

An evaluation of computer aided design of below-knee prosthetic sockets

A. K. TOPPER and G. R. FERNIE

Centre for Studies in Aging, University of Toronto Department of Surgery, Toronto, Canada

Abstract

Forty-eight below-knee amputees compared sockets designed using CANFIT computer aided design (CAD) software with sockets designed using conventional methods. Each subject was fitted by one prosthetist who used conventional techniques and one who used the CANFIT system to design the socket. Prosthetists alternated design methods for each new subject. The prosthetist using the conventional techniques was allowed up to 2 design attempts and the prosthetist using the CANFIT system was allowed up to 5 design attempts. After 2 design attempts with each method 21% of the subjects preferred the CANFIT design socket. Following up to 5 attempts 54% preferred the CANFIT designed socket. A jury of experts made an assessment of the CANFIT system and of CAD in prosthetics. The jury did not think that the version of the system tested was cost effective but that at the rate that it was improving it would become such within 3 to 5 years. The jury noted that, as well as monetary benefits, CAD presents the possibility of benefits in other areas such as research and teaching. A number of specific suggestions regarding the use and development of CAD in prosthetics were also made.

Introduction

Computer aided design and manufacturing (CAD CAM) systems in prosthetics provide an alternative to traditional methods for producing a positive mould which can be used to make a prosthetic socket (Lord and Jones, 1988; Michael, 1989). CANFIT is one such system that

has been developed by the University of British Columbia and Shape Technologies Inc. (Saunders *et al.*, 1985; Saunders *et al.*, 1989). In the 1989 version of this system, a Northwestern casting jig was used to load the tissue of the stump while the prosthetist took the necessary measurements. The anteroposterior diameter was measured at the mid-patellar tendon and the mediolateral diameter was measured at the tibial plateau using calipers. The length of the stump was measured using a tape measure. The cross-sectional area was estimated at 2.5cm intervals along the stump using a handheld tool specifically designed for this purpose.

A starting socket shape was selected automatically for each subject from a matrix of 9 model shapes. This matrix included small, medium and large sockets in tapered, cylindrical, and bulbous shapes. The software selected the model sockets which corresponded most closely with the measurements taken and then interpolated between model sockets to derive the socket shape for the subject.

The prosthetist could view cross-sections of the socket or could view the whole socket as represented by a wire frame or a shaded three-dimensional representation. After viewing the socket, the prosthetist could modify the shape using one of the following three methods:—

1. to make localized changes to the shape the prosthetist could use the patch method which allowed mould material to be added to or removed from a region of any size anywhere on the socket,
2. the prosthetist could change the overall size of the socket using "length" and "ply" modifications. The length mode allowed the distal end of the socket to be extended. The

All correspondence to be addressed to Mr. A. K. Topper, Centre for Studies in Aging, Sunnybrook Health Science Centre, 2075 Bayview Avenue, Toronto, Ontario, Canada M4N 3M5.

overall socket volume could be changed using "ply" mode if the socket was found to be too tight or too loose,

3. a separate option was available which allowed the rear flare to be repositioned.

Once the changes were complete, the software created a file which was used to carve a positive mould, made of polyurethane foam, on a numerically-controlled milling machine.

Changes to the CANFIT software were recommended as a result of a pilot study (Holden and Fernie, 1986) but these changes were not complete by the start of this study. The older version of the software was used until the new version was complete (approximately one quarter of the way through the study). During the course of the study problems with the software were discovered and suggestions for improvements were made, some of which were acted upon by the developers. As a result of this interaction the software evolved over the course of the study. The most current version of the software was used at any given time because it did not make sense to evaluate an out of date system.

The purpose of this study was to give clear and unbiased answers to two questions:—

1. does the CANFIT CAD CAM system fit an amputee as well or better than the conventional method within a similar time frame?
2. what is the potential for CAD CAM in prosthetics?

Single-blind comparative clinical trials were performed in order to determine the quality of fit. The assessment of potential was performed by an independent jury which examined the results of the clinical trials as well as other related information.

Methods

Clinical protocol

Below-knee amputees who had previously been fitted with a limb were recruited for the study. Each amputee was fitted by one prosthetist using conventional casting and hand rectification methods and by a second prosthetist using the CANFIT system. A total of four prosthetists participated in the study. The prosthetists were divided into two pairs according to level of experience in conventional fitting so that the effect of experience on the results could be examined. Each pair fitted 24 subjects. Responsibility for fitting by conventional or

CANFIT methods was alternated within the prosthetist pairs for each new subject.

The measurements and design of the CANFIT sockets were performed at the Centre for Studies in Aging, in Toronto. The shape data were transferred via modem to Vancouver where moulds for the sockets were carved in a stiff polyurethane foam by a numerically controlled milling machine. These moulds were returned overnight by air freight. Both the CANFIT sockets and the conventional sockets were vacuum formed from transparent acrylic in Toronto in such a way that the finished trial limbs were almost identical in appearance.

In this single-blind comparative trial, the subjects were fitted with the limbs in a random sequence and asked to express a preference. A hard socket with only a single one-ply cotton stump sock and/or nylon sheath (to reduce friction) was used since this makes the amputee's task of determining which socket was the better fit simpler. Errors in fit may be masked by thicker socks and flexible sockets.

Up to two attempts with conventional sockets and five attempts with CANFIT sockets were allowed. In the pilot study (Holden and Fernie, 1986) it was found that the first conventional socket was not always ideal. Since the conventional socket was used as the control standard a second attempt was allowed. A minimum of two comparative trials took place to allow the two conventional attempts. A total of five CANFIT attempts were permitted in order to determine if CANFIT could achieve a fit that was as good as the conventional fitting and to determine how many iterations were necessary. As of the second trial the best conventional was compared with subsequent CANFIT sockets. If the CANFIT socket was preferred, then the trials ended.

At each fitting trial the prosthetists adjusted the alignment of the first limb fitted. The subject then walked until both the subject and the prosthetists felt capable of making a judgement regarding the socket fit. This process was repeated with the other trial limb. After the subject had walked on both limbs he/she was asked to select which leg he/she preferred. The subject did not know which limbs were produced by which method — the limbs were marked using a number code. The subject was then asked to express the extent of preference for the chosen limb on a continuous scale. At the end of each trial the prosthetists

completed an evaluation form for the leg they had designed. This information was used as a basis for feedback to the developers.

The design of the clinical protocol has been described in detail elsewhere (Fernie and Topper, 1989). A summary of other evaluations of the CANFIT system can be found in (Saunders *et al.*, 1989)

At the end of the clinical trials the prosthetists completed a questionnaire regarding their experience with the CANFIT system.

Jury assessment protocol

A jury was assembled for one day to make a detailed assessment of CANFIT and a general assessment of CAD CAM in prosthetics. The jury comprised one medical doctor involved in the care of amputees, two people involved in unrelated CAD CAM research, a prosthetist, an orthotist, and an amputee. Background information, including journal papers (Lord and Jones, 1988; Michael, 1989; Saunders, 1988), as well as the results of the clinical study, were sent to the jury members before the assessment day.

After listening to presentations on the CANFIT software, the results of the clinical trials, and cost and time information collected during the trials, the jury was asked to discuss a number of specific issues. The jury was also asked to formulate recommendations on how CAD CAM could be used in clinical prosthetics, prosthetic education and prosthetics research, and on the direction that development of CAD CAM in prosthetics should take. A secretary, chosen from among the jurors, prepared a report which was distributed to all jury members for corrections and approval.

Results

Clinical trials

Fifty-one subjects were recruited for the study. Of these, 48 completed their trial sessions. One subject dropped out due to scheduling problems, one dropped out due to illness and one dropped out due to skin problems. Subjects included 41 men and 7 women aged 23 to 81 years (average 60 years). While the prosthetists were grouped according to level of experience the differences in the levels were not large. The more experienced pair had been practising prosthetics for an average of 6.5 years while the less experienced pair had been practising for an average of 4 years.

The null hypothesis of this study was that an

equal number of subjects would prefer sockets made by each method, i.e. that CANFIT can make sockets that fit as well as those made conventionally. With 48 subjects and an alpha value of 0.12 there was a power of 0.89 for true proportions of 0.30 or 0.70 (i.e. if the true proportion was as low as 0.30 or as high as 0.70 it was more than 89% sure of correctly rejecting the null hypothesis). Of the 48 subjects tested, 26 (54%) preferred the CANFIT socket by the end of their trial sessions. This number is not significantly different from the number expected if the two methods were equally preferred and so the null hypothesis that the proportion of preference for each method is 0.50 is supported. Table 1 shows the number of subjects preferring the CANFIT socket at each iteration as well as the cumulative percent of subjects preferring the CANFIT socket by the end of each iteration.

A statistical analysis (using Spearman correlation coefficient) showed no significant correlation between subject sequence and preference. This indicates that there was no obvious learning curve over the course of the study.

Subject preference versus prosthetist pair was examined and it was found that 16 of the 24 subjects fitted by the less experienced pair preferred the CANFIT socket while only 10 of the 24 subjects fitted by the more experienced pair preferred the CANFIT socket. This is not a statistically significant difference at the 5% level (using Fisher exact probability) but it is at the 7% level. Thus it seems that there was probably some difference in the relative ability to make each type of socket between the pairs.

From the average time taken by prosthetists and technicians to make the test legs for the study it was found that if legs of each type are made in one design iteration then the prosthetist time is less for the CANFIT leg than for the conventional leg while the technician time is slightly greater (the foam takes longer than plaster to break out of the socket). The same result is seen if two legs are

Table 1.
Socket iteration vs subject preference

CASD Socket #	Number of subjects	Number who prefer CASD	Cumulative % who prefer CASD
2	48	10	21%
3	38	8	38%
4	30	3	44%
5	27	5	54%

made by each method. If only one or two conventional design attempts are sufficient to produce a properly fitting leg but three or more CANFIT legs must be made, then using the computer method would significantly increase the time required to produce a good leg. It should be noted that in using an iterative fitting process a large component of the increase in time is for the technician to make the trial legs.

Both the subjects and prosthetists comments about the fit of each trial prosthesis were recorded and were used as the basis for feedback to the developers. This feedback resulted in changes in the system such as the added ability to increase and decrease the overall volume using "ply" mode, the ability to lengthen the socket, shaded image display, and the ability to select the location to be changed on the shaded rather than the outline image.

Prosthetist questionnaire

All four prosthetists expressed doubts about the accuracy of the hand held measurement tool. The tape measure part could be tightened by different amounts and the hard plastic part of the tool did not always fit the contour of the anterior portion of the stump despite the available adjustments. All the prosthetists thought that the computer was unable to produce an accurate base shape from the measurements provided and that, due to the use of a limited range of reference shapes, the system worked best for stumps with "ideal" shapes. No allowance was made for stump features such as bowed tibias.

All the prosthetists thought that the shaded view was the most useful of the three possible methods of viewing the socket (outline, wire frame, shaded). A common complaint about the display was that these prosthetists prefer viewing socket shapes aligned vertically on the screen rather than horizontally.

Three of the four prosthetists considered that making modifications was not "easy" but "OK" while the other prosthetist thought that, in general, modifications were difficult to make. Generally length changes, moderate changes in volume and increases or decreases of relief in small areas were considered easy to make. Changes which were difficult to make include large contour changes, changes which are not in the anteroposterior or mediolateral planes, large volume changes, eliminating gaps between the socket and the skin without causing pressure on

surrounding areas, and reducing areas to produce counter pressure. The prosthetists wanted to be able to "draw" modifications rather than manipulate "dots".

The ratings given to the ease of use of the system were spread across the scale from "very easy" to "very difficult". Estimates of the number of fittings required before being able to fit a client ranged from 2-3 to 12. Estimates of the number of fittings required to become a proficient user of the system ranged from 5 to 100.

All the prosthetists said that, if they were allowed to use a soft liner and wool socks to fit the client, on average, a client could be fitted satisfactorily in three iterations (i.e. first socket design plus 2 chances at making modifications) using the CANFIT system.

Three prosthetists thought that the present system is clinically useful in limited cases while the fourth prosthetist did not think it was clinically useful.

It should be noted that in 1990 the measurement method, viewing methods and modification methods are all being revised based on these comments as well as others which the developers have received.

Jury assessment

Some of the comments in this summary of the jury assessment apply specifically to CANFIT but many apply in general to CAD systems for prosthetics.

The system as evaluated could not deal with all forms and severities of unusual anatomy due to a combination of a measurement method which did not seem to collect sufficient information and the subsequent use of standard reference shapes which assume a more or less standard anatomy and allow for limited types of variations. Use of a detailed digitization of the stump, or of a cast of the stump, as a start shape, followed by a set of prosthetist controlled modifications may resolve this problem. The jury favoured the use of a moulded cast of the stump as input to the system so that some information regarding the bone and tissue structure is incorporated into the start shape.

It was agreed that CANFIT could decrease the time spent designing sockets and that it eliminates plaster drying time. However, other factors militate against amputees realizing the benefits of these time savings. These factors include the

necessity to reorganize present practices (traditional work scheduling and patient booking), and patient preference (if living close to the prosthetics centre) for a few brief visits rather than one all day visit. If current practices could be reorganized to take advantage of the time savings made possible with CANFIT then the system could provide better service for out-of-town patients who could decrease the length of their stay, children who have little patience, and new amputees who require several fits during the period when their stump is shrinking.

Practical remote site service would be valuable in the Canadian context because of vast distances. The jury took the view that, because digitizers, vacuum formers and numerically-controlled machining systems are becoming less expensive and are relatively portable, the fitting and fabrication should be incorporated in a mobile unit to service remote sites. The jury could not see any benefit in having only the design part of the system going with the travelling prosthetist. The prosthetist would then have to wait for the leg to be shipped back so that it can be fitted and then would probably have to repeat the process because it is likely that the first socket will not fit properly. The process is not viewed as an improvement over the prosthetist taking a cast and sending that back to the fabrication facility.

Services for the Third World were thought to be realistic only if the costs were fully underwritten by the Canadian government. It was thought however that, in general, this approach does not work on a sustained basis. Practical Third World services, history has taught, should derive from training of local practitioners and the innovative use of local materials and talents with the emphasis on self sufficiency. Both prosthetists and committee members thought that the shape information accumulated by using CAD could eventually lead to some expert criteria for off-the-rack sockets which would raise the present minimum standards.

The jury agreed that a prosthetics facility can increase its profit by increasing the number of legs produced if:—

1. CANFIT could produce a good fitting socket in the same, or fewer design attempts than the conventional method so that the total time spent by the prosthetists is less than it would be if conventional methods are used, and
2. prosthetics facilities amalgamate so that the facility has more clients per prosthetist and the

time saved by CANFIT can be used to fit more amputees.

The system that was evaluated was not considered cost effective as it was not able to produce legs which fit as well as the conventional legs in 1 or 2 design attempts. However, the new version of the system which was demonstrated and described, was viewed as potentially profitable. In any case, it was agreed that more clients per prosthetics centre would be necessary to justify such systems. Justification of the system would be easier if it included automated cosmetic cover generation, automated alignment of the limbs, automation of paper work, and packages for spinal braces and footwear fabrication.

Although the system that was evaluated was not deemed appropriate for commercial application, the new version of CANFIT which was under development at the time of the jury trial seemed as though it might solve many of the problems that were apparent in the study. This new system should be tested in clinical trials to confirm these expectations.

The jury thought that CAD systems for prosthetics are on the brink of being commercially feasible. Although the systems will probably not be profitable tools for another three to five years it may be wise to consider buying a system in the next year or two so that the technology can be integrated gradually. The changeover period will allow clinicians to restructure their practices so that they can take advantage of the strong points of CAD and also allow them to develop a method of screening to determine which clients are suitable for CAD fittings. Jury members also thought that it is important for prosthetists to use these systems in the near future so that they can have input into the development of this technology. Prosthetists who are considering buying a system should plan to try testing the various systems available by fitting an amputee or two before committing themselves to a particular system. The jury advocated that CANFIT system suppliers be required to allow extensive try-before-buy with real patients in the practitioner's own shop. Prosthetists should be forewarned that in the short run they are likely to lose money by investing in this technology and that their facility must be able to absorb this short term loss. If they do not think they can afford any immediate loss but want to become involved, they should consider sharing CAD resources with other facilities.

Because many prosthetists seem to agree that CAD is "the way of the future" for prosthetics, the jury felt that exposure of students to this new technology and related concepts is highly important. In order to prepare students they should be taught the skills they need to use any of these systems, such as three dimensional visualization and typical methods of manipulating objects on a computer, rather than making them experts on a specific system. Although exclusive learning by CAD workstation sessions should be avoided, CAD can still play a role in prosthetics education as long as traditional manual skills and student control of decisions (not computer algorithm-based decision making) are retained.

Discussion

The lack of statistical evidence of a learning curve could be due to the effect of a thorough training course prior to the start of the study. It seems that there was some difference in the relative ability to make each type of socket between the pairs of prosthetists. From observations made during the course of the study, the authors attribute this difference to varying adaptability to the computer rather than to differences in hand skills required in the conventional method.

Some of the responses of the prosthetists to the questionnaire which they completed at the end of the study were somewhat contradictory. While they were very positive about CAD CAM in prosthetics, they were critical of its present status. The prosthetists wanted a more accurate and detailed measurement system and more control over the shape creation process. The shaded display, which was introduced during the course of the study, was thought to be a great improvement over the outline and wire frame displays. Some types of modifications were found to be easy to make, while others were more difficult. Some of the changes which were difficult to make, however, such as large contour and volume changes, might not occur as often if more detailed and accurate (or more pertinent) initial measurements were made.

In order to cope with varying anatomy, the jury recommended that the system should use a detailed digitization of the stump or a cast of the stump as a starting shape. The modifications to this starting shape should be controlled by the prosthetist. The authors agree that the set of reference shapes and types of measurements used

by the system tested did not provide adequate starting shapes and that, while there is a lack of quantitative data regarding socket shapes, other alternatives may be better. There are many problems inherent with such alternatives however. If a moulded cast of the stump is made then some of the benefits of CAD, including time savings and consistency of results (each prosthetist may produce a different moulded cast), are diminished. On the other hand if a passive cast is taken or a non-contacting shape sensor is used then, while many data points are collected, most of the information about the bone structure and tissue characteristics is lost. The jury suggested that the eventual solution to these problems may involve a combination of imaging systems, which provide more information regarding the stump, and software which can use this information to emulate the prosthetist's moulding techniques to produce appropriate areas of relief and weight bearing. Another possibility is that, as a larger library of reference shapes is built and as more is learned regarding what measurements are necessary to appropriately scale the reference shapes, the use of the reference shape method may become more attractive.

There has been some research into the use of other types of measurements and measurement methods for socket design such as tissue stiffness (Krouskop *et al.*, 1989), ultrasound (Faulkner *et al.*, 1988) and computed tomography (CT) (Faulkner and Walsh, 1989). Krouskop's system combined measurements of tissue stiffness and stump shape to produce a socket shape for above-knee amputees. Faulkner's work with ultrasound resulted only in another method of digitizing surface shape. In Faulkner's work with CT images, below-knee stump shape was measured and then modified by a prosthetist who could view the bone structure while making these changes; no software was developed which integrated the surface and internal anatomy to produce a socket. Faulkner suggested that neither CT nor magnetic resonance (MRI) images are suitable for this application. By viewing the Rehabilitation Research and Development Progress Reports published by the American Department of Veterans Affairs from 1986 to 1989, where much of this work is described, it can be seen that work in the area of alternative measurement techniques seems to have diminished and that most systems use one of the methods previously mentioned

(cast digitization or non-contacting shape sensing). Current research in CAD in prosthetics seems to be focused on methods of graphically representing sockets and on the interactive methods used by prosthetists to change the shape. While this work is important, the key questions regarding the underlying methodologies, deserve more study i.e.

1. what are the crucial measurements necessary to design a socket? (The authors do not believe that a complete description of the stump surface is the solution.)
2. how are these measurements of a stump's characteristics transformed into an appropriate socket shape?

The jury suggested that a remote site service using a mobile clinic with a CAD workstation, a carver and a vacuum former would be beneficial in Canada. There are problems, however, not considered by the jury in suggesting a complete mobile clinic rather than a travelling prosthetist with only a portable design station. These problems include extremely long driving times and many communities that are accessible only by air.

Gradual integration was thought necessary to allow a restructuring of current practices in order to take advantage of the benefits of CAD. This would allow clinicians to become competent and efficient users of the system, and permit a client screening protocol to be developed so that time is not wasted trying to fit amputees not suited to the current CAD technology. Most payback analyses make the assumption that this process happens instantly but there are always growing pains with the introduction of new equipment and new technology.

Conclusion

The CANFIT system (in the version tested) was found, in a controlled single-blind trial, to be capable of fitting below-knee amputees as well as could be achieved with conventional methods. However, more trial fits were required. A jury predicted that the rate of evolution of the system will lead to its profitable application in major centres within 3 to 5 years and recommended prosthetists consider acquiring a system in the next 1 or 2 years in order to facilitate the gradual and orderly introduction to clinical practice.

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