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Results of the pilot phase of a clinical evaluation of computer aided design of trans-tibial prosthesis sockets

J. M. HOLDEN and G. R. FERNIE

West Park Research, Department of Surgery, University of Toronto

Abstract

This study served as a pilot to develop the methodology for a larger number of clinical trials. Ten trans-tibial amputees compared sockets made by conventional methods with sockets made using computer aided socket design (CASD). Prosthetists, paired for experience, fitted each subject with one prosthesis using each method. A preferred socket was selected by the subject on the basis of comfort without knowledge of the method by which the socket was designed. Prosthetists also evaluated the sockets. Three subjects preferred sockets built using CASD and one subject preferred the conventional socket only slightly more than the CASD socket. Six subjects clearly preferred the conventional fitting.

Introduction

A method of computer aided design of trans-tibial prosthesis sockets was developed by the Medical Engineering Resource Unit (MERU) in Vancouver, Canada (Saunders et al, 1985). This paper reports the results of a pilot study of clinical trials conducted at an independent centre. The purpose of this study was to develop a protocol and to determine the sample size required to execute a full series of clinical trials. This larger study will be conducted during the next two years to determine whether computer aided socket design (CASD) is worthy of further investigation and development. The pilot study results are reported at this time, firstly because of a perceived interest in the prosthetics community and secondly to relate experience with the protocol to other research groups planning evaluations of CAD/CAM systems.

All correspondence to be addressed to J. M. Holden, West Park Research, Department of Surgery, University of Toronto, 82 Buttonwood Avenue, Toronto, Canada, M6M 2J5.

Method

CASD socket

The CASD system consisted of an interactive software package operated on an IBM PC/XT microcomputer with a VECTRIX* graphics unit and monitor. The following limb measurements were entered into the computer: length of the residual limb, length of the sound limb, mediolateral diameter at the tibial plateau, anteroposterior diameter at mid patellar tendon level and at one inch intervals below. The program used these initial data to generate a primary modified shape. The prosthetist then examined the shape and had the opportunity to change it using an interactive modification software package. Graphical representations of the modified socket were examined and approved before the data were transferred to a floppy disc.

The disc was then sent to Vancouver where the MERU team used their numerically controlled milling machine to carve the shape from a solid polyurethane foam plug. The plug was returned to Toronto where a socket was vacuum moulded using acrylic orthoglass**. This plug was not smoothed or otherwise altered. The orthoglass was selected because its rigidity and transparency enhanced the quality of the evaluation. The socket was trimmed and attached to temporary alignment apparatus using Seglehartz adhesive**. All legs were set up using a SACH foot fitted with the subject's own shoe.

Conventional socket

Standard measurements and a plaster cast were taken. A plaster positive was developed and modified. This was used to vacuum mould

*Manufactured by Vectrix Corporation, North Carolina, U.S.A.

**Distributed by Otto Bock Orthopedic Industry of Canada, Winnipeg, Canada.

an acrylic socket in the same manner as the CASD socket. After trimming and attachment to an alignment rig the conventional socket limb appeared to be the same as the CASD socket limb.

Subjects

Ten volunteers with trans-tibial amputations were fitted in this pilot phase. Subjects were mentally alert, physically well and had no major problems with their residual limbs. All amputees were active wearers of patellar-tendon-bearing prostheses.

Surgery had occurred at least 18 months previous to the study. Amputations had been caused by peripheral vascular occlusive disease in seven subjects and trauma in the remaining three subjects. Subjects included eight males and two females aged 54 to 72 years (mean 64.6 years).

Prosthetists

Six prosthetists from three centres in the Toronto area volunteered for participation. Prosthetists were paired according to low, medium and high experience levels. They were provided with background material and a CASD study manual before attending a two day, hands-on training course. One subject was measured and fitted with a CASD socket during the course.

Design of study and procedure

Subjects were assigned randomly to one pair of prosthetists. Each prosthetist was then assigned randomly to make either a conventional socket or a CASD socket for the subject. Prosthetists within a pair fitted an equal number of subjects with the two types of sockets. The four more experienced prosthetists fitted two subjects with CASD sockets and two subjects with conventional sockets each, while the two least experienced prosthetists fitted one CASD and one conventional socket each.

Measurements and a plaster cast were taken with both prosthetists present. Within one week the subject returned to be fitted with the conventional and the CASD sockets. Both fittings were done at the same session with both prosthetists present. Every effort was made to conceal the origin of the sockets from the subject in order to eliminate bias. If the socket fitted well enough to permit weight-bearing a routine dynamic alignment was performed. If the socket fitted well enough to permit continued walking the subject was allowed to walk for a period of up to twenty minutes. Prosthetists evaluated the limb using a prepared questionnaire and the subject selected the preferred socket, using a continuous scale (Table 1). The subject's response was not made known to the prosthetists.

Three possible subject choices led to different procedures.

1. If the subject chose the CASD socket the trials ended.
2. If the subject was unable to decide he was asked to take the limbs home for further use to facilitate choosing a socket. In that case the limbs would have been fitted with a footstep monitor to measure the number of steps taken with each limb.
3. If the conventional limb was preferred the trials continued.

If the trials continued the CASD socket was modified on the computer screen and a second limb manufactured in the same manner as the first. The limb was dynamically aligned and compared to the original, unmodified conventional limb using the same method as the first comparison.

On the basis of the subject's choice the procedure was repeated once more if the conventional socket was preferred. Thus, a second modification to the CASD socket was allowed. The trials stopped after the second CASD modified socket was compared to the conventional socket.

All sockets were fitted with a one-ply cotton residual limb sock and a standard patellar-tendon-bearing socket design was used for all limbs. Either hip belt or neoprene sleeve suspension was used depending on which was closest to the subject's accustomed suspension.

Results

All subjects were able to decide which socket they preferred without taking the legs home for extended walking. Only one trial was stopped early because the subject chose the CASD socket after the first socket modification.

Table 1 summarizes the results of the subject evaluation of sockets. Sockets were identified as follows: a=conventional, b=first CASD socket, c=first CASD modification and d=second CASD modification. The first three

Table 1. Subject responses

least exper pros			med. experience pros			most experience pros		
subj	socket	choice	subj	socket	choice	subj	socket	choice
1	a/b	conv: 3	7	a/b	conv: 4	3	a/b	conv: 4.8
	a/c	conv: 3		a/c	CASD: 3		a/c	conv: 5
	a/d	conv: 2					a/d	conv: 4
	b/d	d: 4		b/c	c: 4		b/d	d: 2
2	a/b	conv: 4.4	8	a/b	conv: 4	4	a/b	conv: 3.9
	a/c	conv: 3.7		a/c	conv: 4		a/c	conv: 5
	a/d	CASD: 1.7		a/d	conv: 4		a/d	conv: 5
	b/d	d: 4.3		b/d	d: 4		b/d	d: 2
			9	a/b	conv: 4	5	a/b	conv: 5
				a/c	conv: 3.3		a/c	conv: 4.9
				a/d	conv: 2.7		a/d	CASD: 4
				b/d	d: 3.4		b/d	d: 5
			10	a/b	conv: 4	6	a/b	conv: 4
				a/c	conv: 1.1		a/c	conv: 5
				a/d	conv: 2.0		a/d	conv: 1
				b/d	d: 2		b/d	d: 4

legend: socket a=conventional
b=first CASD socket
c=first CASD modification
d=second CASD modification

Scale for subject evaluation:
For each socket comparison a subject was asked to place an × anywhere on a horizontal scale numbered as follows:

Socket # Socket #

5———4———3———2———1———0———1———2———3———4———5

The numbers were labelled as follows:
0=neutral;
1=slightly better;
2=somewhat better;
3=moderately better;
4=much better;
5=very much better.

comparisons were between the conventional socket and each of three CASD sockets. The last comparison was between the first and last CASD sockets.

One subject preferred the CASD socket on the first modification while a further two subjects chose the CASD socket on the second CASD modification. One subject found the conventional socket to be only slightly better than the second CASD modification and another three found the conventional socket to be somewhat better to moderately better than the second CASD modification. The remaining four subjects found the conventional socket to be much better to very much better than the second CASD modification.

All CASD sockets that were preferred were chosen on the first attempt for each of three different prosthetists. One prosthetist from each of the three experience level groups had a CASD socket chosen by a subject. There did not appear to be a strong relationship between the level of experience and the success of the individual prosthetist.

The prosthetists were asked to state whether the sockets they made were medically safe to wear at home for one week. They were also asked to outline any problems with the socket that were interfering with comfort and safety. Table 2 summarizes their responses. Six of the

Table 2. Prosthetist evaluation

Was the prosthesis safe to wear at home for one week?

	Socket			
Subject	a	b	c	d
1.	No*	No*	No*	No*
2.	No*	No*	No*	Yes*
3.	Yes	No*	No*	No*
4.	Yes	No*	No*	No*
5.	Yes	No*	No*	Yes*
6.	Yes	No*	No*	Yes*
7.	Yes*	No*	No+*	
8.	Yes*	No*	No*	No*
9.	No*	No*	No*	Yes+*
10.	No*	No*	No*	No*

legend: *modifications would improve the fit
+prosthetist unsure, would require longer walking session to be positive
socket a=conventional
b=first CASD socket
c=first CASD modification
d=second CASD modification

ten conventional sockets were considered safe for one week's use, although two of these might have been improved with modifications. Four of the second modifications of the CASD sockets were considered safe to use for one week, with modifications recommended in all cases. CASD sockets fitted to subjects 2 and 5 were preferred by the subject and were also rated as safe for one week's use by the prosthetists. Subject 9 did not prefer the CASD socket and the prosthetist suggested that it might be safe for use, although he requested further walking before making a decision. Subject 7 preferred the CASD socket although the prosthetist was not confident that the socket was medically safe on the basis of the allotted walking. Subject 6 considered the conventional socket to be only slightly better than the CASD socket when both conventional and CASD sockets were considered by the prosthetists to be safe for use for one week.

All four sockets fitted using conventional methods by the most experienced prosthetists required no modifications. All conventional sockets made by the least and medium experienced prosthetists required modifications, with only two considered to be safe for use for one week.

The times required for designing the socket, building the socket and setting up a leg for trial fit are presented in Table 3. The mean time required for making the conventional leg and the first CASD leg was similar. Successive modifications of the CASD legs took less time and there was considerable variability in the amount of time required by each prosthetist. There was no apparent relationship between the amount of time taken on the computer and the success of the CASD fit. Prosthetist A took 9.33 hours for subject 5, prosthetist B took 2.25 hours for subject 2 and prosthetist D took 1 hour for subject 7. Subjects 5, 2 and 7 preferred the CASD over the conventional socket. The other major reason for variation in time was the amount of time taken to break the polyurethane plug out of the socket. This factor depended on the shape of the socket.

Prosthetists were asked a series of questions after the completion of the trials, the responses to which are summarized in Tables 4 and 5. All prosthetists enjoyed using the computer to some extent. Two believed that CASD has a good future, two felt that it has a moderate future and the remaining two felt that CASD has very limited to no future. Five prosthetists felt that

Table 3. Time taken to make prosthesis

	Socket				
	a	b	c	d	b+c+d
Total time (hours)					
mean	3.71	3.61	3.17	3.16	9.55
standard deviation	.56	.92	1.37	.97	3.26
CASD computer time (hours)					
mean		.86	1.18	1.16	3.07
standard deviation		.80	1.08	.69	2.38

Table 4. Prosthetist responses to questionnaire on CASD

	Prosthetist					
Topic	A	B	C	D	E	F
Enjoyed using computer	mod+	mod	mod+	mod+	mod+	mod+
CASD has future	lim	mod	none	good	good	mod
Years to clinical usefulness	7.5	10	infin	5	7.5	4
Frustration making conventional	none	little	little	little	none	little
Frustration making CASD socket	little	strong	strong	little	mod	mod
# Subjects to learn CASD well	30	30	na	2	75–100	3–4
# Modifications needed to get good fit	infin	infin	20–25	2–4	4	4

legend: lim= limited
mod= moderate
infin= infinite
na= no answer

CASD would be clinically useful in four to 10 years. Little frustration in making the CASD sockets was felt by two prosthetists, while two were moderately frustrated and two had strong feelings of frustration. The number of subject fittings prosthetists suggested might be required to learn CASD well varied considerably from two to 100. Three prosthetists felt that four modifications might be required to get a good CASD fit while others felt it would take 20 to an infinite number.

It was believed that several factors might have been related to a prosthetist's success in using CASD. These included experience as a prosthetist, education, experience with computers, ability/experience in translating two dimensional images into three dimensional images. Table 5 summarizes responses to questions related to these factors.

Prosthetists provided a full evaluation of the fit of each socket. The following is a summary of some of the more common shape problems:

1. The posterior shelf was not perpendicular to the anteroposterior plane. It was tighter on the medial border and therefore interfered with the hamstrings tendon.
2. There was too much relief over the tibial tubercle and proximal two-thirds of the tibial crest.
3. There was too little relief in some sockets in the distal posterior and distal anterior regions.
4. There was insufficient convexity of shape to accommodate the patella in some sockets.
5. The socket was too small mediolaterally proximal to and at the femoral condyles.
6. Sometimes the socket was too small anteroposteriorly at the patellar tendon level.
7. There were some areas of non-contact just distal and lateral to the patellar tendon bar.
8. It was extremely difficult to accommodate unusual boney shapes at the fibular head and near the tibial tubercle.
9. The software did not deal well with a cylindrically shaped residuum.
10. Ridges appeared after modification of the posterior aspect.
11. All prosthetists found it necessary to add length to the socket.

Prosthetists had several recommendations to improve their ease of use of the CASD system. These included the following.

1. Use of shape sensor or some other method to provide more accurate and complete input data.

Table 5. Experience and ability

Experience/ability	Prosthetist					
	A	B	C	D	E	F
College/university	y	y		y	y	y
Computer used for:						
games	y	y		y	y	y
wordprocessing				y	y	
programming		y			y	
graphics		y				
Took drafting course	y	y		y	y	y
Art sculpture experience	y			y	y	
Used topographical maps	y	y		y	y	y
Self rated ability to translate 2d cross sections to 3d image	***½	½	*	**	0	*½
Subject preferred CASD	+	+		+		
Prosthetist rated CASD ok for one week	#	#				#
# legs fitted	10,000	960	1880×	1500	350	1680

legend:
0 not good at all
* slightly good
** moderately good
*** very good
**** excellent
+ plus 10 years technical experience

2. Provide more options for the initial modifications done by the computer software before the prosthetist is permitted to alter the shape.
3. Provide more flexibility in modifying sockets, ie. more choices of patch shapes and easier blending of changes into an existing shape.
4. Improve the quality of the graphics; label cross section orientation.
5. Provide the ability to manipulate the perspective of viewing in three dimensions.

Discussion

The use of a one-ply cotton sock and a rigid acrylic socket represented a very rigorous test of socket fit. Prosthetists usually have the option of varying the thicknesses of socks and the rigidity of the socket. In fact, many elderly amputees are fitted with a soft liner in the socket. The level of difficulty encountered in obtaining a good fitting socket for this study was demonstrated by the inability of four of the six prosthetists to make on the first attempt a conventional socket that did not require modifications to improve its fit. However, the most experienced prosthetists had no difficulty achieving a good fit with all their conventional sockets.

One possible advantage of the CAD/CAM approach (Klasson, 1985) is that a permanent record of the socket shape is retained on computer disc. Thus, the opportunity is afforded to use trial sockets and to work toward an optimal fitting by successive modifications. The practicality of this approach will depend on the time taken for each trial and the number of trials needed. The objective of the developers is to reduce the prosthetist's time to a few minutes. This study protocol simulated this suggested process by permitting up to three attempts. A total of 29 CASD sockets were made for the 10 subjects.

One problem with the protocol used in this pilot study was that the conventional socket is not always an excellent fit as a basis for comparison, however, the use of such a rigid test reveals the inadequacies in expertise in both systems. Two of the three CASD sockets that were preferred by the subjects were compared to conventional sockets rated favourably by the prosthetists. The third CASD socket that was preferred by the subject was compared to a socket not rated favourably by the prosthetist. The third CASD socket was, however, rated well by the prosthetist and therefore it can be considered to be a reasonably good fit.

In addition to providing a rigorous test of socket fit the acrylic socket facilitated evaluation of fit because of its transparency. The extent and location of areas of excessive contact and non-contact were more easily identified. However, the process required a considerable expenditure of time. The time required for the vacuum forming technique is similar to that required for making a more flexible polypropylene socket using the techniques outlined by Davies et al, 1985. However, because of its rigidity and brittleness, the acrylic socket took longer to trim and a considerable length of time was needed to dig the foam plug out of the socket.

The validity of the subjective evaluation of the socket fit by both prosthetists and subjects is difficult to assess. There was, however, reasonable agreement on the quality of the socket fit between the prosthetists and subjects. Of the four CASD sockets that were rated better by the prosthetists two of them were preferred by the subjects, one subject preferred the conventional socket only slightly and the last subject found the conventional socket to be moderately better than the CASD socket.

The prosthetists who had greater success with the CASD were not consistently from any one prosthetist pair (experience level). Prosthetist A, who had a reasonable level of success in both CASD sockets he fitted was the most experienced of all six. However, prosthetist C, who had more difficulty with CASD, was also in the most experienced pair. Prosthetist C had no experience with a computer. Prosthetist A, however, had used a computer for games, had done both drafting and artistic sculpture, had used topographical maps, had college education and rated himself as very good to excellent at translating two-dimensional cross sections to three-dimensional images. On the basis of the questions asked regarding experience and ability, there appears to be no clear explanation for the differences in CASD success among the remaining four prosthetists.

Ideally, subjects would be asked to walk with the experimental and conventional limbs for a longer period of time in order to assess comfort and fit. In this pilot phase however all subjects felt that they were able to make a clear choice

between the sockets. Whenever the choice between the sockets was close to neutral the subject was asked if he had sufficient walking to make a choice. No subject requested additional walking. Some prosthetists believe that subjects should be asked to use the limbs for a longer time before choosing a socket. This would require close supervision of subjects over a lengthy period and therefore a considerably greater expenditure. It is unknown whether such measures would have changed the outcome of this study.

It is worthy of note that the method of storing shapes on a computer disc, shipping it to Vancouver and shipping the shapes back for vacuum moulding was very successful. Occasionally, in order to accommodate a subject's schedule the data was transferred by telephone to Vancouver. It was possible to receive the carved plug within 18 hours. This success demonstrates the ease with which such a system could be used to facilitate limb fitting in remote areas. The distance from Toronto to Vancouver is approximately 5,000 kilometres.

Conclusions

Three subjects out of 10 chose CASD fittings in preference to conventional fittings. Therefore, the CASD system, at its present state of development, was not found to be an improvement over conventional fitting methods. However, the results of this pilot study demonstrated that some success has been achieved. Many of the deficiencies encountered were systematic rather than random errors and might be expected to be corrected in future revisions of the system. The results of the larger study with more subjects must be awaited before definitive and statistically valid statements can be made concerning the rate of successful fittings. It will be of particular interest to observe if there are any trends toward improved fittings and reduction in time taken as the prosthetists gain more experience with CASD during the longer trial.

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