Department of Veterans Affairs

Journal of Rehabilitation Research and Development Vol. 31 No. 1, 1994
Pages 42–49

Automated fabrication of mobility aids: Review of the AFMA process and VA/Seattle ShapeMaker software design

David A. Boone, CP; J.S. Harlan, BSME; Ernest M. Burgess, MD
Prosthetics Research Study, Seattle, WA 98122

Abstract—Computer-aided design and manufacture of prosthetic and orthotic devices has recently moved out of the laboratory into clinical use. The Department of Veterans Affairs Rehabilitation Research and Development Service has directed coordinated evaluation and development projects of this emerging technology under the name: Automated Fabrication of Mobility Aids or AFMA. One of the major results of the effort was the creation of mobility aid design software (ShapeMaker™) concurrent with AFMA clinical testing of preexisting systems and development efforts. In order to provide a foundation for future discussions regarding AFMA, this paper provides a descriptive review of the AFMA processes and a review of the conceptual basis for the ShapeMaker AFMA software development.

Key words: *AFMA, computer-aided design, computer-aided manufacturing, computer aided socket design, orthotics, prosthetics.*

INTRODUCTION

Computer software and computer controlled machinery have been developed expressly to facilitate the design and fabrication of prostheses and orthoses. Computer-Aided Design and Computer-Aided Manufacturing (CAD/CAM) (1) are parts of this new clinical development known as the Automated Fabrication of Mobility Aids, or AFMA.[1] The term AFMA was coined in January of 1987 by Ernest M. Burgess, MD at a joint VA/NASA research meeting convened at the Langley NASA research center. AFMA has been our preferred term for all related projects supported by the VA, since CAD/CAM is closely associated with an engineering context which does not reflect the breadth and uniqueness of this clinical application. AFMA technology is intended to improve service to the disabled in need of a mobility aid by increasing production efficiency of the prosthetist/orthotist, thereby reducing the time and financial burdens of fabricating custom prosthetic and orthotic devices. AFMA also provides prosthetists and orthotists with a new tool that has the benefit of numerical accuracy, consistency, and reproducibility that are essential to advancing the *science* of mobility aid design.

The first comprehensive effort to develop a CAD/CAM prosthetic design system was begun by Mr. Jim Foort, Director of the Medical Engineering Resource Unit (MERU) of the University of British Columbia. Foort is considered the progenitor of the entire concept (2). The MERU group, in collaboration with the Bioengineering Centre of University College London (UCL) in England demonstrated a complete working AFMA system at the World Congress of the International Society for Prosthetics and Orthotics in London in 1983. At the 1986 ISPO World Congress in Copenhagen, the UCL group demonstrated a newly developed Computer Aided Socket Design (CASD) software and hardware sys-

Address all correspondence and requests for reprints to: David A. Boone, CP; Prosthetics Research Study; 720 Broadway; Seattle, WA 98122.

This work was supported by the Department of Veterans Affairs Rehabilitation Research and Development Service, Washington, DC.

[1] Prosthetics Research Study Report listed in the *Rehabilitation R&D Progress Reports-1987.*

tem that would be later tested in the VA Rehabilitation Research and Development Service (Rehab R&D) National AFMA Research Project (3). Despite limitations, this generation of design software showed promise in VA sponsored clinical trials (4) (**Figure 1**).

In 1985, the US Veterans Administration (VA), sponsored an international AFMA workshop which brought together the leading AFMA researchers from Canada, England, and the United States, along with interested investigators working with the VA Rehab R&D Service. Following the meeting, VA Rehab R&D accelerated support for a wide range of projects pertaining to AFMA. The centrally directed research culminated in a national cooperative effort among Prosthetics Research Study (PRS) in Seattle, the Prosthetics Research Laboratory of Northwestern University in Chicago, and Rehabilitation Engineering Research Program of the New York VA Medical Center, (NYVAMC). One primary objective of the National AFMA Research Program was clinical use and evaluation of the UCL CASD, and, to a limited degree, the MERU CANFIT systems. This testing program resulted in the development of a stand-alone prosthetic cast digitizer and design software dubbed ShapeMaker (5).

This is the brief lineage of VA AFMA software and hardware development and is not intended to be a complete historical review of the field. Rather, we present a discussion of the conceptual and practical considerations that are the foundation upon which AFMA and the VA/ShapeMaker software is based.

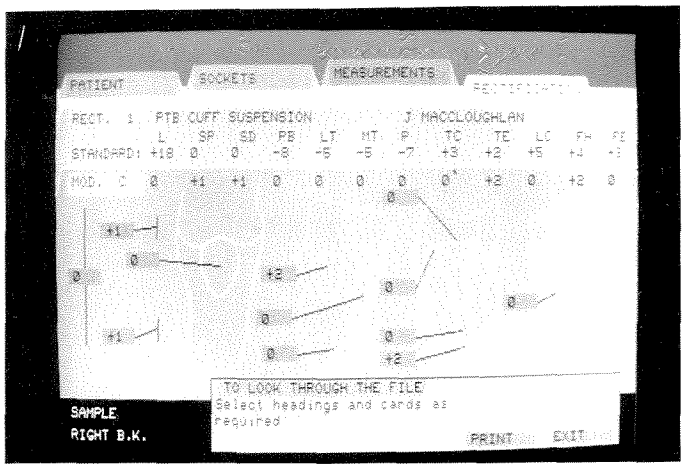

Figure 1.
Schematic screen representation of prosthetic socket design parameters in UCL CASD software.

METHODS

It will be helpful to the reader to review the AFMA process using the example of prosthetics as a basis for later discussion of AFMA software design. The basic principles may be extended to the design and fabrication of a wide range of mobility aids such as custom seating and foot orthotics.

In the design stage of the AFMA process there are three main tasks: input of the anatomical form, design of the prosthesis, and output of the finished design to a fabrication system (**Figure 2**).

First, the residual limb geometry is entered into the computer so that an accurate graphical representation of the limb is displayed on the computer screen. This process is called digitizing. Typically, digitizing begins by taking a plaster negative cast of the residual limb using standard plaster casting bandage (**Figure 3**). The cast of the limb is then placed in a device (digitizer) that digitally measures a series of horizontal profiles on the inner surface of the cast as well as anatomical landmarks labeled by the prosthetist (**Figure 4**). A computer in communication with the digitizer translates the numerical measurements into a three-dimensional representation of the limb. Other technologies for digitizing the limb shape directly are available, but to date the method of digitizing casts has been incorporated into AFMA because of lower cost and applicability to digitizing many levels of lower and upper extremity residual limbs.

After digitizing, the second step in the process is to sculpt the residual limb geometry seen on the

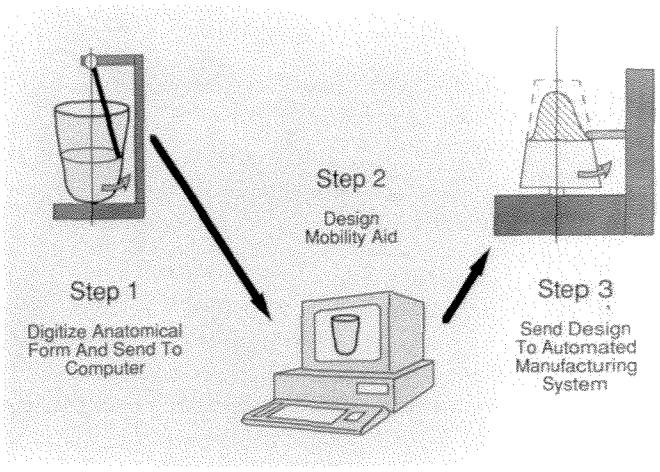

Figure 2.
Diagram of the three primary steps in the AFMA process.

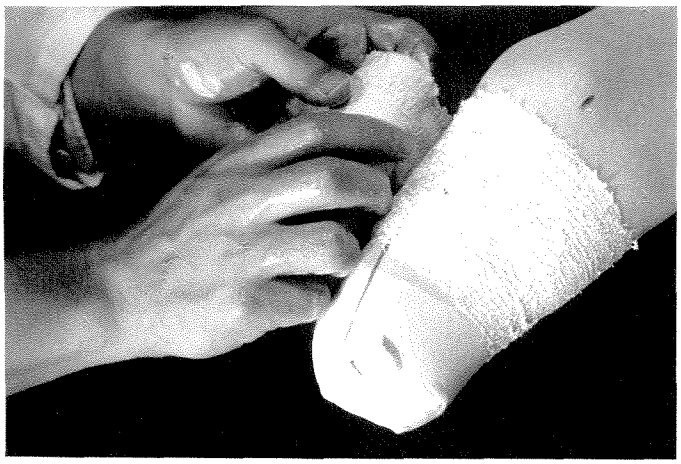

Figure 3.
Plaster wrap cast being made of a below-knee residual limb.

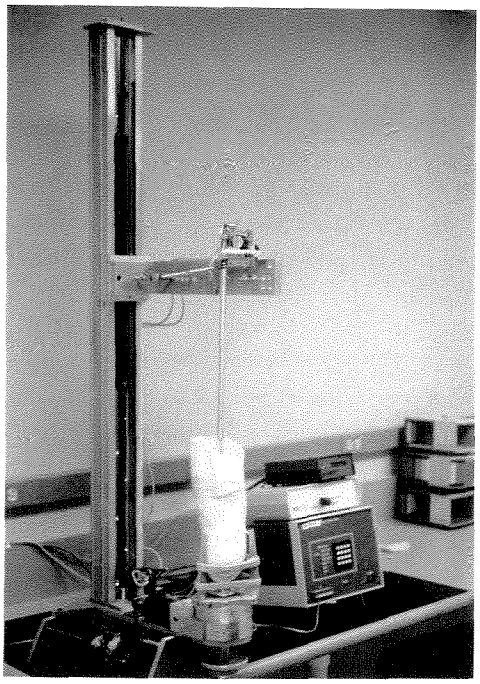

Figure 4.
Plaster wrap cast in electromechanical digitizer designed by PRS.

computer screen into an acceptable prosthetic socket. Modifications to the digitized limb shape are necessary to design a socket capable of comfortably supporting the amputee. Following traditional practice, specific alterations to contours and volumes of the digitized limb are made to create a comfortable socket by supporting the body with compressing forces in areas of the residual limb which can tolerate this stress and relief over those areas which are stress intolerant (**Figure 5**). In both cases, the shape modification is in the form of a smooth deformation contour, either a depression or a relief. This should not suggest that we believe that the deformations based on traditional clinical practice create ideal tissue loading characteristics. Lacking knowledge concerning optimal tissue loading patterns, the software mimics current practice as a matter of expediency. Using AFMA systems to control for design variables may be an important tool for further research in optimizing stress distributions in mobility aid design.

The third computer-based task is to translate the completed socket design shown on the computer screen into a "real object," in this case the prosthetic socket. This manufacturing process is accomplished through computer-controlled carving of a solid model of the socket design shown on the computer screen (**Figure 6**). Once this model is complete, a thermoplastic prosthetic socket is formed over the positive using a standard vacuum forming process (**Figure 7**). After the plastic has cooled, the solid model is removed leaving the negative plastic impression for the socket. The formed plastic socket is attached to the rest of the modular endoskeletal structure of the prosthesis (**Figure 8**). The amputee dons the prosthesis and with the addition of a suspension aid is ready for ambulation.

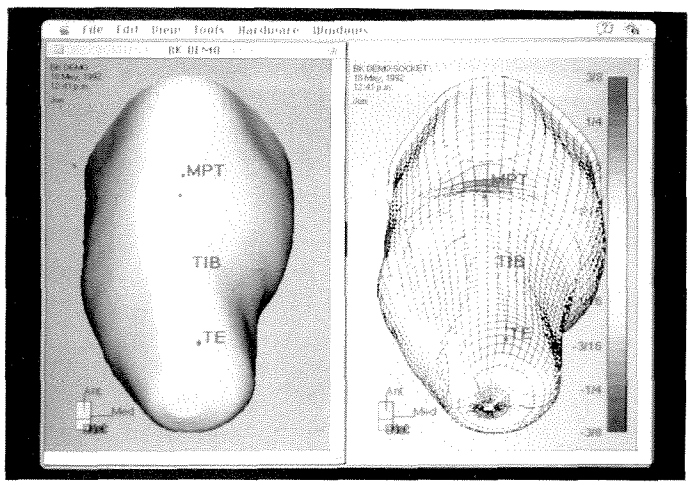

Figure 5.
Modifications to contour to provide supporting or relieving forces within a prosthetic socket are coded as colors on the computer screen.

Figure 6.
A three-dimensional model being carved from a plaster and corn starch mixture that duplicates the form on the computer screen.

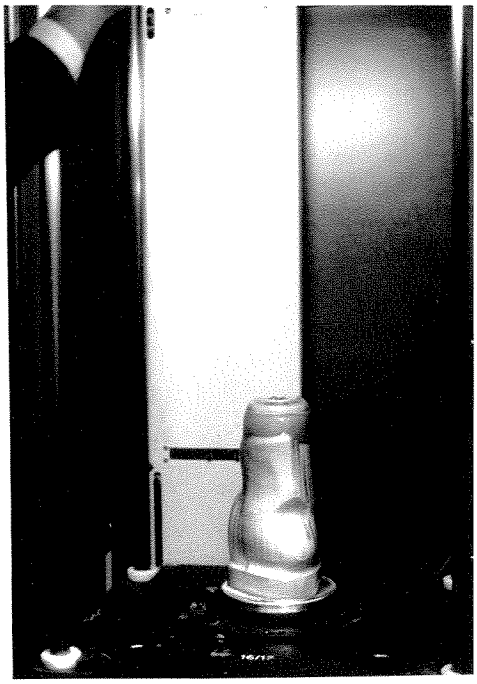

Figure 7.
Thermoplastic socket being formed over the carved model in an automated process oven.

The clinician uses AFMA software such as ShapeMaker to accomplish all three of the tasks mentioned above: digitizing the residual limb shape, rapid design of a custom mobility aid based on clinical assessment and judgment, and, finally, computer-controlled fabrication.

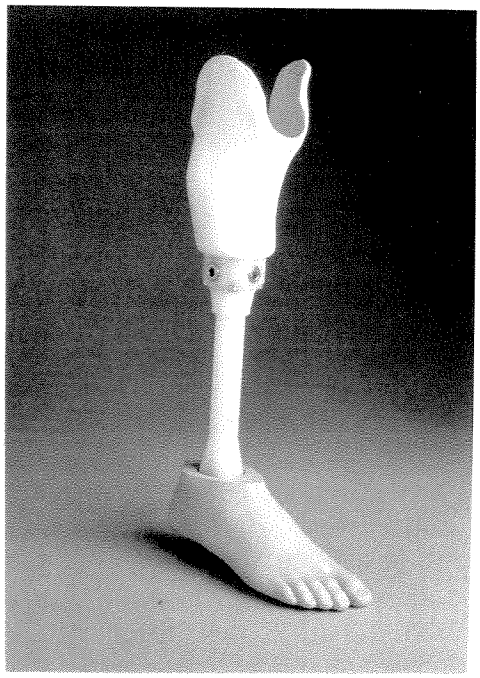

Figure 8.
The modular DVA/Seattle Limb System with AFMA socket.

DISCUSSION

The VA National AFMA Research Program resulted in the validation of the AFMA methods and identification of areas needing further research and development (4,5). For example, Houston, et al. has shown that the method of using standard patterns of modifications superimposed on an individual digitized residual limb form coupled with prosthetist manipulation of the shape using only the computer was more effective in creating prosthetic sockets that, in the amputee subjects' estimation were, "better fitting" and "more comfortable" than manually manipulated socket designs (5). These standardized modifications within the UCL-CASD system being tested were called rectification patterns. They contained regions in which the contour of a limb shape digitized in a cylindrical coordinate system were deformed inward or outward by mathematical addition or subtraction of radius values at coordinates and in amounts predetermined in the definition of the rectification pattern. These altered regions corresponded to areas where the prosthetist traditionally modifies the plaster positive model of the socket using manual sculpting tools and wet plaster. However, while the magnitude of modification over each region could be changed in the CASD

system, position, orientation, and contour of the region could not be changed by the user. Additionally, the definition of new rectification patterns was difficult with this system (6). Based on this and other observations of the National AFMA Research Program, a "wish-list" pertaining to software was created, thus providing the basis for the AFMA software development project initiated by Prosthetics Research Study in March of 1989.[2] Some of the many software requirements outlined were: 1) the software should run on a standard computer platform without requiring additional hardware or software; 2) the application should be designed to be capable of creating most mobility aid forms; 3) the software should be as unobtrusive as possible in achieving clinical results; 4) the prosthetist/orthotist should be able to modify the surface as a realistic three-dimensional projection rather than as a cross-sectional or schematic representation; 5) the user should have non-modal access to surface manipulation tools with varying degrees of fineness; and, 6) the software should have an easy method for automating replication of the technique of an individual user. Software intended to meet these objectives has been completed by PRS and is currently in clinical use under the name of ShapeMaker. Following is a discussion of the AFMA software design considerations which forged ShapeMaker into its present form.

User Interface

One of the most important goals in developing ShapeMaker was to limit the amount of new learning that was required of the clinician. It was our intent that aside from the mechanics of interacting with the computer using a *mouse* cursor controller, the prosthetist should not have to become a computer expert to utilize the computer for prosthetics. This is what is commonly called "user-friendly." Our basic premise with regard to user interface considerations was that the patient's prosthetist/orthotist already knew what to do clinically for him or her and that the software should aid rather than interfere with that process.

The goal of developing easy to use software also governed the choice of a computing platform. Our investigation considered the options of using a high-end UNIX-based graphics workstation, a DOS-based PC, and the Macintosh II series. The Macintosh II was selected for its wide availability, consistent and "user-friendly" interface, and excellent graphics performance without additional hardware or software. The choice of the Macintosh[3] in turn had a profound effect on the design of the software by providing a consistent user-interface (7).

Input and Output

The first and third tasks of the AFMA process described above pertain to the input of the limb shape into the computer and output of the modified shape for fabrication. ShapeMaker has been programmed to be "machine and resolution independent" and is able to communicate with most commercially available digitizing and carving devices through serial and parallel interfaces. In addition, ShapeMaker can also communicate with equipment located at a remote site via modem connection over telephone lines. To extend the utility of the software, newly developed digitizing and carving hardware is similarly interfaced directly to the ShapeMaker program through the addition of machine specific modular software drivers. The task of mobility aid design accounts for most of the programming that comprise ShapeMaker, and the rest of this discussion is devoted to this task of the process.

Generic Modification

One goal in AFMA software design has been to create a software paradigm in which clinicians relate to the graphical representation of prosthetic and orthotic shapes in the same way they relate to the hand-sculpted solid plaster models where material is either removed or built up, using tools to modify the original limb shape. This is one way in which to ease the transfer of clinical skills from the traditional fabrication system to a computer-based one.

ShapeMaker acts as a generic tool chest allowing the user to sculpt general three-dimensional anatomical forms. Since it is not simply an above-knee prosthetics program or an orthopedic shoe program, ShapeMaker helps to fulfill the concept that AFMA technology is applicable to nearly all mobility aids. As such, our laboratory has used the program for most levels of prosthetic sockets as well

[2] Report listed in the *Rehabilitation R&D Progress Reports-1989.*

[3] A version of ShapeMaker has also been developed using the Macintosh-like Windows™ graphical user interface.

as the design of prosthetic cosmesis, knee braces, body jackets, wheelchair seating, shoe insoles, shoe lasts, and maxillofacial modeling. ShapeMaker is appropriate for all of these different applications because each process requires the basic task of three-dimensional shape deformation for which the software was designed. Also, because the same software can be used for all of these different applications, the user interface is the same for each.

Levels of Control

Automated creation of mobility aids for broadly defined patient populations was necessary to achieve the goals of efficiency and consistency afforded through automation. However, in practice there is variation between individual patient anatomy that we feel is most efficiently accommodated through the exercise of clinical judgment and skill to individualize a patient's custom mobility aid design. And so, a dilemma of control versus efficiency arose in the design of ShapeMaker. The program is designed to allow the user to very quickly apply broad modifications to the mobility aid design; however, the user also needs to have tools available for very fine, detailed manipulation of the shape. With global controls, clinicians might feel too restricted at times, while in other cases they might find detailed controls too time-consuming or cumbersome for general use. This defines a trade-off between flexibility and structure. In order to satisfy such divergent design requirements, ShapeMaker was developed around the concept of making different "levels of control" available to the clinician at all times.

ShapeMaker provides three distinct levels of control which could be labeled Automation, Modification, and Creation. Each successive level of control requires more interaction with the software tool, yet yields finer control over the finished product. A good analogy would be different grades of sandpaper. Rougher grades are used for shaping, while finer grades are used for finishing details. ShapeMaker utilizes a non-modal design which allows the user to use functions from any level of control at any time.

The most general controls generally involve creating predefined modifications very quickly, what we term automation. The user does not need to think about fine details, but rather about the "big picture." Automation completes a large part of the work toward a finished result with only a very small effort on the part of the user, such as complete socket modification at the selection of a single computer command. For example, the rectification patterns in the UCL CASD software and the analogous Template commands in ShapeMaker provide this broad level of control. The result of a command at the Automation level of control may encompass many different actions that could also be accomplished individually using finer levels of control, but that at this level are completed automatically. The complex quantitative modification can be described qualitatively in just a few words, "Create a PTB socket for this particular Trans-Tibial limb shape" (**Figure 9**). Because of individual variation among patients, we anticipate that only a small percentage of mobility aids will be finished using only the Automation level of control. The software may also be programmed to take individual patient characteristics into account at this level to achieve a degree of automated customization. For example, ShapeMaker automatically interprets the angular orientation of the long bones relative to the surface topology in order to orient modifications more accurately.

At a finer level of control, the user can take more direct control of the finished product by modifying the results created using the Automation tools. For instance, after applying a socket design template for a below-knee prosthesis, the user might

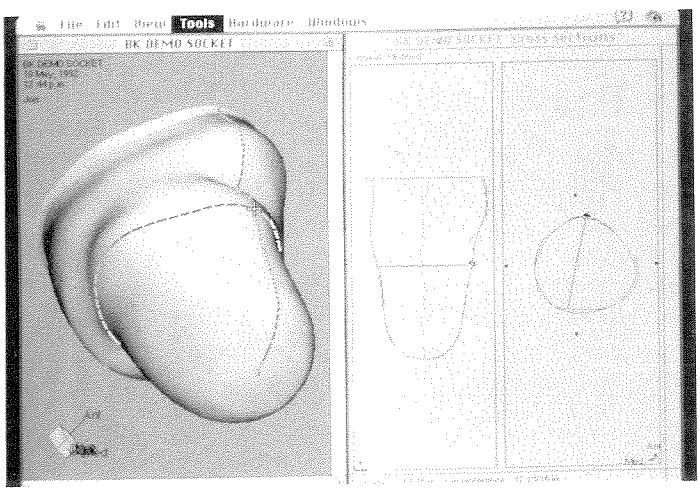

Figure 9.
The Automation level of control is used to produce all the changes between the two shapes shown using the single software command: Apply Template.

wish to increase the depth of the patellar tendon modification or to change the volume, smoothness, or length of the prosthetic socket. Again, the modification can be readily and accurately described in a few words, as in: "Give 2 mm more relief over the head of the fibula" **(Figure 10)**. Surface alterations of this type are generally quantitative or spatial orientation adjustments to modifications made using Automation tools. This level of control will achieve further gains toward the desired end product with only a small increase in the effort required by the user. As demonstrated in an evaluation of the UCL CASD system, many prosthetic socket modifications can be finished using the second level of control (4).

A third level of control gives the user more complete creative control over the finished product. New modifications of the surface may be freely created using dozens of specialized commands in ShapeMaker. The user may manipulate the shape with detailed control limited only by the resolution of the surface data, which in itself may be manipulated in software by resampling the surface at a different coordinate resolution. The most important and powerful command at this level of control is creation of templates that would easily and completely replicate a clinician's own modification technique in a way similar to the UCL CASD rectification patterns. One of the principle shortcomings of previous software developments was that each program included only a small number of automated socket design techniques from which to choose. Every time the prosthetist designed a socket on the computer, the program would modify the socket according to one of the limited techniques. Unfortunately, this scheme forced the prosthetist to adapt to a foreign technique that might be subtly or even radically different from his own design style. To solve this problem, software that would learn from the clinician's own technique was required. Because different clinical situations require different techniques, the prosthetist or orthotist is able to create a library of personally created techniques, or Templates, appropriate for each particular situation. These templates then provide the basis for the Automation level of control.

Early experiences with software for mobility aid design often encountered vocal opposition from practitioners who exclaimed, "No computer is ever going to make a socket as good as one made by a skilled hand!" Given the conceptualization of the software tool as an extension of clinical decision-making, this sentiment was misplaced because the computer is not creating the socket. One may use the analogy of the software as a tool and the computer as a workbench that the clinician uses to create a mobility aid. With all of its levels of control, ShapeMaker allows the clinician to automatically apply his/her own techniques to the design of the mobility aid and then gives the clinician the responsibility and capability of fine-tuning the socket shape to suit the individual patient. And finally, using the creative level of control, the users, can take as much time as they are willing to spend to create an optimal design and then store the design as a template for future use. The time required at this level is generally longer than use of simpler levels of control, and creation of surface modifications generally requires more time than using tools at more generally levels. But as in the Modification level of control, the emphasis is still the translation of a clinical skill to the computer tool, and not the learning of an entirely new skill.

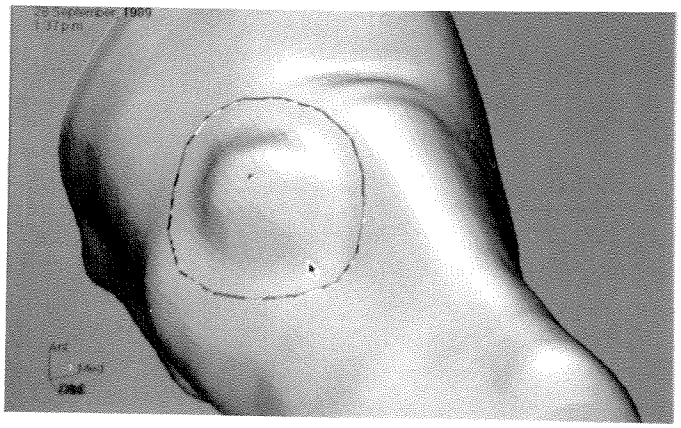

Figure 10.
A ShapeMaker modification region highlighted on the three-dimensional socket model.

CONCLUSIONS

From the outset, AFMA software development has occurred in order to provide clinicians and researchers with control over the variables inherent in mobility aid design. Design software necessarily interacts with a user, and as it is used and the user

gains competency and insight in use of the software tools, the relationship of user to how software is used changes. We conclude that the CASD and CANFIT software which prompted development of the VA/ShapeMaker software were too limiting to the experienced clinician and did not adequately account for the creative aspects of individualizing mobility aid design. Because of this, AFMA software should be constructed within a paradigm of the multiple levels of control which accounts for automation as well as fine artistic manipulation.

Computer-aided design and fabrication, as it is described in this paper, is probably only a beginning for the use of computers in prosthetics and orthotics. This goal has been achieved to some degree, but software development rarely has a distinct end-point. Current and future developments promise to assist clinicians with tasks other than design, such as static and dynamic alignment, integrated digital video, and tissue stress analysis. Clinician access to user-friendly computer-based tools will give more information and control to the rehabilitation team and will benefit the many people who require mobility aids.

ACKNOWLEDGMENTS

The authors wish to thank all of the members of the VA National AFMA Research Group in Seattle, Chicago, and New York for their input and encouragement during the development of DVA/Seattle ShapeMaker. We are also indebted to the amputee research subjects and the prosthetists across the nation who through their participation ensured that software development was always based in the reality of clinical necessity.

REFERENCES

1. Klasson B. Computer aided design, computer aided manufacture and other computer aids in prosthetics and orthotics. Prosthet Orthot Int 1985:9:3-11.
2. Foort J. The Knud Jansen Lecture: Innovation in prosthetics and orthotics. Pros Orthot Int 1986:10:61-71.
3. Dewar M, Jarman P, Reynolds D, Jones K. Clinical trial of the UCL computer aided socket design system. Bioengineering Centre Report 1986, University College London, 1986:13-16.
4. Boone D, Burgess E. Automated fabrication of mobility aids: clinical demonstration of the UCL computer aided socket design system. J Prosthet Orthot 1989:1(3):187-90.
5. Houston, V, Burgess, E, Childress D et al. National program for the automated fabrication of mobility aids (AFMA): below-knee CASD/CAD testing and evaluation program results. J Rehabil Res Dev 1992:29(4):78-124.
6. Dewar M, Reynolds D. Development of The UCL computer aided socket design system. Bioengineering Centre Report 1986, University College London, 1986:11-12.
7. Human interface guidelines: the Apple desktop interface. Reading, MA: Addison Wesley Publishing Co. Inc., 1986.