The Journal of the International Society for Prosthetics and Orthotics

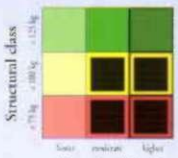
Prosthetics and Orthotics International

April 1999, Vol. 23, No. 1

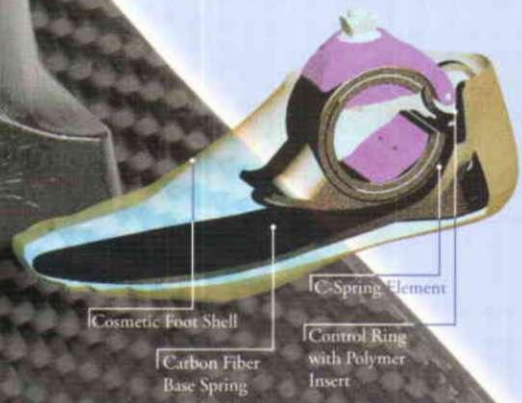
1C40 OTTO BOCK
C-WALK.

All patients look for a prosthetic foot that provides true wearing comfort. Yet they don't want to sacrifice a high degree of dynamic response. Now there's a way to maximize both benefits. **Otto Bock's 1C40 C-WALK** is a unique carbon fiber foot that combines comfort with dynamic response and multi-axial rotation. First, the C-element cushions the foot for a comfortable heel strike. Then, the stored energy in the C-element is released to facilitate a smooth roll-over to mid-stance. As the forefoot loading increases, again the C-element and now the base plate spring begin to load. This energy is returned at toe-off to assist in initiating the swing phase. Finally, regardless of the patient loading or activity level, an integrated control ring that connects the C-element to the base plate regulates the spring characteristics during the entire stance-phase of the gait cycle.

CE



Otto Bock offers an extended 2-year warranty, if exclusively Otto Bock Modular Components have been installed according to the Otto Bock Classification System©.



Comfort & Dynamic Response

Because of the interior contouring, even the thin-walled cosmetic foot shell is a functional part of this foot.

*The foot was developed in cooperation with the French company Cairos.

OAto Bock

ORTHOPÄDISCHE INDUSTRIE

A Company of the Otto Bock Group
Max-Näder-Str. 15 · D-37105 Duderstadt
Tel. (0 55 27) 8 48-0 · Fax (0 55 27) 848 15 14
e-mail: oi@ottobock.de · Internet: www.ottobock.com

PROVEN QUALITY · PRACTICAL SOLUTIONS

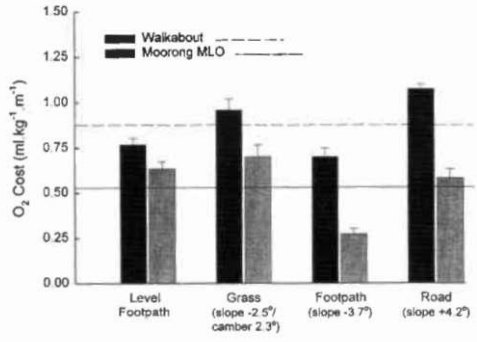
The Journal of the International Society for Prosthetics and Orthotics

December 1998, Vol. 22, No. 3

ERRATA

During the production of the last issue of Prosthetics and Orthotics International, December 1998, Vol. 22, No. 3, the wrong figure 3c was printed on page 262.

The correct version is reproduced below and should be inserted in the appropriate position.



(c)

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. +45 39 20 72 60, Fax. +45 39 20 75 01). The subscription rate for 1999 is GBP90 per annum, single numbers GBP31. The journal is provided free to Members of ISPO. Remittances should be made payable to ISPO.

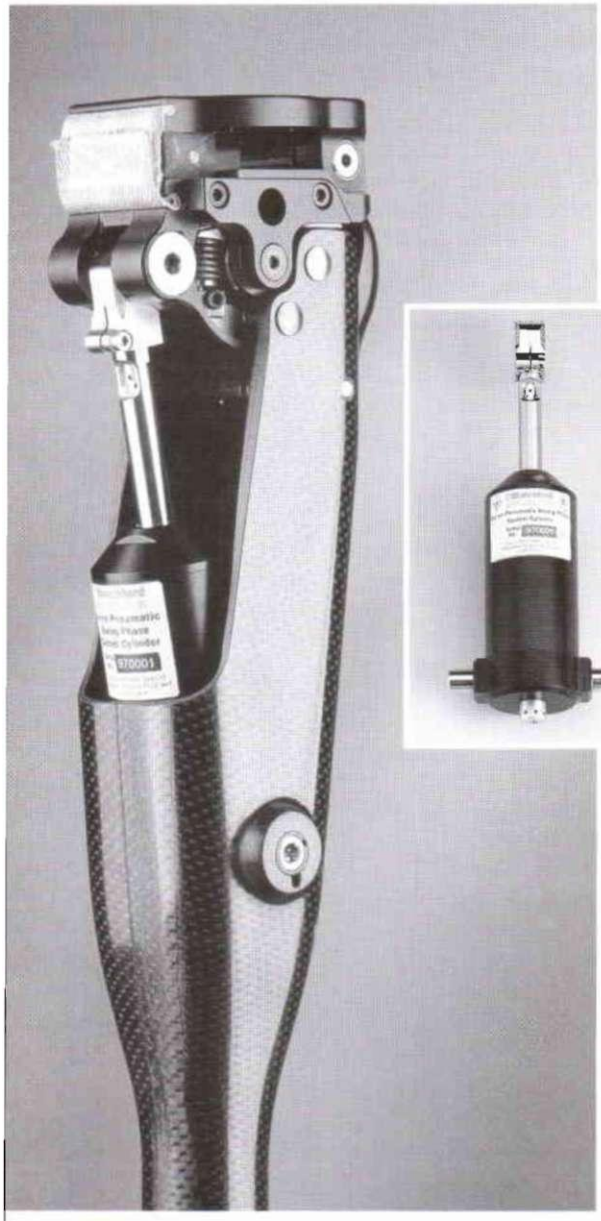
Editorial correspondence, advertisement bookings and enquiries should be directed to Prosthetics and Orthotics International, National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Curran Building, 131 St. James' Road, Glasgow G4 0LS, Scotland (Tel. +44 141 552 4049, Fax. +44 141 552 1283).

ISSN 0309–3646

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

Printed by Beith Printing Company Ltd, Glasgow, Scotland

Servo PSPC



A major advance in pneumatic swing phase control technology

The SERVO valve within the cylinder responds to any increase in flexion rate above the normal setting.

- The 'open circuit' design reduces cylinder heating whilst allowing the unit to automatically pump up to higher resistances
- Light weight 270 g
- Independent adjustment of flexion and extension rates
- Responds immediately to changes in flexion force
- Fully interchangeable within the Endolite Universal shin range
- Structurally tested to ISO10328 - A100 load levels

CE

For more information contact Blatchford Customer Services or your regional distributor.

BSI REGISTERED FIRM
Certificate No.
FM29097
ISO9001
EN46001

THE PRINCE OF WALES AWARD

Chas. A. Blatchford & Sons Ltd
Lister Road, Basingstoke,
Hampshire, RG22 4AH, United Kingdom
Telephone: +44 (0) 1256 465771
Facsimile: +44 (0) 1256 479705

ENDOLITE

The Journal of the International Society for Prosthetics and Orthotics

April 1999, Vol. 23, No. 1

Contents

ISPO

Elected Members of Executive Board:

N. A. Jacobs (President)	UK
S. Heim (President-Elect)	Germany
G. Fitzlaff (Vice-President)	Germany
B. M. Persson (Vice-President)	Sweden
J. G. Craig (Member)	USA
J. H. B. Geertzen (Member)	Netherlands
W. Hessing (Member)	Denmark
J. D. Martina (Member)	Curacao, NA
S. Sawamura (Immediate Past President)	Japan
J. Steen Jensen (Hon. Treasurer)	Denmark
B. McHugh (Hon. Secretary)	UK

Standing Committee Chairmen and Task Officers:

C. Tørholm (Finance)	Denmark
S. Sawamura (Protocol and Nominations)	Japan
J. Hughes (Education)	UK
S. Heim (Congress)	Germany
B. Persson (Publicity and Publications)	Sweden
H. Tebbin (WWW Homepage)	Germany
J. Steen Jensen (Professional Register)	Denmark

International Consultants to the Executive Board

R. Jovanc	Central America
M. Gomez	South America (Northern Region)
C. Schiappacasse	South America (Southern Region)
W. Hessing	Baltic States
Č. Marinček	Central and Eastern Europe
H. Shangali	Africa
E. Tazawa	South East Asia
A. Von der Borch	South Pacific

Chairmen of National Member Societies:

Argentina	O. P Ruiz	Iran	B. Savee
Australia	J. Halcrow	Israel	E. Isakov
Austria	A. Murri	Japan	S. Sawamura
Belgium	E. Deschoolmeester	Korea	J. S. Shin
Canada	G. Martel	Netherlands	J. H. B. Geertzen
Carribean	H. Kamsteeg	New Zealand	G. J. Flanagan
Chile	A. Blanco	Norway	M. Goplen
China	Zhongzhe Wu	Pakistan	N. M Akhtar
Chinese Taipei	I-Nan Lien	Panama	G. A. Tejada
Colombia	F. Serrano	Russia	A. N. Keyer
Denmark	W. Hessing	Slovenia	D. Kaloper
Finland	L. Nummelin	Sweden	A. Stenström
France	J. P. Lissac	Switzerland	J. Vaucher
Germany	R. Forst	Turkey	H. Ozyalcin
Hong Kong	H. H. Kwan	UK	R. Hanspal
Hungary	J. Magyar	USA	T J. Supan
India	B. Joseph		

Past Presidents

K. Jansen (1974-1977)	Denmark
G. Murdoch (1977-1980)	UK
A. Staros (1980-1982)	USA
E. Lyquist (1982-1983)	Denmark
E. G. Marquardt (1983-1986)	Germany
J. Hughes (1986-1989)	UK
W. H. Eisma (1989-1992)	Netherlands
M. L. Stills (1992-1995)	USA
S. Sawamura (1995-1998)	Japan

Secretary

Aase Larsson	Denmark

Editorial

ISPO had again a solid financial result for the fiscal year 1998.

This has mainly been due to a successful outcome of the IXth World Congress in Amsterdam so competently run by the Secretary General, Hans Arendzen, and his team with highly professional advice from the congress organisers, CONGREX Holland bv. This outcome will make it possible to continue with the same level of activities during the present triennium.

The Society has kept adding to its capital over the past years and at the same time having a high activity level while holding the membership fee unchanged since 1989. In spite of a generally low interest rate in the global monetary market the Society has managed to maintain a net interest rate of 5.1% of its assets through carefully considered and continuously monitored investments in builders or bankers bonds.

ISPO financial statements 1992-98							
	1992	1993	1994	1995	1996	1997	1998
Income	1,207,374	1,077,166	1,077,862	1,080,030	1,080,645	1,140,970	1,153,136
– members	1,151,504	1,045,108	1,050,147	1,055,700	1,053,760	1,125,970	1,138,136
– sponsors	55,870	32,058	27,715	24,330	26,885	15,000	15,000
Education Committee	0	0	0	-21,298	-16,431	-30,821	-124,044
Meetings, Other Org	-195,948	-220,534	-137,955	-17,648	-99,143	-2,756	-52,802
Conf., Work-shops	-9,372	-12,983	-196,828	0	0	-645,310	-231,196
Courses	114,642	-54,982	-273,949	-46,115	-187,026	-132,243	-134,017
Congresses	1,521,233	466,355	-59,747	346,399	315,011	0	781,229
POI Journal	-72,504	-90,645	-3,648	4,493	54,111	137,649	118,282
– income	456,250	487,387	576,528	600,378	751,081	896,408	991,869
– expenses	-528,754	-578,032	-580,176	-595,885	-696,970	-758,759	-873,587
Professional Register	0	-9,293	0	-25,067	-146,138	-101,167	-88,692
Publications	-29,880	-22,391	-38,118	-2,940	13,868	7,365	19,877
– income	28,120	21,644	844	1,121	26,746	7,365	19,877
– expenses	-58,000	-44,035	-38,962	-4,061	-12,878	0	0
Activity Result	2,535,045	1,091,342	347,386	1,342,920	1,218,512	368,086	1,530,485
Administration	-854,293	-864,659	-1,049,634	-1,287,383	-924,962	-956,468	-761,376
– secretariat	-543,301	-515,687	-549,019	-544,744	-493,336	-541,846	-497,560
– board	-304, 512	-307, 621	-247,865	-715,570	-365,910	-274,934	-236,554
– meeting expenses	-6,480	0	-22,206	-22,686	-28,495	-15,268	-16,534
– society promotion	0	-41,351	-45,255	-4,383	-37,221	-1,964	-10,728
– International Comm.	0	0	-185,289	0	0	-122,456	0
Primary Result	1,680,752	268,034	-656,993	30,470	147,412	-585,924	-585,381
Capital Yield	412,633	614,754	-373,032	1,106,112	722,982	853,957	530,551
– interest, maturity yield	419,025	614,754	438,275	412,964	495,302	562,831	417,502
– changes in value	-6,392	0	-811,307	693,148	227,680	291,126	113,049
Years Result	2,093,385	882,788	-1,030,026	1,136,581	870,394	268,576	1,227,504
Assets	6,215,429	7,029,128	6,037,788	7,053,168	8,064,208	8,371,682	9,431,084

The good capital yield has given ample room for the international activities of the Society. During the past year these have been related to courses on Amputation Surgery and Related Prosthetics in Vietnam and Cerebral Palsy in Slovenia, together with a seminar on Prosthetics and Orthotics in South-eastern Asia held in Tokorozawa, Japan. Through competent and responsible steering by the programme organisers, together with good collaboration and joint ventures with local professional groups, the expenses have been kept at the most reasonable level for the Society. Representation at meetings with other organisations has been kept at a modest expense level. The Society funded a successful workshop on Quality Assurance in Prosthetics and Orthotics which will lead to a publication on the topic during the coming year.

Education has always been a key issue and the largest area of activity for ISPO. Higher costs than ever before have been accrued under this heading; in part because of involvement in recognition of schools for Orthopaedic Technologists and in evaluation programmes of Appropriate Technology, but most of these costs are to be recovered from the commissioning bodies. Another reason is the high meeting costs because members of the Education Committee from outside the Executive Board have been co-opted from school programmes in Canada, Japan, El Salvador and Tanzania.

The Professional Register also this year has accrued a relatively high cost. Over the past three years the costs add up to DKK 335,997 and will total about 400,000 DKK before completion in 1999. This is the end of the line of a 25 years old dream of having access to a professional profile for the majority of the Society's members, allowing it to formulate a set of search profiles to identify individuals with, for instance, certain language capabilities together with skill in specific areas, experience from work for other organisations and be willing, and have time available, to serve for a specific task at a given place. Further to that the efficacy of the membership register has improved considerably allowing for a number of statistics related to membership recruitment and termination. The Professional Register is built up on Access software, which is part of the Office package from Microsoft. However, most of the costs are related to professional programming and amending the system to be simple and user-friendly for daily operation as well as occasional statistics.

On the income side the Society can note that the journal, Prosthetics Orthotics International, has again given a handsome income.

The Society continues to enjoy office facilities sponsored by, and located in, SAHVA and also the high commitment of the sole employee, Aase Larsson. With such a staffing structure it is only possible to run the activities of the Society through the generous understanding and support from the employers of the core of hard working elected officers and board members who are the corner-stones for a successful ISPO with a strong international profile.

January, 1999

Carsten Tørholm, *Chairman of the Finance Committee*

J. Steen Jensen, *Hon. Treasurer*

Prosthetics and Orthotics International, 1999, 23, 3-6

ISPO Statement of Accounts, 1998

AUDITORS REPORT

We have audited the financial statement as of December 31, 1998 prepared by the officers of the International Society for Prosthetics and Orthotics.

Audit Performance

We planned and performed our audit in accordance with generally accepted auditing standards as applied in Denmark so as to obtain reasonable assurance that the financial statements are free from material errors or omissions.

During our audit we assessed the materiality and risk in order to verify basis and documentation of the amounts and other information disclosed in the annual accounts. Further, we considered the accounting practice and estimates applied by the Board of Directors and the Management, and we evaluated the overall adequacy of the presentation of information in the financial statements.

Our audit did not give rise to any qualification of opinion.

Conclusion

The Financial Statements have been prepared in accordance with statutory requirements, and the constitution of the Society and generally accepted accounting policies. In our opinion, the financial statements give a true and fair view of the state of the affairs of the Society as of December 31, 1998, and of the result for the year.

February 2, 1999

RevisionsGruppen

Søren Wonsild Glud

State Authorised Public Accountant

ACCOUNTING POLICIES

Securities

Bonds have been stated at market value at year end and shares have been stated at the lower of cost or market.

Office Equipment

Computer and office equipment have been stated at cost less accumulated depreciation computed straight line over 5 years.

Accrual Concept

The accrual concept of accounting has been used in these Financial Statements.

Income Statement for the Year 1998

SUMMARY	1998 DKK	1997 DKK
Society membership fees (note 1)	1.138.137	1.125.970
Sponsorship (note 2)	15.000	15.000
Meetings with other organisations (note 3)	(52.802)	(2.756)
Conferences, courses etc (note 4)	291.992	(807.938)
Prosthetics and Orthotics International (note 5)	118.282	137.649
Publications (note 6)	19.877	7.365
Result of Activities	**1.530.486**	**475.290**
Administrative expenses (note 7)	(833.534)	(1.060.671)
Primary Result	**696.952**	**(585.381)**
Interest	380.061	422.908
Dividend	1.692	1.504
Change in market value of securities	113.049	291.126
Exchange rate variance	35.750	138.419
Financial Income	**530.552**	**853.957**
Net Income	**1.227.504**	**268.576**

Balance Sheet as of December 31, 1998

	1998 DKK	1997 DKK
Cash	**76.058**	**354.783**
Accrued interest	106.825	106.753
Advertising receivable	311.810	294.770
Prepayment, World Congress Amsterdam 1998	443.088	443.088
Receivable World Congress Amsterdam 1998	81.912	0
Prepayment World Congress Glasgow 2001	332.569	131.331
Miscellaneous receivables	0	87.599
Other prepaid items	19.808	12.940
Receivables	**1.296.012**	**1.076.481**
Securities (note 9)	**8.059.014**	**6.924.071**
Office Equipment (note 8)	**0**	**16.347**
Total Assets	**9.431.084**	**8.371.682**
Liabilities		
Accrued expenses	149.930	370.759
Prepaid income	135.782	83.055
Short-term liabilities	**285.712**	**453.814**
Equity		
Equity January 1	7.917.868	7.649.292
Net result	1.227,504	268.576
Equity December 31	**9.145.372**	**7.917.868**
Liabilities and capital	**9.431.084**	**8.371.682**

Notes to the Financial Statements

1. Society membership fees
Membership fees consist of fee payments from members.

2. Sponsorship

SAHVA	15.000	15.000
	15.000	**15.000**

3. Meetings with other organisations	**1998**	**1997**
Interbor	(13.800)	0
AOPA	(23.614)	0
WHO Geneva	(3,934)	0
RI-ICTA	(8.300)	0
Miscellaneous	(3.154)	(2.756)
Expenses	**(52.802)**	**(2.756)**
4. Conferences, courses etc.		
Education Committee	(124.044)	(30.385)
World Congress Amsterdam	781.229	0
NMS Education Support	(10.500)	0
ISPO Central Europe	**(8.248)**	0
Consensus Conferences and Seminars		
Poliomyelitis	4.845	(645.310)
Quality Assurance	(128.669)	0
CBR Workshop	(7.243)	0
Tokyo Seminar	(31.859)	0
St. Petersburg	(7.247)	0
Courses – Industrialised world:		
Helsingborg	0	44.705
Courses – Developing world:		
Cerebral Palsy	(42.255)	13.686
Amputation (Vietnam)	(134.017)	0
Amputation (India)	0	(190.634)
Income (expense)	**291.992**	**(807.938)**
5. Prosthetics and Orthotics International		
Advertising	797.224	687.073
Subscriptions	194.645	209.335
	991.869	**896.408**
Printing and mailing postage	(570.646)	(445.860)
Production editor	(40.275)	(37.129)
Meeting expenses	(16.666)	(32.994)
Production secretary	(116.000)	(80.000)
Other direct expenses	(20.000)	(12.776)
Publications committee	(110.000)	(140.000)
	(873.587)	**(758.759)**
Net result	**118.282**	**137.649**
6. Publications		
Booksales	19.304	5.895
Amputation Video	573	1.470
Net result	**19.877**	**7.365**
7. Administrative expenses		
Executive Board and Officers:		
Executive Board meetings	330.020	414.934
Officers representation	16.534	0
IC-meeting	0	122.456
POI publications committee	(110.000)	(140.000)
	236.554	**397.390**

Secretariat, Copenhagen:		
Staff salaries	212.404	254.411
Labour tax	20.216	11.672
Data service	1.175	1.107
EDP	835	3.349
Meeting expenses	14.145	14.231
Postage and bank charges	71.813	74.220
Telephone	12.518	12.304
Stationery	17.480	6.816
Office supplies	19.808	40.941
Auditing	31.431	30.739
Bookkeeping	18.571	15.545
Consulting fees	24.048	22.273
Sundries	(4.296)	27.218
Rental	15.000	15.000
Depreciation	14.824	13.000
Society promotion	10.728	8.000
Insurance	20.547	11.288
Fee Rehabilitation International	7.041	0
	508.288	**562.114**
Professional Register	88.692	101.167
Total	**833.534**	**1.060.671**

8. Office Equipment

Computer equipment, at cost	187.544	187.544
Office equipment, at cost	30.482	32.006
Cost	**218.026**	**219.550**
Depreciation January 1	(203.202)	(190.202)
Depreciation during the year	(14.824)	(13.000)
Accumulated depreciation	**(218.026)**	**(203.202)**
Net book value	**0**	**16.348**

9. Securities

	Nominal Value	Original Cost	Year End Value
Bonds			
6.75% Bayerische Vereinsbank	313.318	318.806	318.806
4% Nykredit 2006	2.333.000	2.302.671	2.302.671
6% Nykredit 2019	3.072.000	3.068.928	3.068.928
5% Nykredit 2009	2.114.000	2.117.171	2.117.171
	7.832.318	**7.807.576**	**7.807.576**
Shares	**Units**	Cost or 1997 Value	Year End Value
Eurostock 50	1.780	141.065	170.880
Den Danske Bank	94	72.560	80.558
Total		**8.021.201**	**8.059.014**

Report from the Executive Board

This report gives an update on Executive Board activities which should be of interest to most members of ISPO. I have included some background information which I hope will be helpful, particularly for new members. If there are other items you would like to see included in future reports, please let me know.

Prosthetic/orthotic education

Over the last triennium we have seen the development of the Category II (orthopaedic technologist) and then the Category I (prosthetist/orthotist) educational packages. The Category II professional would be trained to work in low-income countries where Category I training is not realistically achievable in the short term. However, in he long term, all countries should aim to have Category I professionals. For example, in Tanzania, where there has been a recognised Category II course for some years, a Category I course is now being introduced.

The educational packages contain a professional profile, code of ethics, learning objectives and an indication of the content and procedures for final examinations. Thus they are valuable guidelines for any new school and may prove helpful for existing schools. A school, which provides education and training in accordance with the appropriate ISPO educational package, can seek ISPO recognition. This involves a visit by two inspectors, normally at the time of the examinations, to study the course in detail. The inspectors then report back to the Executive Board which will decide either to recognise the course (possibly with recommendations for minor changes) or advise the school that the standard is insufficient and suggest necessary improvements for recognition to be achieved. The cost of the inspection must be borne by the school. Any professional who graduates from a school at a time when it is recognised by ISPO will be entitled to receive a certificate of ISPO registration. Schools, which pass the inspection, are recognised for three years. In order for its graduates to obtain ISPO registration it is essential that the school should apply for re-inspection promptly. If ISPO recognition is allowed to lapse for a period of time, students who graduate during that period will not be eligible for ISPO registration. Recently, inspections have been carried out at the Cambodian School for Prosthetics and Orthotics (Phnom Penh, Cambodia) and Don Bosco University (San Salvador, El Salvador). Both schools achieved the required standard for ISPO Category II recognition.

Currently the Category III educational package is being developed. The ISPO Category III refers to the technician or bench hand who does not treat patients but is skilled in the manufacture and repair of prostheses and orthoses.

Consensus Conferences

A consensus conference is a gathering of acknowledged experts and individuals with working experience in the topic of the conference. The conference would typically consist of invited papers to establish a knowledge base, syndicate discussions where groups discuss selected issues and seek to identify areas of agreement and conflict, followed by plenary sessions in which the findings of the groups are discussed. The aim is determine areas of general consensus in such matters as patient treatment methods, organisation of services and appropriate materials and components.

Early in the last triennium, in June 1996, there was a consensus conference on Appropriate Prosthetic Technology in the Developing World held in Phnom Penh, Cambodia. This conference has led to improved communication between the different non-governmental organisations working in the region and evaluations of prosthetic systems designed for the developing world. It also set the scene for a conference in Wuhan, China organised by the German agencies DSE and GTZ to plan GTZ activity into the new millennium. Another consensus conference, this time on Poliomyelitis, was held in Hammamet, Tunisia. The report of this conference is due to be published very soon. Already, as a result of the conference, several courses on the management of poliomyelitis are being planned. The Executive Board is currently examining possible topics for the next consensus conference.

World Congresses

The Amsterdam World Congress was very successful with a total of 3428, of whom 1483 attended the scientific programme while 1776 attended the exhibition only. A preliminary verbal report was given by the Secretary General, Hans Arendzen at an early stage and this should ensure that the next World Congress benefits from the experience of the last.

The next World Congress is being planned for Glasgow, UK on 1-5 July 2001. The venue is the Scottish Exhibition and Conference Centre in Glasgow. This centre has excellent facilities and is conveniently located for hotels. Preparations for this congress are progressing well but a great deal of work remains to be done. It seems likely that the exhibition will be large and the programme excellent although this is, of course, affected by the quality of papers submitted.

Bids for the 2004 World Congress are expected to arrive soon. The deadline for receiving these is 30 April 1999.

Executive Board (1998-2001)

The Executive Board is elected every three years. The first stage is the production of the slate of nominations by the Protocol and Nominations Committee. The Committee is helped in this by suggestions received from National Member Societies. There is a special form for this on which the National Member Society should provide all relevant information about the individual suggested. Once composed, the slate then goes before the Executive Board and may be approved or amended at this stage. Once finalised, the slate is presented at the Interim Meeting of International Committee Representatives and sent to all National Member Societies. At this stage any National Member Society may add to the slate. If names are added then an election becomes necessary. This takes the form of a postal ballot of the International Committee. It is always hoped that the slate produced by the Executive Board will be accepted because a great deal of care has been taken to achieve a good professional and geographical balance.

The incoming Executive Board for the triennium 1998-2001 was elected unopposed. The elected members of this Board are as follows:

President	Mr Norman A Jacobs	UK	Engineer
Immediate Past President	Dr Seishi Sawamura	Japan	Orthopaedic Surgeon
President Elect	Mr Sepp Heim	Germany	Prosthetist/Orthotist
Vice Presidents	Mr Gerhard Fitzlaff	Germany	Prosthetist/Orthotist
	Dr Bjorn Persson	Sweden	Orthopaedic Surgeon
Members	Mr John Craig	USA	Prosthetist/Orthotist
	Dr Jan Geertzen	Netherlands	Rehabilitation Specialist
	Mrs Winnie Hessing	Denmark	Physiotherapist
	Dr Juan Martina	Caribbean	Rehabilitation Specialist
Honorary Treasurer	Dr J Steen Jensen	Denmark	Orthopaedic Surgeon
Honorary Secretary	Dr Brendan McHugh	UK	Engineer

The Chairmen of the Standing Committees are also members of the Executive Board. These are:

Education	Prof John Hughes	UK	Engineer
Finance	Dr Carsten Torholm	Denmark	Orthopaedic Surgeon

The election process is now beginning for the Executive Board (2001-2004). Forms have been sent to National Member Societies inviting suggestions.

Brendan McHugh
Honorary Secretary

Prosthetics and Orthotics International, 1999, 23, 9–12

Analyses of prosthetic episodes in trans-tibial amputees

D. DATTA, S. P. VAIDYA and Z. ALSINDI

Mobility and Specialised Rehabilitation Centre, Northern General Hospital, Sheffield, England, United Kingdom

Abstract

The prosthetic episodes, i.e. actual processes of provision, identifying number of prostheses, their maintenance, repairs and replacements were analysed for 104 trans-tibial amputees aged 16 and over, over a 10 year period. The purpose of this investigation was to identify how frequently a new prosthesis is actually required for this group of amputees and what are their maintenance requirements. Variations of requirement between the amputee groups of aged 16-60 and over 60 years are also addressed.

In the 10 years period of the study the amputees needed an average of 5.04 new prostheses, 6.25 refits, 2.28 major repairs and 17.04 day repairs. The younger amputees, i.e. below the age of 60 years, required significantly more new prostheses ($p=0.003$), more refit of sockets ($p=0.0012$) and more day repairs ($p=0.01$). Traumatic amputees below the age of 60 years needed significantly more day repairs compared to the non-traumatic amputees in the older age group ($p=0.003$).

Introduction

The prosthetic rehabilitation programme and prosthetic maintenance need the amputee's commitment to regular attendance at the Prosthetic Centre as well as on-going expenditure related to the cost of the artificial limbs and their maintenance and replacement. In the United Kingdom prostheses are provided free of charge under the National Health Service (NHS) to the patients who need them. The number and type of prostheses provided in the UK are generally related to amputees' rehabilitation needs rather than being strictly controlled by the number and frequency of supply fixed by the payers of the service. It is however, to be noted that the authors' centre do not provide swimming prostheses and certain sporting prostheses, e.g. Flex-foot, under the NHS scheme. This paper describes the results of the above investigation and discusses the prosthetic maintenance needs of 104 unilateral trans-tibial amputees attending a sub-regional prosthetic and amputee rehabilitation centre over a period of 10 years.

All correspondence to be addressed to Dr D. Datta, Consultant in Rehabilitation Medicine, Mobility and Specialised Rehabilitation Centre, Northern General Hospital NHS Trust, Herries Road, Sheffield S5 7AT, UK. Tel: +44 (0) 114 256 1571 Fax: +44 (0) 114 243 1646.

Patients and methods

This retrospective survey was carried out at a sub-regional centre, in the North Trent region of England serving a population of 1.8 million. This centre gets referrals of about 200 new amputees per year and has an active amputee population of around 2,000.

Admission criteria for this study identified unilateral trans-tibial amputees age 16 and above who had been wearing prostheses between 10-20 years at the time of the study. In total 104 amputees met all the criteria and were therefore included. Their medical notes and prosthetic records were reviewed and analysed manually as were their computerised prosthetic records. All prosthetic episodes which occurred over the last 10 years were examined. The mobility level of these patients was not examined. Though a detailed breakdown of various types of prosthesis was not collected for this study, the overwhelming majority of the subjects were using patellar tendon bearing modular endoskeletal prostheses with a multi-axial ankle joint.

Excel software package was used and 2 tailed t-tests were carried out for statistical significance.

Four different types of prosthetic episodes were analysed.

1. New prosthesis

Most of the new amputees have a new prosthesis after assessment at the primary clinic, if it is felt appropriate. This usually happens fairly soon after the amputation, i.e., within the first few weeks. Thereafter, as the stump alters in shape and size, a duplicate prosthesis is prescribed to retain patients' independence if minor adjustments are not adequate or appropriate. The first or the primary prosthesis would then be refitted at some stage depending on the individuals' progress and requirements. Once either of these two prostheses are worn out and become uneconomical to repair they are then usually replaced with new prostheses. It is not the practice to provide a duplicate prosthesis as a matter of routine. This is undertaken only on clinical grounds when it is considered that patients' independence and safety will be at risk without a useable, comfortable and safe prosthesis.

2. Refit socket

If and when the prosthetic socket fitting becomes poor or damaged, the socket is refitted if minor adjustments and repairs cannot resolve the problem. This would be carried out on both prostheses (primary and duplicate) if required, but usually not concurrently.

3. Major repairs

When major repairs and refurbishment work and other components are required which cannot be carried out while the patient waits, the prosthesis is kept in the workshop for a few days. Such repair work is categorised as major repair work. Major repair work due to the work content is usually less expensive than refitting a limb but more expensive than minor day repairs.

4. Minor repairs

Minor repair or refurbishment of prostheses can be accomplished on the same day. Such work is categorised as minor repairs. Examples of this type of repair include adjustments, lining of the socket, renewal of cosmesis, adjustment of ankle joints etc. With the use of modular endoskeletal prostheses, which has been the clinic's usual practice for the last 10-15 years, realignment of limbs, putting on a new ankle joint or foot etc. are also usually carried out as day repairs.

Results

One hundred and four (104) patient records were analysed. Trauma was given as the cause of amputation in 56 patients and 48 had amputations due to non-traumatic reasons. Some 54 patients were aged between 16 years and 60 years and 50 patients were above the age of 60 years. Detailed reasons for amputation are presented in Table 1.

Overall, in a 10 year period each of this group of amputees on average needed 5.04 new prostheses, 6.25 refits, 2.28 major repairs and 17.04 minor/day repairs to their prostheses.

The group of amputees over the age of 60 years required significantly less number of prostheses (p=0.003), less number of refits (p=0.0012) and significantly less number of minor repairs (p=0.01). Overall, the older group had less number of major repairs carried out but this did not reach statistical significance. Details of provision of new prostheses, repairs, and refits are presented in Table 2.

The mean number of minor repairs amongst the traumatic younger amputees (N=36) was significantly higher at 22.17 compared with that of older traumatic amputees (N=20) at 12.95 for 10 years (p=0.003). There was no significant difference in the number of refit sockets carried

Table 1. Causes of amputation for the study group of unilateral trans-tibial amputees

Cause of amputation	No. of amputees (%) 15-60 years (N=50)	No. of amputees (%) 60 years + over (N=54)	No of amputees (%) All ages (N=104)
Trauma	36 (66.6%)	20 (40%)	56 (53.8%)
PVD ± DM	2 (3.7%)	23 (46%)	25 (24.03%)
Malignancy	1 (1.8%)	4 (8%)	5 (7.8%)
Congenital	7 (12.9%)	0	7 (6.7%)
Others	84 (14.8%)	3 (6%)	11 (10.5%)

PVD = Peripheral Vascular Disease

DM = Diabetes Mellitus

Table 2. Details of prosthetic episodes on all patients and comparison between 15 to 60 years over 60 years of age groups

Prosthetic episodes	All age groups over 10 years (N=104)	Average for all ages per year (N=104)	Age group 15-60 over 10 years (N=50)	Age group 60 years and over over 10 years (N=54)	Value
New prosthesis	5.04	0.5	5.68	4.4	0.003*
Refits	6.25	0.6	7.41	5.09	0.012*
Major repairs	2.28	0.2	2.61	1.95	0.17*
Day repairs	17.04	1.7	19.8	14.2	0.01

*=significant

out in these two groups of traumatic amputees (p=0.07). Similar comparisons for patients with peripheral vascular disease between the two age groups could not be carried out as these were only 2 amputees with PVD in the younger age group.

Usually provision of a new prosthesis and the refit of socket need 3 visits to the centre by the patient, the first visit is to have cast and measurements taken, the second visit for a fitting and the third visit when the limb is completed and delivered to the patient following a check-out procedure. Major repairs to the prosthesis usually need 2 visits by the patients to the centre. The authors have extrapolated that over the 10 year period the patients on average needed 5.54 visits per year when all age groups were considered together, 6.42 visits per year for the 15-60 year age group and 4.8 visits per year for the 60+ age group.

Discussion

Provision of a prosthesis and the ensuing maintenance programme is expensive and is important to monitor by continuous analysis of data. Narang and Jape (1982) and Hoaglund and Jergersen (1980) have confirmed this point.

As far as the authors are aware the pattern and frequency of provision of new prostheses and their maintenance in a group of trans-tibial amputees have not been previously reported. Narang and Jape (1982) concluded in their study in India that the average life of a prosthesis is about 5 years and also reported the number of prostheses issued over a 25 year period – but this patient group included all ages and all levels of upper and lower limb amputees.

The question is frequently asked, "How often will an amputee need to have a new prosthesis, how frequently do repairs need to be undertaken and how often will the amputee need to attend the prosthetic centre?" Answers to these questions are important from both the patient's point of view and from the point of costing in compensation claims and to health service providers. Maintenance and the number of visits required for prosthetic maintenance are important for patients, and their employers to allow time off from work.

It is not possible to provide for the individual accurate answers to the above questions regarding frequency of need of new prosthesis and maintenance as there are likely to be considerable discrepancies due to different levels of amputation, level of prosthetic use, availability of services, type of prosthetic hardware used, etc.

The prosthetic provision in the United Kingdom under the National Health Service is very similar throughout the country with only minor variations. As the mobility level of the individual amputee was not examined and used in the patient selection in this study, the authors are confident that the study group is representative of unilateral trans-tibial amputees of a wide range of abilities. Therefore results of this study should be broadly applicable throughout the United Kingdom.

The aim of the study was to obtain information on the overall pattern of prosthetic requirements of a defined groups of amputees over a 10 year period. While general criteria for each of the four areas of prosthetic episodes have been described earlier specific criteria for socket change, day or major repairs were not identified.

Patients under the age of 16 years were not considered due to different prosthetic maintenance patterns due to the growth pattern. Only established patients who had reached a "steady state" and had been wearing prostheses for at least 10 years were considered. The

average number of years of wearing prostheses in the group was 13.9 years. This approach was taken in an attempt to eliminate "untypical" over use or under use of prosthetic services.

The finding of less requirement of new prosthesis, less number of refits and less number of minor repairs for the older age group was not surprising and it is assumed this is due to a more sedentary lifestyle for the older amputees. Significantly higher figures for minor repairs for the younger traumatic amputees compared to the older non-traumatic amputees probably reflects the more active and adventurous lifestyle younger traumatic amputees tend to lead. However this hypothesis has not been specifically tested.

Prosthetic hardware and prosthetic expertise are provided by an external contractor but during the study period of 10 years all individual prosthetists and technicians have remained virtually the same, through their employers changed once during this period. The expertise, principals and policies of prosthetics service provision has not altered during the study period.

Conclusion

Overall, the amputees in the study on average needed about one new prosthesis and one new socket every 2 years, one major repair every 5 years and about 2 day repairs per year. It is however, accepted that the numbers would be higher at the beginning of the prosthetic programme due to change in the stump condition and the patients' continuing progress with the rehabilitation programme until a plateau is reached. The results presented here are an overall average for a 10 year period.

This study has identified the pattern of prosthetic episodes in a defined group of transtibial amputees. As this study is limited to a relatively small number of amputees in one centre – its results cannot be accurately applied universally. However the results could be used as a base line predictor for estimating an amputee's prosthetic needs.

Acknowledgement

We would like to thank Dr Julian Nuttal of the University of Sheffield for statistical advice, Jonathan Wrend and Gloria Baugh for their help with data collection and Karen Parker for typing the manuscript.

REFERENCES

NARANG IC, JAPE VS (1982). Retrospective study of 14,400 civilian disabled (new) treated over 25 years at an artificial limb centre, *Prosthet Orthot Int* **6**, 10-16, 1982.

HOAGLUND FT, JERGERSEN HE (1983). Evaluation of problems and needs of veteran lower-limb amputees in San Francisco Bay Area during the period of 1977-1980. *J Rehabil Res Dev* **20**(1), 57-71.

Prosthetics and Orthotics International, 1999, 23, 13–20

Relaxed versus activated stump muscles during casting for trans-tibial prostheses

M. LILJA, S. JOHANSSON and T. ÖBERG

Department of Biomechanics and Orthopaedic Technology, University College of Health Sciences, Jönköping, Sweden

Abstract

In prosthetic practice, the question often arises as to whether the hand cast should be made from a contracted or from a non-contracted amputation stump. To elucidate this question, the authors have performed a study to quantify the volume difference between these 2 conditions, and to relate the differences to prosthetic fitting. Sixteen (16) trans-tibial amputees participated in the study. All of them were fitted with an ICEROSS silicone socket. Electromyographic studies, with electrodes attached to the anterior tibial and medial gastrocnemius muscles, were carried out to determine muscle contraction levels. Volume determinations were made with the CAPOD laser scanning system. Measurements were performed with and without the silicone liner on the stump. Without a silicone liner, the volume of the stump increased by 5.8% (SD=5.3) as the muscles contracted. This increase was statistically significant. With the liner donned the volume increased 3.5% (SD=3.3). This increase was also statistically significant. The volume of the prosthetic socket was also compared with the stump volume with a silicone liner on. For the relaxed stump, the difference was 1.8% (SD=10.1), and for the contracted stump -1.7% (SD=11.3). Neither difference was statistically significant. The importance of these volume changes and how they influence stiffness of the coupling between the stump and the socket are discussed. It is concluded, that the observed difference in volume between a contracted and a non-contracted stump are large enough to be considered by the prosthetist in his decision on how to make a hand cast.

All correspondence to be addressed to Magnus Lilja, Department of Biomechanics and Orthopaedic Technology, University College of Health Sciences, PO Box 1038, S-551 11 Jönköping, Sweden. Tel: (+46) 36 324769. Fax: (+46) 36 324762.

Introduction

A major deficiency in some modern educational programmes in prosthetics and orthotics is the lack of theoretical knowledge for the production of optimal prostheses and orthoses. During training in prosthetics, one of several questions that arises from the students is whether the patient should activate the stump muscles during the casting process for a trans-tibial prosthesis, or if the casting should be performed on a relaxed stump. Generally, the patient is asked to try to relax all stump muscles, and, depending on which type of socket is to be used, the patient is instructed to keep the knee extended or slightly flexed. However, no theoretical basis for this procedure has been found in the literature. Today, students (and many practising prosthetists) demand a theoretical basis for casting and other procedures.

It is well known that a muscle increases in cross-sectional area over the belly when the muscle is contracted. If the muscles in the trans-tibial amputation stump follow the same pattern, and the prosthetist does not consider this phenomenon, the socket fitting could be jeopardised. The truth behind a well-fitted socket is a total control over all the different parameters. Burgess *et al.* (1974) investigated the possibilities of using trans-tibial muscle activity to control socket suspension.

Radcliffe and Foort (1961) described the traditional way of manual casting for a patellar-tendon-bearing (PTB) prosthesis. They introduced a complete technical procedure for making a PTB prosthesis and their technique has more or less become standard. Today, it is a common opinion that prosthetic fitting should be based on total contact and total weight-bearing (Kapp and Cummings, 1992; Klasson, 1995). One way to achieve this is to use silicone liners together with a controlled hand casting

technique (Kristinsson, 1993; Fillauer *et al.*, 1989). In order to improve total contact with an ICEROSS liner, the ICEX technique can be used, i.e. the socket is produced under hydraulic pressure applied to the stump. This new concept, however, puts new demands on the prosthetist and his/her knowledge and technique. Ever since computer aided design/computer aided manufacture (CAD/CAM) was introduced, it has been seen as a complement to the traditional hand casting technique. The different CAD/CAM systems on the market today can be divided into 2 distinct groups: one using a plaster cast negative as the starting point (e.g. ShapeMakers) and the other using a non-contact scanning technique, measuring directly on the amputation stump (e.g. CAPOD Systems) (Brüssel, 1991). Both techniques have, when correctly used, the potential of producing total contact and total weight-bearing prostheses. The use of a non-contact scanning technique eliminates the necessity to make a correct hand cast. This technique, however, puts new demands on the prosthetist's skill at designing a high quality socket.

The ultimate goal for the prosthetist, no matter what casting technique is used, is always the rehabilitation of the patient by means of a well-fitted prosthesis. This goal can be reached by giving special attention to the interaction between prosthetic socket and amputation stump during prosthetic fitting. The properties of the stump/socket interface depend on the initial hand casting and the subsequent rectification of the positive plaster mould. The aim is to establish a flexible coupling between the stump and the socket that is able to transfer ground reaction forces from the prosthesis to the skeleton (Klasson, 1995). If the stiffness of this flexible coupling is low, the skeleton and the soft tissues inside the socket will move during gait and the patient will experience less stability (Lilja and Johansson, 1993; Grevsten and Eriksson, 1975; Eriksson and Lemperg, 1970). If, however, the coupling is too stiff due to an overly confined fitting, severe problems can occur, for example decreased blood flow. Levy (1983) describes several stump problems related to blood circulation as well as problems related to increased pressure between the stump and the socket e.g. ischemic ulcers, stasis dermatitis.

Muscular activity patterns during gait are dependent on walking speed, fatigue etc. (Whittle, 1991). In the amputation stump, muscle activity during gait is similar to that found during normal gait for non-amputees. This activity can be described as a common activity pattern, but there is a difference between amputees and non-amputees with respect to order of muscle activation, activity level etc. (Whittle, 1991; Basmajian and De Luca, 1985). Grevsten and Stålberg (1975) have described this in electromyographic studies. Among amputees, muscle activity not only accounts for motion of the stump, but even contributes to the suspension of the prosthesis (Burgess *et al.*, 1974; Lilja and Öberg, 1998). With this in mind, the question of relaxed versus contracted stump muscles during casting is relevant and not trivial from the prosthetist's point of view.

The most rigid flexible coupling between the prosthetic socket and the amputation stump should appear when maximum forces are transferred from the prosthesis to the skeleton. If the movements of the skeleton inside the prosthetic socket are not minimised, and if there is a discrepancy between the shape of the amputation stump and the shape of the prosthesis, severe stump problems can occur, for example maceration, abrasion and blister formations (Levy, 1983; Lilja and Johansson, 1993). The volume of the amputation stump fluctuates over time after the amputation (Lilja and Öberg, 1997). The stump volume may also vary due to changes in blood perfusion during muscular activity. The volumes of the amputation stump and the socket are closely related to the fit of the prosthetic socket. Significant differences between the volume of the amputation stump and the volume of the prosthetic socket reduce the possibility of a good fit and thereby a successful rehabilitation. Conversely, a better-fitted prosthetic socket will reduce stump problems and improve the rehabilitation process. Patients' opinions, however, about a good fit do not always correspond with the prosthetist's, and this might be a problem during rehabilitation of the amputee. It is important to stress that the amputee and the prosthetist must share the same goal with respect to prosthetic fitting and rehabilitation.

Very few studies have been published on the influence of muscle contraction on the fit of the prosthesis, and the existing studies are few, and relatively old and incomplete in this respect.

Aim

The aim of the present study was to:

- quantify the difference in volume between a non-contracted and contracted amputation stump;
- discuss such volume differences in relation to prosthetic fitting.

The hypothesis was that the muscle activity influenced stump volume, and this must be considered during hand casting for trans-tibial prostheses.

Material and methods

Subjects

Seven (7) men and 9 women, with a mean age of 72 (57-83), were included in the study. Thirteen (13) patients were amputated due to arteriosclerosis with or without diabetes mellitus and 3 patients were amputated due to trauma. Three (3) patients were amputated with a sagittal flap technique and the remaining patients with a long posterior flap. Before and after amputation all patients were able to walk with or without crutches. Four (4) of the patients had used a temporary prosthesis prior to being fitted with the definitive prosthesis. The patients were included in the study at least 6 months after amputation. All patients were definitively fitted with an ICEROSS silicone liner in their ordinary rehabilitation and 14 of 16 used their prosthesis every day, between 2 and 16 hours a day. One (1) of 16 patients used an ICEROSS silicone liner with a lanyard kit, the others used the ICEROSS with a bayonet coupling. Thirteen (13) amputees used an Otto Bock single axis foot, 2 used an Otto Bock Dynamic Foot and 1 used an Otto Bock Greissinger Foot.

Questionnaire

All amputees were interviewed according to the Prosthetic Profile of the Amputee questionnaire. Grisé *et al.* (1993), who also evaluated the questionnaire according to validity and reliability (Gauthier-Gagnon and Grisé, 1994), designed the questionnaire. To the original questionnaire, a second section, designed for the present study, was added and included questions pertaining to the design and function of the prosthesis, from a prosthetist's point of view. The number of patients was too small to perform a statistical analysis of the results from the questionnaire.

Muscle contraction

Electromyographic (EMG) electrodes were attached epidermally over the anterior tibial muscle and over the medial gastrocnemius muscle. The electrodes used in the study were Blue Sensor, Medicotest. The patients were instructed to activate both the anterior tibial muscle and the medial gastrocnemius muscle simultaneously to a sub-maximal (as much as they could) level possible to contract for about 20 seconds. To guide the patient's activity the EMG signals were visualised as bars on a computer screen, and the magnitude of the signal was recorded. After some practice all patients were able to activate both muscles simultaneously.

Measurement of stump and socket volumes

A black dot (6x6mm) was used as a reference marker, placed on the middle of ligamentum patellae prior to the scanning. The patients' relaxed amputation stumps were scanned with a CAPOD laser scanner, and the stump volume from ligamentum patellae to the distal stump end was calculated. After the first scanning, the patient was asked to activate the muscles to the previously stored EMG magnitude, and a new scanning was performed while the muscles were contracted. Each scanning was completed in 10 seconds. Volume calculations from both scans were carried out and compared. The same procedure was performed with a silicone liner donned and with the EMG electrodes still in place. Positive moulds of all patients' prosthetic sockets were produced, and the volumes of these prosthetic sockets were calculated with the CAPOD System. A comparison between the volume of the socket and the volume of the stump with the silicone liner donned was then performed.

Statistical methods

Means, ranges, standard deviations and student *t*-values were calculated according to standard procedures (Armitage and Berry, 1987). The power of the study was calculated both *a priori* and *post-hoc* with the software GPower (Faul and Erdfelder, 1992).

Results

A limited number of the 168 variables from the questionnaire are described in Table 1. Fourteen (14) of 16 patients were satisfied with the comfort of the prosthesis moderately or better. None of the patients had any wounds on the amputation stump at the time of the study. None of the patients had constant stump pain but

Table 1. Patients satisfaction and use of prosthesis.

Patient	Comfort of prosthesis (Satisfied)	Appearance of gait (Satisfied)	Wear of prosthesis (days/week)	Hours a day
1	Q	M	7	14
2	Q	Q	7	11
3	C	C	7	16
4	M	Q	7	8
5	S	S	7	16
6	C	M	7	14
7	Q	Q	5	4
8	C	S	7	16
9	M	M	7	14
10	M	N	7	12
11	Q	S	7	5
12	S	Q	2	2
13	C	C	7	16
14	Q	S	7	2
15	C	C	7	12
16	Q	M	7	14

C=Completely, Q=Quite well, M=Moderately, S=Slightly, N=Not at all

9 of the patients experienced phantom pain. For 4 patients, during gait, the phantom pain increased but for 1 it decreased. Seven (7) patients experienced increased stump perspiration with the silicone liner donned. None of the above results have been statistically evaluated. The results from the measurements of volume changes, with and without a silicone liner, during muscle contraction yielded a *post-hoc* power of 0.82 (α=0.05). Fourteen (14) of the 16 amputation stumps increased in volume during muscle activity. The mean volume increase was 5.8% (SD 5.3; range -4.2-14.2%) during muscle contraction in the amputation stump (Fig. 1). This increase was statistically significant ($p<0.001$). Stump volume, with contracted stump muscles and the silicone liner donned, increased for 13 of the 16 amputees. The mean volume increase was 3.5% (SD 3.3; range -1.4-11.5%) (Fig. 1). This increase was statistically significant ($p<0.001$). The mean difference between the socket volume of the

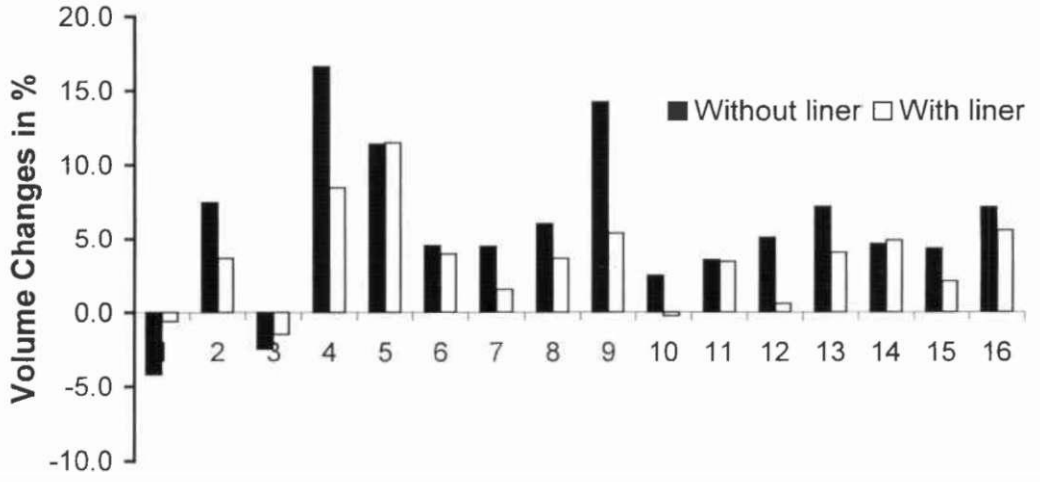


Fig. 1. Volume changes in per cent of relaxed and contracted stump both with and without silicone liner.

amputee's prosthesis and the stump volume was, for the relaxed stump, 1.8% (SD 10.1; range -15.3-18.7%). This difference was not statistically significant. The corresponding figures with the stump muscles contracted were -1.7% (SD 11.3; range -25.1-14.1%) (Fig. 2). This difference was not statistically significant.

Discussion

The primary focus of this study was to examine differences in volume between a relaxed trans-tibial amputation stump and the same stump with the muscles contracted. The study was performed on trans-tibial amputation stumps with a silicone liner donned as well as without any liner. A significant increase was found in volume when the patients contracted the stump muscles compared to that of the relaxed stump, both with and without the silicone liner (Fig. 1). The increase in volume of the stump without a silicone liner approximately equals the volume of 1 terry cloth stocking. However, a comparison between the volume of the prosthetic socket and the stump volume, with the silicone liner, did not show any significant differences (Fig. 2).

It has been common practice to consider the amputation stump, inside the prosthetic socket as a closed hydrostatic system filled with a non-compressible fluid. If this were true, an increase in the cross-sectional area of some part of the system must necessarily be associated with a corresponding reduction somewhere else. This model, however, is not accurate. First of all, the socket is not closed, but open at its upper end. Secondly, the soft tissues do not behave as a non-compressible fluid. Not only the passive properties of these tissues must be considered, but also the biological changes associated with muscle activity. In a state of rest, the muscles are relatively sparsely perfused with blood. At the capillary level, blood is circulating through a relatively coarse metarteriole (preferential channel) which is directly connected to the venous return, and relatively few capillaries are open. At full activity, circulation in the muscle tissue can increase by a factor of 20. This is achieved by the opening of vascular sphincters at the transition between arteriole and capillary. This increase in capillary circulation increases the volume of the soft tissue as well as, probably, the leakage of vascular fluid into the extravascular tissues. Furthermore, during muscle activity, waste products, for example lactate, and other metabolic products accumulate in the muscle. These substances have an osmotic activity. If these substances are not effectively flushed out of the tissues, they will bind water and contribute to a further increase in volume of the soft tissues (Guyton and Hall, 1996).

Muscular activity in the lower limb of trans-tibial amputees during gait has been investigated with electromyography by several authors

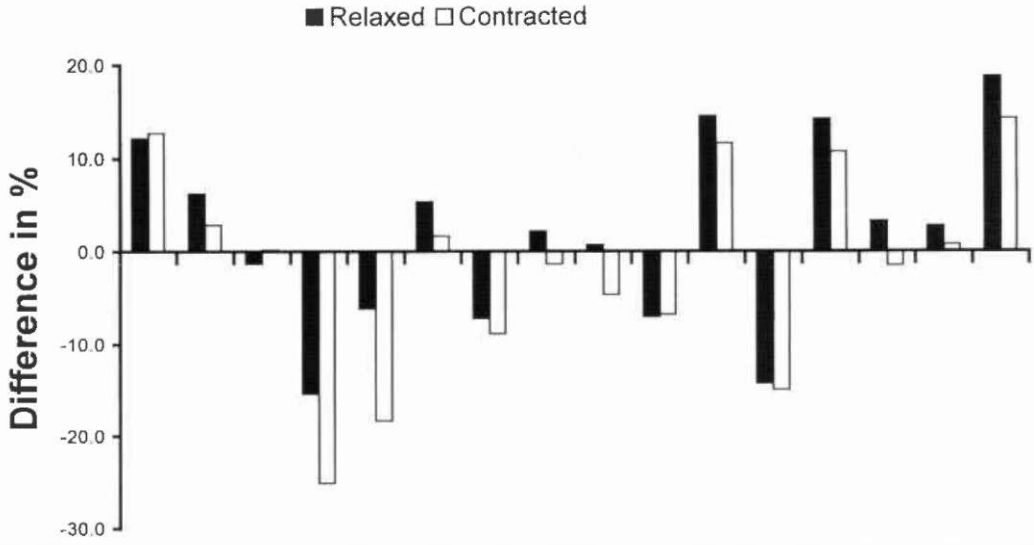


Fig. 2. Differences in per cent between the prosthetic socket and the stump with a silicone liner. Compared both with relaxed and contracted stump muscles.

(Winter and Sienko, 1988; Culham *et al.*, 1986; Grevsten and Stålberg, 1975; Burgess *et al.*, 1974). However, only Grevesten and Stålberg (1975) analysed the activity of the amputation stump muscles while the other authors investigated the thigh muscles of trans-tibial amputees. Among patients with a trans-tibial amputation, fitted with a PTB prosthesis, Grevsten and Stålberg (1975) found a simultaneous contraction of the anterior tibial muscle and the gastrocnemius muscle when the load on the prosthesis was largest. The muscular activity is closely related to the different phases of the gait cycle, and among amputees it may contribute to the fit of the socket (Burgess *et al.*, 1974; Lilja and Öberg, 1998). The present study focuses on volume changes of the stump when the muscles of the stump are activated.

In trans-tibial amputees, as well as among non-amputees, the maximum ground reaction forces during gait exceed 100% of the body weight (Winter and Sienko, 1988; Hermodsson *et al.*, 1994; Hubbard and McElroy, 1994). These forces have to be transferred from the prosthetic socket to the amputation stump and further to the skeleton. The possibility of transferring these forces is influenced both by the biomechancial properties of the amputation stump and the physical properties of the prosthetic liner (Silver-Thorn and Childress, 1996). The soft tissues of the stump have quasi-linear viscoelastic properties with respect to stress and strain while the soft socket liner has properties related to its specific material (Sonck *et al.*, 1970; Fung, 1993; Silver-Thorn and Childress, 1996). These factors increase the complexity of force transmission.

The mechanical relationship between the stump and the socket is utilised to form a coupling, which is able to transfer the ground reaction forces from the prosthesis to the skeleton. The efficiency of this coupling depends on its inherent stiffness. The difference between the volume of the socket and the momentary volume of the stump is an important factor that contributes to regulation of the internal pressure inside the stump. Increased internal pressure results in increased stiffness of the coupling. One consequence of an unsatisfactory coupling (i.e. a coupling with low stiffness) is increased tibial displacement during gait resulting in a loss of energy and influence on proprioception and kinesthesis (Lilja and Johansson, 1993; Grevsten and Eriksson, 1975). Equally important as volume control is the shape of the socket. It is essential to have a high congruity between the socket and the stump, so-called surface matching, especially for non-voluminous amputation stumps with bony prominences. The primary aim of surface matching is to avoid tissue damage due to localised pressure peaks over prominent bony areas (Buis, 1997). Bader and Chase (1993) discussed the mechanics of the patient-orthosis interface, but similar discussions can be applied to prosthetics. They pointed out that tangential forces combined with normal forces increase the risk of obliteration of capillary blood flow. This emphasises the importance of a properly fitted prosthesis and knowledge about volume changes stressed in the present study.

If the prosthetic socket is fitted and the difference in volume between the prosthetic socket and the amputation stump is minimised when the stump muscles are relaxed, the internal pressure of the soft tissues increases as the muscles contract due to the restricted expansion of the stump volume. This results in increased stiffness of the stump-socket coupling. However, the opposite will occur if the volume difference is minimised when the stump muscles are contracted. Then the stiffness in the coupling will decrease as the stump muscles relax, and an inferior suspension of the prosthesis will be the result. When prostheses are fitted without soft-liners the consequences of muscle contraction are more pronounced, with the stiffness curve showing a steeper slope. However, if a thin soft-liner is used between the socket and the stump, the increased stump volume during muscle activity is compensated for through compression of the liner, and the stiffness curve will increase more slowly as muscles contract. At the same time the patient will experience a moderate increase in the stiffness of the coupling between the amputation stump and the prosthetic socket and a tightening of the fitted socket. The present study indicates an increase in stump volume of about 5% when contracting the stump muscles, and many prosthetists have probably experienced the problem with a well-fitted socket as the patient complains about the socket being too tight during gait. This might be the result of an overly tight fitting of the socket, increased pressure inside the stump and an excessively increased stiffness in the coupling between the stump and the socket during muscle activity.

In the authors' opinion, there are difficulties in controlling the stump shape and stump volume using traditional techniques, including hand casting and rectification. One possibility to increase this control is by use of CAD/CAM techniques (Brüssel, 1991; Lilja and Öberg, 1995; Johansson and Öberg, 1998). All CAD/CAM software includes an option for the determination of the volume of the stump and modification of the positive model. In addition, the use of pressurised casting might, however, offer increased possibilities to control the stump volume during the production of a prosthetic socket (Murdoch, 1968).

In the present study, 16 trans-tibial amputees participated. Even if the number of patients was relatively low, a *post-hoc* calculation of power with GPower (Faul and Erdfelder, 1992), yielded a power of 0.82 (α=0.05), indicating a sufficient number of patients for the study. As 14 of 16 patients considered comfort of the prosthesis to be average or better, the fit of the prosthetic socket was good, from the patient's point of view. However, a comparison of the volume of the socket and the stump volume with the silicone liner donned showed considerable differences in volume (Fig. 2). For 1 patient included in the study, the volume difference between the prosthetic socket and the amputation stump was as high as 18% and the patient still considered the comfort to be good. These results indicate that there are variables other than mere volume differences that influence the results of prosthetic fitting. Breakey (1997) studied some psychological aspects of prosthetic fitting, especially the body image using the amputee body image scale. These different psychological aspects of prosthetic fitting probably coincide with other objective variables such as volume and shape.

Differences in amputation technique among the participants in the study, with 3 patients amputated with sagittal technique and 13 patients amputated with a long posterior flap, might have had adverse effects on the results but, in this study, the patient was used as his own control.

The results of the present study are naturally related to the patients' ability to contract the stump muscles. All patients trained their ability to contract the muscles before the first measurement. However, if a patient could not make a maximal contraction due to inability to co-ordinate the muscle activity, the volume changes can only increase as the amputee's ability to activate the muscles increases. An increase in ability to contract the muscles will result in an increase in stump volume. The observed volume changes in the present study can be related to the volume of 1 terry cloth sock, with a volume of approximately 5% (Lilja and Öberg, 1977). This can then be used as a compensation for a discrepancy between the socket volume and the stump volume.

As the profession of prosthetics aims toward a more academic standing, there is an increased need for a theoretical foundation for clinical practices. Today, there remain several areas with a lack of basic theoretical knowledge. According to Pike (1996), there might be a revolution coming to the field of prosthetics and the prosthetists of today have to be prepared. However, the present knowledge of handicraft in the profession is comprehensive, but it has to be supported by a theoretical base. The results of this study may contribute to the theoretical base needed for the future education of prosthetists/orthotists. Prosthetists can implement the results from the present study into their clinical work.

Conclusions

This study had identified and documented trans-tibial volume changes during muscle contraction of the anterior tibial muscle and the medial gastrocnemius muscle. There was a significant increase in stump volume of 5.8% during muscle contraction. With an ICEROSS silicone liner donned, the volume increased significantly by 3.5%.

The results indicate the importance of making a hand cast with the stump muscles relaxed if the subject is to have a stiff coupling between the amputation stump and the prosthetic socket during the stance phase of gait.

Acknowledgement

This study was supported by grants from the Scientific Committee of the Jönköping County Council.

REFERENCES

ARMITAGE P, BEERY G (1987). Statistical methods in medical research. – Oxford: Blackwell.

BADER D, CHASE A (1993). The patient-orthosis interface. In: Biomechanical basis of orthotic management./ edited by Bowker P, Condie DN, Bader DL, Pratt DJ. – Oxford: Butterworth Heinemann. pp58-69.

BASMAJIAN JV, DE LUCA CJ (1985). Muscles alive: their functions revealed by electromyography. – Baltimore: Williams & Wilkins.

BREAKEY JW (1997). Body image: the lower-limb amputee. *J Prosthet Orthot* **9**, 58-66.

BRÜSSEL A (1991). CAD/CAM in protetik und orthetik – stand der technik (CAD/CAM in prosthetics and orthotics – state of the art). *Orthop Tech* **42**, 487-495.

BUIS AWP (1997). Dynamic interface pressure measurement: comparing 2 trans-tibial sockets concepts. Thesis. – Glasgow: National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde.

BURGESS EM, ALEXANDER AG, REBENSTEIN CP (1974). The effect of stump-muscle activity on socket suspensions and prosthetic control: a preliminary report. *Inter-Clinic Information Bulletin* **13(15)**, 11-17.

CULHAM EG, PEAT M, NEWELL E (1986). Below-knee amputation: a comparison of the effect of the SACH foot and single axis foot on electromyographic patterns during locomotion. *Prosthet Orthot Int* **10**, 15-22.

ERIKSSON U, LEMPERG R (1970). Roentgenological study of movements of the amputation stump within the prosthesis socket in below-knee amputees fitted with a PTB prosthesis. *Acta Orthop Scand* **40**, 520-529.

FAUL F, ERDFELDER E (1992). GPower A *priori*, *post-hoc*, and compromise power analyses for MS-DOS (Computer programme). – Bonn: FRG: Bonn Unversity, Dept. Psychology.

FUNG YC, (1993). Bioviscoelastic solids. Biomechanics: mechanical properties of living tissues. – New York: Springer-Verlag. pp242-320.

FILLAUER CE, PRITMAN CH, FILLAUER KD (1989). Evolution and development of the Silicone Suction Socket (3S) for below-knee prostheses. *J Prosthet Orthot* **1**, 92-103.

GAUTHIER-GAGNON C, GRISÉ MC (1994). Prosthetic profile of the amputee questionnaire: validity and reliablity. *Arch Phys Med Rehabil* **75**, 1309-1314.

GREVSTEN S, ERIKSSON U (1975). A roentgenological study of the stump-socket contact and skeletal displacement in the PTB-suction prostheses. *Upsala J Med Sci* **80**, 49-57.

GREVSTEN S, STÅLBERG E (1975). Electomyographic study of muscular activity in the amputation stump while walking with PTB- and PTB-suction prosthesis. *Upsala J Med Sci* **80**, 103-112.

GRISÉ MC, GAUTHIER-GAGNON C, MARTINEAU GG (1993). Prosthetic profile of people with lower extremity amputation: conception and design of a follow-up questionnaire. *Arch Phys Med Rehabil* **74**, 862-870.

GUYTON AC, HALL JE (1996). Membrane physiology, nerve and muscle. Textbook of medical physiology. – Philadelphia: WB Saunders. p43-72.

HERMODSSON Y, EKDAHL C, PERSSON BM, ROXENDAL G (1994). Gait in male trans-tibial amputees: a comparative study with healthy subjects in relation to walking speed. *Prosthet Orthot Int* **18**, 68-77.

HUBBARD WA, MCELROY GK (1994). Benchmark data for elderly, vascular trans-tibial amputees after rehabilitation. *Prosthet Orthot Int* **18**, 142-149.

JOHANSSON S, ÖBERG T (1998). Accuracy and precision of volumetric determinations using 2 commercial CAD systems for prosthetics: a technical note. *J Rehabil Res Dev* **35**, 27-33.

KAPP S, CUMMINGS D (1992). Prosthetic management. In: Atlas of limb prosthetics: surgical, prosthetic and rehabilitation principles /edited by Bowker JH, Michael JW /American Academy of Orthopaedic Surgeons, St Louis: Mosby Year Book. p453-478.

KLASSON B (1995). Appreciation of prosthetic socket fitting from basic engineering principles. – Glasgow: National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde.

KRISTINSSON O (1993). The ICECROSS concept: a discussion of a philosophy. *Prosthet Orthot Int* **17**, 49-55.

LEVY SW (1983). Skin problems of the amputee. – St Louis: Warren H Green, Inc.

LILJA M, JOHANSSON T (1993). Adherent cicatrix after below-knee amputation. *J Prosthet Orthot* **5**, 65-66.

LILJA M, ÖBERG T (1997). Proper time for definitive trans-tibial prosthetic fitting. *J Prosthet Orthot* **9**, 90-95.

LILJA M, ÖBERG T (1998). Morphological changes during early trans-tibial prosthetic fitting. *In print: Prosthet Orthot Int*.

MURDOCH G (1968). The "Dundee" Socket for the below-knee amputation. *Prosthet Int* **3**, 15-21.

PIKE AC (1996). The next revolution in prosthetics: the PRE. *Biomechanics Magazine*, *http://wwwbiomechcom/db_area/archives/special/OandP296/ scopehtml*

RADCLIFFE CW, FOORT J (1961). The patellar-tendon-bearing below-knee prosthesis.–Berkeley, San Francisco: University of California.

SILVER-THORN MB, CHILDRESS DS (1996). Parametric analysis using the finite element method to investigate prosthetic interface stresses for persons with trans-tibial amputation. *J Rehabil Res Dev* **33**, 227-238.

SONCK WA, COCKRELL JL, KOEPKE GH (1970). Effect of liner materials on interface pressures in below-knee prostheses. *Arch Phys Med Rehabil* **51**, 666-669.

WHITTLE MW (1991). Normal gait. In: Gait analysis: an introduction. – Oxford: Butterworth Heinemann. p48-90.

WINTER DA, SIENKO SE (1988). Biomechanics of below-knee amputee gait. *J Biomech* **21**, 361-367.

Prosthetics and Orthotics International, 1999, 23, 21–29

Interface pressures and shear stresses: sagittal plane angular alignment effects in three trans-tibial amputee case studies

J. E. SANDERS* and C. H. DALY**

Departments of Bioengineering and Mechanical Engineering**, University of Washington, Seattle, Washington, USA*

Abstract

Interface pressures and shear stresses at different sagittal plane angular alignment settings were measured on 3 trans-tibial amputee subjects ambulating with patellar-tendon-bearing total contact prostheses. Substantial socket-shank angular alignment modifications in the sagittal plane had minimal effect on stance phase peak interface pressures, though more substantial effects on stance phase peak resultant shear stresses. No consistent trend of a greater stress at misaligned vs nominally aligned settings was identified. Changes in interface stresses from session to session tended to be greater than those for different alignment settings, suggesting that subjects compensated well for misalignments but less well for session differences.

Introduction

The sagittal plane angular alignment of a lower-limb prosthesis, the angular position of the foot relative to the socket in the sagittal plane, influences the distribution of mechanical stress at the stump-socket interface. However, data reported in the literature vary as to the degree of influence of the alignment on interface stresses. Pearson *et al.* (1973) found that 10 degree flexion adjustments (with no translational compensation) on one subject resulted in pressure changes of 99% (285kPa), 51% (135kPa), 26% (26kPa), and 40% (21kPa) for the anterior distal tibia, patellar tendon, lateral tibial condyle, and medial tibial condyle sites respectively. Ten degree extension adjustments resulted in pressure changes of 42% (150kPa), 35% (83kPa), 0% (0kPa), and 40% (21kPa). However, Appoldt *et al.* (1968) on 2 trans-femoral amputee subjects found only a small reduction (complete quantitative data not provided) at every test location for 5 degree flexion and extension adjustments (with translational compensation). Winarski and Pearson (1987), on trans-tibial amputee subjects, found 30% (67kPa) pressure changes for 1 subject and 30% (28kPa) changes for a second subject at a patellar tendon site when 10 degree flexion adjustments were made (with no translational compensation). Ten degrees of extension produced changes of 53% (80kPa) and 54% (46kPa) in the same 2 respective subjects.

The purpose of this research was to extend from and add to this database of interface stress-alignment investigations. An intent here is inclusion of resultant shear stress data with pressure in the analysis so as to determine if the changes of interface resultant shear stresses to alignment follow similar patterns to those for pressures collected at the same site. It was also intended to compare interface pressure sensitivity to alignment with results reported in the literature adding data to analysis of this important issue.

Methods

Subjects

All subjects were male unilateral trans-tibial amputees who regularly wore total contact patellar-tendon-bearing (PTB) prostheses with sleeve suspensions and had been amputees for at least 1 year. Subject No.1 was 23 years of age,

All correspondence to be addressed to J. E. Sanders PhD, Associate Professor, Department of Bioengineering, Harris 309, Box 357962, University of Washington, Seattle WA 98195, USA
Tel: (+1)206 685-8296. Fax: (+1)206 543-6124
E-mail: sanders@limbs.bioeng.washington.edu

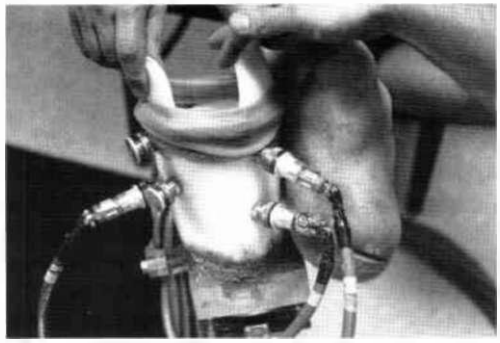


Fig. 1. An instrumented prosthetic socket. Transducers are positioned in mounts at anterior-medial proximal, antero-medial distal, lateral and posterior proximal sites. Dummy transducer plugs fill mounts at sites that are not monitored.

of mass 65.9kg, and had his right limb amputated 4 years prior to this study as a result of a gunshot wound. His stump was very bony with little soft tissue especially distally and was of length 14.6cm from the patellar tendon to the distal end. He regularly used a PTB total contact socket with a 3-ply wool sock, a Pelite™ liner, and a latex or Neoprene sleeve suspension. Subject No.2 was 25 years of age, of mass 68.2kg, and had his right limb amputated 8 years prior to this study as a result of a motorcycle accident. He had a prominent medial distal osteophyte, and his stump was of length 15.2cm. He regularly used a PTB total contact socket with a nylon sheath, a Pelite liner, and a Neoprene sleeve suspension. Subject No.3 was 46 years of age, of mass 86.4kg, and had his right limb amputated 8 years prior to this study as a result of a climbing accident. He had excessive superficial tissue in his stump, a prominent peroneal nerve, and a deep cleft in the antero-distal suture line. He regularly used a PTB total contact socket with a nylon sheath, a Pelite liner, and supracondylar suspension.

Instrumented prostheses

An instrumented prosthesis was designed and manufactured for each subject by certified prosthetists using computer-aided design (ShapeMaker™) and manufacturing methods. Sockets were designed to be slightly smaller than those normally used by the subjects because no socks or sheaths were worn with the instrumented prosthesis. Only a Pelite liner, made during vacuum-forming of the socket, was between the socket and stump and it was bonded with a thin layer of epoxy to the inside of the socket. At selected, relatively flat, locations on the anterior, lateral, and posterior surfaces of each socket, holes of diameter 8.73mm were drilled through the socket wall and Pelite liner. Mounts, carefully aligned to be perpendicular to the inside socket surface, were fixed to the outside of the socket with epoxy. The mounts held custom-designed transducers (Sanders and Daly, 1993) of diameter 6.35mm so that their sensing surfaces were flush with the inside Pelite liner surface (Fig. 1). Each transducer surface was a Pelite disk of the same thickness as the surrounding Pelite, thus no foreign material was introduced to the stump. The transducers measured shear stresses in 2 perpendicular directions in the plane of the transducer surface as well as pressure applied perpendicular to the surface. During a data collection session, stresses were monitored at 4 of 7 possible locations at a time (Table 1). It was not possible to monitor all 7 sites simultaneously because of a limited number of channels in the data acquisition system. Mounts of unmonitored sites were filled with dummy transducer plugs.

The prosthesis was completed with a Berkeley alignment unit, an instrumented pylon (Sanders *et al.*, 1994), and a Seattle™ LightFoot. Because of a limited number of data acquisition channels

Table 1. Transducer locations.

Site	Abbr.	Description of location
Anterior Lateral Proximal	ALP	at the level of the tibial tubercle, lateral side
Anterior Medial Proximal	AMP	at the level of the tibial tubercle, medial side
Anterior Lateral Distal*	ALD	distal stump, anterior tibial border, lateral side
Anterior Medial Distal	AMD	distal stump, anterior tibial border, medial side
Lateral	L	femoral neck, ~2cm distal distal to the fibular head
Posterior Proximal	PP	mid-calf, on the posterior longitudinal midline
Posterior Distal	PD	distal calf, on the posterior longitudinal midline

*for Subject No.3, this site was located in the mid-limb region because of excessive scar tissue more distally.

on the computer data collection system (16 channels total), only 4 of 6 shank forces and moments were monitored simultaneously in a session. Axial force was measured in all sessions. Data were collected at a 125Hz sampling rate. The Berkeley alignment unit was modified to include an apparatus for measurement of angular alignment changes (Sanders *et al.*, 1990). The apparatus added minimal mass to the prosthesis. An instrumented prosthesis weighed approximately 3.1kg, typical of a fitting prosthesis (most of the mass was in the Berkeley alignment unit). Subject No.2 used a suprapatellar strap attached to an elastic belt to facilitate suspension. Subject No.1 used a latex sleeve suspension. Subject No.3 used a latex sleeve suspension and supracondylar socket design.

Data collection sessions

Trials were carried out and data collected with the sagittal plane angular alignment at 1 of 3 settings for each subject. Misalignment settings were selected to be the maximum of the available range on the Berkeley unit but within safety ranges acceptable to the research prosthetists. No translational compensations were made for the flexion and extension adjustments. During each trial, the subject walked the length of an 18m hallway at a cadence controlled to between 94 and 99 steps/min using a metronome. The selected value was the closest to the subject's normal self-selected walking rate. Data collection was initiated 1 step after walking was initiated and lasted for 8 s. At least 4 consecutive trials were conducted at each alignment setting, thus the alignment was changed at least twice over the course of a data collection session. Alignment ordering was randomly selected. As many sessions as possible were conducted on each subject over a 1 month period, with a minimum of 2 sessions on each subject. The purpose of the 1 month time restriction was to limit effects of stump changes on socket fit. It was expected that session effects on interface stresses would not be as drastic as alignment effects thus the 4 sites selected for monitoring in each session were selected randomly rather than systematically.

Data processing

Data from the transducers and instrumented shank were converted into interface pressures and shear stresses and shank forces and moments using calibration data. For the transducers, resultant shear stress magnitudes, which were the resultant stresses in the plane of the interface, and pressure magnitudes at each transducer site were calculated. Only data from complete steps were included in the analysis and the first step in a trial was not included because of possible acceleration effects on the results. Steps in which instrumentation problems occurred were not included in analysis. Steps were segmented into stance and swing phases based on a slope threshold of 0.63N/ms for heel contact and -0.63N/ms for toe-off in the shank axial force channel. For stance phase of each step, the peak magnitude pressures and resultant shear stresses were determined. The basis for using the peak magnitude pressure and resultant shear stress data in analysis is that it is expected that these are threatening times for stump soft tissues and thus are of strong clinical interest.

Table 2. Angular alignment changes for each subject.

Subject	Plantarflexion	Dorsiflexion
1	-12 degrees	4 degrees
2	-9 degrees	5 degrees
3	-5 degrees	8 degrees

Results

Alignment deviations were at least 4 degrees in each direction (plantarflexion, dorsiflexion) for all subjects. Values reflect the maximal acceptable safety ranges for each subject as established by the research prosthetists. In Table 2 angles are specified relative to the centre of rotation for sagittal plane adjustments on the Berkeley alignment unit at the nominal (zero) alignment setting for each subject.

The coefficient of variance (defined as the standard deviation/mean)(COV) was, in general, less for pressure than for resultant shear stress. For pressure, COV was typically greater than 10% for antero-medial proximal and antero-lateral proximal sites (Table 3) but less than 10% at remaining sites. There was not a trend of greater COV for misaligned vs nominally aligned settings.

Alignment changes had minimal effect on pressure maxima and resultant shear stress maxima at most of the sites for most of the alignment modifications. Data shown in Figure 2 are typical. Absolute value pressure changes

Table 3. Interface stress magnitudes and coefficients of variance.

Stance phase maximal magnitudes (kPa) and coefficients of variance (%). Site abbreviations are listed in Table 1.

Pressure

Subj.		No. of	AMP		ALP		AMD		ALD		L		PP		PD		AX	
Sess	Alig	steps	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV
1.1	zero	20	88.0	**22.9%**	92.4	**6.1%**			100.9	**5.6%**			119.4	**10.2%**			860.2	**4.4%**
	dflex	20	60.2	**23.0%**	92.9	**10.5%**			97.7	**5.4%**			111.4	**6.9%**			813.3	**5.2%**
	pflex	19	89.7	**16.0%**	88.9	**7.5%**			100.7	**6.1%**			120.0	**9.4%**			846.1	**3.4%**
1.2	zero	20	66.6	**11.5%**	114.1	**7.0%**			87.7	**4.6%**					72.2	**2.9%**	796.9	**3.2%**
	dflex	20	67.0	**13.8%**	117.9	**15.4%**			88.8	**7.2%**					68.5	**7.0%**	792.1	**2.5%**
	pflex	20	78.2	**15.0%**	112.9	**7.9%**			89.1	**8.1%**					69.4	**3.8%**	774.9	**2.5%**
2.1	zero	16			57.4	**10.0%**			98.0	**6.2%**			92.2	**9.1%**	83.9	**9.9%**	784.8	**3.0%**
	dflex	17			60.0	**8.4%**			98.0	**5.1%**			93.9	**6.1%**	79.7	**5.4%**	758.3	**3.5%**
	pflex	16			73.1	**13.9%**			85.3	**8.3%**			97.6	**4.8%**	93.2	**4.1%**	822.7	**3.9%**
2.2	zero	10					53.4	**21.2%**	98.6	**3.7%**	101.1	**3.3%**	101.2	**4.5%**			798.1	**3.4%**
	dflex	12					53.2	**15.6%**	95.3	**6.2%**	106.0	**5.4%**	112.3	**4.9%**			784.6	**2.3%**
	pflex	11					52.5	**9.5%**	93.4	**9.8%**	105.9	**6.0%**	103.1	**3.2%**			839.4	**3.5%**
2.3	zero	19	91.6	**9.0%**	97.7	**2.8%**							108.5	**5.0%**	82.9	**3.9%**	783.3	**3.0%**
	dflex	23	98.2	**12.2%**	97.5	**4.8%**							111.9	**8.1%**	79.5	**5.0%**	778.6	**3.2%**
	pflex	26	73.5	**10.0%**	91.7	**5.3%**							111.0	**2.9%**	102.4	**3.5%**	862.1	**2.8%**
3.1	zero	5	58.0	**5.2%**			124.8	**6.7%**			183.5	**3.2%**	99.0	**2.1%**			926.1	**3.4%**
	dflex	5	70.1	**6.8%**			124.9	**2.6%**			166.5	**4.1%**	93.2	**3.3%**			929.7	**3.5%**
	pflex	13	51.4	**4.3%**			130.1	**3.7%**			185.9	**5.6%**	104.0	**2.4%**			950.0	**1.8%**
3.2	zero	8			23.7	**26.7%**			111.9	**2.2%**			78.3	**1.9%**	79.1	**3.4%**	930.9	**2.6%**
	dflex	25			28.2	**28.9%**			105.5	**2.9%**			78.8	**2.8%**	77.5	**2.7%**	905.0	**2.3%**
	pflex	7			25.9	**37.1%**			121.7	**6.2%**			85.1	**1.6%**	83.4	**2.8%**	933.2	**1.4%**
3.3	zero	16			33.1	**20.3%**	154.1	**3.6%**			164.3	**9.4%**			82.0	**3.0%**	950.4	**2.4%**
	dflex	16			29.9	**17.9%**	134.0	**5.1%**			156.4	**4.8%**			76.0	**3.9%**	882.1	**2.6%**
	pflex	17			31.2	**30.3%**	141.0	**5.8%**			171.2	**8.5%**			89.4	**3.2%**	969.8	**3.3%**
3.4	zero	16	52.8	**5.0%**	35.9	**20.4%**					159.3	**4.2%**	107.3	**2.0%**			931.3	**2.2%**
	dflex	16	59.1	**6.5%**	38.1	**23.8%**					148.3	**4.7%**	99.3	**2.0%**			875.5	**2.7%**
	pflex	20	48.9	**5.5%**	36.6	**14.5%**					167.0	**4.5%**	110.8	**2.2%**			946.6	**2.2%**

Resultant shear stress

Subj.		No. of	AMP		ALP		AMD		ALD		L		PP		PD	
Sess	Alig	steps	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV
1.1	zero	20	7.7	**33.0%**	13.5	**10.3%**			31.7	**9.5%**			40.7	**3.9%**		
	dflex	20	8.0	**15.7%**	13.7	**8.7%**			33.1	**6.3%**			38.0	**6.2%**		
	pflex	19	8.2	**23.4%**	13.0	**12.5%**			32.6	**9.5%**			39.8	**3.6%**		
1.2	zero	20	8.2	**30.6%**	18.9	**17.0%**			29.2	**16.1%**					8.1	**6.6%**
	dflex	20	6.4	**31.5%**	20.6	**18.3%**			29.0	**12.2%**					7.7	**7.3%**
	pflex	20	10.8	**32.8%**	17.4	**18.7%**			27.7	**20.4%**					8.5	**9.4%**
2.1	zero	16			22.1	**18.7%**			29.9	**12.9%**			35.9	**6.8%**	23.5	**46.7%**
	dflex	17			22.7	**24.2%**			29.3	**17.3%**			40.4	**9.6%**	16.0	**59.6%**
	pflex	16			19.6	**16.8%**			39.6	**9.7%**			36.4	**10.3%**	15.4	**41.8%**
2.2	zero	10					20.7	**20.1%**	16.7	**12.1%**	11.0	**7.4%**	16.6	**7.3%**		
	dflex	12					22.0	**15.2%**	18.7	**10.6%**	11.3	**9.9%**	18.6	**6.3%**		
	pflex	11					22.2	**8.8%**	22.1	**10.9%**	12.3	**13.3%**	16.5	**7.1%**		
2.3	zero	19	11.3	**24.9%**	22.2	**12.1%**							19.7	**5.2%**	11.8	**22.0%**
	dflex	23	12.2	**25.9%**	20.7	**10.3%**							20.8	**4.7%**	13.2	**15.8%**
	pflex	26	8.5	**22.1%**	34.8	**17.9%**							16.2	**6.3%**	17.4	**31.4%**
3.1	zero	5	5.7	**13.9%**			40.3	**9.0%**			43.8	**4.4%**	10.7	**7.8%**		
	dflex	5	9.6	**20.9%**			36.2	**13.7%**			44.4	**5.6%**	10.4	**8.0%**		
	pflex	13	5.8	**23.8%**			40.4	**16.0%**			45.7	**7.4%**	11.2	**12.1%**		
3.2	zero	8			14.0	**24.2%**			9.2	**10.7%**			8.2	**7.8%**	5.0	**36.8%**
	dflex	25			12.6	**18.3%**			7.2	**14.0%**			8.4	**6.6%**	8.2	**19.2%**
	pflex	7			13.3	**27.3%**			13.7	**43.8%**			8.2	**10.5%**	7.2	**20.8%**
3.3	zero	16			7.8	**13.5%**	39.0	**14.4%**			31.8	**10.2%**			6.8	**10.0%**
	dflex	16			9.7	**15.5%**	37.6	**14.1%**			33.0	**6.2%**			6.3	**14.0%**
	pflex	17			6.2	**14.6%**	47.3	**15.3%**			33.9	**8.5%**			8.6	**13.5%**
3.4	zero	16	5.6	**15.5%**	10.8	**13.9%**					36.2	**3.7%**	13.5	**6.1%**		
	dflex	16	6.8	**13.2%**	10.6	**11.0%**					34.3	**3.5%**	13.0	**7.2%**		
	pflex	20	6.3	**14.6%**	11.5	**11.1%**					37.4	**11.2%**	13.1	**6.0%**		

Table 4. Effects of changes in alignment of interface stresses.
Changes in interface stresses for dorsiflexion (dflex) and plantarflexion (pflex) alignments relative to the nominal (zero) alignment.
Magnitudes (kPa) and fractions of the mean (%). Site abbreviations are listed in Table 1.

Pressure

Subj. Sess	Alig	AMP Mag	AMP Fr Mn	ALP Mag	ALP Fr Mn	AMD Mag	AMD Fr Mn	ALD Mag	ALD Fr Mn	L Mag	L Fr Mn	PP Mag	PP Fr Mn	PD Mag	PD Fr Mn	AX Mag	AX Fr Mn
1.1	dflex	-27.8	**-37.6%**	0.5	**0.5%**			-3.2	**-3.2%**			-8.0	**-6.9%**			-46.9	**-5.6%**
	pflex	1.6	**1.8%**	-3.5	**-3.8%**			-0.2	**-0.2%**			0.6	**0.5%**			-14.1	**-1.7%**
1.2	dflex	0.4	**0.6%**	3.9	**3.3%**			1.2	**1.3%**					-3.8	**-5.3%**	-4.7	**-0.6%**
	pflex	11.5	**15.9%**	-1.2	**-1.0%**			1.4	**1.6%**					-2.8	**-3.9%**	-22.0	**-2.8%**
2.1	dflex			2.5	**4.3%**			0.0	**0.0%**			1.7	**1.9%**	-4.2	**-5.1%**	-26.5	**-3.4%**
	pflex			15.7	**24.1%**			-12.7	**-13.8%**			5.3	**5.6%**	9.3	**10.5%**	37.8	**4.7%**
2.2	dflex					-0.2	**-0.3%**	-3.3	**-3.4%**	4.9	**4.8%**	11.1	**10.4%**			-13.5	**-1.7%**
	pflex					-0.9	**-1.6%**	-5.2	**-5.4%**	4.8	**4.7%**	1.9	**1.9%**			41.3	**5.0%**
2.3	dflex	6.6	**7.0%**	-0.2	**-0.2%**							3.3	**3.0%**	-3.4	**-4.2%**	-4.6	**-0.6%**
	pflex	-18.1	**-21.9%**	-6.0	**-6.4%**							2.5	**2.2%**	19.5	**21.0%**	78.8	**9.6%**
3.1	dflex	12.1	**18.9%**			0.1	**0.1%**			-16.9	**-9.7%**	-5.8	**-6.0%**			3.6	**0.4%**
	pflex	-6.6	**-12.1%**			5.3	**4.2%**			2.4	**1.3%**	5.0	**4.9%**			23.9	**2.5%**
3.2	dflex			4.5	**17.4%**			-6.5	**-5.9%**			0.5	**0.6%**	-1.6	**-2.1%**	-25.9	**-2.8%**
	pflex			2.3	**9.2%**			9.7	**8.3%**			6.7	**8.3%**	4.3	**5.3%**	2.2	**0.2%**
3.3	dflex			-3.2	**-10.1%**	-20.2	**-14.0%**			-7.9	**-4.9%**			-6.0	**-7.7%**	-68.3	**-7.5%**
	pflex			-1.9	**-5.8%**	-13.1	**-8.9%**			6.9	**4.1%**			7.4	**8.6%**	19.4	**2.0%**
3.4	dflex	6.4	**11.4%**	2.2	**5.9%**					-10.9	**-7.1%**	-8.0	**-7.8%**			-55.7	**-6.2%**
	pflex	-3.8	**-7.6%**	0.7	**1.9%**					7.8	**4.8%**	3.5	**3.2%**			15.3	**1.6%**

Resultant shear stress

Subj. Sess	Alig	AMP Mag	AMP Fr Mn	ALP Mag	ALP Fr Mn	AMD Mag	AMD Fr Mn	ALD Mag	ALD Fr Mn	L Mag	L Fr Mn	PP Mag	PP Fr Mn	PD Mag	PD Fr Mn
1.1	dflex	0.2	**2.6%**	0.2	**1.4%**			1.4	**4.4%**			-2.7	**-6.9%**		
	pflex	0.5	**5.8%**	-0.5	**-3.7%**			0.9	**2.7%**			-0.9	**-2.2%**		
1.2	dflex	-1.9	**-25.6%**	1.7	**8.5%**			-0.2	**-0.8%**					-0.4	**-5.0%**
	pflex	2.6	**27.2%**	-1.5	**-8.2%**			-1.5	**-5.2%**					0.4	**4.5%**
2.1	dflex			0.7	**2.9%**			-0.5	**-1.8%**			4.5	**11.8%**	-7.6	**-38.3%**
	pflex			-2.5	**-12.0%**			9.8	**28.1%**			0.5	**1.5%**	-8.2	**-41.9%**
2.2	dflex					1.3	**6.2%**	2.0	**11.3%**	0.3	**2.8%**	2.0	**11.1%**		
	pflex					1.5	**6.7%**	5.4	**24.5%**	1.3	**10.5%**	-0.1	**-0.7%**		
2.3	dflex	0.9	**7.8%**	-1.5	**-6.8%**							1.1	**5.3%**	1.4	**11.1%**
	pflex	-2.8	**-28.8%**	12.6	**44.2%**							-3.5	**-19.7%**	5.6	**38.4%**
3.1	dflex	4.0	**52.0%**			-4.2	**-10.9%**			0.6	**1.3%**	-0.3	**-3.1%**		
	pflex	0.1	**2.6%**			0.0	**0.1%**			1.9	**4.2%**	0.5	**4.2%**		
3.2	dflex			-1.3	**-9.9%**			-2.0	**-24.1%**			0.3	**3.2%**	3.2	**48.0%**
	pflex			-0.6	**-4.5%**			4.5	**39.2%**			0.1	**0.6%**	2.2	**36.3%**
3.3	dflex			1.9	**21.3%**	-1.4	**-3.8%**			1.1	**3.4%**			-0.5	**-7.8%**
	pflex			-1.6	**-22.3%**	8.3	**19.2%**			2.1	**6.3%**			1.7	**22.4%**
3.4	dflex	1.3	**20.5%**	-0.2	**-2.1%**					-2.0	**-5.6%**	-0.6	**-4.3%**		
	pflex	0.7	**12.5%**	0.7	**6.6%**					1.2	**3.3%**	-0.4	**-2.9%**		

were less than 10% of the mean in 14 of 16 cases for Subject No.1; 18 of 24 cases for Subject No.2; and 26 of 32 cases for Subject No.3 (Table 4). Pressure changes were larger than 20% of the mean in 1 of 16 cases for Subject No.1; 3 of 24 cases for Subject No.2; and 0 of 32 cases for Subject No.3. Axial force changes were less than 10% for all subjects for all misalignment settings.

Resultant shear stresses (kPa) showed lower absolute magnitude changes than pressures in all cases but greater percentage changes. Resultant shear stress changes for different alignments were less than 10% in 14 of 16 cases for Subject No.1; 10 of 24 cases for Subject No.2; and 20 of 32 cases for Subject No.3. Resultant shear stress changes were larger than 20% in 2 of 16 cases for Subject No.1; 7 of 24 cases for Subject No.2; and 9 of 32 cases for Subject No.3.

Typically a change of more than 10% in pressure was accompanied by a corresponding greater than 10% change in resultant shear stress at the same site. This occurred in 1 of 2 cases for Subject No.1; 6 of 6 cases for Subject No.2; and 3 of 6 cases for Subject No.3. However, in a number of cases a greater than 10% change in resultant shear stress occurred without a correspondingly greater than 10% change in pressure. This occurred in 1 of 2 cases for Subject No.1; 8 of 14 cases for Subject No.2; and 9 of 12 cases for Subject No.3.

Pressure changes for alignment modifications in the dorsiflexion direction were not always opposite of those for the plantarflexion direction, i.e. there was a maximum or minimum at the zero alignment relative to the dorsiflexion and plantarflexion values. This result occurred in 4 of 8 cases for Subject No.1; 8 of 12 cases for Subject No.2; and 6 of 16 cases for Subject No.3. For resultant shear stress, there was a maximum or minimum at the zero alignment relative to the dorsiflexion or plantarflexion alignments in 4 of 8 cases for Subject No.1; 6 of 12 cases for Subject No.2; and 8 of 16 cases for Subject No.3.

Inspection of Tables 3 and 4 also demonstrates that the magnitude changes between sessions were in some cases substantial compared with those for different alignments within a session. Investigation of session to session differences was not an aim at the outset of the study. The study protocol was not designed to make these

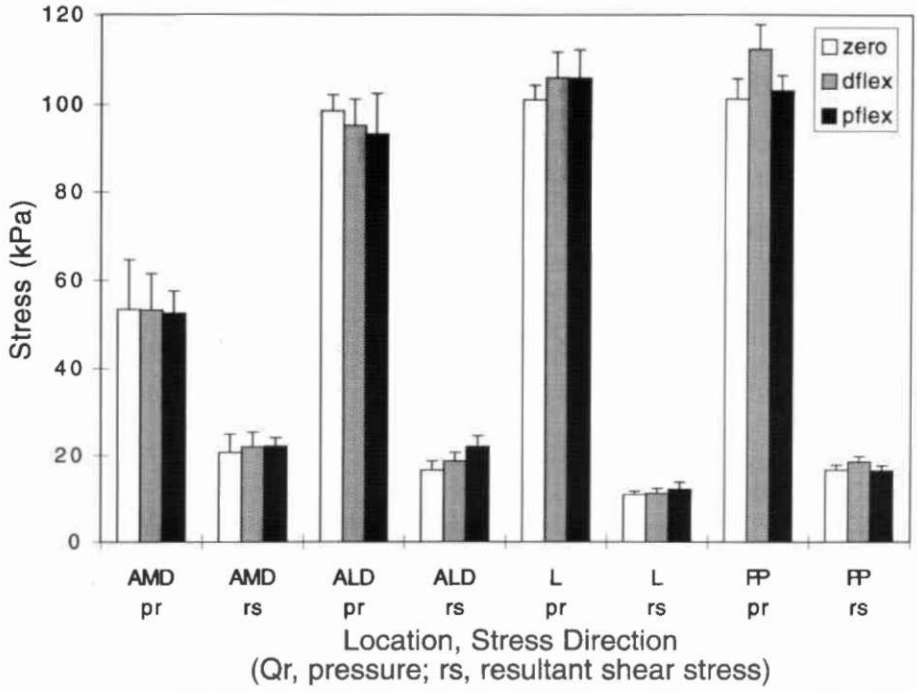


Fig. 2. Changes in pressure (pr) and resultant shear stress (rs) for different alignments. Stance phase peak stresses for Subject 2, session 2 are shown.

comparisons thus only limited data are available. However, analysis of available data demonstrated substantial session to session changes. For pressure, 2 of 3 cases for Subject No.1 had changes greater than 20%; 1 of 6 cases for Subject No.2; 5 of 12 for Subject No.3 (Table 5). For resultant shear stress 1 of 3 for Subject No.1 had changes greater than 20%; 4 of 6 for Subject No.2; and 8 of 12 for Subject No.3. Thus for all subjects session to session changes had a greater proportion of cases with changes greater than 20% than did alignment modifications. Data comparing alignment and session to session changes for Subject 1 are shown in Figure 3. Axial force changes between sessions were less than 10% for all possible pairs of sessions within a subject. The results suggest a more complete investigation of session to session differences on interface stresses is warranted.

Discussion

Interface pressure data presented here are consistent with those reported by Appoldt *et al.* (1968). Alignment effects on interface pressures were low. For each subject, very few sites demonstrated changes greater than 20% for pressure.

The minimal effects of alignment are inconsistent with the results of Pearson *et al.* (1973) and Winarski and Pearson (1987), where substantial changes in interface pressures for

Table 5. Effects of changes in session on interface stresses.
Changes in interface stresses from session to session. Magnitudes (kPa) and fraction of the mean (%).
Site abbreviations are listed in Table 1.

Pressure

Subj. Sess	Time btwn Sess (d)	AMP Mag	AMP Fr Mn	ALP Mag	ALP Fr Mn	AMD Mag	AMD Fr Mn	ALD Mag	ALD Fr Mn	L Mag	L Fr Mn	PP Mag	PP Fr Mn	PD Mag	PD Fr Mn	AX Mag	AX Fr Mn
1.1 v 1.2	0*	21.4	**27.7%**	-21.7	**-21.0%**			13.2	**14.0%**							63.4	**7.6%**
2.1 v 2.2	12							-0.6	**-0.6%**			-9.0	**-9.3%**			-13.3	**-1.7%**
2.2 v 2.3	19											-7.3	**-7.0%**			14.8	**-1.9%**
2.1 v 2.3	31			-40.3	**-51.9%**							-16.3	**-16.3%**	1.0	**1.2%**	1.6	**0.2%**
3.1 v 3.2	5											20.7	**23.3%**			-4.8	**-0.5%**
3.1 v 3.3	9					-29.4	**-21.0%**			19.2	**11.0%**					-24.3	**-2.6%**
3.1 v 3.4	9	5.2	**9.4%**							24.2	**14.1%**	-8.3	**-8.0%**			-5.2	**-0.6%**
3.2 v 3.3	4			-9.4	**-33.2%**									-2.9	**-3.6%**	-19.5	**-2.1%**
3.2 v 3.4	4			-12.3	**-41.2%**							-29.0	**-31.2%**			-0.3	**0.0%**
3.3 v 3.4	0			-2.8	**-8.3%**					5.0	**3.1%**					19.1	**2.0%**

* '0' days indicates that morning and afternoon session were conducted on the same day

Resultant shear stress

Subj. Sess	Time btwn Sess (d)	AMP Mag	AMP Fr Mn	ALP Mag	ALP Fr Mn	AMD Mag	AMD Fr Mn	ALD Mag	ALD Fr Mn	L Mag	L Fr Mn	PP Mag	PP Fr Mn	PD Mag	PD Fr Mn
1.1 v 1.2	0	-0.5	**-6.0%**	-5.4	**-33.1%**			2.5	**8.2%**						
2.1 v 2.2	12							13.2	**56.5%**			19.2	**73.3%**		
2.1 v 2.3	19			-0.1	**-0.5%**							16.2	**58.2%**	11.7	**66.3%**
2.2 v 2.3	31											-3.1	**-16.9%**		
3.1 v 3.2	5											2.6	**27.1%**		
3.1 v 3.3	9					1.3	**3.3%**			12.0	**31.6%**				
3.1 v 3.4	9	0.1	**1.9%**							7.6	**19.0%**	-2.8	**-22.9%**		
3.2 v 3.3	4			6.1	**56.4%**									-1.8	**-31.2%**
3.2 v 3.4	4			3.2	**25.7%**							-5.3	**-49.2%**		
3.3 v 3.4	0			-3.0	**-31.9%**					-4.4	**-12.9%**				

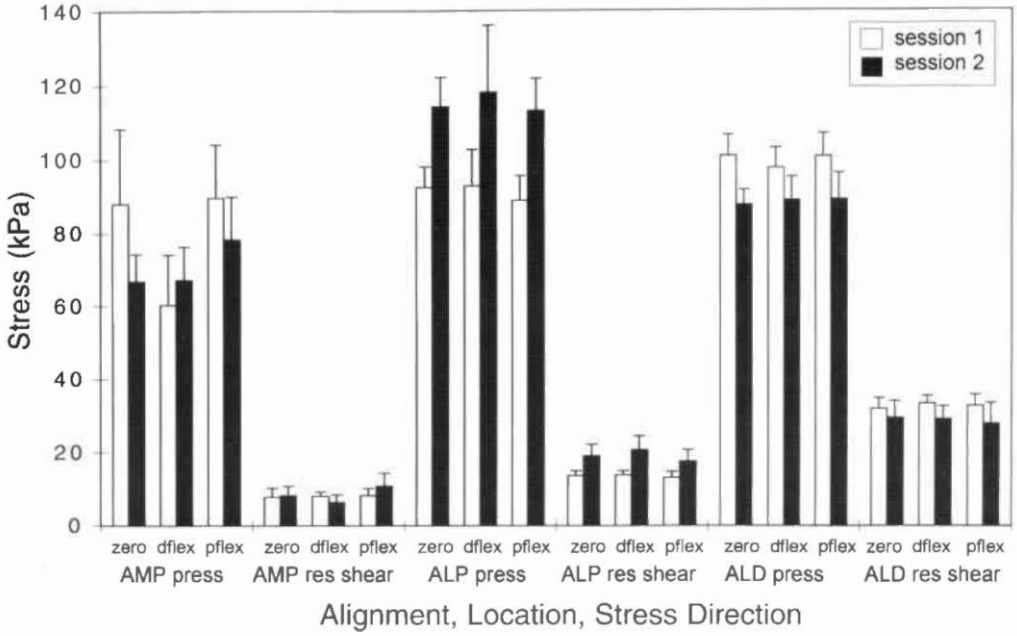


Fig. 3. Changes in pressure and resultant shear stress for different alignments and different sessions. Stance phase peak stresses for Subject 1, sessions 1 and 2 are shown.

alignment changes in trans-tibial amputees were reported. Differences could reflect protocol differences, subject variations, or amputation level differences. Another possibility that all the data supports, however, is that in cases in which the transducers were flush with the interface (Appoldt *et al.* (1968) and this study) results showed substantially lower pressure changes for misaligned vs nominally aligned trials compared with studies in which the transducers protruded into the skin (Pearson *et al.* 1973; Winarski and Pearson, 1987). Effects of sensor protrusion on interface pressure measurement have been investigated (Appoldt *et al.*, 1969; Patterson and Fisher, 1979) and shown to have an important influence on measurement repeatability, particularly at sites with thin skin over bone. Thus data from Pearson's and Winarski and Pearson's studies may reflect instrumentation design limitations.

The coefficients of variance, in general, were higher for resultant shear stress than for pressure. Thus resultant shear stress is less consistent from step to step than is pressure. Fluctuations in frictional coefficient with changes in skin temperature and surface moisture could be part of the reason. Frictional coefficient sensitivity to temperature has been reported (Naylor, 1955).

The percentage changes in pressure magnitude reported here for the different alignments are comparable in magnitude to the coefficients of variance expressed as a percentage for steps at a setting within a session. Thus compared to the variability from trial to trial, misalignment effects were not substantial. It is important to note that the alignment changes were extreme, the maximal range of the Berkeley alignment unit at which alignments were considered safe. More subtle changes, as would be typical during a fitting session would be expected to have a reduced impact on changes in interface stresses. It is important to note, however, that the 3 subjects evaluated in this study were experienced prosthesis users; they adapted their gaits well to the alignment changes, based in part presumably on interface stress sensations on their stumps. It is interesting to note that, a greater number of sites showed greater than 10% changes for resultant shear stress than for pressure, suggesting that alignment changes influenced resultant shear stress more than they did pressure. Possibly the subjects used pressure sensation more than resultant shear stress sensation as feedback to compensate for the alignment modifications, resulting in more

consistent pressure values than resultant shear stress values.

Though not part of the original study design, analysis of session to session differences showed that session changes had a greater impact on interface stresses at a greater proportion of sites than did alignment changes within a session. Differences from session to session were not accompanied by greater changes in shank axial force. Possibly, changes in stump shape or material properties were responsible for the session to session differences. To investigate their relative influence, further studies need to be conducted in which stump shape and/or material properties as well as interface stresses are measured. Appoldt *et al.* (1968) also noted significant session to session differences but he reported for the 2 subjects tested that only in sessions weeks or months apart were the effects significant. Day to day variations were typically within the larger of ±7kPa or ±20%. It is clear from Appoldt's results and those presented here that the relative influence of session to session effects compared with alignment changes or other modifications to the prosthesis is an area worthy of further investigation. If session to session changes were shown to be more influential on interface stress magnitude changes, then more intensive design and fitting concentration on techniques to overcome shape changes would be warranted.

Acknowledgements

Financial support from the Whitaker Foundation, the Department of Veterans' Affairs, and the National Institute of Child and Human Development as well as clinical assistance from Dr Ernest Burgess, prosthetists David Boone and Albert Rappoport, and the staff of the Prosthetics Research Study in Seattle are gratefully acknowledged.

REFERENCES

APPOLDT F, BENNETT L, CONTINI R (1968). Stump-socket pressure in lower extremity prostheses. *J Biomech* **1**, 247-257.

APPOLDT FA, BENNETT L, CONTINI R (1969). Socket pressure as a function of pressure transducer protrusion. *Bull Prosthet Res* **10 (11)**, 236-249.

NAYLOR PFD (1955). The skin surface and friction. *Br J Dermatol* **67**, 239-248.

PATTERSON RP, FISHER SV (1979) The accuracy of electrical transducers for the measurement of pressure applied to the skin. *IEEE Trans Biomed Eng* **26**, 450-456.

PEARSON JR, HOLMGREN G, MARCH L, OBERG K (1973) Pressures in critical regions of the below-knee patellar-tendon-bearing prosthesis. *Bull Prosthet Res* **10 (19)**, 52-76.

SANDERS JE, DALY CH, BOONE DA, and DONALDSON TF (1990) An angular alignment measurement device for prosthetic fitting. *Prosthet Orthot Intl* **14**, 143-144.

SANDERS JE, DALY CH (1993). Measurement of stresses in 3 orthogonal directions at the residual limb-prosthetic socket interface. *IEEE Trans Rehabil Eng* **1**, 79-85.

SANDERS JE, DALY CH, CUMMINGS WR, REED RD, MARKS RJ II (1994) A measurement device to assist amputee prosthetic fitting. *J Clin Eng* **19**, 63-71.

WINARSKI DJ, PEARSON JR (1987) Least-squares matrix correlations between stump stresses and prosthesis loads for below-knee amputees. *J Biomech Eng* **109**, 238-246.

Prosthetics and Orthotics International, 1999, 23, 30–44

Validation of a quantitative method for defining CAD/CAM socket modifications

E. D. LEMAIRE*, P. BEXIGA*, F. JOHNSON**,
S. E. SOLOMONIDIS*** and J. P. PAUL***

**The Rehabilitation Centre, Ottawa, Ontario, Canada*
***University of Ottawa, Medical Engineering Research Affiliation, Ottawa, Ontario, Canada*
****University of Strathclyde, Bioengineering Unit, Wolfson Centre, Glasgow, Scotland*

Abstract

A quantitative method was developed for defining manual socket modifications, averaging these modifications over a series of amputees, and using the average modifications as a template in commercial CAD/CAM systems. The CADVIEW programme (i.e. software for viewing and analysing CAD sockets) was rewritten to provide comparison functions for aligning sockets to a common axis, visualising the differences between sockets, generating modification outlines, assigning apex point values, and averaging the modification outlines. A CAD template generated in this manner should be the best general representation of a prosthetist's modification style. To test this hypothesis, 13 people with trans-tibial amputations were fitted with both a manual and a CAD/CAM socket. Questionnaires were completed by the subjects and by the prosthetist to obtain information on prosthetic comfort, function, and overall satisfaction. Ground reaction force and stride parameter data were also collected for each prosthesis during gait laboratory testing. No significant differences were found between the manually designed socket and the CAD/CAM designed socket for all data except the vertical peak forces on the amputated side. These results support the clinical application of this quantitative technique for making the transition from manual to CAD/CAM prosthetic modification procedures.

All correspondence to be addressed to Edward Lemaire, Institute for Rehabilitation Research and Development, The Rehabilitation Centre, 505 Smyth Road, Ottawa, Ontario, Canada K1H 8M2.

Introduction

CAD/CAM (Computer Aided Design/ Computer Aided Manufacture) has become a viable clinical tool in the field of prosthetics and orthotics. The CAD/CAM process provides a controlled method for shape modification, an accurate method for positive mould fabrication, a decrease in production time, and a more efficient platform from which to service remote areas (Lemaire and Johnson, 1996; Torres-Moreno *et al.*, 1995). Improvements in CAD software have enabled clinicians to make almost any stump shape modification. Generally, a prosthetist uses computer modification tools to outline a modification region, specify points of maximum change, and set modification amounts. While these tools are effective, the prosthetist must be able to visualise socket modifications on a 2-dimensional screen – as opposed to hand-sculpting modifications on a physical object. Experience with clinical CAD/CAM applications has shown that transferring manual prosthetic modification skills to a computer system is neither easy nor time-efficient. This knowledge-transfer problem is compounded when the individuality of clinical modification procedures is considered (i.e. modification styles are particular to each prosthetist). In most cases, a prosthetist will learn to modify a shape on a CAD system by trial and error.

One approach to easing the manual-to-CAD/CAM transition is to develop a method of quantitatively defining manual socket modifications. Once a manual modification technique has been quantitatively defined, these

digital modifications can be transferred to a CAD system as a template or overlay. A template will allow the user to apply an individual's modification technique to a shape in 1 step. Custom modifications can then be made to the averaged modification pattern. This process should improve the efficiency and effectiveness of moving from traditional to computer socket design.

This document describes a project for quantitatively defining manual socket modifications and then using these modifications to produce a template for CAD/CAM socket fabrication. Template validation involves comparing CAD/CAM produced sockets with manually manufactured sockets.

Methods

Subjects

All subjects were recruited through the Prosthetics and Orthotics Service at the Rehabilitation Centre, Ottawa, Canada and the protocols for the investigation were approved by the Centre's ethical committee. These transtibial (TT) amputees used their patellar-tendon-bearing (PTB) prostheses with supracondylar suspension as their main ambulatory assistive device. If the person agreed to participate in the study, they were informed of the project protocol and asked to complete a consent form. Each subject's stump was evaluated by a prosthetist before starting the project to ensure that there were no tissue problems that would affect socket fitting.

Seven (7) subjects with TT amputations were recruited to define the standard modification pattern. These people provided a good representation of the prosthetist's typical clients. An additional 4 experienced prosthesis wearers were recruited for a pretest of the CAD/CAM rectification pattern. Long term prosthesis users were chosen to assist in refining the standard modification pattern since they should be better at communicating their concerns to the clinician and providing informed feedback. Thirteen (13) subjects with TT amputations, who were more than 1 year postoperative, were recruited for the project's validation phase.

Equipment

All CAD/CAM software and hardware were available in the Prosthetics and Orthotics Service of the Rehabilitation Centre. The average modification pattern shapes were digitised with the CANFIT-PLUS CAD system. The Shapemaker software package was used to produce all test sockets. Both CANFIT-PLUS and Shapemaker use a cast digitiser for shape input and are capable of generating output for a variety of numerically controlled carvers. An IPOS carver was used to produce the positive models.

Each socket consisted of a polyethylene inner socket (liner) and a polypropylene outer socket. An Otto Bock thermoplastic socket attachment plate and pylon were used to connect the socket to the subject's foot/ankle unit. A soft, Pelite liner was used for 2 subjects. Gait testing facilities at the Rehabilitation Centre included 1 AMTI force platform (AMTI, 176 Waltham Street, Watertown, MA, 02172, USA), an Ariel Performance Analysis System (APAS – video kinematic/kinetic analysis), electrogoniometers, and a proprietary EMG data collection system.

Modification pattern

To develop a quantitative approach for defining prosthetist-specific socket modification patterns, new software routines were added to the CADVIEW programme (software for viewing and analysing CAD sockets (Lemaire, 1994)) to compare original and modified stump shapes. By entering a series of pre- and post-modification socket shapes into CADVIEW, common modification areas could be averaged to produce a generalised rectification pattern suitable for use with a CAD/CAM system (Lemaire and Johnson, 1996).

To define a personal modification pattern for the research prosthetist, 7 people with TT amputations were fitted using manual modification techniques. After a cast was taken of a subject's stump, a mandril was placed inside the cast and the cast was filled with plaster. The mandril was visually aligned to the middle of the longitudinal section that was distal to the mid-patellar tendon (MPT) region. After the plaster had set, the cast was stripped off the model and residual plaster outcrops were trimmed. A nail was driven into the model at a right angle to the mandril and at the MPT landmark location (i.e. the main reference point). This model was digitised into the computer using CANFIT-PLUS and a Seattle Digitizer. A special mounting adapter was used to hold the mandril

in the same vertical position for the pre- and post-modification digitisations. A consistent main reference point location was also location was also maintained on the model during modification and during digitising. After the first digitisation, the prosthetist modified the model by hand to produce a PTB socket with supracondylar suspension. While modifying, the nail at the MPT location was driven into the cast so that material could be removed without losing the main reference point. The modified plaster model was digitised using the same procedure as the first digitisation.

All the pre-modification and post-modification shapes were loaded into the CADVIEW software to visually determine common modification areas for each subject (Fig. 1). The following steps were used to generate a comparison shape:

- each subject's pre- and post-modification shapes were viewed individually as shaded 3D and cross-section images. This step served as an initial data quality check and allowed the prosthetist to see how each shape looked as 3D rendered and 2D cross-section images;
- the 2 shapes were compared using CADVIEW's *Compare Sockets* function and displayed using the colour-mapped view;
- printouts were produced that showed anterior, posterior, medial, and lateral views of all colour-mapped comparison images. The printouts were laid out on a table so that common modification areas could be identified;
- common modification boundaries were defined for each socket using CADVIEW's *Outline Generation* function;
- in cases where 2 modifications were blended into each other, the *Break Outline* tool was used to separate the larger shape into the desired outlines;
- in some cases, the *Edit Outline* function was used to change the "broken" edge of the new boundary so that it better conformed to the colour-mapped image;
- each separated outline was saved to disk;
- the peak difference value for each modification was determined by using the *Show Difference Value* function. This number was recorded on a data sheet;

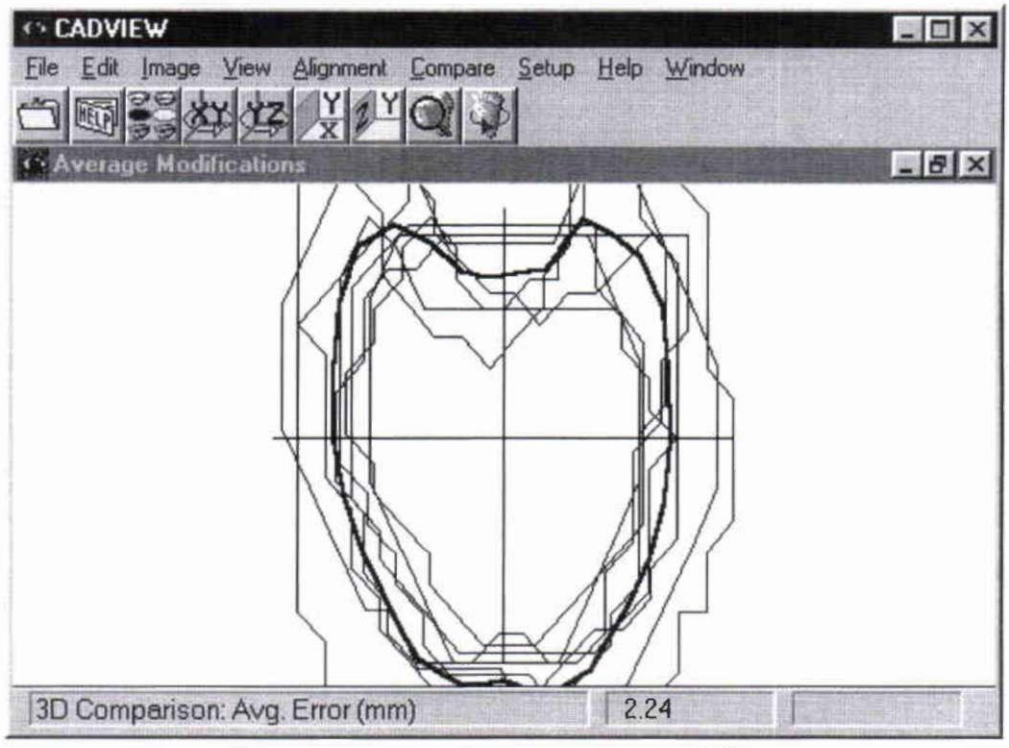


Fig 1. Average modifications at the patellar tendon. Thin lines represent normalised PTB modification outlines from seven subjects. The thick line represents the average PTB modification outline.

- similar outlines (i.e. outlines from the same area on each socket) were selected and averaged to generate 1 typical modification. All selected modifications and the averaged modification were displayed on-screen for visual confirmation;
- the peak difference values were averaged and recorded on the data sheet;
- after all modification outlines had been processed, the averaged outlines were rendered on 1 subject's original socket (using CADVIEW). The same socket shape was loaded into the Shapemaker CAD/CAM software;
- using Shapemaker, the averaged modifications were redrawn to match the images in CADVIEW. Since each prosthetic CAD/CAM system has its own outline definition idiosyncrasies, the size of each modification and the amount of overlap between modifications were defined to suit the Shapemaker programme. The average modification shapes and modification magnitudes were consistent between Shapemaker and CADVIEW. When all modifications had been redrawn, the set of modifications was saved as a template;
- the size and position of the modification outlines were adjusted by applying the new template to 3 of the original socket shapes, saving the resulting socket, and using CADVIEW to compare the results to the related modified socket file.

The standard modification pattern was used for all CAD/CAM produced sockets in this study. Since CAD systems can be used to make fine modifications to the socket shape, software modifications were allowed after applying the template. These modifications were divided into minor and major groups. Minor modifications were expected since most sockets will require shape customisation to accommodate the subject's characteristics. These modifications include depth/height changes over a modification area, volume changes, length changes, relocation of modification areas, and modification surface shape changes on modification areas. Major modifications included extensive modification outline reshaping, creating new modification areas, and point editing.

Clinical evaluation

Before formally validating the CAD/CAM technique, a pre-test was performed involving 4 experienced users of TT sockets. After each subject was fitted with a CAD/CAM produced socket, the prosthetist and the end-user assessed the success of the standardised modification pattern. The success was based on clinical criteria and whether major modifications were required. If the rectification pattern was found to be unsatisfactory, the "Modification Pattern Development" stage would have been repeated with additional subjects.

Validation

Thirteen (13) validation subjects were fitted with a CAD/CAM produced socket and, if their current socket was unsatisfactory, fitted with a new conventional socket (mean age 55.9 years – s.d=14.7, mean height 1.78m – s.d=0.1, mean mass 82.1kg – s.d=13.9). The same components were used for both prostheses. The subjects wore their new prosthesis for at least 2 weeks before completing a questionnaire and having their gait evaluated.

A clinician questionnaire and a subject questionnaire were used to assess satisfaction with the conventional and CAD/CAM produced sockets. The clinician questionnaire recorded information on the prescribed device, the time required to fit the subject, clinician satisfaction with the manufactured socket, the number and type of modifications required for final fitting, and a qualitative assessment of walking gait. This questionnaire also recorded the subject's personal data; such as, date of birth, occupation, gender, height, weight, amputation site, date of amputation, medical conditions, date of last prosthesis, number of years of prosthetic use, and mobility aids. Before gait testing, 1 questionnaire was completed for each socket.

The subject questionnaire inquired about comfort, security, ease of gait, pain and pressure problems, general satisfaction, and general comments. This questionnaire was administered 2 weeks after the device had been dispensed.

Quantitative gait analysis was used to ensure that no significant walking pattern differences were produced by wearing either a CAD/CAM or a conventional socket. Examination of the ground reaction forces was considered an acceptable means of quantitatively assessing the differences between the 2 test cases (Prince *et al.*, 1992; Seliktar and Mizrahi, 1986; Yang *et al.*, 1991).

All gait testing took place in the Gait and Motion Analysis Laboratory at the Rehabilitation Centre. APAS was used to collect/filter all analogue data and digitise video clips of the subjects. Post-processing was completed on a Quattro Pro 7 spreadsheet. An additional software programme was written to display APAS force output and calculate impulses.

When a subject arrived in the laboratory, the test procedures were re-explained and reflective markers were attached at the toe, ball, heel, ankle, knee, hip, and shoulder locations. While only the toe marker was used for this study, the other marker data were collected as part of a standard data collection procedure. After all the markers were attached, the subjects walked at a natural cadence along a 10 metre walkway until they felt comfortable in the laboratory and consistently stepped on the force platform.

For the first 3 subjects, data were collected from the amputated side. The subject walked in the same direction for all 12 trials. For the other 10 subjects, data were collected from both sides of the body. In these cases, the subjects walked back and forth along the walkway while data were collected on the side that was closest to the video camera. Twelve (12) trials were collected for each side of the body (total of 24 trials per session). For each trial, 2 seconds of ground reaction force data were sampled at 200Hz.

Following each data collection session, the force data were digitally filtered at 12Hz (dual pass 4th Order Butterworth filter) and transferred to the data processing computer. The APAS system was used to capture a digital video clip of each trial and digitise the 2D marker positions. After the data had been transformed, most marker data were digitally filtered at 10Hz. In a few instances, 6 or 8Hz filter settings were required to smooth the data. The APAS graphing utility was used to obtain stride length, stride time, and walking speed by subtracting toe marker positions and times at successive toe-off events. Stance time was calculated from the ground reaction force data.

Force post-processing involved importing a subject's filtered data into Quattro Pro so that all 12 trials could be averaged. Each trial was normalised to 100% of stance using linear interpolation. The average and standard deviations were calculated at 1% intervals. Peak forces for each trial were calculated from the filtered data (i.e. data not normalised and not averaged). These peaks included the maximum mediolateral force (Fx), the maximum value of the decelerating force (Fy-brake), the maximum push-off force (Fy-push), and the maximum vertical forces (Fz-brake, Fz-push). Impulse values for Fx, Fy-brake, Fy-push, Fz-brake, and Fz-push were calculated using a separate Microsoft Windows programme and then copied into Quattro Pro for statistical analysis. The force and impulse ratio measures were calculated by dividing the braking value by the push-off value.

Data analysis

All questionnaire data were analysed using descriptive statistics. Below average client satisfaction with the CAD/CAM sockets, as compared to a satisfactory response with the conventional sockets, would contra-indicate continued use of the new modification pattern.

Force and impulse values obtained from the gait analyses were compared between sockets using a paired t-test ($p<0.05$). The average ground reaction force curves were also compared using Pearson product moment correlation coefficients and root mean square error (RMSE) statistics. Since ground reaction forces are sensitive to increases in walking speed, the walking speed data were analysed to ensure that any differences were not due to a faster gait.

If no differences were found between gait results for the 2 fabrication methods, or if the results for the CAD/CAM produced leg were clinically different but closer to gait results for normals, the CAD/CAM template generation procedure was considered appropriate for clinical use.

Results

Pre-test

While each subject's socket required specific modifications, some common changes were required for all 4 pre-test subjects. To accommodate individual variations in anatomical structure, modification locations were change for each subject. For the same reason, apex point positions were changed for some modifications. The size of certain modifications also had to be changed due to Shapemaker's inability to adequately scale the template for long or short shapes. Creation of a

"long socket" modification outline, while maintaining the same modification shapes, alleviated some of these template application problems. The medial tibial flare modification was split into 2 sections to create an appropriate medial tibial flare relief when applying a Shapemaker template. The revised modification template was considered appropriate for clinical use and full validation testing.

Validation

Questionnaire results

A subject questionnaire was used to obtain each subject's perspective on comfort and function for the manual and CAD/CAM prostheses (Fig. 2). Wilcoxen signed ranks test results showed no significant differences ($p<0.05$) between the 2 prostheses based on comfort, ability to walk, and overall satisfaction. McNemar test statistics also showed no significant between-group differences ($p<0.05$) on the basis of pain and perceived safety during prosthetic use. These results supported the premise that the new CAD/CAM design technique can produce a socket that the client considers as good as a manually produced socket.

The prosthetist questionnaire results also supported the premise that the CAD/CAM technique could produce a socket of equal quality as a manually produced socket (Fig. 3). No significant differences ($p<0.05$) were found between the 2 groups for walking gait and socket fit (Wilcoxen signed ranks test at $p<0.05$).

The prosthetist graded CAD/CAM socket fit as superior in 4 cases and manual socket fit as superior in one case. These results compared well with the results from the subject questionnaire; however, the prosthetist and subject differed in opinion in 2 instances. In both these cases, the subject liked the manual socket better but the prosthetist rated both sockets the same. One (1) case that differed was for a long term prosthetic user who did not like a hard socket. For the other case, the subject experienced some medial patellar discomfort when using the CAD/CAM prosthesis. This discomfort was resolved after the second gait analysis session by using a heat gun to modify the socket.

Individual results

Examination of individual subject data showed that, in 4 cases, the CAD/CAM prosthesis was considered superior to the manual prosthesis. In each case, the ratings were only 1 level higher. Three (3) other subjects considered their manual prosthesis superior. These subjects

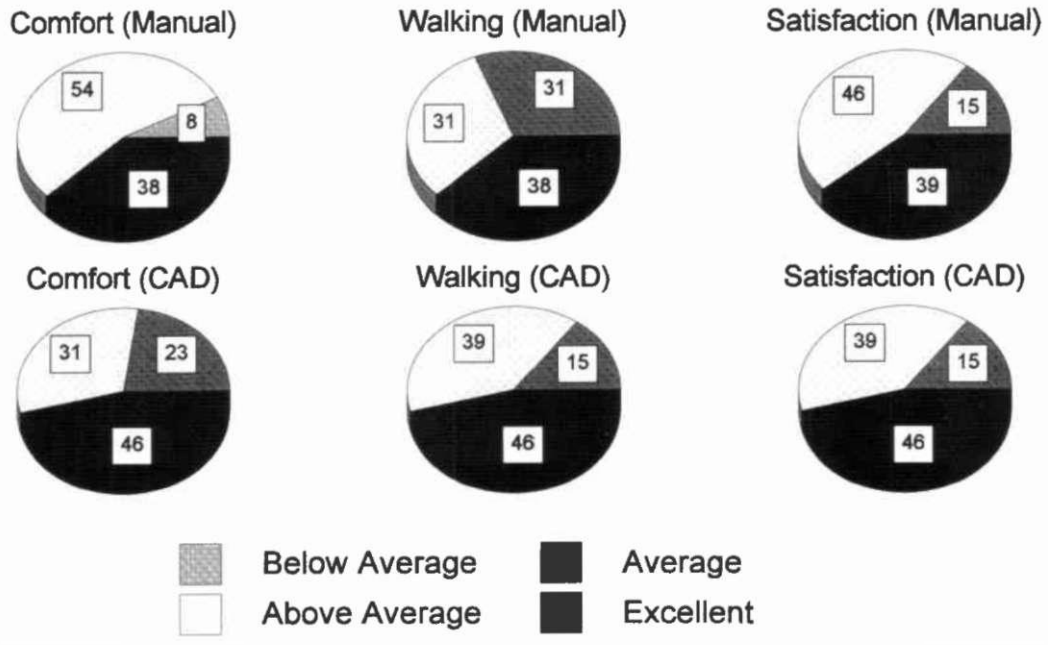


Fig 2. Subject questionnaire results for comfort, walking and satisfaction (percent of responses).

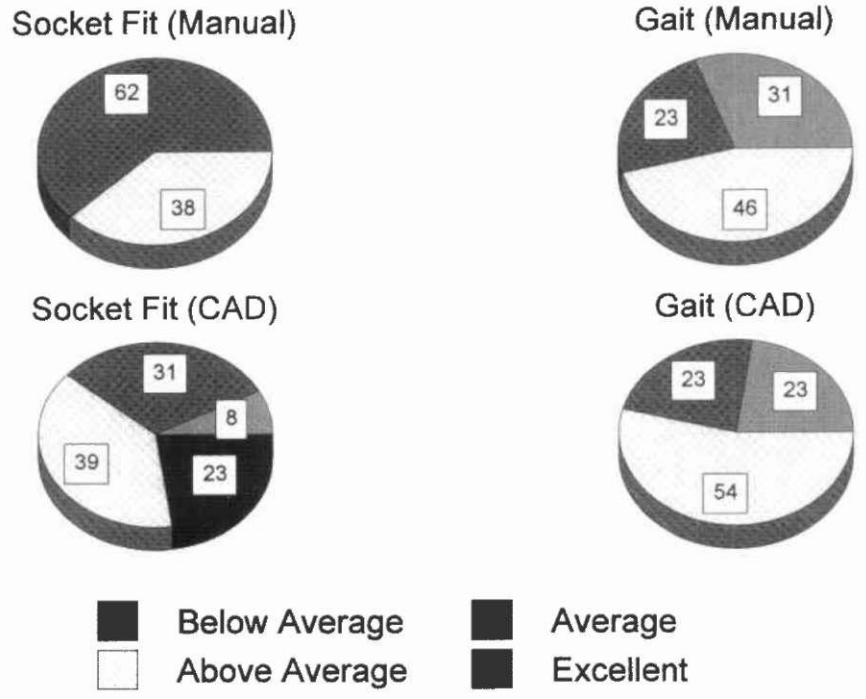


Fig 3. Prosthetist questionnaire results (percent of responses).

were long-term prosthetic users who were very satisfied with their current prosthesis. Two (2) of these subjects experienced some discomfort in the fibular head and medial patellar regions when ambulating with their CAD/CAM prosthesis. All of the CAD/CAM sockets were considered safe to use; however, 1 subject did not consider the original prosthesis safe. The subject was not able to explain this opinion.

On average, 1.5 (s=0.63) CAD/CAM sockets were required to produce an acceptable device. Eight (8) out of 13 sockets were acceptable on the first attempt and 1 socket required 3 attempts to obtain a satisfactory result. Three (3) attempts were necessary for the 1 successful trial (i.e. the trial when the subject and the prosthetist considered the manual socket to be superior).

To obtain a satisfactory socket, minor template modifications were required in 7 cases and major template modifications were required in 8 cases. The major modifications involved either boundary reshaping or, in 1 case, the addition of a new modification. Boundary reshaping was required to compensate for long stumps, stumps with bulbous distal ends, or a prominent distal fibular region. For 5 subjects, 38% of the cases, no heat gun modifications were required. Heat gun modifications refer to using a heat gun to warm up the thermoplastic socket so that the prosthetist can adjust the socket shape during fitting.

The main areas that required attention during fitting were the fibular head region, the supracondylar suspension region, the posterior shelf, and the distal end. For most subjects, Shapemaker did not correctly cap the socket's distal end. This problem was corrected by lengthening the socket before carving and then, after carving, manually modifying the distal end of the foam blank. Most fitting problems occurred with people who liked their manual socket better.

Gait results

Gait analysis results from the manual and CAD/CAM socket groups were very similar (Tables 1, 2 and 3). T-test analysis results showed no significant differences between groups ($p<0.05$) in all cases except peak vertical forces on the amputated side. Data from both groups were significantly correlated ($p<0.05$) for all measures. When examined as a percentage of the data ranges from the manual socket trials, the average differences between the manual and

Table 1. Summary of stride parameter analysis for the amputated side. Standard deviations are in parentheses

		Mean	Correlation	Significance
Speed (m/s)	CAD	1.15 (0.23)	0.87	0.965
	Manual	1.15 (0.21)		
Stride length (m)	CAD	1.42 (0.19)	0.87	0.615
	Manual	1.41 (0.17)		
Stride time (s)	CAD	1.25 (0.14)	0.9	0.371
	Manual	1.24 (0.13)		
Stance time (s)	CAD	0.88 (0.10)	0.868	0.193
	Manual	0.85 (0.09)		

Table 2. Summary of force analysis for the amputated side (in N). Standard deviations are in parentheses. Force directions x, y and z are respectively in the following directions, M/L, A/P and vertical

		Mean	Correlation	Significance
Force (x)	CAD	47.89 (11.63)	0.901	0.45
	Manual	49.69 (17.06)		
Force (y-brake)	CAD	93.31 (27.23)	0.824	0.499
	Manual	96.46 (27.66)		
Force (y-push)	CAD	91.94 (41.34)	0.92	0.227
	Manual	97.67 (36.68)		
Force (y-ratio)	CAD	1.02 (0.41)	0.662	0.917
	Manual	1.03 (0.29)		
Force (z-brake)	CAD	840.02 (138.83)	0.985	0.001
	Manual	869.15 (131.51)		
Force (z-push)	CAD	785.90 (121.63)	0.991	0.024
	Manual	797.68 (117.49)		

Table 3. Summary of impulse analysis for the amputated side (in N.s). Standard deviations are in parentheses. Force directions x,y and z are respectively in the following directions, M/L, A/P and vertical

		Mean	Correlation	Significance
Impulse (x)	CAD	21.77 (6.08)	0.829	0.698
	Manual	21.26 (8.18)		
Impulse (y-brake)	CAD	19.51 (6.09)	0.937	0.106
	Manual	20.61 (6.48)		
Impulse (y-push)	CAD	16.97 (7.52)	0.847	0.988
	Manual	16.96 (6.72)		
Impulse (y-ratio)	CAD	1.29 (0.65)	0.452	0.797
	Manual	1.25 (0.33)		
Impulse (z)	CAD	465.53 (78.44)	0.933	0.69
	Manual	462.12 (83.88)		

CAD/CAM groups were less than 6.5%. The majority of measures had a difference of less than 4.0%. No significant differences ($p<0.05$) were found for any measures from the non-amputated limb. All measures on the non-amputated side were significantly correlated ($p<0.05$).

Since all but 1 Pearson correlation coefficients were greater than 0.93, it can be concluded that the CAD/CAM prostheses did not affect the force/time curve shapes. For most subjects, the RMSE values were low. This suggested that the CAD/CAM prosthesis did not affect the force/time curve magnitudes. All cases with a RMSE over 5% were from subjects with the most variable gait. The Fx force component was

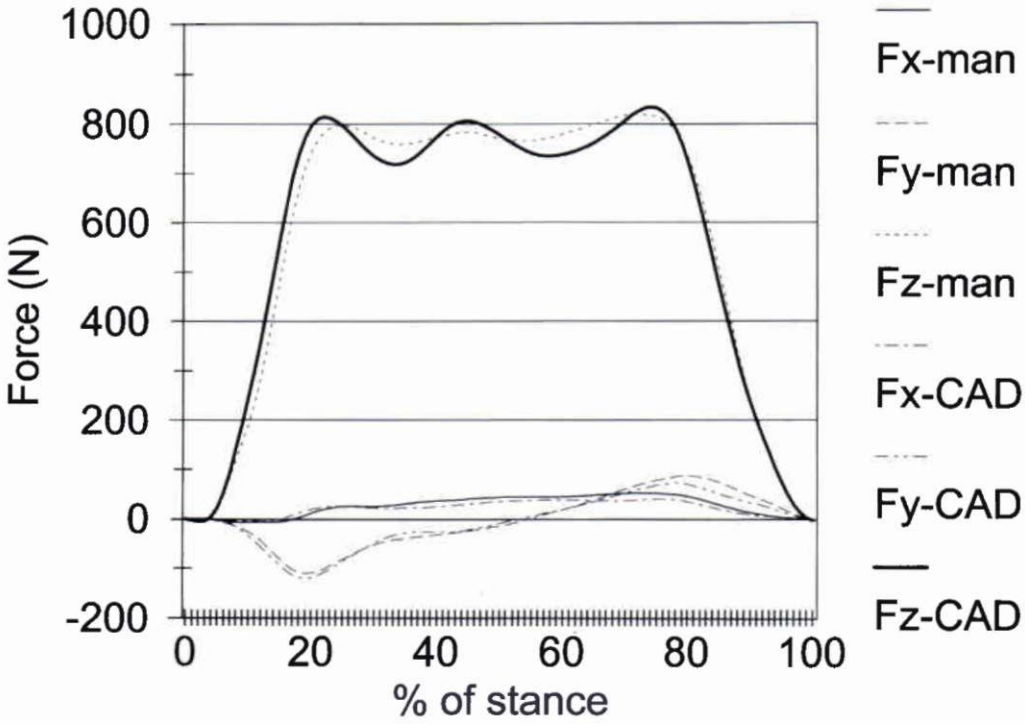


Fig 4. Ground to prosthetic foot force data from the manual and CAD sockets – representative trial with three vertical force peaks.

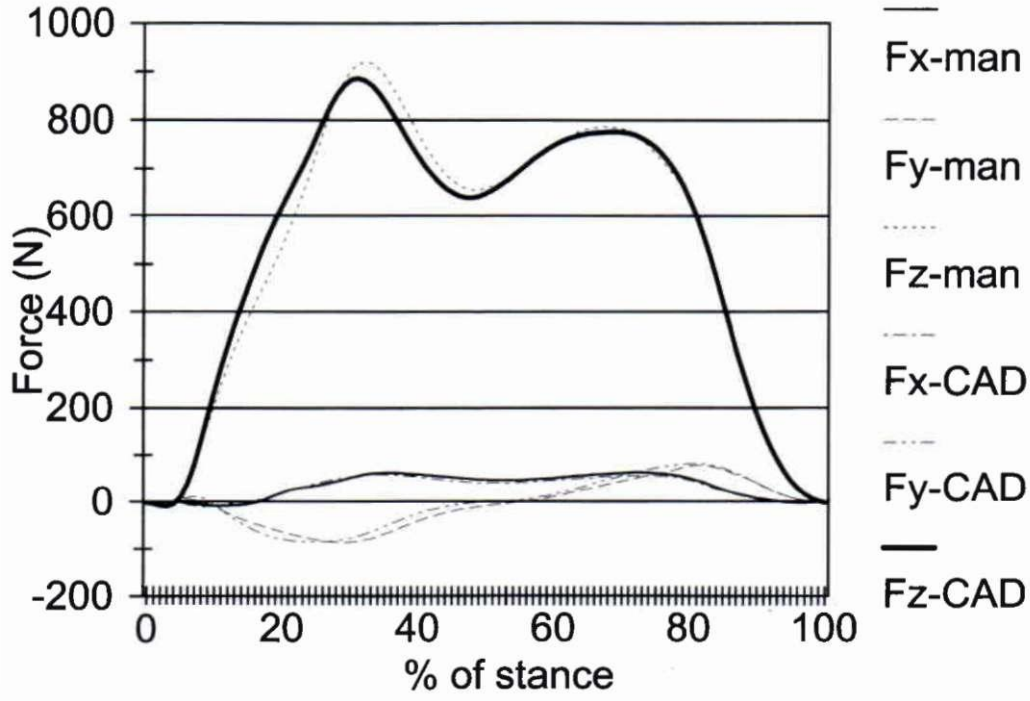


Fig 5. Force data from the manual and CAD sockets – representative trial showing higher peak force.

the most variable within-subject measure and had the largest relative RMSE values.

Discussion

The reliance on hand-sculpting techniques in the field of prosthetics has contributed to the development of prosthetist specific methods for socket design. Since the optimal method for designing a functional and comfortable socket has yet to be discovered, the patient must rely on an individual prosthetist's clinical judgement to design and fit a TT prosthesis.

Though a prosthetist can modify a socket successfully, many are unable to define exactly what was done to the positive model. During modification, the original shape is lost as material is added and removed. Because modifications are made over the entire shape and not as a series of individual changes, picking out exactly how the stump shape was modified is difficult. The inability to define how individual prosthetists modify a socket can impede the transition from manual techniques to CAD/CAM. To address this issue, a Microsoft Windows software programme was written to display, analyse, and compare manual and CAD/CAM socket shapes.

CADVIEW was used to generate a CAD modification template that was specific to the prosthetist's manner of working. The variability in prosthetic modification styles made it essential that this template produced a shape that was visually acceptable to the prosthetist; otherwise, the clinician would likely reject the template. Averaging a series of modifications from 7 subjects produced an acceptable and functional design.

The averaged modifications varied in size and shape. Even with these variations, it was observed that the averaged modification shapes conformed well with theoretical modification procedures. This variability also supported the idea that 1 template is not sufficient to fit all amputees without some fine-tuning. By analysing a large database of prosthetic socket modifications, a series of templates could be developed to better accommodate the wide variety of stump contours.

Some operator experience was necessary to translate the averaged modifications into a Shapemaker, CANFIT-PLUS, or ipoCAD template because all these software packages differed in the way they applied overlays and blended outlines into the socket surface. Since Shapemaker was used for the validation portion of this study, only Shapemaker templates were produced.

It was necessary to fine-tune the Shapemaker template for different socket lengths and to blend modifications into the surface. Unfortunately, current template functions are not able to retain inter-modification relationships when accommodating various socket lengths, accommodating some socket volumes, and maintain blending between overlapping areas. Currently, these problems are corrected by the prosthetist after a template is applied.

Most of the template fine-tuning occurred during the initial pre-test trials. The pre-test trials were also beneficial for identifying areas that could be expected to differ between subjects. While examining socket modifications for the template generation subjects, it became apparent that the fibular head and tibial crest regions were more variable than other areas on the socket. The variability in fibular head position, shape, and orientation was supported by the template changes that were made during the pre-test. While the new template gave a good starting point, it was unreasonable to assume that the prosthetist would not have to change the fibular head modification in some manner to provide a proper fit.

The tibial crest modification did not require as many changes since variations in orientation and position were accommodated by the template. Since the template was linked to the proximal and distal tibial landmarks, Shapemaker skewed the tibial crest modification to correspond to the current landmark positions. While using multiple landmarks helped, Shapemaker had difficulty scaling the tibial crest modification for length.

Even though the clinician was satisfied with the system, it was unfortunate that major template modifications were required for 62% of the sockets. In all but 1 case, the major modifications only involved reshaping 1 or 2 modification boundaries. Many of the boundary changes were required to compensate for Shapemaker's inadequacies in maintaining the relationship between modifications on different limb shapes. The adjustments were done to maintain the template shape, rather than make alterations.

Some boundary reshaping was also needed to accommodate the individual's anatomy. In 1 case, the distal portion of the lateral tibial crest modification was expanded to conform to the bulbous distal end of the subject's stump. For the 3 subjects with long stumps, the medial tibial flare modification was extended posteriorly so that it overlapped the popliteal modification. This change was needed for soft tissue control. Supracondylar modification changes were required in 2 other cases to provide relief for the lateral tibial condyle.

Since the same major modifications were necessary to fit the subjects with long stumps, it may be necessary to create a long stump template to accommodate these shapes properly without making major changes to the socket modifications. A bulbous stump template may also be required; however, more subjects would have to be evaluated to determine if the template modifications were related to individual characteristics or general trends. A larger sample would also be needed to determine the long and bulbous template shapes.

It should be noted that most of the template modifications did not require major changes (a typical socket design will have 14 discrete modifications). In fact, 7 of the 8 sockets that had major modifications only required that 1 template modification be reshaped. Since the same modification was not changed in each instance, this type of reshaping may be an expected occurrence due to individual differences. Another possible explanation is that, as mentioned in the previous paragraph, a series of general templates are likely required to accommodate different stump types.

From a functional point of view, the amount of time savings that would be gained by providing a large number of different templates and individual modification shapes must be considered. Contemporary prosthetic CAD software has been designed to allow a prosthetist to complete boundary point changes very quickly (a few minutes per modification). If only 1 modification is being altered, it may be more efficient for the clinician to use 1 familiar template and customise the modifications as needed.

It was encouraging that heat gun modifications were not required in 42% of the cases. This indicated that almost half of the sockets produced with the CAD template were able to be fitted directly on the subject. Since minor socket adjustments are often required during the fitting process, this result is at least as good as the results during manual fittings.

One area that was not accommodated by the CAD/CAM system was the socket's distal end. Since the cast digitiser's tracking wheel does not reach the bottom of a cast, the distal end is mathematically closed by the CAD software. Unfortunately, the generated shape does not necessarily conform to the subject. The CAD endcap was often too flat and, as a result, produced a socket that was too short. In these cases, the prosthetist used the CAD programme to lengthen the socket before carving a positive model. He would then manually modify the distal end to produce the correct shape. This complication was not related to the template but to current, cast-based, prosthetic CAD/CAM systems. Progression to more sophisticated digitising methods should eliminate this problem.

The posterior shelf was another region that was defined by the CAD programme and caused some difficulty for the prosthetist. While the shape of this modification was usually acceptable, the posterior shelf height was occasionally difficult to set. More experience with the Shapemaker programme was required before the prosthetist could consistently set the correct shelf height.

The people who preferred their manually produced socket had specific fitting requirements. For the case where the subject and prosthetist agreed that the manual socket was superior, the client had a short stump and walked with excessive knee hyperextension. When these factors were combined with excessive soft tissue in the posterior popliteal region, it became difficult to control the tissue while maintaining the appropriate posterior shelf height. This subject also required extra work on the fibular head region. Upon discussion with this subject's regular prosthetist, it was found that months of trial and error were necessary to fit this person successfully with a prosthesis (using manual methods). This person is also very stoical and will put up with some discomfort before asking for an adjustment. Even though the CAD/CAM socket was not as good as the subject's usual device, the level of success was considered typical for this client. Although this does help to explain the results, it does not change the fact

that the socket fitting was unsuccessful.

The second subject had a trigger point distal to the fibular head that made fitting this region difficult. The subject was also very sensitive to pain. It took more than 8 modification sessions totally to relieve pain associated with his manually produced socket. This person also indicated that the hard CAD socket was too different from his old, Pelite lined, socket. To correct this, a second socket was made that incorporated a soft liner. The subject felt more comfortable with the soft liner; however, he was unable to explain why he still preferred the manual socket. It was interesting to note that this subject was the only person that did not return for adjustments after the initial fitting. This may have meant that the socket did not require adjustments or that the subject did not want to make the effort to have an optimally fitting CAD socket.

The third subject had a very bony stump (i.e. very light subcutaneous tissue). He also had a scar in the medial patellar region that camouflaged pressure problems since the skin did not discolour after wearing the prosthesis. Unfortunately, the subject did not report any medial patellar discomfort to the prosthetist until returning for post-evaluation. The prosthetist could easily have corrected this problem with a heat-gun modification. Since this discomfort was not present when ambulating with his regular prosthesis, it is understandable that the subject would assign higher ratings to his manually designed socket. There were no special stump characteristics for the people who preferred their CAD/CAM socket.

Questionnaires

Since the prosthetist and subject questionnaires produced similar results, the opinions rendered in these questionnaires can be considered valid. The results indicate that the prosthetist and the subjects considered sockets designed using the CAD/CAM technique to be at least as good as the manually designed sockets.

The questionnaire data from individual cases provided insight into the clinical realities of using a CAD modification template. Of the 13 test cases, 1 socket fitting can definitely be considered unsuccessful since both the prosthetist and client had lower ratings for the CAD/CAM socket. In 2 other cases, fitting success was not as clear. These 2 subjects preferred the manual socket over the CAD/CAM socket; however, the prosthetist considered the CAD/CAM sockets to be as good as the manually produced ones.

In 4 cases, the client considered the CAD/CAM socket superior. The prosthetist concurred on 3 of these cases – he considered the fourth case to be as good a fit as the previous socket. This consensus between the subject and the prosthetist suggests to the authors that the new CAD/CAM modification technique is capable of creating a prosthetic socket that is better than a person's current device. Although it was clear that some subjects preferred the CAD/CAM socket, the reasons for this preference were diverse.

In 1 case, the subject was experiencing some pain when walking with the old prosthesis. This pain was not present when the subject was re-tested with the new prosthesis. The resolution of this pain may have been related to the new socket or the pain may have resolved itself over the 2 week inter-test interval. For the second and third cases, the new socket required 3 to 4 ply fewer socks than the manually produced socket. The reduction in socket volume may have led to better prosthetic control during gait. A tighter socket may also have felt more comfortable since it would have had to conform to the subject's anatomy. It was difficult to identify one factor that could describe why the last subject preferred the CAD/CAM socket. Since the fitting session was extremely easy, it may be concluded that the prosthetist made the correct choices to produce an optimal socket for this patient.

Since each CAD/CAM prosthesis was compared with the subject's current prosthesis, it was not possible to blind the subject or the prosthetist as to what device was being tested. The novelty of using a new socket may also have contributed to a superior rating; however, bias against a new device may also have contributed to the inferior ratings.

Both manual and CAD/CAM methods sometimes require that more than 1 socket be fabricated before a successful fit is achieved. For this study, the average of 1.5 iterations was comparable with CAD/CAM results in the literature and falls within the expected clinical range (i.e. 1-2 sockets). It was not surprising that the subject who was not successfully fitted required 3 iterations before an acceptable socket

was designed. There were no visible trends between satisfaction with one type of prosthesis and the number of iterations that were required to obtain an acceptable result.

Gait analysis

The gait analysis results supported the hypothesis that there was no difference between the CAD/CAM socket group and the manually produced socket group. In almost all cases (Tables 1-3), there were high correlations and small between-mean differences. These results were consistent for discrete measures and for ensemble averaged curve comparisons.

The stride parameter results from this study were comparable with similar results in the literature (Torburn *et al.*, 1990; Winter and Sienko, 1988; Barth *et al.*, 1992; Robinson *et al.*, 1977). These results were also very similar when comparing the 2 groups. Since the stride length, stride time, and walking speed results were so close, between-group gait comparisons should not be substantially affected by variations in walking speed.

Between-group ground reaction force comparisons produced the only significantly different measures. On the amputated side, vertical ground reaction forces from the manual socket trials were significantly higher than vertical forces from the CAD/CAM socket trials. The average vertical peak forces were also lower on the non-amputated side; however, these results were not significant. Since the differences in vertical impulse values were small, it can be concluded that the vertical forces on weight acceptance and push-off were redistributed over each of these phases. Examination of the average force/time curves for each subject supported this idea since curves with lower peak forces compensated by having a lower slope, and hence a more equal area. Other methods for achieving similar vertical impulses included a reduced unweighting phase and a more abrupt push-off (thereby increasing the area under the force-time curve).

The medial-lateral horizontal force component was the most variable measure. This is not an uncommon finding when testing people with, or without, a lower limb amputation. Even with the high variability, each curve had the same general shape. There were no clinically identifiable between-group differences for the medial-lateral ground reaction force curves.

It was interesting to note that people who preferred the CAD/CAM socket had the largest reduction in peak vertical ground reaction forces. No such trend was apparent for the people who preferred their manually designed socket. The people who liked their CAD/CAM prosthesis also had lower Fx impulse values, higher Fy braking impulses, and larger push-off impulse values. While these results were not significant, they may help explain the success of these new prostheses. Lower Fx impulses may have indicated that there was less total body centre of gravity movement away from the midline. This could improve the subject's perception of balance. The higher braking and push-off impulse values could indicate that these subjects were making better use of their prosthesis for reducing their forward acceleration. Improved force transfer from the prosthesis to the ground should result in overall improvements in walking gait and, as a result, in improved client satisfaction.

The averaged force/time curve shapes were similar in almost all cases. Some of the differences that were observed by examining the ensemble averaged data included the following:

- CAD/CAM trials produced some Fz force/time curves that were closer to typical, non-amputee walking results. These changes usually involved improved symmetry and similar peak forces at early and late stance;
- smoother horizontal braking and push-off curves. There was no relationship between this measure and the type of socket;
- more symmetrical braking and push-off periods. There was no relationship between this measure and the type of socket;
- perturbations in the force/time curves in early stance were present for the poorer walkers in both groups. While the use of a CAD/CAM socket usually changed the shape of these curves, the new socket did not necessarily minimise these perturbations.

Even with these documented variations, the force/time curves from the CAD/CAM trials were usually within 1 standard deviation of similar data from the manual trials.

Except for the differences in peak vertical forces, there were no clinically or statistically relevant differences between gait parameters with the manual socket and CAD/CAM socket groups. This result supports the use of the modification outline generating process to

develop a clinically viable CAD/CAM template. The modification outline generating process may also help prosthetists make the transition from manual socket design to computer-aided design.

Conclusion

This document has described a process for defining manual socket modifications and, by averaging these modifications over a series of TT prosthetic sockets, generating a personal CAD/CAM template. Test results confirmed that this method produced sockets as good as sockets designed by traditional methods.

Since the CAD/CAM manufacturing process can be more efficient and more consistent than the manual modification process, this study supports the use of CAD/CAM in some clinical environments. By using CADVIEW to help define a CAD design strategy, the process of moving from traditional design methods to computer design methods should also be more efficient. The process of making a modification template that is specific to an individual prosthetist can ease the transition from hands-on socket design to computer aided methods.

Other beneficial side effects are suggested by this study. Educators could use the socket comparison feature to examine student modifications. The students could use CADVIEW to compare their socket modifications with the instructor's modifications. CADVIEW could also be used in orthotics to examine the progression of spinal deformities over time or to chart the changes in head shape when applying a head orthosis to a client with cranial plagiocephaly. Further research would be required to confirm these advantages.

This study has led to the other questions regarding prosthetic fitting. The CAD/CAM modified socket was not exactly the same shape as the subject's previous socket; however, the majority of subjects were successfully fitted using both design methods. These results suggest that there is a certain tolerance within which a prosthetist can work. This tolerance might be expected when you consider that a person with a TT amputation walks with a mechanical device fixed, or strapped to their leg. Part of the fitting process is helping the patient adapt to a socket shape. It would be advantageous to know what this tolerance is so that decisions can be made regarding CAD approaches (i.e. measurement or limb digitising) or manual modification accuracy (i.e. can the manual modification time be reduced by working within, and not beyond, the tolerance range). The CADVIEW programme could be used to document inter-clinician variations when fitting the same subject. These data would help in an investigation to document prosthetic fitting styles and to define fitting tolerances.

Since people accommodate to a prosthetic socket, it is understandable that long term prosthetic users prefer their existing socket shape. The socket comparison functions could be beneficial when a prosthetist is having a problem fitting a new socket on a subject who is only satisfied with a certain style and feel. By using CADVIEW to examine the differences between the old socket and the new socket, the prosthetist could refine the design to better accommodate the individual's previous preferences.

While looking at future applications is important, the main application of note from this project is the successful implementation of a quantitative method for defining and averaging manual prosthetic socket modifications. These results are both academically and clinically relevant.

REFERENCES

BARTH DG, SCHUMACHER L, SIENKO-THOMAS S (1992). Gait analysis and energy cost of below-knee amputees wearing 6 different prosthetic feet. *J Prosthet Orthot* **4**, 63-75.

LEMAIRE ED (1994). A CAD analysis programme for prosthetics and orthotics. *Prosthet Orthot Int.* **19,** 112-117.

LEMAIRE ED, JOHNSON F (1996). A quantitative method for comparing and evaluating manual prosthetic socket modifications. *IEEE Trans Rehabil Eng* **4,** 303-309.

PRINCE F, ALLARD P, THERRIEN RG, MCFADYEN BJ (1992). Running gait impulse asymmetries in below-knee amputees. *Prosthet Orthot Int* **16,** 19-24.

ROBINSON JL, SMIDT GL, ARORA JS (1977). Accelerographic temporal and distance gait factors in below-knee amputees. *Phys Ther* **57,** 898-904.

SELKITAR R, MIZRAHI J (1986). Some gait characteristics of below-knee amputees and their reflection on ground reaction forces. *Eng Med* **15,** 27-34.

TORBURN L, PERRY J, AYYAPPA E, SHENFIELD SL (1990). Below-knee amputee gait with dynamic elastic response prosthetic feet: a pilot study. *J Rehabil Res Dev* **27,** 369-384.

TORRES-MORENO R, LEMAIRE ED, WOOD IR, VÁZQUEZ-VELA SÁNCHEZ E, MARTEL GG, MORRISON JB, DALY CH (1995). The evolution of CAD/CAM technology in the design and manufacture of lower limb prosthetic sockets. *Revista de la Sociedad Mexicana de Medicina Fisica y Rehabilitacion* **7(4),** 85-100.

WINTER DA, SIENKO SE (1988). Biomechanics of below-knee amputee gait. *J Biomech* **21,** 361-367.

YANG L, SOLOMONIDIS SE, SPENCE WD, PAUL JP (1991). The influence of limb alignment on the gait of above-knee amputees. *J Biomech* **24,** 981-997.

Prosthetics and Orthotics International, 1999, 23, 45–49

The efficacy of physiological cost index (PCI) measurement of a subject walking with an Intelligent Prosthesis

T. CHIN, S. SAWAMURA, H. FUJITA, S. NAKAJIMA, I. OJIMA, H. OYABU, Y. NAGAKURA, H. OTSUKA and A. NAKAGAWA

Hyogo Rehabilitation Centre, Kobe, Japan.

Abstract

The Intelligent Prosthesis may enable lower limb amputees to walk faster than with conventionally damped prostheses and as a result the physical burden involved in walking could be expected to be considerably higher. The aim of this study was to investigate whether or not physiological cost index (PCI) is applicable as an indicator for monitoring the amount of exercise load involved in walking with an Intelligent Prosthesis. The method used a treadmill and monitored gas exchange, ventilation and heart rate (HR) in 6 unilateral trans-femoral amputees, ages were between 17 and 34 with an average age of 23.1. The exercise protocol was as follows: for each person speeds at 0.8 times the subject's free level walking speed, 1.0 times, 1.2 times, 1.4 times and for some 1.6 times were applied. In each case the index of correlation between PCI and oxygen uptake in response to walking speed was calculated. A significant correlation was observed between PCI and oxygen uptake in each case, which indicated a close relationship between cardiopulmonary factor and energy consumption while walking. These results suggest that PCI is of use as an indicator for ascertaining the amount of exercise load in walking with an Intelligent Prosthesis.

Introduction

The, so called, Intelligent Prosthesis is electronically controlled to dynamically regulate the degree of opening of the needle valve of a pneumatic damping cylinder at the prosthetic knee joint in response to walking speed. A microcomputer is used for swing phase control. The Intelligent Prosthesis may allow lower limb amputees to walk faster than was possible with conventionally damped prostheses (Zahedi, 1993). The authors' centre offers an additional Intelligent Prosthesis walking training programme to teach amputees the techniques of walking rapidly. In this circumstance the exercise load involved in prosthetic walking can be expected to be considerably higher than normal. Consequently the exercise load while walking with the prosthesis must be appropriately monitored to make walking training safer. In many cases in clinical situations physical therapists are responsible for training and their work would be facilitated by a simple, convenient and real-time monitoring method.

PCI is one of the cardiopulmonary factors suggested by MacGregor as an indicator of energy cost. (MacGregor, 1979; MacGregor, 1981). This indicator is the value of the heart rate (HR) at rest subtracted from the HR under load and divided by the walking speed, which is comparatively simple to measure. The research reported here aims to investigate whether or not PCI is applicable as an indicator for monitoring the amount of exercise load involved in walking with an Intelligent Prosthesis.

Subjects

The subjects were 6 unilateral trans-femoral amputees (5 male, 1 female) aged between 17 and 34 with average age of 23.1 who had been hospitalised in the authors' centre and completed the Intelligent Prosthesis walking training programme. The amputees had been well trained

All correspondence to be addressed to Dr T. Chin, Hyogo Rehabilitation Centre, 1070, Akebono-Cho, Nishi-Ku, Kobe, 651-2181, Japan.

in the use of the Intelligent Prosthesis and were skilled in its use. The fit of prosthesis was clinically reviewed by certified prosthetists. Optimum adjustment of the Intelligent knee joint for each amputee was carried out by certified physical therapists. The physical characteristics of the subjects are shown in Table 1.

Method

Firstly most comfortable walking speed for each subject using an Intelligent Prosthesis, i.e. the free level walking speed (FWS), was measured prior to testing. HR at rest was recorded after the subject had been seated for 15 minutes. Laboratory environmental conditions were controlled at a temperature between 20°C and 23°C, and relative humidity at 60%. Informed written consent was obtained before entry into the study. In this research a treadmill was used. The exercise protocol was as follows: for each subject after 5 minutes of warm-up at 0.8 times the subject's FWS, the speed was increased continuously in steps every 5 minutes by 0.2 times the subject's FWS until the maximum speed was achieved. The treadmill was held level for the duration of testing. During exercise the respiratory gas was monitored with a respiromonitor (Minato RM-300 system, Osaka, Japan) on a breath by breath basis. At the same time the ECG and HR were monitored during exercise by Stress Test System (ML-5000, Fukuda Denshi, Tokyo, Japan), and cuff blood pressure was determined every minute with an autoelectrocardiometer (Colin STPB-780, Japan). Treadmill walking is used in the Intelligent Prosthesis walking training and it was judged that the subjects were skilled in its use. Consequently the measurements were taken only once. To guard against falling during measurement the subjects were allowed to lightly grip a support bar in both hands, but they were directed not to grip strongly (Fig. 1). The parameters during the last 2 minutes of the 5 minutes of each exercise stage were averaged. PCI was calculated as (HR while walking – HR at rest) / walking speed. The Pearson Product-Moment technique was used in all correlation analysis. Differences were considered significant at $p<0.05$.

Table 1. Physical characteristics of the subjects

Case no.	1	2	3	4	5	6
Sex	F	M	M	M	M	M
Age (yr)	19	23	20	26	34	17
Mass (kg)	47.8	66.0	57.0	64.0	70.0	58.5
Height (cm)	168	175	172	176	170	176
Amputation cause	T	T	T	T	T	T
Ambulatory aid	no	no	no	no	no	no
FWS (km/hr)	4.0	4.5	4.0	3.5	3.0	4.0

FWS: free level walking speed T: trauma

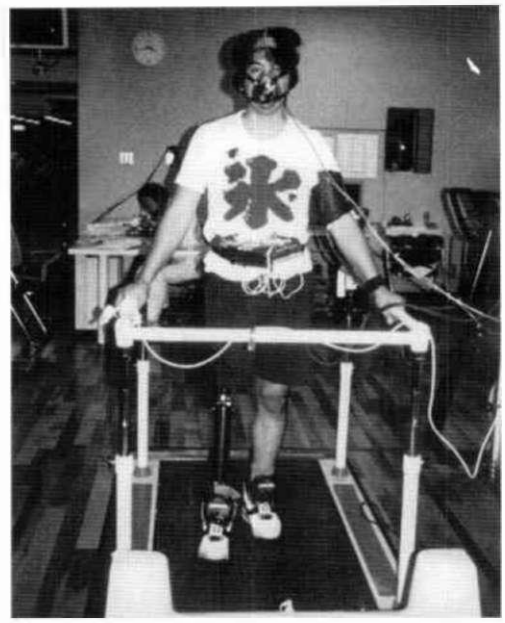


Fig. 1. Experimental subject undergoing respiratory gas analysis. Subject is instructed to hold the support bar lightly with both hands to avoid the danger of falling during measurement.

Results

The relationship between walking speed and oxygen uptake

In all cases oxygen uptake increased with increasing walking speed (Fig.2).

The relationship between walking speed and PCI

With the exception of case 5 PCI increased with increasing walking speed in each case. In case 5 PCI fell slightly at FWS and 1.2 times that speed, but there was a rising trend at 1.4 times and 1.6 times (Fig.3).

The relationship between PCI and oxygen uptake

In each case the index of correlation between PCI and oxygen uptake in response to walking

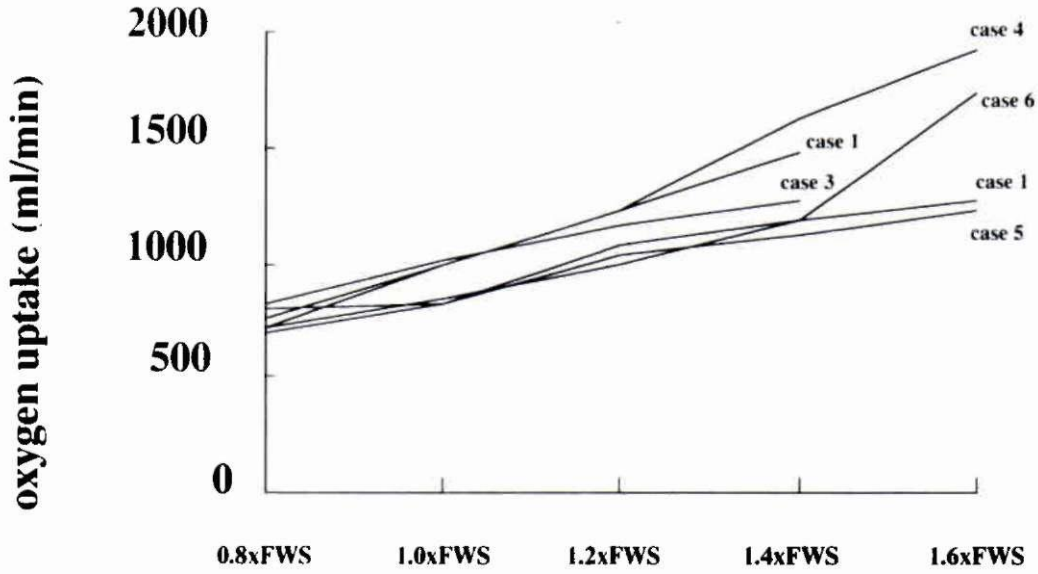


Fig. 2. The relationship between walking speed and oxygen uptake for each case.

speed was calculated. A significant correlation was observed between PCI and oxygen uptake in each case. In case 1 the correlation coefficient for the relationship between PCI and oxygen uptake was 0.926, indicating a significant correlation between the two ($p<0.05$). In case 2 the correlation coefficient was 0.972 ($p<0.001$). In case 3 the correlation coefficient was 0.751 ($p<0.001$). In case 4 the correlation coefficient was 0.997 ($p<0.01$). In case 5 the correlation coefficient was 0.907 ($p<0.05$). In case 6 the correlation coefficient was 0.903 ($p<0.05$). Figure 4 shows an example of the correlation for case 4.

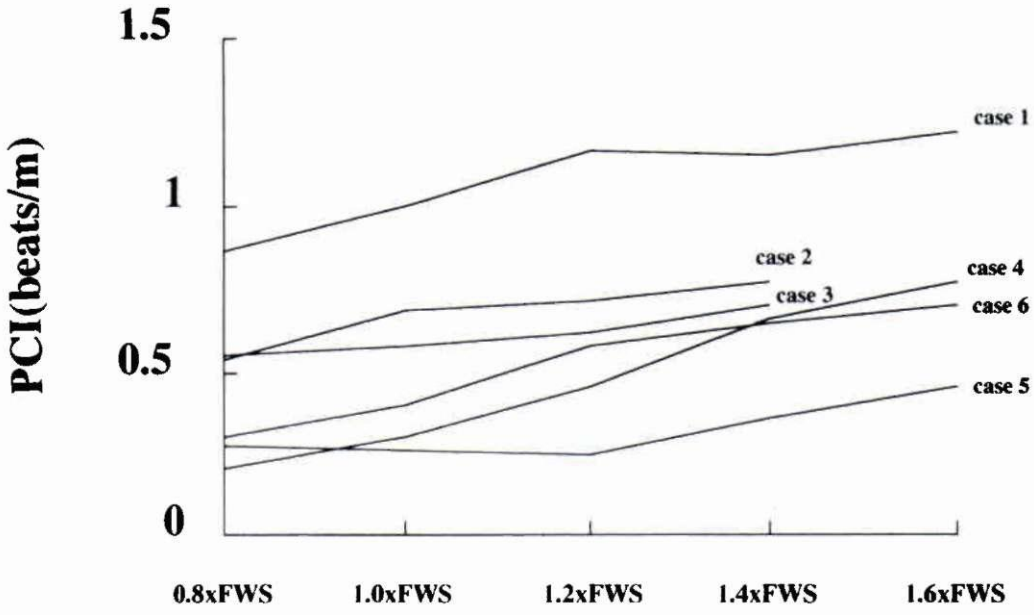


Fig. 3. The relationship between walking speed and PCI for each case.

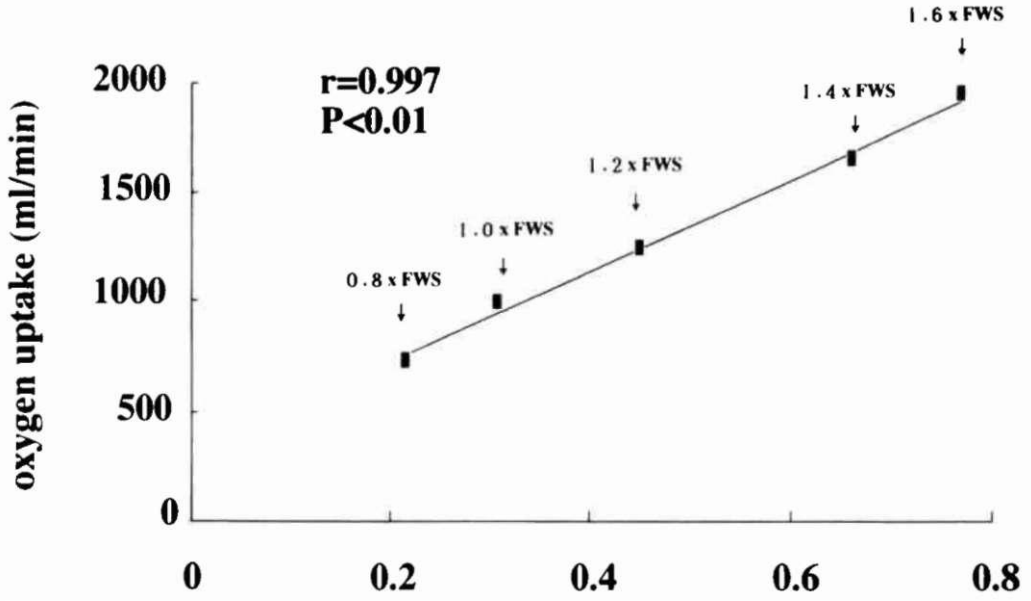


Fig. 4. Single correlation chart for case 4. Examination of relationship between PCI and oxygen uptake in response to walking speed gives a significant correlation between the two ($r=0.997$, $p<0.01$).

Discussion

The aim of the study was to investigate whether or not PCI is applicable as an indicator for monitoring the amount of exercise load involved in walking with an Intelligent Prosthesis. PCI is one of the cardiopulmonary factors, which combine the elements of HR and walking speed, suggested by MacGregor (MacGregor, 1979; MacGregor, 1981). Steven *et al.* (1983) have reported that PCI is effective in judging the efficacy of medication on patients with rheumatoid arthritis. Butler *et al.* (1984) demonstrated that in a comparison of PCI between children with impaired walking and children with normal walking, the PCI is a useful indicator for the diagnosis of walking. Nene and Jennings (1992) measured the PCI of patients with spinal cord injury walking with the aid of the ORLAU ParaWalker and found it useful in comparison with other movement measurement methods. In Japan, Wada *et al.* (1993) have observed a significant correlation between PCI and walking energy consumption in patients suffering from osteoarthritis of the coxa. Thus PCI is known as an indicator for evaluation of walking efficiency.

It is well known that for lower limb amputees, particularly trans-femoral amputees, the energy consumption required for walking with a prosthesis is high (Gonzalez *et al.*, 1974; Waters *et al.*, 1976). The characteristics of an Intelligent Prosthesis may allow a higher walking speed than with conventionally damped prostheses (Zahedi, 1993). In this circumstance the energy consumed in walking would be higher and the burden on the cardiopulmonary function greater. It is therefore important to ascertain accurately the exercise load involved in walking with an Intelligent Prosthesis to provide safety in its use. The best means of accurately ascertaining the exercise load is to directly measure oxygen uptake. However, it is not easy to measure this directly due to the complexity and awkwardness of the equipment and measurement technique. Furthermore, it is not possible to make direct measurement during prosthetic walking training in the ordinary place of rehabilitation. Therefore in place of oxygen uptake a simple objective indicator which will allow the estimation of exercise load is required.

In this research the energy consumption of walking with an intelligent prosthesis was measured by oxygen uptake at a wide range of walking speeds and the relationship with PCI was investigated. In each case it was observed that an increase in walking speed was accompanied by a tendency toward increased PCI and oxygen uptake. Furthermore, in each

case there was a significant correlation between PCI and oxygen uptake as they varied with walking speed, which indicates a close relationship between cardiopulmonary factor and energy consumption factor while walking. PCI can be measured easily in a clinical environment while it makes it potentially useful as an indicator for ascertaining the amount of exercise load involved in walking with an Intelligent Prosthesis and monitoring the cardiopulmonary function under exercise load.

Conclusion

The applicability of PCI measurement as an indicator for monitoring the amount of exercise load involved in walking with an Intelligent Prosthesis has been established. This study indicated the feasibility of the clinical application of PCI in Intelligent Prosthesis walking training for amputees.

REFERENCES

BUTLER P, ENGELBRECHT M, MAJOR RE, TAIT JH, STALLARD J, PATRICK JH (1984). Physiological cost index of walking for normal children and its use as an indicator of physical handicap. *Dev Med Child Neurol* **26**, 607-612.

GONZALEZ EG, CORCORAN PJ, PETERS RL (1974). Energy expenditure in below-knee amputees: correlation with stump length. *Arch Phys Med Rehabil* **55**, 111-119.

WADA I, IKEDA T, HAYASHI N, MATSUI N, HORIBA M (1993). The energy consumption and cadiac tasks during free level walking in preoperative patients with osteoarthritic hip. *Jap J Rehabil Med* **35**, 49-53.

MACGREGOR J (1979). The objective measurement of physical performance with long term ambulatory physiological surveillance equipment (LAPSE). Proceedings of 3rd International Symposium on Ambulatory Monitoring./edited by Stott FD, Raftery EB, Goulding L, London: *Academic Press* p29-39.

MACGREGOR J (1981). The evaluation of patient performance using long term ambulatory monitoring technique in the domiciliary environment. *Physiotherapy* **67**, 30-33.

NENE AV, JENNINGS SJ (1992). Physiological cost index of paraplegic locomotion using the ORLAU ParaWalker. *Paralegia* **30**, 246-252.

STEVEN MM, CAPELL HA, STURROCK RD, MACGREGOR J (1983). The physiological cost of gait (PCG): a new technique for evaluating nonsteroidal anti-inflammatory drugs in rheumatoid arthritis. *Br J Rheumatol* **22**, 141-145.

WATERS RL, PERRY J, ANTONELLI D, HISLOP HJ (1976) Energy cost of walking of amputees: influence of level of amputation. *J Bone Joint Surg* **58A**, 42-46

ZAHEDI S (1993). The results of the field trial of the endolite Intelligent Prosthesis. In: Proceedings of the XII International Congress of INTERBOR, September, 1993.

Prosthetics and Orthotics International, 1999, 23, 50–54

Bilateral lower limb amputations as a result of landmine injuries

A. S. ATESALP, K. ERLER, E. GÜR, E. KÖSEĞLU, V. KIRDEMİR and B. DEMİRALP

Department of Orthopaedics and Traumatology, Gülhane Military Medical Academy, Ankara, Turkey

Abstract

Landmine explosions cause most of the war injuries in the battlefield. Amputations resulting from severe injuries reveal serious problems despite the improvements in surgery. Bilateral lower limb amputations have more impact than unilateral on social life.

Some 29 cases with lower limb amputations due to landmine injuries were treated in the Department of Orthopaedics and Traumatology, Gülhane Military Medical Academy between January 1992 and December 1996. Amputation levels were as follows: 1 case had hip disarticulation and a trans-femoral amputation, 6 had bilateral trans-femoral amputations, 6 had trans-femoral and trans-tibial amputations, 12 had bilateral trans-tibial amputations, 1 had trans-femoral and Chopart amputations and the remaining 3 cases had trans-tibial and Chopart amputations.

The initial treatment was done for all cases in the first 6-8 hours after injury at the field hospitals. Aggressive debridement, excision and primary closure were performed. None of the stumps required reamputations and/or revision. No case had gas gangrene or tetanus.

Postoperative, pre-prosthetic training programme which ranged between 30-120 days with an average 48 days; and prosthesis fitting and adequate post-prosthetic training programme which ranged 32-126 (average 94) days was applied. All the cases were followed-up with a mean of 38.5 months (14-72 months). Nine (9) cases (31%) returned to their previous occupation, while 20 (69%) cases had to change their jobs.

All correspondence to be addressed to A. S. Atesalp. Department of Orthopaedics and Traumatology, Gülhane Military Medical Academy, 06018, Etlik, Ankara, Turkey.

Introduction

The trade of weapons and explosive materials is a huge market where much investment is made. Since there are conflicts in different parts of the world, money and time is spent in treating the complications of resulting injuries, instead of on human welfare.

Surgeons have learned new treatment techniques and would care on the battlefield (King and Rne, 1969; Coupland and Howell, 1988). Landmines cause most war traumas. They are often used since they are explosive, easily installed and effective in discouraging personnel on the battlefield (Baise and Baumgartner, 1990). Amputation for war wounds is difficult and different (Coupland and Korver, 1991). Failure to appreciate the disparities between amputation in war surgery and civilian practice result in unhealed stumps, bone exposure and serial proximal amputations.

Lower limb traumatic amputations and/or severe limb injuries result from landmines. Therefore, the treatment and rehabilitation of cases with bilateral lower limb amputations is important in social life.

Material and methods

A total of 29 male patients with bilateral lower limb amputations due to landmine injuries were treated and followed up at the department of Orthopaedics and Traumatology, Gülhane Military Medical Academy between January 1992 and December 1996.

Age average was 22.4 (21-23.5) years old.

Patients were divided into 6 groups in terms of amputation level and are presented in Table 1.

First aid and prophylaxis for tetanus were applied in all cases with evaluation at the field hospitals of Mangled Extremity Severity Score (MESS) (Robertson, 1991) within the first 6-8 hours following the injury. Appropriate

Table 1. Amputation levels of the cases.

Group number	Amputation level	Case number
1	Trans-tibial and Chopart	3
2	Trans-tibial and trans-tibial	12
3	Trans-femoral and Chopart	1
4	Trans-femoral and trans-tibial	6
5	Trans-femoral and trans-femoral	6
6	Hip disarticulation and trans-femoral	1
Total		29

amputation level was determined after aggressive excision and debridement of the contaminated, contused and dead tissues under tourniquet control; then the wound was closed with primary myoplasty technique. Antibiotics were given for 5 and 7 days. (Crystallized Penicillin $5x4.10^6$ IU, iv. + Aminoglycoside 80mg 2x1im).

One (1) case with bilateral trans-femoral amputation had a perineal wound, one (1) with bilateral trans-femoral amputation had upper limb trans-humeral amputation, one (1) with bilateral trans-tibial amputation had tibia diaphysis fracture which was treated with internal fixation at the same time as the amputation. All cases were referred to physiotherapeutic training immediately and transported from the field hospital to the authors' hospital between 2 and 8 (average 3.4) days after operation.

An intense training programme including postoperative and pre-prosthetic exercises, was initiated for all cases. This programme comprised contraction prevention and strengthening. Bandaging and pain treatment were also used.

Prosthetic fitting was applied between 30 and 120 (average 48) days. Three (3) Group-1 amputees were provided with PTB (patellar-tendon-bearing) prostheses and Chopart prosthesis. Group-2 amputees had PTB prostheses. One (1) Group-3 amputee was provided with a suction socket prosthesis with free knee motion and a Chopart prosthesis. All of Group-4 amputees had a suction socket prosthesis with free knee motion and a PTB prosthesis. A suction socket prosthesis with free knee motion and the same socket type prosthesis with knee lock were applied to Group-5 amputees. One (1) Group-6 amputee was provided with a total contact socket hip disarticulation prosthesis with knee lock and a suction socket prosthesis with free knee motion.

After prosthetic fitting, a training programme

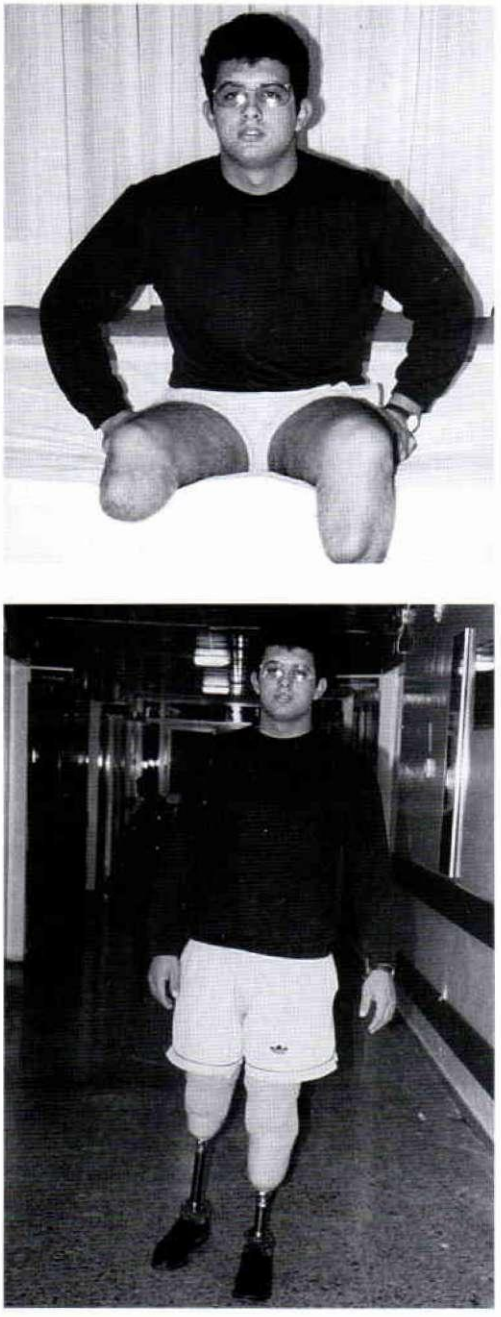


Fig. 1. Above: the appearance of the patient with bilateral trans-tibial amputation before prosthetic fitting. Below: same patient after prosthetic fitting and training.

including standing, balance training and walking training were also initiated. Post-prosthesis training period was 32-126 (average 94) days.

Samples from the cases are presented in Figures 1 and 2.

The average follow-up period was 38.5 (14-72) months.

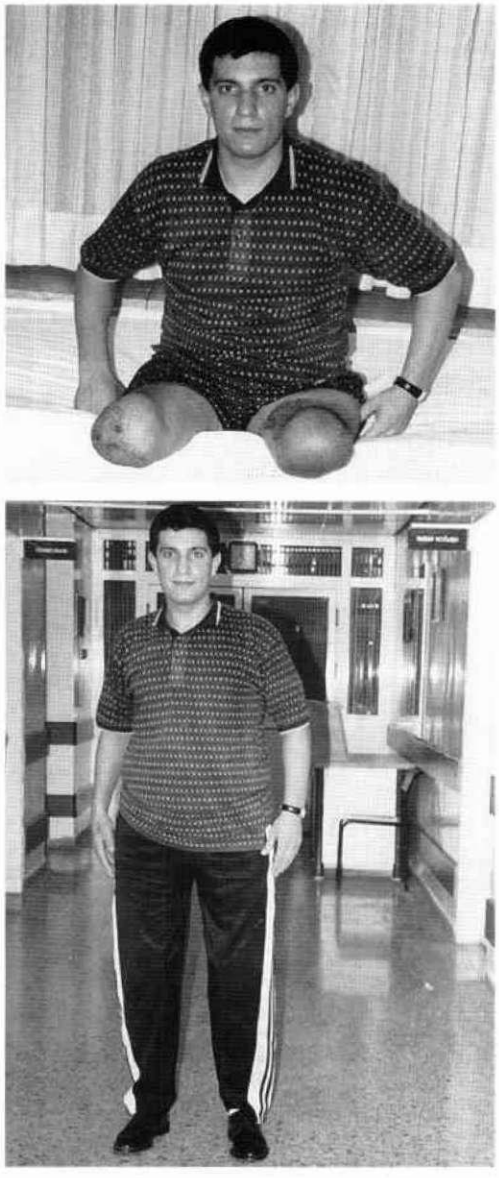


Fig. 2. Above: the appearance of the patient with bilateral trans-femoral amputation before prosthetic fitting. Below: same patient after prosthetic fitting and training.

Results

No early complication such as bleeding and/or infection was encountered in any case. One (1) case with trans-femoral and trans-tibial amputation had skin necrosis on the stump and was treated with skin graft. Six (6) cases had phantom pain.

No case had neuroma, protrusion, or limitation in range of motion or joint contracture.

Revision or reamputations were not performed in any case.

All of the patients used their prosthesis every day. Group-1,2,3,4 amputees were able to put on their prosthesis by themselves. As for the Group-5 amputees, 4 managed to put on their prosthesis without any assistance, while 2 required assistance from others. The Group-6 amputee also required assistance from others.

For determination of the outcome in relation to the objective for amputees supplied with prosthesis various definitions were established: bad result, fair result, and good result (Christensen *et al.*, 1995) as outlined in Table 2

The result of the evaluation of the functional level of the patients is stated in Table 3.

Group-1,2,3 amputees were able to walk without any aid. Group-4,5 amputees used 1 or 2 canes. The Group-6 amputee used 2 canes.

All the patients thought that the training period was adequate. As to the quality of the

Table 2. Definition of bad, fair and good result.

Bad	Fair	Good
-does not use prosthesis	-indoor walking	-does not use wheelchair
-uses prosthesis for cosmetic purposes	-mainly indoor walking but also slight outdoor walking	-goes for walks
-uses prosthesis for transfer	-walking on stairs	-leads an active, outgoing life

Table 3. Functional level – result.

Group number	Result		
	Good	Fair	Bad
1	3	-	-
2	8	4	-
3	1	-	-
4	3	3	-
5	2	4	-
6	-	1	-

training 20 patients thought it was good. Nine (9) patients found that it was acceptable.

At follow-up it emerged that 9 cases (31%) returned to their previous occupation while 20 cases (69%) had to change their jobs.

Discussion

For amputation surgery, the preservation of the joints during the urgent intervention is of the utmost importance for rehabilitation and prosthetic fitting (Atesalp *et al.*, 1995). The amputation level should be determined according to the extent of the wound (Bowen and Bellamy, 1988). Reamputation will be inevitable when the surgeon tries for too low a level where there is an infection risk (Coupland, 1989).

Amputation in war surgery must eliminate all dead, contaminated and contused tissue. The stump should be covered with enough soft tissue using the myoplasty technique. In trans-tibial amputation medial gastrocnemius myoplasty technique should be preferred (Coupland, 1989).

Most authors recommend delayed primary closure of the wound in order to prevent infection. (Trong, 1972; Bowen and Bellamy, 1988; Coupland, 1989; Simpler, 1993). In case of early wound closure, there is a high risk of anterolateral compartment syndrome in lower limb amputations (Coupland, 1989).

In open amputation, muscle edema and/or proximal skin retraction within 4-5 days may cause problems for delayed primary wound closure, and even may result in reamputation. (Baise and Baumgartner, 1990).

In the authors' clinical experience, the wound may be closed primarily following aggressive excision and debridement within the first 6-8 hours in the treatment of traumatic limb amputations as a result of landmine injuries. The wound should be left open for 3-7 days after excision, and debridement; then delayed primary closure should be applied if the patient is transported more than 8 hours after the primary impact.

Two hundred and ninety-eight (298) (78.2%) patients out of 381 with lower limb amputation transported to the authors' department within the first 6-8 hours between 1989 and 1994 were treated by primary closure and 83 (21.8%) patients who arrived more than 8 hours after injury had delayed primary closure. Only 24 cases (8%) out of 298 with primary closure had superficial infection, which was treated in a short period by daily wound care, dressing, and antibiotic therapy. None of them had severe stump infection, toxemia septicemia and gas gangrene. Some 7 cases (8.4%) out of 83 with delayed primary closure had muscle edema and skin retraction and required reamputation. These patients are usually distressed in the expectation of a new operation (Atesalp *et al.*, 1995).

Surgical intervention should be gentle since the disability ratio is 80% in cases with bilateral lower limb amputation. In addition to the orthopaedic surgeon, plastic and microsurgery specialists should be in the operating team.

The bilateral amputee has specific problems during the rehabilitation process. Not only does the patient have to train with two prostheses but also the increased energy requirement needs special attention (Rommers *et al.*, 1996). Improving technique in fitting, improved availability of sizes and types of sockets and appropriate patient selection should decrease failure or rejection rate (Kerstein *et al.*, 1975).

It is recommended that the bilateral amputee should be trained and encouraged in self-strengthening exercises for the muscles of the amputated limb. Stronger muscles will improve standing balance and quality of gait, especially among those with a short stump (Kerstein *et al.*, 1975). Training of the bilateral amputee consists of 4 periods: preoperative, postoperative, pre-prosthetic and post-prosthetic periods (Millstein *et al.*, 1985; Thornhill *et al.*, 1986).

Preoperative period; since all the amputations were unplanned and resulted from landmine injuries a preoperative rehabilitation programme could not be initiated. Postoperative period; appropriate position of the stump should be maintained. For trans-femoral amputees flexion, abduction, and external rotation and for trans-tibial amputees a flexion position should be avoided. The programme should include upper limb muscle strengthening, breathing exercises, paravertebral and abdominal muscle exercises. Active exercises for stump muscles for contraction prevention and strengthening is also necessary. No contractures were observed in this series.

Pre-prosthetic period; in addition to the postoperative exercises, bandage application in order to relieve edema and give a suitable position to the stump is necessary. Post-prosthetic period; includes muscle

strengthening, standing, balance and walking training.

Suitable prosthetic fitting and training including the rehabilitation periods described above may provide free walking without aids in young bilateral amputees as resulted in this study group.

Conclusion

Intense physical therapy at the postoperative and pre-prosthetic periods, proper prosthetic fitting with postoperative training programme offers the young traumatic bilateral amputee patients mobility and often the possibility to return to their previous occupation as soon as possible.

REFERENCES

ATESALP AS, AYDOGAN NH, KIRDEMIR V, BASBOZKURT M, GÜR E, KÖMÜRCÜ M (1995). Lower limb amputations in war surgery. *Turkish J Bone Joint Surg* **2**, 32-36.

BAISH M, BAUMGARTNER R (1990). Comparative study on amputation techniques proposed in a variety of military manuals, part II. *Med Corps Int* **415**, 11-17.

BOWEN TE, BELLAMY RF (1988). Emergency war surgery NATO handbook. Second United States revision. – Washington: US Department of Defense.

CHRISTENSEN B, ELLEGAARD B, BRETLER U, ØSTRUP E-L (1995). The effect of prosthetic rehabilitation in lower limb amputees. *Prosthet Orthot Int* **19**, 46-52.

COUPLAND RM (1989). Amputation for antipersonnel mine injuries of the leg: preservation of the tibial stump using a medial gastrocnemius myoplasty. *Ann R Coll Surg Engl* **71**, 405-408.

COUPLAND RM (1989). Technical aspects of war wound excision. *Br J Surg* **76**, 663-667.

COUPLAND RM, HOWELL PR (1988). An experience of war surgery and wounds presenting after 3 days at the border of Afghanistan. *Injury* **19**, 259-262.

COUPLAND RM, KORVER A (1991). Antipersonnel mine injuries: the experience of the international Committee of the Red Cross. *Br Med J* **14 December**, 1509-1512.

KERSTEIN MD, ZIMMER H, DUGDALE FE, LERNER E (1975). Rehabilitation after bilateral lower extremity amputation. *Arch Phys Med Rehabil* **56**, 309-311.

KING KF, RNE M (1969). Orthopaedic aspects of war wounds in South Vietnam. *J Bone Joint Surg* **51B**, 112-117.

MILLSTEIN S, BAIN D, HUNTER GA (1985). A review of employment patterns of industrial amputees factors influencing rehabilitation. *Prosthet Orthot Int* **9**, 69-78.

ROBERTSON PA (1991). Prediction of amputation after severe lower limb trauma. *J Bone Joint Surg* **73B**, 816-818.

ROMMERS GM, VOS LDW, GROOTHOFF JW, EISMA WH (1996). Clinical rehabilitation of the amputee: a retrospective study. *Prosthet Orthot Int* **20**, 72-78.

SIMPLER LB (1993). Below knee amputation in war surgery: A review of 111 amputations with delayed primary closure. *Trauma* **34**, 96-98.

THORNHILL HL, JONES GD, BRODZKA W, VAN BOCKSTAELE P (1986). Bilateral lower limb amputations: experience with 80 patients. *Arch Phys Med Rehabil* **67**, 159-163.

TRONG MJ (1972). Septic complications of war wounds. *JAMA* **219**, 1044-1047.

Prosthetics and Orthotics International, 1999, 23, 55–58

Save that arm: a study of problems in the remaining arm of unilateral upper limb amputees

L. E. JONES and J. H. DAVIDSON

Prince Henry Hospital, Little Bay, NSW, Australia

Abstract

A study has been made by questionnaire, personal examination and telephone interview of unilateral upper limb amputees seen at the Prince Henry Hospital, Australia between 1994 and 1997. There were 60 questionnaires posted. Replies were received from 46. Problems were noted in the remaining arm of 23 (50%). The respondents' problems not only consisted of overuse symptoms, but also of an exacerbation of pre-existing arthritis and injury due to trauma to the remaining arm during the accident. Case histories are given in 3 typical cases. Treating professionals are warned about the hazards that one arm amputations present to the remaining arm.

Introduction

The loss of one arm is followed by the transfer of that arm's function to the other arm. The increased workload for the remaining arm may, at some time in the person's life, produce minor aches and pains or the more serious conditions of impingement in the shoulder, tenosynovitis in the abductor pollicus longus tendon, epicondylitis or other overuse syndromes.

A literature survey has not revealed any published articles on arm conditions in the remaining arm of a unilateral amputee. As there have been amputees attending the Prince Henry Hospital, Australia with conditions in the remaining arm, a simple study has been performed to note the extent of these conditions. Overuse injuries of workers with both arms have had extensive worldwide coverage (Cullen and Molloy, 1994; Hales and Bernard, 1996; Novak and Mackinnon, 1997; Robert *et al.*, 1995; Von Schroeder and Bolte, 1996). Conditions such as tenosynovitis, epicondylitis, carpal tunnel syndrome, shoulder impingement and diffuse repetition overuse injuries are the syndromes precipitated. The following study illustrates how common such conditions are in unilateral upper limb amputees.

All correspondence to be addressed to Dr L. E. Jones, Heffron House, 2nd Floor, Prince Henry Hospital, Anzac Parade, Little Bay, NSW, 2036, Australia. Tel: (+61) 2 9382 5847. Fax: (+61) 2 9382 5602.

Method

All unilateral upper limb amputees, who were treated at the Prince Henry Hospital between January 1994 and January 1997, were sent a questionnaire asking if they had any problems with their remaining arm; if they used a prosthesis; and if they worked. Repeat questionnaires were sent to those who failed to reply. Where possible, those who replied and had arm problems, were given an appointment to be seen. Those, who could not be reviewed, were questioned by telephone. Where contact could not be made by telephone, their replies were classified into "unspecified arm pain".

Results

Questionnaires were sent to 60 upper limb amputees. Replies were received from 46 (76%). Of the 13 who did not reply, 1 had died and 6 were returned "addressee unknown". Of those who responded, the sex distribution was 5 females and 41 males. Amputation levels of all the respondents are shown in Table 1.

Age at amputation ranged from 6 to 71 years. The mean age was 32 years at the time of amputation. At the time the questionnaire was sent out, the ages ranged from 13 to 84 years. The mean age was 38 years. Prostheses were

Table 1. Prince Henry Hospital upper limb amputees

Amputation level	No. of respondents	No. of amputees with pain in remaining arm
Partial hand	9	1
Trans-carpal	1	1
Wrist disarticulation	4	2
Trans-radial	13	8
Trans-humeral	15	8
Shoulder disarticulation	2	1
Forequarter amputation	2	2
Total	46	23

worn by 29 (63%) of these people. Of the 26 who were working, 19 (73%) wore a prosthesis. In the unemployed, prosthetic use was more evenly divided, with 10 wearing a prosthesis and 11 not wearing a prosthesis.

Problems with the remaining arm were noted by 23 (50%) of the respondents. Amputation levels of these people are also shown in Table 1. The people who had problems with their arm, are listed in Table 2. Some people had several problems.

The time from amputation until the first onset of symptoms varied widely, as did the response to treatment. Some had symptoms and signs soon after the amputation. With others, the onset of symptoms took years. The following case reports illustrate some of the problems these patients have had.

Case report 1

Mr N. B. was 24 when he underwent a traumatic trans-humeral amputation in 1995 on his way home from work. He returned to his job as an electrician in an electricity plant, after 6 months, where he carried out his usual duties wearing a prosthesis. He had no problems with his remaining arm until just prior to Christmas 1996. At that time he had a flat car tyre on his way to an emergency at work. He had to undo stiff nuts on his car tyre with one arm. Then at work, he also had to undo some stiff nuts on bolts, following which he noted pain along the abductor pollicus longus tendons and flexor tendons of his wrist. He then found that repetitive nut and bolt work aggravated his symptoms. He presented at the Prince Henry Hospital after 1 month with classical tenosynovitis. This was treated with splinting, local physiotherapy techniques and non-steroidal anti-inflammatories. He was placed off work for three months. He then returned to part-time work on selected duties.

Table 2. Problems noted with remaining arm

Diagnosis	No.	WORKING		NOT WORKING	
			No. wearing prosthesis		No. wearing prosthesis
Epicondylitis	5	2	1	3	1
Shoulder Impingement	3	–	–	3	–
Tenosynovitis	3	3	2	–	–
Osteoarthritis	3	–	–	3	2
RSI-type symptoms	3	1	–	2	–
Carpal Tunnel Syndrome	1	1	1	–	–
Trigger finger	1	–	–	1	1
Non-specific problems	4	3	2	1	1
Arm injury from accident	3	3	3	–	–
Total	26	13	9	13	5

Plans were made to change to a voice-activated computer instead of a keyboard, but his job appeared to depend on a return to normal duties. However, by that time his tenosynovitis had resolved itself and he returned to work on normal duties. He is now undergoing part-time retraining to do Human Resource Management. The tenosynovitis does not trouble him now, but he now has symptoms and signs of epicondylitis.

Case report 2

Other people continue to suffer problems over a prolonged period. The following case report illustrates the distribution and severity of 1 patient's problems.

Mr G. W. was 40 years old when his left hand was crushed in a press in 1989. He underwent a left trans-radial amputation. He was right-hand dominant. He was fitted with a body-powered prostheses and returned to his former work as a factory foreman. He was an extremely good worker and in the next 2 years did extensive house renovations, wearing out his prostheses in the process. His medico-legal claim, except for medical costs, prosthetic costs and wages, was settled in 1992.

In 1993 he reported burning discomfort in the right first web space, forearm and shoulder. He had signs of impingement in his right shoulder which was treated with physiotherapy and steroid injections. The shoulder problems were exacerbated by the harness of his prosthesis. He also developed epicondylitis and a right carpal tunnel syndrome. He underwent a right carpal tunnel release in 1995. His prosthesis was changed to a myoelectric prosthesis in 1995. He had not wished for a myoelectric prosthesis formerly. His shoulder problems diminished for several years. When reviewed in 1998, Mr. G. W. had a further exacerbation of the supraspinatus tendonitis in his right shoulder. He had ceased using his prosthesis because of a recurrence of sensitivity in his stump of his amputated arm. The static forearm contraction required to activate the electrodes precipitated pain. He requested a further body powered prosthesis. He is now 59 and his problems with both arms threaten his employability.

Case report 3

Even if an amputee is not working, symptoms in the remaining arm may limit lifestyle as shown in the following report.

Mr K. H. underwent a traumatic short left trans-humeral amputation at the age of 17 in Syria. He was fitted with cosmetic prostheses in Germany. He studied in the US. He has not been employed since migrating to Australia 21 years after his amputation and 4 years prior to the onset of the right arm pain. This arm pain was along the right epicondyle and the thenar abductor tendon. He was noted to have epicondylitis and tenosynovitis of the abductor pollicus and longus tendon. He was advised to reduce his heavy lifting and writing. He can control his arm pain by this lifestyle adjustment, but is limited in his physical activity.

Discussion

It is surprising that no one has formally described overuse injuries in the remaining arm of upper limb amputees. The above study has noted that 50% of upper limb amputee respondents in this study had overuse problems of varying severity and type. These problems are found throughout the non-amputee population, but are not so prevalent. It was noted by Cullin and Molloy (1994) that people with tasks which require repetitive hand movement are at increased risk of carpal tunnel syndrome. It was also noted by Hales and Bernard (1996) that long-term exposure to excessive loading will result in soft tissue damage depending on duration, frequency and load. How much more repetitive work is done by the one-armed person! A prosthesis is at best a tool aiding activities. It is not suitable for the fine sensory work done by the remaining arm. We note the damage done to shoulders, elbows and wrists of the champion sports person with two arms repetitively playing tennis, cricket or golf. These are people in superb physical condition whose bodies respond to overuse with injuries similar to the amputee population.

The distribution of the injuries, shoulder impingement, epicondylitis, tenosynovitis and diffuse aching illustrate that the stress may fall on different parts of the body depending on the physical stress.

Many of this group of patients unfortunately tried to carry on life as though no injury had occurred to their physical detriment. The rehabilitation implications of this should be noted by those involved in the care of the upper limb amputee. These people should be advised that they are at significant risk of damage to their

remaining arm. They are not able to perform at the same level as formerly. This has medico-legal implications. The former manual worker may be able to continue in the same job for some years, but that person has a 50% chance of developing problems in the remaining arm.

The problems may continue with a carpal tunnel syndrome being followed with shoulder impingement so that, in the long-term, the person is no longer employable.

Counselling about the risk of overuse injuries should certainly be undertaken. This will help amputees to recognise these problems when they do occur and seek immediate medical advice. Until now there has been little research, indicating the prevalence of problems in the remaining arm and therefore, it is suspected that therapeutic staff have not been advising amputees of the potential problems. People may need to prove to themselves that they are still competent with only one arm and so do themselves further damage. It may also be that, despite counselling, amputees are aware that unless they resume their pre-injury duties they are unlikely to be employable in the short and long-term.

Once the person is symptomatic, then conservative management is most desirable. The only surgical intervention in this study was that of the carpal tunnel release in Mr. G. W. In his review of the patterns of a carpal tunnel syndrome and cumulative trauma, Dittmars (1993) notes that symptoms can usually be controlled without surgical intervention. Occupational therapy advice regarding work situations and specific interventions with employers for job modification may well be required. Vocational retraining to assist the amputee to change occupations is vital, especially for those who were previously doing manual work. Local physiotherapy techniques for inflamed tendons and shoulders, as well as medical intervention with steroid injections, have also been useful. In the long-term, the person with an overuse injury of any type in the remaining arm has to come to terms with the problem and avoid those activities which precipitate symptoms. Neither lack of employment nor presence of prosthetic use is protective of the remaining arm.

Conclusion

It is a sad fact that in half of the amputees in this study, problems of varying severity were noted in the remaining arm. The more proximal the amputation, the more likely the person is to suffer problems in the remaining arm. Prosthetic use and lack of employment are not protective of the remaining arm.

The amputee needs to pace work and leisure activities so that these problems do not occur. Therapists need to warn their patients of the hazards they face, so that problems can be avoided. The patient with a legal claim, should have this factored in to protect them. With advice, the risk of these problems may diminish.

REFERENCES

Cullen DE, Molloy CJ (1994). Occupational and carpal tunnel syndrome. *Med J Aust* **161,** 552-555.

Ditmars DM (1993). Patterns of carpal tunnel syndrome. *Hand Clin* **9**, 241-252.

Hales TR, Bernard BP (1996). Epidemiology of work-related-musculo-skeletal injuries. *Orthop Clin North Am* **27**, 697-709.

Novak GB, Mackinnon SE (1997). Repetitive use and static postures: a source of nerve compression and pain. *J Hand Ther* 151-159.

Robert EP, Brody H, Dillman JL, Groppel JL, Schultheiss JM (1995). The biomechanics of tennis elbow. *Clin Sports Med* **14**, 47-57.

Von Schroeder HP, Bolte MJ (1996). Carpal tunnel syndrome. *Hand Clin* **12**, 643-655.

Prosthetics and Orthotics International, 1999, 23, 59–62

Patient compliance and effect of orthopaedic shoes

A. B. PHILIPSEN, N. ELLITSGAARD, M. R. KROGSGAARD and S. SONNE-HOLM

Department of Orthopaedic Surgery, University Hospital in Hvidovre, Hvidovre, Denmark

Abstract

Orthopaedic shoes are individually handmade after a prescription from an orthopaedic surgeon, hence relatively expensive. Bad compliance is mentioned in the literature but not investigated. In order to evaluate patient compliance and the effect of orthopaedic shoes, 85 patients who were prescribed orthopaedic shoes at the authors' department during a 3 year period received a questionnaire concerning relief of symptoms and daily use of the shoes. The answers from 74 patients were correlated to the prescription procedure and the degree of medical follow-up.

Only 60 of 74 patients used their shoes. Some 51 patients had some benefit while 23 had no effect or even worse symptoms. Some patients even used their shoes despite no symptomatic relief. However, patients who felt they were well informed about the purpose and function of their shoes had more benefit than the rest. Only 12 patients of the 74 were checked by the orthopaedic surgeon after delivery of the shoes.

In conclusion the authors believe there is a great need for information to be given to the patients about the functions and limitations of orthopaedic shoes and that every patient should be offered a control check-up by the surgeon. Further investigations of the effect of orthopaedic shoes should be carried out to optimise the use of these expensive devices.

Introduction

Orthopaedic shoes are individually made which makes them expensive. If the shoes are uncomfortable or do not have the desired subjective effect, minor corrections are possible after the shoes are manufactured. McDermott *et al.* (1987) found that response to shoe modifications often varied among patients with the same foot deformities and Brodsky *et al.* (1988) emphasised the lack of literature dealing with objective evaluation of inserts for orthopaedic shoes.

Patient compliance with prescribed regimens is well investigated in chronic diseases such as diabetes (Friedman, 1988). Bad patient compliance with orthopaedic shoes is mentioned by several authors (Wickstrom and Williams, 1970; McDermott *et al.*, 1987; Hollingshead, 1991; Sauvain *et al.*, 1991) but no literature was found investigating this problem.

The aim of this study was to evaluate the compliance and effect of orthopaedic shoes.

Patients and methods

All patients (in total 100, 30 males and 70 females) who were prescribed orthopaedic shoes in the authors' department, during the period of 1.1.90 – 31.12.92, were included in the investigation. At the time of the inquiry 15 were dead, thus 85 patients received a questionnaire concerning relief of symptoms (defined in 5 degrees ranging from total relief of symptoms to worsening), and daily use of the shoes (every day, occasionally, never). These questions, were correlated to disease and other circumstances in connection with the prescription and manufacturing.

Information about the doctor's prescriptions was taken from the hospital files and prescription forms. Information about the manufacturing of the shoes was taken from the orthopaedic shoemaker's files. The value of the written prescriptions was assessed as detailed, fair or with no details. Median age of the 85

All correspondence to be addressed to Anders Boye Philipsen, Godthåbsvej 36, 4300 Holbæk, Denmark. Tel: (+45) 59444078.

Table 1. Effect and use of orthopaedic shoes. The value of factors that could increase the effect of orthopaedic shoes.

Effect			Use of shoes		Prior experience		Written prescription			Control by surg.		Information[a]	
			Use	No use	No	Yes	Detailed	Fair	None	+ control	- control	Informed	Not informed
Benefit	Excellent	10	50	1	30	20	30	15	6	6	43	35	10
	Good	38											
	some	3											
No benefit	None	3	10	13	17	7	15	6	2	6	19	5	16
	Worsening	20											
No.		74	60	14	47	27	45	21	8	12	62	40	26
p-value					(Fisher) 0.25		(chi-square test for trend) 1.0			(Fisher) 0.33		(Fisher) <0.01	

[a] 8 patients did not answer this question

patients who were still alive was 64 (percentiles: 55-84) years.

Distribution of disease was: 44 rheumatoid arthritis, 10 diabetes, 10 arthrosis, 7 traumatic deformity, and 14 with other diseases.

Some 74 patients returned the questionnaire. Only 5 patients were still working, 64 were on a pension, 2 were on sickness benefit, and 3 had unknown working status.

The time between prescription and delivery was less than 2 months in 19 cases, 2-5 months in 42 cases, longer than 5 months in 11 cases and not specified in 2 cases.

For comparison of relief of symptoms/effect of shoes with other parameters, Fishers test was used. Answers concerning the main questions were divided into 2 groups (Table 1):

1. Patients using the shoes to some degree and patients with some benefit from the use,

versus

2. no use/relief at all.

A significance level of $p<0.05$ was chosen. The value written prescriptions was tested by use of chi-square test for trend.

Results

In all 51 patients had some benefit from the use of shoes. In 23, the shoes had no effect or even made symptoms worse (Table 1).

Some 42 patients used the shoes every day, 18 used them intermittently and 14 never. Two (2) patients used their shoes although they gave no relief. Eight (8) used their shoes even though they made symptoms from the feet worse (Table 1).

The 3 most frequent complaints were heaviness of the shoes, the lack of style of the shoes and pain when using them. Thirteen (13) patients reported that ulcers developed during the use of the shoes (Table 2).

Applying a rocker-sole, a forefoot pad and a heel were the 3 most common modifications (Fig. 1). Comparing the 3 most common modifications with the effect of shoes only change of the heel for unequal length of legs was significantly bad in outcome according to the patients' answers ($p=0.03$). Twenty-seven (27) patients who were experienced with orthopaedic shoes did not have better compliance than 47 patients with a first time prescription ($p=0.25$) (Table 1).

A detailed written prescription did not result in a better function of the shoe ($Chi^2=0.306$, $p=1.0$) (Table 1).

Only 12 of the 74 patients were controlled by

Table 2. Seventy-four (74) patients complaints of orthopaedic shoes.

	No complaint	Too heavy	Pain from shoes	Bad look	Developing of ulcer	Difficult handling	Other complaints
No. of patients	23	27	21	17	13	9	11

26/74 patients had 2 complaints or more

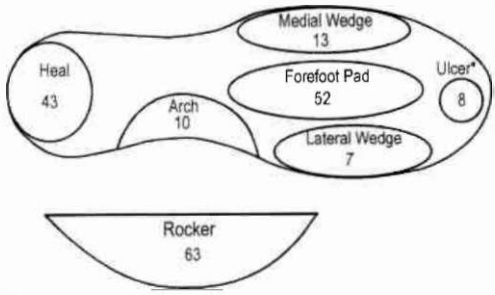


Fig. 1. Total number and location of modifications on 74 pairs of orthopaedic shoes. Each modification is related to 1 pair of shoes without regards to different build up or right and left shoe.
*Modification to relieve direct pressure on a foot ulcer.

the orthopaedic surgeon after the shoes were delivered. These patients did not have a better effect from the shoes ($p=0.33$) (Table 1).

Patients who felt informed about the purpose and function of the shoes had a better result from them ($p<0.01$) (Table 1).

Discussion

The majority of patients in this material had rheumatoid arthritis and were on pension. Younger, working patients would probably make other demands on orthopaedic shoes. Two thirds of the patients had some result from the shoes justifying the prescription. The fact that 13 patients were using badly functioning shoes, indicates that they are in a great need of further evaluation by the orthopaedic surgeon, even though the 12 patients that were checked in this study, did not benefit significantly from this (Table 1).

The span of time before the shoe is finally tested, and the problems with emphasising to the patient the need for reattendance (Armstrong *et al.*, 1990) can explain some of the problem. A note from the orthopaedic shoemaker to the surgeon when the shoes are finished followed by a call for a check-up visit, would probably be the easiest and most important contribution to better functioning shoes and better compliance especially when the patients are given information about the purpose and function of the shoes and realistic expectations.

Complaints about the weight and appearance of orthopaedic shoes are well known (Wickstrom and Williams, 1970). Computing techniques and new materials have been developed to design more modern and light styles. Some degree of pain must be expected among some of these patients with serious chronic diseases even with well manufactured shoes. Ulcers developing during the use of the shoes should not be accepted. As several of these patients have diabetic neuropathy, the high incidence of ulcers among the patients in this series stresses the need for check-up consultations several times after the shoes are delivered. In some cases the written prescription was discussed with the orthopaedic shoemaker during a weekly meeting at the hospital. This could add necessary information to a non-detailed prescription. The surprising fact that shoes made from a detailed written prescription did not produce a better result than shoes made from very short, non-detailed prescription could indicate difficulties for the orthopaedic shoemaker in implementing the surgeons theoretical prescriptions for the shoes.

Applying orthopaedic shoes as an orthopaedic treatment is chiefly a matter of experience and skill (Chen and Lord, 1995). The theoretical considerations for proper fit of shoes and selection of the specific modifications have been discussed in several papers (Brodsky *et al.*, 1988; Cracchiolo, 1979; Janisse, 1992; Wickstrom and Williams, 1970). It is suggested that the modifications, if possible, should be tested before the shoe last is made, and the use of a generic shoe is suggested as an adjunct to decision-making and as a predictor of patient compliance (McDermott *et al.*, 1987; Chen and Lord, 1995).

In conclusion there was a need for better information to patients about the purpose, function and limitations of the shoes. Every patient should be checked not only by the orthopaedic shoemaker, but also by the surgeon after the shoes have been in use for a while.

Further investigations of the effect of modifications on orthopaedic shoes should be carried out to optimise the use of these expensive devices.

Acknowledgements

The study was supported by grants from the Danish Rheumatism Association. The authors also thank Nyrop & Maag for technical and manufacturing information of the shoes included in this investigation.

REFERENCES

ARMSTRONG D, GLANVILLE T, BAILEY E, O'KEEFE G (1990). Doctor-initiated consultations: a study of communication between general practitioners and patients about the need for reattendance. *Br J Gen Pract* **40**, 241-242.

BRODSKY JW, KOUROSK S, STILLS M, MOONEY V (1988/89). Objective evaluation of insert material for diabetic and athletic footwear. *Foot Ankle* **9**, 111-116.

CHEN R C-C, LORD M (1995). A comparison of trial shoe and shell shoe fitting techniques. *Prosthet Orthot Int* **19**, 181-187.

CRACCHIOLO A (1979). The use of shoes to treat foot disorders. *Orthop Rev* **8**, 73-84.

FRIEDMAN M (1988). Compliance with chronic disease regimens. *J Diabetic Comp* **2**, 140-144.

HOLLINGSHEAD TS (1991). Pathophysiology and treatment of diabetic foot ulcer. *Clin Podiatr Med Surg* **8 (4)**, 843-855.

JANISSE DJ (1992). The art and science of fitting shoes. *Foot Ankle* **13**, 257-262.

MCDERMOTT JE, LIPPERT FG, HAYES S, KALIVAS TL (1987). The generic shoe: a prescription tool. *Bull Hosp Joint Dis* **47**, 228-234.

SAUVAIN MJ, BROCK D, GERBER NJ (1991). Fussprobleme bei cronischer polyarthritis: schuhberatung und fusspflege. *Ther Umsch* **48**, 640-644.

WICKSTROM J, WILLIAMS RA (1970). Shoe corrections and orthopaedic foot supports. *Clin Orthop* **70**, 30-42.

Prosthetics and Orthotics International, 1999, 23, 63–71

Comparison of bending stiffness of six different colours of copolymer polypropylene

R. S. ROSS*, R. J. GREIG** and P. CONVERY***

**Mobility and Rehabilitation Service, Woodend Hospital, Aberdeen, Scotland*
***Orthotics Department, Hospital for Sick Children, Yorkhill, Glasgow, Scotland*
****National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Glasgow, Scotland*

Abstract

This paper compares the bending stiffness of 5 different colours of copolymer polypropylene (CCP) with that of natural copolymer polypropylene (NCP). Flesh coloured and natural sheets are supplied thicker than other pigmented sheet. The bending stiffness of a specimen may be defined as EI, i.e. the product of E, Young's modulus of elasticity and I, the 2nd moment of area.

Strips of "as supplied" (AS) and "post-draped" (PD) specimen were clamped and subjected to bending to assess the effect of pigmentation on bending characteristics. The gradient of the graph of bending deflection δ versus bending moment enables EI to be estimated. The process of thermoforming polypropylene reduces EI, the bending stiffness. However, the manual draping and vacuum procedure introduces so many variables that it is difficult to quantify the effect of pigmentation. The E of a bent specimen may be estimated from the gradient of the graph of δI versus bending moment. In the case of AS sheet, the effect of pigmentation on E is inconclusive. PD specimens indicate a significant reduction in E due to thermoforming. This was verified by an electron-microscope study of AS and PD specimens.

Draping an ankle-foot orthosis (AFO) results in a non-uniform wall thickness. The results of this study with respect to the effects of pigmentation on the bending stiffness of AFOs are inconclusive. More detailed studies require to be completed in order to confirm which factors are responsible for this non-uniformity in wall thickness and consequent variation in bending stiffness.

All correspondence to be addressed to Peter Convery, National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, 131 St. James' Road, Glasgow G4 0LS, Scotland. Tel: (+44)141 548 3525. Fax: (+44)141 552 1283. E-mail: p.p.convery@strath.ac.uk

Introduction

The use of CCP in paediatric orthotics has grown in popularity over recent years, in an attempt to improve the "cosmesis" or acceptability. This use of CCP has been associated with uncertainty as to the consistency of the mechanical properties between colours.

One of the major clinical concerns of the orthotist is the ability of an AFO to resist bending in the sagittal plane. The AFO bending normally occurs in the vicinity of the ankle joint. The success or failure of most AFOs lies with the ability of the orthosis to control ankle joint position and/or motion.

This study establishes the bending stiffness of NCP and compares it with that of 5 different colours of CCP.

A number of researchers have studied the bending stiffness of different AFOs. Yamamoto *et al.* (1993) reported on the plantar/dorsiflexion and inversion/eversion bending stiffness of a selection of different orthoses fitted to a normal limb. The 3-dimensional bending stiffness of a polypropylene AFO was reported by Klasson *et al.* (1998). Lunsford *et al.* (1994) reported on the variation in wall thickness of 3 AFOs thermoformed from the same sheet over the same plaster model. The variation in wall

thickness of 4 AFOs thermoformed from the same sheet over a plaster model was as reported by Golay *et al.* (1989).

Method

Typically 3mm thick extruded polypropylene is used in paediatric orthotics. The following colours of polypropylene sheet were obtained from an established supplier of "prosthetic/ orthotic" grade materials:

natural	flesh tone
royal blue	poppy red
asian brown	fluorescent green

The supplier's thickness specification of flesh coloured and natural sheets was 3.1mm ±5% and for the other four colours 3.0mm ±5%. All sheets were copolymer polypropylene with approximately 5% ethylene and <2% pigment. The test specimens were prepared as follows.

Three (3) strips of each colour, each 200mm long and 30mm broad, were cut from the AS sheet by a technician. A 3mm hole was drilled on the centre line of each strip, 30mm from the end of the AS specimens, as shown in Figure 1.

As a monitor of the effect of a typical orthotic manufacturing process, single sheets of each colour were heated in an oven at 180°C for 9 minutes. The hot sheets were then vacuum moulded over a steel rectangular mould and left overnight to cool. PD specimens were cut from the moulded sheet by another technician to provide 3x200mm long strips, 30mm broad. As with the AS specimens, a 3mm hole was drilled on the centre line of each strip, 30mm from the end of the PD specimens.

The thickness and breadth dimensions of the AS and PD specimens were measured using a micrometer at 2 locations, one at mid-length and the other 10mm from the end with the 3mm hole. The measures were taken by 3 orthotists in order to take account of individual differences in using the micrometer. The variation in breadth measurements identified the accuracy to which the 2 technicians cut the specimens, following

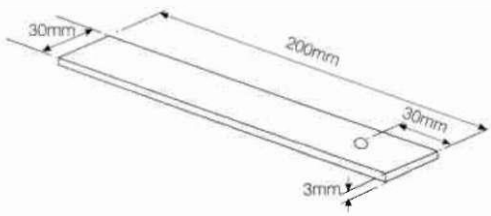


Fig. 1. "As supplied" test specimen.

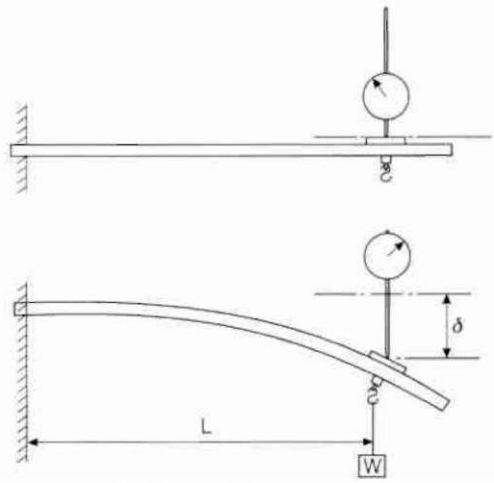


Fig. 2. Bending test apparatus.

the same instructions. The variation in the thickness measurements identified whether thermoforming had any effect on the thickness dimension.

The AS and PD specimens were positioned horizontally and clamped at one end. When subjected to a load W at a distance L from the clamp, as shown in Figure 2, the deflection of the specimen (δ) at the load point in the direction of the applied load is:

$$\delta = WL^3/3EI \qquad \text{(Equation 1)}$$

Where W =m x g

m =the suspended mass (kg)

g =acceleration due to gravity 9.81ms^{-2}

L =horizontal distance from the clamped end to the load point

WL =applied moment

E =Young's modulus of elasticity

I =2nd moment of area of the beam =(breadth x thickness^3)/12

EI =Bending stiffness or flexural rigidity

A clamped dial gauge measured the vertical deflection at the load point of each AS and PD specimen. A metal adaptor was fitted to the 3mm hole in the specimens. The dial gauge contacted the flat top surface of the adaptor while masses were suspended from the hook on the under-surface of the adaptor. A 0.05kg hanger was suspended from the hook at a distance L=80mm from edge of the clamp. Incremental masses of 0.05kg were applied in a consistent "cushioned" procedure and left for 1 minute before measuring the vertical deflection. Deflections δ were measured during increasing and decreasing load cycles specimens to minimise any

differences caused by the effects of creep and shock loading. Bending moments of 39Nmm, 79Nmm, 119Nmm and 159Nmm were applied and the corresponding deflections δ were noted. This procedure was repeated for all AS and PD specimens.

Equation 1 may be expressed as:

$$\delta = (L^3/3EI)\text{Moment}$$

$L^3/3EI$ may be determined by plotting δ versus the applied moment and determining the gradient of the graph. The bending stiffness may be estimated from this gradient and the effect of pigmentation and thermoforming on the bending stiffness of the coloured specimens may be assessed by comparing the differences between the AS and PD specimens.

If the thickness or breadth dimensions vary along the length of the specimens, this affects I of the specimen and hence the deflection. As an approximation for variations of I, rather than plotting δ versus applied moment the Equation 1 may be re-written as:

$$\delta I = (L^3/3E)WL$$

Deflection x 2nd Moment of Area = $(L^3/3E)$ Moment

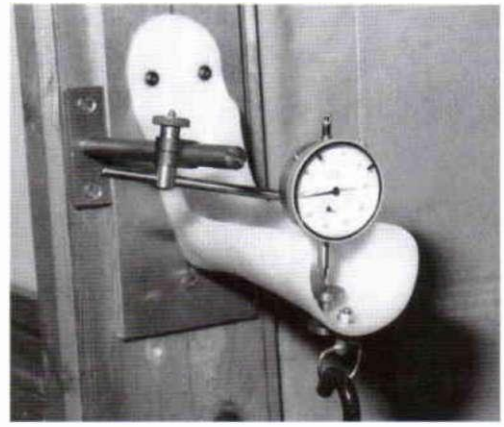
By plotting δI versus the applied moment and determining the gradient of the graph, E may be estimated. The effect of pigmentation and thermoforming may be assessed by comparing the differences in the estimated E values of the AS and PD specimens.

Single sheets of each colour were heated in an oven at 180°C for 9 minutes and then vacuum moulded over identical plaster casts to form AFOs. Each AFO was trimmed to the same landmarks to allow direct comparisons. The wall thickness of the 6 AFOs was measured with a micrometer at the following locations:

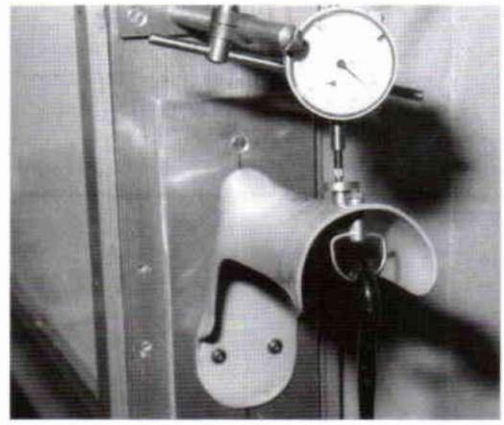
- the medial malleolus;
- the lateral malleolus;
- the sole plate;
- the proximal aspect of the calf section.

A set procedure was adopted for the bending tests on the AFOs. First, an outer acrylic resin shell was laminated over an AFO and the master mould. A metal plate was then drilled and threaded with 3x5mm holes. These 3 holes were transferred to the sole plate of the laminated shell. An additional 2 holes, 3mm and 5mm, were drilled on the centre line of the calf section of the laminated shell, at 30mm and 20mm respectively from the edge of the proximal calf. Each of the AFOs was fitted intimately within the inner wall of the laminated shell. The 5 holes in the laminated shell were transferred accurately to each of the AFOs.

The metal plate, incorporating the 3 threaded 5mm holes, was attached to a vertical wall so that each AFO could be bolted to the plate with the calf located in a "horizontal" position. A metal adaptor, with 2 flat platforms, was fitted to each AFO through the 3mm hole located 30mm from the proximal calf edge. A clamped dial gauge in contact with the platform of the adaptor accurately measured vertical displacements. Masses were suspended from the AFO using the D ring attached to the 5mm hole located 20mm from the proximal calf edge. A 0.4kg hanger was suspended from the adaptor at the proximal calf edge and masses were added to the hanger in increments of 1kg up to a maximum of 5kg. The corresponding deflections were noted 1 minute after each increment of load was applied. The



(a)



(b)

Fig. 3. (a) AFO plantarflexion test. (b) AFO dorsiflexion test.

maximum mass of 5.4kg suspended from the D ring resulted in the application of a maximum moment of 9.2Nm.

With each AFO bolted to the metal plate as shown in Figure 3a, plantarflexion moments were applied and the dial gauge measured the corresponding deflections. The mounting plate was freed, inverted and re-attached to the vertical wall. Each AFO was re-bolted to the metal plate as shown in Figure 3b, with the D ring re-attached to apply dorsiflexion moments while the dial gauge measured the corresponding deflections. This test procedure was adopted to establish if the bending stiffness of the AFOs was influenced by:

(1) the addition of pigments; or

(2) the typical orthotic production procedure.

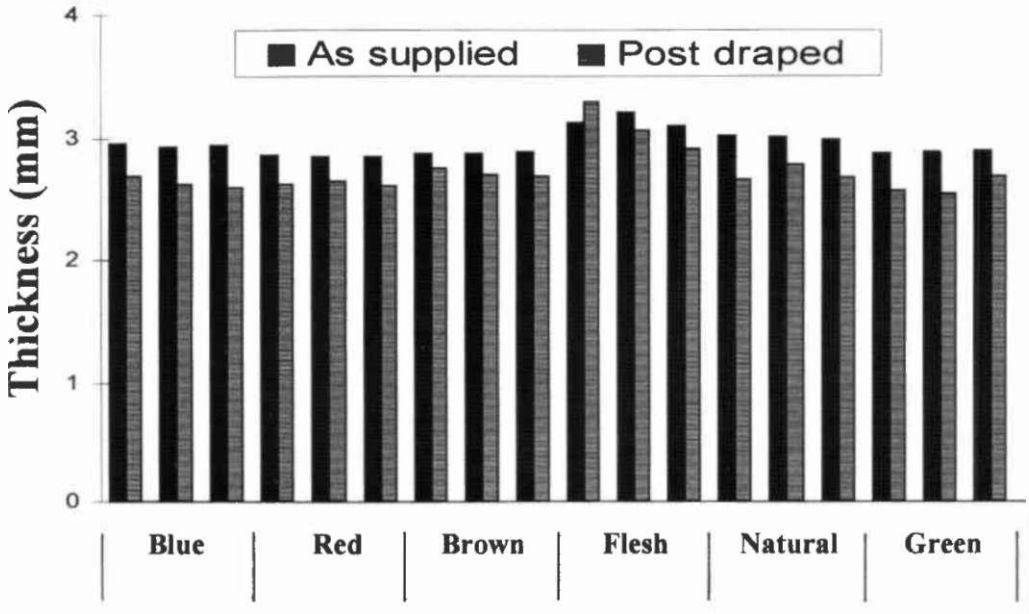
Results

The mean thickness and breadth measurements of AS and PD specimens are presented in Graphs 1 and 2 respectively. The I values, calculated from Graph 1 and 2, are presented in Graph 3.

Table 1 lists the bending stiffness of the AS and PD specimens, calculated from the gradient of the deflection versus moment graphs. Table 2 lists the estimated E values from the gradient of δI versus bending moment graphs of the AS and PD specimens. The mean AFO wall thickness measurements are presented in Graph 4. Graph 5 illustrates the dorsiflexion and plantarflexion

Table 1. Bending stiffness EI (Nmm^2)

	As supplied		Post-draped	
	Nmm^2	Ave	Nmm^2	Ave
Blue	90780		49844	
Blue	95665	92800	52675	51818
Blue	91954		52936	
Red	72810		58129	
Red	75117	73662	56889	56762
Red	73059		55268	
Brown	84656		57041	
Brown	79306	81692	63682	58905
Brown	81115		55993	
Flesh	90395		99225	
Flesh	99688	93750	78721	83258
Flesh	91168		71829	
Natural	84321		54841	
Natural	81115	81980	56288	53814
Natural	80503		50314	
Green	84656		59590	
Green	92352	89787	53872	68472
Green	92352		91954	



Graph 1. Variations in thickness.

stiffness of the coloured AFOs.

Discussion

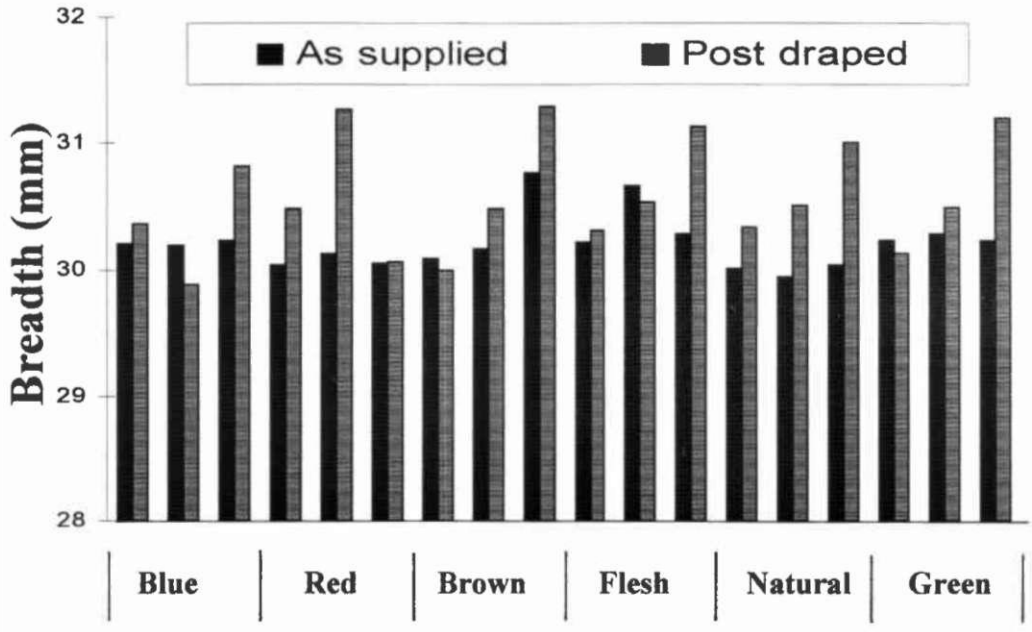
The variation in thickness of the AS specimens in Graph 1 corresponds to the supplier's specification of thickness of sheet, i.e. the flesh coloured and natural sheets were marginally thicker. Graph 1 indicates that in general the fabrication process reduces the thickness of the PD specimens relative to the AS specimens. As a rough approximation the thickness of the PD specimens reduced by 0.3mm or approximately 10% of the original thickness. However, the PD specimens were not necessarily draped from the same sheets used to cut the AS specimens. (This may explain the exception with the PD specimen, flesh 10, which indicated an increase in the PD thickness measurement).

Graph 2 illustrates that the technician who cut the PD specimens to an instructed breadth of 30mm was not as consistent as the technician who cut the AS specimens. This highlights a typical variable in workshop standards.

The breadth and thickness dimensions at a particular location were consistent when measured by the 3 orthotists. However, there was a variation along the length of all the specimens. For example, the average breadth and thickness dimensions of the PD specimen Blue 3 at mid-length were 31.08mm and 2.64mm whereas at the hole end the corresponding dimensions were 30.56mm and 2.54mm. Based on these dimensions the I of this specimen may be estimated as 47.7mm^4 at mid-length and as 41.7mm^4 at the hole end. Some specimens "taper" towards the loaded end while others "taper" towards the clamped end. These factors influence I and hence the bending characteristics of the specimen.

For a given applied load bending deflection decreases with increasing I. The I characteristics illustrated in Graph 3 represent the average I, calculated between the mid-length and loaded end of the specimens. In general, the AS specimens display a larger I value than that of the PD specimens. However, without confirmation of the original thickness data of the pre-draped sheets, it is not possible to verify that the reduction in I was due to the drape process. (Note that the I value of each specimen is significantly influenced by the thickness of the specimen, I = (breadth x thickness^3)/12).

The bending stiffnesses listed in Table 1 do not correlate with the I values presented in Graph 3. This may be due to the variation of I along the length of individual specimens. A comparison of the AS and PD rows in Table 1



Graph 2. Variations in breadth.

suggests that the thermoforming process reduces EI.

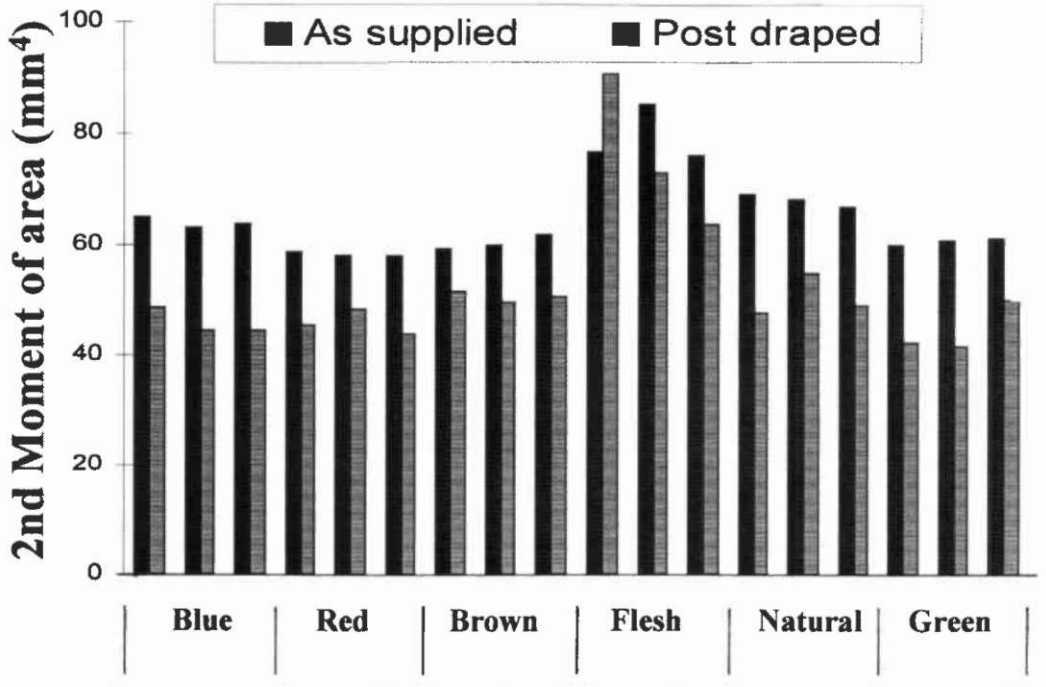
In order to allow for variations of I, the monitored bending deflections were multiplied by the appropriate I presented in Graph 3. The Young's modulus of elasticity, E, of the AS and PD specimens were estimated from graphs of δI versus moment and the results are listed in Table 2. The effect of pigmentation is inconclusive. Table 2 indicates only a small variation in E in the AS specimens. Relative to natural AS sheet, the addition of flesh, blue and green pigments may increase E, whereas red and brown pigments may reduce E. In general, the E values of the PD specimens were significantly smaller than the AS specimens. This indicates that thermoforming reduces E and that this reduction in E may be greater for particular pigments.

Single AS and PD specimens of each colour were examined with an electron-microscope. The electron-microscope results were inconclusive although the following were noted:

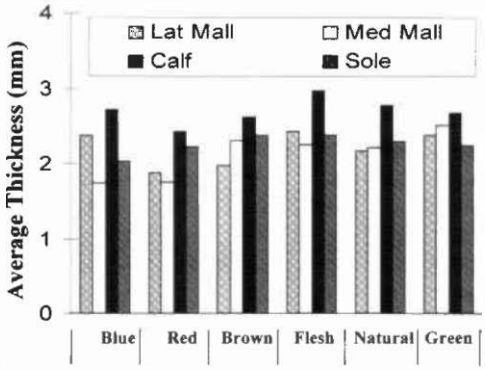
- significant differences in the AS and PD specimens were observed confirming that differences in E may be anticipated between AS and PD specimens;
- the extrusion process to produce the original sheet introduced a longitudinal formation to the polymer chains;

Table 2. Young's modulus of elasticity E (Nmm^{-2})

	As supplied		Post-draped	
	Nmm^{-2}	Ave	Nmm^{-2}	Ave
Blue	1400		1025	
Blue	1512	1452	1181	1131
Blue	1443		1188	
Red	1238		1276	
Red	1294	1265	1178	1236
Red	1262		1253	
Brown	1430		1103	
Brown	1323	1356	1281	1163
Brown	1314		1105	
Flesh	1603		1091	
Flesh	1168	1322	1082	1101
Flesh	1196		1129	
Natural	1225		1150	
Natural	1192	1207	1030	1068
Natural	1203		1025	
Green	1418		1408	
Green	1523	1483	1292	1513
Green	1507		1839	



Graph 3. Variations in 2nd moment of area.



Graph 4. Average thickness of AFO.

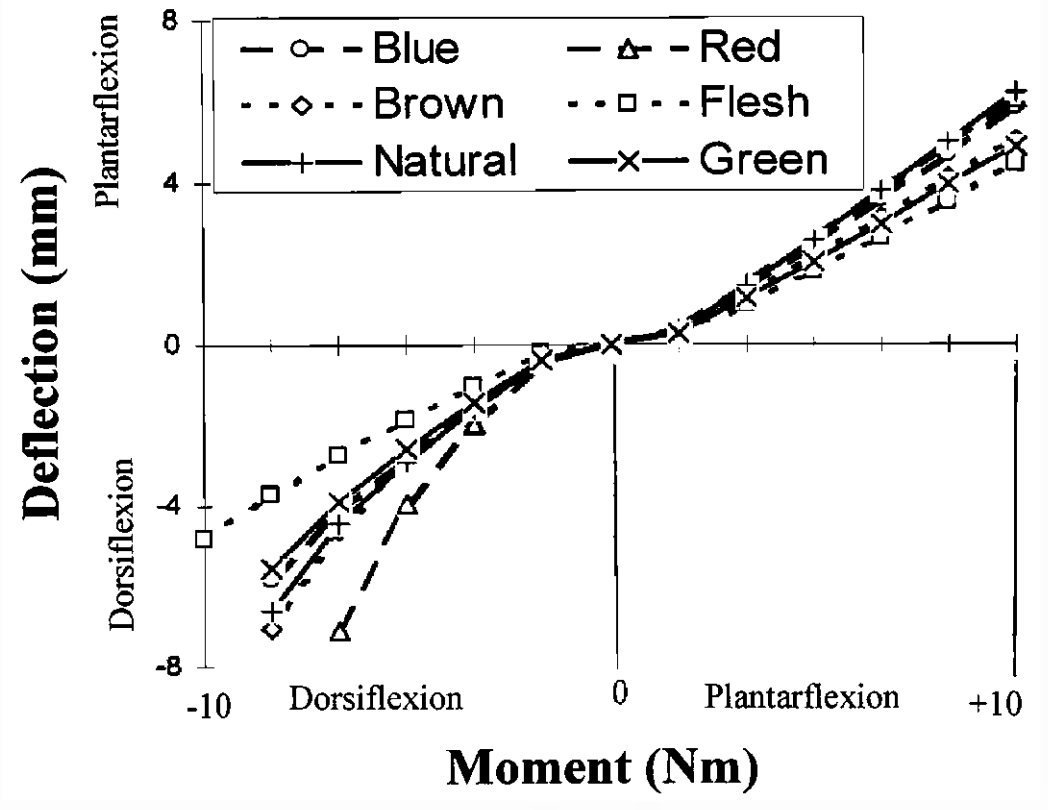
- during the extrusion process, turbulence of the "molten" copolymer occurs, resulting in non-uniformity or surface effects;
- pigmentation may encourage crystallisation of the copolymer but the degree of crystallisation varies dependent on the pigment added.

Graph 4 illustrates a significant variation in wall thickness of the different coloured polypropylene AFOs. Lunsford *et al.* (1994) and Golay *et al.* (1989) reported similar variations in wall thickness of draped AFOs. The following factors may be responsible for variations in the wall thickness of an AFO:

(1) the thickness consistency of the original sheet;
(2) the pigmentation of polypropylene;
(3) the repeatability of the manual draping procedure;
(4) the vacuum or lack of vacuum applied.

In the same way as it is not possible to distinguish the exact reason for the variation in the bending stiffnesses of the PD specimens, so also the results for the AFOs are inconclusive. The manual draping procedure is the most likely reason for the non-uniformity of wall thickness demonstrated in Graph 4.

Graph 5 illustrates that the plantarflexion stiffness of the coloured AFOs exceeded that of the dorsiflexion stiffness. For example, the deflection of the Natural AFO when subjected to a plantarflexion and dorsiflexion moment of



Graph 5. Bends stiffness of AFO.

7.5Nm was 5.0mm and 6.6mm respectively (approximately 2° angular motion). This agrees with other researchers such as Yamamoto *et al.* (1993). The thicker Flesh coloured AFO demonstrated maximum bending stiffness or least deflection.

The theoretical predictions of the influence that trimlines or wall thickness may have on the stiffness of an AFO are presented in the Appendix. The bending stiffness and bending stress of an AFO are influenced more by the removal of material from the front edge of the AFO than by a ± 0.5mm variation in the wall thickness. In the case of a 2.5mm thick AFO, the effect on bending stiffness of a reduction in wall thickness of 0.5mm, is the equivalent to trimming only 2.6mm from the front edge of this AFO.

Conclusions

Thermoforming polypropylene reduces EI, the bending stiffness of the material. This may be due to: (a) a reduction in the thickness and hence the I characteristic; (b) a reduction in E due to the heating cycle; and (c) strain created during the vacuum thermoforming. Pigmentation of the polypropylene may have an influence on EI characteristics of the PD specimen. However, the manual draping procedure introduces so many variables that it is difficult to devise a mechanical test procedure which clearly identifies the effect of pigmentation. No conclusions can be established regarding the effect of certain pigments on the bending characteristics of AS sheet. Particular pigments may influence the bending characteristics of PD specimens.

The manual draping of an AFO and the application of vacuum results in a non-uniform wall thickness. The results of this study with respect to the effects of pigmentation on the bending stiffness of AFOs are inconclusive.

Electron-microscopy studies of the physical structure of the pigmented specimens suggest that thermoforming relieves the chain formation induced during extrusion thereby changing the structural and physical properties of the AS and PD specimens. Comments from experienced polymer researchers suggest that additional studies of pigmentation may be fraught with insurmountable problems.

Appendix

The bending stiffness of an AFO is a function of EI. For calculation purposes it is assumed that a constant moment of 10Nm is applied. It is possible theoretically to predict the influence that the trimlines or the wall thickness may have on I of an AFO.

At the anterior edge of the AFO, σ, the bending stress, may be expressed as:

$$\sigma = My/I$$

where M = the bending moment applied,
I = the 2nd moment of area, and
y = the distance from the centroidal axis to the anterior edge.

It is assumed that initially the AFO extends to the malleoli such that a semi-circular arc is formed, of inner radius R = 30mm and thickness t = 2.5mm. Figure 4a illustrates the horizontal cross-section of an unmodified semi-circular arc while Figure 4b illustrates the horizontal cross-section of the modified AFO with the trimline cut back by a distance d.

I about the XX axis passing through the centroid of the cross-section of the unmodified AFO (Figure 4a), may be calculated as $I_{XX} = 22.8 \times 10^3 mm^4$. The distance from the XX axis to the anterior edge of the AFO, y, may be estimated as 19.9mm and the bending stress, σ, may be estimated as $8.7 Nmm^{-2}$.

A similar procedure may be followed to assess the effect of altering the trimline of the AFO.

Theoretical trimline effects are presented in

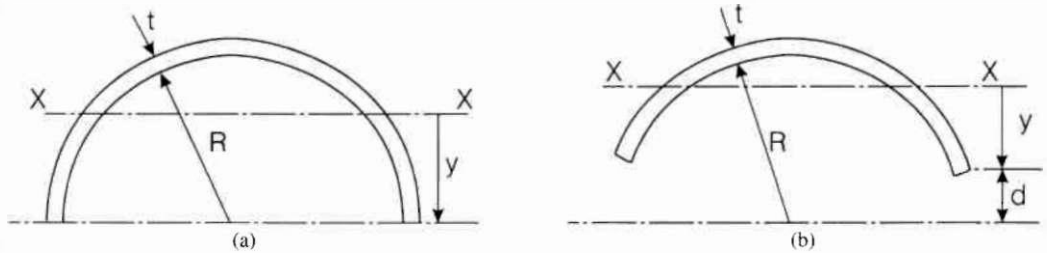


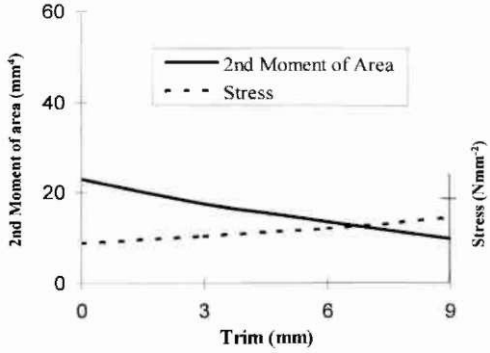
Fig. 4. (a) Cross-section of semi-circular arc. (b) Cross-section of modified AFO with trimline d.

Table 3. Effect of trimline variation

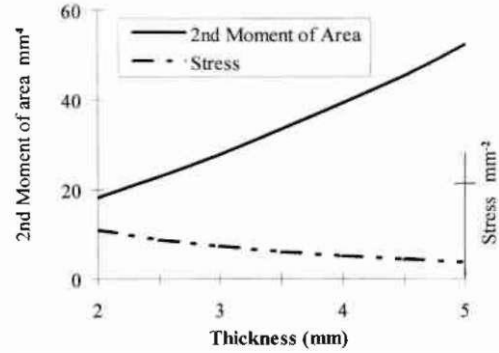
Trimline d (mm)	$I_{xx} \times 10^3$ (mm^4)	y (mm)	Bending stress σ (Nmm^{-2})
0	22.8	19.9	8.7
3	17.4	18.1	10.4
6	13.4	16.2	12.1
9	9.7	14.2	14.6

Table 4. Effect of wall thickness variation

Wall thickness t (mm)	$I_{xx} \times 10^3$ (mm^4)	y (mm)	Bending stress σ (Nmm^{-2})
2.0	18.1	19.7	10.9
2.5	22.8	19.9	8.7
3.0	27.7	20.1	7.3
5.0	52.5	20.7	3.9



Graph 6. Effect of trimline on 2nd moment of area (I) and bending stress (σ)



Graph 7. Effect of AFO wall thickness on (I) and (σ).

Table 3. Graph 6 illustrates the predicted effect of varying the trimline on second moment of area (I) and the bending stress (σ). Theoretically, removal of 9mm from the front edge of this AFO reduces the stiffness by 57% and increases the bending stress by 68%.

Similarly, it is possible to predict the influence wall thickness may have on the stiffness of an AFO. It is assumed that the inner radius of the AFO remains constant at R = 30mm and that the trimline of the AFO is not modified (i.e. d = 0mm). Graph 4 indicated that the AFO wall thickness varied from 2.5mm ±0.5mm. The effect of varying the wall thickness of the AFO cross-section illustrated in Figure 4a, is presented in Table 4. Graph 7 illustrates the effect of varying the wall thickness on second moment of area (I) and the bending stress (σ). Theoretically increasing t, the wall thickness of this AFO, from 2.5mm to 3mm increases the stiffness by 21% and reduces the bending stress by 25%. Reducing t from 2.5mm to 2mm reduces the stiffness by 21% and increases the bending stress by 25%. However, an increase in t from 2.5mm to 5mm increases the stiffness by 130% and reduces the bending stress by 55%.

From these calculations it may be concluded that removal of 3mm from the anterior trimline of an AFO has the same reduction in the AFO stiffness as a reduction of 0.5mm in the wall thickness of the untrimmed AFO.

REFERENCES

GOLAY W, LUNSFORD T, LUNSFORD BR, GREENFIELD J (1989). The effect of malleolar prominence on polypropylene AFO rigidity and buckling. *J Prosthet Orthot* **1**, 231-241.

KLASSON B, CONVERY P, RASCHKE S (1998). Test apparatus for the measurement of the flexibility of ankle-foot orthoses in planes other than the loaded plane. *Prosthet Orthot Int* **22,** 45-53.

LUNSFORD TR, RAMM T, MILLER JA (1994). Viscoelastic properties of plastic pediatric AFOs. *J Prosthet Orthot* **6,** 3-9.

YAMAMOTO S, EBINA M, IWAASAKI M, KUBO S, KAWAI H, HAYASHI T (1993). Comparative study of mechanical characteristics of plastic AFOs. *J Prosthet Orthot* **5,** 59-64.

Prosthetics and Orthotics International, 1999, 23, 72–74

Technical note

Creating a model for fabricating a partial hand glove prosthesis using the realigned casts of the contralateral digits

M. E. L. LEOW, A. K. KOUR, W. K. M. NG and R. W. H. PHO

Department of Orthopaedic Surgery, The National University of Singapore, Singapore

Abstract

A method for creating a model for fabricating a partial hand glove prosthesis is described. The realigned casts of the corresponding digits of the contralateral uninjured hand were used to substitute for the lost digits on a cast of the stump. The technique allows an exact reproduction of the anatomical and fine surface details of the digits. It has the advantage of customisation, allowing a close match in the size, shape and surface characteristics of the prosthesis to that of the remaining digits of the hand.

Introduction

The first step involved in producing a custom fabricated prosthesis for aesthetic restoration of lost digits of the hand is to create a finger model from which an impression is made for moulding the prosthesis. Conventionally, the finger model is created by sculpting in wax to reproduce the skin details, size and shape of the lost digit using the cast of the corresponding digit of the contralateral uninjured hand as reference (O'Farrell *et al.*, 1996; Alison and Mackinnon, 1992; Buckner, 1992). However, when more than one digit is involved as in partial hand amputations, sculpting becomes time consuming. The method also requires the trained hands of a skilled sculptor and good results are not readily achieved.

The authors describe in this paper a method for creating a model for fabricating a partial hand glove prosthesis. The realigned casts of the corresponding digits of the contralateral uninjured hand, with the skin details fully duplicated, are attached to a cast of the stump as substitution for the lost digits. The technique allows an exact reproduction of the anatomical and fine surface details of the digits. It has the advantage of customisation, allowing a close match in the size, shape and surface characteristics of the prosthesis to that of the remaining digits of the hand. Using this technique, the authors have fabricated and fitted prostheses to over 165 patients since 1990 (Leow *et al.*, 1997; Leow *et al.*,1996; Pereira *et al.*, 1996).

All correspondence to be addressed to Professor Robert W. H. Pho, Department of Orthopaedic Surgery, The National University of Singapore, 10 Kent Ridge Crescent, Singapore 119260, Singapore. Tel: (+65) 7724340. Fax: (+65) 7732558.

Materials and method

Case example

Patients who sustain the loss of the digits of their hand are assessed for suitability for prosthetic fitting. The case example used in this technical note involved a 41-year-old male who sustained a machine injury to his right hand with loss of the ring and little digits at the level of the metacarpophalangeal joint (Fig. 1).

Impression taking

Impressions of the stump and of the digits of the contralateral uninjured hand which correspond to the lost digits were taken using dental silicone (Dent Silicone-V, Shofu Inc., Kyoto, Japan). Both hands were cast with the digits in the semiflexed and relaxed position. The impression moulds were reinforced externally with 2 layers of plaster of Paris to ensure structural integrity and filled with epoxy resin (Chemi R77N, Ciba-Geigy, Switzerland) which was then allowed to cure at room temperature (24°C). The skin details of the

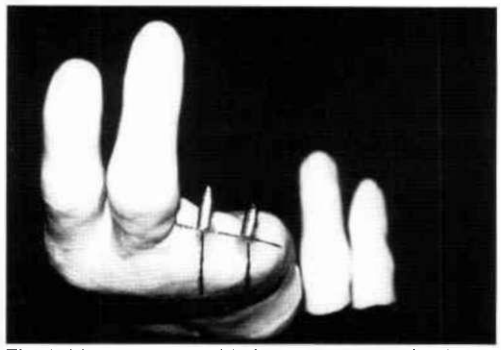


Fig. 1. The stump cast with the tapered screws implanted and showing the alignment lines drawn to guide the positioning and fixation of the finger casts.

contralateral digits would be exactly duplicated in the finger casts obtained from the impression moulds.

Alignment modification of the finger casts

The right and left hands are mirror images of one another. The corresponding digits of the right and left hands are invariably skewed in opposite directions – the tips of the middle, ring and little fingers are aligned somewhat radially while that of the thumb and index finger are oriented ulnarly when the hand assumes a relaxed position.

Before the finger casts can be used to substitute for the lost digits, some alignment changes are necessary. After allowing the resin to cure for 18 hours, the finger casts were withdrawn from the impression moulds. The resin had solidified but remained malleable at this stage. A light lateral bending force was applied manually (proximal and distal interphalangeal joints are fulcra) on the finger casts to produce the respective mirror alignment. The finger casts were "frozen" in reversed orientation by immersing them in cold water (4°C) for 1 hour. The tips of the realigned finger casts should be somewhat radially deviated when positioned on the stump cast to substitute for the lost digits.

Preparation of the stump cast for fixation of the finger casts

Two dorsal alignment lines were marked out on the stump cast along the location of the fourth and fifth metacarpals to guide the positioning of the realigned finger casts for fixation (Fig. 1). A lateral alignment line equally dividing the thickness of the "palm" was marked on the ulnar aspect of the stump cast. A 10mm hole about 15mm deep was made at each digit at the points of intersection of, and parallel to, the alignment lines for implanting tapered screws (length 38mm) on to which the finger casts would be attached. The screws were implanted into the drilled holes and fixed with fast-curing resin (Araldite™ Rapid, Ciba-Geigy, Switzerland).

Fixation of the finger casts on the stump cast

The next step involved the positioning and fixation of the finger casts on the stump cast (Fig. 2). With the dorsal and the lateral alignment lines as guides, the appropriate position for the fixation of the finger casts was established. The location for drilling the holes into which the threads of the screws on the stump cast would go were mapped and marked out on the proximal base of the finger casts. The holes were made (bit size 7/32 inches) along the longitudinal axis of the finger casts following which they were "screwed" on to the stump cast. The orientation and the lengths of the finger casts in relation to the remaining digits were checked, making the necessary alignment changes to ensure conformity to the contour of the hand.

Bridging the defects between the finger casts and the stump cast

With the finger casts attached to the stump cast, the defects around the metacarpophalangeal joint area were bridged using plaster to restore the contour of the hand (Fig. 3). Skin details can be imprinted on these built-up areas using silicone impression of the corresponding

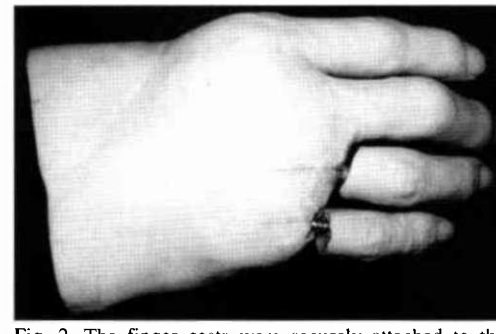


Fig. 2. The finger casts were securely attached to the stump cast after their orientation and lengths in relation to the remaining digits were adjusted to conform to the contour of the hand.

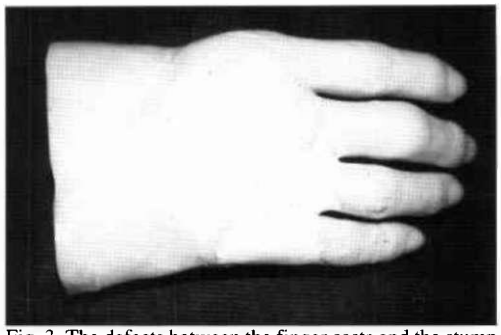


Fig. 3. The defects between the finger casts and the stump cast were "bridged" with plaster to restore the contour of the hand.

segment of the skin on the contralateral hand.

Fabrication and trial-fitting of test prosthesis

An impression of the completed model was made for the fabrication of a test prosthesis which was trial-fitted on the patient (Fig. 4). The test prosthesis was moulded in layers of silicone rubber, tinted but not matched to the patient's skin colour. In addition to anchorage onto the adjacent intact digit, the fixation of the prosthesis on the stump was augmented with the use of a skin adhesive. When an aesthetic appearance is achieved and the prosthetic fit is sufficiently secure, the final prosthesis can be fabricated and colour-matched to the patient's skin. The edge of the finished prosthesis can be trimmed and ground to taper at the proximal edges to flush and blend with the skin.

Discussion

A significant advantage of this technique is the exact duplication of the anatomical and the fine surface details of the digits. This allows the surface characteristics of the prosthesis to be closely matched to that of the remaining digits of the hand. With the appropriate alignment modifications, the technique can be applied to cases of partial hand amputations involving the other digits, including the thumb. The technique is especially useful in cases of multiple-digit loss through the level of the metacarpals with no residual length remaining to allow individual digital fitting.

The realignment of the finger casts before they were used to substitute for the lost digits on the stump cast constituted a pivotal procedure of this technique. The choice of resin used (Chemi R77N, Ciba-Geigy, Switzerland) to cast the contralateral digits allows this alignment change to be effected. This resin has a slow and gradual curing process whereafter 16 to 18 hours, the material would have solidified but would still remain malleable, allowing bending and alignment changes.

The strength of this technique also lies in the exact duplication of the skin details of the contralateral digits with the use of silicone rubber as the impression material. The use of screws to attach the finger casts onto the cast of the stump has the benefit of allowing their orientation and lengths to be adjusted in relation to the remaining digits to conform to the contour of the hand.

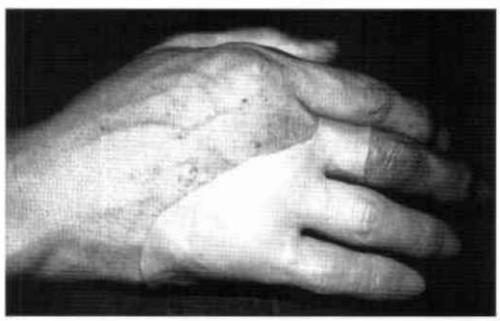


Fig. 4. The test prosthesis was trial-fitted on the patient to check the results before the final prosthesis was fabricated.

REFERENCES

ALISON A, MACKINNON SE (1992). Evaluation of digital prostheses. *J Hand Surg* **17A**, 923-926.

BUCKNER H (1992). Functional cosmetic silicone prostheses and orthoses. In: Proceedings of 7th World Congress of the International Society for Prosthetics and Orthotics, Chicago, June 28 – July 3, 1992. – Alexandria VA: ISPO. p64.

LEOW EL, KOUR AK, PEREIRA BP, PHO RWH (1996). Colourmatching in hand and finger prostheses: the Asian perspective. *Hand Surg* **1**, 37-43

LEOW EL, PEREIRA BP, KOUR AK, PHO RWH (1997). Aesthetic life-like finger and hand prostheses: prosthetic prescription and factors influencing choices. *Ann Acad Med* **26**, 834-839

O'FARRELL DA, MONTELLA BJ, BAHOR JL, LEVIN LS (1996). Long-term follow-up of 50 Duke silicone prosthetic fingers. *J Hand Surg* **21B**, 696-700.

PEREIRA BP, KOUR AK, LEOW EL, PHO RWH (1996). Benefits and use of digital prostheses. *J Hand Surg* **21A**, 222-228.

Prosthetics and Orthotics International, 1999, 23, 75–81

Technical note

Analysis of body-device interface forces in the sagittal plane for patients wearing ankle-foot orthoses

B. McHUGH

National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Glasgow, Scotland, UK

Abstract

An ankle-foot orthosis (AFO) is employed principally to treat musculoskeletal disorders of the ankle and/or subtalar joints although, occasionally, it may be prescribed to provide stance phase control of the knee. In order to function satisfactorily, an AFO must apply appropriate forces to the lower leg in a manner which does not cause local tissue damage or discomfort. Equally the leg will apply forces to the AFO which it must be capable of withstanding without breakage or loss of function. Thus it is useful to know where the body-device interface forces act during walking and to be able to estimate their magnitudes. This is not well understood and has not been satisfactorily documented. This paper explains the force actions between the AFO and the leg, in the sagittal plane, where there is absence of muscle power. Furthermore, it explores the possibility of estimating the magnitudes of these forces. It is found that the forces are greatest when orthotic assistance is needed to compensate for plantar flexor insufficiency in late stance phase. On the other hand, where the AFO is used to support the foot, in the absence of dorsiflexion power in swing phase, the forces are relatively small. Understanding these force levels is relevant to the design of the AFO in terms of choice and use of materials and components.

Introduction

The AFO may be employed to treat musculoskeletal disorders at the ankle and/or subtalar joints. In this analysis, the specific case of insufficiency of the plantar flexors and of the dorsiflexors will be considered and the analysis of forces and moments will be confined to the sagittal plane. The aim is to show that the configuration of body device interface forces can be determined and their magnitudes estimated for key points in the gait cycle (early stance phase, late stance phase and swing phase).

In analysing AFO body-device interface forces, it is important to understand the function of the AFO and this, in turn requires a knowledge of the functional deficit that the AFO is intended to correct. An AFO may be prescribed to treat one or more of a number of different pathological conditions which have been described previously (Sarno and Lehneis, 1971; Rubin and Dixon, 1973; McHugh and Campbell, 1987). It will be helpful to briefly describe the function of an AFO which is prescribed to provide assistance for two of these conditions: dorsiflexor insufficiency and plantar flexor insufficiency.

AFO function in dorsiflexor and plantar flexor insufficiency

Firstly, reduced or absent dorsiflexion power will be considered. The dorsiflexors contribute significantly to ankle joint control in swing phase and early stance phase of walking. During swing phase they exert the small dorsiflexion moment required to support the weight of the foot. In early stance, between heel strike and foot-flat they control the plantar flexion of the foot induced by the ground reaction force acting posterior to the ankle. Weakness of this muscle group can result in rapid plantar flexion in early

All correspondence to be addressed to Dr B. McHugh, National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, 131 St. James' Road, Glasgow G4 0LS, Scotland, UK.

stance phase ending with a characteristic audible foot slap. If the weakness is more marked, there may be insufficient power even to support the foot in swing phase. This leads to the danger of toe contact with the ground (drop-foot, toe-drag) and a consequent tripping hazard. If proprioceptive feedback is intact, the danger can be averted by increased knee and hip flexion during swing phase. Toe clearance could also be achieved by circumduction (swing phase abduction of the non-supporting hip), hip hiking (elevation of the pelvis and non-supporting leg during mid-stance) or vaulting (mid-stance plantar flexion of the supporting foot). In more severe cases it is likely that heel strike will be replaced by flat footed contact or even toe contact. The orthotic requirement is to support the foot in swing phase and resist (but not prevent) plantar flexion in early stance phase.

The second condition to be considered is reduced or absent plantar flexion power. One consequence of severe plantar flexor insufficiency is an inability to oppose the external dorsiflexion moment, induced by the ground reaction acting anterior to the ankle joint, during late stance phase between the instants of mid-stance and toe-off. This reduces stability and eliminates the contribution of ankle motion, at this stage, to preventing excessive lowering of the body centre of gravity. During the mid-stance phase, the role of ankle control by the plantar flexors in stabilising the knee may be replaced by knee extensor activity. An effective AFO can be of great assistance in preventing the unwanted dorsiflexion in late stance. Weakness of the plantar flexors will also result in the absence or impairment of the active plantar flexion which contributes significantly to the forward propulsion of the body during the normal push-off. An AFO is less able to provide this function but some compensation by means of increased hip extensor activity is possible.

In this analysis, total loss of dorsiflexion and plantar flexion power will be assumed. A common prescription in this instance would be an AFO which would prevent motion at the ankle joint. As a side effect, movements such as subtalar rotations may be suppressed but this is usually considered an acceptable compromise. There are alternative designs of AFO which can provide this type of control. The traditional design consists of a calf band (metal covered by leather) connected by metal bars to a robust shoe. The more modern designs include a plastic foot section which is contained within the shoe but is not attached to it. However, in a functional sense, the shoe is an essential part of the AFO and will be considered as such in this analysis. The analysis presented herein may be selectively applied to cases where there is isolated absence of plantar flexion power (affecting late stance phase) or of dorsiflexion power (affecting early stance phase and swing phase).

Force actions

When analysing the force systems which act on the patient and on the AFO, the gait cycle may be considered in two distinct phases: stance phase and swing phase. Stance phase may be subdivided into early stance and late stance although, as will be seen, the method of analysis for these is essentially the same.

Early stance phase

During stance phase (Fig. 1), the ground reaction force, R, is equal and opposite to the force denoted by B which is a combination of body weight and body inertia force. The ground reaction force exerts a moment about the ankle joint (Fig. 2) equal to $(R * a)$ where a is the perpendicular distance from the ankle joint to the line of action of the force R. The moment about the ankle due to the ground reaction is normally opposed by muscle action. If the muscle force is F_D, and the perpendicular

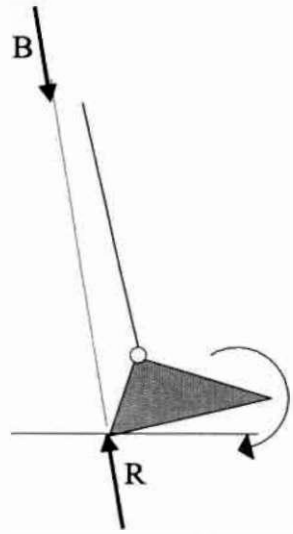


Fig. 1. The ground reaction force R is equal and opposite to body weight and inertial effects B in stance phase.

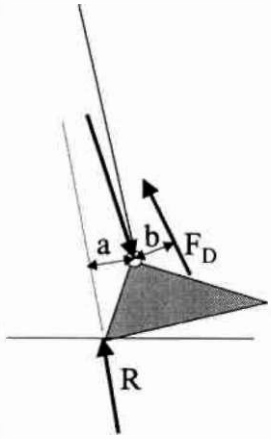


Fig. 2. Forces acting on the foot in early stance phase with normal muscle activity.

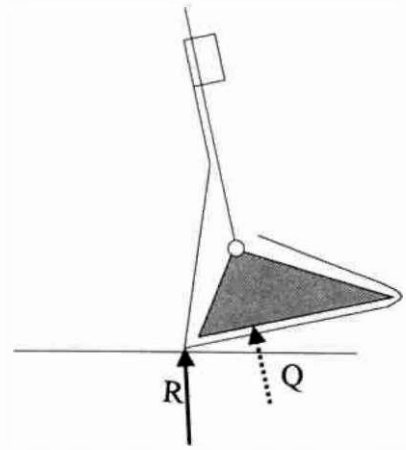


Fig. 3. In the absence of muscle activity, the support force Q applied to the plantar surface of the foot by the AFO will act through the ankle joint.

distance from the ankle to the line of action of the muscle force is b, then the moment exerted by the muscle is $(F_D * b)$. If the foot is stationary, or travelling with constant velocity, the moments acting about the ankle joint are in equilibrium, and thus $(F_D*b) = (R*a)$.

If there is muscular insufficiency such that $(F_D*b) < (R*a)$, this will cause the foot to accelerate and produce the aforementioned audible slap. The weight of the foot makes a small contribution to the plantar flexion moment but in stance phase this may be considered to be negligible, compared with the ground reaction force, and will be ignored in this analysis. If an AFO is used to compensate for dorsiflexor insufficiency, the ground reaction force, in early stance phase, acts directly on the heel of the AFO. The AFO, in turn, exerts a supporting force Q on the foot (Fig. 3). If this force were to act posterior to the ankle joint, the foot would plantar flex involuntarily (since it has no dorsiflexion power) until it reached a position in which there was no plantar flexion moment; that is, the force Q would move forwards until it acted directly through the ankle joint. The precise orientation of the force Q can be determined by further analysis. Since every action has an equal and opposite reaction, a force equal to Q is applied by the foot to the AFO as shown in Figure 4. The AFO would plantar flex were it not for the calf section which experiences the proximal force P. If inertial effects (related to acceleration) are considered to be negligible, then the AFO may be assumed to be in equilibrium. In this case, the forces P, Q and R must satisfy the following criteria:

(i) they must be concurrent (all meet at one point);
(ii) when they are drawn as vectors, head to tail, in any sequence, they must form a closed triangle;
(iii) their components, in any direction, must sum to zero;
(iv) their moments about any point must sum to zero.

The first criterion allows the line of action of force Q to be drawn more precisely since two points through which it must pass (the ankle

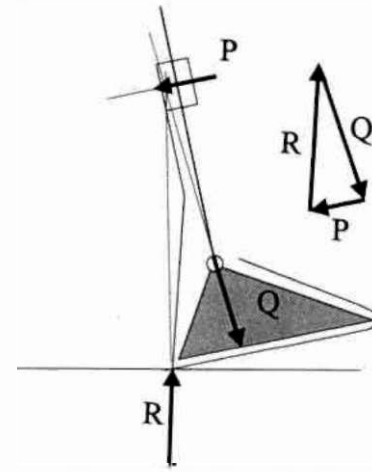


Fig. 4. Forces acting on AFO during early stance phase in the absence of muscle power about the ankle joint.

joint and the intersection of R and P) are known. There are several different ways to proceed with the analysis. The method presented here entails drawing a vector triangle as follows.

(i) Draw a vector representing R (magnitude, line of action and direction known) using an appropriate scale (for example 10mm: 200N).
(ii) From one end of vector R draw a line parallel to force P.
(iii) From the other end of R, draw a line parallel to force Q.
(iv) These lines form a triangle. The lengths of the sides representing P and Q are measured and the forces are calculated using the scale originally used to draw vector R.

Late stance phase

So far, a method for estimating body device interface forces during early stance phase has been described. However the same approach can be used for late stance phase.

The large dorsiflexion moment which occurs between heel-off and toe-off is normally opposed by the gastrocnemius and soleus, which act powerfully though the Achilles tendon (force F_P in Figure 5). Moreover these muscles are capable of producing the active plantar flexion which occurs during this phase. In the absence of plantar flexion power, an orthosis may be prescribed to prevent dorsiflexion. The ground reaction force is borne by the anterior portion of the AFO footplate as seen in Figure 6. It cannot be transferred to the metatarsal heads because, in the absence of plantar flexion power, the foot

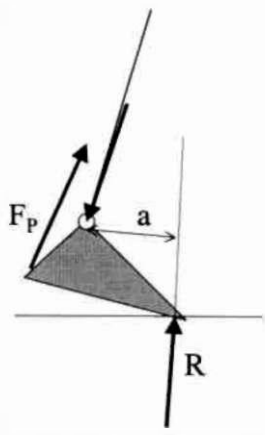


Fig. 5. Forces acting on the foot in the late stance phase.

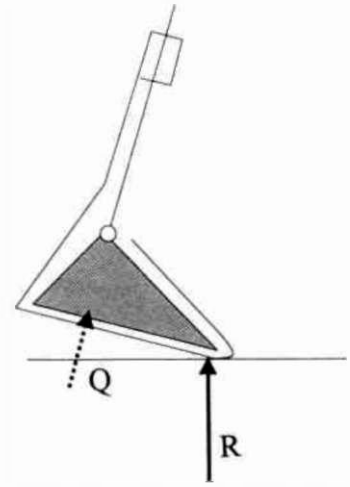


Fig. 6. In the absence of muscle activity, the support force Q applied to the plantar surface of the foot by the AFO will act through the ankle joint.

would passively dorsiflex until the line of action of the force Q between the AFO and the foot passed through the ankle joint. Using the same method as described above, for lack of dorsiflexion power in early stance phase, the body device forces can be estimated as indicated in Figure 7.

It is valid to treat each body-device force as a vector acting at a single point in a force analysis of the kind presented here. However, it must be recognised that, in reality, each force would be distributed over an area which should be large

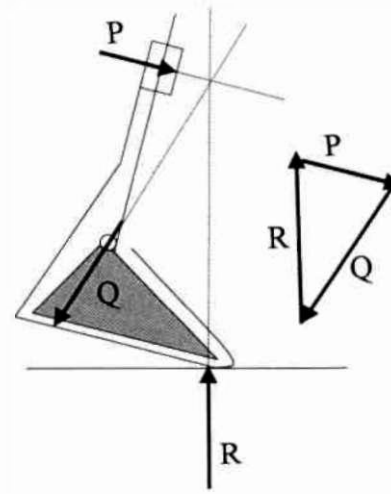


Fig. 7. Forces acting on AFO in late stance phase in the absence of plantar flexion power.

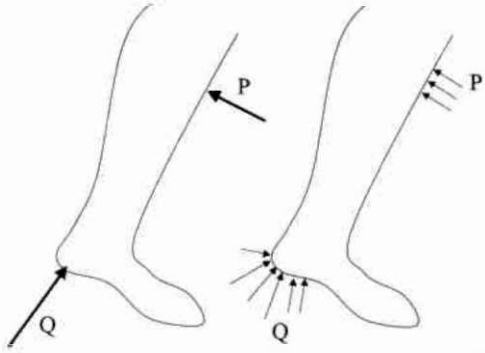


Fig. 8. A force should not act at a single point. It should be distributed over a sufficient area to give an acceptable pressure level.

enough to avoid excessive pressure as, for example, indicated in Figure 8. The precise manner in which each force is distributed is dependent on the way the orthotist shapes the orthosis in the location of that force.

Swing phase

In normal swing phase (Fig. 9), the foot exerts a plantar flexion moment *(W*x)* due to its weight *W* effectively acting through its centre of mass at a distance *x* anterior to the ankle joint. This is counteracted by the dorsiflexors which produce an equal and opposite moment. If dorsiflexion power is lacking, the foot will plantar flex and there will be a risk of tripping. If an AFO is fitted, and the foot attempts to plantar flex contact will occur between the body and the orthosis at the points indicated in Figure 10. The force applied by the AFO to the leg are shown in Figure 11. The foot will apply a downward force

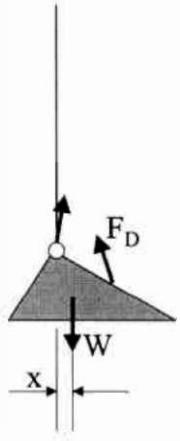


Fig. 9. Forces acting on the foot in normal swing phase.

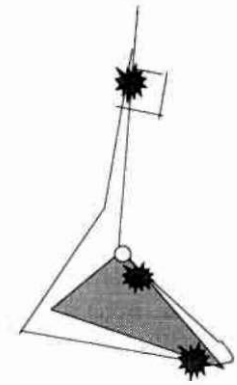


Fig. 10. Body-device contact points as the foot plantar flexes inside an AFO during swing phase. The AFO is shown larger that the foot for the purpose of illustration.

Q on the AFO in the forefoot region and downward motion of the orthosis will be prevented by a force *S* exerted by the dorsal surface of the foot. As the foot and AFO try to plantar flex, the force *P*, acting in the posterior proximal zone provides a moment *(P*c)* about the ankle which counteracts the plantar flexion moment *(W*x)* due to the weight of the foot. The three forces *P*, *Q* and *S* are in equilibrium and thus can be estimated by means of a vector triangle as shown in Figure 11. To achieve this it is helpful to calculate force *P* from the fact that *(P*c)=(W*x)*. Then the vector *P* can be drawn and lines parallel to *Q* and *S* added at either end of it to form a vector triangle. Again, it must be emphasised that the orthotist determines the precise manner in which these forces are distributed by the shaping of the AFO in the vicinity of each force.

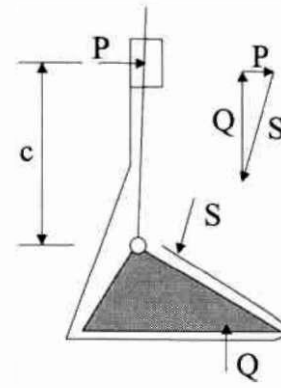


Fig. 11. Force system applied by AFO to body to compensate for dorsiflexor insufficiency in swing phase.

Effect of location of proximal force *P* on its magnitude

It should be noted that, if the aim was to determine only the proximal force *P* in stance or swing phase this could be found relatively easily as shown in the previous paragraph. The force *P* must exert a moment about the ankle joint equal to the external moment M_E due to the ground reaction force in stance phase or the weight of the foot in swing phase. If *P* acts at a distance *c* from the ankle joint, then, summing moments about the ankle gives $(P*c=M_E)$. This shows that, for a given external moment, the further the force *P* is from the ankle, the smaller its magnitude will be.

Magnitudes of ankle moments and design of AFO

As an approximate order of magnitude, the ankle moments, due to the ground reaction, in early and late stance phases are 10Nm and 100Nm respectively. In swing phase the moment, due to the weight of the foot, is less than 1Nm. This is relevant to the design of the AFO. In the case of dorsiflexor insufficiency, the AFO must be able to prevent plantar flexion during swing phase when the moment is 1Nm and permit controlled plantar flexion in early stance phase when the moment is around 10Nm. Where there is an absence of plantar flexion power, the AFO must oppose an ankle moment during push-off, of the order of 100Nm with minimal deformation. Thus an AFO, which compensates for lack of plantar flexion power in late stance phase, must be considerably more rigid than one which is prescribed for dorsiflexor insufficiency in early stance and swing phase. Since the ankle moment to be controlled in late stance, in the case of dorsiflexor insufficiency, is of the order of 100Nm, the correspondingly large proximal orthotic force may present problems at this stage in the gait cycle and requires careful design of the proximal body-device interface.

Effects of spasticity

The foregoing analysis does not take account of the possible presence of inappropriate muscle action related to spasticity. If this occurs during swing phase, due to contraction of the plantar flexors, the resulting force configuration is the same as that shown in Figure 11 for dorsiflexor insufficiency. However, the force magnitudes would be greater depending on the intensity of muscle contraction and it may be noted the calf muscles are clearly capable of producing ankle moments of the order of 100Nm in late stance phase. Thus, if they were to produce a comparable moment in swing phase, it is possible that the body-device force levels could be as much as two orders of magnitude greater than those experienced in the case of absence of muscle power. In reality, the force levels would depend on the severity of the spasticity and should be reflected in the rigidity of the prescribed AFO. During early stance phase the situation would differ from that described above for lack of muscle power. The force *Q* would no longer act through the ankle joint, but would be displaced anteriorly such that its moment about the ankle balanced that due to the force through the Achilles tendon. The proximal force *P*, acting during early stance phase, would be greater than that estimated for the case of absence of muscle power. This is because it must provide the additional ankle moment required to oppose the plantar flexion moment caused by spasticity.

Conclusions

Where an AFO is prescribed to compensate for dorsiflexor and/or plantar flexor insufficiency, the configuration of the body-device interface forces can be determined for any specified point in the gait cycle.

It is possible to estimate the body-device interface forces acting throughout the gait cycle for a person wearing an AFO to compensate for muscular insufficiency, if the configuration of the orthosis and the ground reaction force are known. These body-device interface forces are found to be greatest in late stance phase and least in swing phase.

The distribution of each force cannot be predicted theoretically without precise knowledge of the geometry and mechanical properties of the body-device interface. Each force may be distributed over an area or split into two or more equivalent components which may themselves be distributed in their respective locations.

The ankle joint moments to be controlled by an AFO vary greatly throughout the gait cycle and it is important to identify clearly those periods during the gait cycle orthotic assistance

is required before deciding on the structure of the AFO.

The presence of spasticity can increase force levels by an amount which depends on its severity.

The magnitude of the proximal orthotic force is inversely proportional to its distance from the ankle joint and proportional to the magnitude of the ankle moment which it is required to control.

REFERENCES

McHUGH B, CAMPBELL JC (1987). Below-knee orthoses. *Physiotherapy* **73**, 380-385.

RUBIN G, DIXON M (1973). The modern ankle-foot orthoses. *Bull Prosthet Res* **10 (19)**, 20-41.

SARNO JE, LEHNEIS HR (1971). Prescription considerations for plastic below-knee orthoses: a system for prescription. *Arch Phys Med Rehabil* **52**, 503-510.

Prosthetics and Orthotics International, 1999, 23, 82–84

Technical note

Use of a gas spring contracture correction orthosis for the management of a fixed flexion contracture of the elbow

P. KEEPING* and R. MAJOR**

**Department of Orthotics, The Robert Jones and Agnes Hunt Orthopaedic and District Hospital NHS Trust, Oswestry, Shropshire, UK*
***Orthotic Research and Locomotor Assessment Unit (ORLAU), The Robert Jones and Agnes Hunt Orthopaedic and District Hospital NHS Trust, Oswestry, Shropshire, UK*

Abstract

This paper describes the application of low level controlled torque to an elbow contracture through the use of an active orthosis. Over a period of twenty months the lack of elbow extension range was reduced from 105 degrees to 57 degrees. A description of the important orthotic design factors which led to significant functional improvement is provided.

Introduction

The use of gas springs incorporated into an orthosis in order to augment conventional stretching of hips and knees by physiotherapy has been reported previously (Moore *et al.*, 1990). One advantage of using adjustable gas springs is that the active torque can be closely controlled to match the clinical need. Other applications of dynamic or lively orthoses have been described (Chalmers and Hamer, 1985; Parker, 1987; Nuismer *et al.*, 1997) but in general the correcting torques are not noted. This is not surprising given that the use of elasticated members does not lend itself to precise settings and these settings change rapidly as soft tissue deformation takes place in a viscoelastic manner (Nordin and Frankel, 1980; Moore *et al.*, 1990). The general impression is that most systems are tensioned so as to provide the highest correcting force consistent with comfort and safety. This paper describes the application of a gas spring orthosis where torques needed to be restricted to very low values in order to cope with clinical conditions and reports on the outcome

All correspondence to be addressed to Richard Major, Head of Bioengineering, Regional Medical Physics Department, Newcastle General Hospital, Newcastle Upon Tyne, NE4 6BE, UK.

Patient and method

A female patient, in her mid-twenties, with an elbow contracture which had persistently failed to respond to conventional treatment was keen to co-operate with the examination of the effectiveness of a gas spring orthosis. The patient, suffering from a recurrent bilateral shoulder dislocation, had bilateral capsular reefing undertaken within the shoulder joints and, following this surgery and the rest period afterwards, had developed bilateral elbow contractures. Her left elbow had been very successfully straightened by routine physiotherapy. The right elbow, however, had failed to respond to this treatment and the patient was left with a range of motion which allowed her full flexion, but with extension lacking 105°. The restricted range prevented her from carrying out many tasks of daily living including ironing and tying shoelaces. Her referring orthopaedic consultant confirmed the suspicion that the restraint was due to soft tissue problems as opposed to bony deformity and that orthotic stretching could be applied. The main objective was to improve function by increasing the range of elbow motion through orthotic intervention.

Design criteria for the orthotic device included the need for the patient to apply the orthosis herself with one hand; that the forces applied through the orthosis must be tolerable and that it must be possible for these to be overridden so that any discomfort could be alleviated through

voluntary flexion of the elbow. Given that the cause of the initial shoulder problem was unknown it was decided that any applied correcting torque should be kept to a minimum.

The orthosis was constructed from above elbow and below elbow sections moulded in polypropylene lined with three millimetre "Evazote". The fastenings were "Velcro" through ring and return, and the above elbow and below elbow sections were joined by a single lateral stem with a freely hinged joint. The gas spring incorporated a pressure relief valve to allow precise setting of the restoring moment. To prevent the orthosis from fully extending when not being worn a strap to hold it in the flexed position was incorporated. Thus the donning procedure was as follows:

1. offer the orthosis to the arm;
2. apply the fasteners;
3. slightly flex the elbow to remove tension from the strap;
4. release the strap and relax the flexors to allow the desired function.

Doffing the orthosis was the reverse of this procedure.

The elbow extension torque which could be applied by the device and still be voluntarily overridden was recorded using a simple myometer with the force applied through a measured moment arm. This was used in determining the correct setting of the gas spring combined with the moment arm acceptable within the orthotic design. It was decided, with the aid of the myometer, that it would be safe to apply a corrective moment produced by a force of 10N applied at a distance of 200mm from the elbow joint (2Nm) and that this could actively be overcome by the patient's flexors. These figures were then designed into the orthosis and a force of 100N acting through a moment arm of 20mm resulted in an appropriate orthotic solution. It should be noted that the force applied to the upper and lower arm was distributed by the moulded sections.

After a period of becoming accustomed to the system the patient self-administered the treatment on a daily basis, wearing the device for most of the day. The available elbow extension range was monitored over a 20-month period.

Results

Attempts were made to review the subject on a regular basis but lifestyle limitations prevented this from taking place. Thus measurements of the elbow contracture were recorded on an irregular basis. The range of movement, shown in Figure 1, shows that initially full extension was reduced by 105° and during the first two months no improvement was noticed. When seen at month three it was found that the reduced extension had moved from 105° to 82°. This figure continued to improve to 78° at month four, but then increased over the next three months to 90°. Continued use of the orthosis led

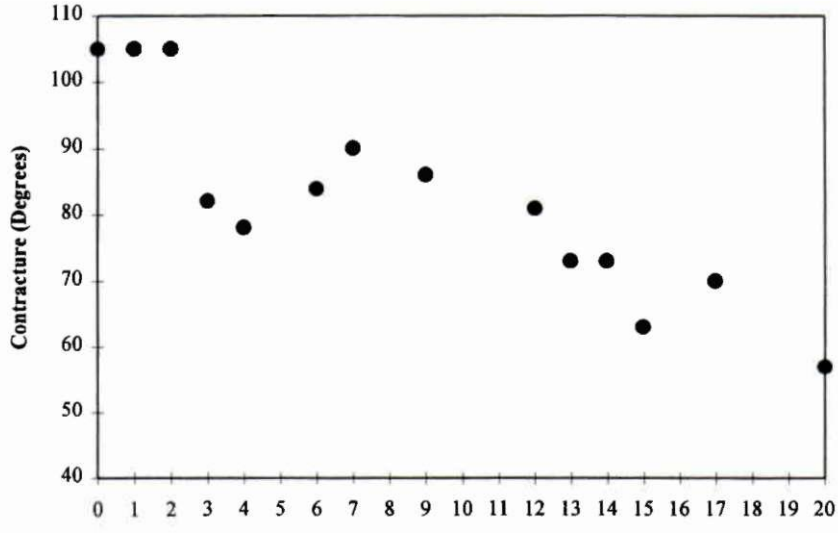


Fig. 1. Right elbow contracture results

to a range restriction of 57° at 20 months when many of the desired functions were achievable.

With regard to restoration of function the patient is now able to lift her young son from the floor; tie her own shoe laces and undertake a range domestic tasks, including ironing, all of which she had previously been unable to do. She has found these activities extremely important to her lifestyle and continues to use the device in the hope of achieving yet further improvement in her condition.

Discussion

The successful outcome of this intervention is quite surprising given the very low torque applied by the orthosis. This orthotic solution was only attempted since other conservative methods had failed and the clinic team was not very optimistic. Indeed with no change after two months use the decision had been taken to withdraw the orthosis if no change was seen by month three. The improvement at month three continued until the available range started to decrease for a period. On discussion with the patient, this was thought to be due to the fact that she was then in the late stages of pregnancy and found the orthosis rather tiring and unhelpful. After the birth of her child she continued once more to wear the orthosis and the improvement shown is clearly visible.

The extension of this technique to other conditions must be approached with caution since the original aetiology is unknown but the results are encouraging and suggest there is merit in using low torque devices where the action can be carefully controlled. An important implication of this work is that low torque applied in a consistent manner may be able to achieve correction of intransigent contractures. It therefore suggests that it may be possible to apply the techniques at the ankle.

Acknowledgements

The authors wish to thank all their clinical and research colleagues who helped and encouraged this work.

REFERENCES

CHALMERS DD, HAMER GP (1985). Three point dynamic orthosis. *Prosthet Orthot Int* **9**, 115-116

MOORE P, MAJOR RE, STALLARD J, BUTLER PB (1990). Contracture correction device for arthrogryposis *Physiotherapy* **76**, 303-305.

NORDIN M, FRANKEL VH (1980). Basic biomechanics of the musculoskeletal system./2nd edition. – Pennsylvania: Lea & Febiger.

NUISMER BA, EKES AM, HOLM MB (1997). The use of low-load prolonged stretch devices in rehabilitation programmes in the Pacific Northwest. *Amer J Occup Ther* **51**, 538-543.

PARKER BC (1987). A dynamic elbow extension splint. *Am J Occup Ther* **41**, 825-826.

Calendar of Events

17-19 May, 1999
Annual Meeting of the Pediatric Orthopaedic Society of North America, Orlando, USA.
Information: POSNA, 6300 North River Road, Suite 727, Rosemont, IL 60018, USA.

26-28 May, 1999
11th European Congress of Physical Medicine and Rehabilitation, Gothenburg, Sweden.
Information: Gunnar Grimby, Kongresshuset AB, Massans gata 14, 4 tr, S-41251 Gothenburg, Sweden.

18-20 June, 1999
38th Annual Scientific Meeting of the International Medical Society of Paraplegia, Copenhagen, Denmark.
Information: Congress Secretariat, Fysiurgisk Hospital, Havnevej 25, DK-3100 Hornbaek, Denmark.

21-25 June, 1999
26th Annual Meeting of the International Society for the Study of the Lumbar Spine, Hawaii, USA.
Information: Dr. E. Hanley, Secretary, ISSLS, Sunnybrook Health Science Centre, Room A 401, 2075 Bayview Avenue, Toronto, Canada, M4N 3MS.

24-26 June, 1999
25th Canadian Medical and Biological Engineering Conference, Ontario, Canada.
Information: CMBEC Secretariat, c/o National Research Council of Canada, Bldg M-55, Rm 382, Ottawa, ON K1A 0R8, Canada.

3-6 July, 1999
33rd Annual Meeting of the Canadian Orthopaedic Research Society, Newfoundland, Canada.
Information: CORS, 1440 O.Ste.-Catherine W., Suite 320, Montreal, Quebec H3G 1R8, Canada.

14-17 July, 1999
14th INTERBOR World Congress, Boston, USA.
Information: AOPA, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

8-13 August, 1999
17th Congress of the International Society of Biomechanics, Calgary, Canada.
Information: Secretary General, 1999 ISB Congress, Faculty of Kinesiology, University of Calgary, 2500 University Drive N.W. Calgary, Alberta T2N 1N4, Canada.

12-15 September, 1999
4th Asian-Pacific Conference of Medical and Biological Engineering, Seoul, Korea.
Information: Sun I. Kim, Secretary General APCMBE 99, Dept. of Biomedical Engineering, Graduate School Hanyang University,17 Heungdang-dong, Sungdong-ku, Seoul 133-791,Korea.

6-9 October, 1999
AOPA National Assembly, Nevada, USA.
Information: AOPA, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

7-8 October, 1999
14th Annual Meeting of the Japanese Orthopaedic Association, Nara City, Japan.
Information: Susumu Tamai MD., Congress President, Dept. of Orthopaedic Surgery, Nara Medical University, Kashihara, Nara 634-8522, Japan.

14-17 October, 1999
76th Annual Meeting of the American Congress of Rehabilitation Medicine, Orlando, USA.
Information: ACRM, 4700 W Lake Ave., Glenview, IL 60025-1485, USA.

20-23 October, 1999
14th Annual Meeting of the North American Spine Society, Chicago, USA.
Information: The North American Spine Society, 6300 North River Road, Suite 500, Rosemont, IL 60018-4231, USA.

11-14 November, 1999
13th World Congress of the International Federation of Physical Medicine and Rehabilitation, Washington, USA.
Information: AAPM&R, One IBM Plaza, Suite 2500, Chicago, Il 60611-3604, USA.

2000
15-18 March, 2000
American Academy of Orthotists and Prosthetists Annual Meeting, San Diego, USA.
Information: AAOP, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

15-19 March, 2000
American Academy of Orthopaedic Surgeons Annual Meeting, Orlando, USA.
Information: AAOS, 6300 North River Road, Suite 727, Rosemont, IL 60018, USA.

1-4 May, 2000
Annual Meeting of the Pediatric Orthopaedic Society of North America, Vancouver, Canada.
Information: POSNA, 6300 North River Road, Suite 727, Rosemont, IL 60018, USA.

30 May -2 June, 2000
Orthopädie + Reha-Technik, Trade Fair and Congress, Leipzig, Germany.
Information: B. Wünschmann, Bundesinnungsverband für Orthopädie-Technik (BIV).
Fax: +49(0)231/55 70 50-70 E-mail: info@ot-forum.de Internet: www.ot-forum.de

1 June -31 October, 2000
Health Futures, Expo 2000, Hanover, Germany.
Information: Ms. Monika Gehner, Office of the Director, Division of Health Promotion, Education and Communication, World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland.

3-7 October, 2000
American Orthotic and Prosthetic Association Annual Assembly, Washington, USA.
Information: AOPA, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

2001
1-5 July, 2001
10th World Congress of the International Society of Prosthetics and Orthotics, Glasgow, Scotland.
Information: ISPO Congress Secretariat, c/o Meeting Makers, Jordanhill Campus, 76 Southbrae Drive, Glasgow G13 1PP,Scotland. Tel: +44 (0) 141 434 1500. Fax: +44 (0) 141 434 1519. E-mail: ispo@meetingmakers.co.uk