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A CAD CAM method for custom below-knee sockets

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Abstract

The purpose of this investigation was to develop a numerical method for fabricating prosthetic sockets for below-knee amputees. An optical/laser digitiser scans an amputee's stump and collects three dimensional numerical data describing the surface of the limb and describing specific modification site locations. The numerical data from the laser camera representing the stump and modification sites are altered by the prosthetist using a custom computer aided design software system running on a personal computer. Using the altered numerical data a programme is created for a high resolution numerically controlled milling machine and a mould is made. The prosthetist then fabricates a socket. While the system has been tested with below-knee amputees it has been designed for application in most areas of prosthetics and orthotics. Utilising this method 15 patients were fitted. All patients sujectively stated that their "computer designed" socket fitted better than their conventionally made socket. As the research progressed and experience was gained with the system patients were normally fitted with the first socket iteration. The system overcomes five limitations existing with some of the other numerical systems:
1) accurate high resolution surface topography, 2) specific identification of subject modification sites, 3) flexible, user friendly software, 4) high resolution numerically controlled milling, and 5) integrated expansion to other prosthetic and orthotic areas.

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Introduction

The most important aspect of a below-knee (BK) prosthesis is the manner in which external loads from the prosthetic socket are transferred to the stump. Unlike a normal limb where external loads from the ground are transferred through tissues of the foot which are intended to bear high loads, the loads for an amputee are transferred from the ground to an artificial foot and leg, to a socket, and finally through tissues on the stump, which were not intended to bear high loads. Despite this it has been established that these tissues can accept load to some degree. However this ability to tolerate load is not homogeneous (New York University Medical Centre, 1980). Therefore the prosthetist must direct the load from the socket to specific areas on the stump that can tolerate load and direct load away from areas that cannot tolerate load. If the loads are directed correctly then the socket is comfortable, the stump is healthy, and the BK amputee is able to engage in activities without pain or discomfort. If the loads are not directed correctly then the socket is uncomfortable, the stump is unhealthy (i.e., chafing, bleeding, bruising, and pressure sores may occur), and the BK amputee is limited in his/her activities.

The current subjectivity associated with the traditional casting and subsequent modification of a positive mould to fabricate a socket prohibits the objective determination of the specific requirements for loading between the socket and the stump. Developing objective quantitative methods for the fabrication of sockets and the numerical evaluation of socket fit will help in the establishment of the basic principles for well fitting comfortable sockets. A first step in this regard and the purpose of this investigation was to develop a numerical method for fabricating prosthetic sockets for BK amputees.

Review of other numerical systems

Several groups in the world have investigated the numerical quantification of the fabrication of BK sockets. Jim Foort was the first investigator to address the possibility of a quantitative method of socket fabrication. Working with Foort, Saunders *et al.* (1985) used mechanical devices to gather a sample set of measures on a stump. They then selected a positive mould from a small library of computerised positive mould reference images and used the measures to scale and make modifications to the selected image. Finally they utilised numerically controlled (NC) milling to create a modified positive mould. Over time this method of using a library of reference images proved to be unsuccessful and was abandoned.

The Bioengineering Centre (1986) digitised the inside of a negative cast with a mechanical digitiser to obtain a three-dimensional (3D) numerical representation of the stump. They modified this data according to some predetermined criteria, milled out a mould with an NC milling machine and developed a vacuum forming machine for fabricating the socket. Oberg *et al.* (1989) obtained a topographical image of the stump with an optical/laser digitiser and then followed the same general procedure as the Bioengineering Centre (1986) to eventually produce a mould.

Limitations of systems

At least five limitations are present with some or all of these methods. The first is that except for Oberg *et al.* (1989) none of the other investigators has been able to consistently obtain high resolution residual limb topography. The digitising of the inside of a negative cast to obtain an exact duplicate of the stump is only as good as the skill of the prosthetist fabricating the cast. In other words, if that cast is not an accurate representation of the stump neither will be the digitised data of that cast. The resolution of the mechanical digitiser is not high. One hundred and forty-four data points can be obtained from the mechanical digitiser for a 2.54cm band around the stump. Finally, it is difficult or impossible to use the mechanical digitising method to fit all children since the digitiser stylus cannot fit into small casts.

The second limitation is that none of the investigators has developed a system integrated method to individually identify specific regions for modifications. They typically each use one orientation marker and then identify modifications sites from that single marker. The anatomical variation for any given segment of the human body is well documented and it is therefore necessary for these researchers to rely on broad modification site regions or estimate the locations of specific landmarks. In the case of pressure relief modification regions, a larger than necessary modification area reduces the surface area available for higher pressure application. Thus the regions that can accept higher pressures must accept more load than if the pressure relief regions were kept as small as possible.

A third limitation with these systems and one that is gradually being eliminated is the computer software. In general, the software has been based on a two-dimensional (2D) view of the image. While a 3D image may appear on the screen the actual modification is performed on a 2D cross-sectional or profile view. There 2D views may not always provide adequate information from which to make proper modifications to the data and may be difficult to use. In addition, some of the software has not been flexible enough to allow for both standard and individual modifications.

A fourth limitation that exists with some of the systems is that in contrast to the very smooth surface of the positive mould created by the prosthetist, low resolution milling of the positive moulds produces moulds with ridges. These ridges are produced because the cutting tool, at best, can make only eight cutting passes for a 2.54cm band around the mould.

Finally, the fifth limitation is that these methods have been designed for BK and possibly above-knee (AK) amputees. The utilisation of the methods for other applications has not been built into the components.

Methods

A method has been developed for fabricating BK sockets utilising quantitative techniques believed to have overcome the limitations

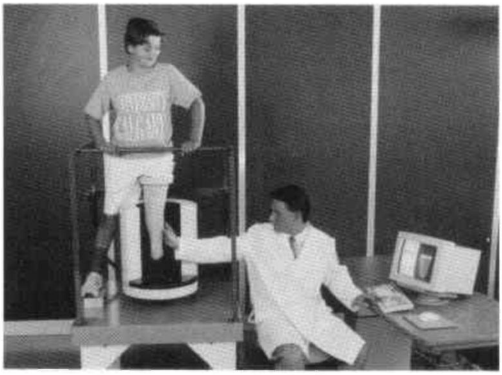

Fig. 1. Digitising parlour including support device, laser camera and computer.

outlined above. To overcome the first two limitations, an optical/laser digitiser (#4012 Cyberware Laboratory Inc.) scans the amputee's stump and collects numerical data describing the surface and describing specific modification site locations (error less than ± 1.5mm) (Fig. 1). A low powered laser projects a line along the length of the stump. The projected line is viewed obliquely by a CCD camera. Then by triangulation, 3D co-ordinates can be obtained from the 40.5 cm laser line. The digitiser assembly rotates 1.4 degrees about the longitudinal axis of the limb, the laser projects another line, and the process is repeated (i.e., 256 lines for 360 degrees) until a topographical mapping of the entire surface of the stump is obtained. The collection of the data by the digitiser is completed in about 10 seconds with 65,536 data points obtained for the full 40.5cm (i.e., 256 lines times 256 points per line). For comparison, 4,110 data points can be obtained from the laser digitiser for a 2.54cm band around the stump. These data are then numerically recorded and stored on a computer. While the scanning only takes about 10 seconds, the entire scanning procedure requires about 20 minutes.

To determine the modification site locations, the prosthetist uses a method similar to that currently employed in the traditional casting method. The prosthetist marks a stockinette placed on the stump of the patient. Marks are made for areas of relief, pressure, alignment, and other relevant modifications as determined by the prosthetist. The laser camera then identifies these marks during the scanning procedure and displays them on the computer screen along with the stump surface topography.

The 3D numerical information from the laser camera representing the stump (or positive mould) and modification sites is altered by the prosthetists using a custom computer aided design (CAD) software system running on a personal computer (PC) (Fig. 2). The CAD system displays any desired view of the positive mould as a 3D wire-frame drawing. The prosthetist further clarifies each modification region that has been specifically identified with the laser scanner using the keyboard and mouse. Each modification region can have any size or shape and the amount of build-up or relief is specified numerically as a displacement. A blending range and shape can also be specified to smoothly merge the modifications with the surrounding surface, thus avoiding abrupt ridges and providing maximum contact with the surface of the stump.

To aid the prosthetist in performing modifications, a standard set of modifications has been developed which can be applied to most BK stumps. The modification set serves as a first best estimate for each modification and reduces the amount of time needed to modify a positive mould. The prosthetist highlights the location of each modification region and the other parameters such as the shape of the region, the displacement, and the blending range are filled in automatically. The prosthetist may then "fine tune" the parameters as required.

The standard modification set represents a consistent numerical procedure for the prosthetist to follow when modifying a positive mould. However, since no two stumps are alike

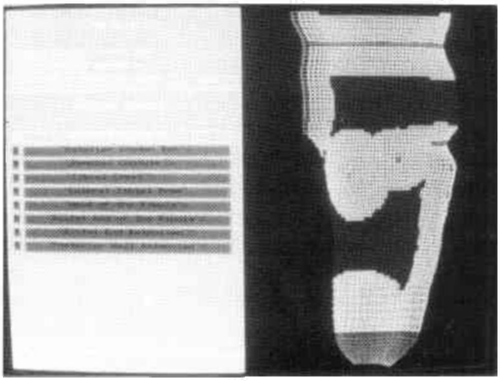

Fig. 2. Image of stump limb after a series of modifications.

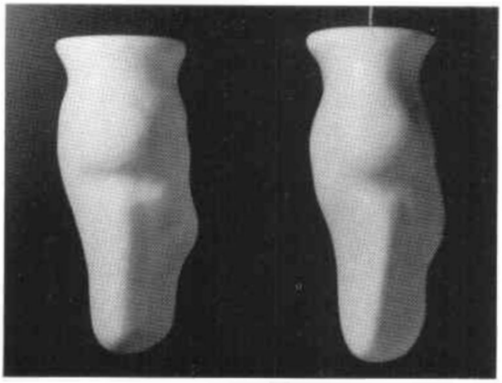

Fig. 3. Positive mould (left) created by the milling machine and positive mould (right) created by the prosthetist for the same patient.

all parameters of each modification can be customised for each individual positive mould. New modifications can be added, unneeded modifications can be omitted and modifications can be blended together. When the prosthetist has completed all modifications to the positive mould the CAD system saves a data file representing the modified positive mould. This process presently takes about 20 minutes to complete.

Using the altered numerical data representing the modified positive mould, a programme is created for an NC milling machine. This high resolution machine mills out a smoothly shaped positive mould by making 256 individual cutting passes down the long axis of the mould (Fig. 3). For comparison with other milling machines 11 to 34 cutting passes can be made for a 2.54cm band around the mould. The number of cutting passes is variable in this comparison since the radius of any transverse section of the mould varies both between and within subjects. In other words, the greater the radius of the cross-section, the greater the distance between cutting passes.

The positive mould information is used as a reference when generating the path for the cutting tool. Complex geometries are considered, taking into account the shape of the cutting tool and the contours of the positive mould to achieve maximal accuracy without gouging. Using a typical industrial milling machine with an old controller and cutting at a higher resolution than other systems, it presently takes about two hours to create the mould. The authors are currently in the process of developing an NC machine that will mill out the BK mould at the current level of resolution in 20 minutes. In addition, the mill will be general enough to mill out moulds in the prosthetic/orthotic applications.

Results and discussion

The purpose of this investigation was to develop a numerical method for fabricating prosthetic sockets for BK amputees. The purpose was not to perform a numerically objective evaluation of the fit and comfort of the sockets that were produced. Investigations designed to evaluate objectively the fit and comfort of sockets are on-going in the laboratory. Hence the evaluation of the functional results of the work in this investigation was entirely subjective in nature.

Utilising this method the writers have fitted 15 patients. As the research progressed and experience was gained it was possible to fit the patients after the first iteration. All the patients have subjectively stated that their "computer designed" socket fits better than their conventionally made socket. This belief may be reasonable since modifications can be applied with the custom software that are virtually impossible utilising conventional methods. For example, it is possible to perform an exact uniform shrink of all or any portion of the stump data set. In contrast, it would be highly unlikely that a prosthetist could file down an entire plaster mould or a large portion of it as precisely, or with as much uniformity. In addition, further confirmation of an adequate fit exists since the 15 patients have been wearing the sockets on a regular, full-time basis without complaint.

This procedure solves the five limitations which the authors suggest currently exist with some of the other CAD CAM systems. The laser scanner records surface topography directly from the stump and does not rely on the inconsistent and potentially inaccurate casting method. The error of the laser scanner is less than ± 1.5mm and appears accurate enough to meet the needs of the system. The number of data points describing the surface topography of the stump is about 28 times as many using the laser scanner than using a mechanical digitising method (4,110/144). The number of data points needed to provide sufficient description of the stump for developing a positive mould has not been established. However, it is very easy with this system to reduce the number of data points if that proves adequate, but very difficult for many other systems to increase the number of data points.

The laser camera is also used to identify the specific sites for modification. It does not rely on a library of data or averages from past subjects. It identifies these sites directly thus allowing for more accurate modification.

The root of the CAD software of the other system referred to above is in the original work of Jim Foort. It presently appears that, except for the CAD software developed at the University of Washington (Sidles *et al.*, 1989), the basic ideas existing with Foort's original software is still used by many systems. On the other hand, CAD software described in this paper has been collaboratively designed and developed in recent years by professionals in the fields of prosthetics, orthotics, mechanics, computer geometric modeling, and user interface design. It is very difficult to demonstrate the concept that a computer programme is user friendly. However, insight into this concept can be gained by knowing that at the onset of the project the prosthetist knew nothing about computers and the computer scientist knew nothing about prosthetics and orthotics. This lack of knowledge about each others areas of expertise resulted in software that is familiar and natural to the prosthetist and takes best advantage of the power of the computer. For example, the prosthetist can view the model in 3D from any perspective and select the exact regions for modification by directly pointing at the model with a mouse.

Some of the other systems produce a positive mould that contains ridges. These ridges are not like traditionally smooth positive moulds produced by the prosthetists. It is presently unconfirmed whether sockets with ridges are as comfortable for the patients as the smooth sockets produced using the traditional method. While it is possible to sand the ridges and make a smooth positive mould, the process loses the numerical quantification of the socket size, shape and volume and reduces the effectiveness of this tool for determining the basic principles for socket fabrication. The milling process described produces a smooth positive mould that is as smooth as that produced by the prosthetist using the traditional procedure. No sanding is required and thus the numerical information describing the shape of the positive mould is not lost. Figure 3 illustrates a mould milled out by the NC machine and also presents a modified mould for the patient using the traditional plaster process.

When the CAD CAM research in this area originally began the task was to fit BK amputees. Hence, all the tools (i.e. mechanical digitiser, CAD software, NC milling machine) developed were designed for that task. Thus when it becomes desirable to expand to other areas these tools will have to be redesigned to accommodate different size segments (e.g. body jackets, children's prostheses). When the authors began their CAD CAM research the general objective was to develop a system to fit patients for all types of prosthetic/orthotic applications. However, it is believed that before advancing to all levels of amputation or application it was necessary to develop methods that could successfully fit patients at one level. Having solved the problems at one level will make it easier when the methods are applied to other areas. The initial test population were BK amputees. Hence the software and the milling machine were designed with that general objective in mind. The basic software is object independent and therefore is not concerned with the object's size or shape. The modifications are specific for BK sockets. However, the aspect of the software has been designed to be easily changed to the modifications required for any application. These modifications are generally based upon the markings by the prosthetists on the stump.

The new milling machine will be a five axis mill (i.e., 3 translational axes and 2 rotational axes) capable of cutting moulds necessary for all prosthetic and orthotic applications. The two rotary axes will allow for the cutting of moulds for such things as ankle foot orthoses and wheelchair seating. The mill will be able to cut a mould with a volume of up to 700mm x 700mm x 1250mm. Thus a mould of a trunk can easily be milled out for a body jacket. The feed rate of the machine will be up to 5120 mm/min to allow for the rapid cutting of the moulds. For example, at this speed a mould for a BK socket can be cut in 20 minutes.

Summary and future work

The writers have developed a numerical system for fabricating prosthetic sockets. The system overcomes five limitations existing with some of the other numerical systems: 1) accurate high resolution surface topography, 2) specific indentification of subject modification sites, 3) flexible, user friendly software, 4) high resolution NC milling, and 5) integrated expansion to other prosthetic and orthotic areas. Fifteen patients have had trial fittings and they have subjectively stated that their "computerised" socket fits better than their traditionally made socket. Future objective evaluation of socket fit including blind fittings, independent prosthetist evaluation, pressure recording between the socket and stump, and quantification of soft and hard tissues in the stump will eventually add to the understanding of these subjective evaluations.

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REFERENCES

Bioengineering Centre Report 1986 (1986). — London: University College London. Department of Mechanical Engineering, p 9–82.

Engsberg JR, Clynch GS, Lee AG, Allan JB, Harder JA (1990). A quantitative method of prosthetic socket construction for below-knee amputees. 1990 Summer Computer Simulation Conference, Calgary. 568–571.

New York University Medical Centre (1980). Lower Limb Prosthetics. — New York: NYU.

Oberg K, Kofman J, Darisson A, Lindstorm B, Sigblad G, (1989). The CAPOD system — a Scandinavian CAD CAM system for prosthetic sockets. *J Prosthet Orthot* **1**, 139–148.

Saunders CG, Foort J, Bannon M, Lean D, Panych L (1985). Computer aided design of prosthetic sockets for below-knee amputees. *Prosthet Orthot Int* **9**, 17–22.

Sidles JA, Boone DA, Harlan JS, Burgess EM. (1989). Rectification maps: a new method for describing residual limb and socket shapes. *J Prosthet Orthot* **1**, 149–153.