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Clinical evaluation of trans-tibial prosthesis sockets: a comparison between CAD CAM and conventionally produced sockets

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Abstract
This study is an evaluation, from the patient's point of view, of CAD CAM prosthesis sockets compared with conventional sockets. Twenty-two trans-tibial amputees were divided into two groups. One group was provided with a CAD CAM (CAPOD) socket, the other with a conventionally made one. After one month the groups were evaluated with regard to subjective experience, the judgement of a prosthetist and a physiotherapist, social variables and objective gait parameters. Then the groups switched over to the other type of socket, and after another month a new evaluation was performed. The study design was a single-blind study. In total 175 variables were evaluated. No difference was found between the two types of socket, except for a lower number of terry cloth stockings used in the CAD CAM socket. As the standard of conventional prosthetics in Sweden is considered to be high, the results were considered as satisfactory. The quality of the CAD CAM sockets was at least at the same level as conventionally made ones.

Introduction

This study is an evaluation, from the patient's point of view, of prosthesis sockets made with a modern CAD CAM technique compared with a conventional technique. Economical aspects, aspects of time saving, and documentation have not been included.

During the 20th century there has been a rising incidence of amputation in the whole western world, mainly due to the increasing age of the population. In Scandinavia the reported annual incidence of lower limb amputation has been 28-47 amputations per 100,000 inhabitants (Hierton *et al.,* 1980; Liedberg and Persson, 1983; Pohjolainen and Alaranta, 1988; Kald *et al.,* 1989; Larsson and Risberg, 1988; Öberg and Öberg, 1990; Eneroth and Persson, 1992). However, since the middle 1980s there has been a break in this trend, with a reduction of the amputation frequency in Scandinavia (Larsson and Risberg, 1988; Persson *et al.,* 1989; Pohjolainen *et al.,* 1989) as well as in other countries (Coddington, 1988). Vascular cases dominate. Between ½ and ⅔ are trans-tibial amputations, i.e. about 30 new amputations per 100,000 inhabitants per year. At least 50% of these patients will be supplied with a prosthesis. On top of this must be added the renewal of old prostheses of about the same magnitude.

In technical research and engineering the use of CAD CAM has been a standard for several years. The accelerated development of software and hardware has resulted in an increased number of applications for the CAD CAM technique. However, it is not until recent times that CAD CAM has been used in medical applications. Dentistry was one of the first medical professions that started to use CAD CAM. Today at least one thousand CAD CAM systems are in routine use in dental practice (Rekow, 1992). Other areas of medicine where the use of CAD CAM has started are, for example, cardiology and reconstructive plastic surgery (Cutting *et al.,* 1988; Knierbein *et al.,* 1992). The most successful application for CAD CAM technology in medicine can probably be found in orthopaedics and related fields. Production of plastic models for surgeons may

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give global impressions and understandings of bone and joint disorders. It is possible to design and model an exact shape of standard endoprosthesis. In education 3D-imaging can be used to display the anatomy of the patient, and the CAM allows exact models of anatomy to be milled out (Goh *et al.*, 1990; Mankovich *et al.*, 1990; Schmitz *et al.*, 1990).

Orthopaedic technology is based on traditional craftsmanship, which in Scandinavia is considered to be at a fairly good level of quality. The prosthesis socket in the conventional technique is made from a plaster cast. However, during handcasting there is a risk for the uncontrolled deformation of the soft tissues, leading later on to a bad fit of the socket (Murdoch, 1968). The purpose of prosthetic fitting is not only the provision of a prosthesis with a good technical quality, but also the rehabilitation of the patient to a social life of good quality. Many prostheses are never used, others are used for cosmetic reasons only. This may due to lack of training, but also to bad fitting of the prosthesis. The manufacturing of a prosthesis is time consuming, demands skilled craftsmen and is expensive for the community. Thus, it is important that the prostheses are made with a quality, that is accepted by the patient.

In the middle 1980s CAD CAM techniques were introduced in the field of orthopaedic technology (Klasson, 1985). The form of the amputation stump is fed into a computer by for example, a laser scanner or some other device. The software in the various CAD CAM systems is especially developed for use in prosthetics and orthotics. Different systems have been designed for different applications, such as wheelchair seats, prostheses, lasts for orthopaedic footwear and for manufacturing of individually shaped insoles (McAllister *et al.*, 1991). Several of these systems can be used for cosmetic applications in prosthetics and orthotics (Bok *et al.*, 1990; Brüssel, 1991). The final form is transferred to a computer controlled carving-machine. From this is obtained a former for the socket, made from plaster or some plastic material (e.g. polyurethane foam). A socket can then be moulded on this form (Brüssel, 1991).

A relatively new concept is CIM (Computer Integrated Manufacturing), i.e. conventional CAD CAM technique is integrated with systems for administrative routines, handling of materials, economy, quality control etc. (Pärletun *et al.*, 1986). In the future the CIM techniques probably will be used more extensively. Case records and other patient related data can be stored in the system. Check routines can be included for quality control, e.g. dates for yearly follow-up. Tolerance limits can be implemented in the system. Volume and form changes can be objectively recorded and easily followed. With the integration of finite element (FEM) techniques, local stress and strain can be calculated in the amputation stump and the prosthesis socket (Quesada and Skinner, 1991). The socket can be optimised and simulations can be performed before the final socket is made for the patient.

There are a few systems in the world for CAD CAM manufacturing of prosthesis sockets (Fernie, 1984; Foort *et al.*, 1985; Klasson, 1985; Lawrence *et al.*, 1985; Saunders *et al.*, 1985; Lord and Jones, 1988; Engsberg *et al.*, 1992). Brüssel (1991) has described currently available systems in a review article.

At the Department of Biomechanics and Orthopaedic Technology, Jönköping, a CAD CAM system, the CAPOD system, (Computer-Aided-Prosthetic-and-Orthotic-Design), has been developed for prosthetic and orthotic applications. The system consists of a laser scanner, a CAD software and a milling machine. The scanner is made to scan all different parts of the human body and the software is adapted to modelling of these different parts (Öberg *et al.*, 1989).

In a world of economic realities, there is a need for evaluation of new systems, both with regard to cost-benefit and with regard to the satisfaction of the patient. Can we reduce the cost for the community? Can we give the patient a better quality of life? Do we have other benefits from a new technique?.

The aim of the present study was to evaluate trans-tibial prostheses made with a CAD CAM technique compared with a conventional technique, from the patients point of view. The evaluation was made in collaboration with the Swedish Handicap Institute.

Materials and methods

Patients

Some 22 patients, 17 men and 5 women, new trans-tibial amputees as well as prosthetic

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Trans-tibial amputation Unilateral amputation Healed wound, minimum of adherence Presumed walker Good mental status Good physical status
Exclusion criteria	Prolonged healing Ulcerations Other specific problems

renewals, were included in the study. Inclusion and exclusion criteria are listed in Table 1. The mean age was 61.5 years for the men and 70.2 years for the women. Ten patients had their amputations on the right side, 12 on the left side. Each patient was informed about the study, and given an opportunity to break participation at any time.

Experimental layout

The study was designed as a single-blind, cross-over study. All patients tried two prosthetic sockets, one made by CAD CAM technique and one by conventional technique. Except for the socket, the patients were given a prostheses according to standard routines. The patients were collected from three county hospitals. They were divided into two groups. The first group started with a conventional socket, the other group with a CAD CAM socket. After one month they switched to the other type of socket. The patients were evaluated at the start, after one month and after two months. The patients did not know what type of socket had been provided, but it was not possible to keep such information secret from the prosthetist.

All patients were interviewed and examined according to a protocol with 175 variables. The variables were grouped in the following subgroups:

- general background data (e.g. sex, age, diagnosis etc.)
- the patient's subjective evaluation of the prosthesis
- evaluation from a professional examiner (prosthetist and physiotherapist)
- objective measurements (gait analysis, joint angle diagrams, VIFOR)
- social function
- degree of usage

Initially the patients were interviewed by a prosthetist. Background data were collected, and the patients were randomized into one of the two groups. Two sockets were made by the prosthetist, one conventional socket and one CAD CAM socket. By this procedure, the patient did not know which socket he was going to test. The involved prosthetists were required to have made three CAD CAM sockets on training patients, to be accepted. In one group the conventional socket was kept and the CAD CAM socket was discarded. In the other group the CAD CAM socket was used, and the conventional socket discarded. After one month the patient was followed-up. He was then interviewed and examined according to the protocol by an independent prosthetist and by a physiotherapist. These examiners made the same type of evaluation. Objective variables were evaluated in the gait laboratory of the department. After that, a new pair of sockets was made for each patient. The first group now retained the CAD CAM socket and the other group the conventional socket. After one month the patients were re-examined by a prosthetist and by a physiotherapist with the same routines as before. A new evaluation of objective variables was performed. The patient was now asked which socket he preferred, the first one or the second one.

Statistical methods

All statistical computations were made with a commercial statistics package, Systat 5.0/ Sygraph 1.0, for the personal computer. Ordinary numerical variables were calculated with standard parametric statistical methods (Armitage and Berry, 1987; Snedecor and Cochran, 1980). However, many variables were of nominal or ordinal scale type. These variables were evaluated with non-parametric methods (Siegel and Castellan, 1988).

Results

Some 175 variables were evaluated as single variables or in different combinations. A part of all results will be presented.

General background data

Fourteen patients were amputated because of arteriosclerosis with or without diabetes mellitus. Seven patients were amputated because of trauma and one because of

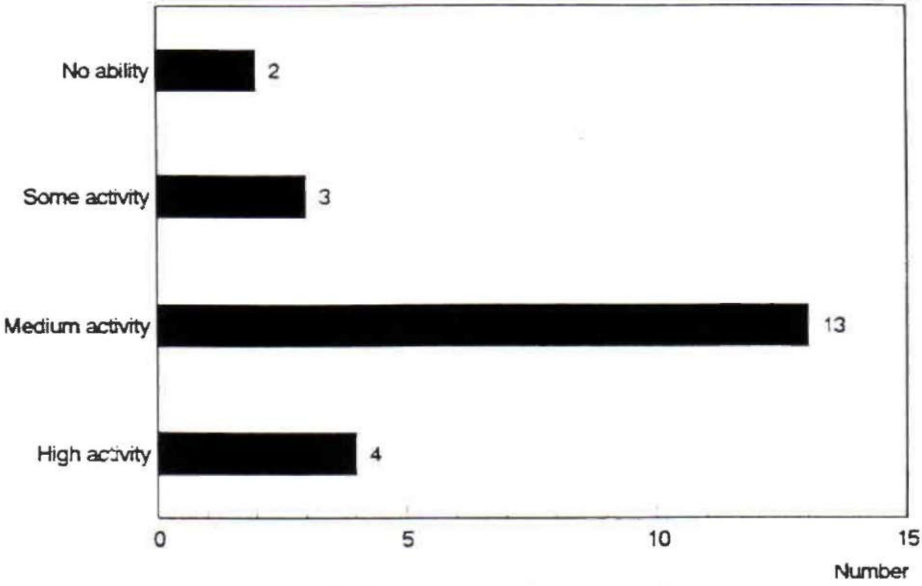

Fig. 1. Gait ability among the amputees.

malformation. Six stumps were of cylindrical form and 13 had a conical form, two stumps had a pear form and one stump another form. Thus, most of the stumps were well formed. Seventeen of the patients had excellent wound healing. In one case there was irritation, in one case infection and three patients had adherent scars. Seventeen patients had no skin problems. Two patients had reddened skin, two had wounds, and in one there were other problems. The present gait ability of the amputees is shown in Figure 1.

Subjective evaluation

Differences between CAD CAM and conventionally made sockets with respect to the patient's own judgement are shown in Table 2. The interview was made separately by a prosthetist and a physiotherapist. There were no statistically significant differences. The distribution of answers to the question "Are you satisfied with the prosthesis?" is illustrated in Table 3. Subjective preferences were evaluated by the prosthetist and by the physiotherapist. The prosthetist found twelve patients to prefer the CAPOD socket and six to prefer the conventional socket. Four patients could not decide. The corresponding figures for the physiotherapist were ten patients preferring the CAPOD socket, ten preferring the conventional socket and two patients that could not decide.

Table 2. The patients subjective evaluation of the prostheses. Difference between conventional socket and CAPOD socket. X^2-test.

Variable	Examiner	
	Prosthetist	Physiotherapist
Satisfied with the prosthesis	N.S.	N.S.
Unpleasant pressure from the prosthesis	N.S.	N.S.
Resting pain on use of the prosthesis	N.S.	N.S.
Movement pain on use of the prosthesis	N.S.	N.S.
Tenderness of the stump on use of the prosthesis	N.S.	N.S.

N.S. = No significant difference between conventional prosthesis and prosthesis with CAPOD socket

Table 3. Answers to the questions "Are you satisfied with your prosthesis?"

Patient group	Number	CAPOD	
		Satisfied	Dissatisfied
Patients satisfied with conventional prosthesis	17	8	9
Patients dissatisfied with conventional prosthesis	5	1	4
Total	22	9	13

Table 4. Professional evaluation of the prostheses. Difference between conventional socket CAPOD socket. X^2-test.

Variable	Examiner	
	Prosthetist	Physiotherapist
Number of adjustments of the outer socket	N.S.	–
Number of adjustments of the inner socket	N.S.	–
Number of sockets	N.S.	–
Number of stockings, thick	p<0.001	–
Number of stockings, thin	N.S.	N.S.
Function of the prosthesis	N.S.	N.S.
Fit of the socket	N.S.	N.S.
Technical quality of the socket	N.S.	N.S.

N.S. = No significant difference between conventional prosthesis and prosthesis with CAPOD socket

Professional evaluation

The specialist evaluation of a number of variables is listed in Table 4. There were no significant differences, except for the number of terry cloth stockings used in the socket. There were significantly less stockings used in the CAPOD made socket compared with the conventionally made socket. Function of the prostheses was considered very good, good or as neither/nor in 86% of the conventional and 82% of the CAPOD made sockets. With respect to the fit of the sockets, 77% of the CAPOD and 91% of the conventionally made were ranked as very good, good or as neither/nor. The technical quality of the sockets was considered very good, good or as neither/nor by 91% for both the conventional and the CAPOD sockets. The mean number of adjustments of the sockets was 0.59 for the conventional sockets, and 0.86 for the CAPOD sockets.

Table 5. Gait parameters between conventional socket and CAPOD socket. Test with Students *t*-test.

Variable	Examiner: Prosthetist
Walking distance, metres	N.S.
Gait speed	N.S.
Gait frequency	N.S.
Step length	N.S.
Step length/leg length	N.S.
Duration of gait cycle	N.S.
Duration of stance phase	N.S.

N.S. = No significant difference between conventional prosthesis and prosthesis with CAPOD socket.

Gait analysis

The results are listed in Table 5. There were no significant differences. The gait speed was 0.86 m/s for patients with CAPOD sockets, and 0.76 m/s for patients with conventionally made sockets. The difference between the two groups was not significant.

ADL and social variables

There was no significant difference between the two groups in any variable (Table 6).

Discussion

The number of patients in this study was small. Amputees are generally old and many patients have other diseases which reduce their general condition. To participate in the study, the patients had to fulfil the inclusion criteria. A test session took some two hours. A number of patients who were used as training patients for CAD CAM could not be included in the study. In spite of the fact that the study was running for more than a year and with three county hospitals involved, it was only possible to collect 22 patients that could be accepted for the study.

Table 6. ADL-functions and social functions. Difference between conventional socket and CAPOD socket. X^2-test.

Variable	Examiner	
	Prosthetist	Physiotherapist
Need of help from other person	N.S.	N.S.
Ability to take on/off the prosthesis	N.S.	N.S.
Ability to walk indoors with the prosthesis	N.S.	N.S.
Ability to rise from a chair with the prosthesis	N.S.	N.S.
Ability to sit down on a chair with the prosthesis	N.S.	N.S.
Ability of stair climbing with the prosthesis	N.S.	N.S.
Ability to walk outdoors with the prosthesis	N.S.	N.S.
Ability to enter a car with the prosthesis	N.S.	N.S.
Ability to enter a bus with the prosthesis	N.S.	N.S.
Ability to enter a train with the prosthesis	N.S.	N.S.
Degree of usage (Couch *et al.*, 1977)	N.S.	N.S.

N.S. = No significant difference between conventional prosthesis and prosthesis with CAPOD socket.

The goal of prosthesis fitting is not only a technically good quality of the prosthesis, but the rehabilitation of the patient to an active life, and with an acceptable ability to manage activities of daily living. Thus, the evaluation includes objective laboratory measurements as well as the subjective experience of the patient. Many aspects of prosthesis fitting are difficult to measure. For this reason they are evaluated with non-quantitative or semi-quantitative methods.

There was no possibility to perform a double-blind study, because a skilled prosthetist can easily see the difference between a conventionally made and a CAD CAM socket. Of course the evaluation can be biased by the prejudices of the prosthetist. For this reason, an independent evaluation was made by a physiotherapist. It is believed that a physiotherapist has no specified opinion or interest in the technique used for manufacturing a socket, and consequently the risk for prejudice would be correspondingly less.

Except for the number of terry cloth stockings, no statistically significant differences were found in any of the 175 variables: subjective variables, objective measurements and social variables. This result can be due to two factors — either there was no difference, or the small number of patients gave a low power in the statistical tests. In the authors' opinion both factors applied. The results agree with those of the few other studies that have been published (see below). All studies are too small into be conclusive, but they can give a preliminary indication of the present status of the different CAD CAM techniques.

The technical systems have been reviewed by Brüssel (1991). Holden and Fernie (1986) performed a study with 10 trans-tibial amputees who received one socket made with a CAD CAM technique (CASD) and one conventionally made socket. The patients did not know what manufacturing technique had been used. They were asked which socket they preferred. Seven of the ten patients preferred the conventional socket.

Köhler *et al.* (1987) performed a study where CAD CAM trans-tibial sockets were compared with conventionally made ones. The CAD CAM technique used in their study was developed at the Bioengineering Centre, Roehampton, University College London. It was a fairly small study, including eight patients. All patients got two prostheses, one made with either technique. Every prosthesis was evaluated on seven occasions during two weeks regarding comfort, pressure and pain. There was no difference between the different types of prostheses. These results agree with the results of this study.

In another study Topper and Fernie (1990) examined trans-tibial sockets in 48 patients. CAD CAM sockets (CANFIT) were compared with conventionally made sockets. With the conventional technique the prosthetist was allowed to have two trials per socket, but with the CAD CAM socket he was permitted more trials. After two trials 21 of the patients preferred the CANFIT socket. After five trials 54% preferred this socket, but still 46% preferred the conventionally made socket.

In a very limited study Torres-Moreno *et al.* (1991) examined one patient who was fitted with a trans-femoral socket made with the CASD CASM technique. Comfort was good, but no comparison was made with any other socket.

Ruder (1992) describes a comparison between a CAD CAM trans-tibial temporary prosthesis and an established technique. Thirty patients were fitted with either a conventional or a CAD CAM socket. Ruder describes how the trans-tibial amputees were successfully fitted using CAD CAM, but the time and number of appointments necessary to rehabilitate the patient were notably greater using CAD CAM than using the conventional technique.

The use of CAD CAM techniques has probably just begun in orthopaedic technology. In the future they will probably be used more extensively, for example, for scanning of all parts of the body (Mankovich *et al.*, 1990), but also CIM techniques can be integrated with present CAD CAM technique. With finite element modelling it will perhaps be possible to optimise the socket and simulations can be performed before the final socket is made for the patient.

When a new technique is introduced, the users will find new fields of applications and they will formulate new demands for the technique. Klein *et al.* (1992) have tried to describe some future CAD CAM applications.

However, without any doubts computers will have a prominent position in prosthetics and orthotics in the future.

Conclusions

No statistical differences were found between the two manufacturing techniques in any, but one, of 175 variables in this study. Conventional manufacturing techique was used as a reference. In Sweden orthopaedic technology has a relatively high standard. The primary goal of the new CAD CAM technique — to obtain at least the same results as with a conventional technique — has been achieved. More studies must be performed to examine cost-benefit aspects and also to examine new potential in this technique.

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