The Journal of the International Society for Prosthetics and Orthotics

Prosthetics and Orthotics International

December 1996, Vol. 20, No. 3

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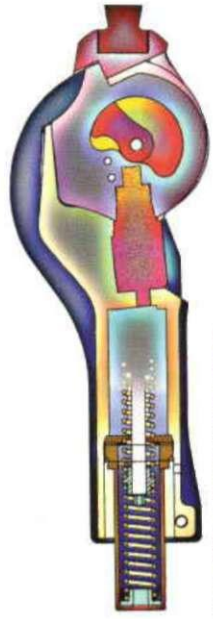

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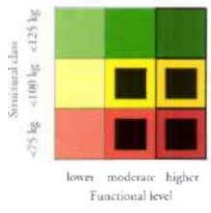

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Editorial correspondence, advertisement bookings and enquiries should be directed to Prosthetics and Orthotics International, National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Curran Building, 131 St.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

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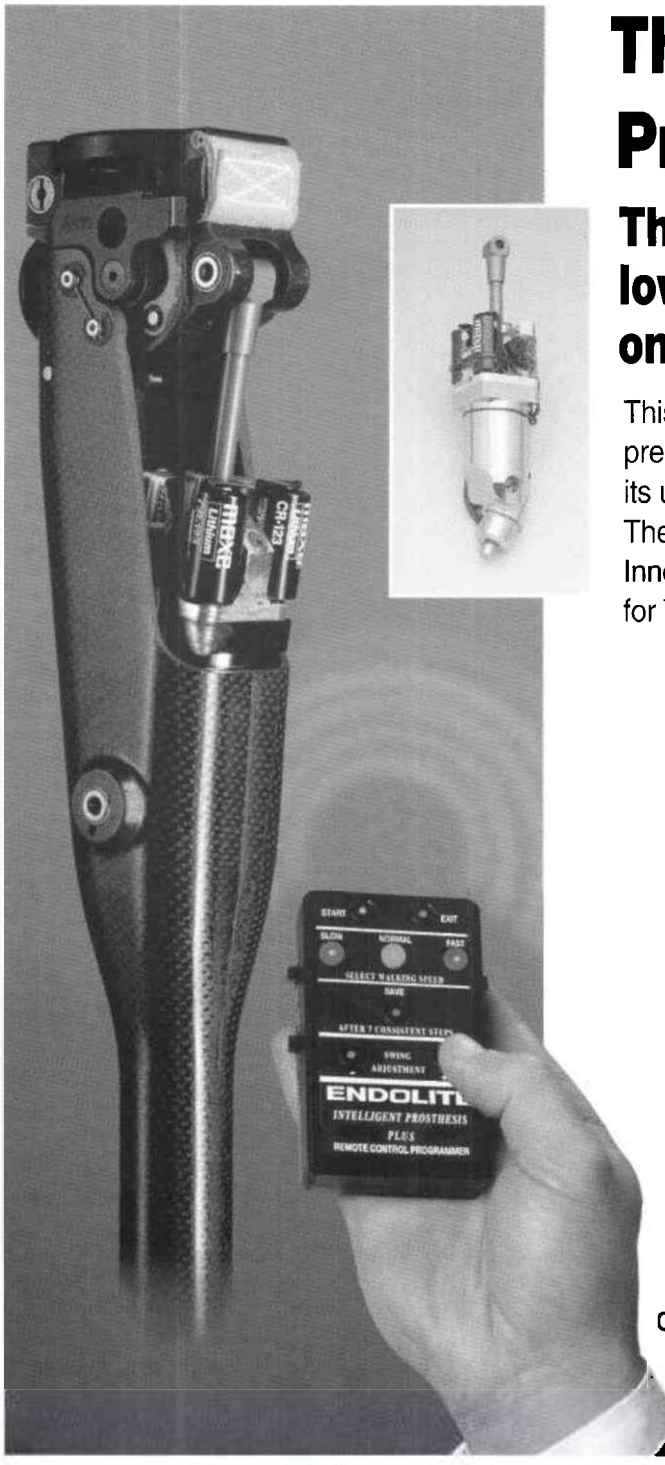

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December 1996, Vol. 20 No. 3

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Editorial

In recent years significant advances have been made with regard to establishing standards for education, training and clinical services in prosthetics and orthotics in developing countries. Although ISPO has been instrumental in setting these standards through its conferences on education, training and clinical services held in Moshi, (1984), Toronto, (1984), Jönköping, (1985), Glasgow, (1987) and Phnom Penh, (1995) it must be seen in a wider context.

The success of these conferences lay in the fact that they brought together the major international and national agencies involved in working in prosthetics and orthotics in developing countries and drew on their individual experiences. The outcome of these meetings have not only influenced the attitudes of ISPO but also those of the other organisations involved. For example, in 1990, the World Health Organisation (WHO) held a consultation in Alexandria, Egypt which was attended by advisers from seven schools in developing countries who prepare personnel in prosthetic and orthotics and from five organisations, including ISPO, who have been involved in the development and support of training programmes in developing countries. This meeting produced a report *Guidelines for training personnel in developing countries for prosthetic and orthotic services* which endorsed the recommendations and conclusions of the preceding meetings. This report will be used by developing countries who are considering training in this field.

During the 4-9 November 1996, the German Agency for Technical Cooperation (GTZ) and the German Foundation for International Development (DSE) held an international conference on Orthopaedic Technology in Wuhan, People's Republic of China.

The conference concentrated on the following priority areas:

- rehabilitation as part of primary health care including community-based rehabilitation
- financing orthopaedic healthcare in developing countries
- education and training in orthopaedic technology in developing countries
- appropriate technology : methods and problems.

The participants in the conference consisted of personnel from the various GTZ projects in orthopaedic technology, orthopaedic technologists from developing countries and representatives of selected non-governmental organisations and representatives of international organisations. ISPO had a strong representation at the meeting. This conference endorsed the findings of the ISPO meetings on education and training and took forward the discussions from the ISPO Consensus Conference on Appropriate Prosthetic Technology in Developing Countries, Phnom Penh. The findings of this conference will be published as the *Wuhan Declaration* and it is intended that this will be reprinted in the next issue of ***Prosthetics and Orthotics International.***

Through these various meetings, ISPO has built a good working relationships with WHO, GTZ, DSE, the International Committee of the Red Cross (ICRC) Handicap International (HI), World Orthopaedic Concern (WOC) and United States Agency for International Development (USAID) amongst many others. It is only through these good relationships and mutual collaboration that it is possible to advance prosthetics and orthotics services in developing countries in an effective manner. ISPO should continue to promote cooperation between all the organisations involved in this field.

Norman A. Jacobs
President-Elect

Obituary
Robert A. William Klein MBE (1914-1996)

- MB, BS Adelaide 1939
- FRACMA 1968
- FACRM 1980
- DPRM 1970
- RMO Adelaide Hospital 1939-1940
- Registrar Royal Adelaide Hospital 1939-1942
- Captain 2/9th AGH 1942-1946
- Consultant Dept Of Veterans' Affairs 1962-1984
- Honorary Consultant Royal Children's Hospital 1961-1978
- Consultant Princess Alexandra Hospital, Sydney 1963
- Honorary Fellow Lincoln Institute Health Sciences 1980
- Honorary Fellow ISPO 1984
- Honorary Consultant Prostheses Repatriation Commission 1987
- AAPRM

Bob Klein was the father of prosthetics and orthotics in Australia and was unique in being a graduate of both medicine and prosthetics/orthotics.

He promoted the growth of prosthetics and orthotics in Australia from a manual craft to a clinical science setting up high standards of education and treatment to a level which was rare even overseas. This included standards for such as prosthetics and orthotics prescribing doctors, speciality amputee teams and clinics, and biomedical (rehabilitation) engineering involvement.

In 1961 he established the Central Development Unit to maintain standards and introduce high levels of training and research.

Through his international work with Rehabilitation International and ISPO he introduced ISPO into Australia in 1971 and founded the Australian National Member Society of ISPO.

Through his initiative and work with Government and educational institutions he established in 1975 the Lincoln School for Prosthetics and Orthotics, now the National Centre for Prosthetics and Orthotics, LaTrobe University, Melbourne. He also initiated a number of training courses for other health professionals and was a planner of the Upper Limb course in 1986. This course is now run by REHAB Tech in conjunction with ISPO.

Our sympathies go to all this family and friends.

He will be remembered fondly by all patients and professionals who knew him for his kind nature, controversy in discussions, his enthusiasm for his garden, dogs, cigarettes and dry martinis!

Valma Angliss

Prosthetics and Orthotics International, 1996, 20, 147-152

Relative mortality in lower limb amputees with diabetes mellitus

L.B. EBSKOV

The Danish Amputation Register, Department of Orthopaedic Surgery, Herlev Hospital, University of Copenhagen, Denmark

Abstract

A nationwide epidemiological study included 3516 primary major lower limb amputations in diabetic patients, during the period 1982 to 1992. On this well defined diabetic amputee population the relative mortality (Standard Mortality Ratio, SMR) has been analysed. The mortality rate was found to be 8 times the expected during the first year following amputation. The relative mortality is higher for females than males. An inverse relation between age and SMR was found, and the SMR was significantly related to the level of amputation. No significant difference could be detected when analysing SMR in relation to subdiagnosis (NIDDM vs IDDM) or SMR in relation to the period of treatment 1982-87 versus 1988-92.

Introduction

Diabetic lower limb amputation continues to represent a major socioeconomic and health problem. In Denmark the number of individuals with diabetes mellitus (DM) is estimated to increase by about 1-2 per cent per year. The number of individuals older than 75 years has increased significantly (i.e. 25 per cent during the eighties), as well as the percentage of individuals suffering from severe overweight. The percentage of heavy smokers (i.e. more than 25 cigarettes per day) is unchanged. In spite of these developments, which in fact should lead to an increasing number of amputations, the Danish Amputation Register (DAR) has noted a significant decrease in the number of DM amputations in Denmark (Ebskov, 1991a). The reason for this decrease during the last decade is probably multifactorial, involving the effect of an increased activity of vascular surgery, better diabetic control and better medical treatment of complications, but also significantly improved podiatric care. These epidemiological considerations render it important to follow the development of diabetic amputations. Mortality is an important epidemiological factor. A large number of studies have described different types of mortality (i.e. the in-hospital, the postoperative mortality, the third month mortality, the relative mortality). However many of these epidemiological studies cover only a sub-area or a single department, and could be influenced by local demographic factors. The author suggests that the relative mortality is the most true type of mortality description because it relates the mortality in a specific group of patients with the expected mortality. Further, it is of major importance to include a substantial number of patients from a large geographic area. This study therefore is nationwide.

Material and methods

Since 1978 the Danish Amputation Register (DAR) has based its statistics on data from the National Patient Register (Ebskov, 1977; Ebskov, 1986), as also is the case in the present study. Further information is used from the Central Bureau of Personal Registration (CBPR), in which all Danish residents are recorded by means of a personal identification number. The CBPR also contains information concerning death. The DAR and the CBPR have been linked to identify the diabetic amputees

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who died during the observation period (January 1982 to December 1992).

The present study analyses the relative mortality (Standard Mortality Ratio, SMR). The reference population for computation of the SMR is the Danish population.

The material consists of 3516 primary lower limb amputations on 3516 patients performed during the period January 1982 to December 1992. None of the patients had suffered a major (defined as the transmetatarsal level or more proximal) amputation before entering the study in 1982. It was estimated that about 20 per cent of the diabetic patients entering this study had already suffered one or more toe amputations.

Data concerning age at diagnosis of diabetes and data on degree of control is not accessible.

Definitions

Primary amputation: the first admission of a person for amputation of the lower limb excluding toes.

Following amputations: any admission for amputation of the limb, ipsi- or contralateral, after the primary amputation.

Assumptions

Primary amputees suffering a following amputation during a re-admission were excluded. During the first admission when the primary amputation is executed about 18% of the patients are exposed for a revision, or a re-amputation on the ipsi- or contralateral limb.

The rationale for exclusion of the toe amputations in this study is primarily that NPR data only includes information concerning patients admitted to a hospital, whereas information from out-patient clinics, where some of the toe amputations are carried out, is not registered in the NPR.

Statistical methods

When analysing factors influencing the SMR a Cox-like analysis was used. Level of significance 5%. Confidence limits have been calculated for all relevant data. Cross-matching analysis, calculations and statistical analysis was conducted on a mainframe computer, as well as on personal computers.

Results

The male to female ratio is 1:0.86. The mean age is 71.3 yrs (min 25 yrs, max 97 yrs, median 73 yrs). At the time of amputation 14 per cent of the amputees were 59 yrs or younger; 24 per cent were between 60 and 69 yrs; 40 per cent were between 70 and 79 yrs and 22 per cent older than 80 yrs. Amputation at foot level (excluding toe amputations) accounts for 23 per cent; trans-tibial (TT) amputation for 52 per cent; knee disarticulation (KD) for 6 per cent and trans-femoral (TF) including hip disarticulation accounts for 19 per cent of the amputations. About 60 per cent of the amputees are classified as Non-insulin Dependent Diabetes Mellitus (NIDDM or Type 2 DM) and 40 per cent as Insulin Dependent Diabetes Mellitus (IDDM or Type 1 DM). Mean age for amputees with IDDM is 67 yrs, and mean age for NIDDM amputees is 73 yrs.

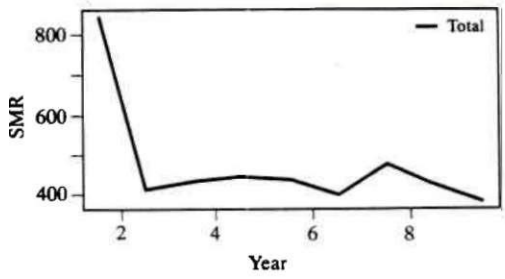

Fig. 1. The relative mortality (SMR) for the total material, with 11 years observation period.

Figure 1 shows the SMR for the total material

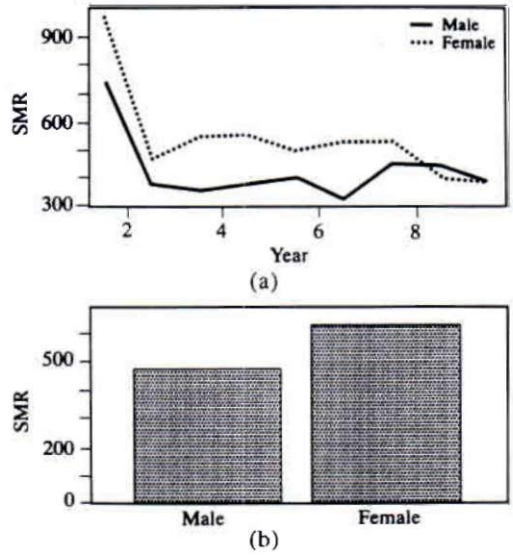

Fig. 2. (a) The relative mortality (SMR) for men and women respectively for each year in the observation period.
(b) SMR overall values for men and women.

(n=3516) as a function of year since amputation. The mortality is 8.4 times the expected mortality (95% confidence interval 7.95 - 8.9) in the first postoperative year. In the second year the mortality is 4.13 (95% confidence limits 3.8 - 4.5) times the expected mortality. During the rest of the period under study some non-significant variations are observed ranging from 4.1 to 3.8.

Figure 2a shows the SMR for men and women respectively. The tendency is obviously that the female group has the highest relative mortality in year 0 to 8. In the end of the observation period the curves tend to converge towards the same SMR.

Figure 2b show the overall values for the period, thus emphasising the higher SMR in the female group (510) versus the male group (490).

Figure 3a shows the SMR in the different age groups i.e. 0-59 yrs, 60-69 yrs, 70-79 yrs, 80 yrs and older. There seems to be an inverse relation between age and the SMR. In all but one year (i.e. year 5) the yougest amputees have the highest relative mortality and the oldest amputees have the lowest relative mortality.

Figure 3b shows the overall values for the period.

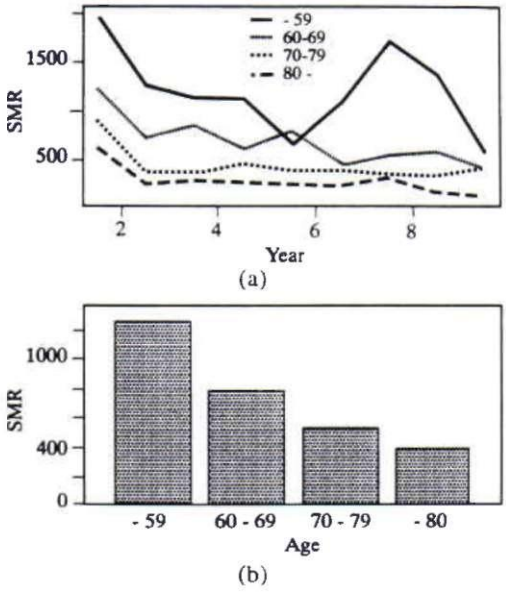

Fig. 3. (a) The relative mortality (SMR) for the age groups: <= 59 yrs; 60-69 yrs; 70-79 yrs and >= 80 yrs during the period.
(b) SMR overall values for the different age groups.

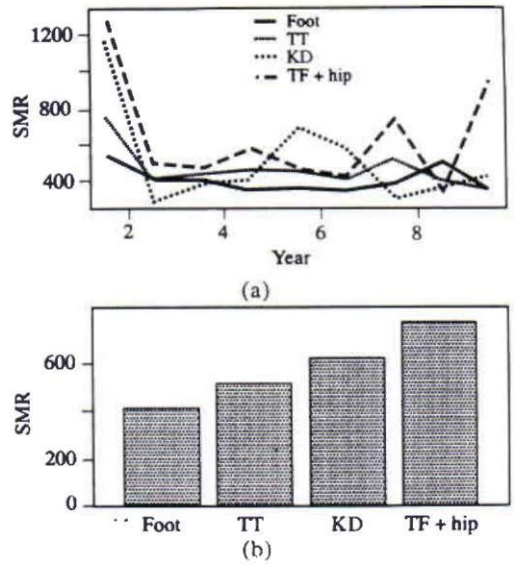

Fig. 4. (a) The relative mortality (SMR) for the level groups: foot (excl. toes); trans-tibial (TT); knee disarticulation (KD) and trans-femoral (TF) and hip.
(b) SMR overall values for the level groups.

When the relation between the relative mortality and the level of amputation is analysed a somewhat surprising pattern is found (Fig. 4a). In year zero the relative mortality is significantly related to the level of amputation so that amputation at foot level implies the smallest SMR (5.39 times the expected mortality, 95% confidence limits 4.57 - 6.36), trans-tibial amputation has a significantly higher relative mortality (7.59 times the expected, 95% confidence limits 6.99 - 8.24), knee disarticulation and trans-femoral amputation again show a similar and significantly higher relative mortality (about 13 times the expected). This strong relation between level of amputation and SMR in year zero is found to be much less pronounced in the remaining period. The overall values (Fig. 4b) shows the differences for the period in total.

Analysis of NIDDM versus IDDM (Figs. 5a and 5b) shows that amputees with IDDM have a higher relative mortality.

It was not possible to detect any period-related (year 1982-87 versus year 1988-92) differences in the SMR.

A Cox-like multivariate analysis was performed regarding SMR and the confounders under study. It was found that sex, age and level of amputation significantly influence the SMR.

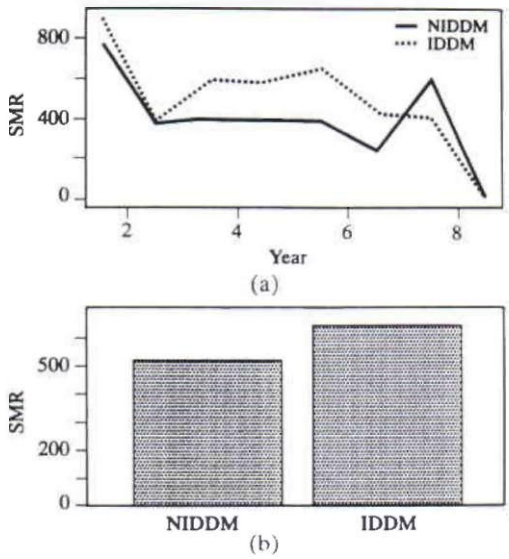

Fig. 5. (a) The relative mortality (SMR) for NIDDM respectively IDDM during the period.
(b) SMR overall values for NIDDM and IDDM.

Discussion

Denmark has a population of 5.1 million. In 1976 the Danish National Health Board established the NPR ordering all somatic hospitals to submit standardised registration on all in-patients admitted. In several studies the NPR has been found valid for epidemiological studies. The DAR was established in 1972 and from 1978 DAR has based its statistics on data from the NPR, as was the case in the present study. Data from the CBPR - especially the date of death - has been used in this study, in order to identify the diabetic amputees who died during the period of observation i.e. January 1982 to December 1992.

The present study represents the first published study analysing the SMR with a full national coverage, thus excluding local demographic factors. The overall epidemiologic characteristics i.e. age, sex, and amputation level distribution for the material is comparable to most other studies dealing with amputation on patients suffering from DM. The author has (Ebskov, 1991a) previously discussed the discrepancy at the national level, between the decrease in the number of DM amputations and the increasing number of diabetic patients, who have a 15-fold higher risk of amputation (Most and Sinnock, 1986) than non-diabetic individuals. Other authors have detected significant local reductions in the number of lower limb amputations (Edmonds *et al.*, 1986; Falkenberg, 1990; Runyan, 1975; Lippman, 1979; Larsson, 1994).

A large number of authors (Lippman, 1979; Larsson, 1994; Hansson, 1964; Whitehouse *et al.*, 1968; Kolind-Sørensen, 1974; Ebskov and Josephson, 1980; Finch *et al.*, 1980; Mandrup-Poulsen and Jensen, 1982; Burgess and Romano, 1971; Persson and Suden, 1971; Ebskov, 1991b; Pohjolainen and Alaranta, 1988; Stewart *et al.*, 1992) have analysed the mortality (in-hospital, postoperative, SMR) or the long term survival for vascular insufficiency amputations (with or without diabetes). Fewer have examined exclusively diabetic cases (Larsson, 1994; Hansson, 1964, Pohjolainen and Alaranta, 1988; Stewart *et al.*, 1992; Silbert, 1952; Nelson *et al.*, 1988). As mentioned by some authors (Mandrup-Poulson and Jensen, 1982; Stewart *et al.*, 1992) there are major differences in defining the materials as regards important determinants like post-operative period, hospitalisation time, age, amputation level (especially inclusion of toe-amputations) and etiology of amputation cause. Further the materials are of variable size and the degree of specialisation for the clinics involved is different. All these factors have a major influence on the results. It is evident that the variations between definitions as stated above lead to severe difficulties in comparison of the results from different studies. This study attempted to exclude or minimise some of these limitations by analysing the SMR on a national level.

It has only been possible to find two studies (Larsson, 1994; Stewart *et al.*, 1992) analysing the relative mortality exclusively for diabetic amputees, with a longer observation period, but no studies have had an observation period of 12 years as in the present study.

The main finding is that mortality is about 8 times more than normal during the first year after amputation. Thereafter the mortality is about 4 times the normal. The magnitude of the mortality during the first year is probably a consequence of the direct post-operative mortality or the in-hospital mortality, which in Denmark accounts for approximately 10 per cent during an average length of stay for an amputation admission of about 37 days. One year after amputation the mortality of the amputated diabetic patients is similar to the

mortality of the non-amputated diabetics, but still significantly higher than the background population. The mortality for non-amputated diabetics varies considerably. In Denmark Deckert *et al.*, (1979) found a relative mortality of 200-600 per cent (IDDM, Decrement analysis) Borch-Johnsen (1989) found that when 10 per cent of the background population are dead, more than 50 per cent of the diabetic (IDDM) population are dead. Concerning NIDDM patients the mortality is about 2-3 times the background population (Beck-Nielson *et al.*, 1990). Kessler (1971) found a relative mortality about 140-240 per cent (SMR, NIDDM and IDDM), and Garcia *et al.*, (1974) found a relative mortality from cardiovascular causes for males of 200 per cent and females 450 per cent (SMR, NIDDM and IDDM). This relation between background population, diabetic non-amputees and diabetic amputees as regards relative mortality can be explained by the presence, the degree and the severity of their diabetes. Nelson (1988) found significantly higher death rates in diabetic amputees than in diabetic non-amputees (death rate ratio from 1.4 to 3.9).

In this study sex was found to be significantly related to the relative mortality. The higher mortality among women corresponds to the findings of Nelson (1988) concerning death rates for female NIDDM patients (above 45 years).

The relation between age and SMR was expected, as well as the relation between level and SMR, but it was surprising to find the differences much less pronounced after the first year, even though the differences between the mean values from the period are significant. Most studies concerning diabetic amputations do not distinguish between NIDDM and IDDM. In the present study it was possible to differentiate between IDDM and NIDDM from 1987 onwards. With reservation for the limited observation period no significant difference was found in SMR for NIDDM in relation to IDDM. However the tendency was obviously a higher SMR in the IDDM group.

In Denmark the only major epidemiological factor which could have altered the mortality for the patients is the increase in vascular surgery (Seidelin and Eickhoff, 1995; Ebskov *et al.*, 1994) so that a larger proportion of patients (about 40%) before amputation has been operated on one or several times in vascular surgical limb salvage procedures. It is important to emphasise that the mean age in the period under study is unchanged. No other studies have analysed SMR over time but Stewart *et al.* (1992) found that survival has improved significantly during the last 25 years. The author could not demonstrate any significant change in SMR, possibly because of the limited period under study.

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Prosthetics and Orthotics International, 1996, 20, 153-158

Influence of speed on gait parameters and on symmetry in trans-tibial amputees

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Abstract

Normal gait is characterised by a high level of inter-leg symmetry of gait parameters. Therefore, efforts in rehabilitation of amputees are directed at the construction of a prosthesis which provides normal leg function and allows a more symmetrical gait. Analysis of the gait of trans-tibial amputees was performed when they were ambulating at their own freely selected speed and at a faster speed. The effect of speed on selected gait parameters in each leg was evaluated and the influence on symmetry established by comparing the inter-leg changes for each of the selected parameters. The faster gait trail affected significantly all temporal and distance parameters in both legs but not the level of symmetry between legs. At the faster speed, the hip angles at heel-strike and during swing and the knee angle during load response, in the normal leg, and the knee angle during swing in the amputated leg, all increased significantly. Speed of gait significantly affected symmetry between knee angles as reflected by the increased differences measured during load response (from 2.62 ±5.2 to 7.06 ±4.2 degrees) and during toe-off (from 1.80 ±7.4 to 9.50 ±9.1 degrees). Timing and sequence of selected gait events, as related to stride time, were not significantly affected by speed of gait. These results might contribute to a better understanding of gait characteristics in trans-tibial amputees and provide design guidance for prosthetic components.

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Introduction

Gait is a complex process which differs between individuals and also from step to step in any individual. Normal gait is characterised by almost identical movements performed by both lower limbs with only small differences in kinematic and kinetic parameters. Symmetry of gait can be measured by different methods and can be reflected through various gait parameters.

Temporal and/or distance variables have been used to identify symmetry of gait in amputees and the literature suggests that amputees demonstrate asymmetrical gait patterns. Duration of stance time on the prosthetic and normal legs have been measured and symmetry defined as the difference, in seconds, between both legs. At the final stage of prosthetic rehabilitation, an asymmetry of 0.02 second between stance phases has been measured (Baker and Hewison, 1990). In other studies it was noted that during amputee gait, step-length performed with the normal leg was shorter and accomplished in less time (Robinson *et al.*, 1977), and stance time was longer on the normal leg than on the opposite leg (Breakey, 1976). Symmetry of gait has been evaluated also by comparing the ground reaction forces measured in both limbs by means of double force-plates (Isakov *et al.*, 1992). In that study, complete symmetry between limbs was considered to reflect a state where the acting forces are of equal magnitude in each leg. In trans-tibial amputees with optimally fitted prostheses, asymmetry of mediolateral forces was measured as 1.6%, of anteroposterior forces 15%, and of vertical forces 6.9%, Another

method to establish symmetry of gait was based on bilateral leg/thigh angle-angle measurements (Hurley *et al.*, 1990). An estimate of congruity between two angle-angle configurations was obtained and a calculated recognition coefficient served as the criterion for intercurve comparisons expressing degree of symmetry. The mean symmetry obtained for trans-tibial amputees was 0.802 ±0.044 while lower limb mean symmetry in normals was 0.881 ±0.011. Symmetry of temporal and distance parameters was measured also in normals during gait with three speeds; slow, free/comfortable, and fast. Symmetry was determined by the use of equations where results obtained in the left leg were divided by those of the right leg (Hirokawa, 1989). During free speed, the highest value of symmetry was obtained for step length, 0.98, for stance time, 0.96, for step width, 0.93, for double limb support, 0.90, and foot angle, 0.74. When comparing slow and fast speeds, it was noted that symmetry of gait became higher when speed increased. However subjects who had the highest symmetry for one parameter did not always show high values for all others.

Gait symmetry evaluation can be applied to the process of prosthetic rehabilitation and used for different purposes. Gait symmetry has been monitored during the rehabilitation period to evaluate rate of progress. Baker and Hewison (1990) showed that symmetry in stance time improved by comparing results obtained at the initial and final stages of rehabilitation. Gait symmetry was also used to evaluate the contribution of better stability of the stump-socket complex to the quality of gait (Isakov *et al.*, 1992). In that study a Swedish knee cage was attached to a patellar-tendon-bearing prosthesis for trans-tibial amputees with very short stumps. The obtained improvement in stability was reflected in increased symmetry in stance duration and ground reaction forces measured in both limbs. Symmetry of temporal and kinematic gait parameters (Boonstra *et al.*, 1993) and electromyographic activity (Culham *et al.*, 1986) have been used to evaluate the effect on gait of different prosthetic components.

Evaluation of lower limb symmetry may contribute to a better understanding of factors interfering with normal patterns of gait in trans-tibial amputees. Therefore, this study was directed to investigate gait characteristics of two different speeds in trans-tibial amputees and the influence of speed on symmetry of selected gait parameters obtained.

Subjects

Fourteen trans-tibial amputees (3 women and 11 men) volunteered to participate in the present study. The subjects' mean age was 40.5 ±12.7 years, (range; 27 to 65 years). Amputation was performed on the right lower limb in 5 subjects and on the left in 9 subjects. Twelve amputations were a result of trauma, one was due to thrombosis, and one due to peripheral arterial disease.

The mean time elapsed from amputation to the reported test was 16.9 ±14.6 years (range; 3 to 46 years). The mean time for receiving the first prosthesis was 5.2 ±4.1 month (range; from one to 18 months). Nine prostheses were patellar-tendon-bearing, and five were patellar-tendon-supracondylar prostheses and all had a solid-ankle-cushion-heel foot. All subjects were excellent walkers who used their prostheses on a regular basis and were conducting an active normal family life. Subjects walking distance at free speed ranged from 0.5 to 10 km with mean distance of 3.14 ±1.4 km.

Methods

Subjects underwent two tests; first while walking at their own comfortable free speed and then when asked to walk at a faster speed. In one subject only the first test was performed. Before testing, all subjects were assessed by a prosthetist to ensure optimal fit and function of the prosthesis. None of the subjects had stump problems (blisters, sores, swelling, pain etc.) on the testing session. All subjects were tested ambulating with no supporting aids. The following gait parameters were measured; temporal parameters of stance, swing, double-limb support, step time and length. Hip joint angle was measured at heel-strike (1), at peak stance extension (2), at toe-off (3), and at peak swing flexion (4). Knee joint angle was measured at load response (5), at toe-off (6), and at peak swing flexion (7). Sequence and time of occurence, relative to stride period, of the following gait events; knee peak load response (a), peak extension of hip during stance (b), toe-off (c), peak knee flexion during swing (d), and peak hip flexion during swing (e) (Fig. 1).

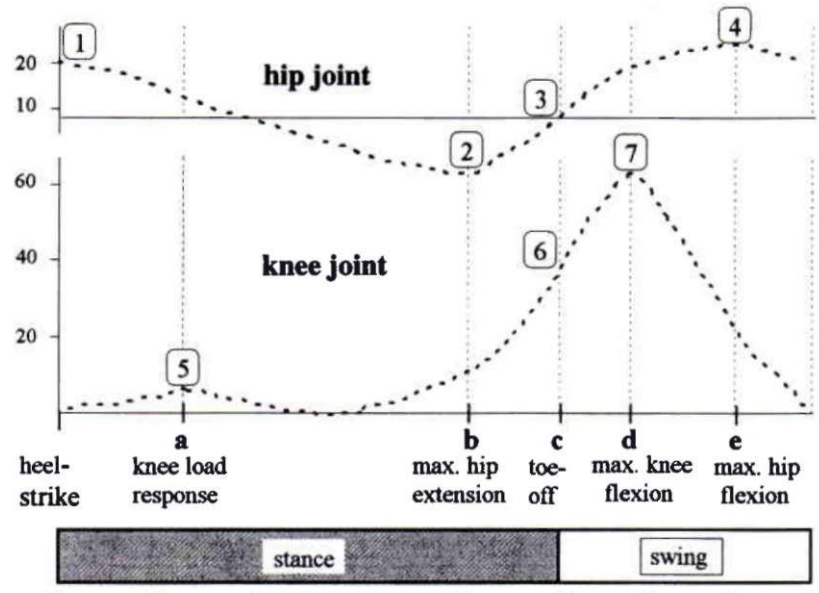

Figure 1. Sequence and time of occurrence, relative to stride period, of the measured gait events.

Temporal and distance parameters were measured by means of a 10 m long x 2 m wide non-slip conductive rubber walkway. Strain gauge goniometers were used to measure angular movements of the knee and hip joints. Signals from the electric contact system walkway and from the electrogoniometers were routed to an on-line computer and analysed. Data were analysed using commercial software for computation and processing and for statistical analysis. The significance level of the differences was determined by using Student's t-test. Results were deemed to be statistically significant at $p<0.05$.

Table 1. Means and standard deviations of gait variables measured during free and fast speed ambulation. * Differences are significant at $p<0.001$

	Speed of gait	
Gait variables	Free	Fast
steps no.	21.71 ±4.0	20.76 ±3.7
stride time (s)	1.32 ±0.1	1.07 ±0.0*
stride length (cm)	123.28 ±12.1	147.15 ±9.9*
cadence (steps/min)	91.79 ±9.2	111.51 ±9.5*
speed (cm/s)	94.85 ±15.6	138.00 ±13.0*

Results

Values of the main gait variables measured during free and during fast speed are summarized in Table 1. At the fast speed there was a significant change of all variables ($p<0.05$). The mean number of steps analysed in each of the two tests was about 21. Table 2 details the means and standard deviations of the selected temporal and distance parameters measured on the amputated and normal sides

Table 2. Means and standard deviations of gait parameters measured separately on the amputated and on the normal sides during free and fast speed of ambulation. All differences are significant at $p<0.001$

	Amputated side		Normal side	
Gait events	Free speed	Fast Speed	Free speed	Fast speed
Stance (s)	0.89 ±0.10	0.71 ±0.05	0.92 ±0.13	0.73 ±0.06
Swing (s)	0.42 ±0.07	0.35 ±0.05	0.40 ±0.07	0.34 ±0.06
DLS (s)	0.217 ±0.05	0.166 ±0.03	0.274 ±0.08	0.206 ±0.05
Step time (s)	0.68 ±0.07	0.55 ±0.05	0.64 ±0.08	0.52 ±0.06
Step length (cm)	63.50 ±6.9	77.00 ±6.1	60.92 ±6.5	72.15 ±5.9

Table 3. Results are means and standard deviations of differences between the amputated and the normal sides measured during free and fast speed ambulations. All differences are insignificant($p>0.05$)

Gait events		Amputated – normal side differences during: Free speed	Fast speed
Stance	(s)	0.022 ±0.05	0.013 ±0.05
Swing	(s)	0.023 ±0.04	0.013 ±0.04
DLS	(s)	0.056 ±0.05	0.040 ±0.04
Step time	(s)	0.034 ±0.08	0.027 ±0.08
Step length	(cm)	2.28 ±4.7	5.00 ±7.1

during two different speeds of gait. All values were significantly affected by speed but not the inter-leg differences (Table 3). In Table 4, means and standard deviations of hip and knee angles measured at selected gait events are compared in each leg during free and fast gait. Speed significantly affected normal leg hip angle during heel-strike and swing, and knee angle during load response. On the amputated side, knee angle increased significantly on swing only. Inter-legs angle changes were significant for load response and toe-off between free and fast speed of gait (Table 5). Timing of occurrence of selected gait events as related to stride time (expressed in percentage of stride time) are detailed in Table 6. Results obtained in free speed are compared with fast speed for each leg separately. Differences are insignificant as were inter-legs changes (Table 7).

Discussion

Gait inter-leg symmetry is considered to be perfect when all measured gait parameters in both lower limbs are equal. Symmetry between legs indicates a normality of gait, and therefore prosthetic rehabilitation aims at fitting amputees with an artificial limb which will reproduce as closely as possible the performances of a normal leg. Gait analysis is therefore used to evaluate the benefit of certain prosthetic components by measuring how they affect level of inter-legs symmetry as well as the energy cost of gait (Isakov *et al.*, 1985; Barth *et al.*, 1992; Boonstra *et al.*, 1993).

In the present work the authors aimed at identifying gait parameters in trans-tibial amputees, and explored whether their symmetry is speed related. For this purpose, chosen gait parameters were measured during free and fast gait trails and inter-leg symmetries were compared. The mean speed performed in the fast gait trail was higher than the comfortable

Table 5. Results are means (±SD) of differences in joints angle (in degrees) measured between both limbs. Free and fast ambulation speed are compared. *Differences are significant at $p<0.05$

Joint angle measured at	Amputated – normal side differences during: Free speed	Fast speed
Hip:		
heel-strike	2.81 ±6.0	2.30 ±4.7
max. stance extension	0.74 ±3.3	0.16 ±3.2
toe-off	2.73 ±2.4	3.97 ±3.3
max. swing flexion	1.80 ±5.2	1.43 ±5.0
Knee:		
load response	2.62 ±5.2	7.06 ±4.2*
toe-off	1.80 ±7.4	7.79 ±5.2*
max. swing flexion	5.24 ±9.0	9.50 ±9.1

Table 4. Means and standard deviations of hip and knee joints angle (in degrees) measured in various gait stages. Free and fast gait speed are compared. *Differences are significant at $p<0.05$

Joint angle measured at	Amputated side Free speed	Fast speed	Normal side Free speed	Fast speed
Hip:				
heel-strike	19.64 ±5.8	22.43 ±6.2	16.83 ±3.56	20.12 ±4.6*
max. stance extension	7.31 ±2.6	8.11 ±2.3	6.57 ±2.6	7.95 ±2.9
toe-off	3.32 ±4.1	4.21 ±4.0	3.98 ±4.8	3.10 ±5.3
max. swing flexion	24.01 ±5.7	27.28 ±5.9	22.16 ±3.8	25.85 ±3.7*
Knee:				
load response	6.55 ± 2.8	7.76 ±3.8	9.17 ±3.74	14.82 ± 3.3*
toe-off	44.99 ±12.5	52.07 ±10.9	43.19 ±10.9	44.30 ±11.0
max. swing flexion	58.43 ± 6.9	64.31 ± 7.3*	53.18 ± 5.4	54.81 ± 6.1

Table 6. Sequence and timing of gait events occurrence during stride. Results, expressed in percentage, are means and standard deviations of events set during stride time. All differences are insignificant (p>0.05)

	Amputated side		Normal side	
Gait events	Free speed	Fast speed	Free speed	Fast speed
Knee load response	14.51 ±6.5	18.61 ±7.4	15.77 ±5.4	16.82 ±4.5
Hip max. stance extension	56.54 ±3.5	55.32 ±4.4	58.08 ±2.3	55.92 ±3.2
Toe-off	63.38 ±4.5	67.48 ±3.7	70.16 ±5.2	68.20 ±4.5
Knee max. swing flexion	76.08 ±3.3	74.96 ±3.1	76.51 ±2.6	74.96 ±1.8
Hip max. swing flexion	90.13 ±3.7	89.79 ±4.1	88.63 ±2.0	88.64 ±2.6

free speed to an extent that induced a significant change in all temporal and distance values in both legs. Values of temporal parameters of stance, swing, double limb support, and step time decreased significantly while values of distance parameter of step length increased significantly. The effect of increased speed on inter-legs temporal and distance parameters symmetry was insignificant.

The hip and knee angles on the amputated and normal sides were monitored and the effect of speed was established by comparing the angles measured at selected instances of gait. It was noted that a faster speed of gait induced a significant increase in flexion of the hip joint in the normal leg when measured at heel strike (from 16.83 ±3.56 to 20.12 ±4.6 degrees) and during swing (from 22.16 ±3.8 to 25.85 ±3.7 degrees). In the same leg, knee flexion increased significantly during load response (from 9.17 ±3.74 to 14.82 ±3.3 degrees). As for the amputated side, speed of gait significantly affected flexion only of the knee during swing (increased from 58.43 ±6.9 to 64.31 ±7.3 degrees). Joint angles might also serve as indicators of gait symmetry. The effect of increased speed did not affect the symmetry of hip angles as indicated by the almost similar differences between hip angles measured in free and fast speed. At the knees, speed significantly affected symmetry of angles during load response by increasing inter-leg differences (2.62 ±5.2 to 7.06 ±4.2 degrees) for the free and fast speeds respectively. This increase was due to a significant increase in knee flexion in the normal leg only. The normal load response, occurring during the initial phase of weight acceptance, is characterised by a slight flexion of the knee under the control of the eccentrically contracting quadriceps muscle. The "shock-absorbing" effect obtained by such movement is very important in the prevention of wear and tear of weight-bearing joints (Light *et al.*, 1980). Speed significantly affected symmetry of knee angles during toe-off by increasing inter-leg differences (1.80 ±7.4 degrees to 7.70 ±5.2 degrees) in the free and fast speeds respectively. This resulted from increased knee angle under influence of speed on the amputated side only. It is assumed that the exaggerated knee flexion on the amputated side is related to the prosthetic rigid ankle-foot component (Bagley and Skinner, 1991). The inability of the artificial ankle to dorsiflex (and plantarflex) during stance, is expressed also by the inability to lower the heel and straighten the knee. Thus, during toe-off, the knee on the amputated side is being "pushed" into flexion by the rigid ankle, an outcome which increases significantly in faster speed of gait.

Table 7. Sequence and timing of gait events occurrence during stride. Results express the mean (±SD) differences between both limbs measured during free and during fast speed ambulation. All differences are insignificant (p>0.05)

	Amputated – normal sides differences during:	
Gait events	Free speed	Fast speed
Knee load response	1.26 ±8.3	1.78 ±8.5
Hip max. stance extension	1,53 ±3.1	0.59 ±4.9
Toe-off	1.77 ±4.2	0.72 ±4.4
Knee max. swing flexion	0.40 ±3.3	0.03 ±3.2
Hip max. swing flexion	1.50 ±4.1	1.14 ±4.1

Timing of occurrence and the sequence of gait events relative to stride time might also indicate symmetry of gait. The following gait events were chosen; peak angle on knee load response, maximal hip extension during stance, toe-off occurrence, maximal knee flexion during swing, maximal hip flexion during swing. The exact time of their occurrence (expressed in percentage of stride time) relative

to stance period was measured. This assumption was found to be erroneous as the timing of occurrence of the chosen gait events did not significantly change under the effect of speed.

In conclusion, under the conditions of the present tests, speed of gait in trans-tibial amputees significantly affected the symmetry of all temporal and distance parameters as well as the symmetry of knee angles during load response and toe-off. Analysis of gait in amputees can identify asymmetrical parameters and provide the necessary information for focusing research and development on prosthetic components which duplicate normal leg functions.

Acknowledgement

The authors would like to thank the physical therapist, Mr. Bevetek Tomaz, for his assistance during the testing procedures.

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Prosthetics and Orthotics International, 1996, 20, 159-171

Synthesis of a cycloidal mechanism of the prosthetic ankle

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Introduction

Most prosthetic feet are designed to mimic shock absorption and push-off (Gitter *et al.*, 1991). Such materials as fibreglass and carbon graphite in Seattle Foot, Flex-Foot, Carbon Copy II, so-called Energy Storing (ES) prosthetic feet, enable a greater portion of energy of the "falling" body to be accumulated and released before plantar flexion (Barticus *et al.*, 1994). The ES feet provide some amount of eversion/inversion as well in the Genesis Foot, Seattle-Light, and Dual Ankle Springs (DAS).

Certain positive outcomes of using ES feet have been reported, e.g. improved ankle range of motion and gait symmetry (Wagner *et al.*, 1987); a smaller number of skin problems like abrasions compared to the "conventional" SACH foot (Alaranta *et al.*, 1994). The amputees preferred ES feet as transmitting less shock and having greater damping properties (Wirta *et al.*, 1991).

Nevertheless, ES feet have not shown sufficient improvement in overall performance (Childress *et al.*, 1974; Torburn *et al.*, 1990; Lehmann *et al.*, 1993) in comparison with the conventional SACH foot (Goh *et al.*, 1984). No significant differences in frequency of stump pain were observed (Alaranta *et al.*, 1994). No improvements have been found in such amputee gait characteristics such as the performance of the existing knee in trans-tibial patients (Edelstein, 1990). During the early stance, the patient's knee bends notably less than normal because the prosthetic foot, either conventional, or ES does not produce the controlled plantar flexion obtained naturally by eccentric contraction of dorsiflexors. Knee flexion is also less than normal during late stance.

The author believes, that the reason for this is that both SACH and ES feet have a similar mechanical outcome in the dorsiflexion phase, namely, the moment of resistance to dorsiflexion, and this characteristic does not mimic the moment of resistance to dorsiflexion in normal gait.

The moment of resistance (resistive curve) to dorsiflexion in a normal ankle typically has a concave downwards shape shown in Figure 1a (Scott and Winter, 1991). The beginning of dorsiflexion during regular level gait occurs with practically no resistance from plantar flexor muscles. Then, resistance slowly increases as the dorsiflexion progresses, while at the end of dorsiflexion the resistance rapidly increases nonlinearly. In contrast with this concave shape of resistive curve seen in the normal ankle, existing prostheses demonstrate a convex shape of their resistive curves (Fig. 1b).

If one agrees that a concave resistive curve in the prosthetic ankle is beneficial for an amputee's gait and wants to build an initially compliant prosthesis, the conflict between compliance and durability must first be overcome. Mechanically there are two basic structures employed in the ES foot design. The first is an L-shaped leaf spring (Seattle Foot, Flex-Foot, Carbon Copy II). The second is a multi-bar linkage with elastic elements (Genesis Foot, DAS, College Park Foot). Both types of mechanisms have similar resistive curves (Fig. 1b) with at least non-concave shape (convex or

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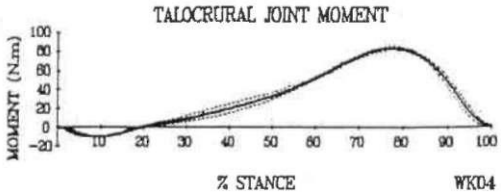

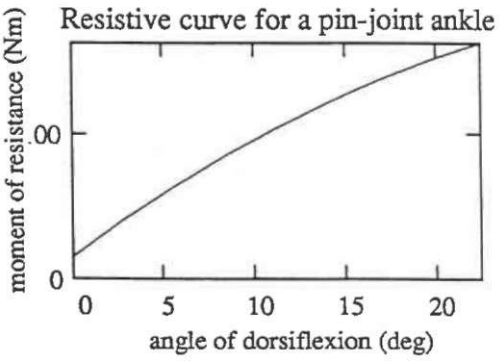

Fig. 1.(a). Moment of resistance (resistive curve) to dorsiflexion in the ankle during normal walking (from Scott and Winter (1991), with kind permission from Elsevier Science Ltd., Kidlington OX5 1GB, UK.
(b). Typical resistive curve in the current prosthetic ankle unit either of bending or pin-joint type. The curve is shown from the vertical position of the shank; M_0 is an initial moment to be applied to start the articulation.

linear). Both types of mechanisms provide an initial moment of resistance M_0, which must be applied to a tibial component of the prosthesis to deviate from a vertical position and to articulate the ankle. As this analysis indicates, the initial resistive moment M_0 cannot be made zero in both kinds of mechanisms. In a mechanism based on the L-shaped leaf spring, for example, the structure acts simultaneously as a resistor to deflection and as a feature for load bearing. If a designer intends to lower M_0, he is at risk of losing durability.

The purpose of this work was to synthesise a mechanism of a prosthetic foot with more natural moment of resistance in the dorsiflexion phase.

Method

Biomechanical aim of the design

The moment of resistance to dorsiflexion in the normal ankle during level gait has been chosen as a biomechanical aim in the design of a new prosthetic ankle. During dorsiflexion in normal walking and running, a period of almost free mobility in the ankle joint is followed by a period of almost total fixation. This phenomenon is referred to as a deceleration during dorsiflexion (Winter, 1979), and is explained as a means to slow down the movement of the body's centre of mass and facilitate heel lift. The EMG pattern of the foot plantar flexors supports this statement both for walking (Crenna and Frigo, 1991) and running (Reber *et al.*, 1993). A normal pattern of the foot plantar flexors' performance (EMG signal versus stance events) correlates to the moment of resistance in the ankle. The mostly concave shape of the curve in the dorsiflexion period of stance suggests that initiation of dorsiflexion does not face a large amount of resistance from the foot plantar flexors. This resistance rapidly increases nonlinearly to the end of the dorsiflexion period, which results in deceleration of articulation of the ankle and lifting of the heel. The maximal value for the moment around the talocrural joint (articulation of the ankle in sagittal plane) is averaged from 80 to 120 Nm. A similar concave nonlinear pattern is seen in the subtalar joint (frontal articulation) with the maximal moment of resistance of 23-25 Nm (Scott and Winter, 1991).

Dorsiflexion period is followed by the rapid plantar flexion which occurs during late stance until "toe-off." It is well documented that during the plantar flexion, foot flexor muscles generate much less power than at the end of dorsiflexion period when the heel has to be raised (Perry, 1992). This means that the major loss in performance of foot flexor muscles after trans-tibial amputation, affects not the plantar flexion, but the preceding dorsiflexion. It opens consequently a possibility to mimic the performance of the lost muscles by a passive elastic system "charge-release", where "charge" corresponds to dorsiflexion and "release" corresponds to the following plantar flexion. One can say that the level of approximation of the prosthetic foot/ankle performance to those demonstrated by the real foot/ankle, depends on how well a "charge-release" mechanism is designed. The power released and the resistive curve, are two typical characteristics of any "charge-release" mechanism. Both characteristics can be used as targets in a

synthesis of a new mechanism. Power released in the plantar flexion period in the real ankle, was chosen as a target in designing most ES feet (Gitter *et al.*, 1991). While that "release" goal was achieved for plantar flexion, not enough attention has been paid to the "charge" component, namely, to the resistive curve in the dorsiflexion period. Indeed, in all ES feet on the market, the charge during dorsiflexion is provided by activation of bending or compression of elastic elements. The analysis shows that thes types of mechanisms have non-concave (convex or linear) pattern (Fig. 1b), opposite to the concave pattern seen in the real ankle. Thus, the beginning of dorsiflexion in bending type designs results in greater resistance, than in the biological prototype. This is also true for structures like Genesis and SACH feet, employing compression/extension. The term "rigid" will be used in relation to those prosthetic ankles, in which the resistive curve has a convex shape, and does not match the design target to be reached by the present simulation.

Disadvantages of a "rigid" prosthetic ankle

It is hypothesised here that a low initial compliance of the prosthetic ankle has at least two negative consequences on an amputee's performance.

• The first consequence of a "rigid" ankle is a decrease in range of motion (ROM) in the existing knee of a trans-tibial amputee during the stance phase of locomotion. The knee activity (flexion/extension) during stance phase has been known as a "third determinant of normal gait" (of six) (Saunders *et al.*, 1953). This mechanism contributes shock absorption after heel strike, and decreases energy consumption by lowering the maximum elevation of the centre of gravity of the body in mid-stance. The average ROM in the trans-tibial amputated limb knee joint is approximately one half that of normals (7° versus 15° in norm) and even more notably decreased in trans-femoral patients (Zuniga *et al.*, 1972; Breaky, 1976). However, in trans-tibial patients there is no anatomical basis for reduced flexion of the existing knee. This leads to the suggestion that presently available "rigid" foot and ankle prostheses are responsible for the decreased ROM in the existing knee.

• The second consequence of a "rigid" ankle is an excessive pressure applied to the stump from the socket. Assuming that fit and alignment are optimal, the ultimate mechanical cause of excessive pressures on the stump is the resistance of the prosthesis in the process of its deformation or its resistive curve. The deformation of the prosthesis is provided by the forces and moments generated by stump and ground reactions in combination with the internal resistive characteristics of the joints of the prosthesis. Analysis of the classical Radcliffe's diagrams of moments from the socket affecting an amputee's stump during the gait cycle (Radcliffe, 1962), shows that these moments can be substantially decreased if resistance in the ankle joint is reduced. The rationale for that conclusion can be seen in (Fig.2), which is a modification of Radcliffe's diagram (1962). Two types of ankle joints are considered: completely solid with no articulation (Fig. 2a), and partially solid with initial compliance at 5° (Fig. 2b). In both cases, the prostheses are forced to perform roll-over around metatarsal zone *B*, the so-called "third rocker" (Perry, 1962). The confirmation in (Fig. 2a) has a vertical initial position of the shank, and the patient's stump produces the couple of forces, whose normal components are $F,-F$. The couple $F,-F$ acts on the socket and provides the moment $M_B=rF$ about the point *B* of application of ground reactions in the metatarsal zone,

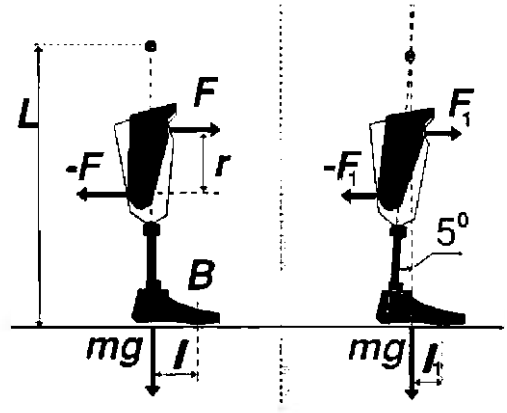

Fig. 2.(a). A minimal force couple $F,-F$ provided by a stump, which tends to bend the metatarsal area (the point *B*) of a prosthetic foot when the moment $M_B=rF$ becomes greater than the moment $M_g=mgl$ of the force of gravity. The elevation of the centre of mass *m* is *L*. (b). Decreased moment's *Mg* arm l_1 when free deflection is allowed in the ankle up to 5° of dorsiflexion and corresponding couple $F_1,-F_1$.

where r is a distance between parallel lines of action of F and $-F$. The moment M_B results in a heel lift of the prosthetic foot. The force of gravity mg with centre of mass elevated at L, gives a moment $M_g=mgl$ about the point B, where l is a distance from the projection of the force of gravity on a horizontal plane to the centre of a metatarsal joint B. The moment M_g acts in the opposite direction relative to the M_B, and the heel could be lifted when M_B becomes greater than M_g:

$$M_B > M_g. \qquad (1)$$

Ground reaction forces in the configuration presented in (Fig. 2) when the heel is just lifted, are applied to the metatarsal area through the point B. Their moments around point B yield zero, and do not contribute to the condition of heel-off (1). The feet with solid ankle (Fig. 2a) provide heel-off with a leg position close to vertical, when the l has its maximal value. If the prosthetic ankle has a greater initial compliance to allow heel-off at 5° of dorsiflexion (Fig. 2b) it would give a new lever arm l_l for the force of gravity:

$$l_l = l - L\sin(5°). \qquad (2)$$

Averaged anthropometric data (McConville *et al.*, 1980) for elevation L of the male adult's centre of gravity, suggest L = 1 m; and for the length l of the portion of the foot from ankle to metatarsal joints: l = 0.2 m. Due to (2), we have l_l almost half l. Therefore, the moment M_{Bl}, which lifts the heel, and consequently forces F_l,-F_l could be approximately half of M_B and F,-F correspondingly. In accordance with Newton's third law, forces of the same magnitude act on the stump from the socket. Hence, the longer heel off can be delayed due to greater ankle compliance (more dorsiflexed ankle at the moment of heel-off), the less pressure would be applied to the patients' stump. The tendency of facilitating rollover by permitting more dorsiflexion before heel-off, has however a natural limitation. When the maximal angle of dorsiflexion exceeds a maximal normal value (13°-15°), as in the Flex-Foot with (19.8°±3.3°) (Torburn *et al.*, 1990), the force of gravity acts anterior to the metatarsal joint projection, and the moment of the force of gravity acts in the same direction as the bending moment from the stump. This results in an excessive delay in heel-off, which leads to an excessive lowering of the centre of mass due to the continuing second rocker (Perry, 1992). To compensate for this lowering of the centre of mass, some additional movements of the body segments are needed. Amputees might associate this with discomfort. Thus, excessive compliance of the ankle zone in the Flex-Foot at the later dorsiflexion phase could be a reason why amputees, when they had a choice, showed a preference for other energy storing feet in the study by Torburn *et al.*(1990).

The importance of reducing normal and shear stresses on the stump in a prosthetic socket has been widely discussed in the literature, and experimental and model studies have been conducted (Sanders *et al.*, 1993; Vannah and Childress, 1993). Stress magnitude ranges have been reported: up to 205 kPa for normal stress and 54 kPa for shear stress with the highest stresses on the posteroproximal or lateral sites of the stump. Waveforms of stresses were double-peaked, with the first and greater peak 25-40% into stance. This timing of the first peak of the stresses corresponds to the initiation of the dorsiflexion phase, which is affected by the level of the ankle joint compliance. However, there has been no discussion on the connection of these measurements to the design of prosthetic feet.

Even more important would be a reduction of normal and shear stresses on the stump in the perspective of direct skeletal attachment for leg prostheses (Eriksson and Brånemark, 1994). It seems reasonable to suggest that a terminal device (foot prosthesis) which produces less moment to a connector with bone will better prolong a sound "connector-bone" attachment.

Mathematical model of a new rolling ankle

A new rolling joint prosthetic foot and ankle (RJA) with self-adjustable rigidities in the hinges has been invented (Pitkin, 1994a). A mathematical modeling of the prosthetic cam rolling ankle joint has been conducted to determine the design parameters, which provide the match with the biomechanical aim. Limitations: a) the model represents not the real ankle joint, but a mechanism which simulates one characteristic of the real ankle, namely, its resistive curve or moment of resistance to dorsiflexion in level walking; b) the mechanism

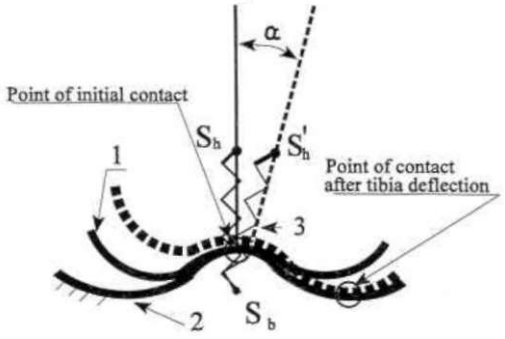

Fig. 3. Basic design of a new Rolling Joint Prosthetic Foot and Ankle (RJA): 1- tibial component; 2 - rear-midfoot component; 3 - extension spring generating the moment of resistance to deflection when the tibial component rolls along the rear-midfoot component.

is "passive", i.e. no powered elements are included; c) the mechanism comprises two solids with the capability of relative rolling without slip; d) the solids are connected by an elastic extension tie with linear characteristics. Assumptions and theoretical basis: a) the higher-pair (cycloidal) mechanism is adequate for the simulation and practical purposes; b) the passive mechanism with linear elastic tie is able to produce the resistive curve of concave shape seen in the real ankle controlled by muscles; c) the mechanism is simple enough to be prototyped; d) rolling without slip can be technically provided.

The input of the model is the tibia articulation angle α (Fig. 3). The mathematical model describes the design by a set of geometrical (contacting surfaces) and mechanical (elastic element) parameters, which determine the model's output. The output of the model is the moment $M(\alpha)$ of resistance to the tibia articulation measured about the articulation angle α. This moment is generated by the extension spring 3 when the tibial component rolls component 1 along the rear-midfoot component 2. The moment $M(\alpha)$ is calculated against the instantaneous point of a contact between curved surfaces of the tibial and the rear-midfoot components.

The contacting surfaces are analytically simulated by the combinations of circular arcs (Figs. 4 and 5), and constructed from the equations developed. A similar method was developed and published elsewhere (Pitkin, 1975) to describe the nonlinear relationship between vertical load applied through the shank to the real foot and elongation of the foot (Wright and Rennels, 1964).

The talar surface of the rear-midfoot is simulated by the arc b of the circle of radius R_b, which will be a base wheel of the cycloidal motion and whose centre O_b coincides with the origin of the absolute coordinate system (Fig. 4). The base arc b is given by the parametric equation

$$x(t) = R_b\cos(t),$$
$$y(t) = R_b\sin(t);\ t = (-\alpha_b;\alpha_b). \qquad (3)$$

where angle α_b determines the possible range of motion (rolling with contact between arc b and arc h) in the artificial ankle. Fore part of the arc b is connected to the convex arc bf of radius R_{bf}. The coordinates of the arc centre are $R_{bfx} = (R_b + R_{bf})\sin(\alpha_h R_h/R_b)$; $R_{bfy} = (R_b + R_{bf})\cos(\alpha_h R_h/R_b)$. The equation of the arc bf is:

$$x(t) = R_{bfx} + R_{bf}\cos(t),$$
$$y(t) = R_{bfy} + R_{bf}\sin(t);\ t = (\frac{\pi}{2} - \alpha_h; 3\frac{\pi}{2} - \alpha_h), \qquad (4)$$

where the angle α_h is determined through the angle α_b by the condition of rolling of one arc along another without slip: $\alpha_b R_b = \alpha_h R_h$.

The tibial surface comprises the middle arc h of radius R_h and and two even sided arcs e of radii R_e (left arc is not shown). The arc h is located in the centre of the tibial component, and has the equation

$$x(t) = R_h\cos(t),$$
$$y(t) = (R_b - R_h) + R_h\sin(t);\ t = (-\alpha_h;\alpha_h). \qquad (5)$$

Right sided arc e has equation

$$x(t) = (R_h + R_e)\sin(\alpha_h) + R_e\cos(t),$$
$$y(t) = (R_b - R_h) + (R_h + R_e)\cos(\alpha_h) + R_e\sin(t). \qquad (6)$$

Equations 3-6 are plotted in Figure 4 using the MathCad PLUS 5.0 software (MathSoft Inc., Cambridge, MA, USA). Figure 4 displays the contacting surfaces of the tibial and rear-midfoot components in the initial neutral position. Both tibial and rear-midfoot

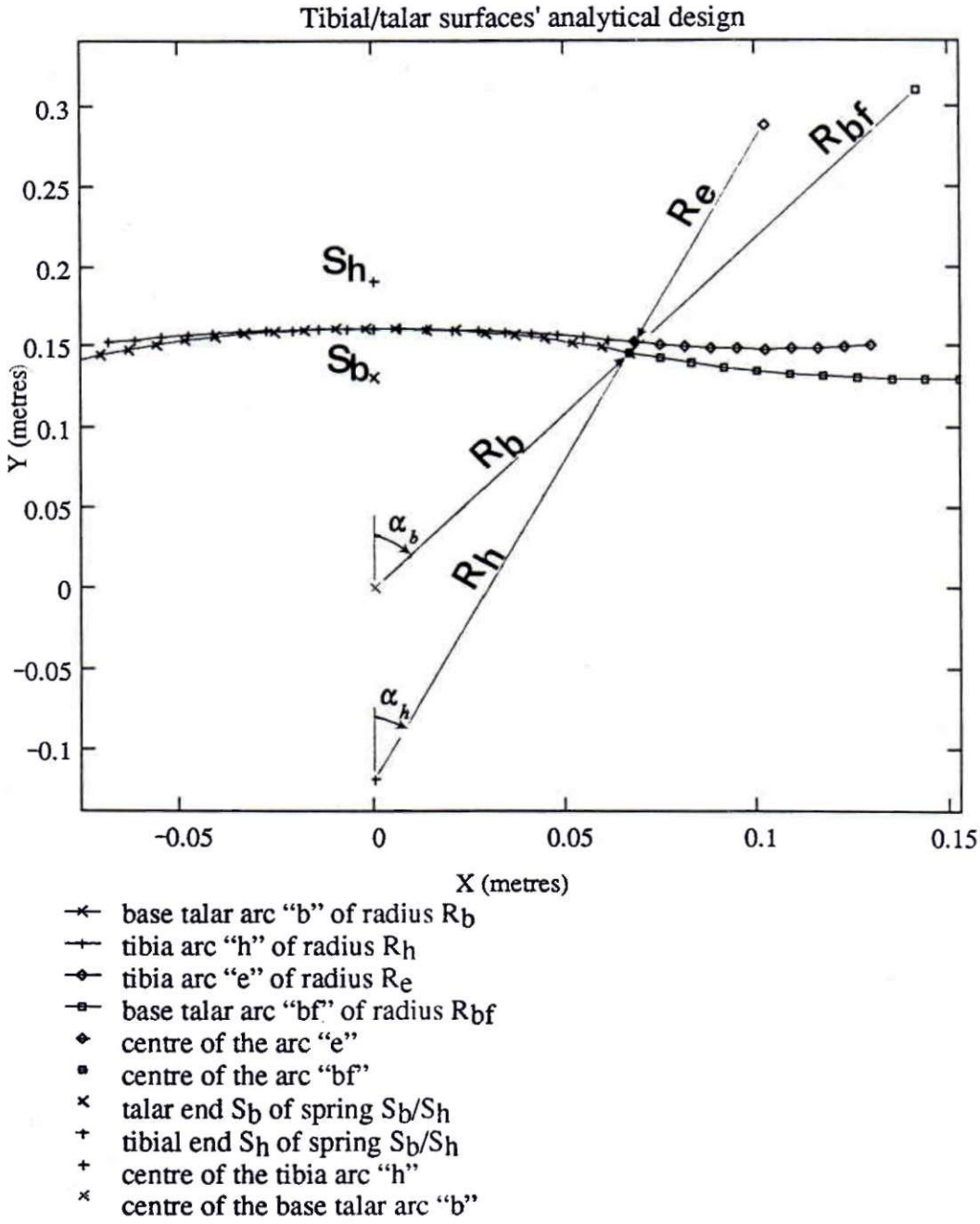

Fig. 4 Analytical design of the contacting surfaces. Tibial surface is built accordingly to the equations 3-4; the talar surface of the rear-midfoot component (Fig 3, 1-2) is built by the equations 5-6

components are connected by the linear elastic spring with rigidity μ and initial length l_0. Points of attachment of the spring to the rear-midfoot and tibial components have coordinates S_b = $(0;R_b-a_b)$ and S_h = $(0;R_b+a_h)$ correspondingly. The tibial component rolls clockwise along the rear-midfoot component. The middle arc h generates an inverted hypotrochoidal trajectory of the tibial end of the spring (point S_h), which has the equation.

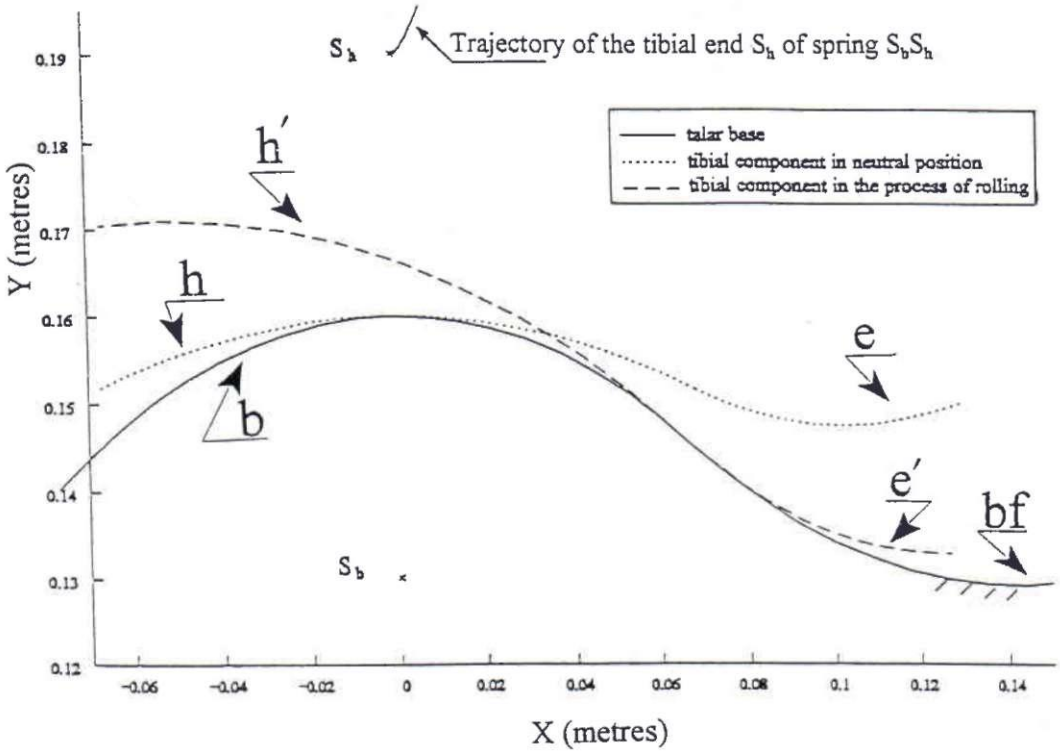

Fig. 5 Analytical representation of the cycloidal motion (rolling without slippage) of the tibial component along the talar surface of the rear-midfoot component. A trajectory of the tibial end (point S_h) of the connecting spring (see Fig.3.3) is defined by the equations 7-8.

$$x_{th}(\alpha) = (R_b - R_h)\sin(\frac{R_h}{R_b}\alpha) + (R_h + a_h)\sin((\frac{R_h}{R_b} - 1)\alpha),$$

$$y_{th}(\alpha) = (R_b - R_h)\cos(\frac{R_h}{R_b}\alpha) + (R_h + a_h)\cos((\frac{R_h}{R_b} - 1)\alpha), \quad (7)$$

where $\alpha = (\pi/2 - \alpha_h R_b/R_h;\ \pi/2 + \alpha_h(2\text{-}R_b/R_h))$ is the current angle of dorsiflexion.

When rolling progresses and arc *e* becomes involved in a contact with the arc *bf*, a trajectory of the point S_h is described by the equation of a regular hypotrochoid:

$$x_{rh}(\alpha) = R_{bfx} - (R_{bf} - R_e)\sin(\alpha_b - \frac{R_e}{R_{bf}}\alpha) - a_e\sin((1 - \frac{R_e}{R_{bf}})\alpha + \beta + \alpha_b),$$

$$y_{rh}(\alpha) = R_{bfy} - (R_{bf} - R_e)\cos(\alpha_b - \frac{R_e}{R_{bf}}\alpha) - a_e\cos((1 - \frac{R_e}{R_{bf}})\alpha + \beta + \alpha_b), \quad (8)$$

where $a_e = ((R_h + R_e)^2 + (R_h + a_e)^2 - 2(R_h + R_e)(R_h + a_e)\cos(\alpha_h))^{1/2}$; $\alpha_e R_e = \alpha_{bf} R_{bf}$ is a condition of rolling of the arc *e* along the arc *bf* without slip; and $\beta = a\sin((R_h + a_h)\sin(\alpha_h)/a_e)$. A combination of the arc *b* with the arc *bf* has been a new development of the initial design RJF (Pitkin, 1995), in which the arc *e* continued epytrochoidal rolling along the base arc *b*. The current addition has resulted in better prevention against slip of the tibial component along the talar component, and in better approximation to the targeted resistive curve at the end of the dorsiflexion phase.

Both trajectories of the inverted and regular hypotrochoids for the point S_h are plotted in Figure 5. This shows also the middle arcs *b* and *h*; the right arcs *e* and *bf* in initial neutral

position along with an intermediate position e' - bf' of the tibial contacting surface. The talar end of spring (point S_b) belongs to the base wheel and does not move. Parameters R_b, R_h, R_e, R_{bf}, α_h, μ, a_h and a_b determine dimensions and mechanical outcome (moment $M(\alpha)$ of resistance to dorsiflexion) of the ankle unit. The particular values of parameters for the plots in Figure 5 were: $\alpha_h = \pi/16$; $R_h = 0.28$ m; $R_b = 0.16$ m; $R_e = 0.14$m; $R_{bf} = 0.18$ m; $\mu = 3\text{x}10^5$ N/m; $a_b = a_h = 0.03$m. This set of the model's parameters, as can be seen further, provides a desired match to the biomechanical target and is acceptable from the technological point of view. An analytical dependence $M(\alpha)$ comprises two dependencies: $M_{ih}(\alpha)$ and $M_{rh}(\alpha)$ which correspond to the consecutive inverted and regular hypotroichoidal parts of the trajectory of the tibial end S_b of the spring:

$$M_{ih}(\alpha) = (T_0 + \mu\Delta l_{ih}(\alpha))L_{ih}(\alpha),$$
$$M_{rh}(\alpha) = (T_0 + \mu\Delta l_{rh}(\alpha))L_{rh}(\alpha), \quad (9)$$

where elongations $\Delta l_{ih}(\alpha)$ and $\Delta l_{rh}(\alpha)$ of the spring in two consecutive rollings, generating inverted and regular hypotrochoids for the tibial end S_b of the spring are:

$$\Delta l_{ih}(\alpha) = \sqrt{x_{ih}(\alpha)^2 + ((R_b - a_b) - y_{ih}(\alpha))^2} - (a_b + a_h),$$

$$\Delta l_{rh}(\alpha) = \sqrt{x_{rh}(\alpha)^2 + ((R_b - a_b) - y_{rh}(\alpha))^2} - (a_b + a_h),$$

and corresponding instantaneous lever arms $L_{ih}(\alpha)$ and $L_{rh}(\alpha)$ are:

$$L_{ih}(\alpha) = \left| \frac{R_b x_{ih}(\alpha)\cos(\frac{R_h}{R_b})}{\Delta l_{ih}(\alpha) + (a_b + a_h)} + \frac{R_b((R_b - a_h) - y_{ih}(\alpha))\sin(\frac{R_h}{R_b})}{\Delta l_{ih}(\alpha) + (a_b + a_h)} - \frac{(R_b - a_h)\, x_{ih}(\alpha)}{\Delta l_{ih}(\alpha) + (a_b + a_h)} \right|,$$

$$L_{ih}(\alpha) = \left| \frac{Y_{cbf}x_{rh}(\alpha) + X_{cbf}((R_b - a_h) - y_{rh}(\alpha))}{\Delta l_{rh}(\alpha) + (a_b + a_h)} - \frac{(R_b - a_h)x_{rh}(\alpha)}{\Delta l_{rh}(\alpha) + (a_h + a_h)} \right|,$$

with substitutions:

$$X_{cbf}(\alpha) = (R_b + R_{bf})\sin(\alpha_h \frac{R_h}{R_b}) - R_{bf}\sin(\alpha_h \frac{R_h}{R_b} - \frac{R_e}{R_{bf}}\alpha),$$

$$Y_{cbf}(\alpha) = (R_b + R_{bf})\cos(\alpha_h \frac{R_h}{R_b}) - R_{bf}\cos(\alpha_h \frac{R_h}{R_b} - \frac{R_e}{R_{bf}}\alpha).$$

T_0 in (9) is an initial tension of the spring S_bS_h, necessary for durability and integrity of the whole ankle-foot assembly. It is important that the value of T_0 does not affect an initial zero-value of the moment $M_{ih}(\alpha)$ ($M_{ih}(0) = 0$), since $L(0) = 0$.

The analytical representation of the contacting surfaces (equations 3-6) and the outcome function $M(\alpha)$ (equation 9) permits the synthesising of a mechanism, which mimics the resistive curve in the real ankle.

Synthesis of the cycloidal mechanism of RJA

Hartenberger and Denavit (1964) define the synthesis of a mechanism as the determination of the parameters that will yield an approximation to a desired function between the input and output. The synthesis could be approached by geometric and algebraic methods. Algebraic methods are based on displacement equations, i.e. equations relating the input and output variables of a mechanism in terms of its fixed parameters. In this work the algebraic approach is used with equations (9). These equations link the displacement of the tibial end of the connecting spring with the moment of resistance to the related ankle articulation.

The problem of "four accuracy points" synthesis of a planar joint (Freudenstein and

Sandor, 1959) must be considered. The cam-rolling joint is a higher-pair linkage such that to four given positions of the tibial member, defined by dorsiflexion angles α_1, α_2, α_3 and α_4 there correspond four prescribed values of the moment $M(\alpha)$: $M_1(\alpha_1)$, $M_2(\alpha_2)$, $M_3(\alpha_3)$ and $M_4(\alpha_4)$. A substitution of these values to the left of the equation (9) yields a system of four equations with respect to the design parameters. This approach permitted the determination of four design parameters that solve the problem of synthesis of the mechanism. The other parameters may be fixed or chosen for any specific reasons. Those reasons could be, for example, performance requirements and technological limitations. The performance requirements are stability, spatial mobility, shock absorption, and self-controlled rigidity. The technological limitations are durability, mass, and dimensional fit to the cosmetic shell.

The contacting surfaces of the prosthetic ankle mechanism in the RJA were synthesised using the MathCad PLUS 5.0 software. The four points of accuracy: $M_1(0)=0$; $M_2(5)=5.3$ Nm; $M_3(10)=42.2$ Nm; $M_4(15)=124.1$ Nm (Fig. 6) were a reasonable approximation to the resistive curves of the real ankle. To get that approximation, a joint moment curve $M(t)$ on a

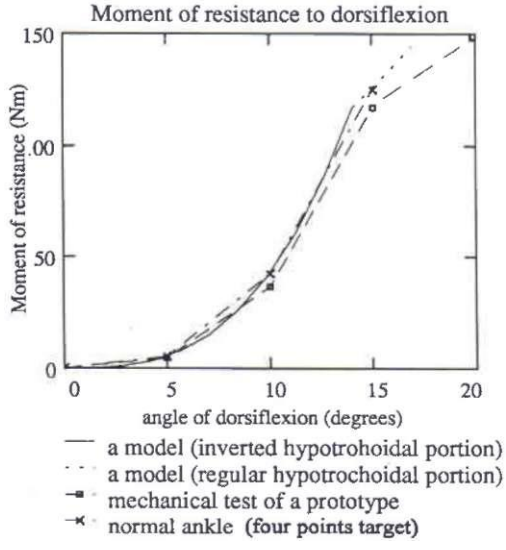

Fig. 6. The resistive curves for the biomechanical target that is a typical normal gait pattern in the ankle joint (Fig. 1(b)), for the RJA prototype and for the mathematical model (equation (9)). The curve of the RJA (mechanical tests) is in a reasonable agreement with the mathematical model, and with the nonlinear moment of resistance in the real ankle.

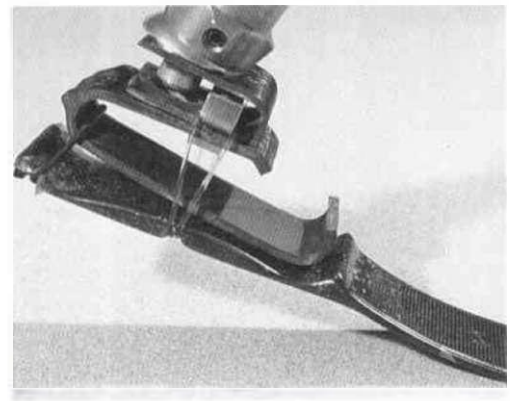

Fig. 7 The sample manufactured by The Ohio Willow Wood Co., Mt. Sterling, OH, USA. Besides the basic design (see Fig. 3), the tibial component has the S-shaped member for better vertical shock absorption, and an elastic loose O-ring in the rear for better frontal stability

time base (Fig. 1a) measured and calculated by Scott and Winter (1991), was combined with a typical ankle angle dependence $\alpha(t)$ from (Perry, 1992, p.53) also against time. Numerical exclusion of time has yielded a dependence $M(\alpha)$, shown in Figure 6, which appears to be a typical sagittal resistive curve of the real ankle joint. The synthesis procedure yielded the following geometrical characteristics of a mechanism: R_h = 0.28 m; R_b = 0.16 m; R_e = 0.14m; R_{bf} = 0.18 m, while the remaining model's parameters were chosen from the technological considerations as $\alpha_h = \pi/16$; $\mu = 3\text{x}10^5$ N/m; $a_b = a_h = 0.03$m.

The samples of the RJA were manufactured by the Ohio Willow Wood Co., Mt. Sterling Ohio, USA, following these findings (Fig. 7). The rear-midfoot member is coated with polyurethane to get a layer of high friction to provide rolling of contacting surfaces without slip. The tibial member is mounted on the rear-midfoot and has an additional S-shaped member, compared to Figure 3. This member provides the vertical shock absorption and affects the tension of the middle elastic bands when compression of the S-shaped member changes the distance between the hooks and the bottom of the rear-midfoot. The first peak of the vertical component of the ground reastion force decreases the initial tension in the bands. It eases the initiation of the mobility in the ankle joint during the first third of dorsiflexion, and makes the dependence "moment-deflection"

more similar to the norm. An additional elastic O-ring in the rear is provided which is loose during most of the midstance. It contributes to the moment of resistance to dorsiflexion at the final stage of midstance, prior to heel-off, and increases the frontal stability of the entire assembly.

Two principal requirements have been fulfilled in this design: relatively free articulation in the artificial ankle joint at the beginning of dorsiflexion, and nonlinearly increased resistive counterforces at the end of the dorsiflexion phase.

Results

Verification of the model and mechanical tests

Mechanical tests of the RJA prototypes were conducted by the Ohio Willow Wood Company. The tests included verification of the mathematical model and comparison of the resistive curves of the RJA prototype and some feet and ankle units in the market.

The existing prostheses were Carbon Copy II Symes with regular toe resistance and fixed ankle; Carbon Copy II Symes with Endolite Multiflex Ankle; Carbon Copy II Symes with DAS MARS ankle unit 1401; Carbon Copy II Symes with DAS MARS ankle unit 1402. All feet except RJA were 26 cm long. The RJA is 15 cm in length. Each foot and ankle unit was mounted to an Interlaken servohydraulic test frame at angles of 0, 5, 15 and 20 degrees, and loaded using displacement control (0.3 mm/second) until a given load or position was reached. The amount of displacement at each angle increased significantly.

In Figure 6 there are three resistive curves which relate to the biomechanical target, to the RJA prototype and to the mathematical model (equation (9)). The curve of the RJA is in reasonable agreement with the mathematical model, and with the nonlinear moment of resistance in the real ankle (Fig. 1b). The other result is that by easily acquiring a foot flat position, the RJA would seem to provide greater stability throughout the stance period. The ease with which foot-flat is achieved may be controlled by varying the geometry of the foot and the elasticity of the RJA's elastic bands.

Pilot gait study

One subject, a male bilateral traumatic trans-tibial amputee, 27 years of age, wearing Flex-Feet, was involved in the pilot biomechanical gait study. In the experiment, knee and ankle angles were measured during the stance phase of level walking. The RJA was attached to the left prosthetic socket, and the Flex-Foot was attached to the right socket. Parallel use of the new and existing designs gave the subject and investigators quick feedback and data for a pilot comparison of the gait parameters. The subject was accustomed to using both prosthetic feet. He walked down a 10m runway at a comfortable speed of 1.3 m/s±10%. A high speed video camera mounted perpendicular to the runway at hip height was used to film the subject's gait. The video data were digitised manually at a frequency of 50 Hz using the computer interfaced system LabVIEW. In Figure 8 an increased ROM in the knee during the first half of the stance period 15°±1.2° for the RJA versus 6°±0.6° for the Flex-Foot is presented. Times of foot-flat and heel-off are shown. In addition, an increase in the ankle plantar flexion with the RJA immediately after heel strike is shown. This effect of the rolling joint foot and ankle on existing knee performance seems to be normalising.

In addition, the subject felt that the stress on his stump was lower when he used the RJA prototype than when he used the Flex-Foot (Pitkin, 1994b).

Two additional subjects have qualitatively tested the RJF prototypes at the OWW site in November 1994. They also reported lowering of stress at their stumps, and pointed on high rotational compliance as a benefit of the new prosthesis.

Discussion

A mechanism of the angle of dorsiflexion adjustment in the normal is controlled by calf muscles and lost by trans-tibial amputees along with plantar flexion. Many attempts have been made to improve plantar flexion of the prosthetic foot (Hittenberger, 1986; Phillips, 1989; Kristinsson, 1992; Colwell, 1994). However, the amputee's performance might be of greater normality if more attention was given to emulating normality dorsiflexion.

The moment of resistance to deflection (resistive curve) in the ankle joint during the stance period of gait is considered in this study as a determinant or mechanical outcome of normal dorsiflexion. The pattern of that

mechanical outcome is nonlinear with low resistance to deflection in the ankle at the beginning of dorsiflexion and rapidly increasing resistance prior to the heel-off (Crenna and Frigo, 1991; Scott and Winter, 1991). In the contrast with this concave pattern, prosthetic foot and ankle units in the market and in the patent literature available, demonstrate convex dependence "moment-angle" with the higher slope at the beginning of dorsiflexion and the lower slope at its end.

The mechanical outcome of the real ankle was taken as an aim for prosthetic design, and synthesis of a cam rolling mechanism with higher-pair connection was provided. The newly developed rolling joint prosthetic foot and ankle (RJA) (Pitkin, 1994a; 1995) shows nonlinear mechanical outcome (moment of resistance to deflection) in the dorsiflexion phase, similar to the biological prototype.

Two positive consequences of using the rolling joint prosthetic foot and ankle prototype have been found in the pilot biomechanical study on a bilateral trans-tibial amputee wearing Flex-Feet. The first is a better performance of the subject's sound knee joint. The average range of motion in the amputated limb knee joint is approximately half the normal in trans-tibial patients (7° versus 15° in norm) and even more notably decreased in trans-femoral patients (Breakey, 1976; Zuniga *et al.*, 1972), In the case of trans-femoral amputee gait, the lowering of the knee range of motion is directly affected by the prosthesis knee design, which has to substitute the lost knee joint functions. However, in trans-tibial patients there is no

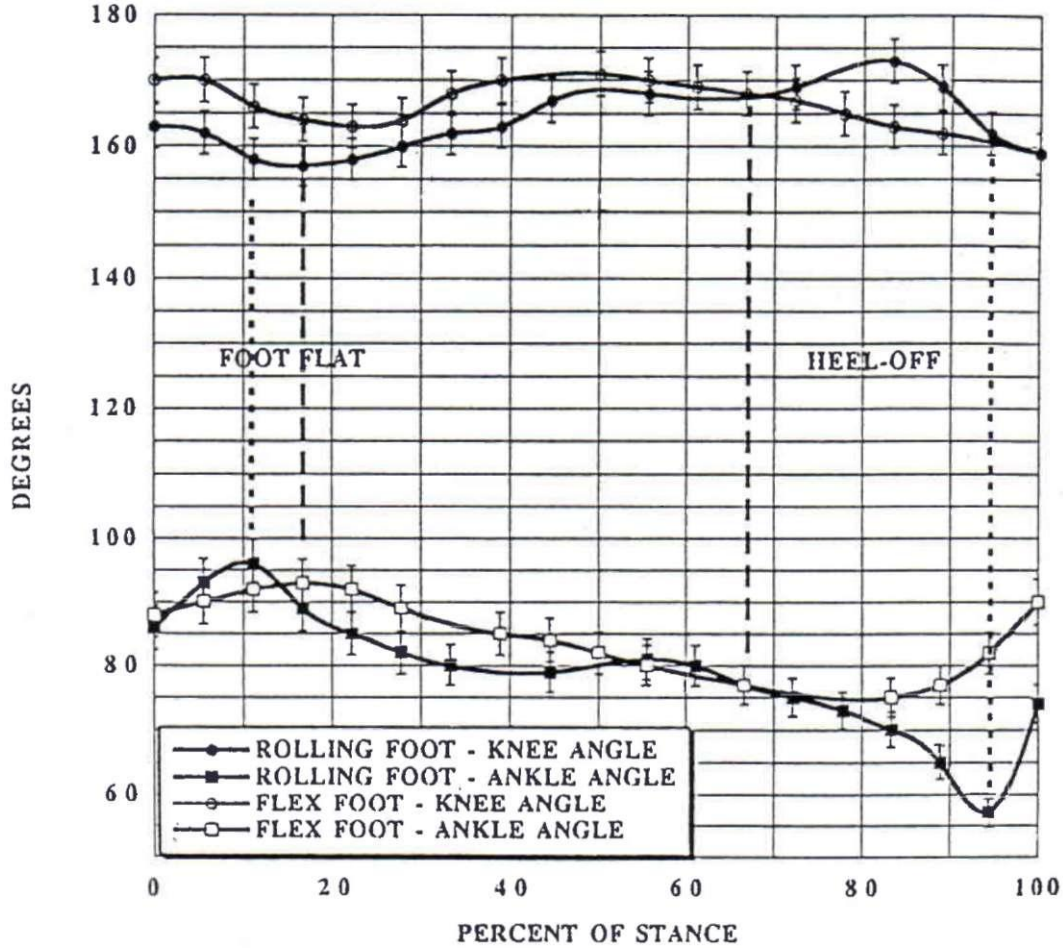

Fig. 8 Knee (existing) and ankle (prosthetic) angles in the RJA and Flex-Foot.

anatomical basis for reduced flexion of the existing knee in stance. A pilot gait study of the subject with trans-tibial bilateral amputations has proved an increased range of motion in the knee (15° versus 6°) with the RJA in comparison with the Flex-Foot (Fig. 8).

The second positive consequence of using the rolling joint prosthetic foot and ankle prototype was the subject's feeling of easiness in the beginning of flexion in the ankle during the first third of the stance period. A smooth transfer to the area of the metatarsals took place at the end of the second third of stance, and the heel of the RJA was lifted. One should recognise that it is not exclusively the magnitude of the stress that causes skin breakdown. The combination of such parameters as magnitude, frequency, and loading in other directions, tissue conditions, etc., may all simultaneously contribute to skin breakdown (Radcliffe and Foort, 1961; Sanders *et al.*, 1993). The reduction of normal and shear stresses on the stump would be even more important in the perspective of direct skeletal attachment for leg prostheses (Eriksson and Brånemark, 1994).

There might be a concern that the RJF does not mimic the resistive curve of the ankle at different walking speeds and under conscious control of the amputee. A mathematical model of a mechanism developed is not "sensitive" to the speed of ambulation, since the nonlinear resistive curve was intentionally provided by a linear elastic tie included in a rolling structure. However, the design of the RJF has an ability to respond to speed and correlated load changes. The distance between points of attachment of the elastic tie (and consequently the resistive curve) depends not only on the angle of dorsiflexion as in the mathematical model, but also on vertical loads from the prosthetic tibial connector (Fig. 6). This additional component of the moment of resistance might become a means for self-adjustment of the prosthesis to changes in speed. Further research and prototyping work is required to establish this.

Conclusions

1. The technique of synthesis of a cycloidal prosthesis mechanism with a given outcome has been developed, which would be useful for the design of prosthetic devices.
2. Further investigation in cam rolling (cycloidal) prosthetic joint design and usage should be conducted, since a more biological output appears possible.

Acknowledgements

This work was supported in part by NIH Institutional Research Training Grant #HD 07415 and the Ohio Willow Wood Company, Mount Sterling, Ohio. Initial sample was manufactured at United Prosthetics, Inc., Dorchester, MA.

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Prosthetics and Orthotics International, 1996, 20, 172-175

The use of Methenamine as an antiperspirant for amputees

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Abstract

The socket of a prosthesis is a tightly closed container. Sweating inside the socket is annoying and may also irritate the skin over the stump or lead to local infection such as folliculitis. The most effective method of preventing sweating is by the use of astringent agents. Formaldehyde is a very strong astringent but is not pleasant to use and may cause skin irritation and systemic reactions. Methenamine, in water or when applied to the skin, decomposes to generate formaldhyde in small quantities which do not cause side effects. Methenamine was used on the stump of sixteen amputees. The trial was conducted as a double blind study using two different solutions market as solution A and as solution B. The effectiveness , of the solutions as an antiperspirant was evaluated clinically by the subjects and the physician. Solution A containing Methenamine, was found significantly effective, both by the subjects and physician when compared with the solution B the blank one. The use of Methenamine as an antiperspirant is recommended in amputation stumps.

Introduction

A prosthetic socket is a closed container usually made of plastic materials. Sweating within the socket is considerable, especially in hot countries. In addition to the unpleasantness, sweating may cause damage to the skin of the stump; evaporation is impaired in the closed socket, the sweat collects and becomes a growth medium for bacteria. Also, the properties of the skin are changed and danger of abrasion and infection increases (Levy, 1983).

Several techniques were tried to prevent or decrease sweating of the stump inside the socket. Mechanical methods such as fabrication of the socket from porous material or drilling holes in it are not very effective. Pharmacological methods including creams of botanical origin have only a soothing effect on the skin. Anticholinergic drugs such as Probanthine have been proposed (Rollinson, 1971). As there are no preparations available for use on the skin it was proposed to crush pills, mix the powder with talcum and apply to the stump. The value of this method has not been proven.

An effective method to prevent sweating is the use of agents which have an astringent effect on the sweat glands (Walker and Swafford, 1971). Salts of aluminium and zinc are in wide use in deodorants but their astringent action is very weak (Rollinson, 1971). Formaldehyde is a material with very strong astringent action. Application of a solution of 3% formaldehyde once or twice is enough to prevent sweating for a prolonged period. However, formaldehyde is contraindicted because of the danger of allergic reactions and its strong odour (Rollinson, 1971). Methenamine (Fig. 1) is a chemical substance which converts into formaldehyde in water or in an acid environment (Cullen, 1975; Goodman and Gilman, 1975; Rollinson, 1971). It is usually used in treatment or prevention of urinary tract infections in cases of spinal cord injury, administered orally in a dose of 2-4 gr daily. As

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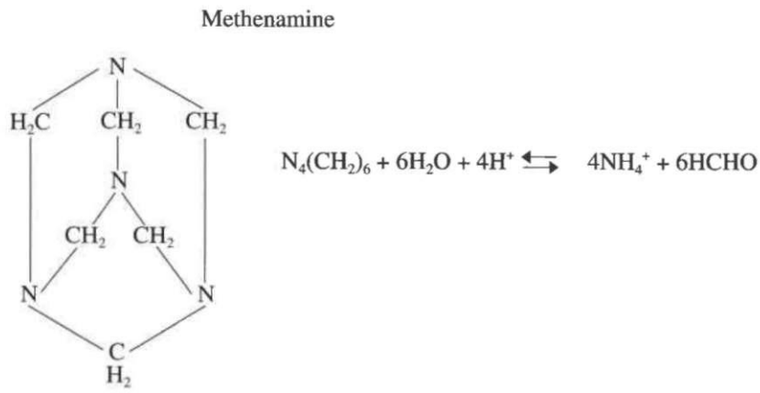

Fig. 1. Methenamine decomposes in water to generate formaldehyde.

a result, the bactericidic effect of formaldehyde can be used without danger for topical application. Methenamine was found effective in the treatment of hyperhidrosis (Cullen, 1975).

On the basis of these considerations a solution was prepared and a double blind study has been conducted to test its antiperspirant effectiveness on amputation stumps.

Subjects and methods

Sixteen amputees, four female and twelve male, participated in the study. Eleven were trans-femoral amputees and five trans-tibial amputees. All suffered from a considerable sweating of the stump inside the prosthetic socket, especially during the summer. Their mean age was 43.5±7.1 with range 27-52 years. Mean time since amputation was 11.2±5.2 years with range 3-12 years. All were excellent users of their prosthesis and apart from excessive sweating they did not suffer from stump problems or difficulties in fitting of the prosthesis.

The solution provided to the subjects were either active solutions (A) containing Methenamine or blank solutions (B) without Methenamine. The formula of the active substance was: Methenamine 25 gr, Alcohol 95% 52.6 ml, Aqua Distilata ad to 250 ml. The blank solution contained: Alcohol 95% 52.6 ml, Aqua Distilata ad to 250 ml. The solutions were supplied by the pharmacist in 100 ml identical bottles marked by numbers.

The study lasted for two years. The main period of treatment took place in the summer months. The subjects were instructed to apply the solution to the stump each evening and let it dry. They were instructed to continue the treatment until the entire solution (one bottle of 250 ml) had been used even if they did not experience any effect. In total 96 bottles of solution were supplied. Every subject received six bottles, three per year. Whenever a subject used up a bottle, he visited the outpatient clinic and informed the physician on the usefulness of the treatment.

The subjects were asked to wear their prosthesis continuously, for at least 2 hours, prior to evaluation. In the examination room, the subject took off his prosthesis and the stump was evaluated for level of sweating as follows; first - the subject's feeling of reduction of sweating, second - the physician's examination and impression on amount of stump sweating. The results were graded as; 1 - poor or no antiperspirant effect, 2 - moderate effect, 3 - excellent effect. None of the subjects reported negative side effects such as rashes, allergies, or skin breakdown manifested during the period of usage of the solutions. When the study was completed the code of the bottles was broken. The grades of effectiveness attributed by the subjects and the physician to solutions A and B were matched. The active solution was tested after twelve months and it was found to remain stable when stored in a glass bottle.

Statistical analysis was performed by the SAS computer programme using T-test and probability (Cary, 1989).

Results

After the code of the bottles was broken the results of the effectiveness of each bottle, as

Table 1. Antiperspirant activity of solution A and B as evaluated by the patient and physician (raw results after the code of the bottles was broken), sol. - solution, S - subject, P - physician.
1 - Poor or no antiperspirant effect, 2 - Moderate effect, 3 - Excellent effect.
A - Active solution (containing Methenamine), B - Black solution (without Methenamine).

Subject	Amput. level	Bottle 1 sol. - S - P	Bottle 2 sol. - S - P	Bottle 3 sol. - S - P	Bottle 4 sol. - S - P	Bottle 5 sol. - S - P	Bottle 6 sol. - S - P
1	AK	B - 1 - 1	B - 2 - 1	A - 3 - 3	A - 3 - 3	A - 3 - 3	A - 2 - 3
2	AK	B - 2 - 1	B - 1 - 2	B - 1 - 2	A - 3 - 3	A - 3 - 3	B - 1 - 1
3	AK	A - 2 - 3	B - 1 - 1	A - 3 - 3	B - 1 - 2	B - 1 - 2	A - 3 - 3
4	AK	A - 3 - 2	A - 3 - 3	B - 2 - 1	B - 1 - 1	A - 2 - 3	A - 3 - 3
5	BK	B - 2 - 1	A - 3 - 3	B - 1 - 2	A - 3 - 3	A - 3 - 3	B - 3 - 2
6	BK	B - 1 - 1	A - 3 - 3	B - 3 - 2	A - 3 - 3	B - 1 - 1	B - 3 - 2
7	AK	B - 1 - 1	A - 3 - 3	B - 1 - 1	A - 3 - 3	A - 3 - 2	A - 3 - 3
8	AK	A - 2 - 3	B - 1 - 2	A - 3 - 3	A - 3 - 2	A - 3 - 3	B - 1 - 1
9	BK	B - 2 - 1	A - 3 - 3	A - 3 - 3	B - 3 - 2	B - 1 - 2	B - 1 - 1
10	AK	B - 1 - 1	A - 3 - 3	B - 1 - 1	A - 3 - 3	A - 2 - 3	B - 1 - 2
11	AK	B - 1 - 1	B - 1 - 1	A - 3 - 2	B - 2 - 1	B - 1 - 1	A - 3 - 3
12	BK	A - 3 - 3	A - 3 - 3	B - 2 - 1	A - 3 - 2	B - 1 - 1	A - 3 - 3
13	AK	A - 3 - 2	A - 3 - 3	B - 1 - 2	B - 1 - 1	A - 2 - 3	A - 3 - 2
14	BK	A - 3 - 3	A - 3 - 2	A - 3 - 3	B - 3 - 1	B - 1 - 1	B - 2 - 1
15	AK	B - 1 - 1	B - 2 - 1	A - 3 - 3	B - 1 - 1	A - 3 - 3	A - 2 - 3
16	AK	A - 3 - 3	A - 3 - 3	B - 1 - 1	A - 2 - 3	B - 1 - 1	A - 3 - 3

graded by the subjects and the physician, were matched (Table 1). The normalised factors (Table 2) represent the average grades (total grades divided by total number of bottles) attributed by the subjects and by the physician to bottles marked A and B. Table 3 presents the final normalised factors obtained in each of the compared groups; subjects, physician, solution A, solution B. The final normalised factors represent the sum of the obtained normalised factors divided by the total number of the subjects.

The effectiveness of the treatment (final normalised factors) attributed to solution A and

Table 2. Values of total bottles, total grades, and normalised factor obtained for solution A (containing Methenamine) and for solution B (without Methenamine). The normalised factor is obtained by dividing total grades by the total number of bottles.

	Solution A					Solution B				
	Subject			Physician		Subject			Physician	
Subject	Total bottle	Total grades	Normal. factor	Total grades	Normal. factor	Total bottle	Total grades	Normal. factor	Total grades	Normal. factor
1	4	11	2.750	12	3.000	2	3	1.500	2	1.000
2	2	6	3.000	6	3.000	4	5	1.250	6	1.500
3	3	8	2.666	9	3.000	3	3	1.000	5	1.666
4	4	11	2.750	11	2.750	2	3	1.500	2	1.000
5	4	12	3.000	11	2.750	2	2	1.000	2	1.000
6	4	11	2,750	11	2.750	2	2	1.000	3	1.500
7	3	8	2.666	9	3.000	3	3	1.000	4	1.333
8	2	6	3.000	5	2.500	4	5	1.250	4	1.000
9	4	11	2.750	10	2.500	2	2	1.000	3	1.500
10	3	8	2.666	9	3.000	3	4	1.333	3	1.000
11	4	11	2.750	12	3.000	2	2	1.000	2	1.000
12	3	9	3.000	9	3.000	3	6	2.000	5	1.666
13	2	6	3.000	6	3.000	4	8	2.000	6	1.500
14	2	6	3.000	6	3.000	4	7	1.750	6	1.500
15	4	12	3.000	11	2.750	2	3	1.500	2	1.000
16	3	9	3.000	8	2.666	3	6	2.000	3	1.000

Table 3. Comparison between the final normalised factors (the sum of the normalised factors divided by the total number of subjects) obtained for each of the groups.

	Solution A	Solution B	p<
Subjects	2.859±0.14	1.380±0.38	0.001
Physician	2.854±0.18	1.260±0.27	0.001
p	ns	ns	

solution B by the subjects was compared with that of the physician (Table 3). No significant differences were found between the evaluations of the subjects and the physician for solution A and solution B. The difference between solutions A and B was found highly significant when evaluated by the subjects (p<().()01) and by the physician (p<0.001).

Discussion

A double blind study on the effectiveness of Methenamine as an antiperspirant in amputation stumps is reported. Although the evaluation of the solutions was made subjectively by the amputee and by the physician it is assumed to be reliable because there was no difference between the two evaluations. On the other hand there was a strong significant difference between the solution containing Methenamine and the solution without it.

It is therefore concluded that Methenamine is an effective antiperspirant and is recommended for use on amputation stumps. Although no allergic reactions were noted in the trial, it is noted that allergic reactions are not uncommon and vigilance should be maintained.

Acknowledgement

The authors would like to thank Mr. E. Yucha for his help in the statistical evaluation.

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Prosthetics and Orthotics International, 1996, 20, 176-181

Painful neuromata following upper limb amputation

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Abstract

Painful neuromata occurring after upper limb amputation are a significant cause of stump pain and limit the success of prosthetic training and use.

There is little information in the literature regarding incidence, consequences or outcomes of painful neuromata subsequent to upper limb amputation. This article reports an analysis of thirty-two consecutive upper limb amputees. Of these 25% had moderate-to-severe stump pain and clinical signs suggestive of neuromata.

All patients with neuromata were limited in their ability to use a prosthesis prior to surgery and following failure of conservative measures, were referred for surgical opinion. Six patients have undergone surgical management. The results of surgery, with respect to pain and prosthetic usage, are discussed.

Introduction

Pain following upper limb amputation may for the patient concerned be a major problem, causing significant distress and hindering rehabilitation, a prosthetic training programme and subsequent prosthetic use. The pain experienced may be due to a painful phantom or secondary to local stump problems. Phantom pain is defined as persistent painful feeling of the presence of the body-part even after the part has been excised, whereas stump pain may be considered as pain arising from the remaining body-part. Jenson *et al.* (1983) reported the incidence of phantom and stump pain eight days after amputation, as 72% and 57%, respectively. By six months the incidence had decreased to 67% and 22%.

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The cause of stump pain are many and varied. They include — poor prosthetic fit; neuromata; joint problems (e.g. arthritis); sympathetic pain (e.g. reflex sympathetic dystrophy); referred pain; ischaemic pain; abnormal stump tissue (e.g. heterotrophic ossification or adherent scar) and skin problems such as dermatitis or ulceration (Davis, 1993). Formation of a neuroma following transsection of a nerve is a normal occurrence (Omer, 1981). The neuroma may occasionally cause spontaneous pain, but usually unless it is trapped in scar tissue or located in a vulnerable position in the stump, it dos not cause any significant problems. However, it is well-known that for some patients, neuromata are a major concern causing ongoing pain and inability to use a prosthesis successfully.

The diagnosis of neuroma is made clinically in most cases. The pain is usually localised and described as sharp, shooting or electric shock-like. It may be elicited by light tapping over the area (Tinel's sign) and may be felt to be transmitted proximally or distally along the transected nerve.

The initial management of painful neuromata is usually conservative with surgical intervention reserved for intractable cases. Conservative treatment consists of pharmacological management, e.g. anti-convulsants or antidepressants, local injection with steroid and desensitisation techniques including local percussion, massage, ultrasound or TENS.

Many surgical techniques have been attempted in the management of neuromata. They all involve attempts to either inhibit axonal growth or to reposition the neuroma or residual nerve away from the noxious stimuli. Inhibition of axonal growth has been attempted through such techniques as chemical treatment, ligation, cauterization, capping the nerve with

an inert material as well as nerve-to-nerve repair grafting techniques. Repositioning may involve excision and retraction, implantation into soft tissue, muscle, bone or vascular structures or en bloc translocation away from the stimulus (Whipple, 1988).

Barbera and Albert-Pamplo (1993), reported twenty-two cases of neuromata in lower limb amputees, who were treated with the technique of centrocentral anastomosis. This involves the end-to-end connection of paired fascicular groups of the proximal stump of the severed nerve across interposed autologous nerve grafts. The aim was to prevent neuroma formation by allowing the nerve fibres to regenerate in a physiological environment (the autologous nerve graft). All of these patients had been unable to use a prosthesis prior to surgery and conservative measures had failed in all cases. At one year follow-up the typical neuroma pain had disappeared in all cases, but there was residual diffuse pain in four patients. Wood and Mudge (1987) treated five patients with intractable neuroma pain by resecting the neuroma and anastomosing the nerve to another nerve and burying it under the muscles of the forearm. Patients reported a 80-90% reduction in pain. Martini and Fromm (1989) treated sixty-eight painful neuromas in thirty-six patients by shortening single nerve fascicles, pulling the epineurium forward to cover them and sealing with tissue glue. At an average follow-up of seventeen months, all but three of the patients were improved or pain-free. Whilst the literature details extensively the surgical management of painful neuromata, there is little information regarding either the incidence in upper limb amputation or the influence of surgery on the ability to use the prosthesis.

The aim of this study was to find the incidence of painful neuromata in upper limb amputees, the rate of referral for surgical management and the effect of the neuromata and subsequent surgery on pain levels and prosthetic usage.

Methods

The study involved the analysis of the medical records of thirty-two consecutive patients with upper limb amputation, who underwent rehabilitation at the Royal South Sydney and Prince Henry Hospitals between 1991 and 1995, to identify those who had painful neuromata. All patients had been managed by the same rehabilitation specialist (one of the authors) at the time of their initial rehabilitation programme and those with neuromata diagnosed by clinical examination. The records of all thirty-two patients were reviewed to obtain details of demographics, severity of pain and rate of referral for surgical opinion and those patients with painful neuromata further surveyed using a questionnaire.

The questionnaire focused on the occurrence of stump pain — before, immediately after surgery (within the first month), at the time of follow-up and on the degree to which a prosthesis could be used before and following neuroma surgery. Pain levels were measured using a visual analogue scale, as was the patient's overall satisfaction with the results of the surgical procedure.

Prince Henry Hospital is the main tertiary referral centre for upper limb amputation in the State of New South Wales and as such manages patients from all over the State. For this reason not all patients were available for personal interview, but where possible this was done. In other cases a telephone interview was conducted. The surgical technique used and the number of neuromas treated in each patient was obtained by reviewing the surgical record.

Results

Thirty-two patients underwent a rehabilitation and prosthetic programme for upper limb amputation during the study period. Demographic details of the group are displayed in Table 1 and Figure 1 shows the age distribution of the group.

Table 1. Demographic details of upper limb amputees treated at RSSH and PHH between 1991 and 1995

Mean age	35 (range 15-78)	
Sex	29 male/3 female	
Level of amputation		
	trans-radial	11
	trans-humeral	16
	partial hand	5
TOTAL:		**32**
Cause of amputation		
	trauma	27
	carcinoma	4
	infection	1
TOTAL:		**32**

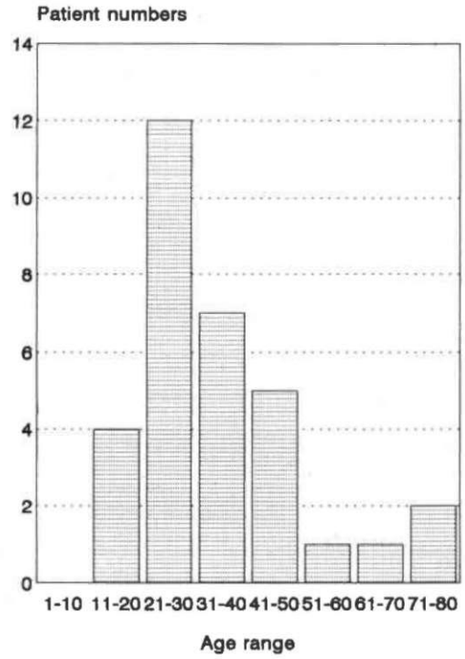

Fig. 1. Age distribution of upper limbs amputees

Pain

Of the thirty-two patients — twenty reported some degree of stump pain, seven reported mild pain, seven moderate and six severe pain. Twenty-five patients reported a painful phantom, with six mild, eleven moderate and eight severe. Eight patients (25%) had clinical signs suggestive of neuromata and all of these reported moderate to severe stump pain. All the eight patients identified with painful neuromata were contacted and the questionnaire administered either in person or by telephone. The demographic details of those eight patients are shown in Table 2.

Onset of stump pain

The time between amputation and the onset of the stump pain characteristic of neuromata is shown in Figure 2. The average time was 11.6 weeks with a range of one to thirty-six weeks.

Referral for surgical opinion

All eight patients had undergone conservative management techniques to control the neuroma pain including pharmacological treatment, desensitisation and in some cases, local injection. All where subsequently referred for surgical opinion. Several different surgeons were involved during the period of the study.

Table 2. Demographic details of upper limb amputees with painful neuromata

Mean age	31 (range 21-56)	
Sex	all male	
Occupation		
(prior to amputation)	butcher	2
	farmer	2
	process worker	2
	miner	1
	teacher	1
TOTAL:		**8**
Level of amputation		
	trans-humeral	4
	trans-radial	3
	partial hand	1
TOTAL:		**8**
Cause of amputation		
	all traumatic	

Time to follow-up

The average time from amputation to follow-up was 11.5 months with a range from one month to forty-five months. At the time of

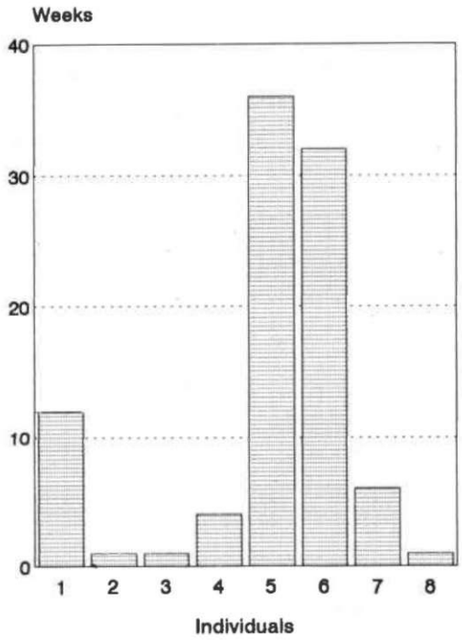

Fig. 2. Time onset of pain

follow-up six of the eight patients had undergone surgical procedures and two were awaiting surgery.

Surgical intervention

The average time from amputation to surgical intervention was eleven months with a range of three to twenty-two months. A variety of surgical procedures was employed. In two cases, the neuromata were divided and the nerve buried in soft tissue as proximally as possible. In one case after excision, the nerve was buried in the wrist and proximal metacarpals, then in a further instance the terminal nerve was implanted into a vein. In one other case the neuroma was simply excised.

Number of neuromata

A total of nine neuromata were surgically treated in the six patients. The painful neuroma occurred on the ulnar nerve in three cases, on the median in five cases and on the radial in one case. Three patients had neuromata treated on two nerves.

Pain in patients with neuromata

In the amputees with neuromata, pain levels were further investigated using a visual analogue scale. Patients were asked to identify the degree of pain experienced on a scale of zero to ten where zero was no pain and ten was the worst pain they could imagine. There were asked the same question regarding the pain — before surgery, immediately after surgery (within one month) and at the time of follow-up. For one patient the time of follow-up was within one month of neuroma surgery. Stump and phantom pain were investigated separately.

Results revealed that the average Visual Analogue Scale (VAS) score for phantom pain was 5.8 and for stump pain 7.4 prior to surgery. The average reduction in pain immediately post-operatively as 0.6 for phantom pain and 4.6 for stump pain. At the time of follow-up, the reduction was 0.6 and 1.5 respectively. As would be expected, the results indicate that there was little effect of neuroma surgery on phantom pain. There was a reduction in the severity of stump pain immediately, but this was not maintained by the time of follow-up and there was large variability in response to surgery. Several patients had large reductions in pain levels which were maintained at the time of follow-up. However, several reported little, if any, reduction and one patient had a good result immediately but, by the time of follow-up, pain had returned to pre-surgery levels.

Prosthetic use

Patients were asked to indicate the degree to which they were able to use their prosthesis prior to and following surgery. Constant use, was defined as use for six hours a day, five days a week. Occasional use, as anything less than this.

Results indicated that six of the patients were never able to use the prosthesis prior to surgery, whilst two were occasional users. Following neuroma surgery, two of the non-users remained non-users. One of these was due to continuing severe stump pain and the other due to an increase in phantom pain.. This patient had excellent reduction in stump pain post-surgery. One patient, who had good reduction in pain, was able to use the prosthesis occasionally following surgery. Another patient stated that the prosthesis was used constantly immediately after surgery, but unfortunately the pain returned by the time of follow-up and prosthetic use again became impossible.

The patient with the partial hand amputation had two prostheses. The first, a cosmetic glove, was used constantly prior to surgery despite considerable pain and with much improved comfort following the surgery. A functional orthotic device was used occasionally prior to surgery and more often following surgery. One patient did not have the opportunity to re-use prosthesis at the time of follow-up.

Outcome

As a measure of overall outcome, patients were asked to indicate their satisfaction with the surgical procedure, using a visual analogue

Table 3. V A S scores for patient satisfaction with outcome following surgical intervention for painful neuromata in upper limb amputees

Patient	1	2	3	4	5	6	7	8	Av.
VAS score	1	5	10	5	–	8.5	8	–	6.25

scale. The average VAS score was 6.25, but again there was wide fluctuation in individual results (Table 3).

Discussion

Whilst painful neuromata are known to occur and to influence prosthetic usage following upper limb amputation, this study revealed a higher than expected incidence. Eight of thirty-two patients (25%) were found to have clinical signs indicative of neuroma and all of the patients described moderate-to-severe stump pain. The demographic features of this group of patients was an accurate reflection of upper limb amputees in general. They tended to be younger males in "at risk" occupations, in whom trauma was the cause of the amputation.

The onset of the pain in this group of patients was highly variable with not all patients experiencing pain immediately after amputation. Several did not experience the characteristic pain until months later. The reason for this is unclear. However, it can be hypothesised that in these cases it is not until the neuroma becomes large, scar tissue contracts or other soft tissue/bony structures intervene, that enough pressure or irritation is caused around the neuroma to induce pain. It is also likely that the pressure caused with the first attempts at wearing a prosthesis, may be the trigger which activates an otherwise non-painful neuroma.

The relatively long period between amputation and surgical intervention — eleven months, is not unexpected as in many cases pain occurring soon after amputation resolves spontaneously or with pharmacological and/or conservative management. Surgery is usually reserved for cases of ongoing pain, which has been unresponsive to these measures. In particular it is used when the pain interferes with the rehabilitation programme, prosthetic usage or lifestyle in general. However, as was the case for several patients in this study, an argument can be made for earlier surgery where the diagnosis of a neuroma is clear-cut with pain being severe and disabling, in an attempt to avoid ongoing difficulties.

All patients were eventually referred for surgical opinion and in all cases an attempt at surgical remediation felt to be appropriate. Six patients had undergone a variety of procedures. The variety of surgical procedures employed by different surgeons in this study would seem to confirm review of the current literature which indicates that no one technique has been proven to be more successful than any other. The studies by Barbera and Albert-Pamplo (1993), Martini and Fromm (1989), Wood and Mudge (1987) all showed significant reduction in pain. It is not possible, from this study, to make any meaningful comments on the success of any particular surgical techniques, but further investigation of one particular procedure or a comparison of procedures, performed by the same surgeon, would be informative.

All the patients with painful neuromata in this study reported moderate-to-severe pain in the stump prior to surgery with VAS scores ranging from 5 to 10. Whilst there was an overall reduction in the VAS score immediately post-operatively, this was not uniform. Several patients reported little change in pain levels. The good immediate response was maintained at the time of follow-up for several patients. At lease two reported further increases in pain and one of these to pre-operative levels. In the instances where pain is unaffected or recurs, the patient should be carefully re-examined to exclude complicating or intervening causes of pain and at some point, a decision made to attempt a further surgical procedure.

Surgery for pain neuromata was found to have little influence on the occurrence of phantom pain in this group of patients, either immediately or at follow-up. Current theories of the aetiology of phantom pain are theories of either initiation or magnification. The first is thought to involve plasticity in the dorsal horn neurons, induced by damage to peripheral nerves, which causes the neurons to generate pain impulses that are directed rostrally (Dubner, 1991). The second is that, due to the loss of the body-part, there is lack of inhibition of peripheral inhibitory afferent input which leads to pain magnification (Melzac, 1971).

There is not doubt that, for the patients in this study, the pain produced by the neuromata severely limited prosthetic use prior to surgery. Six of the eight patients were unable to use their prosthesis at all, whilst two used them occasionally. All patients indicated that pain was the dominant reason for lack of prosthetic use. Post-operatively at least three patients used their prosthesis more frequently, although only one of these reached constant usage and in this

case, the pain subsequently recurred again causing difficulty with use. Two patients remained unable to use their prostheses at all, but in one of these cases it was not stump pain, but the emergence of severe phantom pain which was the cause.

This latter case illustrates the difficulty in analysis of prosthetic use following upper limb amputation. Studies have previously shown that the overall rate of usage is low and that prostheses are discarded or not used at all for a variety of reasons. Jones and Davidson (1995), in a recent review of forty-one upper limb amputees, found a rate of prosthetic use for more than eight hours per day by only 37% and occasional use by 18.5%. Common reasons for lack of prosthetic use include — insufficient cosmesis; the cumbersome nature of the prosthesis; the sweating and irritation produced by use; and reduction rather than improvement, in functional abilities.

The results of the outcome assessment reflected other results clearly, in that there was a spectrum that ranged from highly-satisfied to totally dissatisfied. All patients who reported a high level of satisfaction, had excellent reduction in pain following surgery. The most dissatisfied patient had no reduction in pain. Interestingly, only one of those who were highly satisfied, described constant prosthetic use following surgery and even the patient, who was unable to commence prosthetic use, due to intercurrent phantom pain, was highly satisfied with the diminution of the stump pain. This perhaps, emphasises that at lease from the patients point-of-view, the endpoints of surgery for painful neuromata, are pain reduction primarily and only secondarily, prosthetic usage.

Conclusion

This study has demonstrated a rate of 25% for painful neuromata following upper limb amputation. This rate was higher than expected and indicates that neuromata may be a more significant cause of disabling stump pain than has been previously thought.

All patients suffered from moderate-to-severe stump pain and most were completely unable to use their prosthesis prior to surgery. All patients were referred for surgical opinion and a variety of surgical procedures was performed.

Analysis of pain reduction and prosthetic use was somewhat hampered by the differing surgeons and techniques involved, but overall there appeared to be a reduction of pain in the first month following surgery. However, there was some loss of this immediate reduction by the time of follow-up. As with pain reduction, analysis of prosthetic usage following surgery, revealed wide variability. This was dependent primarily, but not only, on reduced pain levels following surgery.

This study involves only a small number of upper limb amputees and further studies involving larger groups of patients, should be undertaken. The problem of the most appropriate surgical technique is difficult, but ideally one surgeon performing one type of procedure, or comparing it to an alternative, would allow more accurate assessment of pain reduction and subsequent prosthetic usage.

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Prosthetics and Orthotics International, 1996, 20, 182-190

Objective measurement of use of the reciprocating gait orthosis (RGO) and the electrically augmented RGO in adult patients with spinal cord lesions

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Abstract

The purpose of the study was to measure objectively the home use of the reciprocating gait orthosis (RGO) and the electrically augmented (hybrid) RGO. It was hypothesised that RGO use would increase following provision of functional electrical stimulation (FES). Five adult subjects participated in the study with spinal cord lesions ranging from C2 (incomplete) to T6. Selection criteria included active RGO use and suitability for electrical stimulation. Home RGO use was measured for up to 18 months by determining the mean number of steps taken per week. During this time patients were supplied with the hybrid system. Three alternatives for the measurement of steps taken were investigated: a commercial digital pedometer, a magnetically actuated counter and a heel contact switch linked to an electronic counter. The latter was found to be the most reliable system and was used for all measurements. Additional information on RGO use was acquired using three patient diaries administered throughout the study and before and after the provision of the hybrid system. Testing of the original hypothesis was complicated by problems in finding a reliable measurement tool and difficulties with data collection. However, the results showed that overall use of the RGO, whether with or without stimulation, is low. Statistical analysis of the step counter results was not realistic. No statistically significant change in RGO use was found between the patient diaries. The study suggests that the addition of electrical stimulation does not increase RGO use. The study highlights the problem of objectively measuring orthotic use in the home.

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Introduction

Long term compliance with the reciprocating gait orthosis (RGO) has been found to be poor (Sykes *et al.,* 1995). One contributory factor for this may be the energy requirements associated with its use. It has been suggested that reducing the energy cost of walking will allow the patient to use the device "over longer distances and periods of time, and thereby incorporate it in his daily living" (Hirokawa *et al.,* 1990). To achieve this the mechanical orthosis has been combined with electrical stimulation of the thigh muscles to produce a "hybrid" system (Solomonow *et al,* 1989). Stimulation is used to assist the propulsion of the patient. This system has been reported to improve ambulatory efficiency (Hirokawa *et al,* 1990; Petrofsky and Smith, 1991; Phillips and Hendershot, 1991; Isakov *et al,* 1992). The authors were unable to demonstrate substantial improvements in energy cost during ambulation following its introduction (Sykes *et al,* 1996).

Evaluation of the RGO and hybrid orthoses has been carried out largely in the laboratory environment and has concentrated on physiological benefits. Little attention has been paid to their use in the home environment. The clinical significance of laboratory based results can only be interpreted by comparison with objective measurement of patients customary use of the orthoses "in the home". This should be considered when evaluating either orthosis.

Methods of measuring normal daily activity include observation or self-reporting techniques using, for example, questionnaires or the diary

method. However, use of these methods has limitations in that they rely on retrospective recall or are restricted to only a part of the patient's life. There is a need, therefore, to find methods of objectively measuring patient activity over a continuous time span, with an acceptable accuracy and with minimal disturbance to the subject's daily routine. One method is to measure the number of steps taken by the subject. This approach was adopted by Bassey *et al.* (1988) who successfully used a pedometer to measure the step score of elderly patients over the course of a week, thus measuring their level of walking activity. One aim of the present study was to find a reliable method of objectively measuring the number of steps taken in the RGO (with or without electrical stimulation) in patients with spinal cord lesions. The evaluation of three alternative systems is described. The most reliable system was used to test the hypothesis that RGO use would increase following the addition of electrical stimulation.

This study forms part of an 18 month evaluation of the FES augmented RGO walking system.

Method

Subjects

Five adult subjects participated in the study (Table 1). Using the ASIA impairment scale, neurological level of lesions ranged from C2(C) to T6(A). Four subjects had suffered traumatic lesions (median time since injury **of** 10.5 years, range 8-14 years). Subject 4 was diagnosed as having had myelitic illness. This subject had some preserved motor function below the neurological level. All subjects were successfully using the RGO at the start **of** the study (median time since RGO supply of 5.7 years, range 4.1-7.3 years). Subject 4 was the only community walker.

Hybrid walking system

Each subject was supplied with stimulation equipment after a period of muscle conditioning and gait training with the hybrid system. The stimulation protocol was derived from Solomonow *et al.* (1989) and is described elsewhere (Sykes *et al,* 1996). A four channel stimulator was used to apply surface stimulation to the left and right quadriceps and left and right hamstring muscles. Four stimulators were supplied by Louisiana State University (LSU II) and one was manufactured by the Medical Physics Department, Hope Hospital, Salford. Parameters of stimulation were a frequency of 20Hz, pulse width of **350jUS** (Medical Physics) and 400//s (LSU II), and an output of 0-115mA (Medical Physics) and 0-200mA (LSU II). Values assume an output impedance of lkQ. During muscle conditioning the on/off duty cycle was 1.5s.

RGO 'step' counter

Three alternatives were tried for the measurement of steps taken in the RGO and hybrid orthosis. Firstly, a commercial, digital pedometer was used (GB, Allsports). This pedometer records the acceleration and deceleration movements in one direction. At rest, an arm, balanced by a delicate spring, is displaced upwards and the circuit is disconnected. When the arm moves downwards (caused by jolts as the wearer moves) the circuit is completed and one step is registered on the pedometer. The manufacturer's instructions are for the pedometer to be fixed to the waist. It was found to give inaccurate results when used in conjunction with an RGO. More accurate recordings were achieved when the pedometer was placed on the thigh strap of the RGO. The main problem with the pedometer was that it required operation by the patient. Therefore, it was not adopted in the study.

Table 1. Subject details

Subject	Age (yrs)	Neurological level of lesion*	Time since RGO supply (yrs)	Walking aid	Place of RGO use
1	29	T6 (A)	5.7	Rollator	Home
2	34	T6 (B)	5.5	Rollator	Home
3	24	C8 (A)	4.1	Rollator	Home
4	37	C2 (C)	7.3	Crutches	Community
5	35	T1 (A)	7.0	Rollator	Home

*including ASIA impairment level

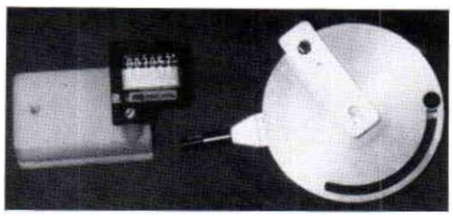

Fig. 1. Magnetically actuated counter.

Secondly, a magnetic switch counter was tried (Fig. 1). This comprised a 6-digit magnetically actuated counter (RS, 260-375) which was sited on the thigh upright of the RGO. The counter had a switching rate of 20 digits/second. A small magnet, fixed onto the end of a metal arm, was pivoted from the centre of the orthotic hip joint. As one step was taken the arm (and hence the magnet) moved through an arc and past the counter causing one step to be registered. The main problem with this method was the bulk required at the hip joint in order to get a sufficient lever arm and range of movement. The device tended to catch on clothes and was frequently pulled off. It also obstructed the hip joint release mechanism on the RGO and was abandoned.

Finally, a contact switch was used which was combined with an electronic counter (Syrelec, Farnell) (Fig. 2). This was the most reliable system. The contact switch comprised two thin pieces of aluminium foil (approx. 30mm x 30mm), separated by a piece of plastic sponge foam (approx. 4mm thick) into which a circular hole was cut. The whole switch was contained in a vinyl pocket and taped onto the heel area at the base of the ankle-foot orthosis (AFO) on the RGO. The switch was connected via a jack plug and socket to a counter which was sited on the thigh upright of the RGO. When the contact switch was compressed during weight bearing one step was registered. The counter displayed up to 999999 steps and was powered by lithium battery (RS). The reset mechanism was not accessible to the patient, so that the value on the counter represented a cumulative total of steps. In order to obtain the number of steps taken during any one particular time period, readings were taken at intervals and the previous recordings subtracted from the new recording. Values were doubled to allow for reciprocal walking. Where possible the counter was attached to the RGO as soon as the patient consented to participate in the stimulation programme. The counter reading was recorded for approximately 18 months. During this time patients were supplied with the hybrid orthosis.

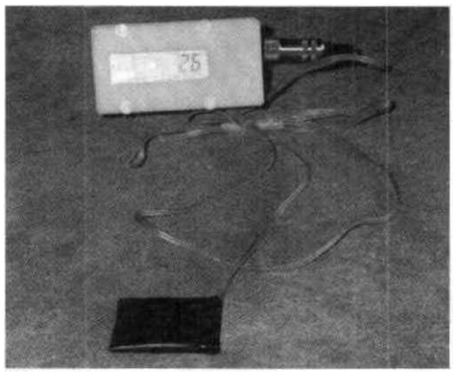

Fig. 2. Contact switch and electronic counter.

Validity and reliability

The validity and reliability of the step counting device were assessed in the laboratory where a sound box was used instead of a counter. The position of the contact switch was adjusted until the "beep" emitted from the sound box coincided with one step. Once it was clear that accurate information was being obtained the sound box was replaced with the digital, electronic counter. For each patient the position of the switch was altered until an accurate recording was achieved when the patient walked around a large laboratory area. The researcher counted the total number of steps taken by the patient using a hand held mechanical counter (itself assessed for reliability) and checked the electronic counter to ensure that this was recording accurately. The position of the contact switch was altered until three "test walks" produced accurate results. At subsequent review appointments the actual number of steps taken during one or more 90m walks was counted and compared with the counter reading in order to establish the reliability of the counter mechanism. The mean of the counter readings was used to determine the approximate steps/unit distance covered by the subjects.

Patient diary

In order to strengthen the results obtained using the step counter, subjects were

Table 2. Mean error (%) of the step counter (± 1 S D)

Subject	Mean error (%) ± 1SD	Relationship to actual number of steps taken
1	11.1 ± 1.9 n=7	higher
2	8.7 ± 1.6 n=4	lower
3	8.0 ± 2.7 n=4	higher
4	9.6 ± 5.9 n=7	higher
5	8.9 ± 1.1 n=3	higher

periodically issued with a diary which was formatted in a simple manner to allow self-recording of RGO use over 14 consecutive days. Each day was divided into 15 minute periods. The subject was required to tick the appropriate time period to indicate use of the RGO (or hybrid). A tick was required for each whole or part time period. Time taken to don/doff the RGO was not included. Subjects were asked to record information relating to a typical fortnight and not to wait until a time when they felt that they would be using the RGO more often or for longer periods. Diaries were issued:

(i) as soon as the subject had agreed to participate in the study (subject using RGO only);

(ii) 6 months after the start of the stimulation protocol;

(iii) 6 months after the end of gait training with the hybrid system, i.e. when the subject had been using the system at home for 6 months.

Results

Reliability

The step counters for Subjects 1, 3, 4 and 5 gave consistently higher readings than the actual number of steps taken. The counter for Subject 2 always gave a lower reading. The mean error obtained for each patient is shown in Table 2 and varied between 8.0% and 11.1%.

Step counter

Figure 3 shows the mean number of steps taken per week by each subject. The point at which the hybrid system was taken for home use is indicated by an arrow. Prior to this the patient used the RGO only. The vertical dashed lines indicate the time period during which data collection occurred. The overall mean number of steps taken per week for each subject is shown in Table 3. In the case of Subject 1, 3, and 4 values are also shown after the exclusion of periods of non-use of the RGO which could be accounted for by valid reasons. At Week 32, Subject 1 developed a pressure sore, unrelated to the RGO, but which prevented him using the RGO until approx. Week 47. Subject 3 did not use the RGO between approximately Week 15 and 30 while he was in USA playing sport. Subject 4 had a long period when she was unable to use the RGO because of mechanical problems with the orthosis, a deterioration in balance and unrelated health problems. Taking these periods of non-use into account the mean number of steps taken per week varied between 306 and 1879 steps. This was calculated to be between approximately 99m (Subject 5) and 845m/week (Subject 4). RGO use by Subject 5 who was known to be the poorest user was the lowest of the group. Subject 4 was known to be the best RGO user and the only subject to use crutches and walk in the community. In the

Table 3. Overall mean number of steps/week and approximate m/week before and after exclusion of accountable periods of non-use

Subject	Overall mean steps/week	Overall approx. m/week	Mean steps/week after excluded data	Approx. m/week after excluded data
1	431	231	585	313
2	968	449	968	449
3	547	246	779	350
4	784	353	1879	845
5	306	99	306	99

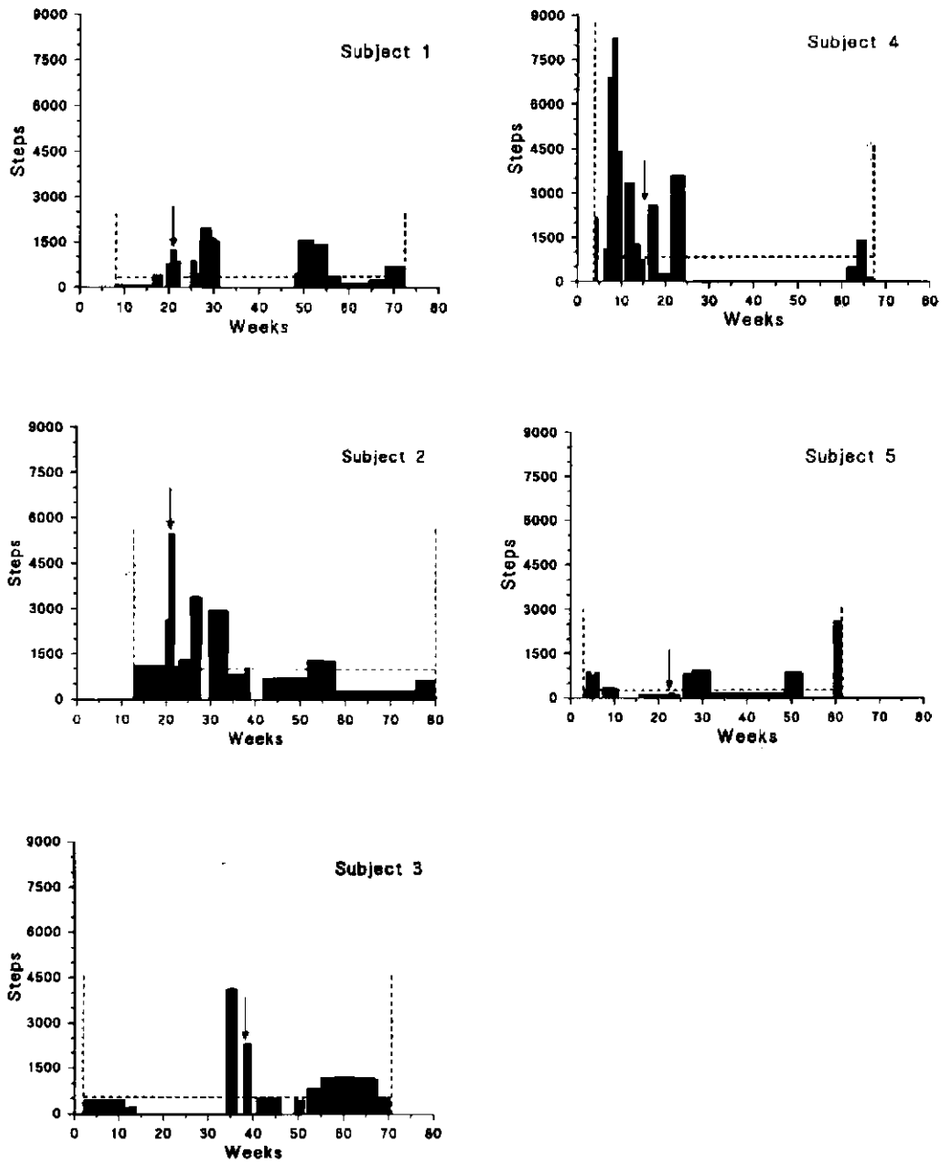

Fig. 3. Mean number of steps taken in RGO/week against weeks after start of FES programme (arrow indicates when the hybrid walking system was taken for home use; data collection occurred between the vertical dashed lines; horizontal dashed line shows overall mean steps taken).

early part of the study her step counter reading far exceeded that of the other subjects (Fig. 3). No subject showed a consistent pattern of RGO use, i.e. there was considerable variability. This variability was greater than can be accounted for by errors in the measuring system. Overall use of the RGO whether with or without stimulation was low and there was no trend to

increasing use following supply of the hybrid system. Statistical analysis of the results was not realistic.

Patient diary

The results from the patients diaries for Subjects 1-4 are shown in Figure 4. Subject 5 did not return any of the diaries. RGO use by Subjects 1, 2, and 3 was low, varying between a mean of 0.20 hours/day and 1.75 hours/day. The poor use shown by Subjects 1, 2, and 3 (Fig. 4) is a reflection of the low counter readings shown in (Fig. 3). Subject 4 demonstrated a high level of RGO use in Diary 1 with a mean of over 7 hours a day, which far exceeded that of the other subjects. This was also seen in the step counter results (Fig. 3). The problems mentioned earlier which resulted in a drop in use are reflected in Diaries 2 and 3. Subject 5 was known to be the poorest user at the start of the study. Despite written and verbal reminders, this patient never returned a diary. Statistical analysis using Wilcoxon matched pairs signed ranks test for the group showed no significant difference (at $p<0.05$) between Diary 1 and Diary 2 ($p=0.465$), Diary 2 and Diary 3

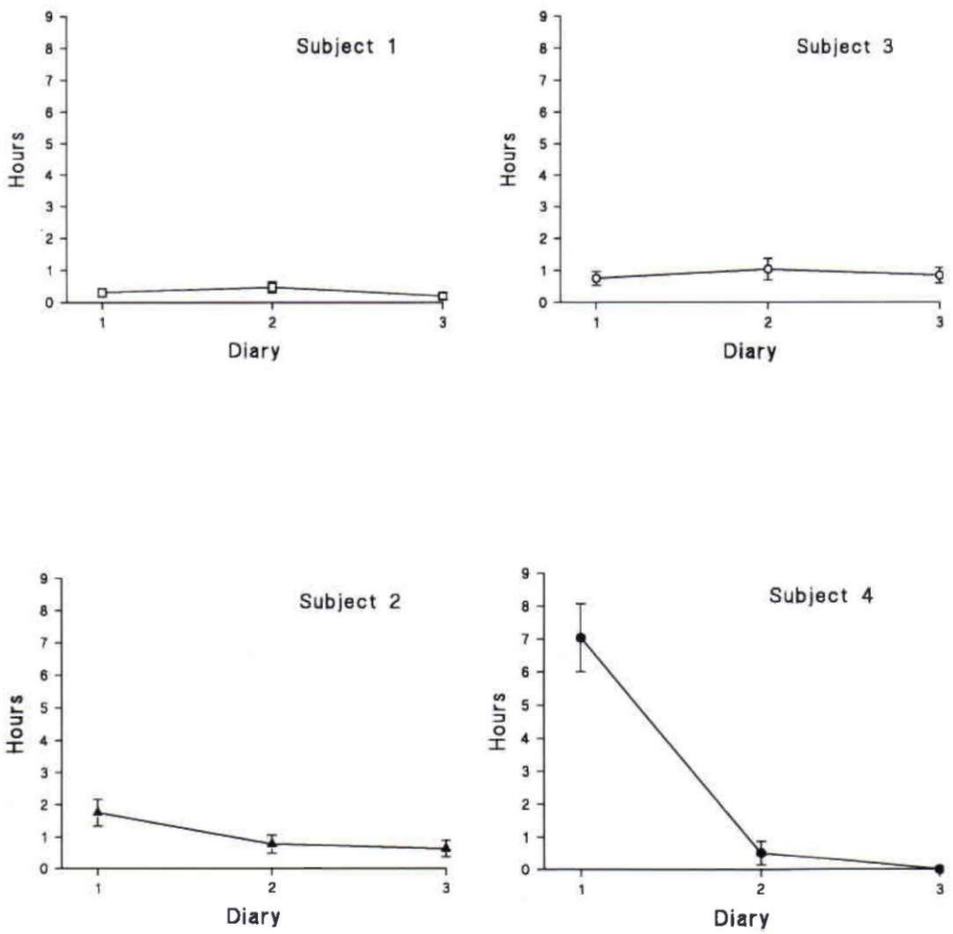

Fig. 4. Mean hours in RGO/day (± 1 SEM) determined from each of three "14-day" diaries. Diary 1 = before stimulation (subject using RGO only); Diary 2 = 6 months after the start of stimulation; Diary 3 = 6 months after the hybrid system taken home (where error bars are not visible they are smaller than the symbol used).

(p=0.109), or Diary 1 and Diary 3 (p=0.285).

Discussion

Compliance with the RGO and the hybrid system was poor and there was no apparant increase in RGO use following supply of electrical stimulation. No improvement in efficiency of ambulation was found when subjects used the hybrid system (Sykes *et al.*, 1996). This may account for the lack of an increase in RGO use in the present study.

However the step counter results have to be looked at critically. Objective measurement of RGO home use is undoubtedly problematic and it would be inappropriate to claim that the step counter measured steps and only steps. Firstly it proved difficult to find a reliable measurement tool. Bassey *et al.* (1988) found a mechanical pedometer to be successful and reliable in elderly subjects. The commercial pedometer tried in the present study gave inaccurate results when used in conjunction with an RGO. Waters *et al.* (1978) used a heel contact switch in the shoe of one leg of their able bodied and disabled subjects to provide an ongoing measurement of step frequency during walking tests. They do not comment on the reliability of this system which was presumably good throughout the span of an individual walking test. Indeed, reliability of the step counter in the subject reported here was good whilst it was being assessed in the laboratory. However, accuracy deteriorated once the subject started using the RGO at home. It is suspected that this was related to the shoe (e.g. tightness of the laces) and deterioration of the sponge within the contact switch.

Interpretation of the results is complicated by the fact that practical problems were encountered in the search for a reliable measurement tool (outlined previously) which resulted in the loss of data, particularly baseline data for Subjects 1 and 2. This makes testing of the original hypothesis difficult. Whilst both diary and step counter results suggest no increase in RGO use following supply of the hybrid walking system, such a conclusion should be treated with caution on the basis of limited data. Nevertheless, the counter did highlight the variable, intermittent and overall poor use of the RGO amongst these adult patients. Equally it should be noted that in four subjects the results seen actually overestimate the RGO use.

Poor use of the RGO was not surprising given a knowledge of the patients and their lifestyles. All subjects had extensive hobbies or work commitments. The RGO and subsequently the hybrid system was used for exercise only in four of the five patients. Only Subject 4 used either system in a functional sense. It is suspected that failure of the RGO and hybrid systems to show high levels of use is due to their inability to increase function. Subjectively, none of the five subjects said that their function had improved since being supplied with the hybrid system. This contrasts with reports from Solomonow (1992) that some patients use the hybrid system daily in the workplace or for home ambulation for over 40 hours per week.

It is not believed that other studies have objectively measured RGO home use. Other published reports on the use of the RGO have relied on subjective information recalled by the patient. Guidera *et al.* (1993) assessed RGO use in children with myelodysplasia by interviewing the patient and family. Mean daily usage of the RGO was 6.9 hours. Adult patients were not included in the study. Sykes *et al.* (1995) used a questionnaire format. Median RGO use by patients aged under 18 was 3 hours/day compared with 2 hours/day by adult patients. Median weekly usage was 5 days by patients aged under 18 and 3.5 days by adult patients. However, such subjective measures rely on retrospective recall by the patients and an estimate of their daily usage. Such observational methods do not allow for the fluctuations in use clearly seen in the objective data reported here.

Self-reporting of behaviour has been used successfully in other studies (Stephens *et al*, 1983). In the present study self-reporting techniques proved to be problematic due to poor patient compliance. This was found with requests to the patients to record their step counter readings. The plateaux on the step counter graphs represent the mean number of steps taken per week during a particular time period. However, it is not possible to tell if a particular plateau should really represent a peak and a trough. There are two reasons for this inability to interpret the graph more accurately. Firstly, in order to reduce the placebo attention effect and get a more realistic picture of patients

use of the RGO, review appointments were made 3-4 weeks apart once treatment was completed. This meant, however, that the researcher was only able to check the counter reading every few weeks. This was further exacerbated by cancellation of appointments by patients. Attempting to overcome this problem, patients were issued with a "step counter" form. They were asked to write the date and the counter reading on the form once a week. In this way it was anticipated that more detailed data on RGO use could be obtained without involving more frequent contact with the patient. However, patient compliance was poor and only minimal additional data was obtained in this way. Whilst problems with data collection could affect the pattern of variability, the overall mean number of steps taken during the study remains low whether with or without electrical stimulation. This low use was reflected in the patient diaries.

Compliance with the diaries was also a problem, particularly in the case of Subject 5 who failed to return any of the diaries. The diary results for the remaining four subjects do, however, strengthen the reliability of the step counter results.

There may be many reasons why the subject group showed limited responsiveness for requests for information: they did not perceive the system as of any great benefit; they did not appreciate the importance of the information; the study took a low priority in their lives and/or they were not using the RGO. Non-use of the RGO was a major factor in the poor compliance of Subject 5 who often commented that he was going to start using the RGO more often and would then return his diary. It is impossible to know the extent to which the investigators persuasion to return a diary affected its result. The accuracy of the diary self-report could only be confirmed by an independent observer. This would obviously not be practical, and would itself influence RGO use.

Clearly problems have been demonstrated in measuring RGO use in the home, firstly in establishing a reliable objective measurement tool and secondly in overcoming problems of compliance with self-reporting techniques. The step counter was able to pick up gross changes in ambulatory behaviour with an accuracy of approximately 10%. The development of a more accurate and reliable mechanism for measuring home use would be an asset in measuring the outcome of orthotic changes made in the research environment. Indeed the authors feel that there is a need to find a means of measuring home use in order to interpret the clinical significance of objective measures determined in the laboratory. It is immaterial if any number of parameters can be shown to improve performance in the research environment, if the system under investigation is not used in the home. Therefore, an objective measurement of use should form part of the assessment of any new orthotic device for upright mobility of patients with spinal cord lesions.

Acknowledgements

This work was supported by a Medical Innovation Grant from the North West Region of the NHS. Thanks to Professor Peter Bowker, School of Prosthetics and Orthotics University College Salford for kindly providing facilities for the present study and to the Department of Medical Physics, Hope Hospital, Salford for technical help.

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IXth World Congress of the International Society for Prosthetics and Orthotics

June 28-July 3, 1998
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in collaboration with

The Triennial World Congress of the International Society for Prosthetics and Orthotics is intended to highlight the aims of the Society. For many delegates at previous World Congresses the scientific exchange and the multidisciplinary consultation which it enables have been the main reason to participate.

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LOCATION AND DATES

The Congress will take place from Sunday, 28 June to Friday, 3 July 1998 in the Amsterdam RAI, International Exhibition and Congress Centre, in Amsterdam, The Netherlands.

SCIENTIFIC PROGRAMME

The Scientific Programme will contain conventional as well as innovative parts. The programme will permit a broad view of all matters within the scope of prosthetics, orthotics, and rehabilitation technology. An integral view of the use of technology in relation to the total environment in which it is used will be emphasised. Special topic sessions will be organised which combine invited papers with papers which are received as a result of the call for papers.

OFFICIAL LANGUAGE

The official Congress language will be English.

APPLICATION PROCEDURES

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In conjunction with the IXth World Congress of ISPO, a large industrial exhibition will be organised. Companies interested in this exhibition are requested to contact the Congress Secretariat. More information on the exhibition will be mailed to all interested companies.

CLIMATE

It will be summer at the time of the Congress and you may expect temperatures of around 20°C, however we advise you to bring a warm sweater and raincoat for the unexpected breezes or rain showers.

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The Accompanying Persons Programme will show you the Netherlands at its best from the famous windmills to modern architecture, from wooden shoe factories to modern fashion shops and from the meadows and endless stretches of water to the picturesque little towns with their canals. Old Dutch traditions will, alongside the achievements of modern Dutch society, provide you with more than sufficient entertainment. Get the taste of the Dutch 'gezelligheid!' (coziness).

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Calendar of Events

National Centre for Training and Education in Prosthetics and Orthotics
Short Term Courses 1996-97

Courses for Physicians, Surgeons and Therapists

NC505 Lower Limb Prosthetics; 27-31 January, 1997
NC517 Trans-Tibial Pressure Casting Techniques; 12 February, 1997
NC514 Orthotic Management of the Diabetic Foot; 26-27 February, 1997
NC515 Orthotics and G.P. Fundholders; 25 March, 1997
NC516 Clinical Audit and Outcome Measurement for Lower Limb Amputees; 9 April, 1997
NC511 Clinical Gait Analysis; 10-11 April, 1997
NC510 Wheelchairs and Seating; 15-17 April, 1997
NC506 Fracture Bracing; 28 April-2 May, 1997

Courses for Prosthetists and Orthotists

NC220 Upper Limb Prosthetics (in conjunction with BAPO);
Module 1 20-24 January, 1997
Module 2 19-23 May, 1997
Module 3 13-15 October, 1997
NC219 Orthotic Assessment for Orthotists, 6-7 February, 1997
NC517 Trans-Tibial Pressure Casting Techniques, 12-13 February, 1997
NC218 The TEC Interface System; 10-12 March, 1997

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) 141-552-4400 ext. 3298, Fax: (+44) 141 552 1283, E-mail: Annette.Hepburn@strath.ac.uk.

23-25 January, 1997

13th International Seating Symposium, Pittsburgh, USA.
Information: Patty Simko, Conference Planner, Center for Continuing Education in Health Services, Nese-Barkan Bldg., 5th Floor, 3811 O'Hara St., Pittsburgh, PA 15213, USA.

13-18 February, 1997

American Academy of Orthopaedic Surgeons Annual Convention, San Fancisco, USA.
Information: AAOS, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

8-9 March, 1997

Annual Scientific Meeting of British Association of Prosthetists and Orthotists, Blackpool, England.
Information: The Secretariat, BAPO, Studio 38, Sir James Clark Building, Abbey Mill Business Centre, Paisley PA1 1TJ, Scotland. Telephone: (+44) 141-561-7217. Fax: (+44) 141-561 7218.

12-15 March, 1997
American Academy of Orthotists and Prosthetists Annual Meeting, San Francisco, USA.
Information: Annette Suriani, 1650 King St. Suite 500, Alexandria, VA22314, USA.

17-20 March, 1997
1st Gulf Congress in Medical Rehabilitation, Kuwait.
Information: Congress Secretariat, Physical Medicine and Rehabilitation Hospital, PO Box 4079, 13041, Kuwait.

11-14 April, 1997
ISPO Update Course on Amputation and Prosthetics, Helsingborg, Sweden.
Information: May-Christine Friberg, Ortopediska Kliniken, Helsingborgs Lasarett, S-251 Helsingborg, Sweden.

11-13 April, 1997
34th Annual Rocky Mountain Bioengineering Symposium, Dayton, USA.
Information: Rocky Mountain Bioengineering Society, Dr. Hamed Benghuzzi, Dept. of Health Sciences, University of Mississippi Medical Center, 2500 N. State St., Jackson, MS 39216, USA.

4-5 May, 1997
International Symposium on CAD-CAM in Pedorthics, Prosthetics and Orthotics, Nuremberg, Germany.
Information: Mrs. B. Goeke, Sekr. SG11, Symposium Secretary, Technical University of Berlin, Institute for Micro and Medical Technology, Dovestr. 6, D-10587 Berlin, Germany.

6-9 May, 1997
Orthopaedic and Rehabilitation Technology Trade Fair and World Congress, Nuremberg, Germany.
Information: Bundesinnungsverband für Orthopadie-Technik, PO Box 10 06 51, D-4406 Dortmund, Germany.

2-6 June, 1997
International Society for the Study of the Lumbar Spine, Singapore.
Information: Prof. A. Nachemson, Dept. of Orthopaedics, Sahlgren Hospital, S-41345, Goteborg, Sweden.

20-25 June, 1997
RESNA 97, Pittsburgh, USA.
Information: RESNA, Suite 1540, 1700 N. Moore Street, Arlington, VA 22209, USA.

28-31 August, 1997
10th Conference of the European Society of Biomechanics, Leuven, Belgium.
Information: J. Vander Sloten, Katholieke Universiteit Leuven, Division of Biomechanics and Engineering Design, Celestjinelaan 200A, B-3001 Heverlee, Belgium.

31 August-5 September, 1997
8th World Congress of the International Rehabilitation Medicine Association, Kyoto, Japan.
Information: Japan Convention Services Inc., Nippon Press Center Bldg., 2-1, 2-chome, Uchisaiwai-cho, Chiyoda-ku, Tokyo 100, Japan.

8-12 September, 1997
Dundee 97: International Conference on Wheelchairs and Seating, Dundee, Scotland.
Information: The Secretariat, Dundee 97, Dundee Limb Fitting Centre, 13 Queen St., Broughty Ferry, Dundee DD5 1AG, Scotland.

9-13 September

American Orthotic and Prosthetic Association National Asssembly, Charlotte, USA.
Information: Annette Suriani, 1650 King St. Suite 500, Alexandria, VA22314, USA.

14-19 September, 1997

World Congress on Medical Physics and Biomedical Engineering, Nice, France.
Information: Nice 97, SEE-48, Rue de la Procession, F 75724 Paris Cedex 15, France.

18-21 September, 1997

12th National Congress of FIOTO, Bari, Italy.
Information: Consulta Umbria, Piazza Italia, 9-06121 Perugia, Italy.

22-25 October,1997

REHA 97, Dusseldorf, Germany.
Information: Dusseldorf Trade Shows Inc., 150 N. Michigan Ave., Suite 2920, Chicago, IL 60611, USA.

22-26 October, 1997

North American Spine Society Annual Meeting, New York, USA.
Information: North American Spine Society, 6300 N. River Rd., Suite 500, Rosemont, IL 60018-4231, USA.

23-25 October, 1997

25th Annual Scientific Meeting of ISPO UK National Member Society, Scotch Corner, near Darlington, England.
Information: Mrs. P. McLauchlan, 58 Station Road, South Queensferry, Lothian EH30 9JX, Scotland.

13-16 November, 1997

American Academy of Physical Medicine and Rehabilitation Annual Meeting, Atlanta, USA.
Information: AAPM&R, 1 IBM Plaza, Suite 2500, Chicago IL 60611, USA.

1998

28 June-3July, 1998

9th World Congress of the International Society for Prosthetics and Orthotics, Amsterdam, The Netherlands.
Information: Congrex (Holland) B. V., Keizersgracht 782, 1017 EC Amsterdam, The Netherlands. Tel: +3120 626 13 72. Fax: +3120 625 95 74.

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