Validation of a quantitative method for defining CAD/CAM socket modifications

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Abstract

A quantitative method was developed for defining manual socket modifications, averaging these modifications over a series of amputees, and using the average modifications as a template in commercial CAD/CAM systems. The CADVIEW programme (i.e. software for viewing and analysing CAD sockets) was rewritten to provide comparison functions for aligning sockets to a common axis, visualising the differences between sockets, generating modification outlines, assigning apex point values, and averaging the modification outlines. A CAD template generated in this manner should be the best general representation of a prosthetist's modification style. To test this hypothesis, 13 people with trans-tibial amputations were fitted with both a manual and a CAD/CAM socket. Questionnaires were completed by the subjects and by the prosthetist to obtain information on prosthetic comfort. function, and overall satisfaction. Ground reaction force and stride parameter data were also collected for each prosthesis during gait laboratory testing. No significant differences were found between the manually designed socket and the CAD/CAM designed socket for all data except the vertical peak forces on the amputated side. These results support the clinical application of this quantitative technique for making the transition from manual to CAD/CAM prosthetic modification procedures.

Introduction

CAD/CAM (Computer Aided Design/ Computer Aided Manufacture) has become a viable clinical tool in the field of prosthetics and orthotics. The CAD/CAM process provides a controlled method for shape modification, an accurate method for positive mould fabrication, a decrease in production time, and a more efficient platform from which to service remote areas (Lemaire and Johnson, 1996; Torres-Moreno et al., 1995). Improvements in CAD software have enabled clinicians to make almost any stump shape modification. Generally, a prosthetist uses computer modification tools to outline a modification region, specify points of maximum change, and set modification amounts. While these tools are effective, the prosthetist must be able to visualise socket modifications on a 2-dimensional screen - as opposed to hand-sculpting modifications on a physical object. Experience with clinical CAD/CAM applications has shown that transferring manual prosthetic modification skills to a computer system is neither easy nor time-efficient. This knowledge-transfer problem is compounded when the individuality of clinical modification procedures is considered (i.e. modification styles are particular to each prosthetist). In most cases, a prosthetist will learn to modify a shape on a CAD system by trial and error.

One approach to easing the manual-to-CAD/CAM transition is to develop a method of quantitatively defining manual socket modifications. Once a manual modification technique has been quantitatively defined, these

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digital modifications can be transferred to a CAD system as a template or overlay. A template will allow the user to apply an individual's modification technique to a shape in 1 step. Custom modifications can then be made to the averaged modification pattern. This process should improve the efficiency and effectiveness of moving from traditional to computer socket design.

This document describes a project for quantitatively defining manual socket modifications and then using these modifications to produce a template for CAD/CAM socket fabrication. Template validation involves comparing CAD/CAM produced sockets with manually manufactured sockets.

Methods

Subjects

All subjects were recruited through the Prosthetics and Orthotics Service at the Rehabilitation Centre, Ottawa, Canada and the protocols for the investigation were approved by the Centre's ethical committee. These transtibial (TT) amputees used their patellar-tendonbearing (PTB) prostheses with supracondylar suspension as their main ambulatory assistive device. If the person agreed to participate in the study, they were informed of the project protocol and asked to complete a consent form. Each subject's stump was evaluated by a prosthetist before starting the project to ensure that there were no tissue problems that would affect socket fitting.

Seven (7) subjects with TT amputations were recruited to define the standard modification pattern. These people provided a good representation of the prosthetist's typical clients. An additional 4 experienced prosthesis wearers were recruited for a pretest of the CAD/CAM rectification pattern. Long term prosthesis users were chosen to assist in refining the standard modification pattern since they should be better at communicating their concerns to the clinician and providing informed feedback. Thirteen (13) subjects with TT amputations, who were more than 1 year postoperative, were recruited for the project's validation phase.

Equipment

All CAD/CAM software and hardware were available in the Prosthetics and Orthotics

Service of the Rehabilitation Centre. The average modification pattern shapes were digitised with the CANFIT-PLUS CAD system. The Shapemaker software package was used to produce all test sockets. Both CANFIT-PLUS and Shapemaker use a cast digitiser for shape input and are capable of generating output for a variety of numerically controlled carvers. An IPOS carver was used to produce the positive models.

Each socket consisted of a polyethylene inner socket (liner) and a polypropylene outer socket. An Otto Bock thermoplastic socket attachment plate and pylon were used to connect the socket to the subject's foot/ankle unit. A soft, Pelite liner was used for 2 subjects. Gait testing facilities at the Rehabilitation Centre included 1 AMTI force platform (AMTI, 176 Waltham Street, Watertown, MA, 02172, USA), an Ariel Performance Analysis System (APAS – video kinematic/kinetic analysis), electrogoniometers, and a proprietary EMG data collection system.

Modification pattern

To develop a quantitative approach for defining prosthetist-specific socket modification patterns, new software routines were added to the CADVIEW programme (software for viewing and analysing CAD sockets (Lemaire, 1994)) to compare original and modified stump shapes. By entering a series of pre- and postmodification socket shapes into CADVIEW, common modification areas could be averaged to produce a generalised rectification pattern suitable for use with a CAD/CAM system (Lemaire and Johnson, 1996).

To define a personal modification pattern for the research prosthetist, 7 people with TT amputations were fitted using manual modification techniques. After a cast was taken of a subject's stump, a mandril was placed inside the cast and the cast was filled with plaster. The mandril was visually aligned to the middle of the longitudinal section that was distal to the midpatellar tendon (MPT) region. After the plaster had set, the cast was stripped off the model and residual plaster outcrops were trimmed. A nail was driven into the model at a right angle to the mandril and at the MPT landmark location (i.e. the main reference point). This model was digitised into the computer using CANFIT-PLUS and a Seattle Digitizer. A special mounting adapter was used to hold the mandril in the same vertical position for the pre- and post-modification digitisations. A consistent main reference point location was also location was also maintained on the model during modification and during digitising. After the first digitisation, the prosthetist modified the model by hand to produce a PTB socket with supracondylar suspension. While modifying, the nail at the MPT location was driven into the cast so that material could be removed without losing the main reference point. The modified plaster model was digitised using the same procedure as the first digitisation.

All the pre-modification and postmodification shapes were loaded into the CADVIEW software to visually determine common modification areas for each subject (Fig. 1). The following steps were used to generate a comparison shape:

 each subject's pre- and post-modification shapes were viewed individually as shaded 3D and cross-section images. This step served as an initial data quality check and allowed the prosthetist to see how each shape looked as 3D rendered and 2D cross-section images;

- the 2 shapes were compared using CADVIEW's *Compare Sockets* function and displayed using the colour-mapped view;
- printouts were produced that showed anterior, posterior, medial, and lateral views of all colour-mapped comparison images. The printouts were laid out on a table so that common modification areas could be identified;
- common modification boundaries were defined for each socket using CADVIEW's *Outline Generation* function;
- in cases where 2 modifications were blended into each other, the *Break Outline* tool was used to separate the larger shape into the desired outlines;
- in some cases, the *Edit Outline* function was used to change the "broken" edge of the new boundary so that it better conformed to the colour-mapped image;
- each separated outline was saved to disk;
- the peak difference value for each modification was determined by using the *Show Difference Value* function. This number was recorded on a data sheet;



Fig 1. Average modifications at the patellar tendon. Thin lines represent normalised PTB modification outlines from seven subjects. The thick line represents the average PTB modification outline.

- similar outlines (i.e. outlines from the same area on each socket) were selected and averaged to generate 1 typical modification. All selected modifications and the averaged modification were displayed on-screen for visual confirmation;
- the peak difference values were averaged and recorded on the data sheet;
- after all modification outlines had been processed, the averaged outlines were rendered on 1 subject's original socket (using CADVIEW). The same socket shape was loaded into the Shapemaker CAD/CAM software;
- Shapemaker, using the averaged modifications were redrawn to match the images in CADVIEW. Since each prosthetic CAD/CAM system has its own outline definition idiosyncrasies, the size of each modification and the amount of overlap between modifications were defined to suit the Shapemaker programme. The average modification shapes and modification magnitudes were consistent between Shapemaker and CADVIEW. When all modifications had been redrawn, the set of modifications was saved as a template;
- the size and position of the modification outlines were adjusted by applying the new template to 3 of the original socket shapes, saving the resulting socket, and using CADVIEW to compare the results to the related modified socket file.

The standard modification pattern was used for all CAD/CAM produced sockets in this study. Since CAD systems can be used to make fine modifications to the socket shape, software modifications were allowed after applying the template. These modifications were divided into minor and major groups. Minor modifications were expected since most sockets will require shape customisation to accommodate the subject's characteristics. These modifications include depth/height changes over a modification area, volume changes, length changes, relocation of modification areas, and modification surface shape changes on modification areas. Major modifications included extensive modification outline reshaping, creating new modification areas, and point editing.

Clinical evaluation

Before formally validating the CAD/CAM

technique, a pre-test was performed involving 4 experienced users of TT sockets. After each subject was fitted with a CAD/CAM produced socket, the prosthetist and the end-user assessed the success of the standardised modification pattern. The success was based on clinical criteria and whether major modifications were required. If the rectification pattern was found to be unsatisfactory, the "Modification Pattern Development" stage would have been repeated with additional subjects.

Validation

Thirteen (13) validation subjects were fitted with a CAD/CAM produced socket and, if their current socket was unsatisfactory, fitted with a new conventional socket (mean age 55.9 years – s.d=14.7, mean height 1.78m - s.d=0.1, mean mass 82.1kg – s.d=13.9). The same components were used for both prostheses. The subjects wore their new prosthesis for at least 2 weeks before completing a questionnaire and having their gait evaluated.

A clinician questionnaire and a subject questionnaire were used to assess satisfaction with the conventional and CAD/CAM produced sockets. The clinician questionnaire recorded information on the prescribed device, the time required to fit the subject, clinician satisfaction with the manufactured socket, the number and type of modifications required for final fitting. and a qualitative assessment of walking gait. This questionnaire also recorded the subject's personal data; such as, date of birth, occupation, gender, height, weight, amputation site, date of amputation, medical conditions, date of last prosthesis, number of years of prosthetic use, and mobility aids. Before gait testing, 1 questionnaire was completed for each socket.

The subject questionnaire inquired about comfort, security, ease of gait, pain and pressure problems, general satisfaction, and general comments. This questionnaire was administered 2 weeks after the device had been dispensed.

Quantitative gait analysis was used to ensure that no significant walking pattern differences were produced by wearing either a CAD/CAM or a conventional socket. Examination of the ground reaction forces was considered an acceptable means of quantitatively assessing the differences between the 2 test cases (Prince *et al.*, 1992; Seliktar and Mizrahi, 1986; Yang *et al.*, 1991). All gait testing took place in the Gait and Motion Analysis Laboratory at the Rehabilitation Centre. APAS was used to collect/filter all analogue data and digitise video clips of the subjects. Post-processing was completed on a Quattro Pro 7 spreadsheet. An additional software programme was written to display APAS force output and calculate impulses.

When a subject arrived in the laboratory, the test procedures were re-explained and reflective markers were attached at the toe, ball, heel, ankle, knee, hip, and shoulder locations. While only the toe marker was used for this study, the other marker data were collected as part of a standard data collection procedure. After all the markers were attached, the subjects walked at a natural cadence along a 10 metre walkway until they felt comfortable in the laboratory and consistently stepped on the force platform.

For the first 3 subjects, data were collected from the amputated side. The subject walked in the same direction for all 12 trials. For the other 10 subjects, data were collected from both sides of the body. In these cases, the subjects walked back and forth along the walkway while data were collected on the side that was closest to the video camera. Twelve (12) trials were collected for each side of the body (total of 24 trials per session). For each trial, 2 seconds of ground reaction force data were sampled at 200Hz.

Following each data collection session, the force data were digitally filtered at 12Hz (dual pass 4th Order Butterworth filter) and transferred to the data processing computer. The APAS system was used to capture a digital video clip of each trial and digitise the 2D marker positions. After the data had been transformed, most marker data were digitally filtered at 10Hz. In a few instances, 6 or 8Hz filter settings were required to smooth the data. The APAS graphing utility was used to obtain stride length, stride time, and walking speed by subtracting toe marker positions and times at successive toe-off events. Stance time was calculated from the ground reaction force data.

Force post-processing involved importing a subject's filtered data into Quattro Pro so that all 12 trials could be averaged. Each trial was normalised to 100% of stance using linear interpolation. The average and standard deviations were calculated at 1% intervals. Peak forces for each trial were calculated from the

filtered data (i.e. data not normalised and not averaged). These peaks included the maximum mediolateral force (Fx), the maximum value of the decelerating force (Fy-brake), the maximum push-off force (Fy-push), and the maximum vertical forces (Fz-brake, Fz-push). Impulse values for Fx, Fy-brake, Fy-push, Fz-brake, and Fz-push were calculated using a separate Microsoft Windows programme and then copied into Quattro Pro for statistical analysis. The force and impulse ratio measures were calculated by dividing the braking value by the push-off value.

Data analysis

All questionnaire data were analysed using descriptive statistics. Below average client satisfaction with the CAD/CAM sockets, as compared to a satisfactory response with the conventional sockets, would contra-indicate continued use of the new modification pattern.

Force and impulse values obtained from the gait analyses were compared between sockets using a paired t-test (p<0.05). The average ground reaction force curves were also compared using Pearson product moment correlation coefficients and root mean square error (RMSE) statistics. Since ground reaction forces are sensitive to increases in walking speed, the walking speed data were analysed to ensure that any differences were not due to a faster gait.

If no differences were found between gait results for the 2 fabrication methods, or if the results for the CAD/CAM produced leg were clinically different but closer to gait results for normals, the CAD/CAM template generation procedure was considered appropriate for clinical use.

Results

Pre-test

While each subject's socket required specific modifications, some common changes were required for all 4 pre-test subjects. To accommodate individual variations in anatomical structure, modification locations were change for each subject. For the same reason, apex point positions were changed for some modifications. The size of certain modifications also had to be changed due to Shapemaker's inability to adequately scale the template for long or short shapes. Creation of a "long socket" modification outline, while maintaining the same modification shapes, alleviated some of these template application problems. The medial tibial flare modification was split into 2 sections to create an appropriate medial tibial flare relief when applying a Shapemaker template. The revised modification template was considered appropriate for clinical use and full validation testing.

Validation

Questionnaire results

A subject questionnaire was used to obtain each subject's perspective on comfort and function for the manual and CAD/CAM prostheses (Fig. 2). Wilcoxen signed ranks test results showed no significant differences (p<0.05) between the 2 prostheses based on comfort, ability to walk, and overall satisfaction. McNemar test statistics also showed no significant between-group differences (p<0.05) on the basis of pain and perceived safety during prosthetic use. These results supported the premise that the new CAD/CAM design technique can produce a socket that the client considers as good as a manually produced socket.

The prosthetist questionnaire results also supported the premise that the CAD/CAM

technique could produce a socket of equal quality as a manually produced socket (Fig. 3). No significant differences (p<0.05) were found between the 2 groups for walking gait and socket fit (Wilcoxen signed ranks test at p<0.05).

The prosthetist graded CAD/CAM socket fit as superior in 4 cases and manual socket fit as superior in one case. These results compared well with the results from the subject questionnaire; however, the prosthetist and subject differed in opinion in 2 instances. In both these cases, the subject liked the manual socket better but the prosthetist rated both sockets the same. One (1) case that differed was for a long term prosthetic user who did not like a hard socket. For the other case, the subject experienced some medial patellar discomfort when using the CAD/CAM prosthesis. This discomfort was resolved after the second gait analysis session by using a heat gun to modify the socket.

Individual results

Examination of individual subject data showed that, in 4 cases, the CAD/CAM prosthesis was considered superior to the manual prosthesis. In each case, the ratings were only 1 level higher. Three (3) other subjects considered their manual prosthesis superior. These subjects



Fig 2. Subject questionnaire results for comfort, walking and satisfaction (percent of responses)



Fig 3. Prosthetist questionnaire results (percent of responses).

were long-term prosthetic users who were very satisfied with their current prosthesis. Two (2) of these subjects experienced some discomfort in the fibular head and medial patellar regions when ambulating with their CAD/CAM prosthesis. All of the CAD/CAM sockets were considered safe to use; however, 1 subject did not consider the original prosthesis safe. The subject was not able to explain this opinion.

On average, 1.5 (s=0.63) CAD/CAM sockets were required to produce an acceptable device. Eight (8) out of 13 sockets were acceptable on the first attempt and 1 socket required 3 attempts to obtain a satisfactory result. Three (3) attempts were necessary for the 1 successful trial (i.e. the trial when the subject and the prosthetist considered the manual socket to be superior).

To obtain a satisfactory socket, minor template modifications were required in 7 cases and major template modifications were required in 8 cases. The major modifications involved either boundary reshaping or, in 1 case, the addition of a new modification. Boundary reshaping was required to compensate for long stumps, stumps with bulbous distal ends, or a prominent distal fibular region. For 5 subjects, 38% of the cases, no heat gun modifications were required. Heat gun modifications refer to using a heat gun to warm up the thermoplastic socket so that the prosthetist can adjust the socket shape during fitting.

The main areas that required attention during fitting were the fibular head region, the supracondylar suspension region, the posterior shelf, and the distal end. For most subjects, Shapemaker did not correctly cap the socket's distal end. This problem was corrected by lengthening the socket before carving and then, after carving, manually modifying the distal end of the foam blank. Most fitting problems occurred with people who liked their manual socket better.

Gait results

Gait analysis results from the manual and CAD/CAM socket groups were very similar (Tables 1, 2 and 3). T-test analysis results showed no significant differences between groups (p<0.05) in all cases except peak vertical forces on the amputated side. Data from both groups were significantly correlated (p<0.05) for all measures. When examined as a percentage of the data ranges from the manual socket trials, the average differences between the manual and

Quantitative CAD/CAM template generation

		Mean	Correlation	Significance
Speed (m/s)	CAD	1.15 (0.23)	0.87	0.965
	Manual	1.15 (0.21)		
Stride length (m)	CAD	1.42 (0.19)	0.87	0.615
	Manual	1.41 (0.17)		
Stride time (s)	CAD	1.25 (0.14)	0.9	0.371
	Manual	1.24 (0.13)		
Stance time (s)	CAD	0.88 (0.10)	0.868	0.193
	Manual	0.85 (0.09)		

Table 1. Summary of stride parameter analysis for the amputated side. Standard deviations are in parentheses

Table 2. Summary of force analysis for the amputated side (in N). Standard deviations are in parentheses. Force directions x, y and z are respectively in the following directions, M/L, A/P and vertical

		Mean	Correlation	Significance
Force (x)	CAD	47.89 (11.63)	0.901	0.45
	Manual	49.69 (17.06)		
Force (y-brake)	CAD	93.31 (27.23)	0.824	0.499
	Manual	96.46 (27.66)		
Force (y-push)	CAD	91,94 (41.34)	0.92	0.227
	Manual	97.67 (36.68)		
Force (y-ratio)	CAD	1,02 (0,41)	0.662	0.917
	Manual	1.03 (0.29)		
Force (z-brake)	CAD	840.02 (138.83)	0.985	0.001
	Manual	869.15 (131.51)		
Force (z-push)	CAD	785,90 (121.63)	0.991	0.024
	Manual	797.68 (117.49)		

Table 3. Summary of impulse analysis for the amputated side (in N.s). Standard deviations are in parentheses. Force directions x, y and z are respectively in the following directions, M/L, A/P and vertical

		Mean	Correlation	Significance
Impulse (x)	CAD	21.77 (6.08)	0.829	0.698
	Manual	21,26 (8.18)		
Impulse (y-brake)	CAD	19.51 (6.09)	0.937	0.106
	Manual	20.61 (6.48)		
Impulse (y-push)	CAD	16.97 (7.52)	0.847	0.988
	Manual	16.96 (6.72)		
Impulse (y-ratio)	CAD	1.29 (0.65)	0,452	0.797
	Manuał	1.25 (0.33)		
Impulse (z)	CAD	465.53 (78.44)	0.933	0.69
	Manual	462.12 (83.88)		

CAD/CAM groups were less than 6.5%. The majority of measures had a difference of less than 4.0%. No significant differences (p<0.05) were found for any measures from the non-amputated limb. All measures on the non-amputated side were significantly correlated (p<0.05).

Since all but 1 Pearson correlation coefficients

were greater than 0.93, it can be concluded that the CAD/CAM prostheses did not affect the force/time curve shapes. For most subjects, the RMSE values were low. This suggested that the CAD/CAM prosthesis did not affect the force/time curve magnitudes. All cases with a RMSE over 5% were from subjects with the most variable gait. The Fx force component was



Fig 4. Ground to prosthetic foot force data from the manual and CAD sockets – representative trial with three vertical force peaks.



Fig 5. Force data from the manual and CAD sockets - representative trial showing higher peak force.

the most variable within-subject measure and had the largest relative RMSE values.

Discussion

The reliance on hand-sculpting techniques in the field of prosthetics has contributed to the development of prosthetist specific methods for socket design. Since the optimal method for designing a functional and comfortable socket has yet to be discovered, the patient must rely on an individual prosthetist's clinical judgement to design and fit a TT prosthesis.

Though a prosthetist can modify a socket successfully, many are unable to define exactly what was done to the positive model. During modification, the original shape is lost as material is added and removed. Because modifications are made over the entire shape and not as a series of individual changes, picking out exactly how the stump shape was modified is difficult. The inability to define how individual prosthetists modify a socket can impede the transition from manual techniques CAD/CAM. To address this issue, a Microsoft Windows software programme was written to display, analyse, and compare manual and CAD/CAM socket shapes.

CADVIEW was used to generate a CAD modification template that was specific to the prosthetist's manner of working. The variability in prosthetic modification styles made it essential that this template produced a shape that was visually acceptable to the prosthetist; otherwise, the clinician would likely reject the template. Averaging a series of modifications from 7 subjects produced an acceptable and functional design.

The averaged modifications varied in size and shape. Even with these variations, it was observed that the averaged modification shapes conformed well with theoretical modification procedures. This variability also supported the idea that 1 template is not sufficient to fit all amputees without some fine-tuning. By analysing a large database of prosthetic socket modifications, a series of templates could be developed to better accommodate the wide variety of stump contours.

Some operator experience was necessary to translate the averaged modifications into a Shapemaker, CANFIT-PLUS, or ipoCAD template because all these software packages differed in the way they applied overlays and blended outlines into the socket surface. Since Shapemaker was used for the validation portion of this study, only Shapemaker templates were produced.

It was necessary to fine-tune the Shapemaker template for different socket lengths and to blend modifications into the surface. Unfortunately, current template functions are able to retain inter-modification not relationships when accommodating various socket lengths, accommodating some socket volumes, and maintain blending between overlapping areas. Currently, these problems are corrected by the prosthetist after a template is applied.

Most of the template fine-tuning occurred during the initial pre-test trials. The pre-test trials were also beneficial for identifying areas that could be expected to differ between subjects. While examining socket modifications for the template generation subjects, it became apparent that the fibular head and tibial crest regions were more variable than other areas on the socket. The variability in fibular head position, shape, and orientation was supported by the template changes that were made during the pre-test. While the new template gave a good starting point, it was unreasonable to assume that the prosthetist would not have to change the fibular head modification in some manner to provide a proper fit.

The tibial crest modification did not require as many changes since variations in orientation and position were accommodated by the template. Since the template was linked to the proximal and distal tibial landmarks, Shapemaker skewed the tibial crest modification to correspond to the current landmark positions. While using multiple landmarks helped, Shapemaker had difficulty scaling the tibial crest modification for length.

Even though the clinician was satisfied with the system, it was unfortunate that major template modifications were required for 62% of the sockets. In all but 1 case, the major modifications only involved reshaping 1 or 2 modification boundaries. Many of the boundary changes were required to compensate for Shapemaker's inadequacies in maintaining the relationship between modifications on different limb shapes. The adjustments were done to maintain the template shape, rather than make alterations. Some boundary reshaping was also needed to accommodate the individual's anatomy. In 1 case, the distal portion of the lateral tibial crest modification was expanded to conform to the bulbous distal end of the subject's stump. For the 3 subjects with long stumps, the medial tibial flare modification was extended posteriorly so that it overlapped the popliteal modification. This change was needed for soft tissue control. Supracondylar modification changes were required in 2 other cases to provide relief for the lateral tibial condyle.

Since the same major modifications were necessary to fit the subjects with long stumps, it may be necessary to create a long stump template to accommodate these shapes properly without making major changes to the socket modifications. A bulbous stump template may also be required: however, more subjects would have to be evaluated to determine if the template modifications were related to individual characteristics or general trends. A larger sample would also be needed to determine the long and bulbous template shapes.

It should be noted that most of the template modifications did not require major changes (a typical socket design will have 14 discrete modifications). In fact, 7 of the 8 sockets that had major modifications only required that 1 template modification be reshaped. Since the same modification was not changed in each instance, this type of reshaping may be an expected occurrence due to individual differences. Another possible explanation is that, as mentioned in the previous paragraph, a series of general templates are likely required to accommodate different stump types.

From a functional point of view, the amount of time savings that would be gained by providing a large number of different templates and individual modification shapes must be considered. Contemporary prosthetic CAD software has been designed to allow a prosthetist to complete boundary point changes very quickly (a few minutes per modification). If only I modification is being altered, it may be more efficient for the clinician to use I familiar template and customise the modifications as needed.

It was encouraging that heat gun modifications were not required in 42% of the cases. This indicated that almost half of the sockets produced with the CAD template were able to be fitted directly on the subject. Since minor socket adjustments are often required during the fitting process, this result is at least as good as the results during manual fittings.

One area that was not accommodated by the CAD/CAM system was the socket's distal end. Since the cast digitiser's tracking wheel does not reach the bottom of a cast, the distal end is mathematically closed by the CAD software. Unfortunately, the generated shape does not necessarily conform to the subject. The CAD endcap was often too flat and, as a result, produced a socket that was too short. In these cases, the prosthetist used the CAD programme to lengthen the socket before carving a positive model. He would then manually modify the distal end to produce the correct shape. This complication was not related to the template but to current, cast-based, prosthetic CAD/CAM systems. Progression to more sophisticated digitising methods should eliminate this problem.

The posterior shelf was another region that was defined by the CAD programme and caused some difficulty for the prosthetist. While the shape of this modification was usually acceptable, the posterior shelf height was occasionally difficult to set. More experience with the Shapemaker programme was required before the prosthetist could consistently set the correct shelf height.

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The people who preferred their manually produced socket had specific fitting requirements. For the case where the subject and prosthetist agreed that the manual socket was superior, the client had a short stump and walked with excessive knee hyperextension. When these factors were combined with excessive soft tissue in the posterior popliteal region, it became difficult to control the tissue while maintaining the appropriate posterior shelf height. This subject also required extra work on the fibular head region. Upon discussion with this subject's regular prosthetist, it was found that months of trial and error were necessary to fit this person successfully with a prosthesis (using manual methods). This person is also very stoical and will put up with some discomfort before asking for an adjustment. Even though the CAD/CAM socket was not as good as the subject's usual device, the level of success was considered typical for this client. Although this does help to explain the results, it does not change the fact that the socket fitting was unsuccessful.

The second subject had a trigger point distal to the fibular head that made fitting this region difficult. The subject was also very sensitive to pain. It took more than 8 modification sessions totally to relieve pain associated with his manually produced socket. This person also indicated that the hard CAD socket was too different from his old. Pelite lined, socket. To correct this, a second socket was made that incorporated a soft liner. The subject felt more comfortable with the soft liner; however, he was unable to explain why he still preferred the manual socket. It was interesting to note that this subject was the only person that did not return for adjustments after the initial fitting. This may have meant that the socket did not require adjustments or that the subject did not want to make the effort to have an optimally fitting CAD socket.

The third subject had a very bony stump (i.e. very light subcutaneous tissue). He also had a scar in the medial patellar region that camouflaged pressure problems since the skin did not discolour after wearing the prosthesis. Unfortunately, the subject did not report any medial patellar discomfort to the prosthetist until returning for post-evaluation. The prosthetist could easily have corrected this problem with a heat-gun modification. Since this discomfort was not present when ambulating with his regular prosthesis, it is understandable that the subject would assign higher ratings to his manually designed socket. There were no special stump characteristics for the people who preferred their CAD/CAM socket.

Questionnaires

Since the prosthetist and subject questionnaires produced similar results, the opinions rendered in these questionnaires can be considered valid. The results indicate that the prosthetist and the subjects considered sockets designed using the CAD/CAM technique to be at least as good as the manually designed sockets.

The questionnaire data from individual cases provided insight into the clinical realities of using a CAD modification template. Of the 13 test cases, 1 socket fitting can definitely be considered unsuccessful since both the prosthetist and client had lower ratings for the CAD/CAM socket. In 2 other cases, fitting success was not as clear. These 2 subjects preferred the manual socket over the CAD/CAM socket; however, the prosthetist considered the CAD/CAM sockets to be as good as the manually produced ones.

In 4 cases, the client considered the CAD/CAM socket superior. The prosthetist concurred on 3 of these cases – he considered the fourth case to be as good a fit as the previous socket. This consensus between the subject and the prosthetist suggests to the authors that the new CAD/CAM modification technique is capable of creating a prosthetic socket that is better than a person's current device. Although it was clear that some subjects preferred the CAD/CAM socket, the reasons for this preference were diverse.

In 1 case, the subject was experiencing some pain when walking with the old prosthesis. This pain was not present when the subject was retested with the new prosthesis. The resolution of this pain may have been related to the new socket or the pain may have resolved itself over the 2 week inter-test interval. For the second and third cases, the new socket required 3 to 4 ply fewer socks than the manually produced socket. The reduction in socket volume may have led to better prosthetic control during gait. A tighter socket may also have felt more comfortable since it would have had to conform to the subject's anatomy. It was difficult to identify one factor that could describe why the last subject preferred the CAD/CAM socket. Since the fitting session was extremely easy, it may be concluded that the prosthetist made the correct choices to produce an optimal socket for this patient.

Since each CAD/CAM prosthesis was compared with the subject's current prosthesis, it was not possible to blind the subject or the prosthetist as to what device was being tested. The novelty of using a new socket may also have contributed to a superior rating; however, bias against a new device may also have contributed to the inferior ratings.

Both manual and CAD/CAM methods sometimes require that more than 1 socket be fabricated before a successful fit is achieved. For this study, the average of 1.5 iterations was comparable with CAD/CAM results in the literature and falls within the expected clinical range (i.e. 1-2 sockets). It was not surprising that the subject who was not successfully fitted required 3 iterations before an acceptable socket was designed. There were no visible trends between satisfaction with one type of prosthesis and the number of iterations that were required to obtain an acceptable result.

Gait analysis

The gait analysis results supported the hypothesis that there was no difference between the CAD/CAM socket group and the manually produced socket group. In almost all cases (Tables 1-3), there were high correlations and small between-mean differences. These results were consistent for discrete measures and for ensemble averaged curve comparisons.

The stride parameter results from this study were comparable with similar results in the literature (Torburn *et al.*, 1990; Winter and Sienko, 1988; Barth *et al.*, 1992; Robinson *et al.*, 1977). These results were also very similar when comparing the 2 groups. Since the stride length, stride time, and walking speed results were so close, between-group gait comparisons should not be substantially affected by variations in walking speed.

Between-group ground reaction force comparisons produced the only significantly different measures. On the amputated side, vertical ground reaction forces from the manual socket trials were significantly higher than vertical forces from the CAD/CAM socket trials. The average vertical peak forces were also lower on the non-amputated side; however, these results were not significant. Since the differences in vertical impulse values were small, it can be concluded that the vertical forces on weight acceptance and push-off were redistributed over each of these phases. Examination of the average force/time curves for each subject supported this idea since curves with lower peak forces compensated by having a lower slope, and hence a more equal area. Other methods for achieving similar vertical impulses included a reduced unweighting phase and a more abrupt push-off (thereby increasing the area under the force-time curve).

The medial-lateral horizontal force component was the most variable measure. This is not an uncommon finding when testing people with, or without, a lower limb amputation. Even with the high variability, each curve had the same general shape. There were no clinically identifiable between-group differences for the medial-lateral ground reaction force curves.

It was interesting to note that people who preferred the CAD/CAM socket had the largest reduction in peak vertical ground reaction forces. No such trend was apparent for the people who preferred their manually designed socket. The people who liked their CAD/CAM prosthesis also had lower Fx impulse values. higher Fy braking impulses, and larger push-off impulse values. While these results were not significant, they may help explain the success of these new prostheses. Lower Fx impulses may have indicated that there was less total body centre of gravity movement away from the midline. This could improve the subject's perception of balance. The higher braking and push-off impulse values could indicate that these subjects were making better use of their for reducing their prosthesis forward acceleration. Improved force transfer from the prosthesis to the ground should result in overall improvements in walking gait and, as a result, in improved client satisfaction.

The averaged force/time curve shapes were similar in almost all cases. Some of the differences that were observed by examining the ensemble averaged data included the following:

- CAD/CAM trials produced some Fz force/time curves that were closer to typical, non-amputee walking results. These changes usually involved improved symmetry and similar peak forces at early and late stance;
- smoother horizontal braking and push-off curves. There was no relationship between this measure and the type of socket:
- more symmetrical braking and push-off periods. There was no relationship between this measure and the type of socket;
- perturbations in the force/time curves in early stance were present for the poorer walkers in both groups. While the use of a CAD/CAM socket usually changed the shape of these curves, the new socket did not necessarily minimise these perturbations.

Even with these documented variations, the force/time curves from the CAD/CAM trials were usually within 1 standard deviation of similar data from the manual trials.

Except for the differences in peak vertical forces, there were no clinically or statistically relevant differences between gait parameters with the manual socket and CAD/CAM socket groups. This result supports the use of the modification outline generating process to develop a clinically viable CAD/CAM template. The modification outline generating process may also help prosthetists make the transition from manual socket design to computer-aided design.

Conclusion

This document has described a process for defining manual socket modifications and, by averaging these modifications over a series of TT prosthetic sockets, generating a personal CAD/CAM template. Test results confirmed that this method produced sockets as good as sockets designed by traditional methods.

Since the CAD/CAM manufacturing process can be more efficient and more consistent than the manual modification process, this study supports the use of CAD/CAM in some clinical environments. By using CADVIEW to help define a CAD design strategy, the process of moving from traditional design methods to computer design methods should also be more efficient. The process of making a modification template that is specific to an individual prosthetist can ease the transition from hands-on socket design to computer aided methods.

Other beneficial side effects are suggested by this study. Educators could use the socket comparison feature to examine student modifications. The students could use CADVIEW to compare their socket modifications with the instructor's modifications. CADVIEW could also be used in orthotics to examine the progression of spinal deformities over time or to chart the changes in head shape when applying a head orthosis to a client with cranial plagiocephaly. Further research would be required to confirm these advantages.

This study has led to the other questions regarding prosthetic fitting. The CAD/CAM modified socket was not exactly the same shape as the subject's previous socket; however, the majority of subjects were successfully fitted using both design methods. These results suggest that there is a certain tolerance within which a prosthetist can work. This tolerance might be expected when you consider that a person with a TT amputation walks with a mechanical device fixed, or strapped to their leg. Part of the fitting process is helping the patient adapt to a socket shape. It would be advantageous to know what this tolerance is so that decisions can be made regarding CAD approaches (i.e. measurement or limb digitising) or manual modification accuracy (i.e. can the manual modification time be reduced by working within, and not beyond, the tolerance range). The CADVIEW programme could be used to document inter-clinician variations when fitting the same subject. These data would help in an investigation to document prosthetic fitting styles and to define fitting tolerances.

Since people accommodate to a prosthetic socket, it is understandable that long term prosthetic users prefer their existing socket shape. The socket comparison functions could be beneficial when a prosthetist is having a problem fitting a new socket on a subject who is only satisfied with a certain style and feel. By using CADVIEW to examine the differences between the old socket and the new socket, the prosthetist could refine the design to better accommodate the individual's previous preferences.

While looking at future applications is important, the main application of note from this project is the successful implementation of a quantitative method for defining and averaging manual prosthetic socket modifications. These results are both academically and clinically relevant.

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