Prosthetics and Orthotics International, 1992, 16, 189–195

CAD CAM trans-tibial temporary prosthesis: analysis and comparison with an established technique

G. K. RUDER

West Park Prosthetics/Orthotics, Toronto, Canada

Abstract

The purpose of this study was to evaluate the application of CAD CAM in the production of temporary trans-tibial prostheses. The CAD CAM system was assessed based on the number of socket attempts, number of prosthetic appointments, and temporary prosthesis rehabilitation time. These parameters were considered to be related to the quality of socket fit and were influenced by the entire interdisciplinary team including the patient. A concurrent prospective comparison between the CAD CAM system and an established fibreglass/pelite liner technique was also performed. Patients (n=30), were fitted with either a conventional or a CAD CAM socket. Records were kept before and after discharge until the interdisciplinary team considered the patient ready for definitive prosthesis casting. After approximately 90 post-operative days, patients were deemed fit to proceed from their initial plaster cast prostheses to their temporary prostheses. The group fitted with conventional sockets had an in-patient rehabilitation phase of 10.5+/-60 days and required 2.9+/-1.1 prosthetic appointments. In-patients fitted with CAD CAM sockets required 5.1+/-1.8 appointments and were hospitalised for 23.6+/-15.0 days. The significantly increased rehabilitation duration and number of appointments (p=0.01), were generally due to incorrect socket volume and/or inadequately modified relief/loading areas. In this study 67% of the patients fitted with CAD CAM sockets required at least one additional attempt. The clinical evaluation and modification of the temporary prostheses, including the decision to remake a particular socket, were carried out by the same prosthetist who cast the patients. During the out-patient phase, the type of socket design was not observed to influence either duration of out-patient rehabilitation or frequency of appointments. Out-patient rehabilitation included on average 4 appointments and ended after 90 days. Multidisciplinary discharge criteria and standardised follow-up procedures rendered the measured parameters less relevant to this study's purpose in the out-patient phase.

All correspondence to be addressed to Gordon K. Ruder, West Park Prosthetics/Orthotics, 82 Buttonwood Ave., Toronto, Ontario, Canada M6M 2J3.

Introduction

Five quantitative studies of the outcome of CAD CAM fitting have been found in the literature. Topper and Fernie (1990) compared conventional sockets to sockets designed using computer aided design and manufacture (CAD CAM), in 48 trans-tibial (TT) amputees cared for by 4 prosthetists. Socket materials and sock ply were standardised. Patients were fitted and aligned with either their CAD CAM socket or their conventional one. The two prostheses were worn for as long as it was required to develop a preference, after which they were evaluated with reference to a continuous scale. After 5 CAD CAM attempts the patients were as likely to accept the CAD CAM socket as they were the conventional socket design. In another study, similar findings were demonstrated (Kohler *et al.*, 1989). A group of

five prosthetists made fittings of two patients each by conventional means. Negative casts from these patients were sent elsewhere and the CAD CAM sockets were then developed by another group of prosthetists. After fitting and alignment was completed, the patient was given both his/her CAD CAM prosthesis and his/her conventional prosthesis. The prostheses were assessed based on perceived comfort, pain, and pressure on seven occasions over a twenty day period. Seven out of eight unilateral TT patients were shown not to display a significant difference in preference between their conventional PTB and their CAD CAM socket, providing that 2 CAD CAM attempts were permitted. Earlier research, where sample size ranged from 2 to 17 patients and wearing time ranged from single fittings to 2–6 months, demonstrated moderate success with various CAD CAM systems (Krouskop *et al.*, 1987; Holden and Fernie, 1986; Foort *et al.*, 1985). Krouskop *et al.* (1987), noted that the two amputees they had studied had worn their prostheses for 6–12 hours over a period of 2–6 months. In the study by Foort *et al.*, (1985), 26 out of 36 patients were able to stand or walk for up to ½ hour with some discomfort in the CAD CAM sockets. Holden and Fernie (1986) reported findings in which 10 amputees were given prostheses with a conventional or a CAD CAM socket, and then asked to compare the two within a single fitting based on comfort. Three of the patients preferred the CAD CAM socket. In summary, studies have strived to assess the quality of CAD CAM socket design based on the opinions of the patient, in some cases comparing it to sockets produced by conventional techniques. CAD CAM sockets were worn for the duration of the experiment and not supplied to the patient indefinitely. Previous CAD CAM studies have focused on patients with mature, load tolerant, and atrophied stumps.

In order to maximise the reliability and objectiveness of the quantitative assessment, the study reported here was performed in a normal hospital setting. The prosthesis was worn for the duration of the rehabilitation period and the entire interdisciplinary team, including the patient, had an influence on socket fit evaluation. Precise total contact and aggressive loading are less critical factors in the recent amputee wearing a temporary prosthesis (Michael, 1989). Thus it was seen to be of interest to evaluate the application of CAD CAM technology under the somewhat less critical conditions of the temporary prosthesis.

The purpose of this study therefore was to evaluate the application of CAD CAM in the production of temporary TT prostheses. A comparison of the CAD CAM system to an established fibreglass socket/pelite liner technique was also performed.

Methodology

West Park Prosthetics has implemented the Applied Biotechnology (ABT) Computer aided socket design and manufacture (CASDaM) system to digitise, modify, and manufacture temporary trans-tibial (temp-TT) prostheses since August 1990. The temporal boundaries of the patient population requiring temp-TT prostheses were from when they were ready to proceed from their initial plaster cast prosthesis until they were referred for definitive casting. The study group consisted of relatively healthy amputees (n=15) with generically shaped stumps fitted with CAD CAM sockets. These patients were supervised by a single prosthetist (14 years of experience). It was found that abnormally shaped stumps (excessively bulbous, bony prominences, tibial valgus/varus), could not be successfully fitted using the CAD CAM system, regardless of the number of attempts. These patients were consequently excluded from the study. Thus stringent selection criteria were imposed which removed less than ideal patients from the study group. Patients seen within the first 3 months of the CAD CAM installation were excluded to minimise any learning influences. The study group patients were provided with a high temperature thermoplastic socket based on a plaster positive generated using the CAD CAM system. Firstly a negative cast was taken, with the prosthetist actively modifying the stump with his hands, accentuating the weight bearing areas and relieving the load intolerant surfaces. Next the negative cast was digitised using the ABT Digitform, thus transferring the socket's shape from the analogue to the digital domain. The Screenform One software package permitted digital modification of the socket to be completed. The ABT Carveform milling machine returned the digitally modifed socket

to the analogue domain in the form of a milled plaster positive. The ABT Socketform oven and vacuum system was then used to mould a high temperature thermoplastic socket over the plaster positive.

The control group represented an equal number of randomly selected patients supervised by the same prosthetist over approximately the same time period—June 1990 to January 1991. A fibreglass socket/pelite liner technique was the control standard for comparison. This technique employed the wrapping of a fibreglass casting material over a low density pelite liner. As the fibreglass wrap cured on the stump, the prosthetist actively modified the socket. Fork belt suspension, Otto Bock pylon and couplings mounted on SACH feet were used to set up both socket types.

A comparative prospective concurrent design was employed for this study. The time frame of the experiment was from the amputation until time of definitive casting. Within this continuum, a post-operative phase, an in-patient phase, and an out-patient phase were defined. During the post-operative phase primary wound healing occurred and the patient went through a series of initial plaster cast prostheses. The in-patient phase began with the first temporary casting (CAD CAM or conventional), and ended with discharge. During in-patient rehabilitation the temp-TT prosthesis (CAD CAM or conventional) was fitted and aligned to the patient. As the stump matured with respect to volume and load tolerance, sock ply was altered (3–10 ply), partial linings were added, and alignment was refined. The out-patient phase spanned the time from discharge to first definitive casting. Prosthetic follow-up after discharge ensured that the temp-TT prosthesis was safe and was still an adequate fit.

The outcome parameters compared were the number of socket attempts, the number of prosthetic appointments, and the rehabilitation time within and across the time blocks. Rehabilitation time and number of appointments were influenced by the professional opinions of the entire interdisciplinary team — including the patient. In-patient appointments were usually the result of the physiotherapist, nurse, or the clinic team reviewing the patient during rounds and identifying a prosthetic problem. The prosthetic problems were primarily due to the patients expressing discomfort or pain, skin irritation/breakdown, or as a result of improper fit. Reduced suspension, doffing-donning difficulty, changing gait patterns, and stump shrinkage also required prosthetic appointments to be made. The prosthetist involved in this study carried out the required changes and was responsible for determining whether they could be done on the existing prosthesis or if a repeat attempt was required. Finally, the prostheses were worn for up to 7 months during their temporary prosthesis rehabilitation. It is suggested that the outcome parameters of prosthetic appointments and rehabilitation time represented an objective, reliable quantitative indicator of a prosthetic device's success.

The null hypothesis was that there was no significant difference between the control and the study group for any of the studied outcome parameters. A significant difference ($p \leq 0.01$), greater or less than the control was the hypothesis being tested. If a difference of 2 appointments or 10 days was required and given standard deviations of 1.5 appointments or 7 days, then the power of the comparison would be 0.95.

Results

Table 1 lists the descriptive characteristics of the patient groups. The average ages of the control group and study group were 62.7+/-9.8 and 69.3+/- 11.3 years respectively. The cause of amputation was either due to diabetic complications or peripheral vascular disease. Control group patients were cast for their fibreglass socket/pelite liner temporary prosthesis, on average, 80.3 days after their amputation. After 103.5 days post-operatively the study group patients were cast for their first CAD CAM socket. The variability of the post-operative period in both the control and the study groups was; +/-41.8 and +/-49.8 days respectively. The patients in this study required 1 to 3 initial plaster cast prostheses, but averaged around 1.3. In summary the control and study group patient characteristics were not found to differ significantly ($p>0.20$).

In the control group none of the fibreglass sockets had to be replaced before the patients were ready for definitive casting. Sixty-seven percent of the study group required at least 1 additional attempt at fitting with a temp-TT prosthesis. Repeated socket attempts were necessary due to insufficient volume (5/15),

Table 1. Study and control group characteristics.

Control group (established technique)				Study group (CAD CAM system)			
Number (gender)	age (yrs)	post-op time int.	No. PCPs	Number (gender)	age (yrs)	post-op time int.	No. PCPs
1 (m)	50	163	2	1 (m)	72	117	2
2 (m)	67	41	1	2 (m)	76	107	2
3 (m)	66	76	1	3 (m)	73	70	2
4 (m)	70	96	1	4 (m)	84	40	1
5 (f)	69	49	1	5 (m)	68	171	1
6 (m)	70	25	1	6 (f)	50	48	2
7 (m)	66	122	1	7 (m)	65	103	1
8 (m)	62	21	1	8 (m)	77	103	1
9 (m)	70	45	3	9 (m)	74	118	2
10 (f)	68	89	1	10 (m)	72	45	1
11 (m)	69	49	1	11 (m)	54	69	1
12 (m)	64	84	1	12 (m)	49	85	2
13 (m)	47	77	1	13 (m)	81	108	2
14 (m)	36	145	1	14 (m)	58	239	1
15 (m)	66	122	1	15 (m)	84	129	2
mean	62.7	80.3	1.2		69.3	103.5	1.5
SD	9.8	41.8	0.5		11.3	49.8	0.5

Post-op time int.: number of days from amputation to first temp-TT casting.
No. PCPs: number of initial plaster cast prostheses required.

inadequately modified relief areas—especially the tibial crest, tibial tubercle, and the fibular head (3/15), or a combination of the above causes (2/15). These problems were identified by the interdisciplinary team, but the final judgement as to whether an existing socket could be modified or if a repeat attempt was required, was made by the prosthetist involved in the study.

Table 2 demonstrates the duration trends which emerged with the established technique and the CAD CAM system. In-patient rehabilitation time was less for the control group (10.5+/-6.0 days), than for the study group (23.6+/-15.0 days). Out-patient times were similarly longer for the study group than the control; 96.7+/-39.1 and 81.8+/-28.8 days

Table 2. Control and study group in-patient, out-patient, and total rehabilitation time in days.

Patient No.	Control group			Study group		
	(in)	(out)	(tot)	(in)	(out)	(tot)
1	13	62	75	41	87	128*
2	3	95	98	19	47	66
3	4	142	146	18	47	65*
4	18	74	92	25	87	112*
5	13	48	61	3	100	103
6	14	90	104	9	143	152*
7	8	118	126	52	105	157*
8	7	79	86	17	146	163*
9	12	63	75	17	110	127*
10	3	111	114	19	184	203*
11	18	64	82	13	107	120*
12	22	71	93	55	47	102*
13	1	55	56	18	112	130
14	13	37	50	10	80	90*
15	8	118	126	38	49	87
mean	10.5	81.8	92.3	23.6	96.7	120.3
SD	6.0	28.8	26.6	15.0	39.1	36.5

in: from first temp-TT casting to discharge
out: from discharge to referral for definitive casting
tot: total time temp-TT prosthesis was worn

* — additional CAD CAM socket(s) required.

Table 3. Control and study group in-patient, out-patient, and total number of prosthetic appointments.

Patient No.	Control group			Study group		
	(in)	(out)	(tot)	(in)	(out)	(tot)
1	3	4	7	6	4	10*
2	2	4	6	4	3	7
3	3	4	7	9	3	12*
4	5	4	9	9	4	13*
5	3	3	6	2	2	4
6	3	5	8	4	6	10*
7	2	6	8	5	4	9*
8	3	4	7	5	5	10*
9	4	3	7	5	4	9*
10	2	4	6	4	10	14*
11	3	3	6	3	5	8*
12	4	3	7	5	3	8*
13	1	5	6	6	5	11
14	3	2	5	4	4	8*
15	2	6	8	5	3	8
mean	2.9	4.0	6.9	5.1	4.3	9.4
SD	1.1	1.1	1.0	1.8	1.8	2.4

in: from first temp-TT casting to discharge
out: from discharge to referral for definitive casting
tot: total time temp-TT prosthesis was worn

* — additional CAD CAM socket(s) required.

respectively. Consequently total temp-TT rehabilitation time was also longer in the study group (120+/-36.5 days), than in the control group (80.3+/-41.8 days).

Similar trends were observed when the patient's rehabilitation was quantified using the number of prosthetic appointments required, as listed in Table 3. The number of out-patient appointments before definitive casting was possible did not differ significantly between the control and the study group; 4.0+/-1.1 and 4.3+/-1.8 respectively. However the number of prosthetic appointments required while the amputee was an in-patient and over the entire temporary prosthesis rehabilitation period, was significantly greater for the study group (Table 4). Control and study group in-patient appointments were 2.9+/-1.1 and 5.1+/-1.8 respectively. The total number of appointments for the control group was 6.9+/-1.0 while it was 9.4+/-2.4 for the study group.

Statistically, only control in-patient rehabilitation duration was significantly less than that of the equivalent study group (Table 4).

Recently the fabrication of the CAD CAM temp-TT prosthesis was altered to include a pelite liner. Although an insufficient number of patients have been treated in this manner to be included in this study, initial findings were interesting. Rehabilitation time, number of prosthetic appointments, and the reasons for having them appeared no different than when the pelite liner was not included. The primary advantage of the pelite liner was that doffing/donning was considerably easier—especially once partial linings were required. Furthermore, socket modification and partial linings were more easily and successfully applied, thereby increasing the longevity of the thermoplastic socket.

A group of 10 in-patients fitted with the CAD CAM system still using the Screenform One package up to 10 months after the completion of this study, were evaluated. In-patient rehabilitation required on the average, 6.3 appointments over 22.3 days. These values compare closely with what has been reported in this study. Thus the outcome parameters of this study did not appear to have been significantly

Table 4. Comparison of the control and the study group in-patient, out-patient, and total rehabilitation times number of prosthetic appointments.

Outcome parameter	p value		
	(in)	(out)	(tot)
Duration	0.01	0.30	0.05
Number of appointments	0.01	0.66	0.01

in: from first temp-TT casting to discharge
out: from discharge to referral for definitive casting
tot: total time temp-TT prosthesis was worn

changed after the prosthetist had gained more experience with the CAD CAM system.

Discussion

Due to the non-laboratory setting of this study, the subject groups could not be randomly assigned, the socket materials could not be standardised, and more than one prosthetist could not be involved in the study. However, age, gender, cause of amputation, post-operative phase, and number of initial plaster cast prostheses did not differ between the two groups studied. Furthermore, since the eligibility criteria for the CAD CAM group removed patients with irregular stumps, this would have biased the results in favour of the study group. It was not possible to unequivocally determine if the difference between the control and the study group was influenced by the difference in socket materials. The most significant difference between the two in this respect was that the CAD CAM socket did not have a pelite liner. Patients (N=6) not included in this study but treated using CAD CAM with a pelite liner did not require fewer appointments, did not complete rehabilitation any earlier, or require fewer socket modifications than the average of the study group. Independent of socket type, patients wore 3 to 10 ply prosthetic socks between the skin and the socket. Furthermore, studies which have involved control of socket materials have reported similar findings to those reported here (Kohler *et al.*, 1989; Topper and Fernie, 1990). The outcome parameters assessed to analyse the CAD CAM system and compare it to the established conventional technique were number of socket attempts, in/out-patient number of appointments and rehabilitation time. Rehabilitation time and the number of prosthetic appointments required revealed several trends. The latter was more sensitive in detecting a difference between the two subject groups. For this study patients were generally ready for their first temp-TT after 90 post-operative days. At this time the characteristics of the stump were still quite dynamic and most prosthetic appointments resulted in the fitting of partial linings, altered sock ply number, and/or alignment adjustments being carried out. CAD CAM sockets often required easing over bony prominences or custom tailored distal end pads in addition to the expected volume and alignment changes. Furthermore, 67% of the CAD CAM sockets had to be repeated. As a result of these complications the patients of the study group required on average 5 in-patient appointments and the first phase of rehabilitation lasted 24 days. In comparison the control group had on average 3 in-patient appointments and the first phase of rehabilitation lasted 10 days.

In-patient rehabilitation was not considered complete until various physical, functional, social, psychosocial, and prosthetic criteria were met. Also a standardised follow-up procedure was implemented upon discharge. These two factors tended to standardise a patient's rehabilitation with respect to duration and number of appointments after discharge. Thus it was not surprising that out-patient outcome parameters were about 90 days duration and 4 appointments independent of whether the patient was fitted with sockets fabricated using the established or the CAD CAM system.

Quantitative assessments of CAD CAM systems and comparisons to present prosthetic/orthotic techniques are useful. They provide feedback to the clinician, indicating the applications and limitations of the various CAD CAM systems. Ideally quantitative CAD CAM studies will assist prosthetists/orthotists in communicating their experience to the system designers.

Conclusions

A group of elderly trans-tibial amputees with normally shaped stumps were successfully fitted using the CAD CAM system. However, the time and number of appointments required to rehabilitate an in-patient were considerably greater than when the conventional technique was used. The CAD CAM system was evaluated based on the number of socket attempts, number of prosthetic appointments, and temporary prosthesis rehabilitation time. Thus socket design assessment relied not only on the patient's feedback during their rehabilitation, but was also influenced by the professional critique of the entire interdisciplinary team. During the prosthetic appointments it was demonstrated that more attention was required for the CAD CAM group. Besides the normally required volume

and alignment changes, CAD CAM temporary prostheses required various modifications over bony prominences and load tolerant surfaces.

Acknowledgements

The author would like to thank West Park Prosthetics/Orthotics for allowing this study to be carried out. The assistance of Ken Roczniak C.P.O., the prosthetist caring for the patients in this study, was greatly appreciated.

REFERENCES

FOORT J, SPIERS R, BANNON M (1985). Experimental fittings of sockets for below-knee amputees using computer aided design and manufacturing techniques. *Prosthet Orthot Int* **9,** 46–47.

HOLDEN JM, FERNIE GR (1986). Results of the pilot phase of a clinical evaluation of computer aided design of trans-tibial prosthesis sockets. *Prosthet Orthot Int* **10,** 142–148.

KOHLER P, LIDH L, NETZ P (1989). Comparison of CAD-CAM and hand made sockets for PTB prostheses. *Prosthet Orthot Int* **13,** 19–24.

KROUSKOP TA, MUILENBURG AL, DOUGHTERY DR (1987). Computer-aided design of a prosthetic socket for an above-knee amputee. *J Rehabil Res Dev* **24,** (2), 31–38.

MICHAEL JW (1989). Reflections on CAD CAM in prosthetics and orthotics. *J Prosthet Orthot* **1,** 116–121.

TOPPER AK, FERNIE GR (1990). An evaluation of computer aided design of below-knee prosthetic sockets. *Prosthet Orthot Int* **14,** 136–142.