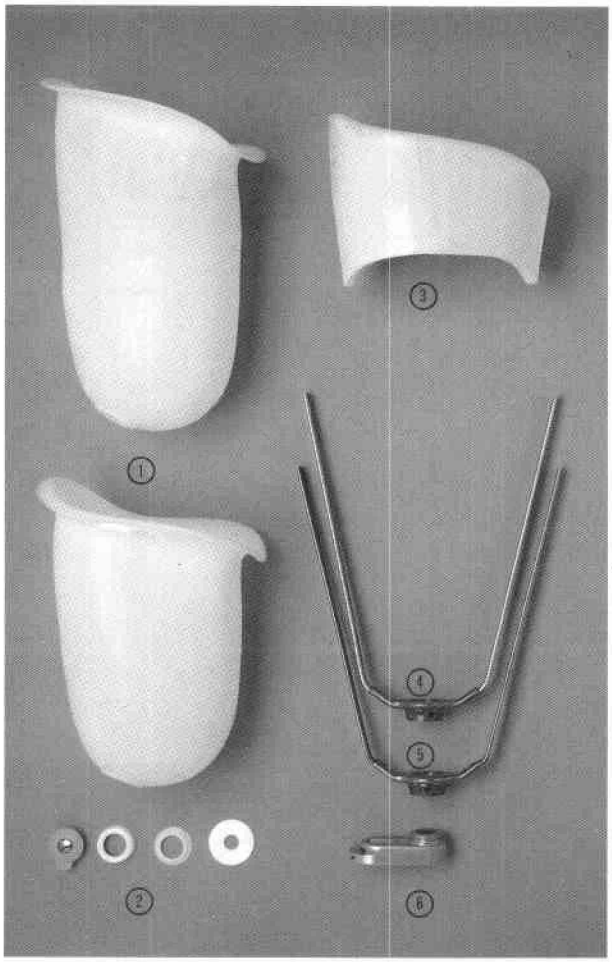
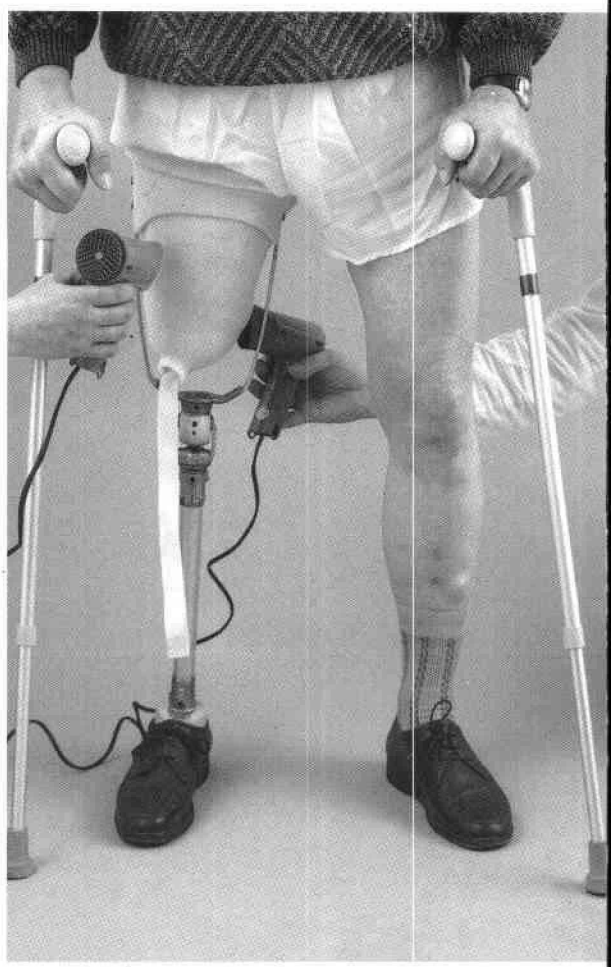
The Journal of the International Society for Prosthetics and Orthotics

Prosthetics and Orthotics International

April 1988, Vol. 12, No. 1





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Prosthetics and Orthotics International

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. (01) 20 72 60). Subscription rate is £42 per annum, single numbers £15. 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. 041–552 4049).

ISSN 0309–3646

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ENDOLITE

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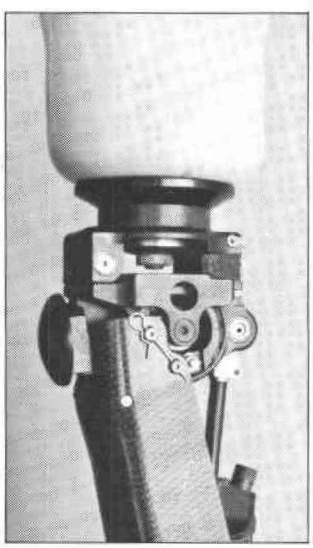

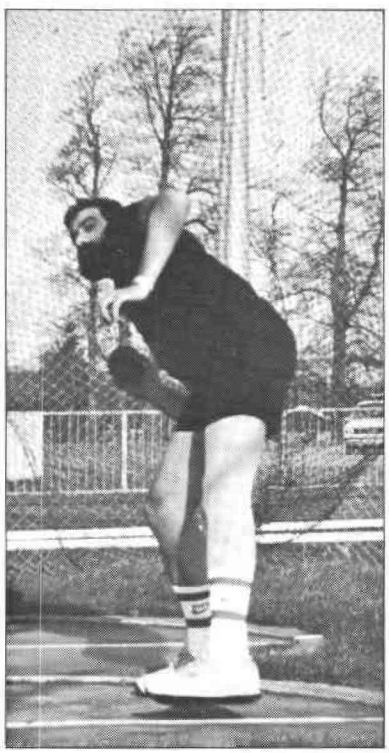

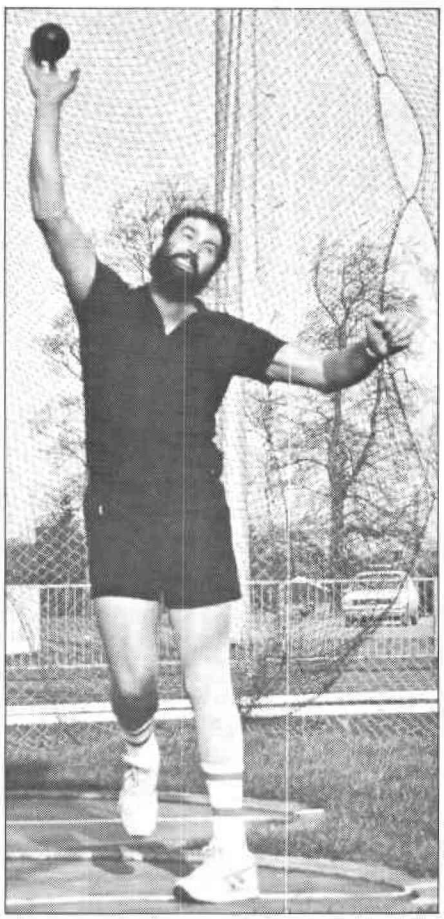

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The Journal of the International Society for Prosthetics and Orthotics

April 1988, Vol. 12, No. 1

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ISPO

Prosthetics and Orthotics International, 1988, 12, 1

Editorial

This issue of the Journal displays the financial statement for the year 1987.

A superficial view of this year's accounts could appear rather depressing. For the first time for many years the Society has a substantial deficit. This deficit, however, was the result of a deliberate policy of the Executive Board to use some of the Society's accumulated assets, surplus to our reserves, in order to increase our activities and influence in both the industrial and developing worlds.

The Society has spent more than 0.5 million DKK on conferences and workshops. No doubt the expenses related to the educational workshop at Strathclyde and the Cairo conference, with the International Labour Office and the African Rehabilitation Institute, is an investment in the future development of educational programmes in the developing countries, which, hopefully, will have an impact in improving the quality of fitting disabled patients in these parts of the world. ISPO has certainly been recognised for our participation in such work, which is in accord with one of the major goals of our Constitution.

The controversy in the developed world, arising from the various new designs of socket for the above-knee level, prompted the organization of a workshop, held in Miami, last year. The meeting brought together world experts, both in the more traditional designs and in the newer systems. The report from that Workshop will do much to enlighten the clinic team and, consequently, improve the care of our patients. ISPO also supported the Israeli conference on "Traumatic Amputations and their Management", which had an international interest, not only for areas with warfare, but also from the industrialized and developing countries with numerous high-energy and crush injuries of the limbs.

The Journal this year displays a deficit, which is mainly due to expenses being allocated in accordance with Danish tax legislation. Thus, parts of the travel and lodging expenses for the Executive Board members, who constitute the Publications Committee and meet in connection with the Board meetings may be set against Journal expenses, so avoiding excess tax payments.

ISPO did change investment policy in 1986 by placing about one-third of the securities in investment trust units and was consequently hit by the international financial crisis in October 1987. This investment was, however, longsighted and should not bring the Society into financial problems. The stock market is slowly regaining its confidence!

The expenditure of running the Society is not only related to the Copenhagen office, which apart from our hard-working employee of many years, Aase Larsson, now has been extended to include a part-time secretary, but also includes the costs of the Executive Board meetings and the participating of officers in important meetings with other organizations and governmental bodies dealing with problems for the disabled. These costs cannot be covered by the membership fees alone, but sponsorship from the War Amputations of Canada and the Society and Home for the Disabled, who also provide us with office facilities, still keeps the wheels running. Furthermore, the National Centre in Glasgow puts in a lot of unpaid effort for the same purpose. ISPO expresses its gratitude to these bodies for their continuing support.

In spite of the increasing cost levels for transportation, living and professional assistance, the Executive Board has decided to keep the individual membership fee to the Society constant at 400 DKK again for 1989, but will inevitably need to increase the fee from 1990. Our National Member Societies are encouraged to arrange local meetings and workshops, which may provide economic support at national level.

In conclusion, we find that the level of activity is increasing internationally, as nationally, and we express our gratitude to our keen members and, not least, to our sponsors for their eager support.

J. Steen Jensen
Honorary Treasurer

Prosthetics and Orthotics International, 1988, 12, 2–5

I.S.P.O. Statement of Accounts, 1987

Auditors' Report

We have audited the financial statements for the year ended December 31, 1987.

The audit has been performed in accordance with approved auditing standards and has included such procedures as we considered necessary. We have satisfied ourselves that the assets shown in the financial statements exist, have been fairly valued and are beneficially owned by the association and that all known material liabilities on the balance sheet date have been included.

The financial statements have been prepared in accordance with statutory requirements and the articles of association and generally accepted accounting principles. In our opinion the financial statements give a true and fair view of the state of the association's affairs on December 31, 1987 and of the profit for the period then ended.

Copenhagen, March 18, 1988
Schøbel & Marholt
Søren Wonsild Glud
State Authorized Public Accountant

Accounting Policies
Securities
Bonds and shares have been valued at the lower cost on market.

Office equipment
Computer and office furniture have been valued at cost.
Depreciation is computed, straight line over 5 years.

Income Statement for the Year 1987

			1986
SUMMARY			
Society membership and administration (note 1)		(28.525)	130.873
Sponsorship (note 2)		102.583	134.424
Conferences, courses etc. (note 3)		(537.185)	254.893
Prosthetics and Orthotics International (note 4)		(83.474)	(12.075)
Publications (note 5)		7.326	3.206
Investment income (note 6)		292.612	539.433
Primary result		(246.663)	1.050.754
Depreciation (note 7)		(24.313)	—
Write-down of securities to market value		(124.000)	—
Result for the year	DKK	(394.976)	1.050.754

Balance sheet as of December 31, 1987

ASSETS		
Cash	15.746	148.742
Accounts due		
Advertising due	0	13.510
Dividend tax due	16.463	779
Prepayments	30.235	—
Accrued interest	109.487	157.733
Advance funding of World Congress 1980	87.437	119.690
	243.622	291.712

			1986
Securities (note 8)		2.998.037	3.317.768
Office equipment (note 7)		97.254	—
	Total Assets	DKK 3.354.659	3.758.222
LIABILITIES AND CAPITAL			
Liabilities			
Short-term liabilities			
Bank dept		141.271	—
Accrued expenses		35.766	59.469
Prepaid advertising income		26.249	72.408
Prepaid subscription income		—	79.996
		DKK 203.286	211.873
Provision		DKK 87.437	119.690
Capital			
Capital January 1, 1987		3.426.659	2.495.595
Receipt of Advance Funding of World Congress 1980		32.253	(119.690)
		3.458.912	2.375.905
Result for the year		(394.976)	1.050.754
Capital December 31, 1987		DKK 3.063.936	3.426.659
	Total Liabilities and Capital	DKK 3.354.659	3.758.222
Contingent liabilities (note 9)			

Notes to the Financial Statements

1. SOCIETY MEMBERSHIP AND ADMINISTRATION

Income			
Membership — fees			709.289
Expenditure			
Executive Board and officers:			
Travel and hotel		(226.906)	
Meeting expenses		(45.427)	
Meeting in other organizations		(61.953)	(334.286)
Secretariat, Copenhagen:			
Travelling expenses, Honorary Secretary and Treasurer		(40.343)	
Staff salaries		(252.811)	
Data service		(14.084)	
Stationery printing		(16.716)	
Office supplies		(2.499)	
Accountant		(47.720)	
Telephone		(4.759)	
Postage		(20.652)	
Maintenance		(3.427)	
Sundries		(517)	(403.528)
		DKK	(28.525)

2. SPONSORSHIP

Contribution from the War Amputations of Canada		27.583
Contribution from SAHVA		75.000
	DKK	102.583

3. CONFERENCES, COURSES etc.

World congress 1986		1.015
World congress 1989		(1.423)
Miami AK socket Workshop		(144.682)
Strathclyde Education Workshop		(238.022)
Cairo Developing Countries Conf.		(47.575)
Israel, Traumatic Amputee Conf.		(106.735)
Heidelberg 88, Limb Deficient Child Course		237
	DKK	(537.185)

4. PROSTHETICS AND ORTHOTICS INTERNATIONAL

Income		
Advertising		110.997
Subscriptions		172.104
	DKK	283.101
Expenditure		
Printing		(241.763)
Mailing inclusive of labels		(48.671)
Editorial costs		(35.864)
Committee meeting, Publication		(40.277)
	DKK	(366.575)
		(83.474)

5. PUBLICATIONS

Book sale		7.326
	DKK	7.326

6. INVESTMENT INCOME

Bonds		
Maturity yield		(10.749)
Interest		228.926
	DKK	218.177
Shares		
Dividends	DKK	74.060
Bank account		
Interest		5.307
	DKK	5.307
Expenditure		
Safekeeping fee, bank expenses etc.	DKK	(4.932)
Result	DKK	292.612

7. DEPRECIATION

Office equipment		
Computer equipment (at cost)		95.347
Office furniture (at cost)		26.220
	DKK	121.567
Depreciation (20% p.a.)	DKK	(24.313)
Office equipment	DKK	97.254

8. SECURITIES

	Rate		Face value	Market value 31/12–87
Bonds	31/12–87			
12% Dansk Statslån S.2001	100,00		692.000	692.000
10% Dansk Statslån S.2004	90,20		482.000	434.764
12% Kreditf. Danmark 22.S.2007	96,25		805.000	774.813
		DKK	1.979.000	1.901.577
Investment trust units				
Sparinvest, D	194,50		90.000	175.050
Privatinvest 2	430,00		38.000	163.400
Privatinvest 5	91,00		450.000	409.500
Investor-Maximum	95,00		343.000	325.850
		DKK	921.000	1.073.800
Shares				
Københavns Handelsbank EM 87	221,00		2.000	4.420
Handelsbank	228,00		8.000	18.240
		DKK	10.000	22.660
Total result		DKK	2.910.000	2.998.037

9. CONTINGENT LIABILITY

The association is involved in a court trial in connection with the World Congress 1980. The association might be liable to additional cost in this connection. The outcome is at present uncertain.

ERRATUM

Mechanical assessment of polyurethane impregnated fibreglass bandages for splinting.

R. Wytch, C. B. Mitchell, D. Wardlaw, W. M. Ledingham and I. K. Ritchie, Prosthetics and Orthotics International, Vol. 11 No. 3, 128–134.

Please note that the illustrations which form Figures 3 and 4 of the above paper should be transposed.

Prosthetics and Orthotics International, 1988, 12, 6–8

Executive Board Meeting

9th and 10th January, 1988

The following paragraphs summarize the major discussions and conclusions of the last Executive Board Meeting held in Copenhagen. They are based on the draft minute of that meeting which has not yet been approved by the Executive Board.

Chairman and Task Officer Reports

The Honorary Treasurer submitted a preliminary report of the expenditure for 1987, an account of which can be seen elsewhere in this edition of the Journal. He indicated that there was a relatively large deficit, mainly due to the Society's high level of activity during the year, and specifically related to the organization of the workshops on Narrow Mediolateral Sockets and on the Upgrading of Short Course Trained Technicians in Developing Countries. The Honorary Treasurer presented the proposed budget for 1988 in which he anticipated a net gain of 80,000 Danish Kroner. However, a number of ongoing activities would require further funding for which reserves are available. The net effect might be a deficit for the year. The International membership fee for 1989 was set at 400 Danish Kroner. This fee has now been steady for the past seven years and it is anticipated that it will have to be raised in 1990 in order that the Society may continue with its diverse activities.

The Protocol Committee had discussed certificates for locally run courses. The Executive Board agreed that the issue of such certificates should not be the responsibility of the International Society, but rather that of the organizing National Member Society. These certificates should carry the ISPO logo, the name of the National Member Society and should be signed by the Chairman of the National Member Society concerned. The Protocol Committee is preparing a suggested layout for such a certificate and this will be submitted to the next Executive Board meeting. The Protocol Committee had also discussed guidelines for the production of printed material to assist people organizing meetings for the Society. The draft of these guidelines would be prepared for the next Board meeting.

The Executive Board formally approved the formation of the Indian National Member Society. An announcement of this can be seen elsewhere in this edition of the Journal. The Honorary Secretary reported that there had been a modest increase in the total membership and in the number of subscribers to the Journal over the past year. Current membership is 1865 and there are also 360 subscribers to the Journal. The possibilities of establishing National Member Societies in the German Democratic Republic, Taiwan and France are currently being explored.

The Task Officer for Education reported on a successful meeting on the Upgrading of Short Course Trained Technicians in the Developing Countries held in Scotland in July 1987. The Report of that meeting was nearing completion and would be published in the near future. The protocol for the inspection of prosthetics and orthotics education centres was now almost complete. This document would then be used to inspect centres requesting recognition by the Society. At present the schools in Moshi, Tanzania and Lome, Togo have been approved. Enquiries with regard to recognition had been received from the schools in Iraq and Jordan.

The Chairman of the Publications Committee reported that the Dundee '85 publication was now at proof stage and would be printed in the near future. The first International Newsletter was published in the December 1987 issue of the Journal and the membership is encouraged to send news items to the Editors, Ms. J. Edelstein (USA) and Mr. D. Condie (UK). Plans are being made to publish the Proceedings of the Heidelberg Conference on the Limb Deficient Child, and the President Elect indicated that there were also plans to publish the Proceedings of Protech II.

Work is continuing in the International Standards Organizations Technical Committee 168, "Prosthetics and Orthotics". The Working Groups of this Technical Committee have been examining Nomenclature and Classification, Medical Aspects, and Testing of Lower Limb Prostheses and have prepared draft standards which will be discussed by the Technical Committee in April.

The Task Officer for the Limb Deficient Child indicated that it was hoped to form a committee for this area, the first meeting of which would take place prior to the Heidelberg Meeting.

It was agreed to hold a workshop on CAD/CAM and Socket Design in Seattle in June 1988. It was the intention that this workshop should bring together people active in this field world-wide. A report of this meeting would be presented at the ISPO World Congress in Japan and also be made available to National bodies as a guide to future policy and action.

Work on the Professional Register was progressing and it was indicated that a pilot study of the proposed questionnaire would be carried out using the Executive Board Members as subjects.

International Organizations

The President of INTERBOR thanked the Society for their collaboration in the successful Barcelona meeting. He assured the Board that INTERBOR would collaborate with the Japanese organizers to ensure the success of the Society's VI World Congress in Japan. It was suggested that a meeting of the ISPO/INTERBOR Education Commission should be arranged in the near future in order to discuss prosthetics and orthotics education and training in light of the proposed Directive on reciprocal recognition of vocational training within the European Economic Community (EEC).

The Honorary Secretary had attended the meeting convened by the World Health Organisation (WHO) which examined matters related to the improvement of production and delivery of lower limb appliances in developing countries. The main outcome of the meeting was that WHO wished to identify appropriate devices for use in developing countries, establish technical criteria for them, select a few models of each type of device and produce manuals which would fully describe their manufacture and fitting. In addition, WHO hoped to look at curricula for professional and para-professional groups involved in the provision of devices and prepare and publish suitable educational material for them. The Executive Board agreed that the Society should collaborate with WHO in this project. The Honorary Secretary, the Task Officer for Education and Andries Du Bont (Netherlands) had attended a workshop organized by the African Rehabilitation Institute (ARI) in Cairo. The purpose of this meeting was to examine the provision of low-cost aids and appliances for use in Africa. Amongst the recommendations made by the meeting was the need to develop an information bank with regard to the availability of materials in Africa as well as suitable components and devices which could be produced in Africa. Additionally, the workshop confirmed the need to have properly educated and trained personnel to fit these devices.

The Executive Board agreed to collaborate with Internationaler Verband der Orthopadie-Schuhtechniker (IVO), the international association of orthopaedic shoe-makers, in the form of reciprocal representation at Executive Board Meetings. The Society had run a joint session with World Orthopaedic Concern (WOC) at the Societe Internationale de Chirurgie Orthopedique et de Traumatologie (SICOT) meeting in Munich, 16th–21st August, 1987 which proved to be very successful. The President was invited to attend the next WOC Board meeting to be held in April in the UK during which ways of extending the Society's collaboration with WOC would be explored.

The Board agreed that ISPO's representatives to the United Nations (UN) should be Melvin Stills and Dick Lehneis at New York, and Sepp Heim and Jean Vaucher at Geneva/Vienna. The United Nations Development Programme (UNDP) is arranging a meeting in Tanzania in July 1988 which would be held in conjunction with Deutsche Gesellschaft fur Technische Zusammenarbeit (GTZ) and in collaboration with ISPO. This meeting would attempt to help develop awareness, amongst rehabilitation professionals from the developing world, of the possibilities of producing simple and indigenous devices in their countries.

Congresses

The organization of the VI World Congress was now well advanced. The Scientific programme was finalized and the Japanese Organizing Committee were given authority to make any further decisions with regard to finalization or minor modification of the programme. It was agreed that the Blatchford and Forchheimer Prizes be presented at the next World Assembly of the Society associated with the World Congress. Seishi Sawamura agreed to report to the next Executive Board meeting any further developments with regard to the Japanese Congress.

The Executive Board asked for further information from Sweden, USA and Israel with regard their invitations to host the 1992 Congress.

Conferences

a) The Symposium on the 'Traumatic Amputee' was successfully held in September 1987 in Israel and was attended by 150 people.

b) Protech II was held in Groningen, Netherlands in October 1987 and attracted large numbers of participants from the Netherlands, Belgium and Germany. More than 300 people attended.

c) Arrangements for the Symposium on the 'Limb Deficient Child' to be held in Heidelberg, Federal Republic of Germany, 27th August to 1st September, 1988 had now reached an advanced stage. A number of queries were raised with regard to budget, venue and social events. It was agreed that Ernst Marquardt, Sepp Heim and Rene Baumgartner should meet with the Symposium Organizers with regard these questions. Publication of the Proceedings was presently being explored.

d) Planning for the Symposium, on "Wheelchairs and Special Seating", Dundee, Scotland, 12th–16th September 1988, was well advanced. Further details will be circulated shortly.

e) A proposal to hold a Conference in Sweden on the "Deformed Foot and Orthopaedic Footwear" was being examined. It was suggested that this should be held in June, 1990. It was agreed that the Swedish National Member Society should continue with the planning of this Conference and report to the next Executive Board meeting.

Tape Slide Set

Melvin Stills reported that a set of slides and a marked text had now been prepared. Copies are now available to National Member Societies on request.

Interim meeting of the International Committee

The Executive Board discussed the possibility of an Interim Meeting of the International Committee at the time of the next Board Meeting in Heidelberg. It was decided that the Society's financial situation did not allow for such a meeting to be held.

Fellowships

Fellowships have been awarded to M. K. Goel (India), M. Dewar (UK), P. Christianssen (Denmark).

Norman A. Jacobs
Honorary Secretary

Prosthetics and Orthotics International, 1988, 12, 9–18

Lower limb amputations in Southern Finland 1984–1985

T. POHJOLAINEN and H. ALARANTA

Invalid Foundation Orthopaedic Hospital, Helsinki, Finland

Abstract

To assess the current epidemiological situation concerning lower limb amputations in southern Finland the data on all amputations made in the catchment area of the Helsinki University Central Hospital were analysed for the period 1984–85. During the two-year period, 880 amputations of lower limbs were performed on 705 patients. The amputation rate was 32.5 per 100,000 inhabitants in 1984 and 28.1 in 1985. Patients requiring amputation were arteriosclerotics in 43.1 per cent. and diabetics in 40.7 per cent. Diabetics underwent amputation 3 years younger on average than the arteriosclerotics. The most common site of unilateral amputations was above-knee (42.0 per cent) followed by below-knee (27.7 per cent) and toe amputations (22.2 per cent). The level of amputation tended to become more proximal with increasing age of the patients. The overall mortality figure during three postoperative months was 27.0 per cent. Amputation incidence increased sharply with increasing age. On the base of predictions, the overall age structure of the Finnish population will shift upward causing an increase in the proportion of elderly age groups. A 50% increase in amputation rate is expected in Finland within the next 20–30 years.

Introduction

In the last few years, there has been an increase in the number of amputations in Scandinavia and other Western countries (Hansson, 1964; Lindholm, 1964; Tibell, 1971; Kihnm et al., 1972; Hierton & James, 1974; Mooney et al., 1976; Liedberg & Persson, 1983). Vascular insufficiency is a major cause of peace-time amputations of the lower limbs. Amputations resulting from end-stage peripheral vascular diseases are an increasingly common health problem (Mooney et al., 1976; Fleurant & Alexander, 1980; Bodily & Burgess, 1983). Although advances in peripheral vascular surgery have salvaged a great number of limbs, many arterial occlusions in lower extremities are still irreversible, and amputation remains the only answer if arterial reconstruction is not possible or has failed (Finch et al., 1980). New, refined or alternative methods of treatment of osteomyelitis, neoplastic tumours and traumatic conditions have lessened the need for amputations in these conditions (Vilkki & Göransson, 1982; Chen & Zeng, 1983; Vilkki, 1986).

Despite the extensiveness of Finnish medical statistics compiled by the National Board of Health, no regular reports are available on the number and types of amputations performed nor on the constitution and size of the amputee population. There are no general official statistics on the number and types of prostheses prescribed in Finland. In Scandinavia, there is an amputation register in Denmark (Ebskov, 1983; Ebskov, 1986), and in Sweden Hansson (1964) has published a well-documented study on the amputee population.

There is a specific requirement for amputee statistics for the planning of prosthetic rehabilitation of amputee patients and the evaluation of future needs in personnel, facilities and funds. To assess the current epidemiological situation concerning amputations in southern Finland, the data on all limb amputations made in the catchment area of the Helsinki University Central Hospital were collected for the period 1984–1985. The purpose of the study was to determine the incidence, causes and levels of lower limb amputations.

Material and methods

The catchment area of Helsinki University Central Hospital (HUCH) had a population of 1,159,000 in 1984 and 1,171,000 in 1985.

All correspondence to be addressed to Mr. T. Pohjolainen, Invalid Foundation Orthopaedic Hospital, Tenholantie 10,00280 Helsinki, Finland.

corresponding to 24 per cent of the population of Finland. A total of 82.9 per cent of the population under study lived in 14 cities and 17.1 per cent in rural areas.

The HUCH catchment area includes 16 surgical hospitals where amputations can be performed. During the period 1984–85 data concerning amputees in all the 16 operative units were collected. Every patient's hospital record was examined thoroughly with any data concerning demographic factors, diagnoses, amputation levels and postoperative complications being recorded manually. Mortality and times of death were investigated in collaboration with the national Social Insurance Institution. All the collected data were computerized for analysis.

Results

During the two-year period, 880 amputations of the lower limbs were performed on 705 patients. Of the 705 patients, 382 (54.2 per cent) were female and 323 (45.8 per cent) male. The amputation rate was 32.5 per 100,000 inhabitants in 1984 and 28.1 in 1985. Some 29.3 and 25.0 per 100,000 of the population underwent an amputation for the first time in 1984 and 1985, respectively. Lumbar sympathectomy, vascular reconstructive operation, arterial embolectomy, trombendarterectomy or a combination of these preceded the amputation in the case of 168 patients, corresponding to 23.8 per cent of all the amputees and 27.1 per cent of vascular amputees.

A total of 73 patients (10.4 per cent) had undergone an amputation prior to 1984 at a lower level or in the contralateral limb. Of these 73 patients, 72 were amputated because of vascular disease. Of the latter, 40 (54.8 per cent) were diabetics, 30 (41.1 per cent) arteriosclerotics and 2 (2.7 per cent) had Buerger's disease. There were 27 (37 per cent) above-knee amputations, 33 (45.2 per cent) below-knee amputations and 13 (17.8 per cent) metatarsal or toe amputations.

Diagnosis, sex and age

Obliterative arteriosclerosis was the diagnosis of 591 amputees (83.8 per cent). Of the 705 patients of the study, 304 (43.1 per cent) had arteriosclerosis without diabetes and 287 (40.7 per cent) had diabetic microangiopathy (Table 1). Vascular insufficiency resulting from embolic disease was the primary cause of amputation in 27 patients and Buerger's diseases in three patients. Tumours were the cause in 17 cases, trauma in 14 cases and frostbite in 31 cases. A total of 17 amputations were performed for other reasons.

Diagnosis, age and sex distributions of the

Table 1. Diagnosis and mean age of amputees at the time of first amputation

Diagnosis	Amputees				Age (years)					
	Women	Men	Total	Per cent of diagnoses	Women $\bar{x}$	SD	Men $\bar{x}$	SD	Total $\bar{x}$	SD
Arteriosclerosis without diabetes	149	155	304	43.1	79.6	8.4	71.0	10.7	75.0	11.2
Arteriosclerosis with diabetes	187	100	287	40.7	74.8	10.0	66.9	12.7	72.0	11.6
Frostbite	4	27	31	4.4	47.5	19.8	51.3	13.6	50.8	14.2
Embolism	19	8	27	3.8	73.1	10.8	67.4	4.8	71.4	9.6
Tumour	8	9	17	2.4	50.4	23.9	29.4	23.4	39.3	25.6
Trauma	5	9	14	2.0	43.6	26.3	39.4	18.9	40.9	20.9
Deformity	6	3	9	1.4	71.8	10.0	54.0	30.0	65.9	19.1
Osteomyelitis	1	5	6	0.9	87.0		59.8	19.6	63.3	20.7
Buerger's disease		3	3	0.5			44.0	8.7	44.0	8.7
Vasculitis	2		2	0.3	38.0	2.8			38.0	2.8
Artery aneurysm		2	2	0.3			74.5	3.5	74.5	3.5
Congenital deformity		1	1	0.1			4.0		4.0	
Chronic ulcer		1	1	0.1			73.0		73.0	
Total	382	323	705	100.0						

amputees are shown in Table 2. Most of the arteriosclerosis patients, 73 per cent, were over 70 years of age. The proportion of under 70-year-olds was 14.1 per cent among the female and 39.4 per cent among the male arteriosclerotic patients. The largest arteriosclerotic amputation group, 39.8 per cent, were the over 80-year-olds. Most of the diabetics, 61.3 per cent, were amputated at the age of 60-79 years. Among the diabetics, 23.5 per cent of the female and 55 per cent of the male patients underwent amputation before the age of 70. Patients undergoing amputation for embolism were mostly (92.6 per cent) over 60 years of age. Men dominated among traumatic amputees. The majority of traumatic amputees, 11 patients (78.6 per cent), were younger than 60. After vascular disease the second most common reason for amputation was frostbite. The patients amputated for frostbite were mostly men (87.1 per cent) and the largest group, 48.4 per cent, were the 50–59-year-olds. Patients amputated for tumours were encountered mostly in the younger age groups, with 76.5 per cent being amputated before the age of 60. Of all the 20 patients amputated before the age of 30, 40 per cent were amputated for tumours, 25 per cent for trauma, 15 per cent for frostbite, 15 per cent for deformities and one person for diabetic complications.

The diabetics as a rule were somewhat younger at the time of amputation than were those with arteriosclerotic gangrene. The mean age was 72 years for diabetics and 75 years for non-diabetics (Table 1). The proportion of men and women was equal in the group of arteriosclerotic gangrene amputees, while in the group of diabetics the majority were women. The male diabetics and non-diabetics were distinctly younger than the corresponding female groups.

Patients who underwent amputation for embolism did not differ much in age from the arteriosclerotic and diabetic patients. Only two persons amputated for embolism were under 80 years of age. Embolectomy preceded amputation in the case of 14 patients.

Amputees with tumours and trauma were considerably younger than average, their mean ages being 39.3 years and 40.9 years, respectively (Table 1). The mean age of the two women with LED vasculitis was 38 years. The mean age of the three men with Buerger's disease was 44 years.

Figure 1 shows the distribution of amputees according to age. The proportion of the total number of amputees in each age group increased progressively up to the 70–79-year-group. The latter constituted the largest ten-year cohort, representing 33.6 per cent of all the 705 amputees. More amputations were performed on males than on females in all age groups under 60 years; but females formed the majority among amputees over 70 years of age. The overall ratio of men to women in the entire material (705) was 0.8.

The annual incidence of amputations was also estimated in relation to the population of

Table 2. Diagnosis, age and sex of amputees

Cause of amputation	n	Men/Women	Age at time of amputation (years)				
			0–49	50–59	60–69	70–79	80–
Arteriosclerosis without diabetes	304	155/149 = 1.0	6	25	51	101	121
Arteriosclerosis with diabetes	287	100/187 = 0.5	18	13	68	108	80
Frostbite	31	27/4 = 6.8	9	15	2	5	
Embolism	27	8/19 = 0.4	1	1	8	14	3
Tumour	17	9/8 = 1.1	10	3	1	2	1
Trauma	14	9/5 = 1.8	8	3	2	1	
Deformity	10	4/6 = 0.7	3	2	1	3	1
Osteomyelitis	6	5/1 = 5.0	1		3		2
Buerger's disease	3	3/0	2	1			
Miscellaneous	6	3/3 = 1.0	1	1	1	3	
Total	705	323/382 = 0.8	59	64	137	237	208
Per cent			8.4	9.1	19.4	33.6	29.5

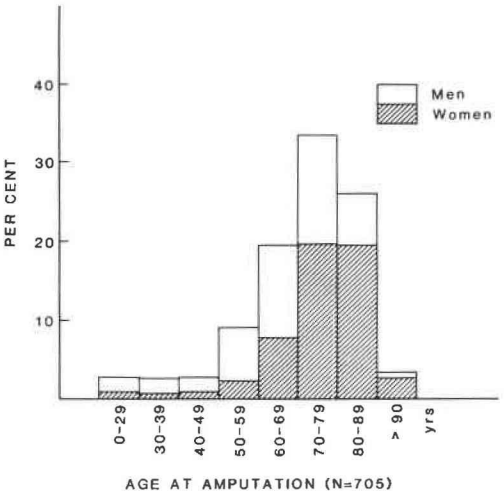

Fig. 1. Proportions of different age groups and sex among the amputees.

different age groups in the study area. No significant differences in incidence were found between males and females. A logarithmic increase in the frequency of amputations was noted with increasing age (Fig. 2). The annual incidence of new amputations in the over-80 age group exceeded 400 per 100,000 inhabitants in both sexes.

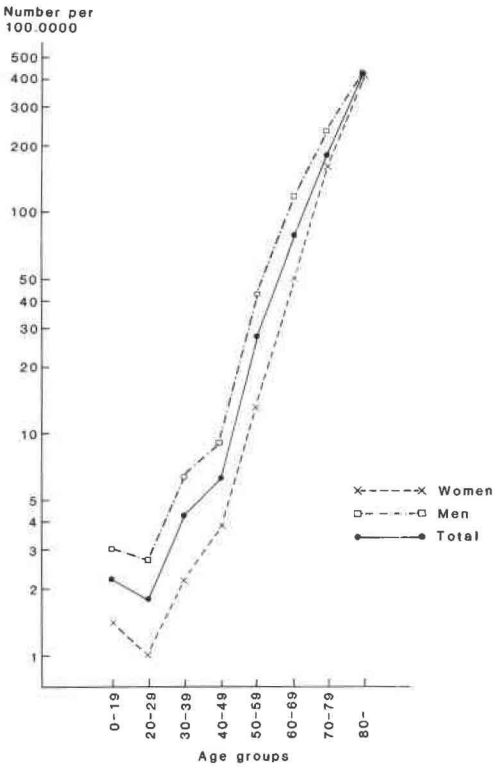

Fig. 2. Annual incidence of amputation in different age groups (logarithmic scale).

Levels of amputation

Two-thirds of all the amputations were performed at a level requiring a prosthesis: at the thigh, shank, ankle or foot. There were 841 unilateral (95.6 per cent) and 39 bilateral (4.4 per cent) amputations. The most common unilateral amputations regarding site were the above-knee amputations (42.0 per cent) followed by below-knee (27.7 per cent) and toe amputations (22.2 per cent) (Table 3). Of the 195 toe amputations, two-thirds required amputation of only one toe. Other types of amputations were quite rare.

Table 3. Distribution of 841 unilateral amputations according to level of amputation.

Type of amputation	Number of amputations	Per cent
Hemipelvectomy	1	0.1
Hip disarticulation	8	0.9
Above-knee	353	42.0
Below-knee	233	27.7
Syme	4	0.5
Chopart and Pirogoff	3	0.4
Lisfranc	11	1.3
Transmetatarsal	33	3.9
Toe amputation	195	23.2
Total	841	100.0

The level of amputation tended to become somewhat more proximal with increasing age of the patients (Fig. 3). Amputation level was also correlated with diagnosis and cause of amputation. Tumours at a young age often appeared to be associated with above-knee amputations. Of the 17 tumour patients, 13 (76.5 per cent) had above-knee amputation, one had hemipelvectomy, one had hip joint disarticulation, one had below-knee amputation and one had toe amputation. Of the 14 traumatic amputations, only three (21.4 per cent) were above-knee. Some 61.7 per cent of the female arteriosclerotic patients and 36.9 per cent of female diabetics were amputated above-knee. The corresponding figures for men were 51 and 28 per cent. The group of 27 embolic patients included 19 (70.4

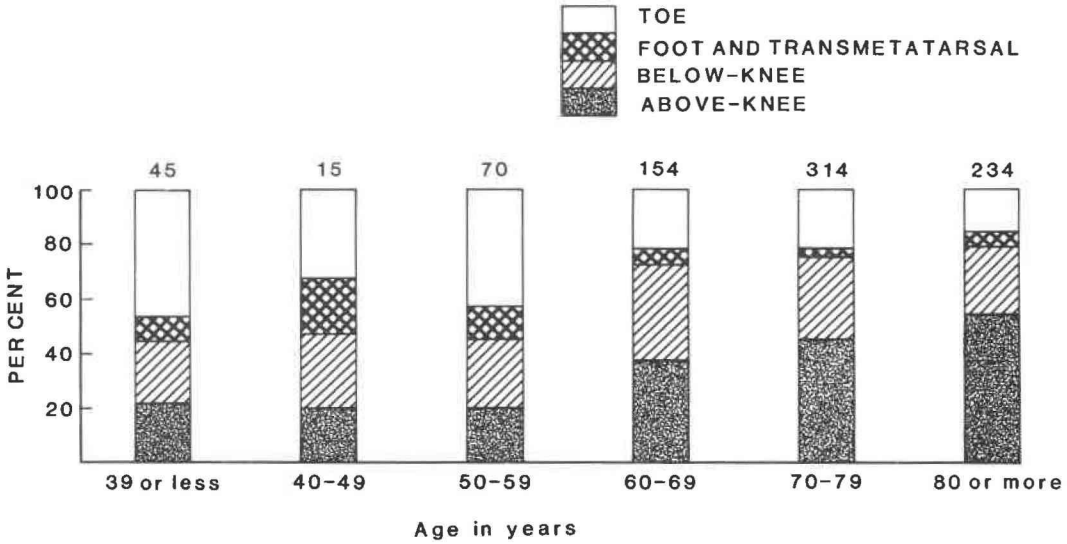

Fig. 3. Level of amputation in relation to age in 832 unilateral amputations (one unilateral hemipelvectomy and eight unilateral hip disarticulations not included).

per cent) unilateral above-knee amputations and one hip joint disarticulation, six below-knee amputations and two bilateral above-knee amputations.

Bilateral amputations

Concurrent bilateral amputation was performed on 39 patients (Table 4), 25 men and 14 women. Among these bilateral amputees, the 70–79-year-group was the most numerous with 12 patients, followed by the 50–59-year-group with 11 amputees. There were five patients younger than 50: one woman amputated for LED vasculitis and four men amputated for frostbite. The largest group according to site were the bilateral toe amputees with 12 patients, followed by a group of nine bilateral above-knee amputees. The cause of bilateral amputation was peripheral vascular disease in 20 patients (51 per cent). Diabetic gangrene was the cause in eight and arteriosclerotic gangrene in 12 patients. Frostbite was the cause of a bilateral amputation in 15 patients (38.5 per cent). Other causes included embolism in two patients, LED vasculitis in one patient and chronic ulcer in one patient.

Table 4. Bilateral amputations

Type of amputation	n	Per cent
Above-knee/above-knee	9	23.1
Above-knee/below-knee	1	2.6
Below-knee/below-knee	5	12.8
Below-knee/toe	5	12.8
Tmt/tmt	7	17.9
Toe/toe	12	30.8
Total	39	100.0

Table 5 shows the situations of the 705 amputees at the end of 1985. Previous amputations, amputations during the study period, reamputations and contralateral amputations are included. There were 82.4 per cent unilateral and 17.6 per cent bilateral amputees.

Mortality

Of all the 705 patients, 127 (18 per cent) died during the postoperative hospitalization period. The immediate causes of death are shown in Table 6, indicating that the majority died because of cardiac (37.8 per cent) and pulmonary (27.5 per cent) diseases.

The overall mortality figure during three postoperative months was 190 (27 per cent). A total of 135 patients died during the first month, 31 during the second month and 24 during the third month.

Only five (2.6 per cent) of the deceased patients were under 60; three of these were male arterio-sclerotics, one a male and one a female diabetic. All five died within the first postoperative month.

A total of 187 (98.4 per cent) of the 190 patients who died during the first three months

Table 5. Amputation levels of the 705 amputees at the end of the study period.

Type of amputation	n	Per cent
Unilateral		
Above-knee	288	40.9
Below-knee	156	22.1
Toe amputation	110	15.6
Foot amputation[1)]	19	2.7
Hip disarticulation	7	1.0
Hemipelvectomy	1	0.1
Bilateral		
Above-knee/above-knee	41	5.8
Below-knee/below-knee[2)]	25	3.6
Above-knee/below-knee	23	3.3
Tmt/tmt[3)] or toe/toe	13	1.8
Below-knee/toe	11	1.6
Below-knee/foot	5	0.7
Above-knee/tmt	3	0.4
Foot/toe	2	0.3
Hip disarticulation/ aboveknee	1	0.1
Total	705	100.0

1) Includes Pirogoff, Chopart, Lisfranc and transmetatarsal amputations.
2) Includes one Syme/Syme amputation.
3) Tmt = transmetatarsal.

were amputated for vascular insufficiency. Patients who died within three months of the amputation comprised 95 (50 per cent) arteriosclerotic and 79 (41.6 per cent) diabetic gangrene amputees, 12 (6.3 per cent) embolic amputees, one tumour amputee, one patient was amputated for aortic aneurysm, one for chronic bilateral leg ulcer and one for leg deformity. Of the 95 arterio-sclerotics, 50 (52.6 per cent) were female and 45 male (47.4 per cent). Of the 79 diabetics, 56 (70.9 per cent) were female and 23 (29.1 per cent) male. All the 12 deceased amputees with embolism were female and 11 of them died during the first month. Thirty (24.2 per cent) of the 124 patients amputated bilaterally died during the first three months.

In the group of arteriosclerotics who died postoperatively, 64 (67.4 per cent) had undergone above-knee amputation, nine (9.5 per cent) below-knee amputation and eight (8.4 per cent) bilateral amputation. For the deceased diabetics, the amputation level was above-knee in 34 (44.3 per cent) and below-knee in 20 (25.3 per cent) cases; bilateral amputation was done in 20 (25.3 per cent) cases. Other amputations were distal ones. The deceased embolic patients had been amputated above-knee in eight (66.7 per cent) and below-knee in two cases; there was one hip jont disarticulation and one bilateral above-knee amputation.

Table 6. Causes of death during hospitalization.

Cause of death	n	Per cent
Myocardial infarction	27	21.3
Other heart disease	21	16.5
Pneumonia	21	16.5
Pulmonary embolus	14	11.0
Septicaemia	10	7.9
Gangrene of lower limb	7	5.5
Cerebrovascular	4	3.2
Diabetes mellitus	2	1.6
Other causes	14	11.0
Unknown	7	5.5
Total	127	100.0

Discussion

Any conclusions drawn from the foregoing data are, strictly speaking, valid only regarding the catchment area of the Helsinki University Central Hospital. The criteria for amputation applied by different hospitals may vary; also, the rate of amputation will be affected by the age distribution and geographic background. The study area and whole of Finland are quite similar in demographic structure. In the study area, the proportion of under 60-year-olds was 83.8 per cent, that of 60-69-year-olds 8.1 per cent and that of over 70-year-olds 8.1 per cent at the time of study. The corresponding figures for the whole of Finland were 82.5, 8.9 and 8.6 per cent. This close demographic similarity allows some nationwide conclusions to be drawn from the results presented here.

The rate of amputations has clearly increased in the studied area compared with 1972. In 1972, 190 lower limb amputations were done on 151 patients in the same area (Solonen et al., 1973), whereas in 1984 and 1985, the number of amputees was 376 and 329, respectively. These figures correspond to an amputee rate of 15.2 per 100,000 inhabitants in 1972, 32.5 in 1984 and 28.1 in 1985. These yearly incidences are in the same order as that reported for Malmöhus County in Sweden, where the incidence was

32.0 per 100,000 inhabitants in 1979 (Liedberg & Persson, 1983). In 1970, the number of lower limb amputations was estimated at 800 for the whole of Finland (Solonen et al., 1973). Similarly, the incidence for 1984–85 reported here corresponds to a national total of 1,592 amputations in 1984 and 1,375 in 1985.

In Finland, the proportion of over 60-year-olds has increased between 1970 and 1984 – 1985. In 1970, 75 per cent of all lower limb amputees were over 60 years of age (Solonen et al., 1973) whereas in 1984–85 85 per cent of all lower limb amputees and 89 per cent of vascular amputees were over 60 years old. In Alffram & Holmquist's (1961) series in Sweden, 76.5 per cent of amputees were over 60 years old. In their survey, Finch et al. (1980) reported 89 per cent as the corresponding figure in British population. In Finland, in 1970 the proportion of 60-69-year-olds among lower limb amputees was 29 per cent, that of the 70–79 age group 31 per cent and that of the over-80 age group 15 per cent (Solonen et al., 1973). The figures for 1984–85 were 19.4 per cent, 33.6 per cent and 29.5 per cent, respectively.

Figure 2 illustrates the sharp increase of amputation incidence with increasing age. Most of the demonstrated overall increase in amputation rate is explained by increases in the older age groups, by the growing number of gangrene amputees as well as by the increase in the incidence of vascular diseases often making amputation unavoidable. The proportion of elderly amputees has increased during the last 40 years in the Western countries (Table 7). It is predicted that the overall age structure of the population will continue to shift upward causing an increase in the proportion of elderly age groups (data supplied from the Central Statistical Office of Finland). On the base of these predictions and the observed amputee incidence in different age groups in 1984-85, an estimate of the future trend in the number of amputations in the whole of Finland is drawn up in Figure 4. The increase in the proportion of the over-60 population will be responsible for an increase in amputation rate because the risk of becoming an amputee rises with increasing age (Hansson, 1964; Fleurant & Alexander, 1980; Borssén & Lithner, 1984). It is conceivable, however, that the future increase in amputations may turn out to be even higher than that estimated on the basis of demographic changes (Liedberg & Persson; 1983).

Table 7. Proportion of patients aged 80 or older among those amputated for vascular diseases.

Period	Authors	n	Proportion
1949–59	Alffram & Holmquist	125	0.08
1947–61	Hansson	261	0.19
1950–63	Vankka	184	0.12
1961–71	Christensen	326	0.18
1965–71	Weaver & Marshall	105	0.14
1973–77	Renström[1)]	200	0.27
1979	Liedberg & Persson	161	0.38
1984-85	Present study	621	0.33

1) Below-knee amputations only.

According to Western statistics, over 80 per cent of all lower limb amputations result from complications of peripheral vascular diseases (Alffram & Holmquist, 1961; Hansson, 1964; Kihn et al., 1972; Fleurant & Alexander, 1980; Helm et al., 1986). In this study vascular diseases were found to be the cause of amputation in 88 per cent of patients. This proportion has increased compared with 1970

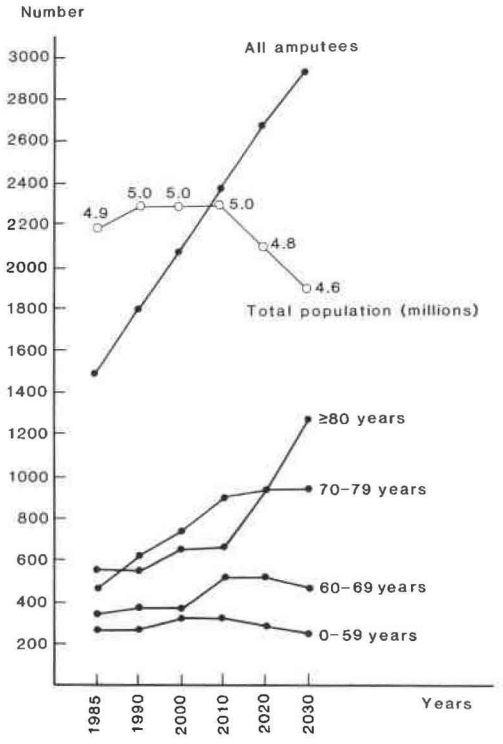

Fig. 4. Future trend in the number of amputees and separately in different age groups in the whole of Finland estimated on the basis of the age-related incidences in the study area in 1984–85. Predicted Finnish population is also shown.

when 75 per cent of amputations were caused by vascular insufficiency (Solonen et al., 1973). Arteriosclerosis has been found to be the dominating cause of amputations in patients with vascular disease (Warren & Kihn, 1968; Burgess et al., 1971; Christensen, 1976; Helm et al., 1986), as also in this study. In Sweden, the United States and Singapore diabetic microangiopathy has been the most common diagnosis (Table 8). The proportion of diabetes as the cause of amputation in Finland does not differ from that found in other Western countries. The possibility cannot be ruled out, however, that some patients with arteriosclerosis may become included in the embolism group and vice versa because the emboli can complicate primary arteriosclerosis. There was a decrease between 1970 and 1984–85 in the relative number of victims of accidents. In 1970, trauma caused 12 per cent of all amputations (Solonen et al., 1973) whereas the corresponding figure was only 2 per cent in 1984–85. The decrease in the number of amputations due to trauma may be largely explained by improved industrial safety, and also by the advance in replantation surgery (Cheng & Zeng, 1983; Øestrup & Vilkki, 1986).

The age of amputated diabetic gangrene patients was lower than that of arteriosclerotic gangrene patients, a situation also observed in Swedish studies (Hansson, 1964; Christensen, 1976). An even more pronounced age difference was found between female and male arteriosclerotic and diabetic gangrene patients.

Table 8. Proportion of diabetics among patients amputated for vascular diseases.

Period	Authors	n	Proportion
1947–61	Hansson	269	0.53
1949–59	Alffram & Holmquist	125	0.49
1959–65	Lindahl & Bolund	183	0.40
1961–71	Christensen	326	0.46
1964–70	Burgess et al.	193	0.52
1967–69	Hierton & James	94	0.60
1965–71	Weaver & Marshall	105	0.31
1966–71	Persson & Sunden	143	0.37
1971–73	Mooney et al.[1)]	190	0.66
1973–77	Renström[1)]	183	0.54
1974–78	Finch et al.	133	0.32
1976–79	Helm et al.	231	0.24
1979	Liedberg & Persson	161	0.37
1978–80	Tan et al.	262	0.59
1984–85	Present study	621	0.46

1) Below-knee amputations only.

The degree of male dominance among amputees varies according to the age distribution of patients studied. Series of younger amputees show a more marked preponderance of men (Jansen, 1960; Hirch, 1961). In this study, too, men dominated in age groups younger than 70 with a proportion of 67 per cent, whereas women were in majority among the over 70-year-olds with a proportion of 66 per cent. In the 30–39 age group amputation was three times as common among men as among women, but the situation was reversed in the over-80 group. During the last 50 years, there has been no significant change in the sex ratio of amputated because of ischaemia (Table 9). The fact that the majority of younger amputees are men may reflect the earlier onset of arteriosclerosis in men. Traumatic and frostbite amputations are more common among men than among women.

The amputation level shifted in the proximal direction with increasing age of the patients.

A comparison between the years 1984–85 and 1970 shows a decrease in above-knee amputations. In 1970, 71 per cent of all amputations were above-knee and 19 per cent below-knee amputations (Solonen, 1973). During the period of the present study, 42.0 per cent of the above-knee amputations and 27.7 per cent of the below-knee amputations were unilateral. Taking into account previous amputations and reamputations, 40.9 per cent of all the 705 amputees underwent unilateral amputation above-knee, 22.1 per cent unilateral amputation below-knee and 17.6 per cent bilateral amputation. The proportion of above-knee amputations was, however, higher in this study than in series studied by Alffram & Holmquist (1961), Mooney et al. (1976), Finch et al. (1980) or Steinberg (1985), in which the proportion of above-knee amputations was 26–36.6 per cent.

Table 9. Proportion of men among patients amputated for vascular diseases.

Period	Authors	n	Proportion
1930–60	Lindholm	531	0.60
1947–61	Hansson	261	0.54
1950–63	Vankka	184	0.60
1967–69	Hierton & James	94	0.44
1967–72	Harris et al.	75	0.56
1973–77	Renström[1)]	200	0.53
1974–77	Finch et al.	133	0.60
1979	Liedberg & Persson	161	0.54
1984–85	Present study	621	0.43

1) Below-knee amputations only.

In the present study above-knee amputations were less common than in Denmark in 1961–71 (Christensen, 1976).

The need for saving the knee joint in an amputation must be balanced against the rising morbidity if healing of the stump cannot be achieved. The general status and local condition of the limb is equally important. If the patient is likely to be bedridden or moved with a wheelchair because of other diseases, a high amputation level may be chosen with a better healing prognosis.

The high mortality rate of 30.1 per cent during the first postoperative months among amputees with vascular diseases bears testimony of advanced state of the disease. This is also indicated by the fact that 11.3 per cent of patients amputated for ischaemia had undergone a prior amputation, 27.0 per cent of those amputated for vascular disease had a history of sympathectomy, reconstructive surgery, embolectomy or a combination of these. Along with the advances of reconstructive surgery for limb salvage patients coming into hospitals are older than previously and have a more advanced generalized vascular disease. The mortality during hospitalization found in this study was higher than that reported by other investigators (Weaver & Marshall, 1973; Harris et al., 1974; Coch et al., 1977; Finch et al., 1980). The rate of death (27 per cent) within three months following initial surgery was higher than in Denmark 16.6 per cent (Ebskov & Josephsen, 1980). This difference may be partly due to the higher mean age of the present series compared with earlier studies.

Acknowledgements

The study was granted from Professor Langenskiöld Fund delivered by the Factory of Prosthetic Foundation, Helsinki.

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Prosthetics and Orthotics International, 1988, 12, 19–40

Development and testing of thermoplastic structural components for modular prostheses

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Abstract

The wider use of thermoplastic structural components in modular artificial limbs would enable their general properties of low density, corrosion resistance and mouldability and more specific properties of certain thermoplastics such as shock absorption, fatigue and wear resistance to be used to the advantage of patients and manufacturers. They provide an alternative to metal and carbon fibre reinforced resin systems.

Emphasis has been placed on the development of rotationally moulded Nylon 11 shank sections, using Philadelphia recommended load levels as the design criteria for structural integrity. Laboratory testing underlined the importance of fatigue testing of thermoplastic components since structural deterioration due to creep—a time dependent mechanical property of thermoplastics—can be ascertained in fatigue testing but would not be evident on the shorter timescale of the static test. Experimental below-knee prostheses incorporating suitably designed plastic shanks and alignment devices can withstand high static loads and exhibit long fatigue lifetimes in excess of 2 million cycles.

The shank design offered an opportunity for testing under service conditions the validity of the Philadelphia Static Load level (2.5 kN) since shank failure loads are around this figure. Patient trials of experimental prostheses based on various combinations of plastic shanks and alignment devices and conducted over 33 months indicate that the Static Load Level along with fatigue testing is a satisfactory test criterion for general service use of thermoplastic prosthetic components.

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Introduction

Although thermoplastics are accepted for socket production, relatively little use is made of them for the structural components of modular prostheses where their properties of lightweight, corrosion resistance, easy mouldability and shock absorption could be used to the advantage of patients and manufacturers. There are some notable exceptions such as the Seattle foot (Hithenberger, 1986) which incorporates an Acetal keel. The good spring characteristics of this material are used to advantage to provide an energy return function which has been welcomed enthusiastically by patients. An experimental prosthesis featuring several of the thermoplastic components which will be considered in the following text will illustrate further the scope for thermoplastics usage in artificial limbs (Fig. 1). Rapidform polypropylene sockets of the type shown have been described by Davies and Russell (1979). They have established an impressive service record in terms of patient comfort and durability. The experimental uniaxial ankle unit shown in Figure 1 was produced by machining from Nylon 66 with the eventual aim of production by injection moulding. Medial and lateral slots allow access to the fixing bolt for alignment adjustment while the good bearing properties of nylon enable a simple circlip fastening to be used for spindle retention. Magnesium alloy uniaxial ankle units on the other hand require the spindle to be locked to the unit to prevent wear. The four-jack alignment device at socket and foot level is produced from Nylon 66 and glass filled nylon. It is based on the Staros-Gardner alignment

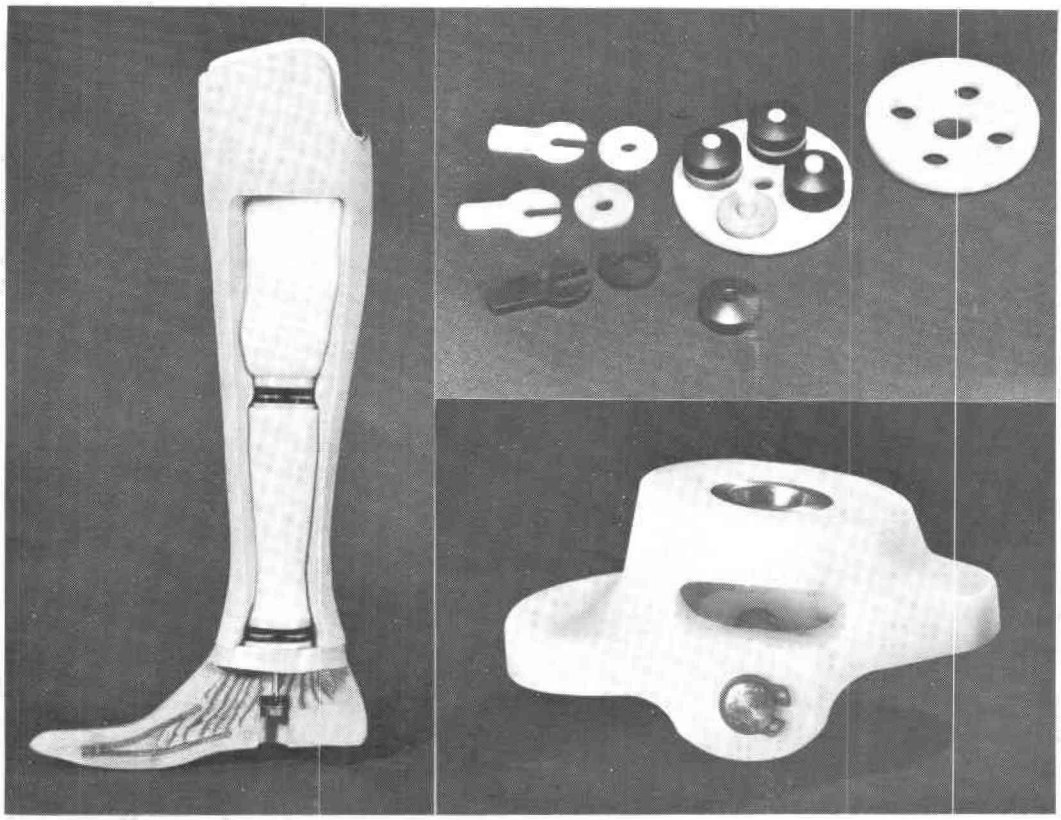

Fig. 1. Left, experimental prosthesis incorporating Rapidform polypropylene socket, rotationally moulded Nylon 11 shank and 4-jack alignment devices. Top right, 4-jack alignment device—component parts. Bottom right, uniaxial ankle unit produced from Nylon 66.

coupling, using the vertical travel of threaded jacking nuts along support columns to accomplish socket tilt. Colour coded spacers inserted below the nuts enable the alignment condition to be established and recorded with certainty. The 4-jack angulation device and slide module for linear adjustment of socket position relative to the shank have been described in detail elsewhere (Coombes et al, 1985a).

Rotational moulding is one production option for thermoplastic shank sections (Coombes et al, 1985b). The type shown in Figure 1 is hollow, rotationally moulded in Nylon 11 and incorporates metallic inserts at distal and proximal ends for single bolt fixing of socket and foot unit via the selected alignment device. These inserts are moulded in during processing and so avoid the need for a separate tube adaptor. The rotational moulding process is characterized by low costs of moulds and moulding machinery. This is advantageous since shank design changes can be readily accommodated at both prototype and production stages. A further advantage is that the wall thickness of mouldings can be varied to suit patient weight and activity level by simply adjusting the weight of starting material. Drawbacks of the method include long production times—30 minutes is not uncommon—and the limited range of thermoplastics which are suitable for rotational moulding.

The first part of this paper will detail the rotational moulding conditions found satisfactory for Nylon 11 shanks and the quality control procedure adopted for the product. The shank geometries used in both laboratory and service testing will be described together with the insert designs which gave long fatigue lifetimes. The successful insert designs which evolved are generally applicable to other

thermoplastic structural components used in artificial limbs such as knee units, ankle and foot units.

Testing of shank sections, prosthesis sub assemblies and complete prostheses together with the results of patient trials are documented later with particular reference made to the applicability of Philadelphia standards (ISPO, 1978) as design criteria for structural integrity.

General process conditions for rotational moulding

Production of Nylon 11 shank sections by rotational moulding was outlined by Coombes et al (1985b). During the moulding operation, the shank mould containing a predetermined amount of thermoplastic powder is heated in an oven and rotated about two perpendicular axes in the conventional method so that the powder is tumbled over all mould surfaces. A layer of molten polymer forms at the mould wall and solidifies during the mould cooling stage to give the finished moulding. The system of rotational moulding developed at the Bioengineering Centre provides shank sections for patients on an individual basis. A mould is assembled from a set of low cost aluminium alloy mould segments which enable mould length to be varied by 1mm increments. The resultant mouldings are hollow and incorporate metallic inserts moulded-in at distal and proximal ends of the shank (Fig. 2).

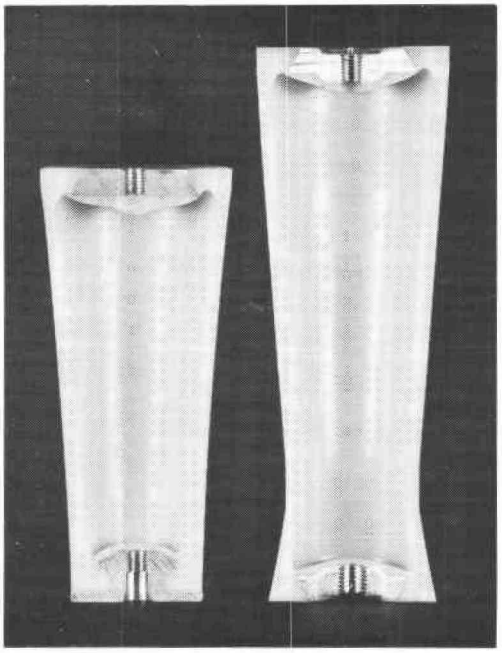

Fig. 2. Sectioned shank mouldings.

Double axis technique

The Bioengineering Centre's 'Autoform' rotational moulder is based on the conventional moulding method where rotation of the (shank) mould occurs on two perpendicular axes; the speed of rotation on both axes being controllable. The oven is electrically heated and thermostatically controlled. After the heating cycle, the oven retracts and the mould is cooled by an air blast of certain duration. Mould rotation continues during the cooling cycle. Typical process conditions are shown in Table 1. The rotation ratios listed (X is the rotation speed about the horizontal axis and Y is the rotation speed about the vertical axis) have been found to give an even wall thickness distribution and good insert encapsulation as illustrated in Figure 3. As a guide to powder weight requirements for the shank geometries under consideration, one subtracts 10g from the figure for shank length i.e. for a 200mm flared ankle shank, the weight of powder would be 190g. For the shorter more cylindrical shanks 20g is added to the figure for shank length.

The minimum shank length produced was 70mm using a nearly cylindrical mould (Fig. 3)—to increase the weight of starting powder.

Single axis technique

During the course of development of nylon shanks, it was found that a modification of the

Table 1. Recommended processing conditions for rotationally moulded nylon 11 shanks

Conventional double-axis technique			
Oven temperature	275°C		
Heating time	24 mins.		
Cooling time	14 mins.		
Mould rotation rate (rpm)	X-axis (horizontal)	Y-axis (vertical)	Shank length (mm)
	9–12	11	70–100
	10–13	11	100–180
	11–14	11	180+
Single-axis technique			
Oven temperature	360°C		
Stage 1 heating time	22 mins		
Stage 2 heating time	3 mins		
Cooling time	12 mins		
Mould rotation rate	50 rpm		
Mould tilt speed	10 cpm		
Tilt angle	12°–shank length 78–120mm 9°–shank length 120+		

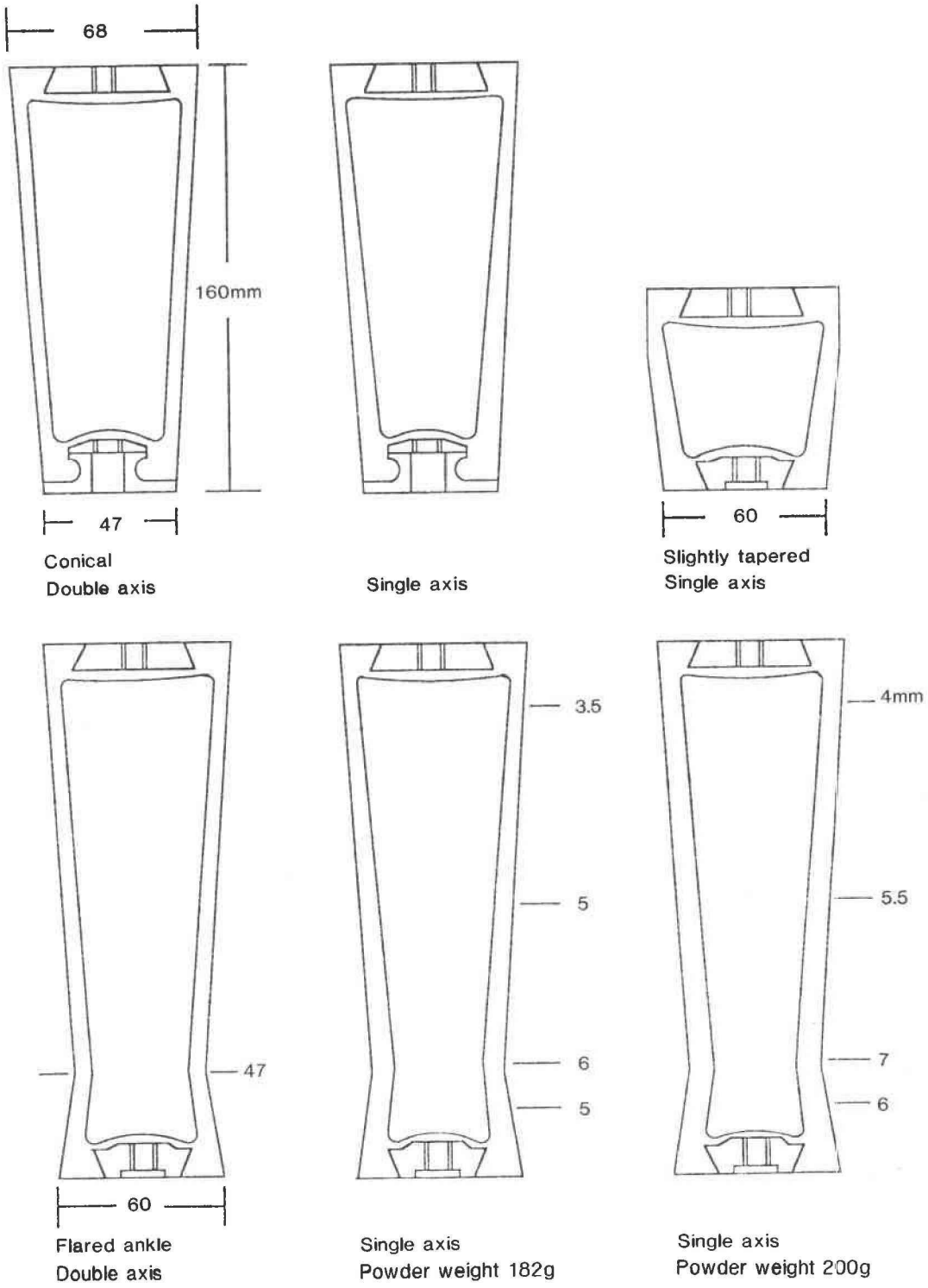

Fig. 3. Shank designs and material distribution.

simpler 'tilt and turn' rotational moulding technique was adequate for producing shank sections. A semi-automatic, compact moulding machine was constructed giving accurate control over oven temperature, mould heating and cooling time, mould rotation, tilt speeds, and tilt angles (Coombes et al, 1985b).

Mould rotation (about the shank axis) coupled with continuous oscillation (or tilt) of the mould in the vertical plane does not yield satisfactory mouldings. Only a thin coating of plastic is obtained on the surface of distal and proximal inserts rather than complete embedding of the insert in plastic.

A two-stage tilt technique was developed for producing nylon shank sections in lengths ranging from 78 to 220mm. This involves continuously rotating the assembled mould containing a predetermined weight of powder in an oven. The mould is inclined at a particular angle below the horizontal to coat the proximal end of the mould first (Stage 1). After a certain heating time the mould is automatically tilted by the same angle in the opposite direction to coat the distal end of the mould. The mould is then cooled in the Stage 2 attitude to solidify the plastic.

The process conditions found satisfactory for producing nylon shank sections of length ranging from 78 to 220mm are listed in Table 1. and the following guidelines apply for the two-stage moulding technique.

1. Mould residence time in Stage 1 and Stage 2 must be optimized to ensure satisfactory embedding of inserts and wall thickness distribution.
2. Material distribution throughout the moulding can be varied by altering the weight of powder, mould residence time in each moulding stage and tilt angle.
3. The distal end of the shank is moulded in the second stage of the process since more control is available over thickness distribution at this point. A gradually increasing wall thickness towards the base of the moulding is achieved which is advantageous for the highly stressed ankle region of the shank (Fig. 3).

Maximum shank length is governed by the existing machine dimensions. The minimum length of shank produced by the 2-stage tilt method was 78mm. Mould and inserts volume limit the amount of nylon powder which can be packed into the shorter moulds. In extreme cases overpacking of the mould prevents free movement of powder to the mould walls and results in a solid core of plastic bridging the gap between proximal and distal insert attached to the mould end plates. It should be noted that shank sections less than 120mm are produced from larger volume moulds to ensure that sufficient nylon powder is available to meet insert embedding and wall thickness requirements. This feature is a disadvantage of rotational moulding for shank production since the increased diameter of short mouldings could cause problems of cosmetic finishing of the prosthesis.

A useful feature of rotational moulding is the ability to vary moulding wall thickness if required to match patient weight and activity level by adjusting the amount of starting material. As a guide to powder weight requirement for the shank geometries under consideration, one subtracts between 0 and 20g from the figure for shank length i.e. for a 150mm flared ankle shank, the weight of powder would be between 130 and 150g. For the shorter, more cylindrical shanks below 120mm in length, 20g is added to the length figure. A typical wall thickness distribution for rotationally moulded shanks used in laboratory testing and service is shown in Figure 3. Wall thickness tapers from approximately 6mm at the distal end to 4mm at the proximal end.

Rotationally moulded nylon shanks—quality control aspects

A quality control system was set up to monitor the following features of rotationally moulded shanks.

1. Moulded appearance-mouldings were examined for the presence of voids and large bubbles (millimetre scale) in the moulding wall, satisfactory insert encapsulation, and evidence of over-heating during processing indicated by the presence of a fine grained 'bubble' effect in the moulding surface.
2. Moulding wall thickness.
3. Moulding deflection under static loading conditions.

Moulding Appearance

Since nylon materials are hygroscopic, Nylon 11 powder was routinely stored in an oven

maintained at a temperature of 30°C to prevent moisture pick-up from the atmosphere. Excessive moisture content of the rotational moulding powder could result in large bubbles in the moulding wall. These defects are revealed by visual inspection sometimes aided by internal illumination of mouldings. The extent of insert encapsulation can also be assessed using internal illumination. The thicker wall section around the insert appears darker than the rest of the moulding. Poor encapsulation in one area for example may be revealed by rotating the moulding and observing a corresponding increase in intensity of the transmitted light.

Ultrasonic testing using a Panametrics 5222 thickness gauge based on the 'pulse-echo' principle was also used in quality control procedures. Scattering of sound energy from internal surfaces such as pores reduces the ability of the sensor to discriminate a valid return echo from the back face of the material. The ability to gauge the material ultrasonically is thereby limited. In a few cases moulding wall thickness was not registered ultrasonically despite a visually satisfactory surface appearance. These mouldings were rejected on the basis of unacceptable porosity.

Mouldings exhibiting rough internal surfaces or powder remnant due to poor material coalescence or densification were rejected. This characteristic of rotational mouldings is a result of insufficient heating time or low moulding temperatures and results in brittle failure of the moulding at low loads on static testing.

Wall thickness measurement

Investigations of the behaviour of rotationally moulded shanks under cyclic loading indicated that the minimum wall thickness should be set at 3mm to withstand fatigue loading to a million cycles. Wall thickness of mouldings was determined prior to laboratory testing and patient trials by means of a Panametrics 5222 ultrasonic thickness gauge. A flared ankle shank section fatigue tested to over 2 million load cycles for example had a wall thickness of 4.3mm at the proximal end and 7.3mm at the distal end. These wall thickness figures are also applicable to rotationally moulded shanks which can withstand static testing to the Philadelphia Static Load level.

Moulding deflection characteristics under static loading

Static testing of shanks was carried out using an offset, compressive loading arrangement to apply a bending moment to the test sample. Shank deflection measured in terms of tensometer crosshead movement at 1.35kN axial force was used for quality control purposes and to characterize shanks prior to patient trials and fatigue testing. For example an 'allowed' deflection of 6mm could be assigned to a 70mm shank (Table 3). Repetition of the test after rotating the shank by 90, 180 and 270° enables the homogeneity of the moulding to be assessed. This procedure, in combination with a visual examination, was used to reveal any incidence of poor insert encapsulation.

Shank and insert design

The shank section designs used in the evaluation programme of rotational moulding as a programme production technique for load bearing components were based on three types namely a conical form, flared ankle design and a slightly tapered cylindrical type (Fig. 3).

Conical type shanks offer production advantages since mould construction is simple and they permit easier cosmetic finishing of the limb at the ankle.

Flared ankle shanks were produced to enable highly stressed areas in the ankle region to be obviated by increasing load bearing area. The base diameter of the flared ankle section (60mm) was based on the largest dimension which could be blended cosmetically with SACH feet. They were produced using a split mould and give a good illustration of the relative ease of incorporating design changes in rotationally moulded components.

Slightly tapered, cylindrical shanks This shank design was necessarily adopted for shorter mouldings (<120mm) to ensure that an adequate volume of starting powder was available to meet insert embedding and wall thickness requirements. The increased diameter of these mouldings is a disadvantage as far as cosmetic finishing of the prosthesis is concerned.

The rotationally moulded Nylon 11 shanks in question are hollow and contain threaded

metallic inserts moulded-in at distal and proximal ends to provide attachment points for socket and foot unit by means of single bolt fixings. Inserts were generally produced by machining from aluminium alloy, grade HE30TF, which offers lightweight and rapid heat conduction to assist polymer encapsulation of the insert during moulding. This particular grade of aluminium alloy is a medium strength wrought alloy which is recommended for structural purposes and displays good fatigue resistance and corrosion resistance. The design of these inserts must satisfy three requirements:—

1. The shape must allow powder movement around the insert during moulding to give complete encapsulation by thermoplastic without voids.
2. Insert anchorage in the shank must be adequate to withstand forces tending to pull them from the moulding during service.
3. Insert strength must be sufficient to resist failure by overload or fatigue during service.

Insert design for encapsulation by plastic during moulding

In rotational moulding, only the tumbling action of powder is available for coating mould walls and inserts unlike injection moulding of thermoplastics for example where high pressures force the molten plastic into the mould cavity and around inserts. Rotational moulding trials established the insert geometry necessary for complete coverage by thermoplastic at particular mould rotation ratios. Minimum flange height or flange separation (h) and span (s) for top-hat type inserts for example were established as 5mm× 5mm as shown in Figure 4. The minimum distance between mould wall and insert to achieve encapsulation without bridging of thermoplastic and voiding occurring was also established during the course of moulding trials as 7.5mm. Unfavourable insert geometry and/ or rotation ratio can result in large voids, ranging from 0.5 to several millimetres, in the moulding. Pin-hole voids can be formed in the angle of top hat type inserts for example unless the insert is radiussed in this region. Careful

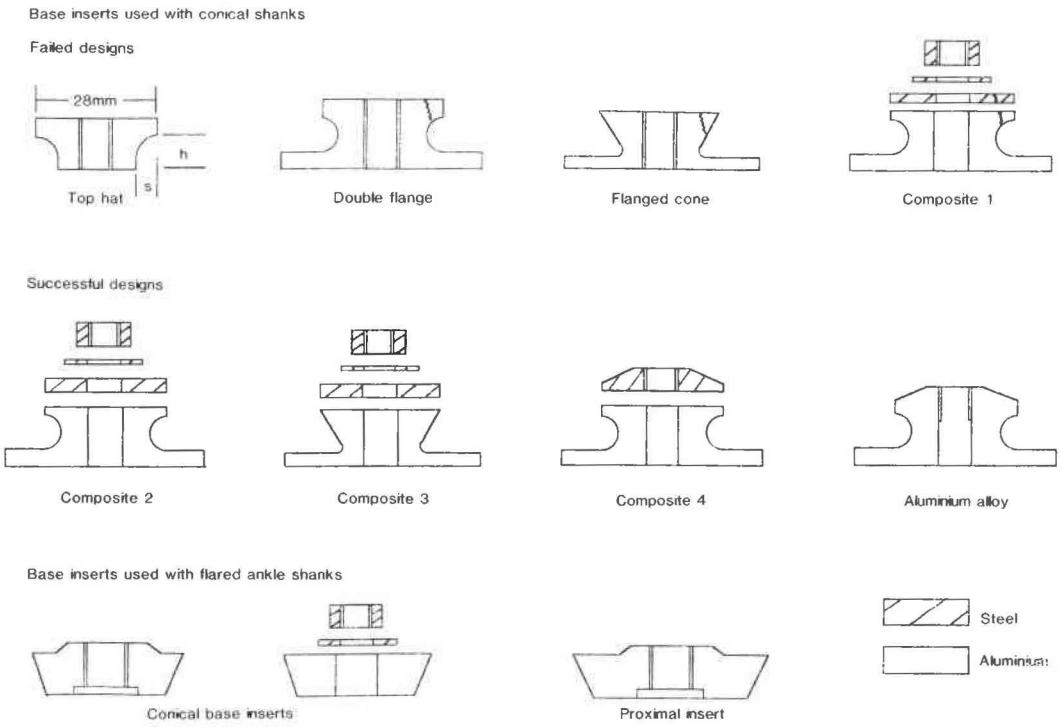

Fig. 4. Metallic inserts for rotationally moulded, Nylon 11 shanks.

choice of insert design and rotation ratios do however result in good encapsulation of inserts as illustrated in Figure 2.

Mechanical testing

An investigation of the mechanical performance of various designs of rotationally moulded Nylon 11 shanks containing specific types of inserts was instigated to test the behaviour of the shank/insert interface under load, and to provide information on the load-deflection characteristics of various shank geometries. Philadelphia recommended load levels for below-knee (BK) prostheses were selected as the design criteria for structural integrity (ISPO, 1978). Two loading regimes are of interest.

1) *The cyclic loading condition.* Where a 1350 N compressive force is applied to the limb structure to generate a bending moment at the knee of 120Nm and a bending moment at the ankle of 140Nm.

2) *The static loading condition.* A STATIC LOAD LEVEL was defined during the Philadelphia proceedings such that application of a compressive force of 2500N which produces a bending moment at knee and ankle of 230Nm and 250Nm respectively should not produce permanent deformation of the limb structure. In addition a MAXIMUM STATIC LOAD or FAILURE LOAD was discussed of 1.5x and twice this value for ductile and brittle-type failure of the limb structure respectively.

Static testing is used to reveal structural or design weaknesses associated with severe loading conditions while fatigue testing aims to simulate prostheses loading under normal service conditions.

Specimen preparation and test procedure

Nylon 11 shanks containing inserts of various designs (Fig. 4) were produced initially using the Bioengineering Centre's 'Autoform' double-axis rotational moulder and subsequently using the single-axis technique described earlier. Before testing, samples were inspected for satisfactory insert encapsulation moulding quality and wall thickness distribution as detailed earlier. Moisture conditioning (apart from exposure to laboratory conditions) was not carried out on samples and these were usually tested within one week of production.

Static testing

The mechanical testing procedure followed the Philadelphia recommendations. Moulded shank sections were static tested using a Zwick Universal Testing machine and an arrangement whereby pivoted extension bars were attached to proximal and distal ends of the shank to give equal offsets of 100mm from the load axis. This system of offset loading enabled AP bending moments to be applied to the test sample. The extension bars were bolted directly to the shank by means of the threaded, moulded-in inserts. Samples were characterized on the basis of deflection and failure mode by loading them to 1350N axial force and recording the resultant crosshead movement and then testing to failure.

Static tests were also carried out on assemblies of rotational moulded shank, plastic alignment devices and plastic uniaxial ankle unit (socket and foot unit are not included in the test). Shanks were confined to the Flared Ankle type containing conical metallic inserts. For SACH foot systems the shank was bolted to the test fixture via the selected alignment device using 8mm, high tensile, socket cap head bolts in combination with a spherical washer/seating arrangement. Offsets from the load axis were measured, as previously, with respect to the distal and proximal fixing bolts. When a plastic uniaxial ankle unit formed part of the test assembly it was connected to the test fixture using a Hangers standard T-bolt fixing, cradle and spherical foot nut. An aluminium alloy replica was substituted for the instep rubber. In this case the bottom offset from the load line was measured with respect to the ankle unit pivot.

Fatigue testing

Shank designs selected for fatigue testing were those which exhibited the least deflection under static loading conditions. As for static testing, pivoted extension bars were attached to each end of the moulding to give equal offsets from the load axis. In this case offsets of 103mm were arranged at distal and proximal ends of the shank to generate bending moments of 140Nm under an axial force of 1350N. Samples were first characterized by loading to 1350N axial force using the Zwick tensometer and measuring the resultant crosshead movement. They were subsequently fatigue tested to

investigate the effect of insert design and moulding wall thickness on shank fatigue performance.

The bulk of the cyclic testing programme on rotationally moulded shanks was carried out using a pneumatically powered fatigue rig which applied a force of 1350N to the specimen at a frequency of 52 cpm for five minutes followed by one minute at zero load then 40 cpm for five minutes and so on. In this way the cyclic test procedure aimed to simulate patient activity to a certain extent by varying the loading rate (a minimum loading time of one minute is available on the present rig, one load level can be programmed and two loading frequencies (apart from zero) may be selected up to a maximum of 1 Hz). A Si-plan servo hydraulic testing machine was used for fatigue testing limb assemblies consisting of alignment devices, shank and socket. See 'Systems Testing'. Computer control of loading frequency, maximum and minimum loads, time of loading etc., is available so that patient activity may be simulated in greater detail than is possible using the pneumatic fatigue rig.

Results of static and cyclic testing

The results of characterizing by static testing rotationally moulded Nylon 11 shanks of various lengths and insert designs are presented in Table 2. Shank deflection under load as reflected by the values for tensometer crosshead movement at 1.35kN axial force are recorded in Table 3. Although the effect of shank geometry and wall thickness has not been investigated systematically, there is in general an expected trend for shank deflection to increase with length of moulding representing a tendency for 'bowing' of the longer columns under load. Static test results for limb

Table 2. Static testing of rotationally moulded shanks
Speed of testing 100 mm/min.

Shank type	Conical	Flared ankle				
Moulding technique	Double axis			single axis		
Shank length (mm)	175	200	205	163	188	216
Power weight (g)	—	190	180	165	198	207
Wall thickness range (mm)	5.2–6.1	4.9–6.4	4.9–5.6	4.5–6.4	—	—
Shank base insert	Top hat	Composite 4	Composite 4	Composite 4	Conical	Conical
Maximum axial force (kN)	3.3	4.6	3.1	3.3	3.1	2.5
Failure mode	Brittle shank failure				Base insert pull-out	

Table 3. Fatigue testing of rotationally moulded nylon 11 shanks

Shank type	Conical					Flared ankle		
Moulding technique	Double axis						Single axis	
Shank length (mm)	70	70	205	205	205	220	172	207
Power weight (g)	75	75	160	160	160	200	178	208
Wall thickness range (mm)	3.5–4.5	3.2–4.6	—	3–4	3–4.5	4.3–5.5	—	4.6–7.2
Shank base insert	Flanged cone	Composite 3	Top hat	Double flange	Composite 2	Conical	Compsite 4	Conical
Ankle fixing bolt (mm)	8	8	8	8	8	8	8	10
Cross head movement (mm) at 1.35 kN	—	5.6	—	—	10.5	12	7.6	7.7
Cycles completed	91,000	964,500	60,000	90,000	1,189,000	1,867,000	705,800	2,035,000
Failure mode	Base insert shear	Shank cracked in ankle region	Ankle bolt failure	Base insert shear	Shank cracked in ankle region	Shank cracked at base–excessive insert pull-out	No failure	Excessive base insert pull-out

Shank deflection measured in terms of tensometer crosshead movement at 1.35 kN axial force was recorded at a test speed of 100mm/min.

Table 4. Static testing of limb assemblies—combined compressive and bending loads

	Speed of testing 10mm/min.				Speed of testing 20mm/min.				
Shank type	Cylindrical	Flared ankle	———		———		Flared ankle	———	
Shank length (mm)	116	163	208	208	———		202	———	
Power weight (g)	136	165	215	215	———		182	———	200
Thickness of base insert (mm)	10	10	10	10	7	8	9	10	9
Alignment device	4-jack	Double wedge	4-jack	4-jack	———		4-jack	———	
Plastic uniaxial ankle unit	—	—	—	Yes	———		Yes	———	
Max. axial force applied (kN)	2.3	2.9	3.3	2.6	2–2.4	2.1–2.3	2.3–2.6	2.3–2.5	2.6–2.8
Failure mode	Pull-out of shank's base insert				Pull-out of shank's base insert				

Shank proximal insert–conical type, Figure 4.
Shank base insert–conical type, Figure 4.
The same type of alignment device is located at both proximal and distal ends of the shank.

assemblies are presented in Table 4. The failure characteristics of the shank dominate those of the assembly.

Shank failure characteristics can be categorized as follows:—

1. Brittle failure of the shank occurs between 3.1 and 4.6kN when insert pull-out is restricted by using flanged type inserts.
2. Insert pull-out loads for the isolated shank containing conical inserts have ranged from 2 to 3.3 kN depending on embedded insert depth and shank wall thickness.
3. Poor quality rotationally moulded shanks showing powder remnant will fail in a brittle manner at low loads.

Although Philadelphia Static Load Levels can be exceeded, the failure loads do not meet U.K. Department of Health test requirements for safety/structural purposes. These state that in the case of ductile failure, failure loads should exceed 1.5x Philadelphia Static Load Levels i.e. 3.75kN. For brittle failure 2× Philadelphia Static Load Level is required i.e. 5kN.

Insert pull-out from rotationally moulded shanks

Pull-out of conical inserts on overload from rotationally moulded shanks (Fig. 5) is preferable as a failure mechanism to brittle failure since it is progressive and can be detected at prosthesis inspection. Conical inserts are gradually pulled from the shank giving the type of load-deflection curve shown in Figure 5. Insert pull-out can provide a useful indication of the actual loads applied to a prosthesis in service by building in a particular failure load. It provides a convenient method for testing the validity of the Philadelphia Static

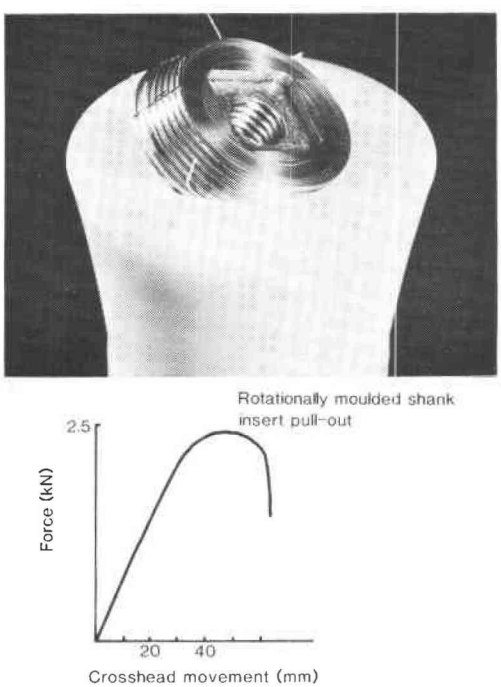

Fig. 5. Pull-out of a conical base insert from a rotationally moulded, Nylon 11 shank and typical force-deflection curve.

Load Level in patient trials for example if pull-out strength can be confined to a load range about this level.

The effect of certain shank design variables such as embedded insert depth, on insert pull-out force was investigated by static testing BK limb assemblies. The same system of offset loading was employed as described above to apply bending loads to a test assembly consisting of:

1. 4-jack angulation modules at distal and proximal ends of the shank.
2. Rotationally moulded, nylon shank section (202mm long, flared ankle type).
3. Plastic uniaxial ankle unit.

Embedded insert depth was varied by altering the height of the insert so maintaining the cone angle constant. The effect of reduced insert diameter on pull-out strength has been assumed to be negligible. Insert pull-out force is presented in Table 4 in terms of the applied compressive force. The results reveal that:—

1. The depth embedding of the insert in plastic at the shank base over 7–10mm has relatively little effect on pull-out strength. Pull-out strengths ranged from 2–2.6kN with an expected tendency to increase with increased depth of embedding.
2. Pull-out strength appears more sensitive to the wall thickness in the shank base i.e. the resistance to spreading of the shank base by the insert is increased with increasing wall thickness in this area. Pull-out strength was raised to 2.6–2.8 kN by increasing the starting powder weight and consequently the wall thickness in the ankle region. Typical wall thickness distributions for 182 and 200g powder weight are illustrated in Figure 3 to emphasize this point.
3. Insert pull-out from the shank may be confined to a fairly narrow load range of 2.3–2.6 kN for test assemblies by suitable control of insert dimensions and moulding conditions.

Only one example of insert pull-out from the proximal end of the shank has been recorded during laboratory testing. In this case the standard conical insert was embedded to a depth of 6mm by plastic and the pull-out force was 2.3kN.

Factors influencing the fatigue performance of rotationally moulded shanks

The results of cyclic testing rotationally moulded shanks of various lengths and containing various insert designs are presented in Table 3. It must be emphasized that each type of shank had been tested to the Philadelphia Static Load Level without failure occurring. Early fatigue failure (i.e. before 700,000 cycles) can be assigned to three main factors namely:—

1. Creep of the thermoplastic resulting in early flexural fatigue failure of ankle fixing bolts.
2. Insert shear.
3. Buckling of the shank.

The types of observed fatigue failure are analysed below since they highlight some of the factors influencing the fatigue behaviour of thermoplastic shanks.

Creep of the thermoplastic during fatigue loading

Conical type shanks (Fig. 3) containing 'top-hat' base inserts and conical proximal inserts (Fig. 4) can withstand static loading to Philadelphia Static Load Levels. Both inserts were machined from aluminium alloy and had tapped 8mm holes to enable attachment to the test machine (and ultimately the socket and foot unit) by single bolts. Fixing bolts were of the socket cap head type, high tensile steel, grade 12.9.

Under fatigue loading conditions frequent ankle bolt failure occurred generally at the threaded section within the shank insert. In all, eight bolts sheared during the course of testing to 319,500 cycles. Deformation of the shank base away from the planar form was also significant. The proposed mechanism for repeated fixing bolt failure is outlined below and illustrated in (Fig. 6).

1. Compressive creep of the shank base occurs in the region x on each loading cycle removing the planar form. Creep may be defined as increasing deformation of a plastic material with time under constant load and is a result of the viscoelastic nature of plastics materials (Powell, 1974).
2. The test fixture or base plate (ultimately the foot unit) is now allowed to pivot about the edge of the insert base. This

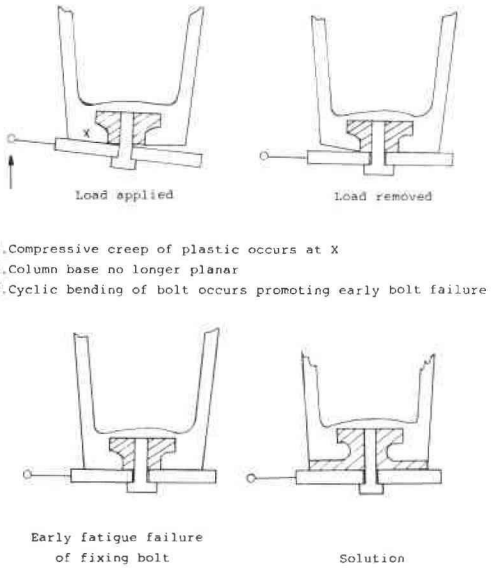

Fig. 6. Proposed mechanism for frequent ankle bolt failure due to creep of thermoplastics.

mechanism is aided by the small area of the insert in contact with the base plate.

3. Repeated bending or flexural loading of the fixing bolt results leading to early fatigue failure.

To avoid early fixing bolt failure by this mechanism, bending or flexing of the bolt must be minimized. This was accomplished by ensuring that shank insert and test fixture (or foot unit in service) were locked together rigidly by the bolt thereby behaving as a single unit under load. A large diameter base flange was added to the insert (Figs. 4 and 6) to satisfy this requirement. The larger insert clamping area prevents pivoting of the test fixture about the insert so that polymer creep and flexure are allowed while fixing bolt flexure is minimized. The effect of this modification is to raise the fatigue lifetime of shank sections to over a million load cycles as illustrated by Sample 5 in Table 3.

Insert shear under fatigue loading

During static and fatigue testing of shank sections there is a tendency to pull the distal and proximal inserts from the moulding. Under the conditions of offset loading employed the shank tends to pivot on its leading edge thereby concentrating the load over a reduced base area (Fig. 6). This condition would result in 'toppling' of the shank in the absence of restraining tensile forces (Gordon, 1978) generated by the top anchoring flange of the insert and the plastic below it as they flex to counteract the bending moment applied to the shank. The incidence of ankle insert fatigue failure by shear, typical fatigue lifetimes and the insert designs prone to this type of failure are listed in Table 3 and illustrated in Figure 4.

Shank fatigue failure due to buckling

Buckling of the shank during fatigue testing generally occurred at extremely low numbers of cycles i.e. less than 50,000 and has been observed under two conditions:

1. Insert failure which results in a marked shift of load onto the shank's leading edge.
2. Poor insert encapsulation or void formation below the insert anchoring flange which reduces the surrounding polymer section thickness.

In both cases the magnitude of forces due to polymer flexure which oppose toppling or pivoting of the shank on its leading edge are reduced. Compressive loads are consequently localized over a smaller area of the shank base promoting buckling. A combination of voids in the moulding wall, low wall thickness or hysteresis losses during cyclic testing causing material softening (Hertzberg and Manson, 1980) will accentuate the problem.

Guidelines for insert design

Certain design features of metallic inserts are necessary if rotationally moulded shanks are to exhibit extended fatigue lifetimes under combined compressive and bending loads. The guidelines for insert design which have evolved are generally applicable to thermoplastic load bearing components for prostheses. Successful and unsuccessful insert designs, as far as the present fatigue loading study is concerned, are shown in Figure 4.

Conical aluminium alloy inserts have been used exclusively at the proximal end of rotationally moulded shanks satisfying both criteria of polymer encapsulation during moulding and resistance to static and fatigue loading. Moulded-in inserts at the ankle interface of rotationally moulded nylon shanks constitute the more difficult design problem

due to the high stresses generated in this area during service and the reduced load bearing area occasioned by the need to accommodate cosmetic finishing of the limb. Conical inserts have been used successfully at the distal end of flared ankle shanks. Successful ankle inserts for conical shanks in particular, classed as those which survived fatigue testing to over 700,000 cycles, have several features in common.

1. A large diameter base flange counteracts creep of the shank base to minimize fixing bolt flexure. Early fatigue failure of the bolt is thereby avoided.
2. The top anchoring flange of aluminium alloy inserts is braced against flexural loading by suitable dimensioning or the use of steel reinforcing washers (composite type inserts) to improve fatigue resistance.

   Adequate clearance is essential between the fixing bolt and bolt hole in the aluminium alloy component of composite type ankle inserts to prevent the threaded section of the bolt digging into the softer aluminium component during testing. This condition can result in loading of the thin aluminium alloy top flange independently of the steel reinforcing washer leading to early fatigue failure of the flange.

Moulding wall thickness for extended fatigue lifetimes

A minimum recommended wall thickness of 3mm has been assigned to rotationally moulded nylon shanks to confer resistance to cyclic loading under laboratory conditions. This figure is based on wall thickness data obtained from Sample 5 in Table 3 which survived over a million loading cycles before failure. Failure of the plastic moulding was observed prior to insert failure when the shank wall thickness was 2mm and below. In general shank wall thickness is above 4mm.

Systems testing—fatigue loading conditions

Fatigue testing of rotationally moulded shanks in combination with other prosthetic components such as plastic alignment devices and plastic uniaxial ankle units was carried out to determine the mechanical response of the prosthetic system to simulated service loading. Data was required for instance on the structural integrity of the interfaces between components.

The fatigue test procedure was as described earlier for shank sections. For SACH foot systems the shank was bolted directly to the fatigue machine's test fixtures via the selected alignment device using a single bolt fixing and a spherical washer/seating arrangement mentioned and illustrated in an earlier publication (Coombes et al, 1985a). Bending moments of 140Nm were arranged at positions corresponding to the ankle fixing bolt and top shank fixing bolt respectively. When plastic uniaxial ankle units formed part of the test assembly, they were attached to Hanger moulded foot units using the standard T-fixing and foot nut. A simplified spindle and circlip arrangement is used with the plastic uniaxial ankle unit as previously described (Fig. 1). The instep or heel rubber of the foot unit was replaced by a uPVC replica during testing to limit the deflection of the system. Offsets at proximal and distal ends of the test assembly were arranged such that an applied force of 1350N produced a bending moment of 140Nm at positions corresponding to the ankle unit pivot and top shank fixing bolt respectively.

The results of fatigue testing various combinations of rotationally moulded shank, plastic alignment devices and plastic uniaxial ankle unit are presented in Table 5. An enhanced fatigue performance and a more preferable failure mode are apparent for systems based on flared ankle shanks.

Socket–shank interface

The structural integrity of the socket interface was investigated by fatigue testing a limb assembly incorporating a Rapidform polypropylene socket with soft PElite polyethylene foam liner (Fig. 7). The socket contained a Blatchford cup (Manufacturer's code DP 11) at the distal end for single bolt attachment to the shank. A 200mm long, flared ankle, rotationally moulded shank and 4-jack angulation modules distal to the socket and at ankle level completed the assembly; 10mm fixing bolts in high tensile steel, grade 8.8 to BS3692 were used to connect shank to socket and shank to test fixture via the alignment device. Bolts were Cadmium plated but not passivated or de-embrittled, Aluminium alloy spherical washers completed the socket fixing and ankle fixing.

Table 5. Fatigue testing of limb assemblies

Shank type	Conical			Flared ankle		
Moulding technique	Double axis			Single axis		
Shank length (mm)	118	180	190	128	211	200
Power weight (g)	125	165	175	138	216	210
Wall thickness range (mm)	4.5–5.8	4.5–6.5	4.4–5	4–5	–	4.3–7.3
Shank base insert	Composite 4	Composite 4	Alum. alloy	Conical	Conical	Conical
Alignment device (socket)	Double wedge	Double wedge	4-jack	Double wedge/ slide unit	–	4-jack
Alignment device (ankle)	–	Double wedge	Double wedge	–	Double wedge	4-jack
Plastic uniaxial ankle unit	–	–	–	Yes	Yes	–
Ankle fixing bolt (mm)	8	8	8	10	10	10
Cycles completed	817,000	710,900	1,057,000	1,466,000	947,000	2,023,000
Failure mode	No failure	Ankle bolt failure	Ankle bolt failure	Excessive base insert pull-out	Excessive base insert pull-out	Partial proximal and base insert pul -out

Test Procedure

Testing was carried out in accordance with UK Department of Health procedure and supervised by officials of that department. Philadelphia recommended load levels for dynamic testing were applied to the test assembly using an offset loading arrangement such that a bending moment at the knee and ankle of 120Nm and 140Nm respectively were produced by an axial compressive force of 1350N. Loading was transmitted to the socket by means of a loading bar embedded in a stump replica, produced from microballoon (castable polyester resin filled with hollow phenol formaldehyde spheres) incorporating a 70mm diameter thick pad of Plastazote polyethylene foam at the distal end. The test assembly was set-up on the fatigue testing machine such that the following offsets from the load line applied.

Offset at knee	89mm
Offset at ankle	104mm
Offset at alignment device distal to socket	104mm

In accordance with the Department of Health test procedure, the knee centre reference for BK test limbs (used for measuring the offset) was taken 19mm above the centre of the patellar tendon bar on the centre line of the loading bar. The ankle centre for SACH base is taken 12.5mm below the base (i.e. below the angulation module at the ankle in this case) on a vertical line through its centre. Offsets were measured under an applied load of 1350N. The length of the limb from knee centre to ankle centre was 435mm which is above the recommended length of 370–420mm. The test frequency was 1Hz and the test machine used was a 'SI-PLAN' servo hydraulic, programmable model.

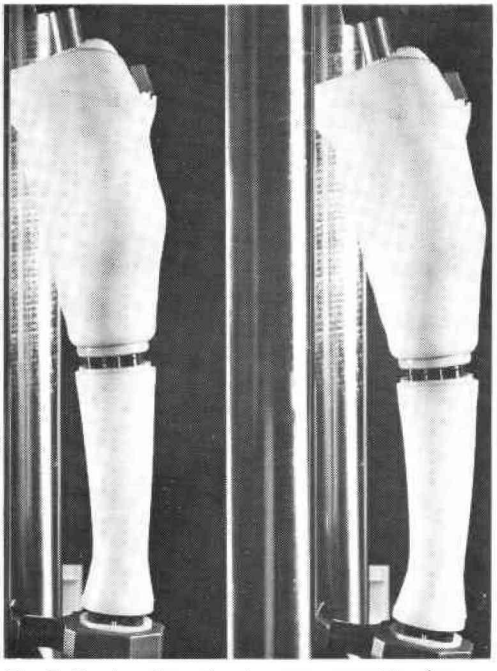

Fig. 7. Bowing distortion in a test assembly after two million loading cycles. Under zero load (left). Under 1.35 kN load (right).

Test Results

The limb assembly completed over 2,023,000 loading cycles without failure and the test was terminated at this point. 2 million cycles is

deemed equivalent to a service life of 5 years by the UK Department of Health. A small amount of wear debris from the spherical seatings of the 4-jack angulation device had collected on the surface of the jacking nuts. No visible signs of deterioration were recorded for the remaining plastic components of the alignment device nor was any joint loosening discernible in the structure.

Bowing distortion of the prosthesis occurred in the AP plane as illustrated in Figure 7 coupled with pull-out of the proximal insert and distal insert to the extent of 0.5mm and 1mm respectively in the posterior region of the shank. Insert pull-out results in progressive 'gap opening' between the shank and alignment devices as the test proceeds. This effect coupled with bowing of the shank account for bowing of the complete structure under load with the resulting increase in offsets at the end of the test to 94mm at the knee (89 initially) and 120mm at the socket alignment device (104 initially).

Patient trials

Laboratory based fatigue and static testing of sub-assemblies incorporating thermoplastic shank and alignment devices to Philadelphia test levels demonstrated that such components could be expected to exhibit long service life. Patient trials were initiated both in the UK and abroad to generate data on the mechanical behaviour of components and the response of patients and prosthetists to the system as a whole.

Limb build

The limb build of experimental prostheses based on thermoplastic structural components is shown in Table 6. Patient weight, age and occupation for each of the patients involved in the trial is also included.

Rotationally moulded nylon shanks were confined to the flared ankle type or slightly tapering cylindrical form dependent on length requirements (Fig. 3). These incorporated conical aluminium alloy inserts (10mm thick) at distal and proximal ends of the shank. As well as increasing load bearing area in the highly stressed ankle region by using flared ankle shanks, the conical inserts are pulled from the moulding under overload conditions so avoiding brittle failure of the shank.

All trial patients were fitted with Rapidform polypropylene sockets. The experimental prostheses were mainly based on the non-neutral pylon system where angular adjustments in the antero-posterior (A/P) plane and mediolateral (M/L) plane are carried out at two levels immediately distal to the socket and at ankle level respectively. Alignment devices used were either a plastic serrated double-wedge device or the 4-jack angulation module

Table 6. Patient trial results

Patient Details				Prosthesis construction						
Age	Weight (kg)	Occupation	Prosthesis service use (months)	Alignment device: Double wedge	Alignment device: 4-jack	Shank length (mm)	Plastic ankle unit	Foot unit	Fixing bolts (mm): Socket	Fixing bolts (mm): Ankle
A 22	74	Student	31	/				Otto Bock SACH	–	8
B 37	89	Soldier	22	/				Hanger SACH	–	10
C 37	75	Soldier	16	/		69		SACH	8	8
D 25	**82**	**Hotel Work**	**9**	/		**74**		**Modified Pirogoff**	**8**	**10***
.. ..	..	.. ..	**2**	/		**74**		**Modified Pirogoff**	**8**	**10**
.. ..	..	.. ..	15		/	74		Modified Pirogoff	8	10
E 65	84	Survevor	9	/		171		Hanger SACH	10	10
F 41	**75**	**Businessman**	**15**		/	**107**		**Hanger SACH**	**8**	**8**
G 66	81	Retired	15	AK		124	/	Hanger Uniaxial (wooden)	–	10
H 66	105	Retired	7	/	/	200	/	Hanger Uniaxial (wooden)	10	10
J 77	**78**	**Retired**	**5**		/	**166**	/	**Hanger Uniaxial (moulded)**	**8**	**10***
K 65	75	Retired	19		/	168		SACH	8	8
L 68	79	Retired	6		/	145		SACH	8	8
M 60	113	Retired	11		/	183		SACH	8	10
N 36	71	Unemployed	11		/	193		SACH	8	10
P 69	76	Retired	4		/	158		SACH	8	10

* Ankle bolt type – hex. head, high tensile steel, grade 8.8
Data in bold type refers to those patients who experienced prosthesis failure.

described previously (Coombes et al, 1985a). Thermoplastic uniaxial ankle units were incorporated in two BK modular systems and one AK prosthesis.

In two cases (patients A and B) the patients involved had very long amputation stumps. Their experimental prostheses consisted simply of a 'long draw' Rapidform PP socket, wedge angulation device, SACH foot unit and a nylon spacer, machined to patient requirements (Fig. 8). A single bolt fixing joined socket to foot unit. The low overall height of the plastic alignment device (less than 25mm) means that an alignment capability can easily be incorporated in prostheses for long stump amputees. In one case, (patient D) height restrictions were such that the prosthesis incorporated a rotationally moulded shank of minimum mouldable length (78mm–single axis technique), one angulation module distal to the socket and a low-profile foot unit based on a modified Otto Bock Pirogoff unit.

One above-knee amputee (patient G) was involved in the trial. His prosthesis was based on the British Modular Assembly Prosthesis (MAP) system having a plain uniaxial knee unit with an internal calf spring (kicker spring) and back check. A rotationally moulded shank was attached to the knee cradle by means of a machined, aluminium alloy tube adaptor. The adaptor was connected to the shank by a 10mm bolt onto the moulded-in insert at the proximal end. The tube adaptor was pinned to the knee cradle using the standard method of attachment for alloy shin tubes in the British MAP prostheses namely by using a 5mm dia. roll pin in conjunction with engineering adhesive applied to the joint surfaces.

Fig. 8. Prosthesis fitted to patients with long amputation stumps incorporating Rapidform PP socket, wedge alignment device and Nylon 66 spacer.

For patients K-P involved in the American part of the trial, 'Lightcast' Fibreglass casting tape was wrapped around the distal end of the socket, alignment device and top of the shank. The tape was wound loosely down the shank and then wrapped around the distal end of the shank, ankle alignment device and the top 10mm of the proximal part of the foot unit. The efficiency of this extra support structure and its influence on the service performance of the primary structure is questionable but nonetheless should be borne in mind when analysing the results of the patient trial.

Spherical aluminium alloy seatings and washers were used in conjunction with fixing bolts within the socket and foot unit of each prosthesis to allow angulation between these units and the shank. Socket fixing bolts are M8, hex.hd.bolts, 60mm long, high tensile steel, grade 8.8 unless otherwise stated. Ankle fixings were either 8mm or 10mm bolts, socket cap head type, high tensile steel, grade 12.9 unless otherwise stated. The 10mm bolts were incorporated in prostheses fitted to patients over 76 kg (168 lb). Ankle fixing bolts used with plastic ankle units were 10mm, hex hd. bolts, 50mm long, high tensile steel, grade 8.8.

The SACH foot units incorporated in experimental prostheses were modified to allow a) some degree of linear movement of the fixing bolt within the bolt hole b) adequate angulation of the fixing bolt c) incorporation of a spherical seating and washer arrangement. The modifications involved increasing the bolt hole diameter to 15mm and the counterbore to 30mm.

Results

Although patients expressed an appreciation of the light weight of their trial prostheses, the limb systems, particularly those incorporating

SACH foot units, are unsatisfactory as far as alignment procedures are concerned. Access to fixing bolts at socket and ankle level for alignment adjustment necessitates removal of the prosthesis from the patient. The provision of medial and lateral slots in the uniaxial ankle unit eliminates this problem at ankle level.

Experimental prostheses incorporating various thermoplastic structural components have been in use for the time shown in Table 6. The main results have been tabulated as follows:—

Patients	14
Age range (years)	22–77
Weight range	75–113kg
Service use	5–33 months
Prosthesis failures	4
Type of failure	3 ankle bolt failures 1 partial pull-out of the proximal shank insert
Duration of use prior to failure	5 months–patient J 9 months–patient D 2 months–patient D (insert pull-out) 18 months–patient F

In the three cases of ankle bolt failure, flexural fatigue loading of the bolt, which is known to be detrimental to service performance, is considered the most likely cause of failure. In case 1 (Patient J) this condition was accentuated by the stress raising effect of the thread run-out at the point of failure and possible loosening of the shank-ankle unit joint in service.

It should also be noted that the type of high tensile fixing bolt (grade 8.8) used in this prosthesis, although Cadmium plated for corrosion resistance is not usually de-embrittled after plating. Commercially used ankle fixing bolts are generally socket cap head types produced from grade 12.9 high tensile steel. These are recommended by the DHSS to be Cadmium plated, de-embrittled and passivated to BS3382 since hydrogen absorption by steel can occur on plating or acid cleaning leading to lowered ductility—hydrogen embrittlement (Larrabee & Mathay, 1963). A time delay is necessary for embrittlement to occur and this delay may be related to a critical or threshold amount of stress. The high tensile stresses generated in the surface of a bolt in flexure must focus attention on the possibility of hydrogen embrittlement contributing to early failure of the fixing bolt under conditions of flexural loading.

The second prosthesis failure (patient D) also occurred by ankle bolt failure at the thread run-out. In this case the thread run-out coincided exactly with the foot/shank interface which is known to emphasize stress-raising effects. It is recommended that the thread run-out is kept remote from component interfaces.

Crushing of the wood keel of the Pirogoff foot unit observed in the anterior region of shank/keel contact corresponding to the 'toe-off' walking phase is considered the main factor contributing to failure of this particular prosthesis. Joint loosening results and the bolt is thereby subjected to flexural loading during service precipitating early fatigue failure. Parallels can be drawn with the case of frequent ankle bolt failure under laboratory fatigue loading where compressive creep of the shank base away from the planar form resulted in flexural loading of the fixing bolt and its early failure (Fig. 6). It should also be noted that the Pirogoff foot unit used in this prosthesis is usually laminated to a prosthesis rather than fixed by a single bolt so distributing loads over a large area of the keel's surface. Foot units of this type fitted to experimental prostheses were subsequently modified by adding a hardwood top layer to reduce the tendency for crushing. The merit of this approach has been demonstrated by the fact that Patient D has worn his present prosthesis for 15 months without failure occuring.

Another factor contributing to early failure of the limb structure in service is the high activity level of Patient D which includes five-a-side football, hill walking, running, skiing, water skiing and badminton. These activities would be expected to impose much higher stresses on the prosthesis than is normally experienced and would promote early failure. While this prevents a rigid analysis of the effect of 'normal service use', on the experimental prosthesis it does mean that trial components are being severly tested in this case and that any real improvement can be expected to lead to an overall benefit if transferred to other prostheses at the design and development stage.

The same patient was responsible for partial pull-out of the proximal insert from the shank, fitted to his second prosthesis. Insert pull-out

occurred from the posterior region of the shank indicating that large forces were developed on 'toe-off'. This particular shank had been in service for just over two months. A similar shank moulding incorporated in the patient's original prosthesis functioned satisfactorily for nine months without insert pull-out occurring. Partial pull-out of the proximal shank insert has not been noted in the remaining prostheses undergoing patient trials. This behaviour is also rarely observed in laboratory fatigue and static testing—pull-out of the base insert being more usual. Proximal insert pull-out has been observed in one case in fatigue testing but only after two million loading cycles (generally assumed equivalent to five years service use). Proximal insert pull-out in static testing has been observed in one case at 2.3 kN due to unsatisfactory insert encapsulation by the polymer.

A further illustration of the heavy usage imposed on a prosthesis by the patient in question (D) is presented by the occurrence of failure in a British MAP prosthesis two months after issue. A helicoil insert in the ankle tube adaptor of this system was dislodged.

Prosthesis failure for patient F occurred after 18 months, again due to ankle fixing bolt failure. An 8mm high tensile bolt, grade 12–9, was used at the ankle, Cadmium plated, passivated and de-embrittled in accordance with DHSS recommendations. The patient is also highly active, participating in a range of sporting activities such as skiing and cycling using his experimental prosthesis. The DHSS recommend that 10mm ankle fixing bolts are used for male amputees while 8mm bolts are said to perform satisfactorily in prostheses fitted to women patients. The result for patient F tends to support this recommendation, the 8mm ankle fixing bolt proving inadequate for resisting the type of loading imposed by this particular patient on his prosthesis.

Discussion

The continuing increase in thermoplastics usage in all sectors of engineering, underlines the advantages to be gained on both a structural and economic level. While thermoplastics are accepted for socket production little use is made of them for other structural components of modular prostheses. Although emphasis in this paper has been placed on the production of Nylon 11 shank sections by rotational moulding the test results and observations can be used as design guidelines for thermoplastic shanks produced by other methods such as injection moulding.

Shank sections have been produced on an individual basis using a segmented mould, taking advantage of the simplicity of mould construction and the low cost of moulding equipment associated with rotational moulding. Development of a single-axis moulding technique for shank sections has further simplified and scaled down the process and moreover allows greater control over wall thickness in the highly stressed ankle region compared with the conventional double-axis method. Process conditions and quality control procedures have been recommended in the text for Nylon 11 shank production by rotational moulding. Although the process is simple it is characterized by long production times. Mould heating and cooling time is about 34 minutes for instance. In addition it has been found that shank sections less than 120mm in length need to be produced from larger volume moulds to ensure that sufficient material is available to meet wall thickness and insert coverage requirements. The large diameter of these shorter shank sections can cause problems of cosmetic finishing of the prosthesis. The minimum length of shank produced by the single-axis and conventional technique was 78mm and 70mm respectively. The minimum value of wall thickness recommended for a fatigue life in excess of a million load cycles is 3mm. Samples static tested to the Philadelphia Static Load Level typically tapered from 4mm at the proximal end to 6mm at the distal end resulting in lightweight components. A 195mm shank weighs 270g for instance.

The Nylon 11 shanks are hollow and contain metallic inserts moulded-in at distal and proximal ends to provide attachment points for socket and foot unit by single bolt fixings. Moulding trials established optimum insert dimensions to ensure complete encapsulation by plastic during moulding while the mechanical testing programme identified the design features of shanks/inserts which are essential for good fatigue performance and for resisting large static loads. Conical type inserts are preferred. The design is simple, manufacturing costs are low, encapsulation by

thermoplastic is facilitated and the strength of insert anchorage in the components can be readily adjusted to give a progressive pull-out type of failure mode if required. The design of the ankle insert for rotationally moulded, Nylon 11 conical type shanks presents greater problems due to the high stresses generated on the prosthesis in this region accentuated by the requirement for good cosmetic finishing which reduces load bearing area at the ankle. Flanged inserts increase the fatigue performance of this type of shank by reducing bolt bending caused by creep of the shank base. Insert anchorage is secure but as a result failure is transferred to the plastic component under overload conditions which is undesirable if brittle failure characteristics are exhibited by the material. Although emphasis has been placed on shank production the insert designs which have evolved are generally applicable to load bearing prosthetic components such as foot and knee units which could be produced for example by injection moulding.

The structural integrity of shank sections was assessed using the Philadelphia recommended Static Load Level and cyclic loading conditions. Laboratory fatigue testing in particular highlighted the pronounced effect which creep of thermoplastics could have on the service performance of shank sections unless offset or minimized by suitable design or choice of materials. Creep is a time dependent property of thermoplastics defined as increasing strain or deformation with time at constant stress. Specifically, deterioration due to creep can be ascertained over the long time scale of a fatigue test but would not be evident in the shorter time scale of a static test.

The role of component design in mitigating the effect of creep on the fatigue behaviour of rotationally moulded shanks is well illustrated by the case of conical type shanks containing a top hat type ankle insert. Compressive creep of the shank base induced bending of the ankle fixing bolt and joint loosening which precipitated fatigue failure of the bolt. Fatigue performance was increased by a factor of almost 20 to over a million cycles by adding a large diameter base flange to the insert. In this case creep of the plastic is tolerated but flexure of the bolt is minimized by locking the insert rigidly to the test fixture or foot unit.

The increase in fatigue performance of flared ankle shanks relative to the conical type may simply be attributed to reduced creep of the shank base due to increased load bearing area in the ankle region. The stress is reduced locally with a consequent reduction in the magnitude of the creep strain (Powell, 1974).

A drawback of rotational moulding is the limited range of thermoplastics which are suitable for processing by this technique. Nylon 11 for example can be considered a relatively weak thermoplastic with the same stiffness as polypropylene ~1 GN/m^2 and strength of 57 MN/m^2 which is double that of polypropylene. There is therefore limited scope for varying the material to reduce creep unlike injection moulding for instance. Glass fibre reinforcement of thermoplastics substantially increases creep resistance (Powell, 1974) but these materials are not suitable for rotational moulding. A further advantage of fibre reinforced thermoplastics is the attendant increase in material stiffness and strength (5 GN/m^2 and 160MN/m^2 respectively for 30% glass reinforced Nylon 66) which presents opportunities for reducing the component wall thickness and radial dimensions—the latter being important for cosmetic finishing of the limb.

Despite being limited to an unfilled grade of Nylon 11, optimization of shank and insert design does result in fatigue resistant shank sections. A fatigue life in excess of two million cycles was recorded for an experimental prosthesis incorporating Rapidform polypropylene socket, 4-jack alignment devices and rotationally moulded shank. The scope for improvement based on material variation or speed of processing is extensive.

The results of the patient trials focus attention again on the deleterious effect of ankle joint loosening on the service performance of prostheses. The resultant flexural loading of ankle bolts leads to early fatigue failure of the bolt. Joint loosening in service is clearly indicated in the case of the highly active patient where crushing of the wood keel under the anterior region of the shank occurred. Parallels can be drawn in this case with the fatigue behaviour of conical shanks containing top hat type inserts where creep distortion of the shank base away from the planar form resulted in flexural loading of the fixing bolt and its early failure. A further

illustration of the effect of joint loosening on the fatigue behaviour of prostheses is given by the test results of Durance and Wevers (1986). Frequent ankle bolt failure occurred unless the bolt tightening torque was maintained during dynamic testing. Deterioration of the ankle joint was not noted for the third patient indicating that indadequate bolt size is the primary cause of failure.

Apart from one case of service failure due to insert pull-out (which could be caused by overload and/or cyclic loading), all prosthesis failures resulted from fatigue failure of the ankle fixing bolt and not from overload which would result in insert pull-out. This behaviour emphasizes the importance of fatigue testing components and systems at an early stage of development, which could be neglected in an attempt to attain the required static strength figures. Static testing is used to reveal the behaviour of the prosthesis under overload or severe loading conditions but it is worth repeating that static testing will not reveal design weaknesses associated with compressive creep of thermoplastics since this is a time dependent characteristic of these materials. The ability of conical shanks containing top hat ankle inserts to withstand Philadelphia Static Load Levels and yet exhibit early ankle bolt failure as a result of creep of the shank base is a case in point.

Pull-out of conical type inserts from rotationally moulded shanks on overload is preferable as a failure mechanism to brittle failure since it is progressive and can be detected at prosthesis inspection. Moreover pull-out loads are in the region of 2.5kN which provides a convenient method for testing directly the validity of the Philadelphia Static Load Level as a design criterion in patient trials. It should be noted that failure loads recorded due to insert pull-out are well below the UK Department of Health test requirements for safety/structural purposes. These state that in the case of ductile failure, failure loads should exceed 1.5×Philadelphia Static Load Level, i.e. 3.75 kN. For brittle failure 2×Philadelphia Static Load Level is required, i.e. 5kN.

It is significant that partial insert pull-out in service from rotationally moulded shanks was only observed in one case, after two months use, and that for a particularly active patient who also broke a British MAP after two months. A similar shank functioned satisfactorily for nine months without insert pull-out occurring. Partial pull-out of the proximal insert occurred. This is unusual, occurring in laboratory testing after two million fatigue loading cycles for one experimental prosthesis and during static testing at approximately 2.3kN applied axial force due to poor insert encapsulation in a second case. Pull-out of ankle inserts from rotationally moulded shanks in combined compressive/bending tests is more usual between 2.3 and 3.3kN applied axial force. The patient trials indicate then that in general such forces are not applied to limbs in service. These findings fit the pattern of prosthesis loading established during laboratory based ambulation tasks (Biomechanical Research and Development Unit, 1978) and more recent investigations of prosthesis loading by amputees on various types of terrain outside the laboratory. A limited study of prosthesis loading on different surfaces outside the laboratory conducted by Boenick et al, (1977) is also of interest. An instrumented pylon system was used in each case to record the values of prosthetic loading. Maximum values of axial load and ankle AP bending moment recorded during the three studies for BK amputees have been reproduced in Table 7. These can be considered the most damaging loads on a prosthesis.

The most recent Strathclyde study which

Table 7. Maximum recorded values of axial load and ankle AP bending moment

Maximum axial load (kN)	Terrain	Maximum ankle bending moment (Nm)	Terrain	Source/reference
2.2	Up, ramp	220	Up ramp	BRADU/Bioengineering Unit
1.46	Up, pavement	138	Up, gravel	Bioengineering Unit University of Strathclyde (S. Solomonidis)
1.2	Level, rubble	140	Level, rubble	Boenick et al.

recorded prosthetic loading patterns outside the laboratory is more representative of normal service. Their findings tend to confirm the applicability of Philadelphia cyclic load levels as a design criteria for use of a prosthesis under normal service conditions. The Philadelphia Static Load Level is 71% higher than the maximum axial load recorded at Strathclyde indicating that a prosthesis designed to the Static Load Level can be considered to have a safety factor of 1.7.

The present findings indicate that prostheses able to withstand static loading only to the Philadelphia Static Load Level and fatigue testing to Philadelphia cyclic load levels generally function satisfactorily over extended time periods without failing by overload. In only one case was partial insert pull-out noted during routine inspection but whether due to overload or fatigue loading cannot be ascertained. The DHSS Maximum Static Load for definitive limbs is 5kN for brittle failure and 3.75 kN for ductile failure. This test standard appears excessive on the basis of the findings presented here and the amputee loading studies mentioned above. Restrictions are thereby imposed on weight reduction in prostheses and design progress. It is proposed that the Philadelphia Static Load Level is an adequate test requirement for safety-structural purposes when accompanied by a ductile or progressive failure mode of the prosthesis.

Summary and conclusions

The wider use of thermoplastic structural components in artificial limbs would enable their general properties of low density, corrosion resistance and mouldability and more specific properties of certain thermoplastics such as shock absorption, fatigue and wear resistance to be used to the advantage of patients and manufacturers.

Rotational moulding has been investigated in depth for producing thermoplastic shank sections as an alternative to the metal and carbon fibre reinforced resin systems currently available. Moulding conditions have been established which will yield shank sections capable of withstanding Philadelphia recommended static and fatigue loads. The resulting wall thickness distribution has been indicated for various shank geometries and minimum values recommended to ensure mechanical performance to the Philadelphia recommended Static Load Level coupled with long fatigue life. Quality control procedures applied to shanks prior to laboratory and service testing have also been listed.

The design of the metallic inserts moulded-in at distal and proximal ends of the shank to provide attachment points for the shank to other components of the prosthesis has been detailed. Final recommended designs ensure satisfactory encapsulation by plastic during moulding, long fatigue life and a progressive shank failure mode under overload conditions by insert pull-out. The insert designs which have evolved over the course of the investigation are generally applicable to load bearing prosthetic components such as foot and knee units.

Static and fatigue testing of experimental prostheses incorporating plastic shanks and alignment devices demonstrated that they could withstand static loading to Philadelphia Static Load Levels and exhibit long fatigue lifetimes in excess of two million cycles. Laboratory testing underlined the necessity for both fatigue and static testing of thermoplastic components since a high static test value is not necessarily indicative of long fatigue life. Specifically, deterioration due to time dependent mechanical properties such as creep, can be ascertained in fatigue testing. Whilst this property of thermoplastics can exert a major influence on service performance of components its effect would not be evident in the shorter timescale of the static test.

Fourteen patients have been fitted with experimental prostheses based on various combinations of plastic shanks and alignment devices. The longest period of use is 33 months. Four service failures occurred at 2, 5, 10 and 18 months respectively, three due to ankle bolt failure, one due to partial pull-out of the proximal shank insert. Flexural fatigue failure of the fixing bolt is indicated due to distortion and loosening of the ankle joint in two cases. Poor selection of fixing bolt size (i.e. 8mm rather than 10mm for a highly active male patient) is proposed as the dominant reason for failure in the third case.

The shank design gave the opportunity for testing the validity of the Philadelphia Static Load Level for prostheses by building-in failure loads around this figure (2.5kN) based on insert

pull-out. Patient trials revealed only one case of insert pull-out although whether due to overload or fatigue loading cannot be ascertained. This finding focuses attention on the ability of prostheses designed to Philadelphia Static Load Levels and cyclic load levels to withstand service loading over extended periods. In addition it indicates that the DHSS static test standards for prostheses are probably excessive. It is concluded that the Philadelphia Static Load Level along with fatigue testing is a satisfactory test criterion, at least over the timespan of the present patient trials, for general service use of thermoplastic prosthetic components.

Acknowledgements

Thanks are due to Professor Vergil Faulkener, CPO of the Audie L. Murphy Memorial Veterans Hospital, San Antonio, Texas for fitting the patients involved in the American based trial and monitoring the performance of the prostheses. Thanks are also due to Professor G. Bentley of the Royal National Orthopaedic Hospital, Stanmore for providing medical supervision and to Mr. L. Bass for finishing off the prostheses.

This work was funded in part by the U.K. Department of Health and Social Security as part of the programme of the Bioengineering Centre. Funding was also provided by the British Limbless Ex-Service Men's Association and by the Mechanical Engineering Department of University College London.

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Prosthetics and Orthotics International, 1988, 12, 41–45

Preliminary assessment of three new designs of prosthetic prehensors for upper limb amputees

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Abstract

At present, upper-limb amputees have a basic choice of a hook or a hand for the prosthetic prehensor. In the USA about two-thirds of upper-limb amputees wear hooks and about one-third wear hands. Either of these options represents a compromise. The hook is more functional and the hand is more cosmetic. Some amputees solve the dilemma by having one of each and interchanging them as work and social situations dictate. However, they would prefer to have one acceptable prehensor, and they want one which is functional, is attractive, and does not necessarily have to look like a hand.

In an attempt to meet the desires of upper-limb amputees, three prosthetic prehensors or "terminal devices" have been designed and developed into models. This article describes the preliminary assessment of these new designs.

Description of new designs

The concept is to have a prehensor which is neither hook nor hand to satisfy the desires of upper-limb amputees (LeBlanc et al, 1987 ab). One notable attempt has been made to accomplish this. That is the work of the creative prosthetist Carl Sumida and his evolution of the CAPP I prehensor for children and the CAPP II prehensor for adults.

The authors took a three-pronged approach to the challenge of designing new prehensors based on (a) the anatomy of the human hand, (b) function of grasping, and (c) appearance.

Prehensor A

This prehensor (Fig. 1, top left) is derived from study of the anatomy of the human hand. It is voluntary closing (VC), uses primarily three-jaw-chuck grasp, has curvatures for multi-point grasp of cylindrical objects and has a cut-out in the dorsum for use of pencils and utensils.

Prehensor B

This prehensor (Fig. 1, top right) is based mainly on aesthetics. It is unique in that it has a rotary thumb which, when positioned for fingertip grasp is VO, and when rotated for palmar grasp is VC.

Prehensor C

This prehensor (Fig. 1, bottom left) is based mainly on functional considerations and has two modes of operation, fingertip grasp in the VO position and palmar grasp in the VC position. The fingertips handle objects up to 1½ inches in diameter and the proximal area handles 1½–3 inches in diameter. Prior work has indicated that 90% of activities can be handled with a 1½ inch opening or less.

Prehensor D

Standard Hosmer-Durrance 5X hook for comparison (Fig. 1, bottom right).

The operation of the Prehensor A design is conceptualized as normally closed, thumb opening completely with a slight pull on the cable, and thumb closing with further pull on the cable.

The Prehensors B and C designs are unique in that they offer different grasping surfaces and the option of using VO or VC prehension. That is, one could hold objects in the VO position with fixed prehension force and no harness pull, or could hold objects in VC position with variable prehension proportional to harness pull.

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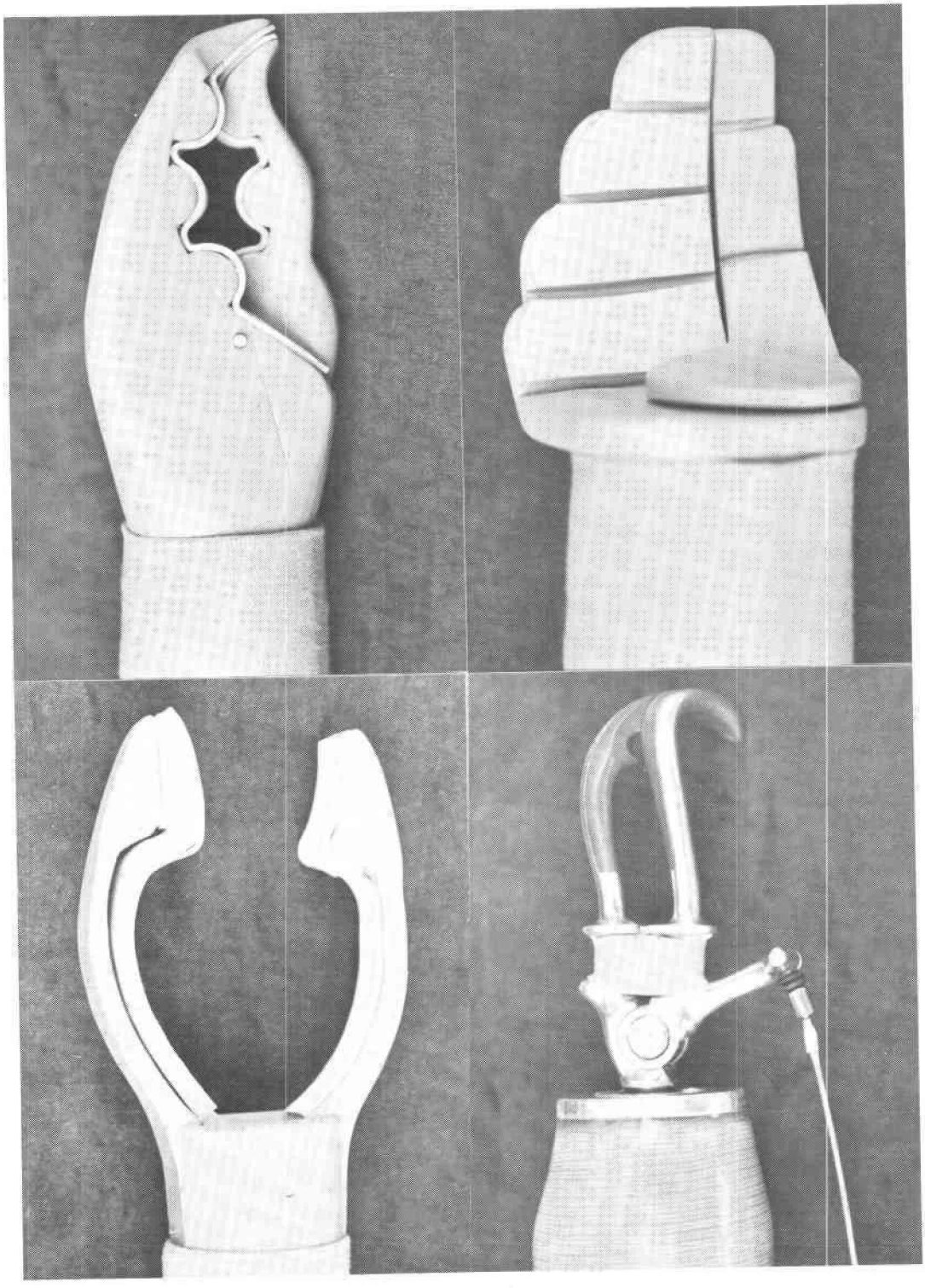

Fig. 1. Prosthetic prehensors.

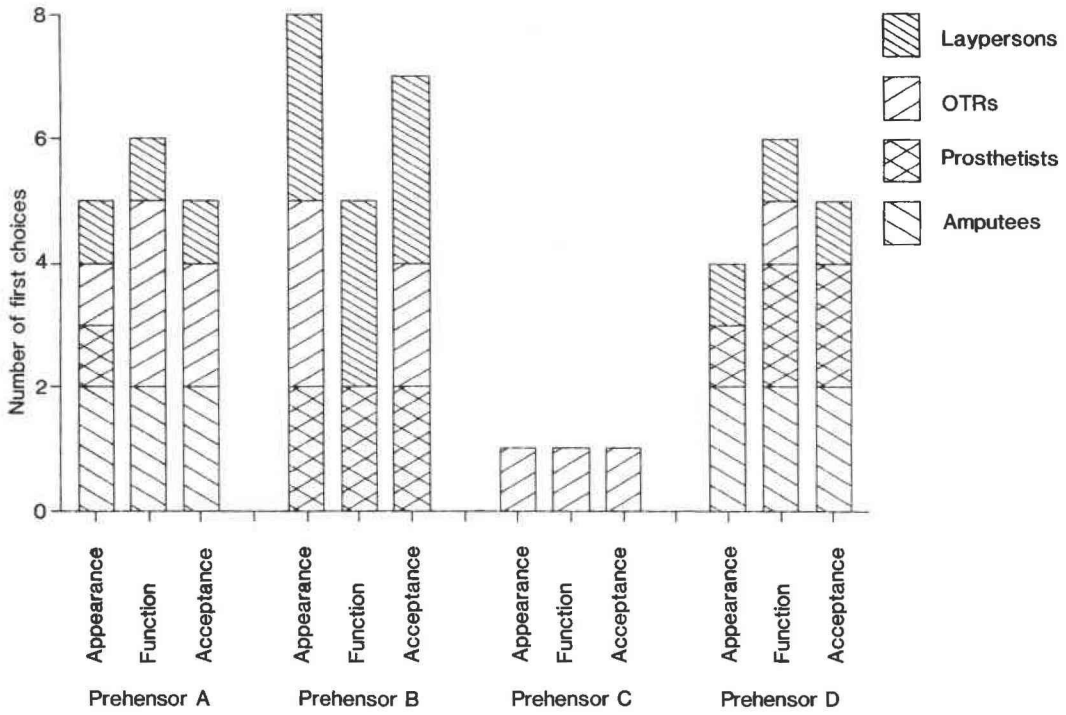

Fig. 2. Ranking of the four prehensors.

All three models were made of hard plastic painted grey with a grey fabric covered forearm and a white dress shirt sleeve to the wrist.

Method of assessment

A questionnaire was developed to help ascertain if any of the three models appeared worthy of further development. Three major areas of importance were addressed: appearance, function and acceptance.

The questionnaire was administered face-to-face to a cross section of 18 people as follows:

4 below-elbow amputees
4 prosthetists
5 occupational therapists
5 lay persons

18 total

Each person was shown models of the three prehensor designs and asked for their reactions to them.

The questionnaire was in two parts. The first part elicited responses to the three new designs. The second part included the common, "standard" Hosmer-Dorrance 5X Hook for comparison and re-examination of preferences with the three new designs. A ranking system was used to determine 1st, 2nd and 3rd choices.

In addition, subjective comments were solicited on design features that were felt to be positive or negative, including ideas of modification for improvement.

Of the 18 people participating in completion of the questionnaire, nine were women and nine were men. The five lay people included (1) the father of a 19-year-old boy with a below-elbow congenital amputation, (2) the wife of a man with a below-elbow amputation for 43 years, (3) a special education teacher of 25 years experience, (4) a hospital recreation therapist with 15 years experience, and (5) a psychology counselor with minimum exposure to upper-limb amputees.

Results

Figure 2 shows the ranking of all four prehensors by the different groups of people.

Comments

Subjective comments made about all four prehensions are listed below.

Prehensor A	
Positive	Negative
multifunctional; versatile; large surface area for grasp; fits well in pocket; attractive; resembles hand; graceful contours; good vision for grasp; simplicity of design; durable	beak nose; bird-like; reptilian; claw-like; too much bulk; no lateral grasp; problem holding large handles
B	
not threatening; nice contours; two function thumb; intriguing; fascinating; presents additional options; artistic, different; two types of grasp; graceful; not weapon-looking; large, adaptable grasp; can be scoop or shovel	alien; turtle hand; looks funny; one-sided; looks unstable; awkward angles of grasp; large excursion required; science-fiction-like
C	
VO and VC grasp option; capacity for small and large tension; simple, streamlined in appearance; good vision for grasp; small bulk; not cumbersome; easy to use	too wide; too much open space; looks like R2D2; claw resembles a hook; limited approach to objects; robot-like; awkward use
D	
metal good for working around heat and chemicals; durable; can be tool or weapon if necessary; small point good for fine grasp; good vision for grasp; can get into small spaces; small bulk, low profile; hook around object for pulling; nicely machined; quality look to it	external cable activation; Captain Hook stigma; metallic, shiny; cold-looking; crush styrofoam cups or eggs; threatening, weapon-like; looks heavy; can tear clothes; dangerous in sports; too much weight during hot weather; uncomfortable from perspiration

In addition to the positive and negative comments people suggested modifications to the prehensors for enhancement of quality.

Modifications suggested

Prehensor A
have thumb curving inward rather than outward for better appearance; make locking mechanism like APRL hand and hook; change alignment for improved grasp; VC should be actively researched; try different colours and materials; change scallops to flat surface with texture; less bulk
B
good idea to have hole or slot for carrying handles, such as luggage; if made of stainless steel, could cut down on bulk; cant down (flex) the wrist slightly; make rotating thumb very strong; put ridges on flat surfaces; have "fingers" come to a point for fine grasp
C
have flat versus curved surfaces for better grasp; have the stationary fingers pre-positional; have ends come to point for fine grasp; have less bulk
D
have inside activation; make plastic for warmth and more social appearance; make light as possible and neutral in colour.

Assessment of prosthetic prehensors

A suggestion was made and supported by three raters for continued exploration of voluntary closing prehensors. The geriatric and very small child populations are unwilling to have voluntary closing prehensors currently. It was felt that focus on new technology with different materials and designs could promote the voluntary closing principle as a viable and practical answer to current problems.

Conclusions

Prehensor B was ranked the highest overall. It had the highest scores for appearance and acceptance.

Prehensors A and D (5X Hook) were close to one another for 2nd place. Both scored slightly higher in function than Prehensor B, but were

lower in appearance and acceptance. It is the feeling of the authors that Prehensor B ranked lower in function because it is the biggest departure in design and the most unknown and untested functionally.

Prehensor C was clearly last as 4th choice among the four prehensors.

These conclusions suggest that (1) there are viable alternatives to the standard hooks and hands and (2) Prehensor B is worth pursuing.

Acknowledgements

This work is being supported in part by Field-Initiated Grant No. 133MH70021 from the National Institute on Disability Rehabilitation and Research, U.S. Department of Education and the Morris Stulsaft Foundation, San Francisco. Also significant was the opportunity to exchange ideas in Europe by means of a Fellowship to the secondary author from the International Exchange of Experts and Information in Rehabilitation, World Rehabilitation Fund, New York. The authors thank Douglas Williams, Ph.D., for assistance in data analysis.

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Prosthetics and Orthotics International, 1988, 12, 46–49

A conductive walkway system for measurement of temporal and distance parameters of gait

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Abstract

This work describes a system used in gait analysis studies. The system is based on a continuous conductive walkway, made of ordinary aluminium foil. It measures the length of each single step, as well as those temporal parameters of gait that relate to the position of the feet on or off the ground. The system is relatively simple and inexpensive to build and run. Data collection and reduction is not excessively time consuming and does not require particularly high training of the operator. In conjunction with a microcomputer the system could be suitable for routine testing in the clinical environment. The present setup has been tested and proved consistent and sufficiently accurate.

Introduction

A variety of gait analysis systems has been developed around the world. They can be classified according to the parameters they measure and the technique they use to measure the specific parameters. A detailed description of human locomotion calls for the employment of rather sophisticated systems. These systems are costly and require relatively high expert knowledge by the operator. On the other hand, more often than not, they are inconvenient, from the point of view of the patient, and time consuming, from the point of view of the data analyst. For these reasons such systems are restricted to the major gait analysis laboratories. Smaller units, particularly those attached to the clinical environment, have to adopt a compromise between the fullest possible gait picture on the one hand, and cost, work man-hours, and patient convenience on the other. Some of the systems that have been used in gait analysis so far do provide a useful compromise. One of them is the conductive walkway system, which records the temporal parameters of gait that relate to the position of the feet on or off the ground. Such a system was described by Drillis (1958) and later, in a developed version, by Gardner and Murray (1975). Basically it consists of a conductive walkway connected to one of the poles of a battery. Electrodes attached to the soles of the shoes are connected, through appropriate resistors, to the other pole. The system electrode-walkway works like an ON-OFF switch. The magnitude of the current through the circuit corresponds to the combination of electrodes that make contact with the walkway. A conductive walkway, split longitudinally, was also used by Cheung et al (1983). In their application the two sides of the walkway acted as the contacts of an ON-OFF switch. Electrodes placed at the soles of the shoes were short-circuited. Thus the circuit was ON only during the double support.

All systems based on the conductive walkway principle measure only temporal parameters of gait, such as cycle duration, duration of single and double support and duration of swing of each leg. In conjunction with a dual light beam/photocell system it can provide the mean step length.

The magnitude of each individual single step length is an important parameter of gait. In order to determine its value various methods can be used. Wall et al (1978) used a walkway consisting of a series of parallel conducting rods connected between resistors that formed a linear array. Electrodes positioned on the soles of the shoes short-circuited two adjacent rods and produced an electric signal proportional to the position of the shorting point along the walkway. An array of conducting strips was also

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employed in a system developed by Gifford and Hutton (1980). Gabel et al (1979), described a walkway consisting of an array of flat linear pressure sensitive switches. Draganich et al (1980) produced a sheet transducer consisting of a matrix of 7168 switches. Their status (ON or OFF) defined the weight bearing pattern of the supporting foot. In principle this system could be used to measure step length.

The production of systems that can provide single step length, like those described above, imposes some difficulties, especially when long walkways are required. The purpose of this work was to produce a simpler system that could provide single step length, as well as the temporal parameters of gait that relate to the position of the feet on or off the ground.

System description

The system consists of a continuous conductive walkway, 22 m long, 1 m wide. The walkway is connected to one side of an electronic circuit. The other side of the circuit is connected to electrodes applied to the soles of the shoes. The system can be divided in two sub-systems having in common only the walkway. One of the sub-systems measures step length and the other the temporal parameters of gait.

In general terms the system can be described as follows: One end of a conductive walkway is raised to a potential voltage (V) relative to the other. Then electrodes positioned on the soles of the shoes measure the potential of the specific point of the walkway, where they make contact, relative to the end of the walkway. As the voltage gradient is nearly linear along the walkway (disregarding points close to its ends), the potential difference sensed by the electrodes is proportional to their distance along the long axis of the walkway. Instead of actually measuring the potential difference sensed by electrodes on the shoes, the signals from the electrodes are input to a differential amplifier. The amplifier is balanced when the distance of the electrodes along the long axis of the walkway is zero. Then when the electrodes are positioned anywhere along the walkway, the output from the differential amplifier is proportional to the distance of the electrodes along the axis of the walkway, or in other words proportional to the step length. A block diagram of the system is shown in Figure 1. The diagram shows both the sub-systems into which the whole system can be broken, the step length measuring system and the temporal parameters measuring system. The set-up basically consists of the conductive walkway, a generator, two

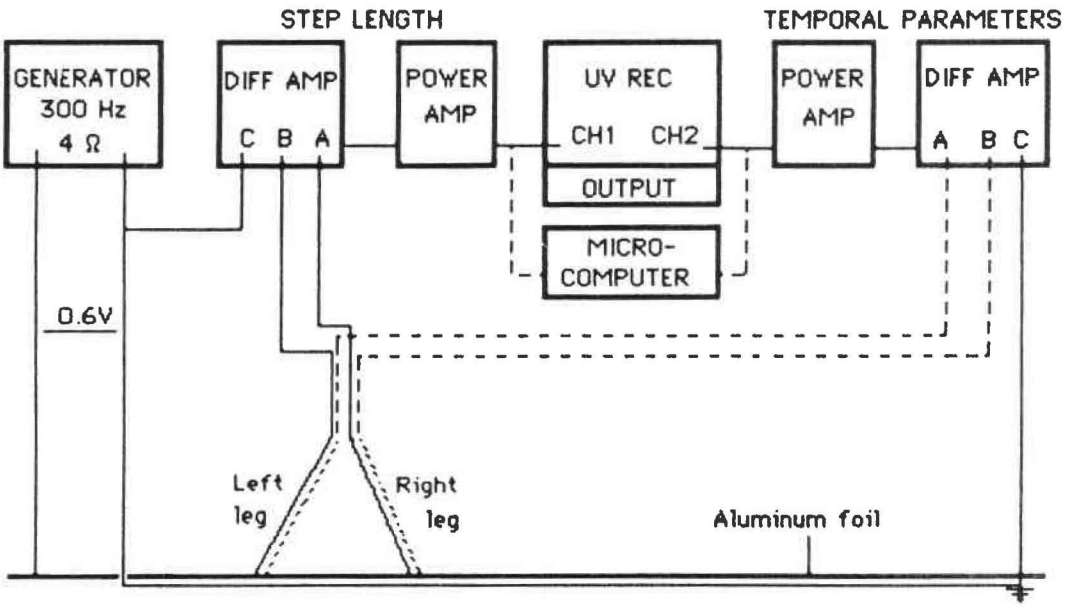

Fig. 1. Block diagram of the system.

sets of differential-power amplifiers and the U.V. recorder and/or, optionally, a microcomputer.

To achieve a good step length resolution a conductive walkway that will show sufficiently steep voltage gradient is required. To this end ordinary aluminium foil (kitchen foil) was used. It is thin enough (0.015 mm) to present appreciable resistance per unit length.

Current to the walkway was taken from a low impedance generator at 0.6V at the output and a frequency of 300 Hz.

The two differential amplifiers shown in Figure 1 work quite differently. The one measuring step length provides an output proportional to the step length when both the respective electrodes-one on each foot–make contact with the walkway. When only one foot is on the ground the differential amplifier saturates, a diode circuit is activated at the output of the power amplifier, and zero current is driven to CH1 of the U.V. recorder.

The differential amplifier associated with the measurement of the temporal parameters saturates and provides at its output a signal +V or −V according to which leg is on the ground. When both legs are on the ground it provides a signal oscillating at 300Hz between +V and −V, unless the distance of the corresponding sensing electrodes is less than 15cm. In that case (only possible in severely handicapped patients), the temporal parameters amplifier will function similarly to the step length amplifier and provide a signal proportional to the distance of the sensing points.

There are two sets of sensing electrodes on each shoe. The electrodes associated with the measurement of step length are two 5mm dia. thin copper discs fixed one at the heel and the other at the toe section of each shoe. They are short circuited. This configuration allows one specific point of one shoe to be related in distance with another specific point at the other shoe. The points related are the toes of the trailing leg and the heel of the forward. To get the actual step length one should add to the distance of the above points the distance of the two electrodes on the shoe (and probably correct roughly for the foot angle).

The electrodes associated with the measurement of the temporal parameters are formed from thin steel wire and attached to the soles of the shoes in a way that secures contact with the ground during the whole stance phase.

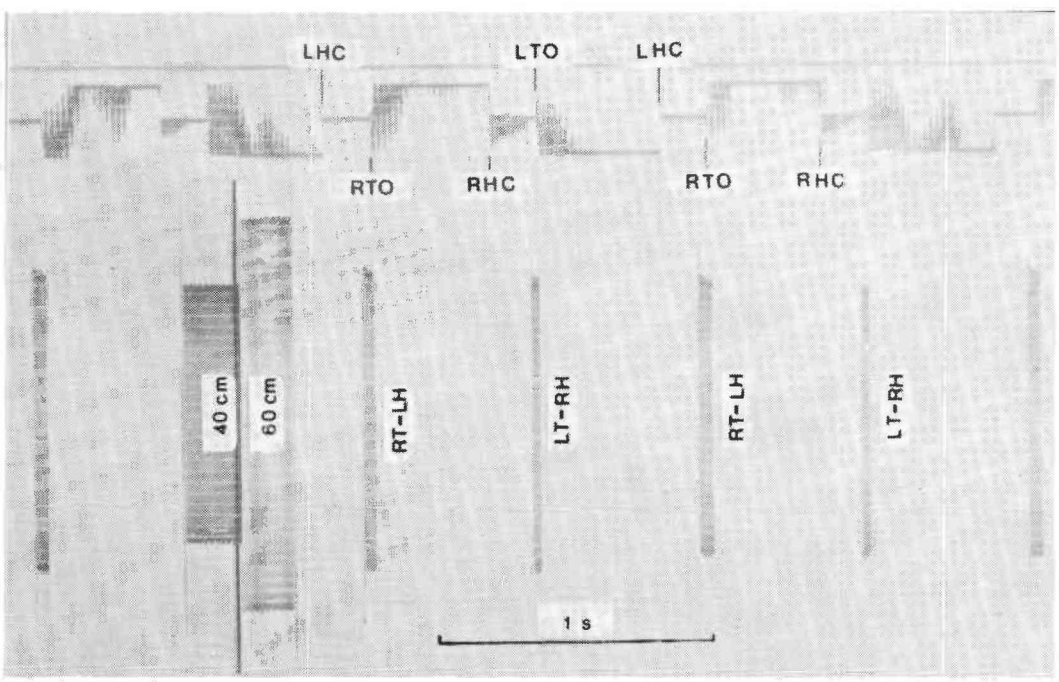

Fig. 2. Part of a typical record obtained at the U.V. output of the system. LHC, LTO: left heel contact, left toe off; RHC, RTO: right heel contact, right toe off; RT-LH: right toes to left heel; LT-RH: left toes to right heel.

Discussion

Part of a typical record of a gait analysis test using this technique is shown in Figure 2. Whether a particular step is a left or a right one can be inferred from the temporal parameters trace, obtained on the same record.

The step length sizes measured on the U.V. paper are entered into the microcomputer and analysed. The step length as measured by this method was compared with the step length measured physically on the walkway. The difference was typically smaller than 1cm.

The system reserves the merits of the conductive walkway systems that measured only temporal parameters of gait. It is rather simple and relatively inexpensive to build and run. It is simpler than other systems measuring step length since it does not require the construction of arrays of resistors, or matrices of switches. It can be made any practical length, without any appreciable extra cost. This is desirable, because it allows for a sufficient number of steps to be analysed and averaged. Routinely the author analyses and averages 20 consecutive steps for each run of a patient.

The aluminium foil that is used as the conductive walkway material is cheap, but is mechanically weak. Materials of higher resistivity can be selected for sufficient mechanical strength and high resistance per unit length.

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Prosthetics and Orthotics International, 1988, 12, 50–52

Traumatic amputation of the upper limb: the use of body-powered prostheses and employment consequences

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Abstract

Forty three patients with unilateral traumatic amputations were reviewed as to the use of prostheses and employment consequences of the amputation. Seventeen of 19 below-elbow amputees, and 12 of 24 above-elbow amputees used their prostheses. Non-users compared to users of prostheses were characterized by: 1) Higher level of amputation 2) Non-dominant arm amputation and 3) Younger age at the time of amputation. However non-users usually did well on the labour market for various reasons.

Introduction

The rejection rate for upper limb, body powered prostheses varies in different reports from 3% to 68% (London, 1970; Jacobs, 1975; Vitali et al. 1986). Provision of a myoelectric prosthesis may increase the number of users to more than 90% (Heger et al. 1985). The present study was undertaken to identify the number of prosthetic users following a traumatic amputation of an arm, and to elucidate which factors made the patients reject the prostheses. The consequences of an amputation with special emphasis on employment were also investigated.

Patients and methods

In the period 1970–1986, 59 patients were referred to the authors' department, for fitting of a prosthesis following a unilateral traumatic amputation of the upper limb. It is supposed that the vast majority of the patients from Eastern Denmark have been referred as the department has a centralized fitting service. Twelve patients were lost to follow up. In six cases the patients had died from unrelated causes, and the remaining six patients could not be traced. Three patients fitted with myoelectric prostheses and one patient fitted with a cosmetic prosthesis were omitted from the study. The follow up series thus comprised 43 patients (6 women and 37 men). Nineteen patients were amputated below the elbow and 24 patients above–, or in one case through the elbow. The mean age at the time of amputation was 30 (2–70) years and 11 patients were below 18 years of age. The mean follow up was 7.4 (0.5–17.5) years and the mean age at follow up was 37 (15–76) years with 3 patients being below 18 years of age. All patients were fitted with a conventional body powered cable operated prostheses.

The patients were interviewed about their use of prosthesis, occupation before the amputation and at the time of follow up, persistent stump pain, time elapsed before fitting of the final prosthesis and possible rejection of the prosthesis. For statistical analyses the Chi-square test was applied.

Results

At the time of the amputation 31 patients were in employment, one was unemployed and one was receiving retirement pension. Seven of the patients below the age of 18 were attending school and three were below school age.

At the time of follow up, 19 patients were employed, four were unemployed, six were under rehabilitation and the three patients

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below 18 years of age were all attending school. Three patients were receiving a retirement pension, and eight patients disablement pension (in five patients primarily granted for concomitant diseases). In six of these patients rehabilitation had been tried but had failed.

Fourteen patients claimed that they never used their prostheses. The user group consisted of 29 patients, 15 patients using the prostheses all day; 10 patients every day and 4 patients occasionally. Twenty one patients used their prostheses at work outside their home, 25 patients at home, 17 while eating and 24 patients claimed that they also used the prostheses for cosmetic reasons. One patient used the prosthesis only for cosmetic reasons. The mean age of the users was 38 years compared to 32 years of the non-users. There were no major differences between the groups concerning sex distribution; persistent stump pain (total of 22 cases); time elapsed from amputation until fitting of the final prosthesis (26 weeks) or follow up. The non-users rejected the prostheses within a few months in 10 cases and after 3–16 years in the remaining four cases. These four cases were all above-elbow amputations. The reason for rejection was in three cases change of occupation to a job where the use of a prosthesis was not needed. The fourth patient suffered from recurrent dislocation of the shoulder joint which made prosthetic use impossible.

Below-elbow amputees became users in 17/19 cases (Table 1) compared to 12/24 cases among the above-elbow amputees ($p<0.01$, Chi-square test).

Table 1 shows the relationship between prosthetic use and dominance of the arm. It is seen that patients with non-dominant arm amputations especially above the elbow had the lowest proportion of users (6/13). The highest proportion of users (10/10) was found in the below-elbow dominant arm amputees. Table 2 shows that 8/14 non-users of prostheses had employment, and none were unemployed, compared to only 11/29 users being employed but four being unemployed. There was a tendency for non-users primarily to be employed as skilled workers or in non-strenuous jobs.

Table 1. The relationship between prosthetic use, dominance of the arm and level of amputation.

	Users	Non-users
Dominant arm		
Above-elbow	6	5
Below-elbow	10	0
Non-dominant arm		
Above-elbow	6	7
Below-elbow	7	2

Table 2. Occupational pattern in users and non-users of prostheses following a traumatic amputation of an arm.

Occupation	Users	Non-users
Available for the labour market		
Skilled workers	1	4
Unskilled workers	6	1
Non-strenuous work	4	3
Unemployed	4	0
Not available for the labour market		
Retirement pension	2	1
Disablement pension	6	2
Studying (School, rehabilitation)	6	3

Discussion

The reported rate of prosthetic users at about two thirds accords well with those previously described in regard to body powered prostheses (Vitali et al. 1986), but are inferior to the user rate described for myoelectric prostheses (Heger et al. 1985). The authors found a higher rate of users among below-elbow amputees, compared to above-elbow amputees, which seems reasonable as a below-elbow prosthesis is lighter and allows better function than an above-elbow prosthesis. There was a tendency towards non-dominant arm amputees becoming non-users, which seems understandable as they had suffered a relatively lesser functional loss and learned to manage with the intact dominant arm.

A higher employment rate was found among the non-users of prostheses than among the users. This might be explained by the fact that patients occupying a job which they could manage with one hand probably stayed in that job and did not become motivated to use their prostheses; whereas patients needing rehabilitation had to leave the labour market for a period and then had difficulties getting a new job. Supporting this theory is the fact that non-users in contrast to users generally were occupied as skilled workers or in non-strenuous jobs.

In summary, the only statistically significant factor found was that the level of amputation seems to be a major factor in the determination of prosthetic use following a traumatic amputation of an arm. In addition there was a tendency towards younger patients and patients with non-dominant arm amputations becoming non-users. Although there was a tendency towards non-users of prostheses having a higher employment rate, this difference was not statistically significant and could be accounted for by the type of employment in the two groups.

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Calendar of events

June, 1988
Congress of the World Federation of Occupational Therapists, Australia.
Information: Ms. S. Degilio, Plaistow Hospital, Samson St., London E13, U.K.

June, 1988
1st Independent Meeting of Society for Disability Studies, Washington, D.C., U.S.A.
Information: Jessica Scheer, 204 Spring Avenue, Takoma Park, MD 20912, U.S.A.

1–5 June, 1988
Joint Spring Meeting of the French and Italian Societies for Surgery of the Hand, Taormina, Sicily.
Information: Yves Allieu, 1133 rue des Bouisses, 34070 Montpellier, France.

2–3 June, 1988
26th Annual General Meeting and Conference of the Canadian Rehabilitation Council for the Disabled, Saskatoon, Canada.
Information: Christine Archibald, CRCD, One Yonge Street, Suite 2110, Toronto, Ontario M5E 1E5, Canada.

3rd June, 1988
Wheelchairs and Seating, Derby, England.
Information: Mrs. A. M. Lees, Course Secretary, National Demonstration Centre in Rehabilitation, Derbyshire Royal Infirmary, London Rd., Derby DE1 2QY, England.

8–10 June, 1988
3rd European Conference on Research in Rehabilitation, Rotterdam, The Netherlands.
Information: Office for Post Graduate Medical Education, Erasmus University Rotterdam, PO Box 1738, 3000 DR Rotterdam, The Netherlands.

8–11 June, 1988
44th Congress of the Scandinavian Orthopaedic Association, Aarhus, Denmark.
Information: Otto Sneppen, Aarhus Turistforenings Kongresbureau, Park Alle 9, DK-8000 Aarhus C, Denmark.

9–11 June, 1988
BME-Austria 88, Graz, Austria.
Information: BME-Austria 88, Institute for Biomedical Engineering, Technical University Graz, c/o Univ.-Doz, Dr. N. Leitgeb, Inffeldgasse 18, A-8010 Graz, Austria.

12–15 June, 1988
2nd Meeting of the Cervical Spine Research Society, Marseilles, France.
Information: Ghislaine Louis, Congress Co-ordinator, Sud Congrès Services, 4 bis Impasse du Roc Fleuri, 13008 Marseilles, France.

12–16 June, 1988
Joint Congress of the Canadian Physiotherapy Association and the American Physical Therapy Association, Toronto, Canada.
Information: Congress Secretary, Canadian Physiotherapy Association, 44 Eglington Avenue West, Suite 201, Toronto, Ontario M4R 1A1, Canada.

13–16 June, 1988
14th Annual Meeting of the American Orthopaedic Society for Sports Medicine, California, U.S.A.
Information: American Orthopaedic Society for Sports Medicine, 70 West Hubbard Street, Suite 202, Chicago, Illinois 60610, U.S.A.

20–22 June, 1988
American Orthopaedic Association Annual Meeting, Hot Springs, Virginia.
Information: AOA, 222 South Prospect, Park Ridge, IL 60068, U.S.A.

20–23 June, 1988
7th Congress of the International Society of Electrophysiological Kinesiology, Enschede, The Netherlands.
Information: ISEK–88, Congress Secretariat, PO Box 310, 7500 A H Enschede, The Netherlands.

25–30 June, 1988
International Conference of the Association for the Advancement of Rehabilitation Technology – ICAART 88, Montreal, Canada.
Information: ICAART 88, 3631 rue St. Denis, Montreal, Quebec, H2X 3L6, Canada.

26 June–1 July, 1988
Spinal Disorders, 1988, Gothenburg, Sweden.
Information: Spinal Disorders 1988, Prof. Alf L. Nachernson, Dept. of Orthopaedics, Sahlgren Hospital, S–413 45 Gothenburg, Sweden.

5–8 July, 1988
REHAPROTEX '88 International Symposium on Technical Aids in Rehabilitation, Brno, Czechoslovakia.
Information: J. E. Purkynē, Czechoslovak Medical Society, Vitēzného Ūnora 31, PO Box 88, CS-12026 Praha 2, Czechoslovakia.

6–13 August, 1988
World Congress on Medical Physics and Bio-engineering, San Antonio, U.S.A.
Information: David T. Kopp, Dept. of Radiology, Univ. of Texas, HSCSA, 7703 Floyd Curl Drive, San Antonio, TX 78284, U.S.A.

16–19 August, 1988
Vth Biennial Conference of the Canadian Society for Biomechanics: Biomechanics—Occupational, Rehabilitation, Sport Applications, Ottawa, Canada. A Symposium on Human Locomotion will be held in conjunction with the conference.
Information: Dr. D. G. E. Robertson, Kinanthropology Dept., University of Ottawa, 35 McDougal Lane, Ottawa, Ontario, Canada, K1N 6N5.

17-20 August, 1988
15th Federal Conference of the Australian Association of Occupational Therapists, Sydney, Australia.
Information: Zorica Rapaich. A.A.O.T. Conference, PO Box 142, Ryde, N.S.W., 2112, Australia.

17–21 August, 1988
76th Annual Meeting of the American Podiatric Medical Association, California, U.S.A.
Information: APMA Headquarters, 9312 Old Georgetown Rd., Bethesda, Maryland 20814–1621, U.S.A.

27 August–1 September, 1988
ISPO Symposium on the Limb Deficient Child, Heidelberg, Germany.
Information: Mrs. I. Hillig, c/o Stiftung Orthopädische Universitäts Klinik, Abteilung für Dysmelie u. Technische Orthopädie, PO Box 104329, Schlierbacher Landstr. 200 a D-6900 Heidelberg 1, Germany.

5–9 September, 1988
16th World Congress of Rehabilitation International, Tokyo, Japan.
Information: Secretary General, 16th World Congress of Rehabilitation International, Japanese Society for Rehabilitation of the Disabled, 3–13–15, Higashi, Ikebukuro, Toshima-ku, Tokyo 170, Japan.

6–9 September, 1988
International Congress of Orthopaedics, Prague, Czechoslovakia.
Information: J. E. Purkynē, Czechoslovak Medical Society, International Congress of Orthopaedics, Vitēzného Ūnora 31, 12026 Praha 2, Czechoslovakia.

7–9 September, 1988
Biological Engineering Society Annual Scientific Meeting, Salford, England.
Information: Ms. J. Upton, BES, The Royal College of Surgeons, Lincoln's Inn Fields, London WC2A 3PN, England.

11–14 September, 1988
European Society of Biomechanics Meeting, Bristol, England.
Information: Dr. A. E. Goodship, School of Veterinary Science, Park Row, Bristol BS1 5LS, England.

11–16 September, 1988
East and West Combined Orthopaedic Meeting, Belgrade, Yugoslavia.
Information: Sava Centre, Milentija Popovica 9, Y-11070 Novi Beograd, Yugoslavia.

12–16 September, 1988
ISPO International Conference on Wheelchairs and Special Seating, Dundee, Scotland.
Information: The Secretariat, Dundee '88, Dundee Limb Fitting Centre, 133 Queen St., Broughty Ferry, Dundee DD5 1AG, Scotland.

17–19 September, 1988
11th Annual Meeting of the American Society of Hand Therapists, Baltimore, U.S.A.
Information: Georgiann Laseter, OTR, FAOTA, Hand Rehabilitation Services, 3707 Gaston Avenue, Suite 520, Dallas, TX 75246, U.S.A.

20–23 September, 1988
Scoliosis Research Society, Baltimore, U.S.A.
Information: Vern Tolo, SRS, 222 South Prospect, Park Ridge, IL 60068, U.S.A.

22–23 September, 1988
2nd Biomechanics and Orthotic Management of the Foot Meeting, Newcastle, England.
Information: Dr. D. J. Pratt, Orthotics and Disability Research Centre, Derbyshire Royal Infirmary, London Rd., Derby DE1 2QY, England.

23–24 September 1988
ISPO Australian National Member Society Annual Scientific Meeting, Repatriation General Hospital, Hollywood, W.A. Information: The Honorary Secretary ISPO, C.D.U., P.O. Box 211, Kew, Vic. 3101. Tel: (03) 862 2944.

26–28 September, 1988
3rd European Congress of Occupational Therapy, Lisbon, Portugal.
Information: Ana Palma, Associacáo Portuguesa de Terapia Ocupacional, A Joao Crisostoma 65, 1000 Lisboa, Portugal.

28–30 September, 1988
British Orthopaedic Association Scientific Meeting, Oxford, England.
Information: BOA, 35-43 Lincoln's Inn Fields, London WC2A 3PN, England.

7 October, 1988
Basic Splintmaking, Derby, England.
Information: Mrs A. M. Lees, Course Secretary, National Demonstration Centre in Rehabilitation, Dept. Rheumatology and Rehabilitation, Derbyshire Royal Infirmary, London Road, Derby DE1 2QY, England.

12–16 October, 1988
Eastern Orthopaedic Association, Puerto Rico.
Information: EOA, 301 8th St., Suite 3F, Philadelphia, PA 19106, U.S.A.

15–21 October, 1988
Western Orthopaedic Association, Hawaii.
Information: WOA, 2975 Treat Blvd, –E5, Concord, CA 94518, U.S.A.

25–30 October, 1988
American Academy of Orthotists and Prosthetists Annual National Assembly, Washington, DC.
Information: American Academy of Orthotists and Prosthetists, 717 Pendleton St., Alexandria, VA 22314, U.S.A.

26–29 October, 1988
American Academy of Cerebal Palsy and Development Medicine Annual Meeting, Toronto, Canada.
Information: AACPDM, PO Box 11083, Richmond, VA 23230, U.S.A.

27–28 October, 1988
Functional Foot Orthoses, Derby, England.
Information: Mrs A. M. Lees, Course Secretary, National Demonstration Centre in Rehabilitation, Dept. Rheumatology and Rehabilitation, Derbyshire Royal Infirmary, London Road, Derby DE1 2QY, England.

27–28 October, 1988
Seventh Southern Biomedical Engineering Conference, South Carolina, U.S.A.
Information: David D. Moyle, Conference Chairman, Dept. of Bioengineering, Clemson University, Clemson, South Carolina 29634-0905, U.S.A.

November, 1988
Joint Conference on Biomedical Engineering, Hangzhou, China.
Information: Yi-ping Li, Secretary CIE/BMES, Shanghai Institute of Physiology, Chinese Academy of Sciences, 320 Yue Yang Road, Shanghai, China.

3–7 November, 1988
10th Annual Conference on IEEE Engineering in Medicine and Biology, New Orleans, U.S.A.
Information: Cedric F. Walker, Dept. of Biomedical Engineering, Tulane University, New Orleans, LA 70118, U.S.A.

9–12 November, 1988
Children's Orthopaedics, Washington, U.S.A.
Information: Raymond Morrissy, AAOS, 222 South Prospect, Park Ridge, IL 60068, U.S.A.

3 December, 1988
Shriners Hospital Pediatric Orthopaedic Seminar, Philadelphia, U.S.A.
Information: Randal Betz, Shriners Hospital, 8400 Roosevelt Blvd, Philadelphia, PA 19152, U.S.A.

1989
9–14 January, 1989
American Academy of Orthopaedic Surgeons Annual Meeting, Las Vegas, U.S.A.
Information: AAOS, 222 South Prospect, Park Ridge, IL 60068, U.S.A.

14–15 April, 1989
Conference on The Changing role of Engineering In Orthopaedics – Call For Papers. London, England.
Information: Andree Johnson, Conference Department C384, The Institution of Mechanical Engineers, 1 Birdcage Walk, Westminster, London SW1H 9JJ, England.

3–6 May, 1989
British Orthopaedic Association Scientific Meeting, Rhodes, Greece.
Information: B.O.A., 35-43 Lincoln's Inn Fields, London, WC2A 3PN, England

4–7 May, 1989
Pediatric Orthopaedic Society, South Carolina, U.S.A.
Information: POS, 222 South Prospect, Park Ridge, IL 60068, U.S.A.

11–15 June, 1989
American Physical Therapy Association Annual Conference, Nashville, U.S.A.
Information: Bonnie Polvinale, Director of Conference/Meeting Services, A.P.T.A., 1111 N. Fairfax St., Alexandria, VA 22314, U.S.A.

12–15 June, 1989
American Orthopaedic Association Annual Meeting, Colorado Springs, U.S.A.
Information: AOA, 222 South Prospect, Park Ridge, IL 60068, U.S.A.

13–16 June, 1989
International Conference of the Netherlands Society for Physiotherapy, The Hague, Netherlands.
Information: Nederlands Genootschap voor Physiotherapie, PO Box 248, NL-3800 AE Amersfoort, Netherlands.

13–15 September, 1989
British Orthopaedic Association Scientific Meeting, London, England.
Information: BOA, 35–43 Lincoln's Inn Fields, London WC2A 3PN, England.

2–8 October, 1989
American Orthotic and Prosthetic Association Annual National Assembly, Reno, U.S.A.
Information: AOPA, 717 Pendleton Street, Alexandria, VA 22314, U.S.A.

11–15 October, 1989
Eastern Orthopaedic Association, Montreal, Canada.
Information: EOA, 301 8th St., Suite 3F, Philadelphia, PA 19106, U.S.A.

November, 1989
3rd World Congress of Disabled People's International, Bogota, Colombia.
Information: DPI General Secretary, Box 36033, S-10071 Stockholm, Sweden.

12–17 November, 1989
ISPO World Congress, Kobe, Japan.
Information: Secretariat, 6th ISPO World Congress, c/o International Conference Organisers Inc., 5A Calm Building, 4-7 Akasaka 8-chome, Minato-Ku, Tokyo 107, Japan.

April, 1990
British Orthopaedic Association Scientific Meeting, Glasgow, Scotland.
Information: BOA, 35-43 Lincoln's Inn Fields, London WC2A 3PN, England.

September, 1990
British Orthopaedic Association Scientific Meeting, Birmingham, England.
Information: BOA, 35-43 Lincoln's Inn Fields, London WC2A 3PN, England.

DUNDEE '88
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WHEELCHAIRS AND SPECIAL SEATING
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Topics which will be considered include: needs, basic principles, assessment and prescription, seating and wheelchair systems and associated devices, information sources, standards and testing, service organizations and research and development priorities. A major scientific and commercial exhibition will be mounted in association with the conference.

For Registration Forms and Preliminary Programme contact:

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International Society for Prosthetics and Orthotics
Symposium on the Limb Deficient Child
Heidelberg, 27 August – 1 September, 1988

It is our great pleasure to invite you cordially to the First ISPO Symposium on the Limb Deficient Child, which will be held from 27 August to 1 September, 1988 in Heidelberg, Germany.

The International Society for Prosthetics and Orthotics (ISPO) has had a multidisciplinary approach to the treatment of the limb deficient child from its very beginning.

A most important result of ISPO's worldwide effort is the international nomenclature of limb deficiencies (H. Kay 1975)* which makes international understanding and cooperation easier and more effective.

In our Symposium on the Limb Deficient Child we will discuss each kind of longitudinal and transverse deficiency on the basis of this nomenclature as well as problems of children with acquired amputations.

The subjects will be examined from many points of view such as:

- Medical aspects
- Psycho-social aspects
- Special surgical procedures
- Physical Therapy
- Occupational Therapy
- Prosthetics and Orthotics including Engineering
- Mobility aids
- Education
- Sports

The accepted papers and the most important remarks of the discussions will be published as the most comprehensive international knowledge on the limb deficient child currently available.

The city and the University of Heidelberg as well as the surroundings and the social events will present a most suitable setting for the Symposium.

Professor John Hughes
President of ISPO

Prof. Dr. Ernst Marquardt
ISPO Committee on the Limb
Deficient Child

*) Clinical Applications of the New International Terminology for the Classification of Congenital Limb Deficiencies by H. W. Kay. InterClinic Information Bulletin, March 1975, Vol. XIV, No. 3, p. 1-24.

Venue	Kongreßhaus Stadthalle Heidelberg, FRG
Official Language	English (translation into German will be provided)
Call for Presentations	Deadline 31 January, 1988 (Please use only the Abstract Form obtainable from the Symposium Secretariat)
Further Attributes	Industrial Exhibition; Poster, Film and Video Sessions; special Facility Visits
Social Programme	Get-together-Reception; Wine-Tasting in the Heidelberg Castle; Concert Dinner in the Castle of Schwetzingen; Organ Recital in the Heilig Geist Church Heidelberg; Excursions in and around Heidelberg
Symposium-Secretariat	Mrs. I. Hillig c/o Stiftung Orthopädische Universitätsklinik Abteilung für Dysmelie u. Technische. Orthopädie P.O. Box 10 43 29, Schlierbacher Landstr. 200 a D–6900 Heidelberg 1 Telephone (0 62 21) 80 62 58
Symposium-Office	Congress Organization Company COC P.O. Box 10 03 65 D–6050 Offenbach/Main 1 Telephone (0 69) 81 30 28 Telex 4 152 730 coc d

The Brian Blatchford Prize

The Brian Blatchford Prize has been established by the Blatchford family to honour the memory of Brian Blatchford. It will be awarded every three years at the World Congress of the International Society for Prosthetics and Orthotics.

The first Brian Blatchford Prize will be awarded at the Sixth World Congress of ISPO to be held in Kobe, Japan from November 12th–17th 1989. On this occasion the Prize will be £2,000 and will be awarded for the most outstanding innovation in prosthetics and/or orthotics practice over the previous three year period. The innovation should be related to a piece of prosthetic and/or orthotic hardware, or a scientifically based new technique which results in a better prosthesis or orthosis. The innovation should have reached a sufficiently advanced stage to ensure that it can be used successfully on patients.

The applicant or nominator should initially present evidence detailing the innovation, together with a sample of the device if appropriate, and send it to reach the President of ISPO by 31st December 1988 at the following address:

Professor J. Hughes,
National Centre for Training and Education
in Prosthetics and Orthotics,
Curran Building,
131 St. James Road,
Glasgow G4 0LS
Scotland

The innovation shall be presented at the Sixth World Congress and duly published in 'Prosthetics and Orthotics International'.

The President and Executive Board of the International Society for Prosthetics and Orthotics and the Blatchford family reserve the right to withhold the Prize should no suitable application be submitted.

The Forchheimer Prize

The Forchheimer Prize has been established by the Forchheimer family to honour the memory of Alfred Forchheimer. It will be awarded every three years at the World Congress of the International Society for Prosthetics and Orthotics.

The first Forchheimer Prize will be awarded at the Sixth World Congress of ISPO to be held in Kobe, Japan from November 12th–17th, 1989. On this occasion the Prize will be 4000 SEK and will be awarded for the most outstanding paper on 'Objective Clinical Assessment', 'Clinical Evaluation', or 'Clinical Measurement' published in 'Prosthetics and Orthotics International' during the three years prior to the Congress.

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