The Journal of the International Society for Prosthetics and Orthotics

Prosthetics and Orthotics International

December 1993, Vol. 17, No. 3

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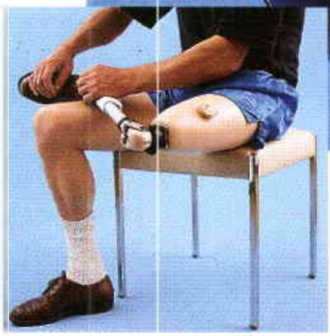

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Prosthetics and Orthotics International is published three times yearly by the International Society for Prosthetics and Orthotics (ISPO), Borgervaenget 5,2100 Copenhagen Ø, Denmark, (Tel. +45 31 20 72 60). The subscription rate for 1994 is GBP70 per annum, single numbers GBP24. The journal is provided free to Members of ISPO. Remittances should be made payable to ISPO.

Editorial correspondence, advertisement bookings and enquiries should be directed to Prosthetics and Orthotics International, National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Curran Building, 131 St. James' Road, Glasgow G4 0LS, Scotland (Tel. +44 41 552 4049).

ISSN 0309-3646

Produced by the National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Glasgow

Printed by David J. Clark Limited, Glasgow

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Editorial

Regional and inter-regional collaboration in prosthetics and orthotics has long been an important consideration within ISPO. The recent workshop of key medical and technical personnel in prosthetics and orthotics for Western Asia and the Eastern Mediterranean region held in Amman, Jordan, 8-15 October 1993 provided the opportunity for such collaboration in this area.

The meeting was organised by the University Rehabilitation Institute, Ljubljana, Slovenia and the United Nations Economic and Social Commission of Western Asia (ESCWA) and hosted by the Ministry of Health, Jordan. ISPO collaborated in programme planning and participated in the workshop.

The ESCWA region comprises of 14 countries with a population of over 100 million people. Eleven countries were represented at the meeting, namely – Bahrain, Egypt, Jordan, Lebanon, Oman, Palestine, Saudi Arabia, Turkey, Qatar and Yemen. It was the first time that these countries had met to discuss the status of prosthetics and orthotics services on a regional basis and presentations from each country gave a good background in order to analyse the present situation. Whilst there are many common practices in prosthetics and orthotics provision from country to country, there are also many differences as a result of different community, national and regional circumstances. Many problems were identified in the delivery of prosthetic and orthotic services at both national and regional levels, mainly related to policy, manpower, education and training of the prosthetic and orthotic professionals, education of the rehabilitation team, technology, components and materials. One of the main obstacles identified was the lack of information exchange about the existing and available practices from country to country in the region, as well as a lack of cooperation between the different bodies within individual countries. The workshop recommended that –

1. accurate, up to date data related to the types and incidence of disability should be collected and periodically updated by responsible authorities in each country of the region.
2. responsible authorities in each country of the region should estimate the number of prosthetic and orthotic professionals required to provide suitable and affordable prosthetic and orthotic services.
3. prosthetic and orthotic education should be an integral part of health education planning and development in each country of the region and that it should be similar to that of other rehabilitation professionals such as physiotherapists and occupational therapists.
4. definitions of the professionals involved in prosthetics and orthotics as outlined in the Moshi (IPSO, 1985) and Jönköping (IPSO, 1987) reports be adopted. The workshop further recommended that the professionals involved should not be used above the level of their competence in order to ensure the success of the prosthetic and orthotic management of disabled persons.
5. responsible authorities in each country of the region collaborate in the planning and establishment of suitable national and regional training and education programmes for all categories of prosthetic and orthotic professionals. The workshop further recommended that ESCWA should play a coordinating role in this matter. Possibilities that exist are the re-opening of the school in Amman, the plans for the school in Beirut and the proposals for a school in Cairo. In all schools the teaching language should be Arabic.
6. efforts should be made, as early as possible, to develop the rehabilitation team to ensure the successful rehabilitation of the physically disabled. The core members of the team should be the specialist rehabilitation doctor, the prosthetic/orthotic professional, the physiotherapist and the occupational therapist. Other members such as the social worker, nurse and the family, should contribute when necessary and possible.
7. in recognition of the fact that there are materials and components production capacities available in the region, the responsible authorities within the region investigate the possibilities of local materials and component resources. The workshop further recommended that ESCWA should play a coordinating role in this matter.

8. the rehabilitation team ensures that the patient and his/her family are properly trained and informed in the objectives, use and maintenance of any prosthetic or orthotic device that is supplied.
9. means be established whereby professional and technical information may be exchanged within the region. This ideally should be accomplished through education establishments in the region, the creation of national and regional associations and collaboration with international associations.
10. the UN include family awareness programmes of the problems of disability in the International Year of the Family (1994).

It is hoped that this meeting will encourage the development of prosthetics and orthotics services within the individual countries of the region and the region as a whole. It is also hoped that other regions will take similar steps in encouraging open discussion and collaboration in their areas.

Norman A. Jacobs
Honorary Secretary

Prosthetics and Orthotics International, 1993, 17, 145–146

Proposed Amendments to the Constitution

The following amendments to ISPO's Constitution have been formulated by the Executive Board and will be discussed and voted on by the International Committee at its meeting which will be held in association with the World Congress in Melbourne, 2nd-7th April, 1995.

The proposed amendments to Clauses 2.3.2, 2.3.3, 2.5.1, 4.2.1, 4.2.4, 4.3.1, 4.3.5, 4.5.5, 4.5.7 and 4.6.3 remove the privileges associated with Fellowship related to International Committee representation and Executive Board membership whilst retaining the title Fellow as a special tribute for deserving Members.

The proposed amendments to Clause 4.5 and the proposed addition of Clause 4.5.10 recognise the role of International Consultants to the Executive Board.

Before the International Committee discusses these proposals, the Constitution requires they be published to the International Committee and Members and Fellows for comment. Any such comments should be received by the Honorary Secretary before 1st November, 1994.

Original Clause	Proposed Clause
2.3.2 FELLOW: the highest level of individual member who by professional achievement, integrity, reputation, and by his activities as a Member in the opinion of the Executive Board of the International Committee has contributed to a high degree to the objectives of ISPO.	**2.3.2** FELLOW: the recognition of the individual member who by professional achievement, integrity, reputation, and by activities as a Member in the opinion of the Executive Board of the International Committee has contributed to a high degree to the objectives of ISPO.
2.3.3 HONORARY FELLOW: those Fellows who have been selected by the International Committee for special recognition.	**2.3.3** HONORARY FELLOW: those Members or Fellows who have been selected by the International Committee for special recognition.
2.5.1 An individual may resign at any time. Members who fail to pay the specified fees will be automatically severed.	**2.5.1** An individual may resign at any time. Members or Fellows who fail to pay the specified fees will be automatically severed.
4.2.1 The International Committee of the ISPO will consist of Fellows selected by National Committees of National Member Societies of ISPO.	**4.2.1** The International Committee of the ISPO will consist of Members or Fellows selected by National Committees of National Member Societies of ISPO.
4.2.4 The International Committee shall elect by majority vote from the Fellows at large the Officers of ISPO and others to serve on the Executive Board, all to take office at the conclusion of the Assembly.	**4.2.4** The International Committee shall elect by majority vote from the Members or Fellows at large the Officers of ISPO and others to serve on the Executive Board, all to take office at the conclusion of the Assembly.
4.3.1 The Executive Board will consist of the President, the President-Elect, two Vice-Presidents, and four other Fellows of ISPO. The Honorary Secretary, the Honorary Treasurer, the Immediate Past-President and all Standing Committee Chairmen join the Executive Board as non-voting members. The President, with majority approval of the Board, may appoint non-voting consultants to the Board.	**4.3.1** The Executive Board will consist of the President, the President-Elect, two Vice-Presidents, and four other Members or Fellows of ISPO. The Honorary Secretary, the Honorary Treasurer, the Immediate Past-President and all Standing Committee Chairmen join the Executive Board as non-voting members. The President, with majority approval of the Board, may appoint non-voting consultants to the Board.

(Contd.)

Original Clause	Proposed Clause
4.3.5 In the event of a vacancy arising in the Executive Board during the Triennium through illness or other reason, the Executive Board may co-opt from the Fellowship at large to fill that vacancy. A Fellow co-opted in this way, where applicable, enjoys full voting rights and has the same status as those members of the Executive Board elected in the normal way.	**4.3.5** In the event of a vacancy arising in the Executive Board during the Triennium through illness or other reason, the Executive Board may co-opt from the membership at large to fill that vacancy. A Member or Fellow co-opted in this way, where applicable, enjoys full voting rights and has the same status as those members of the Executive Board elected in the normal way.
4.5 Standing Committees, Ad Hoc Committees and Task Officers.	**4.5** Standing Committees, Ad Hoc Committees, Task Officers and International Consultants.
4.5.5 The Protocol and Nominations Committee shall comprise the President, the immediate Past-President, the President-Elect, two Fellows from the membership at large, the Honorary Secretary (ex officio) and up to two Past-Presidents nominated by the President.	**4.5.5** The Protocol and Nominations Committee shall comprise the President, the immediate Past-President, the President-Elect, two Members or Fellows from the membership at large, the Honorary Secretary (ex officio) and up to two Past-Presidents nominated by the President.
4.5.7 The two Fellows on the Protocol and Nominations Committee shall be appointed by the Executive Board for a three year term and may be re-appointed.	**4.5.7** The two Members or Fellows on the Protocol and Nominations Committee shall be appointed by the Executive Board for a three year term and may be re-appointed.
	4.5.10 The President, with the approval of the Excutive Board, may appoint International Consultants with regard to identified tasks in relation to specific countries or geographical regions.
4.6.3 A National Member Society consisting of five Members and Fellows is entitled to apply to the Executive Board for representation on the International Committee. The representative(s) must have Fellow rank or meet the requirements of Fellowship. Any membership in excess of 15 Members and Fellows will entitle the National Member Society to appoint two representatives. In no case will any member society be entitled to more than two representatives. To ensure proper representation at any given meeting, the National Committee may appoint alternatives acceptable to the International Committee. Where two representatives are involved they shall be different professional disciplines.	**4.6.3** A National Member Society consisting of five Members and Fellows is entitled to apply to the Executive Board for representation on the International Committee. Any membership in excess of 15 Members and Fellows will entitle the National Member Society to appoint two representatives. In no case will any member society be entitled to more than two representatives. To ensure proper representation at any given meeting, the National Committee may appoint alternatives acceptable to the International Committee. Where two representatives are involved they shall be of different professional disciplines.

Prosthetics and Orthotics International, 1993, 17, 147–156

Amputee population in the Kingdom of Saudi Arabia

H. S. AL-TURAIKI and L. A. A. AL-FALAHI

The Joint Centre for Research in Prosthetics and Orthotics and Rehabilitation Programmes, Riyadh, Saudi Arabia.

Abstract

A 14 year retrospective study was conducted of 3210 amputees who attended during the period 1977-1990 at Riyadh Medical Rehabilitation Centre (RMRC), the first and the largest rehabilitation centre in the Kingdom of Saudi Arabia. The mean age was 30.5 years, male slightly older than female. The mean age of the lower limb amputees was 32.6 and of the upper limb amputees 21.8 years. An overall predominance of male to female with a ratio of 6.1:1 was observed. Males outnumbered females by 5 to 1 in the upper limb and 6.3 to 1 in lower limb amputees. The ratio of lower limb to upper limb and multiple limb amputees was 15:3.7:1. Trauma was the leading cause of upper limb amputations (86.9%). In the lower limb, although trauma (52.9%) was the prominent cause, 35.9% was due to disease. Major specific causes of trauma were road traffic accidents, machine accidents, and falls from height. The most common site of unilateral amputations was trans-tibial (45.2%), followed by trans-femoral (21.6%), trans-radial (7.6%), partial hand (4.8%), and trans-humeral (4.7%). Comparison with other studies shows a higher mean age and fewer trans-tibial amputees than in Autralia and other Western countries, while studies in Asia show greater similarities to the present investigation as regards trauma and disease incidence which occur in similar patterns. These patterns of amputee population indicate the demand for prosthetic service and provide guidelines for future development.

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Introduction

Prosthetic and orthotic services were introduced into the Kingdom of Saudi Arabia in 1974 with the establishment of the Riyadh Medical Rehabilitation Centre (RMRC). For a number of years, it was the only place to which all amputees from all over the Kingdom were referred for prosthetic management. Amputees represented 15.2% of the total number of cases attending the centre during the 1977-1990 period (Fig. 1). Prostheses are provided at no cost to citizens, residents and amputees from the neighbouring countries.

Extensive studies of amputees and their fitting with prostheses have been made in different parts of the world. Glattly (1964) conducted a survey of 12,000 new amputees over the 1961-1963 period in the USA and found a predominance of trans-humeral amputees among the lower limb prosthesis

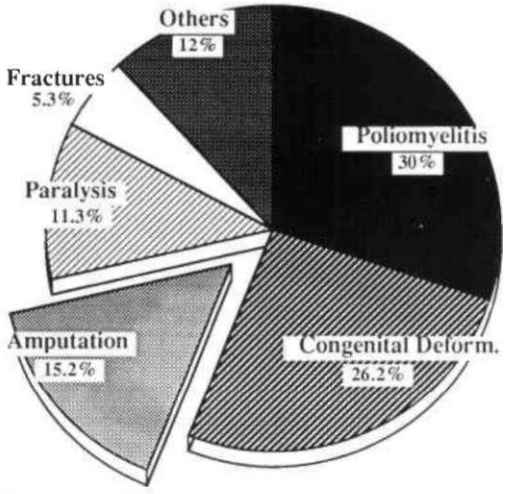

Fig. 1. Incidence of different cases during the 1977-1990 period.

users. Twelve years later in their study Kay and Newman (1975) found that the number of trans-tibial amputees presenting for prosthetic fitting had increased to 53.9% in the USA. Many studies have reported high percentages of amputation due to disease. Warren and Kihn (1968), in a 1964 study of Veterans Administration Hospitals, reported that 76% of the amputations were for vascular insufficiency. Vascular disease and infection were the reasons for amputation in 98% of the 172 cases between 1964 and 1968 reported by Burgess (1969). Of 194 cases 85% were found to be due to vascular disease in a study by Kerstein (1974), and 95% of 292 trans-tibial amputations reported by Murray (1965). Hansson (1964) reported 85% lower limb amputations for peripheral vascular disease in 586 amputees in Sweden from 1947 to 1963. Pohjolainen and Alaranta (1988) reported that during the 1984-85 period, there were 880 amputations of lower limbs performed on 705 patients in Southern Finland. Patients in this study requiring amputation were arteriosclerotic in 43.1% of cases and diabetic in 40.7%. The most common site of unilateral amputation was trans-humeral (42%) followed by trans-tibial (27.7%) and toe amputation (22.2%). In Denmark, Ebskov (1983) also reported that the combined share of arteriosclerotic and diabetic gangrene consistently accounted for more than 85% of all lower limb amputations and the changes within each aetiology, including trauma, were not statistically significant. Jones (1977 and 1990) stated that in Australia most amputees who had lost their lower limbs had amputation due to peripheral vascular disease. In another study by Katrak and Baggott (1980), it was shown that trans-tibial amputation was more common than trans-humeral amputation in Australia. Jones (1989) also found that trans-tibial prostheses made up to 58.7% of all prostheses prescribed under the free limb schemes in Australia (1981-1985). Children were predominant users of Syme's and trans-radial prostheses. A five-year review of referrals to 23 disablement services centres for prosthetic treatment in England, Wales and Northern Ireland (1981-1985) by Ham *et al.* (1989) showed a decrease in the number of both upper and lower limb referrals and a 4% increase in arteriosclerosis as the primary cause of amputation.

Pohjolainen and Alaranta (1988) reported that trauma was the most common cause of upper limb amputation in Southern Finland between 1984-85. Trauma was also the main cause for upper limb amputation which represented 3% of all major amputations in Denmark between 1978 and 1983 as reported by Andersen-Ranberg and Ebskov (1988).

Other studies published from India, Hong Kong and Burma showed a different pattern. Chan *et al.* (1984) presented results of a 24 year retrospective study of 1,821 amputees treated by the prosthetic and orthotic unit of the Kowloon Rehabilitation Centre in Hong Kong and demonstrated a rising trend of amputee populations with a 1.88:1 ratio of lower limb to upper limb amputees. The mean age was 39 years. The commonest cause of upper limb amputation was trauma, and of lower limb amputation was disease. A study in Burma by Hla Pe (1988) found that trauma was the leading cause of upper and lower limb amputations (87% and 47% respectively) though disease was a close second in lower limb amputations. The studies in Asia had great similarities to each other, as trauma and disease incidence occur in similar patterns, whereas the patterns are different in America, Denmark, Finland and Australia.

The disability following limb amputation is permanent and can also be enormous: in many cases amputation makes the patient heavily dependent on other people. The amputee requires considerable in-patient and out-patient care and frequently makes demands upon the social services and welfare workers. Every attempt must be made to return the individual to as near normal functional status as possible and to his original environment. However, the services which plan and organize the provision of prostheses and rehabilitation for amputees would benefit from information concerning the extent of the problems, which obviously differ from one country to another. To the authors' knowledge, no major study has previously been carried out in Saudi Arabia on the population of amputees and prosthesis users.

The current investigation presents the data for a fourteen year period from 1977 to 1990 on amputees and prostheses prescribed for them through RMRC mainly to identify the incidence, causes and levels of upper and lower limb amputations. However, the primary purpose of this retrospective study is to

investigate the current epidemiological situation and assess general characteristics of amputees for the planning of prosthetic rehabilitation and for better evaluation of future needs in personnel, facilities and funds.

Methodology

RMRC had maintained patient forms, for all new cases, recording the common vital characteristics dealing with age, sex, the onset and date of amputation, and causes and levels of amputation. In addition, the educational, marital and vocational status were recorded. Forms on the length, shape and condition of the stump and ranges of motion were recently included. Also included was information on prosthetic prescription, date of prescription, duration of prosthetic fabrication, status of check-out and overall period of prosthetic rehabilitation.

Every patient's record was examined identifying any data concerning demographic factors and general characteristics. Then the data from these forms were processed and entered into a microcomputer-system (Apple Macintosh SE/30), using a data management software (Microsoft File). For scientific investigation, individual researchers and medical institutions may be provided with information according to their speciality and needs. Naturally a certain set of rules must be applied in order to safeguard the privacy of the amputees.

The current study looks at data from 1 January, 1977 to 31 July, 1990 on amputees and the prostheses prescribed, fabricated and fitted at RMRC. Data analysed in this investigation were mainly limited to those related to the number, age and sex of amputees; educational, marital and vocational status; and the level and cause of amputation, and their respective relationship to different age groups and vocational status.

Results

Number, age, and sex

During the 1977-1990 period, the total number of amputees was 3,210. There has been a general increasing trend in new cases since 1981 (Fig. 2). Among the 3,210 amputees, there were 75.9% lower limb, 19% upper limb and 5.1% multiple limb amputees, the ratio being 15:3.7:1. Multiple limb amputees had bilateral, one-sided or triple limb involvement.

The mean age of amputees was 30.5 years, but the distribution ranged from less than 1 to 95 years of age. Male amputees had a slightly higher mean age than females (31 and 28.5 years respectively). The mean age of lower limb amputees was 32.6 years. The mean age of upper limb amputees was 21.8 years. When the age distribution was studied it was found that

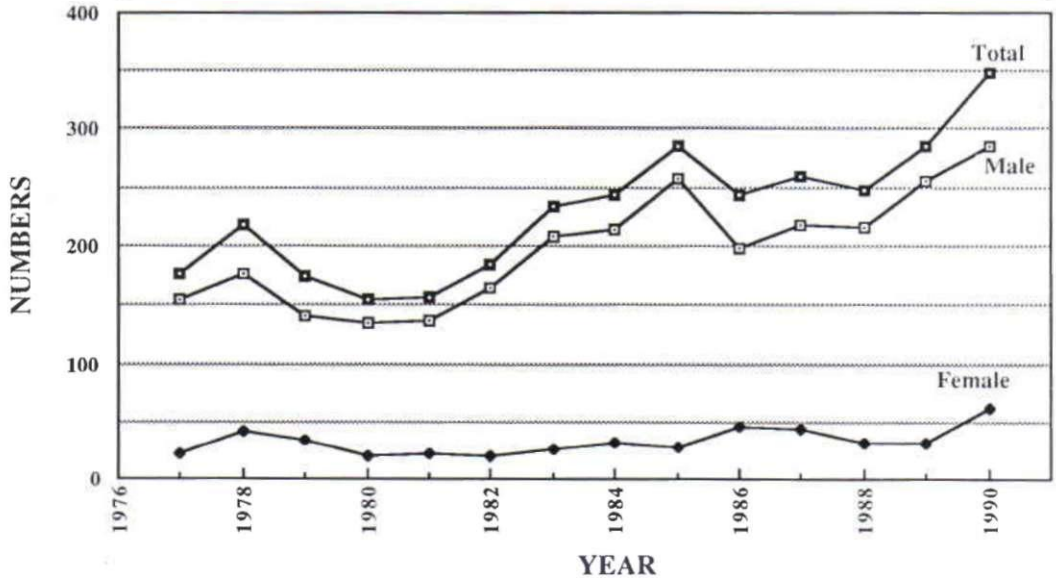

Fig. 2. Number of new amputees presenting during the 1977-1990 period.

the greatest number of amputees were less than 10 years of age (19.5%), immediately followed by the 11-20 age group (18.5%) and the 21-30 (18.1%); while those between 31-40 (12.6%) formed the fourth majority group (Fig. 3).

There was a strong preponderence of males (85.8%) compared with females (14.2%). The overall male to female ratio was 6.1:1. On comparing the sex distribution within the specific age groups, several interesting features were identified. Among the younger amputees of 10 years or below, the ratio of male to female was 3.2:1, compared to the overall pattern of 6.1:1. This was immediately followed by an increase in the ratio of male to female in the 11-20 and 21-30 age groups (12.5:1 and 18.3:1 respectively). A sudden decline in the predominance of males started with the 31-40 age group (5.7:1) and continued up to the 51-60 age group (3.9:1). The peak of male predominance (19.3:1) was reached in the 71-80 age group.

Causes of amputation

The causes of amputation are categorized into four groups: congenital, tumour, disease, and trauma. The data indicated that the majority of amputations were due to trauma (59.7%). The next most common causes were disease (30.1%), tumour (5.5%), and congenital (4.7%) (Table 1). Specific causes of trauma were classified, in order of frequency, as road traffic accident followed by machine accident and fall from height.

Table 1. Causes of amputation

Causes of amputation	Upper limb	Lower limb	Multiple limb	Total
Trauma	530	1289	97	1916 *(59.7%)*
Disease	36	876	54	966 *(30.1%)*
Tumour	6	170	—	176 *(5.5%)*
Congenital	38	102	12	152 *(4.7%)*
Total	610	2437	163	3210 *(100%)*

Specific causes of amputation, as analysed against ten different age groups, are shown in Table 2. Among the trauma amputees, the 11-20 age group (25.8%) was most affected and closely followed by the 21-30 age group (25.6%). The leading specific cause in the 11-20 and 21-30 age groups was road traffic accident (57.4% and 51.5% respectively), followed by machine accident (14.8%) in the 21-30 age group, while the second main cause, in the 11-20 age group, was war injuries (10.4%). Amputation resulting from disease was greatest

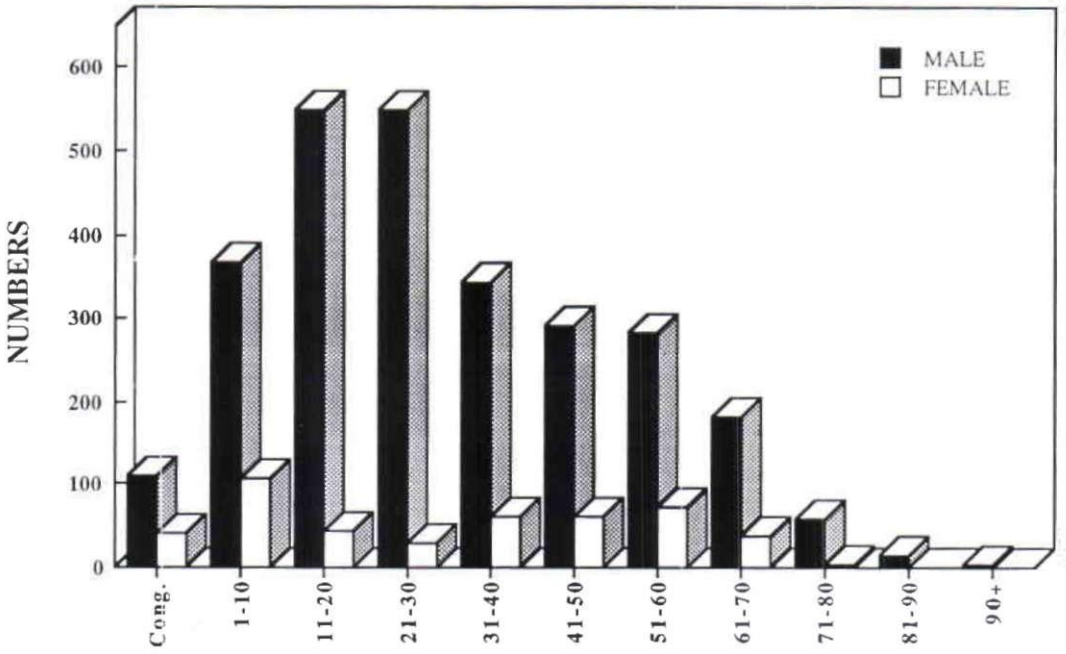

Fig. 3. Different age groups and sex among the amputees.

Table 2. Percentage of amputation due to tumour, trauma, and disease by age

Age group	Trauma %	Disease %	Tumour %
<10	21.5	6.3	3.4
11-20	**25.8**	5.9	**22.4**
21-30	25.6	6.6	19.0
31-40	14.3	11.0	12.1
41-50	7.9	16.0	20.7
51-60	3.3	**27.6**	19.0
61-70	1.0	19.4	3.4
71-80	0.6	5.3	—
81-90	—	1.6	—
>90	—	0.3	—
	100%	100%	100%

in the 51-60 age group (27.6%), followed by 61-70 age group (19.4%), with 54.2% being found in the combined over 50 age groups.

The percentage of amputation owing to tumour was largest in the 11-20 age group (22.4%), which is similar to that found in the survey in USA by Glattly (1964). The percentages in the 41-50 and 51-60 age groups (20.7% and 19% respectively) were much higher than in the 61-70 age group (3.4%).

Amputation in males by reason of trauma was 10 times as frequent as in females, while congenital deformities of the limbs that were fitted with prostheses occurred with a 2.7:1 male to female ratio (Table 3).

Levels of amputation

There were 2,437 (75.9%) lower limb, 610 (19%) upper limb, and 163 (5.1%) multiple limb amputees, the ratio being 15:3.7:1. The

Table 3. Ratio of male to females by cause of amputations

Cause of amputation	Males	Females	Ratio (Males:Females)
Trauma	1741	175	10:1
Tumour	143	33	4.3:1
Disease	760	206	3.7:1
Congenital	111	41	2.7:1
Total	2755	455	6:1

Table 4. Levels of amputation

Levels of amputation	Number	%
Upper limb		
Shoulder disarticulation	18	0.6
Trans-humeral	152	4.7
Elbow disarticulation	15	0.5
Trans-radial	243	7.6
Wrist disarticulation	27	0.8
Partial hand	155	4.8
Subtotal	610	19
Lower limb		
Hindquarter	6	0.2
Hip disarticulation	9	0.3
Trans-femoral	694	21.6
Knee disarticulation	94	2.9
Trans-tibial	1452	45.2
Ankle disarticulation	49	1.5
Partial foot	133	4.2
Subtotal	2437	75.9
Multiple limb		
Bilateral upper limb	17	0.5
Bilateral lower limb	136	4.3
Upper and lower limb	10	0.3
Subtotal	163	5.1
Grand total	3210	100%

levels of amputation are indicated in Table 4, the commonest variety being trans-tibial amputation (45.2%); followed by trans-femoral (21.6%), trans-radial (7.6%); and trans-humeral (4.7%) and partial hand (4.8%) amputations. The predilection for the left side (55%) was higher than for the right side (45%) in the lower limb amputees, while the right side (53.6%) involvement was 7% higher than the left side (46.4%) in the upper limb amputees.

Upper limb amputees

Of the 3,210 amputees, 19% were upper limb amputees. Trans-radial amputees are the largest single group, comprising 39.8% of all upper limb amputees. Partial hand amputees formed the second largest group (25.4%). Trans-humeral amputees are the next most frequent group. They formed 24.9% of the upper limb amputees, with a mean age of 23 years. Shoulder disarticulation formed ony 2.9%, followed by elbow disarticulation amputees 2.5%. Trauma was the main cause of the upper limb amputations (88.8%), of which 26.8% were due to machine accident.

The mean age of upper limb amputees was 21.8 years. The highest age was a 63-year-old male. 23.6% were in the 21-30 age group and immediately next was the 11-20 age group (21.6%). 72.6% of upper limb amputees were below 30 years of age; unlike the lower limb amputees, of whom only 52% were below the age of 30. There were only six upper limb amputees over 60 years of age at time of amputation in the fourteen year period. Children below 10 years (27.2%) composed the highest percentage of the trans-tibial amputees. This is because trans-tibial limb deficiency is the commonest congenital upper limb defect in children and accounts for 76.9% of all congenital upper limb amputations.

Lower limb amputees

Among the 3,210 amputees, there were 2,437 (75.9%) lower limb amputees. Of the lower limb amputees, trans-tibial represented 59.6% which was the most common site, followed by trans-femoral (28.5%) and partial foot (5.5) amputees. When the age distribution of lower limb amputees was analysed, a different picture was revealed compared with upper limb amputees. Of all lower limb amputees, 52% were under 30 years of age, while 11.3% were over 60. The commonest age group was the 21-30 group (17.5%), followed by the 11-20 age group (17.2%). In lower limb amputation, trauma (52.7%) was also the main cause of amputation, followed by disease (35.9%). The majority of lower limb amputations owing to trauma related to road traffic accidents (67%).

Multiple limb amputees

Multiple limb amputees had bilateral, one-sided or triple limb involvements. Among the 3,210 amputees, there were 163 (5.1%) multiple limb amputees, including only 3 females. The mean age was 28.6 years. Bilateral upper limb amputees were 17 in number (10.4% of the multiple limb amputees). All those cases were male with bilateral trans-radial amputation due to trauma. Most bilateral lower limb amputees (83.4%) had either trans-tibial amputation (69.4%) bilaterally, or trans-femoral amputation on one side and a trans-tibial amputation on the other side (14.3%). Only 10 (6.1%) amputees had one trans-radial amputation combined with a trans-tibial or trans-femoral amputation. The common age groups of the multiple limb amputees was the 11-20 (23.4%) group and those less than 10 years of age (22.2%). In multiple limb amputations, trauma was the main cause.

Educational, vocational, and marital status

On admission, a high percentage of amputees had little or no education and could be considered illiterate (47.4%) and 20% had an elementary level of education, while 5.5% had completed a university degree. Children below school age constituted only 3.7%.

On admission, the majority of amputees were married (65.8%). Married males (88.7%) presented a higher proportion than married females (11.3%). The pre and post-amputation marital status of both sexes was not available on the forms.

Regarding the vocational status of the amputees on admission, a high percentage were labourers (23%), followed by the retired (19.6%) then clerical workers (17.5%) and students (16.7%). When specific causes of amputation were analysed against different vocational groups, it was evident that labourers were most affected by trauma constituting 28.8% of the cases. Only 19.8% of them were affected by machine accidents, whereas the remainder were the victims of road traffic accidents. Students formed the second largest group of the traumatic amputee population (21%), just over 57% of them victims of road traffic accidents. Clerical workers were the next largest group of victims of trauma (19.3%). They were also more prone to road traffic accidents, which claimed 59.8% of them, Retired persons were the primary victims of disease (59.8%) and the leading cause was gangrene (80.7%). The next most common victims of disease were housewives (16.9%), closely followed by clerical workers (16.6%).

Discussion

The total number of amputees reported here includes all those who received prostheses from RMRC during the 1977-90 period only. Since it was for a long time the only place to which all amputees from all over the Kingdom were referred, this investigation reveals, to a certain extent, the vital characteristics related to age, sex, onset and date of amputation, cause and site of amputation, and the educational, marital and vocational status of the amputee

population in the Kingdom; thus allowing some nationwide conclusions to be drawn from the presented results.

On looking at the total number of new amputees presenting annually at RMRC (Fig. 2), we notice a general upward trend from 1977-90 with a remarkable and steady rise in the numbers of amputees in the 1980-85 period, probably related to the well-known spurt of rapid growth and industrialization occurring during this period. The subsequent decline in the next period 1986-88 was related to the diversion of a significant proportion of the amputee population to new regional prosthetic and orthotic centres which were developed as part of the expansion programme in medical services in the Kingdom.

The overall male to female ratio was 6.1:1. This is seen to be because males are more susceptible to amputation due to road traffic accidents and work accidents than women who are not permitted to drive and are rarely employed. Women are also less likely to seek prosthetic management. The number of female amputees increased sharply during various intervals. There were three such periods in 1978/79, 1986/87 and 1990, when they increased to over 20% of the total number of amputees. The male sex proportion of lower limb amputees is higher than in upper limb amputees, the male to female ratio being 6.4:1 and 4.9:1 respectively. The ratio for upper limb to lower limb amputations was 3.87:1. Thus the proportion of upper limb amputees was far less than their proportion either in India or Hong Kong, and similar to the ratio in Burma.

The mean ages of upper limb amputees, 21.8 years, and lower limb amputees, 32.6 years, were younger than in earlier reported studies on Western countries and similar to the mean ages in the studies in Asia. This reflects the predominantly younger age pattern of the Saudi population and the effect of the increasing incidence of traumatic amputation. Consequently, the number of traumatic amputees using prostheses would be expected to increase in future studies, as the present amputees will live a normal life span and continue to use lower limb prostheses. Trauma was the leading cause of amputation of upper and lower limbs in both sexes (affecting 59.7%). In lower limb amputations, although trauma was the main cause of amputation (52.7%), disease accounted for more than one-third (36%) of the lower limb amputees. Most traumatic amputations occurred in the 11-20 and 21-30 age groups, affecting 25.8% and 25.6% respectively; while disease affected more in the 51-60 age group (27.6%) and, to some extent, in the 61-70 age group (19.4%). This investigation has also revealed a significant difference in proportion between right and left side amputations in the upper and lower limbs. Amputations resulting from trauma are expected to occur more frequently in the dominant limb, especially upper limb amputations.

The overall trans-tibial to trans-femoral ratio was 2.1:1. A comparison between the years 1977 and 1990 shows a decrease in trans-femoral amputation. In 1977, 29.5% of all amputations were trans-femoral and 52.3% trans-tibial. In 1990, there was a slight reduction in the percentage of trans-tibial (to 45.4%) and a great reduction in trans-femoral amputations (to 16.4%). This may be attributable to the fact that surgeons are now more aware of the importance of trying to save the knee on the affected side and the fact that elderly trans-femoral amputees may not have the fitness to learn to use a prosthesis and even those who have learned to use a prosthesis may not necessarily continue to use it because it is easier to use crutches or a wheelchair. All these factors decrease the prevalence of trans-femoral prosthesis users.

Ankle disarticulation amputees constituted only 2% of the lower limb amputees. There were only 6 amputees with Syme's prostheses under 10 years of age. Jones (1989) showed that this type of prosthesis was commonest in childhood, often used for congenitally limb deficient children. The Syme's amputation is performed as a treatment method for certain congenital abnormalities. It was noted from examining the data on individual children that frequently the child for whom a Syme's prosthesis was initially prescribed, later received a patellar-tendon-bearing (PTB) prosthesis. Thus such children comprised 5.4% of trans-tibial amputees who were supplied with total contact PTB prostheses. This may explain some of the decline in prescription numbers and individuals above the age of twenty. In adults, the Syme's amputation is used mostly after trauma. Some 50% of such amputations

occurred in the 11-40 age group; and there were no amputees over 60 years old, as expected, due to the fear concerning wound healing and blood supply problems in this age group.

Knee disarticulation amputees formed only 3.9% of lower limb amputees. Considering the excellent prostheses available to this group of amputees, the application of this type of surgery is surprisingly rare. Some 35% of the prescribed lower limb prostheses were fitted to children under 10 years who mainly had congenital anomalies that required amputation.

The peak occurrence (41.5%) in the 11-30 age group demonstrates the non-vascular cause of this amputation. Jensen and Mandrup-Poulsen (1983) reported that the statement that the knee joint should be preserved at any price seemed to be no longer valid, as patients with knee disarticulation amputations generally did better than trans-tibial amputees and the majority of trans-femoral amputees failed to achieve satisfactory gait. The high success rate following knee disarticulation has been pointed out by many studies (Early, 1968; Howard and Chamberlain, 1969; Chilvers *et al.*, 1971; Newcombe and Marcuson, 1972; Jensen and Mandrup-Poulsen, 1983; Houghton *et al.*, 1989). The explanation for the high success rate of knee disarticulation prostheses probably lies in the undisturbed strength of hip and thigh muscles, the end-bearing capacity of the stump and a feeling of stability and security in the socket. Another explanation might be that the prostheses can easily be supplied with a knee lock in case the patient demonstrates instability or incapacity in walking with a mobile knee joint. This is in contrast to a trans-tibial prosthesis, where a preliminary PTB or comparable prosthesis has to be exhanged for a conventional prosthesis with a knee lock in a similar situation. Based on these considerations, it is suggested that the knee disarticulation level of amputation should be selected in all possible instances as an alternative to a trans-femoral amputation, as the prosthetic fitting is highly superior. It is also suggested that the knee disarticulation level should be considered as an alternative to the trans-tibial amputation in all old and feeble patients if the postoperative fitting is likely to be problematic, as such patients are more likely to be able to walk on an artificial, although stiff, limb after knee disarticulation.

Among the upper limb amputees, trauma is the single commonest cause (88.8%). The majority of these injuries were related to road traffic accidents and occupational hazards. It is therefore not surprising to find in this study that the majority of upper limb amputees are relatively young, 72% of them having ages under 30 years. The same reason might explain the male and right-handed predominance.

This study has shown upper limb prostheses to be infrequently used in the Kingdom. This may relate partially to the infrequency of upper limb amputation and partially to the dissatisfaction experienced with upper limb prostheses. Sturup *et al.* (1988) reviewed 43 patients with unilateral traumatic amputations as to the use of prostheses and employment consequences of amputation and found that 17 of 19 trans-radial and 12 of 24 trans-humeral amputees used their prostheses. Non-users were characterised by: higher amputation level, non-dominant arm amputation and younger age at the time of amputation. They usually did well on the labour market. It has been shown that trans-radial prosthesis is commonest in children. Similarly, Jones (1989) found that trans-radial prostheses were the commonest upper limb prostheses, with children being the most frequent users. This is because trans-tibial limb deficiency is the commonest congenital upper limb defect in children.

In this study, the distribution of upper limb amputation over different age groups showed a characteristic pattern. From the age of one to ten years, the incidence is highest and can be attributed mostly to house accidents, since there were few congenitally limb deficient children. Thus, 27.4% of trans-tibial amputees were under ten years of age. Partial hand amputees were the second largest group of upper limb amputees, closely followed by trans-humeral amputees. The peak occurrence in the 11-40 age groups demonstrates the dominance of the traumatic cause of trans-humeral amputation.

When one reviews the developments of upper limb prostheses, it becomes quite apparent that, apart from externally powered prostheses, there have been no revolutionary changes. The hook remains the most universally used terminal device as it has been for several centuries. The electronic hand does not provide any more additional function to the

amputee, apart from the three-jaw chuck grip, which is not much different from the old mechanical hand. Possibly for these reasons, the rejection rate of prostheses by unilateral arm amputees still remains rather high.

The majority of the causes of amputation are preventable and may be reduced by appropriate primary and secondary preventive measures. Since, in Saudi Arabia, trauma is the leading cause of the amputation of upper and lower limb in both sexes, as revealed by this study, it is extremely important to improve medical care of traumatized limbs and to up-grade the safety measures of road traffic and work conditions. It is also possible that the need for amputation due to lower-limb ischaemia could probably be reduced by earlier detection and vascular surgical evaluation of arterial insufficiency (Larsson and Risberg, 1988). A review of amputation statistics by Jonsson *et al.* (1984) on amputations in diabetic patients in Gotland and Umea counties 1971-1980 showed a lower instance of amputation in Umea than in Gotland. They considered the lower frequency of amputations in Umea as probably the consequence of a restricted period of systematic search for early signs of gangrene, as part of the research programme.

The present study should be extended to other regional prosthetic and orthotic centres in order to get a panoramic view of the real need for prosthetic services. It is only through comprehensive surveys that reliable statistics may be obtained to make planning the provision of facilities and manpower for such services truly meaningful.

Summary

The following comments and observations on this statistical material are worthy of note.

1. The majority of amputees were below the age of 30 years and the proportion of male to female amputees was 6.1:1. Congenital deformities of the limbs that are fitted with prostheses occur with a 2.7:1 male to female ratio.
2. There was a surprisingly small number of amputees over 70 years of age who were fitted with prostheses. In this series, they numbered 77 or 2.5% of the total number of amputees. There was no patients over 70 years among upper limb amputees.
3. The leading cause of amputation was trauma for both lower limb (52.7%) and upper limb (88.8%). Amputation in males on account of trauma is more than 10 times as frequent as in females, whereas amputation due to disease is only 3.7 times as frequent in males as in females. This is due to the vocational and other hazards to which males are exposed.
4. The ratio between lower limb, upper limb and multiple amputations was 15:3.7:1. The commonest level of amputation in lower limbs was trans-tibial (59.6%) and in upper limbs trans-radial (39.8%).
5. There were 163 cases of multiple amputations, of which 17 were bilateral upper limb cases, 136 were bilateral lower limb amputations, and ten involved one upper and one lower limb.
6. The predilection for the left side was higher than for the right side in lower limb amputations, while the right side involvement was 7% higher than the left side involvement in the upper limb amputees.
7. The majority of amputations in Saudi Arabia are preventable if the citizens are taught to minimize the hazards to which their children are exposed in the home environment and on the road, and if the safety measures in road traffic and work conditions are effectively upgraded, with a greater medical care given to traumatized limbs and vascular problems of the lower limbs.

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ADDENDUM

The following acknowledgement should have been included with the paper entitled *Continuous passive motion in hand rehabilitation* by J. A. Dent (published in *Prosthetics and Orthotics International* 17, 130–135, 1993). The work on the continuous passive motion machine in this paper was carried out in the Dundee Institute of Technology by David Carus, Graeme Logan, John Thorpe, Amar Jain and Ian Sutherland. Clinical application of the machine was carried out in the Osku-Helene-Heim and the Free University of Berlin by Professor Dr. Med. Georg Neff. Grants from the British Council and the German Academic Exchange Service (DAAD), The Fraser Trust, Dundee and the Arthritis and Rheumatism Council for Research.

Prosthetics and Orthotics International, 1993, 17, 157–163

Consumer concerns and the functional value of prostheses to upper limb amputees

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Abstract

This paper reports a study of 66 upper limb amputees in County Funen, Denmark who were visited in their homes by the author. The purpose of the study was to evaluate the consumer concerns about their prostheses and to see if these were related to cessation of prosthetic use. It was also intended to estimate functional levels of both prosthetic users and non-users. The number of amputees investigated corresponds to the annual number of persons becoming upper limb amputees in Denmark.

There were 3 prosthetic systems in use, two active systems and one passive system. At review there was a group of 18 amputees which did not use a prosthesis at all.

It appeared that active and partially active users are younger persons with a relatively short time-lapse since amputation. Passive users are older persons with a long time-lapse since amputation. Only 4 out of 18 prosthetic non-users stopped prosthetic use as a consequence of prosthetic problems or discomfort.

Active prostheses had the highest number of consumer problems. Most problems were concerned with the socket, and for the body powered prostheses also with the suspension and control system.

It was shown that an awareness of the amputee's working conditions is important at the fitting stage, especially the daily working situation. As a consequence strictly individual fitting is needed with attention being given to the manner in which the individual will use the prosthesis.

This investigation clearly shows that active fitting is a worthy effort. In daily living the active users have a superior performance over the passive and non-users. It was observed that amputees despite many years of training still have problems with activities of daily living, particularly in relation to independent functions.

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Introduction

In Denmark upper limb amputation represents 3% of all amputations (Andersen-Ranberg and Ebskov, 1988). In other countries such as Israel and the USA upper limb amputations constitute from 10-25% (Steinbach, 1979; Davies *et al.*, 1970).

One of the main goals is to restore functional possibilities as fully as possible, with or without a prosthesis. In a well developed country with a high grade social system such as Denmark all new amputees are offered a prosthesis (Kejlaa, 1992). Today there is one passive and three active prosthetic systems available.

The standard supply has for many years been a body-powered active prosthesis, or alternatively a passive prosthesis. The body-powered system is based on an idea which is over 150 years old and with the Dorrance split hook in 1909 the system became the main prosthetic choice. After World War II, a number of research programmes started and improvement began to appear in socket design and materials. Externally-powered prostheses were developed in Germany and the UK in the fifties spurred by the Thalidomide tragedy. The pneumatic system is not in regular use in Denmark. However, from the early seventies myoelectric prostheses have become more predominant in Denmark.

The purpose of this investigation was to

evaluate the prosthetic consumer concerns about their prostheses and to see if these were related to cessation of prosthetic use and also to estimate the functional levels of both prosthetic users and non-users.

Method

The number of upper limb (UL) amputees in the County of Funen, Denmark was not known. The Amputation Register (Ebskov, 1986) could only provide information from 1972. Therefore the material was collected from all the hospitals and prosthetic centres in the county. All registers were examined. The material therefore includes all amputees who have been treated in the County of Funen in the period 1 January, 1900 to 31 December, 1987.

All amputees were visited in their homes by the author. This gave the opportunity to see and register their daily surroundings and their prostheses and function as well as to meet their families.

Two sets of questionnaires were constructed, one for amputees under 18 years and one for amputees over 18 years of age.

All prosthetic users were divided into two groups, one group which used their prostheses more than 8 hours a day and one group which used their prostheses less than 8 hours a day. The amputees were characterised as active users (i.e. active prosthesis use more than 8 hours a day), partially active users (i.e. active prosthesis use less than 8 hours a day), passive users (i.e. only users of a passive prosthesis) and prosthetic non-users (i.e. no use of prosthesis at all).

The amputees were divided according to the cause of amputation, prosthetic type and to the functional group in which they were placed.

The amputees were classified by their prosthetic type in relation to their age, mean time since amputation, loss of dominant hand and loss of elbow and their working conditions.

Table 1. Working conditions for the amputees scaled according to their daily loading.

Load scale	Working conditions
0	Unemployed; pensioners
I	Light sitting work
II	Light standing work
III	Combined sitting/standing work
IV	Heavy variable work
V	Heavy monotonous work
VI	Exceedingly heavy work

Table 2. Total number of upper limb amputees registered.

Cause of amputation	Female	Male	Total	Percent
Trauma	4	49	53	50
Congenital	9	5	14	13
Brachial plexus lesion	1	5	6	6
Vascular disease	13	8	21	20
Tumour	4	7	11	11
Total	31	74	105	100

The working conditions were classified in accordance with Table 1.

The consumer concerns were related to prosthetic types. The prosthetic users and non-users were investigated in relation to their activities of daily living (ADL). These activities were classified in main groups as: eating; hygiene, grooming and dressing; employment activities; communication; recreation activities. When more than 25% of the amputees had problems it was identified as a major task problem, when 10-25% had problems it was denominated a general task problem and as a minor task problem when less than 10% had problems. The task problems for active, passive and non-users were correlated with the number of amputees in each prosthetic group, the mean years the amputees had been in the relevant functional group at the time of review, the mean time lapse since amputation and age at review.

Results

Some 105 UL amputees were registered; 32 were dead and 7 would not participate (3 were in conflict with the hospital system, one had psychiatric reasons and 3 did not give any reasons) (Table 2). Consequently 66 amputees were included in the survey and visited in their homes by the author (Table 3). The mean age at amputation was 24.5 years (0-72 years). Mean age at review was 45.1 years (4-83 years).

Table 3. Number of upper limb amputees visited.

Cause of amputation	Female	Male	Total	Percent
Trauma	3	40	43	65
Congenital	6	4	10	15
Brachial plexus lesion	1	5	6	9
Vascular disease	3	1	4	6
Tumour	1	2	3	5
Total	14	52	66	100

Table 4. Amputees' characteristics correlated to the three prosthetic systems used.

Prosthesis	use >8h	use <8h
Mechanical		
number	20	5
mean age at review	38.2 (4-77) years	47.2 (25-83) years
loss of dominant hand	13	4
loss of elbow	1	2
mean age at amputation	23.7 (0-51) years	26.6 (18-38) years
mean working load	III (0-IV)	I (0-III)
Myoelectric		
number	6	1
mean age at review	32.8 (21-51) years	26.0 (26) years
loss of dominant hand	5	1
loss of elbow	1	0
mean age at amputation	19.0 (0-31) years	20.0 (20) years
mean working load	II (I-III)	I (I)
Passive		
number	11	5
mean age at review	62.8 (43-79) years	71.2 (64-75) years
loss of dominant hand	6	1
loss of elbow	6	0
mean age at amputation	23.5 (13-40) years	27.0 (18-38) years
mean working load	I (0-IV)	0 (0-I)

The mean time lapse from amputation to review was 20.6 years (0-63 years).

At review 32 were active prosthetic users of which 6 used their prostheses less than 8 hours a day; 16 were passive users of which 5 used their prostheses less than 8 hours a day; 18 did not use a prosthesis at all. These functional groups were related to the cause of amputation (Fig. 1).

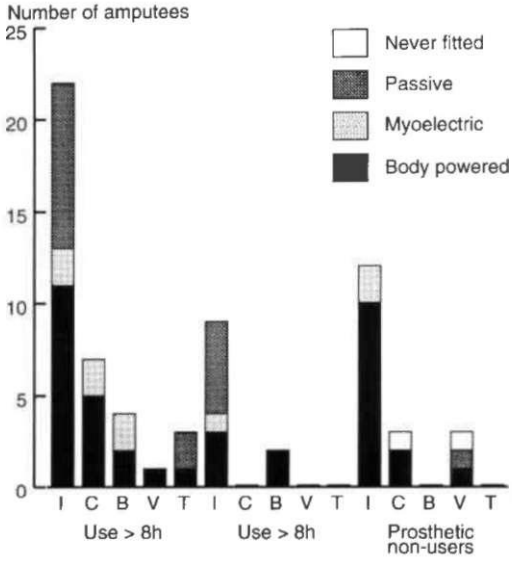

Figure 1. Amputees' functional groups at review correlated to the cause of amputation and primary fitting. I: Trauma; C: Congenital; B: Brachial plexus lesion; V: Vascular disease; T: Tumour.

There were 3 prosthetic systems used. Two active systems, a body powered mechanical system and a myoelectric system and one passive system.

The relation of the three prosthetic systems to the age of the amputees, time lapse since amputation, loss of dominant hand and elbow and the amputees' working conditions are shown in Table 4. It is seen that active and partially active users are younger persons with a relatively short time lapse since amputation. Passive users are older persons with a long time lapse since amputation and the youngest were using their prostheses more than 8 hours a day. The working conditions reflect the use of prostheses and the system used. Heavy workers used a conventional prosthesis and the myoelectric prosthesis was used by amputees with office work or undergoing education. Passive prosthetic users were either light workers or pensioners. Partially active users were all light workers.

The main consumer concerns for the three prosthetic systems studied in this investigation are illustrated in Figure 2.

Body powered prostheses were heavy and warm to wear. The suspension system gave irritation in the axillae, and were often wet with perspiration which could lead to operation failure. When washed the suspension system curls up. The control system could fail when wires slackened or broke. Control wires connected to the socket often damaged clothing

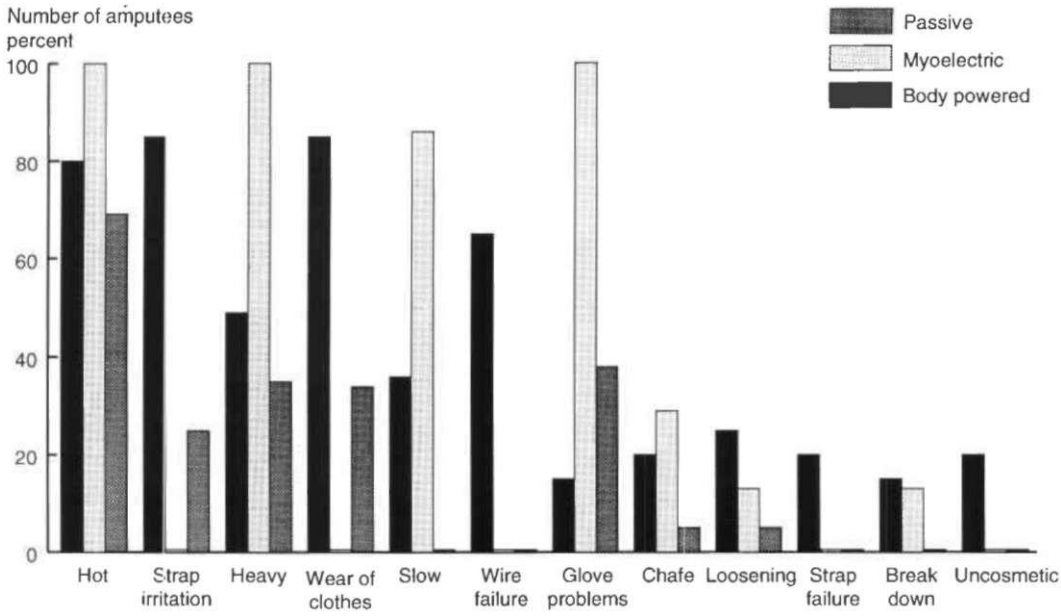

Figure 2. Main consumer concerns for the three prosthetic systems studied in this investigation.

at the wrist and elbow. Underwear was also damaged by the suspension system. Women had problems with low cut dresses and men had to wear an undershirt otherwise the suspension system could be seen under their shirts. Sixty per cent of those who primarily were fitted with a conventional prosthesis were given a mechanical hand, only 2 used this device regularly at review. The hand was too heavy and slow, became dirty and required more power to operate than the hook. Those in heavy work such as farming or working in industry experienced socket problems sometimes leading to pressure sores. Heavy workers also had problems with loosening of the prosthesis, especially when lifting with an extended arm or flexed elbow, when the socket pressed the upper arm. These problems were solved to some extent with auxiliary suspension and a U-shaped relief on the volar side of the socket. Some experienced cosmetic problems with the hook, especially in the early years after fitting.

All amputees who used myoelectric prostheses had 3 major complaints: their prostheses were heavy and hot and their gloves were difficult to keep clean. Especially those (n=3) who had primarily been fitted with a conventional prosthesis considered that the myoelectric prostheses were slower in action and more difficult to don. The close fitting Munster socket could give discomfort with heavy loads. When there was a prosthetic failure it was always necessary to contact a prosthetic centre or a prosthetist.

Passive prostheses are lighter and the socket and suspension system are only required to maintain the prosthesis in position. The main problems for the passive users were concentrated on the socket and the suspension system, expressed as heat problems in the socket and worn clothing. Otherwise there were glove problems. Forequarter amputees had an

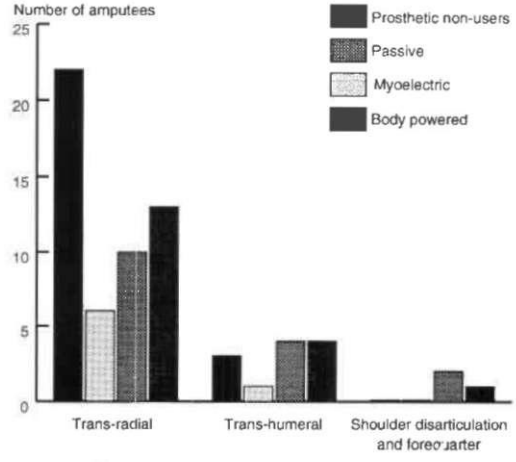

Figure 3. Amputation level correlated to prosthetic types and prosthetic non-users.

Table 5. Main causes of cessation of prosthetic use correlated to body powered (BP), myoelectric (ME) and passive (PAS) prosthetic systems and prosthetic non-users (NOP).

Cause of cessation	BP	ME	PAS	NOP
Prosthetic failure	0	1	0	0
Prosthetic discomfort	2	1	0	0
Delayed prosthetic supply	3	0	0	1
No prosthetic need	4	0	0	0
Illness and attenuation	2	0	1	1
Phsychological reasons	2	0	0	0
Total	13	2	1	2

extensive socket and harness system and complained of heaviness and worn clothing.

Figure 3 shows the level of amputations correlated to prosthetic types and to prosthetic non-users.

Seventy-seven percent were trans-radial amputees, 18% were trans-humeral amputees and 5% were amputated at or above shoulder level. Eleven out of 15 (73%) who had lost the elbow were either passive or prosthetic non-users. One person amputated at trans-humeral level was fitted with both a myoelectric elbow and hand. No bilateral amputees were identified.

Table 5 illustrates the main causes of cessation of prosthetic use. It is seen that only 2 amputees had never used a prosthesis. Only one from the passive functional group had stopped prosthetic use. The rest were all active users. Only 4 had stopped prosthetic use as a consequence of prosthetic problems or discomfort, all were active users two of whom were myoelectric users. So in this investigation 22% (4 out of 18) of cessation of prosthetic use was related primarily to prosthetic problems.

The activities of daily living (ADL) were of interest for active users versus passive users and non-users. In this regard it is important to know that most passive and non-users formerly had used an active prosthetic system. The passive users and non-users lack a pinch grip and cannot perform tasks controlled by this grip. Figure 4 illustrates the loss of function and task problems for the 3 groups. It is seen that active users had fewest problems, that non-users had the greatest number of amputees with major problems, but passive users had the most problems. The active and passive users had equal percentages of amputees in the 3 identified task groups.

The results show that active users had significantly fewer problems than the other two

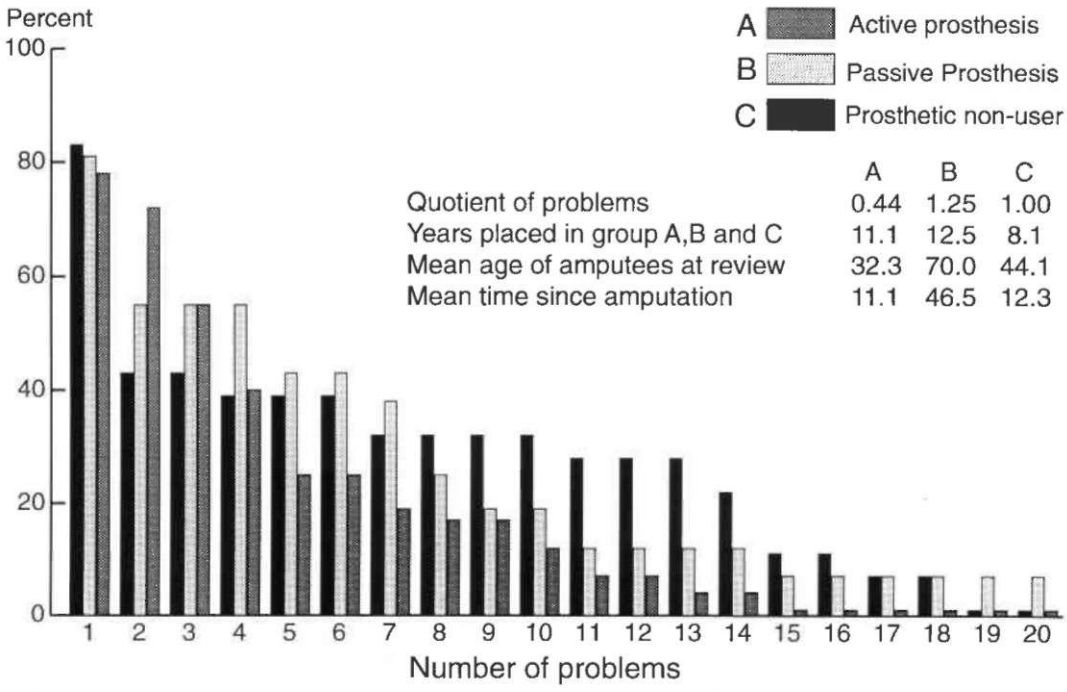

Figure 4. Functional loss and task problems for active prosthetic users, passive users and prosthetic non-users.

functional groups, but the passive users had the highest number of task problems. When correlated with the mean years in the relevant functional group the sequence was that active users had the fewest problems followed by passive users and finally the non-users. The non-users had the lowest experience as a group in years. It is seen that the longer time lapse since amputation the fewer task problems there are, and that older amputees have a lower activity level.

Figure 5 shows that there were most problems in hygiene, grooming and dressing, then employment activities followed by eating. It was noted that the amputees did not have any task problems in communication and recreational activities.

Discussion

The number of amputees investigated happens to correspond with the annual number of persons who become UL amputees in Denmark (Andersen-Ranberg and Ebskov, 1988).

The good social system in Denmark has been of great importance to the amputees. All have been offered a prosthesis and have had the opportunity to become rehabilitated (Kejlaa, 1992). With time there is a prosthetic progression from active to passive prosthesis or prosthetic cessation (Kejlaa, 1991).

All prostheses are hot to wear. The higher the level of amputation and the more complex the prosthesis, the heavier it is.

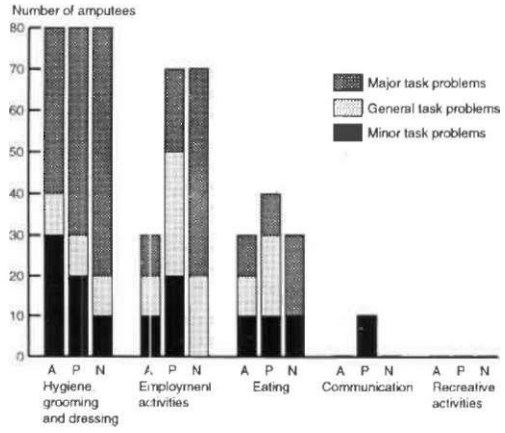

Figure 5. The main groups of ADL correlated to major, general and minor tasks problems and the prosthetic functional groups. A: Active prosthesis, B: Passive prosthesis, N: No prosthesis.

Improvement of conventional prostheses should be concentrated on the suspension and control systems. Wires in the system should be re-positioned to avoid interference with clothing. Straps should be constructed from another material to avoid curling and the resulting irritation. These changes would improve the use of prostheses in a safe and comfortable manner.

It is demonstrated here how important it is at the time of fitting to be aware of the amputees working conditions, especially the daily working load.

Therefore strictly individual fitting is needed, not only concentrated on the conditions of the stump, but certainly to the manner in which the individual will use the prosthesis.

The socket must be properly designed for heavy work to minimize the load or force at the stump. Also it is necessary to consider the conditions at elbow level for amputees where heavy lifting is performed providing a U-shaped relief on the volar side in the socket or auxiliary suspension on the dorsal side of the elbow to ensure that the socket does not become loose. In the socket design the prosthetist must be aware of the pressure areas at the stump especially with heavy loads.

The mechanical hand seems to be unpopular with amputees. It is too heavy and difficult to use. When the amputee gets used to his handicap he prefers the hook to the hand, and he does not need the cosmesis of the more troublesome hand.

Myoelectric prostheses are preferred by amputees where cosmesis is important and who are employed in clean and light work. It is important to be aware of the stump condition when fitting an amputee with a myoelectric prosthesis. The stump will become more muscular with time especially when the amputee formerly had used a conventional prosthesis and this can give problems with electrode contact and may lead to consumer problems.

Passive prostheses have the same socket problems as the two active prosthetic systems and also some lesser problems from the suspension system.

Effort in the future must be concentrated on new socket designs and also reconstruction of the suspension and control system for body powered prostheses. This may minimize

consumer problems without loss of function, and may reduce the number of amputees who cease prosthetic use.

The glove problem is well known. The relatively new silicone gloves have the advantages of easy cleaning, but do not seem to be as durable as PVC gloves. They are also more expensive. Research work must continue in this area.

This investigation clearly shows that active fitting is worth the effort involved. In ADL the active users are superior in performance to the passive and non-users. Attention must be given to the time lapse from amputation to primary fitting. This interval must not exceed 6 months otherwise there are risks for prosthetic failure (Carter *et al.*, 1969; Kejlaa, 1991).

It is seen that amputees despite many years of training still have problems with activities of daily living. The problems are concentrated on activities of daily necessity which make a person an independent individual. The amputee must wash and care for him or herself and eat. Employment activity is required for daily survival. Communication was not identified as a problem. With the years, amputees adjust themselves in recreation and the activities which they select for pleasure. It is interesting to note the security of daily existence, supported by the amputees' lower divorce rate and by the fact that only 14% live alone (Kejlaa, 1992).

The perfect prosthesis has not yet been found and may never be found. However, with continued research and the application of current knowledge individual fitting can give this group of patients a secure life as independent persons, and can minimize cessation of prosthetic use.

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Prosthetics and Orthotics International, 1993, 17, 164–171

Clinical evaluation of trans-tibial prosthesis sockets: a comparison between CAD CAM and conventionally produced sockets

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Abstract

This study is an evaluation, from the patient's point of view, of CAD CAM prosthesis sockets compared with conventional sockets. Twenty-two trans-tibial amputees were divided into two groups. One group was provided with a CAD CAM (CAPOD) socket, the other with a conventionally made one. After one month the groups were evaluated with regard to subjective experience, the judgement of a prosthetist and a physiotherapist, social variables and objective gait parameters. Then the groups switched over to the other type of socket, and after another month a new evaluation was performed. The study design was a single-blind study. In total 175 variables were evaluated. No difference was found between the two types of socket, except for a lower number of terry cloth stockings used in the CAD CAM socket. As the standard of conventional prosthetics in Sweden is considered to be high, the results were considered as satisfactory. The quality of the CAD CAM sockets was at least at the same level as conventionally made ones.

Introduction

This study is an evaluation, from the patient's point of view, of prosthesis sockets made with a modern CAD CAM technique compared with a conventional technique. Economical aspects, aspects of time saving, and documentation have not been included.

During the 20th century there has been a rising incidence of amputation in the whole western world, mainly due to the increasing age of the population. In Scandinavia the reported annual incidence of lower limb amputation has been 28-47 amputations per 100,000 inhabitants (Hierton *et al.*, 1980; Liedberg and Persson, 1983; Pohjolainen and Alaranta, 1988; Kald *et al.*, 1989; Larsson and Risberg, 1988; Öberg and Öberg, 1990; Eneroth and Persson, 1992). However, since the middle 1980s there has been a break in this trend, with a reduction of the amputation frequency in Scandinavia (Larsson and Risberg, 1988; Persson *et al.*, 1989; Pohjolainen *et al.*, 1989) as well as in other countries (Coddington, 1988). Vascular cases dominate. Between ½ and ⅔ are trans-tibial amputations, i.e. about 30 new amputations per 100,000 inhabitants per year. At least 50% of these patients will be supplied with a prosthesis. On top of this must be added the renewal of old prostheses of about the same magnitude.

In technical research and engineering the use of CAD CAM has been a standard for several years. The accelerated development of software and hardware has resulted in an increased number of applications for the CAD CAM technique. However, it is not until recent times that CAD CAM has been used in medical applications. Dentistry was one of the first medical professions that started to use CAD CAM. Today at least one thousand CAD CAM systems are in routine use in dental practice (Rekow, 1992). Other areas of medicine where the use of CAD CAM has started are, for example, cardiology and reconstructive plastic surgery (Cutting *et al.*, 1988; Knierbein *et al.*, 1992). The most successful application for CAD CAM technology in medicine can probably be found in orthopaedics and related fields. Production of plastic models for surgeons may

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give global impressions and understandings of bone and joint disorders. It is possible to design and model an exact shape of standard endoprosthesis. In education 3D-imaging can be used to display the anatomy of the patient, and the CAM allows exact models of anatomy to be milled out (Goh *et al.*, 1990; Mankovich *et al.*, 1990; Schmitz *et al.*, 1990).

Orthopaedic technology is based on traditional craftsmanship, which in Scandinavia is considered to be at a fairly good level of quality. The prosthesis socket in the conventional technique is made from a plaster cast. However, during handcasting there is a risk for the uncontrolled deformation of the soft tissues, leading later on to a bad fit of the socket (Murdoch, 1968). The purpose of prosthetic fitting is not only the provision of a prosthesis with a good technical quality, but also the rehabilitation of the patient to a social life of good quality. Many prostheses are never used, others are used for cosmetic reasons only. This may due to lack of training, but also to bad fitting of the prosthesis. The manufacturing of a prosthesis is time consuming, demands skilled craftsmen and is expensive for the community. Thus, it is important that the prostheses are made with a quality, that is accepted by the patient.

In the middle 1980s CAD CAM techniques were introduced in the field of orthopaedic technology (Klasson, 1985). The form of the amputation stump is fed into a computer by for example, a laser scanner or some other device. The software in the various CAD CAM systems is especially developed for use in prosthetics and orthotics. Different systems have been designed for different applications, such as wheelchair seats, prostheses, lasts for orthopaedic footwear and for manufacturing of individually shaped insoles (McAllister *et al.*, 1991). Several of these systems can be used for cosmetic applications in prosthetics and orthotics (Bok *et al.*, 1990; Brüssel, 1991). The final form is transferred to a computer controlled carving-machine. From this is obtained a former for the socket, made from plaster or some plastic material (e.g. polyurethane foam). A socket can then be moulded on this form (Brüssel, 1991).

A relatively new concept is CIM (Computer Integrated Manufacturing), i.e. conventional CAD CAM technique is integrated with systems for administrative routines, handling of materials, economy, quality control etc. (Pärletun *et al.*, 1986). In the future the CIM techniques probably will be used more extensively. Case records and other patient related data can be stored in the system. Check routines can be included for quality control, e.g. dates for yearly follow-up. Tolerance limits can be implemented in the system. Volume and form changes can be objectively recorded and easily followed. With the integration of finite element (FEM) techniques, local stress and strain can be calculated in the amputation stump and the prosthesis socket (Quesada and Skinner, 1991). The socket can be optimised and simulations can be performed before the final socket is made for the patient.

There are a few systems in the world for CAD CAM manufacturing of prosthesis sockets (Fernie, 1984; Foort *et al.*, 1985; Klasson, 1985; Lawrence *et al.*, 1985; Saunders *et al.*, 1985; Lord and Jones, 1988; Engsberg *et al.*, 1992). Brüssel (1991) has described currently available systems in a review article.

At the Department of Biomechanics and Orthopaedic Technology, Jönköping, a CAD CAM system, the CAPOD system, (Computer-Aided-Prosthetic-and-Orthotic-Design), has been developed for prosthetic and orthotic applications. The system consists of a laser scanner, a CAD software and a milling machine. The scanner is made to scan all different parts of the human body and the software is adapted to modelling of these different parts (Öberg *et al.*, 1989).

In a world of economic realities, there is a need for evaluation of new systems, both with regard to cost-benefit and with regard to the satisfaction of the patient. Can we reduce the cost for the community? Can we give the patient a better quality of life? Do we have other benefits from a new technique?.

The aim of the present study was to evaluate trans-tibial prostheses made with a CAD CAM technique compared with a conventional technique, from the patients point of view. The evaluation was made in collaboration with the Swedish Handicap Institute.

Materials and methods

Patients

Some 22 patients, 17 men and 5 women, new trans-tibial amputees as well as prosthetic

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Trans-tibial amputation Unilateral amputation Healed wound, minimum of adherence Presumed walker Good mental status Good physical status
Exclusion criteria	Prolonged healing Ulcerations Other specific problems

renewals, were included in the study. Inclusion and exclusion criteria are listed in Table 1. The mean age was 61.5 years for the men and 70.2 years for the women. Ten patients had their amputations on the right side, 12 on the left side. Each patient was informed about the study, and given an opportunity to break participation at any time.

Experimental layout

The study was designed as a single-blind, cross-over study. All patients tried two prosthetic sockets, one made by CAD CAM technique and one by conventional technique. Except for the socket, the patients were given a prostheses according to standard routines. The patients were collected from three county hospitals. They were divided into two groups. The first group started with a conventional socket, the other group with a CAD CAM socket. After one month they switched to the other type of socket. The patients were evaluated at the start, after one month and after two months. The patients did not know what type of socket had been provided, but it was not possible to keep such information secret from the prosthetist.

All patients were interviewed and examined according to a protocol with 175 variables. The variables were grouped in the following subgroups:

- general background data (e.g. sex, age, diagnosis etc.)
- the patient's subjective evaluation of the prosthesis
- evaluation from a professional examiner (prosthetist and physiotherapist)
- objective measurements (gait analysis, joint angle diagrams, VIFOR)
- social function
- degree of usage

Initially the patients were interviewed by a prosthetist. Background data were collected, and the patients were randomized into one of the two groups. Two sockets were made by the prosthetist, one conventional socket and one CAD CAM socket. By this procedure, the patient did not know which socket he was going to test. The involved prosthetists were required to have made three CAD CAM sockets on training patients, to be accepted. In one group the conventional socket was kept and the CAD CAM socket was discarded. In the other group the CAD CAM socket was used, and the conventional socket discarded. After one month the patient was followed-up. He was then interviewed and examined according to the protocol by an independent prosthetist and by a physiotherapist. These examiners made the same type of evaluation. Objective variables were evaluated in the gait laboratory of the department. After that, a new pair of sockets was made for each patient. The first group now retained the CAD CAM socket and the other group the conventional socket. After one month the patients were re-examined by a prosthetist and by a physiotherapist with the same routines as before. A new evaluation of objective variables was performed. The patient was now asked which socket he preferred, the first one or the second one.

Statistical methods

All statistical computations were made with a commercial statistics package, Systat 5.0/ Sygraph 1.0, for the personal computer. Ordinary numerical variables were calculated with standard parametric statistical methods (Armitage and Berry, 1987; Snedecor and Cochran, 1980). However, many variables were of nominal or ordinal scale type. These variables were evaluated with non-parametric methods (Siegel and Castellan, 1988).

Results

Some 175 variables were evaluated as single variables or in different combinations. A part of all results will be presented.

General background data

Fourteen patients were amputated because of arteriosclerosis with or without diabetes mellitus. Seven patients were amputated because of trauma and one because of

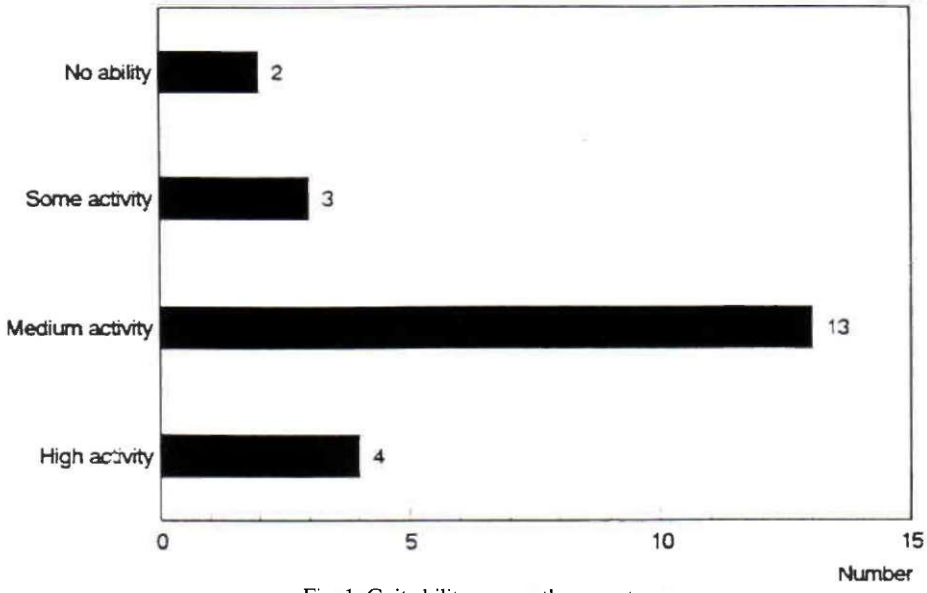

Fig. 1. Gait ability among the amputees.

malformation. Six stumps were of cylindrical form and 13 had a conical form, two stumps had a pear form and one stump another form. Thus, most of the stumps were well formed. Seventeen of the patients had excellent wound healing. In one case there was irritation, in one case infection and three patients had adherent scars. Seventeen patients had no skin problems. Two patients had reddened skin, two had wounds, and in one there were other problems. The present gait ability of the amputees is shown in Figure 1.

Subjective evaluation

Differences between CAD CAM and conventionally made sockets with respect to the patient's own judgement are shown in Table 2. The interview was made separately by a prosthetist and a physiotherapist. There were no statistically significant differences. The distribution of answers to the question "Are you satisfied with the prosthesis?" is illustrated in Table 3. Subjective preferences were evaluated by the prosthetist and by the physiotherapist. The prosthetist found twelve patients to prefer the CAPOD socket and six to prefer the conventional socket. Four patients could not decide. The corresponding figures for the physiotherapist were ten patients preferring the CAPOD socket, ten preferring the conventional socket and two patients that could not decide.

Table 2. The patients subjective evaluation of the prostheses. Difference between conventional socket and CAPOD socket. X^2-test.

Variable	Examiner	
	Prosthetist	Physiotherapist
Satisfied with the prosthesis	N.S.	N.S.
Unpleasant pressure from the prosthesis	N.S.	N.S.
Resting pain on use of the prosthesis	N.S.	N.S.
Movement pain on use of the prosthesis	N.S.	N.S.
Tenderness of the stump on use of the prosthesis	N.S.	N.S.

N.S. = No significant difference between conventional prosthesis and prosthesis with CAPOD socket

Table 3. Answers to the questions "Are you satisfied with your prosthesis?"

Patient group	Number	CAPOD	
		Satisfied	Dissatisfied
Patients satisfied with conventional prosthesis	17	8	9
Patients dissatisfied with conventional prosthesis	5	1	4
Total	22	9	13

Table 4. Professional evaluation of the prostheses. Difference between conventional socket CAPOD socket. X^2-test.

Variable	Examiner	
	Prosthetist	Physiotherapist
Number of adjustments of the outer socket	N.S.	–
Number of adjustments of the inner socket	N.S.	–
Number of sockets	N.S.	–
Number of stockings, thick	$p<0.001$	–
Number of stockings, thin	N.S.	N.S.
Function of the prosthesis	N.S.	N.S.
Fit of the socket	N.S.	N.S.
Technical quality of the socket	N.S.	N.S.

N.S. = No significant difference between conventional prosthesis and prosthesis with CAPOD socket

Professional evaluation

The specialist evaluation of a number of variables is listed in Table 4. There were no significant differences, except for the number of terry cloth stockings used in the socket. There were significantly less stockings used in the CAPOD made socket compared with the conventionally made socket. Function of the prostheses was considered very good, good or as neither/nor in 86% of the conventional and 82% of the CAPOD made sockets. With respect to the fit of the sockets, 77% of the CAPOD and 91% of the conventionally made were ranked as very good, good or as neither/nor. The technical quality of the sockets was considered very good, good or as neither/nor by 91% for both the conventional and the CAPOD sockets. The mean number of adjustments of the sockets was 0.59 for the conventional sockets, and 0.86 for the CAPOD sockets.

Table 5. Gait parameters between conventional socket and CAPOD socket. Test with Students *t*-test.

Variable	Examiner: Prosthetist
Walking distance, metres	N.S.
Gait speed	N.S.
Gait frequency	N.S.
Step length	N.S.
Step length/leg length	N.S.
Duration of gait cycle	N.S.
Duration of stance phase	N.S.

N.S. = No significant difference between conventional prosthesis and prosthesis with CAPOD socket.

Gait analysis

The results are listed in Table 5. There were no significant differences. The gait speed was 0.86 m/s for patients with CAPOD sockets, and 0.76 m/s for patients with conventionally made sockets. The difference between the two groups was not significant.

ADL and social variables

There was no significant difference between the two groups in any variable (Table 6).

Discussion

The number of patients in this study was small. Amputees are generally old and many patients have other diseases which reduce their general condition. To participate in the study, the patients had to fulfil the inclusion criteria. A test session took some two hours. A number of patients who were used as training patients for CAD CAM could not be included in the study. In spite of the fact that the study was running for more than a year and with three county hospitals involved, it was only possible to collect 22 patients that could be accepted for the study.

Table 6. ADL-functions and social functions. Difference between conventional socket and CAPOD socket. X^2-test.

Variable	Examiner	
	Prosthetist	Physiotherapist
Need of help from other person	N.S.	N.S.
Ability to take on/off the prosthesis	N.S.	N.S.
Ability to walk indoors with the prosthesis	N.S.	N.S.
Ability to rise from a chair with the prosthesis	N.S.	N.S.
Ability to sit down on a chair with the prosthesis	N.S.	N.S.
Ability of stair climbing with the prosthesis	N.S.	N.S.
Ability to walk outdoors with the prosthesis	N.S.	N.S.
Ability to enter a car with the prosthesis	N.S.	N.S.
Ability to enter a bus with the prosthesis	N.S.	N.S.
Ability to enter a train with the prosthesis	N.S.	N.S.
Degree of usage (Couch *et al.*, 1977)	N.S.	N.S.

N.S. = No significant difference between conventional prosthesis and prosthesis with CAPOD socket.

The goal of prosthesis fitting is not only a technically good quality of the prosthesis, but the rehabilitation of the patient to an active life, and with an acceptable ability to manage activities of daily living. Thus, the evaluation includes objective laboratory measurements as well as the subjective experience of the patient. Many aspects of prosthesis fitting are difficult to measure. For this reason they are evaluated with non-quantitative or semi-quantitative methods.

There was no possibility to perform a double-blind study, because a skilled prosthetist can easily see the difference between a conventionally made and a CAD CAM socket. Of course the evaluation can be biased by the prejudices of the prosthetist. For this reason, an independent evaluation was made by a physiotherapist. It is believed that a physiotherapist has no specified opinion or interest in the technique used for manufacturing a socket, and consequently the risk for prejudice would be correspondingly less.

Except for the number of terry cloth stockings, no statistically significant differences were found in any of the 175 variables: subjective variables, objective measurements and social variables. This result can be due to two factors – either there was no difference, or the small number of patients gave a low power in the statistical tests. In the authors' opinion both factors applied. The results agree with those of the few other studies that have been published (see below). All studies are too small into be conclusive, but they can give a preliminary indication of the present status of the different CAD CAM techniques.

The technical systems have been reviewed by Brüssel (1991). Holden and Fernie (1986) performed a study with 10 trans-tibial amputees who received one socket made with a CAD CAM technique (CASD) and one conventionally made socket. The patients did not know what manufacturing technique had been used. They were asked which socket they preferred. Seven of the ten patients preferred the conventional socket.

Köhler *et al.* (1987) performed a study where CAD CAM trans-tibial sockets were compared with conventionally made ones. The CAD CAM technique used in their study was developed at the Bioengineering Centre, Roehampton, University College London. It was a fairly small study, including eight patients. All patients got two prostheses, one made with either technique. Every prosthesis was evaluated on seven occasions during two weeks regarding comfort, pressure and pain. There was no difference between the different types of prostheses. These results agree with the results of this study.

In another study Topper and Fernie (1990) examined trans-tibial sockets in 48 patients. CAD CAM sockets (CANFIT) were compared with conventionally made sockets. With the conventional technique the prosthetist was allowed to have two trials per socket, but with the CAD CAM socket he was permitted more trials. After two trials 21 of the patients preferred the CANFIT socket. After five trials 54% preferred this socket, but still 46% preferred the conventionally made socket.

In a very limited study Torres-Moreno *et al.* (1991) examined one patient who was fitted with a trans-femoral socket made with the CASD CASM technique. Comfort was good, but no comparison was made with any other socket.

Ruder (1992) describes a comparison between a CAD CAM trans-tibial temporary prosthesis and an established technique. Thirty patients were fitted with either a conventional or a CAD CAM socket. Ruder describes how the trans-tibial amputees were successfully fitted using CAD CAM, but the time and number of appointments necessary to rehabilitate the patient were notably greater using CAD CAM than using the conventional technique.

The use of CAD CAM techniques has probably just begun in orthopaedic technology. In the future they will probably be used more extensively, for example, for scanning of all parts of the body (Mankovich *et al.*, 1990), but also CIM techniques can be integrated with present CAD CAM technique. With finite element modelling it will perhaps be possible to optimise the socket and simulations can be performed before the final socket is made for the patient.

When a new technique is introduced, the users will find new fields of applications and they will formulate new demands for the technique. Klein *et al.* (1992) have tried to describe some future CAD CAM applications.

However, without any doubts computers will have a prominent position in prosthetics and orthotics in the future.

Conclusions

No statistical differences were found between the two manufacturing techniques in any, but one, of 175 variables in this study. Conventional manufacturing techique was used as a reference. In Sweden orthopaedic technology has a relatively high standard. The primary goal of the new CAD CAM technique — to obtain at least the same results as with a conventional technique — has been achieved. More studies must be performed to examine cost-benefit aspects and also to examine new potential in this technique.

Acknowledgements

This study was supported by a grant from the Swedish Handicap Institute. The authors also want to thank the prosthetist and physiotherapists in Jönköping, Göteborg and Vänersborg-Trollhätan, who participated in this study.

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Prosthetics and Orthotics International, 1993, 17, 172–179

Computer-aided socket design for trans-femoral amputees

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Abstract
Computer-aided socket design (CASD) is a technique for the design of prosthetic sockets using the advantageous features of computer graphics and calculation. This paper describes a computer-aided technique used to design sockets for patients with trans-tibial lower limb amputations.

Introduction

The application of CAD CAM techniques to the production of prosthetic sockets was first suggested by Novicov and Foort (1982). The system which Foort and his co-workers developed was initially for the design of trans-tibial patellar tendon bearing sockets and had two components — a software programme to design the socket and a computer-controlled milling machine to carve the finished design as a solid model, over which the socket itself was then formed. The socket design programme was based on the principle of having a "reference" shape of a socket held in the computer. This was then scaled and modified by the programme to fit the patient on the basis of a relatively small number of measurements of the patient's stump, made using calipers and tape measure. Subsequently the initial database was extended by including further reference shapes to cope with different types of stump shape.

A different approach was followed in the system developed at University College London (Dewar *et al.*, 1985). In this, the starting point for the design software, rather than being the shape of a finished socket, is the unmodified shape of the patient's stump. Obtaining this shape involves measuring the stump at a large number of points on its surface and transferring the data to the computer. The system therefore comprises three components: a software programme and carver as in a Foort's system, and in addition a stump measuring device. The latter works by measuring the inside surface of a plaster wrap cast which had been taken of the stump. The cast is rotated about a longitudinal axis as a measuring arm whose tip rests on the inside of the cast moves along this axis (Fig. 1). The tip of the probe therefore traces a helical path round the inside of the cast and its displacement

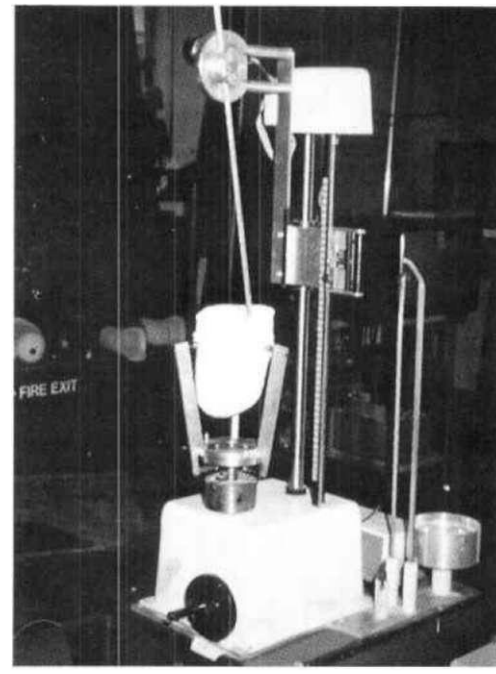

Fig. 1. The digitiser measuring the inside surface of a plaster wrap cast of the stump.

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from the axis is measured. The resulting data file then represents the shape of the stump with each data point being the polar co-ordinate of a point on the surface, relative to an arbitrary axis through the stump. Because the prosthetist using the programme will be familiar with working with a plaster model the shape is displayed on the screen as a white positive model, rather than as a negative socket. This shape is then modified by a procedure analogous to that carried out conventionally: the radial measurement values at particular points are increased or decreased. Increasing a measurement value is equivalent to adding material at that point to a plaster model of the stump in conventional practice, while decreasing it is the equivalent of removing material. The changes are described in terms of a number of discrete regions where the shape was modified. Each of these regions is known as a "patch". They correspond to the areas normally marked on the positive model by the prosthetist when he is modifying a cast. A complete set of these patches is designated as a "rectification pattern". In order to apply the pattern to a region it needs to be (a) located in the correct position and (b) adjusted to fit the size of the stump. The location is achieved by means of a reference point — an anatomical landmark which is identified on the stump prior to digitising it and transferred to the measurement file on the computer. The pattern is scaled by means of an algorithm which moves the distal-most patches in relation to the distal end of the stump, keeps some in the same place relative to the reference point and adjusts the proximal to distal dimension of the remainder to match the length of the stump.

A further kind of change that can be made is termed "sculpting". In this each point on the surface of the socket model can be raised or lowered individually, enabling any shape to be created.

There are therefore various ways in which the prosthetist can determine the shape of the final socket: he can modify the initial shape by moulding the plaster on the stump to "pre-shape" the cast; he can select a particular rectification pattern; for each patch in the pattern he can modify the amount of pressure or relief provided; he can "sculpt" individual points.

The system described above formed the basis of the commercial system marketed as Computer Shape in the late 1980's. Shortly afterwards another version, marketed as CASDaM, added the facility of being able to move the patches within a rectification pattern.

Although a number of other systems are now available with a varied range of facilities, these are generally used for producing trans-tibial sockets. Producing trans-femoral sockets has some particular problems. The stump is generally much less defined in its shape. The skeletal elements, the section of femur and the pelvic girdle, are buried within a large amount of mobile soft tissue. An ischial weight-bearing socket needs to fit firmly up to the ischial tuberosity. It is difficult to locate this landmark using a non-contact measuring method and even recording its position using a plaster of Paris wrap cast requires care and consistency.

The aim of the work presented here was to develop the UCL CAD CAM system so that it is applicable to trans-femoral socket design. Again it was decided that a desirable approach would be to follow a conventional philosophy such as that described by Foort (1963). This philosophy involved fitting the patient with a socket of which the proximal portion was of a standard 'brim' shape, sized correctly, and of which the distal portion conformed to a cast of the patient's stump. This involved development of a casting and measuring procedure together with a brim sizing method and computer software to fit the two shapes together, ensuring the smoothness of the generated socket shape. The final stage of design using patching and sculpting, together with the computer graphics viewing procedure, were similar to the techniques employed in the trans-tibial method, again giving wide flexibility to the system.

After an account of how the shape is stored as a computer file, the following sections of this paper describe the methods for establishing the correct brim shape, casting and digitising from the patient, the software for formulating the socket shape, modifying and sculpting the socket and producing the socket. Further information on the precise formulation of the algorithms involved in the computer modelling can be found in Travis (1991).

Shape storage on a computer

This section explains how the shape of a

prosthetic socket is stored as a numerical file on a computer. The shape is considered as a series of "slices" at fixed intervals along a central axis. In each slice, points are recorded at regular angular intervals, and it is the radii of these points from the central axis which are actually stored in the file (Fig. 2a). The regular nature of the file also gives rise to the term "strip" in addition to "slice" (Fig. 2b). When a shape is altered or modified in any way, the effect is that some of the radii are changed, and the new shape is stored as a new set of radial values. The angular spacing between strips and the regular spacing between slices could be altered but in practice it appears that 10° and 6.35 mm (¼") are sufficient without being too dense to slow down the computer operation unnecessarily.

Method

Brim shape

In widely-used conventional procedures for the production of trans-femoral sockets the prosthetist has a number of "brims" of similar shape but different sizes available to him. One of these is chosen and fitted to the patient after certain measurements have been taken of the patient's stump to determine the correct size. Although it is likely that no brim will fit the patient's measurements exactly, the prosthetist will choose the best fit from the range of sizes. There may thereafter be some minor adjustments which he can make to the brim mechanically. This brim shape will form the proximal portion of the socket.

In the CASD approach it was recognised that if different brim sizes were essentially scalings of the same shape then the computer need only store one shape and scale it to the appropriate size using the measurements taken from the patient. One brim shape was therefore digitised and stored in the computer. In use, four key measurements are taken from the patient, three of which are used to scale the brim correctly, the fourth being used to determine the correct proximal-distal length of the final socket. The four measurements are as follows:-

1. An anteroposterior (AP) dimension is taken with the patient seated on a hard surface. The dimension is measured from the upper extent of the adductor longus tendon to the ischial tuberosity (Fig. 3a).
2. A mediolateral (ML) dimension is measured from the adductor longus tendon to the lateral extent of the head of the trochanter (Fig. 3b).
3. A circumference (Circ) dimension is measured with a tape measure tensioned so that there is just no slack, at the height of the perineum (Fig 3c).
4. The fourth measurement is a length (Len) measured from the perineum to the distal end of the stump (Fig. 3d).

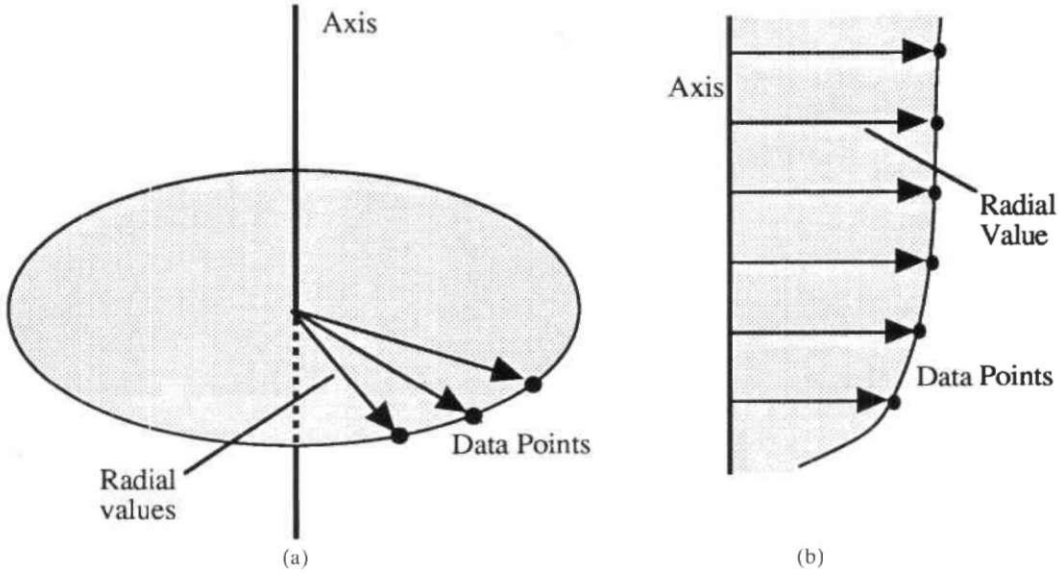

Fig. 2. (a) A slice consists of the radial values of points spaced at regular angular intervals about an axis. (b) A strip of the data consists of the points lying in a vertical plane through the axis.

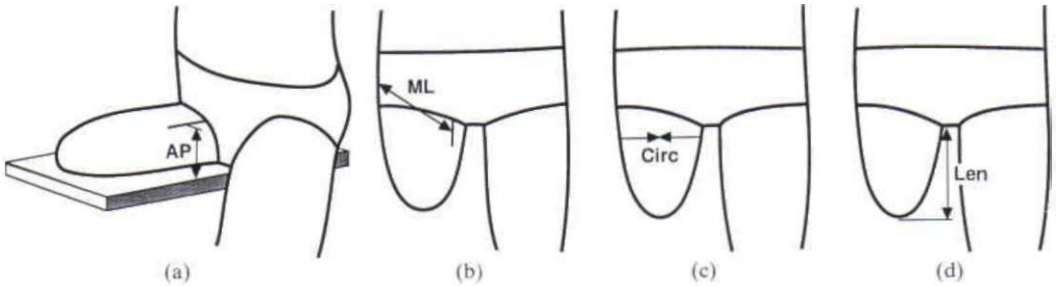

Fig. 3. Dimensions of the stump used for computer scaling. (a) The anteroposterior dimension: with the patient seated, the vertical distance between the top of the adductor longus tendon and the horizontal surface supporting the ischial tuberosity is measured.
(b) The mediolateral dimension: with the patient standing, the distance between the adductor longus tendon and the greater trochanter is measured.
(c) The circumference dimension: with the patient standing, the circumference of the stump is measured at the height of the perineum.
(d) The length dimension: with the patient standing, the distance from the perineum to the distal end of the stump is measured.

After the AP, ML and Circ dimensions have been inputted to the computer, the brim shape is scaled accordingly, dependent upon how these dimensions match appropriate points on the stored brim shape.

Casting

In the trans-tibial version of CASD there is no procedure analogous to that of fitting a brim to the patient; there the entire stump which is to be in contact with the total-contact socket is cast. A digitisation of this cast then becomes the initial shape for the design of the socket.

In conventional trans-femoral procedures the prosthetist fits the patient with the desired brim shape as described, and then casts that portion of the stump which protrudes. In the CASD system for trans-femoral sockets, the brim shape is stored in the computer, and the aim was to carry out the procedure without physically fitting a brim shape to the patient. However, since the brim alters the shape of the stump to a considerable extent, taking a cast with no allowance made for this gave unpredictable results. The adopted procedure involves the use of that portion of the brim which in practice transmits much of the weight through the ischial tuberosity (Fig. 4). To allow for the alteration in stump shape, the brim segment is positioned against the patient after he has been fitted with a stump sock: a horizontal mark and a tick to indicate the central point of this posterior view are made at the stump's distal end (Fig. 5). After the brim portion is removed the stump is cast up to the horizontal mark, and the cast is digitised. The point marked by the tick is used as the reference point for orientation of the data file during the shape generation.

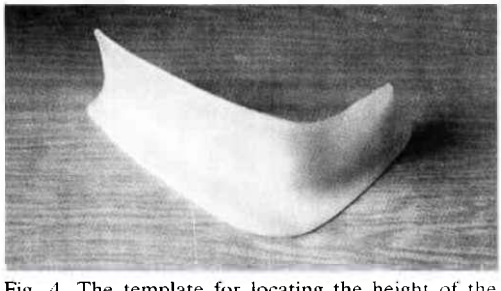

Fig. 4. The template for locating the height of the reference point is a replica of the medial posterior portion of a socket shape.

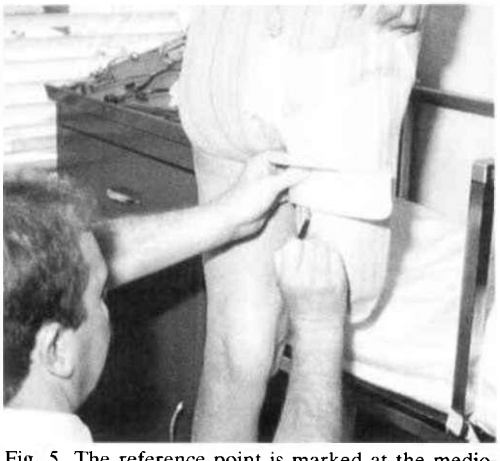

Fig. 5. The reference point is marked at the medio-lateral centre of the stump on the horizontal line under the template.

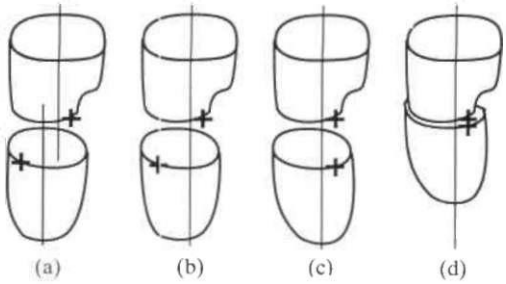

Fig. 6. The stages of creating an initial socket shape from separate brim and distal portions: (a) two separate data files on distinct vertical axes; (b) the two files with their axes aligned; (c) the distal part is oriented so that the reference point on the two parts match; (d) the files are linked together ready for smoothing.

Socket shape generation

After measuring, casting and digitisation are complete, the computer contains two data files, namely the brim shape scaled appropriately and the digitisation of the distal portion of the limb. Using the reference point in each file, the two files are oriented correctly and the co-ordinates recalculated to be radial values from one central axis (Fig. 6). However, at this stage, the two data files will not match smoothly, and so software has been developed which blends the two files together and, if necessary, at the same time adjusts the length of the shape to match the length dimension taken earlier. The result is a smooth socket shape shown graphically on the computer (Fig. 7).

Modifications and sculpting

Although at this stage an initial socket shape has been designed, adjustments may be required. The software incorporates two types, namely "modifications" and "sculpting".

Modifications are adjustments which affect large areas of the socket shape. A screen is presented to the prosthetist showing graphically six modifications which are available. These are adjustments to the ML, AP, and Circ dimensions and to the overall length of the socket and the introduction of flexion/extension and adduction/abduction to the socket. After any of these modifications, the socket is redesigned to fit the new requirements.

Sculpting is a procedure which affects only one point of the socket at any one time. The prosthetist can alter the radial value at any point of the shape. With a continual visual feedback of how the socket is affected this feature means that the prosthetist is able to introduce either very localised alterations to the shape or to combine sculpting of many points to affect broader regions or "patches".

The result of these alteration features is that the prosthetist is able to determine the socket shape he desires. The fact that all these modifications and sculptings are stored on the computer means that any subsequent sockets can use the current socket shape as a starting point, therefore increasing their predictability and repeatability.

Socket production

After a socket shape has been designed, the production of the socket is very much as for the trans-tibial CASD system. The same equipment is used, but larger plaster blanks are required for the milling process because the sockets are of greater volume. In summary, the procedure is as follows:

The file containing the shape data for the socket is sent to a numerically controlled three-axis milling machine which carves the shape out of a plaster blank. The carved shape is removed and placed in a Rapidform oven where a pre-heated polypropylene sheet is lowered over the plaster and conformed to the shape by use of a vacuum pump. When cooled, the plaster is broken out and the plastic trimmed so that the desired socket shape remains. This is then fitted to the patient with the necessary fittings and attachments.

Results

A key part of the procedure is the design of the brim portion of the socket. The

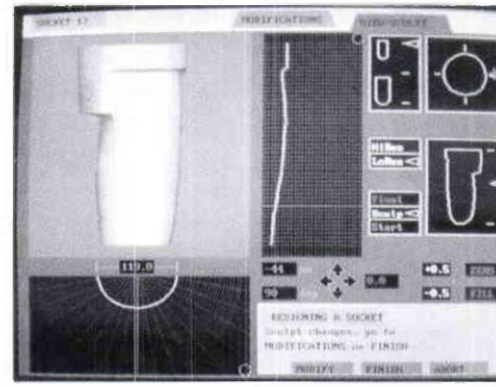

Fig. 7. The socket shape is displayed graphically on the computer. The final image shown is the resulting socket shape.

conventional philosophy followed suggests that the socket should fit with the patient's ischium resting approximately 10 mm posteriorly on the posterior shelf with the tendon of the adductor longus muscle fitting in the anterior medial corner and the head of the trochanter contained within the lateral wall. If this is achieved then the ramus is positioned above the medial shelf. The relationship between brim shape and the measured dimensions is demonstrated in Figure 8. An approximate guide for the relative sizes of these dimensions is as follows, and indeed the computer programme allows for entering of the Circ value only, the other values being estimated by these formulae:-

$AP = (^1/_5)\,Circ$

$ML = (^1/_3)\,Circ$

In initial patient trials, a comparison was carried out and a good degree of correlation observed between the AP, ML and Circ dimensions measured on the patient for subsequent input into the computer, and the dimensions as they occur on a brim adjusted by a prosthetist to fit the patient under conventional practice. It was found that the dimensions of the brim were correct to within the accuracy of measurements taken with calipers and tape-measure, and that the Circ dimension is particularly difficult to measure accurately. It was found that for the first socket produced for each patient, the Circ value required adjustment. However, because of the ability of the computer programme to build on previous socket designs, in each case the second socket fitted satisfactorily. This shows that even though a prosthetist may need experience with the system, for example to know how tight to pull the tape measure to produce a predictable

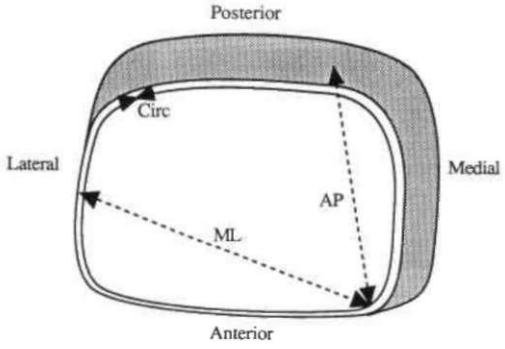

Fig. 8. The relationship between the anteroposterior, mediolateral and circumference dimensions and the brim shape.

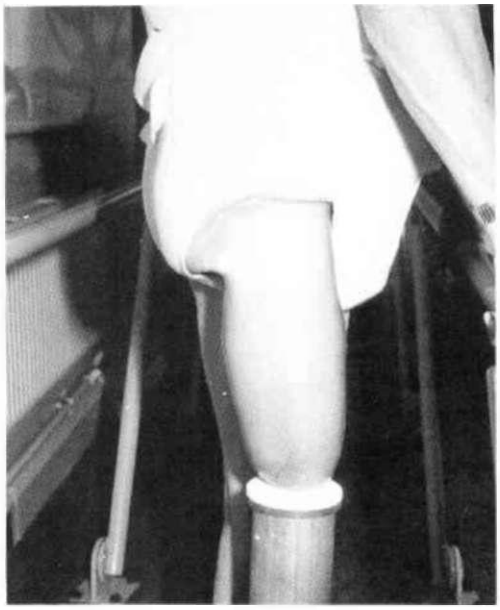

Fig. 9. A patient wearing a transparent test socket produced by the CAD CAM system.

socket size, the consistency of the system built in by the memory of previous designs can enable him to produce predictable designs. An example of a socket made from clear perspex can be seen in Figure 9.

Discussion

Two alternative approaches are apparent for the design of a trans-femoral total contact socket. The first is to mimic the method commonly used for trans-tibial sockets and employ a "patch" approach based upon a cast of the entire stump as described in Dewar *et al.* (1985). However, this would not have followed conventional trans-femoral procedure and, as mentioned above, would have led to difficulties because of the flexible nature of the body tissue in the proximal portion of the leg. After initial consideration and tests, using this approach alone was rejected because of these difficulties.

A second approach is that used by Torres-Moreno *et al.* (1992) and consists fundamentally of the judicious scaling of one of several "reference shapes" previously stored in the computer, the scalings and adjustments being decided by certain measurements taken from the patient's stump. This approach has particular advantages in the proximal portion of the socket where in conventional practice the overall shape of a total contact socket is largely

independent of the individual patient – only the scale of the proximal portion is adjusted to ensure a good fit.

The method adopted is a combination of the two: it has the advantage of the second approach in the proximal portion of the socket, since a predetermined brim shape is adjusted according to certain anatomical dimensions taken from the patient's stump, but also uses the shape of the distal portion of the stump as the starting point for the distal portion of the socket, with the advantage of accurate fit which this involves.

The advantages of a computer graphics approach were demonstrated with the trans-tibial CASD system. They include the ability to view the socket on the computer before production, which enables any large defects to be detected and removed. The ability to base a design on a previous socket and to use a modification or sculpting technique is a considerable advantage over conventional methods where the initial plaster shape is destroyed in the manufacture of the socket. This means that if a socket is a good fit except in localised areas, for example, a new socket can easily be designed and a predictable fit produced. Moreover, if a first socket design is not correct, then a second one has a greater chance of being satisfactory.

The measured dimensions chosen were selected because they are measurements which prosthetists commonly take already, allowing quicker adaptation to the new system. However, it may be that other prosthetists decide that different measurements would result in a better prediction of the desired brim shape. These could readily be included within the computer software.

Only one brim style was used in fitting of most of the patients. It would be straightforward to introduce further styles by producing a plaster cast of the desired brim shape and digitising it. One advantage of the CASD approach is that it does not limit the prosthetist to a standard range of sizes of his chosen brim style. Rather, because the computer can scale up to any degree, a complete range of sizes is available. Moreover, the approach allows individual prosthetists the freedom to develop their own brim styles, or particular styles to suit particular types of patient.

A further stage in this research is currently being investigated, and that is the possibility of introducing surface modelling of the type discussed by Travis (1991) into the socket design and to determine the extent to which such surface modelling is an advantage and to what extent it is an unnecessary feature whose effect is to slow down the graphical representation by the requirement of further calculations.

Conclusions

The major advantages of computer-aided design over conventional design are that because the entire shape is kept on the computer in a digital form, an accurate record of the shape and modifications made to it can be maintained. This has the benefit of increasing the predictability of the fit of a socket, especially where the design of a new socket for a patient is based upon the design of a previous socket for that patient but with minor alterations. Furthermore, the CASD system for trans-tibial amputees has introduced the powerful concept of computer graphics in the visualisation of the socket before its manufacture. This, together with the techniques of "patching" and "sculpting" the shape whereby regions ("patches") or individual points on the surface have their shape modified in a predictable and consistent manner, introduces a wide flexibility into the system.

An extension of the CASD approach for trans-tibial prosthetic sockets to trans-femoral prosthetic sockets has been developed, and a good degree of success is indicated by initial trials. The system offers to trans-femoral prosthetic socket design the considerable advantages of repeatability, consistency, ease of use and computer graphics visualisation before production, as offered by the trans-tibial CASD.

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Prosthetics and Orthotics International, 1993, 17, 180–188

Fatigue testing of energy storing prosthetic feet

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Abstract

This paper describes a simple approach to the fatigue testing of prosthetic feet. A fatigue testing machine for prosthetic feet was designed as part of the programme to develop an energy storing prosthetic foot (ESPF). The fatigue tester does not simulate the loading pattern on the foot during normal walking. However, cyclic vertical loads are applied to the heel and forefoot during heel-strike and toe-off respectively, for 500,000 cycles. The maximum load applied was chosen to be 1.5 times that applied by the bodyweight of the amputee and the test frequency was chosen to be 2 Hz to shorten the test duration. Four prosthetic feet were tested: two Lambda feet (a newly developed ESPF), a Kingsley SACH foot and a Proteor SACH foot. It was found that the Lambda feet have very good fatigue properties. The Kingsley SACH foot performed better than the Proteor model, with no signs of wear at the heel. The results obtained using the simple approach was found to be comparable to the results from more complex fatigue machines which simulate the load pattern during normal walking. This suggests that simple load simulating machines, which are less costly and require less maintenance, are useful substitutes in studying the fatigue properties of prosthetic feet.

Introduction

In the development of prostheses, all prosthetic assemblies and components are subjected to structural acceptance tests which include static and fatigue tests. Static tests are required to determine the structural strength of the foot to ensure performance and safety. These are carried out on a universal testing machine. While this is important, fatigue tests to reveal the fatigue strength of the components must also be performed. Fatigue tests are designed to study performance under load for the equivalent of the expected service life during normal use.

As part of the programme to develop an energy storing prosthetic foot, called the Lambda foot, a simple fatigue testing machine for prosthetic feet was designed. Fatigue testing is essential as the foot is expected to be subjected to repetitive loading during normal usage. Marsden and Montgomery (1972) conducted a survey to measure the number of steps taken by individuals during their normal activities of daily life. It was found that the number of steps taken is heavily dependent on the amount of objective walking which an individual does. A wide range in the step frequency of the individuals (in steps per hour) was recorded. It ranged from a low of 145 steps per hour for a schoolboy to a high of 1780 for a postman. Fatigue testing thus forms an integral part in the design of the prosthetic foot.

A simple approach to fatigue testing of prosthetic feet was adopted. The fatigue tester does not replicate loads acting on the foot under normal walking conditions, but a peak load equivalent to about 1.5 times that of the body weight was applied to the foot during heel-strike and toe-off. Altogether, four prosthetic feet were tested: a size 5 Lambda

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foot, a size 8 Lambda foot, a size 5 Proteor SACH foot and a size 5 Kingsley High Profile SACH foot.

The primary objective of the development of the fatigue tester was to check the fatigue strength of the Lambda foot. At the same time, it was intended to demonstrate that a simple approach to fatigue testing of prosthetic feet, which is low cost and easily reproducible, can produce comparable results obtained using more complicated machines. However, the results obtained must be treated with a certain degree of caution due to the small sample size involved. Further work is needed to obtain a more conclusive result. This paper describes the fatigue testing machine and examines the test results obtained.

The Lambda foot

The paper introduces a prosthetic foot in the class of the so called energy storing prosthetic feet, called the Lambda foot. The Lambda foot is designed to replicate the biomechanics of the normal foot-ankle assembly and to help conserve energy in amputees' ambulation. It is designed to store energy at heel strike. The energy stored during heel strike is returned to effect smooth transition from heel strike to foot flat and subsequently heel rise. From heel rise, the energy stored in the forefoot is later released in a combined forward (thrust) and upward (lift) direction which complements the gait cycle. The foot behaves like a spring where the potential energy is stored when it is loaded and the energy is returned to the system when the load is removed. This lift effect also helps to maintain the centre of gravity of the amputee at a constant level which makes locomotion less tiring.

The Lambda foot consists of a forefoot portion and a heel portion interchangeably bonded at the "ankle", which is located close to the natural ankle, by a bolt (Fig. 1). The forefoot portion extends horizontally from the ankle region anteriorly towards the toe region of the foot whereas the heel portion extends horizontally and anteriorly from the ankle region and curves downward and extends to the posterior of the foot. Both the forefoot portion and heel portion are formed by using carbon fibre laminae reinforced with a hardened, flexible epoxy polymer and are designed to serve as flat spring-like leaves so that the foot

Fig. 1. Lateral view of the Lambda foot.

provides a strong cushioning and energy storing effect.

The upper portion of the ankle region defines a platform which engages the inferior aspect of a conventional prosthetic pylon. The platform is planar and is substantially rigid to sustain torsional, impact and other loads acting on the forefoot portion and the heel portion. For connecting the foot to the pylon, the ankle region has a centrally located hole through which a bolt extends and engages the threaded bore at the lower end of the pylon.

Review of fatigue testing in lower-limb prostheses

The International Society for Prosthetics and Orthotics (ISPO) (1978) recommended standards for fatigue testing of lower limb prostheses which included axial cyclic loads of 1350 N and anteroposterior (AP) cyclic bending moments about the ankle of 140 Nm. The maximum frequency for cyclic tests should be 1 Hz for assemblies containing non-metallic

components and 10 Hz for assemblies of an all metallic nature. The applied load should be gradual, like a smooth sinusoidal waveform. These proposals were quite similar to those proposed by the Veteran Administration Prosthetic Centre (VAPC) during the ISPO conference, which included axial loads of 1020N and AP bending moments of 110 Nm. The VAPC (ISPO, 1978) also recommended for foot/ankle assembly, each sample should withstand 500.000 cycles under 150 lbf (667 N) load without failure and the permanent deformation should not exceed ⅛ inch (3.2 mm).

Daher (1975) published the fatigue test results of various makes of SACH feet using a fatigue tester developed in his laboratory. The prosthetic foot was loaded to simulate the loading on the foot during normal walking by air pressure cycling in pneumatic cylinders. The loading sequence was controlled by time cams. One advantage of Daher's tester is the ability to test two feet simultaneously. Wevers and Durance (1987) developed a fatigue loading machine for lower limb prostheses following the standards proposed by ISPO. The machine uses a cam drive mechanism to mimic normal gait. Both the fatigue testers represent attempts by researchers to reproduce the loading on the prosthetic foot during normal walking. Despite considerable effort, time and cost spent to design such complex machines, it is often not quite possible to reproduce all the load components acting on the foot during normal walking. It is therefore proposed that a simple approach to fatigue testing of prosthetic feet be adopted by loading the prosthetic foot using only major load components, such as the vertical force and AP bending moment about the ankle.

Design methodology

Figure 2 shows the set-up of the fatigue testing machine developed in this study. The fatigue tester is designed mainly for testing prosthetic foot/ankle assemblies. It does not simulate the loading pattern on the foot during normal walking. However, cyclic vertical loads are applied to the heel and forefoot during heel-strike and toe-off respectively. It allows the user to set a peak axial load which can be varied. Once the peak load is set, the AP bending moments about the ankle becomes dependent on the foot dimensions. The fatigue tester has no provisions for axial torsion and mediolateral bending about the ankle.

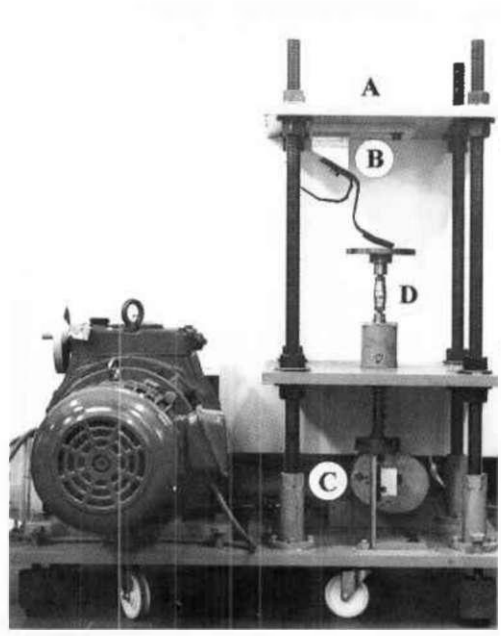

Fig. 2. Fatigue testing machine.

Components of the machine are designed for infinite life. The foot to be tested is mounted onto plate A via an ankle block B. A 30° block and a 15° block are used interchangeably for testing the forefoot and the heel respectively. The 30° block which inclines the foot at an angle of 30° to the horizontal is used for dorsiflexion and toe extension tests and the 15° block is used for plantarflexion test as recommended by the VAPC (ISPO, 1978). Cam C drives a reciprocating shaft which pushes against the foot. The required deflection on the foot to produce the desired load is pre-determined from a load deflection test conducted on the foot. Various load values can easily be obtained by adjusting the level of plate A. The maximum load acting on the foot is chosen to be equivalent to 1.5 times that of the bodyweight of the amputee. Load cell D is a Kistler Force Link 9321A and is attached to the top of the reciprocating shaft to monitor the load applied to the foot. The voltage signal from the load cell is first amplified by a Kistler miniature charge amplifier 5039A331 before it is digitised by a Keithley Metrabyte DAS-8 data acquisition card. A simple programme written in

Quickbasic stores and displays the applied load on a computer monitor.

The machine is driven by a variable speed induction motor at a frequency of 2 Hz. The loading frequency of 2 Hz is chosen over the frequency of 1 Hz adopted by Wevers and Durance (1987) to shorten the duration of the test. The Seattle foot, another energy storing prosthetic foot, was also dynamically tested at 2 Hz by Burgess *et al.* (1985). Each foot was tested to 500,000 cycles as recommended by the VAPC (ISPO, 1978). With the help of a contact relay and a timer switch, the tester can be optimised to operate approximately 80,000 cycles a day.

Test procedure

Four feet were tested: a size 5 Lambda foot, a size 8 Lambda foot, a size 5 Proteor SACH foot and a size 5 Kingsley High Profile SACH foot. Both the SACH feet had firm heel densities. In order to control the number of test parameters for the purpose of comparison, all the size 5 feet were chosen to be of about the same stiffness. However, the selection was difficult because the Lambda foot and the SACH foot are structurally different. The size 5 Lambda foot, intended for an amputee of mass 50 kg, was subsequently tested at a peak load of 736N, while the size 8 Lambda foot, intended for an amputee of mass 65 kg, was tested at a peak load of 957N. Both the SACH feet were tested at 736N to compare their durability, and ultimately their performances were compared with the Lambda feet. The feet were tested without protective footwear, as it was reported by Wevers and Durance (1987) that footwear added extra fatigue failure parameters and altered the fatigue resistance of the feet tested.

Static load deflection tests were first conducted for the heel and the forefoot portions of each foot on a Shimadzu universal testing machine, according to the standards proposed by the VAPC (ISPO, 1978). A brief description of the static tests is presented here.

The forefoot was tested by applying load to the plantar surface of each foot in the area of the toe to approximate the forces applied to the foot during the period of mid-stance to push off. The foot was placed in a dorsiflexion position at an angle of 30° to the horizontal (Fig. 3a). Vertical loads in increments of 100N were applied to the foot until a maximum of 600N was reached and the corresponding deflections were recorded.

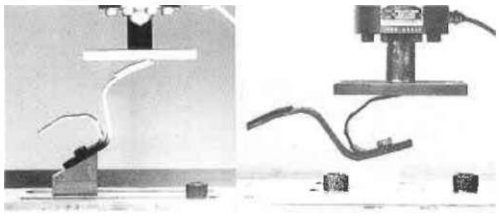

Fig. 3. (a) Static test on the Lambda forefoot. (b) Static test on the Lambda heel.

The heel was tested by applying load to the apex of the heel to approximate the forces applied to the foot during the period of heel contact to foot flat. The foot was placed in a plantarflexion position at an angle of 15° to the horizontal (Fig. 3b). Vertical loads in increments of 100N were applied to the foot until a maximum of 600N was reached and the corresponding deflections were recorded.

During the static test, a "reference position", i.e. the crosshead position of the universal testing machine at the instant when the loading plate of the universal testing machine just touches the prosthetic foot, was noted. The instant when the foot just touches the loading plate was reflected by the presence of a small load value on the universal testing machine. Hereafter, this "reference position" is called the "original reference position" and the value is required in order to obtain the permanent deformation of the foot.

The foot was then transferred from the universal testing machine to the cyclic tester (Fig. 2) for cyclic testing. Cyclic tests were completed at 5,000, 10,000, 20,000, 50,000 and 100,000 cycles. Additional tests were completed at every 100,000 cycles until 500,000 cycles was reached. The above procedure was also adopted by Daher (1975). Static load deflection tests were conducted between the cyclic tests to determine if there had been any change in the mechanical properties of the foot. For each static test, a new "reference position" was also noted, which when subtracted from the "original" reference position", yielded the permanent deformation of the foot.

Results

The results of the fatigue tests of the Lambda feet and SACH feet are represented graphically

in Figures 4, 5 6 and 8. The deflection-load curves at 0, 5,000 cycles and 500,000 cycles (or end of test, depending on which happened first) are plotted in each figure. It can be seen from the slope of the deflection-load curve that the stiffness of each foot increases with load. When two curves in the same figure are compared, the curve which lies below the other is said to have a higher resistance because a higher load is required to achieve the same deflection. The permanent deformations of the forefoot/heel of each foot are given in Tables 1 and 2. The permanent deformation was obtained by finding the difference between the new "reference position" after cycling and the "original reference position" before cycling.

Size 5 Lambda foot

Figure 4a shows that there is hardly any change in the forefoot resistance of the Lambda foot during cyclic testing. It is noted that the deflection-load curves at 5,000 cycles and 500,000 cycles are almost identical to the original curve at 0 cycle. Figure 4b shows the heel deflection-load curves of the Lambda foot. Like the forefoot, its resistance has not changed after the fatigue test and the deflection-load curves are almost identical before and after fatigue testing. The above observations reveal that the material and the design of the forefoot and the heel of the Lambda foot are capable of withstanding cyclic loads of up to 500,000 cycles. Table 1 shows that the permanent deformations at the end of 500,000 cycles for the forefoot and heel are 0.5 mm and 0.3 mm respectively, both values being very much lower than the permanent deformation of 3.2 mm allowed by the VAPC.

Table 1. Permanent deformation of Lambda feet.

Foot type	Size 5 Lambda foot		Size 8 Lambda foot	
Cycles completed	δ*(mm) forefoot	δ*(mm) heel	δ*(mm) forefoot	δ*(mm) heel
0	0	0	0	0
5,000	0	0.3	0.3	0
500,000	0.5	0.3	1.1	0.3

*permanent deformation

Size 8 Lambda foot

Figures 5a and b show that the deflection-load curves at 0 cycle, 5,000 cycles and 500,000 cycles are superimposed on one another, indicating minimal changes in resistance in the forefoot and heel portions after cycling. The forefoot is deformed permanently by 1.1 mm while the heel is deformed by only 0.3 mm, both values being lower than the permanent deformation of 3.2 mm allowed by the VAPC (Table 1).

Proteor SACH foot

Figure 6a shows the changes in the forefoot resistance of the SACH foot. At the end of 5,000 cycles, the resistance of the forefoot has reduced slightly. The cyclic test was stopped at 300,000 cycles as a crack, which was visible to the naked eye, had developed in the sole of the forefoot causing a large permanent deformation of 13 mm (Table 2). It is noted that the resistance of the forefoot has increased at the

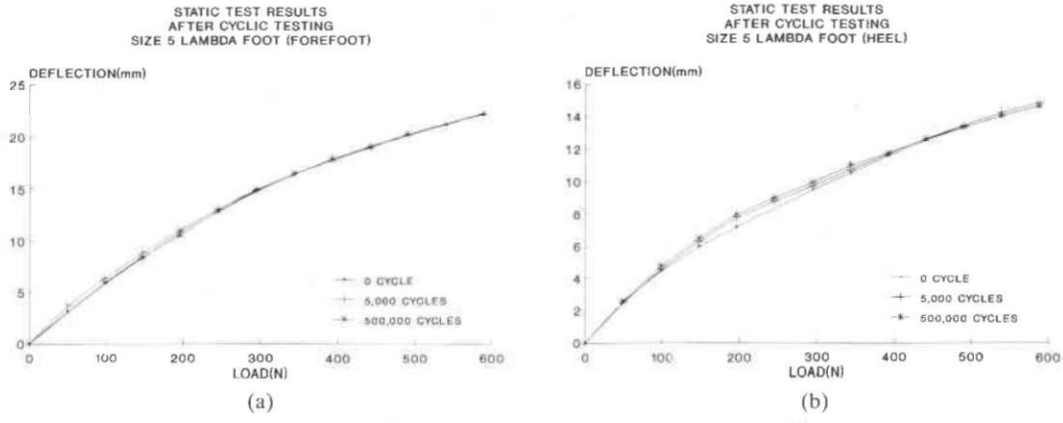

Fig. 4. (a) Forefoot resistance of size 5 Lambda foot. (b) Heel resistance of size 5 Lambda foot.

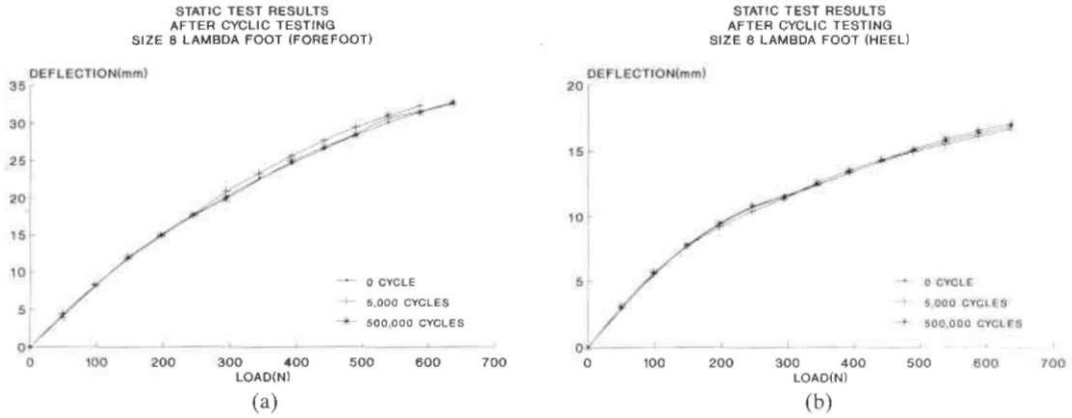

Fig. 5. (a) Forefoot resistance of size 8 Lambda foot. (b) Heel resistance of size 8 Lambda foot.

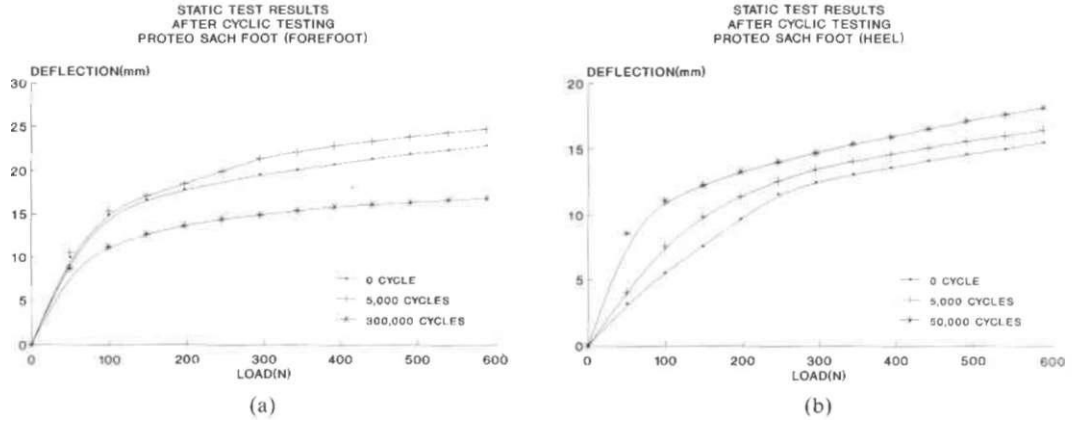

Fig. 6. (a) Forefoot resistance of Proteor SACH foot. (b) Heel resistance of Proteor SACH foot.

Table 2. Permanent deformation of SACH feet.

Foot type	Size 5 Proteor SACH foot		Size 5 Kingsley SACH foot		Size 5 Lambda foot	
Cycles completed	δ (mm) forefoot	δ (mm) heel	δ (mm) forefoot	δ (mm) heel	δ (mm) forefoot	δ (mm) heel
0	0	0	0	0	0	0
5,000	0.4	0.8	1.0	0.3	0	0.3
500,000	13.3*	3.1+	8.0#	0.7	0.5	0.3

*test discontinued at 300,000 cycles +test discontinued at 50,000 cycles #test discontinued at 400,000 cycles.

end of the test (the reason is discussed later in the paper). Figure 6b shows that there is a reduction in heel resistance at the end of 5,000 cycles. It was observed that the wedge sponge-like material at the heel began to wear at 10,000 cycles. The cyclic test was stopped at 50,000 cycles due to the breakdown of the heel. Figures 7a and b are photographic reproductions of the X-ray lateral views prior to and subsequent to the testing respectively. Figure 7b shows the wear of the wedge sponge-like material at the heel. The stiffener attached to the wooden keel was deformed which explains the large permanent deformation of 13 mm for the forefoot. Further, the foam at the region where the stiffener is joined to the keel

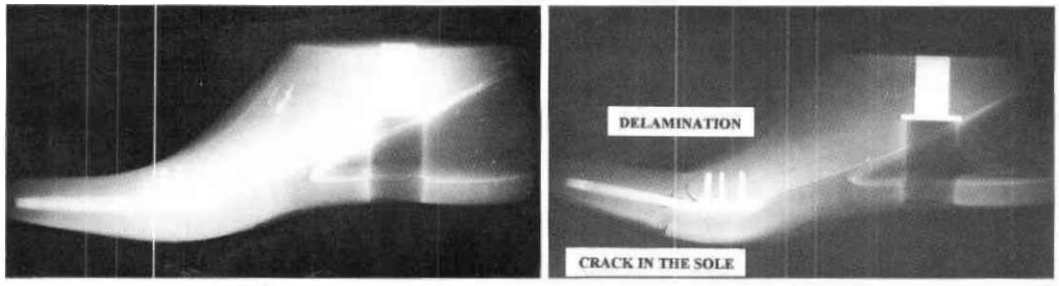

Fig. 7. (a) X-ray lateral view of Proteor SACH foot before cycling. (b) X-ray lateral view of Proteor SACH foot after cycling.

exhibited cracks and delamination from the keel.

Kingsley SACH foot

Figure 8a shows that the forefoot resistance of the Kingsley SACH foot has reduced slightly at the end of 5,000 cycles as also observed in the Proteor SACH foot. The test was stopped at 400,000 cycles as a crack had developed in the sole of the forefoot. Very interesting behaviour during the testing of the SACH foot is reflected in the deflection-load curve at the end of 400,000 cycles. The resistance of the forefoot has increased. Referring back to Figure 6a, the Proteor foot also exhibited similar behaviour, but its increase in resistance is more than the Kingsley foot due to its larger permanent deformation. The reason for the above is that once the foot has been deformed permanently, the wooden keel of the SACH foot makes a greater contribution thereby increasing the resistance considerably. A permanent deformation of 8 mm was recorded for the Kingsley forefoot (refer to Table 2). However, the heel of the Kingsley SACH foot is very durable. Figure 8b shows that the resistance varied very little during the testing and no visible wear on the heel wedge was observed. A permanent deformation of 0.7 mm was recorded for the heel.

Discussion

It was mentioned earlier that the machines designed by Daher (1975) and Wevers and Durance (1987) simulate loading on the prosthetic foot during normal stride by including various forces and moments. It is interesting to compare the results obtained by both researchers with the results obtained from the simple approach adopted here. However, the comparison is not absolute because the test parameters are not completely identical. Daher tested the prosthetic feet with shoes and the average peak load was 981N. The main objective of Wevers' experiment was to evaluate the fatigue strength of prosthetic

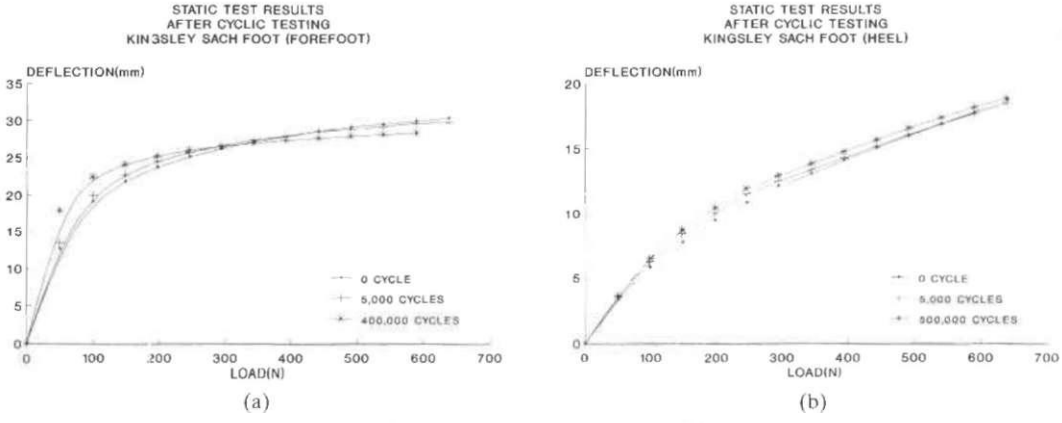

Fig. 8. (a) Forefoot resistance of Kingsley SACH foot. (b) Heel resistance of Kingsley SACH foot.

sockets and the recommended peak load of 1350 N was used. Further, the prosthetic feet may not be of the same sizes. Nevertheless, it is useful to compare the results.

The Kingsley High Profile SACH foot in Daher's test was deformed permanently by 8.9 mm and 3.8 mm for the forefoot and the heel respectively at the end of 500,000 cycles. From Table 2, the Kingsley SACH foot tested here was deformed by 8.0 mm and 0.7 mm for the forefoot and the heel respectively. Both the results are comparable and it is believed that the larger values in Daher's test is because of the higher loads used. The fact that the sole of the SACH foot in Daher's test did not show any cracks at the end of the test could be because the foot was tested with shoes. Daher also mentioned that the heel of the Kingsley SACH foot is very resilient. No internal physical breakdown was observed by X-ray in both cases. It was seen earlier that the forefoot deflection-load curves for both the Proteor and Kingsley SACH feet show an initial reduction in resistance at the end of 5,000 cycles, but the resistence increased at the end of the test. This was because once the foot was deformed permanently, the wooden keel of the foot would be stressed. Similar observations were observed in almost all the deflection-load curves for the forefeet in Daher's work, but the phenomenon was not reported.

Wevers reported that the Kingsley SACH foot failed at 105,800 cycles. The fatigue life was shorter than that obtained by the simple approach because of the higher load used by Wevers. All the SACH feet [US Manufacturing, Otto Bock (German Winnipeg) and Kingsley] showed cracks in the soles at the end of the test.

The above discussion shows that the results obtained from the simple approach are consistent with the results obtained from the more complicated machines. It is also noted that a Proteor foot worn by an amputee over a period of six months shows similar wear at the sole and heel to the one that was dynamically tested.

It is felt that the axial load of 1350 N proposed by ISPO for lower limb prostheses is too high for the SACH foot. All the SACH feet tested by Wevers at such a high load failed prematurely. Although, the SACH feet tested by the simple approach were subjected to loads smaller than 1350 N, the feet failed before 500,000 cycles. It is also felt that the load value is designed more for Caucasians as Asians generally have lower body mass. Such high loads are normally experienced by active amputees during sport activities but are only occasionally experienced by less active amputees during unforeseen events like stumbling over obstacles. However, the cyclic load of 667 N proposed by the VAPC for foot/ankle assemblies may be too low. With the proliferation of ESPF, amputees will be motivated to engage in sport activities and the loads experienced will be higher. Prosthetic feet tested at such low loads would not be reliable. A compromise between the recommended loads of 1350 N and 667 N would be ideal. So far, publications relating to ESPF only mentioned the feet have been dynamically tested, but no details of such tests have been given.

The simplicity in the design of the fatigue tester is its main advantage. This results in lower cost and less maintenance requirement. A further advantage is that the peak load is easily reproducible and can be varied easily. However, the present design does not allow the forefoot and the heel to be tested together. This will increase the duration of the test. In Daher's and Wevers' design, because the foot is taken through the complete walking cycle, both the forefoot and the heel are tested simultaneously.

Although the results obtained by the simple approach are comparable to that obtained using more complex machines, it is cautioned that the results obtained are not conclusive because of the small sample size. It is recommended that further work using the simple approach be carried out using more specimens.

Conclusion

The fatigue tester has been used successfully to study the durability of the Lambda feet and the SACH feet. It was found that the Lambda feet have very good fatigue properties as the deflection-load curves at the beginning and at the end of the cyclic test were almost identical and the maximum permanent deformation for both the Lambda feet was 1.1 mm which was below the 3.2 mm allowed by the VAPC. However, the cyclic test on the Proteor SACH foot was hampered by the wear and breakdown of the rubber sole and sponge heel, which caused the test to be terminated prematurely.

The forefoot of the Kingsley SACH foot performed better than the Proteor model but also broke down prematurely. However, the heel of the Kingsley model was very durable with no wear at all. The results obtained were also found to be comparable to the results obtained using more complex fatigue testers.

Acknoweledgements

The authors gratefully acknowledge the financial assistance of a research grant (RP900327) from the National University of Singapore and the technical assistance of Singapore Aerospace Manufacturing Pte. Ltd. for fabricating the Lambda feet.

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Prosthetics and Orthotics International, 1993, 17, 189–195

The neuropathic foot

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Abstract

The neuropathic foot is described with relation to cause, presentation, dysfunction and identification. The various mechanisms of neuropathic foot lesions are outlined — overload, diabetic gangrene, continuous pressure, direct injury and cutting and temperature effects. The orthotic treatment of the foot is discussed and in particular the importance of proper shoe provision and patient education and indoctrination emphasised. The use of plaster casts and fenestrations to control pressure distribution is described. Finally results of an intensive treatment programme are presented to identify the effect on outcome, as measured by delay in amputation.

Neuropathy

Diabetes is the most common cause of neuropathic feet. Leprosy, syphyilis, pernicious anaemia, lesions to the spinal cord, spina bifida cystica and polyneuropathies of different aetiology cause insensitive feet unprotected because of the loss of pain reaction.

The patient is unaware of this insidious dysfunction. Even when the neuropathy is discovered, there is no mechanism to compensate for this loss of sensory protection. Other ways must be found to avoid lesions of the feet, one of which is education.

Later the patient will notice numbness or tingling in the feet or uncharacteristic pain. Sometimes the pain can be severe, burning or lancinating, with hypersensitivity to touch and sometimes rest pain. The painful neuropathy is self-limited as the sensory loss proceeds.

The sensory neuropathy is often combined with motoric and autonomic neuropathy.

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Dysfunction of the autonomic nervous system gives among other symptoms, anhidrosis with dry, shiny skin, that often is atrophic and easily cracks. The loss of the autonomic sympathetic tone in the peripheral vessels can result in arteriovenous shunting of the blood flow. When the venous blood pressure increases, neuropathic oedema may develop. The thermoregulatory mechanism is also out of function.

Motoric neuropathy mostly affects the short muscles of the foot seen as claw-toes or claw-foot.

Sensory nerve disorder must be diagnosed early to prevent lesions. It is easy to detect, if one just cares to examine the feet. The vibration from a struck 128-cycle tuning fork should be perceived from the toes and at least from the malleoli. For comparison the fork is placed at the skeleton of the hand and in the case where the patient has neuropathic feet, he can evaluate the difference.

Perception of pressure could be tested by a 5.07 Semmes Weinstein nylon probe. Proprioception is examined by letting the patient tell in what direction a toe is moved. If both the Achilles reflexes are missing, there is probably neuropathy.

Mechanism of neuropathic foot lesions

Ulcers and neuropathic bone disorders develop by:

- overload, repetitive mechanical stress and shear;
- diabetic gangrene from metabolic and vascular factors;
- direct injury or cutting;
- continous pressure resulting in ischaemia;
- heat or cold.

Overload

Overload is the primary cause of plantar

ulcers (Brand, 1989). The repetitive compression and friction in the soft tissues under the weight-bearing metatarsal heads generates energy transformed to heat. At temperatures above 44 degrees Celsius the enzymatic system of the cells is ruined and they die. Dependent on the severity of the lesion an inflammatory hyperemic reaction develops and will give:

- callosity of the skin;
- some loss of soft tissue;
- a greater loss of soft tissue, autolysis and a bursa;
- a bigger bursa from continuous damage will cause a breakdown of the skin;
- the repetitive stress might also give a neuropathic osteopathic breakdown or an osteitis from an infected ulcer.

The neuropathic foot is at greater risk from overloading than the normal foot in the same circumstances. The combined sensory and motor neuropathies facilitate the development of ulcers. For example the motor nerve dysfunction makes the short muscles of the foot become paretic, while the long flexors and extensors are active, which causes the common claw-toe and claw-foot deformity. The share of weight-bearing normally taken by the toes is added to the load on the metatarsal heads. Further the sensory loss implies balance dysfunction and makes the patient stand and walk with slightly flexed knees and increases the load on the forefoot (Delbridge *et al.*, 1985; Ctercteko *et al.*, 1982).

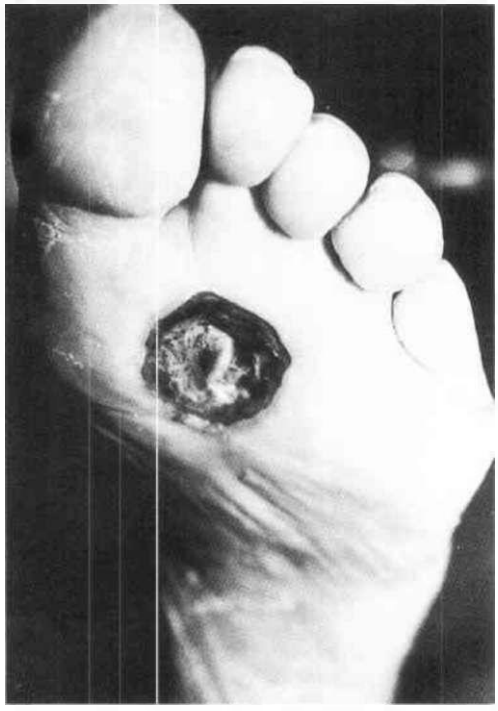

Fig. 1. A neuropathic ulcer of grade 2 exposing the capsule of the metatarsophalangeal joint.

Overload in the presence of normal sensation makes one change to a protective gait, limp or rest, but the neuropathic patient continues to stand and walk. The patient has been walking on the grade 2 deep uninfected ulcer shown in Figure 1 for some months.

Diabetic gangrene

The arteriovenous shunting of the blood by the autonomic nerve dysfunction aggravates any type of oedema. A combination of metabolic disorder, reduced peripheral blood flow and micro-vascular damage may lead to a necrosis of the skin in the central area. It may be the same mechanism for acute osteopathic breakdown.

Continuous pressure

If pressure is applied for a long enough time, it will give ischaemic pressure sores. The lower the foot blood pressure the higher the risk of getting an ulcer.

Direct injury and cutting

Mechanical trauma to the neuropathic foot will occur unnoticed by the patient and lead to complications. The patients must always protect their feet and never walk barefoot or perform any "bathroom surgery".

Heat and cold

With the loss of sense of touch and pain the patient also becomes insensitive to temperature. Further the perception of heat and cold is disordered. The patient may feel his feet are cold although they are not and burn them by exposing them to a heater or water which is too hot. A patient of several years standing forgot his foot in the massage bath while looking at television. He got an ulcer that cost him his foot (Fig. 2).

Orthotic treatment

The majority of patients with neuropathy in the western world have diabetes mellitus.

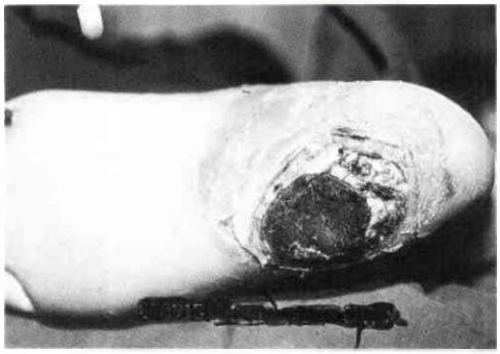

Fig. 2. An infected foot ulcer as a result of an apparatus for massage bath.

Patients with insulin dependent diabetes mellitus will develop neuropathy after ten years' duration of the disease, but with non-insulin dependent diabetes mellitus, the neuropathic symptoms often precede other symptoms of diabetes. Preventive measures are essential to decrease suffering and the enormous economic loss (Malone *et al.*, 1989). Neuropathic lesions of the feet are a defeat to the foot care team.

The orthotic treatment of ulcers is an integrated part of the treatment programme developed by Wagner and built on the Meggit grading of the lesions by severity 0-5 (Wagner, 1981).

Grade 0 designates a foot with no sores, but with a risk of developing an ulcer because of unfavourable loading, deformity, shoe pressure or other factors capable of inducing lesions.

Grade 1 designates a foot with a superficial lesion only involving the skin.

Grade 2 designates a deep lesion extending through the skin down to subcutaneous tissue.

Grade 3 designates a second grade lesion complicated by invasive infection, such as an abscess, arthritis, osteitis or tendon sheath infection.

Grade 4 designates partial gangrene of toes or part of the foot.

Grade 5 designates gangrene of the entire foot, making amputation above the ankle unavoidable.

Apart from meticulous medical care, such as control of metabolism, infection, surgical indications, the feet must be relieved of harmful mechanical factors by orthotic management, which implies:

— education of the patient;
— shoe therapy;
— Unna's paste boots;
— total contact walking casts; and
— other weight-bearing orthoses.

The patients must be educated to follow a well organized life-long treatment programme taught by a team of different specialists to help the patient to co-operate and to promote changes in behaviour.

Shoe therapy

Patients must be motivated to assimilate information and learn about foot care and proper shoes. Every patient is asked to bring all their shoes, old and new, which are examined to find some of the causes of lesions. This is a good way of teaching patients, pointing out which shoes should be avoided and which are proper footwear.

A pair of worn out shoes might be useful by means of cut-outs to unload lesions from pressure (Fig. 3) or used as a temporary footwear dressing following foot surgery.

Shoe principles

Basic mechanical shoe principles considered are:

1. the shoe should be fixed to the foot between the lacing and the heel counter;
2. the sole of the shoe should be stiff from the heel down to the axis of the metatarso-phalangeal joints to harmonize with the movements of the foot;
3. the medial side of the shoe should be straight to avoid medial pressure on the big toe;
4. the shoe should be broad enough to avoid causing ischaemic pressure to the side of the first or fifth metatarsal head;

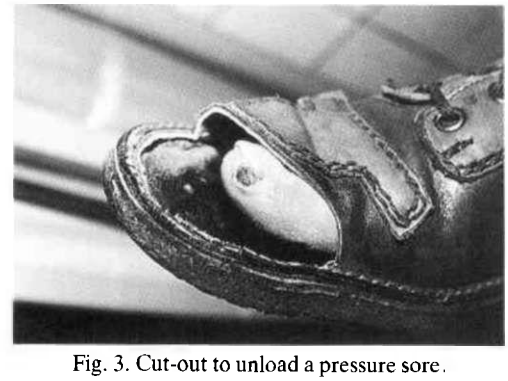

Fig. 3. Cut-out to unload a pressure sore.

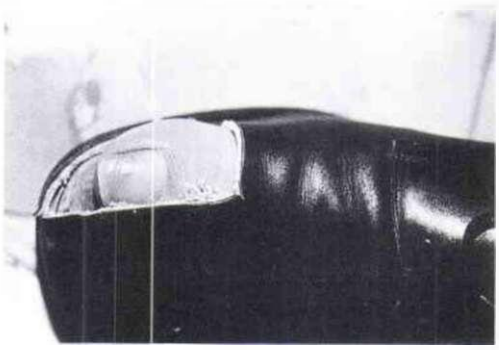

Fig. 4. The narrow toe box of an orthopaedic shoe demonstrated by a cut-out.

5. the toe cap should be spacious enough to give free distance and movement of the toes;
6. the shoe must be 1.5 cm longer than the weight-bearing foot. The tip of the toes must not reach to the toe-cap at toe-off, not even during running.

Very seldom does a patient's shoes fulfil these criteria, which are essential for protection even of a normal foot and Figure 4 shows that even an orthopaedic shoe can have a medial side which is not straight enough for a normal big toe. The patients at risk must be recognized and it must be understood that repetitive stress to the foot and ill-fitting shoes are the most frequent external factors leading to lesions (Apelqvist, 1990; Edmonds *et al.*, 1986; Borssén *et al.*, 1990). As the footwear and walking in combination with loss of sensation are the essential causes of the lesions, it is important to analyse the patients shoes, their mechanical behaviour, examining the soles as well as the inserts to protect each foot from further damage (Bergholdt and Brand, 1975; Mathews, 1988; Holstein *et al.*, 1976).

The feet of grade 0 are subdivided according to Joseph Reed (Coleman, 1988) into five categories, A-E, with respect to protective sensation, healed plantar ulcers, foot deformity and added osteopathy (Table1.)

Principles of relief of weight-bearing

Distribution of the reactive forces from the ground to the foot by inserts is mostly achieved by instinct. The following methods are used to reduce the pressure on an area:

1. elevation of pressure on other areas by pads or build-ups will hopefully reduce the pressure on a selected area, but it is uncertain how the soft tissue is compressed under the weight-bearing parts of the foot skeleton during walking;
2. a mould of the foot in a certain position can, by the hydraulic property of soft tissue, distribute the weight-bearing forces equally to all parts of the foot in that position. During walking however forces are generated inside the foot by the muscle action on the skeleton. The shear forces are unknown;
3. to retain this hydraulic property of the soft tissues of the foot during walking, the foot must be enclosed in a rigid shoe or a plaster cast, hopefully even reducing the propelling action of the foot skeleton;
4. if an area is windowed in a rigid cast or shoe the pressure of weight-bearing is eliminated;
5. when the foot skeleton cannot take weight a rigid ankle tibial condylar weight-bearing orthosis is needed.

Research on foot pressure measurements during weight-bearing and walking are ongoing. Several methods, the EMED system (Schaff, 1987); the pedobarograph (Hughes and Klenerman, 1989; Betts *et al.*, 1980); and the electrodynogram, are used to find ways to measure and control the pressure on the foot sole by design of insoles and shoes.

Table 1. Subdivisions of feet of Grade 0

Category controls	Protective sensation	Healed ulcer	Deformed foot	Shoe measure	Yearly
A	Yes	No	Yes/No	Corrections	1
B	No	No	Yes/No	Load care	2–4
C	No	Yes	No	Footbed+RRBS[1]	3–4
D	No	Yes	Yes	CM-Shoe[2]+RRBS	4–6
E	No	Yes/No	Osteop	CM-Shoe+TCWO[3]	6–9

1: Rigid rocker bottom sole
2: Custom made shoe
3: Tibial Condylar weight bearing orthosis

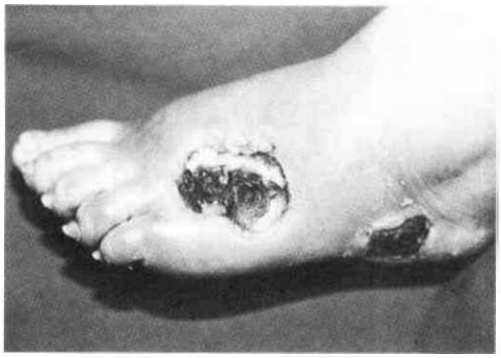

Fig. 5. Central necrosis in a red, hot, swollen and neglected foot, with autonomic neuropathy.

Oedema

Oedema is a precipitating factor to diabetic gangrene and ulcers (Lithner and Törnblom, 1984). The red, hot, swollen foot gives an impression of good arterial perfusion, but on the contrary the nutritive blood flow is reduced by arteriovenous shunting of the blood. A central necrosis of the skin may develop (Fig. 5) and it is urgent to treat the oedema. Besides the treatment of the cause of oedema a zinc paste stocking (Unna's paste boot) should be applied as soon as possible (Fig. 6).

To eliminate the oedema the leg is elevated above the level of the heart during the night and the stocking is applied early next morning.

Hairy legs should be shaved. A tubular stockinette is pulled on. The paste (gelatini zinci oxidi) is turned to solution on a hot water-bath and painted on. Gauze bandage is stuck in small pieces to reinforce the paste. When it is covered, a second layer of paste is brushed on. Generally 3-5 layers are sufficient to give a firm resistance to the muscle contractions so that the venous blood is squeezed centripetally. When the muscles relax, the veins are free to fill which is contrary to the situation with elastic stockings or bandages which always give resilient resistance. The zinc paste stocking is dried by cold air from a hair-drier.

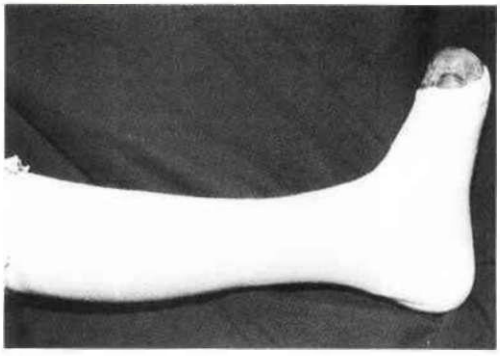

Fig. 6. A zinc paste stocking in the treatment of the oedema. The toes of the foot have been autoamputated.

Total contact casting

Plantar ulcers of grade 1-4 heal more quickly and with less complications in a total contact walking cast (Coleman *et al.*, 1984; Sinacore, 1988; Helm *et al.*, 1984; Mueller *et al.*, 1989; Borssén and Lithner, 1989; Myersen *et al.*, 1992). Ischaemic ulcers of grade 1-2 on the dorsum or sides of the toes could be treated by pressure-relieving cut-outs in a pair of shoes.

Fenestrated walking cast is indicated to;
1. eliminate the pressure on the ulcerated area;
2. immobilize the skin layers and reduce shear;
3. control oedema;
4. maintain ambulation.

Contraindications for walking cast:
1. invasive infection;
2. oedema. Oedema must be minimized before application of the cast;
3. acute osteopathic breakdown. In the case of acute osteopathic breakdown a plaster cast is applied to protect the foot and prevent oedema, but weight-bearing is not allowed.

Cast application

The cast is applied with the patient in a supine position. In a prone position with the knee flexed, the proximal end of the cast will become too spacious, because the heads of gastrocnemius muscle are not stretched during the casting. On a thin stockinette and a minimum of padding on the leg, two rolls of fast setting creamy plaster are applied and carefully rubbed to conform to the shape of the foot and leg till the plaster has set. To make immediate mobilisation and weight-bearing possible the full set cast is reinforced by outer layers of polyurethane impregnated fibreglass. Saw wires make the removal of the synthetic layers easier and when used two tubes should be placed on each side before these layers are applied. The synthetic cast material also provides the support of the sole and the fixation of the heel splint.

A window, just a little bigger than the ulcer is cut out to make it possible to absorb any

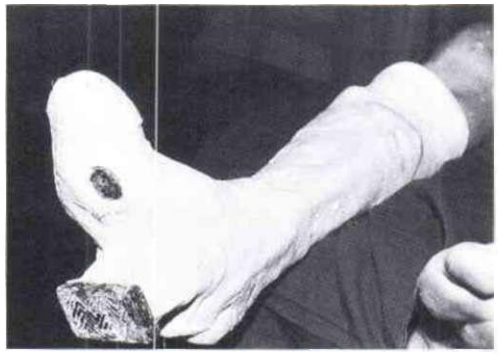

Fig. 7. The walking cast is windowed under the ulcer.

suppuration from the ulcer. The cast in Figure 7 is not reinforced by fibreglass.

The first cast must be checked within a few days. In 10% of the cases the casts become loose and have to be changed because of residual oedema. While changing the walking cast and when obvious healing is taking place, a plaster model is taken from the foot to make a last. Later when the ulcer has healed the individually prepared treatment shoe is ready. It has an individual foot bed made on the last and a rigid rocker bottom sole to give the same mechanical conditions that made the ulcer heal.

In a study of 50 consecutive fenestrated walking casts A. Starkhammar (personal communication) found no fractures, visible deformations or new decubital sores. Six patients developed superficial chafes without effect on the course of treatment.

Casts for heel ulcers are combined with a thermoplastic protector. At 80-90 degrees Celsius the thermoplastic becomes transparent and is fixed with adhesive straps. It can easily be molded to the plaster cast with a wet cold towel. When it becomes cold it will be stiff enough to be taken off without being deformed and further cooled in cold water till it gets hard. The walking cast is fenestrated and the protection replaced, relieving the ulcer from any pressure.

Acute osteopathic breakdown

The diagnosis of neuropathic osteopathy must be made on clinical findings. When roentgenologic signs appear, the breakdown is already in process. The bones must be protected when the inflammatory reaction starts and the foot immobilized in a non-weight-bearing cast. That will arrest the breakdown and give healing with recalcification. Otherwise the architecture of the foot skeleton is lost and so is the weight-bearing function of the forefoot resulting in a requirement for a rocker bottom foot (Fig. 8).

It is difficult to decide how long the patient should be treated without weight-bearing. The neuropathic patient cannot control partial weight-bearing. When increasing weight is taken on the foot, the sign of recurrent breakdown will be a local rise of temperature.

Results

Neuropathic ulcers will mostly heal when relieved from weight-bearing. Healing is dependent on the nutritive blood flow. Ninety-four percent of the diabetic patients with an ankle index >0.7 (ankle blood pressure/arm blood pressure) had ulcers which healed, with an index of 0.45-0.7, 71% healed and <0.45 healing was still achieved in 52% of the patients. Reduced ankle index correlated to a longer time of healing, 47% of 197 diabetic ulcers healed in 3 months, 83% within a year, but still 17% needed more than a year to heal.

The problem in any case is to avoid recurrences and new ulcers. Out of 299 ulcers 194 healed (65%). Eighty-four (43%) remained healed during the time of observation, 3.6-5.6 years, while 66 (34%) healed reulcerations. This makes the education of the patient a very imporant factor.

It is difficult to evaluate the orthotic treatment when there are so many factors involved and to find comparable groups of patients. In a longitudinal study of the diabetics seen at the orthopaedic department of

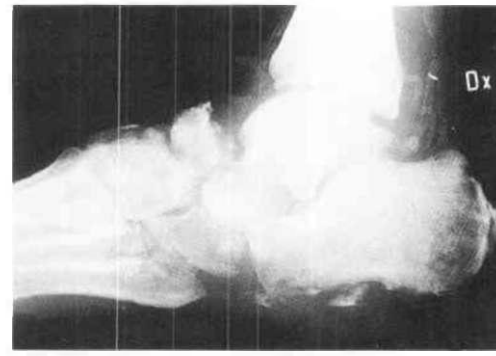

Fig. 8. The second roentgenologic picture of a red, swollen, neuropathic foot left weight-bearing since the first roentgenologic picture was normal.

Norrköping the effect of the total treatment programme was measured by an increase of age at primary amputation and consequently reduced time of survival after primary amputation.

The diabetic amputees' mean age at primary amputation was 72.5 years during the period 1974-1977 and increased by 3.7 years to 76.2 years in 1984-87 (p=0.994). The mean lengths of the amputees' lives was increased 2.6 years (p=0.957) through the same periods. Consequently the mean survival time was 1974-1977, 3.3 years and 1984-87, 2.7 years (p=0.994). In the second group 13 out of 117 patients are still alive, but will give an estimated mean delay of the primary amputation of 0.4 years. The number of amputations was 5% less than expected. The Swede's mean length of life had an increase of 2.2 years through the same years.

Obviously it is hard to prove that it is the effect of the treatment programme, but the effect of the general improved health would be eliminated when the increased length of life is subtracted, but no corrections can be made for a general better care of the diabetics.

Better results ought to be achieved if education and prevention are started early to prevent the normal foot from becoming deformed by traditional shoe fashion.

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NC510 Wheelchairs and Seating; 12–14 April, 1994
NC511 Clinical Gait Analysis; 11–13 May, 1994
NC506 Fracture Bracing; 23–27 May, 1994

Courses for Prosthetics

NC221 Trans-Tibial Suction Socket; Date to be announced
NC218A Ischial Containment Prosthetics; 5–14 January, 1994
NC212 Hip Disarticulation Prosthetics; 21 February–4 March, 1994
NC218B Ischial Containment Prosthetics; 25 April–6 May, 1994

Course for Orthotists and Therapists

NC217 Ankle-Foot Orthoses for the Management of the Cerebral Palsied Child; 20–22 April, 1994

Course for Rehabilitation Engineers

NC801 CAD CAM; 8–10 March, 1994

Seminar

NC719 CAD CAM; 7 March, 1994

Further information may be obtained by contacting Prof. J. Hughes, Director, National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Curran Building, 131 St. James' Rd., Glasgow G4 0LS, Scotland. Tel: 041–552 4400 ext. 3298.

1994

9–11 February, 1994
ISPO (UK) Annual Scientific Meeting, Blackpool, England.
Information: Mr. D. Simpson, ISPO Blackpool '94, NCTEPO, University of Strathclyde, 131 St. James' Rd. Glasgow G4 0LS, Scotland.

16–18 February, 1994
Annual Scientific Meeting of the European Society for Surgery of the Elbow and Shoulder, London, England.
Information: Metaphor, 21 Kirklees Close, Farsley, Pudsey, West Yorkshire LS28 5FT, England.

3–6 March, 1994
International Congress of the German Society of Orthopaedics and Traumatology and Instructional Course on "Surgery of Peripheral Nerves and the Plexus Brachialis", Cologne, Germany.
Information: Dr. C. Jantea, Orthopaedic Department, Heinrich Heine University, D-400 95 Dusseldorf, PO Box 260 214, Germany.

5–6 March, 1994
10th Annual Conference of the Association of Prosthetists and Orthotists, Liverpool, England.
Information: Mr. W. Dykes, APO Conference Co-ordinator, NCTEPO, University of Strathclyde, Curran Building, 131 St. James' Rd. Glasgow G4 0LS, Scotland.

20-23 March, 1994
Annual Scientific Meeting of the Australasian Faculty of Rehabilitation Medicine, Adelaide, Australia.
Information: Conference Secretariat, PO Box 153, Naire, South Australia 5252, Australia.

23-26 March, 1994
American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium, Nashville, Tennessee, USA.
Information: AAOP, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

7–9 April, 1994
BME '94 International Conference on Biomedical Engineering, Hong Kong.
Information: Conference Secretary, BME '94, Rehabilitation Engineering Centre, Hong Kong Polytechnic, Hunghom, Kowloon, Hong Kong.

9–16 April, 1994
7th World Congress of the International Rehabilitation Medicine Association, Washington, USA.
Information: Ms. D. Jones, 1333 Moursund A-221, Houston, Texas 77030, USA.

11–12 April, 1994
Combined Meeting of the European Orthopaedic Research Society and the British Orthopaedic Research Society, London, England.
Information: EORS Conference Secretariat, Biomechanics Section, Mechanical Engineering Department, Imperial College, London SW7 2BX, England.

13–14 April, 1994
Combined Meeting of the British, Dutch and Scandinavian Orthopaedic Associations, London, England.
Information: BOA, 35-43 Lincoln's Inn Fields, London WC2A 3PN, England.

17–22 April, 1994
11th Congress of the World Federation of Occupational Therapists, London, England.
Information: British Association of Occupational Therapists, 6–8 Marshalsea Rd., London SE1 1HL, England.

18–22 April, 1994
5th European Congress of Knee Surgery and Arthroscopy, Berlin, Germany.
Information: Dr. Urs Munzinger, Secretary General, Klinik Wilh. Schulstess, Neumunsterallee 3, CH-8008 Zurich, Switzerland.

31 May–2 June, 1994
Annual Meeting of International Medical Society of Paraplegia, Japan.
Information: IMMSOP '94 Annual Meeting, Japan Organising Committee, Orthopaedic Department of Tokusima University, Kuramotocho, Tokushima-shi, 770, Japan.

31 May–3 June, 1994
8th World Congress of Orthopädie + Reha Technik International, Essen, Germany.
Information: Verlag Orthopädie Technik, 4600 Dortmund 1, Reinoldestrasse 7–9, Postfach 10 06 51, Germany.

July, 1994
1st International Rehabilitation Medicine Conference, Kuala Lumpur, Malaysia.
Information: The Secretariat, Rehabilitation Unit, University Hospital, Lembah Pantai, 59100 Kuala Lumpur, Malaysia.

5–8 July, 1994
Dundee '94—International Conference on Clinical Gait Analysis, Dundee, Scotland.
Information: Dundee '94 Secretariat, Dundee Limb Fitting Centre, 133 Queen St., Broughty Ferry, Dundee DD5 1AG, Scotland.

10-12 July, 1994
Society for Research in Rehabilitation Summer Meeting, Nottingham, England.
Information: Dr. N. Lincoln, Stroke Research Unit, General Hospital, Park Row, Nottingham, NG1 6HA, England.

10–15 July, 1994
2nd World Congress of Biomechanics, Amsterdam, The Netherlands.
Information: Biomechanics Section, Institute of Orthopaedics, University of Nijmegen, PO Box 9101, 6500 HB Nijmegen, The Netherlands.

20–26 August, 1994
17th International Conference on Medical and Biomedical Engineering, Rio de Janeiro, Brazil.
Information: Dr. C. G. Orton, International Organization for Medical Physics, Gershenson Radiation Oncology Center, Harper-Grace Hospitals, 3990 John R., Detroit, MI 48201, USA.

4–9 September, 1994
6th European Regional Conference of Rehabilitation International, Budapest, Hungary.
Information: Rehabilitation Secretariat, ISM Ltd., The Old Vicarage, Haley Hill, Halifax HX3 6DR, England.

21–23 September, 1994
Biological Engineering Society AGM and Annual Scientific Meeting, Keele, England.
Information: Mrs. B. Freeman, BES, RCS, 35 Lincoln's Inn Fields, London, England.

9–13 October, 1994
6th Biennial Conference of the International Society for Augmentative and Alternative Communications, Maastricht, The Netherlands.
Information: Van Namen and Westerlaken, PO Box 1558, 6501 BN Nijmegen, The Netherlands.

11–15 October, 1994
American Orthotic and Prosthetic Association: Annual National Assembly, Washington, USA.
Information: AOPA, 1650 King Street, Suite 500, Alexandria, VA 22314, USA.

7–10 December, 1994
8th International Conference on Biomedical Engineering, Singapore.
Information: The Secretary, 8th ICBME 1994, Department of Orthopaedic Surgery, National University Hospital, Lower Kent Ridge Road, Singapore 0511.

1995

27–31 March, 1995
12th World Congress of the International Federation of Physical Medicine and Rehabilitation, Sydney, Australia.
Information: IFPMR Congress Secretariat, DC Conferences, PO Box 629, Willoughby NSW 2068, Australia.

2–7 April, 1995
8th World Congress of the International Society for Prosthetics and Orthotics, Melbourne, Australia.
Information: Congress Secretariat, 8th World Congress of the International Society for Prosthetics and Orthotics, 84 Greenbridge Street, South Melbourne 3205, Victoria, Australia.

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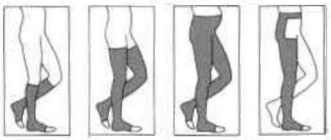

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