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Preliminary experiences with modified SACH feet manufactured and used in a tropical developing world setting

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Abstract

In a prospective study of polypropylene (PP) prostheses for trans-tibial amputees four different modified SACH feet were used. These are identified as:

1. BAVI from the national manufacturer of componentry in BaVi;
2. HCMC a design initiated by the International Committee of the Red Cross (ICRC) together with the Army Factory in Ho Chi Minh City;
3. HI from Handicap International;
4. VI from Veterans International, Cambodia.

Four (4) from 5 BAVI feet, 7 from 9 HCMC feet and 4 from 10 HI feet failed after about a year on average, whereas none of 10 VI feet had failed after 19 months.

Dimensional differences in the ankle part and in the height of the foot in the different designs made interchangeability impossible.

Introduction

The prosthetic foot is a known problem in the tropical part of the developing world (Day, 1995), but no results on differences between feet from clinical follow-up investigations have been published. There are different designs and fabrication methods for feet, ranging from the Jaipur rubber foot, that has a good credibility in India, to a number of SACH foot modifications manufactured locally, in the best situation at a national level (Kijkusol, 1986). The SACH foot is the most popular model in the developing world, because it is easy to make from local materials (Meanley, 1995).

In Vietnam two SACH foot modifications have principally been in use. One is supplied by the national manufacturer of componentry in BaVi. Further to that ICRC initiated in 1989 a development of a vulcanised foot (HCMC) together with the Army Factory in Ho Chi Minh City. When the Ministry of Labour, Invalids and Social Affairs (MOLISA) in 1996 requested ISPO to undertake an evaluation of the application of polypropylene (PP) prosthetic technology for trans-tibial amputees, ISPO decided together with the German technical collaboration project, VIETCOT, the Vietnamese Education and Training Centre for Orthopaedic Technologists, that this was a good possibility of field testing these two foot modifications together with the HI foot from Handicap International which is nearly universally applied in Cambodia and the VI foot from Veterans International Cambodia, which also is somewhat used in the neighbouring country.

Patients and methods

In two communities of the Vinh Phu province west of Hanoi 32 patients with 34 trans-tibial amputations were provided with PP prostheses at the BaVi orthopaedic workshop during the period March through July 1997. The patients were nearly all veteran amputees from 1951-94 with an average age of 45 (26-73) years at follow-up. The patients were followed prospectively after 10 and 19 months, and the general results of the survey will be reported in a separate paper.

The 4 different types of feet were supplied by random selection with bilateral amputees receiving the same type of foot for each limb.

The BAVI foot has a large wooden keel, rubber forefoot and a rubber foam heel cushion.

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The components are glued together, and the sole covered with an outer textile layer.

The HCMC foot has a PP keel, rubber foam at forefoot and heel cushion, and reinforced tyre rubber for the sole. The components are vulcanised together.

The HI foot has a longer PP keel, rubber forefoot and heel cushion; and reinforced tyre rubber for the sole. The components are vulcanised together.

The VI foot is in principle identical to the HI foot, but the heel extends further towards the forefoot. This foot is also vulcanised.

At follow-up technical failures were recorded together with the reported level of daily use.

In 22 cases the patients already had an Automated Fabrication of Mobility Aids (AFMA) prosthesis provided in 1996 by the Prosthetics Outreach Foundation (POF). Partial information on the performance of the feet was available. Of these, 6 patients had a failed foot replaced at the first follow-up with a prototype, the V-M foot, developed by POF together with the BaVi factory.

Results

The overall results are displayed in Table 1, showing that 4 out of 5 BAVI feet, 7 out of 9 HCMC feet, 4 out of 10 HI feet had broken down, whereas none of the VI feet were worn out. The VI foot performed significantly better than the other fabrications ($p<0.02$, Student's t-test).

The feet failed at an average of 11 (2-19) months. The feet had been subject to intensive use in 12/15 of the failures with 14 (10-16) hours of daily use; and a walking distance of more than 2km in 11 cases. The time-related breakdown of the of the feet is shown (Fig. 1) in a Kaplan-Meier plot.

In 8 of 15 failures slipping of the keel with disruption between keel and rubber was the cause of failure. In 1 HI foot the bolt attachment had failed. In 6 of 15 cases the sole was badly worn or had cracked.

With the HCMC and HI feet only 4 out of 8 non-failures were subjected to intensive use; from the remainders only one being used at all.

The stress pattern for the VI foot did not differ from the others; 8/10 being subjected to intensive use with 14 (10-18) hours of daily use and walking distances of more than 2km for half of the patients.

With regard to the AFMA prosthesis 6 out of

Table 1 Results of prospective clinical testing of prosthetic feet for trans-tibial amputees.

	BAVI foot (n = 5)		HCMC foot (n = 9)		HI foot (n = 10)		VI foot (n = 10)
	Failure (n = 4)	OK (n = 1)	Failure (n = 7)	OK (n = 2)	Failure (n = 4)	OK (n = 6)	OK (n = 10)
Significance (p<value)	0.00005		0.00003		0.02		
Time to failure (months)	13 (2-19)		9 (4-19)		12 (8-18)		
Intensive use	3		5	1	4	3	8
Light/moderate use	1	1	2	1		3	2
Body mass, kg	51 (48-55)	52	50 (43-55)	57 (53-60)	50 (45-55)	47 (40-52)	52 (45-60)
Hours/day in use	14 (10-16)	18	14 (12-15)	16 (15-16)	15 (15-16)	17 (15-18)	14 (10-18)
Walking distance							
<500m			1			3	3
0.5-2km	1	1	2	1		2	2
>2km	3		4	1	4	1	5
Foot dorsiflexed	1		2			1	2
Failed bolt					1		
Failed keel	3		4		1		
Failed sole	1		3		2		
Follow-up (19 months)	4	1	5	2	3	4	9
Follow-up (10 months)			2		1	2	1
Wet rural area			1		1	2	4
Dry rural area	4	1	6	2	3	4	6

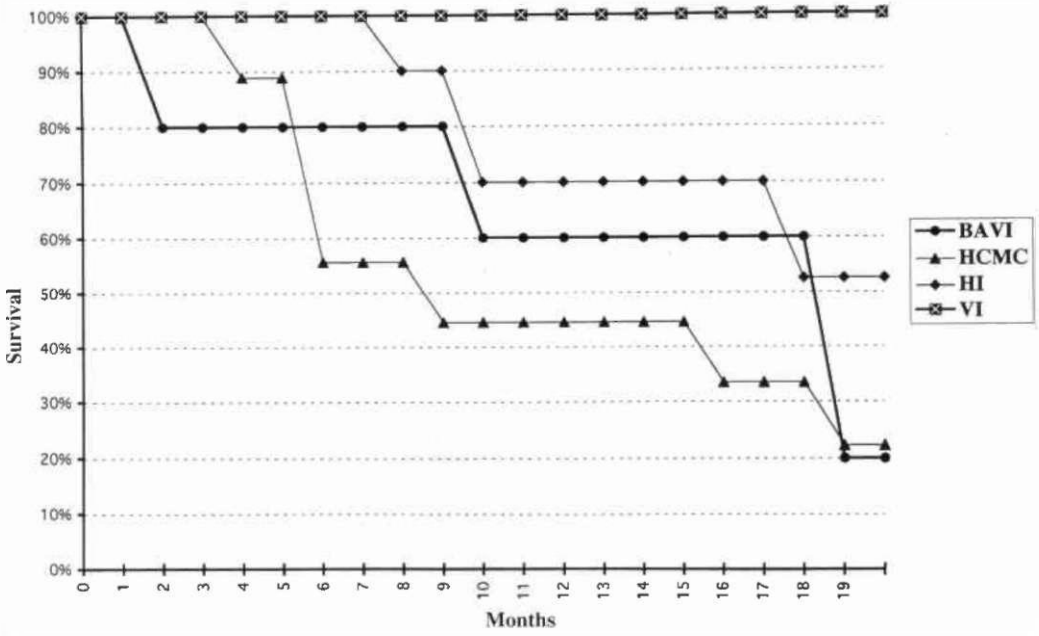

Fig. 1. Prosthetic foot failures.

19 patients reported failure of the foot within a few months; loosening from the attachment to the shank in 4 cases, and broken down in 2 cases. Three (3) prostheses had not been used because the sockets were too narrow. Only 1 prosthesis was in regular use and 2 more in light use at the time of the follow-up.

With the V-M foot only 1 patient was satisfied; whereas 2 of the 3, who disliked the new foot, had gone back to a BAVI and a HI foot, respectively. One (1) foot had broken down, and the last patient did not show up for follow-up, because he was away ill in another part of the country.

Discussion

This small study quantified the durability of modified SACH feet produced and used in a tropical area, although only a few were subjected to wet paddy field working. It showed that the vulcanised rubber foot from Veterans International in Cambodia did significantly better than any of the others in the test series, and that these feet lasted under intensive use for at least 19 months. It also showed that the durability of the different feet was longer than anticipated at the Consensus Conference on Appropriate Prosthetic Technology (Day, 1996). The life time of the foot can be the determinant for the life time for use of that particular prosthesis, if there is not an effective service and repair system accessible.

One of the many problems in the developing world is that sustainability of local manufacture must be secured because of financial constraints limiting the import of finished goods like feet (Kijkusol, 1986). Such limitations might also apply to import of certain raw materials.

Materials and equipment can be prohibitively expensive so that their use can lead to aid dependence rather than independence (Meanley, 1995). It has been pointed out, however, that the price of some thermoplastics is not higher than natural rubber and some can be reused (Öberg, 1995), as is the case with the keel being made of recycled PP scrap in 3 of the feet included in this study. In Cambodia it has apparently been possible to convince the non-governmental organisations to use the HI foot together with PP components from ICRC (Day, 1996; Simon 1996). This was an important reason for including the HI foot in this study. The ICRC programme in Ho Chi Minh City has been self-supportive by applying the HCMC foot together with the PP technology. The BAVI foot has for many years been produced at the national component manufacturing centre.

It appears that at least 3 types of feet did not

live up to the anticipated life time of a trans-tibial prosthesis, which is supposed by MOLISA to be three years, as this is the time interval of providing renewal of limbs to Vietnamese war amputees. This problem was not realised, probably because of the lack of repair service and outreach follow-up systems. From the information collected a similar problem seems to relate to the outreach provision of POF, which also does not include any follow-up service. This problem has been previously identified (Kijkusol, 1986). It is an obvious suggestion to the country that the prosthetic provision systems should make service follow-up and repairs available.

There is currently ongoing development of new feet in different areas of the developing world. In Vietnam the HCMC foot is against the background of results of the first assessment visit in this study undergoing a radical change in design and manufacturing. The BaVi manufacturing plant is in collaboration with POF developing a new rubber foot of sandwich construction with layers of woven textile reinforcement of the midfoot. The final model is several generations younger than the V-M foot tested in the latter part of this study, is now mass produced and that latest version has been provided to a significant number of patients with AFMA prostheses.

The results of the presented study clearly show the need for independent comparative surveys of new foot devices before such are released for general use in higher numbers without any effective control and repair service. It may also be appropriate to centralise component production at a few places in a country with the application of quality control to ensure uniformity of the end product. The production of terminal devices should not be left to smaller local workshops that can not live up to such demands.

Another significant problem identified in the study was the lack of interchangeability of the different types of feet. There are considerable differences in the height of the foot device, both with and without heel height. Furthermore there are both dimensional and geometrical differences of the ankle profile. This makes it impossible to achieve an acceptable cosmetic result when changing to a foot design different from that initially used, as we experienced with the few patients in the current series. It is recommended that these crucial dimensions should be harmonised at least among the manufacturers in a given geographical region, and absolutely within the same country. It is certainly essential if changing a worn foot should become part of the service that can be provided in a community-based rehabilitation (CBR) programme sometime in the future.

Cummings (1996) had scrutinised 33 years of technical publications before the 1995 consensus conference and reported that there were few outcome studies, and very few documented component production techniques for developing countries; that there appeared to be a significant need for durable prosthetic feet than can be manufactured in-country; and that many facilities fabrication their own components should collaborate to aid the quest for the ideal, low cost, durable, locally manufactured system. These statements still stand.

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