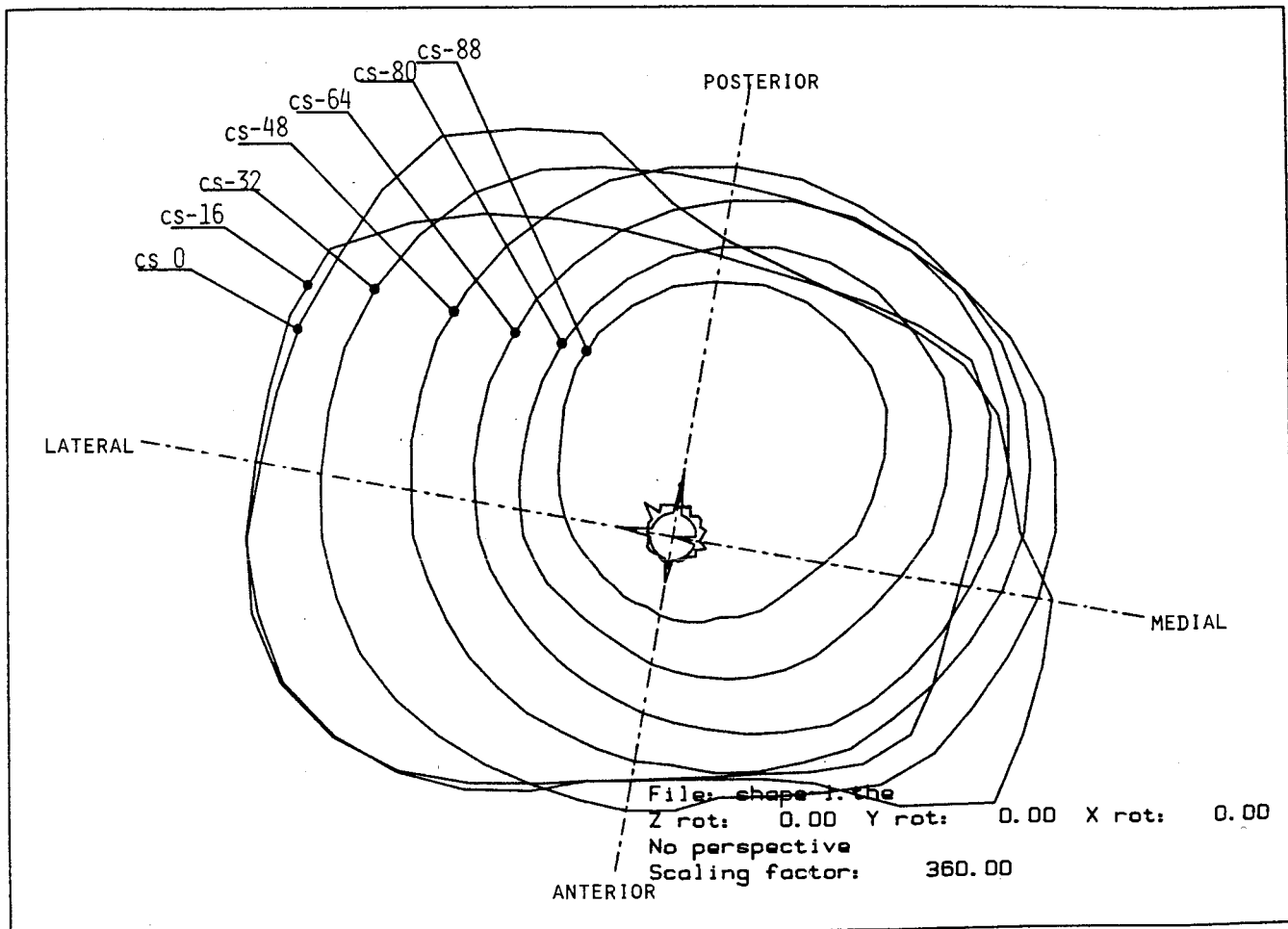


Figure 8.10: Vertical view through the longitudinal axis, showing the relative tissue orientation of *Shape-1* (plaster model of residuum).

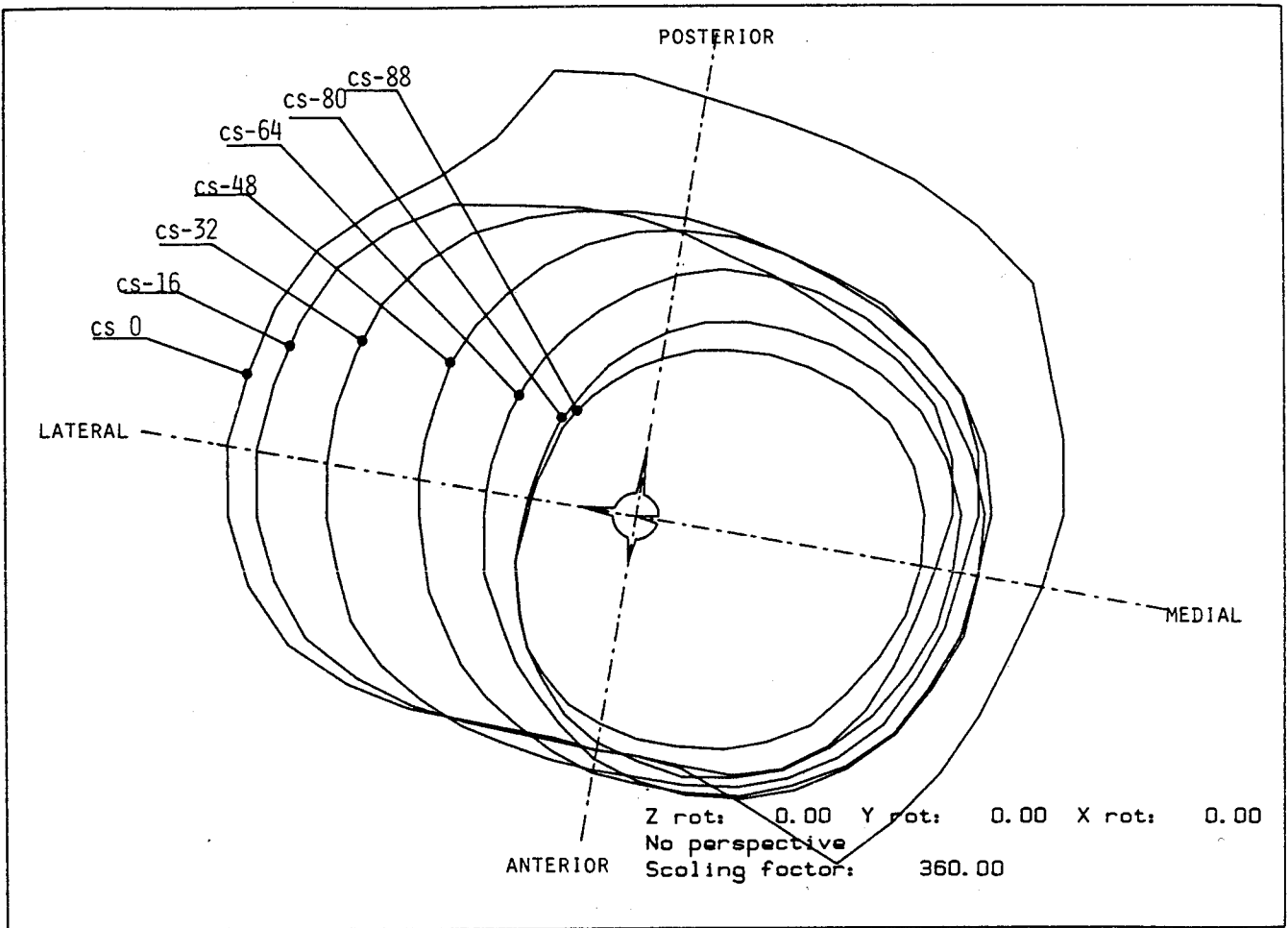


Figure 8.11: Vertical view through the longitudinal axis, showing the relative tissue orientation of *Shape-2* (socket shape produced by modification of shape-1 using conventional techniques).

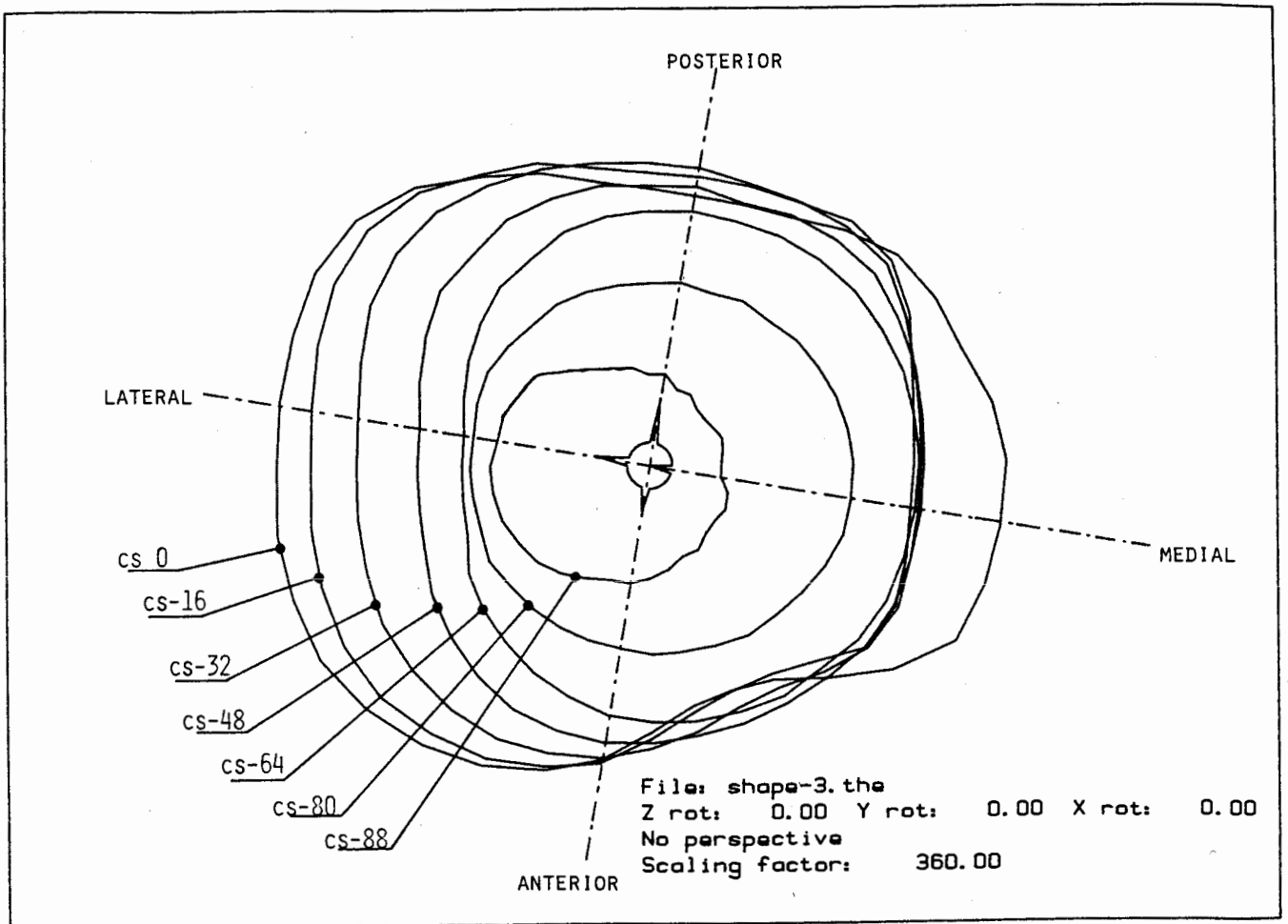


Figure 8.12: Vertical view through the longitudinal axis, showing the relative tissue orientation of *Shape-3* (socket worn by *Patient*).

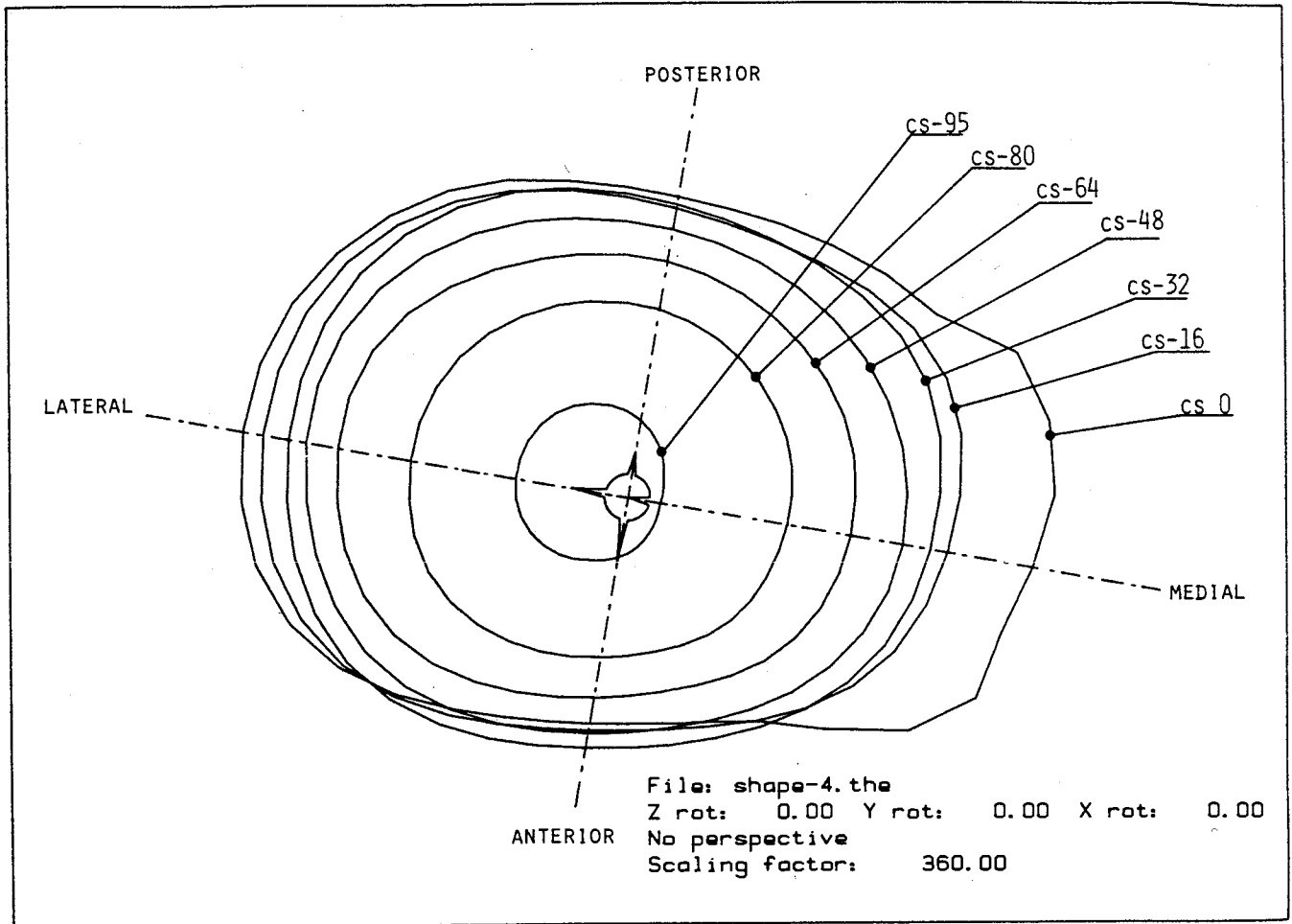


Figure 8.13: Vertical view through the longitudinal axis, showing the relative tissue orientation of *Shape-4* (CASD primitive socket shape).

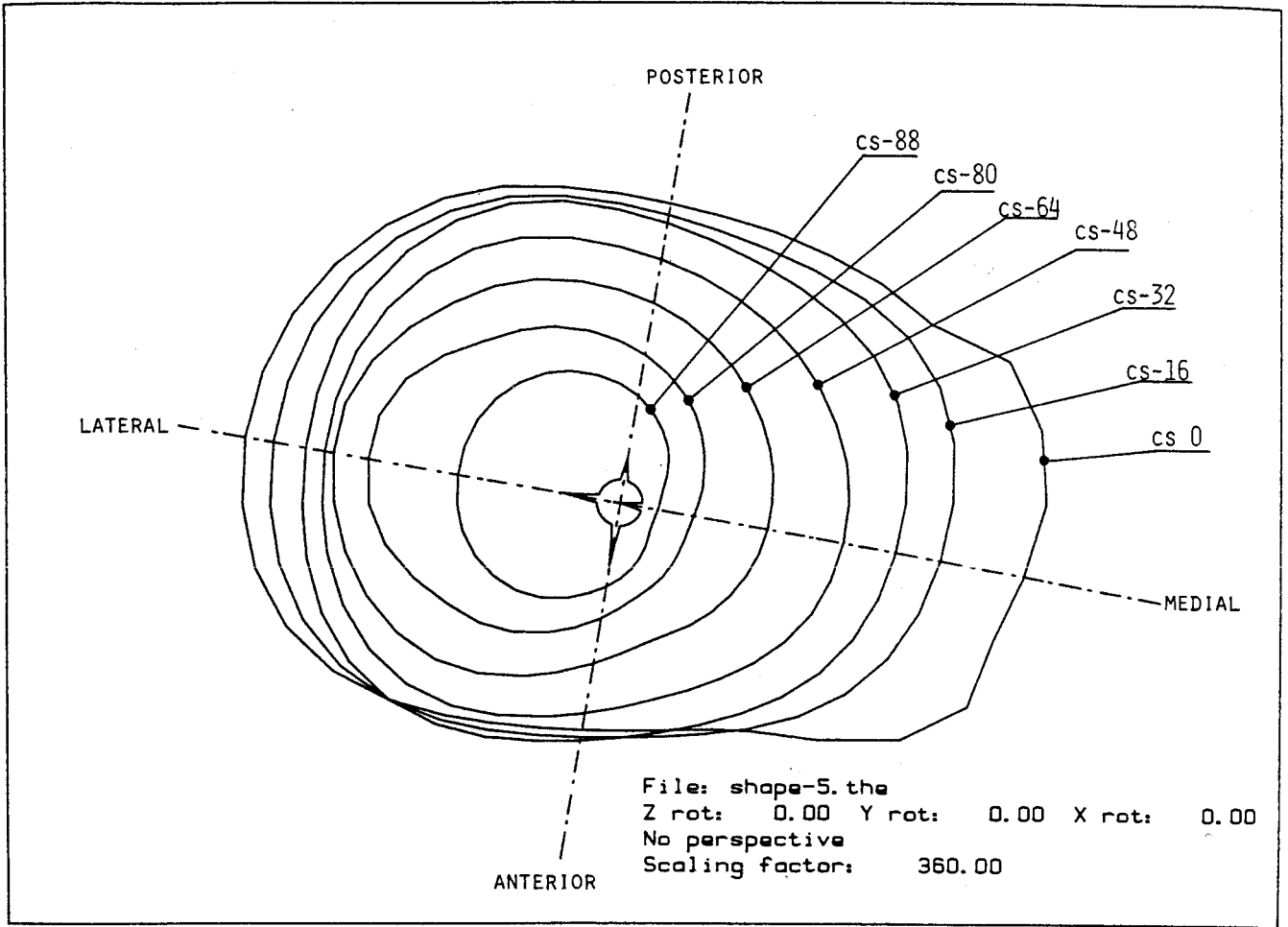


Figure 8.14: Vertical view through the longitudinal axis, showing the relative tissue orientation of *Shape-5* (CASD final socket shape).

Table 8.4: Dimensional comparison between socket shapes.

	Volume (cm ³)	Perineal Area (cm ²)	Midlength Area (cm ²)	Distal End (cm)
Shape-1	3010 **	193	128	23.50
Shape-2	2847 **	221	114	25.50
Shape-3	2462 **	165	107	22.00
Shape-4	2647 *	173	110	24.00
Shape-5	2200 *	170	87	22.00
Shape-10ILF	3726 *	205	150	26.25
Shape-13ILA	2925 *	176	118	26.25
Shape-16ILK	2407 *	161	93	26.25

* Accuracy of the CNC milling machine was ± 0.001 cm (at a radius of 7.6 cm).

** Radial measurements had two independent errors, a systematic error of +0.056 cm and a random error of ± 0.036 cm. This resulted in an overestimation of the socket's volume of +1.6% due to the systematic error, and a tolerance of $\pm 1.1\%$ due to the random error. With respect to the area tolerance, refer to the "note" in figure 8.7.

other three sockets present a general oval shape throughout the socket.

Comparing shapes-3, 4 and 5 for any given level, the residuum has been fitted with two distinct shapes (4 and 5 are relatively similar in cross-sectional shape). Both provided support, comfort and control of the prosthesis. This indicates that the residuum can be fitted with different socket configurations. While shape-3 provides relief in the lateral **AP** dimension, this is spread gradually along the lateral side of shape-5.

Figures 8.7, 8.8, 8.9, 8.10 and 8.13 demonstrate the amount of "sculpture" (for the required area, volume and shape) that shape-4 (primitive socket shape) saves the prosthetist in modifications from the residuum cast (shape-1) to an acceptable fitting socket configuration (shape-3, 4 or 5) by simply using basic anthropometric measurements taken from the residuum. Shape-5 deviates further from shape-3 than shape-4. This was the choice of the prosthetist after feedback from fitting of shape-4. Whereas the socket worn by the *Patient* required 2 wool socks; shape-5 was designed deliberately to provide a closer fit and to be worn with 1 wool sock.

Table 8.4 provides data of the overall dimensions of the 5 socket shapes, together with those of the three reference shapes selected from the computer socket shape library. This indicates the extent of modification of the reference shapes by the CASD algorithms in order to create the unique socket shape tailored to the anthropometric measures of the patient.

As seen in table 8.4, although the primitive socket shape (shape-4) was not further modified (no interactive modification performed) for the first fitting trial, its characteristics matched closely with the socket worn by the *Patient* (shape-3). At this point, only critical discrepancies are left to be modified by the prosthetist using the interactive routines provided by the CASD system. With this, the prosthetist relies on the computer to perform the "gross" construction, leaving the prosthetist to concentrate on the analysis of critical spots which need to be defined more precisely. The prosthetist is able to apply "fine" details to the design a short time after measurements are taken from the patient, and is able to get an certain image of the end-product before the patient leaves the facility.

CHAPTER 9

CONCLUSIONS

The basis of a computer aided socket design procedure (CASD) has been developed, whereby the unique configuration of an above-knee amputee's socket can be systematically created based on measurements of skeletal structure, residuum length and girths taken from an amputee. The limited fitting trials described in this thesis provided positive results which support the initial hypothesis. Extended clinical trials are expected to follow in order to evaluate and improve the CASD system.

The most valuable assessment and validation of the Adjust Bulk procedure of the CASD system was that the socket (shape-5) obtained by this computerized system provided comfort and control to the amputee comparable to that of a socket manufactured by conventional methods. Results from the numerical analysis showed an acceptable degree of "good fit" which shape-4 and shape-5 provided to the amputee with respect to the dimensions of the patient's own socket (shape-3) and that made by James Foort (shape-2). Cross-sectional area comparisons between shape-3 and shape-4 were within 4% over most of the socket (with the exception of 4 cm in the midportion of the socket where of shape-4 was within + 10% of the socket worn by the amputee).

Although it was not possible to quantify shape congruency due to the difference of longitudinal alignment between shapes-4 and 5 and shape-3, with the help of collapsed cross-sectional diagrams, it was possible to highlight some shape differences between the two approaches. These shape discrepancies are due to different fitting techniques which vary from prosthetist to prosthetist, and from centre to centre.

Despite the fact that the residuum's length was 24.1 cm, shapes-3 and 5 (22.0 cm in length) provide sufficient proximal support to prevent the residuum from reaching the distal end of the socket. In these designs not only is weight bearing relieved from the ischial tuberosity and the gluteus maximus, but a sensitive bony prominence (femoral end) is being prevented from compression and tissue stretching. With this discrepancy in length, a positive pressure cavity is produced at the distal end providing support to the soft tissue. Due to the absence of a "suction end", the pressure should not become

negative (*ie.* below atmospheric) preventing any possible edema.

The fitting of this particular residuum was a difficult one, due to the sensitive bony prominence presented by the diminished cushioning surrounding the distal end of the femur and, an extensive invaginated scar in the lateral side of the residuum which should not be stretched. It was predicted by the prosthetist (J. Foort) that the degree of comfort and acceptability experienced by the patient with shape-5 could not be achieved by conventional methods without several fitting trials (in view of the complex nature of the residuum shape, two to four fittings were considered probable to obtain best results).

Despite the good "fit" obtained in this first clinical trial, some improvements to this system are indicated. With respect to the cross-sectional area acquisition, it is not known the most suitable loading state at which the residuum should be measured. The ***Adjust Bulk*** procedure relies on a series of cross-sectional areas that we expect to be close to those presented by the residuum in the actual loaded stage. For the accurate determination of those areas, it has been proposed that two measuring techniques be used to acquire those measurements: one with the *Patient* laying down laterally having the residuum wearing a sock to give consistency to the tissue (providing that the elasticity of the sock be relatively constant for any given level), the second, by having the patient in the standing position and the residuum supported by a elastic sock mounted on a jig and distributing half of his weight on either leg (standing on a scale). Comparing cross-sectional areas recorded by these two method with the area of the final socket, trends could be obtained between the measurements, yielding a factor by which, the areas obtained by either method, could be modified to determine the required dimensions of the socket.

It was found that curvatures of the brim area are distorted by the longitudinal scaling routine, hence, the support provided by the inguinal flare and the rounded contours of the ischial gluteal shelf is diminished. This effect is increased with the interpolation routine when the gap between cross-sections is reset to the original dimension. This was corrected in shape-5 by the CASD interactive modification routine. With improvements to the shape modification algorithms, this effects could be corrected

automatically.

The selection of the length subgroup from the Reference Matrix by the *Pick* procedure is now based on a single measurement, the residuum's length (RL). It is proposed that this measurement should be used to calculate the length ratio between the amputated and the intact femur lengths. This ratio is then compared to the corresponding ratios between the three preselected socket lengths and the disarticulated knee model, in order to take account of subject size prior to the selection.

A major contribution of the CASD design procedures developed in this thesis is that the system provides the prosthetist with a systematic approach to the handling of area and shape of the above-knee socket. The system allows for documentation of previous socket shapes and of the shape modifications introduced by the prosthetist thus leading towards improved standards in socket fitting.

APPENDIX A

REFERENCE SHAPE LIBRARY

The complete series of the Above-Knee Numerical Socket Shape Data files, which describe the 27 Reference Shapes for the Computer Aided Socket Design system, have been stored on magnetic tape in the Research Data Library (RDL) at Simon Fraser University. The data files may be accessed by the general public, without restrictions, through the MTS operating system on SFU's main computer.

The 27 data files of the Reference Shape Library are catalogued in a SPIRES subfile called DATALIB. In order to access the data, users should follow the RDL procedures and the user's guide available at the Simon Fraser University Library. To run SPIRES and select DATALIB, use the following commands:

1. \$RUN UNSP:SPIRES
2. ?SELECT DATALIB
3. ?FIND TITLE ABOVE-KNEE NUMERICAL SOCKET SHAPE DATA
4. ?TYPE

DATALIB provides the variables in each data file, 28 "catnames" to access the files, and the file size and format information. The first "catname" (codebook) contains a brief description and the code for the 27 reference socket shapes for which the numerical data are contained in the 27 subsequent "catnames". Once you have selected the desired "catname", sign off from the SPIRES program and run the mount tape file program to access the data by following these commands:

1. STOP
2. \$RUN DLIB:MOUNT
3. *catname* (ie. ak.num.skt.shp.cd)
4. ENDFILE

For further information, refer to chapter 4 of the thesis, or contact Research Data Librarian (local 4349) at Simon Fraser University.

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