The Journal of the International Society for Prosthetics and Orthotics

Prosthetics and Orthotics International

August 1999, Vol. 23, No. 2

Prosthetics and Orthotics International

Prosthetics and Orthotics International is published three times yearly by the International Society for Prosthetics and Orthotics (ISPO), Borgervaenget 5,2100 Copenhagen Ø, Denmark, (Tel. +45 39 20 72 60, Fax. +45 39 20 75 01). The subscription rate for 1999 is GBP90 per annum, single numbers GBP31. The journal is provided free to Members of ISPO. Remittances should be made payable to ISPO.

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

ISSN 0309–3646

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

Printed by Beith Printing Company Ltd, Glasgow, Scotland

The Journal of the International Society for Prosthetics and Orthotics

August 1999, Vol. 23, No. 2

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Editorial

In the 1970s the World Health Organisation (WHO) introduced a new approach to disability prevention and rehabilitation known as Community-Based Rehabilitation (CBR). Its aim was to provide rehabilitation services to all people with disabilities whether they are rich or poor or whether they live in a city or the countryside.

This approach involves measures taken at community level to use and build upon the resources of the community as well as making use of the services offered at district, provincial, and central level. Thus, all in all, the complete rehabilitation structure of this model consists of four levels: community, district, provincial and central, of which the three latter constitute the referral system of the first, i.e. the community level.

The personnel of institutions belonging to the central and provincial levels are the professionals that one would expect to be working in conventional rehabilitation and health services. The professionals that are found at district level, however, are not likely to possess any specialisation in rehabilitation. They are usually general physicians and nurses who are involved with the provision of primary health care services. Nevertheless they may play an important role in the referral system and in the transfer of knowledge and skills in rehabilitation to the community level. Finally, at community level there are no professionals at all. The persons working there – usually called community health workers or community rehabilitation workers - often do their work on a voluntary or part-time basis besides their normal duty in the community. Since they are likely to have limited or minimal education, they need to receive training and support from personnel of the referral system.

The success of this approach to rehabilitation will depend on the development of an integrated and coordinated programme with the activities at each level being clearly defined. It will also rest with the development of an educated and trained workforce with the role of the different types of personnel being well defined.

It has been suggested by WHO that although most basic rehabilitation can be carried out in the disabled person's own community a large number of disabled persons have to be referred to other rehabilitation services outside their own community. Amongst this group are those people requiring prostheses and orthoses. This is because prosthetic and orthotic devices of an acceptable quality cannot realistically be made in every single community within a country. This means that for the successful, widespread provision of prosthetics and orthotics services there should be a strong relationship between these specialised services and CBR programmes.

With regard the provision of prosthetics and orthotics services ISPO has gone some way in defining the job descriptions and educational requirements for the different categories of professionals directly involved in this field, that is, prosthetists/orthotists (Category I), orthopaedic technologists (Category II) and prosthetics/orthotics technicians (Category III). More recently ISPO has given some consideration as to the role of these categories of professionals in WHO's referral system and, in particular, to the role and training of primary health care staff and the community health/rehabilitation worker in prosthetics and orthotics.

ISPO has prepared a position paper on the relationship between prosthetics and orthotics services and CBR. This was prepared with advice from WHO as well as input from other agencies working in these fields. The purpose of this paper is to offer guidance on how CBR and the referral system may be used and to help promote and improve prosthetics and orthotics services in low-income countries. In particular it examines the role and educational needs of the community health/rehabilitation worker in prosthetics and orthotics as well as the educational needs of the prosthetics and orthotics professional in CBR. It should be noted, however, that the training of community health/rehabilitation workers is not a replacement for training professionals in prosthetics and orthotics. They are a different type of worker and their skills lie in acting as a link between the disabled person in the community and the rehabilitation services.

This paper will be widely circulated and it is hoped that it will help clarify the relationship between prosthetics and orthotics services and CBR in low-income countries.

Norman A. Jacobs
President

Prosthetics and Orthotics International, 1999, 23, 88–92

Epidemiology of lower limb amputees in Southern Finland in 1995 and trends since 1984

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Abstract

The purpose of this study was to look at the current epidemiological trends of lower limb amputees in 1995 and the trends since 1984 in the area of Southern Finland with 1.3 million inhabitants.

During the one-year period, the lower limb amputation was performed on 366 patients. The overall amputation rate has been unchanged since 1984 being 28.0 per 100,000 inhabitants in 1995. The mean age was 71.4 years. The overall amputation rate was 28.0 per 100,000 inhabitants. Of the 366 patients in the study 30% had arteriosclerosis without diabetes mellitus and 49% had diabetes. Diabetes mellitus has become the most common cause of amputation since 1985. Tumours were the cause in 2% and trauma in 4%. The most common unilateral amputations were trans-femoral amputations (29%) followed by trans-tibial amputations (28%) and toe amputations (24%). The unilateral trans-tibial/trans-femoral ratio was 0.54 in 1984 and 0.95 in 1995. The one-year mortality rate was 39% in 1984 and 40% in 1995.

The rate of amputation has been relatively constant over the last ten years. The age related incidence in the older age groups has also been unchanged over the last ten years. Better control of diabetes and prophylactic foot care of diabetics can have a positive contribution in preventation of lower limb amputations. The current rehabilitation and prosthetic services of the lower limb amputees can be planned in the south of Finland on the basis of the incidence of 28 per 100,000 inhabitants.

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Introduction

Amputations resulting from end-stage peripheral vascular diseases are a common health problem. Amputations of the lower limb have been increasing in number not only because of the increasing number of elderly people in the population (Jones, 1990; Pohjolainen and Alaranta, 1988; Rommers *et al.*, 1997) but also because of factors such as diabetes, smoking, nutrition and lowered physical activity. Diabetes mellitus appears to accelerate both the progression and the initial development of occlusive peripheral arterial disease (Coffman, 1991; Lepäntalo and Lassila, 1991). Some studies have found that hypertension, high serum cholesterol and high triglyseride levels are associated with an increased risk of peripheral arterial disease (Fowkes, 1989; Siitonen *et al.*, 1993).

Despite the extensiveness of Finnish medical statistics compiled by the National Board of Health, no regular official reports are available on the number and types of amputation and size of the amputee population. There are no general official statistics on the number and type of prostheses prescribed in Finland. In Denmark (Ebskov, 1986) and in the Netherlands (Rommers *et al.*, 1997) there are amputation registers. These register data concerning all major lower limb amputations performed in the Danish and Dutch hospitals. In Finland, there is a specific requirement for lower limb amputee statistics for the planning of preventative, operative and rehabilitative activities and evaluation of future needs in personnel, facilities and funds. The aim of the study was to

Table 1. The trends in the amputees in four surveys of the same area.

	1984-85	1989	1992	1995
Incidence per 100,000	32.5-28.1	22.0	27.4	28.2
TT/TF* ratio	0.54	0.57	0.78	0.95
Mortality during two post-operative months among unilateral amputees				
TF	32%	28%	32%	28%
TT	17%	16%	19%	17%
Mortality of all the amputees during the first postoperative year	39%	36%	37%	40%

*TT=trans-tibial
TF=trans-femoral

determine the incidence, causes and levels of lower limb amputations and the survival of amputees. Similar cross-sectional analyses have been performed earlier three times by the same research group for the years 1984-1985 (Pohjolainen and Alaranta, 1988), 1989 (Lääperi *et al.*, 1993) and 1992 (Alaranta *et al.*, 1995). Local and national data would be compared with these previously published studies about amputation surgery and rehabilitation of the lower limb amputees over the last 10 years.

Material and methods

To assess the epidemiological situation concerning amputees in Southern Finland the data on all limb amputations made in all the 13 operative units in the catchment area of the Helsinki University Central Hospital were collected for the period 1995. The data are based on the population of 1,305,550 inhabitants. The patients' hospital records were examined and data concerning demographic factors, diagnoses and amputation levels and postoperative complications were recorded. Mortality during the one-year follow-up was investigated in collaboration with the national Social Insurance Institution.

Results

During the one-year period, lower limb amputation was performed on 366 patients. Of the 366 patients, 188 (51%) were female and 178 (49%) male. The mean age was 71.4 years. The overall amputation rate was 28.0 per 100,000 inhabitants (Table 1). Of the 366 patients in the study 30% had arteriosclerosis without diabetes mellitus and 49% had diabetes (Table 2). During the survey period 1984-1995 diabetes mellitus has become the most common reason for lower limb amputation. Vascular insuffiency resulting from embolic disease was the primary cause of amputation in 3%. Tumours were the cause in 2% and trauma in 4%.

The most common unilateral amputations were the trans-femoral amputations (29%) followed by trans-tibial amputations (28%) and toe amputations (24%) (Table 3). The ratio between the trans-tibial and trans-femoral

Table 2. The causes of amputations and the mean age of amputees in this study (1995) and in the same catchment area in 1984-1985, 1989, 1992 and 1995.

Cause of amputation	1984-1985 (%)	1989 (%)	1992 (%)	1995 (%)
Diabetes mellitus	40.7	42.5	47.7	49.2
Arteriosclerosis	43.1	36.2	30.7	30.1
Embolism	3.8	2.6	4.9	2.7
Tumour	2.4	2.2	1.2	1.9
Trauma	2.4	6.4	6.6	4.4
Frostbite	4.4	1.5	2.3	0.5
Miscellaneous	3.5	8.6	6.6	11.2
Total	100	100	100	100
Age (yrs)	71	70	70	71

Table 3. Distribution of amputations according to level of amputation in 1995.

Type of amputation	Number of amputations	Per cent
Hemipelvectomy	4	1
Trans-femoral	106	29
Trans-tibial	101	28
Ankle*	4	1
Tmt+toe amputation	89	24
Bilateral amputations	62	17
Total	366	100

*Includes Chopart, Pirogoff and Boyd amputations

amputations was 0.95. Among the 366 patients 40% died within the first postoperative year (Table 1). The mortality was higher in patients with the trans-femoral amputation than the trans-tibial amputation.

Discussion

Apart from the data in this study and the earlier studies of the same study group (Alaranta *et al.*, 1995; Lääperi *et al.*, 1993; Pohjolainen and Alaranta, 1988) only two studies (Jones, 1990; Rommers *et al.*, 1997) give an overview of all amputations of all hospitals of the defined area. In most other studies the data refers only to a single hospital or only the vascular groups are taken into account (Dawson *et al.*, 1995; Siitonen *et al.*, 1993; Tunis *et al.*, 1991; Wahlberg *et al.*, 1994) or bilateral amputees (Cumming *et al.*, 1987) and traumatic and tumorous amputations (Liedberg and Persson, 1983) and foot amputations (Ebskov *et al.*, 1994) are excluded.

The amputee rate was 15.2 per 100,000 inhabitants in 1972 in the same area (Solonen *et al.*, 1973). The rate of lower limb amputations has clearly increased in the studied area compared with 1972 (Solonen *et al.*, 1973). The age related incidence in the older age groups has been the same over the last ten years also (Table 4) and the rate of amputation has been relatively constant over the last ten years (Table 1). According to the predictions of the Central Statistical Office of Finland the overall age structure of the population will continue to shift upwards causing a twofold increase in the proportion over 60-year-olds in the next 25-30 years and an increase in the amputation rate may be expected in Finland within the next 30 years.

The incidences reported above are very close to the figures reported by Liedberg and Persson (1983) 32.0 per 100,000 inhabitants in Sweden and Eickhoff (1993) 32.2 in 1983 and 25.0 in 1990 in Denmark and Tunis *et al.* (1991) 28-32 in 1979-1985 in the USA. Jones (1990) found lower incidences in three Australian states 23.6 in 1984 and Rommers *et al.*, (1997) 18-20 in 1982-1993 in the Netherlands.

Lindholt *et al.* (1994) and Luther (1993) have concluded that vascular surgery can decrease lower limb amputations 25-65%. Some operative units in Southern Finland have developed their vascular laboratory service. Good results are reported for femorocrural vein bypass. The results are less good for prosthetic femorocrural bypass (The Vascular Surgical Society of Great Britain and Ireland, 1996). However, no reduction in amputation rate in association with an increase in the rate of bypass surgery has been shown in the USA (Tunis *et al.*, 1991). It was suggested that this observation contradicts the importance of improving and increasing vascular surgical services in prevention of amputations.

It was found in this study that 82% of the lower limb amputations were due to vascular and diabetic pathology. Diabetes mellitus has become the most common cause of amputation and the proportion of diabetes mellitus as the cause of amputation is increasing. Diabetes mellitus is a particularly important risk factor for severe ischaemia and amputation, since it is

Table 4. Annual incidence of amputations in different age groups in 1985 and 1995.

Age group	1985	1995
0-59 yrs		
Number of amputees	68	67
Population	985,963	1,103,001
Number per 100,000	6.9	6.1
60-70 yrs		
Number of amputees	70	78
Population	88,594	100,212
Number per 100,000	79.0	77.8
> 70 yrs		
Number of amputees	190	221
Population	90,060	102,337
Number per 100,000	211.0	216.0
All age groups		
Number of amputees	328	366
Population	1,164,617	1,305,550
Number per 100,000	28.2	28.0

frequently associated with distal disease less suitable for arterial reconstruction (Golledge, 1997). Better control of diabetes mellitus in diabetic patients, patient education regarding foot care, early recognition of foot lesions, local care of lesions and aggressive treatment of infection play important role in prevention of amputations and can decrease lower limb amputations. Smoking is the most important actiological factor for peripheral arterial disease (Golledge, 1997). In Finland, smoking habits have changed and smoking is decreasing. These factors may be explanations of why the numbers of amputations have not increased although the numbers of people in older age groups have increased in the study area.

After the earlier epidemiological surveys there were increasing activities to inform medical and rehabilitation staff about amputee problems. The ratio between trans-tibial and trans-femoral amputations was 0.54 in 1984 and in this study 0.95 (Table 1). There is little positive trend concerning amputation levels.

Survival figures showed that 60% of the patients were alive after one year. The mortality rate during the first postoperative year has not changed (Table 1). Patients undergoing lower limb amputation for arterial occlusive disease have multisystem medical problems that complicate their care and contribute to mortality. There is a very high prevalence of disability associated with feet among persons aged 65 and over (Williamson *et al.*, 1987). Many foot problems and abnormalities are poorly reported to physicians, and there is also the possibility that some doctors have managed to convey an impression of low interest in these conditions and little optimism about their ability to help (Williamson *et al.*, 1987). Limb ischaemia may worsen and extensive necrosis, uncontrolled sepsis and other complications increase the postoperative mortality. Prophylactic foot care is encouraged and medical personnel are taught to give attention to arteriosclerotic and diabetic feet.

Conclusions

The study shows that the incidence of lower limb amputations has been relatively constant over the last ten years. The current rehabilitation and prosthetic services of lower limb amputees can be planned in the south of Finland on the basis of the incidence of 28 per 100,000 inhabitants.

The risk of becoming an amputee rises with increasing age. The age structure of the population should be taken into account with a view to planning the rehabilitation of lower limb amputees.

More efforts to activate both prevention of amputations and prosthetic rehabilitation should be continuously emphasised. Diabetes has become the most common cause of amputation. Better control of diabetes and prophylactic foot care of diabetics can make a positive contribution in prevention of lower limb amputations.

The low trans-tibial/trans-femoral ratio of 0.54 in 1984-1985 has improved but is not yet satisfactory. More emphasis must be put on the concept of preserving the knee joint and the importance of preoperative assessment of vascular patients.

Acknowledgements

This study was kindly supported by the Professor Langenskiöld Fund which is provided by the Prosthetic Foundation, Helsinki. The authors are in deep gratitude to Mrs. Raija Alaranta due to the kind help in gathering the basic data.

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Prosthetics and Orthotics International, 1999, 23, 93–101

A closer look at amputees in Vietnam: a field survey of Vietnamese using prostheses

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Abstract

This study aims to improve the quality and effectiveness of follow-up data on prosthetics in developing countries. In order to bridge the gap between members of non-governmental organizations and their international patients, a field survey was conducted via direct interviews in Vietnam. Eighty-three (83) patients in 5 different geographic regions were interviewed using a standardized assessment tool designed by the author. Demographic information, questions of prosthetic history, inquiries into function, lifestyle and occupation, and queries of social and family integration were asked of each patient.

While the overall results prove salutary for those who serve the amputees of developing countries, it is clear that amputation presents a substantial challenge to the Vietnamese patient. On one hand, respondents wore their prostheses over 12 hours each day on average, rated their prostheses as quite comfortable, and were altogether satisfied with their prosthetic treatment. In addition, the provision of care for Vietnamese with amputations has improved markedly over the past few decades. On the other hand, many patients related the barriers they encountered due to their amputation, including their departure from previous careers, inability to perform rigorous physical activities, and difficulties with social interactions. Furthermore, discrepancies in care were noted between demographic groups and amongst different regions.

The questionnaire developed for this study may provide a useful evaluative tool for agencies working throughout the developing world. The use of such a standardized questionnarie could greatly improve the evaluation and comparison of prosthetic programmes and help guide the efforts of such organizations in developing countries.

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Introduction

As Western agencies look to assist the prosthetic efforts of developing nations, a number of impediments persist. The prolonged international debate on "appropriate technology", sustainability and durability continues as various organisations attempt to serve the underserved. While numerous theories are championed, an undeniable fact prevails: most organisations do not have quality data on the services they provide for their most remote and alienated patients (Cummings, 1996). Hughes (1996) writes that while "all the agencies are well intentioned.....there is an almost complete failure to evaluate the outcome of their efforts. No matter what technology is used, all countries and agencies involved have to answer the same questions: how to best utilise the resources which can be made available and how to measure the outcome and effectiveness of their programmes?"

More specifically, many authors have called for field studies in the actual living environment of the patients, Staats (1996) writes, "What is often overlooked is the evaluation of results for the amputee in the village, far from the workshops where the limbs are manufactured... This is rarely understood by modern or third world prosthetists until they visit amputees in their living and working situations". Cummings

(1996) refers to the work of P. K. Sethi when he notes that the scientific approach in designing prostheses is "subject to failure if it ignores the lifestyles and cultures of the patients being served". This study evaluates patients served by the Prosthetic Outreach Foundation (POF) by interviewing the subjects directly in their living and working environments.

Vietnam was selected as the research site because of the persisting acute condition of Vietnamese amputees. The number of amputees in Vietnam in 1996 was estimated at 200,000 and increasing by 3-4% per year (Day, 1996). Like many developing countries savaged by wars in the twentieth century, Vietnam continues to suffer the human costs of undetonated landmines. However, mines are not solely responsible for losses of limbs. Road traffic accidents claim an increasing number of victims as the country shifts towards motorized transport. In Hanoi, the number of compound fractures of the lower limb increased 400% between 1990 and 1991. Train accidents, tumors and work-related accidents take their tolls as well. Citizens of Vietnam continue to lose their limbs at an alarming rate. Immediately after the Vietnam War, war victims accounted for 75% of amputees; by 1996, war victims comprised only 46% of the total Vietnamese amputee population (Day, 1996). Through personal interviews, this study helps define the prosthetic needs and the working and social environments of Vietnamese amputees.

Methods

In the weeks between June 1 and July 14, 1997, the author conducted personal interviews with 83 Vietnamese amputees in 5 different locations. Each interview followed a standard questionnaire designed by the author and the members of the POF in Seattle, USA (Appendix 1). Follow-up questions and questions of clarification were added as needed. A member of the Orthopaedic Institute of Rehabilitation Sciences and the Prosthetics Outreach Center served as interpreter in all the interviews. At least two photographs were taken of each patient: one focusing on the prosthetic leg of the patient and one of the entire person (Fig. 1).

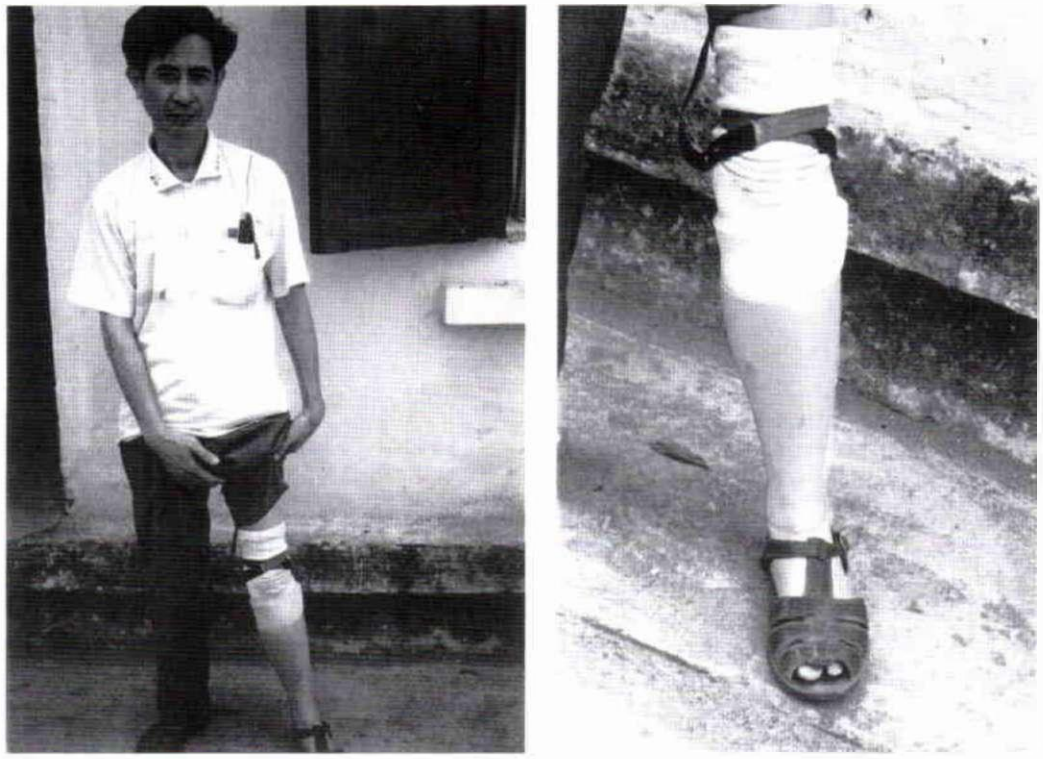

Fig. 1. Sample photographic record of a Prosthetics Outreach Foundation patient.

Interviewees were identified by a variety of methods. In Hanoi, members of the POF clinic called patients at their homes to ask if an interview could be conducted. The author then travelled to the home or business of the patient. Six (6) interviews were conducted at the Hanoi Disabled Sports Association, where numerous amputee athletes congregate. In addition, a number of impromptu interviews were arranged when a patient visited the clinic for prosthetic care.

Patients in outlying areas were identified in a different manner. Interviews were conducted in conjunction with POF outreach trips during which the team delivered new legs or adjusted and repaired legs delivered previously. Members of the Hanoi POF clinic called the local government office when planning a trip. These district or sub-district offices of the Ministry of Labor, Invalids and Social Affairs then notified patients by letter that the POF team would be visiting the area. The 4 regions visited outside of Hanoi include: the Quang Tri Province south of the former Demilitarized Zone, the Vinh Phu Province in northwest Vietnam, and the towns of Phu Ly and Bac Giang. Approximate distances from interview sites to major prosthetic centers are provided in Table 1. In interpreting the results of this study, one should bear in mind the differing methods of patient selection on the levels of both prosthetic care and interview arrangement. Notably, a random sampling of patients proved impossible to achieve, given the government preference of care for veterans and other non-identifiable factors.

Results

Table 2 presents the demographics and questionnaire responses for the whole study group as well as for each of the 5 interview sites individually. While satisfaction with prosthetic treatment was found to be high at 87% of those surveyed, functional ability could be improved. The acceptance of the amputee by family, friends and the public scored much higher in Hanoi than in other areas. Table 3 exhibits data regarding the number of prosthetic legs received, occupation, level of amputation and cause of amputation. Figure 2 depicts the relationship between the year of amputation and the delay to the fitting of the prosthesis.

Discussion

The results of this study reveal an encouraging picture of the efforts to serve the amputees of a developing country. Most of the 83 Vietnamese amputees have achieved a degree of functional normality in their lives thanks to their prosthesis. A number of different survey result point towards this conclusion (Table 2). On average, the subjects in this study wore their prostheses 12.7 hours per day, found their prostheses quite comfortable, experienced little pain and did not suffer from pressure sores. They could walk up and down stairs, ride a bicycle, walk 2-3km without resting, and carry a load of 20kg. Furthermore, 87% were satisfied with their prosthetic management.

Despite these promising results, it remains clear that many amputees have experienced disruptions in their working lives (Table 2). Although 83% of the amputees describe themselves as "working", only 49% work outside of their homes, whether farming in the fields, working at a skilled trade, or selling commodities. In the estimation of the author,

Table 1 Distance from interview site to prosthetic center (km)

	Interview site				
Prosthetic Center	Hanoi	Quang Tri	Vinh Phu	Phy Ly	Bac Giang
Prosthetic Outreach Foundation, Hanoi		620	60	35	50
27th July Center Hanoi		620	60	35	50
Ba Vi	50		20		90
Thuan Thanh	40		100		40
Ninh Binh	85		120		120
Tam Diep	100		150		140
Hue		65			
Da Nang		150			

Table 2

Category	Whole group	Hanoi	Quang Tri	Vinh Phu	Phu Ly	Bac Giang
Number of patients	83	21	16	25	7	14
Urban	41%	86%	63%	0%	71%	7%
Rural	59%	14%	38%	100%	29%	93%
Height (cm)	161 ± 10	161	158	162	161	163
Weight (kg)	50 ± 9	54	48	49	48	52
Birth date	1950 ± 13	1951	1947	1952	1948	1950
Male	94%	86%	94%	96%	100%	100%
Date of amputation	1974 ± 10	1973	1973	1975	1973	1975
Married	93%	81%	94%	100%	86%	100%
Amputation year - marriage year[1]	-0.5	-2.6	0.4	0.3	-2.3	1.5
Hours prosthesis worn per day	12.7 ± 3.8	11.0	12.9	13.2	13.0	13.8
Comfort scale (0 low, 3 high)[2]	2.4 ± 1.1	2.6	2.7	2.0	2.1	2.5
Pain scale (0 low, 2 high)[3]	0.61	0.67	0.38	0.64	0.43	0.86
Pressure sores	13%	5%	6%	20%	0%	29%
Assistance device for walking (0 low, 2 high)[4]	1.2 ± 0.9	0.8	0.9	1.6	1.4	1.5
Walk up and down stairs step over step	93%	90%	88%	96%	86%	100%
Able to walk while carrying a load	78%	81%	63%	76%	71%	100%
Average load carried (kg)	20 ± 12	21	13	25	4	19
Distance able to walk without resting (km)	2.3 ± 2.9	3.1	1.9	2.1	2.8	1.8
Able to ride bicycle	87%	81%	81%	96%	57%	100%
Able to run	22%	38%	19%	16%	14%	14%
Participate in sports regularly	48%	76%	44%	28%	29%	57%
Of sports, percent morning exercises	55%	36%	57%	57%	100%	43%
Collect Government pension	78%	76%	31%	92%	100%	100%
Working	83%	62%	94%	84%	57%	86%
Employed outside of house	49%	62%	69%	32%	57%	36%
Work is "same as before"[5]	58%	86%	75%	48%	57%	29%
Work is due to amputation	30%	14%	19%	48%	14%	50%
Work rigor scale (0 low, 2 high)[6]	0.80	0.57	0.63	0.92	0.86	1.07
Change in life after amputation (-1 low, +1 high)	-0.6	-0.4	-0.4	-0.6	-0.9	-0.8
Reaction of family and friends (0 low, 2 high)[7]	1.5 ± 0.7	1.9*	1.6	1.6	1.1	0.9
Reaction of public (0 low, 3 high)[8]	1.9 ± 1	2.43	2.13	2.08	0.86	1.21
Years delay before care	4.7	5.8	8.9	3.0	4.5	1.8
Satisfied with prosthetics treatment	87%	95%	N/A[9]	84%	86%	86%
Total number of legs from a center	5.6[10]	4.9	2.9	10.3	7.0	6.1
Satisfied with surgery	73%	74%	86%	80%	43%	64%
Number of surgeries	1.9	1.8	1.7	1.8	2.6	2.1
Satisfied with real leg	75%	89%	56%	74%	71%	79%
Wear shoes usually	34%	55%	63%	16%	43%	0%
Wear sandals usually	66%	45%	38%	84%	57%	100%

* Score for Hanoi significantly ($p<0.005$) better than for the other sites combined.

[1] This value shows the difference between the year of amputation and the year of marriage. No data are included for those never married.

[2] The patient was asked to evaluate the comfort of his prosthesis. In analysis, a scale of 0 to 3 was used with the following delineations: 3 = very comfortable; 2 = comfortable; 1 = OK; 0 = not at all comfortable.

[3] The patient was asked if he experienced pain in his residual limb. The following scale was used: 2 = yes; 1 = sometimes; 0 = no.

Table 3

Number of Legs[11]	Whole group	Hanoi	Quang Tri	Vinh Phu	Phu Ly	Bac Giang
0 to 1	23%	14%	38%	4%	0%	7%
2 to 3	17%	19%	31%	12%	0%	7%
4 to 6	23%	38%	19%	8%	29%	36%
7 to 10	23%	19%	13%	24%	71%	43%
11 to 24	10%	10%	0%	40%	0%	7%
> 20	4%	0%	0%	12%	0%	0%
Occupations	Whole group	Hanoi	Quang Tri	Vinh Phu	Phu Ly	Bac Giang
House farmer[12]	29%	4.8%	19%	52%	0%	50%
Farmer	14%	0%	6%	24%	14%	29%
Retired/unemployed	18%	29%	0%	16%	43%	14%
Business/skilled trade	17%	14%	44%	4%	43%	0%
Seller[13]	8%	19%	6%	4%	0%	7%
Government	5%	10%	13%	0%	0%	0%
Academics	2%	10%	0%	0%	0%	0%
Student	4%	10%	6%	0%	0%	0%
Other	2%	4.8%	6%	0%	0%	0%
Level of amputation	Whole group	Hanoi	Quang Tri	Vinh Phu	Phu Ly	Bac Giang
Short TT	51%	52%	50%	44%	86%	43%
Long TT	23%	14%	31%	24%	14%	29%
Mid TT	16%	0%	19%	24%	0%	29%
Short TF	4%	14%	0%	0%	0%	0%
Mid TF	4%	14%	0%	0%	0%	0%
Bilateral TT	2%	0%	0%	8%	0%	0%
Bilateral TF	1%	5%	0%	0%	0%	0%
Cause of amputation	Whole group	Hanoi	Quang Tri	Vinh Phu	Phu Ly	Bac Giang
Mine	49%	24%	56%	64%	43%	57%
Bullet/projectile	19%	19%	6%	24%	43%	29%
Vehicle accident[14]	17%	33%	25%	4%	0%	7%
Bomb	12%	19%	13%	8%	14%	0%
Infection/tumor	2%	4.8%	0%	0%	0%	7%

[4] This scale includes: 2 = daily; 1 = sometimes; 0 = never.

[5] This value is a subjective evaluation by the author as to whether the patient is participating in the same or similar work he would have without the amputation.

[6] The patient was asked to describe his type of work and the following scale was used in analysis: 2 = heavy; 1 = light; 0 = sedentary.

[7] The patient was asked how his family and friends responded to his amputation. The scale was: 2 = well; 1 = OK; 0 = poorly.

[8] This scale includes: 3 = well; 2 = "I ignore any problems"; 1 = OK; 0 = poorly.

[9] Given that these patients were receiving their POF legs on the day of the interview, this question was not asked in Quang Tri.

[10] Prosthetic Outreach Foundation legs comprised 1.5 prostheses out of this total on average. Other types of legs in use included those from the following centers: Ba Vi, Tam Diep, Da Nang, Thuan Thanh in Ha Bac Province, Handicap Foundation, Hue Hospital, Ninh Binh, Ho Chi Minh City, 27th July Center in Hanoi, and homemade legs. The policy of the Ministry of Labor, Invalids and Social Affairs is to provide 1 leg and 10 prosthetic socks every 3 years.

[11] Number of legs the patient has received from a Prosthetics Center, whether one run by the Vietnamese government or by a Non-Governmental Organisation.

[12] One who gardens, tends livestock and maintains the household of a farming family.

[13] Purveyor of food, cigarettes, alcohol or lottery tickets.

[14] Refers to both traffic and train accidents.

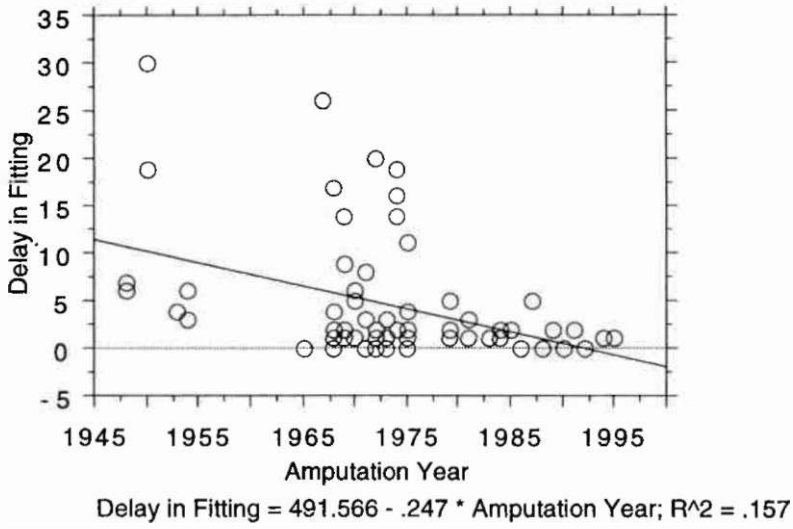

Fig. 2. Relationship between amputation year and delay to prosthesis fitting including a regression analysis for the relationship.

only 58% currently hold the same or similar job they would have without their amputaton. Many patients have moved from the rice field to "house farmer"; others had moved from government official to the life of a seller. The average work rigor scale value of 0.80 indicates that most participate in "light" to "sedentary" work, suggesting a shift from more labor-intensive careers (Table 2). Certainly, a similar survey of the non-amputated population of Northern Vietnam would provide a basis for comparison. Nonetheless, these data indicate reduced functionality of the amputee in the developing world setting. To the majority of patients, amputation presents a formidable barrier to the continuation of their old way of life.

Such an interpretation is borne out in the results pertaining to the amputees' sense of integration within society, which reveal a challenge existence for amputees particularly in those locales outside of Hanoi. The "Change in Quality of Life", "Reaction of Family and Friends", and "Reaction of Public" data expose a particularly pronounced sense of disjointedness in Phu Ly and Bac Giang. Even though patients as a whole were married half a year later than their amputation on average, stories of courting difficulties emerged in interviews. In a society where physical strength translates into prosperity, many amputees conceded that it had been difficult to convice potential spouses of their ability to work. Others said their families considered them a burden initially, and indeed that their families had grown poorer as a result of their disability. The preponderance of "house farmers" suggests that many amputees were looking for a way to contribute after losing their ability to work in the fields (Table 3).

These data also reveal that universal access to care remains a daunting problem. Because international prosthetics agencies in Vietnam must channel their efforts through the centralized, communist government and its district and sub-district offices, patient selection heavily favours war veterans. The patient population interviewed was remarkably homogeneous: patients on average were 47-year old males amputated in 1974 due to a landmine explosion. Rarely treated are those victims who have stepped on mines or suffered traumatic accidents in the course of their daily lives ("social amputees"). The author gained the impression that veterans are served preferentially over other social groups, and receive a substantially higher number of prosthetic legs. For example, 3 veterans in Vinh Phu Province had received 20 or more legs, compared to an average of 5.6 legs for the whole group. In contrast, one 66-year old woman in the same province had used only one leg for 29 years, which she herself repaired. No clear

rationale for this high number of legs provided to certain patients was proffered at the time of the interview, although it is noteable that these 3 patients were all veterans living in relatively close proximity to the Ba Vi Prosthetics Center.

There remains an apparent discrepancy in the number of limbs supplied in differing regions. Quang. Tri Province lies south of the former Demilitarized Zone of the Vietnam War. The number of legs its amputees have received (average 2.9) is about half the number received by the subject population as a whole (average 5.6) (Tables 2 and 3). Caring for the broad population of amputees remains a challenge in Vietnam.

This study suggests that differences in the quality of care and level of integration in urban versus rural areas may exist, although the high standard deviations and relatively small sample size did not yield statistical significance for most of these differences. Patients in Hanoi proved to be the one exception: they were significantly better integrated into their families than those in rual areas (Table 2). Although these patients had received fewer legs than those in Vinh Phu, they certainly had better access to care if their legs needed repair. Furthermore, city life demands less of a person physically, allowing smoother integration back into the patient's pre-amputation lifestyle.

The number of years patients wait on average before care is diminishing with time, but continues to vary dramatically across regions. In Bac Giang, for instance, patients waited on average only 1.8 years, while in Quang Tri patients waited nearly five times as long (average 8.9 years) before their first government-provided leg. This statistic correlates strongly with the rate at which government pensions are allotted to the patients of the province. Those areas in which 100% of those surveyed received pensions also featured the lowest waited period for a leg. This finding complements the perception that the government provides first for those it deems essential to national vitality. The observed order of hierarchy generally privileges North Vietnamese war heroes, followed by revered public officials and North Vietnamese veterans, then "war mothers", those women deemed essential in the fight for independence, proceeded by civilian casualties of the war and "social amputees", those injured traumatically or medically. Given the long wait for a leg provided by the government, many patients had improvised a prosthesis or borrowed one from a friend.

Generally, pensions are awarded for service to the state, either after a lifetime of government work, or as particularly apt in this population, for service in the armed forces. A definitive percentage of veterans vis-à-vis the patient population at large was not obtained, although 82% of the injuries leading to amputation were war-related. The rate at which pensions were awarded ranged from 31% in the province of Quang Tri to 100% in Phu Ly and Bac Giang. As Quang Tri sits south of the former Demilitarized Zone, a number of patients there were veterans of the South Vietnamese Army, and therefore ineligible for pensions. Given its rural aspect and distance from a major center of government, Quang Tri also includes a relatively limited number of former government officials.

The connection between the rate at which patients received government pensions on one hand and worked on the other appear to follow an inverse relationship. The low pension rate (31%) in Quang Tri was associated with a 94% work rate, while the high rates of pension receipt in Phu Ly (100%) and Hanoi (76%) were associated with lower work rates (57% and 62% respectively). A relationship between occupation and the collection of government pension is not obvious when comparing Tables 2 and 3. Instead, it is most helpful to consider occupation in terms of the opportunities and vocational culture of the region.

The conclusion form this study are limited by its relatively small sample size and by the fact that a random sampling proved impossible to achieve.

Conclusion

This study has demonstrated the importance and the challenge of collecting meaningful data on the efficacy of a prosthetics programme in a country such as Vietnam. The geographic dispersion of the served individuals in this largely rural setting requires going into the field to assess the prosthesis wearer in his living and working environment. The results of this investigation indicate that many individuals enjoy restoration of activity with a prosthesis. However, it remains apparent that functional rehabilitation has not yet advanced to the point where most amputees can resume occupations

such as farming. Furthermore, reaching individuals living far from prosthetic fitting and repair centers continues to be an impediment.

Field data collected using standardized assessment tools, such as that used in this study, will help direct future efforts to improve the quality of life for individuals with amputations in developing countries.

Acknowledgements

This study was generously supported by the Prosthetics Outreach Foundation, the Patrick J. Leahy War Victims Fund of the United States Agency for Interantional Development, and the Morehead Foundation of the University of North Carolina at Chapel Hill, USA. The author wishes to thank all the patients for their particpation. This study would not have been possible without the help and cooperation of the Prosthetics Outreach Clinic and the Ministry of Labor, Invalids and Social Affairs in Hanoi.

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Appendix 1

Prosthetics Outreach Foundation Patient Chart

DEMOGRAPHICS

Date
Patient Name
Location (urban or rural)
Height
Weight
Birth Date
Gender
Occupation
Date of Amputation
Level of Amputation
Right or Left
Cause of Amputation

QUESTIONNAIRE

1. Have you had an artificial limb before the one from POF? If so, where did you obtain it and when?
2. At what date did you receive the prosthesis from POF?
3. Is the prosthesis in need of repair? How and when will it be repaired?
4. Have any components or has the complete prosthesis been replaced? If yes, which?
5. Is the prosthesis comfortable? If not, what hurts?
6. On an average day, how many hours do you wear the prosthesis?
7. Do you have trouble with your residual limb? (e.g. phantom pain, pressure sores...)
8. How has your lifestyle changed since your amputation? (social life, employment...)
9. Has your lifestyle changed since receiving your POF prosthesis? (social life, employment...)
10. Are you currently employed? Job Requirements:
11. Do you collect a government pension?
12. Work:
    (1) retired and stay at home
    (2) part-time
    (3) full-time
    (4) able to work, but unemployed
    (5) unable to work due to reasons other than amputation (explain)
    (6) presently working, but new job due to amputation
    (7) child, at school
    (8) other (specify)
13. Type of work:
    (1) do not work
    (2) sedentary work
    (3) stand mostly
    (4) heavy lifting involved
    (5) great deal of walking involved
    (6) other (specify)

14. How satisfied are you with the appearance of your prosthesis? (1 low - 5 high)
15. Does your prosthesis make squeaking, clicking or other noises? If so, which?
16. Can you go up and down stairs step over step?
17. Can you walk while carrying a load? If so, how much?
18. Approximately how far can you walk without resting?
19. Can you ride a bicycle?
20. Can you run?
21. Do you regularly participate in sports? Has this changed since receiving your POF prosthesis?
22. What kind of footwear do you normally wear?
    (1) sandals
    (2) shoes
    (3) none
23. Do you have enough prosthetic socks to use a clean one daily?
24. Are you married? If yes, when did you get married?
25. How have your family and friends responded to you as an amputee?
26. How do you feel the public responds to you as an amputee?
27. Are you satisfied with the results of your surgery? How many operations have you had on your amputated leg?
28. Are you satisfied with the results of your prosthetic treatment?
29. Are you satisfied with the condition of your non-amputated limb? If not, what is the problem?
30. Do you use any assistance devices to walk such as canes or crutches? If yes, which?

Additional Comments:

Prosthetics and Orthotics International, 1999, 23, 102–106

An epidemiological study of war amputees and the cost to society

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Abstract

The purpose of this study was to assess the overall financial cost of the prosthetic care which war amputees have incurred since the injury occurred.

Records of 98 war veteran amputees who had attended the Dundee Limb Fitting Centre were scrutinised, they revealed 52 survivors and 46 who had died by 1997 and represented all the records available at the time of the review. The number and nature of visits, the number of prosthetic limbs ordered were counted and using today's costs, the cost of these services calculated.

The costs of stump socks, transport and social security payments were not included.

The cost of the artificial limbs was calculated at £(GBP)69 million with the recognition that it is an underestimate and approximation. Despite this it shows that the cost, allowing for the underestimation, has been relatively insignificant in the total cost of a major war and the war machinery.

The cost however to the individuals has been considerable with a substantial disability occurring at the prime of life resulting in a significant handicap.

It is a continuing legacy that society is responsible for, as a direct result of armed conflict.

Introduction

In all armed conflicts there is considerable advantage in maiming rather than killing one's foes. The injuries thus sustained occupy much time and medical resources which if the individual had died would not have been incurred, tying up manpower that could be used in a more "war effective" way.

Upper and lower limb amputees have been one of the sequelae of war since man began to become involved in conflict. They represent a significant number of survivors who, following discharge from the services, continue to need clinical services to maintain their independence.

A clinical record review of all war pensioners who are attending or those who have attended the Dundee Limb Fitting Centre (DLFC) since 1945 was undertaken.

Records at DLFC consist of both a medical file and a limb file.

Limb files of the survivors contain details of the prosthetic activities since the injury.

Medical records from 1965 are still held for both alive and deceased patients although limb files for those patients who are deceased have been destroyed. This valuable source of data has been scrutinised and using the current costs for limbs and clinical events an estimated overall cost of the care has been calculated.

At the end of World War I there were at least 29,400 British lower limb amputees and 11,600 upper limb amputees, and at the end of World War II a further 12,000 amputees. The Falkland conflict produced a further 32 limbless servicemen. In addition there are amputees from other conflicts but the numbers are not available. (Source British Limbless Servicemen's Association personal communication).

It is salutary to note that by the end of 1938 in the United Kingdom there were only 3,400 amputees who had between them had 142,600 artificial legs and 31,600 arms (Ministry of Pensions, 1939).

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Method

Medical records and limb file records were retrieved for the war pensioners identified from the authors' data base. The medical records for those patients who had attended the Limb Fitting Centre since 1965 were available and the limb files of those surviving patients were available from the date of their injury to the present date. For the deceased patients only medical records were available for those who had been seen at the Limb Fitting Centre from 1965 onwards. These are those from Tayside and North East Fife two counties of Scotland.

The details were not always complete although some information could be obtained by comparing both limb file and the medical records. Where the records conflicted with each other the data was ignored.

There were some 98 patients identified, 87 from World War II, 8 from World War I, 2 from the Korean War and 1 from the Falklands.

It should be noted that the World War I files were extremely sparse in their information with an extraordinary lack of detail. World War II patients' records however, had slightly more information.

Table 1. Level of amputation

Upper limb:			
Trans-radial		12	
Trans-humeral		9	
Hand		2	
		23	
Lower limb:			
Trans-tibial		40	
Knee disarticulation		1	
Trans-femoral		34	
		75	98 – Total all male
38 Left	31 Right	19 side not recorded	

Discussion

War related amputees are a group of individuals who present with continued need for health service provision.

This group of patients displayed a similar distribution of level of amputation as that reported by Soloren *et al.* (1965) with a significantly higher proportion of upper limb amputees than all others attending limb fitting centres in Scotland with 23 (23%) out of the 98.

For those for which the information was available, 38 (55%) had left and 31 (45%) had right-sided amputations which is similar to the Centre's vascular related patients experience (Table 1). Although not statistically significant it is an interesting similarity which is difficult to explain.

Those from World War I were reported as having been injured in "France" with only 8 surviving in the Tayside catchment area (Table 2).

The average age of the amputee at the time of the trauma was 25.9 years which seemed at first sight a little old to the authors. However conscripts were enlisted up to the age of 50 years. This contrasts with the average age of the vascular amputee of 70 years (Stewart and Jain, 1993).

The average of death in the 16 for whom records were available containing this information was 50 years, with the arm amputees surviving to 80 years, although the numbers are small and significance is questionable. In this fairly young age group of lower limb amputees death might perhaps relate to other injuries sustained, but this data is not available. This survival contrasts with the current survival for vascular amputees of 6 years 6 months (Stewart *et al.*, 1992).

Soloren *et al.* (1965) report of 311 Finnish war veterans found very little evidence of increasing circulatory disease but Weiss (1990) reported

Table 2. Area of conflict where the subjects lost their limbs.

Africa	11	Holland	1	Singapore	1
Belgium	1	Italy	16	Syria	2
Burma	2	Korea	2	UK	5
Falklands	1	India	1	Not recorded	22
France	17	Malta	1	World War I	8
Germany	6	Palestine	1		
Those "not recorded" appear to be from the WWII on account of their age					

Table 3. Age and survival details.

Age at amputation	25.9 years
Current age of survivors	(52) 74 years (range 70-101)
Average age of those deceased	(46) for whom records were available (16) was 50 years
Average age of deceased upper limb amputees	(3) 81 years
46 had died by the time of the study	
52 survivors	

75% in a series of 97 amputee veterans as having vascular disease. The war related amputees in the Dundee group have never had a further amputation for vascular disease which contrasts significantly with the other reported paper.

Each patient had an average of 7 new prosthesis in the 52 year period, each limb lasting about 7 years, this is much longer than that reported by Lowry (1967) of 3.3 years. This latter report is of United States (US) veterans as opposed to United Kingdom (UK) veterans and the explanation may be in the different funding arrangements. The current DLFC data indicate that in the first 5 years after the amputation each vascular related amputee has on average 2 new artificial limbs and at least 1 socket change. This is similar to the war amputees who were always supplied with 2 limbs.

Fourteen (14) of the 18 trans-tibial amputees for whom continued data is available, were converted to Patellar Tendon Bearing prostheses with 4 still preferring the old thigh corset prosthesis with which they were initially issued. It is significant that despite modern technology some patients still prefer the original device.

None of the arm amputees changed their prosthesis type and this perhaps is a reflection of lack of development of upper limb services although some patients have converted from leather to plastic sockets, but the basic device remains the same.

Table 4. Visits – limb and socket delivery. For surviving amputees (52)

Each patient had:	
7 new limbs	
4 socket changes	
Trans-tibial	3 /patient
Trans-femoral	4 /patient
Each patient attended:	
Upper limb	48 visits
Lower limb	72 visits
Trans-tibial	66 visits
Trans-femoral	80 visits

Table 5. Estimated cost of outpatients' visits.

Cost – Average at today's prices – UK/Scotland (Source: CSA Edinburgh)		
8 upper limb @ 48	=	384 visits
44 lower limb @ 72	=	3,168 visits
	=	3,552 visits @£50/visit consultation fee
	=	£177,600

The trans-femoral amputees in the study, 6 of the 15 for whom accurate records remain still use metal sockets although some of the 6 have tried plastic and modern technology but have still preferred the original device.

In this study 8 upper limb amputees attended 384 times (48 per patient) which is much less than the 44 lower limb amputees who attended 72 times per patient, This represents a total of 3,552 visits which at today's cost of £50 per visit

Table 6. Prosthetic expenses in today's terms.

New limb costs			
8 upper limb patients			
	6 BE	x £960 x 7 =	£40,320
	1 AE	x £960 x 7 =	£6,730
	1 Hand	x £500 x 7 =	£3,500
44 lower limb patients			
	20 TF	x £803 x 7 =	£112,420
	23 TT	x £1,660 x 7 =	£267,260
	1 KD	x £1,500 x 7 =	£10,500
Socket costs			
8 upper limb patients			
	6 BE	x £450 x 4 =	£10,800
	1 AE	x £450 x 4 =	£1,800
	1 Hand	x £500 x 4 =	£2,000
44 lower limb patients			
	20 TF	x £400 x 4 =	£32,000
	23 TT	x £400 x 4 =	£27,600
	1 KD	x £400 x 4 =	£1,600
Total costs			
Limbs £440,720			
Sockets £76,800			
= £517,520			
($853,908 @ $1.65/£1)			

Table 7. Limb types.

Initial limb supplied	
Trans-tibial	Thigh corset leather socket
Trans-femoral	Metal socket 'H' type
Current limb being used	
6 patients have	Metal socket trans-femoral
9 patients have	Plastic (4 ICS; 5 Quad)
4 patients have	Thigh corset, leather socket trans-tibial prosthesis
14 patients have	PTB
4 patients have	FI 'below elbow worker'
7 patients have	BI above elbow prostheses
1 patient has	Commuted arm
1 patient has	Partial hand

($82.5 US) represents £177,600 in total ($293,040) for the attendances alone.

The new limb and socket costs for this period were £517,520 ($853,908) at present day costs.

The number of original amputees who came from this area at the end of 1945 is not known. In 1965 there were 98 which represents about 1% of the number known (7,000 WWII and 3,700 from WWI) at the end of the conflict. The number who had died by this time is not known but the 1% in this area would seem a reasonable basis for the rough calculations.

Therefore extrapolating this figure to the whole of the UK bearing in mind that Tayside and North Fife have approximately half a million people and the UK has 55.5 million people, the cost to the UK in today's terms of the war amputees is at least £69,512,000 which is equal to $114,694,800 (Table 8).

Conclusion

This group of individuals represents an important continuing responsibility for the UK Government. The continued cost implication is not insignificant and represents a continuous responsibility that war imposes on society.

Table 8. National costs.

Accepting the approximations
Population of Tayside and North Fife, Scotland as 550,000
This is about 1% of UK population (55 million)
The costs of out-patient appointment for surviving war pensioners since 1965
= £177,600 x 100 = £17,760,000
The costs of the service for the war pensioners from 1945 to date
is £51,752,000 + £17,760,000
= £69,512,000
($114,694,800 @ £1.65/£1)

In this study all amputees were male and the majority were as the result of World War II.

There was a high incidence of upper limb amputees which is significantly different from the current primary limb referral pattern. This has implications in that the expertise in caring for the upper limb amputee which was significant in the post-war years is reduced. This potentially means that as the war amputee population declines the expertise reduces. This may result in the need for specialist centres where sufficient numbers of patients are seen, enabling a high standard of care to be maintained.

This also is true for the surgical skills which were learnt during the wars. In the western world the expertise for repairing blast injuries and gunshot wounds is limited to a few specific centres. The development of such skills in the light of modern orthopaedic and vascular advances is resultantly difficult but for those of us fortunate to live in a peaceful environment this is a small price to pay for peace. For those less fortunate however the limited surgical developments may be to the overall detriment of the casualties

As expected the amputees were young at the time of injury and therefore have required care for over 50 years.

The cost, in today's terms, of the supply of artificial limbs has been considerable at £69 million and this figure is probably a significant under-calculation as waiting repairs and incidental costs, e.g. stump socks, pain medication and pension costs have not been measured. The records are admittedly not complete and do not indicate the hidden costs of potentially reduced earnings, mobility costs and the huge psychological cost to both the amputee and family.

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Prosthetics and Orthotics International, 1999, 23, 107-112

Socket/stump interface dynamic pressure distributions recorded during the prosthetic stance phase of gait of a trans-tibial amputee wearing a hydrocast socket

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Abstract

Force sensing resistors (FSR) have been used to measure dynamic stump/socket interface pressures during the gait of a trans-tibial amputee. A total of 350 pressure sensors were attached to the inner wall of a hydrocast socket. Data were sampled at 150Hz during approximately 0.8 seconds of prosthetic stance of gait. The dynamic pressure distributions within a hand cast socket reported by Convery and Buis (1998) are compared with those monitored within a hydrocast socket for the same amputee. The pressure gradients within the hydrocast socket are less than that of the hand cast Patellar-Tendon-Bearing (PTB) socket. The proximal "ring" of high pressure in the hand cast PTB socket is replaced with a more distal pressure in the hydrocast socket.

Introduction

The characteristics of the Tekscan FSR transducer, which incorporates 96 sensors, has been previously reported by Buis and Convery (1997). By adopting a strict test protocol, 4 transducers may be bonded to the inner socket wall and calibrated *in situ*. This calibration technique minimises inaccuracies. When subjected to repeated pressures of 100kPa the variation of the "average" pressure of a transducer was ±2% with a maximum variation of ±10% for any individual sensor in the array of 96.

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The hydrocast socket is based on a system developed by Murdoch (1968). One of the uncertainties of pressure casting in general has been to determine the pressure magnitude and duration required in order to create a good socket fit. Gardner (1968) recommended an applied pressure of 13kPa. Kristinsson (1993) proposed pressure levels of 23 to 34kPa, commenting that applying pressures of less than 23kPa often resulted in a slack fit. Krouskop *et al.* (1987) stated that stump tissue is not compressible which implies that tissue fluid will migrate from the stump with the application of constant pressure.

Method

Figure 1 illustrates the hydrocast procedure. Weight transfer through the stump may be supported if the stump is immersed in a sealed water tank. Increasing or decreasing the volume of water within the sealed tank raises and lowers the stump. The Icecast pressure cylinder was modified by introducing a flexible sleeve as a barrier between the water in the cylinder and the plaster of Paris (POP) covering the amputee's stump. A close fitting template was fitted to the amputee's thigh in order to ensure that, during weight bearing, minimum support was being provided by the sleeve. Immediately after application of the POP, the stump was inserted into the cylinder and the cylinder was raised until the brim contacted the template on the amputee's thigh. The template was locked to the cylinder brim and the cylinder was then filled with water at body temperature. As the amputee transferred full body weight through the stump, the volume of water in the cylinder was increased until the stump was lifted marginally

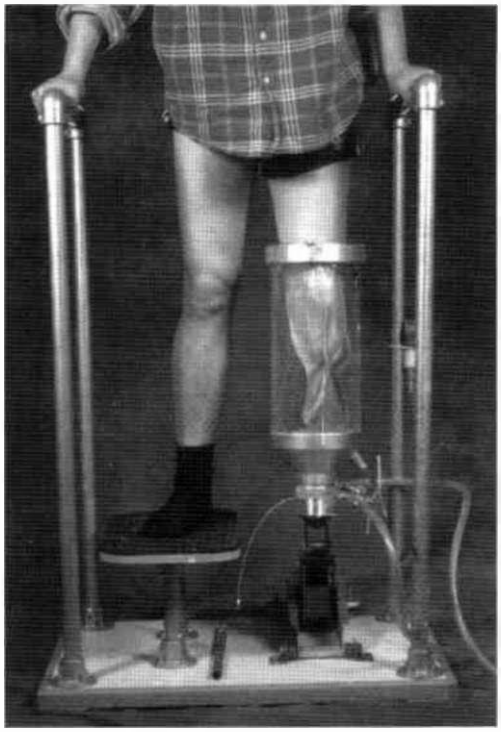


Fig. 1. Hydrostatic casting

out of the template. As the POP cured, the amputee maintained weight bearing through the stump, while resting his hands on adjacent hand rails. The positive cast was not rectified but was used directly for socket lamination.

The patient, an active 37 year old male, was a traumatic, unilateral amputee with 10 years prosthetic experience and typical stump characteristics. He was fitted with a trans-tibial prosthesis incorporating an acrylic resin laminated hydrocast socket. The hydrocast prosthesis was aligned to the satisfaction of the patient and two prosthetists. The alignment was measured using a socket axis locator. A duplicate prosthesis was fabricated so that the hydrocast prosthesis that incorporated the transducers was used only during the pressure studies. The alignment was duplicated on the instrumented hydrocast prosthesis. Figure 2a illustrates the alignment of both hydrocast prostheses. Figure 2b illustrates the alignment of a conventional hand cast/rectified PTB socket used in a previously reported pressure study (Convery and Buis, 1998). No socket liners were supplied with either prosthesis to avoid any effect the liner might have on pressure distributions. A single towel sock was used with both types of socket and a silicone sleeve was supplied for suspension of the prostheses.

A sensor reference grid was established for positioning the 4 transducers, using a socket axis locator. As in the case of the hand cast prosthesis, the 350 sensors were positioned with an accuracy of ±0.75mm and attached to the inner socket wall using non-aggressive spray adhesive. The transducers were to the anterior, posterior, medial and lateral walls of the hydrocast socket. The lower posterior socket brim permitted some sensor cells from the posterior transducer to be located at the distal end of the socket.

A strict test protocol was adopted. The patient used the non-instrumented hydrocast prosthesis for approximately 3 hours in the morning to become accustomed to the socket. The pressure

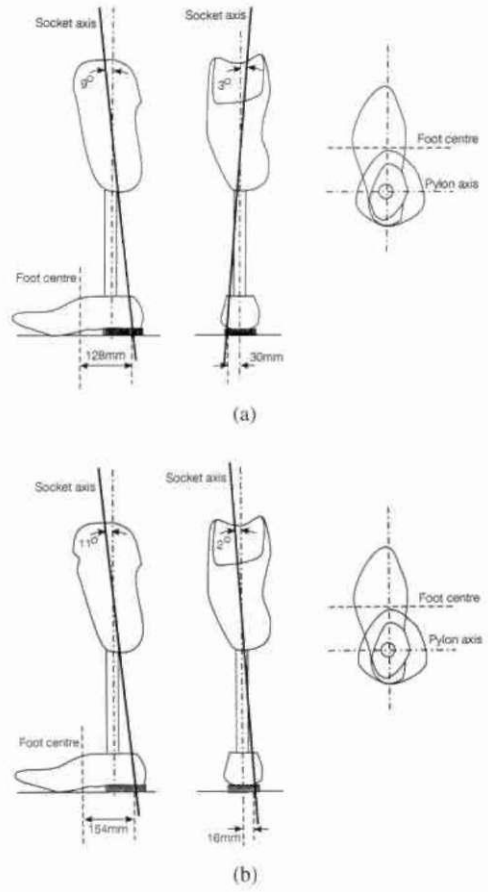


Fig 2(a). Alignment of hydrocast prosthesis.
(b). Alignment of hand cast prosthesis.

study with the hydrocast prosthesis incorporating the transducers was undertaken that afternoon. A pre-conditioning sequence of taking approximately 30 steps was adopted before simultaneously recording data of walking velocity, pressure and the force plate outputs. After each recording session the patient was seated for at least 3 minutes to allow the pressure

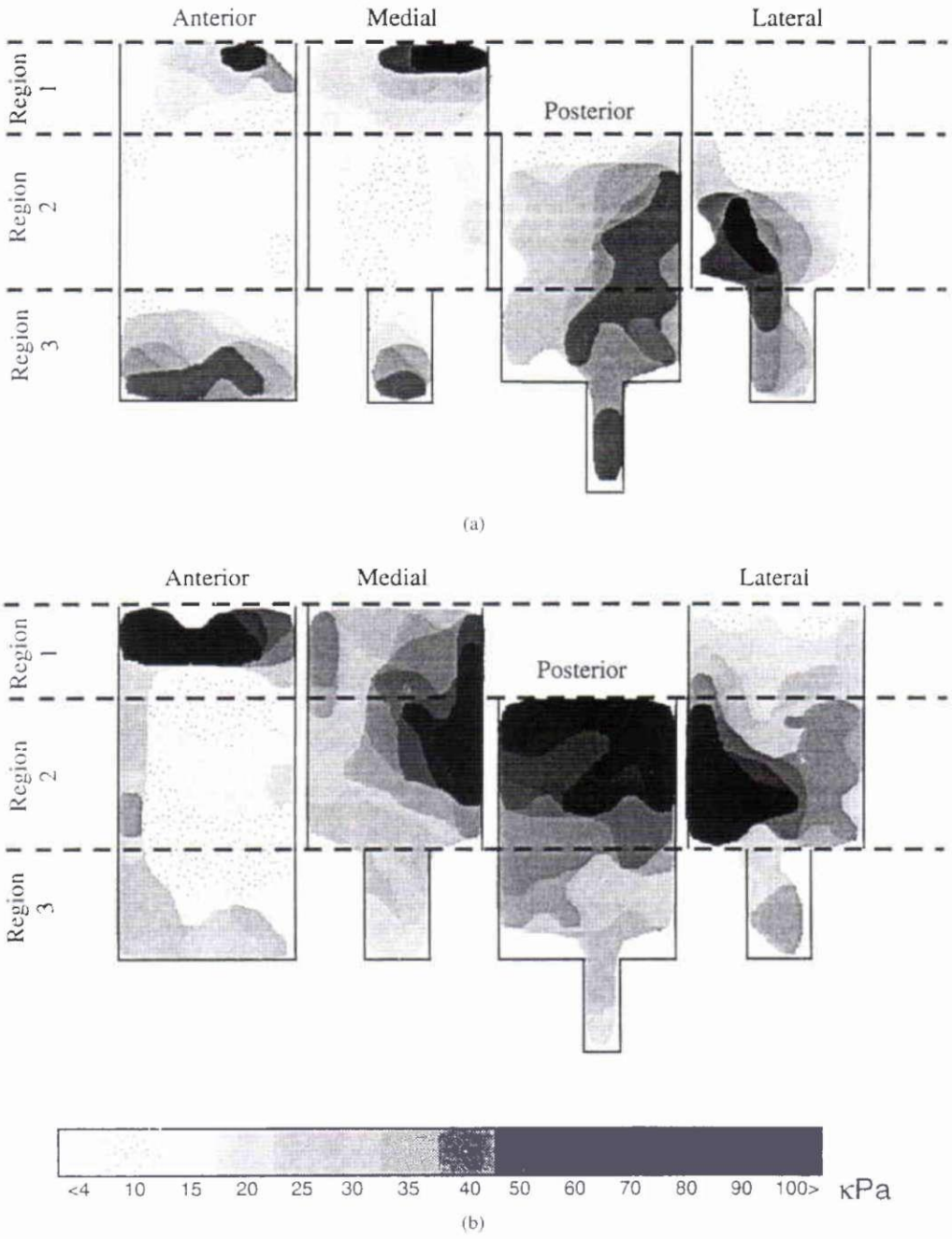


Fig. 3(a). Hydrocast socket pressure distribution after mid-stance.
(b). Hand cast socket pressure distribution after mid-stance.

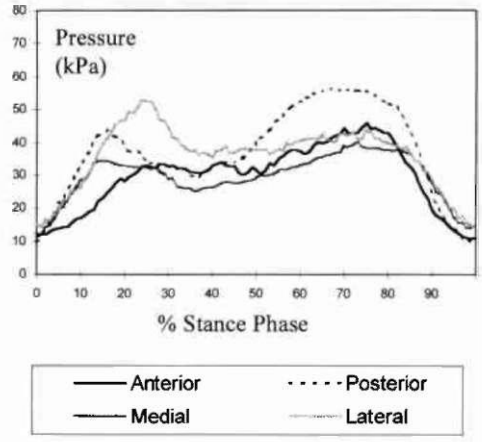
sensors to recover before repeating the exercise. This procedure was repeated 15 times, monitoring the 2 transducers attached to the anterior/posterior aspects of the socket and then 15 times monitoring the 2 transducers attached to the medial/lateral aspects of the socket. The force plate and walking speed data were reviewed and, using statistical analysis, 2 particular steps were selected which were considered to be most representative of the patient's average gait. The pressure data from these 2 selected steps were combined to provide a pressure distribution from all four transducers during a "single" prosthetic stance phase of gait. The pressure studies of the hand cast prosthesis and the hydrocast prosthesis were completed on consecutive days.

Results

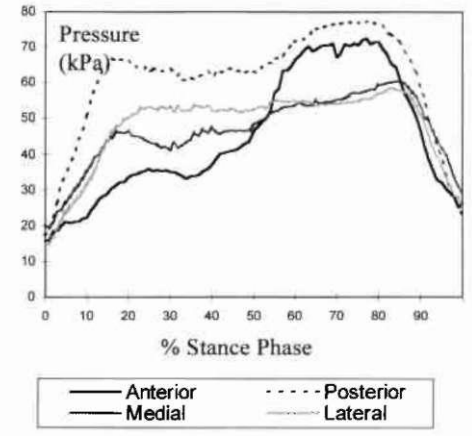
Three axial regions within the socket may be identified, similar to that adopted previously with the hand cast prosthesis. Figure 3a illustrates the typical pressure distribution of all 4 transducers displayed in a 2D configuration for the hydrocast prosthesis. For comparison Figure 3b illustrates the typical pressure distribution of all 4 transducers displayed in a similar 2D configuration for the hand cast prosthesis. The anterior, medial, posterior and lateral pressure data results are illustrated, from left to right, during an instant shortly after mid-stance. During gait, some areas within the physical boundary of the transducers may be displayed in "white". The white scale indicates that the pressures experienced in these areas are below the minimum measurable threshold pressure of 4kPa. This does not imply that there is no contact between the stump tissue and socket wall in these regions.

The pressure distributions, illustrated in Figures 3a and 3b, vary throughout the stance phase of gait. A sample rate of 150Hz for 0.8 seconds provides for each socket a total of 120 versions of pressure distribution patterns throughout prosthetic stance.

Figure 4a illustrates the variation of the "average" pressure of each of the four transducers in the hydrocast socket during the stance phase of gait. Figure 4b illustrates the variation of the "average" pressure of each of the four transducers in the hand cast socket. However, the "average" pressures in Figures 4a and 4b indicate the mean of approximately 96



(a)



(b)

Fig. 4(a). Hydrocast socket – transducer "average" pressures during stance.
(b). Hand cast socket – transducer "average" pressures during stance.

sensors and therefore peak pressures within the sensor array are concealed.

Discussion

Significant differences in pressure magnitude and pressure distributions were noted for the hand cast and hydrocast sockets. Both prostheses were considered satisfactory by the patient and the prosthetist. One would not expect the final alignments of both prostheses to be identical. The difference in final dynamic alignment of both prostheses, as demonstrated in Figures 2a and 2b, will influence pressure data.

Relative to the socket of the hydrocast prosthesis the prosthetic foot of the PTB prosthesis was dorsiflexed an additional 2° and the foot was aligned with an additional anterior displacement.

Relative to the socket of the hydrocast prosthesis the prosthetic foot of the PTB prosthesis has been everted by 5° and the foot was aligned with an additional lateral displacement. A review of the pressure data suggests no obvious influence resulting from this difference in alignment. The effect of the additional 2° dorsiflexion of the foot may have been nullified by the additional anterior displacement of the foot. No reduction of lateral/distal and medial/proximal pressure due to the "wider" walking base in the PTB prosthesis was noted. No alternating pressure patterns were recorded in the sagittal or coronal planes.

Detailed stump pressure distributions, such as those illustrated in Figures 3a and 3b, have not previously been published. Although this study was restricted to only one patient, for a particular socket the pressure patterns were repetitive.

Interpretation of these pressure distributions is possible if influencing factors are recognised. The relationship of the line of action of the ground reaction force (GRF) to the socket during the stance phase of gait may influence the pressure data. Throughout the prosthetic stance phase of gait the line of action of the GRF always passed ahead of the socket of both prostheses, for this particular patient. This relationship is not typical of trans-tibial gait.

Generally, the dynamic pressure levels during gait were lower and more evenly distributed in the hydrocast socket. It may be assumed that the weight transfer force applied by the same stationary patient is approximately common to both sockets. Studies of GRF data during gait suggest similar weight transfer through both prostheses. Therefore the higher pressures recorded in the hand cast socket may be due to dynamic stabilising forces. A review of the pressure distributions during gait did not indicate a logical explanation or agreement with the biomechanical principles proposed by Radcliffe (1961).

Peak pressures (>100kPa) may be considered potentially dangerous. This patient demonstrated peak pressures (>100kPa) just after mid-stance. Using Tekscan software, 2 specific areas of the hydrocast socket which experienced pressures in excess of 100kPa were identified, namely the medial knee at mid-knee level and the fibular head. Table 1a highlights the number of sensors within these 2 specific areas, the maximum "average" pressure experienced and the maximum pressure experienced by an individual sensor within both areas of the hydrocast socket. Four (4) specific areas of the hand cast socket experienced pressures in excess of 100kPa.

Table 1(a). Hydrocast socket: pressures in excess of 100kPa
(b). Hand cast socket: pressures in excess of 100kPa

Local area	No. of sensors within local area	Maximum "average" pressure of all sensors within area (kPa)	Maximum pressure of single sensor within area (kPa)
Medial knee	12	111	121
Fibular head	8	126	148

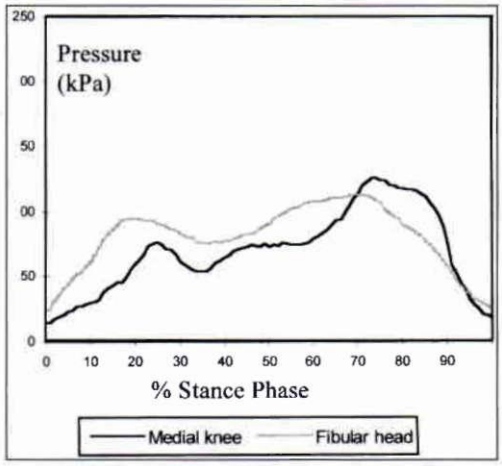
(a)

Legend	No. of sensors within local area	Maximum "average" pressure of all sensors within area (kPa)	Maximum pressure of single sensor within area (kPa)
Patellar bar	12	244	417
Proximal popliteal	8	128	168
Posterior medial flare	10	119	132
Fibular head	9	103	114

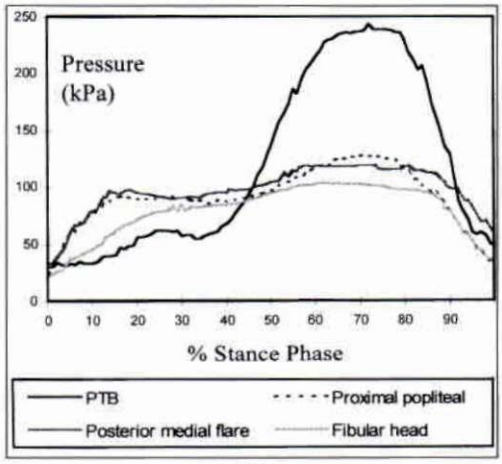
(b)

Table 1b lists the number of sensors within these 4 specific areas, the maximum "average" pressure experienced and the maximum pressure experienced by an individual sensor within each of the 4 local areas of the hand cast socket. The variation of the average pressure in these localised areas may be compared from Figures 5a and 5b.

Tekscan software system has improved such that all 4 sensors may be recorded simultaneously. This will avoid the need in future to undertake a series of 15 tests to "combine" data to simulate pressure distributions for a typical prosthetic stance.



(a)



(b)

Fig. 5(a:) Hydrocast socket - localised "average" pressures>100kPa
(b:) Hand cast socket - localised "average" pressures >100kPa

Conclusions

Distinctly different pressure patterns were demonstrated in this study of a single patient fitted with hand cast and hydrocast sockets.

A ring of pressure at the patellar bar level in the hand cast socket was noted with no major distal end pressure. The pressure gradient was less pronounced with the hydrocast socket and more distal pressure was noted.

Higher localised pressures were noted on the hand cast socket as compared with the hydrocast socket.

Both prostheses incorporate different alignments. The effect of these alignment changes on socket pressure distribution is inconclusive.

Recommendations

The effectiveness of different socket designs may be confirmed by investigating interface pressures with a wide range of stump characteristics.

FSR technology provides future studies with the potential of examining the effect of alignment modifications and long term volume changes on stump/socket interface pressure.

Additional studies are necessary to confirm the anticipated differences in alignment between prostheses incorporating hand cast and hydrocast sockets.

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Prosthetics and Orthotics International, 1999, 23, 113–122

Static structural testing of trans-tibial composite sockets

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Abstract

The purpose of this investigation was to quantify the structural strength of various trans-tibial composite sockets. To conduct the study, loading parameters and methods were developed that emulate the International Standards Organisation (ISO) standards for structural testing of lower limb prostheses since specific guidelines for the testing of the trans-tibial socket portion of a prosthesis have not yet been established. The experimental set-up simulated the instant of maximum loading during the late stance phase of gait. Ten trans-tibial sockets were evaluated. Five different reinforcement materials and two resin types were used to construct the sockets. A standard four hole distal attachment plate was used to connect the socket and pylon. Each sample was loaded to failure in a servo-hydraulic materials test machine at 100 N/s.

None of the composites in the study met the ISO 10328 standards for level A100, loading condition II (4025 N), as required for other prosthetic componentry. All failures occurred at the site of the pyramid attachment plate. Ultimate strength and failure type were material dependent. Load point deflection was significantly different for the resin variable ($p<0.05$). Statistical differences according to reinforcement material were noted in composite weight and strength-to-weight ratio ($p<0.05$). The fibre volume fraction was also estimated and recorded. Reinforcement material type was the primary determinant of performance for the tested samples. Carbon reinforcements performed better than fibreglass reinforcements of similar weave type. The greatest ultimate strength and strength-to-weight ratio was observed with the unidirectional carbon reinforcement.

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Introduction

The use of fibre reinforced plastic (FRP) composites in orthotics and prosthetics has primarily involved the transfer of technologies from the marine and aerospace industries. While the application of these materials in prosthetics is widely practised, specific information on their structural properties as they relate to the unique geometry of the trans-tibial socket is not reported in the scientific literature. This has resulted in a diversification of fabrication techniques within the profession. The material properties of composites vary greatly and depend on composition, lay-up, and processing method (Hubbard, 1995). The predominant processing method in prosthetics and orthotics is the vacuum bag moulding lamination technique. The type and amount of material applied determines the composition while the sequence in which they are applied dictates the lay-up. More recently, the introduction of hybrid resins has added to the variety of composite structures available in prosthetics and orthotics.

Faulkner *et al.* (1987) evaluated the tensile strengths of composites used in prosthetics and orthotics utilising standard coupon test samples. While this is valuable when the general

mechanical properties of materials are needed, these samples do not represent the geometry of the clinical devices. This creates difficulties in the translation of the data into socket design criteria. Head (1994) states: "Material design data are normally derived from the testing of specimens. For maximum reliability the specimens and test conditions should represent as closely as possible the materials and conditions of use of the final product."

The fabrication of FRP composites is riddled with several points of debate. One issue focuses on the use of reinforcement materials. Klasson (1995) reports that when using carbon fibre (CF) instead of fibreglass (FG) in equal amounts the strength will be about the same. Roberts (1984) states that using CF will result in a 30% to 40% increase in strength. Berry (1987) reported higher increases in strength, claiming that under compression CF is twice as strong as FG. All authors agree that replacing FG with CF will result in a reduction in weight. Klasson (1995) predicts a 10-15% lighter composite while Roberts (1984) predicts about a 30% savings in weight.

Excellent fatigue resistance can be achieved with the use of CF as compared to FG because the CF are approximately three times stiffer than FG. However, due to its high stiffness, CF is more susceptible to impact forces. For this reason both Berry (1987) and Roberts (1984) recommend mixing CF with either FG or Kevlar. Klasson (1995) recommends caution when mixing fibre types due to possible mismatches in the strengths of the fibres.

Several authors have recognised the fact that strength can be increased and weight reduced by using unidirectional materials instead of plain woven cloths (Roberts, 1984; Luger, 1982; Strong, 1989; Taylor, 1996). One of the problems associated with plain woven fabrics is that the fibres tend to bind or cut each other when stress is applied. In contrast, alternating layers of unidirectional fabric will provide strength in two directions without binding (Roberts, 1984; Luger, 1982; Taylor, 1996). Another advantage of unidirectional composites with regard to strength is that more fibres can be packed into a given space, thus increasing the fibre volume fraction (Roberts, 1984, Taylor, 1996). An interesting compromise can be reached between the two types using satin or long-shaft weave cloths (Strong, 1989; Humphrey, 1981; Mohr *et al.*, 1973; Taylor, 1996).

The last subject relevant to this study is the minimum allowable inside radius (MAIR). The MAIR= *r(fibre)/r(curve)* and must be less than the fracture strain. Woven fabrics have a greater MAIR than unidirectional fabrics due to the initial bend applied to the fibres by the weave. The tighter the weave the greater the MAIR. Mohr *et al.* (1973) and Sonneborn (1954) report a MAIR of 6.35mm and 12.7mm respectively while using the vacuum bagging lamination technique. Taig (1972) claims that the MAIR can be as small as 1mm for fibreglass materials and 11.6mm for large CF materials without damaging the fibres. Klasson (1995) recommends a MAIR of 40mm. Levan (1996) states that in order to determine the MAIR the fibres modulus and diameter must be known. For this information he recommends contacting the supplier or the manufacturer. All of the authors agree that larger radii are preferred over smaller ones though a measure of the optimal radii for socket design is still in question.

Understanding the material properties of composite design is important to ensure the structural integrity of the devices being fabricated. The purpose of this investigation was to quantify the strengths of various FRP trans-tibial sockets utilising a four hole attachment system. Techniques and materials used reflect those currently in widespread use within the United States of America. Testing was limited to the static load test. The static load test is used to reveal structural or design weakness associated with severe loading conditions. Ultimate strength, load point deflection curves and failure mode were adopted as the measures to assess structural properties of the trans-tibial socket. Additional comparisons were made between the sockets according to composite weight, strength-to-weight ratio rankings. To the authors' knowledge there are no studies evaluating structural testing of trans-tibial composite sockets.

Methods

Trans-tibial structural test model

In order to produce identical test samples for each composite type, a trans-tibial model was developed using a prosthetic CAD/CAM software package (Shape Maker, MIND Corp., Seattle, WA, USA). The model was created by averaging the measurements of 25 definitive

trans-tibial limbs which contain the customary modifications performed by an experienced prosthetist. The model was milled by conventional means with additional modifications completed by hand to remove any undercuts. Holding the model in normal bench alignment a distal attachment plate (AP-04, Prosthetic Design Inc., Dayton, Ohio, USA) was hand modified onto the distal end using plaster. Additional plaster was applied until the build-up followed the shape of the model body. This modification left a sharp angle between the model body and the distal end. Final modifications to this region resulted in a 10-12mm radius. To produce accurate and consistent corner radii, first the angle was flattened with an abrasive tool so that there was a surface of regular width for the full length of the angle. Then, the flat cut was blended in with the rest of the surface without making it any deeper (Humphrey, 1981).

The designated knee centre represented a point 19mm proximal to the mid-patellar tendon (MPT) (Coombes and MacCoughlan, 1988). This measurement was necessary for alignment of the proximal lever arm fixture used to load the prosthesis.

Socket fabrication and alignment

All sockets were fabricated from the trans-tibial test model a minimum of 14 days prior to testing. Lamination was done using the vacuum bagging method in the vertical position at room temperature. All resin was catalysed between 2.8 and 3 percent by weight and no pigment was used. All laminations were completed under a minimum of 2666 Pa (20mmHg) of vacuum and left under vacuum a minimum of one hour from the time the resin was catalysed. Gel times were all within normal limits. Following curing of the composite material, both the socket and the waste materials were again carefully weighed. The weights were taken for estimating the fibre-volume fraction.

A total of 10 sockets was fabricated in which the reinforcement material type was the primary variable and the resin type was the secondary variable. Two sockets were fabricated for each of the 5 types of reinforcement material (Table 1). One socket was laminated using acrylic resin and the other using carbon acrylic resin.

Composite lay-up was held constant for non-reinforcement materials. Each socket included

Table 1. Fibre reinforcement material types evaluated in static structural tests of trans-tibial sockets.

Unidirectional Carbon	Bock#616B2
Carbon-fibreglass stockinette	Bock#616G14
Fibreglass stockinette	Bock#616G13
Carbon fibre cloth	Bock#616G12
Fibreglass cloth	Bock#616G18

an inner and outer layer of nylon stockinette (623T10=9 Otto Bock Nylon, Duderstadt, Germany) and 4 intermediate layers of fibreglass-nylon stockinette (623T11=9 Otto Bock Nylglass, Duderstadt, Germany). Three (3) layers of reinforcement were added to each socket, 1 layer between each layer of fibreglass-nylon stockinette. Each layer of nylon and fibreglass-nylon stockinette was cut to length and one end was sewn closed. In addition, between the outer layer of fibreglass-nylon stockinette and the final layer of nylon, there was a single piece (½oz - 14gm) of dacron felt covering, but not overlapping, the distal end. This piece was added to allow surfacing of the distal end without affecting the integrity of the reinforcing materials. The end result for all sockets provided 6 plies of reinforcement material over the distal end, 3 plies of reinforcement material in the body of the socket, and 2 plies of reinforcement material in the proximal medial/lateral extensions. The sockets were cut to near identical trim lines and attached to an endoskeletal system (Otto Bock, Duderstadt, Germany). Components were assembled according to the manufacturer's instructions, with the socket and distal attachment plate connected with 4 bolts.

The alignment of the lever arms in relationship to the prosthesis equated to the parameters for structural testing strength of lower limb prostheses (ISO 10328 Standards for Load Level A100, Loading Condition II). Due to the specific offsets required, a method was needed to align the lever arms attached to the prosthesis quickly and accurately. Furthermore, the technique had to affix the proximal lever arm to the socket without affecting the performance of the device (Fig. 1). To achieve these goals a Socket Loading Fixture (SLF) was fabricated out of polyurethane elastomer (H.B. Fuller, Co. St. Paul, MN, USA) which held the proximal lever arm's force reaction point at the specified height and offsets. The SLF extended

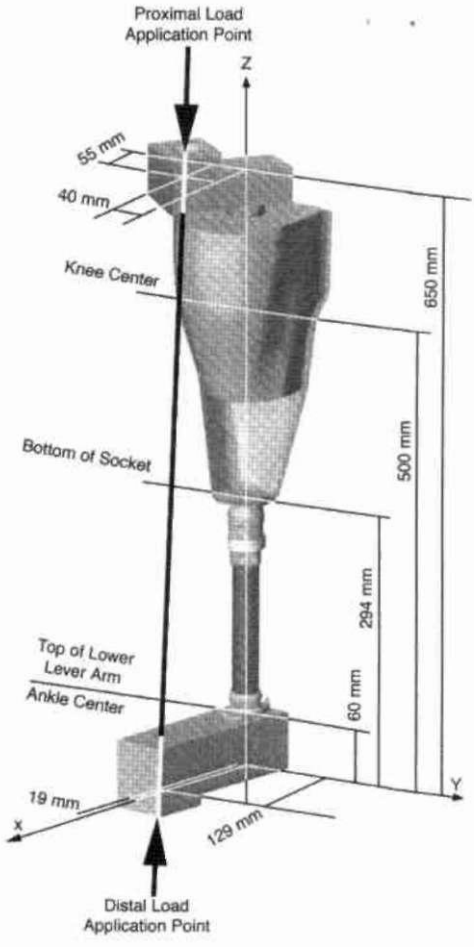

Fig. 1. Computer-generated image of the test apparatus used for static structural testing of trans-tibial prosthetic sockets. A cut-out sectional view of the sockets reveals the position of the Socket Loading Fixture (SLF). The illustration shows the reference planes, reference lines, dimensions, load application points and components.

approximately 9cm into the socket distal to the knee centre and the remainder of the socket was left hollow. The SLF has been used successfully in previous studies to load trans-tibial sockets (Coombes *et al.*, 1988; Wevers and Durance, 1987). However, it was not used for the explicit purpose of testing the structural integrity of the socket.

For alignment of the test samples, the SLF was inserted into the socket and a plumb line situated at the forward axis of the proximal lever arm. The alignment screws were adjusted on the endoskeletal system for each socket to ensure the loading surface of the proximal lever arm was parallel to the distal lever arm. The socket was then rotated at the tube clamp until the plumb line was aligned with the forward axis on the distal lever arm. With the components properly positioned and all the set screws torqued to manufacturer's specifications, the entire system was mounted in a materials test machine. This configuration is not in accordance with ISO 10328 which requires the alignment to be set to the manufacturer's guidelines and then set to a "worst condition."

Test procedure

Testing was conducted on a closed-loop computer controlled 100kN capacity servo-hydraulic test system. The tests were conducted in displacement control at a rate of 100mm/s. A +/- 80kN load cell was calibrated to standards traceable to NBS before and after testing. Linearity of the load cell was to 0.05% of full scale. Displacements were measured with a +/- 50mm LVDT, which was also linear to within 0.05% of full scale. All samples were loaded at the specified offsets and loading rates until failure was achieved. The offsets used relate to the instant of maximum loading occurring in the late stance phase of the gait cycle. The load was transmitted to the lever arms through a ball and socket joint design. Two (2) 47.6mm (1 7/8in) diameter automotive trailer hitch balls rated to 8.9kN (2000lbs) were attached to the testing apparatus. These pieces mated with the lever arms attached to the socket and pylon to provide a reaction point in which pure vertical force could be applied to the prosthesis as it deflected. A set force of 920N (ISO standard 19328) was applied as described above, held for 30 seconds, and then removed. The test device was then loaded to failure. Ultimate failure was designated as the point at which the prosthetic socket lost the ability to support an increasing load.

Data analysis

The results of this pilot study were evaluated using descriptive measures as well as Analysis of Variance (ANOVA). Specifically, a two-factor main effects ANOVA was performed with Duncan's Multiple Range test used for follow-up comparisons. The two factors were Resin consisting of 2 levels, and Materials, were consisting of 5 levels. Statistical significance

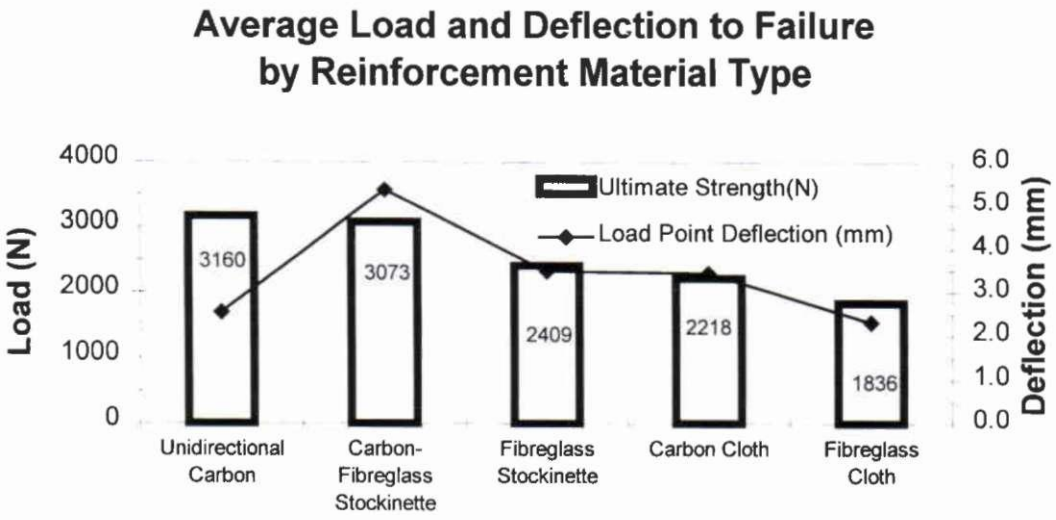

Fig. 2. Comparison of load point deflection and ultimate strength for each material, evaluated.

was set at the 5 percent level, although given the pilot nature of this work, specific p-values were also examined.

Results

The only significant statistical difference found between composites in regard to resin type was for load point deflection ($p<0.05$). This fact allowed the authors to increase the sample size by combining the results of these two groups for each reinforcement material type

Figure 2 shows the loading profile of each composite socket up to 18mm of load point deflection. It should be noted that the load point deflection also includes the deflection of the loading fixtures, the prosthetic hardware and the socket. The ultimate strength of fibreglass cloth approached a significantly lower value as compared to that of the unidirectional carbon and the carbon fibreglass stockinette ($p=0.06$) (Fig. 2). The ultimate strengths and load point deflection at failure were averaged by

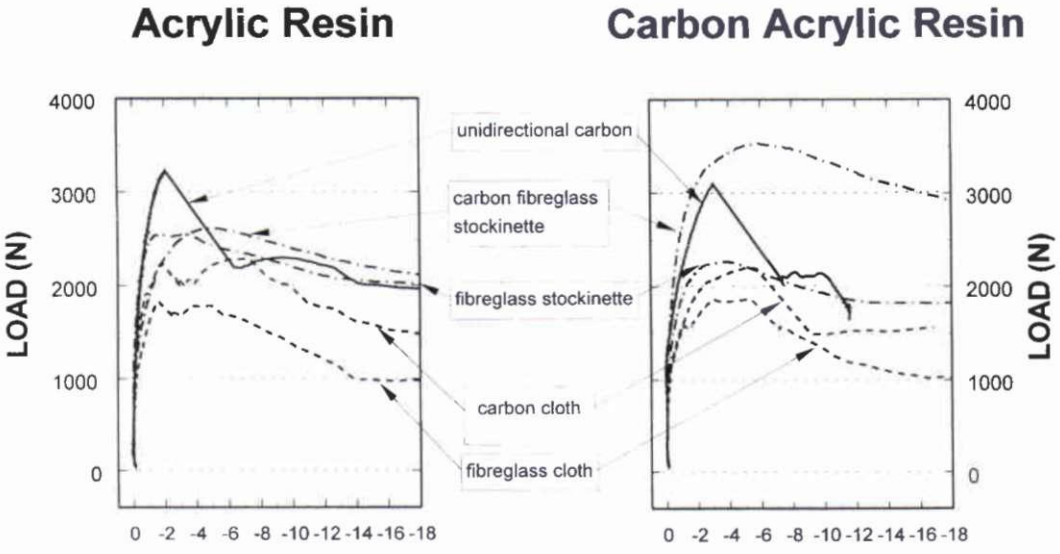

Fig. 3. Load point deflection curves of acrylic resin and carbon acrylic resin with the five different fibre reinforcement materials.

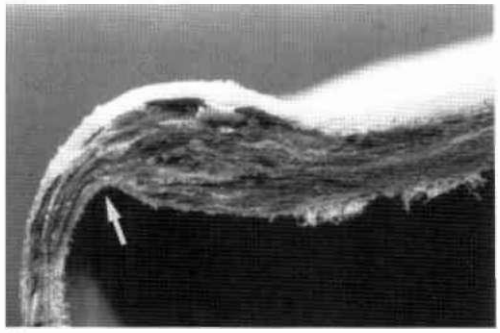

Fig. 4. Photograph of a cross-sectional view of a "buckle" type failure.

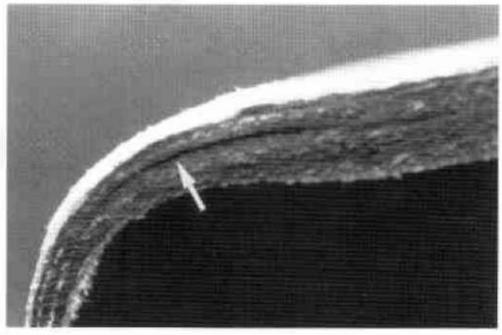

Fig. 5. Photograph of a cross-sectional view of an "inter-laminate" shear type failure.

reinforcement material type for further comparison.

The load point deflection of the carbon fibreglass stockinette approached a statistical difference (p=0.08) as compared to unidirectional carbon and fibreglass cloth

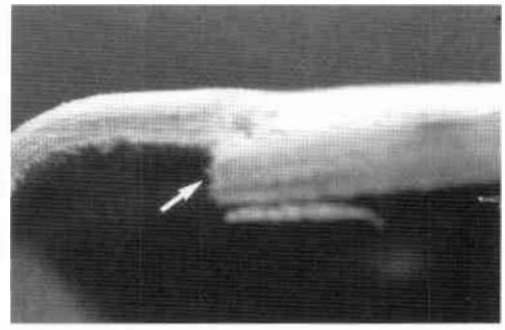

Fig. 6. Photograph of a cross-sectional view of a "tear" type failure.

(Fig. 3). The deflection was calculated with the position and load data collected by the materials test machine using linear regression D^*=Pos*-(mLoad+b) where mLoad+b = slope of the position vs load data in the linear elastic region. The increasing negative values indicate the compressive nature of the test procedure. All failure types were brittle but 3 failure modes were found; buckling in the stockinette reinforced composites, tension in the cloth reinforced composites, and inter-laminate shear in the unidirectional carbon reinforced composites (Figs. 4-6).

There was a significant difference in the testing weight of the composites. Fibreglass stockinette reinforcement was found to be statistically greater (p=0.002) than all the others and the carbon cloth to be statistically less (p=0.002) than the stockinette reinforced composites (Table 2). This difference is directly related to the amount of reinforcement material

Table 2. Material characteristics of trans-tibial sockets tested and mode of failure.

Reinforcement material type	Testing weight (N)	Strength: Weight ratio ranking	Reinforcement material dry weight (N)	Fibre-volume fraction	Failure mode
Unidirectional carbon	3.56	100.00%	1.25	34.2%	Shear
Carbon-fibreglass stockinette	3.75	92.24%	1.43	27.7%	Buckling
Fibreglass stockinette	4.41	61.47%	2.27	32.4%	Buckling
Carbon cloth	3.28	76.02%	0.90	28.7%	Tension and shear
Fibreglass cloth	3.51	58.88%	1.25	29.1%	Tension and shear

(by weight) in each composite, which was also found to be significantly different. The stockinette reinforcement weight was found to be statistically greater (p=0.0001) than all the others.

The strength-to-weight ratio of the unidirectional carbon reinforcement was statistically greater (p=0.02) than that of the fibreglass cloth reinforcement, carbon cloth reinforcement, and the fibreglass stockinette reinforcement, but not the carbon fibreglass stockinette. The carbon fibreglass stockinette reinforcement's strength-to-weight ratio was statistically greater (p=0.02) than the fibreglass cloth and the fibreglass stockinette but not the carbon cloth (Table 2).

Although a statistical analysis was not done, differences were also found among reinforcement material types for the estimated fibre volume fraction. The unidirectional carbon reinforced composites had a greater estimated fibre volume fraction than all other composites. The estimated fibre volume fraction is the percentage of material (everything except the resin) by volume within the entire composite. Volumes were calculated using weight and density (Table 2).

The deflection occurring with carbon acrylic resin was statistically greater than with the acrylic resin (p=0.05). This was the only statistical difference between resin variables. However, in the case of the carbon-fibreglass stockinette the ultimate strength of the carbon acrylic socket was notably greater than its acrylic counterpart (Fig. 2). This is the only case where a notable difference was seen for the reinforcement material between resin types. No explanation can be given for the difference with this sample size.

No statistical difference was found among the following variables: total non-reinforcement materials, total resin used, percent promoter used, and resin gel times.

Discussion

This study compared the strengths of various trans-tibial composite prosthetic sockets. A technique was developed for testing trans-tibial sockets that incorporated the loading parameters and methods established by the International Standards Organisation (ISO) for structural testing of lower limb prosthetic components. Failures of the test samples were similar to those reported in clinical situations. None of the composites in the study met the specified parameters for structural testing of lower limb prosthetic componentry (ISO 10328 Standards for Level A100, loading condition II).

Increasing the amount of reinforcing material is one method of improving strength properties. However, the relationship between the amount of reinforcing material and the ultimate strength is not linear. One should not assume that doubling the amount of reinforcing material will double the ultimate strength (Klasson, 1995; Humphrey, 1981). If the cause of failure is inter-laminate shear or buckling a change in the composite profile may be necessary to increase ultimate strength. If the cause of failure is tension then simply increasing the amount of material may be of benefit.

Two (2) of the 4 cloth reinforced composite sockets tested, 1 fibreglass cloth and 1 carbon cloth reinforced composite, had a complete failure at the pyramid attachment plate. This break resulted in the anterior edge of the pyramid attachment plate being pushed completely through the socket's distal end. These were the only 2 cases where the composite actually broke completely through. These 2 composites were deemed incapable of providing ambulation while the other 2 cloth reinforced composites returned to a position where ambulation might have been possible.

Because all of the sockets failed at the site of the pyramid attachment plate it can be assumed the amount of reinforcement in the socket body and proximal extensions was sufficient. It is not known if increasing the amount of material over the distal end would cause failure in the socket body. The authors suggest that the material in the socket body need only be enough to provide continuous fibre coverage from the body to the distal end. The attachment plate design appears to be an important component to the structural integrity of the socket. This is evidenced by the consistent failure seen in this region of the socket both clinically and in the laboratory.

The weakest point of the attachment system used in the composite design was the anterior edge of the pyramid attachment plate as it interfaced with the distal end of the socket. The anterior edge of the pyramid attachment plate appears to act as a focal point for a stress raiser. If the focal point were reduced by spreading the stress over a larger surface area such as a round

pyramid attachment plate system instead of a square one, premature socket failure might be reduced. The focal stress point could be further reduced by rounding the sharp edge of the attachment plate in contact with the socket surface, thus increasing the bend radius for the fibre as it deflects.

Finally, the shape of the distal end may also be a factor with regard to the blending of the attachment plate interface at the distal end of the positive model. If one accepts that the geometry of the distal end radii could change the strength characteristics of the socket as some authors have suggested (Klasson, 1995; Roff, 1956; Taig, 1972), various sized radii could yield different results from that which is reported herein. Inspection of the strength characteristics of different attachment systems is also needed to optimise the composite profile. In addition, further study is necessary to establish the amount of reinforcement needed at the distal end of the socket to maintain high levels of loading for the trans-tibial composite prosthesis.

The primary factor shown by this study to affect ultimate strength is the choice of reinforcing material. The 2 materials that produced the greatest ultimate strengths were the carbon-fibreglass stockinette and the unidirectional carbon webbing. The unidirectional carbon webbing appears to be the best choice when considering all other performance aspects.

Care must be taken when referring to the force deflection curves as they differ from a stress strain curve. A stress strain curve has normalised the data by cross-sectional area. The stress strain curve will be the same for different composites made by identical methods and of identical materials, it would not matter if one composite contained 6 layers of reinforcement and the other 10 or 12 layers. However, using the load deflection curve the difference in ultimate strength between reinforcement material types and/or between the total ply of reinforcement used can be seen instantly. With this data long mathematical calculations can be avoided when trying to determine the proper lay-up needed to obtain any given ultimate strength.

Force deflection curves indicate that the carbon fibreglass stockinette had the greatest amount of deflection at the point of failure. By calculating the area under the curve it can be determined that these composites absorb a greater amount of energy prior to reaching ultimate failure than the other test samples resulting in less recovery. Because the unidirectional carbon absorbed less energy than the carbon fibreglass stockinette reinforced composites, and due to the unidirectional carbon's failure mode, it was capable of better recovery following removal of the load. Both of the carbon fibreglass stockinette reinforced composites and 1 of the 2 fibreglass stockinette reinforced composites were permanently deformed upon removal of the load to the point that they were deemed incapable of assisting the amputee in functional ambulation.

Some of the test devices may be capable of providing limited ambulation immediately after ultimate failure. The load deflection curves of the majority of the samples appear to plateau shortly after failure (Fig. 3). The "plateau" load level of each respective composite tested represents the maximum load these devices could continue to function at on a limited basis. The amount of deflection at the plateau load following a load to failure will be slightly greater than the point at which it levelled off in the graph.

Three (3) primary types of failure occurred. (Figs. 4-6). All of the composites utilising the stockinette reinforcing material failed with a buckling type of deflection at the transition from the socket body to the distal end. Two (2) of the 4 cloth reinforced composites failed by fibre breakage at the anterior edge of the 4 bolt pyramid attachment plate. In this instance the pyramid attachment plate appeared to act as a focal point to increase stress on the fibres and cause them to break under tension. The other 2 cloth reinforced sockets failed via inter-laminate shear. The unidirectional carbon reinforced composites also failed as a result of inter-laminate shear. All of these failure modes were correlated to the reinforcement material. These mechanisms of failure have been reported in the literature (Klasson, 1995; Humphrey, 1981; Luger, 1982; Titterton, 1951). Coupon testing can be used to confirm the failure mode. This type of testing can be very useful in helping one decide on the composite profile. Complete coupon testing includes tests of: tension, compression, torsion and sharp beam. Although these tests are important for engineering a composite socket, coupon samples do not represent the geometry of a trans-tibial socket.

The testing weight of the sockets was directly related to the type of reinforcement material used. When trying to optimise for weight this information is important. Carbon cloth, when comparing equal plies of material, was notably lighter than both types of stockinette reinforcements tested. Also, when using carbon cloth or carbon fibreglass stockinette in place of their corresponding fibreglass reinforcement material types a 20.8% and 27.5% reduction in weight was noted respectively. Even though the carbon cloth produced the lightest socket it did not produce the greatest strength-to-weight ratio for the composite profiles tested. The greatest ratio was produced by the unidirectional carbon and was notably greater than all the other materials tested except for the carbon fibreglass stockinette. The fact that the unidirectional material produced the greatest ultimate strength and the greatest strength-to-weight ratio is consistent with the literature (Strong, 1989; Roberts, 1984; Luger, 1982; Humphrey, 1981; Mohr *et al.*, 1973).

Determining the fibre volume fraction is an expensive and time consuming process that requires specialised equipment. Because of cost and time constraints, a crude approximation was made by carefully weighting the materials prior to and after fabrication and then converting to volumes using the densities. Using this technique some error is expected in the values reported, the extent of which is unknown. These values seem low compared to the 70% often reported as being the standard (Klasson, 1995; Taylor, 1996). However, those composites which approach the 70% level do not contain any nylon or nylglass. The nylon and nylglass tend to retain more resin and reduce the fibre volume fraction. These materials weaken the composite by reducing the inter-laminate shear strength but increase toughness with their ability to reduce crack propagation.

The acrylic based composites had a statistically lower amount of local deformation than the carbon acrylic ones. This may have been a result of the additive the manufacture added to the resin to provide better "wet-out" of materials. However, better "wet-out" does not necessarily mean greater strength. Three (3) of the 5 different reinforcement material types, unidirectional carbon, carbon cloth, and fibreglass stockinette, had a greater ultimate strength using the acrylic resin.

The data derived from this study is specific unto itself. Any change in the design parameters used herein may produce different results. Such examples would include changes in the composite profile, in the shape or length of the trans-tibial structural test model, or in the socket-pylon attachment system. The data is also limited by the lack of cyclic or torsional loading. Future studies are needed to determine the optimal lay-up of fibre materials based on the patients' pathology, activity, and weight. The methods described in this study could be adapted to establish such guidelines. A more diverse knowledge base of composite fabrication principles for orthotics and prosthetics is essential to meet the specific design criteria for each clinical application.

Conclusion

A new method was developed for the static structural testing of trans-tibial prosthetic sockets. Loading parameters and procedures established by the International Standards Organisation for testing lower limb prosthetic componentry were adopted as the design criteria for test apparatus and methods. The test protocol produced consistent, reproducible results for evaluating the performance of the trans-tibial socket. Although there are no standards for the testing of the trans-tibial socket portion of a prosthesis, it is noteworthy that none of the composite sockets in the study were able to meet the specified parameters set for other prosthetic componentry (ISO 10328 Standards for Level A100, loading condition II). All trans-tibial socket failures occurred at the distal segment near the anterior border of the pyramid attachment plate. Three failure modes were identified: inter-laminate shear, buckling, and tension. Unidirectional carbon and carbon fibreglass stockinette performed similarly with regard to ultimate strength and strength-to-weight ratio. In general, the carbon reinforced sockets were lighter and stronger than their fibreglass reinforced counterparts. Future studies are needed to establish guidelines on material lay-up and structural design features that may increase the ultimate strength of the trans-tibial socket for various clinical situations.

Acknowledgements

The authors gratefully acknowledge Otto Bock for the generous contribution of materials used for the fabrication of the composites in the study. They would also like to thank the

University of Illinois AMTEL research and testing laboratory where the tests were conducted. For his assistance and suggestions on the test apparatus design the authors thank Dr. Chi Lee, Research Engineer for the Ohio Willow Wood Co.

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Prosthetics and Orthotics International, 1999, 23, 123–129

Improvement of control cable system of trans-humeral body-powered prostheses

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Abstract

For the purpose of improving the efficiency of a body-powered prosthesis, a control cable system was developed which uses a pulley and a cable housing which includes a highly slippery plastic liner. Improvements were also made to the harness. In this paper, the mechanism of these systems is firstly described and then, the results of a clinical evaluation test of a practical model is presented along with an efficiency evaluation by a testing instrument. For the design of each system, the material and size suitable for the conditions of cosmetic and general versatility were considered. The clinical test was performed on 12 subjects to prove the effectiveness of the system. This test procedure was repeated. These tests proved the effectiveness of the systems.

Introduction

A body-powered prosthesis with a terminal device, and an elbow joint is operated by using a body movement which is mainly produced by scapular motion. It is important to transfer the effect of the body action efficiently for improved prosthetic function. Where body action is transferred through a harness, an ordinary upper limb amputee may produce a cable excursion of about 100mm and a force of about 100N or more. A body-powered prosthesis becomes more effective when both excursion and force are used efficiently. For this purpose a force transfer mechanism using a pulley and a harness and utilising a housing containing a highly slippery plastic (UHMW) liner was developed (Fig. 1). As a result, the cable movement was more effectively used and the force was more efficiently transferred. The following are the details of the system and the results of evaluation.

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Mechanisms

On a body-powered prosthesis, the cable excursion (L) and force (F) are obtained by transferring the action of the scapula and other trunk movements to a harness. These are then transferred to a cable to operate an elbow joint or a terminal device. Although F and L must be as large as possible, they are greatly influenced by the selection of the harness system and its fitting to the amputee. It follows then that the loss in

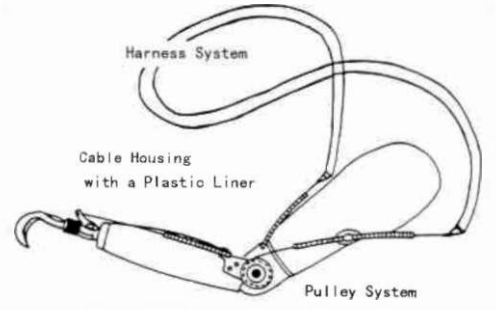

Fig. 1. Modified control cable system.

transferring F and L must be as small as possible. An explanation follows about a system developed for better force and excursion transfer.

The mechanism and design of a pulley system

In contrast with a method using a conventional forearm lift system (a lever system) for flexion of the elbow joint and the opening-closing of a terminal device, a pulley system is used with a cable reeled around a pulley which is attached to an elbow joint. The following study shows that the new system decreases the excursion of the cable necessary for elbow flexion. This is especially useful for high level upper limb amputees, who have less excursion capacity.

The operating principle of the system is as follows:

When the cable is pulled during the time the elbow is unlocked, the cable is reeled around a pulley to flex the elbow joint. When the cable is pulled after the elbow is locked, the pull is transferred through the pulley to open and close the hook. With these mechanisms, this method offers a function equivalent to a conventional dual controlled cable system. It also has the characteristics that only a very small loss of cable movement occurs in elbow flexion and the loss in transfer efficiency is minimal if the pulley rotates easily.

In order to be functional the pulley system is required to be of small bulk and as light as possible, with a low friction pulley and without friction at the cable, the system must also be stable in the transverse direction of the pulley, and durable. The basic specifications of the pulley and axle developed (Fig. 2) are:

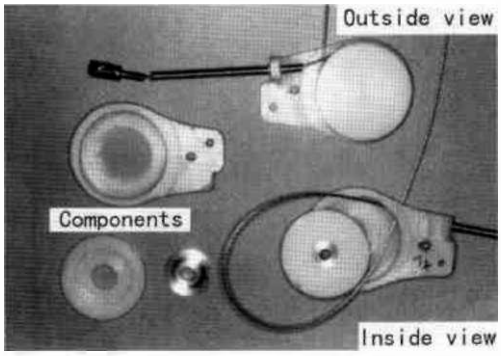

Fig. 2. Components and external appearance of the pulley system.

- the outside diameter of pulley = 38mm
- the inside diameter of pulley = 11mm
- the diameter of pulley groove = 35mm
- the thickness of pulley = 5mm
- material = high density polyethylene
- material of pulley axle = aluminium alloy
- weight = 7g (including the axle)

The following points were considered in developing a test model:

Because the pulley system is structured to be attached to the outside of the elbow joint, its volume must be as small as possible. However a pulley with a smaller diameter requires increased force to produce elbow flexion. With a prosthesis using an ordinary duralumin hook, the torque about the elbow axis is about 0.43Nm when the terminal device is not holding an object. With a 35mm outside diameter (17.5mm radius) of the pulley, the cable pull required for operation is calculated as 0.43/0.0175 i.e. about 25N theoretically when the pulley has no loss due to friction. With an outside diameter of 29mm a pull of about 30N is necessary for upper arm flexion. This means the smaller the diameter of the pulley the greater is the cable force requirement. Therefore, it is desirable to make the outer diameter as large as possible so that less force is required for the users. For comparison even Hosmer Corporation's 3/64 inch (1.19mm) cable needs an outside diameter of 32mm or more due to the minimum bending radius.

Another important factor about the design of pulley diameter is the controllability during the process of flexing the elbow to a desired angle. Amputees are required to operate the procedure swiftly by pulling a cable. If the excursion of the cable is inadequate, the angle of flexion hoped for cannot be achieved. In a pulley system as indicated, the cable force required is determined by the pulley diameter. In the above-mentioned 35mm pulley an excursion of about 41mm (35mm x π x 135 degrees $\div$ 360 degrees) is required for elbow flexion; a pulley with an outside diameter of 40mm requires 47mm excursion; a 30mm pulley requires 35mm. Preferably the diameter should be large from the viewpoint of operation only. But it cannot be unconditionally big because a bigger diameter results in a larger force requirement. Moreover, it must be noted that the elbow part gets bulky when the pulley has a bigger diameter.

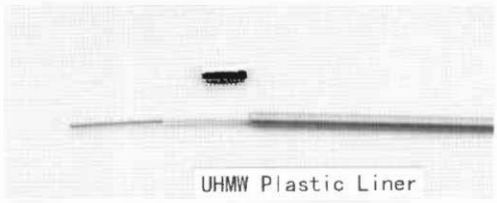

Fig. 3. Cable housing with a liner.

In summary, the pulley is preferably big for better operation of elbow flexion. Its outside diameter must be at least 35mm. A bigger pulley is also preferable for better control of elbow flexion. Its outside diameter must be 30mm at least. The pulley should be small so that the excursion can be kept to a minimum. The pulley is preferably smaller than 38mm for a better appearance. The outside diameter should be more than 32mm for the cable to have a sufficient bending radius.

In consideration of these points, the suitable external diameter of the pulley is between 32mm and 37mm. In this study the median of 35mm was adopted.

The pulley is preferably thin, but it must at least have the thickness to accommodate two grooves as wide as the cable diameter (Hosmer Corporation, 3/64 inch) plus the thickness of the groove wall. To satisfy these minimum requirements, the pulley was designed to be 5mm thick.

Cable housing with a liner (Fig. 3)

The housing has a highly slippery plastic liner within it. The present system had been marketed for heavier operations, but no liner usable for a cable housing with an ordinary diameter is available. So a liner was designed and produced which can be installed in a space between the outer rim of the 3/64 inch cable and the inner rim of an ordinary housing.

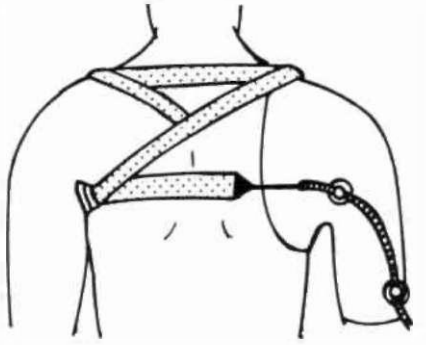

Fig. 4. Modified harness system.

Harness fitting

A body-powered prosthesis was used with a figure of 8-shaped harness. In the case of high level amputees or those with a less movable stump, an improved harness must be provided. The authors have had good results by adding either an elastic or non-elastic chest strap and by using a harness as shown in Figure 4.

Evaluation system

The test system shown in Figure 5 was

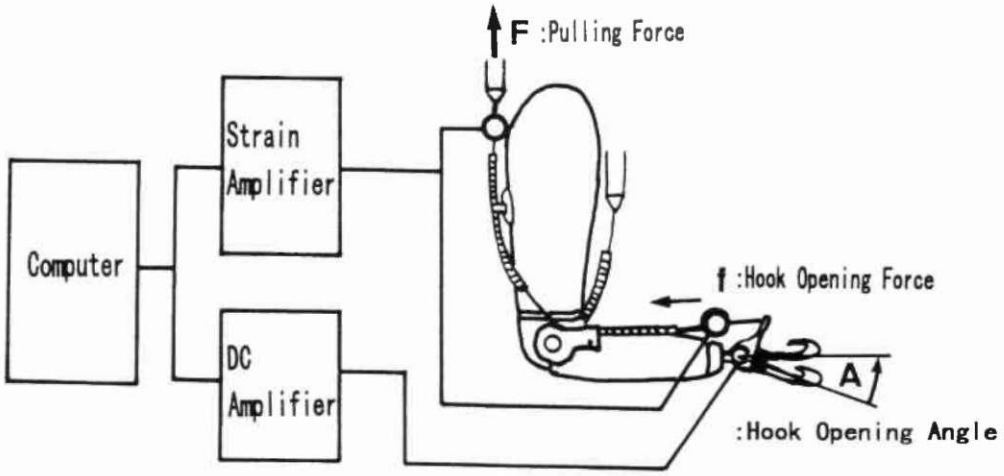

Fig. 5. Measuring system.
Pulling force, hook opening force and hook opening angle are measured.

manufactured to examine the operating capability of the prosthesis. It is designed to measure the hook angle with a goniometer and pulling force with an annular-shaped tensile sensor. Data from this system is transferred to a computer through an amplifier and AD transmitter for recording. Moreover, the efficiency of the prosthesis was measured by pulling its cable forcibly using an AC motor. The excursion and the force on the terminal device were simultaneously recorded.

Methods

Both mechanical and clinical tests were performed.

In the former, the pulling force to open the hook of the prosthesis locked at various elbow angles was measured for evaluation of the effect of the pulley system. The effect of the liner and pulley was also evaluated dynamically by pulling the cable of the prosthesis using an AC motor (Fig. 6).

With a total of 12 amputees i.e. 2 trans-radial (2), 9 trans-humeral shoulder disarticulations (7, 2) and one forequarter (1), the effects of the elements of the system were evaluated under various conditions; with or without a liner, with or without a pulley and with or without a harness (Fig. 7).

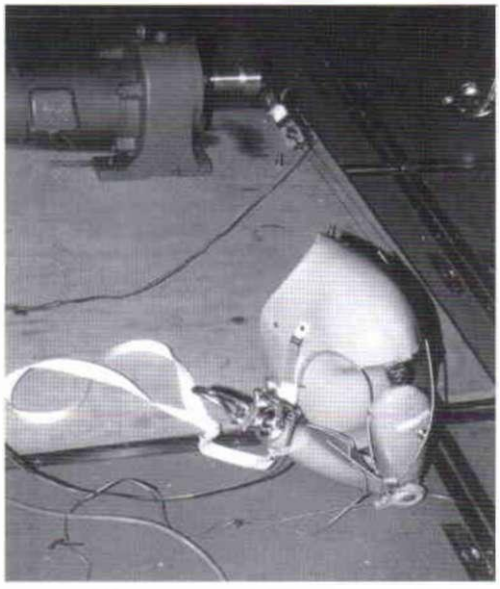

Fig. 6. Dynamic pulling test of a prosthesis. Pulling force, hook opening force and hook opening angle are measured while pulling a cable using an AC motor.

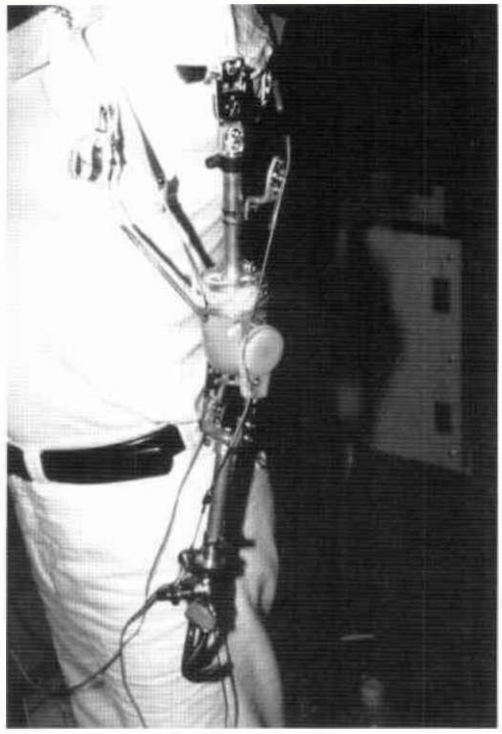

Fig. 7. Dynamic pulling test by a subject. Pulling force, hook opening force and hook opening angle are measured while the cable is pulled by a subject.

Results

The results are described below separately for the pulley and the liner.

Pulley system

Figure 8 shows the result of the static mechanical test. As compared with a conventional system, the pulley system required less increase in the force for cable movement in relation to elbow flexion, Especially when the

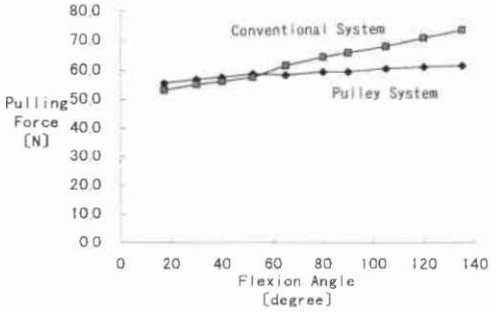

Fig. 8. Results of a static pulling test. Pulling force is measured when a hook opens 20mm at finger tips.

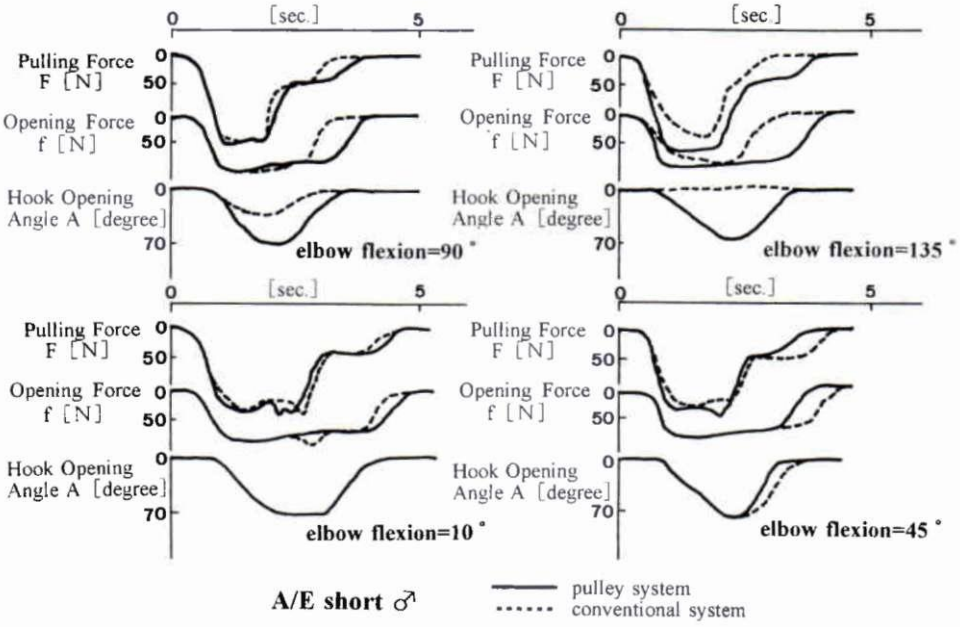

Fig. 9. Result of a dynamic pulling test.
Pulling force, hook opening force and hook opening angle are dynamically measured while a cable is pulled by a subject with a locked elbow joint.

angle of elbow flexion exceeded 60 degrees, the new system proved superior. The pulley system also ensured the maximum opening of the hook because the excursion required for elbow flexion was small. In Figure 9, the amputees' pulling force (F) at each angle of elbow flexion as measured by the test system is shown with transferred opening force (f) and the opening angle (A) of the hook. When the pulley system was used, an almost full opening angle of the hook was obtained for all angles of elbow flexion. For the conventional system the opening angle of the hook was extremely small for elbow flexion angles exceeding 90 degrees. These results show that the pulley system effectively increased the opening angle of the hook. Two examples of hook opening width against elbow flexion are shown in Figure 10. This also shows the system was more effective at increased elbow flexion.

It is clear from the figure that the possibility of opening the hook can be increased by improving the harness. On the other hand, an efficiency assessment performed at the same time showed the use of the pulley resulted in little efficiency increase when the elbow was at the angle of 90 degrees.

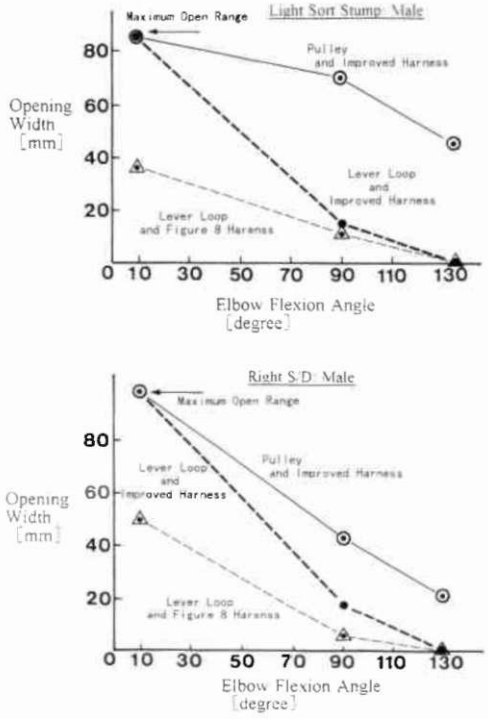

Fig. 10. Result of maximal hook opening width.
Prostheses with or without a pulley, and/or an improved harness are used.

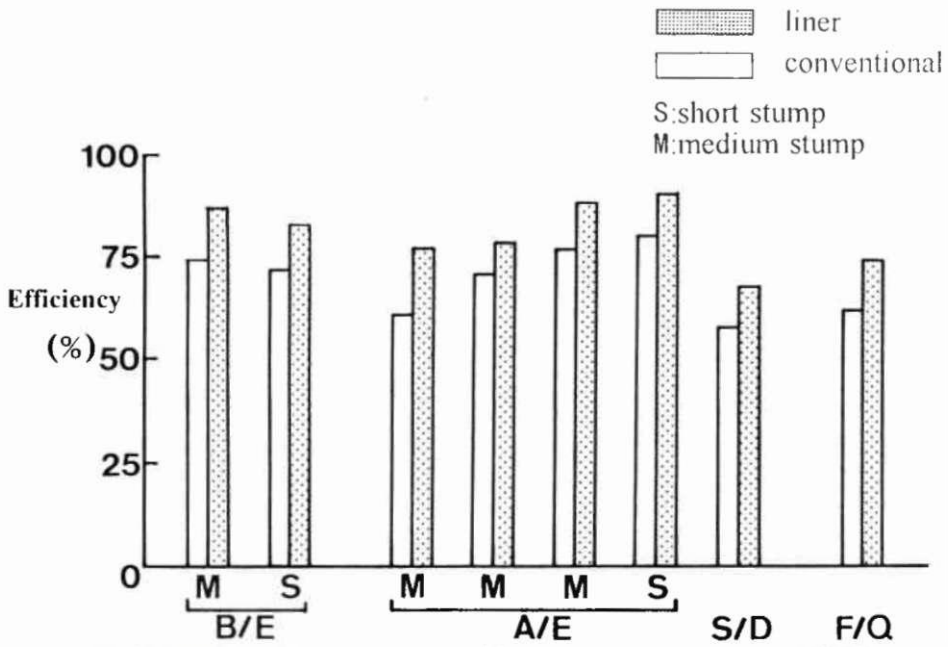

Fig. 11. Comparison of operating efficiency of prostheses with and without plastic liiner.

Efficiency is defined as $\frac{\text{hook opening force}}{\text{pulling force}} \times 100\%$.

Liner housing

The changes caused by the use of the liner housing are shown in Figure 11. All patients using a liner housing on the same prosthesis showed an efficiency increase. In order to assess the effects of pulley and liner under the same conditions, the pulling force and hook opening

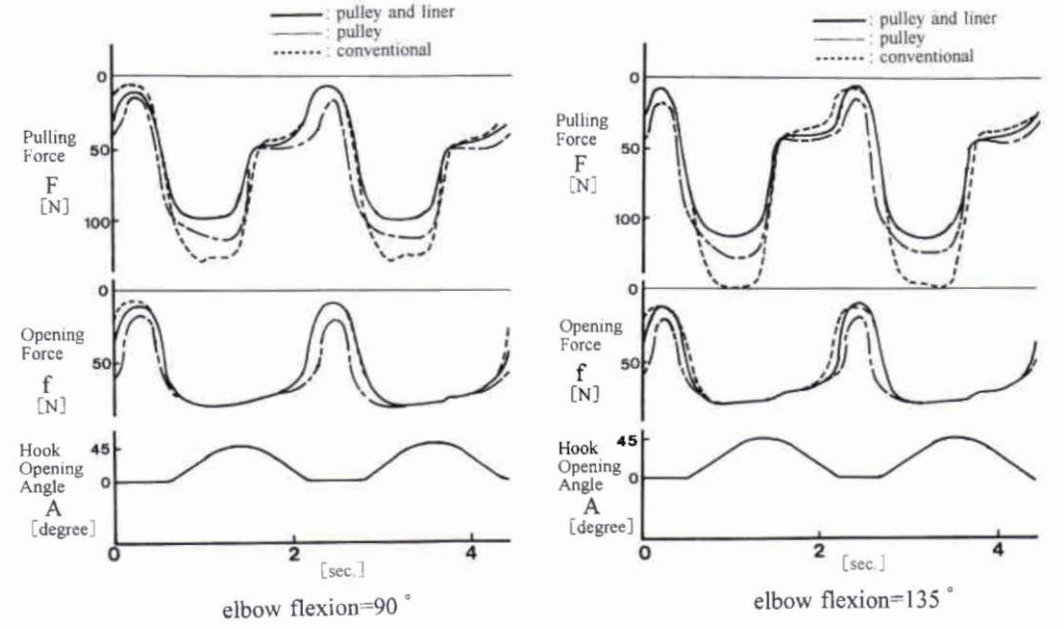

Fig. 12. Result of a pulling test.
Pulling force, hook opening force and hook opening angle are dynamically measured in a test rig.

force were measured on a fixed upper arm prostheses by operating the open-close action with a dynamic test rig using an AC motor. The results are given in Figure 12. This experiment shows the comparison of the pulling force required for the same hook opening in the same prosthesis with and without the housing and also display chronological changes. These results also show the use of pulley and liner (the full line) decreases the force necessary to obtain the same opening force at the terminal device (f), compared with the conventional method (the broken line).

Discussion

It was shown that the pulley system contributed to an improvement in efficiency when the elbow was flexed. A pulley is therefore effective for working conditions at a desk, in which the elbow is consistently kept flexed. In this system, the trunk actions can be used effectively because the cable excursion for elbow flexion is small. In addition, it was confirmed that the use of a low friction liner housing increased the transfer efficiency by 10%. As for the prosthesis operation, it was found through tests using measuring instruments and patients that the combination of this housing, the above pulley system and harness system improved the operation of the body-powered prosthesis. A pulley is effective for a body-powered prosthesis in the situation mentioned above. But in case the elbow is flexed with the hook gripping something heavy, the action cannot last indeterminately. Although a liner housing is effective for transfer efficiency, some force is necessary to keep the hook open because the force is directly transferred. It is important, therefore, to apply these improvements selectively to suitable cases.

Conclusion

Various improvements and developments were made to make a body-powered prosthesis more operable. Their effectiveness was evaluated experimentally. The authors hope to conduct further research so that the newly developed system can be widely used.

Acknowledgement

The authors wish to acknowledge their gratitude to Dr. Dudley S. Childress, director of Rehabilitation Engineering Program and Prosthetics Research Laboratory in Northwestern University, for his helpful comments for this study.

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Prosthetics and Orthotics International, 1999, 23, 130–134

Effectiveness of prosthetic rehabilitation of children with limb deficiencies present at birth

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Abstract

This study was performed to investigate the efficacy of prosthetic rehabilitation in children with congenital malformations, also to determine whether there were any factors related to family history and pregnancy which could have affected the formation of such deficiencies.

Twenty-five (25) limb deficient children were provided with prostheses and received rehabilitation. A detailed family and pregnancy history was researched through the records. The ability of performing activities of daily living was scored on a four point scale.

Thirteen (13) lower and 12 upper limb deficient children with a mean age of 4.88±2.52 years were included in the study. Ten (10) children had longitudinal and 15 transverse deficiencies. Traditional marriages amongst close cousins were observed in 31%. Five (5) mothers used medications, 2 received radiodiagnostic tests and 2 had bleedings during pregnancy.

Some 84.7% of the lower limb group became independent walkers without requiring walking aids while 15.3% of them required Canadian crutches for independent ambulation. A total of 61.5% of these children actively participated in recreation with peers. In the upper limb group 41.6% were completely independent in self-care, feeding and hand skills; 33.3% showed independence with self-help devices while 25% tended to use the prostheses for assistive purposes. Participation in recreational activities was 58.2%.

The author's results have shown that the children gained a functional activity level although the prostheses were provided in a late period. It can be concluded that success in rehabilitating these children is a true challenge.

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Introduction

Congenital anomalies are classified as being either transverse, in which all the skeletal elements distal to the level of loss are absent as in an acquired amputation, or longitudinal in which some distal skeletal elements remain (Day, 1991; Krebs *et al.*, 1991; Jain, 1996; Esquenazi and Meier, 1996).

The prosthetic rehabilitation of children with congenital limb deficiency differs little from the acquired amputations, especially if the anomaly is transverse. Usually the limb deficient child not need pre-prosthetic care and is considered to be an essentially normal child who happens to have limb deficiency. In the case of longitudinal limb deficiency the prosthetic care may be combined with amputation or surgical reconstruction (Krebs *et al.*, 1991; Rosenfelder, 1980; Czerniecki, 1996).

Appropriate prosthetic treatment, proper rehabilitation, the family attendance and interest in therapy are the key points leading the child to independence. However, it is important to separate the concept of function from that of wearing a prosthesis. Each child is unique and must be evaluated in a detailed perspective by the orthopaedic surgeon, physiotherapist and prosthetist. The anticipated functional benefits or loss must be discussed before the prescription and initiation of the treatment (Krebs *et al.*, 1991; Rosenfelder, 1980; Jain, 1996).

Age of fitting is another important

consideration; when the developmental readiness occurs the child must be provided with a prosthesis (Rosenfelder, 1980). Unilateral lower limb deficient children at any level and those with bilateral loss from below the knees are ready for their prosthetic fitting when they pull to stand between 9 and 12 months. In upper limb deficiencies, fitting should be done when independent sitting is achieved about 6 to 8 months of age (Curran and Hambrey, 1991; Hirons *et al.*, 1991; Krebs *et al.*, 1991; Lovett, 1991; Rosenfelder, 1980; Jain, 1996; Esquenazi and Meier, 1996).

This study was performed to investigate the efficacy of prosthetic rehabilitation in congenital malformations, also to determine whether there were any factors related to family history and pregnancy which could have affected the formation of such deficiencies.

Patients and methods

Twenty-five (25) unilateral limb deficient children consisting of 15 girls (60%) and 10 boys (40%), with a mean age of 4.88±2.52 years were included in the study. Thirteen (13) children had lower and 12 had upper limb deficiencies.

Limb deficiency was longitudinal in 10 children while 15 had transverse deficiencies. Seven (7) children (54%) had transverse and 6 (46%) had longitudinal deficiencies in the lower limb group while 8 children (67%) had transverse and 4 (33%) had longitudinal deficiencies in the group with upper limb involvement (Table 1).

All the patients were referred by orthopaedic surgeons and 7 children had undergone surgical reconstruction because of bony growths.

In the initial visit, a detailed evaluation was performed including muscle strength and shortening, range of joint motion, the type of deformity, current and expected functional level, activities of daily living and the discussion about the requirements for prosthetic treatment.

Table 1. Deformity type of the amputees.

Type of deformity	Lower limb		Upper limb		Total	
	N	%	N	%	N	%
Longitudinal	6	46	4	33	10	40
Transverse	7	54	8	67	15	60
Total	13	100	12	100	25	100

Existence of traditional marriages amongst close cousins, other congenital malformations in the family, pregnancy age, inappropriate care including alcohol, cigarettes, any medications, radiodiagnostic tests and bleedings during pregnancy were researched through hospital records.

The design of the prostheses and the selection of materials were carried out considering individual needs depending on the level or type of the deformity. During their rehabilitation period all the patients received unfinished prostheses; alignment adjustments and modificaitons in the socket were made as required.

Extension prostheses were made for 6 children with Proximal Femoral Focal Deficiency. Transfemoral prostheses with knee joints and quadrilateral sockets were given to 2 children with transverse deficiencies at above-knee level, while 5 children with loss at below-knee level were fitted with Patellar Tendon Bearing-Suprapatellar-Supracondylar Suspension transtibial prostheses using soft sockets. SACH (Solid Ankle Cushion Heel) feet were utilised in all lower limb prostheses (Bochman, 1981).

In the upper limb group, 9 trans-radial prostheses were made for 7 with forearm deficiencies and 2 children with longitudinal ulnar deficiencies, while 1 child with longitudinal deficiency was fitted with a modified elbow disarticulation prosthesis consisting of two sockets with lateral joints for attaining elbow flexion. Shoulder disarticulation prostheses were made for one with a gross longitudinal deficiency and one transverse deficiency at the level of the shoulder.

During the socket fit and the alignment of lower limb prostheses the following criteria were applied:

- child could stand with equal weight on both feet;
- there were no soft tissue rolls over the socket brims;
- child was comfortable and stump/involved limb was free from any pain during standing and sitting;
- skin was in good condition, free from cyanosis, excessive redness after prosthesis was removed;
- top of prosthetic foot and prosthetic joints were parallel to floor when standing;
- suspension of the prosthesis was adequate;

- the length of the prosthesis was 1.5cm longer than the sound limb and a shoe rise of the same length was placed under the sole and heel of the shoe of the sound limb for ease in lengthening the prosthesis when necessary due to growth.

Upper limb deficient children were given mechanical prostheses with a voluntary opening terminal device and the following criteria were applied for comfort and function:

- the brims of the sockets were appropriate and not preventing mobility of the related joints;
- the length of the prosthesis was equal to the sound side;
- the mechanism and cables of the control system were modified for ease in terminal device operation;
- harness system was properly designed, not producing excessive pressure under axilla and providing sufficient suspension and functional support;
- the child was comfortable and free of pain during activities;
- the skin was free of excessive colour changes and discomfort when the prosthesis was removed.

Not boring the child was an important factor therefore the duration of prosthetic training sessions naturally varied from child to child.

In the lower limb deficient children training started with free walking in order to give the child a chance for adapting to the prosthesis, and to feel that walking was not a dangerous pursuit. Balancing and weight-shifting activities were assisted by exercise but more emphasis was given to comfort, functional alignment, overcoming insecurity and participation in games with peers rather than the fine points of walking. The prosthetic training continued with activities such as ascending and descending stairs and inclines, walking on uneven terrain, crossing obstacles, picking up objects from the floor, getting on and off a vehicle.

Initial training of the child with upper limb deficiency focused on teaching the child to open the terminal device (prosthetic hand). Since all the prostheses were cable-operated and had voluntary opening terminal devices (TD), an object was placed in the TD by the physiotherapist. The therapist then performed scapular abduction passively by moving the child's arm to open the TD. This was followed by active participation of the child to open the TD, close it on an object, and release the object. Treatment primarily consisted of games and play activities to stimulate use of the prosthesis. When the child was successful in control motions of TD, training was directed towards the activities of daily living. Self care such as dressing, brushing teeth and hair, feeding activities and hand skills including holding the telephone receiver, pencil and paper, holding and opening jars, catching a ball using two hands, opening and closing doors were experienced by the child. Adequate time was given to the child to perform the activity and assisted only when necessary. Active positioning, locking and unlocking of the elbow joint was taught to the children with shoulder disarticulation prostheses.

At the end of the training period, the children were assessed for their ability to perform activities of daily living on a four point scale.

The child was considered independent when an activity was performed without using any aids or assistance. If the activity was done independently with the aid of a walking or self-help device he/she was considered independent with the help of a device. When the child could perform the activity with the assistance of someone else he/she was partially independent with assistance and dependent for particular activity if he/she could not perform it at all.

Findings

When the factors related to family history and pregnancy which could have affected the formation of such deficiencies were researched, traditional marriages amongst close cousins were present in 8 (32%) parents. Five (5) mothers (20%) used medications during pregnancy, 2 (8%) received radiodiagnostics tests, 2 (8%) had bleedings during the first trimester of pregnancy. There were no other specific factors in the remainder (32%) (Table 2).

Table 2. Family history and pregnancy care.

	N	%
Traditional marriages	8	32
Medications during pregnancy	5	20
Radiodiagnostic tests during pregnancy	2	8
Bleedings during pregnancy	2	8
No specification	8	32
Total	25	100

The mean pregnancy age was found to be 27.14±6.49, while the fathers' mean age was 32.03±8.61 at this period.

When the place of the limb deficient child among siblings was observed it was seen that 4 patients (16%) were the first children of the family, 8 of them (32%) were the second children, 7 (28%) were the third children, 3 (12%) were the fourth, 2 (8%) were the fifth children of the family and 1 (4%) was the sixth child of the family.

The average prosthetic rehabilitation period was 18 days. Before prosthetic treatment, all of the lower limb deficient children were ambulating with walking aids. When the 13 children with lower limb malformation were reassessed after rehabilitation, it was seen that 11 of them (84.6%) became independent walkers performing the ambulatory activities without necessitating walking aids while 2 children (15.3%) required Canadian crutches for independent ambulation. Eight (8) of these children (61.5%) actively participated in recreational activities with peers. Five (5) children played football while 3 children were successful in table-tennis.

Before prosthetic treatment, children with upper limb deficiency performed activities of daily living with difficulty either by using their sound limb or by the assistance of the parents. After prosthetic rehabilitation, 5 children (41.6%) became completely independent in self care, feeding and hand skills, 4 children (33.3%) showed independence with self-help devices while 3 children (25%) required assistance from someone else and tended to use the prostheses for assistive purposes. Those were the children with proximal amputations or deficiencies; one with gross longitudinal deficiency, one with shoulder disarticulation and one with ulnar longitudinal deficiency whose elbow joint was ankylosed in extension. Seven (7) children (58.3%) participated in recreational activities. They played games such as constructing different objects from cubes and Lego toys just like their peers.

Discussion

The results showed that the children gained a functional activity level although the prostheses were provided in a late period. Krebs *et al.* (1991) reported that about 16% of children with congenital amputations do not receive prosthetic care before they begin school (Rosenfelder, 1980; Jain, 1996). In this study the mean age of the children was 4.88±2.52 years. Some of them were about to begin primary school while the others were going to nursery school. When the reason for the delay of prosthetic treatment was enquired of the parents, it was seen that some had received unsufficient and wrong advice such as the prosthesis could prevent the growing process. It was also determined that the family's financial resources played an important role in this delay especially in the case of lack of public insurance.

Results of the study showed that 33% of upper limb deficiencies consisted of longitudinal deficiencies and 54% of lower limb deficiencies were transverse. When one compares this results with the literature, it can be seen that this is an unusual finding (Bochman, 1981; Hirons *et al.*, 1991).

As we know in many other countries upper limb deficiencies are more common than lower limb deficiencies and the upper are predominantly transverse while the lower are predominantly longitudinal (Bochman, 1981).

In this study family history records showed that traditional marriages between close cousins were present in the parents of 8 (32%) children. Three (3) of them were the children with longitudinal upper limb deficiency, 3 of them had transverse lower limb deficiency and 2 of them had longitudinal lower limb deficiency. Due to this finding it can be said that there was probably a connection between the traditional marriages and longitudinal upper limb deficiencies while there was also a relation between the traditional marriages and transverse lower limb deficiency.

Although it is not possible to give accurate statistical data in such a limited number of patients, the outcome of this pilot study revealed that traditional marriages amongst close cousins are still popular in Turkey especially in the eastern parts and 52% of families have more than two children. This result shows the requirement of extensive community health programmes on family planning and pregnancy care.

At the end of the rehabilitation period, the limb deficient children reached a functional activity level. However, 2 children using trans-femoral prostheses showed certain gait deviations such as abduction gait and wide step

width. Since they were given trans-femoral prostheses without knee joints, this was an expected result. After an adaptation period to the prostheses, these deviations were corrected by using knee joints.

In the upper limb group 41.6% were completely independent while 33.3% required self-help devices for independence. The self-help devices were designed for especially holding spoons and forks because of the difficulty in grasping such thin objects by the terminal device. Some 25% of the children (1 phocomelia, 1 shoulder disarticulation, 1 ulnar deficient child who had an ankylosed elbow joint) required assistance from someone else and used prostheses for assistance purposes because of the severity of malformations. Another reason for this tendency probably arises from the family's over protective attitude.

The authors are continuing to evaluate and rehabilitate new patients with limb deficiencies, and hope to gather more comprehensive data in the future.

On the basis of this study it can be concluded that succeeding in rehabilitating limb deficient children is a true challenge. With well-fitted prostheses and rehabilitation at a suitable age many children can learn functional skills and can find the opportunity of living equally with their peers.

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Prosthetics and Orthotics International, 1999, 23, 135–141

In vivo friction properties of human skin

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Abstract

In vivo frictional properties of human skin and five materials, namely aluminium, nylon, silicone, cotton sock, Pelite, were investigated. Normal and untreated skin over six anatomic regions of ten normal subjects were measured under a controlled environment. The average coefficient of friction for all measurements is 0.46±0.15 ($p<0.05$). Among all measured sites, the palm of the hand has the highest coefficient of friction (0.62±0.22). For all the materials tested, silicone has the highest coefficient of friction (0.61±0.21), while nylon has the lowest friction (0.37±0.09).

Introduction

Frictional properties of human skin depend not only on the skin itself, its texture, its suppleness and smoothness, and its dryness or oiliness (Lodén, 1995), but also on its interaction with external surfaces and the outside environment. Investigation of skin frictional properties is relevant to several research areas, such as skin physiology, skin care products, textile industry, human friction-dependent activities and skin friction-induced injuries.

Frictional properties of the skin surface may become an objective assessment of skin pathologies. It has been shown that frictional properties can reflect the chemical and physical properties of the skin surface and thus depend on the physiological variations as well as pathological conditions of skin (Lodén *et al.*, 1992; Lodén, 1995; Comaish and Bottoms, 1971; Elsner *et al.*, 1990; Cua *et al.*, 1995). The measurement of skin friction may be useful in studying the progress of individual disease processes in skin (Comaish and Bottoms, 1971). Lodén *et al.* (1992) found experimentally that the friction of skin with dry atopic subjects was significantly lower than that for the normal skin.

Skin frictional data have been used to evaluate skin care and cosmetic products (El-Shimi, 1977). Friction of skin forms an integral part of tactile perception and plays an important role in the objective evaluation of consumer-perceptible skin attributes (Wolfram, 1983 and 1989). Cosmetic products, which aim at conferring smoothness to the skin, are thought to perform their function by depositing sufficient amounts of desirable ingredients leading to a perceptible change in the adhesion and friction properties of skin. Some experiments (Nacht *et al.*, 1981; El-Shimi, 1977; Gerrard 1987; Hills *et al.*, 1994; Highley *et al.*, 1977) investigated friction changes induced by hydration and emollient application and the correlation with perceived skin feel. The changes in skin friction coefficient immediately after product use are inversely proportional to the subjective after-feel of "greasiness", that is, the higher the increase in skin friction coefficient, the less greasy the product is perceived (Nacht *et al.*, 1981). In textile industry, skin friction to clothing materials may be related to sensation, comfort or fabric cling (Kenins, 1994).

Skin friction properties are also relevant to some friction-dependent functions, such as grasping, gripping and locomotion (Cua *et al.*, 1990; Johansson and Cole, 1994; Smith and Scott, 1996). An understanding of these properties is very important in the design of handles, tools, controls and shoes. Buchholz *et al.* (1988) investigated the frictional properties of human palmar skin and various

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materials, using a two-fingered pinch grip and studying the effects of subjects, materials, moisture and pinch force. Taylor and Lenderman (1975) measured the coefficient of static friction between finger tips and aluminium (0.6) and found the value dropped by at least 75% when the surfaces were covered with soap. Foot-insole friction was investigated to study the characteristics of locomotion and damage to the foot skin.

The investigation of the skin frictional properties is also helpful in understanding skin friction-induced injuries (Naylor, 1955; Sulzberger *et al.,* 1966; Dalton, 1982; Armstrong, 1985; Akers, 1985). The injurious effects of friction on the skin and the underlying tissues can be divided into two classes, those without slip and those with slip. The former may rupture the epidermis and occlude blood and interstitial fluid-flows by stretching or compressing the skin. The latter adds an abrasion to this damage. Research showed that the skin shear force, produced by frictional force combining with pressure, is effective in occluding skin blood flow (Bennett *et al.,* 1979; Zhang and Roberts, 1993; Zhang *et al.,* 1994). Repetitive rubbing causes blistering and produces heat which may have uncomfortable and injurious consequences.

In lower-limb prosthetic socket and orthotic design, achieving a proper load transfer is the key issue since the soft tissues, such as those of the stump, which are not suited for loading, have to support the body weight as well as other functional loads. Skin and prosthetic device forms a critical interface, at which skin friction is an important determinant in the mechanical interactional properties. Friction plays significant roles in supporting the load and in causing discomfort or skin damage (Zhang, 1995; Zhang *et al.,* 1996). To optimise frictional actions, there is a requirement to understand adequately the friction properties between the skin and its contact surface.

Fig. 1 Skin friction meter.

In spite of its importance, there is however a paucity of knowledge about the frictional properties of skin and those materials used in prosthetic and orthotic devices. The objective of this study is to investigate the friction properties of skin in contact with those materials, and the variation of friction with load magnitudes, rotation speeds, anatomical sites and subjects.

Materials and methods

Skin frictional force was measured using Measurement Technologies Skin Friction Meter (Aca-Derm Inc., California), described in details by Elsnau (1995). The main part of the meter is a hand-held probe unit, including a DC motor, a rotating Teflon disk probe and rotary position transducer. When resting on the skin surface, the rotating disk probe contacts with skin and the torque resulting from frictional force can be measured. The normal force cannot be monitored, but depends on the relative position of the rotary probe to the base plate. The normal force applied to the probe is assumed to be constant, if only the weight of the probe unit is applied and the relative position of the rotary probe to the base plate is unchanged. However the weight supported by the base plate or by the sensing area depends on the geometry and stiffness of the soft tissue and the underlying bone in the measurement sites.

The Friction Meter is used in this investigation had two improvements. First, normal force was monitored by an additional spring balance. A critical factor in the accurate and consistent measurement of the coefficient of friction is the normal force applied. In this study, a spring balance (capacity 1kg) was connected to the hand-held probe, as shown in Figure 1. The base plate did not contact the skin surface. The weight applied to the skin surface can be read from the spring balance. A high accuracy electronic balance (AS200, OHAUS) was used to validate the accuracy of the spring balance reading. In 20 trials with application of an intended load of 100 grams, results showed that the weight recorded ranged from 93 to 108 grams, with an average 100.5±4.7 grams.

Table 1. Coefficients of friction measured at six sites (DH = dorsum of hand, PH = palm of hand, AF = anterior side of forearm, PF = posterior side of forearm, AL = anterior leg, PL = posterior leg) to five materials for 10 subjects.

Subject		sub 1	sub 2	sub 3	sub 4	sub 5	sub 6	sub 7	sub 8	sub 9	sub 10	Mean
Al	DH	0.37±0.04	0.27±0.02	0.47±0.04	0.50±0.05	0.45±0.03	0.58±0.02	0.35±0.06	0.38±0.02	0.36±0.03	0.48±0.05	0.42+0.09
	PH	0.57±0.04	0.40±0.03	0.55±0.02	0.58±0.02	0.58±0.01	0.57±0.02	0.58±0.11	0.32±0.06	0.75±0.06	1.00±0.11	0.59+0.18
	AF	0.36±0.02	0.34±0.03	0.39±0.02	0.43±0.04	0.44±0.03	0.52±0.04	0.32±0.02	0.46±0.06	0.47±0.08	0.32±0.03	0.40+0.08
	PF	0.32±0.02	0.33±0.03	0.40±0.01	0.39±0.04	0.32±0.03	0.58±0.03	0.28±0.02	0.37±0.03	0.29±0.03	0.29±0.02	0.36+0.09
	AL	0.24±0.03	0.24±0.02	0.40±0.03	0.45±0.04	0.32±0.01	0.50±0.03	0.31±0.02	0.32±0.02	0.32±0.03	0.33±0.06	0.34+0.09
	PL	0.27±0.01	0.26±0.02	0.32±0.04	0.37±0.03	0.29±0.02	0.51±0.04	0.29±0.02	0.32±0.02	0.37±0.02	0.41±0.04	0.34+0.08
	mean	0.36±0.11	0.32±0.06	0.42±0.08	0.45±0.08	0.40±0.11	0.54±0.05	0.36±0.11	0.36±0.06	0.43±0.16	0.47±0.25	0.42+0.14
Nylon	DH	0.37±0.03	0.30±0.02	0.43±0.03	0.47±0.02	0.41±0.03	0.45±0.03	0.29±0.01	0.29±0.08	0.43±0.02	0.31±0.03	0.38+0.08
	PH	0.42±0.02	0.38±0.03	0.49±0.04	0.43±0.03	0.46±0.02	0.49±0.03	0.40±0.02	0.36±0.06	0.58±0.01	0.70±0.08	0.47+0.10
	AF	0.40±0.02	0.32±0.02	0.38±0.05	0.40±0.01	0.39±0.01	0.37±0.02	0.33±0.04	0.32±0.02	0.37±0.02	0.42±0.07	0.37+0.05
	PF	0.35±0.03	0.31±0.02	0.30±0.02	0.33±0.01	0.34±0.02	0.43±0.03	0.31±0.04	0.33±0.03	0.29±0.02	0.34±0.01	0.33+0.04
	AL	0.30±0.02	0.30±0.03	0.42±0.02	0.32±0.01	0.36±0.03	0.35±0.03	0.28±0.01	0.23±0.02	0.27±0.02	0.38±0.02	0.32+0.06
	PL	0.33±0.02	0.26±0.02	0.41±0.04	0.34±0.02	0.29±0.02	0.39±0.04	0.28±0.01	0.24±0.04	0.27±0.02	0.38±0.02	0.32+0.06
	mean	0.36±0.05	0.31±0.04	0.40±0.06	0.38±0.06	0.38±0.06	0.42±0.06	0.32±0.05	0.29±0.06	0.37±0.11	0.42±0.14	0.37+0.09
Silicone	DH	0.44±0.03	0.40±0.03	0.75±0.07	0.66±0.04	0.54±0.02	0.60±0.02	0.86±0.22	0.44±0.05	0.50±0.06	0.51±0.04	0.57+0.16
	PH	0.80±0.04	0.67±0.05	0.98±0.05	0.98±0.04	0.88±0.05	0.84±0.07	1.26±0.11	0.63±0.03	1.16±0.11	1.06±0.09	0.93+0.20
	AF	0.48±0.02	0.46±0.02	0.65±0.03	0.61±0.02	0.57±0.04	0.58±0.03	0.68±0.01	0.41±0.02	0.61±0.12	0.47±0.05	0.55+0.10
	PF	0.38±0.04	0.44±0.03	0.50±0.03	0.51±0.05	0.56±0.04	0.63±0.03	0.64±0.13	0.60±0.04	0.43±0.04	0.43±0.05	0.52+0.10
	AL	0.39±0.04	0.44±0.03	0.46±0.04	0.68±0.02	0.45±0.01	0.59±0.02	0.57±0.02	0.40±0.06	0.37±0.04	0.42±0.03	0.48+0.10
	PL	0.46±0.04	0.53±0.01	0.44±0.03	0.51±0.03	0.45±0.03	0.62±0.03	0.51±0.06	0.41±0.07	0.35±0.04	0.40±0.09	0.47+0.09
	mean	0.49±0.15	0.50±0.09	0.63±0.19	0.66±0.17	0.58±0.15	0.64±0.10	0.75±0.27	0.48±0.11	0.57±0.29	0.55±0.24	0.61+0.21
Sock	DH	0.39±0.04	0.43±0.04	0.50±0.03	0.64±0.02	0.59±0.02	0.56±0.04	0.47±0.09	0.46±0.01	0.57±0.03	0.53±0.04	0.52+0.08
	PH	0.46±0.06	0.44±0.02	0.53±0.04	0.66±0.04	0.57±0.07	0.63±0.03	0.58±0.11	0.42±0.03	0.72±0.03	0.95±0.07	0.60+0.16
	AF	0.42±0.02	0.42±0.03	0.63±0.03	0.57±0.03	0.49±0.01	0.50±0.04	0.55±0.07	0.49±0.02	0.66±0.08	0.53±0.05	0.52+0.08
	PF	0.43±0.02	0.46±0.02	0.50±0.03	0.50±0.03	0.56±0.04	0.58±0.03	0.52±0.06	0.44±0.03	0.49±0.07	0.39±0.02	0.49+0.07
	AL	0.39±0.04	0.35±0.02	0.49±0.02	0.52±0.04	0.39±0.02	0.52±0.04	0.52±0.02	0.41±0.03	0.42±0.05	0.36±0.03	0.44+0.07
	PL	0.48±0.02	0.42±0.03	0.35±0.02	0.42±0.01	0.34±0.03	0.53±0.05	0.49±0.02	0.43±0.04	0.42±0.04	0.37±0.02	0.43+0.06
	mean	0.43±0.05	0.42±0.05	0.50±0.08	0.55±0.09	0.49±0.10	0.55±0.06	0.52±0.07	0.44±0.04	0.54±0.13	0.52±0.21	0.51+0.11
Pelite	DH	0.43±0.03	0.46±0.02	0.44±0.03	0.41±0.02	0.44±0.01	0.42±0.02	0.49±0.09	0.37±0.02	0.49±0.05	0.46±0.03	0.44+0.05
	PH	0.56±0.03	0.56±0.04	0.49±0.02	0.47±0.01	0.47±0.01	0.46±0.04	0.42±0.03	0.44±0.02	0.54±0.05	0.65±0.05	0.51+0.07
	AF	0.49±0.02	0.50±0.04	0.52±0.02	0.39±0.03	0.44±0.01	0.42±0.03	0.36±0.02	0.42±0.03	0.51±0.03	0.48±0.08	0.45+0.06
	PF	0.46±0.02	0.43±0.02	0.45±0.02	0.45±0.02	0.42±0.02	0.47±0.05	0.58±0.11	0.44±0.03	0.39±0.03	0.41±0.03	0.45+0.07
	AL	0.37±0.03	0.42±0.03	0.43±0.03	0.44±0.03	0.42±0.02	0.40±0.03	0.53±0.05	0.40±0.03	0.38±0.02	0.42±0.05	0.42+0.05
	PL	0.47±0.02	0.51±0.05	0.38±0.03	0.38±0.01	0.39±0.01	0.45±0.02	0.50±0.04	0.38±0.02	0.30±0.02	0.42±0.04	0.43+0.06
	mean	0.46±0.06	0.48±0.06	0.45±0.05	0.42±0.04	0.43±0.03	0.44±0.04	0.48±0.09	0.41±0.04	0.45±0.07	0.47±0.09	0.45+0.07
MEAN		0.42±0.11	0.41±0.10	0.48±0.14	0.49±0.14	0.45±0.12	0.52±0.10	0.49±0.21	0.40±0.09	0.47±0.18	0.49±0.20	0.46±0.15

Table 2. Mean coefficients of friction at the six anatomical sites (DH = dorsum of hand, PH = palm of hand, AF = anterior side of forearm, PF = posterior side of forearm, AL = anterior leg, PL = posterior leg) with all materials for all subjects.

Site	DH	PH	AF	PF	AL	PL
Coefficient	0.47±0.12	0.62±0.22	0.46±0.10	0.43±0.10	0.40±0.10	0.40±0.09

Table 3. Mean coefficient of friction with the five materials at all sites for all subjects.

Material	Aluminium	Nylon	Silicone	Sock	Pelite
Coefficient	0.42±0.14	0.37±0.09	0.61±0.21	0.51±0.11	0.45±0.07

The second improvement was made on the sensing surface, using a plane-ended annulus instead of a solid plane or a hemispherical shape. The pressure distribution in the sensing surface will affect the frictional torque – the product of the force and the distance to the centre.

In practice, the pressure distribution on the sensing surface varies with the geometry and the stiffness of the soft tissues and the underlying bone. An annular surface applying the load over the annulus can eliminate the error caused by the load distribution. In this study, all the probe sensing surfaces were annular with an outer diameter of 16mm and an inner diameter of 10mm.

Five (5) materials, namely, aluminium, nylon, silicone (soft liner material for trans-tibial suction sockets), cotton sock (often worn with a prosthesis) and Pelite (soft liner material for lower limb prostheses) were measured. The sensing surfaces of aluminium and nylon were machined with fine turning. An annular disk of silicone, cotton sock or Pelite was glued on the tip of the metal probe.

Ten (10) normal subjects, age from 19 to 40, with no visible signs of skin diseases, voluntarily participated in this investigation. For each subject, 6 anatomical sites, namely the palm of hand (PH), dorsum of the hand (DH), anterior side of the forearm (AF), posterior side of the forearm (PF), middle anterior leg (AL), and middle posterior leg (PL) were investigated. The skin was untreated but clean. Since the skin frictional properties may be affected by the ambient environment, all experiments were carried out in a room with controlled temperature of 20-24°C, and relative humidity of 55-65%. The subjects were required to enter the test room for at least 20 minutes before the tests. During the test period, they were asked to sit down and stay relaxed.

For each test, 5 trials were repeated. The coefficient of friction was calculated as the ratio of frictional force to the normal force (μ=F/N). The mean value and standard deviation were calculated with T-test statistical analyses.

Various normal forces were applied to investigate the effect of load on the coefficient of friction. Various probe rotation speeds from 25rpm to 62.5rpm were used to investigate the effect of speed.

Results

Table 1 gives the coefficients of kinetic friction at 6 skin sites with 5 materials for 10 subjects. Each datum comprises mean and standard deviation obtained from the 5 tests. The load applied was 100 grams (average pressure of 80kPa) and the probe rotation speed was 25rpm (average linear speed of 1m/min). The 'Mean' on the right column means the average coefficient of friction between one material and one site of skin for all subjects. The 'mean' on the bottom row for each material shows the average value of this material on all the measured sites for each subject. The 'MEAN' on the bottom row of the table means the average coefficient of friction between all the measured sites and all materials for each subject.

In all the measurements, the coefficient of friction ranged from 0.24 to 1.26, and the average value for all tests was 0.46±0.15 ($p<0.01$). The coefficients of friction with different materials and at different anatomical sites are shown in Tables 2 and 3. The highest coefficient of friction of skin was found over the site of the palm of the hand with the silicone. The palm of the hand has the highest coefficient of friction in all the sites measured. Of all the materials tested, the silicone shows the highest coefficient of friction.

Figure 2 shows the change in coefficient of friction with the normal force applied to the skin surface in the 10 trials. The results show there is a slight decrease in coefficient of friction with an increase of the load. When the load increases from 25 grams to 100 grams, the average coefficient of friction was decreased by 9.5±6% ($p<0.05$).

Figure 3 displays the effect of the probe rotation speed on the coefficient of friction in the 8 trials. The coefficient of friction increases slightly with an increase of the rotation speed. When the rotation speed increased from 25rpm to 62.5rpm, the coefficient of friction increased by 7±2% ($p<0.05$).

Discussion

Skin frictional properties have been reported by several groups, and the results show they varied with interface materials, subjects, anatomical sites, ambient environment and skin conditions (Naylor, 1955; Comaish *et al.*, 1971;

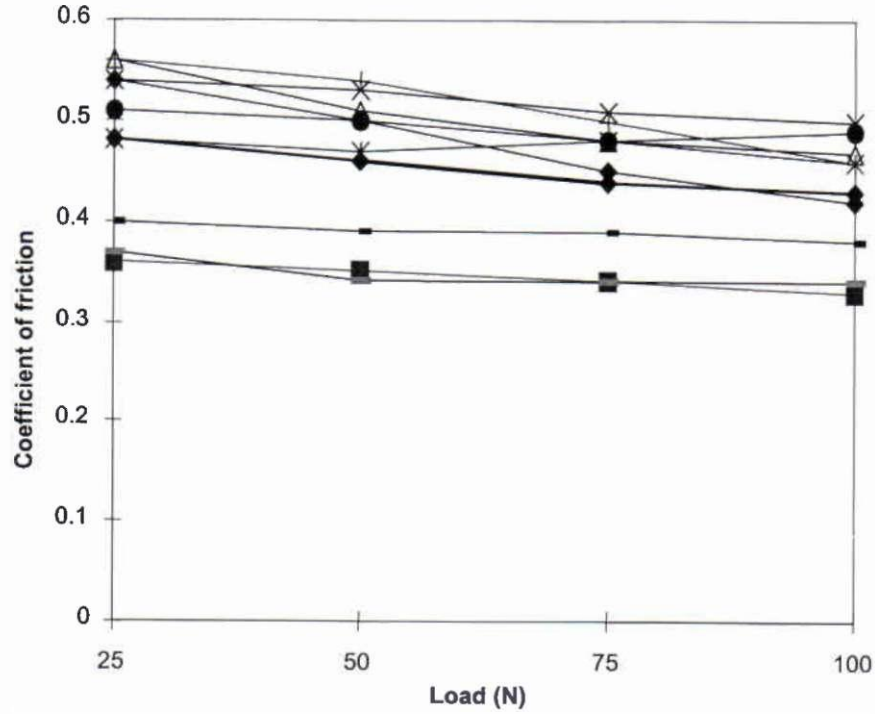

Fig. 2 Change in friction with normal load.

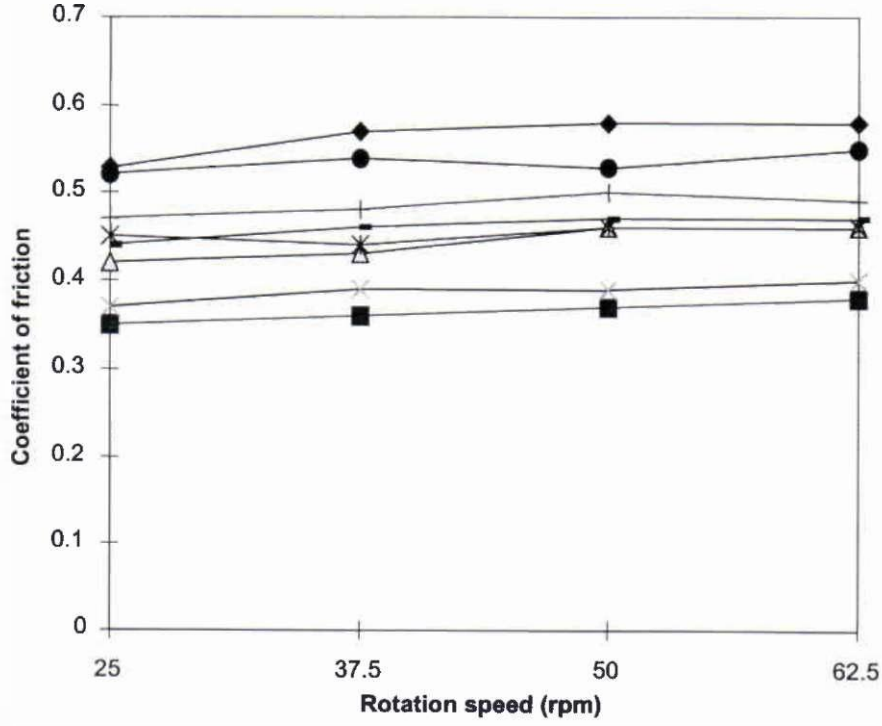

Fig. 3 Change in friction with rotation speed.

Highley *et al.*, 1977; El-Shimi, 1977; Nacht *et al.*, 1981; Cua *et al.*, 1990). The data reported in this study are particularly relevant to prosthetics and orthotics. These results provide the information needed for better understanding of the biomechanics of load transfer at the body support interface. The coefficient of friction obtained will be used in the computational biomechanical models of the load transfer characteristics between the human body and its supporting devices (Zhang, 1995; Zhang and Mak, 1996; Zhang *et al.*, 1997).

The findings in this investigation are in agreement with previous reports. The coefficients of friction reported for skin were generally within the range of 0.1-1.3 (Wolfram, 1989). In general, the coefficient of friction decreases with increasing load, especially in the range of a small load (El-Shimi, 1977; Comaish *et al.*, 1971). The effect of rotation speed was noted to be negligible over the range examined 3.6 - 585rpm (El-Shimi, 1977).

Frictional forces can be generated via two actions, one from the "ploughing" action, and the other one from the force required to overcome adhesion between the two surfaces. The former produces friction forces due to the mechanical interlocking of surface roughness elements. The latter generates friction forces due to dissipation when the atoms of one material are plucked out of the attractive range of their counter-parts on the material surface. The relative contribution from these two mechanisms depends on the physical and chemical properties of the contact surfaces. Generally speaking pairs of materials will compatible properties will have a larger friction if the second part is the major contributor. This may be the reason why silicone has the highest friction among the test materials.

The high coefficient of friction found in the palm of the hand may also be related to the fact that this is very rarely sweat free (Comaish *et al.*, 1971). Thus the physiological state of the skin at any one time must have a profound effect. Other geometric features such as the epidermal ridges may play an important part.

Acknowledgements

The first author thanks the Hong Kong Polytechnic University for a postdoctoral research fellowship. Help from the undergraduate students in the BSc (Hons) programme in Prosthetics and Orthotics is appreciated.

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Prosthetics and Orthotics International, 1999, 23, 142-151

Biomechanical assessment of gait in below-knee walking casts

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Abstract

The introduction of modern synthetic casting bandages for splinting of fractures and soft tissue injuries has allowed the development of new casting techniques. Casts can be constructed with a greater degree of function so that controlled motion and stabilisation can be provided within the same cast. This study has shown that a very efficient gait can be achieved with modern synthetic bandages, if they are correctly applied. The authors have compared the gait of volunteer subjects fitted respectively with below-knee walking casts constructed from a rigid glass fibre bandage and a flexible glass fibre bandage which is reinforced. These casts were wrapped so that minimal amounts of bandage were used whilst appropriate strength and stiffness was provided. The temporal and spatial factors of cast gait were not statistically different from normal gait. The cast gait was found to be slightly more asymmetrical (dominant versus non-dominant leg) when a cast was worn and there was also a greater Physiological Cost Index (PCI). The flexible bandage has some advantages compared with the rigid bandage as normal footwear can be worn, the casts are more comfortable and they could be removed with shears, obviating the need for a power saw.

Introduction

Following trauma and injury to the limbs causing fracture of a long bone, it was the practice to immobilise the joint above and below the affected region with a cast. This is so that alignment, control of rotation, correct anatomical position and pain relief are achieved. In fractures and injuries affecting joints, the limb segments above and below the joint are immobilised. However, it is now established that the beneficial effects of rest following injury or trauma can have a deleterious effect on surrounding tissues resulting in dystrophy and atrophy if prolonged beyond 7-10 days (Berg and Tesch, 1996; Berg *et al.*, 1997; Klein *et al.*, 1982). Muscle mass and muscle function decreases, ligaments, tendons and the joint capsule are weakened and shortened, and cartilage can develop degenerative changes. Moreover maintaining muscle tone contributes to normal circulation (Williams and Goldspink, 1978). The maintenance of nutrition on soft tissues and the preferred orientation of collagen fibres has been shown to exist when functional joint motion is permitted (Woo *et al.*, 1987). Functional treatment of femoral fractures such as cast bracing has been shown to promote healing of fractures at a much faster rate than prolonged immobilisation by traction. Micromovement at the fracture site has been shown to promote healing of fractures by increasing blood flow in bone and by efficient remodelling (Kenwright and Goodship, 1985). However, many factors are implicated in the biological response of tissues that have been damaged, such as pain, the degree of trauma, duration of immobilisation etc. It is logical to expect that where function is allowed, as compared to a non-functional situation, the rehabilitation phase will be shorter.

Plaster of Paris (PoP) bandage applied in the form of a cast has been the mainstay of conservative management of fractures and soft

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tissue injuries for over 130 years and is designed to immobilise the joints rigidly. PoP casts are heavy, bulky and brittle and do not allow functional loading and controlled activity during healing. Modern synthetic casting materials comprising a knitted fabric bandage impregnated with a polyurethane resin (e.g. Scotchcast, 3M Healthcare, Leicestershire, England) are more versatile materials with improved mechanical properties and have significant benefits during application and removal (Wytch *et al.,* 1990[a]). Most below-knee walking casts (BKWCs) fabricated from synthetic bandages are applied to provide rigid ankle immobilisation in a similar way to PoP and similarly affect the biomechanics of gait.

The effect of a rigid BKWC on gait has been reported in numerous studies (Nuzzo, 1983[a]; Nuzzo 1983[b]; Hullin and Robb, 1991; Pratt *et al.,* 1986; Hellberg *et al.,* 1987; Wytch *et al.,* 1990[b]; Hamzeh *et al.,* 1988). Rigid ankle immobilisation does not allow the foot to plantarflex after heel strike and foot flat is delayed. The ankle is unable to dorsiflex after mid-stance and there is early rotation of the foot on the metatarsal heads. Consequently, there is an increase in the vertical displacement of the knee centre and its maximum excursion occurs after heel off. There is also an abrupt inflexion of the knee pathway (Pratt *et al.,* 1986). However, in order to achieve a more natural gait to compensate for these effects a cast shoe or sole is recommended (Nuzzo, 1983[a]). This allows progression of the leg over the stationary foot which is unable to dorsiflex due to the rigidity of the cast. A shoe with a cushioned heel to tilt the cast so that the knee centre is ahead of the ankle at mid-stance reduces this disability. Nuzzo (1983[a]) also states that much of the disability associated with wearing a BKWC is a result of the treatment rather than the disease.

To produce a functional cast whilst maintaining stabilisation of the injured limb requires a cast with the correct amount of strength and stiffness. The strength and stiffness can easily be increased by adding more layers of bandage but this makes the cast bulky and cumbersome. The stiffness is determined not only by thickness but also by shape. Curves or corrugations can significantly stiffen a cast. The natural curves of the body can be used to advantage when higher stiffness is required and moulding the cast can increase its stiffness. Adding reinforcement to specific regions of the cast increases both its strength and stiffness. Reinforcing the casts at specific points rather than wrapping extra rolls of bandage is more economical of materials and casts are also quicker to apply and to remove.

A technique described by Schuren (1994) uses a flexible glass fibre bandage (Softcast) which is reinforced with rigid layers of synthetic material (Scotchcast) so that both stabilisation and controlled motion can be provided within the same cast (Combicast). When wrapped in the form of a BKWC this type of cast attempts to give the patient a more natural gait and allows normal footwear to be worn. Both Scotchcast and Softcast are knitted glass fibre bandages impregnated with a polyurethane resin. However, the resins differ in their composition so that Softcast is significantly more flexible than the other glass fibre bandages (Schuren, 1994).

In this study the authors compared the gait of healthy volunteer subjects when fitted with below-knee walking casts constructed from a flexible reinforced cast (Combicast) with that when fitted with the conventional type of rigid synthetic bandage (Scotchcast). A minimal amount of material compatible with providing both stabilisation and allowing controlled motion was applied in both cases in order to assess the functional benefits of different casting methods and materials. The volunteers were divided into two groups and given the treatment appropriate for a closed, undislocated, ankle fracture. Volunteer subjects were used so that a high degree of activity would be attempted and because they provide less variability than a patient group with fractures.

Biomechanical measurements during gait

Force platform

The study of foot-ground reaction forces is important in the identification and evaluation of gait abnormalities and has been used in numerous studies. Force platforms are commonly used for this purpose and measure the three orthogonal forces between the foot and the ground (Begg *et al.,* 1990). In order to record ground reaction forces a Kistler, Type 9281B, multi-component force platform system was used running Bioware analysis software (Kistler Instruments, Hants, England). The signals from the force platform were sampled at a rate of

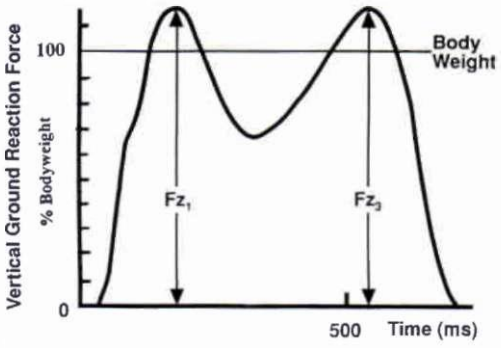


Fig. 1 shows a typical graph of the foot-ground reaction forces during normal gait. The two peak values (Fz_1 and Fz_3) were compared in this study.

1kHz. The force platform data was exported from Bioware from further analysis using Microsoft Excel (Microsoft Corporation, USA).

Aberdeen Video Vector System

The Aberdeen Video Vector System (AVVS) is a hybrid system that includes both kinetic and kinematic aspects of human locomotion (Begg *et al.*, 1990). The output of the AVVS comprises a video image of the subject with the resultant GRF vector, acquired from the Kistler force platform superimposed onto the subject in real time (Fig. 2). Also displayed on the video image are the magnitudes of the three orthogonal forces and a frame counter recorded every 20 milliseconds (50Hz). Gait can be recorded in both the coronal and sagittal planes. In this study only videotape data were analysed.

Gait symmetry indices

Symmetrical human gait occurs when there is complete agreement of the external kinetic and kinematic parameters of the left and right legs. This will rarely, if ever, occur given the complexity of the human body. Hertzog *et al.* (1989) devised a method for quantifying the degree of asymmetry in the foot-ground reaction forces, the stance time and the step and stride lengths in normal gait. The symmetry index was calculated by using Equation 1 and will have a mean value of zero for symmetrical gait. Equation 2 calculates the upper and lower limit limits such that 95% of all symmetry indices obtained from a gait variable associated with normal gait are within these limits.

$$\textit{Symmetry Index (SI)} = \frac{X_D - X_N}{0.5(X_D + X_N)} 100\% \quad \text{Eq.1}$$

where X_D = gait variable recorded for dominant leg

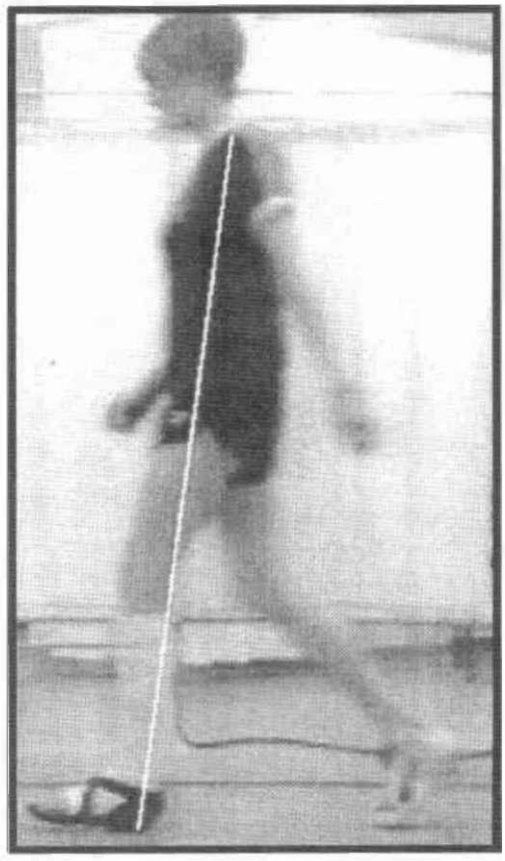
X_N = gait variable recorded for non-dominant leg

Upper and lower limits of symmetry indices were calculated for baseline values using the following equation:

$$SI_{ul} = 0 \pm t_{df\,(0.05)}.\ SD \quad \text{Eq.2}$$

where $t_{df\,(0.05)}$ = critical value of t-distribution

df = number of subjects – 1 (i.e. the number of degrees of freedom)



Fx=8N Fy=60N Fz=91% of bodyweight

Fig. 2 shows a typical real time display of a volunteer fitted with a rigid cast and a cast shoe using the Aberdeen Video Vector System. The forces in the mediolateral, anteroposterior and vertical directions are represented by the subscripts x, y and z respectively.

The SIs of cast gait were then compared against SI_{ul} to determine if there was any difference in the symmetry of gait when wearing a cast.

Physiological Cost Index (PCI)

Normal human locomotion is extremely economical in terms of energy expenditure and few other useful activities can be accomplished at a lower net energy cost than walking. Wheelchair propulsion requires somewhat less energy than normal locomotion since two of the major energy consuming factors of normal gait, vertical and horizontal oscilliation of the centre of gravity are eliminated. Pathological gait or gait deviations are usually characterised by increased energy costs often resulting from inefficient use of muscular energy in body movements. A measure of energy expenditure therefore provides an objective assessment of the efficiency of a person's gait. A satisfactory and practicable measurement of energy expenditure is by means of heart rate monitoring. It has been shown that for a given individual the increase in heart rate during exercise is linearly related to the work load (Astrand and Rodahl, 1970).

Heart rate can be significantly affected by factors other than work-load. Emotional stress, in particular, can invoke a cardiovascular response. Other factors include illness and medication, effects of food, alcohol and tobacco, environmental temperature and walking speed (Astrand and Rodahl, 1970; Hamzeh *et al.,* 1988). For these reasons test conditions must be carefully controlled. No food or cigarettes should be taken within 2 hours prior to the test, and heavy physical exercise should be avoided during this period. Alcohol should be avoided for 24 hours before testing.

In any individual, heart rate is affected by speed of walking, and comparisons of speed and heart rate have been used by a number of researchers in their studies on energy expenditure (Blessey, 1978; Davies, 1977; Rose *et al.,* 1985; Rose *et al.,* 1990; Waters *et al.,* 1983; Waters and Lunsford, 1985; Waters *et al.,* 1988). Many studies have shown that monitoring walking speed in conjunction with the measurement of heart rate as a means of assessing energy expenditure has been consistently reproducible (McGregor, 1981; Waters *et al.,* 1988). It has also been shown that the preferred walking speed (self-selected), for an individual, corresponds closely with that at which the energy cost is a minimum (Bard and Ralston 1959; McGregor, 1981; Hellberg *et al.,* 1987).

The Physiological Cost Index (PCI) was developed by McGregor (1981), as a measure of the efficiency of gait. It is defined as the difference between the walking heart rate, H_W, and the resting heart rate, H_R, divided by the speed of walking and is expressed in terms of heart beats per metre (bt/m) walked.

$$\textit{Physiological Cost Index (PCI)} = \frac{H_W - H_R}{\textit{Walking Speed}} \qquad \textbf{Eq.3}$$

Previous studies have found the mean value of the PCI in healthy adults to be 0.35bt/m and ranges from 0.11 to 0.66bt/m (McGregor, 1981; Waters *et al.,* 1988).

The heart rate can be reliably recorded during walking using a Polar heart rate monitor (HRM). The Polar HRM is a lightweight, portable microprocessor manufactured by Polar Electro Oy, Professorintie 5, SF-90440, Finland. The monitor consists of a chest band, containing two contact electrodes and a lithium battery powered electronic ECG sensor and radio frequency transmitter, and a battery powered wrist watch receiver. The band is fastened round the chest, just below the level of the nipples, and the electrodes detect the electrical impulse of the heart. The heart rate can be recorded continuously every 5 seconds, displayed on the wrist watch face and stored in the receiver memory. The data can be uploaded to a personal computer using a serial port connection, processed and displayed on the computer screen using the Polar Edge software and the mean heart rate calculated.

Experimental procedure

Eight (8) healthy volunteers participated in this study, 5 males and 3 females, with a mean age, body mass and height of 22.9 years, 68.5kg and 173.9cm respectively. Written informed consent was obtained from all volunteers and the institutional ethical committee approval was granted. All of the participants were fit and healthy without any history of injury, illness or pathology that could affect the cardiovascular, respiratory or locomotor systems.

A baseline (initial) assessment of each subject's gait was recorded using the Kistler Force Platform running Bioware Software, AVVS and the Polar HRM. All subjects wore flat shoes and shorts and were randomly assigned to either group A or group B. Below-knee walking casts were applied to their non-dominant leg by the same orthopaedic technician (JS) to achieve maximum functional and efficient use of the bandage materials. Two (2) volunteers (subject 6 and 7) wore casts on their right legs and the other 6 volunteers wore casts on their left legs. Each cast was worn for 3 days (72 hours) and the same gait recordings were made as in the baseline assessment.

Group A

Four (4) subjects were fitted with a BKWC made from rigid glass fibre bandage impregnated with polyurethane resin (Scotchcast, 3M Healthcare, Leicestershire, England). Two (2) rolls of 10cm wide bandage were used with minimal undercast padding to protect bony prominences. A Cellacast cast shoe was fitted to improve gait and to protect the heel and plantar surface of the cast (Lohmann GmbH, Germany).

Group B

Four (4) subjects were fitted with a BKWC made from Softcast and reinforced with a Scotchcast U-splint around the ankle to produce a Combicast (Fig. 3). Two (2) rolls (7.5 and 10cm wide) of Softcast reinforced with 7.5cm wide Scotchcast Longuette were used (3M Healthcare, Leicestershire, England). No undercast padding was used and the malleoli were protected with one layer of synthetic padding. This type of functional combination cast is designed to prevent subtalar joint movement by the use of U-splint reinforcing strip (Fig. 3) whilst allowing movement in the ankle and forefoot. All subjects in this group wore their own shoes.

Video and force platform recordings

Subjects were asked to walk at their self-selected comfortable speed along a 12 metre walkway in the gait laboratory. The Kistler force platform collected data at 1kHz. This process was repeated until each subject had achieved at lease 3 clean foot strikes on the force platform for each leg. The following recordings were made of each subject's gait before a BKWC was fitted (i.e. a baseline recording) and 3 days after it was fitted:

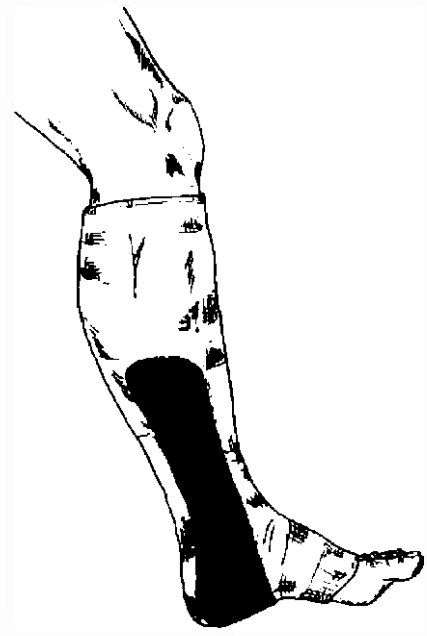


Fig. 3 shows the reinforcing U-strip in a below- knee Combicast. The flexible softcast glass fibre bandage is reinforced with the rigid Scotchcast glass fibre bandage.

a) the peak vertical foot ground reaction forces (Fz_1 and Fz_3):
   Recorded from the force platform and acquired by Bioware:
b) temporal aspects recorded from videotape:
   gait cycle (stride) time
   stance/swing phase times (stance time also recorded from force platform)
   step/stride length
   walking speed, calculated from the product of step time and step length
c) gait symmetry indices:
   force platform
   temporal aspects (stance time)

PCI recording

Each subject was asked to avoid food, cigarettes and heavy physical exercise for 2 hours prior to the test and alcohol for 24 hours prior to testing. The test procedure required each subject to rest, seated quietly for 4 minutes, stand for 1 minute and then walk freely at their self-selected comfortable speed round a 20m

long track (parallel sided with semicircular ends) for 4 minutes. Each subject walked for about 300 metres. The heart rate was recorded every 5 seconds throughout the 9 minute test period using a Polar Edge Heart Rate Monitor and the data transferred to a personal computer via the serial port interface for subsequent analysis. The average walking speed was obtained by counting the number of complete and partially complete circuits of the track and dividing by the 4 minute walking period. This procedure was carried out three times and the mean values of the resting heart rate, walking heart rate, and walking speed were calculated for each subject.

Statistical analysis

Statistical analysis was carried out using Microsoft Excel Spreadsheet (Microsoft Corporation, USA). A paired 't' test was used to determine differences in samples means for the gait cycle time, stance time, cadence, step and stride length, walking speed and PCI. The force platform data (Fz_1 and Fz_3), stance time, step and stride length were assessed using the Gait Symmetry Index (SI).

Discussion of results

This study has compared the gait of volunteers with a BKWC constructed from a rigid glass fibre casting bandage and wearing a cast shoe with a Combicast in which the volunteers wore their own footwear. The temporal and spatial factors of gait in 8 volunteers showed only small variations compared to normal gait (Table 1). The gait cycle time, stance phase time, step and stride length and walking speed were not significantly different ($p>0.05$) when a BKWC was applied.

A slightly higher walking speed with cast gait and a longer step length compared with normal gait were recorded for straight and level walking when recording the force platform data. These are well within the natural variability of gait parameters (White *et al.*, in press) but could be due to the fact that the volunteers walked faster when wearing a cast in order to establish a consistent rhythm to their gait and also because the recordings were made 72 hours after the baseline recordings. However, when the volunteers walked around the 20 metre track to record their PCI the walking speed was slightly

Table 1. Force platform/AVVS data

Group A – Rigid Cast

Subject	Mean gait cycle time (s)		Mean stance time (s)		Stance: Swing (%)		Cadence (step/min)		Stride length (m)		Walking speed (m/s)	
	Baseline	Cast	Baseline	Cast	Baseline	Cast	Baseline	Cast	Baseline	Cast	Baseline	Cast
3	1.09	1.09	0.69	0.69	63:37	63:37	110.3	109.7	1.32	1.32	1.19	1.21
4	0.98	0.99	0.61	0.61	62:38	62:38	122.7	121.7	1.31	1.44	1.33	1.46
5	1.09	1.10	0.71	0.69	65:35	63:37	110.1	109.3	1.50	1.50	1.37	1.36
8	1.08	0.98	0.68	0.61	63:37	62:38	112.9	112.2	1.36	1.27	1.26	1.29
Mean	1.06	1.04	0.67	0.65			113.5	115.7	1.36	1.38	1.29	1.33
s.d.	0.05	0.06	0.04	0.05			6.1	7.2	0.10	0.11	0.08	0.11

Group B – Combicast

Subject	Mean gait cycle time (s)		Mean stance time (s)		Stance: Swing (%)		Cadence (step/min)		Stride length (m)		Walking speed (m/s)	
	Baseline	Cast	Baseline	Cast	Baseline	Cast	Baseline	Cast	Baseline	Cast	Baseline	Cast
1	1.07	1.11	0.66	0.72	62:38	65:35	112.6	108.5	1.22	1.55	1.15	1.4
2	0.99	1.00	0.60	0.60	60:40	60:40	121.0	119.5	1.37	1.54	1.38	1.53
6	1.07	1.15	0.67	0.74	63:37	64:36	112.4	104.2	1.34	1.22	1.26	1.06
7	1.21	1.15	0.78	0.72	64:36	63:37	101.2	104.2	1.45	1.48	1.22	1.28
Mean	1.09	1.10	0.68	0.70			111.8	109.1	1.35	1.45	1.25	1.32
s.d.	0.09	0.07	0.08	0.06			8.12	7.25	0.10	0.15	0.10	0.20

slower when casts were worn than for their normal gait. This is probably due to much greater distance walked and having to walk around an elliptical track so that the speed would be modified when negotiating a change of direction.

The PCI increased by 9% when the volunteers wore a rigid cast and by 3.5% for the Combicast (Table 2). The PCI of walking in a rigid cast was found to be significantly greater than normal gait ($p=0.022$) but this was not the case for the Combicast ($p=0.113$). The restults of this study are similar to those reported by Ralston (1965) who found a 6% increase in the PCI of gait in 3 subjects with an immobilised ankle and by Fowler *et al.* (1993) who reported a 14.4% increase in PCI in 14 young adult male subjects. However, these results differ significantly from the study carried out by Hamzeh *et al.* (1998) who found that the PCI increased by 47.6% in 10 young adult subjects when fitted with standard plaster of Paris BKWCs. The PCI increased by over 400% when these same volunteers were fitted with a plantarflexed cast (115°).

Table 2. Physiological Cost Index (PCI) data
Group A – Rigid Cast

Subject	Average walking speed (m/min)		Increase in heart rate during walking (beats/min)		PCI (beats/m)	
	Baseline	Cast	Baseline	Cast	Baseline	Cast
3	72.5	75.0	13.0	15.8	0.179	0.209
4	67.8	66.7	21.1	22.0	0.311	0.33
5	73.8	66.7	28.9	30.5	0.392	0.457
8	80.8	78.5	30.6	32.1	0.383	0.408
Mean	73.73	71.73	23.40	25.10	0.316	0.351
s.d.	5.37	6.60	8.07	7.62	0.10	0.11
					p=0.022	

Group B – Combicast

Subject	Average walking speed (m/min)		Increase in heart rate during walking (beats/min)		PCI (beats/m)	
	Baseline	Cast	Baseline	Cast	Baseline	Cast
1	86.3	88.3	28.7	24.4	0.325	0.276
2	80.8	78.3	27.6	30.6	0.342	0.391
6	69.2	66.3	17.0	13.1	0.246	0.211
7	62.5	65.8	8.70	14.0	0.139	0.202
Mean	74.70	74.68	20.50	20.53	0.263	0.270
s.d.	10.81	10.77	9.47	8.45	0.09	0.09
					p=0.113	

Gait asymmetry increased with a cast gait compared to normal gait (Table 3). However, only the mean Symmetry Index (SI) of the first peak (Fz_1) in the force platform data was significantly greater than for normal gait ($p>0.05$). This was determined by comparing SI_{ul} of 5.7% for normal gait with the mean SI for the rigid bandage (10.3%) and for the Combicast (8.1%) (Table 4). Although the other parameters showed higher mean SI values than for normal gait they did not reach statistical significance ($p<0.05$). Volunteers also complained of discomfort when the rigid casts were used and discomfort was felt internally around the ankle and at the toe end of the casts due to the roughness of the bandage. No discomfort was reported in the Combicast. The rigid types of polyurethane casting materials are not forgiving and produce discomfort if not meticulously applied with appropriate padding and good technique. Softcast, however, is very forgiving and provides the necessary support when used in a Combicast.

In 1967 Sarmiento introduced functional below-knee walking casts which allowed early weight bearing and mobilisation of adjacent joints. The 1980s saw the introduction of a range of lightweight synthetic (polyurethane/glass fibre) bandages for conservative management of fractures and soft tissue injuries. They have much greater strength and durability than PoP and can be weight bearing within 30 minutes (Wytch *et al.*, 1987). The recent introduction of glass fibre materials with greater inherent flexibility allows combination casts to be fabricated with the appropriate strength and stiffness throughout the cast so that the optimum characteristics of a functional cast can be achieved. The benefits of combining materials minimises dysfunctional activity, allows better moulding of the casts to the limb and is more comfortable for the patient.

Conclusions

This study has shown that a very efficient gait can be achieved with modern synthetic bandages, if they are correctly applied. The temporal and spatial factors of cast gait were not statistically different from normal gait although cast gait was found to be slightly more asymmetrical (dominant versus non-dominant leg) and had a greater PCI. The Combicast has some advantages compared with the rigid glass

Table 3. Peak vertical ground reaction forces (Fz).

Subject	Cast type	Leg	Forces	Baseline (% bodyweight)		Cast (% bodyweight)	
				Mean	SD	Mean	SD
1	Combicast	Right	Fz_1	114.00	4.04	121.60	5.47
			Fz_3	111.80	2.05	111.00	5.70
		Left	Fz_1	116.00	5.57	115.20	5.63
			Fz_3	109.50	2.05	113.00	5.54
2	Combicast	Right	Fz_1	124.00	4.00	134.00	5.1
			Fz_3	112.20	3.11	113.90	4.24
		Left	Fz_1	124.50	4.43	120.20	2.92
			Fz_3	106.25	1.71	106.60	3.51
6	Combicast	Right	Fz_1	116.50	5.07	107.40	1.34
			Fz_3	113.25	1.50	108.60	0.89
		Left	Fz_1	119.67	3.06	119.40	4.28
			Fz_3	110.33	2.08	104.60	2.61
7	Combicast	Right	Fz_1	104.20	5.22	106.50	2.08
			Fz_3	106.40	5.73	103.50	3.11
		Left	Fz_1	104.25	3.30	108.75	7.37
			Fz_3	108.25	3.40	111.50	1.91
3	Scotchcast	Right	Fz_1	103.39	4.75	115.33	4.16
			Fz_3	116.75	0.96	120.33	2.08
		Left	Fz_1	103.18	2.45	102.60	2.70
			Fz_3	113.60	1.67	108.40	2.07
4	Scotchcast	Right	Fz_1	112.40	3.21	123.40	2.07
			Fz_3	107.80	3.03	103.80	1.79
		Left	Fz_1	115.00	5.21	109.40	3.05
			Fz_3	108.33	0.58	104.00	2.12
5	Scotchcast	Right	Fz_1	115.40	4.04	125.80	2.39
			Fz_3	111.00	3.00	113.40	2.61
		Left	Fz_1	110.00	3.94	107.00	4.00
			Fz_3	111.00	3.00	106.00	2.04
8	Scotchcast	Right	Fz_1	107.00	2.92	116.60	7.02
			Fz_3	101.40	1.67	101.80	4.38
		Left	Fz_1	112.67	4.93	116.20	3.11
			Fz_3	106.67	1.53	104.60	1.95

A BKWC was worn on the right leg in subjects 6 and 7 and on the left leg in the other subjects.

fibre bandage as normal footwear can be worn, the casts are more comfortable and they could be removed with shears. This obviates the need for a power saw.

Although the concepts of functional immobilisation are well established they are not widely practised in the conservative management of musculo-skeletal injuries. The

Table 4. Gait Symmetry Indices: dominant vs non-dominant leg.

Baseline	Mean SI (%)	SD (%)	SI_{ul} (±) (%)
Fz_1	-1.0	2.4	5.7
Fz_3	-0.7	3.0	7.1
Stance time	1.0	3.2	7.6
Step length	1.5	3.3	7.8
Stride length	1.2	3.7	8.7
Soft cast			
Fz_1	8.1	5.5	Greater
Fz_3	3.0	4.3	OK
Stance time	4.5	3.3	OK
Step length	3.2	4.0	OK
Stride length	1.2	2.6	OK
Rigid cast			
Fz_1	10.3	6.9	Greater
Fz_3	5.1	4.5	OK
Stance time	6.5	2.8	OK
Step length	1.3	4.2	OK
Stride length	0.9	2.6	OK

use of combination casts is likely to encourage functional immobilisation as an efficient and comfortable gait can be produced. This type of cast provides an advance in the treatment of fractures and soft tissue injuries.

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Prosthetics and Orthotics International, 1999, 23, 152–162

The functional use of the reciprocal hip mechanism during gait for paraplegic patients walking in the Louisiana State University reciprocating gait orthosis

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Abstract

Reciprocally linked orthoses used for paraplegic walking have some form of linkage between the two hip joints. It has been assumed that flexion of the swinging leg is driven by extension of the stance leg. The aims of this study were to investigate the moments generated around the hip joint by the two cables in a Louisiana State University Reciprocating Gait Orthosis (LSU-RGO). Six (6) subjects were recruited from the Regional Spinal Injuries Centre at Southport, who were experienced RGO users. The cables were fitted with strain gauged transducers to measure cable tension. Foot switches were used to divide the gait into swing and stance phases. A minimum of 20 steps were analysed for each subject. Moments about the hip joint for each phase of gait were calculated.

There were no moments generated by the front cable in 4 of the subjects. In only 2 subjects did the cable generate a moment that could assist hip flexion during the swing phase. These moments were very low and at best could only have made a small contribution to limb flexion. The back cable generated moments that clearly prevented bilateral flexion. It was concluded that the front cable, as used by these experienced RGO users, did not aid flexion of the swinging limb.

Introduction

Walking in a reciprocal manner with the aid of an orthosis for people with a thoracic level spinal cord injury requires bracing from hip to ankle, and often includes trunk support. A range of devices is available, most of which consist of bilateral knee ankle foot orthoses (KAFO) and a trunk section. Knee and ankle joints are fixed and hip joints provide a limited range of motion in flexion and extension. Where options differ most markedly is in the method of limiting flexion and extension at the hip joint. These orthoses generally fall into two categories, reciprocally linked orthoses which have some form of reciprocal linkage between the hip joints, and free swing orthoses which allow free hip movement in flexion and extension between stops. Examples of reciprocally linked orthoses include the Advanced Reciprocating Gait Orthosis (ARGO) (Jefferson and Whittle, 1990) which has a single cable link, the Isocentric Reciprocating Gait Orthosis (IRGO) (Davidson, 1994) which has a rocker bar link, and the Louisiana State University Reciprocating Gait Orthosis (LSU-RGO) (Douglas *et al.*, 1983) which has a dual cable reciprocal link. The LSU-RGO was developed from previous designs by Motloch (Durr-Fillauer, 1983). The ParaWalker (Stallard *et al.*, 1986) which has trunk support, and the Walkabout (Middleton *et al.*, 1997) which has a pair of medially linked KAFOs , are examples of free swing orthoses.

Walking in all of these orthoses is achieved with the help of walking aids, either a rollator or crutches. The user inclines the trunk to one side by pushing with their hands on the contralateral side of their walking aid to produce vertical clearance for the swinging leg. The trunk is then moved forward over the stance foot using the walking aid. While the trunk is progressing over the stance foot, the swing leg moves from hip extension to flexion. In reciprocally linked

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orthoses it is reported that swing hip flexion is driven by stance hip extension through the reciprocal link. Additionally the reciprocal link provides support for both hip joints during double support periods (Beckman, 1987). In free swing orthoses, hip flexion on the swing side is achieved by gravity and inertia from the previous step. The hip joints guide the path of the hip joint in adduction and abduction, but allow free swing in flexion and extension between stops (Moore, 1988).

The benefit of the reciprocal link in an orthosis has been assessed indirectly by comparing the energy expenditure of patients walking in reciprocally linked orthoses and in free swing orthoses. Hirokawa *et al.* (1990) measured the energy expenditure per metre walked in the LSU-RGO (reciprocally linked orthosis) over a range of walking speeds (0.1 to 0.4m/s) and compared this to values from the literature on the ParaWalker (free swing orthosis). At low speeds the energy expenditure per metre for walking in the LSU-RGO was lower than the energy expenditure per metre for walking in the ParaWalker. The energy expenditure per metre for walking in the ParaWalker became lower than that when walking in the LSU-RGO at higher speeds. In the double support phases of the gait cycle, the reciprocal linkage of the LSU-RGO supports the hip joints so that less energy is expended resisting bilateral hip flexion. During the swing phase the ParaWalker has a freely swinging leg, the hip joint has lower friction and the swing leg is not constrained by the action of the stance leg, thus the leg requires less energy to be expended in moving it forward. As the speed of walking increases the double support phases of gait decrease proportionally compared to the swing phase. Therefore at slower speeds (where double support is a greater proportion of the gait cycle) walking in the LSU-RGO uses less energy, and at faster speeds (where the swing phase becomes more important) walking in the ParaWalker uses less energy.

The ParaWalker differs from the LSU-RGO in other areas besides the reciprocal linkage. It has a higher lateral stiffness than the LSU-RGO (Jefferson and Whittle, 1990), and the angle of ankle fixation is often different (Isakov *et al.*, 1992; Stallard *et al.*, 1986). The effect of those differences means that it is uncertain whether the relative changes in orthotic function shown by Hirokawa *et al.* (1990) are entirely due to the reciprocal linkage. Ijzerman *et al.* (1997) addressed these problems by measuring oxygen cost and speed of patients walking in the ARGO (reciprocally linked orthosis) and walking in the same orthosis with the reciprocal link replaced by flexion stops (free swing orthosis). The patients in the study with T4 lesions generally walked slower than those with lower level lesions (T9 - T12). In line with the findings of Hirokawa *et al.* (1990) the oxygen cost of patients with high thoracic lesions (slower gait) walking in the ARGO was lower than in the free swing orthosis, while the oxygen cost of patients with lower level thoracic lesions (faster gait) walking in the ARGO was higher than walking in the free swing orthosis.

The most effective way of assessing the action of the reciprocal link is to measure the use to which the cable is put during gait. Petrofsky and Smith (1991) attached load cells to both cables of an LSU-RGO and measured the force in them while spinal cord injured patients were walking. The force measured in the cables was less than 230N during level walking. The distribution of the cable force with respect to the phase of the gait cycle was shown graphically, but the beginning and end of the phases are difficult to determine precisely. Unfortunately no attempt was made to distinguish between force patterns in the two cables.

In order to assess the effect of the reciprocal link on the gait of a person with spinal cord injury it is necessary to quantify the variation in tension in each cable with time during gait. The aim of this project was to measure the forces in the cables of an LSU-RGO and the resultant moments developed at the hip joints with respect to the phases of the gait cycle during walking of spinal cord injured subjects.

Equipment

All the subjects in the study walked using a dual cable Louisiana State University Reciprocating Gait Orthosis (LSU-RGO). The LSU-RGO is shown in Figure 1.

At the hip joint Bowden cables were used which would only transmit forces and motion when in tension. Each cable consisted of an inner cable attached to the lower section of the hip joint, and an outer conduit, which is attached to the trunk section of the orthosis. The lower member of the hip joint was in the form of a T-

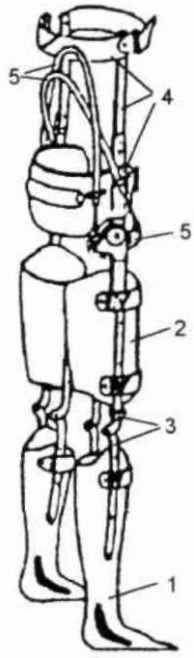

Fig. 1: The LSU-RGO (drawing adapted from Davidson 1994). 1 – polypropylene AFO section; 2 – polypropylene thigh sections; 3 – steel side-members with posterior offset knee joints and bale locks for sitting; 4 – a trunk section which consists of two steel uprights, polypropylene sacral band, stomach pad, and posterior and anterior Velcro straps at chest height; 5 – two uniaxial hip joints; the flexion and extension of which is constrained to reciprocate by a dual cable system. (Douglas *et al.*, 1983)

piece and a cable was attached to the front and back of each joint (Fig. 2). The cable attaching to the front of the left hip joint was also attached to the front of the right hip joint and is hereafter referred to as the front cable. The cable that was attached to the back of the right hip joint was also attached to the back of the left hip joint and is hereafter referred to as the back cable. When both feet are on the ground the back cable prevents bilateral hip flexion and the front cable prevents bilateral hip extension.

Therefore when a subject is in double support the walking frame is only needed for balance. During swing, when only one foot is in contact with the ground, the cables act in a reciprocal manner. Thus when one hip is flexed, the other hip extends by an equal angle. If one hip is driven into flexion by extension of the contralateral hip, the front cable will be in tension. Conversely if one hip is driven into extension by flexion of the contralateral hip, the

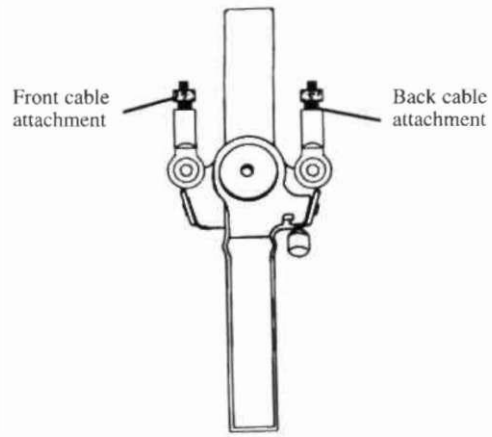

Fig. 2: Schematic representation of the hip joints and reciprocal cable link of an LSU-RGO.

back cable will be in tension. In theory during paraplegic gait in the LSU-RGO the back cable is in tension during standing and double support phases to prevent the patient collapsing into flexion at the hips. On the other hand the front cable is in tension during swing phase as the stance leg hip extension is used to drive contralateral hip flexion.

To measure cable tension two strain gauge transducers were constructed. Four strain gauges connected in a bridge arrangement were attached to an aluminium alloy cylinder (40mm by 12mm diameter) for each transducer, so that axial force was measured. The transducers were fitted between the cable and its attachment to the lower member of the hip joint (Fig. 3). Since the effective length of the cable was increased by insertion of the transducer a bracket was constructed to hold the outer cable. A slot in this bracket meant that the relative length of the front and back cables could be adjusted to fit each subject. One transducer was fitted to each of the front and back cables of the orthosis used by each subject.

To distinguish between stance and swing phases of the gait cycle, foot switches were attached to the heel and toe of each foot. Square force sensitive resistors (FSR) (Interlink Electronics, Luxembourg) 35mm square were placed on the sole of the AFO. The gain of the amplifier to which the FSRs were connected was set so that the output was at base line when the switch was not in contact with the floor and saturated high when the switch was in contact

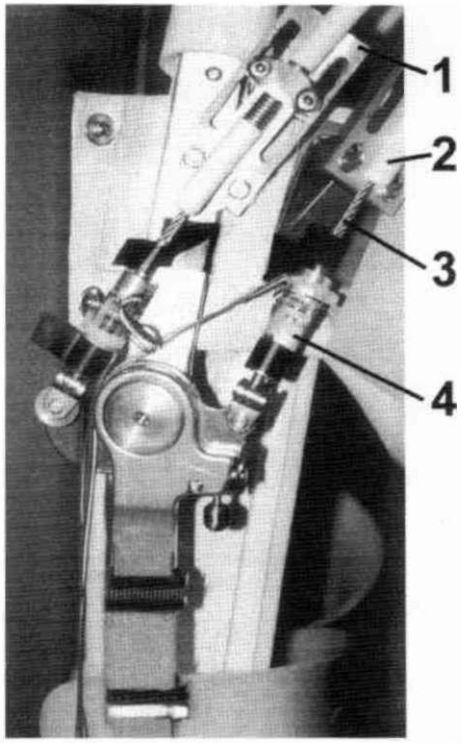

Fig. 3: Cable force transducers on the front and back cable of an LSU-RGO. 1 – extension bracket; 2 – outer conduit; 3 – inner cable; 4 – cylinder with strain gauge transducer setting.

with the floor and minimal weight on the foot.

During walking trials data were collected from the force transducers and foot switches by a computer, sampled through an A/D converter at 50Hz, via an umbilical cable.

Method

Six (6) adult spinal cord injured subjects participated in the study (Table 1). All were using the LSU-RGO as part of an exercise programme at the Regional Spinal Injuries Centre, Southport. Five (5) subjects walked with a rollator and one subject (F) walked with crutches.

Before the trial commenced each orthosis was modified to fit a force transducer and associated bracket to each cable. On arrival the subject donned the orthosis and foot switches were attached. The subject walked at a self-selected speed along a straight 10 metre track. The subject then turned and rested for a few minutes before repeating the trial. The trial was repeated at least four times so that between 20 and 40 steps were available for analysis for each subject. A sagittal plane video of the trials was taken to provide a record of the walking action.

Analysis

The data for each cable were divided into phases of the gait cycle. These were double support right leg back, double support left leg back, right swing and left swing. Division into four sections was chosen, as the patients' gait was not assumed to be symmetrical with respect to left and right steps. The swing phase was defined to start from toe off and end with heel strike. The transition between low and high saturation took approximately 0.2 seconds (approximately 10 data points), so it was necessary to set a threshold to pinpoint where toe off and heel strike occurred. If extraneous switch signals were present, for example if the subject scuffed their foot during swing phase, these were edited manually so that they did not affect gait phase determination.

The time scale of the data for each gait phase was transformed to a percentage scale. Graphs of the mean force and standard deviation for each subject and cable were plotted over the entire gait cycle. Maximum force in the cable and the percentage of gait phase that the cable was in

Table 1. Details of subjects included in the study. Walking speed is the average speed measured during the trials.

Subject	Sex	Injury level	Complete/ incomplete	Age	Body mass (kg)	Time since injury (years)	RGO use	Walking Aid	Walking speed (m/s)
A	M	T5	complete	37	54	15	17 months	rollator	0.18
B	M	T12	complete	44	67	10	7 months	rollator	0.17
C	M	C5/6	complete	54	63	6	17 months	rollator	0.16
D	M	T4/5	complete	28	63	2	5 months	rollator	0.18
E	F	T11/12	complete	28	54	1	6 months	rollator	0.17
F	F	T7	incomplete	40	84	15	11 years	crutches	0.42

tension were calculated. The moment arm of the front and back cables at the hip joint of the orthosis with the joint in neutral was measured. The mean distance was determined and used to calculated the moment produced about the hip joint of the orthosis by the tension in each cable during the gait cycle. The maximum moment during a gait phase for each cable and patient was calculated. To eliminate artefact caused by noise a threshold of 10N (0.3Nm) was chosen and all outcome measures were only calculated using data points that were above this threshold.

The average speed at which each patient walked during a trial was calculated from the video of those trials. The time taken for the patient to walk between lines of known spacing marked on the gymnasium floor was timed using a stopwatch.

Results

Force cable data, for front cable and back cable, transformed so that each gait cycle is the same length are shown in Figure 4 for 2 subjects. From this information the mean and standard deviation of cable force throughout the gait cycle was determined. A plot of the mean value is shown for all subjects in Figure 5. For most subjects the front cable showed no tension above 10N (0.3Nm) at any point in the gait cycle. Subject B had a peak in front cable tension at the end of the double support phase (left leg back) (Fig. 4). Two (2) subjects had peaks in the front cable in swing phase, subject A for both swing phases and subject E for the right swing phase only. Typically the back cable force was high during stance phase, and tailed off during the first half of swing phase to rise again towards the end of swing phase. The back cable force often built up during double support to a maximum in a series of peaks during double support phases (Fig. 4), but this detail was lost when the traces were averaged.

The means and standard deviations of percentage time above threshold and maximum moment developed at the front cable, for all subjects grouped by gait phase, are shown in Figures 6 and 7.

During stance phase the percentage time that the front cable was in use was less than 20% for all subjects, and was close to 0% in both double support phases for 4 subjects and in one double support phase for 1 subject (B). The front cable was in tension for 60% to 80% during swing phase for 1 subject (A) and was in tension for 25% during the right swing phase for 1 subject (E). For the other subjects and the left swing of subject E, the front cable was not in tension during the swing phase. For subjects C, D and F the maximum force in the front cable during stance and swing phases was 0N and therefore the effective moment at the hip was 0Nm (underneath the 0.3Nm threshold). The maximum hip moment produced by the front cable by subject A was around 3Nm in both double support phases and right swing, and 4Nm in the left swing phase. For subject B the maximum moment produced by the front cable during double support left leg back was 3Nm and 0Nm for all other gait phases. There was a maximum moment produced in the front cable of 5Nm during the right swing phase of subject E, and 0Nm for the other swing phase and both double support phases.

For the back cable the means and standard deviations of the percentage time of gait phase that the cable force was above threshold and maximum moment for all subjects by gait phase are shown in Figures 8 and 9, grouped by gait phase. The back cable was in tension between 97% to 100% of stance phase for all subjects. During swing phase the back cable was in tension for less than 100% of the phase in 4 patients. The other 2 patients had the back cable in tension 100% of swing phase for one leg but not for the other. Excluding these the back cable was in tension from 40% to 90% of the swing phase. The maximum moment in the back cable during stance was greater than during the swing phase for 5 out of 6 subjects. The range of maximum moments was greater in the double support left leg back phase than the double support right leg back phase. The maximum moment ranges from 35Nm to 12Nm during double support. The maximum moment during swing phase was more consistent between subjects than for the double support phases with little difference between right and left leg swing phases. The maximum moment during swing phase ranged from 8Nm to 14Nm, apart from the left leg swing for subject F which produced a maximum moment of 18Nm.

Discussion

The pattern of front cable use showed distinct variations between subjects, although the pattern was consistent within subjects. The pattern of

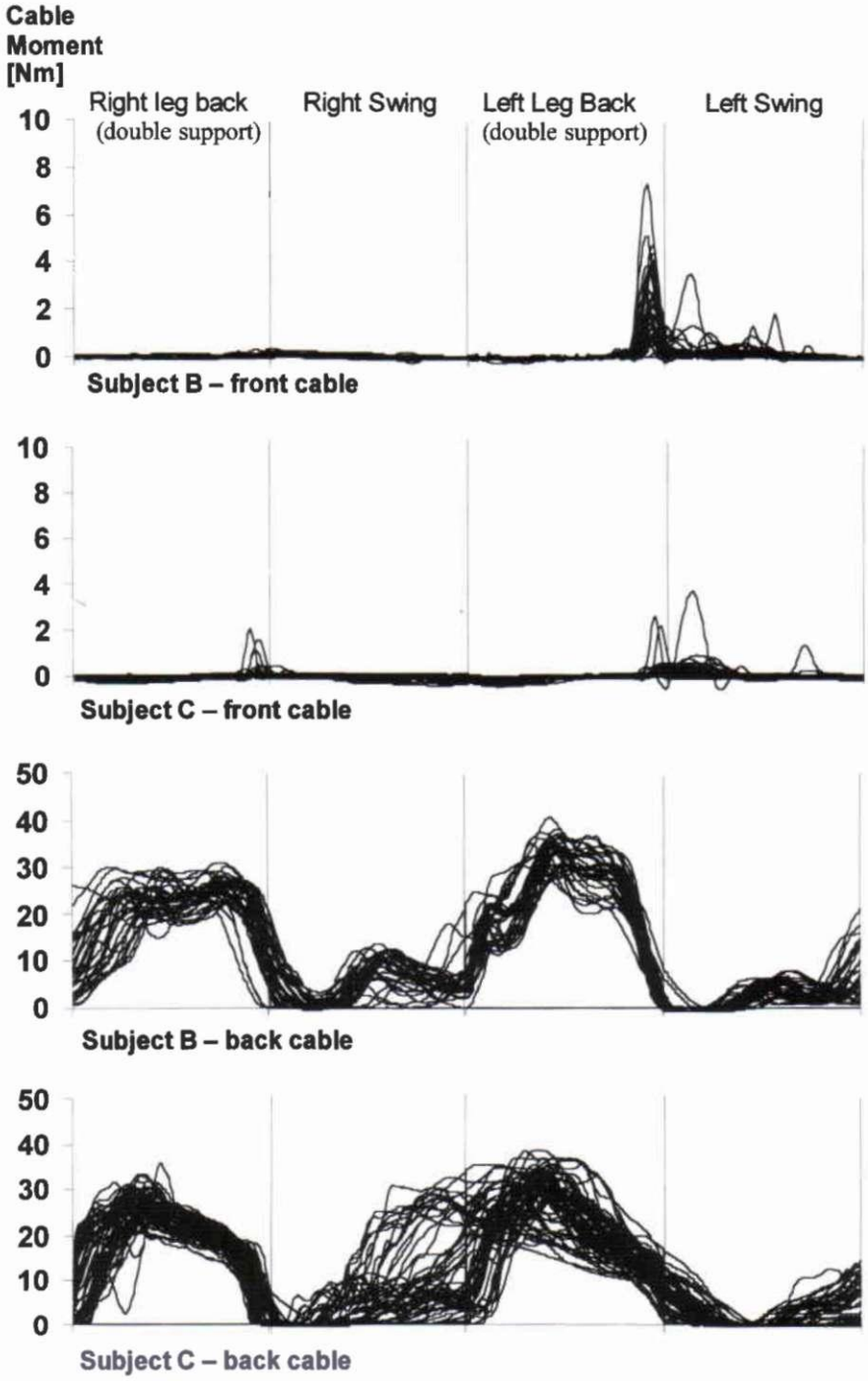

Fig. 4: The hip moment (Nm) produced by cable force in the front and back cables during the gait cycle, for each step taken by two subjects. The time scale of the graph has been modified so that each phase of the gait cycle is the same length for each step taken.

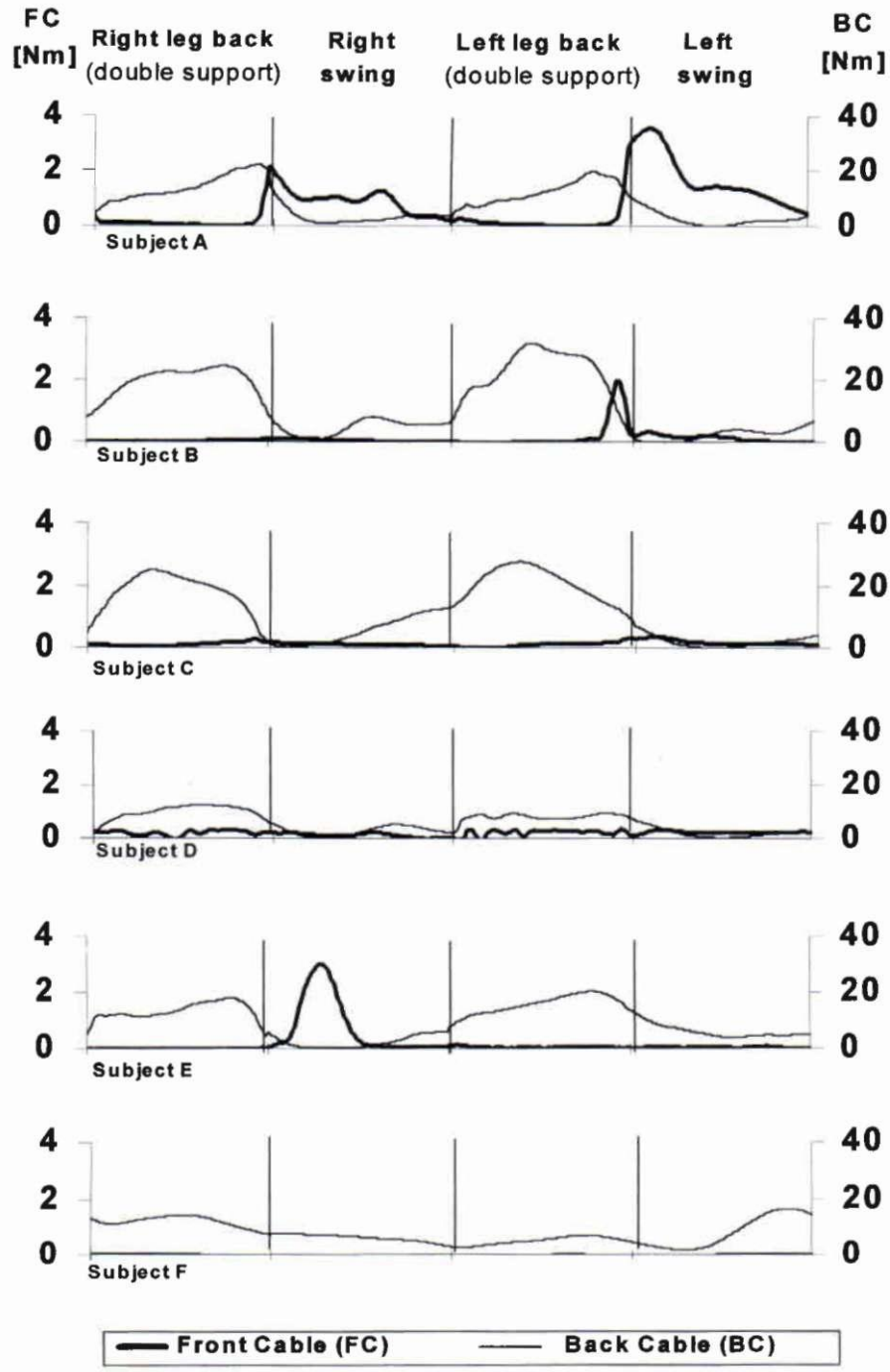

Fig. 5: Mean hip moment (Nm) produced by cable force in the front and back cables during the gait cycle for each subject. The time scale of the graph has been modified so that each phase of the gait cycle is the same length for each step taken.

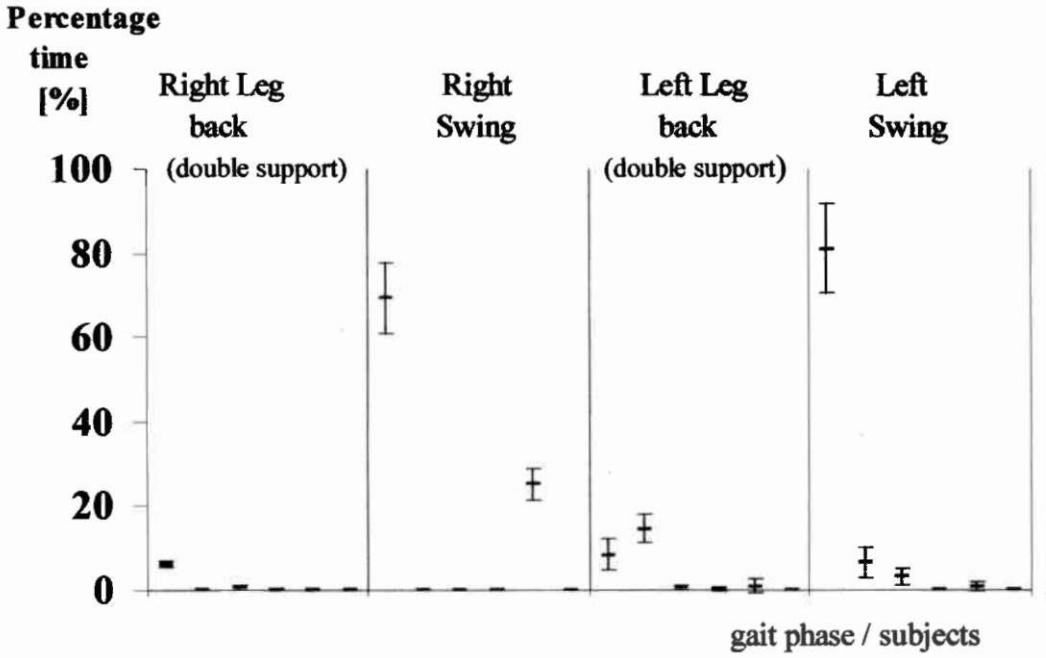

Fig. 6: Mean and standard deviation of the percentage that the front cable force was above the threshold, grouped by gait phase, for all subjects. Within each phase subjects are shown in order (A-F).

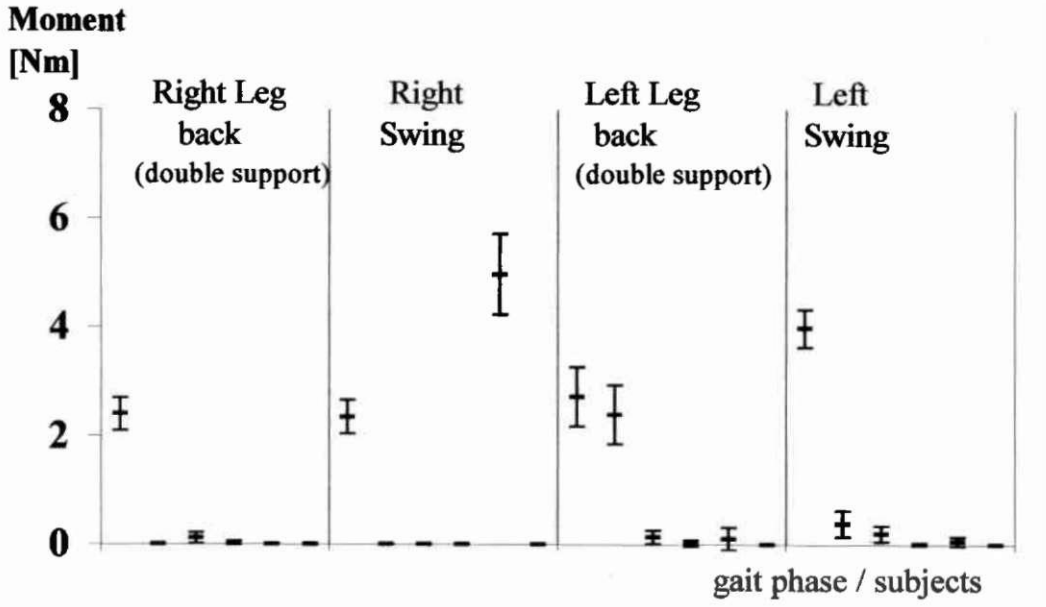

Fig. 7: Mean and standard deviation of the maximum hip moment produced by cable force in the front cable, grouped by gait phase, for all subjects. Within each phase subjects are shown in order (A-F).

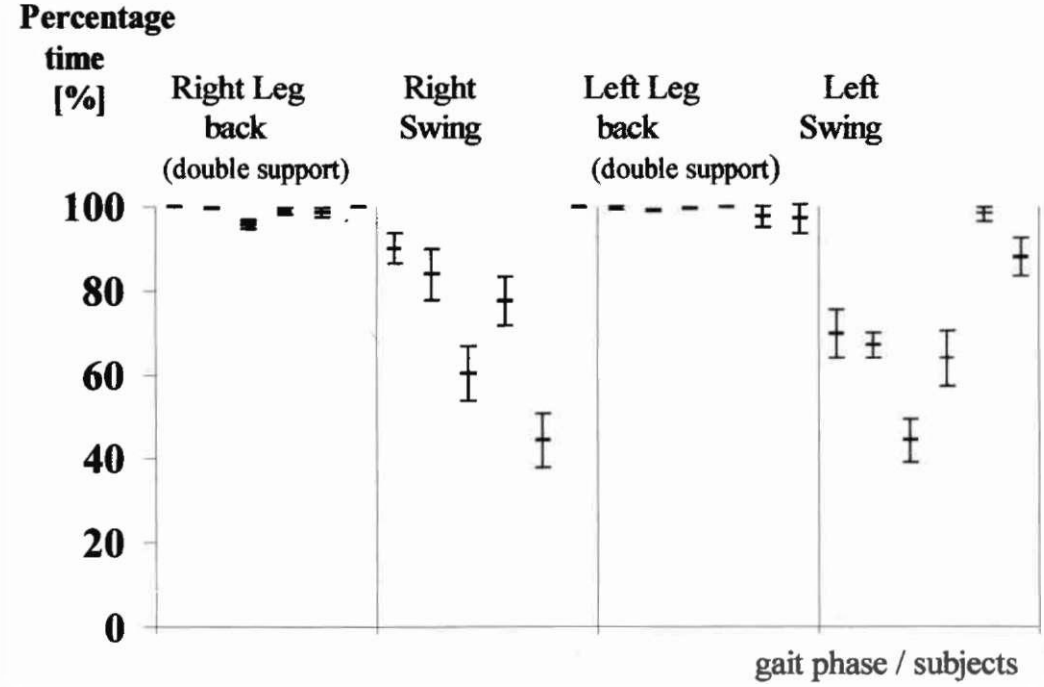

Fig. 8: Mean and standard deviation of the percentage time that back cable force was above threshold, grouped by gait phase, for all subjects. Within each phase subjects are shown in order (A-F).

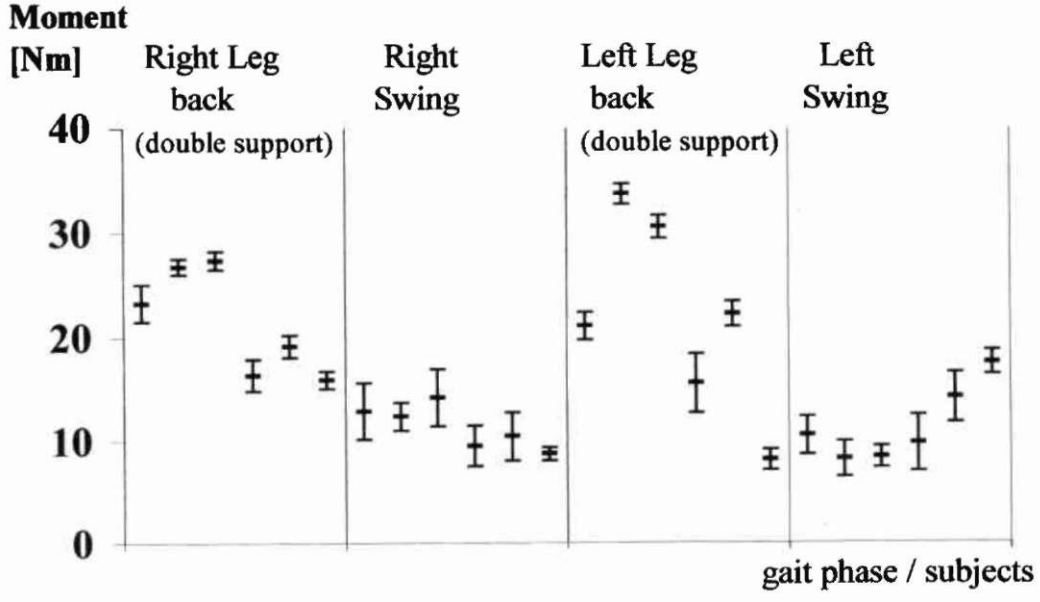

Fig. 9: Mean and standard deviation of the maximum hip moment produced by cable force in the back cable, grouped by gait phase, for all subjects. Within each phase subjects are shown in order (A-F).

back cable use was more consistent between subjects.

It has been assumed that the reciprocal link is used during swing phase, so that swing hip flexion is driven by stance hip extension. Thus tension in the front cable is thought to be generated and dissipated during the swing phase. This was clearly not the case for the majority of patients in this study. For 3 subjects the front cable was not in tension for the whole gait cycle and had a maximum moment in the cable of 0Nm, demonstrating that the cable was not being used at all during gait. There was tension in the front cable of subject E, during the right swing phase of the gait cycle. The force built up and declined from 10% to 50% of the swing phase with a peak value of 5Nm aiding swing hip flexion. The build up of tension in the front cable during swing phase indicated that stance hip extension was the cause of tension in the cable. Subjects A and C built up tension in the front cable during the last 5% of the double support phase to a hip flexion moment of 3 Nm, which, since both feet were on the ground, must have been caused by bilateral hip extension. The tension in the front cable of the orthosis of subject C dissipated before toe off and so did not contribute in any way to swing hip flexion. The tension built up in the front cable of subject A during double support was reduced during swing phase. Thus during the initial part of swing phase, swing hip flexion was being assisted by tension in the cable to a value of 3Nm.

Winter (1990) measured the moments acting on the hip joint during normal walking. The maximum hip flexion moment was 0.7Nm/Kg body mass, which for subjects in this study would be approximately 40Nm. The maximum moment created to aid hip flexion during the swing phase of gait in the front cable in this study was 5Nm. Thus the moment produced at the hip in those 2 users who were using the front cable to aid hip flexion was one eighth of that used during normal walking, and could not have been the sole driving force of hip flexion in the leg.

The pattern of use of the back cable was consistent between subjects and full use of the back cable was made during the double support phase resisting a hip flexion moment of 12Nm to 35Nm. At the start of swing phase all subjects showed a reduction in the tension in the back cable. The percentage of the gait phase over which this happened varied considerably, between 10% and 50% of gait phase, but could generally be said to have been a continuation of the decline in force started at the end of double support. Force in the back cable is built up during the stance phase as the subject leans forward towards the walking aid, some subjects relax this flexed position by standing straighter just prior to swing, whereas others try to stand straighter during swing phase itself. Those who stand straighter before the start of swing relax the force in the cable earlier, so the fall is shorter during the swing phase.

During the second half of the swing phase the moment produced by the back cable at the hip built up to between 3Nm and 14Nm. One foot was not in contact with the ground so the cable, at this point, was acting in a reciprocal fashion. Tension in the back cable should therefore drive hip extension. However, as the weight of the swinging hip was less than the weight of the trunk, this was unlikely to be the case. The swing leg continued to flex and it is likely that the back cable was acting as a retarding force on the swinging hip, possibly restricting the length of swing and slowing down gait speed.

The build up of force in the back cable during double support did not generally occur as one smooth motion, but rose to the maximum force in a series of peaks and troughs. Subjects with higher level lesions built up tension in the back cable in a smoother fashion than subjects with lower level lesions. It is assumed that subjects with lower thoracic level lesion placed less reliance on the use of the back cable during stance phase as this support could be periodically reduced, whereas subjects with higher level lesions relied on the back cable to support their hips far more. Hence back cable support was more continuous.

Maximum moment and percentage that cable force was above threshold were not related to the subject's age, lesion level or time since injury. Subject F, the only incomplete user, had been using the LSU-RGO for 11 years, 9 years longer than any other subject in the study, and was the only user to walk with crutches. She walked substantially faster than the other subjects and had a lower maximum moment in the back cable during stance than the other patients. It was impossible to conclude whether this difference in use of the back cable and speed of progression were due to the incomplete nature of subject F's

injury, to the length of time she had been using the orthosis, to the use of crutches as the walking aid, or to her own natural ability. Excluding subject F, maximum moment and percentage that cable force is above threshold were not related to length of time using the LSU-RGO, or speed of progression.

Conclusions

1. The front cable was not used to any effect in 4 out of 6 subjects.
2. There were two subjects that used front cable tension to assist hip flexion of the swing leg, but each used a different action to produce this assistance. Subject A used bilateral hip extension in double support to generate tension in the front cable. Subject E used hip extension prior to stance phase to assist swing hip flexion.
3. The maximum hip flexion moment induced by front cable tension was 5Nm; at best one eighth of normal hip moments.
4. The back cable was mainly used during double support to resist bilateral hip flexion to a maximum of 12Nm to 35Nm.
5. Tension was built up in the back cable during the latter part of swing phase, to between 3Nm and 14Nm, and may have restricted stride length.

It is suggested that the reciprocal linkage with respect to the front cable is not being used as expected, and that an orthosis providing the function of the back cable in double support and with no provision for front cable function will be as effective as the current LSU-RGO.

Acknowledgements

P. M. Dall was funded by the Medical Research Council.

B. Müller is funded by the European Union (TMR ERB-4001-GT-96-3830).

J. Edwards and I. Stallard were funded by the Dunhill Medical Trust.

The authors would like to thank the staff and patients of the Spinal Cord Injuries Centre, Southport for their help and support.

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Prosthetics and Orthotics International, 1999, 23, 163–168

Technical note

Preliminary clinical experience of a contracture correction device

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Abstract

Joint contractures which do not respond to conventional physiotherapy can be difficult to treat. Serial plastering has been used effectively but is expensive, inconvenient to the patient and does not permit daily hygiene or clinical inspection. A mechanical device has been developed consisting a hinged orthosis which spans the affected joint to which is attached a gas strut to provide a corrective moment about the anatomical joint. Such an arrangement enables prescribed corrective moments to be applied accurately following clinical assessment using routine physiotherapy techniques. The inherently low spring rate of a gas strut ensures that the specified corrective torque is maintained as correction occurs.

Initial treatment experience under the control of the developers had generated wider interest in the system. A geographically distant independent orthotic supply centre was trained in the techniques of application. They treated nine elbow and three knee joints in patients who had not responded to physiotherapy treatment. All of the patients experienced improvement. The average for elbow joints was a reduction in the contracture of 25.6° with a corrective moment of 6.8Nm over a period of 3.9 weeks. For the knee joints the averages were a reduction in contracture of 10.7° with a corrective moment of 12.7Nm over a period of 4 weeks.

The results confirmed the practicality of transferring the system to independent clinical centres and provide evidence to support funding for a formal prospective clinical trial of the treatment approach.

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Introduction

The treatment of joint contractures which do not respond to conventional physiotherapy stretching techniques creates problems which are sometimes difficult to overcome. Surgical intervention is not always an acceptable option and the inconvenience of serial plastering can make it impractical for some patients.

Stretching a joint contracture is very demanding of physiotherapy time and for some patients the resources required to achieve a successful outcome are beyond that which it is practical to make available. Orthoses with a turnbuckle have been provided to achieve stretching. Whilst these do apply a corrective moment to the joint it is not normally possible to control that with the sensitivity which a physiotherapist is trained to provide. Such devices are set in a fixed position until a decision is taken to adjust the turnbuckle to increase the stretch still further. Consequently any plastic change in patient tissue achieved by stretching the contracture with the turnbuckle diminishes the effectiveness of the device until adjustment to accommodate the improvement is made. Lively devices employing conventional springs across the orthotic joint have also been provided, but these are usually more bulky than patients would wish. The comparatively high rate of springs which can provide sufficient force in the limited space available also means that their effectiveness diminishes more quickly than is desirable (with changes in spring length) as the joint responds to treatment.

To overcome these problems a design has been developed which employs a gas spring to

provide the corrective moment (Butler *et al.*, 1988; Moore *et al.*, 1990). A gas spring (the device used on the tailgate of many family cars) has the advantage that it is very compact and produces a large force combined with a very low spring rate (i.e. the force deviates only slightly as the device changes in length). These properties make it particularly suited to the requirements of a mechanical device for correction of joint contractures. Recent developments in the supply of gas springs has led to convenient availability in a variety of force ratings, and also with an option for a release valve to permit pressure reductions to accommodate specific force requirements.

Moore *et al.* (1990) described a system in which a physiotherapist (or other appropriate clinician) specifies the corrective moment they wish to apply for stretching the contracture by estimating this with a force transducer and measurement of the moment arm of their input to the patient. The force transducer, fitted with a curved patient interface pad, has a range of 160N with a resolution of 2N and an accuracy of 5%. Moment arms for the physiotherapist force application are measured with a standard orthotists tape, calibrated to ISO9000 requirements. The corrective moment is calculated by multiplying the force by the measured moment arm.

Once the moment has been clinically specified an orthosis, hinged at the joint being treated, is manufactured which enables the selected corrective torque to be applied to the patient via location points at the thigh, the bottom of the shank and through a strap located just below the patella. Levers of standard design are attached to the metal side member of the orthosis. These provide location points for the gas spring on either side of the orthosis hinge and are arranged to ensure that the 20mm moment arm for the gas spring is only minimally affected by the magnitude of the contracture. An appropriate gas spring is then selected (and if necessary adjusted) to achieve the required moment through the lever arms. The geometrical arrangement which minimises changes of the moment arm with variations in the degree of contracture also ensures that corrections of the joint contracture under the influence of treatment do not significantly affect the corrective moment. A typical set up is shown in Figure 1.

When fitted, the contracture correction device (CCD) produces a constant moment against the contracture to achieve correction, in the absence of any voluntary muscle activity across the joint being treated. The clinically specified moment is normally at a level which the patient can voluntarily overcome for reasons of comfort or function. Unlike serial plastering the device can be removed so that it may be used for any prescribed period each day. This facility also permits it to be taken off for reasons of hygiene.

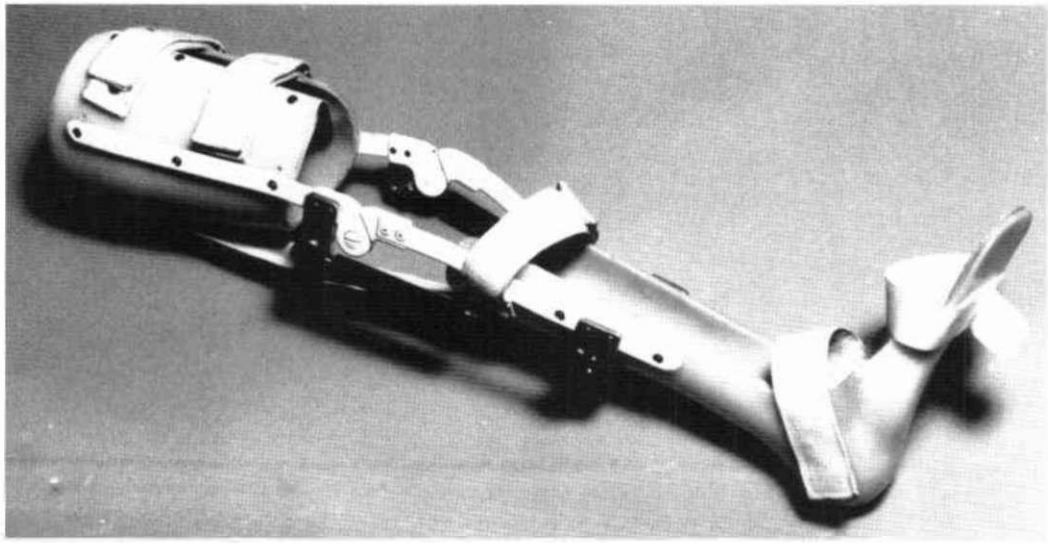

Fig. 1. A contracture correction device for a knee joint

Where a patient has loss of sensation the CCD allows regular inspection of skin in the area where the corrective moment is applied, so as to ensure the pressure sores or other adverse effects are not developing.

Initial clinical experience

Original development work was undertaken as specialist rehabilitation engineering for a girl with arthrogryposis. Physiotherapists were concerned that despite providing routine stretching therapy of both knees and hips for as long as practicably possible each day all of the contractures were continuing to increase. Her status as an independent ambulator was considered to be under threat as the increasing contractures were making it progressively more difficult to maintain that function. A device was produced which applied corrective moments simultaneously to knees and hips. This was used regularly each evening under the supervision of the child's parents. The results (Moore *et al.*, 1990) were better than anticipated in that not only were the contractures prevented from increasing still further (the original objective), significant correction in all treated joints was achieved.

Several additional *ad hoc* cases of knee contractures were subsequently treated as part of a routine clinical rehabilitation engineering service. Corrections were achieved in every case, but the improvement varied between patients. The magnitude of the corrective moments in all the cases treated within *ad hoc* rehabilitation engineering services varied from 7-10Nm. Successful local outcomes generated increased clinical interest in the potential of the device for patients with intransigent joint contractures. As a result a patient with an elbow contracture was referred for provision of rehabilitation engineering services. Assessment by the multi-disciplinary team ascertained that bilateral elbow contractures had occurred from unknown aetiology. The left elbow had responded to routine physiotherapy treatment, but the right elbow resisted that clinical approach and the patient was left with a residual flexion contracture of 105°. This severely restricted routine function and the patient was unable to perform many activities of daily living. Some anxiety was experienced in considering the potential of the CCD to achieve a successful outcome. Previous devices had used moments significantly higher than the 2Nm which was estimated as being clinically acceptable for an elbow joint. The patient was clearly well motivated and keen to proceed with treatment in the hope that she could undertake additional activities to enhance her role as the mother of a young family. As reported by Keeping and Major (1999) a successful outcome was achieved with a reduction of the contracture to 60° over a period of 18 months, after which the patient could undertake many routine activities which were previously impossible (e.g. pick up her young child, iron, tie her own shoe laces).

A review of the *ad hoc* clinical experience in supplying the CCD suggested that the technique could usefully be applied in a wider context. A decision was taken, therefore, to produce a prototype system which could be applied in different clinical environments and at distant geographical locations. When this was completed arrangements where made for a preliminary trial with a separate United Kingdom National Health Service (NHS) orthotics contractor to establish whether or not the initial experience could be replicated in an environment independent of the developers.

The prototype CCD system

Measurement of the appropriate corrective moment is an essential element of the system. A force gauge with the relevant range, which could be directly applied to the patient, and a tape measure for establishing the moment arm through which the clinician applies the input forces to identify the required moment was specified. A range of gas struts with appropriate force rating and length, and incorporating a pressure relief valve were identified. Standard orthotic hinges suitable for knees and elbows and with a suitable section for mounting the brackets for the gas strut to provide the appropriate lever arm were indicated. Training of orthotist staff from the participating company was undertaken so that they could select patients, monitor the required corrective moment in collaboration with a relevant clinician, specify the design of the CCD orthosis for manufacture in the workshop, verify its specification on delivery, fit the system and adjust to accommodate the patient.

Methods

The purpose of the preliminary trial was to establish whether or not the encouraging results achieved under the direct control of the developers (Moore *et al.*, 1990; Keeping and Major, 1999) could be repeated when the principles were applied independently in a routine clinical setting. When training of three orthotists from the selected contractor (JC Peacock Ltd) was completed they discussed the system's potential with orthopaedic surgeons and physiotherapists amongst their routine clientele. This led to the referral of 12 patients for which existing therapeutic regimes were not achieving reduction in contractures of their anatomical joints. The orthotists assessed patient requirements in collaboration with prescribing clinical teams and specified a CCD for each patient in accordance with the training which had been provided.

Prior to the commencement of treatment the degree of joint contracture was measured using a long arm goniometer. When the system had been produced to the specification provided by the orthotist the patients and/or their carers were instructed in application of the device. The referring clinician specified the regime to be followed by the patient. Arrangements for routine review were established and the degree of contracture was measured at each clinical visit. The trial continued for between 3 and 5 weeks for each patient. At the completion of the established regime the degree of contracture correction was calculated by subtracting the end result from the initial degree of contracture.

Results

Table 1 shows the joints treated, the corrective moment applied, the time over which the regime was conducted and the degree of correction achieved in each patient.

All the joints treated were either elbows or knees. A measurable degree of contracture correction was achieved in each of the patients. The magnitude of correction ranged from 7° to 43°. Applied moments ranged from 6Nm to 8Nm for elbows and 12Nm to 14Nm for knees. Treatment time was 3 to 5 weeks for elbows and 4 weeks for knees. Average results for all the joints treated were:

Elbows

Degree of correction = 25.6°
Applied moment = 6.8Nm
Period of treatment = 3.9 Weeks

Knees

Degree of correction = 10.7°
Applied moment = 12.7Nm
Period of treatment = 4 Weeks

Overall

Degree of correction = 21.8°
Applied moment = 7.4Nm
Period of treatment = 3.9 Weeks

Since many of the patients had developing contractures it was not possible to determine the length of time these had existed prior to the point when treatment was sought by the referring clinicans. However, it is known that some

Table 1. Results of preliminary trials of the contracture correction device

Patient	Sex	Age (yrs)	Pathology	Joint	Correction (degrees)	Moment (Nm)	Period (weeks)
A	M	37	Trauma	Elbow	27	6	4
B	M	10	CP	Elbow - left	20	7	4
				Elbow - right	35	7	4
C	F	58	CVA	Elbow	18	8	3
D	M	63	CVA	Elbow	43	7	5
E	F	10	CP	Elbow	10	7	5
F	F	34	CP	Knee	12	14	4
G	M	73	Trauma	Knee	10	12	4
H	M	27	Trauma	Knee	10	12	4
I	M	37	CVA	Elbow	7	7	4
J	M	41	Trauma	Elbow	30	6	3
K	F	8	CP	Elbow	40	6	3

contractures had been considered a problem for periods in excess of one year, whilst others had been recognised as such more recently than this.

Discussion

The outcomes achieved in a variety of conditions and patients over short treatment periods in contractures which had existed over a range of periods were encouraging. In none of the patients was there failure to achieve correction, though in one case the improvement was only just outside the resolution of the contracture measuring system. The preliminary trial was undertaken with close clinical control and patients were selected because it had not been possible to apply more conventional physiotherapy. Previous *ad hoc* experience with the system had suggested that success should be achieved, so the results were to be anticipated, particularly as the device merely provides a more convenient means of applying long established widely applied physiotherapy stretching practices. The most likely explanation for the success in patients for which it had not been possible to achieve correction previously is that the treatment can be applied over considerably longer periods than is practicable with a direct physiotherapy input.

It was noticeable that the torque applied to elbow joints (6-8Nm) was higher than the 2Nm previously reported (Keeping and Major, 1999). No significance should be attached to this difference which is a reflection of particular patient circumstances and individual clinical opinions. It is significant that estimations of appropriate torque for elbow joints is consistently lower than for knees.

There are some obvious parallels between the CCD and serial plastering. Both seek to apply a corrective moment by direct mechanical means. However, serial plastering is unable to maintain its corrective moment as contracture is reduced and has to be re-applied with the joint stretched to its new limit. This is inconvenient in that it requires the patient to re-attend the clinic, and it ties up valuable resources at the Hospital. Initial cost of a CCD is likely to be greater than that of a single application of a plaster. However, successive re-applications of a plaster is an expensive option, particularly if proper consideration is given to overheads and staff time. Lehmkhul (1992) reported that re-applications of plasters on an approximately 3 day cycle over a 3 to 6 week period was necessary to achieve effective correction. Re-application of plasters required two staff working for 1 to 1.5 hours. It is clear on that basis that CCD would, in comparison, be an economically viable option. The ability to specify periods of treatment each day also provides the possibility of the patient maintaining functional activity involving the limb with the affected joint when the device is removed. Daily hygiene and clinical inspection are also possible with a system which can be removed. Patient comfort is also likely to be enhanced by an ability to move the joint against the corrective moment in order to relieve cramp or cope with an unexpected functional requirement.

Conclusion

The main purpose of the trial has been vindicated in that similar clinical outcomes to those demonstrated by the developers have been achieved by a routine orthotic supply service working in collaboration with clinicans faced with difficult joint contracture problems. It was not intended at the current stage of development to establish a full prospective clinical trial of the treatment system. The limited ambitions of the project and the successful outcome are nevertheless an important step forward in providing the confidence needed to support any future proposals for a full prospective trial of the system.

Physiotherapists who routinely apply stretching techniques will recognise that the system does not propose radically new treatment options, but merely provides a more convenient means of maintaining their routines over longer periods. Serial plastering and the CCD are clearly analogous and any clinical condition for which serial plastering is contemplated is equally appropriate for the CCD. The consistency of the success achieved without complications is greatly encouraging and supports continuing clinical application of the system in situations where more conventional clinical options are not possible, or may be inappropriate.

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Prosthetics and Orthotics International, 1999, 23, 169–173

Technical note

RTV silicone elastomers in hand prosthetics: properties, applications and techniques

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Abstract

In this technical note, an overview of RTV (room-temperature-vulcanising) silicone elastomers is provided. The properties and applications of 3 different types of RTV silicones in producing prostheses for the hand are discussed. Vinyl polysiloxanes are excellent silicone impression materials that offer the advantages of a rapid cure, near exact duplication of fine details and ease of removal of the cured impression without permanent deformation. RTV-2 dimethyl polysiloxanes are ideal for mould-making and fabricating prostheses given their favourable qualities that range from ease of pigmentation, adjustable consistency, manageable curing rate and accuracy in recording fine details in the liquid state to excellent stain-resistance, elasticity and biodurability in the vulcanised state. RTV-1 dimethyl polysiloxanes are self-curing, ready-for-use silicones that adhere adequately well to most substrates and are useful for extrinsic hue modifications and waterproofing of the prosthesis. The basic techniques for each of these applications are also discussed.

The cure-inhibition of addition-curing RTV silicones by sulphur-, tin- and nitrogen-containing contaminants and its damaging consequence is highlighted. A compilation of known contaminating agents is provided so that prior contact with these objects can be avoided when working with addition-curing silicones. The precautionary measures to prevent the problem are also outlined.

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Introduction

Silicone elastomers, because of their unique combinations of qualities, have expanded the armamentarium available to prosthetists and added to the quality of rehabilitation for many patients. Silicone elastomers are now being used to produce roll-on suction sockets for both lower and upper limb prosthetics, prostheses for the upper limbs and maxillo-facial region, in addition to insoles in podiatry. However, many practitioners are inadequately familiar with silicone materials and their fabrication techniques, particularly as applied to hand prosthetics. There are several reasons for the unfamiliarity. Firstly, silicone products are readily available from established manufacturers without the need for the practitioner to be directly involved with their fabrication. Secondly, prosthetic programmes offered by educational institutions worldwide do not normally include laboratory instruction on the fabrication of aesthetic upper limb prostheses which must include silicone as a material of choice. Thirdly, the number of published reports on the exploitation of silicones in prosthetics did not seem to match their application growth in this field. However, the future will likely see a continued widespread use of silicones in prosthetics and present a challenge to the general practitioners to broaden their scope of capabilities to include silicone impression/fabrication techniques.

The authors have worked with the various grades of silicones over the past 11 years in the course of developing and fitting hand and finger prostheses (Leow *et al.*, 1998, 1997 and 1996; Pereira *et al.*, 1996). Despite their many qualities, a sound understanding of the physical properties and manipulative variables of silicone

materials is essential in achieving predictable results. This technical note is intended to: 1) provide an overview of RTV (room-temperature-vulcanising) silicones; 2) discuss the properties and applications of 3 different types of RTV silicones in hand prosthetics and the techniques for each of their application; and 3) highlight the cure-inhibition of addition-curing RTV silicones by sulphur-, tin- and nitrogen-containing contaminants and outline precautionary measures to prevent the inhibition problem.

Types of RTV silicones: an overview

The name silicone denotes polymer having the formula:

$$(R_nSiO_{(4-n)/2})_m$$

where n=1-3 and m ≥2 (Kroschwitz and Howe-Grant, 1997). It contains a repeating silicon-oxygen backbone and has organic groups, R, attached to a significant proportion of the silicon atoms by silicon-carbon bonds. In dimethyl polysiloxanes, the largest group of commercial silicones used in the industry and in medicine (including prosthetics), most of the R groups are methyl, thus their common name methyl silicones. In vinyl polysiloxanes or vinyl silicones which are widely used as a dental impression material, vinyl groups are substituted to improve the vulcanisation characteristics.

RTV silicones can be divided into the *two-component* (RTV-2) and *one-component* (RTV-1) type in respect of their curing systems (Hechtl, 1991). As their name suggests the curing process for RTV-2 silicones is initiated when the base material is mixed with a catalyst, the two components being supplied separately. Vulcanisation proceeds evenly throughout deep sections. The curing time a 24°C is generally of the order of hours. In contrast, RTV-1 silicones cure by themselves on exposure to atmospheric moisture. They are packaged in airtight tubes or cartridges in pourable to soft paste consistency. Curing starts from the surface and progresses inwards to the material. The time taken for a complete cure depends on the thickness of the section and ambient humidity. At 24°C and 50% relative humidity, their surfaces will become tack free in 20-30 minutes. The basic properties of cured RTV-2 and RTV-1 are essentially similar despite their different curing mechanisms.

RTV-2 silicones are subdivided into 2 types, namely *addition-curing* and *condensation-curing* type (Kroschwitz and Howe-Grant, 1997; Hechtl, 1991). In addition-curing silicones, reaction is with vinyl end groups of the polymer by addition with no formation of by-products during curing. Vulcanisation can proceed in a closed system with the vulcanate being resistant to reversion – rapid vulcanisation is possible at high temperatures. The commonly used catalysts are platinum and chloroplatinic acid. In condensation-curing silicones, vulcanisation occurs by reaction of the hydroxyl end groups of the polymer with a crosslinking agent (e.g. silicic-acid esther) by condensation and release of a volatile by-product (e.g. ethyl alcohol). The reaction is catalysed by a tin catalyst such as dibutyl tin dilaurate. If vulcanisation occurs in a closed system, a reversal of reaction (refluidisation) will result from the heat released. Curing rate depends primarily on the amount of catalyst used.

RTV silicones in hand prosthetics: properties and techniques

The authors have used 3 different types of RTV silicones in the different stages of producing prostheses for the hand. The section that follows discusses their properties and manipulation in relation to each of these applications and the basic techniques involved. While the grades within each of these types of silicone can be numerous, the techniques are essentially similar.

Vinyl polysiloxanes – for impression taking

Vinyl polysiloxanes are a class of quick-vulcanising addition-curing RTV-2 silicones widely used by dentists for taking impressions of the oral cavity. Their curing times at 24°C is in the range of 6-8 minutes (Craig *et al.*, 1996). The base material and the catalyst are supplied in separate tubes in a number of viscosities ranging from putty-, regular- to injection-type. Manufacturers often add opaque pigments to the base or catalyst to aid in evaluating the completion of mixing.

In upper limb prosthetics, the creases and the fine details of the hand are important aesthetic features that need to be faithfully reproduced. One method of achieving this in finger prostheses is to use the impression of the corresponding digits of the patient's

contralateral hand. For partial and total hand prostheses, the impression of a suitable "donor" hand can be used. The authors have exploited this method successfully using vinyl polysiloxane impression materials (Leow *et al.*, 1998 and 1997; Pereira *et al.*, 1996).

Although manufactured for dental applications, 3 properties of vinyl polysiloxanes make them ideal for taking the impression of the hand: 1) they can readily reproduce a V-shape groove with a width of 0.025mm (Craig *et al.*, 1996); 2) they cure quickly and thus shorten the time for impression taking process; and 3) the cured material is sufficiently supple to allow easy removal without permanent deformation – although the cured impression is somewhat stiff compared to the more elastic methyl silicones, this rigidity is nowhere near that of a plaster cast.

The impression taking technique involves mixing *equal* amounts of the base and catalyst on a mixing pad and applying it on the hand with a spatula to a thickness of about 2-3mm. A noteworthy disadvantage with this material is the opacity which precludes the viewing and immediate assessment of the impression results. Nonetheless, any air voids which may be introduced at the skin-material interface during the impression taking process will be recorded alongside the fine details of the skin in the impression mould, from which a model of the hand is made for defect rectification.

When using a fast-curing impression material, the working time available for the impression taking process becomes a critical consideration. The working time can be defined as the time (from catalysis) within which the mixture can be transferred and applied onto the subject (Craig *et al.*, 1996). With the standard use of two grades of vinyl polysiloxanes (Dent Silicone-V, Shofu Inc., Japan; Zerosil-light, Dreve-Dentamid GmbH, Germany), the working time available (2-3 mins. at 24°C) is generally sufficient to complete the impression of the digits. However, when working on the hand having a larger surface area, working time needs to be extended. This can be achieved by: 1) refrigeration of the material prior to use; 2) addition of a retarding agent to the material during mixing (Dent Silicone-V Retarder, Shofu Inc., Japan).The combined application of these two factors has been found to provided a longer working time than obtainable from both their individual effects (Leow, 1993). However, even with the increased working time, the impression of the hand is usually completed in 2 to 3 stages or sections.

RTV-2 dimethyl polysiloxanes – for mould-making and prosthesis-fabrication

The elasticity, stability and anti-staining properties of RTV-2 methyl silicones and their ability to replicate minute details make then widely popular in prosthetics. Two grades that have been used by the authors include the KE1300T silicone (Shin-Etsu Chemical Co., Ltd., Japan) and 617h43 silicone gel (Otto Bock, Germany), both of which addition-curing silicones. When used for making moulds and fabricating prostheses, these silicones offer the following versatility: 1) they are often supplied in clear viscous liquids and thus can be easily pigmented to match the wide range of skin tones; 2) their curing process is initiated upon addition of the catalyst and therefore can be timed after the colour-matching process is completed; 3) their slow curing rate allows sufficient time for the catalysed mixture to be degassed to remove air bubbles prior to moulding; 4) their curing rate can be hastened by oven-curing to meet tight work schedules; and 5) they can be made less viscous and pourable by the addition of silicone oil or organic solvents such as 111-trichloroethane and trichloroethylene. Silicone oil, which would remain in the cured material and reduce the tear strength of the silicone, may be used for mould-making purposes. However, in applications in which physical properties cannot be compromised, such as when moulding a prosthesis, the use of the volatile organic solvent (which will all evaporate) is recommended.

When making moulds, the authors suggest tinting the clear silicone material blue. This will serve to make conspicuous, against blue contrast, any air bubbles which may be entrapped in the material during the moulding process. The material is applied on the finished hand model using a spatula, spread evenly with an air jet and rotation-moulded on a single axis rotary fixture to maintain even thickness and left to cure at room temperature.

When used to fabricate a prosthesis, a very thin coat of release agent (e.g. petroleum jelly) is first applied on the internal surfaces of the cured silicone mould. The colour-matched liquid silicone (after degassing) is poured into the

hollow mould which is then inverted to drain off the excess material, leaving behind a thin layer of silicone adhering to the inner surfaces. The silicone layer is cured to a solid but supple prosthesis and withdrawn from the mould.

A significant drawback of silicones lies in their poor tear strength which, depending on grades, ranges 14-27kg/cm, die B (Lynch, 1978). For prosthetic application, tear strength can be increased by reinforcing the prosthesis with nylon fabric where it is prone to tearing, such as the proximal section which is subject to repeated stretching during donning and doffing. Reinforcement can be achieved by lamination of the fabric between silicone layers. For a strong reinforcement, the moulding mixture must be fluid enough to permeate the intricate mosaic of fibres and pores of the fabric

RTV-1 dimethyl polysiloxanes – for finishing prostheses

RTV-1 methyl silicones are ready-for-use, self-curing silicones widely used in the industry as sealants, adhesives and coating agents. The time-consuming process of colour-matching that would expose the material to atmospheric moisture and trigger the curing process makes them unsuitable as a base material for fabricating prostheses. However, because of their self-curing property and good adhesion to substrates as varied as wood, glass, masonry, metals, plastics and all types of silicones, RTV-1 methyl silicones are useful when finishing a prosthesis. The clear soft paste grades can be pre-mixed with colour pigments and used to render subtle shades extrinsically on a completed prosthesis to camouflage minor colour discrepancies. They can also be used to seal and waterproof the foamed material used to fill the hollow segment of the prosthesis – keeping a prosthesis dry at all times is important in preventing fungal growth (Leow *et al.*, 1997). Another advantage is that small amounts of the material usually needed for these thinly coated finishings can be readily dispensed and cured.

Cure inhibition of addition-curing RTV silicones

A property peculiar to addition-curing RTV silicones is their susceptibility to cure-inhibition by sulfonates, amines, urethanes, unsaturated hydrocarbon plasticisers, organometallic salts and materials containing sulphur, tin and nitrogen (Hechtl, 1991; Lynch, 1978). When addition-curing silicones come into contact with these materials, the curing process is inhibited, leaving an uncured or tacky surface at the contaminated areas. the cure-inhibition is caused by the "poisoning" of the platinum catalyst by the contaminants which impairs the crosslinking process necessary for full vulcanisation.

Despite its detrimental effect, documentation on the subject of cure-inhibition of addition-curing silicones has been scarce and brief, even in textbooks on silicone technology.

More deserving attention was confined to dental literature but these reports concerned only vinyl polysiloxane impression material, with latex gloves being solely incriminated as the contaminating agent (Browning *et al.*, 1994; Kahn and Donovan, 1989). The fact that RTV-2 methyl silicones, widely used for mould-making and fabricating prostheses, are equally susceptible to cure-inhibition cannot be overstated. A completed prosthesis so affected would have to be rejected as no subsequent attempts can cure it into a resilient rubber.

Unfortunately, since it is frequently not possible to tell the chemical contents (e.g. as sulphur-containing) of the objects around from the outset, a contaminating agent is often identified only after a cure-inhibition has occurred. A beneficial contribution would therefore be a compilation of a list of known contaminating agents so that prior contact with these objects can be avoided when working with addition-curing silicones. Many commonly used items are unsuspecting menaces that loom large in a laboratory. Based on the authors' experience and printed information from two leading silicone manufacturers, some common contaminating agents include:

(i) soft PVC tapes (adhesive side);
(ii) masking tapes (adhesive side);
(iii) modelling clay containing sulphur;
(iv) neoprene;
(v) polyesters;
(vi) plastics containing residual plasticisers;
(vii) RTV silicones containing organo-tin catalyst;
(viii) latex gloves;
(ix) vinyl gloves;
(x) rubber bands;
(xi) ink erasers and any such rubbery items.

New contaminating agents can be added to the list as and when they are discovered. As an

added insurance against a potential cure-inhibition, the following precautionary measures should be observed working with addition-curing RTV silicones:

1. a pre-test to ascertain full care is recommended whenever new modelling material is to be used;
2. use a clean brush when applying release agent on models or moulds;
3. use disposable vinyl or polyethylene gloves – latex and vinyl gloves are forbidden;
4. if bare hands are to be used to handle models, be mindful of any prior contact with known contaminating agents (e.g. hands that had previously worn latex gloves!);
5. as an added protection, wash hands thoroughly with washing liquid;
6. discard any contaminated models or moulds and start anew – do not wash and re-use.

When a cure-inhibition has occurred, it is important to identify and eliminate the source of the contamination so that it is not carried onto the subsequent procedures. Although thorough washing of the contaminated surfaces reduces the extent of the problem, the contaminants are extremely stubborn and difficult to remove completely. It certainly helps to know that just a minute amount of contaminant is sufficient to produce a damaging effect.

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Prosthetics and Orthotics International, 1999, 23, 174-180

Technical note

Metamerism in aesthetic prostheses under three standard illuminants – TL84, D65 and F

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Abstract

This study looks at the effect of metamerism in colour-matching and the assessment of multi-layered silicone rubber finger prostheses. The aim was to identify the choice of illuminants for colour matching the prostheses that would give rise to the least metameric effect between the prostheses and the human skin or the best colour match. The prostheses were prepared and colour matched to a fair-skinned subject under 3 reference illuminants – TL84, D65, F and a combination of illuminants – TL84, D65 and F. The prostheses were then measured for colour using a spectrophotometer based on the CIE indices L^*, a^*, b^* with each prosthesis assessed separately against the subject's index finger under the reference illuminants – TL84, D65 and F. The prostheses were also assessed by a panel of 50 observers and scored according to colour-match. Colour differences between the skin and prosthesis were measured in the illuminant under which the prostheses were prepared and then under the other reference illuminants. A relationship was obtained between the measured mean colour difference, ΔE^*, and the mean visual assessment score for each prosthesis. This paper points out the concerns related to the optical phenomenon of metamerism with the colour pigments used. This can affect the colour match of the prosthesis as perceived by the patient. The findings seem to suggest that this metameric colour difference can be minimised if the prosthesis is matched under a combination of lights, which were found to give the best-perceived match.

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Introduction

In the restoration of the upper limbs and maxillofacial region with aesthetic prostheses, an accurate colour reproduction is always crucial to acceptance and use. However, the quality of the colour match can differ when viewed under different light sources. Most often a good colour match between the prosthesis and the skin obtained under one light source may not have similar match under a different light source. This is attributed to the difference in the pigments present in the skin and in the prosthesis. This optical phenomenon, whereby the reflectance spectrum of objects with dissimilar pigment contents changes under different illuminant, is known as metamerism (Judd and Wyszecki, 1975).

The colour of human skin is mainly characterised by five pigments interspersed within its stratified architecture (Anderson and Parrish; 1981; Williams and Warwick, 1980; Agache *et al.*, 1989; Leow *et al.*, 1996). They are melanin (brown), melanoid (brown), and carotene (yellow to orange) in the dermis layers, and the haemoglobin (purple and bluish-green) and oxyhaemoglobin in the vascular system. Prostheses are usually coloured using synthetic pigments. When a colour reproduction of a prosthesis is matched against the skin of the patient, the prosthetist attempts to adjust the amount and type of pigments used with the prosthetic base material until what he sees or, the reflectance spectrum, is similar to that of the skin. That is, under the illuminating light source, a colour match would be reached when the same wavelength of light is reflected from both matching surfaces. When different illuminants are used, the same prosthesis and skin surfaces may give a different reflectance spectrum,

resulting in metameric colour differences.

Menough (1986) suggested that metamerism can be reduced by colour-matching objects under 3 separate light sources, viz, artificial daylight, white-light and yellow light, all of which are the more common household or office light sources. However, achieving a good match under 3 separate light sources would be too precarious and time consuming. A review of the literature failed to identify any study on metamerism in aesthetic prostheses under different light sources. This is expected as prosthetic developments worldwide have been preponderantly focused on the functional rather than the aesthetic aspects of physical loss.

This study compared the colour differences in multi-layered silicone rubber finger prostheses under 3 reference illuminants. The colour reproduction is based on a fair-skinned individual. The aim was to identify the choice of illuminants for colour matching the prostheses that would give rise to the least metameric effect between the prostheses and the human skin or the best colour match.

Material and methods

Preparation of sample prostheses

Moulding and prosthesis design: Four (4) finger prostheses (Fig. 1) were made from the same master negative impression mould of the left index finger of the Subject C (NKM). Each prosthesis was moulded with an outer translucent layer and an inner opaque layer of silicone rubber. Colour pigments (Cosmesil, Cosmedica Ltd, UK) were intrinsically mixed into clear liquid silicone elastomer (Cosmesil, Cosmedica Ltd, UK) prior to moulding. A layer of coloured touch-ups between the two layers of silicone was added to impart a life-like appearance to the prosthesis. This technique of colouring prostheses is based on the multiplier anatomy and optical characteristics of the human skin (Leow *et al.*, 1997; Pereira *et al.*, 1996).

Colour-matching and standard light sources: Colour-matching of the prostheses was carried out in a standardised colour-matching/ assessment cabinet (Verivide, Leslie Hubbell Ltd., UK) under 3 reference illuminants as standardised by the Commission Internationale de l'Eclairage (CIE). The three reference illuminants used were "TL84" or whitelight (colour temperature of 4400K); "D65" or artificial daylight (colour temperature of 6500K); and "F" or yellow light (colour temperature of 2000K) (also known as CIE illuminant "A"). The assessment cabinet also allowed for simultaneous operation of the 3 illuminants and hence the 4 prostheses were colour-matched under this condition. The illumination levels measured by a Luk-meter for TL84, D65, F and the combined illuminations were 2100, 1540, 1500 and 4880 lux, respectively. The intensity of the ambient light outside the cabinet was recorded at 634 lux.

Fig 1. The spectrophotometric unit used for assessing the colour match results and the four prostheses which were prepared under illuminant TL84, F, D65 and a combination of TL84-F-D65.

The same prosthetist (MELL) who has been fabricating and colour-matching custom-made prostheses over the last 10 years, did all colour-matching steps. The colour hue was adjusted by varying the amount and the type of pigments used. The degree of opacity of the silicone layers was controlled by varying the volume of pigments to the base material. For a translucent layer, a density of 0.15ml of pigments per 10g of silicone rubber was used. For an opaque layer, it ranged between 0.5 to 1.0ml of pigments per 10g of silicone rubber.

Table 1. L^*,a^*,b^* values (under D65 light source) and colour formulation of the inner and outer layers of the prostheses. The colour for the outer layer was similar for all 4 prostheses while that for the inner layer varied according to the colourmatch under the given lighting conditions.

Prosthesis	Type of lighting used for colour-matching	Mean (SD) L^*, a^*, b^* values under D65 light source				Colour pigments used to obtain the L^*,a,b^* values (ml / 1kg of silicone rubber)							
		Layer	L^*	a^*	b^*	#1	#2	#3	#4	#5	#6	#7	#8
1	TL84 (White light)	Outer	79.00 (0.04)	9.56 (0.06)	24.71 (0.11)	5	8	2	–	–	–	–	–
		Inner	56.44 (0.37)	12.87 (0.08)	23.06 (0.09)	60	12	5	–	2	–	–	–
2	D65 (Daylight)	Outer	79.00 (0.04)	9.56 (0.06)	24.71 (0.11)	5	8	2	–	–	–	–	–
		Inner	56.81 (0.09)	7.91 (0.07)	25.55 (0.03)	50	–	–	40	6	–	–	–
3	F (Yellow light)	Outer	79.00 (0.04)	9.56 (0.06)	24.71 (0.11)	5	8	2	–	–	–	–	–
		Inner	53.75 (0.13)	20.33 (0.04)	11.47 (0.02)	–	–	–	–	30	31	115	32
4	Combined (TL84-D65-F)	Outer	79.00 (0.04)	9.56 (0.06)	24.71 (0.11)	5	8	2	–	–	–	–	–
		Inner	57.98 (0.11)	12.29 (0.09)	21.18 (0.06)	60	–	4	5	–	–	7	–

Pigment used:
#1 –Basic Medium Brown; #2 –Basic Yellow;
#3 –Master Brown; #4 –Master Yellow;
#5 –Master Blue; #6 –Master Sienna;
#7 –Master White; #8 –Master Red.

The 4 prostheses were colour-matched to Subject C's index finger under different reference illuminants. Extraneous light was excluded during the colour-matching processes. The colour formulation for the inner opaque silicone layer was achieved from previous trials (Leow *et al.*, 1996 and 1997) such that when laminated with the outer translucent layer, the composite colour of the prosthesis matched the left index finger of Subject C. The colour for the outer translucent silicone layer was the same for all 4 prostheses (Table 1).

CIE 1976 (L^*,a^*,b^*) colour standardisation of layers: The colour of the silicone layers was measured and recorded in L^*, a^* and b^* values using a tristimulus colorimeter (Chroma Meter CR-300, Minolta, Tokyo, Japan) under a D65 light source (Fig. 1). This was done to standardise the colour and hue of the layers used in the prostheses (Table 1). Under the CIE, 1976 L^*, a^*, b^* Colour Scales, a colour measurement in the $+a^*$ direction indicates a shift towards red in the spectrum while - a^* measurement indicates that the colour shifts to green in the spectrum (Table 2). A $+b^*$ measurement is a shift towards the yellow end while a - b^* is a shift towards blue. The L^* measurement gives the lightness value of the colour with L^*=100 representing purest white L^*=0 represents the deepest black.

Assessment of the colour match of sample prostheses

Quantitative spectrophotometer measurement: A spectrophotometer (CM-508d, Minolta, Tokyo, Japan) was used to measure the colour differences of each of the completed prostheses against the index finger of the subject under the 3 reference illuminants. Measurement under the combination of the 3 reference illuminants was not possible with this system and hence was not included in this study. The L^*, a^* and b^* values recorded by the spectrophotometer were based on the reflectance spectrum of the dorsal skin of the digit and by matching the same area on the prosthesis, under the given illuminant. Three readings were taken for each sample, within an area of radius 5 mm. The size of the colour difference, ΔE^*, between the prosthesis and the skin would give an indication of the accuracy of

Table 2. A reference table of the attributes in the differences in the CIE colour co-ordinates.

Difference in CIE colour co-ordinates		Attribute characteristics
ΔL^*	Increase	Darker shade
	Decrease	Lighter shade
Δa^*	Increase	More red
	Decrease	More green
Δb^*	Increase	More yellow
	Decrease	More blue

the colour match. ΔE^* is calculated by the equation:

$$\Delta E^* = \sqrt{(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2}$$

where ΔL^*, and Δb^* are the respective differences between the prosthesis and the index finger of the subject. In short the smaller the ΔE^* the better the colour-match.

Visual assessment: A total of 50 observers from various occupational backgrounds participated in the visual assessment of the prostheses. Individuals with a history of a defective colour vision were excluded from the study. All visual observations were made within the colour-matching/assessment cabinet (Verivide, Leslie Hubble Limited, UK). The colour discrimination of the prostheses against the subject's finger was ranked and scored between a scale of 1 to 10 for each of the reference illuminants. Sufficient time was given to allow for the observers to adapt to the light source. Each prosthesis was placed adjacent to the left index finger of the subject during the visual assessment and ranking.

Results

Colour difference measurement under reference illuminants using the spectrophotometer

The L^*, a^* *and* b^* values assessed under the 3 different reference illuminants, on equivalent areas of the dorsal skin of the standard subject's index finger and the 4 prostheses were taken and summarised in Table 3a. The mean CIE colour differences ΔL^*, Δa^*, Δb^* and ΔE^* between the subject index finger and each prosthesis were calculated (Table 3b). An Analysis of Variance (ANOVA, α=0.05) with a Scheffe post-hoc multiple range test was done to test these colour differences in the prostheses prepared and assessed under the 3 reference illuminants.

Prosthesis colour-matched under TL84: The prosthesis prepared under TL84 was measured to have a smaller colour difference under TL84 (ΔE^* = 2.51) and D65 (ΔE^* = 2.53) than F (ΔE^* = 3.69). The Δa^* increased under illuminants D65 and decreased under F. The Δb^* was also higher under F. This means that the prosthesis compared to the skin was measured to be more red under D65 but more greenish-yellowish shade under F.

Table 3a. Mean spectrophotometry L^*, a^*, b^* values measured under the three reference illuminants were taken from an equivalent area on the dorsal side of the finger and the prosthesis.

	Assessed under different illuminants								
	TL84			D65			F		
	L^*	a^*	b^*	L^*	a^*	b^*	L^*	a^*	b^*
Standard - (subject's dorsal skin on the finger)	58.81	14.71	21.78	57.83	10.90	18.26	60.17	17.25	20.39
Prosthesis 1 (TL84)	57.36	12.66	21.80	56.00	12.44	19.09	58.55	14.94	22.77
Prosthesis 2 (D65)	57.77	11.17	21.89	56.42	11.40	19.26	58.87	13.85	22.81
Prosthesis 3 (F)	56.49	15.26	18.56	55.23	14.78	16.11	57.91	17.28	20.28
Prosthesis 4 (TL84-D65-F)	57.80	13.51	21.58	56.38	13.28	18.85	59.03	15.67	22.76

Table 3b. The mean CIE colour determinants differences ΔL^*, Δa^*, Δb^* values of prosthesis prepared under different illuminants compared to an equivalent area on the standard subject's dorsal skin. The mean colour difference, ΔE^*, was calculated based on the assessment done under the three reference illuminants.

	Indices based on assessment under reference illuminants											
	TL84				D65				F			
Prosthesis prepared under different illuminants	ΔL^*	Δa^*	Δb^*	ΔE^*	ΔL^*	Δa^*	Δb^*	ΔE^*	ΔL^*	Δa^*	Δb^*	ΔE^*
Prosthesis 1 (TL84)	-1.45	-2.05	+0.02	2.51	-1.83	+1.54	+0.83	2.53	-1.62	-2.31	+2.38	3.69
Prosthesis 2 (D65)	-1.04	-3.54	+0.11	3.69	-1.41	+0.50	+1.00	1.80	-1.30	-3.40	+2.42	4.37
Prosthesis 3 (F)	-2.32	+0.55	-3.22	4.01	-2.60	+3.88	-2.15	5.14	-2.26	+0.03	-0.11	2.26
Prosthesis 4 (TL84-D65-F)	-1.01	-1.20	-0.20	1.58	-1.45	+2.38	+0.59	2.58	-1.14	-1.58	+2.37	3.07

Prosthesis colour-matched under D65: The prosthesis prepared under D65, had the lowest overall colour difference when measured under D65 light (ΔE^* = 1.80) as compared to assessment under TL84 (ΔE^* = 3.69) and F (ΔE^* = 4.37). The Δa^* was lower under TL84 but higher under F while the Δb^* was higher under both illuminants TL84 and F, more under F. This means that the prosthesis was measured to have a little greenish shade (Δa^*=-3.54, Δb^*=+0.11) under TL84 with a more greenish-yellowish shade (Δa^*=-3.40, Δb^*=+2.42) under F.

Prosthesis colour-matched under illuminant F: For this prosthesis, the spectrophotometric colour difference was the lowest under F (ΔE^*=2.26) then under TL84 (ΔE^*=4.01) and D65 (ΔE^*=5.14). The prosthesis was measured to have a more reddish-bluish shade (Δa^*=+0.55, Δb^*=-3.22) under TL84 and even more reddish shade (Δa^*=+3.88, Δb^*=-2.15) under the D65.

Prosthesis colour-matched under the combined illuminants of TL84-D65-F: The prosthesis colour-matched under the combined illuminants was best assessed under TL84. In fact, overall, between this prosthesis and the subject's actual finger the ΔE^* was lowest (=1.58) although under D65 the prosthesis was measured to have a more reddish shade (Δa^*=+2.38, Δb^*=+0.59).

Visual assessment of the prosthesis

A summary of the aggregate mean qualitative scores of the prosthesis under 3 reference illuminants and based on visual assessment by 50 observers is shown in Table 4. The prosthesis that was prepared under the combined light source was ranked highest by the observers when assessed under TL84 (aggregate score = 8.28, SD=1.22). The mean scores for the assessment were significantly higher (ANOVA; F=7.75, p=0.001) when the prosthesis was assessed under the same light in which it was prepared.

The mean visual scores were compared against the colour difference, ΔE^* measured by the spectrophotometer (Fig. 2).

Discussion

The common reported causes of colour discrepancy in digital prostheses are due to changes in blood volume arising from changes to the position of the hand, the ambient temperature and to skin tones from sun-tanning. During the 2-month period over which the study was done, the subject made special efforts to maintain minimal outdoor activities so as to reduce the influence of tanning and its effect on the colour of the skin. The authors note that the more significant cause of colour discrepancy resulted from the effect of metamerism (Kovan *et al.*, 1981; Leow *et al.*, 1996). Often patients complain that their prosthesis, which has been well-matched to the colour of their skin under the office light source, would seem to have lost its colour match under natural daylight. This study demonstrates this effect comparing the visual assessment by a random group of observers to colour difference measured by a spectrophotometer.

The authors found that assessment under illuminant F had the skin always appearing to be darker with a more reddish shade, such that the prostheses when matched to the skin under F, would appear more red and blue when assessed under the other light sources, like daylight. Prostheses that were prepared and assessed

Table 4. Summary of the mean (SD) qualitative scores of the visual ranking by the panel of observers (n=50). The observers were asked to rank between 1 and 10, the colour difference between the standard subject's finger and the prosthesis that were prepared under the different reference illuminants.

Prosthesis prepared under	Aggregate mean (SD) qualitative score		
	Visual assessment of prosthesis under the reference illuminants		
	TL84	D65	F
1 (TL84)	8.00 (SD, 1.11) [a]	6.20 (SD, 1.74) [b]	5.73 (SD, 1.81) [b]
2 (D65)	7.03 (SD, 1.58) [b]	7.55 (SD, 1.41) [b]	2.93 (SD, 1.85) [c]
3 (F)	5.90 (SD, 1.57) [b]	5.53 (SD, 1.41) [b]	8.05 (SD, 1.18) [a]
4 (TL84-D65-F)	8.28 (SD, 1.22) [a]	7.33 (SD, 1.58) [b]	6.05 (SD, 1.41) [b]

The superscript indicates the homogenous subsets (a-c) from a Scheffe post-hoc multiple range test based on a ANOVA, F=39.472, p<0.001.

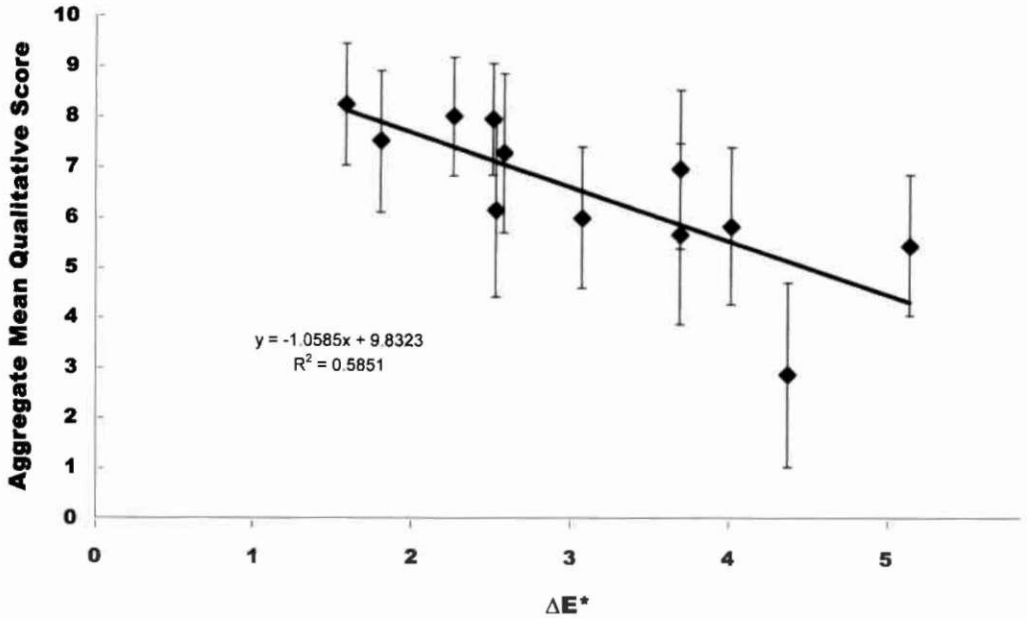

Fig 2. The prosthesis colour matched to the standard subject's index finger under TL84, D65, F and the combination of TL84-D65-F, was assessed by a panel of observers. The visual assessment was scored between 1 to 10 for its colourmatch and measured for its colour difference with a spectrophotometer using the CIE index of L^*, a^*, b^*. Assessment of the prosthesis against the finger was done under 3 reference illuminants – TL84, D65 and F. This graph shows the relationship between the aggregate mean qualitative score from the visual assessment against the CIE colour difference index, ΔE.

under the same light source as compared to assessment under different light sources were found to have a lower ΔE. (The ΔE^* were 1.80 for D65, 2.26 for F and 2.51 for TL84, in ascending order). However, the lowest ΔE value was the prosthesis that was matched under combined light and assessed under illuminant TL84 ($\Delta E^* = 1.58$).

The authors were not able to quantitatively measure the colour-match under the combined light source, but the findings suggest that a prosthesis prepared under a combined light source appeared to have the best match. Both the spectrophotometric and the qualitative assessment by the panel, indicated that the prosthesis prepared under a combined light gave the best results when assessed under illuminant TL84.

The results of this study may be specific to the pigments used in this study and cannot be generalised for other prosthetic pigments. This paper simply points out the concerns related to the optical phenomenon of metamerism with the colour pigments used (Cosmesil™) which can affect the colour match of the prosthesis as perceived by the patient. The findings seem to suggest that this metameric colour difference can be minimised if the prosthesis is matched under a combination of lights, which were found to give the best perceived match.

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Book Review

Who is amelia? Caring for children with limb deficiencies
Hugh G. Watts, Mary Williams Clark
The American Academy of Orthopaedic Surgeons
Illinois, USA, 1998
ISBN 0-89203-179-4, pp59

The preface makes it clear that this small volume is not intended to be a complete guide to prosthetics but is addressed to orthopaedic residents to make them familiar with the principles involved in the care of children with limb deficiencies.

The authors use an attractive format, consisting of case histories (each given an appropriate and amusing name), followed by "Issues to Ponder" which ask specific questions about the case, and "Comments" which are the teaching material. The first chapter includes two examples for which amputation is required, and the comments deal with the choice of level and the importance of considering the relative growth of the various epiphyses. Chapter 2, entitled "A pedantic overview", considers those features which differentiate child amputees from adults. It deals with these comprehensively, though one might mention that phantom sensation (and even mild pain) does occur in a small number of children with congenital deficiency. The third chapter includes another 11 case histories and looks at associated anomalies and syndromes. It does this very adequately, though I am sorry that Radia's sister, U(1)na de Fissionsea, was omitted!

The fourth chapter gives succinct advice to the resident on how to deal with the family – and I would recommend that any care provider who is likely to be involved with a neonatal child who has a limb deficiency should read, mark, learn and practice this excellent advice.

The last chapter deals with classification and nomenclature and recommends the use of the method published by the International Standards Organisation (ISO 8548-1).

The final section, an Appendix, gives a useful outline of prosthetics so that the reader can recognise the various classes of components used in prostheses for the different levels. It does this by considering "the working end", "positioning", "load transfer" and "security". Although this is an unusual way of describing a prosthesis, it probably provides enough information about the function of these components for the purpose of this book.

It is a pity that the levels are not described as Ankle disarticulation, Trans-tibial, Trans-femoral, Trans-pelvic, Trans-radial and Trans-humeral, as set out in two other parts of the same International Standard (ISO 8548-2 and 8548-3) dealing with the description of the lower limb and upper limb stump.

My sole complaint about this book is at its use of the phrase congenital *amputation.* The word amputation implies that the whole extremity which was present at some stage has been removed or become detached. Intrauterine *amputations* do occur, but most congenital limb deficiencies are examples either of a failure of formation, or of a failure to persist. The authors postulate that the commonest deficiency, transverse upper forearm, may very possibly be an "acquired intrauterine amputation". However the majority of these children demonstrate by the presence of digital buds, often with nails, that even if there was a failure of the forearm and hand to persist, further distal development occurred subsequently. This may seem a small point, but parents are often less troubled by the idea that the limb failed to "grow" rather than use the emotive word "amputation".

The authors are to be congratulated on producing an excellent book which reads as if it were a spoken tutorial with some amusing side remarks which will help the reader to retain the information, and I recommend that it be read not only by every orthopaedic resident or surgeon, but by anyone who is likely to be involved in the care of limb deficient children.

H. J. B. Day

Calendar of Events

National Centre for Training and Education in Prosthetics and Orthotics
Short Term Courses 1999-2000

Courses for Physicians, Surgeons and Therapists

NC504	Lower Limb Orthotics; 22-26 November, 1999
NC505	Lower Limb Prosthetics; 24-28 January, 2000
NC510	Wheelchairs and Seating; 1-3 February, 2000
NC514	Management of the Diabetic Foot; 13-14 March, 2000
NC511(A)	Clinical Gait Analysis; 28-29 March, 2000
NC506	Fracture Bracing; 22-26 May, 2000
NC511(B)	Clinical Gait Analysis; 29-30 August, 2000

Courses for Orthotists and Therapists

NC217	Ankle Foot Orthoses for the Cerebral Palsied Child: 1-3 December, 1999
NC224	Hand Trauma; 18 February, 2000

Courses for Orthotic Technicians

NC606	Orthotic Technician Training	
	Core Knowledge	6-7 December, 1999
NC604	Orthotic Technician Training	
	Module 1	6-17 December, 1999
	Module 2	5-14 January, 2000
	Module 3	2-12 May, 2000
	Module 4	15-26 May, 1999

Further information may be obtained by contacting Prof. J. Hughes, Director, National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Curran Building, 131 St. James' Rd., Glasgow G4 0LS, Scotland. Telephone: (+44) 141-548-3298, Fax: (+44) 141 552 1283, E-mail: annette.hepburn@strath.ac.uk

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

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

30 September-2 October, 1999
ISPO (Chile) Seminar on Orthotics and Prosthetics of the Lower Limb, Santiago, Chile.
Information: ISPO Chile, Av Lib Bdo O'Higgins No. 4620, Santiago, Chile.

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

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

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

16-17 October, 1999
ISPO (UK) Annual Scientific Meeting, South Normanton, England.
Information: Mr. Bill Spence, Bioengineering Unit, Wolfson Centre,106 Rottenrow, Glasgow G4 0NN.

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

11-13 November, 1999
ISPO (USA) Conference on Team Management of Cerebral Palsy, Dallas, USA.
Information: ISPO USA, 1650 King St., Suite 500, Alexandria, VA 22314-2747, USA.
Tel: (+1) 703 836 7114.

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

15-22 November, 1999
ISPO Seminar and Workshop on Treatment of Poliomyelitis, Bangalore, India.
Information: Mr. Chapal Khasnabis, Mobility India, APH Campus, Hennur Road, St. Thomas Town, PO Bangalore 560084, India.

25-27 November, 1999
Orprotec 99- 5th Spanish Fair of Orthopaedics, Rehabilitation and Related Techniques, Valencia, Spain.
Information: Orprotec 99, Feria Valencia, Avenida de las Ferias s/n, E-46035 Valencia, Apdo. (PO Box) 476, E- 46080 Valencia, Spain.

29 November-3 December, 1999
Campaign '99 for the Asian and Pacific Decade of Disabled Persons, Kuala Lumpur, Malaysia.
Information: Campaign '99 Secretariat, 2nd Floor, No. 16 Lorong Utara (A),B.S.S.A.A.S., 46700 Petaling Jaya, Selangor, Malaysia.

17 December, 1999
Prescription Possibilities in Incomplete Paralysis, Cerebral Palsy and Paraplegia, Oswestry, England.
Information: Erica Wilkinson, Course Organiser, Robert Jones and Agnes Hunt Orthopaedic and District Hospital NHS Trust, Oswestry, Shropshire SY10 7AG, England.

2000

6- 8 January, 2000
International Conference on Rehabilitation Medicine, New Delhi, India.
Information: Dr. U. Singh, Conference Secretariat, IAPMRCON 2000, Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, Ansari Nagar, New Delhi 110029, India.

13-14 January, 2000
OPSI XIV National Annual Conference, Mumbai, India.
Information: All India Institute of Physical Medicine and Rehabilitation, Haji Ali Park, Mahalaxmi, Mumbai 400034, India. Tel: (+91) 22 4964331/2; Fax: (+91) 224962737; E-mail: aiipmr@bom2.vsnl.net.in

1-4 March, 2000
ISPO Latin American Multidisciplinary Rehabilitation Congress, Curacao.
Information: ISPO Caribbean, Mauritslaan 8, Emmastad, Curacao, Neth. Antilles. Fax: (+599) 9 737 5985

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

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

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

1-18 May, 2000
ISPO Course on Lower Limb Amputation Surgery and Related Prosthetics: Compound Fractures, Sun City, RSA.
Information: J. Ginsberg, 8 Rosebank Medical and Dental Centre, 11 Sturdee Av., Rosebank 2196, Republic of South Africa.

30 May-2 June, 2000
Orthopaedie and Reha-Technik World Congress, Leipzig, Germany.
Information: BIV, Postfach 10 06 51, D-44006 Dortmund, Germany.

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

7-10 June, 2000
50th Congress of the Nordic Orthopaedic Federation, Tampere, Finland.
Information: NOF 2000 K-Building, Room 307, Medical School, University of Tampere, PO Box 607, FI-33101 Tampere, Finland.

21-28 August, 2000
ISPO Seminar and Workshop on Treatment of Poliomyelitis, Moshi, Tanzania.
Information: Mr. Harold Shangali, Director, TATCOT at KCMC, PO Box 8690, Moshi, Tanzania.

27-30 August, 2000
12th Conference of the European Society of Biomechanics, Dublin, Ireland.
Information: Dr. Patrick J. Prendergast, ESB 2000, Incentive Conference Ireland, 1 Pembroke Place, Ballsbridge, Dublin 2, Ireland.

4-7 September, 2000
3rd Mediterranean Congress on Physical Medicine and Rehabilitation, Athens, Greece.
Information: Congress Secretariat, Triaena Tours, 24 Har. Trikoupi St., 106 79 Athens, Greece.

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

5-7 October, 2000
5th Nordic Orthopaedic Technical Congress, Oslo, Norway.
Information: Jarle Aga, Congress Secretary, Faculty of Health Sciences, Oslo College, Pilestredet 56, N-0167 Oslo, Norway.

9-13 October, 2000
Annual Meeting of the European Spine Society and European Spinal Deformity Society, Antwerp, Belgium.
Information: R. Gunzburg, M.D., Neillonstr. 14, 2600 Berchem, Belgium.

10-14 October, 2000
Eurospine 2000: Annual Meeting of the Spine Society of Europe, Antwerp, Belgium.
Information: Robert Gunzburg, Eeuwfeestkliniek-Kliniek, Harmonicstraat 68, B-2018 Antwerp, Belgium.

21-24 October, 2000
39th Annual Scientific Meeting of the International Medical Society of Paraplegia, Sydney, Australia.
Information: International Society of Paraplegia, Conference Action Pty Ltd., PO Box 1231, North Sydney, NSW 2059, Australia.

25-28 October, 2000
15th Annual Meeting of the North American Spine Society, New Orleans, USA.
Information: The North American Spine Society, 6300 North River Road, Suite 500, Rosemont, IL 60018-4231, USA.

3-5 November, 2000
39th Annual Meeting of the International Medical Society of Paraplegia, Sydney, Australia.
Information: ISP, Conference Action Pty Ltd., PO Box 1231, North Sydney, NSW 2059, Australia.

2001

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

7-13 July, 2001
1st World Congress of the International Society of Physical and Rehabilitation Medicine, Amsterdam, The Netherlands.
Information: Eurocongres Conference Management, Jan van Goyenkade 11, 1075 HP Amsterdam, The Netherlands.