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Comparison of the lightweight Camp Normal Activity Foot with other prosthetic feet in trans-tibial amputees: a pilot study

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Abstract

Clinically relevant information regarding the useability of prosthetic feet is scarce. The industry is not obliged to perform clinical studies before marketing the product. Clinicians however are limited in their possibilities (organisation and finance) to determine the useability of a technical product. This small study is an example of how in general the useability of a technical product is established in clinical practice.

The Camp Normal Activity Foot (CNAF), a carbon prosthetic foot, was compared objectively and subjectively with a number of other prosthetic feet (same price bracket) in three subjects with trans-tibial (TT) amputations.

The CNAF is low in weight and has favourable stiffness and hysteresis properties. The stiffness of the pylon of the CNAF seems to be limited as also is the possibility of adaptation of the CNAF. The CNAF distinguishes itself, in this study, but not convincingly with respect to the energy consumption in walking, the step-time parameters (symmetry) and the subjective judgement of the users. An additional virtue of the CNAF seems to be its light weight.

Introduction

The characteristics of walking with a TT prosthesis are influenced by the prosthetic foot and the socket. The prosthetic foot has two relevant aspects. These are the weight the functional properties, based on stiffness and the ankle mechanism. Both aspects have their objective and subjective effects on gait. Objective effects are identified by kinematic data in the form of joint angles, angular velocities and step time parameters, kinetic data (joint powers and impulses) and energy expenditure data. Subjective findings are: pain (stump load), feeling of heavy weight, exertion and stability.

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Research literature only presents a few articles about the integral study of objective as well as subjective findings in respect of prosthetic feet (Donn *et al.*, 1989; Wirta *et al.*, 1991; Colborne *et al.*, 1992; Ehara *et al.*, 1993). Most studies concern comparisons of different foot designs based on the measurements of objective parameters (Casillas *et al*, 1995; Torburn *et al.*, 1990; Czerniecki and Gitter, 1994; Macfarlane *et al.*, 1991; Lehmann *et al.*, 1993; Nielsen *et al.*, 1988; Perry and Shanfield, 1993; Goh *et al.*, 1994). Differences are measured in the dorsiflexion angle of the ankle, the metabolic or mechanical energy expenditure as well as the comfortable walking speed. In the studies concerned, little attention is paid to subjective findings of the user.

Regarding the weight of the TT prosthesis very little is known about its influence on objective or subjective parameters. Donn investigated the effect of shoe mass on the gait patterns of trans-tibial amputees and their personal preferences (Donn *et al.*, 1989). She concluded that lightweight footwear does not necessarily provide the most symmetrical gait and is not always preferred by the users. Another aspect of the influence of weight is that a relatively large mass at the distal aspect of the TT prosthesis causes large forces acting axially and tangentially on the stump during the swing phase (van de Veen, 1989). These forces can be uncomfortable or even painful. Furthermore the perception of weight is influenced by the fitting of the socket. When the socket is loose, the TT prosthesis is perceived as being heavier than when the socket fits properly.

The findings of the above mentioned research only give a restricted insight into the useability of prosthetic feet, hence they have a restricted value for the user and prescriber of the prosthesis. Product information regarding prosthetic feet contains little information about the useability of prosthetic feet.

De Laat showed that 29 amputees preferred a prosthesis which caused no stump pain, required little exertion when walking as naturally as possible and felt light in weight (de Laat and de Vries, 1993).

Looking at modern prosthetic feet special attention is paid to reducing the weight of the prosthetic feet with the help of carbon fibre. Until now the available lightweight carbon fibre prosthetic feet are expensive. The CNAF (Camp Normal Activity Foot) is an exception.

Comparing the CNAF with other common prosthetic feet of moderate price little is known about their useability. So it was decided to submit the CNAF to comparative investigation concentrating on potentially clinically relevant parameters. Because the study is an orientating comparison it was decided to restrict the number of patients to three. This connects to the daily clinical practice, where regularly a sort of useability determination takes place purely on an empirical basis in the interaction with patients. Any other approach is difficult for financial reasons.

Subjects and materials

Subjects

The study was performed with three healthy adult males each with a unilateral trans-tibial amputation. Each subject was informed about the study and signed an informed consent. Relevant data of the subjects and their TT prostheses are presented in Table 1.

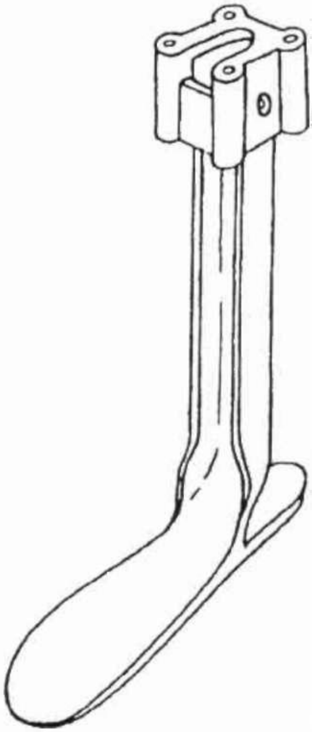

Fig. 1. The CNAF.

Materials

The CNAF is an integration of a prosthetic foot and a pylon (Fig. 1). It is constructed of carbon fibre reinforced plastic except for the adaptor at the top of the pylon which is made of conventional plastic. It has limited alignment facilities because an ankle adaptor is absent. This results in a reduction of mass especially at the distal post of the prosthesis, which raises the centre of mass. The pylon is adjusted to the required length in accordance to the length of the tibial stump. The well fitting sockets of the CNAF prostheses were made as an exact copy of the subjects' own sockets. The adaptor between the CNAF pylon and the socket was a pyramid adaptor with rotation adjustment. The shaping of the CNAF was performed as described in the

Table 1. Subject and prosthetic information

Subject	M/F	Age (yr)	Body mass (kg)	Cause of amputation	Socket type	Own prosthesis mass including socket and shoe (kg)	CNAF mass including socket and shoe (kg), class CNAF
1	M	68	83	traumatic	PTS	2.0 Multiflex	1.5 yellow class
2	M	64	99	traumatic	PTS	2.3 Quantum	1.4 yellow class
3	M	36	82	congenital	KBM	2.0 SACH	1.7 yellow class

Table 2. Price ranking of the foot prostheses including adaptors and pylon in dollars (US).

Foot type	Price
Geriatric SACH	± 119
SACH	± 130
Dynamic	± 178
Lager	± 186
Multi-axial	± 280
Quantum	± 297
Dynamic Pro	± 311
Rax	± 342
CNAF	± 389
Multiflex	± 428
Seattle	± 525

installation manual. The cosmetic foot lower leg cover was made from low density foam. The subjects used their own comfortable shoes which were the same for both prostheses. All prostheses were built up by the same prosthetist. The weight of the CNAF is 0.7kg, while the weight of the Multiflex, Quantum and SACH feet are, including ankle adaptor and pylon, respectively: 1.0kg, 1.1kg and 1.0kg.

In Table 2 some current prosthetic feet, including adaptors and pylon, have been ranked according to price to make them comparable with the CNAF.

Methods

The stiffness/hysteresis of the CNAF were measured because these results give information about the mechanical energy aspect of the rollover pattern of the prosthetic foot. If this pattern differs much from the other prosthetic feet, changes in mechanical energy expenditure cannot be attributed to the lightweight properties of the CNAF. The oxygen uptake was determined because of a reduction in metabolic energy expenditure was expected. Step time was measured determining the symmetry of the gait, being an indicator of the quality of the gait. Questionnaires were used regarding the subjective experiences of walking with a lightweight prosthesis.

Hysteresis

The hysteresis is defined as:

$$\text{hysteresis} = \frac{\text{energy dissipated (A)}}{\text{energy stored (B)}} \times 100\%$$

The energy storage and the release of the CNAF were tested in the test rig of the Biomechanical Department of the University of Twente. It simulates a standardised stance phase of a subject of 80kg mass. It measures the deformations and forces in three directions. With these test results the stiffness and the mechanical energy pattern can be calculated. The energy storage depends on the stiffness of the foot. A supple foot stores much energy, a stiff foot stores less energy. In Figure 2 and example of energy measurement of the CNAF (A) and a SACH (B) foot is given.

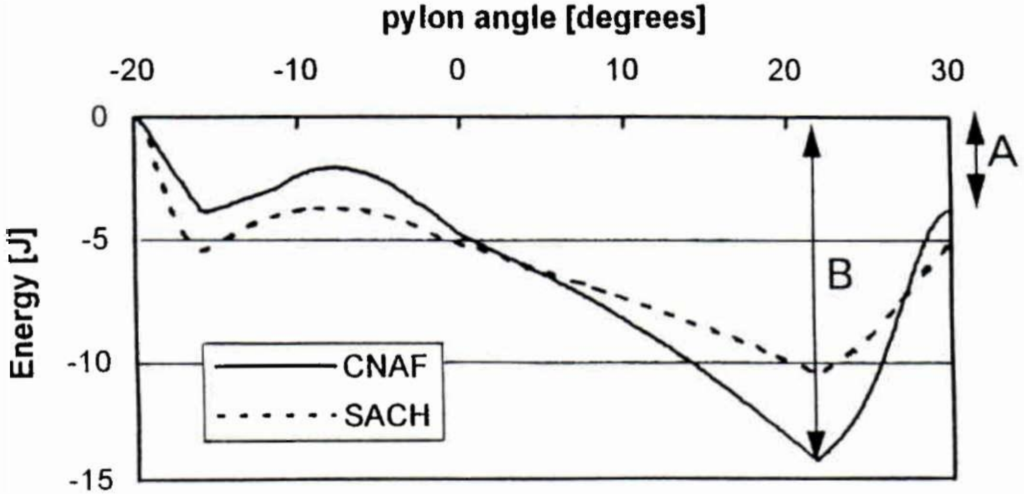

Fig. 2. Energy storage and release patterns of the CNAF and SACH feet.

The measurements performed in the test rig are static. So time dependent features are not taken into account.

Energy cost

Energy cost was measured by oxygen uptake determination, using an Oxycon alpha system. The Oxycon system measures the pulmonary oxygen uptake ($V'O_2$), carbon dioxide output ($V'CO_2$), minute ventilation (V'E) and heart rate (HR). The ratio of $V'CO_2/V'O_2$ is the respiratory quotient (RQ). The RQ is a measure for the kind of nutrition (carbohydrate, fat or protein) used for energy liberation via catabolic processes in the body. The RQ is necessary for calculating the energy because each kind of nutrition liberates a different amount of energy per unit O_2 consumed. So the total amount of energy liberation can be calculated from $V'O_2$ and RQ under the condition that the process is in steady state. The progress of $V'O_2$ and HR is a measure for reaching the steady state. Heart medication (e.g. beta-blockers) can however influence the cardiac reaction on effort (HR not a reliable measure). The measurements performed with the Oxycon alpha system have an accuracy of 5%. Each subject has to walk at three different velocities for 10 minutes, and at least 5 minutes in steady state. A treadmill was used for making the measurements easier and for standardisation of the walking velocities. Before the walking experiments the subject rested for 30 minutes lying on a bed. The last 10 minutes of the resting period the Oxycon measurement started and was stopped after the measurement with the third walking velocity on the treadmill. The subjects were asked not to drink, eat and smoke two hours before the measurements except for drinking some water. They were also asked (not verified) not to perform strenuous activities during the last two days before the measurements.

Step time parameters

A Vicon gait analysis system was used to measure the step time parameters: step time, swing time, stance time, double stance time and step length. These parameters are useful to check the symmetry of walking. Therefore the ratios between the right and left leg are compared. For perfect symmetry these ratios should be 1.

Questionnaires

The questionnaire about standing and walking with a prosthetic foot, developed at our research department, consisted of 23 questions which were grouped in four categories: 1. stability while standing (level and slope), 2. stability while walking (level and slope), 3. functional aspects (e.g. comfortable speed, powerful/powerless push-off, suppleness of roll-off), 4. special activities (e.g. staircase climbing) (Postema *et al.*, 1997[a,b]). All answers to the questions were scored on a 1 to 10 scale, 10 being best. The average score of all questions was supposed to be the general score of the prosthesis. This score has been used to rank the prosthesis in an order of choice. After the first and the second session an unstructured interview took place with emphasis on the low mass properties of the prosthesis.

Study design

The complete test period of each subject consisted of three sessions. The first session was performed with the subject's own prosthesis. Step time analysis and oxygen uptake measurement took place. Afterwards the subject answered the questionnaire concerning his judgements about various properties of his prosthesis. Next he was fitted with the CNAF. The second session took place two weeks later and was the same as the first, but now using the CNAF. The third session, two weeks after the second one, was a repetition of the oxygen measurement of the first session, using original prosthesis. The second and the third measurement were used for further analysis. The first measurement has not been analysed to avoid bias due to not being accustomed to the test situation/equipment.

Results

Because of the limited size useability of this study, the data presented have not been statistically analysed. It is not useful to perform statistical significance analysis with only three subjects. So the results are descriptive and of an indicative character.

First the objective results are presented: concerning the hysteresis, the oxygen uptake and the step time parameters. Secondly the subjective results are presented based on the questionnaire and the unstructured interview.

Objective results

Hysteresis

In Figure 2 the energy storage and release of the CNAF is related to the SACH foot. The

Table 3. Hysteresis classificiation.

Prosthetic foot	Hysteresis
CNAF	26%
Dynamic Pro	27%
Dynamic	28%
Multi-axial	30%
Quantum	31%
Lager	36%
Seattle	40%
SACH	47%
Multiflex	52%
Rax	58%

CNAF curve fits well with the SACH foot which means that the CNAF has average stiffness properties. During the period between shank angle of -20° and -15° the CNAF stores 3.7 J after heel strike. At an angle of -8° 2 J is released. As the foot rolls on till 22° (just before push off) 14 J is stored. A good prosthetic foot returns much energy. Such a foot is often called a dynamic foot. After the release at push-off (shank angle 30°) the energy dissipation of the CNAF is 3.7 J. This is the amount of mechanical energy loss. Looking at Figure 2 the hysteresis of the CNAF is A/B x 100% = 26%.

In Table 3 the hysteresis data of 10 types of prosthetic feet measured with the test rig are presented (Postema *et al.*, 1997; van Jaarsveld *et al.*, 1990).

Oxygen uptake

The data provided by the Oxycon system are shown in Table 4. Net metabolic energy consumption per second is presented as a function of walking velocity. Net metabolic energy is the gross metabolic energy consumption (total energy consumption) minus the basal energy consumption. For subject 1, the prosthesis with the CNAF shows a higher energy consumption than his own prosthesis for all velocities. For subject 2, the values with the CNAF prosthesis are lower for all velocities. Subject 3 also shows lower energy consumption values for the CNAF prosthesis, though the difference is small at the lowest velocity.

Step time parameters

The Vicon system provides step time parameters. With these parameters it is possible to check the symmetry of the gait. Therefore ratios between right and left leg are presented in Table 5.

These symmetry ratios are quite good for all prostheses. For subjects 1 and 3 the symmetry improved slightly with the CNAF prosthesis. For subject 2 the symmetry deteriorated with the CNAF.

Table 4. Net energy cost per second measured at three different velocities (v is velocity [m/s]) with own and CNAF prosthesis, df. = difference.

Subject 1, energy cost [J/s]				Subject 2				Subject 3			
v	Own	CNAF	df. %	v	Own	CNAF	df. %	v	Own	CNAF	df. %
0.74	191.8	202.6	+5.6	0.83	277.8	243.1	-12.5	1.10	276.5	268.0	-3.0
0.87	210.6	237.6	+12.8	1.17	321.3	298.5	-7.1	1.40	382.9	346.3	-9.6
0.98	245.2	266.1	+8.5	1.43	394.7	363.4	-7.9	1.62	489.2	450.8	-7.7

Table 5. Step time parameters, ratios between right and left leg.

	Subject 1		Subject 2		Subject 3	
Ratio R/L	Own	CNAF	Own	CNAF	Own	CNAF
Step time (s)	0.936	0.943	1.026	1.073	1.020	1.014
Swing time (s)	0.919	0.930	1.010	1.040	1.108	1.066
Stance time (s)	1.052	1.044	0.995	0.977	0.940	0.963
Double stance time (s)	1.011	1.019	0.934	0.855	1.264	1.142
Step length (m)	0.980	0.839	0.832	0.893	1.136	1.174

Subjective results

Questionnaire

The questionnaire was divided into four categories:

1. Stability while standing (level and slope): 6 questions. 2. Stability while walking (level and slope): 4 questions. 3. Functional aspects (e.g. comfortable speed, push-off): 9 questions. 4. Special activities (e.g. staircase climbing): 4 questions.

Table 6 shows per patient respectively for each type of prosthesis the average scores of each category and overall scores which are the averages of all 23 questions.

All subjects judged the CNAF performance lower than the prosthetic foot of their own prosthesis. The difference in the judgement by subjects 2 and 3 is very small. This can be interpreted as no preference for either prosthesis. Subject 1 however rated the CNAF 1.2 point lower than the prosthetic foot of his own prosthesis. Especially the categories 1 (stability while standing) and 3 (functional aspects) are responsible for this difference.

Unstructured interview

Each subject was interviewed twice. The first interview concerned their own prosthesis, the second one the prosthesis with the CNAF. Only remarkable differences are reported below.

Subject 1 experienced at the roll over with the CNAF as too stiff. The lateral stability was not sufficient. The judgement of the swing phase was positive: "it swings by itself." At normal walking velocity the CNAF satisfies. He appreciated the low mass of the prosthesis with the CNAF. He preferred a prosthesis with a more supple foot and with more lateral stability.

Subject 2 attached no great value to the reduction of mass. The roll over with the CNAF was said to be good but at toe off the foot turned into exorotation because of limited stiffness of the pylon. In general he judged the prosthesis with the CNAF as good as his own prosthesis. He preferred to use the prosthesis with the CNAF because he got used to it.

Subject 3 did not use the prosthesis with the CNAF during his work as a prosthetist because he experienced torsion stiffness of the pylon as too small. In his leisure time he however used the CNAF prosthesis. The subject is very content with the mass reduction. His opinion was that the heel strike and roll over features were adequate at normal walking velocity. At higher walking velocities the torsion stiffness should be greater. The toe off with the CNAF was good but the foot turns unwillingly into exorotation. Because of the low mass of the foot the swing phase was very much appreciated.

Discussion

Because of the limited size of this study only global indications can be given with respect to the useability of the TT prosthesis with the CNAF. Concerning the useability of the prosthesis those factors were considered which are thought to be of greatest interest to the amputees (de Laat and de Vries, 1993). No statements can be made about the possible influence of the CNAF on stump complaints, because these did not occur using their own prosthesis or the prosthesis with the CNAF. Starting with the objective useability parameters in the literature about prosthetic feet a lot of attention is paid to the storage and release of mechanical energy in the stance phase. From the energy point of view a prosthetic foot is better when this foot releases more of the stored energy at toe off, meaning the loss of mechanical energy = hysteresis is smaller. Based on research with a test rig the CNAF shows the best hysteresis properties compared with the other 9 prosthetic

Table 6. Subjective judgement of the prostheses, 1..10 scale, 10 = best.

	Subject 1		Subject 2		Subject 3	
Categories	Own	CNAF	Own	CNAF	Own	CNAF
1	8.2	6.7	9.0	8.0	6.3	6.3
2	7.5	7.8	9.0	8.0	6.0	5.8
3	8.1	7.1	9.1	9.0	7.1	8.1
4	7.8	7.3	8.0	9.0	7.3	6.5
Overall	8.0	6.8	8.9	8.7	6.7	6.6

feet. To what extent this finding is clinically relevant with respect to aspects of exertion remains however disputable.

The metabolic energy consumption in the application of the CNAF resulted in a reduction for two subjects and in an increase for one subject. The differences are less than 10%. Again the question of clinical relevance of the mentioned difference arises. Looking at the step time parameters the attention was focussed on the factor of symmetry, being a measure for a natural gait. It appears that the symmetry ratios of the CNAF do not differ substantially from those of the other prosthetic feet.

Last but not least, the subjective opinion of the amputee is of interest. Compared with their own prosthetic foot (including ankle adaptor and pylon) a mass reduction of the prosthesis of ± 300g can be achieved with the CNAF. Two subjects perceived the mass reduction of the prosthesis as positive and one subject did not think it was important.

Otherwise it is still a question whether an initially noticed difference in mass of the prosthesis still plays a role in the long run on the subjective judgement of the prosthesis. Prosthetic components are frequently recommended by the industry, just because of their low mass but the practical meaning for the user (objectively and subjectively) is not explained. This theme calls for special attention via research.

The answers of the questionnaire correspond with the clinical practice. Being satisfied about their own prosthesis (including the prosthetic foot) an alteration of the prosthesis, meaning another prosthetic foot, will be judged critically by most amputees. This can explain their opinion about the CNAF.

The subjects walked too briefly with the CNAF to be able to give a definitive subjective judgement concerning its useability. The duration of use of the CNAF was however sufficient for the subject, as previously carried out research foot prostheses shows, to acquire an opinion about the most essential walking characteristics of the CNAF (Postema *et al.*, 1997[a,b]). This concerns the characteristics of the heel strike, the foot landing, the roll over and the stability (sidewards and rotation).

One subject experienced insufficient lateral stability with the CNAF. The roll over of the foot was experienced predominantly as adequate, walking comfortably. However two subjects mentioned a disturbing exorotation with the CNAF at the push-off phase. This aspect needs further attention.

Conclusions

In contrast to the main other literature findings on the meaning of prosthetic feet this study tried to obtain integral insight in the useability of the CNAF on the basis of objective and subjective parameters from an user's perspective. This way of evaluating a product is recommended for clinical purposes because the insights obtained can help in prescribing a technical aid in a responsible manner.

The CNAF is inclusive of ankle adaptor and pylon, clearly lighter in mass than some other types of often used prosthetic feet (Multiflex, Quantum and SACH foot) with low to moderate price (< 555 Dollars). The stiffness of the pylon of the CNAF seems limited just as the possibilities to adapt the CNAF.

The CNAF has favourable stiffness and hysteresis properties compared to 9 other prosthetic feet in the same price range.

With respect to the metabolic energy consumption in walking and the step-time parameters (symmetry), there are no rational convincing variables found between the CNAF and the subject's own prosthetic foot (Multiflex, Quantum or SACH foot).

The date of the subjective judgements of the prosthetic feet, confirms this. In view of the above mentioned the CNAF seems especially suitable for amputees who are very keen on a low mass prosthesis.

The above mentioned conclusion and statements regarding the CNAF are only based on three patients. This number may be considered just to elicit convincing (without the necessity of applying statistical calculations) clinically relevant differences of the CNAF to other types of prosthetic feet. Any other approach is, without any subsidiary finance, hardly possible in clinical practice. In fact, the producers of prostheses components should, on the basis of integral useability research, deliver adequate product information.

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