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Evaluation of use and durability of polypropylene trans-tibial prostheses

T. T. VERHOEFF, P. A. POETSMA, L. GASSER and H. TUNG

International Committee of the Red Cross, Geneva, Switzerland

Abstract

Forty-three (43) trans-tibial prostheses with a mean period of use of 33 months were evaluated in terms of utilisation and durability. The majority of the prostheses (80%) were worn by amputees with demanding occupations, such as farmers, fishermen and tradesmen. The prostheses were in use approximately 9 hours per day. No major or frequent breakdowns of the polypropylene prosthetic components were found. The suspension belts were the parts most frequently affected; a total of 32 needed replacement after an average 11 months of use. Eleven (11) prostheses were completely replaced, more than half at least partly because of socket-fitting problems. In all, socket-fitting problems were found in 15 prostheses, causing pain and consequently limitation of use. While the prosthetic polypropylene components were satisfactory, the rubber foot was a major cause of early breakdown. A total of 40 feet were replaced; their mean period of use before breakdown was 9 months. In practice, parts were frequently replaced at a later stage than desirable, meaning that there was frequent "overuse" of prostheses with worn parts. Measures were taken to increase the life span of the prosthesis: change in the design of the foot; issuing a spare foot with the prosthesis; strengthening the suspension belt. Additional evaluations are necessary to confirm the degree to which the findings are representative.

Introduction

The role of the International Committee of the Red Cross (ICRC) is to assist and protect war victims. The organisation's physical rehabilitation programmes are undertaken to provide patients with assistance while at the same time setting up or strengthening structures capable of meeting the demand for repair and replacement of the orthopaedic appliances in the future. In order to achieve these two objectives, the ICRC focuses on (1) cooperation with the existing health-care system; (2) training of national staff; and (3) introduction of appropriate technology.

Since 1979, the ICRC has supported or established 49 rehabilitation centres in 25 conflict-ridden countries worldwide. Over 130,000 prostheses and over 40,000 orthoses have been produced for more than 110,000 individuals. Of the prosthetic appliances produced, the proportion of polypropylene limbs, introduced in the early nineties, is about 50%. Polypropylene has proved to be a very suitable material for projects in the countries where the ICRC operates. It is cheap, recyclable, light, and easy to transport and store. It is generally well accepted by patients and staff, especially when it has been in use for some time, even in countries with a tradition of using other imported components and materials.

The use of a prosthesis is limited in time because of the development of fitting problems or because worn parts need to be repaired/replaced. In some countries, such as Switzerland, amputees are entitled to a new prosthesis every 2-3 years. In countries in (post-) conflict situations this is often not possible for a variety of reasons: financial constraints, ignorance, problems of accessibility, priority given to fitting new patients. At the same time,

All correspondence to be addressed to T. T. Verhoeff, 19 Avenue de la Paix, 1202 Geneva, Switzerland.

the conditions under which the prostheses are used are often taxing, since a large proportion of the amputees are manual workers or engaged in wet or dry farming. What are the consequences for the patient? Does this mean that the prosthesis is no longer used after a relatively short period? The purpose of this paper is to answer those questions with reference to a specific region of Viet Nam covered by the Ho Chi Minh City (HCMC) Rehabilitation Centre. The centre serves an area of 53,970 sq km with an estimated population of 12,808,194. The ICRC began providing the centre with material and technical assistance, including full-time expatriate staff, in 1989. More than 13,500 amputees have been fitted with prostheses since that date. After 1995, the assistance was scaled down to short technical follow-up visits carried out 2-4 times/year by an expatriate prosthetist.

In November 1997, a retrospective study on the use and life span of prostheses among a small number of amputees was undertaken, and the main reasons for prosthetic breakdown were identified. For reasons of clarity, a distinction is made between the findings relating to the polypropylene prosthesis and those relating to the rubber foot.

Materials and methods

The hand-casting method was practised for plaster moulding and rectification, using self-made plaster bandages (gauze and plaster of Paris powder). No brim was used and rectifications were performed according to anatomical shape. No end-bearing was provided at the distal part of the stump. For trans-tibial prostheses, a patellar-tendon-bearing (PTB) socket with a T-strap was used. The socket was made by heating a 4mm polypropylene sheet at 170° Celsius for 20 minutes and draping it on the plaster cast, covered with a stocking to facilitate suction. No soft socket was made for the trans-tibial prosthesis. A polypropylene pipe (45mm diameter x 35mm thick) with one end concave, receiving a convex disc, was attached to the end of the socket with a washer and M10 bolt. An ankle connector was attached to a rubber foot with a washer and M10 bolt. The length was adjusted by cutting the polypropylene pipe, which was later fixed with a polypropylene rod to the ankle connector. The polypropylene trans-tibial prosthesis can be seen in Figure 1. After

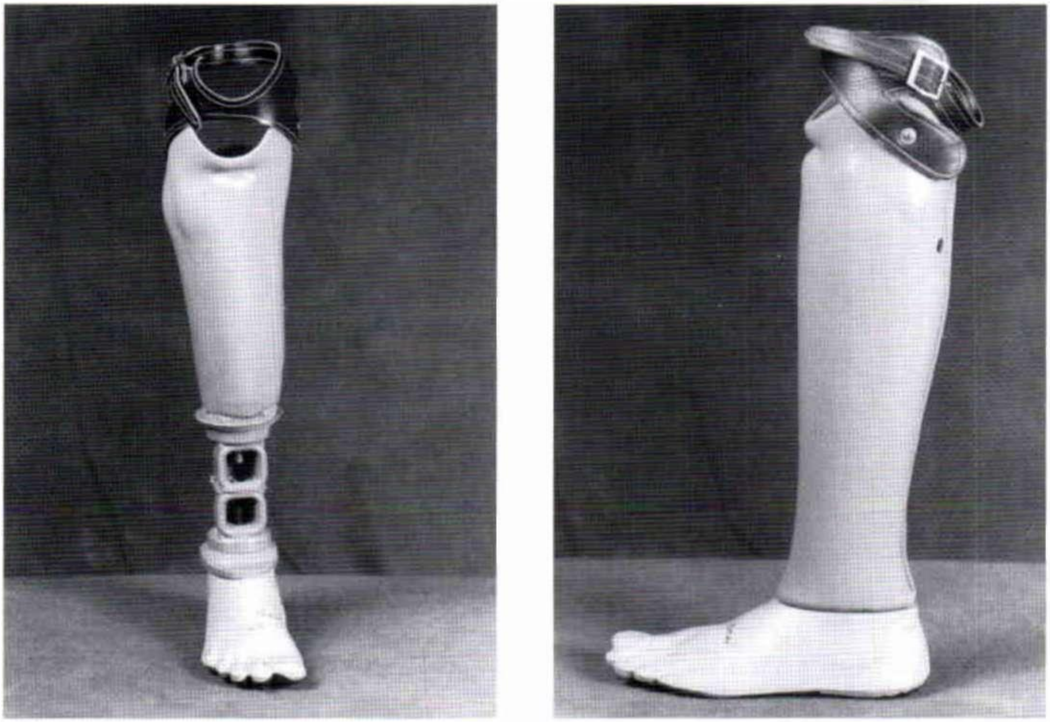

Fig. 1. The polypropylene trans-tibial prosthesis.

successful trial on the patient, the prosthesis was finished by welding all connecting component parts except for the rubber foot with a heating gun and polypropylene rod (3mm or 5mm diameter). Plaster of Paris powder was applied for cosmetic shaping. Later, another 3mm polypropylene sheet was draped over the cosmetic plaster covered with a stocking. The polypropylene cosmesis was removed by cutting both the seam and the plaster. After removal of the plaster of Paris, the cosmesis was replaced and welded with a heating gun and polypropylene rod (3mm or 5mm diameter), while the foot was attached. A PVC T-strap suspension was attached to the socket with either a copper rivet or a polypropylene rivet. Some prostheses had T-straps made of leather.

The polypropylene prosthetic components were manufactured by recycling polypropylene off-cuts. First they were placed in a crushing machine and reduced to pellets (3-5mm diameter), which were oven-heated on a Teflon sheet at 170° Celsius for about 20-30 minutes. Then they were transferred into an aluminium mould, which was preheated to 100° Celsius. Moulds of various shapes, such as concave pipes, convex discs, ankle adapters and concave cups, were placed in a press.

Essential conditions for obtaining good-quality products are consistency in the quality of the raw material, strict observance of temperatures, and avoidance of contamination of the polypropylene with dust, grease, etc.

The Ho Chi Minh Rubber Foot, made in the Z751 Army enterprise, consists of a polypropylene keel made out of pellets which were oven-heated and pressed into a mould (Fig. 2). Three different kinds of unprocessed rubber were mixed with various chemicals. The sole part is similar to the rubber of a car tyre. It is vulcanised and 8-10mm thick. For the dorsal part of the foot, a 1-2mm layer was placed in the mould. Soft foam rubber was placed between the sole, the keel and the dorsal part. The whole was placed in a mould and heated in a vulcanisation press. It is designed to be used barefoot or with slippers.

The HCMC Rehabilitation Centre employs 14 national staff, including 10 technicians, in the prosthetics section, plus 3 more in the component workshop and mechanical section. None of the staff has received training equivalent or superior to ISPO Category II. All employees have received "on-the-job" training of various durations, while some have received additional training elsewhere (3 years' training at the BaVi Orthopaedics and Rehabilitation Centre; 3 years in the former German Democratic Republic; 18 months' training by the World Rehabilitation Fund; various short seminars). The 3 employees in the component production unit have received 3 years' "on-the-job" training in addition to their basic skills as carpenters or mechanics. In 1997 the 10 technicians produced 1743 prostheses, i.e. an average of 14.5 prostheses/technician/month.

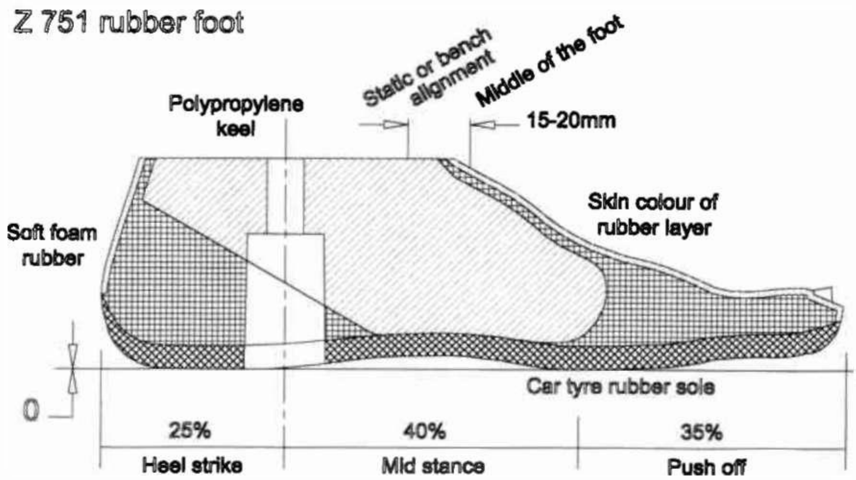

Fig. 2. Z751 Ho Chi Minh foot.

Table 1. Composition of sample group

	Sample 43 amputees	HCMC database 8,991 amputees
Mean age in years (range)	47 y (12 y-60 y)	80%: >40 y
Percentage male	81%	88%
Percentage war-wounded	95%	81%

Sample group

A random sample of 80 unilateral trans-tibial amputees who had been fitted with polypropylene prostheses at the HCMC rehabilitation centre between January 1993 and February 1996 were invited by letter in November 1997 to come to the centre for an evaluation of their prostheses. Thirty-one (31) were living in greater HCMC (8km radius) and 49 in seven surrounding provinces (100km radius). Forty-six (46) amputees (58%) replied; 16 (52%) from greater HCMC and 30 (61%) from the provinces. Of these, 7 were excluded because they came without prostheses (5) or because they were of Symes amputation level (2). Four (4) trans-tibial amputees who happened to attend the HCMC Centre for repairs were included, bringing the total to 43.

Evaluation

The amputees were questioned about their prostheses by the prosthetist and the project administrator, using a standard questionnaire. The questionnaire elicited information regarding the living conditions of the amputee, mean hours of daily use of the prosthesis, the occupation/daily activities of the patient and the repair history of the prosthesis. *Hours of daily use* indicates the average daily use at the time of the evaluation. It could vary between 0 hours, when the prosthesis was not used at all, and 12-16 hours, when it was used full-time. As an indicator of wear and tear, the daily activities of the amputee were translated into a *load level* on the prosthesis with four possibilities: low, medium, high and very high. The amputee was asked for the repair history of the prosthesis, which was also inspected for faults. The *life span* of the prosthetic parts to be repaired/replaced was determined in consultation with the patient: this was the period between the time when the part was first used and the start of signs of wear and tear and/or cracks.

Results

Table 1 shows that the characteristics of the sample group were similar to those of the amputees registered in the ICRC database at the HCMC Rehabilitation Centre, which contained data on 8,991 amputees.

Table 2 indicates the hours of daily use in relation to the load level on the prosthesis (the load levels of 2 amputees were not classified). The table shows that the majority of the prostheses had high load levels and many hours of daily use. Eighty per cent (80%) of the prostheses were used by farmers, fishermen and merchants. Of the 8 women, one was in the medium level, 3 in the high level and three in the very high category of load level (one woman was not classified).

At the time of evaluation, the average patient was still using his/her prosthesis 9 hours per day; this figure varies little in most of the load-level sub-groups.

Table 2. Use and load levels of evaluated prostheses

Load level	Hours of daily use				Total (n)	Mean hrs/day (SD)
	0	1-5	6-11	12-16		
Low (mainly cosmetic, pensioner)	0	1	0	0	1	1 (0)
Medium (office work)	0	4	1	2	7	8 (6.0)
High (walks a lot, merchant)	0	2	1	5	8	11.3 (6.0)
Very high (farmer, fisherman)	4	5	5	11	25	9.1 (6.4)
Total	4	12	7	18	41	91.1 (6.3)

Table 3. Mean life span of prostheses and replaced parts (except feet)

	n	Mean life span in months (SD)
Replaced prostheses	11	37.3 (8.6)
Replaced parts:		
Suspension belts	32	11.0 (11.1)
Sockets (welding seams)	2	11.5 (9.2)
Sockets (fitting problems)	7	26.4 (12.7)

It was found that 9 amputees also used additional prostheses. This group used their evaluated prostheses on average 4.1 hours/day (range 1-8hrs); the additional prostheses were used 10.6 hours/day (range 7-14hrs). These additional prostheses included appliances which had been issued many years before, sometimes by a different centre if the amputee had moved to another area, and home-made prostheses (2 amputees). Frequently these amputees used the older prostheses for work, "saving" the nicer prostheses for other occasions. The majority of the amputees said they were satisfied with their prostheses, in spite of the fact that many were obviously in need of repair or replacement.

Repairs

Table 3 summarises the repairs that needed to be carried out on the prostheses, excluding the rubber feet, which are considered separately.

Eleven (11) prostheses (26%) were replaced. In the majority of these cases (64%), fitting problems were (partly) the cause. The mean life span of these replaced prostheses was 37 months. Two (2) prostheses (5%) did not need repair or replacement. These had hardly been used by the amputees (0-2 hours/day).

Of the components, it was the suspension belts which needed by far the most repairs, with 32 replacements. In addition, two welding seams had to be repaired (both prostheses were still in use 16hrs/day), while 7 sockets were repaired or replaced because of fitting problems (average use: 2.7 hours/day).

Though a small number of prostheses had undergone previous repairs, including 5 repaired by the patients themselves, the majority of the repairs were carried out only at the time of the evaluation. Many patients had continued walking on their prostheses even when some parts were considerably worn.

Table 4 gives a more detailed breakdown of the suspension belt replacements. Although the mean life span of replaced suspension belts was about the same (11 months) in the 3 load-level sub-groups, individual variations in life span were large in all sub-groups. The small number of belts replaced precludes drawing conclusions about an association between load level and life span.

Table 5 gives a more detailed breakdown of replaced feet because of the large number of such replacements. The table shows the relation between replaced feet and load level with a high figure for hours of daily use. Of the replaced feet, 85% were being used between 6-16 hours per day. Quite a number of feet were considerably worn but still used. Three (3) prostheses had had the feet replaced twice and 3 others three times. These 6 prostheses were used on average 12.7hrs/day (SD 3.7), with a high to very high load level. The average life span of replaced feet was 8.9 months and is related more clearly to hours of daily use than to load level. Four (4) patients expressed a preference for a rocker instead of a foot for reasons of sturdiness. Twelve (12) prostheses had no history of foot

Table 4. Replaced suspension belts

Load level	Hours of daily use				Total (n)	Mean hrs/day (SD)	Mean life span in months (SD)
	0	1-5	6-11	12-16			
Low (mainly cosmetic, pensioner)	0	0	0	0	0		
Medium (office work)	0	3	1	2	6	8.8 (6.0)	8.8 (10.8)
High (walks a lot, merchant)	0	2	0	5	7	11.7 (6.3)	10.9 (9.1)
Very high (farmer, fisherman)	2	5	3	9	19	9.2 (6.3)	11.7 (12.3)
Total replaced suspension belts	2	10	4	16	32	9.7 (6.2)	11.0 (11.1)
Mean life span in months (SD)	12.5 (9.2)	6.6 (5.6)	21.0 (20.5)	11.1 (10.3)			

Table 5. Replaced feet

Load level	Hours of daily use				Total (n)	Mean hrs/day (SD)	Mean life span in months (SD)
	0	1-5	6-11	12-16			
Low (mainly cosmetic, pensioner)	0	0	0	0	0		
Medium (office work)	0	2	1	2	5	9.8 (6.3)	8.4 (3.4)
High (walks a lot, merchant)	0	2	3	7	12	11.3 (5.2)	9.4 (7.5)
Very high (farmer, fisherman)	0	2	6	15	23	12.6 (4.3)	8.7 (5.3)
Total replaced feet	0	6	10	24	40	11.8 (4.8)	8.9 (5.7)
Mean life span in months (SD)		12.3 (9.1)	11.7 (6.3)	6.8 (3.3)			

replacements; these were being used on average 1.3hrs/day (SD 1.7) at the time of the evaluation.

In 15 cases there was a poor fit between the stump and the prosthetic socket and consequently 10 of these patients complained of pain. Six (6) amputees were not using the prosthesis at all at the time of evaluation because of fitting problems. Usually such problems were caused by stump changes over the course of time, although one amputee mentioned having had pain ever since the prosthesis was first fitted.

Figure 3 summarises the various replaced parts and their mean life span.

Discussion and recommendations

The study confirmed that polypropylene parts are not a major cause of breakdown of prostheses. The rate of only 2 welding faults on 43 prostheses over an average period of more than 3 years is considered good. The welding faults were probably due to human error.

An overall limitation of this study is that the sample of 43 amputees reflects the experience of only a small number of all prosthesis users and that the response rate for the 80 patients invited to take part was only slightly over 50%. A similar evaluation should be organised for the group of non-respondents so as to determine how representative the findings relating to the respondent group is. Additional evaluations should also include trans-femoral amputees and prostheses which have been used for longer periods.

The high number of hours of daily use, the relatively high number of additional prostheses used and the frequent self-repairs indicate that

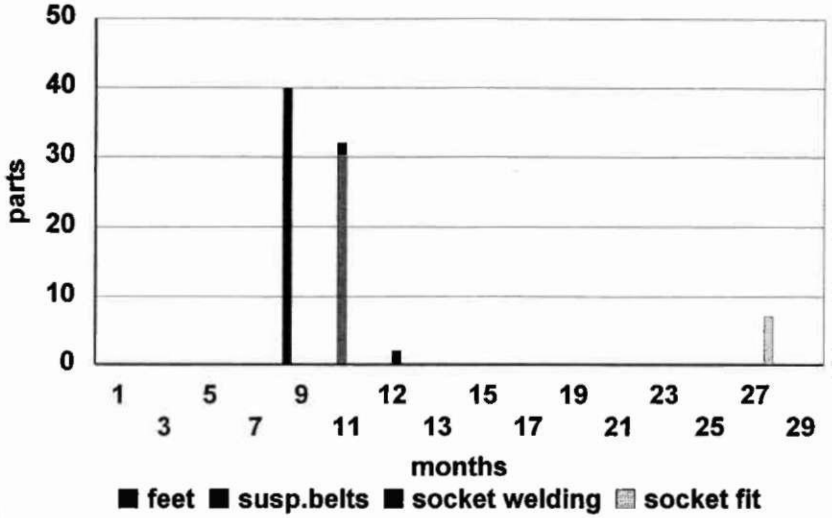

Fig. 3. Mean lifespan replaced parts in months.

the prosthesis plays an important and useful part in the daily life of an amputee. This is supported by the fact that three-quarters of the patients expressed satisfaction with their prostheses, in spite of the problems observed.

An attempt was made to cross-link *mean hours of daily use* with *load level*. The findings should, however, be interpreted with caution. Field conditions for individual amputees can vary widely, and furthermore both indicators depend on the ability and willingness of the patient to provide correct information. Moreover, as the hours of daily use refers to the time of the evaluation, this figure is not necessarily representative for the total period of use. It can be argued that it understates use during the total period, as prosthesis use often decreases over time owing to breakdown or pain. In general, the numbers are too small to permit conclusions being drawn about possible associations between load levels and life span. In future, stratification into a smaller number of groups which are more clearly defined may be a better option.

Although the polypropylene prosthetic parts were generally found to be sufficiently strong, the evaluation showed that some prostheses, or parts of them, were replaced too late. Only a few patients stopped using their prostheses as a consequence, most of them continuing to use prostheses with worn parts. However, the suspension belt was clearly too weak and needed strengthening (or the PTB system needed to be replaced by supracondylar suspension).

A major problem was identified with regard to the rubber foot. Its life span is considered generally too short, and although patients often continue using the prosthesis with a worn prosthetic foot, this problem needs to be addressed. In the process of making a rubber foot, irregularities in laying the unprocessed rubber sheets can contribute to poor quality.

Apart from material problems, the fitting problems observed in about 35% of the patients are a significant cause of reduced use of the prosthesis, mainly because of discomfort and/or pain. As a consequence, six amputees were not using their prostheses at all at the time of the evaluation. The fitting problems appeared mainly due to stump changes over time and highlighted the importance of continued access to rehabilitation services.

The results of the study prompted the following decisions: to contact the foot factory, which subsequently adapted the manufacturing process to increase life span; to issue a spare foot with each prosthesis so as to allow patients living far away to do their own repairs; to use a stronger, leather suspension strap instead of the weaker plastic strap. The findings also supported the decision to develop a different and structurally more robust foot.

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