COMPUTER-AIDED-DESIGN AND MANUFACTURING OF PROSTHETIC SOCKETS FROM STUMP SHAPE DATA - CLINICAL EXPERIENCE

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ABSTRACT

The CAPOD CAD/CAM system produces prosthetic socket molds based on stump-shape data input. Initial clinical testing has been carried out with 35 below-knee stump fitti gs involving 10 prosthetists. Twenty-six fittings were completed with well-fitting sockets. Twenty-two were used by the amputee following fitting while 4 were not used. Seven of the remaining stump fittings were terminated early mainly because of the stumps being highly sensitive, while the last 2 fitting are ongoing. Of the 26 completed fittings, 17 resulted in a good fit on the first socket fit, 8 on the second socket and 1 on the third socket. The average number of fittings per stump for completed fittings with a good socket was 1.4. Clinical use showed the socket modelling by CAD to be quite acceptable by prosthetists, easy to use and quick to learn. Clinical feedback has led to modifications to the system to permit total socket-mold fabrication in 23 minutes: 5 for stumnp-shape measurement, 10 for CAD socket modelling, and 8 for mold machining.

KEY WORDS: Prosthesis, CAD/CAM, Socket, Evaluation.

INTRODUCTION

Since the introduction of Computer-Aided-Design and Manu-facturing (CAD/CAM) to lower-limb prosthetics and the development of the first system that followed at the Medical Enginering Resource Unit (MERU) in Vancouver, Canada (1,2), several systems have come into use. While some of these systems are commercially available (3,4), others are still under development or undergoing clinical testing (5,6,7,8,9).

Most complete systems employ CAD functions which allow the prosthetist to modify the socket shape to produce a socket that is somewhat analogous to the conventionally modelled plaster socket. On the other hand, the input to define the initial socket shape before designing the socket, differs considerably.

The MERU system uses a starting socket shape selected from a library of sockets (3,10) based on physical measurements from hand held tools: caliper, measuring tape, and an additional modified measuring tape used to determine stump corss-sectional area (1,3). The University College of London (UCL) system uses an average rectification pattern based on digitization of the inner surface of a plaster wrap taken of the stump (11). Clinical results using these methods have demonstrated successful fitting of sockets (3,12,13,14).

Another contacting method used for stump shape measuring employs a mechanical sensor used in combination with tissue stiffness measurement for finite analysis modelling of the stump and prediction of the deformation at the stump surface inside a socket (7). Computer-Aided-Tomography has also been used as input to systems for finite element modelling (9) but is less feasible for routine prosthetic fabrication applications (15). Ultrasound shape sensing has also been used to acquire input data for prosthetic CAD/CAM systems (16), however, its use for regular clinical practice has not yet been reported.

Simpler non-contacting methods for obtaining stump shape input to CAD systems employ silhouette (17) and laser (5,6,18) scanners. While these optical stump-shape sensing devices allow methods, few results from clinical use of these devices have been reported.

In an earlier paper, the use of stump-shape data obtained by laser scanner, for the design, production and fitting of prosthetic sockets to below-knee (BK) amputees with the Scandinavian Computer-Aided-Prosthetic-and-Orthotic-Design (CAPOD) system has been described (5). While only some of the first clinical trials were reported earlier, this paper presents the results of a more complete initial phase of clinical testing of the system.

METHOD

Thirty-four BK amputees were included in the clinical trials. This represents 35 stumps as one bilateral amputee had both limbs included in the socket fitting testing. Reasons for amputation were mainly for vascular problems and trauma. The age of amputees ranged from 28 to 83 years with a mean of 61 years. The time of fitting of the CAD/CAM socket after amputation ranged from 8 months to 61 years and 9 months, with a mean of 18 years and 11 months. Some of the subjects who participated in the clinical trials required new proshteses while others took part for testing purposes only.

Ten prosthetists from eight Nordic Institutions participated in the fitting trials. None of them had prior experience in using the CAPOD system. As the first few trials may be considered as training sessions, the ability of the prosthetists to learn to use the computer system could be assessed.

One of the primary goals of the initial clinical testing with the CAPOD system was to determine how easily the prosthetist was able to design a well-fitting socket that would enable the function and comfort requied for normal use.

For each stump fitting trial, the amputee was fitted with a CAD/CAM socket designed by their regular prosthetist. If the socket was not comfortable or was not able to be used, modifications were made to the socket using CAD/CAM and the socket was refit to the amputee. A fitting attempt was considered to be comlete when the prosthetist and patient agreed that the socket fit well for comfort and proshtetic use.

Prosthetists were asked to record the number of sockets necessary to achieve a good fitting. For each new socket made, they were required to include their own evaluation of the fitting as well as that of the patient. Such evaluation was an open-ended observation. For each fitting attempt, the prosthetist also indicated whther the socket was satisfactory in terms of comfort and function, and whether the patient was using the prosthesis following the fitting. After the final socket modification, follow-up evaluations ere made until it was clear whether the amputee would continue to use the CAD/CAM socket or not.

The CAPOD system's CAD software uses stump-shape data input obtained directly from the scanning device. There is no gross shape averaging or use of reference socket shapes following initial stump data input, characteristic of UCL (ii) and MERU (3) CAD/CAM systems. The prosthetist works entirely from the stump shape, except at the extreme distal end which is usually left slightly open, where a small supporting cup aids in positioning the stump. Even in this case the prosthetist can manually design the distal end. In the clinical trials, assessment was made of how well the prosthetists adapted to using the CAD workstation functions to use their previously acquired skills in socket forming from stump shape.

A further goal of the clinical trials was to test the potential of the system in allowing a faster delivery of the prosthesis. The ability of the prosthetists to manipulate the scanning device and position the patient, was therefore also considered to be an important observation in addition to their skill at the CAD workstation.

RESULTS

Of the 35 BK stumps fittings carried out 26 were completed with well-fitting sockets. Seven fittings were terminated early before a satisfactory fitting was achieved while 2 fitting trials are still ongoing.

Of the 26 stump fittings completed with well-fitting sockets, 22 sockets were being used by the amputee following final fitting while 4 sockets were not, as summarized in Table 1. The main reason that some of the sockets were not being used eventhough the fitting was considered to be good was that the subjects participated in the trials only for purpose of testing the CAD/CAM system. In three of these cases where they did not require a new prosthesis and had a slight preference for it over the CAD/CAM socket. In another case, the patient was too heavy to toleate a PTB socket eventhough the fit and volume were considered to be good.

The number of sockets required to achieve a good fit ranged from 1 to 3 sockets, as shown in Table 1, where the frequency of stump fittings requiring each number of sockets is indicated. Of the total 26 stump fittings completed, 17 stumps were fit well on the first socket, 8 required a second socket while only i required a third socket. The average number of sockets made per stump as 1.4.

STUMP - FITTINGS COMPLETED WITH GOOD FITTING			
NO. OF SOCKETS MADE	SOCKET BEING USED	SOCKET NOT BEING USED	TOTAL
1	15	2	17
2	6	2	8
3	1	0	1
TOTAL	22	4	26

Table 1.

For the stump fittings terminated early and those ongoing, the frequency of fittings requiring 1, 2 and 3 sockets designed and fabricated, is summarized in Table 2. The fitting trials which ended early involved difficult or problem cases, where the stump was very sensitive to pain or had many sores, or the residual limb had large flexion contractures at the knee. In these cases either the posthetist or amputee decided to discontinue the CAD/CAM trial and if a new proshtesis was required, they preferred to use the fitting method they were most comfortable with, the conventional method. In 5 of the 7 cases, the CAD/CAM trial ended after only 1 socket was made. In one case 2 sockets were attempted while in another 3 sockets were made. Two stump fittings are currently ongoing after a bilateral amputee was not quite satisfied with the first sockets fit to each limb.

STUMP - FITTINGS NOT COMPLETED			
NO. OF SOCKETS MADE	FITTING TERMINATED EARLY	FITTING ONGOING	TOTAL
1	5	2	7
2	1	0	1
3	1	0	1
TOTAL	7	2	9

Table 2.

Prosthetists learned rather quickly how to transfer their previously acquired skill in socket forming with plaster to the CAD workstation. Five out of 9 prosthetists who completed well-fitting sockets on their first stump-fitting attempt, did so using only one socket.

The potential of the CAPOD system to permit a faster delivery ofthe posthesis was demonstrated during the clinical trials. The approximate durations of the main CAD/CAM processes during most of the clinical trials were: 5 to 25 min for the stump-shape measuring, including stump preparation and patient positioning, 15 to 25 min for CAD socket modelling, 2 to 10 minutes for subsequent socket modifications and 20 min for CAM socket mold machining.

DISCUSSION

The results of the initial clinical testing of the CAPOD system have clearly demonstrated the feasibility of producing prosthetic sockets by CAD/CAM from stump-shape data obtained by laser-scanner. Most stump fittings resulted in well-fitting and functional sockets after only one socket was made with an average of 1.4 sockets made for all completed fittings.

As all prosthetists began the clinical trials with no previous experience in using the CAPOD CAD/CAM system, their experience throughout the testing period was quite low. As shown in Table 3, only 3 prosthetists fit moe than 3 stumps. Considering this low level of experience, it is expected that some of the more problematic fittings which were terminated early before a good fit was achieved, would eventually be done using CAD/CAM once the prosthetist has gained confidence with the system.

PROSTHETIST EXPERIENCE WITH CAD/CAM SYSTEM		
NO. OF STUMPS PER PROSTHETIST	NO. OF PROSTHETISTS	TOTAL NO. OF STUMPS
1	6	6
3	1	3
7	1	7
9	1	9
10	1	10
TOTAL	10	35

Table 3.

Almost all prosthetists obtained good fits on their first stump-fitting attempt and most of those good fits were achieved by using only one socket. The CAD modelling functions of the CAPOD system thus proved to be quite easy to learn to use.

In general, prosthetists found working directly from the stump shape quite acceptable as they remained in full control of the final socket shape with no shaping decisions made for them by the computer software.

With the aim of fitting a first or check socket to the amputee in the first patient visit, effort was made to reduce the socket-mold fabrication time using the CAD/CAM system. Feedback from prosthetists on difficulties in manipulating the stump-measuring laser-scanner and in positioning the patient has led to improvements implemented in a new version of the device. The changes are expected to greatly reduce the maximum time required for stump-shape measurement. Continuing improvements in CAD functions has led to a duration of socket modelling sessions in the later clinical trials of 10 to 20 minutes, while a newly designed numerically-controlled (NC) milling maching now enables a mold to be produced in 8 to 12 minutes. Total socket-mold fabrication can thus be carried out in as little as 23 minutes: 5 for stump-shape measurement, 10 for CAD socket modelling, and 8 for mold mchining.

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