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Computer-aided design of a prosthetic socket for an above-knee amputee

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Abstract—A computer-aided design process for fabricating the rectified cast for an above-knee prosthetic socket is described. The methodology for collecting the parameters required for the computer analysis is discussed. The input variables include the unloaded shape of the residual limb, the mechanical properties of the soft tissues that comprise the limb, and the surface loading that deforms the tissue. The technologies that have been developed to ascertain these parameters are presented, and the clinical experience of using the computer-generated shape is presented.

INTRODUCTION

Advances in acute-care medical practice as well as in rehabilitation make it possible for a growing number of people to continue to live in spite of devastating injuries and the effects of old age. Unfortunately, many of these people are subject to metabolic disorders that result in diminished sensation in the extremities. When these disorders involve the feet, subsequent injuries that occur often result in amputation. Additionally, a growing population in the Veterans Administration system suffers from peripheral vascular disease that results in the loss of lower extremity segments.

With the increasing number of people who require treatment, it is appropriate to consider how technology can be used to increase the capacity of the prosthetic service delivery system. Specifically, technology should be developed to enable the available professionals to serve more people in less time, make better use of available materials, and continue to create products of high quality with fewer trial fittings.

This investigation reflects the conviction that computer-aided design and manufacturing (CAD/CAM) technology can be used effectively to fabricate prosthetic sockets for above-knee amputees. To enhance the impact of computer-aided design and manufacturing processes on the prosthetics and orthotics industry, technology must be developed and used to quantify many aspects of the art of fitting prosthetics.

The amputee's residual limb is a dynamic structure that tries to assume different shapes as the person performs various activities. Predicting the shape of the loaded residual limb so that the body part will experience a loading pattern that relieves areas sensitive to pressure is a primary consideration of the prosthetist in fitting the socket. In current practice, socket shaping is the product of the professional person's experience. As such, it remains an art that requires a considerable investment of time. This study has focused on demonstrating the feasibility of using a CAD process to rectify the limb shape and create data that can be used to fabricate a socket. In this study, advanced stress analysis technology, systems for measuring the properties of materials, and biostereometric techniques for characterizing shapes have been employed to design above-knee prosthetic sockets.

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BACKGROUND

The application of CAD/CAM technology to the fabrication of artificial limbs has become an area of great interest over the past several years. The state-of-the-art in applying computer-aided design to prosthetics fitting has been summarized by Foort (3). Foort and his colleagues at the University of British Columbia have contributed significantly to the creation of a computer-based system for fitting below-knee amputees. The result of that group's work is summarized in several publications (9,11,13), and lends credence to the supposition that CAD/CAM technology can be an economically effective fitting tool. Our study has created information about above-knee fitting that is similar to the information that Foort is developing for below-knee fitting.

The group led by Dr. R. M. Davies and University College London has also made substantial contributions in the area of computer-aided manufacturing of prostheses (4,8,10), and this work was summarized in a presentation by Dr. Davies in September, 1985 (2). The experience of that group reinforces the idea that computer-aided manufacturing can have a significant impact on the problems of providing high quality artificial limbs for the growing population in need of them. A group at the Swedish Institute of Handicapped in Stockholm has also become interested in using computer-aided design and manufacturing to produce artificial limbs. (Personal communication: T Holmquist, Svensk Handikappteknik, December, 1985.) Fernie's program in Toronto is very active in applying technology to the process of fitting lower limb prostheses; the Toronto group has developed a laser-based shape-sensing system (12) that they are now using to measure the fit of a prosthesis.

METHODOLOGY

During the past 24 months, the Rehabilitation Medicine Service at the VA Medical Center in Houston, and the Rehabilitation Engineering Program at Baylor College of Medicine have been experimenting with the feasilibity of using CAD/CAM technology to design sockets for above-knee (AK) prostheses. Our study has built on the concepts that Foort and Davies have developed in their laboratories for using the computer to shape the mold used to fabricate a below-knee (BK) socket, and for using numerical control techniques for rapid fabrication of the actual socket. This present project is believed to represent a major breakthrough in the application of the process originally conceived in Foort's laboratory. It has demonstrated the feasibility of characterizing the mechanical properties of the soft tissues in the amputee's residual limb by using noninvasive ultrasonic technology, and it has demonstrated that computers can create directly the modified model that is used to shape the socket for a prosthesis. The computer-aided design process used in this study is outlined in **Figure 1.**

Shape Sensing

The first step of the process involves characterizing the surface topology of the residual limb and making the data compatible with input requirements for later computer processing. Quantifying the surface topology of an object is the first step in numerous processes, ranging from topographical map-making to making coins and artificial parts for the body. Each application has its own requirements for accuracy, precision, and surface smoothness. To satisfy the diversity of requirements, a number of techniques have been developed over the years and these have met with varying degrees of acceptance when tried in new applications. To select the most effective technology, the investigator must carefully delineate the required results. Sensing the shape of an amputee's residual limb requires a measuring system that can collect the necessary data before the amputee tires. It must also provide data that are at least as precise as those currently collected by a prosthetist, and that can be manipulated to produce the information currently used by the prosthetist. Moreover, the measuring system must be easy to operate and must not have large space requirements, if it is to be clinically usable.

By working with several prosthetists, we have been able to determine a set of criteria that the shape-sensing system must satisfy if it is to emulate the technique used to measure the residual limb in current prosthetics practice. The criteria are:

1. The shape-sensing process should collect the required data in no more than 7 minutes.

2. The measurements should be precise enough to match the current circumferential measurement error of ± 0.63 cm. The requirement means that radial distances must be accurate to ± 0.1 cm.

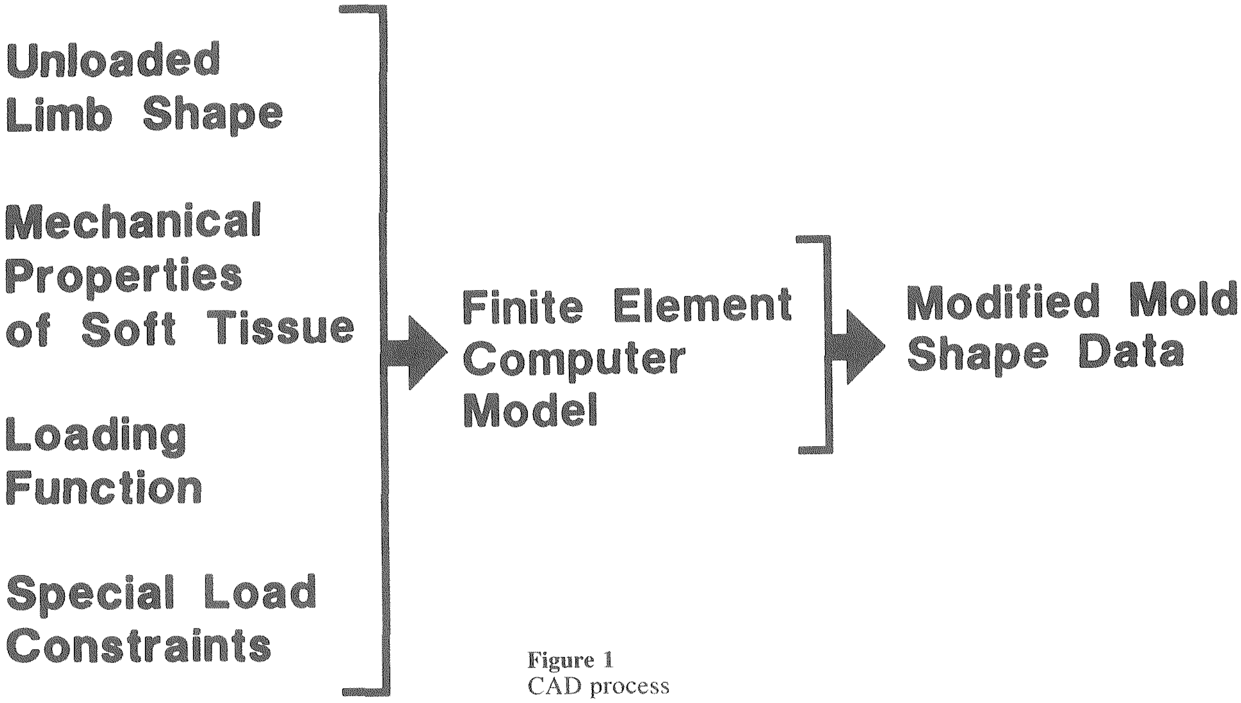


Figure 1
CAD process

3. Vertical measurements should be accurate to ±0.25 cm.

4. Measurements should be reproducible within 2 percent.

These criteria were used to develop a contact type shape-sensing system. This apparatus (**Figures 2 A and B**) was evaluated in the clinic to determine if it satisfied each of the requirements that had been set (7,15). In the course of the evaluation, a system for supporting the distal end of the residual limb was developed. This support, when combined with a handrail, enabled the amputee to maintain the limb's position for the time required to make the measurements.

After the sensing system was evaluated, our automated computer-compatible version was developed. The automated version uses capacitance switches to sense the surface being measured with the result that the pressure required to activate the switches was less than 45 dynes/cm^2, so that the tissue deformation was not detectable (less than 0.01 mm). The instrument collects radial measurements (at intervals that can be adjusted from 3 degrees to 40 degrees) around each cross section to characterize the shape of the cross section. To develop the shape information, the cross section data can be collected at intervals ranging from 0.5 cm to 4 cm; the spacing that is required depends on the complexity of the shape being characterized. The instrument simultaneously measures diametrically opposed points to reduce the measurement errors and reduce topographic data acquisition time so that it is convenient to characterize a 33-cm-long above-knee residual limb (234 points) in 6 minutes.

Material Characterization

The second step involves noninvasively measuring the mechanical properties of the soft tissues that make up the residual limb. To accomplish this, an ultrasonic Doppler system has been designed and fabricated to make the noninvasive measurements (6). (**Figure 3**)

It was found that the soft tissue contains an ample number of randomly spaced points that serve as sound scatterers. But, in using ultrasound to monitor the motion used to perturb the soft tissue, one must be careful not to use the edge of blood vessels larger than arterioles because their motion is not representative of the soft tissue mass, and data from their motion produces extraneous results that do not make sense physically (it produces a negative number for the modulus). Moreover, for the 10-MHz ultrasonic signal that was employed in this study to monitor the tissue motion, it was found that the mechanical perturbation of the tissue needed to be 10 Hz ± 0.5 Hz for optimal results. Data were collected at 0.5-mm intervals through the depth of the tissue.

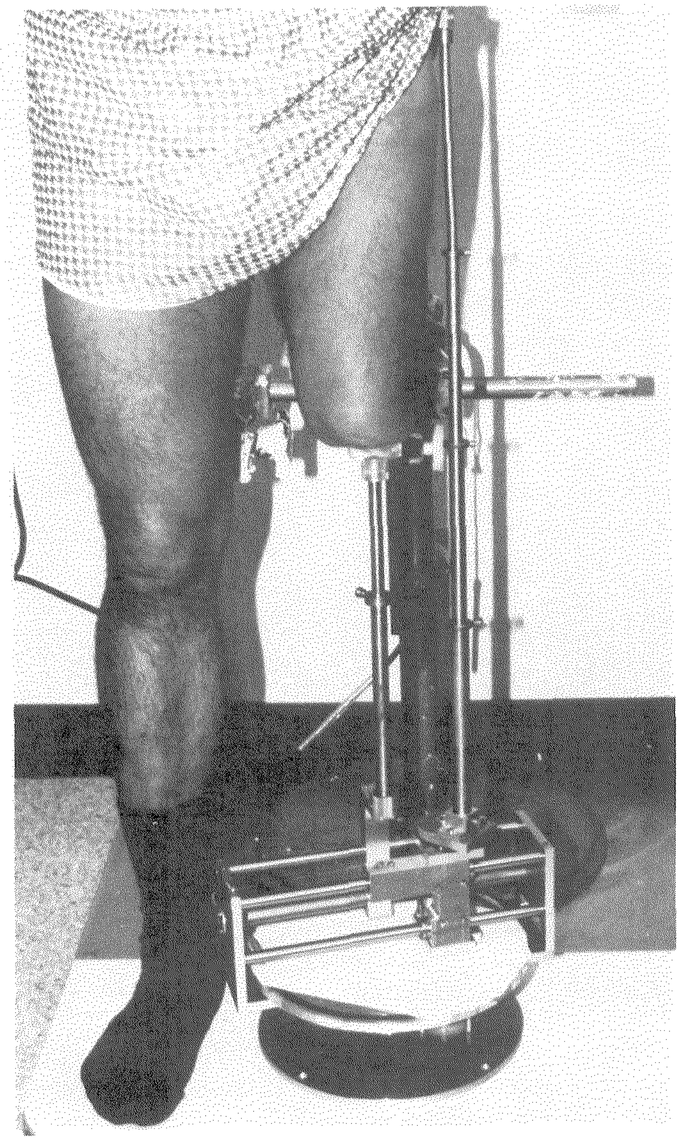


Figure 2A
The shape sensor being used to characterize the shape of an above-knee stump.

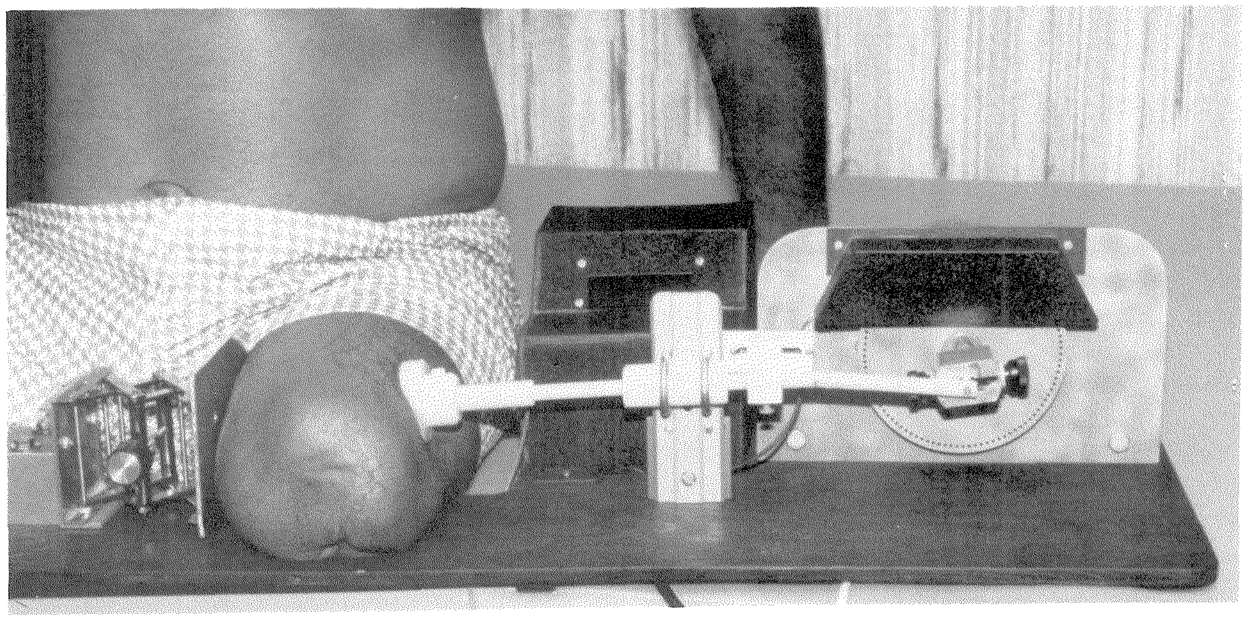
From these data, the weighted average modulus of the soft tissue was calculated using the following equation:

$$E = \frac{3}{2}\rho\omega^2 \frac{u_2(x_3 - x_1)}{\frac{u_1 - u_2}{x_2 - x_1} - \frac{u_2 - u_3}{x_3 - x_2}} \quad [1]$$

where u_i corresponds to the motion amplitude at the point corresponding to the depth x_i, ω is the frequency of the mechanical perturbation displacement, and ρ is the density of the soft tissue.

To study the effect of the tissue density assumption on the modulus calculation, a sensitivity analysis was performed on equation [1]. The density of the tissues comprising a residual limb ranges from 0.92 g/cm^3 for fat to 1.1 g/cm^3 for skin (14). The skin value is a weighted average for the epidermis and dermis. If the value of the tissue density used in the modulus calculation is 1.00 g/cm^3, the maximum error in the modulus is ± 9 percent when the perturbation frequency is 10.0 Hz. If the density of the tissue is adjusted to reflect muscle and fat content (1.02 g/cm^3 for muscle regions and 0.96 g/cm^3 for atrophied regions composed primarily of fat) the maximum error in the calculation is reduced to ± 4 percent.

Figure 3
The Ultrasonic sensor being used to measure the mechanical properties of a residual limb.



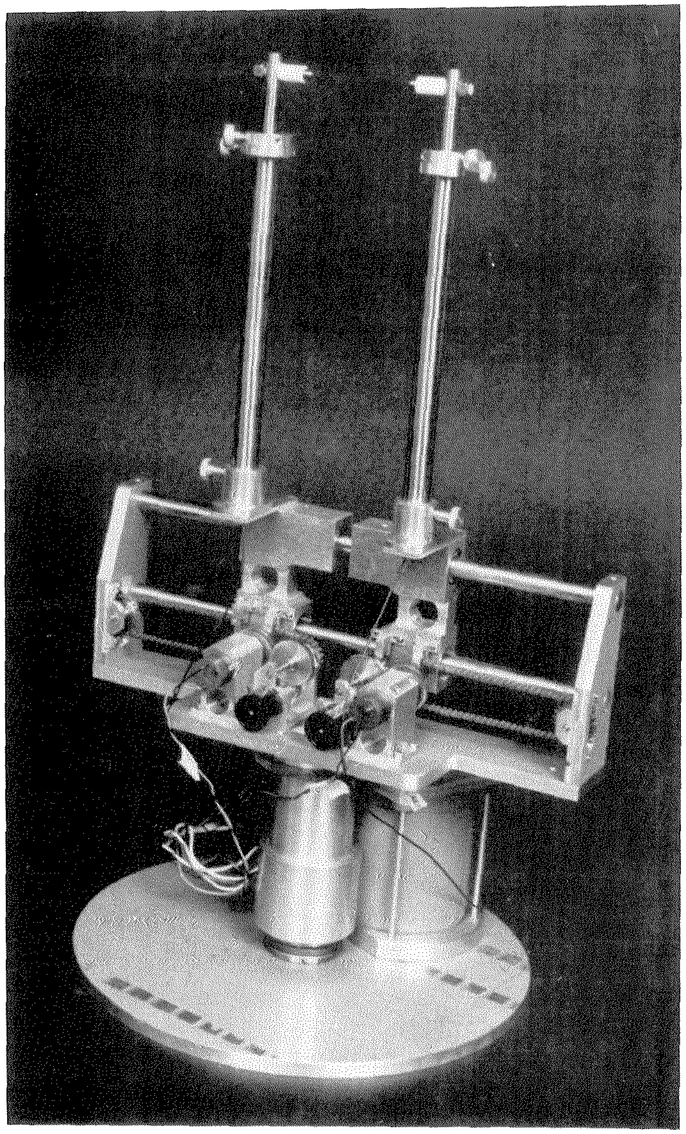


Figure 2B
The automatic computer-compatible sensor used in this study.

To evaluate the validity of the material properties that had been calculated from the ultrasonic system measurements, subjects also were tested using an Instron Testing Machine to load the tissue at the same point used in the ultrasonic experiment. Continuous force/displacement data were collected and the modulus of the tissue was calculated at the point where the displacement was equal to the displacement that had been used to drive the tissue during the data collection done with ultrasound. In these tests, care was taken to position the limb in the Instron so that the load was applied in the same manner as the mechanical perturbation that had been used to excite the tissue. The strain rate for the Instron was adjusted so that it was of the same order of magnitude as the loading rate used in the ultrasonic experiments (6).

A comparison of the results from the Instron testing and the ultrasonic testing is given in **Figure 4**. It can be seen that the modulus calculated using one technique is very close (within 7 percent) to that calculated using the other method. This error is well within the estimated error associated with mechanical testing, ± 10 percent.

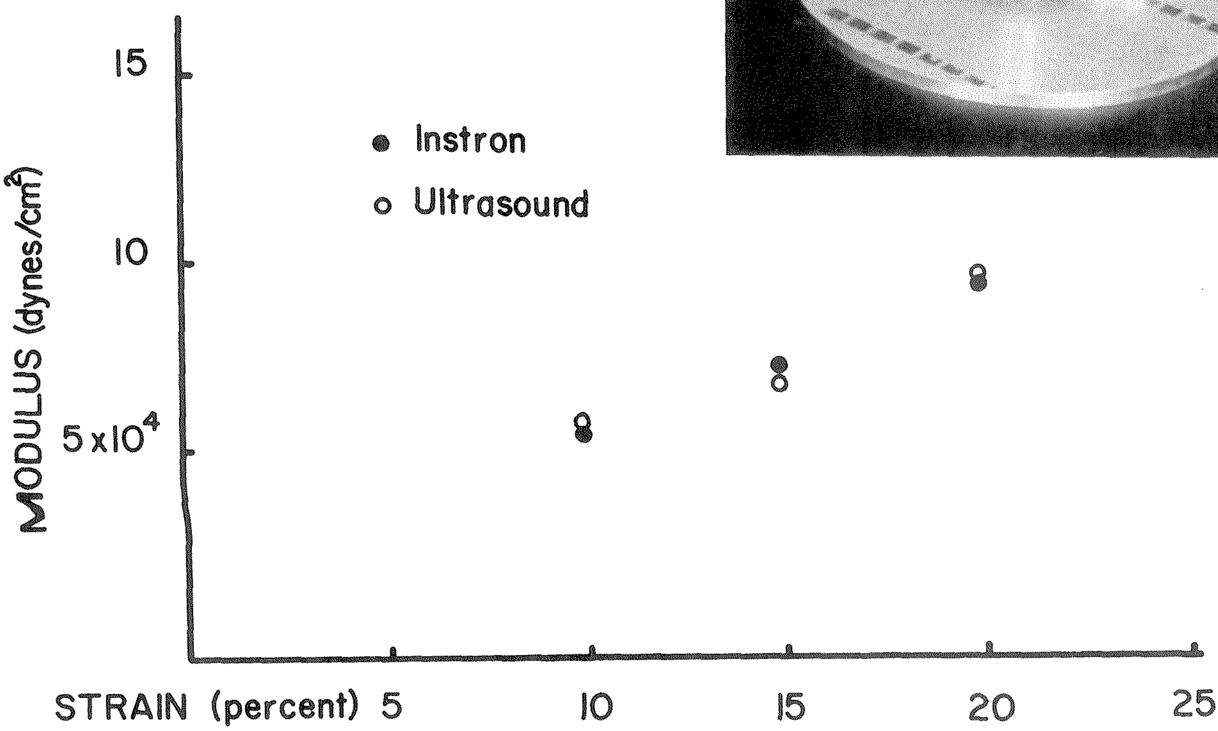


Figure 4
Comparison of the tissue property data collected with the ultrasonic system with data from the Instron Testing Machine.

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The ultrasonic measuring technique appears to provide information consistent with information that can be collected using more conventional (but much less convenient) techniques to characterize the mechanical properties of soft tissue *in vivo*. Also, it was found that care must be taken to locate the skeletal member within the soft tissue mass, because the motion of the soft tissue can be significantly influenced by compression against a bone. The restriction will then cause the technique to yield useless data.

The technique was found to provide reproducible data and if the corresponding data points were repeated and averaged, the composite data points produced results that were quite reproducible.

It was also noted, during the study, that by using the ultrasonic technique, it is possible to calculate the modulus of soft tissue in a very small region; i.e., 0.5 mm $\times$ 0.5 mm. The readings could also be taken over a region corresponding to one-half the distance between the skin surface and the underlying skeleton, for which the technique produces a modulus characteristic of the weighted average for all the tissues comprising the region.

Residual Limb Loading

The third input that is required in the CAD process is the loading function, which can be used to cause the computer program to generate the rectified cast model. A sample of 12 subjects was used. They had quadrilateral-brim above-knee prostheses that fitted them well (e.g., prostheses that did not cause pain and that were worn for extended periods of time such as 10 or more hours each day). Interface pressure profiles for these subjects have been developed that demonstrate a consistent pattern even when the shape of the sockets was different.

The interface pressures were measured using a pneumatic pressure transducer array (**Figure 5**). This array was fabricated from 5 mm urethane film and could resolve the pressures to ± 3 mm Hg. When the pressure profiles were plotted using percent of residual limb length as a variable, only small differences in the profiles were exhibited. By averaging the pressure readings at the corresponding points on each of the subjects, a standard surface loading function was calculated (**Figure 6**). It has been found that well-fitting sockets do not exert pressures on the limb greater than 114 mm Hg, and that the primary loading on the limb takes place in the proximal 10–14 cm of the socket. Below that level, the interface pressures are nominally 60 mm Hg regardless of which prosthetist made the socket. When pressures exceed 145 mm Hg in the proximal third of the socket, the amputee typically complains of tightness and the distal portion of the residual limb discolors rapidly (within 15 minutes of donning the socket) unless the pressure distribution is uniform over the entire distal residual surface. When the peak pressures are less than 10 mm Hg, the socket tends to piston, making it difficult to wear. The fit of the socket requires that the surface pressures fall within a relatively narrow window, and predicting the shape needed to produce the required pressure distribution is a critical step in developing computer-aided design techniques.

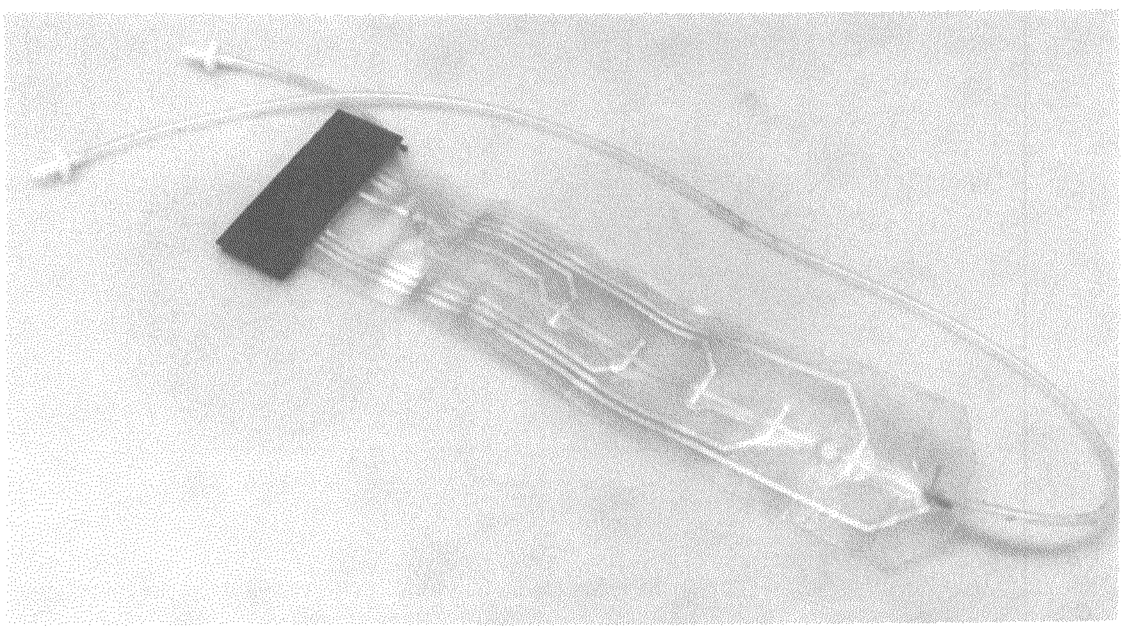

Figure 5
The interface pressure transducer used to measure the interface pressures between residual limb and socket.

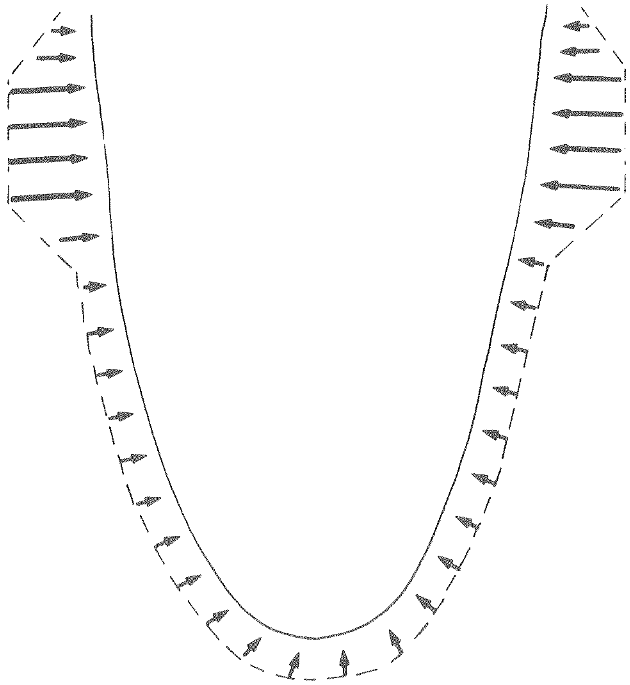

Figure 6
Surface pressure loading on the residual limb.

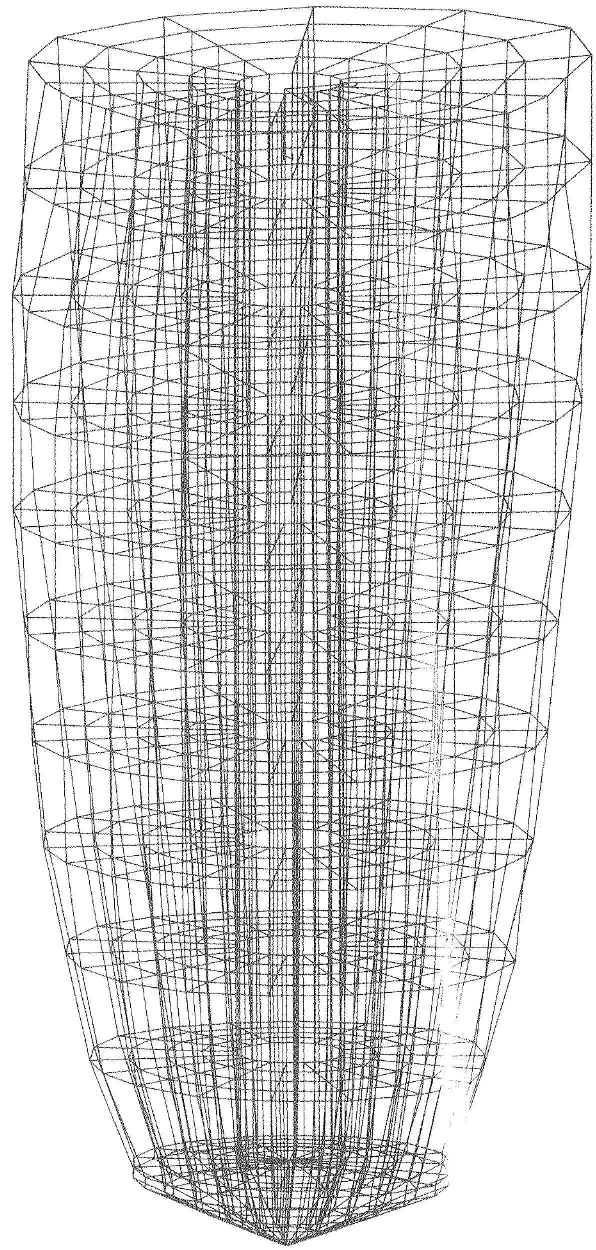

Figure 7
Finite element grid used in the analysis.

Using the ANSYS finite element code (5), a generalized model for the above-knee residual limb was developed (**Figure 7**). By using the shape data and weighted modulus for the material, this finite element model was used to calculate the shape of the residual limb that provides desired surface-loading characteristics.

The finite element model is composed of elastic solid eight-node elements that represent the soft tissue. While the model could be formulated to study the dynamic response of the residual limb to loading, this study has been focused on emulating the process the prosthetist uses to rectify a residual limb cast. Consequently, the model uses a static loading analysis to calculate the shape that the residual limb should have in order to be loaded comfortably. In the finite element model, the tissue is idealized as a series of linear elastic, isotropic, homogenous materials that must satisfy strain compatibility requirements. The current model uses five material regions: lateral, medial, anterior, and posterior quadrants of the proximal 60 percent of the residual limb and its distal 40 percent. The modulus value for each region is a weighted average of the moduli, which are measured with the ultrasonic instrument. The weighting is done on the basis of the amount of tissue present, i.e., the depth of the tissue.

The bone position is set using information gathered with the ultrasonic apparatus. The ultrasonic probe is used to determine the depth of the femur from the surface on four sides at the ischial level and at the distal end. These data then define the region occupied by the bone. In order to reduce the computing time required to analyze the residual limb, the model replaces the bone with a rigid boundary. Since the soft tissue is several orders of magnitude softer than the bone, this idealization was found to have no measurable effect on the outer surface displacements. The stresses and strains predicted by the model for the vicinity of the bone/tissue interface are not necessarily good approximations of reality, but they are of no interest in this study. This model is useful only in predicting the outer shape that the residual limb assumes when it is loaded with the interface pressure loading function. The model has been developed and refined so that it runs on the Cyber 175 computer in less than 25 minutes.

The final step in the CAD process was to transfer the output from the finite element analyses into information that is compatible with the requirements for a numerical control (NC) router. Software was developed that uses the displacement solution from the ANSYS analysis to create an input file that is compatible with the requirements of any NC machine programmer. The software makes use of an interpolation scheme developed by Akima (1), which can be used for both closed curves and open curves. This software is modular in nature and can be used with a variety of mainframe computers or the larger personal computers such as the AT&T 6300.

RESULTS

Using the process described, above-knee sockets have been fabricated and fitted on 2 users. The first socket required no modifications before being used by the subject. The subject was able to use the test prosthesis as effectively as his original prosthesis. The socket continued to fit and be worn for 6 to 12 hours a day for a period of 6 months, during which time the user lost weight. At the end of the 6-month period, the socket no longer fit due to the subject's weight loss. The socket for the second user was also fitted without modification by the prosthetist and had been in use for a period of 2 months at this writing.

DISCUSSION

The results of this investigation indicate that CAD technology can be used to design sockets for above-knee amputees. By using this technology, it should be possible to reduce the amount of time that the prosthetist must spend rectifying a residual limb mold. Moreover, it should be possible to fit most uncomplicated above-knee amputations this way, and a prosthetist would be able to serve a greater number of people who are in need. The prosthetist could then devote more of his skilled time to fitting persons who have complications requiring the intangible art or skill that can only be obtained through extensive fitting experience.

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