The Journal of the International Society for Prosthetics and Orthotics

Prosthetics and Orthotics International

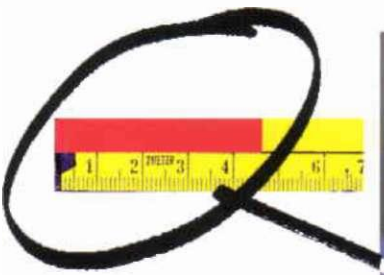
April 1998, Vol. 22, No. 1

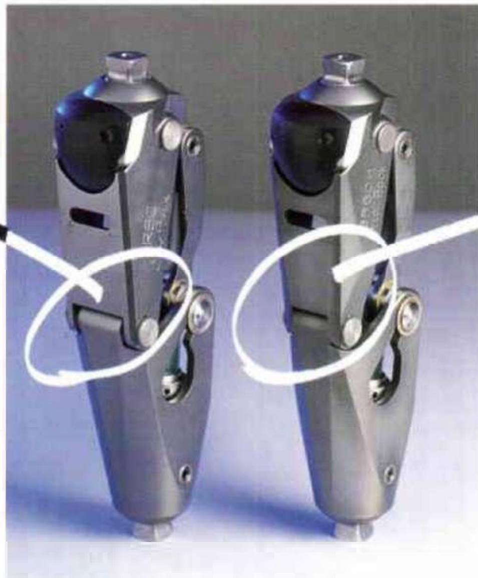
Otto Bock

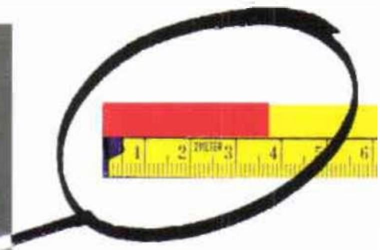
ORTHOPÄDISCHE INDUSTRIE

Natural Walking. With Stability.

3R60 and 3R60=1

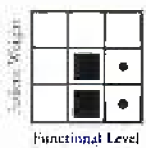






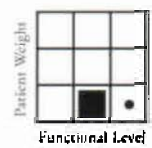
47 mm

up to 100 kg (220 lbs.)



37 mm

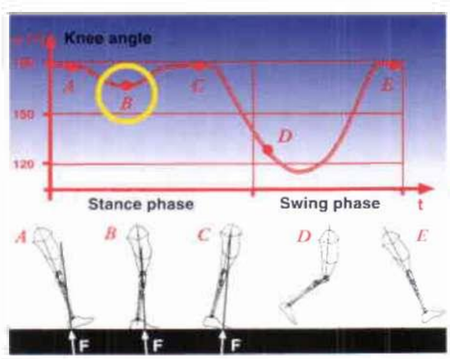
up to 75 kg (165 lbs.)



Though individuals are different, their demands for comfortable walking are equally important. Therefore, Otto Bock offers a **slightly smaller design** of the **successful Otto Bock 3R60 EBS Knee Joint**: the **3R60=1**. The **swing phase hydraulic** unit is specially designed for use by individuals weighing up to 75 kg with a moderate activity level. The **unique stance flexion feature** of the patented EBS Knee Joint offers a more comfortable heel strike and actually increases knee stability during initial flexion. Another advantage of this knee is the generous **knee flexion angle** of 150°. **3R60 and 3R60=1**: natural walking, more comfort and dependable security.

The stance flexion feature provides for more comfort due to controlled knee flexion (phase B) of between 8 - 12 degrees following heel strike. This feature improves knee stability and increases comfort during walking while providing a more natural gait pattern.

EBS = Ergonomically Balanced Stride
F = Force; Ground Reaction Force



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Prosthetics and Orthotics International

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The Journal of the International Society for Prosthetics and Orthotics

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ISPO

Elected Members of Executive Board:

S. Sawamura (President)	Japan
N. A. Jacobs (President-Elect)	UK
D. N. Condie (Vice-President)	UK
H. G. Shangali (Vice-President)	Tanzania
G. Fitzlaff (Member)	Germany
J. Halcrow (Member)	Australia
B. M. Persson (Member)	Sweden
C. M. Schuch (Member)	USA
M. L. Stills (Immediate Past President)	USA
J. Steen Jensen (Hon. Treasurer)	Denmark
B. McHugh (Hon Secretary)	UK

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M. L. Stills (Protocol and Nominations)	USA
N. A. Jacobs (Congress, Membership)	UK
J. Hughes (Education)	UK
S. Heim (Education in Developing Countries)	Germany
M. Schuch (Certification)	USA
G. Fitzlaff (Publications)	Germany
D. N. Condie (Standards)	UK
M. Ellis (ICTA, Consumer Affairs)	UK
B. Klasson (Quality Management)	Sweden
D. Jones (Information Exchange)	UK

Consultants to the Executive Board

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R. Massaro (IVO)	Netherlands
J. Ebbink (Interbor)	Netherlands
G. Neff/H. Watts (WOC)	Germany
T. Lagerwall (RI/ICTA)	Sweden
T. Verhoeff (ICRC)	Switzerland
H. R. Lehneis (WRF)	USA
T. J. Supan (ABC)	USA

International Consultants to the Executive Board:

C. Marincek and E. van Laar	Central and Eastern Europe
J. Craig, R. Jované, J. Gomez, J. Martina, D. E. Suarez and C. Schiappacasse	Central and South America
S. Sawamura and E. Tazawa	Pan Pacific
K. Abadi and M. A. A. El-Banna	Middle East
H. Shangali	Africa
A. Von der Borch	Pacific Rim

Chairmen of National Member Societies:

Argentina	O. P. Ruiz	Iran	B. Savee
Australia	J. Halcrow	Israel	M. Azaria
Austria	A. Murri	Japan	S. Sawamura
Belgium	E. Deschoolmeester	Korea	J. S. Shin
Canada	G. Martel	Netherlands	J. H. B. Geertzen
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India	TBA	USA	T. J. Supan

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

Secretary

Aase Larsson	Denmark

Editorial

The fiscal year, 1997, again ended with a profit, and the President, Seishi Sawamura, can look back on a triennium that added more than 2.2 million DKK to the Society's assets. This has been possible, in spite of a high activity level, only through successful capital gain. The interest rate in 1997 has been low in Denmark, which influenced the market value for bonds and securities. The Executive Board through the Finance Committee continuously monitors the market to secure a maximised outcome with the minimum risk of losing on the market rate of the bonds.

The Executive Board has strived in the past to run the Society, on the income from membership fees i.e. using the fees to meet the Administration and Publications costs. The Board has successfully managed to accomplish this over the past two triennia (Table 1), apart from 1995, in spite of the rather costly educational activities and the Interim Meetings of the International Committee. In Congress years three meetings of the Executive Board are required. The costs of running the Secretariat have been fairly constant. In 1997 ISPO published the first issue of the Information Package on Education of the Category II Professional, the Orthopaedic Technologist, and the work is continuing on a similar description for the Category I Professional, the Prosthetist-Orthotist.

The income from membership has been rather constant over more than 8 years. From 1998 it will be necessary to collect membership fees from the National Member Societies before the end of March in order to ensure an adequate cash flow for the daily operations, and the Journal.

The Society has made a considerable investment in the Professional Register. It has sent out trial application / membership forms to UK and Germany to test out the function before block mailings to the membership at large.

The big cost item for 1997 was the Consensus Conference on the Treatment of Poliomyelitis. Financial support from external sources was limited, but the topic was deemed to be sufficiently important to warrant the magnitude of the costs. The conference turned out successfully with exchange of experiences from both the industrialised and the developing world leading to important agreements about treatment programmes to the benefit of the many polio victims. Another course on Lower Limb Amputation Surgery, Prosthetics and Rehabilitation for the Developing World took place in Jaipur, India. After two courses in two years in India the membership has increased there considerably, and the National Member Society is under reconstruction to meet new goals and objectives. These two activities could just about be financed through the capital yield of the year. The revenue of the Society's could cover one consensus conference every triennium, and at least one course yearly in the developing world. A further two courses, giving profit, took place in Helsingborg, Sweden on Lower Limb Amputations; and in Toronto, Canada on Cerebral Palsy.

ISPO has over the years spent a handsome sum of money on the Journal, Prosthetics and Orthotics International, which has become established as one of a few on the world scene devoted to prosthetics, orthotics, and treatment of the severely disabled. Thanks to the efforts of the Editors the number of advertisers have increased markedly over the past couple of years, making the Journal an income generator for the Society.

The Society has over the past 6 years used significant funds on promotion of the Society and the Journal without visible effect on the membership or subscription, but beyond any doubt adding significantly to the credibility of the Society, as has truly also been the outcome of the expenses for liaison with international agencies and organisations.

The Society has moved office facilities within the house of SAHVA, and has now entered into a formal rental agreement with SAHVA. The Board is happy to announce the continuous support from SAHVA, which has decided to let its companies underwrite the rental costs for 1997, and it looks forward to the continual collaboration with mutual benefits. The Society also acknowledges the financial contributions from all its sponsoring members.

ISPO still has only one employee, Aase Larsson, who has served the Society loyally and faithfully

Table 1.

	1992	1993	1994	1995	1996	1997
Income	1,207,374	1,077,166	1,077,862	1,080,030	1,080,645	1,140,970
– members	1,151,504	1,045,108	1,050,147	1,055,700	1,053,760	1,125,970
– sponsors	55,870	32,058	27,715	24,330	26,885	15,000
Education Committee	0	0	0	-21,298	-16,431	-30,821
Meetings, Other Organisations	-195,948	-220,534	-137,955	-17,648	-99.143	-2,756
Conf., Workshops	-9,372	-12,983	-196,828	0	0	-645,310
Courses	114,642	-54,982	-273,949	-46,115	-187,026	-132,243
Congresses	1,521,233	466,355	-59,747	346,399	315,011	0
POI Journal	-72,504	-90,645	-3,648	4,493	54,111	137,649
– income	456,250	487,387	576,528	600,378	751,081	896,408
– expenses	-528,754	-578,032	-580,176	-595,885	-696,970	-758,759
Professional Register	0	-9,293	0	-25,067	-146,138	-101,167
Publications	-29,880	-22,391	-38,118	-2,940	13,868	7,365
– income	28,120	21,644	844	1,121	26,746	7,365
– expenses	-58,000	-44,035	-38.962	-4,061	-12,878	0
Activity Result	2,535,045	1,091,342	347,386	1,342,920	1,218,512	368,086
Administration	-854,293	-864,659	-1,049,634	-1,287,383	-924,962	-955,431
– secretariat	-543,301	-515,687	549,019	-544,744	-493,336	-541,646
– board	-304,512	-307,621	-247,865	-715,570	-365,910	-274,934
– meeting expenses	-6,480	0	-22,206	-22,686	-26,495	-14,231
– society promotion	0	-41,351	-45,255	-4,383	-37,221	-1,964
– international comm.	0	0	-185,289	0	0	-122,456
Primary result	1,680,752	268,034	-656,993	30,470	147,412	-585,381
Capital Yield	412,633	614,754	-373,032	1,106,112	722,982	853,957
– interest, maturity yield	419,025	614,754	438,275	412,964	495,302	715,538
– changes in value	-6.392	0	-811,307	693,148	227,680	138,419
Years Result	2,093,385	882,788	-1,030,026	1,136,581	870,394	268,576
Assets	6,215.429	7,029,128	6,037,788	7,103,168	8,064,208	8,371,682
Fees-Daily Operation	267,331	158,058	-37,605	-234,623	142,666	177,904
Fees-Daily Op-Prof Reg	267,331	148,765	-37,605	-259,690	-3,472	76,737
Fees+ Sponsors-Daily Op	323,201	180,823	-9,690	-235,360	23,413	91,737
Cap. Yld-Int. Act -Courses	321,955	326,255	-981,764	1,042,349	436,813	73,648

since its start. We thank her for another year of hard work with implementation of continuously new working procedures.

However, the function of the Society is totally dependant on the invaluable work by its officers and the members of the Executive Board. The Society directs its gratitude to their employers for their continuous support, sometimes allowing for a work load beyond that which could be expected from elected officers of a professional society. Without their continuing support the smooth running of the Society would be at risk.

H. C. Thyregod, *Chairman of the Finance Committee*
J. Steen Jensen, *Honorary Treasurer*

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ISPO Statement of Accounts, 1997

AUDITORS REPORT

We have audited the financial statement as of December 31, 1997 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 association as of December 31, 1997, and of the result for the year.

January 10, 1998

RevisionsGruppen A/S

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 market value at year end.

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 1997

SUMMARY	**1997 DKK**	**1996 DKK**
Society membership fees (note 1)	1.125.970	1.053.760
Sponsorship (note 2)	15.000	26.885
Meetings in other organisations (note 3)	(33.141)	(117.323)
Conferences, courses etc (note 4)	(777.553)	178.849
Prosthetics and Orthotics International (note 5)	137.649	(70.888)
Publications (note 6)	7.365	22.236
Result of Activities	475.290	1.093.518
Administrative expenses (note 7)	(1.060.671)	(946.106)
Primary Result	(585.381)	147.412
Interest	422.908	476.833
Dividend	1.504	1.504
Change in market value of securities	291.126	227.680
Exchange rate variance	138.419	16.966
Financial Income	853.957	722.983
Net Income (loss)	268.576	870.395

Balance Sheet as of December 31, 1997

	1997 DKK	1996 DKK
Cash	354.783	650.118
Accrued interest	106.753	93.816
Advertising receivable	294.770	141.171
Prepayment, World Congress Amsterdam 1998	443.088	433.245
Prepayment World Congress Glasgow 2001	131.331	0
Miscellaneous receivables	87.599	0
Other prepaid expenses	12.940	0
Receivables	1.076.481	668.232
Securities (note 9)	6.924.071	6.716.512
Office Equipment (note 8)	16.347	29.347
Total Assets	8.371.682	8.064.209
Liabilities		
Accrued expenses	370.759	184.054
Accrued printing cost	0	153.000
Prepaid membership fees	0	18.273
Prepaid subscription income	83.055	59.590
Short-term liabilities	453.814	414.917
Equity		
Equity January 1.	7.649.292	6.778.897
Net result	268.576	870.395
Equity December 31	7.917.868	7.649.292
Liabilities and capital	8.371.682	8.064.209

Notes to the Financial Statements

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

2. Sponsorship

Contribution from:		
The War Amputations of Canada	0	26.885
SAHVA	15.000	0
	15.000	26.885

	1997	1996
3. Meetings in other organisations		
Education Committee	(30.385)	(46.703)
Certification	0	(16.431)
WHO Geneva	0	(7.053)
World Orthopaedic Concern	0	(5.514)
Hungary	0	(1.750)
Wuhan/GTZ/DSE	0	(17.495)
RI-ICTA	0	(19.386)
IVO	0	(2.992)
Miscellaneous	(2.756)	0
Expenses	(34.141)	(117.323)
4. Conferences, courses etc.		
World Congress	0	315.011
Consensus Conferences		
Appropriate Technology	0	57.477
Cerebral Palsy	13.686	(21.392)
Polio	(645.310)	(33.908)
Courses – Industrialised world		
Helsingborg	44.705	0
Courses – Developing world		
India	(190.634)	(138.339)
Income (expense)	(777.553)	178.849
5. Prosthetics and Orthotics International		
Advertising	687.073	545.105
Subscriptions	209.335	205.977
	896.408	751.082
Printing and mailing	(455.860)	(543.518)
Production editor	(37.129)	(35.434)
Meeting expenses	(32.994)	(35.418)
Production secretary	(80.000)	(82.600)
Other direct expenses	(12.776)	0
Publications committee	(140.000)	(125.000)
	(758.759)	(821.970)
Net result (loss)	137.649	(70.888)
6. Publications		
Booksales	5.895	16.251
Amputation Video	1.470	5.985
Net result (loss)	7.365	22.236
7. Administrative expenses		
Executive Board and Officers:		
Executive Board meetings	414.934	365.910
IC-meeting	122.456	0
POI publications committee	(140.000)	(125.000)
	397.390	240.910

Secretariat, Copenhagen		
Staff salaries	254.411	247.128
Labour tax	11.672	7.529
Data service	1.107	1.157
EDP	3.349	15.149
Meeting expenses	14.231	2.808
Postage and bank charges	74.220	71.368
Telephone	12.304	9.511
Stationery	6.816	7.256
Office supplies	40.941	9.420
Auditing	30.739	43.182
Bookkeeping	15.545	22.091
Consulting fees	22.273	15.465
Sundries	27.218	24.320
Rent	15.000	0
Depreciation	13.000	25.786
Society promotion	8.000	37.222
Insurance	11.288	19.667
	562.114	559.057
Professional Register	101.167	146.139
Total	1.054.634	946.106

8. Office Equipment

Computer equipment, at cost	187.544	187.544
Office equipment, at cost	32.006	32.006
Cost	219.550	219.550
Depreciation January 1	(190.202)	(164.416)
Depreciation during the year	(13.000)	(25.786)
Accumulated depreciation	(203.202)	(190.202)
Net book value	16.348	29.347

9. Securities

	Nominal Value	Original Cost	Year End Value
Bonds			
6% Nykredit 5 c 2011	4.951.000	4.960.641	4.960.641
7% Nykredit 2014	1.857.000	1.890.870	1.890.870
	6.808.000	6.851.511	6.851.511
Shares	Units		
Den Danske Bank	94	22.560	72.560
Total		6.874.071	6.924.071

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Report from the Executive Board

The most recent Executive Board Meeting was held in Kobe, Japan on 27-28 January 1998. The following report is a summary of selected points which may be of interest to you.

Finance

The level of the annual membership fee was considered. It was felt that in view of the healthy state of the Society's finances the fee should not be raised. It was agreed that this would be the Executive Board's recommendation to the International Committee.

International Conferences and Courses

Two significant events which had taken place since the last Executive Board meeting were the Consensus Conference on Poliomyelitis in Hammamet, Tunisia and a course in Amputation Surgery and Related Prosthetics in Jaipur, India. In spite of their complexity, both of these events had been kept within the approved budget. The Consensus Conference had addressed the problems of acute polio, still prevalent in a number of countries and post-polio syndrome. Consensus was sought on the best surgical and orthotic approaches to treatment and on the relationship between these approaches. The report, expected this summer, should prove to be a valuable document for all those who are professionally concerned with orthotics, surgery and rehabilitation related to poliomyelitis. The course in Jaipur was one of a series of such courses held over the years. The most recent had been in Madras, India and Helsingborg, Sweden. It was unprecedented to hold two courses in one country within one year of each other but in this case the country was immense and the infrastructure was in place after the first course (and this proved to be a great asset to the organisation of the Jaipur course).

Education

Issue 1 of the Category II Information Package (including professional profile, code of ethics, learning objectives and description of examination content) had been completed and distributed in October 1997. This package should prove to be of great value to all schools offering or wishing to introduce a Category II (Orthopaedic Technologist) course. It is now intended that a similar package be developed for Category I (which includes prosthetist/orthotists and orthopaedic meisters).
Two events in Japan were being organised under the auspices of the Education Committee. These were: An Educational Seminar in Prosthetics and Orthotics (commemorating the mid-point of the Asia and Pacific Decade of Disabled Persons) in Makuhari, Japan (30 January - 1 February 1998) and an Asian Prosthetics and Orthotics Workshop (2-4 February 1998). These events have since occurred; they were very successful and have helped to promote ISPO, and the principles for which it stands, in Asia.

Publications

An offer had been received from John Michael of the US National Member Society to organise translation of articles from Prosthetics and Orthotics International into Spanish for the benefit of members in Central and South America. There was a pool of native Spanish speaking volunteer translators including orthopaedic surgeons, physiatrists and trauma surgeons.. The Executive Board approved this initiative, subject to confirmation that the translated articles would be distributed only to ISPO members.

Professional Register

The Honorary Treasurer had created a new membership application form which combined the previous application form and professional register form. Following a limited trial distribution, responses had suggested that the form was generally satisfactory with some amendments.

Appropriate Prosthetic Technology

The Society had been invited to carry out an evaluation of the International Committee of the Red Cross (ICRC) Polypropylene System a low cost prosthetic system for low-income countries. ISPO would be represented in this by Sepp Heim and the Honorary Treasurer.

Congresses

Preparations for the next world congresses (Amsterdam, The Netherlands: 28 June – 3 July 1998 and Glasgow, UK: 1-5 July 2001) were going well. The exhibition in Amsterdam would be the largest ever at a world congress. Indications had been given by Argentina and Germany that they intended to bid for the 2004 World Congress.

Executive Board 1998-2001

A slate of nominations had been prepared by the Executive Board assisted by suggestions from National Member Societies. This slate was then presented to the interim meeting of International Committee representatives and finally sent to all National Member Societies for consideration. The National Member Societies had the option to either accept the proposed slate or offer further nominations. All accepted the slate of nominations. As a consequence, the Executive Board for the triennium 1998-2001 will be:

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 new Executive Board will take office at the World Assembly during the World Congress in Amsterdam.

Brendan McHugh
Honorary Secretary

Obituary
Gergely László, MD (1946-1997)

Dr. Gergely László, Vice Chairman of the National Institute for Medical Rehabilitation, died at the age of 51. A splendid career came to a sudden halt.

On a gloomy December afternoon a number of people were hit by a runaway car, he was among them. He was rushed to an Intensive Care Unit with severe head injuries. Relatives and friends were hoping for his recovery but in vain. On the 15th of December his heart stopped.

He started his medical career as a surgeon. Completing his residency programme he started to work at the National Institute for Medical Rehabilitation. He proved to be a an excellent surgeon, taking hardly any days off. It was no wonder that within a short period of time he became the Chief of the Department of Amputation Surgery. One of his many achievements was introducing the latest techniques into his department. He set an example in his job with his exceptionally good demeanour toward his patients. He was revered by his patients for his honesty and straightforwardness.

He was saddled with a huge workload but still he found time to actively participate in the work of professional and civilian organisations. It was these activities that proved his humanity, expertise and determination. He was a workaholic but in a good sense. He demanded the most from himself. He spoke a number of languages fluently and was a member of the board of the Hungarian Society for Rehabilitation of Disabled. His achievements were known in the international professional circles. He was instrumental in founding the Hungarian branch of ISPO, the first in Middle-Eastern Europe. One of his major diplomatic accomplishments was to organise the first Middle-Eastern European ISPO Congress.

He had a long list of publications and the results of his researches were not only in the field of surgery but he also proved to be an expert of economy, finance, medical ethics, and of organisation. For years he was a management teacher and he applied theory in the day-to-day life work. Hence he had the knowledge and skills for his constant battle against the abnormalities in health care. He was fighting for well organised, clearly defined working conditions in his domain.

He was a wonderful father, husband and friend.

It was a privilege to be his colleague, his down to earth humour helped his colleagues through difficulties, he showed us not only leadership but friendship as well.

Good bye friend!

Janos Magyar, MD
Vice President of ISPO Hungary

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Ten-year survival of Finnish lower limb amputees

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Abstract

Data on mortality for the ten years following lower limb amputation were obtained from all the 16 surgical units in Southern Finland and the National Social Insurance Institution. In Southern Finland during the period 1984-1985, amputations of the lower limb were performed on 705 patients, of whom 382 (54%) were women and 323 (46%) men. The majority of the amputations, 47%, were performed for vascular diseases and 41% were performed for diabetes mellitus. The overall survival was 62% at one year after amputation, 49% at two years, 27% at five years and 15% at ten years. The median survival after amputation was 1 yr 5 mth for the women and 2 yr 8 mth for the men. Of the arteriosclerotics, 43% died within one postoperative year while 43% lived longer than two years and 23% longer than five years. The median survival of arteriosclerotics was 1 yr 6 mth. The corresponding figure for patients with diabetes was 1 yr 11 mth. Of the diabetics, 38% died within one postoperative year while 47% lived longer than two years and 20% longer than five years. Of the trauma patients, 86% lived longer than five years and 71% longer than ten years. Of the trans-femoral amputees, 54% lived longer than one year, 36% over two years, 18% over five years and 8% over ten years. The corresponding figures for trans-tibial amputees were 70%, 53%, 21% and 4%. Many elderly vascular and diabetic patients undergoing amputation have a reduced physiological reserve and high mortality. The more proximal the amputation, the greater the risk that the patient will never be able to walk or that the duration of use of the prosthesis will be short. If a prosthesis seems to be a reasonable option for the elderly amputee, any delays in prosthetic fitting should be avoided in older age groups.

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Introduction

About 1500 lower limb amputations are performed annually in Finland. Most amputations involve geriatric patients with peripheral vascular disease (Pohjolainen and Alaranta, 1988). Ths disability following limb amputation is permanent, and in many cases amputees are made dependent on other people. Elderly amputees often have changes in organs other than limbs: they have heart diseases, brain disorders and, in diabetics, eye, kidney and neurological disorders. Arteriosclerosis and diabetes associated lower limb amputations especially represent a major socioeconomic and health problem. The amputee needs considerable in-patient and out-patient care and frequently makes demands upon social and welfare services.

According to the estimate of Finnish statistics, the age structure of the Finnish population will continue to shift upwards causing a twofold increase in the proportion of over 60-year-olds during the next 30 years. The majority of lower limb amputations performed in western society are on elderly people. The main condition leading to amputation is peripheral vascular disease and diabetes mellitus (Ebskov, 1996; Finch *et al.*, 1980; Kolind-Sorensen, 1974; Pohjolainen and Alaranta, 1988; Stewart *et al.*, 1992). In Finland trauma accounts for 2% (Pohjolainen and Alaranta, 1988) of lower limb amputations, in Denmark for 4% (Ebskov, 1988) and in Britain for 9% (Coddington, 1988). The major cause of lower limb amputations in children is trauma, which accounts for 75-80% of cases

(Baumgartner, 1979). Ten per cent of amputations in children are performed due to malignancy (Baumgartner, 1979). Ebskov (1988) reported the percentage of lower limb amputations due to tumour in Denmark from 1978 to 1983 as varying between 1.5 and 2.2% and Murdoch *et al.* (1988) found an almost exactly similar picture in Britain over the period 1965-1988.

Amputee statistics are needed for the planning of amputee rehabilitation. National epidemiological statistics would benefit the organisations responsible for planning services for lower limb amputees and organising the provision of prostheses and rehabilitation. The mortality of amputees is an important epidemiological parameter. Absolute mortality data reported in the literature usually cover only a single health care unit or hospital or a single disease and the statistics are usually influenced by local demographic factors.

The aim of this study was to assess the absolute mortality of lower limb amputees among the population of the defined area in Southern Finland during the ten year follow-up. The survival was analysed according to the subgroups of gender, age, diagnosis and amputation level.

Material and methods

To assess the situation in Southern Finland, data were collected on all lower limb amputations carried out by all the 16 surgical hospitals of the catchment area in the Helsinki University Central Hospital during the period 1984-1985. The catchment area had populations of 1,159,000 in 1984 and 1,171,000 in 1985, corresponding to 24% of the population of Finland.

Every patient's hospital record was examined thoroughly, and all data concerning demographic factors, diagnoses, surgical procedures and amputation levels were recorded. The dates of death were ascertained in collaboration with the National Social Insurance Institution (NSII). NSII contains the database concerning deaths of the whole population of Finland. Mortality data for the amputees studied could thus be obtained 10 years postoperatively. Survival distributions were compared graphically between subgroups by plotting the survival functions against time. Patients who are still alive at the date of the study and whose survival times are known only up to that point, were incorporated using the Kaplan-Meir method (Pocock, 1993; Stewart *et al.*, 1992).

During the period 1984-1985, amputations of the lower limb were performed on 705 patients, of whom 382 (54%) were women and 323 (46%) men. Vascular reconstruction, arterial embolectomy, thrombendarterectomy, lumbar sympathectomy or a combination of these preceded the amputation in the case of 168 amputees (24%).

Table 1 presents the distribution mean age of the patients according to the underlying

Table 1. Distribution and mean age of amputees by underlying diagnoses.

Diagnosis	Amputees				Mean age (years)		
	Women	Men	Total	Per cent	Women	Men	All
Arteriosclerosis	149	155	304	43.1	79.6	71.0	75.0
Diabetes mellitus	187	100	287	40.7	74.8	66.9	72.0
Frostbite	4	27	31	4.4	47.5	51.3	50.8
Embolism	19	8	27	3.8	73.1	67.4	71.4
Tumour	8	9	17	2.4	50.4	29.4	39.3
Trauma	5	9	14	2.0	43.6	39.4	40.9
Deformity	6	3	9	1.4	71.8	54.0	65.9
Burger's disease	–	3	3	0.5	–	44.0	44.0
Miscellaneous	2	4	6	0.8	38.0	50.5	44.3
Total	382	323	705	100.0	75.7	68.1	72.2

diagnoses. The majority of the amputations, 47%, were performed for vascular diseases; 41% were performed for diabetes mellitus (both insulin dependent diabetes mellitus and non-insulin dependent diabetes mellitus); and the third common reason for amputation was frostbite.

A total of 73 patients had undergone an amputation prior to 1984 at a lower level or on the contralateral limb. The cause of the previous amputation was vascular disease in 32 patients and diabetes in 40 patients. Table 2 shows the situations of the 705 amputees at the end of 1985. Previous amputations, amputations during the period 1984-1985, reamputations and contralateral amputations are included.

Table 2. Amputation levels at the end of 1985.

Type of amputation	n	Per cent
Unilateral		
Trans-femoral	288	41
Trans-tibial	156	22
Toe amputations	110	15
Foot amputations	19	3
Hip Disarticulation	7	1
Hemipelvectomy	1	0
Bilateral		
Trans-femoral/trans-femoral	41	6
Trans-tibial/trans-tibial	25	4
Trans-femoral/trans-tibial	23	3
Tmt/tmt or toe/toe*	13	2
Others	22	3

*Tmt = transmetatarsal

Results

The survival curve of both sexes based on the Kaplan-Meir method (Fig. 1) shows a sharp fall, especially in the older age groups (Fig. 2) during the first two years. The overall mortality during the three postoperative months was 190 (27%). A total of 135 amputees died during the first month. The overall survival was 62% at one year after amputation, 49% at two years, 27% at five years and 15% at ten years.

The median survival after amputation was 1 yr 5 mth for the women and 2 yr 8 mth for the men. About 56% of women were alive one year after operation while 42% lived over two years and 23% over five years. The corresponding figures for men were 69%, 56% and 31%. Of the total 382 women, 50 (13%) were alive ten years postoperatively, and of the total 323 men 55 (17%) lived over ten years (Fig. 1).

Figure 2 shows that the older the patient is during the amputation, the shorter is life expectancy. There was a prominent difference in survival comparing the patients aged over 60 to the younger group.

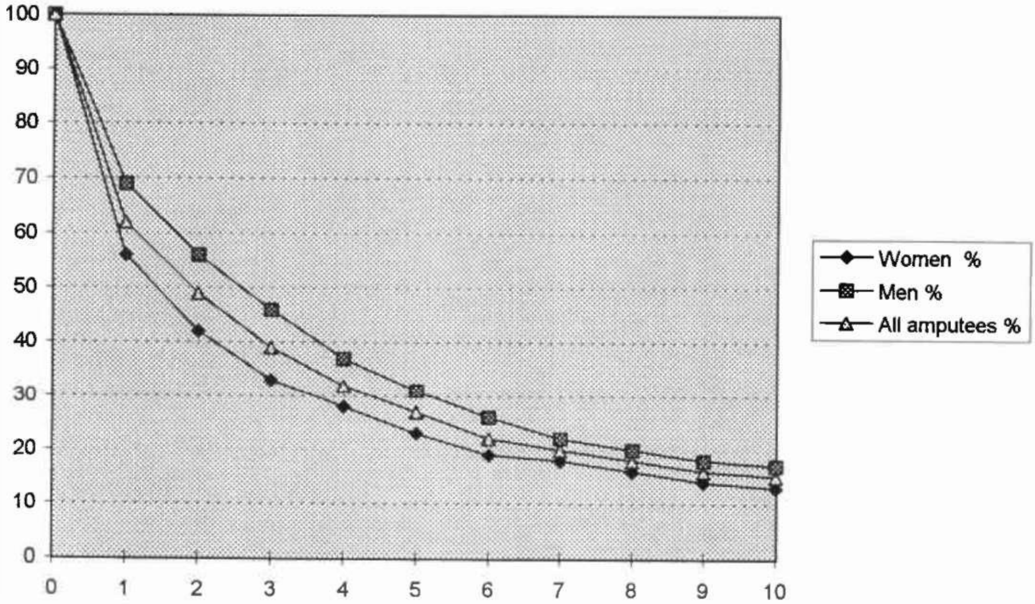

Fig. 1. Per cent survival among women and men during the ten postamputation years.

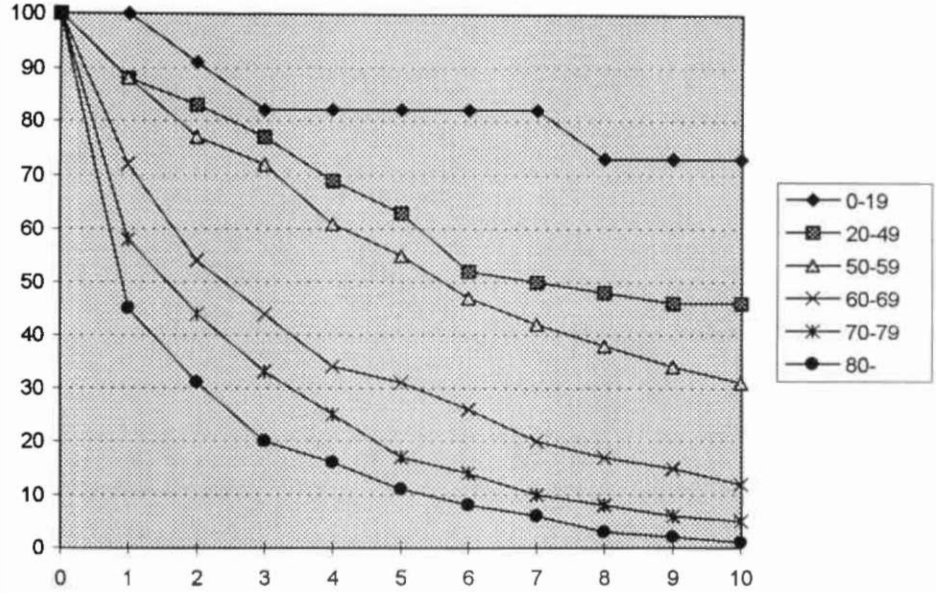

Fig. 2. Per cent survival among different age groups during the ten postamputation years.

Of the 304 arteriosclerotics, 43% died within one postoperative year while 43% lived longer than two years and 23% longer than five years. Of the 287 diabetics, 38% died within one postoperative year while 47% lived longer than two years and 20% longer than five years (Fig. 3). The median survival of arteriosclerotics was 1 yr 6 mth. The corresponding figure for patients with embolism was 8 mth and for diabetics 1 yr 11 mth.

Of the 18 tumour patients, 72% lived over one year, 61% over two years and 50% over five years (Fig. 3). None of the tumour patients died between five and the ten years postoperatively. The median survival of tumour patients was 5 yr 2 mth.

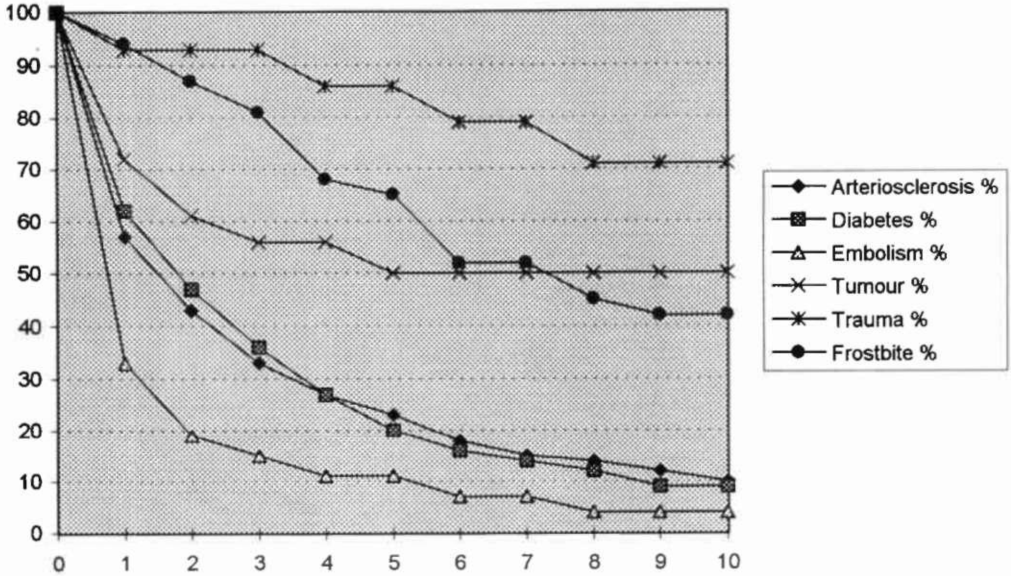

Fig. 3. Per cent survival among different diagnostic groups during the ten postamputation years.

Of the total 14 trauma patients, only one died during the three postoperative years while 12 (86%) lived longer than five years and 10 (71%) longer than ten years.

Two-thirds of the patients amputated for frostbite were alcohol abusers according to their medical histories. About 94% lived over one year, 65% over five years and 42% over ten years.

The median survival for the trans-femoral amputees was 1 yr 2 mth and 2 yr 3 mth for the trans-tibial amputees. Of the total 288 trans-femoral amputees, 54% lived over one year, 36% over two years, 18% over five years and 8% over ten years (Fig. 4). The corresponding figures for trans-tibial amputees were 70%, 53%, 21% and 4%. Of the 129 distally amputated patients (ankle, foot or toe), only 18% died within the first postoperative year while 78% lived longer than two years, 48% over five years and 27% over ten years.

Discussion

Finland had a population of 4.9 million in 1984-1985, about one-fourth of whom lived in the geographical area of the present study. In the study area, under 60-year-olds accounted for 83.8%, 60 to 69-year-olds for 8.1% and over 70-year-olds for 8.1% of the population. The corresponding figures for the whole of Finland were 82.5%, 8.9% and 8.6%. The study area closely resembles the whole of Finland in demographic structure, and thus the study is not influenced by local demographic factors.

Few studies have been published addressing the mortality of amputees with different diagnoses, covering a wide geographical area and extending over longer than a five-year period. Over the years, several studies have investigated the fate of arteriosclerotic or diabetic amputees (Hansson, 1964; Harris *et al.,* 1974; Kolind-Sorensen, 1974; Ebskov and Josephsen, 1980; Rush *et al.,* 1981; Murdoch *et al.,* 1988). Ebskov (1996) published a Danish nationwide epidemiological study including 3516 lower limb amputations in diabetic patients during the period 1982 to 1992. In the Scottish study, Stewart *et al.* (1992) reported that the survival of the trans-tibial and trans-femoral amputees with different diagnoses admitted to the Dundee Limb Fitting Centre increased during the two decades (1970-1979 and 1980-1989) from 3 yr 6 mth to 6 yr 6 mth. In this study, the follow-up was not limited to a single unit or hospital, unlike most of the previous studies. The follow-up included all amputees with different diagnoses and amputees fitted with a prosthesis and those who did not receive a prosthesis.

Regarding mortality, the interest will mainly be focused on vascular and diabetic patients

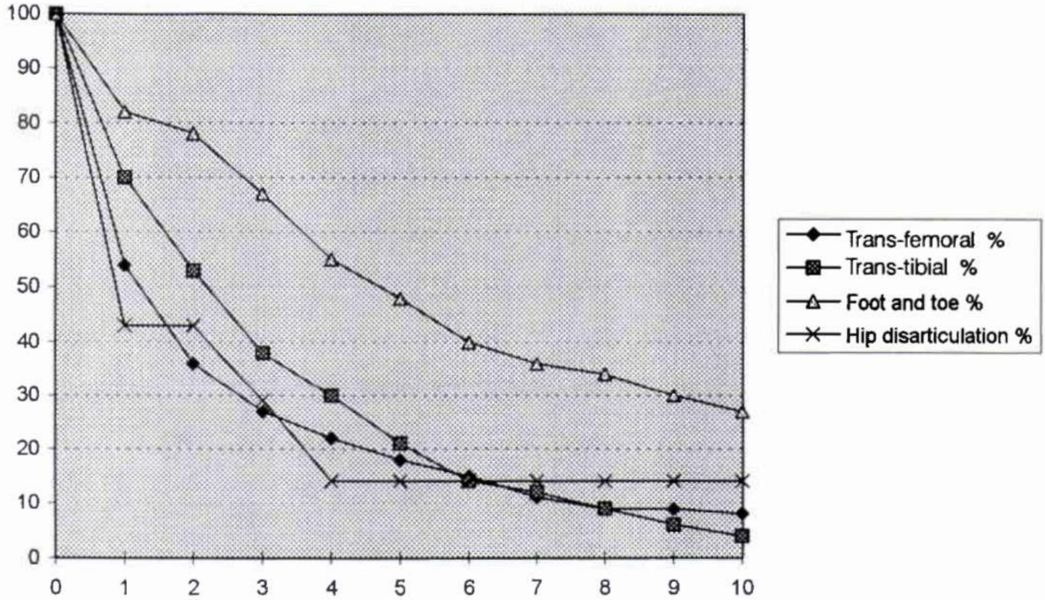

Fig. 4. Per cent survival among patient groups with different amputation levels during the ten postoperative years.

with lower limb amputations, since a majority of limb amputations are performed on these patients. Arterial occlusive disease is pansystemic in its manifestations, and thus amputation of the lower limb carries an associated risk that is different from the technical considerations of the operation. These patients have often had previous vascular operations, and failed revascularisation (Lambert, 1986; Mills, 1993). Vascular operations followed by amputation may cause a higher risk of mortality in elderly patients than does amputation alone. The high mortality rate during the first postoperative months among amputees with vascular diseases bears testimony to the advanced state of the disease. In this study, the rate of death within three months of initial surgery (27%) was higher than that in Denmark (16.6%) (Ebskov and Josephsen, 1980). In view of those figures, it may be that some of the elderly, severely ill patients with arterial gangrene or infection and sepsis should have been treated conservatively.

Trauma and neoplasia constitute a different clinical problem. The mortality during the first two years after amputation was high for amputees with neoplasia; on the other hand none of those patients died after five years from amputation. Most of the frostbite patients were alcoholics. The health of alcoholics may be poor but still only two of them died during the first postoperative year.

The survival rate was higher in the trans-tibial than in the trans-femoral amputation group during the six postoperative years. The highest survival rate was recorded for patients amputated at the feet, transmetatarsals or toes. The severity of the vascular disease and the ischaemia of the affected limb is probably the main reason for the higher mortality of the trans-femoral amputees. The five-year mortality rates in the trans-femoral and trans-tibial groups in this study are not different from those reported in USA (Roon *et al.*, 1977; Rush *et al.*, 1981).

Hansson (1964) reported from Sweden 45%, 58%, 71% and 76% mortality one, two, three and four years postoperatively, respectively. The above figures and the authors' two-year mortality rates of 58% and 57%, respectively, are worse than the figure of 19.2% from the Danish Amputation Register (Ebskov and Josephsen, 1980). The Finnish four-year mortality rate (Fig. 1) is better than the Swedish rate (Hansson, 1964) but clearly worse than the Danish figure (22.5%) (Ebskov and Josephsen, 1980). In an earlier Danish study, Kolind-Sorensen (1974) found a 50% five-year mortality among amputees with different diagnoses, which is also better than the rate in this study. The higher mortality rate of the first postoperative years in Finland may be partly due to the higher mean age of patients compared with other studies and the more advanced state of the vascular disease. Elderly vascular and diabetic patients undergoing amputation have a reduced physiological reserve and high mortality. In Finland, active vascular surgery may delay amputation. The high early mortality after amputation may also be due to postoperative rehabilitation and ambulation being too passive.

In the British study (Finch *et al.*, 1980) of 133 vascular amputees who survived at least one year after amputation; 55% were alive at the end of two years, 37% at the end of three years and 25% at the end of four years. In their studies, Kihn *et al.* (1972) and Huston *et al.* (1980) reported a 59% survival at two years and Couch *et al.* (1977) a 49% survival at three years.

According to the predictions of the Central Statistical Office of Finland the overall age structure of the Finnish population will continue to shift upwards causing twofold increase in proportion of over 60-year-olds in the next 30-40 years. It may influence the number of amputations. However, the incidences of lower limb amputations have not yet increased in Finland. In the authors' three surveys were 32.5-28.1 in 1984-1985, 22.0 in 1989 and 27.4 in 1992 (Alaranta *et al.*, 1995). The basic epidemiological study in 1984-1985 emphasised better appreciation and application of preoperative and postoperative mobilisation, better integration of prosthetic fitting and the total rehabilitation of the patient by his admission from the surgical ward to a residential rehabilitation unit and organised regular follow-up of amputees. Early ambulation has been shown to be advantageous for geriatric patients (Ham, 1986; Condie, 1988). If a prosthesis seems to be a reasonable option for the elderly amputee, any delays in prosthetic fitting must be avoided particularly in older age groups. The importance of this is that patients must be fitted with prostheses whenever possible and offered comprehensive rehabilitation so that the quality of life can be maintained.

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Three dimensional measurements of pelvic tilt in trans-tibial amputations: the effects of pelvic tilt on trunk muscles strength and characteristics of gait

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Abstract

The aim of this study was to determine the degree of pelvic tilt in three dimensions, the trunk muscle strength and effects on gait in trans-tibial amputated patients. This study comprised of 22 unilateral trans-tibial amputated patients who were seen at the authors' Prosthetics and Orthotics Laboratory for the purpose of prosthetic provision. Measurements were made using plurimeter and caliper and gait observations were made by video camera.

In the sagittal and horizontal planes respectively the pelvic tilt was measured to be 12° and 5.73°, and such measurements in relation to the trunk extensor and flexor muscles were shown to be statistically significant ($p<0.05$). On the contrary, the same could not be said for frontal plane measurements. In addition, in 9 cases excessive knee flexion was noted during the stance phase having a direct influence on the pelvic tilt ($p<0.05$).

Introduction

Interactions between the trunk and the lower limb are directly influenced by the adjoining pelvic joints, ligaments and muscles. In addition, posture, living styles and cultural differences also affect posture and pelvis (Steindler, 1970).

Mayer described three types of pelvic obliquity, namely infrapelvic, suprapelvic and pelvic (Crenshaw, 1992). The muscles affecting the infrapelvic obliquity are the abdominals, spinal erectors, abductors and adductors of the hip which are given strength exercises for the abdominal muscles and stretching exercises for the spinal erector muscles and contracture of the hip muscles or are used by orthosis or prosthesis wearers. The lumbosacral muscles, the sacroiliac joints and the bony structures affect the suprapelvic and pelvic obliquity, and they usually necessitate surgery (Crenshaw, 1992; Dontigny, 1985; Tachdjian, 1990; Lavignolle *et al.*, 1983). In the present study measurements were made using infrapelvic pelvises.

Until today, most measurements of pelvic tilt (PT) were taken in the sagittal plane; such results, though consistent, have not definitely illustrated the effects of the strength of the trunk flexors and hip extensors on the PT. To date, photographic measurements, parallelograms, spondylometers, pelvic inclinometers, standard goniometers, gravity goniometers, calipers and trigonometric measurements have all been used (Otman and Alyun, 1991; Gajdosik *et al.*, 1985; Clapper and Wolf 1988; Boone *et al.*, 1978; Low, 1976; Youdas *et al.*, 1991; Alviso *et al.*, 1988; Mayerson and Milano, 1984; Sanders and Stravrakas, 1981; Murray *et al.*, 1970; Walker *et al.*, 1987; Rothstein *et al.*, 1983).

The angle formed by a perpendicular and horizontal line passing through the anterior superior iliac spines (ASIS) and posterior superior iliac spines (PSIS) gives the sagittal plane measurements. If there is a reduction or the angle is 180°, there is said to be posterior pelvic tilt (PPT); if the angle increases, it is

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Fig. 1. Plurimeter and caliper

referred to as anterior pelvic tilt (APT) (Sanders and Stravrakas, 1981; Gajdosik and Bohannon, 1987).

Material and method

Patients ranged from 11 to 73 years of age. Their age, sex, weight, amputated side, length of time of prosthesis use, stump length, the prosthesis type and foot size, the knee joint range of motion, the muscular strength of the trunk, hip and knee, the PT and gait deviations were all noted.

On completion of training in the use of the prosthesis, PT measurements were taken using the Rippstein plurimeter and caliper. This plurimeter contains a very special oil and a large indicator. The caliper's long handle is shown in Figure 1 (Gerhardt *et al.*, 1986; Gerhardt and Rippstein, 1990).

The PT measurements in the horizontal plane were taken in the creeping position with 90° of knee and hip flexion with the caliper placed on a line drawn adjoining both PSIS. Measurements were taken without the prosthesis. The sagittal plane measurements were taken laterally on the amputated side using ASIS and PSIS as landmarks and the frontal measurements were obtained using the bilateral PSIS position measured from the back of the foot (Fig. 2).

Standardised results from previous studies of the PT angle on the frontal, horizontal and sagittal planes were given as 0°, 0-3°, and 9-11° respectively. If the angle exceeds 3° on the horizontal or 11° on the sagittal plane, it is classified as APT. All patients used 18mm SACH (Solid Ankle Cushion Heel) feet in order to offset any deviations in measurements.

Findings

The average age of the 22 patients in this study was 32.3 years (11-73); average mass was 63kg (37-90), 50% were right sided amputees and 50% left. Mean time of prosthetic use was seven years. The stump length was classified into five groups: very short stump (<15%); short stump (15-29%); standard stump (30-44%); long stump (45-59%); and very long stump (>60%). The length of the stump measured from the tibial plateau to the end of the bone was found to be long in 8 patients (36.4%), standard in 6 patients (27.3%) and short in 5 patients (22.7%). Two amputees (9.1%) had very long stumps while the remaining amputee (4.5%) had a very short stump. Some 16 patients (72.7%) used a PTB-SC/SP (Patellar Tendon Bearing Supracondylar/Suprapatellar) type prosthesis, 4 (18.2%) Patellar Tendon Bearing Supracondylar (PTB-SC) and 2 (9.1%) Patellar Tendon Bearing (PTB) type. All of them had SACH feet.

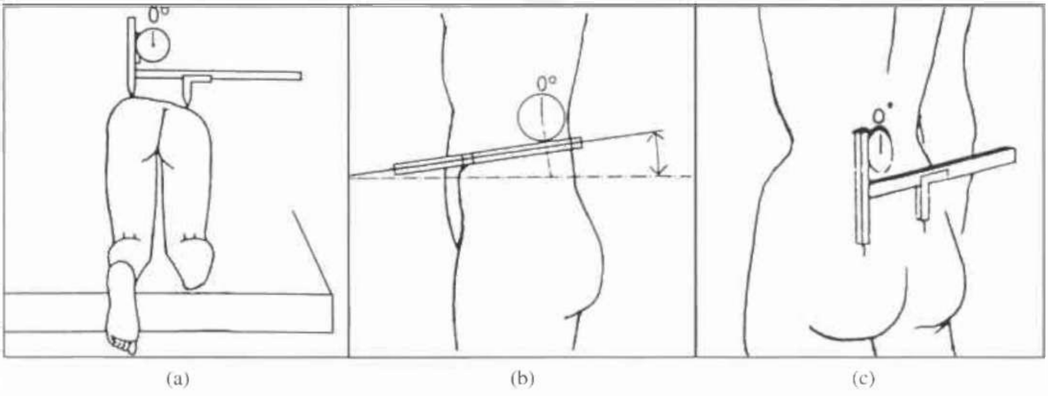


Fig. 2. PT measurements: (a) horizontal plane; (b) sagittal plane; (c) frontal plane.

Table 1.

Case No.	Age	ROM Knee	Muscle Strength	Hip	Knee	Trunk	Pelvic Tilt S	H	F	Gait Deviations
1.	45	5° ex.lim.	f	4	4	3	13°	7°	0°	+
			e	4	4	2				
2.	40	5° rec.	f	5	4	5	10°	0°	0°	-
			e	5	5	5				
3.	29	15° rec.	f	5	4	4	11°	3°	0°	-
			e	5	5	5				
4.	14	4° ex.lim.	f	5	4	3	12°	5°	0°	-
			e	5	4	4				
5.	37	0°	f	5	5	3	14°	10°	0°	+
			e	5	5	4				
6.	55	5° ex.lim.	f	5	4	3	12°	5°	0°	-
			e	5	4	3				
7.	39	0°	f	5	5	5	10°	0°	0°	-
			e	5	5	5				
8.	29	20° ex.lim.	f	5	5	3	13°	8°	0°	+
			e	5	4	3				
9.	19	5° rec.	f	5	5	4	13°	10°	0°	+
			e	5	5	4				
10.	18	17° ex.lim.	f	4	4	4	11°	5°	0°	-
			e	4	4	4				
11.	11	0°	f	5	4	4	12°	7°	0°	+
			e	5	5	4				
12.	22	20° flex.lim.	f	5	5	3	14°	11°	0°	+
			e	5	4	4				
13.	29	0°	f	4	4	4	13°	10°	0°	+
			e	4	4	4				
14.	19	0°	f	5	5	5	10°	0°	0°	-
			e	5	5	5				
15.	70	0°	f	5	5	3	12°	5°	0°	-
			e	5	5	3				
16.	19	5° ex.lim.	f	4	4	4	11°	5°	0°	-
			e	4	4	4				
17.	53	15° ex.lim.	f	3	4	2	15°	10°	0°	+
			e	4	4	2				
18.	13	15° flex.lim.	f	5	5	4	11°	5°	0°	-
			e	5	5	4				
19.	25	5° ex.lim.	f	5	5	3	14°	12°	0°	+
			e	5	5	4				
20.	26	0°	f	5	5	5	10°	0°	0°	-
			e	5	5	4				
21.	73	0°	f	5	5	3	12°	3°	0°	-
			e	5	5	3				
22.	26	0°	f	5	5	5	11°	5°	0°	-
			e	5	5	4				

S: Sagittal
H: Horizontal
F: Frontal

ex.lim.: extension limitation f.: flexor group
flex.lim.: flexion limitation e.: extensor group
rec.: recurvatum + gait deviation

5: normal 3: fair
4: good 2: poor

Range of motion of joints, muscle strength, PT values and gait deviations are presented in Table 1. In the study, it was noted when the PT angle exceeded the normal 0° in the horizontal plane, the muscle strength was reduced. For example, 6 patients with a PT angle of 0-3° on the horizontal plane, had good to normal muscular strength values for both the flexors and extensors; 9 patients with PT values between 4-7°, had fair to good flexor and extensor strength; 6 patients with PT values of 8-11° and another with 12° had fair to good extensor strength (Table 2a).

Similarly, measurements of the PT angle on the sagittal plane demonstrated the same trend. PT values of 9-11°, had a good to normal average flexor and extensor strength. However, in the presence of APT, muscle strength was reduced. For example, when the PT angle was 12-14°, found in 12 cases, trunk flexors were classified as fair and extensors as good. One patient with a value of 15°, was assessed to have poor flexor and extensor strength (Table 2b).

PT measurements in trans-tibial amputees are very different according to the planes and ages. In the sagittal plane the values were between 10 and 15°, with a mean value of 12+1.48. The horizontal plane values varied between 0 and 12°, with a mean of 5.73±3.77. In the frontal plane PT (elevation or depression) was not observed (Table 1). PPT was not observed in

Table 2a.

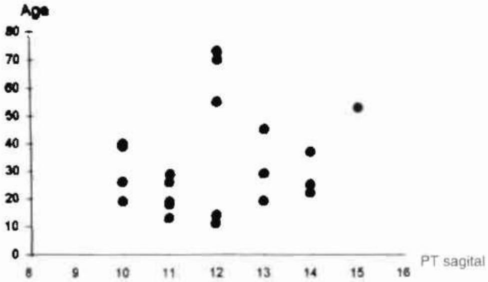
PT horizontal plane	Trunk muscle strength N	f	e
0° – 3°	6	4.5	4.5
4° – 7°	9	3.7	3.6
8° – 11°	6	3.2	3.5
12° – 15°	1	3	4

Table 2b.

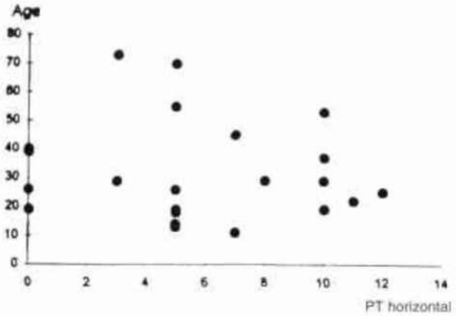
PT sagittal plane	Trunk muscle strength N	f	e
9° – 11°	9	4.6	4.4
12° – 14°	12	3.3	3.5
15° – 17°	1	2	2

f: flexor group
e: extensor group

Graph 1. Relationship between age and PT sagittal plane.



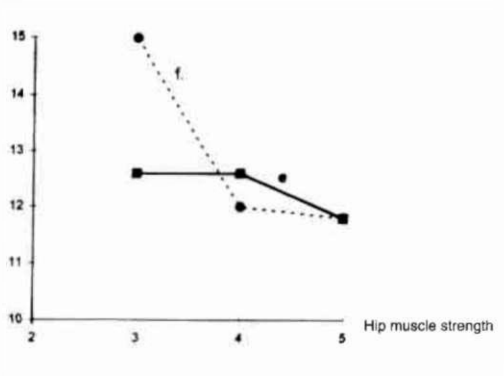
Graph 2. Relationship between age and PT horizontal plane.



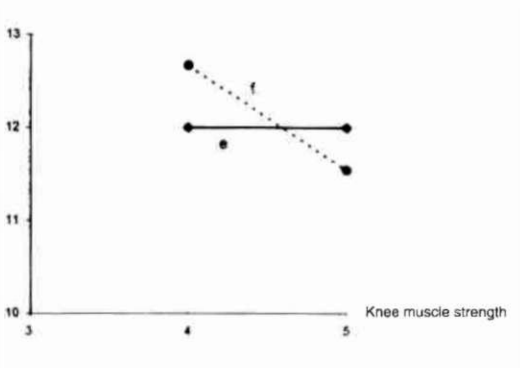
any cases either in sagittal or horizontal planes. However, APT was observed in 16 cases (73%) in the horizontal, and 13 cases (59%) in the sagittal plane (Tables 2a and 2b). The relationship between age and PT angles in the sagittal and horizontal planes are presented in Graphs 1 and 2.

The relationship between the hip, knee, trunk flexors and extensors muscle strength and the PT values obtained in the sagittal plane are presented in Graphs 3, 4 and 5. The same effects in the horizontal plane are presented in Graphs 6, 7 and 8. These relations were compared using the Spearman correlation coefficient to determine whether such a relationship was statistically significant ($p<0.05$) (Table 3). According to Tables 2a and 2b, the relationship was statistically significant, the significance being greater for the flexors. Similarly, PT values were compared to the age, body mass, prosthetic use period and stump length to determine whether there was a statistical significance. According to Table 4, if $p>0.05$ the relationship was not significant.

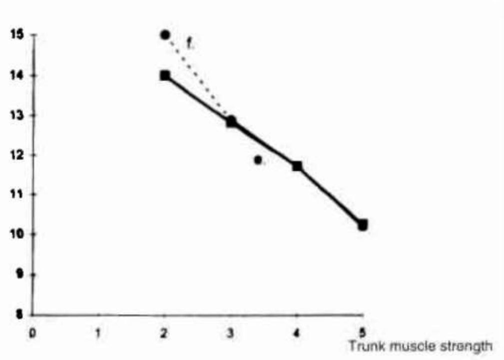
Graph 3. Hip muscle strength effect on PT sagittal.



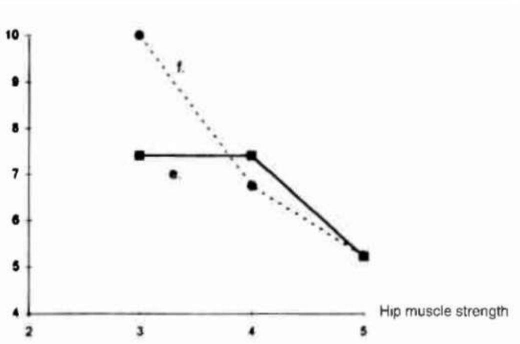
Graph 4. Knee muscle strength effect on PT sagittal.



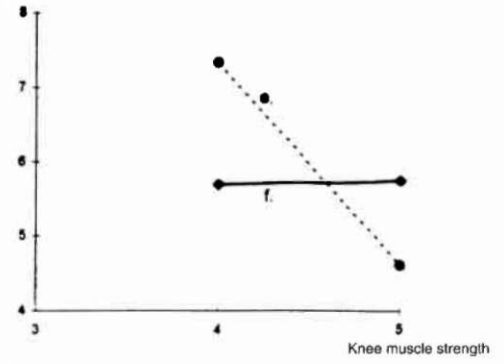
Graph 5. Trunk muscle strength effect on PT sagittal.



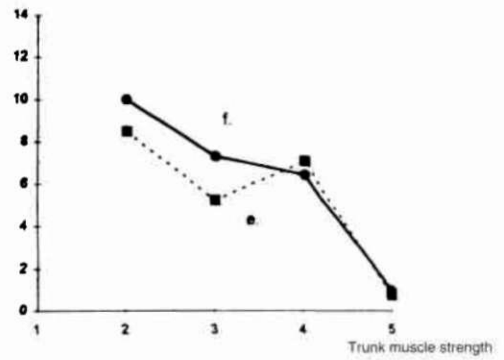
Graph 6. Hip muscle strength effect on PT horizontal.



Graph 7. Knee muscle strength effect on PT horizontal.



Graph 8. Trunk muscle strength effect on PT horizontal.



There were no limitations in hip joint ranges of motion, but in 8 patients (36.4%), there was an average of 9.5° loss in knee extension; in another 2 (9.1%), there was an average loss of 17.5° flexion and there was an average of 8.3° of recurvatum in 3 others (13.6%) (Table 1).

The trunk, knee and hip muscle strength was assessed to range from poor to normal (2-5 grade). In 17 cases 77.3% the hip flexors and extensors were normal and in 10 cases (45.5%) the knee flexors and extensors were normal (Table 1).

Table 3.

		Hip		Knee		Trunk	
		f	e	f	e	f	e
PT horizontal plane	r	-0.260	-0.245	0.015	-0.373	-0.622	-0.429
	N	22	22	22	22	22	22
	p	0.242	0.272	0.948	0.088	0.002*	0.046*
PT sagittal plane	r	-0.232	-0.200	0.007	-0.386	-0.829	-0.600
	N	22	22	22	22	22	22
	p	0.300	0.372	0.974	0.076	0.000*	0.003*

f: flexor group
e: extensor group
r: correletion coefficient
N: case number
p: probability
*: significant

Table 4.

		Age	Mass	Prosthetic use period	Stump length
PT horizontal plane	r	-0.118	-0.156	-0.018	-0.065
	N	22	22	22	22
	p	0.603	0.488	0.940	0.774
PT sagittal plane	r	0.147	-0.015	-0.005	-0.000
	N	22	22	22	22
	p	0.514	0.946	0.984	1.000

In 13 patients gait deviations were not observed; in 9 cases (41%) excessive knee flexion existed. This was reflected in a trunk muscle flexor-extensor strength of fair (3.2-3.4 grade). It was also noted that these patients exhibited high PT values in sagittal and horizontal planes 13.4 and 9.4 respectively, with the presence of APT. This finding was statistically significant $p<0.001$ (Table 5).

Discussion

Various methods have been used to determine PT measurements of normal people in the sagittal plane for example, Murray *et al.* (1970) using a photographic method, determined the average PT value to be 7°; Day *et al.* (1984) using the same method found the value to be 9.9°. Gajdosik and Bohannon (1987), using trigonometric measurement determined the value to be 8.5°. Burdet *et al.* (1986), Yildirim and Uygur (1987) and Cottingham *et al.* (1988) determined the angle to be between 8.4-11.3° using gravitational goniometric measurements.

In this study using the plurimeter and caliper, PT values in the sagittal plane were found to be between 10 and 15°, with an average of 12°. In the horizontal plane they were between 0 and 12°, with an average of 5.73°. In the frontal plane, pelvic angulations were not observed. The outcome of frontal plane assessments

Table 5. The relationship of gait deviation with the PT on the horizontal and sagittal planes.

	Excessive knee flexion	N	$\bar{X}_{PT}$	SD	p
Gait deviation horizontal plane	+	9	9.44	1.74	0.000*
	-	13	3.15	2.30	0.000*
Gait deviation sagittal plane	+	9	13.44	0.88	0.000*
	-	13	11.00	0.82	0.000*

N: case number
$\bar{X}_{PT}$: mean PT
SD: Standard deviation
p: probability
+: Excessive knee flexion existent
- : Excessive knee flexion non-existent

cannot be discussed due to the absence of previous studies.

Day *et al.* (1984), Kendal *et al.* (1993), Christie *et al.* (1995) as well as many other researchers have suggested that the trunk and hip flexors and extensors play an important role in pelvis control. In this study using the Spearman Correlation Coefficiency, it was concluded that the effects of the strength of the trunk extensors and flexors on the sagittal plane PT values were statistically significant ($p<0.05$). A similar conclusion was made for the horizontal plane. In other words, increasing strength of the trunk flexors and extensors results in reduction of PT in both planes.

However, in most of the cases studied (17 patients), the hip flexors and extensors were normal. Consequently, it was not possible to demonstrate such a relationship as above. Those with extension limitations of the knee (4-20°), showed a direct effect on the APT. For example, out of the 8 patients with extension limitations, 6 of them demonstrated higher sagittal and all demonstrated higher horizontal PT values than the normal (9-11° sagittal; 0-3° horizontal.

The relationship of gait deviations on the PT values was also evaluated and it was concluded that those patients with gait abnormalities resulting from excessive knee flexion were statistically significant ($p<0.001$). This evaluation was carried out after correction of the deformity resulting from prosthetic use during the stance phase.

Youdas *et al.* (1996) have shown that aging, a reduction in physical activity and abdominal muscularity, resulted in an increase in PT; Schenkman *et al.* (1996) noted a reduction in axial rotation.

In this study age, sex, mass, amputation side and prosthesis use time span, were compared with the PT angle using the t test, but were shown to be statistically insignificant ($p>0.05$).

Despite the fact, that the values obtained conformed closely to each other, the differences observed are believed to result as a consequence of racial differences, individual's physical characteristics and the researchers criteria.

Conclusion

Just as the trunk flexors and extensors influence the PT in the sagittal plane, in this study, it was concluded that the same effect also occurs in the horizontal plane. In addition, PT angles are also affected when excessive knee flexion compromises gait in the stance phase. In order to verify and strengthen this finding, further research is ongoing.

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Biomechanical gait evaluation of the immediate effect of orthotic treatment for flexible flat foot

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Abstract

Flexible flat foot subjects attending the prosthetics and orthotics units come with prescriptions from orthopaedic surgeons for arch supports. Usually a pair of thermoformed plastic inserts are fabricated and fitted to treat the patients. However the effect of the orthotic treatment is not yet clear. A motion analysis system with two video cameras placed on the lateral and rear sides of the subject together with one force platform was used to investigate the immediate effects of the orthotic treatment. The force platform collected force data and the two cameras captured two-dimensional displacement data of the lower limb.

Eight subjects, all having an arch index (AI) larger than 3.0, participated in the study. For each subject, three successful steps on the force platform were videotaped for both the shod (with shoe only) and the orthotic (with shoe and orthosis) conditions. The kinetic variables were normalized to individual body weight and averaged for each subject. A Paired t-test was conducted to analyse sample means of matched pairs between the shod and the orthotic conditions.

The results showed changes in displacement data with relatively little change in the collected force data. The modified UCBL shoe insert evaluated significantly affected the orientation and movements of the subtalar joint, ankle joint and knee joint. These immediate effects reduced the degree and duration of abnormal pronation during the stance phase and thus had the potential for decreasing strain in the plantar ligaments and reducing abnormal tibial rotation which may be therapeutic for the foot.

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Introduction

Flexible flat foot is one of the most common lower limb conditions in children. Under weight bearing conditions the medial longitudinal arch of a flexible foot is depressed and the subtalar joint is pronated with the calcaneus assuming a valgus position. When weight bearing ceases, the arch remodels to a slightly more arciform shape compared to the loaded situation. There is a great deal of controversy regarding the management of this condition including whether it should be treated or not. Some authors have suggested that the flexible flat foot in young children will be self-correcting, requiring no treatment (Wenger *et al.*, 1989) except for those with congenital defects or neurological problems. In contrast, others suggest that those subjects who fall outside the normal range of parameters require some form of treatment (Rose *et al.*, 1985).

The subtalar joint of a normal foot pronates during the first 25% of the stance phase (Mann, 1982). This unlocks the midtarsal joints and allows the foot to adapt to uneven terrain. Following pronation, supination of the subtalar joint occurs, reaching its neutral position at mid-stance. The foot further supinates to become a rigid lever during the push-off phase. In the case of flexible flat foot, the subtalar joint remains pronated after foot flat. The midtarsal joint is not locked and the forefoot remains a mobile adapter instead of a rigid lever for propulsion. Resupination is delayed. Hypothetically during the push-off phase the pronation moment produced by the ground reaction force flattens the arch by rotating the subtalar joint. Thus the plantar ligaments have to resist the excessive and prolonged tension force caused by the abnormal range of pronation and the delay of resupination.

In addition to stretching the plantar ligaments, the excessive pronation of the subtalar joint produces prolonged internal rotation of the leg. This forces the patella laterally out of the patellar groove of the femur (Ramig *et al.*, 1980). In the patellofemoral articulation the patella normally slides smoothly over the groove in the anterior femur. With subtalar pronation, the patalla rides over the lateral aspect of the patellar groove and the patellar cartilage becomes irritated. Chondromalacia patellae, a painful condition of the knee, can be caused by this extrinsic biomechanical factor (Beckman, 1980).

Conservative management of patients with flexible flat foot is the recommended form of treatment by Lovell *et al.* (1986). Basmajian and Deluca (1985) concluded that muscle activity is not needed to support the arch of the fully loaded foot at rest but only when stress is applied, as at heel off, the aim of exercise is to strengthen the foot muscle only to prevent injuries that may be caused by ligamentous laxity. However in the presence of heelcord contracture, stretching exercises are preferred and orthoses are rarely indicated.

Various orthoses have been used in the management of flexible flat foot. These include a wide variety of corrective shoes, arch supports, and shoe inserts (Miller, 1990). These orthoses are mechanical devices designed to correct and maintain the foot near the optimum position so as to increase the efficiency of foot mechanics during walking or running and thus encourage normal development of the foot (Helfet, 1980). Based on static radiological data, Bordelon (1980), and Bleck and Berzins (1977) reported that significant correction of flexible flat foot deformity could be achieved by the use of orthoses. In contrast, Penneau *et al.*, (1982) and Wenger *et al.* (1989) suggested that the use of orthoses could not make permanent changes to the flexible flat foot. However none of the above reported on the functional outcome of the orthotic treatment.

This study aimed to quantify the immediate effect of orthotic treatment for flexible flat foot before establishing a longitudinal study to investigate long term outcomes. The specific objective of this study was to compare the kinetic and kinematic variables between the orthotic (with orthosis and shoe) and the shod (with shoe only) conditions with a view to evaluating the immediate biomechanical effects of the influences of the orthosis on the ankle-foot complex and the knee joint.

Method

Subjects

Eight subjects, 7 females and 1 male participated in this study. They were between the ages of 4 and 11 years (mean age for all subjects was 6.3 years) and were referred from the paediatric orthopaedic clinic of the Queen Elizabeth Hospital, Hong Kong. Each subject received a lower limb musculoskeletal examination. Measurement of range of motion of the ankle joint and subtalar joint was performed to ensure that they all had various degree of bilateral flexible flat feet that were not compensation of forefoot deformities or other confounding pathology.

Orthosis

Each subject was fitted with a pair of orthoses commonly used in Hong Kong based on the UCBL (University of California Biomechanics Laboratory) shoe insert design (Henderson and Campell, 1967; Kogler *et al.*, 1996). Since the partial weight bearing casting method suggested by Henderson and Campell was not considered ideal by the authors for obtaining a neutral cast of the foot with the subtalar joint in the neutral position, a non-weight-bearing prone casting method was employed (McPoil *et al.*, 1989). Following the application of plaster bandages to the foot to form the negative impression the orthotist used the thumb and index fingers to palpate the head of talus to ensure that the subtalar joint was in the neutral position. The midtarsal joint was fully locked by applying a dorsiflexion force through the thumb of the other hand, placed on the plantar surface of the fourth and fifth metatarsal heads, which dorsiflexed and abducted the forefoot. The negative impression was used to create a positive cast.

Modifications to the positive cast included

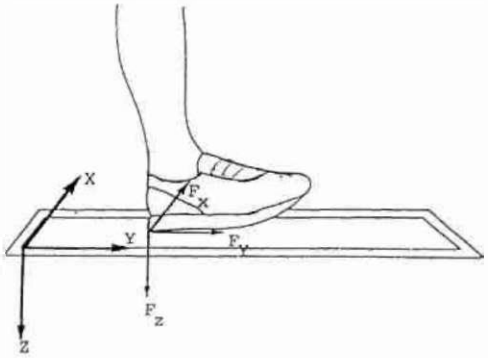

Fig. 1. Force components measured by the force platform.

those in the guidelines suggested by Henderson and Campbell (1967), and Colson and Berglund (1977): to include: (1) removal of plaster along the lateral aspect of the fifth metatarsal and the medial aspect of the head of the first metatarsal to match the measured width of the foot across the first and fifth metatarsal heads to control abduction and adduction of the forefoot; (2) removal of material from the lateral area of the heel to make it about 0.3 cm undersize in order to grip the calcaneus closely; (3) removal of material of about 0.8 cm in depth from the posterior aspect of the medial longitudinal arch so that it blended in with the medial support area above the calcaneal tuberosity in the area of the sustenaculum tali, for support of the calcaneus; and (4) addition of plaster, about 0.4 cm, at the navicular tuberosity to relieve pressure.

Following thermoforming with a 4 mm polypropylene sheet, the medial trimline was kept as high as comfort permitted while the lateral trimline was allowed to be considerably lower. The medial and lateral walls gripped the calcaneus to limit movement toward a valgus position. Under the plantar surface of the foot the distal trimline of the orthosis was located proximal to the heads of the metatarsals. The patients all reported that the orthoses were comfortable when initally fitted and at the follow-up appointment two weeks later.

Instrumentation

The biomechanical analysis of the effect of orthotic treatment for flexible flat foot was carried out through a two-dimensional video-based, computer-interfaced gait analysis system (Areblad *et al.*, 1990; Cornwall and McPoil, 1995) which consisted of a force plate and two video cameras. The force plate was located 5m from the start of the walkway, with the two cameras one at the start of the walkway, and the other 3 m to the right, in line with the force plate. The force plate (Advanced Mechanical Technology Inc., Newton, Massachusetts, USA) was used to measure force data: the vertical force (Fz), the anterior-posterior force (Fy) which was the horizontal force along the line of progression, the medial-lateral force (Fx) which was the horizontal force 90 degrees from the line of progression, and the axial torque measurement which was related to the reaction to the transverse rotation occurring in the lower limb during gait (Fig. 1). The Peak Motion Measurement System (Peak Performance, Inc., Englewood, Colorado, USA) was used for collection of displacement data. The force plate and the two cameras were synchronised. Both force and displacement data were sampled at 50 Hz.

Data collection

The arch index (Cavanagh and Rodgers, 1987) of each subject was calculated to quantify the degree of flatfoot (Table 1). A piece of paper was placed under an inked rubber differential pressure mat to collect the footprint of each subject during a step. When the subject stepped on it, the pressure pressed the ridges of the mat onto the paper and left an inked footprint on the paper. On the footprint (Fig. 2) a line is drawn from the centre of the heel (point X) to the tip of the second toe. This is called the

Table 1. Arch Index of the 8 subjects.

Subject	1	2	3	4	5	6	7	8
Sex	F	F	F	F	F	M	F	F
Age	11	11	11	9	4	5	4	5
Weight (N)	325	277.4	270	341	165.8	170.5	173	206
Arch Index	0.32	0.39	0.35	0.37	0.35	0.34	0.39	0.38

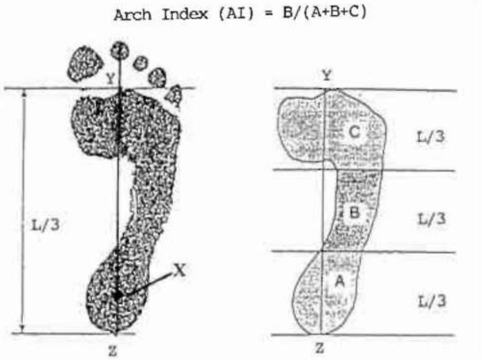

Fig. 2. Arch Index (AI) (after Cavanagh and Rodgers, 1987).

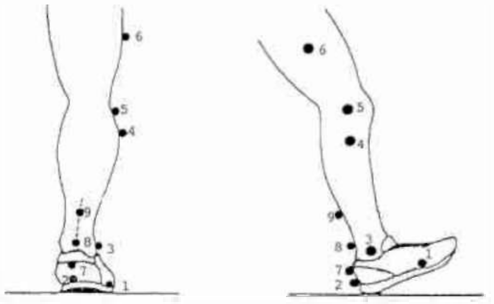

Fig. 3. Locations of the reflective markers. 1. MT5; 2. Cali; 3. LM; 4. FH; 5. Thi; 6. Ths; 7. Cals; 8. Legi; 9. Legs.

foot axis. A second line is drawn perpendicular to this axis such that it is tangential to the most anterior part of the outline of the main body of the footprint in front of the metatarsal heads. The intersection of these two lines is marked (point Y). The line XY is extended to the most posterior part of the heel at a point Z. The line YZ is divided into three equal parts dividing the foot, with the toes ignored, into rearfoot (A), midfoot (B) and forefoot (C). The Arch Index (AI) is the ratio of the area of the midfoot (B) to the total area (A+B+C) of the foot.

$$AI = B/(A+B+C)$$

To measure the motions of the knee and the ankle-foot complex in the sagittal plane and the coronal plane (Nigg, 1986; McCulloch *et al.*, 1993), spherical reflective markers of 1 cm diameter were attached, with double sided adhesive tape, to the right lower limb of each subject at the critical locations as follows:

(1) midsole of the shoe at the location of the head of the 5th metatarsal,
(2) the centre of the sole corresponding to the inferior bisector line of the calcaneus,
(3) the lateral malleolus,
(4) the head of fibula,
(5) the knee joint,
(6) a point proximal to the knee joint and two thirds of the distance on a line from the knee joint to the greater trochanter,
(7) the heel counter corresponding to the superior bisector line of the calcaneus,
(8) centre of Achilles tendon at the height of medial malleolus,
(9) 10 cm above marker of 8, at the centre of the leg as viewed from the rear, below the gastrocnemius heads (Fig. 3).

The reflective markers which appeared bright against the dark background were tracked by the motion analysis system. The components of the foot-floor direct force and the axial moment were measured by the force platform. The displacement data was synchronised with the force data. As the shoe is considered as part of the foot orthotic system and will affect the gait, standard laced leather shoes with firm heel counter and flexible sole were provided during the data collection sessions. Each subject was asked to walk at his/her normal speed with and without orthoses inside his/her shoes on both feet. Data collection trials were run until three successful trials for each condition, shod (without orthosis) and orthotic were obtained.

Data analysis

The raw displacement data were filtered with a Butterworth filter. The cut off frequency was 10 Hz. The conditioned data were then further reduced to obtain the scaled linear

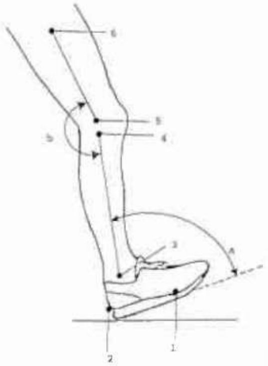

Fig. 4. Segmental angles of the lateral image. Angle a, ankle angle; Angle b, knee angle

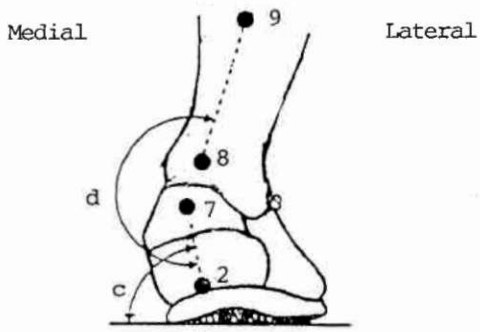

Fig. 5. Segmental angles of the rear image. Angle c, rearfoot angle; Angle d, eversion angle.

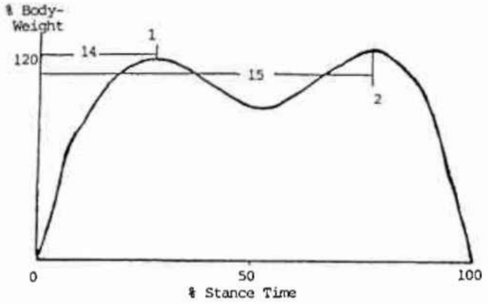

Fig. 6. Selected variables of vertical force component. 1. the first peak vertical force; 2. the second peak vertical force; 14. % stance at first peak vertical force; 15. % stance at second peak vertical force.

displacements of various markers and the angular displacements between line segments. The knee angle was defined as the posterior angle between the thigh and the lower leg in the sagittal plane, and the ankle angle was the anterior angle between the leg and the sole (Fig. 4). In the coronal plane, the rearfoot angle was the medial angle between the bisector line of the calcaneus and the horizontal, and the eversion angle was the medial angle between the bisector lines of the lower leg and the calcaneus (Fig. 5). To take into account the influence of the body weight on the recorded force data, the data was normalised by dividing by the individual subject's body weight. The kinetic and kinematic variables of the three successful trials were separately averaged for each subject, and group means were also calculated. Paired t-test was conducted to analyse sample means of matched pairs between the orthotic and non-orthotic conditions. Each subject served as his/her own control in determining if there was a treatment effect. Statistical significance was claimed for $p<0.05$.

To take into account the influence of the body weight on the recorded force data, the data was normalized by dividing by the individual subject's body weight. The variables (Hamill *et al.,* 1989) that were defined in the force-time data for analysis are listed in Table 2.

The variables (Fig. 9) that were defined in the displacement data in the frontal plane are listed in Table 3.

The variables (Fig. 10) that were defined in the displacement data in the sagittal plane are listed in Table 4.

Table 2. Variables that were defined in the force-time data.

Vertical force	(1)	First peak (Fig. 6)	(2)	Second peak (Fig. 6)
	(3)	Average		
Anterior-posterior force	(4)	Peak anterior (Fig. 7)	(5)	Peak posterior (Fig. 7)
	(6)	Average		
Medial-lateral force	(7)	First peak medial (Fig. 8)	(8)	Second peak medial (Fig. 8)
	(9)	First peak lateral (Fig. 8)	(10)	Second peak lateral (Fig. 8)
	(11)	Average		
Vertical torque	(12)	Peak external (Fig. 9)	(13)	Average
% Stance time at	(14)	First peak vertical force (Fig. 6)	(15)	Second peak vertical force (Fig. 6)
	(16)	Peak anterior Force (Fig. 7)	(17)	Peak posterior force (Fig. 7)
	(18)	Zero A-P force (Fig. 7)	(19)	First peak medial (Fig. 8)
	(20)	Second peak medial (Fig. 8)	(21)	First peak lateral (Fig. 8)
	(22)	Second peak lateral (Fig. 8)	(23)	Peak external torque

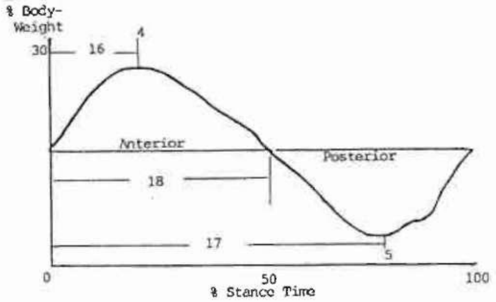

Fig. 7. Selected variables of anterior-posterior force component. 4. the peak anterior force; 5. the peak posterior force; 16. % stance time at peak anterior force; 17. % stance at peak posterior force; 18. % stance at zero anterior-posterior force.

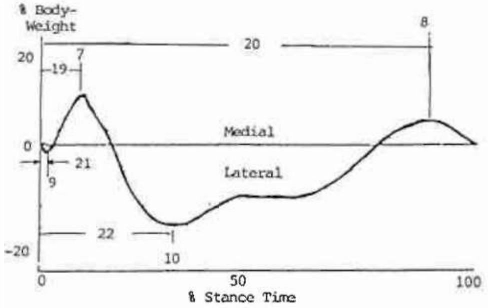

Fig. 8. Selected variables of the medial-lateral force component. 7. the first peak medial force; 8. the second peak medial force; 9. the first peak lateral force; 10. the second peak lateral force; 19. % stance at first peak medial force; 20. % stance at second peak medial force; 21. % stance at first peak lateral force; 22. % stance at second peak lateral force.

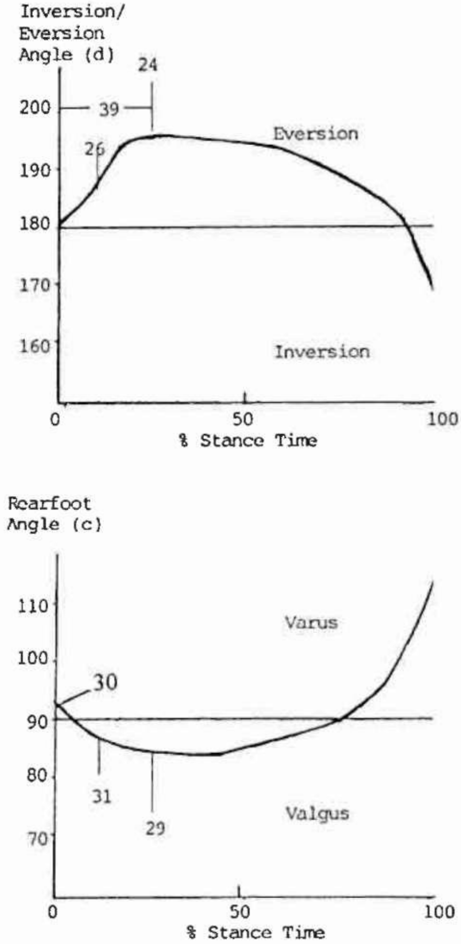

Fig. 9. Selected variables of the kinematic data of the posterior view. 24. the maximum eversion angle; 26. the eversion angle at 10% stance time; 39. % stance at maximum eversion angle. 29. the rearfoot angle at maximum eversion; 30. the rearfoot angle at heel strike; 31. the rearfoot angle at 10% stance time.

Table 3. Variables that were defined in the displacement data in the frontal plane.

Eversion Angle	(24)	Maximum	(25)	At heel strike
	(26)	At 10% stance time	(27)	Initial = (25) - (26)
	(28)	Total = (24) + (25)		
Rearfoot angle	(29)	At maximum eversion	(30)	At heel strike
	(31)	At 10% stance time	(32)	Initial = (31) - (30)
	(33)	Total change = (30) - (29)		
% Stance time at	(34)	Maximum eversion		

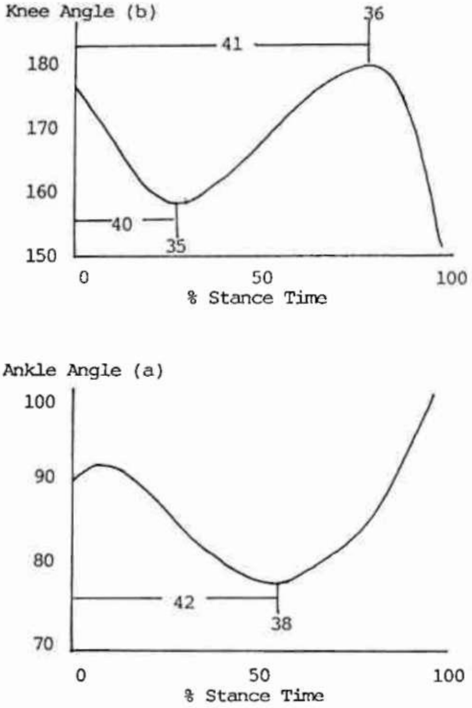

Fig. 10. Selected variables of the displacement data in the sagittal plane. 35. the maximum knee flexion angle; 36. the maximum knee extension angle; 40. % stance at maximum knee flexion angle; 41. % stance at maximum knee extension angle; 38 the ankle angle at maximum dorsiflexion; 42. % stance at maximum ankle dorsiflexion.

Results

Both the vertical force patterns of the shod and orthotic conditions were of the typical two peaks curves. There were no significant differences in the selected variables of the vertical force component. The anteroposterior force component also showed anterior and posterior forces of high degree of symmetry with no significant difference in the selected variables between the shod and the orthotic conditions. Significant differences ($p<0.05$) of the mean values between the orthotic condition and the shod condition were noted and are shown in Table 5.

Discussion

The results showed that selected variables of the vertical force components were not influenced by orthotic use. One of the functions of the pronation of the subtalar joint is to reduce the vertical impact force during the shock absorption phase which lasts from heel strike to foot flat (Berger *et al.*, 1981). The magnitude of the first peak of vertical force, the vertical impact peak force in the two conditions indicated that the shock absorption function was not affected by the use of the orthosis. The orthotic intervention also did not influence the timing of the vertical force components.

In the orthotic condition there was observed to be a 1.8% decrease ($p<0.05$) in the magnitude of the second peak lateral force and a 1.5% increase ($p<0.05$) in the magnitude of the average medial-lateral force over the stance phase i.e. to a less negative value. The delay of 2.5% in stance time ($p<0.05$) at the occurrence of peak external torque indicated the influence on the abduction movement of the foot. The significant changes in the two mediolateral variables might be because orthotic control of the foot reduces internal tibial rotation and resulted in a less abducted forefoot that exerted a lower lateral force. The delay in the occurrence of the external torque peak might also be due to the influence of the orthosis on the abduction movement of the foot. In the orthotic condition, with the exception of the degree of eversion at heel strike, there was reduction in all other eversion variables. The orthotic intervention reduced the maximum eversion by 37.1% and the total eversion by 39.5%. The difference of the initial eversion at heel strike between the shod and orthotic conditions was not significant. This non-significant difference did not show the foot orthosis had an effect on the subtalar joint

Table 4. Variables that were defined in the displacement data in the sagittal plane.

Knee angle	(35)	Maximum knee flexion	(36)	Maximum knee extension
	(37)	At maximum eversion		
Ankle angle	(38)	Maximum dorsiflexion	(39)	At maximum eversion
% Stance time at	(40)	Maximum knee flexion	(41)	Maximum knee extension
	(42)	Maximum dorsiflexion	(43)	Heel off

Table 5. Mean percentage difference of variables between the shod condition and the orthotic condition.

Variables	Description	Mean value	Standard deviation
2	second peak lateral force	-1.8%	2.3%
11	average medial-lateral force over the stance phase	1.5%	1%
23	stance time delay for the occurrence of the external torque peak	2.5%	2.7%
24	maximum eversion	-37.1%	9.1%
28	total eversion	-39.5%	10.8%
34	stance time delay for the occurrence of maximum eversion	16.2%	7.1%
29	rearfoot angle at maximum eversion	3.5%	1.1%
33	total rearfoot angular change	-38%	11.8%
37	knee angle at maximum eversion	2.4%	2.3%
38	ankle angle at maximum dorsiflexion	-2.8%	1.6%
42	atance time delay for the occurrence of the maximum dorsiflexion	4.8%	7%
39	ankle angle at maximum eversion	13.4%	6.8%
43	stance time delay for the occurrence of heel off	8.3%	3.8%

movement during the shock absorption phase. This would explain why the magnitude of the first peak vertical force was not significantly different in the shod and orthotic conditions. The percentage stance time at which the maximum eversion occured in the orthotic condition was reduced by 16.2%. This was much closer to the average value of 28% stance time than the 46.2% stance time in the shod condition. This suggests that, with the orthosis, the subtalar joint of the subject resupinated relatively earlier than that in the shod condition. Should this be the case abnormal stress to the ankle foot complex may be reduced. This presumably leads to a smaller magnitude of and shorter period of excessive tension on the plantar ligaments and also less internal rotation of the tibia, both in terms of duration and range of movement.

The rearfoot angle at heel strike did not change when the orthosis was introduced. As a factor of the eversion angle, the rearfoot angle at maximum eversion increased by 3.5% ($p<0.05$); and the total rearfoot angular change reduced by 38% ($p<0.05$). At maximum eversion, the knee angle increased by 2.4% ($p<0.05$). This agreed with the reduction in maximum eversion angle as supination of the subtalar joint moves the proximal aspect of the tibia backward, thus extending the knee (Root *et al.,* 1977). The reduction of maximum dorsiflexion angle at the ankle by 2.8% ($p<0.05$) would indicate an increase in dorsiflexion in the orthotic condition. The % stance time at maximum dorsiflexion was delayed by 4.8% ($p<0.05$). These indicated that the ankle motion occurred from a relatively supinated position. The ankle angle at maximum eversion increased by 13.4% ($p<0.05$) indicating a less dorsiflexed ankle at that time. The occurrence of heel-off was also 8.3% stance time delayed for the orthotic condition. This allowed a longer period for resupination following maximum pronation.

Conclusions and further research

Results of this study in the control of the motion of the subtalar, ankle and knee joints were comparable with the reports of previous studies on functional foot orthoses (McCulloch *et al.,* 1993; Novick and Kelley, 1990; Rodgers and LeVeau, 1982; Smith *et al.,* 1986) used to modify pronation during running and walking. The modified UCBL insert held the foot in a position that relieved tension on the soft structures, thus forming the arch without excessive pressure on it. The calcaneus was gripped by the medial and lateral walls of the orthosis and supported by the blended surface of the orthosis under the sustentaculum tali to limit movement toward a valgus position. The lateral wall of the orthosis also controlled the abduction of the forefoot at the mid-tarsal joint. The flexible flat foot was held and allowed to function and grow in appropriate alignment with less stressful force on the soft tissue. If the growing foot develops and functions in the shape in which it is held, in the long run, the ligament laxity would be reduced and the dynamic deformity would be corrected.

From the results of this experiment several gait parameters have been quantified that could demonstrate the immediate effect of the modified UCBL shoe insert. The direction and magnitude of the movement of the joints collected by the two-dimensional system suggested that the orthotic intervention had positive effects on the motions of the subtalar, ankle and knee joints. These results suggest that the use of a modified UCBL shoe insert for flexible flat foot subjects may reduce the magnitude and duration of abnormal pronation during the stance phase of gait and this may reduce the abnormally high stress on the plantar ligaments and lessen abnormal tibial external rotation. The reduction of the abnormal motion should also relieve the associated heel and knee pain caused by the pathomechanics. Particularly even after heel-off, without the use of an orthosis the subtalar joint continued to pronate; but with the orthosis earlier resupination of the subtalar joint was encouraged.

The result of this within-subject single measurement experiment only provided information about the immediate effect of the orthotic treatment. The natural history of the flexible flat foot has not been explained. Longitudinal studies with multiple measurements and use of a control group would be necessary. The arch index (Canavagh and Rodgers, 1987) used in this study to quantify the degree of flat foot is based on the cumulative measure of plantar pressure on the foot. As flat foot induces a lot of dynamic changes in the ankle-foot complex during gait, a measure of the transient pedobarographs during certain specific instants should be a more meaningful indicator of foot types. The accuracy of the force platform was 22 Newtons. Thus the force platform could not detect the difference between the shod and the orthotic conditions at less than this value. Devices such as in-sole pedobarograph system could be used to investigate the plantar surface loading distribution (Hennig *et al.*, 1994). The proposed method could also record data of multiple steps instead of the 'one step' approach of the single platform system (Chang *et al.*, 1994). The two-dimensional system has already detected some kinematic and kinetic changes due to the orthotic intervention. To investigate the relationship among the subtle kinematic changes at different joints a three-dimensional analysis system should be attempted.

A high degree of ligament laxity in the Hong Kong population has been reported (Cheng *et al.*, 1991). The normal values of the parameters that have been discussed may not be applicable for the Chinese children in Hong Kong. In parallel to this study, a project was started to develop the norm to classify foot shape by investigating the dynamic foot prints of subjects ranges from 4 to 18 years of age. Future work will be the establishment of an indicator for screening of the abnormal, flexible flat foot, and an evaluation of the efficiency and efficacy of the orthotic treatment in well defined flat foot subjects through the study of the relationships between plantar surface loading on the foot and three-dimensional joint motion of the lower limb. Since the plantar foot pad will not diminish fully until the age of 4 years, taking into account the development of the normal foot, an ideal longitudinal study of orthotic treatment involving subjects of at least 5 years of age should be undertaken. A parallel control group with no treatment should be established to investigate the long term effect of orthotic treatment for flexible flat foot.

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Primary metatarsalgia: the influence of a custom moulded insole and a rockerbar on plantar pressure

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Abstract

The effects of a custom moulded insole and a rockerbar on peak pressure and force impulse as well as on pain scores in subjects with a history of metatarsalgia were studied. In addition the subjects' preference for the type of intervention was determined. Forty-two subjects with a history of primary metatarsalgia were selected. They were all provided with the same brand of extra depth shoes with a ready made insole. The effect of custom moulded insoles, a rockerbar and the interaction between the two interventions were studied by testing the four possible combinations: ready made insole without a rockerbar, ready made insole with a rockerbar, custom moulded insole without a rockerbar and custom moulded insole with rockerbar.

At the most important region, the central distal forefoot, a rockerbar caused a decrease in force impulse of 15.1% and a decrease in peak pressure of 15.7%.

The custom moulded insole produced a decrease of 10.1% in force impulse and of 18.2% in peak pressure.

Pain scores were significantly lower for interventions with a custom moulded insole, while the rockerbar showed no influence on pain scores. Subjects with pain preferred a custom moulded insole more often than subjects without pain.

Decrease of peak pressure or force impulse was not correlated to pain scores.

The use of either a custom moulded insole or a rockerbar produced an important decrease of peak pressure and force impulse at the central distal forefoot and, therefore, either is suitable in any situation which a decrease of pressure is vital.

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Introduction

Foot pain is a highly frequent problem in older adults. Benvenuti *et al.* (1995) claimed a prevalence of 83% in a survey of 459 subjects 65 years or older. In females the prevalence was significantly higher than in males. They suggested that this gender difference is related to both biological characteristics and womens' use of shoes with high heels and a triangular shaped anterior portion. More specifically, pain in the forefoot was the problem most frequently mentioned in a survey of foot-shoe problems among older adults in the Netherlands. Sixty percent of the females and 30% of the males reported having foot problems in general (Herschel and Meel, 1978).

Reynolds (1988) described metatarsalgia as 'pain in and around the head of the metatarsal or the metatarsophalangeal joint and adjacent soft tissue structures'. It is thought of as a syndrome with causes being described as either primary or secondary. Primary metatarsalgia is idiopathic and mostly due to degenerative changes or to ageing. Secondary metatarsalgia is associated with metabolic, neurologic, postsurgical, or traumatic events. The pain might also be related to plantar pressure at the forefoot (Holmes, 1992).

The treatment of primary metatarsalgia generally aims at redistributing the plantar pressure. The following methods to achieve pressure reduction or redistribution are discussed: flat shoe inserts, metatarsal pads, custom moulded inserts, and rockerbars.

- Flat shoe inserts. Ready made flat shoe inserts have shock-absorbing capacities. With a polymeric foam rubber of 6.5mm thickness in the shoe, the loading peak of the ground reaction force is 11% less than in the same shoe without an insert (Shiba *et al.*, 1995). The level of comfort which subjects score for shoe inserts is clearly related to the softness and shape of the inserts (Chen *et al.*, 1994; Hennig *et al.*, 1993). Softer insert materials result in lower peak pressure at the metatarsal head regions (Hennig *et al.*, 1993).
- Metatarsal pads. An easy and frequently used treatment for metatarsalgia is the application of metatarsal pads (Silverskiold, 1991). The pads can differ in shape, thickness, hardness, and location. The use of pads results in a considerable reduction of plantar pressure, mainly at the heads of the metatarsalia II, III, and IV and an increase of pressure at the metatarsal shaft region (Chang *et al.*, 1994; Flot *et al.*, 1995; Holmes and Timmerman, 1990).
- Custom moulded insert. A custom moulded insert, made from a plaster cast, resulted in a reduction in plantar pressure of 7% to 9% at the region of the metatarsal heads (Bennett *et al.*, 1994). Total contact casting can result in a large reduction of pressure at the region of the metatarsal heads. Wertsch *et al.* (1995) found values as high as 32% for metatarsal head 5 (MTH-V) 63% for the MTH-IV and 69% for the MTH-I. Birke *et al.*, (1985) even found reductions upto 84%. Comparing the effect between ready made flat inserts and custom moulded inserts, Lord and Hosein (1994) found statistically significant lower peak pressures with custom moulded inserts.
- Rockerbar. During normal roll off, in a normal step, the line of gravity is shifted from the heel to the metatarsal heads; then the heel is lifted and the foot rotates over the metatarsal heads. The progression of the line of gravity is slowest during this rotation, resulting in relatively long acting ground reaction forces at the metatarsal heads. At push off, when the line of gravity is applied to the region of the metatarsal heads, the ground reaction force shows a high peak. In order to reduce the duration and the amount of plantar pressure, the rotation point can be shifted in the proximal direction by a rockerbar fixed to the sole of the shoe. At the rockerbar, two main aspects can be distinguished: the rotation point and the height. The rotation point is the point around which the shoe rotates forward. Nawoczenski *et al.* (1988) described the position as the distance in percentage of the total length of the shoe with the distance to the rockerbar being measured from the heel of the shoe. The height is considered to be the perpendicular distance from the front edge of the sole to the floor. With a rockerbar proximal to the metatarsal region, the rotation point will, thus, also be proximal to the metatarsal region. This position leads to significant reduction of the plantar pressure and impulse (intergral of pressure) at the forefoot region. The tratitional rocker, without curvature, is even more effective than a rocker with curvature (Coleman, 1985; Nawoczenski *et al.*, 1988; Novick *et al.*, 1991b; Peterson *et al.*, 1985; Schaff and Cavanagh, 1990).

The specific aim of this study is to acquire insight into the redistribution of pressure under four regions of the forefoot in patients with a history of primary metatarsalgia. All selected subjects were provided with the same brand of extra depth shoes with a ready made insole. A custom moulded insole was also made, and on both conditions a rockerbar was also placed in the sole. The second aim was to investigate the effect of a custom moulded insole and a rockerbar on pain at the region of the metatarsal heads and to determine the subjects' preferences for these two treatment methods.

It was expected that the most important pressure points and the largest effects of the interventions would be at the central distal forefoot.

Materials and methods

Subjects

Subjects had a history of primary metatarsalgia and no other walking problems. The inclusion and exclusion criteria for the study were chosen to prevent inclusion of subjects with other problems than primary metatarsalgia. Three orthopaedic shoe technicians, in different regions of the Netherlands, selected patients with metatarsalgia who came to visit them. The final selection was performed by a physician for rehabilitation.

Inclusion criteria:
- pain or a history of pain at the metatarsal region, the primary reason for visiting the orthopaedic technician;
- a walking distance of at least 500 metres without a walking aid;
- a splay foot (forefoot becomes wider when weight bearing);
- prominent heads of the metatarsalia.

Exclusion criteria:
- hallux valgus > 40° (angle between os metatarsale I and first toe);
- hallux limitus; dorsiflexion in the first metatarsal joint < 45° when the subject stands (weight bearing);
- hammer and claw toes with pain;
- toe contact with the floor is lost when standing (mostly due to subluxation of the metatarsal joints);
- valgus or varus of the hindfoot > 20°;
- dorsiflexion < 10° with knee extended;
- plantarflexion < 30°;
- problems which could result in secondary foot problems, such as rheumotoid arthritis, diabetes mellitus, and circulatory problems;
- problems with knees and/or hips;
- metabolic diseases which could cause problems in walking and/or secondary metatarsalgia;
- neurologic diseases which could possibly influence walking.

Forty-two subjects were selected, 41 females and only 1 male. All subjects gave written informed consent. Due to technical problems, the data of the gait analysis for 11 subjects could not be used. A 'non-response' analysis showed no differences in relevant characteristics in participants and 'drop-outs'. Other information from these 'drop-outs' is used in further analysis, as indicated. Table 1 summarises the descriptions of the subjects.

Table 1. Description of the 42 subjects

	Mean (s.d.)	mimimum	maximum
age (years)	58.6 (20.4)	41	81
height (cm)	166 (8)	150	183
weight (kg)	75.6 (10.4)	46.6	95.4

Study design and data analysis

Design

The study was designed as a double blind, randomised trial. Neither the investigator nor the subjects were informed which intervention was applied at what moment. Although subjects could not be kept totally blind to the intervention, they were not informed about the expectations of the different interventions.

Four interventions were tested:
1. ready made insole without rockerbar;
2. ready made insole with rockerbar;
3. custom moulded insole without rockerbar;
4. custom moulded insole with rockerbar.

After each measurement session, only one intervention was changed (insole or rockerbar). The order of interventions was randomly assigned to each subject. Only the orthopaedic shoe technician was informed of the schedule, to allow him to provide the shoe with the correct intervention. He did not perform any assessment regarding pain or plantar pressure.

To compare the last intervention with the initial one, the first intervention was repeated at the end of the trial. The results from questionaire and gait analysis from this latter measurement were used for subsequent calculations. The subjects were not aware of this. At the start of the trial each subject was fitted with standard shoes for a 4 week habituation period. During this period the orthopaedic shoe technician was allowed to change the upper leather of the shoe to prevent pressure points at the medial, dorsal, and lateral sides of the foot. After this period, the scheduled intervention for each subject was followed. An habituation period of 2 weeks was given to allow the subject to adjust to the intervention. At the end of this period, a gait analysis was performed and the questionnaire was filled in. After these measurements, the next scheduled shoe modification was carried out. This procedure was repeated for the remaining three interventions.

Orthotic devices

All subjects were provided with the same brand of extra depth shoes.

Ready made insole

The only difference between the ready made insole and the custom moulded insole is the shape. Therefore, standard ready made insoles were not used, rather the ready made insoles were produced according to a standard model with the same materials as the custom made ones. The heel raise was kept the same as for the custom made insoles.

Custom moulded insole

Measurements of the feet were made according to a fixed protocol. Since the form of the nonweight bearing foot is different from the weight bearing foot, particularly in splay feet, the cast for the insert was made during weight bearing (Novick *et al.*, 1991a). The plaster of Paris cast was made using vacuum cushions with the subject standing. The custom moulded insoles were made according to the following protocol:

- heel raise: 25mm;
- heel socket and medial support according to cast;
- metatarsal (MT) pad directly proximal to the metatarsal heads with height at the level of MT-I of 2mm; MT-II/III: 5mm; and MT-V: 1mm. Length in sagittal plane: 40mm;
- insole model at MT-level is oval in frontal plane, according to cast.

Rockerbar

The rockerbar was designed in such a way that it was usable in daily practice. It was placed perpendicular to the sagittal plane, 40mm proximal to the normal bending point (MT-level). The height, perpendicular distance from the front edge of the sole to the floor, was 20mm. The rockerbar slowly curved to the front edge of the sole. To prevent the shoe from tumbling backwards, the heel height was increased by 10mm.

Questionnaire

A short questionnaire was constructed to obtain information about pain and comfort. The subjects were asked only to consider pain at the plantar side of the forefoot region. A score 0 means no pain and a score of 5 indicates extreme pain. At every measurement the subject was also asked to give a preference for the shoe in use relative to the foregoing one. The subjects were urged to consider only 'function' of the shoes and not cosmetic aspects. If the preferences of a subject did not consistently refer to the same intervention for either one type of insole intervention and one type of rockerbar intervention, the preference was treated as 'no preference'.

Gait analysis

For this project 4 regions of the foot were defined (Fig. 1):

1. medial distal forefoot, MTP-I;
2. central distal forefoot, MTP-II + III;
3. lateral distal forefoot, MTP-IV + V;
4. central proximal forefoot, proximal to MTP-II + III.

The subjects were asked to walk barefoot at a comfortable speed on a walkway that is approximately 12 metres long. A pressure platform (EMED-SF pressure platform, with 62 by 32 pressure sensors (± 2/cm^2), data collection frequency 70 Hz) hidden under a thin black sheet, was used to obtain a dynamic pressure print of the foot. The regions were determined according to a fixed protocol, in which 6 points

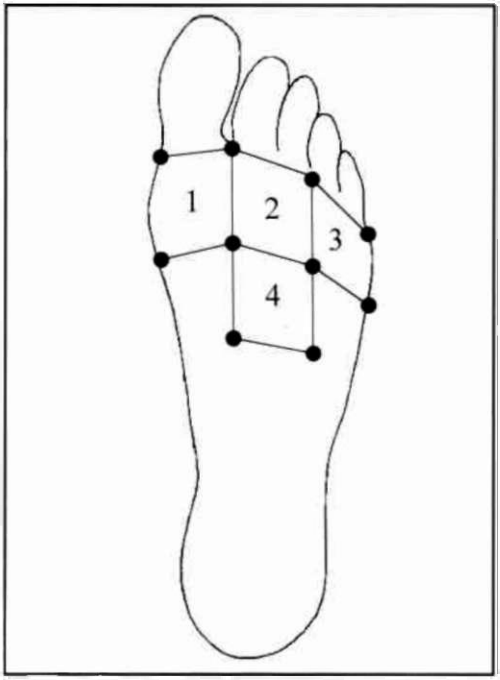

Fig. 1 Foot regions.
1. medial distal forefoot, MTP-I. 2. central distal forefoot, MTP-II+III. 3. lateral distal forefoot, MTP-IV +V. 4. central proximal forefoot, proximal to MTP-II+III.

(A-F) and a permanent length of the regions (fixed proportion of the foot length) are specified, as is seen in Figure 1. The regions are, interactively placed over the insoles.

During the trial, the pressure under the foot was measured with the Mikro-EMED system with Pedar insoles. This system consists of an insole with 99 capacitive pressure sensors. Data were collected with a frequency of 80 Hz and were transferred to a datalogger which is worn around the belt. Three insole sizes are available: 38, 40 and 42 (European sizing system). These sizes correspond to insole lengths of 245mm, 259mm, and 271mm respectively. The insole has a thickness of 2mm. To avoid a volume problem resulting from the measurement insole, a 2mm layer of cork is put under the custom moulded or ready made insole. This extra layer is taken out during the measurements.

The whole system is portable, and, therefore, the measurements were carried out at several locations to avoid long travel distances for the subjects.

Subjects were asked to walk at comfortable speed over a walkway of approximately 15 metres during the different measurements speed differences up to 10% were accepted.

For analysis of the data, 5 steps were selected and data for these were averaged. 'Good' steps were assumed to have approximately the same stance time, to have comparable curves of the vertical ground reaction force and to be consecutive.

For every foot region, peak pressure and force impluse were calculated. The latter yields the force-time intergral which quantifies the 'total' load of the foot during the stance phase.

Results of the measurements for one foot of a subject could influence the results of the other foot. To avoid this kind of dependency of measurements, the results of only 1 foot were processed, for all subjects. The results of the foot for which the subject reported most pain were used for calculations. When no pain was reported a random choice was made.

Statistics

To establish differences produced by the type of intervention, either custom insole or rockerbar, all measurements with a specified intervention were compared with those measurements without this intervention. For analysis the paired T-test was used.

A repeated measures multivariate analysis of variance with difference contrast was used to determine possible interactions between both interventions, and between the interventions and the pain scores. The within-subjects factor was the type of intervention. For analysing pain scores, only subjects who reported pain for at least one intervention were involved. To study the relation between pain and intervention preference, the one-sided Fisher exact test was used. The applied level of significance for all statistic calculations was 0.05.

Results

Gait analysis

Table 2 displays for a rockerbar and the custom moulded insole the force impulse and the peak pressure.

Type of rockerbar and force impluse: the regions 1 and 4 show no statistically significant difference for this variable. Regions 2 and 3 show statistically significant decreases of 15.1% and 10.5% respectively.

Type of rockerbar and peak pressure: again the peak pressure shows no significant difference in the regions 1 and 4. Regions 2 and 3 show a statistically significant decrease of 15.7% and 7.6% respectively.

Type of insole and force impluse: in the proximal forefoot, region 4, where the custom moulded insole provides extra support, there is a statistically significant increase of the force impluse of 82.3%. At the central distal forefoot, region 2, there is a statistically significant decrease of 10.1% while the lateral distal forefoot, region 3, shows a statistically significant increase of 13.8%. Under the medial distal forefoot region 1, no significant differences are measured.

Type of insole and peak pressure: the influence of the type of insole on peak pressure is statistically significant at the central and lateral distal forefoot (regions 2 and 3), where the decrease is respectively 18.2% and 10.8%. At the medial distal forefoot and the central proximal forefoot there is no dignificant difference.

Combination of interventions: custom moulded insole and rockerbar

The effects of the combinations of both interventions and their possible interaction was examined for the central distal forefoot, region

Table 2. Force impulse (N s) and peak pressure (N/cm^2) for shoes with rockerbar and shoes without a rockerbar and also for shoes with a custom moulded insole and shoes with a ready made insole, with standard deviation (s.d.), t-value, and p-value. Degrees of freedom = 30 for all tests (N=31).

ROCKERBAR								
	force impulse (N.s)				peak pressure (n/cm^2)			
Region	with rockerbar (s.d.)	without rockerbar (s.d.)	t-value	p-valve	with rockerbar (s.d.)	without rockerbar (s.d.)	t-value	p-value
1	39.0 (12.9)	40.3 (14.4)	-1.3	.20	29.8 (9.2)	31.2 (8.7)	-1.24	.22
2	53.4 (16.4)	62.9 (20.7)	-5.7	.00	30.6 (11.5)	36.3 (14.1)	-6.49	.00
3	20.5 (8.0)	22.9 (10.1)	-3.2	.003	19.4 (7.8)	21.0 (8.3)	-2.29	.03
4	12.8 (11.4)	11.2 (9.5)	1.6	.12	12.5 (5.6)	13.5 (6.7)	-1.45	.16
INSOLE								
	force impulse (N.s)				peak pressure (n/cm^2)			
Region	custom moulded (s.d.)	ready made (s.d.)	t-value	p-valve	custom moulded (s.d.)	ready made (s.d.)	t-value	p-value
1	40.2 (12.8)	39.1 (15.5)	0.57	.57	30.0 (9.7)	31.0 (9.5)	-0.55	.58
2	55.1 (16.2)	61.3 (21.4)	-2.97	.006	30.1 (10.9)	36.8 (15.2)	-4.68	<.000
3	23.1 (9.9)	20.3 (8.5)	3.04	.005	19.0 (7.8)	21.3 (8.7)	-2.35	.03
4	15.5 (11.7)	8.5 (9.7)	5.34	<.000	13.3 (6.1)	12.6 (7.3)	0.65	.52

2, using the force impluse. The averaged force impulses, for the 4 configurations, for the central distal forefoot are as follows:-
custom moulded insole with a rockerbar:
50.4 N s (s.d. 15.1);
custom moulded insole without a rockerbar:
59.8 N s (s.d. 18.3);
ready made insole with a rockerbar:
56.5 N s (s.d. 19.2);
ready made insole without a rockerbar:
66.1 N s (s.d. 25.1).

A multivariate analysis of variance showed that there was an intervention effect (within-subject factor = intervention, Pillais (3.28) = 0.640, exact F (3.28) = 16.61, $p < .00$).

The force impluse of the ready made insole is greatest. The value of the custom moulded insole without a rockerbar equals the value of the ready made insole with a rockerbar. In order to detect a different influence of the rockerbar on the effects of the 2 insoles and *vice versa* a multivariate analysis within-subject factors (insole and rockerbar) was performed. This analysis showed no interaction (F (1.30) = 0.01, p = .92).

Questionnaire

Twenty-five subjects reported pain with one or more interventions. The individual scores varied for all interventions between 0 and 3. The averaged scores are as follows:
custom moulded insole with a rockerbar:-
0.56 (s.d. 0.92);
custom moulded insole without a rockerbar:
0.76 (s.d. 1.01);
ready made insole with a rockerbar
1.68 (s.d. 1.07);
ready made insole without a rockerbar:
1.72 (s.d. 1.24).

A multivariate analysis of variance showed that there was an intervention effect (within subject factor = intervention, Pillais (3.72) = 0.616, exact F (3.72) = 10.43, $p < .00$).

The scores for custom moulded insole with and without rockerbar do not show a statistically significant difference. The same applies to the scores for ready made insole with and without rockerbar. The scores for both interventions with the custom moulded insole are statistically significantly lower (p-values are lower than .00) than both interventions with the ready made insole.

The preference of the 42 subjects for an intervention, in relation to the existence of pain accompanying each intervention, are found in Table 3. Twenty-five subjects reported pain with one or more interventions. Nineteen of these subjects preferred a custom moulded insole. Of the 17 subjects who reported no pain, only 6 preferred a custom moulded insole. Therefore, subjects with pain prefer statistically significantly ($p = .00$) more often a custom moulded insole.

Only 12 of the 25 subjects who reported pain, preferred a rockerbar while 6 of the subjects who did not experience pain prefered a rockerbar. There is no statistically significant preference for a rockerbar ($p = .23$) between the 2 groups.

Check for two possible confounders

Two effects were checked which could act as confounder: speed and overweight. Speed could act as confounder since it is known to influence force impulse and peak pressure (Kernozek and LaMott, 1995). The average speed in the different situations is as follows (n=31):-
custom moulded insole with a rockerbar:
1.265 m/s;
custom moulded insole without a rockerbar:
1.287 m/s;
ready made insole with a rockerbar:
1.257 m/s;
ready made insole without a rockerbar:
1.270 m/s.

The differences are so small that it is assumed that there is no influence on force impluse and peak pressure.

Overweight could also possibly act as a confounder. The Quetelet Index (QI) was used as measure for overweight and the correlation QI and peak pressure and force impluse were analysed for the ready made insole without a rockerbar. A subject with a QI of 20 to 25 is considered to be not overweight, while one with a QI greater than 30 has a clinically significant obesity.

The mean QI was 26.77 (s.d. = 3.82, n = 42). There was no statistically significant correlation between the QI and peak pressure ($r = 0.328$; $p = .071$) or between the QI and force impulse ($r = 0.185$; $p = .3180$). When only the subjects with a QI greater than 30 (n=6) were analysed there was still no correlation.

Therefore, the results do not support the idea that for subjects with a Quetelet Index < 30, overweight is a factor of risk for high peak pressures and force impluses. This is in agreement with the results of Cavanagh *et al.* (1991) who concluded that body mass is a poor predictor of peak plantar pressure in diabetic men.

Discussion

Redistribution of pressure under the foot as a result of a custom moulded insole and a rockerbar was investigated as the primary aim of this study. Since it is assumed that pressure and the duration of pressure are important in relation to the causes of foot problems, two parameters were selected: peak pressure and force impluse. The force impluse (intergral of pressure) is equally dependent on pressure and loading time.

The peak pressure and force impulse under the central distal forefoot, assumed to be the most important region, decreased considerably with the use of a custom moulded insole. With the use of a rockerbar it also decreased. The effect of the custom moulded insole with and without the rockerbar is of the same order. Further there was no interaction between the use of the custom moulded insole and the rockerbar, that is the use of one intervention did not influence the use of the other intervention.

Table 3. Preference of intervention for the subjects who reported pain (n=25) and those who reported no pain (n=17).

INSOLE				
Pain	Custom moulded	ready made	no preferance	total
present	19	0	6	25
absent	6	5	6	17
ROCKERBAR				
	with rockerbar	without rockerbar	no preference	total
present	12	9	4	25
absent	6	4	7	17

Effect of a rockerbar

A rockerbar, proximal to the metatarsal region, produced a statistically significant decrease of peak pressure (15.7%) and force impulse (15.1%) on the central distal forefoot and 7.6% and 10.5% on the lateral distal forefoot. This is in agreement with the results which are described in literature by Coleman (1985), Nawoczenski *et al.* (1988), Novick *et al.* (1991b), Peterson *et al.* (1985), and Schaff and Cavanagh (1990). These results do not indicate to what extent the decrease of force impluse was due to decrease of pressure and to what extent it was due to shorter loading time.

Contrary to the expectations, there was no statistically significant decrease at the level of the medial distal forefoot. Two possible reasons for this finding are the small number of subjects and a slight external rotation of the foot, which often occurs. The external rotation might alter the effect of the rockerbar, which was placed perpendicular to the sagittal plane of the shoe. Probably it should have been placed perpendicular to the roll off direction. The rockerbar should shift the line of gravity during the push off in the proximal direction. Therefore, at the proximal central forefoot an increase of peak pressure and force impulse were expected. However, there were no statistically significant changes. Force impulse tended to increase, while peak pressure tended to decrease. Possibly the smaller moment arm (Moment = F of calf musculature × perpendicular distance calf musculature to loading point) during the push off leads to smaller push off forces and a decrease of peak pressure. Two opposite mechanisms, longer loading period and decrease of pressure, can be responsible for eliminating changes in the force impulse.

Effects of a custom moulded insole

As expected, with a custom moulded insole the peak pressure and the force impulse of the central distal forefoot were both deceased, 18.2% and 10.1% respectively. At the lateral distal forefoot only the peak pressure decreased, while the force impulse did not change. It is not likely that the loading time increases as a result of the use of a custom moulded insole, and probably therefore, the averaged pressure did not decrease.

At the level of the medial distal forefoot there were no changes in peak pressure and force impulse. Two mechanisms might act in opposition: the oval shape of the custom moulded insole and the metatarsal pad. The oval shape of the insole is more likely to increase the pressure at the medial and lateral distal forefoot than to decrease it, while the metatarsal pad, on the other hand, is likely to decrease the pressure.

At the proximal central forefoot, the force impulse increased by more than 80% while the peak pressure did not change. This must be the result of a longer loading period. There findings support the idea that, due to the influence of time, the force impulse is an important parameter with more impact than pressure.

Interaction between custom moulded insole and rockerbar

No significat interaction of the effects of the custom moulded insole and the rockerbar were found. For practical use this conclusion means that the effects of the custom moulded insole and the rockerbar on pressure distribution can be added and therefore, in daily practice, it is useful to prescribe both interventions simultaneously.

Peak pressure, force impulse, pain and preference

Peak pressure and force impulse, at the central distal forefoot, are significantly lower with the use of a custom moulded insole. Pain scores are also significantly lower. It might be assumed that the differences of peak pressure and force impulse, with and without a custom moulded insole, could be related to the differences of the pain scores for both interventions. In order to analyse this relation a correlation analysis was performed for 18 subjects (from 31 subjects with usable data 18 reported pain), but no statistically significant correlation was found (r-value varies from 0.06 to 0.26, p-value varies between .06 and .83).

Although there is no correlation between peak pressure, force impulse and pain scores, subjects who reported pain during the trial had a clear preference for the custom moulded insole and subjects who did not report pain did not have this preference.

The effects of the rockerbar on the peak pressure and force impulse are approximately the same as the effects of the custom moulded insole. However there is no effect of the rockerbar on pain scores. This means that decrease of peak pressure and force impulse, produced by a rockerbar, could not be related to a decrease of pain scores. Hence, it is not surprising that there is no relation between pain scores and preference for rockerbar. The patients who expressed a preference for the rockerbar could possibly be influenced by such aspects as comfort, stability during walking and the cosmetic appeance of the footwear.

In daily practice it is often presumed that decrease of pressure is the most important factor to prevent pressure sores and to provide relief from pain. The results in this study do not confirm this hypothesis. Several factors might play a role:

- The subjects were asked to give a score for pain at the forefoot region, without distinguishing between medial, central and lateral forefoot. The values of peak pressure and force impulse, used for the calculations, are only for the central distal forefoot. Therefore, some pain scores might not have any relation to these values.
- The experience of pain is influenced by many other factors, which are not likely to be equal in all subjects. This might result in confounding and masking the relationship between pressure and pain.
- The way in which pain is interpreted. Do the subjects experience less pain when walking with a custom moulded insole, or do they experience more comfort, which they then refer to as less pain?
- The increase of force impulse at the proximal central forefoot could possibly provide a sensation of comfort which suppresses the pain sensation at the distal forefoot. This last hypothesis would be supported by the findings of Chen *et al.* (1994) who reported that a shift of pressure from forefoot to midfoot was found in the most comfortable insoles.

Overall it may be concluded that the custom moulded insole and the rockerbar both result in a substantial redistribution of pressure, as expressed by the peak pressure and force impulse, in particular by decreasing the load on the central distal forefoot. Since there is no interaction between the 2 interventions, both should be used together. The subjects who reported pain at the forefoot prefered the custom moulded insole more often, but showed no preferance for the rockerbar. The custom moulded insole and the rockerbar are important tools in the management of foot problems.

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Test apparatus for the measurement of the flexibility of ankle-foot orthoses in planes other than the loaded plane

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Abstract

Previous publications have reported on the flexibility of ankle-foot orthoses (AFO) only in the same plane as the applied load. This paper reports on a test apparatus developed to detect the flexibility of an AFO in 5 degrees of freedom when subjected to a plantar/dorsiflexion moment, a medial/lateral moment or a torque. A moment applied to an AFO in one plane induces angulation and translation in all planes.

Introduction

This work stems from an interest in relating the results of clinical evaluations of AFOs by Raschke (1997) to defined mechanical behaviours of the prescribed ankle joints.

It was observed that AFO cross-coupled deformation effects (motion in planes other than the applied plane) may be influential upon the clinical outcome. Raschke (1997) noted that by selecting a pair of ankle joints with different stiffness characteristics, the orthotic prescription may be more appropriate in matching the patient's requirements. One of the authors has observed that reinforcing an AFO with extremely stiff carbon fibre may produce a superior effect to a typical thermoplastic AFO as far as improved pain relief is concerned. This may be due to a reduction in cross-coupled deformation effects.

Rubin and Dixon (1973), Condie and Meadows (1977), Clark and Lunsford (1978) and Miyazaki *et al.* (1993) have reported on the dorsal/plantar flexibility of AFOs when subjected to dorsi/plantarflexion moments. Chowaniec (1983) reported that when an AFO was subjected to an inversion or eversion moment, load cells detected an apparent dorsi/plantarflexion moment. Chowaniec commented that this was more noticeable with an eversion moment but that applying a dorsi/plantarflexion moment did not create significant cross-coupled effects. Ward (1987) refined to the test rig developed by Chowaniec but did not investigate cross-coupled effects Golay *et al.* (1989) studied the effect of malleolar prominence on the flexibility of polypropylene AFOs in dorsiflexion. Lunsford *et al.* (1994) reported on the dorsal/plantar flexibility of AFOs subjected to cyclic dorsi/plantarflexion moments and commented on the effect of the variation in wall thickness of manually draped AFOs. Sumiya *et al.* (1996) reported on the variation of dorsal/plantar flexibility of AFOs with different trimlines when subjected to dorsi/plantarflexion moments. Yamamoto *et al.* (1993) studied the dorsal plantar flexibility of AFOs when subjected to dorsal/plantarflexion moments and also the inversion/eversion flexibility of AFOs when subjected to inversion/eversion moments.

This paper reports on mechanical measurement system to monitor 5 degrees of freedom and thereby quantify cross-coupled deformation in AFOs.

The motion of a solid body in a space may be identified as the combined effect of three linear (translation) and three rotational (angulation) degrees of freedom in any three-dimensional co-ordinate system. The normal ankle joint system, consisting of several identifiable axes, provides mobility of one "solid" body, the foot, in relation to another solid body, the lower leg.

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Table 1. Translatory and angular motion in each plane.

	Translation movement	Angulation movement
Sagittal plane	Anterior/Posterior (Proximal/Distal)	Plantar/dorsiflexion
Frontal plane	Medial/Lateral (Proximal/Distal)	Inversion/Eversion
Transversal plane	Anterior/Posterior Medial/Lateral	Internal/External Rotation

In anatomy and in prosthetic and orthotic analysis, Anatomic Reference Planes (ARP) are used instead of co-ordinate systems, referring translations and rotations to movements in these planes. In this application, the AFO ankle joint axis was positioned in the frontal plane and the AFO soleplate defined the transverse (horizontal) plane. The six degrees of freedom are expressed in ARP terms in Table 1.

As a plane is two-dimensional, each plane exhibits two translatory degrees of freedom.

Method

The axis of the ankle joint was identified by the orthotist while wrap casting the patient. A "master" plaster model was used to ensure that the axes of the selected ankle joints of all the AFOs were positioned identically. A long pin was attached to the master mould to ensure that this axis was subsequently transferred to all future plaster models and AFOs. The axis of the AFO ankle joint was aligned in the frontal plane. The plantar surface of the plaster model, i.e. the foot base of the plastic AFO, was flattened. A rigid plate, compatible with the inner sole of the AFO, was drilled with three holes (Fig. 1). These three holes correspond to those previously drilled and tapped on the base of the apparatus using a numerically controlled machine. The rigid plate was positioned accurately over the inner sole of the AFOs so that the three holes could be identified and drilled through the plastic AFOs (Fig. 1). The flat foot base of each tested AFO could then be bolted to the base plate of the apparatus in a reproducible way. Allowing for the most unlikely combination of clearance between the bolts and the holes a maximum rotational positioning error of the AFO of 0.1° may occur. This inaccuracy would have a negligible effect on the cross-coupled deformations.

A rigid central metal structure "buried" in a calf model, was used to apply loads and monitor movements. The square cross-sectional column was partially covered by a rigid polyurethane foam dummy formed from the "master" shank mould. Prior to pouring the foam, the central column was positioned vertically above the pre-determined ankle axis. Distally, the central metal structure incorporates four extended members. These four extended members have been drilled and tapped to accommodate four pins or outriggers. Loads may be applied distally to the central column in the anterior, posterior, medial or lateral directions via the four outriggers.

Fig. 1. AFO and the rigid plate.

Fig. 2. Location of medial and posterior plates.

After draping the AFOs over identical plaster cast models, the AFOs were fitted sequentially to the dummy shank. Each AFO was positioned on the foam dummy and located via upper and lower Velcro straps. A long threaded pin with a hot tip was screwed through the accessible distal anterior hole so that the hot tip protruded posteriorly through the AFO, proximal to the ankle level. The hot tipped pin was removed. The distal anterior and posterior outriggers were screwed to the rigid central structure. A similar procedure was adopted after locating the medial hole through the AFO. A hot tipped pin was screwed in the lateral direction through the foam covered metal structure until it protruded laterally through the AFO. This long hot tipped pin was removed. Medial and lateral outriggers were screwed to the metal structure so that they extended beyond the AFO.

Proximally, at approximately "knee height" above the foamed calf, the central metal structure was drilled, tapped and long threaded bolts to outriggers were fitted posteriorly and medially.

The proximal and distal outriggers on the medial aspects of the calf were used to locate a flat aluminium plate external to the AFO as shown in Figure 2.

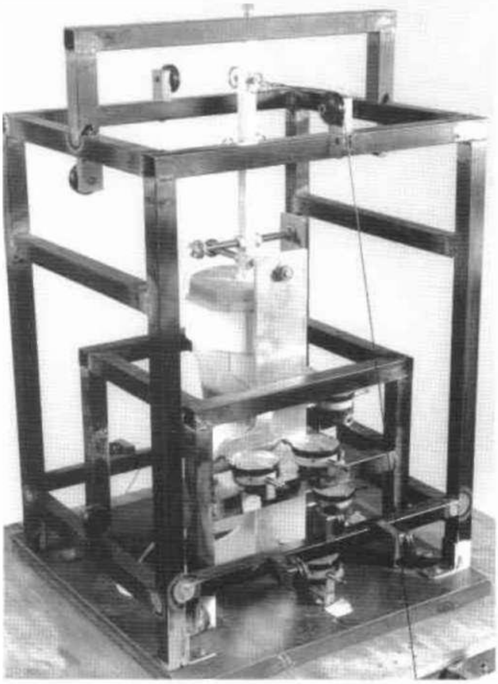
This medial plate effectively defined the sagittal plane when no load was applied to the AFO. Similarly, the proximal and distal outriggers on the posterior aspect of the calf were used to locate a flat aluminium plate external to the AFO. This posterior plate defined the frontal or coronal plane when the AFO was unloaded.

The test apparatus was constructed to enable moments to be applied to the AFO and the resulting movements to be recorded. Proximal loading hooks were attached to the central column at mid-thigh level. A single cable attached to two locations on the "calf model" and passing over pulleys mounted on the outer framework enabled moments (or pairs of forces) to be applied to the AFO. The single cable also passed over a swivel pulley arrangement mounted on the under surface of the base of the apparatus so that loads could be applied through the cable tension generated via the suspended masses, as shown in Figure 3a. This is also illustrated schematically in Figure 3b. The inner framework was used to position dial gauges which monitored corresponding motion.

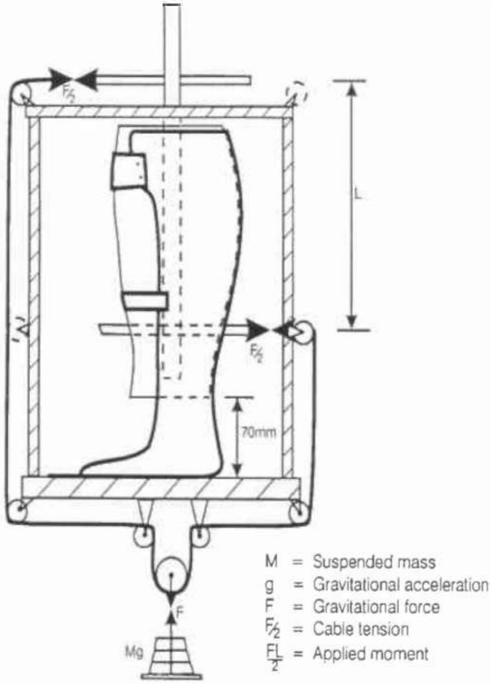
The following test procedure was followed. The selected AFO was fitted to the dummy shank and foot section clamped to the base plate of the test apparatus. Incremental and decremental moments were applied and the motion of the medial and posterior plates relative to the inner frame of the test apparatus was noted. The moments applied in all three planes were representative of moments recorded during gait. The motion of both plates was recorded using six 25mm range dial gauges (accuracy .01mm), as shown in Figure 4. Both the medial and posterior plates were in contact with three dial gauges.

Translations and angular motions were calculated from recordings from pairs of these gauges. For example, plantar and dorsiflexion could calculated from sagittal plane recordings of the upper and lower dial gauges that contact the posterior plate. Rotation in the transverse plane could be calculated from recordings of the upper pair gauges in contact with either the posterior or medial plate. As the six gauges were read sequentially, instantaneous recordings were not possible. Hence the measuring method was sensitive to creep of the plastic AFOs.

This paper presents the flexibility results of a polypropylene AFO that does not incorporate an



(a)



(b)

Fig. 3. The test for apparatus.

ankle joint. However, the AFO was bolted to the base plate of the test apparatus so that the plane of the ankle axis, defined at the casting stage, coincided with the frontal plane and also with the upper and lower dial gauges in contact with the medial plate. Other types of AFOs could be bolted to the rig in the same way.

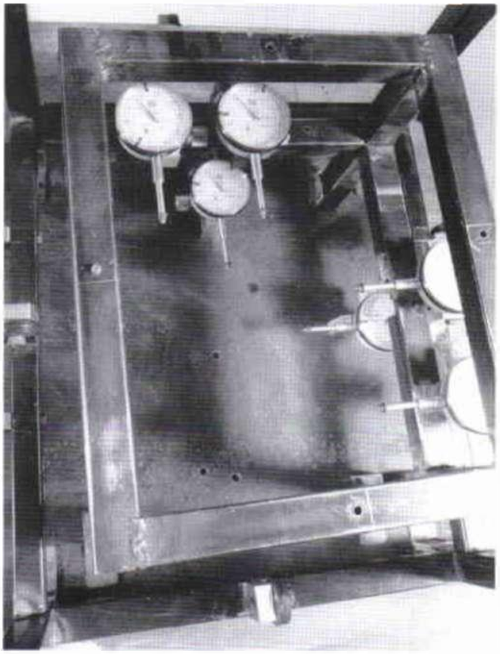


Fig. 4. Position of dial gauges

The gauge readings were transferred to spreadsheets where subsequent calculations presented the results as graphs. For example, the angulations and horizontal translation at the anatomic ankle joint level in the sagittal plane may

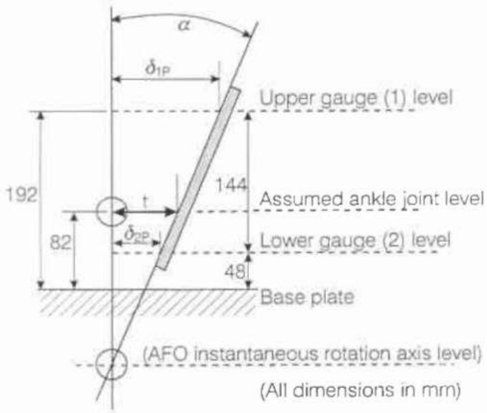


Fig. 5. Geometric configurations of AFO under test.

be calculated from the data presented in Figure 5. The anterior or posterior movements of the upper and lower dial gauges in contact with the posterior plate record the motion in the sagittal plane.

Thus $\alpha = \tan^{-1} (\delta_{1P}-\delta_{2P}) / 144$
$t = \delta_{1P} - (192 - 82) (\delta_{1P} - \delta_{2P}) / 144$

Using the displacements noted from the pair of vertical gauges in contact with the medial plate similar equations enable the horizontal translations and angulations in the frontal plane to be determined.

In summary, angular motion about all axes may be measured together with translations in

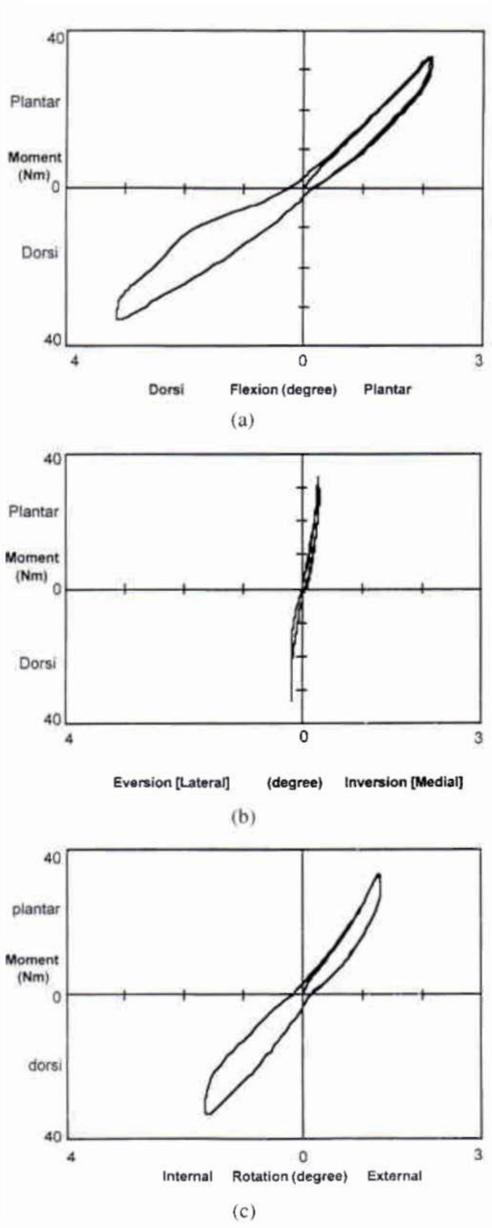


Fig. 6. Angulation due to plantar/dorsiflexion moments. (a) sagittal; (b) frontal; (c) transverse.

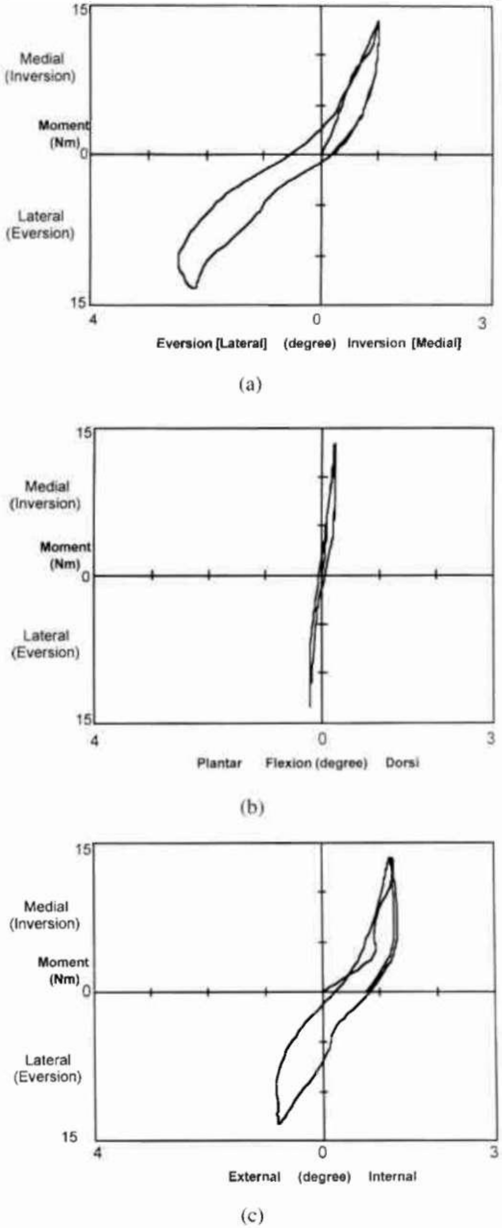


Fig. 7. Angulation due to inversion/eversion moments. (a) frontal; (b) sagittal; (c) transverse.

the transverse plane.

Results

The test apparatus was used to determine the flexibility characteristics of a single AFO subjected to moments applied in the sagittal, frontal and transverse planes. The "calf model" provided support for the calf section of the AFO but the AFO has no restriction from a leg (or flail leg) for the 70mm axial length above the soleplate of the AFO. For each selected load application, the corresponding angulations are presented in all three planes shown in Figures 6, 7 and 8. The corresponding translations in the transverse plane are presented in Figures 9, 10 and 11. These results relate to a "stiff" polypropylene AFO incorporating no orthotic ankle joint.

Repeatability, after removal and re-installation was studied and Figure 12 displays the similarity in the results of two identical tests performed on different days.

The presented graphs illustrate ways to compare the flexibility of AFOs.

Discussion

In an AFO, the function of the joints, the deformations of the soft tissue coupling between

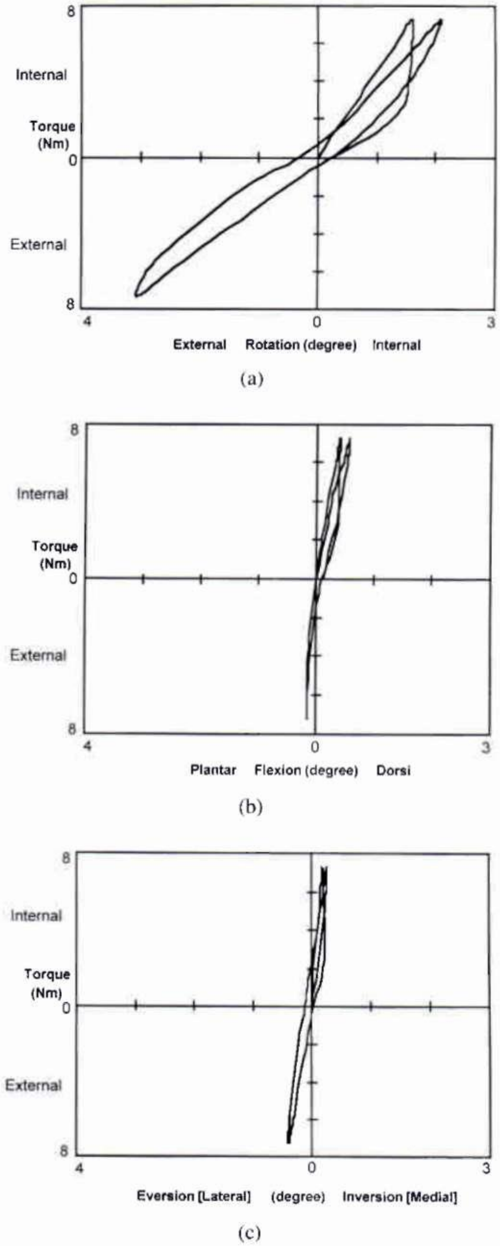


Fig. 8. Translation due to internal/external torques. (a) transverse; (b) sagittal; (c) frontal.

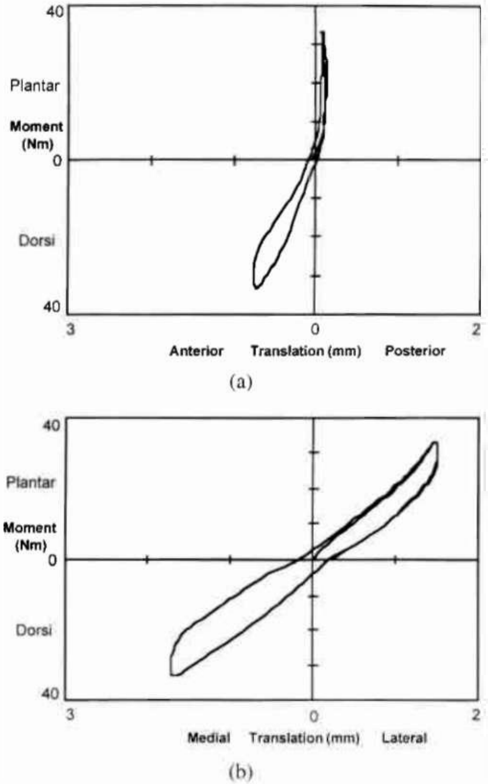


Fig. 9. Translation due to plantar/dorsiflexion moments (a) anterior/posterior; (b) medial/lateral.

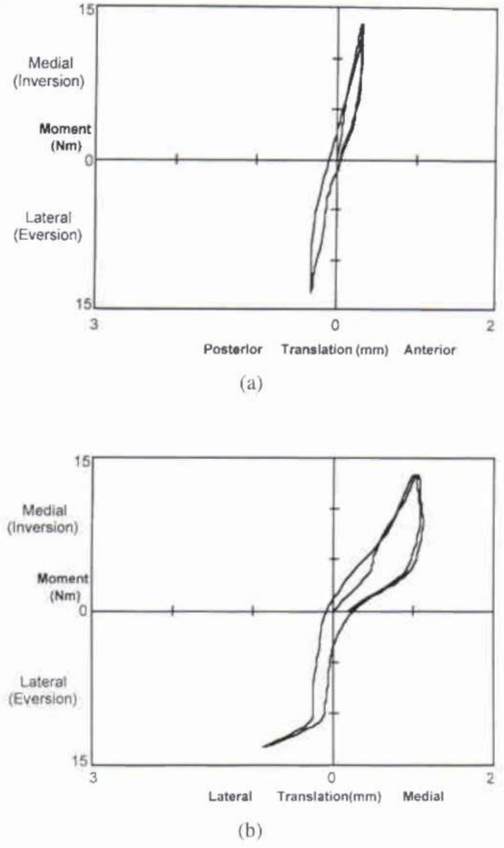


Fig. 10 Translations due to inversion/eversion moments (a) anterior/posterior; (b) medial/lateral.

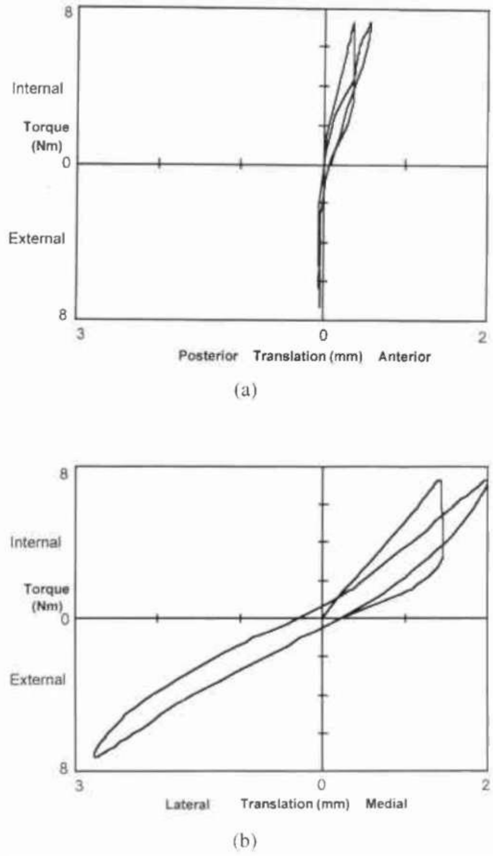


Fig. 11. Translation due to internal/external torques (a) anterior/posterior; (b) medial/lateral.

the orthoses and the skeleton, and the structural deformations of the orthoses interact and must all be taken into account.

This study is limited to the orthotic ankle joint as fitted, including the structural properties of the AFO in the vicinity of the joint, but eliminating the orthoses/tissue interface. This approach also makes no allowance for compliant feet or shoes. Is is considered that attempting to introduce all these factors would introduce too many variables and too many effects to quantify. Since this test apparatus will be used to compare the flexibility of a range of AFOs incorporating different ankle joints this approach was considered valid. This limits the study to investigating the AFO's flexibility over an approximate 70mm axial length of AFO from the top of the soleplate clamp to the distal surface of the foam calf.

A "stiff" polypropylene AFO has been used in this paper to demonstrate the capability of the test apparatus.

In Figures 6 and 7 the (a) graphs illustrate load/deflection characteristics similar to previous researchers. The presented results do

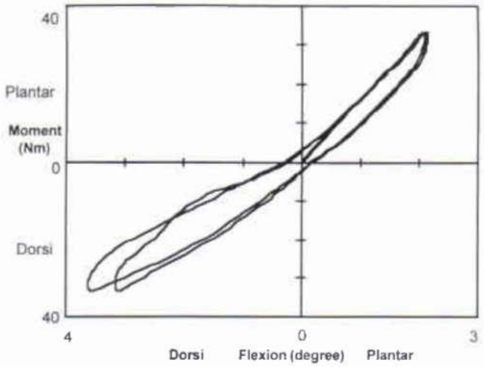


Fig. 12. Repeatability of sagittal angulation due to plantar/dorsiflexion moments.

not correlate exactly with previous studies due to variations in the loading apparatus and the contact area of the AFO with the base plate of the test apparatus and the enclosed "calf model". The other graphs in Figures 6, 7 and 8 illustrate the extent of angular cross-coupled deformation displayed by this particular AFO.

Figure 6 graph (c) illustrates that when subjected to dorsiflexion moments the AFO brim rotated internally relative to the soleplate . Likewise applied plantarflexion moments were accompanied by an external rotation of the AFO brim relative to the soleplate. The magnitudes of the cross-coupled rotations were approximately half that of the magnitude of the plantar/dorsiflexions. Figure 6 graph (b) illustrates that cross-coupled deformations in the frontal plane were significantly less but did follow a similar pattern.

Figure 7 graph (c) illustrates that when subjected to eversion (lateral bending) moments the AFO brim rotated externally relative to the soleplate. Applied inversion (medial bending) moments were accompanied by less internal rotation of the AFO brim. The magnitudes of the rotations were similar to the degree of eversion/inversion produced by the loading condition. Figure 7 graph (b) illustrates that cross-coupled deformations in the sagittal plane were significantly less but did follow a similar pattern. Figure 8 graphs (b) and (c) illustrate that when subjected to external/internal torques the cross-coupled deformations in the sagittal and frontal plane were significantly less as also were the magnitudes of the applied torques which as previously indicated were representative of those encountered during gait.

Figures 9, 10 and 11 illustrate that when subjected to moments in any of the 3 planes mediolateral translation of the AFO was the most prominent translation. When subjected to dorsiflexion moments as in Figure 9 graph (a) the magnitude of the anterior translation at ankle joint level was greater than that of the posterior translation when subjected to plantarflexion moments. Figure 9 graph (b) displays large mediolateral translations with applied plantar/dorsiflexion moments. When the AFO was subjected to eversion (lateral bending) moments as in Figure 10 graph (b) the magnitude of the lateral translation at ankle joint level was greater than the magnitude of the medial translation when the AFO was subjected to inversion moments. Figure 10 graph (a) illustrates corresponding anteroposterior translations when the AFO was subjected to inversion/eversion moments. When the AFO was subjected to internal torques as in Figure 11 graph (a) the magnitude of the anterior translation at ankle joint level was greater than the posterior translation which resulted when the AFO was subjected to external torques. Figure 11 graph (b) illustrates larger corresponding mediolateral translations when the AFO was subjected to internal/external torques.

The asymmetric trimlines of the medial and lateral foot section of the soleplate of the AFO would influence the cross-coupled deformation displayed. The polypropylene AFO was manually draped and vacuum formed. There would be some resulting inconsistency in wall thickness of the AFO which would influence some cross-coupled deformation effects. Examination of asymmetric trimlines and variation in wall thickness will be investigated and reported in future studies.

In this test apparatus the motion of the AFO has been studied with a moment being applied in a single plane. In clinical practice the AFO may be subjected to combinations of all 3 moments at any instant. These combinations of moments may influence cross-coupled deformation effects.

Measurement of the sixth degree of freedom, the proximal/distal translation, is not possible with this test rig, unless a further reference plate and further gauges were added. If the calf is pivoting about its long axis, which may differ from the instantaneous AFO axis, related proximal/distal translation will occur between the calf and the AFO. The recorded gauge movements allow estimation of the instantaneous AFO axis, to predict this relative translation (not presented in this paper).

Conclusions

This test apparatus provides a protocol for applying moments in three planes and recording reproducible angulations and translations with 5 degrees of freedom.

When subjected to moments in the sagittal or frontal plane, rotation is the prominent cross-coupled deformation. When subjected to torques there is no prominent cross-coupled deformation.

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Biomechanical evaluation of the Milwaukee brace

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Abstract

Although, the history of orthotic treatment for idiopathic scoliosis goes back more than fifty years, the mechanism of curve control by spinal orthosis is still controversial. Hypothetical explanations have been provided but few, if any, have been tested clinically. This study aims at the biomechanical evaluation of a spinal orthosis (Milwaukee brace) in order to improve understanding about the mechanism of curves control in orthotic movement.

From the results of the study, the change of the interface pressure between the patient's body and thoracic pad, and the tension of the thoracic strap were highly correlated (r= 0.84) as patients performed different lying postures and daily activities. Lying on the thoracic pad is found to have the highest correctional force among different lying postures that may be favourable for preventing curve deterioration.

The findings indicate that an increase in tension of the thoracic strap will increase the interface pressure on the thoracic pad and thus increase the resultant force exerted on the patient's body by the thoracic pad. Care must be taken as an excessive strap tension will increase discomfort and restrict body shifting exercises. The results also suggest that in scoliosis with thoracic lordosis, a short outrigger (small pulling angle of the thoracic strap) should be used as it will decrease the anteriorly directed force component so as to prevent exaggerating the thoracic lordosis.

Introduction

The Milwaukee brace was designed by Blount and Moe in 1945. It is commonly used for the non-operative treatment of the thoracic curve of adolescent idiopathic scoliosis with moderate severity (Cobb angle: 25°-45°). Clinical experience with the brace has led to many improvements, both in the design of the brace itself and in the manner in which it is used. However, little study had been devoted to the relationship between the forces that the brace elicits, either passively or through muscle action, although it is accepted that these forces are a major factor in whatever correction is obtained.

The Milwaukee brace is a mechanically complex device which is different from low profile spinal orthoses such as the Boston brace and New York Orthopaedic Hospital orthosis which were believed to supply only passive forces (Winter and Carlson, 1977; Laurnen *et al.*, 1983; Willner 1984; Wynarsky and Schmltz, 1990). The Milwaukee brace can apply longitudinal as well as transverse forces (Blount and Moe, 1980; Bradford *et al.*, 1987; Winter *et al.*, 1986) The shoulder sling, thoracic pad and lumbar pad of the brace can apply forces of different magnitudes, in different directions and at different points. The brace may be used to correct single, double and triple scoliotic curves variously situated (Adriacchi *et al.*, 1976).

However, the corrective forces applied to the spine will be limited by the nature of the areas on the body's surface through which force can be transmitted. The spine cannot be directly accessed by external forces but rather through its corresponding ribs and soft tissues. These forces, applied across specific contact areas, may be sufficient to produce substantial stress and strain within the soft tissues, which can impair the blood supply and lymphatic drainage. If these interface conditions are prolonged, cell necrosis will result and may lead to the eventual development of tissue breakdown and

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ulceration. Therefore, the control of the interface pressure distribution in orthotic treatment is very important especially beneath the thoracic pad and pelvic girdle where the pressure is likely to be highest.

A possible method of objectively defining the action of the brace is to study the forces exerted by the brace on the patient. Knowledge of the range and characteristics of these forces could then be used to evaluate the accuracy of fit, efficiency of support and effectiveness of any design modification. It could also lead to a better understanding of the mechanisms of correction involved.

The study of the forces exerted on the patient's body by bracing may be accomplished by measuring the forces in all major brace components such as throat mould, occipital pads, shoulder ring, uprights, thoracic pad, lumbar pad and hip girdle but the measurements involved for all the above components are very complicated and need many brace modifications, and as a result the brace may be too greatly modified to allow the patient to perform normal activities. It is better to simplify the methods of measurement, have the fewest brace modifications and collect those data with greatest clinical value. Therefore, the force/pressure on the thoracic pad and the tension of the thoracic strap were investigated in this study. The thoracic strap is used to fit over and exert forces on the thoracic pad. The variation of the tension and direction of pull of the thoracic strap with have an effect on the magnitude and direction of the correctional forces exerted on the body by the thoracic pad. These are among the most important variables in obtaining optimum performance from a brace (Andriacchi *et al.*, 1976; Winter and Carlson, 1977; Bunch and Patwardhan, 1989).

The objectives of this study are to measure the changes which occur in the interface pressure distribution and the net correctional force of the thoracic pad on the patient's body by altering the posture, activity, thoracic strap tension and pulling direction of the thoracic strap. The correlation between the change of the thoracic strap tension and the pressure on the thoracic pad will also be studied.

Material and methods

Patient source

Scoliotic patients were selected from those attending the Spinal Clinic which is held twice a month in the Duchess of Kent Children's Hospital at Sandy Bay, Hong Hong. The patients attending this clinic were mainly referred from the out-patient clinic of the same hospital or from doctors in private practice.

Each patient had a full clinical evaluation including a detailed medical history (patient's spinal deformity, general health, family history and maturity status). The physical examinations included anthropometric measurements, range of motion of the spine, forward bending test, neurology assessment, cardiorespiratory system and the secondary sexual characteristics. All patients had the following radiographs of the spine: standing anteroposterior, standing lateral, supine anteroposterior and supine bending. From these radiographs, data related to the skeletal maturity, curve pattern and curve magnitude were obtained.

Patient selection criteria

The following criteria were used for selection of patients as subjects within this study:

1. progressive adolescent idiopathic scoliosis (according to Lonstein and Carlson, 1984);
2. age 10-14 years;
3. Skeletally immature patient (Risser sign 4 or less); and
4. Cobb angle ranged from 25 to 40 degrees and undergoing orthotic treatment.

Methods of measurement

There were two measured parameters, strap tension and interface pressure. The measurement methods were as follows:

a) Measurement of thoracic strap tension

A purpose designed buckle force-transducer (Fig. 1) is used to measure the tension in the thoracic strap and may be used in other straps such as the shoulder strap. The device is small (35 x 35 x 5mm). The tension in the strap can be measured *in situ* without modification to the brace or strap. It is simple to install – by taking out the removable pin and placing the transducer on the thoracic strap then inserting the removable pin to the original position.

With the buckle force-transducer placed on the strap, the longitudinal tensile force along the strap generates a bending moment on the central beam of the frame. The relationship between the tensile strap force and the amount of moment

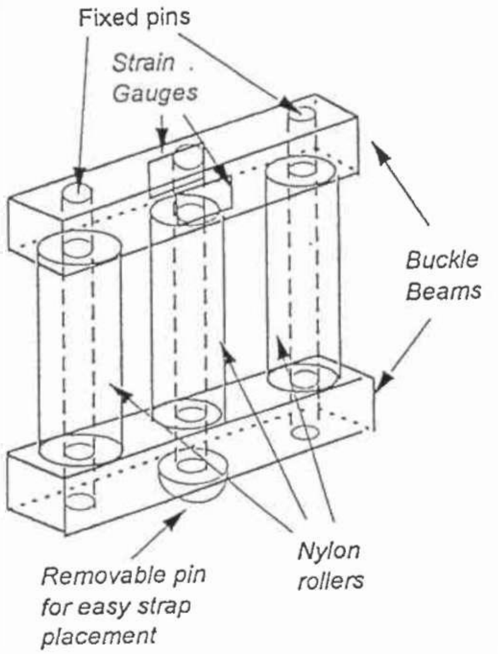


Fig. 1 The structure of the purpose designed buckle force-transducer.

generated depends on the off-set from the longitudinal axis of the strap (Fig. 2). The amount of moment that deforms the central beam is sensed by two stain gauges. The three metal rods of the buckle transducer form the axis for thin nylon rollers which help reduce the friction between the strap and the metal rod during the loading and unloading. Another purpose of the nylon rollers is to increase the amount of strap off-set which will increase the sensitivity of the transducer without significant change of the strap length.

The buckle force-transducer is fitted over the strap of the thoracic pad just behind the attachment to the anterior outrigger. This is the best location for the buckle as it is free from contact with the body, thoracic pad and outrigger. The free length of location for the transducer is about 35mm.

The transducer is connected as a half-bridged system with two strain gauges, each furnished to either side of the buckle frame. The strain gauges of the buckle force-transducer are manufactured by Tokyo Sokki Kenkyujo Co., Ltd. and their specifications are – type: FLA- 3-23, gauge length: 3mm, gauge resistance: 120±0.3Ω and gauge factor (strain - sensitivity factor): 2.15.

The whole recording mechanism of strap tension is that the buckle force-transducer firstly transforms the mechanical signal (tension force) into an electric signal which is amplified by a single conditioner, and then to a XYt recorder (PM8272, Philips, Netherlands) which records the signal in the form of graph plot. The signal conditioner operates at low voltage (3V) and is electrically isolated.

An Instron testing machine (Model 1122, Instron Ltd., High Wycombe, UK) and a strain gauge meter were used in the calibration of the buckle force-transducer. The buckle force-transducer was placed on a double-layer Dacron strap. The two ends of the strap were firmly anchored via special grips to the load cell (to simulate the condition as in the spinal orthosis). The strap was loaded in tension from 0 to 300 N (normal strap tension estimated to be less than 200 N) and then unloaded. The loading and unloading rate was 10mm/min. Hysteresis was observed which may be due to the elastic properties of the Dacron strap, the friction between the strap and buckle transducer, eccentricity in the nylon rollers or the non-rigid frame structure. These adverse factors have been minimised by pre-conditioning the Dacron strap, using concentric nylon rollers and increasing the buckle frame rigidity. After the above improvements, the degree of hysteresis has been reduced to an acceptable level (Fig. 3).

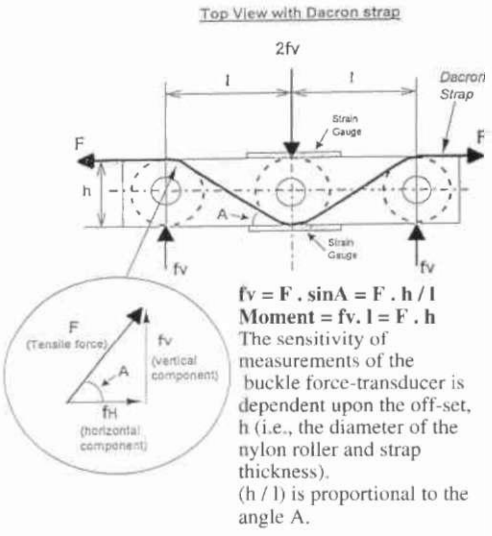


Fig. 2. Force diagram of the buckle force-transducer.

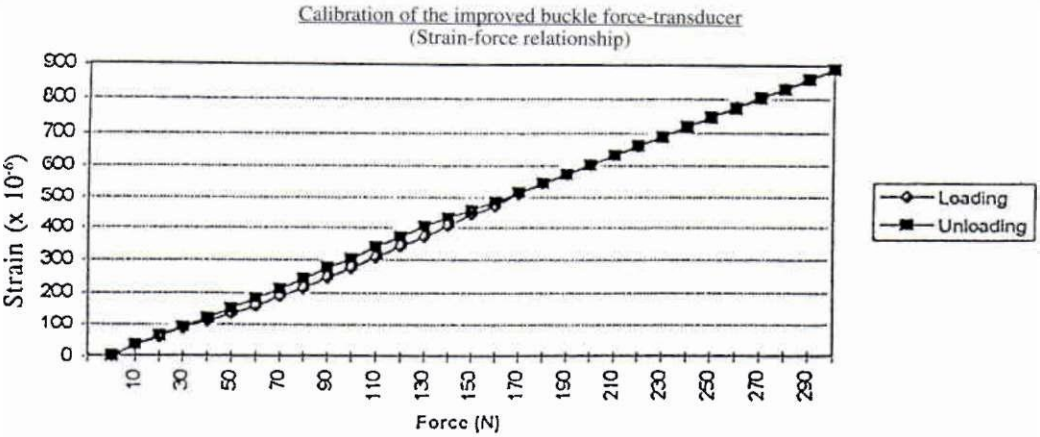


Fig. 3. Calibration of the improved buckle force-transducer

b) Measurement of pressure on the thoracic pad

The thoracic pad was made of thin aluminium alloy (2024-T3: 1.55mm in thickness), the surface facing the patient's body was covered with a soft material (Pelite: 5mm in thickness) and the pad was totally covered with leather (bridle light: 2mm in thickness). The thoracic pad could be bent by bare hands. The bending rigidity of the thoracic pad would affect the pressure readings, thus two precautions have been taken. Firstly, the thoracic pad was contoured according to the patient's body contour with no gap in-between. Secondly, the contour of the thoracic pad was traced before and after the pressure measurements to ensure no distortion of the pad shape.

The metal neck ring totally embraced the neck but with enough clearance to permit breathing and physical exercise. The left and right posterior uprights were aligned by dropping plumb line from the corresponding rivet hole of the posterior part of the metal neck ring. The two posterior uprights were 100mm apart (centre-line to centre-line) from each other. The positioning of the pad depended on the level of the scoliotic curve apex. The medial border of the thoracic pad was placed just medial to the medial border of the right posteriorly upright and was secured in position by two Dacron straps attached posteriorly to the thoracic pad with the other ends attached to the right posterior upright. The thoracic pad could be moved freely in anterior and posterior directions. The design aimed at giving an anterior-directed force to the patient's trunk though the posterior part of the thoracic pad which was further reinforced by the right posterior upright as the thoracic pad came into contact with the posterior upright.

The interface pressure (correcting pressure) between the patient's body and the thoracic pad was measured by the Dynamic Pressure Monitor (DPM 2000C) which was manufactured by Raymar Ltd., in England. It uses an electro-hydraulic system which can operate at high sampling rate (1 Hz for all sensors) unlike other pneumatic-type pressure monitors, which operate at low speed and can only take one sample for each sensor at a time. High sampling rate is required for measuring activities such as body shifting and deep breathing. The measurement range is from 0 to 240 mmHg which is adequate for the measurement purpose.

The Dynamic Pressure Monitor has two measuring matrixes (each covering a total area of 2700 sq mm) and each has four electro-hydraulic sensors (each sensor has a diameter of 14mm) arranged in a parallelogram shape. The two matrixes are arranged on either a horizontal axis or vertical axis (Figs. 4 and 5) and held in place with adhesive tape on the free boundaries on the inner surface of the thoracic pad for measuring the pressure distribution on different portions of the thoracic pad. A Macintosh computer is required to run the software of the DPM 2000C. The collected data can be stored as data file or expressed as line plots or histograms.

In calibrating the Dynamic Pressure Monitor, three pieces of equipment are used. These are a calibration chamber, sphygmomanometer and hand pump. The pressure sensors are inserted

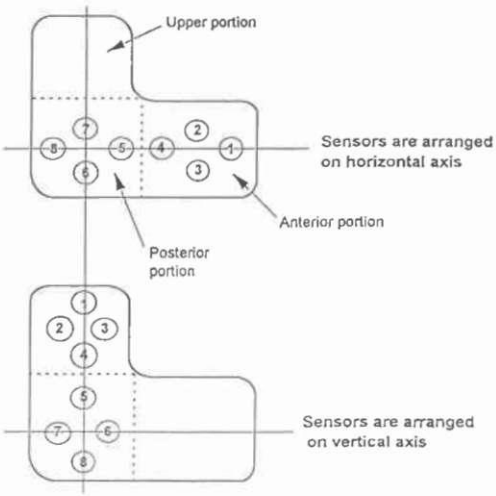


Fig 4. The arrangement of the pressure sensors on the thoracic pad.

into the calibration chamber which is a rectangular wooden box with an opening at one end. The chamber pressure is increased from 0 mmHg to 240 mmHg by using a hand pump and the output from the DPM is recorded. The accuracy of the reading across the whole range is determined. Adjustment of the "scale" potentiometer may be necessary to achieve the best overall accuracy. In the calibration, it was found that the presence of the sensor bulbs would "steal" pressure from the areas being measured if the area being measured was a hard surface. For soft and resiliant surfaces such as the trunk of a human being, the accuracy of measurement could be maintained.

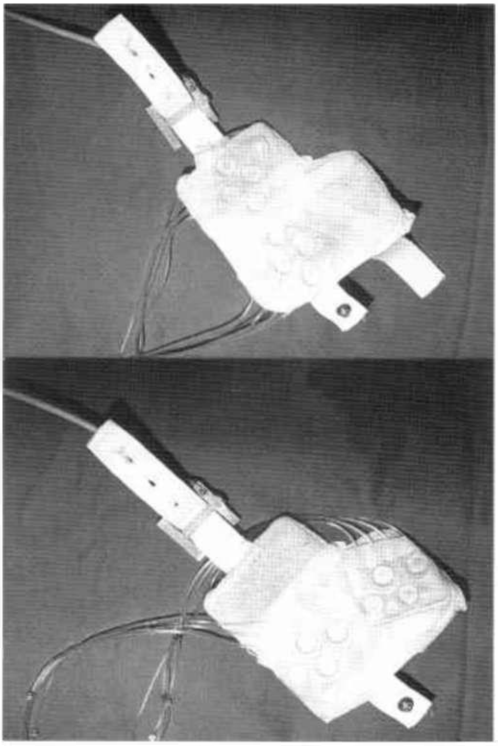


Fig. 5. The pressure sensors are firmly stuck to the thoracic pad in the horizontal axis (above) and vertical axis (below) while the buckle force-transducer is anchored on the anterior part of the thoracic strap.

c) Procedure of measurement

During measurement the pressure sensors were located in between the patient's trunk and thoracic pad for interface pressure measurement while the buckle-force-transducer was placed on the Dacron thoracic strap for tension measurement. Before every measurement, the buckle transducer was recalibrated again at zero load and by applying a weight of 1 Kg or 9.81 N. The measurements of the thoracic pad pressure and strap tension were recorded simultaneously over a period of time.

The patient was required to wear her spinal orthosis with the above set-up and perform different lying postures, normal and deep breathing (in sitting and standing positions) and also in-brace shifting exercises. Measurements taken in these postures and activities are commonly performed in daily living, thus, could reflect the actual effect of bracing on the patient. Different thoracic strap tensions and pulling directions were employed as to investigate their effect on the correctional forces exerted on the patient's body by the thoracic pad.

Fig. 6. Patient is lying on her left side with Milwaukee brace which is furnished with buckle force-transducer and pressure sensors on the thoracic strap and thoracic pad respectively.

The protocol of measurement is as follows:

1. supine lying;
2. left-side lying; (Fig. 6)
3. right-side lying;
4. prone lying;
5. sitting with normal and deep breathing;
6. standing with normal and deep breathing;
7. standing and shifting away from the thoracic pad; (Fig. 7)
8. standing with normal and deep breathing (decrease strap tension by one notch down (2.5cm) from the notch as selected on original fitting;
9. standing with normal and deep breathing (increase strap tension by one notch up (2.5cm) from the notch as selected on original fitting;
10. standing with normal and deep breathing (decrease the pulling angle of the thoracic strap by shortening the outrigger length 8cm from 12cm);
11. Standing with normal and deep breathing (increase the pulling angle of the thoracic strap by lengthening the outrigger length to 18cm from 12cm).

Pressure sensors are arranged on horizontal axis for all the above steps. Pressure sensors are then rearranged on vertical axis and steps 6 and 7 are repeated.

Results and analysis

Nine female patients were selected for this investigation. Their mean age was 13.25 years with a range of 11.5 to 14.8 years. All of them had right thoracic curves (mean=39°, SD=7°) and left lumbar curves (mean=33°, SD=6°), and received Milwaukee brace treatment for more than 3 months before the start of the investigation. Their mean flexibility (the curve reduction achieved from lateral bending which may give some idea about the potential benefit of bracing) was 60%±20% in a thoracic curve and 74%±22% in lumbar curve. After bracing, the curve reduction was 30%±14% in thoracic region and 42%±11% in lumbar region.

Fig. 7. Patient is doing shifting exercises. She is holding the anterior upright with both hands and moving away from the thoracic pad.

The analysis included the correlation between the changes of the thoracic strap tension and the interface pressure of the thoracic pad as the patient performs different lying postures (supine, left-side, right-side and prone) and activities (normal and deep breathing in sitting and standing positions, and shifting exercise), and the change in magnitude and direction of the correctional force exerted on patient's body by the thoracic pad in different lying postures (supine, left-side, right-side and prone), different thoracic strap tension (low, medium and high, and with different angles (small, medium and large) of pull of the thoracic strap.

The sampling period was 30 seconds for every posture or activity. The measurement of strap tension was continuous while the sampling rate of the Dynamic Pressure Monitor was 1 sample per second. There were about 5 to 7 breathing cycles during the measurements of every posture or activity.

The changes of the thoracic strap tension and pressure on the thoracic pad induced by different postures and activities

The mean tension of the thoracic strap and the mean interface pressure (horizontal axis) on the thoracic pad of the nine patients performing different postures and activities are shown in Table 1. Their overall mean value of strap tension and pad pressure are 36 (±11, N and 70 (±10) mmHg respectively. There is a high correlation (mean correlation coefficient = 0.84) between the mean thoracic strap tension and the mean interface pressure of the thoracic pad when the patients performed different postures and activities.

On the horizontal axis of the thoracic pad, the mean interface pressure distribution is higher at the anterior portion (refer to Figure 4) (mean pressure 98mmHg) that at the posterior portion

Table 1. The correlation between the mean thoracic pad pressure and the mean thoracic strap tension of the Milwaukee brace in the treatment of adolescent idiopathic scoliosis.

Case no.	Mean pad pressure sensors on horizontal axis (mmHg)	Mean strap tension (N)	Correlation coefficient r
1	75 ± 32	33 ± 16	0.76
2	55 ± 19	28 ± 8	0.80
3	58 ± 18	23 ± 7	0.91
4	64 ± 20	48 ± 12	0.74
5	68 ± 21	29 ± 8	0.89
6	86 ± 25	52 ± 12	0.90
7	75 ± 23	44 ± 11	0.85
8	68 ± 20	25 ± 7	0.84
9	77 ± 28	43 ± 19	0.88
Mean	70 ± 10	36 ± 11	0.84

(mean pressure 42mmHg) under all activities and postures except in the supine lying posture as shown in Figure 8.

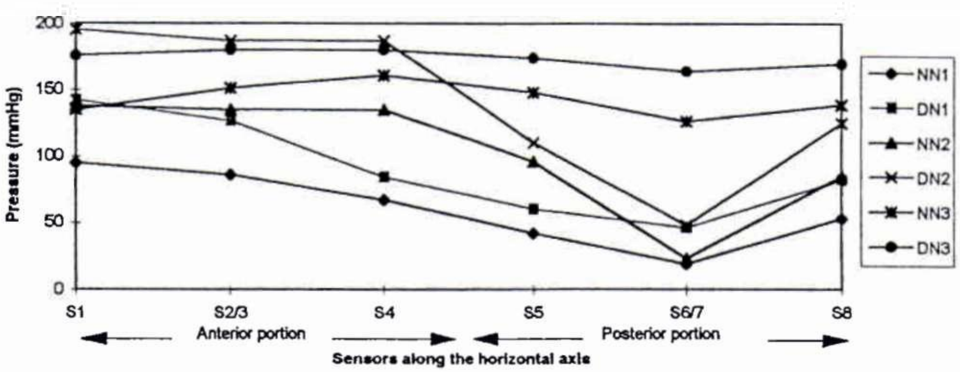
On the vertical axis of the thoracic pad, the mean interface pressure is 37mmHg (44%) at the upper portion and 47mmHg (56%) at the lower portion during standing normal and deep breathing activities (Fig. 9).

The overall mean pad pressure (under all activities and postures) on the horizontal axis and vertical axis are 70mmHg and 42mmHg respectively.

The mean values of the thoracic strap tension (for the nine patients) under different postures and activities are shown in Table 2.

The effect of change of the thoracic strap tension on the interface pressure distribution on the thoracic pad

In this study, the tension of the thoracic strap was set at three magnitudes: low (19 N), medium (38 N) and high (49 N). The adjustment of strap tension could be obtained by changing the length of the Dacron strap (Fig. 10) which was sewn with Velcro Loop. By altering the location of attachment of the Loop to the outer surface of the thoracic pad which was sewn with Velcro Hook fine adjustment of strap tension could be



Supine = Supine lying
L-side = Left-side lying
R-side = Right-side lying
Prone = Prone lying

Sit (N) = Sitting with normal breathing
Sit (D) = Sitting with deep breathing
Sta (N) = Standing with normal breathing
Sta (D) = Standing with deep breathing
Shift = Shifting

S1 - S8 = sensors

Fig. 8. The mean interface pressure distribution on the thoracic pad (along horizontal axis) during different postures and activities.

Table 2. The mean strap tension under difficult postures and activities

Activity	Strap tension (N)	
	Mean	SD
Supine lying	38	10
Left-side lying	23	7
Right-side lying	35	11
Prone lying	13	5
Sitting (N)	37	9
Sitting (D)	66	18
Standing (N)	38	16
Standing (D)	66	23
Shifting	4	2
Overall	36	15

achieved. The pulling angle of the thoracic strap remained constant (60°) in the process of altering the magnitude of strap tension.

The mean pressure distribution along the thoracic pad (horizontal axis) at different thoracic strap tensions is shown is Figure 11.

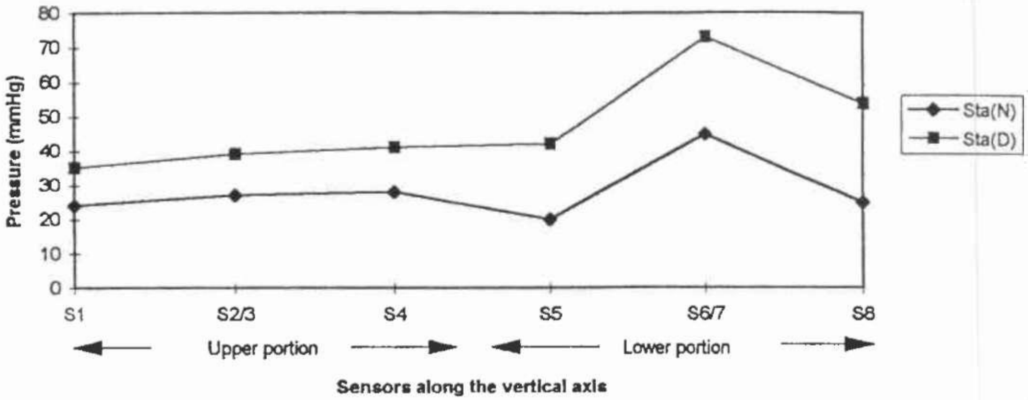
The findings indicate that the distribution of the interface pressure along the horizontal axis of the thoracic pad is similar in the medium-tension and the low-tension conditions, i.e., the anterior portion of the thoracic pad exerts pressure about 3 times higher than that of the posterior portion. In the high tension (shortening of strap length) condition, the pressure distribution along the horizontal axis of the thoracic pad is more even such that the anterior portion and the posterior portion each experiences similar pressure.

The effect of change of pulling angle of the thoracic strap on the interface pressure distribution on the thoracic pad

In this study, the pulling angle of the thoracic strap was set at three magnitudes: low (37°), medium (60°) and high (83°) by altering the length of the outrigger (Fig. 10). The thoracic strap tension at 38 N was maintained (corresponding to the activity of standing with normal breathing) in the process of altering the pulling angle.

The mean pressure distribution along the thoracic pad (horizontal axis) at different pulling angles of the thoracic strap is shown in Figure 12.

The findings show that the distribution of mean interface pressure between the anterior and posterior portions of the thoracic pad changes with the pulling angle of the thoracic strap. In the condition of small angle (37°) of pull, the pressure distribution shows a decrease of 7% at the anterior portion as compared with that of the normal fitting condition. In the condition of large angle (83°) of pull, the pressure distribution shows a decrease of 14% as compared with that of the normal fitting condition.



Sta (N) = Standing with normal breathing
Sta (D) = Standing with deep breathing

S1 - S8 = sensors

Fig. 9. The mean interface pressure distribution on the thoracic pad (along vertical axis) during different postures and activities.

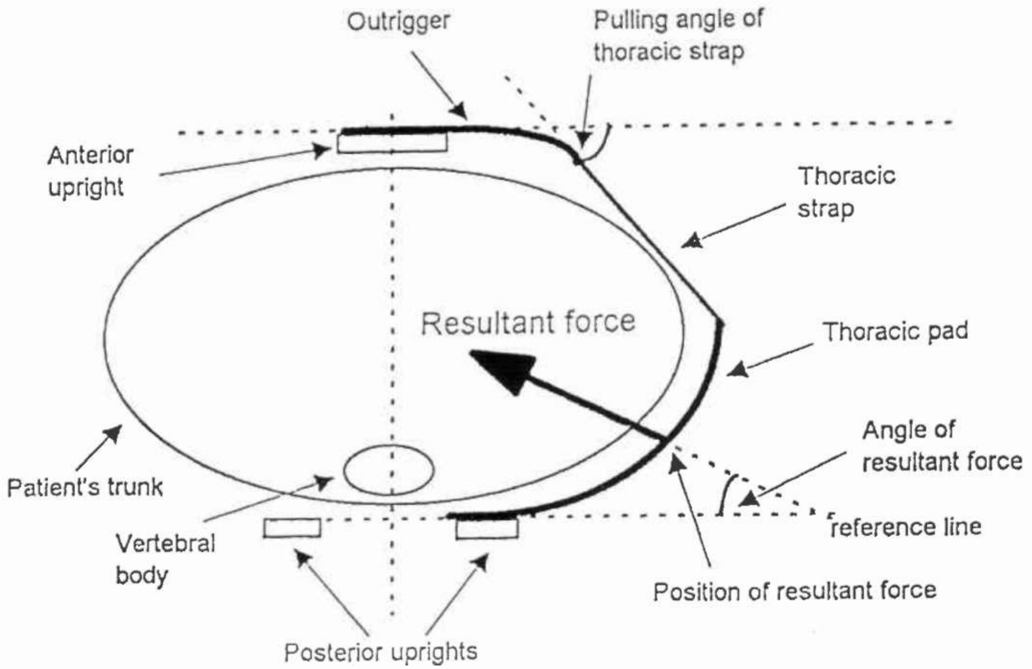
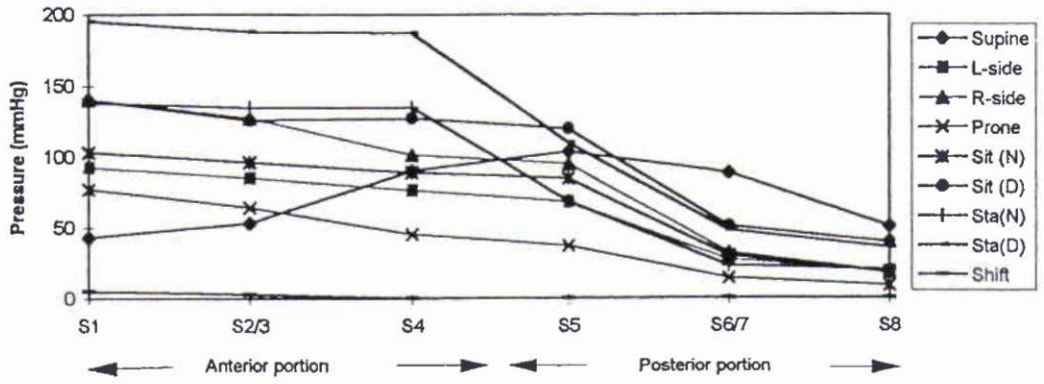


Fig. 10. Transverse view of patient with Milwaukee brace.

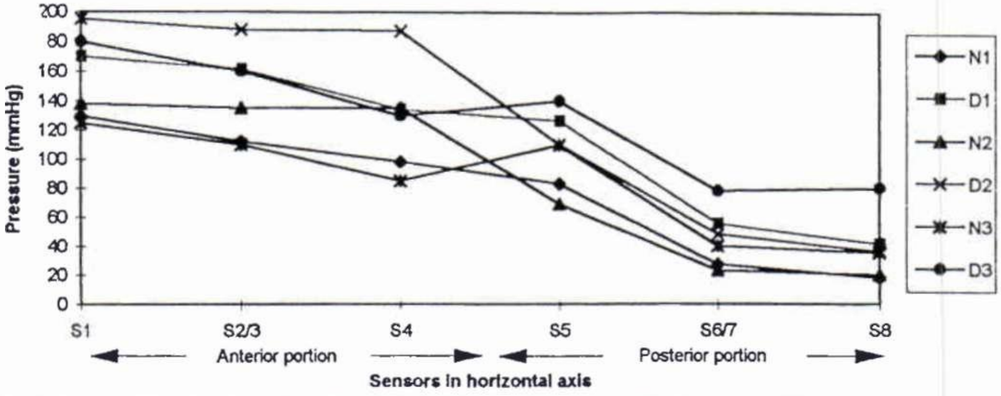
The resultant forces and derotational torques on the patient's trunk

The transverse view of a patient with a Milwaukee Brace is shown in Figure 10. The resultant force and derotational torque exerted by the thoracic pad on the patient's trunk could not be calculated directly unless the forces connecting that pad and the structure of the orthosis were measured. The resultant force vector can be calculated from pressure



N ~ = normal breathing
D ~ = deep breathing
~ N1 = low tension
~ N2 = medium tension
~ N3 = high tension
S1 - S8 = sensors

Fig. 11. The mean interface pressure distribution on the thoracic pad at different thoracic strap tensions (fixed pulling angle of thoracic strap, 60 degrees).



N ~ = normal breathing
D ~ = deep breathing
1 = small angle
2 = medium angle
~ 3 = large angle
S1 - S8 = sensors

Fig. 12. The mean interface pressure distribution on the thoracic pad at different angles of pull of the thoracic strap (fixed thoracic strap tension).

distribution and the known area of pad. To permit the calculation the following assumptions are made: no shear forces at the interface between patient's body and thoracic pad, all thoracic pads having the same curvature and vertical orientation. The location, magnitude and direction of the resultant correctional force and the derotational torque exerted on the patient's trunk by the thoracic pad at different postures and activities were calculated from the collected data.

The calculated mean resultant forces exerted by the thoracic pad on the patient's trunk in different lying postures are shown in Figure 13.

The mean resultant forces in the supine, left-side, right - side and prone lying postures were calculated to be 98, 84, 116 and 55 N respectively. The mean resultant force in the supine lying posture acts on the patient's trunk through the anterior part of the posterior portion

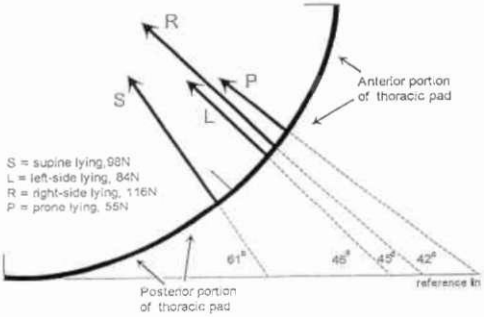
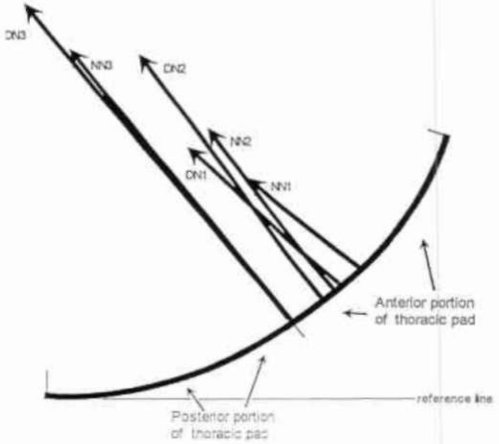


Fig. 13. The resultant forces that the thoracic pad exerts on the patient's trunk at different lying postures.



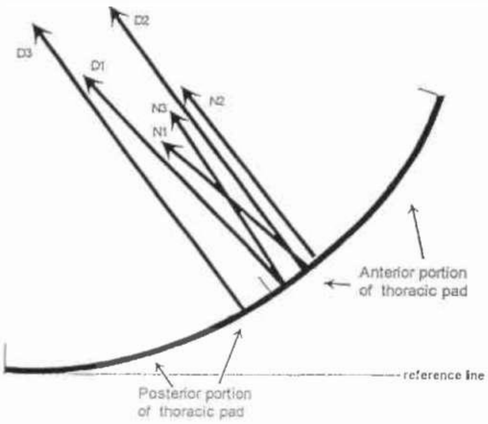
Activity	Strap tension (newton)	Angle of pulling strap (degree)	Resultant force	
			Magnitude (newton)	Angle (degree)
NN1: normal breathing	19	60	74	44
DN1: deep breathing	26	60	110	46
NN2: normal breathing	38	60	120	54
DN2: deep breathing	66	60	176	55
NN3: normal breathing	49	60	188	56
DN3: deep breathing	78	60	220	55

Fig. 14. The resultant forces that the thoracic pad exerts on the patient's trunk at different thoracic strap tensions but with fixed pulling angle.

of the thoracic pad at an angle of 61° while the other three mean resultant forces act through the medical one-third of the anterior portion of the thoracic pad with similar angles (42°, 45° and 46°).

The findings indicate that an increase in strap tension (pulling force) but with fixed pulling angle will increase the magnitude of the resultant force that the thoracic pad exerts on the patient's trunk (Fig. 14). The angle of the resultant force will also increase (move to a more lateral direction). Simultaneously, the point of application at the thoracic pad will shift medially. In the NN3 and DN3 conditions, the point of intersection of the vector axis with the pad is at the middle part.

The resultant forces that the thoracic pad exerts on the patient's trunk at different pulling angles but with fixed thoracic strap tension are shown in Figure 15. The findings show that a smaller pulling angle of the thoracic strap will give a more medially directed resultant force, and *vice versa*, The points of intersection of the resultant forces are within the medial one-third of the anterior portion of the thoracic pad except under the D3 condition. Although, there is a significant increase in the angle of the resultant force (from N1=45 to N3=59) as the pulling angle increase from 37° to 83°, the point of action must be taken into account in considering the derotational torque on the vertebrae.



Activity	Strap tension (newton)	Angle of pulling strap (degree)	Resultant force	
			Magnitude (newton)	Angle (degree)
N1: normal breathing	38	37	107	45
D1: deep breathing	65	37	157	48
N2: normal breathing	38	60	120	54
D2: deep breathing	66	60	176	55
N3: normal breathing	38	83	115	59
D3: deep breathing	68	83	189	55

Fig. 15 The resultant forces that the thoracic pad exerts on the patient's trunk at different pulling angles of the thoracic strap (constant thoracic strap tension).

The resultant forces exerted on the patient's body by the thoracic pad were resolved into the medial-directed component (for curvature reduction) and the anterior-directed component (for hump reduction). Moreover, the resultant forces could also create a derotational moment on the vertebrae through corresponding ribs. The derotational moment generated by the thoracic pad was calculated by multiplying the magnitude of the resultant force and the perpendicular distance from that force to the spinal axis of the same level. The magnitude, angle and point of action of the resultant force must be taken into account in considering the derotational torque in the vertebrae.

In order to compare the effect of changes in posture, tension and pulling angle of the thoracic strap in an easier fashion, the condition where a patient with medium thoracic strap tension (38 N), medium pulling angle (60°) and standing with normal breathing was used as a reference. The comparison of forces and torques at different postures and activities is shown in Table 3.

Of the four lying postures, the patient experiences least forces and derotational torque in the prone posture. Conversely, the patient experiences the largest forces and torques in the right side-lying posture.

In the activity (DN3) with high thoracic strap tension, pulling angle of 60° and deep breathing, the thoracic pad exerts the largest medial and anterior forces.

In the activity (DN2) with medium thoracic strap tension, pulling angle of 60° and deep breathing, the thoracic pad exerts the highest derotational torque.

It was found that the average resultant force increases 45% and the average derotational torque increase 35% from normal breathing to deep breathing.

Discussion

In this study the interface pressure between in the patient's body and thoracic pad, and the tension of the thoracic strap are demonstrated to change with the different postures adopted and activities undertaken. The changes in these two

Table 3. The medial forces, anterior forces and derotational torques exerted on the spine through the ribs by the thoracic pad during different postures, actitivies, thoracic strap tensions and pulling angles of the thoracic strap.

Activities	Medial force		Anterior force		Derotational force	
	N	(%)	N	(%)	Nm	(%)
Supine (S)	48	(68)	86	(89)	10	(69)
Left-side lying (L)	58	(82)	60	(62)	10	(63)
Right-side lying (R)	82	(115)	82	(84)	15	(94)
Prone lying	40	(56)	37	(38)	7	(44)
Small tension (NN1)	53	(75)	51	(53)	8	(50)
Small tension (DN1)	76	(107)	79	(81)	12	(75)
Medium tension (NN2)	**71**	**(100)**	**97**	**(100)**	**16**	**(100)**
Medium tension (DN2)	101	(142)	144	(148)	23	(144)
Large tension (NN3)	105	(148)	156	(160)	19	(119)
Large tension (DN3)	126	(177)	180	(186)	22	(138)
Small angle (N1)	76	(107)	76	(78)	11	(69)
Small angle (D1)	105	(148)	117	(121)	16	(100)
Medium angle (N2)	**71**	**(100)**	**97**	**(100)**	**16**	**(100)**
Medium angle (D2)	101	(142)	144	(148)	23	(144)
Large angle (N3)	59	(83)	99	(102)	15	(94)
Large angle (D3)	108	(152)	155	(160)	19	(119)

*** Use the medial force, anterior force and derotational torque at the NN2 or N2 condition (standing with normal breathing, medium strap tension and medium pulling angle) as force references and torque reference respectively.

parameters are highly correlated (r=0.84).

The mean tension of the thoracic strap for the nine patients is 36±11 N. The mean interface pressure exerted on the patient's body is 70±10 mmHg. Branemark (1976) pointed out that pressure sores and ulceration will occur if pressure is applied on the skin over a long period and over the range of 40-60 mmHg. Clinically, patients seldom complain of pressure sensitivity or tissue break down caused by the thoracic pad. This is probably due to the fact that although the pressure is marginally excessive it can be relieved intermittently by motion of the patient's trunk.

The interface pressure on the anterior portion of the thoracic pad is about twice that on the posterior portion while the value on the upper portion is similar to that of the posterior portion. Based on this distribution of interface pressure on the surface of the thoracic pad (force = area x pressure), the anterior portion contributes about 50% of the total correcting force on the patient's body while the posterior portion and upper portion of the thoracic pad, each exerts about 25% of the total correcting force.

The mean resultant force exerted on the patient's body by the thoracic pad is 108±41 N. Chase *et al.* (1989) used the Oxford Pressure Monitor to measure the forces exerted on a patient's body by the Boston brace and found that the mean force exerted by the thoracic pad was 55±18 N. The mean force exerted by the thoracic pad of the Milwaukee brace was 25 N in the Cochran and Theodore (1969) study, and 38 N in the Mulcahy *et al.* (1973) study. These large differences may be due to different techniques of brace fitting, different methods of measurement and different measuring instruments being employed. The performance of the Dynamic Pressure Monitor (DPM) used in this study was not consistent, even though, calibration was performed on each occasion before taking measurements. The results of the calibration study showed that the DPM can measure true pressure in a hydrostatic situation. However, the results in a plain loading situation showed that the compliance of the interface materials to the sensor bulb surfaces can significantly affect the response of the DPM sensors. Moreover, the abnormal thickness of the sensor bulbs also produces a measurement artefact at the beginning of the pressurising process which increases the output reading of the DPM sensors. In order to improve the accuracy of the DPM, two kinds of artefacts must be reduced: 1) the artefact produced by the disturbance of the original interface so that additional stress is built up on the bulbs before the body and the thoracic pad totally conformed to the sensor bulb surfaces; 2) the artefact produced by the lack of compliance of the body/pad interface to sensor bulb surfaces. These two kinds of artefacts are due to the large uneven thickness (3 to 3.5mm) of the sensor bulbs. Therefore, the primary manufacturing improvement would be sensor bulbs with small and even thickness (<2mm).

Galante *et al.* (1970) reported that there were significant forces through the compression pads in the recumbent position and the presence of these forces was suggested to be still effective in the sleeping hours. From the present study, the resultant forces of the thoracic pad in the four lying postures: supine, left-side, right-side and prone lying have been investigated and found to have different magnitudes, directions and points of application. Based on the biomechanical analysis, the right-side lying posture offers the best "corrective" effect on the right thoracic curve. Conversely, the prone lying posture offers the least effect. It seems that the patient lies on the convexity of her scoliotic curve, the gravitational reaction force becomes a corrective force.

It was found that a large resultant force might not exert a large derotational torque on the vertebrae as the line of action is an important factor to be considered. The average resultant force increases 45% and the average derotational torque increases 35% from the normal breathing to deep breathing. According to this finding, the patient should be advised to take deep breathing exercises.

In this study, it was found that the pulling angle of the thoracic strap does affect the interface pressure distribution on the thoracic pad, thus altering the resultant force exerted on the patient's body. These findings match partly with the postulation of Winter and Carlson (1977). On the other hand, the findings indicate that the derotational torque changes greatly with a small pulling angle but slightly with a large pulling angle of the thoracic strap. This means that the small pulling angle of the thoracic strap will give a larger medial force but a smaller derotational torque on the spine.

In the treatment of scoliosis with rib hump > 1.5cm and thoracic kyphosis < 20° (thoracic lordosis), great care must be taken to treat the scoliosis without aggravating the thoracic lordosis (Winter and Carlson, 1977). The resultant force should be almost entirely medial in direction. To do this, it is suggested that the thoracic strap is attached anteriorly with a short outrigger (i.e., small pulling angle, 35°-40°) and with moderate strap tension, 35-40 N (a high strap tension will medially shift that point of application of the resultant forces and this may aggravate thoracic lordosis, and will also increase discomfort and restrict body shifting exercises.

In scolio-kyphois with a kyphotic curve of more than 40°, it is suggested that a long outrigger (large pulling angle) should be used so as to increase the anteriorly directed force component in an attempt to decrease the kyphotic deformity. Decision in the area between 20° and 40° thoracic kyphosis, is based on the patient's clinical appearance in the orthosis and lateral in-brace radiographs.

During the trunk shifting exercise, the patient will try to move away from the thoracic pad as far as possible (bending to the convex side). This manoeuvre is claimed to help to reduce the lateral curvature. The pressure on the thoracic pad and thus the thoracic strap tension will decrease at the same time as shifting. Therefore, the tension of the thoracic strap may be used as an indicator to the performance of the shifting exercise; the smaller strap tension, the better the shifting exercise being performed and, thus arguably the more the reduction is being achieved in spinal curvature. The value of strap tension measured by the buckle force-transducer could be transformed into either an audible or visible output as the basis of a biofeedback system for assisting the physiotherapist to train scoliotic patients in performing the in-brace shifting exercise.

Additionally, the purpose-designed buckle force-transducer can be combined with a data logger to carry out measurements over a long period (one week or more) of patient's daily activities. Patient's compliance can also be recorded at the same time.

The operation of the Milwaukee brace is supposed to be a three-point force system, thus, the tension of the thoracic strap and shoulder strap are assumed to decrease as the patient performs the in-brace shifting exercise. However, it was found in this study that the tension of the shoulder strap increased as the patient shifted the body away from the thoracic pad. This raises the question as to whether an in-brace shifting exercise just moves the patient's body away from the thoracic pad and the forces generated by the hands on the anterior upright are transmitted to the trunk through the shoulders at the level of the shoulder strap, i.e., list to the concave side rather than attempt to decrease spinal curvature? A further investigation is required to evaluate the contribution of the in-brace shifting exercise in the treatment of scoliosis.

Conclusion

A biomechanical analysis of a conventional spinal orthosis, Milwaukee brace, was carried out. This involved direct and indirect measurements of the forces transmitted to the body and an analysis of the corrective effect they exerted on the spine. The principal measurements were related to thoracic strap tension and the interface pressure distribution between the thoracic pad and the patient's body. There is a high correlations between changes in the thoracic strap tension and the interface pressure of the thoracic pad in different lying postures and during various activities. The change in tension and pulling angle of the thoracic strap can vary in magnitude, direction and line of action of the resultant force which the thoracic pad exerts on the patient's body. A knowledge of the magnitude, direction and line of action of the resultant force can be used to evaluate the accuracy of fit and the efficiency of support, the progress of treatment and the effectiveness of various design modifications.

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Prosthetics and Orthotics International, 1998, 22, 68–70

Case study

Seated-popliteal weight bearing prosthesis for a bilateral amputee

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Abstract

Bilateral lower limb amputees suffer from a lack of stability when seated without prostheses due to lack of ground reaction forces through the stumps. In patients for whom ambulation is not a realistic goal, the seated-popliteal weight bearing prosthesis provides a solution for stability when seated in a wheelchair, without the problem of tibial pressure experienced with patellar-tendon-bearing prostheses.

Introduction

Non-ambulant, wheelchair dependent older patients with peripheral vascular disease and lower limb amputations are often considered unsuitable for prosthetic fitting (Van de Ven, 1981; De Fretes *et al.*, 1987). Standard patellar-tendon-bearing prostheses, cast in 30° flexion, are sometimes prescribed to assist in standing transfers. However in this situation, the patellar-tendon-bearing socket can cause tibial pressure and eventually ulceration, particularly with patients sitting for long periods. This case study presents a successful lower limb prosthesis for improved sitting stability of a bilateral lower limb amputee.

History

A single 80 year old lady with long-standing polyarticular rheumatoid arthritis, a previous left trans-femoral amputation and a recent right trans-tibial amputation was referred for prosthetic fitting. The lady lived in a nursing home and had been using an electric wheelchair following her left trans-femoral amputation in 1988. She had poor visual acuity of 6/60 in spite of cataract extraction and intraocular lens implants in 1984. Her hand function was limited

Fig. 1. Patient in wheelchair: stability in forward leaning was limited.

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by deformity and reduced shoulder abduction. She was able to feed herself and to operate her electric wheelchair and other appliances in close proximity (Fig. 1). Unfortunately, she was not able to lean forward without falling from the chair, which restricted her ability to open drawers or use wheelchair accessible transport. The problems related to the high centre of gravity of the body, compounded by poor hand and upper limb function with decreased visual acuity. The use of a board to support the trans-tibial stump did not significantly improve stability in the chair, nor did the use of a waist belt attached to the wheelchair. A hoist was required for transfers.

Development of prosthetic solution

A patellar-tendon-bearing prosthesis was tried in the hope of improving sitting stability in her chair and assisting in standing transfers from bed to chair and chair to toilet. However, standing transfers were not achievable despite full physical and occupational therapy training of nursing home staff and patient. The patellar-tendon-bearing prosthesis was not tolerated due to pain from pressure on the tibia in the sitting position.

Fig. 2. Finished sitting prosthesis.

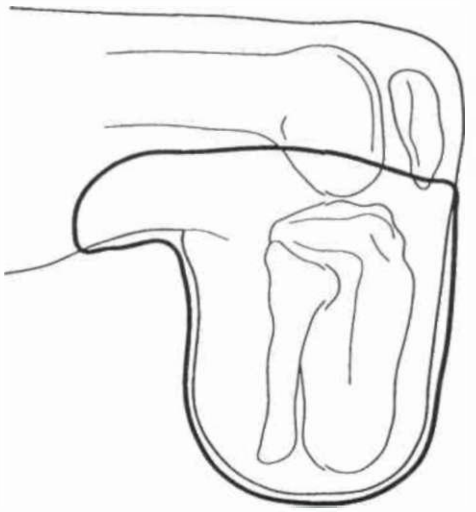

Fig. 3. Socket of plug fit sitting prosthesis showing wide popliteal shelf.

A plug fit prosthesis with extended popliteal shelf, cast in 90° flexion, was fabricated for the right trans-tibial stump (Fig. 2). It was lambswool lined thus requiring no stump sock. A simple supra-patellar stirrup strap was provided for suspension. A pylon with rubber tip was attached to the socket. The wide popliteal shelf of the sitting prosthesis, positioned relatively lower than the posterior lip of a typical patellar-tendon-bearing socket, provided a comfortable support for the flexed limb when seated, and prevented end bearing on the stump (Fig. 3). The combination of a lambswool lined socket and an easy plug fit simplified donning of the prosthesis.

Outcome

At one year follow-up the prosthesis was voluntarily worn by the patient on a daily basis. The only modification had been the addition of a standard supra-patellar-cuff (Fig. 2). The patient was now able to lean forward to open drawers, pick up items from the floor and to travel in a wheelchair accessible taxi without falling from the chair. A hoist was still used for transfers as the prosthesis was not designed for weight bearing when standing.

Discussion

The success of prosthetic rehabilitation for walking in bilateral vascular amputees is poor, and may be as low as 26% (Evans *et al.,* 1987). Quality of life is thus a major issue for those without functional ambulation, particularly when wheelchair use is restricted due to problems arising from lower limb loss.

Where standing or ambulation is not an option, consideration should be given to a prosthesis designed entirely for function in the sitting position. The seated popliteal weight-bearing prosthesis described here is a prototype designed to increase function, independence and quality of life.

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R. Herbert CPO, Repatriation Artificial Limb and Appliance Centre, Sydney for construction of the prosthesis.

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Book Review

Congenital Limb Deficiency: Recommended Standards of Care
Amputee Medical Rehabilitation Society; London, 1997.
Copies available from:
Amputee Medical Rehabilitation Society
c/o Royal College of Physicians
11 St Andrew's Place
Regents Park
London NW1 4LE, UK.
Price: £5.00.

These recommended standards of care for persons with congenital limb deficiencies were developed under the aegis of the London-based Amputee Medical Rehabilitation Society by a panel of medical experts well-qualified in the management of persons with these uncommon but often complex conditions. In addition, the major associations in Britain whose members can be expected to encounter these problems have commented on this report, thus endorsing its value and enhancing its validity. These included medical, surgical, therapy, prosthetic/orthotic and consumer support organisations.

The format is concise and easily read. The skeletal deficiencies are described on an Anatomical Basis per ISO Standard 8548-1, published in 1989. This widely adopted standard replaces the confusing array of descriptive systems based on classical roots, substituting the easily understood and translatable terms, transverse and longitudinal, to describe the basic skeletal deficiencies.

The first sections of the text review normal and abnormal limb development and the known etiologies of limb deficiencies as well as demographics with emphasis on the general needs of the client group over the life span. Specific treatment options for upper and lower limb deficiencies are then concisely described. It is emphasised that treatment should be managed by a dedicated, experienced team in a Limb Deficiency Centre with an adequate client population to allow acquisition and maintenance of the requisite skills. Recommendations for data collection to enhance research and development are given. An adequate reference list is provided as well as useful appendices.

The Amputee Medical Rehabilitation Society has done a great service in making this information readily accessible in a comprehensive form to all interested parties, including parents, clients and policy-makers as well as providers of care.

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ISPO Publications and Videotapes

Standards for Lower Limb Prostheses
Report of a Conference, Philadelphia 1977
$25 (US)

The Deformed Foot and Orthopaedic Footwear
Report of the ISPO Workshop in Stockholm March 1977
Edited by B. Klasson
Co-Editors A. Forchheimer, J. Hughes, G. Murdoch
ISPO Members $25 (US)
Non-Members $40 (US)

Prosthetics and Orthotics International August 1983
Special Issue – Through-Knee Amputation and Prosthetics
Edited by J. Steen Jensen $45 (US)

Prosthetics and Orthotics in the Developing World with Respect to Training Education and Clinical Services
Report of an ISPO Workshop, Moshi, Tanzania
Edited by N. A. Jacobs, G. Murdoch
Published 1985 ISPO Members $20 (US)
Non-Members $30 (US)

Planning and Installation of Orthopaedic Workshops in Developing Countries
Edited by S. Heim (Co-ordinator), W. Kaphingst, N. A. Jacobs
Published 1986 ISPO Members $15 (US)
Non-Members $20 (US)

Training and Education in Prosthetics and Orthotics for Developing Countries
Report on an ISPO Workshop, Jönköping, Sweden
Edited by K. Öberg, G. Murdoch, N. A. Jacobs
Published 1987 ISPO Members $25 (US)
Non-Members $40 (US)

Up-Grading in Prosthetics and Orthotics for Technicians in Developing Countries Trained on Short Courses
Report on an ISPO Workshop, Glasgow, Scotland
Edited by G. Murdoch, N. A. Jacobs
Published 1989 ISPO Members $25 (US)
Non-Members $40 (US)

Above-Knee Fitting and Alignment
Report of ISPO workshops held in Miami, Florida, USA and Chicago, Illinois, USA
Edited by R. G. Donovan, C. Pritham, A. B. Wilson Jr,
Published 1989 ISPO Members $25 (US)
Non-Members $40 (US)

CAD CAM in Prosthetics and Orthotics
Report of an ISPO Workshop, Seattle, Washington, USA
Edited by R. M. Davies, R. G. Donovan, R. W. Spiers
Published 1990 ISPO Members $30 (US)
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Consensus Conference on Amputation Surgery
Report on ISPO Workshop, Glasgow, Scotland
Edited by G. Murdoch, N. A. Jacobs, A. B. Wilson Jr
Published 1992 ISPO Members $30 (US)
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Report of an ISPO Workshop, Durham, NC, USA
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Published 1995 ISPO Members $20 (US)
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Consensus Conference on Appropriate Prosthetics Technology for Developing Countries
Report of an ISPO Workshop, Phnom Penh, Cambodia
Edited by H. J. B. Day, J. Hughes, N. A. Jacobs
Published 1996 ISPO Members $30 (US)
Non-Members $45 (US)

Videotape on Trans-Tibial Amputations
Produced by A. Jain, J. Guy
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2100 Copenhagen Ø, DENMARK

Calendar of Events

20-23 May,1998
16th World Congress of Podology, Gothenberg, Sweden.
Information: Congrex Bokning Gothenberg AB, Massans Gata 18, PO Box 5078,402 22 Gothenberg, Sweden.

20-23 May, 1998
2nd Mediterranean Congress of Physical Medicine and Rehabilitation, Valencia, Spain.
Information: Scientific Secretariat, 2nd Mediterranean Congress of Physical Medicine and Rehabilitation, 214 Avda. del Puerto, E-46023 Valencia, Spain.

31 May-4 June,1998
6th European Congress on Research in Rehabilitation, Berlin, Germany.
Information: Mr.H.Kirsten, c/o BAR, Walter-Kolb-Str.,9-11, D-60594 Frankfurt/M, Germany.

3-6 June, 1998
49th Congress of the Nordic Orthopaedic Federation, Copenhagen, Denmark.
Information: DIS Congress Service Copenhagen A/S, Herlev Ringvej 2C, DK-2730 Herlev, Copenhagen,Denmark.

4-6 June, 1998
2nd Central European Orthopaedic Congress, Budapest, Hungary.
Information: Prof. Tibor Vizkelety, Orthopaedic Dept., Semmelweis University of Medicine, H-1113 Budapest, Karolina u.27, Hungary.

9-13 June, 1998
25th Annual Meeting of the International Society for the Study of the Lumbar Spine, Brussels, Belgium.
Information: Dr. E. Hanley, Secretary ISSLS, Sunnybrook Health Science Centre, Room A 401, 2075 Bayview Ave., Toronto M4N 3M5, Canada.

18-20 June,1998
37th Annual Scientific Meeting of the International Medical Society of Paraplegia, Sao Paulo, Brazil.
Information: Professor Tarcisio EP Barros, Chairman, IMSOP, Chief Physician, Spinal Injury Unit, University of Sao Paulo, Sao Paulo, Brazil.

27-30 June, 1998
12th Congress of the International Society of Electrophysiological Kinesiology, Montreal, Canada.
Information: ISEK Secretariat, Conference Office, McGill University, 550 Sherbrooke Street West, West Tower, Suite 490, Montreal, Quebec, Canada H3A 1B9.

26 June-1 July,1998
RESNA 98, Minneapolis, USA.
Information: Susan Leone, Meetings Director, RESNA, 1700 North Moore St., Suite 1540,Arlington, VA 22209, USA.