



**The Journal of the International Society
for Prosthetics and Orthotics**

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Editorial

The International Society for Prosthetics and Orthotics now has approximately 3000 members from more than 80 countries and has 33 National Member Societies. Through its activities such as congresses, conferences, seminars and courses it brings people from different economic and cultural backgrounds together where experiences and problems can be shared and openly discussed. Through the Society's consensus conferences different aspects of prosthetics and orthotics have resulted in promoting good practice through publications and courses. The Society is presently running a series of courses in different parts of the world on amputation surgery and related prosthetics, the team management of cerebral palsy, and the treatment of poliomyelitis. It is the intention of the Executive Board to enhance this programme by examining further aspects of practice through further consensus conferences and offering new courses based on their outcomes. At present the Board is exploring the possibilities of a consensus conference on congenital foot deformities.

In a world where conflict and disagreement seem to be the order of the day it has been a pleasure working in the field of prosthetics and orthotics where friendship and collaboration have resulted in positive developments especially in those regions of the world where the need is the greatest. Over the years the Society has endeavoured to play its part in creating a forum for individuals, international and national agencies, and non-governmental organisations from all parts of the world to exchange ideas and discuss mutual problems. This has gone some way to allow the field of prosthetics and orthotics to develop in a cooperative rather than a competitive manner.

The Society has developed good working relationships with most of the major international and national agencies working in this field. These include the World Health Organisation (WHO), Interbor, the International Committee of the Red Cross (ICRC), Handicap International (HI), World Rehabilitation Fund (WRF), Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), and the United States Agency for International Development (USAID). Collaboration has included mutual participation in congresses, conferences and meetings, and participation and support in ISPO consensus conferences and courses. These collaborations have helped to bring individuals and agencies closer together working for the common good. A good example of this appears in this issue (p.189), the joint ISPO/WHO statement on *The relationship between prosthetics and orthotics services and community-based rehabilitation*.

The consensus conferences that the Society has organised would not have been so successful if it were not for the support that many other agencies gave in supporting and participating in them. These conferences, in turn, have also provided the means of bringing individuals and agencies together and help promote the concept of collaboration. The best example of this was the consensus conference on *Appropriate prosthetic technology for developing countries* which was held in Phnom Penh, Cambodia in 1995. This conference was held in collaboration with WHO and USAID. Its funding was provided by USAID, ISPO and some individual agencies that provided support for their representatives. The Cambodia Trust and the Cambodia National School of Prosthetics and Orthotics provided the local organisation. The conference brought together 93 individuals representing 33 different agencies or organisations. It was the first time that so many different parties had been under the same roof talking about the same problems. Such openness in the discussions resulted in a very positive conference. One of the major recommendations of the conference was: *In order to optimise the use of resources cooperation between agencies working in the same country or region is strongly encouraged*. As a result there has been much closer collaboration amongst the different agencies involved in providing prosthetics and orthotics services not only in Cambodia but also in the neighbouring countries.

Over the years there has been a very evident move towards closer collaboration amongst all individuals and agencies that are working in the field of prosthetics and orthotics and the work of the International Society for Prosthetics and Orthotics has played an important part in this.

Norman A. Jacobs
President

Obituary

Stig Willner

The orthopaedic community has lost a distinguished member. Over a few weeks in the clear summer of 1999 Stig Willner got ill and died from a blood illness.

From 1969-1996 he was the head of spinal orthopaedics at the University Hospital in Malmö, Sweden. During three years he was chief of the department. He developed orthotics and surgery for scoliosis and designed a three-point loading brace called the WISS-frame for a preoperative test used to evaluate best position in the planning of lumbar fusion. He also developed a brace for patients with drop foot utilising high technology carbon fibre with a lateral bar instead of the usual posterior type which has been successfully marketed with the name Toe Off. For this he was awarded "The Albin Innovation Prize".

For Swedish students he has been a well known teacher and author of a textbook in children's orthopaedics together with Lars Danielsson in Malmö.

Stig Willner was a long-standing member of ISPO and was a Board member of ISPO Sweden. For ISPO members Stig Willner has been an appreciated teacher at conferences and courses. Recently he was an expert in the ISPO consensus conference in Tunisia summarising the literature on surgery for scoliosis in poliomyelitis.

His caring attitude and empathy made him a loved person both to patients, personnel and colleagues, being one of few modern orthopaedic surgeons participating in depth also within development and teaching in prosthetics and orthotics.

*Bertil Allard
Camp Scandinavia
Sweden*

*Björn M Persson,
Vice President of ISPO*

The relationship between prosthetics and orthotics services and community-based rehabilitation

A JOINT ISPO/WHO STATEMENT
OCTOBER 1999

Introduction

In the 1970s the World Health Organisation (WHO) introduced a new approach to disability prevention and rehabilitation known as community-based rehabilitation. The aim was to ensure that rehabilitation services can be provided to all people with disabilities, whether they live in a city or in the countryside or whether they are rich or poor.

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

The personnel of institutions at the central and provincial levels are the professionals who can be expected to work in conventional rehabilitation and health services. At *central level* they may, for example, include specialised physicians, therapists, and prosthetics and orthotics staff. At *provincial level* they may be general physicians, some (though usually few) specialised physicians, therapists, and prosthetics and orthotics staff.

The professionals based at *district level*, however, are not likely to possess any specialised training in rehabilitation. They are usually general physicians and nurses who are concerned with the provision of primary health care services. Nevertheless, as discussed below, they may play an important role in the referral system and in the transfer of knowledge and skills in rehabilitation to the community level.

Finally, at *community level*, there are usually no professionals at all, in either health or rehabilitation. The persons working there - usually called *community health workers* or *community rehabilitation workers* - often do their work on a voluntary and part-time basis in addition to their normal duties in the community. Since they are likely to have limited or minimal education in health and rehabilitation, they need to receive training and support from personnel in the referral system.

The success of this approach to rehabilitation will depend on the development of an integrated and coordinated programme in which the activities at each level are clearly defined. It will also depend on the development of an educated and trained workforce, with clear definition of the role of the different types of personnel.

WHO has recognised that although most basic rehabilitation can be carried out in the disabled person's own community, many persons with disabilities have to be referred to other rehabilitation services outside their own community. Among this group are those people who require prostheses and orthoses. This is because prosthetic and orthotic devices of an acceptable quality cannot realistically be made in every single community within a country. This means that for the successful, widespread provision of prosthetics and orthotics services there needs to be a strong relationship between the specialised services and community-based rehabilitation programmes.

With regard to the provision of prosthetics and orthotics services, the International Society for Prosthetics and Orthotics (ISPO) has gone some way towards defining the job descriptions and educational requirements for the different categories of professionals directly involved in this field. These categories are: prosthetist/orthotists (Category I); orthopaedic technologists (Category II); and prosthetics/orthotics technicians (Category III). Some consideration needs to be given to the use of these categories of professionals in the referral system on which WHO's approach depends and in particular to the role and training in prosthetics and orthotics of primary health care staff and community health/rehabilitation workers.

Ideally, each country should have adequate numbers - possibly many thousands - of community health/rehabilitation workers. While all of these workers need to receive training so that they possess a

certain minimum knowledge of rehabilitation, the obvious challenge with respect to the prosthetics/orthotics component is how to manage the transfer of this knowledge when so few resource persons are normally available in prosthetics and orthotics services in low-income countries. Here the approach of WHO is clear: prosthetics and orthotics personnel cannot be directly involved in the training of community health/rehabilitation workers. At best, they can only contribute to the training of *primary health care staff*, so that these in turn can include prosthetics and orthotics issues in the ordinary training courses for persons serving at the community level.

The following sections offer guidance on how community-based rehabilitation and the referral system may be used to help to promote and improve prosthetics and orthotics services in low-income countries.

Basic community level

The basic community level is situated in the village or community; it is staffed by community health/rehabilitation workers, who usually work under the supervision of a primary health care nurse at district level.

In matters related to prosthetics and orthotics, the basic community level will:

- give priority to the early detection of disabilities;
- consider the socioeconomic situation and needs of persons with disabilities;
- guide persons with disabilities towards sources of funding for treatment;
- act as a link between the person with disability, the family, and the prosthetics and orthotics services;
- explain the treatment programme to the person with disability and the family;
- refer persons with disabilities to the appropriate support or service level together with information about the needs and expectations of the person;
- assist persons with disabilities in preparations for the fitting and use of prosthetic and orthotic devices, including physical therapy and wrapping of residual limbs;
- encourage the person with disability to carry out needed exercises;
- assist with follow-up of the person with disability with regard to the use of, and adaptation to, the device;
- assist with the rehabilitation of the person with disability;
- assist with adaptation of the environment and take measures to facilitate accessibility, good hygiene and activities of daily living;
- help to prevent causes of disability, e.g. through good hygiene, wound treatment, and prevention of secondary deformities such as contractures and bed-sores;
- arrange for maintenance and repairs to prosthetic and orthotic devices. It is important for the community health/rehabilitation worker to recognise what repairs can be done in the community by a local craftsman and what repairs should be referred to the support level;
- help in the provision of simple mobility and rehabilitation devices;
- help persons with disabilities to be integrated into society, e.g. through education and work opportunities;
- promote awareness of the benefits of using prosthetic and orthotic devices;
- provide information to the appropriate support level with regard to follow-up and the acceptance and use of devices;
- provide information to the support level on the numbers of people with disabilities and the types of disabilities found.

District support level (primary health care)

This support level does not normally offer any *specialised* rehabilitation services, since specialised physicians, therapists, and prosthetics and orthotics staff are rarely available here. However, basic and general rehabilitation services may be provided by primary health care staff, such as general physicians and (in particular) nurses since, as stated in the 1978 Declaration of Alma-Ata, primary health care should address the main health problems by providing promotive, preventive, curative *and* rehabilitative services.

At district level, in matters related to prosthetics and orthotics, primary health care services will:

- provide training to community health/rehabilitation workers in rehabilitation, including basic prosthetics- and orthotics-related issues (see duties of community health/rehabilitation workers above). There is a great need to educate and train community health/rehabilitation workers for their role in prosthetics and orthotics. This training should be based on a curriculum set centrally. Supervision and advice on their work in prosthetics and orthotics will continue to be needed as there is no tradition or depth of experience in this field;
- provide support in rehabilitation issues to the community;
- refer persons with disabilities to the appropriate support or service level together with information about the needs and expectations of the person;
- monitor and evaluate prosthetics and orthotics services and programmes of disability prevention from a district viewpoint;
- provide information to the provincial service level on the numbers of people with disabilities, the types of disabilities found and treated, the numbers and types of devices fitted, and outcomes of the services.

Provincial support level

This intermediate support level is situated in a provincial institution and, apart from other medical and paramedical professionals, may be staffed by all categories of prosthetics and orthotics professionals up to and including Category II.

The intermediate support level will:

- provide general prosthetics and orthotics services, including repair and replacement of devices. The services that it should offer must include the most common and most needed prosthetic and orthotic devices, i.e. prostheses and orthoses for the lower limb. However, devices for other levels may be fitted if there is a particular need and demand for such a service;
- refer persons with less common disabilities for specialist treatment to the specialised service level;
- participate in the training of primary health care personnel in prosthetics- and orthotics-related subjects so that all these staff, in turn, can include prosthetics and orthotics issues in the training they provide for community health/rehabilitation workers. As in the case of training for community health/rehabilitation workers, the training of primary health care personnel should be based on a curriculum set centrally;
- provide support in rehabilitation issues to the district level;
- monitor and evaluate prosthetics and orthotics services and programmes of disability prevention from a provincial viewpoint;
- provide information to the specialised service level on the numbers of people with disabilities, the types of disabilities found and treated, the numbers and types of devices fitted, and outcomes of the services.

Specialised service level

The specialised service level is situated in a central or national institution and should be staffed by all categories of prosthetics and orthotics professionals up to and including Category I.

The specialised service level will:

- provide specialised prosthetics and orthotics services, i.e. the full range of prosthetics and orthotics devices and services;
- contribute to the development and coordination of a national policy with regard to prosthetics and orthotics services and referral. The specialised service level is expected to provide help and advice to government in the development of its policy on the planning, organisation and administration of prosthetics and orthotics services and national policies related to people with disabilities. This is of great importance if the concept of community-based rehabilitation in prosthetics and orthotics is to be adopted by a country;
- contribute to the development of a central policy for disability prevention in the field of prosthetics and orthotics;
- contribute to the organisation of programmes of education and training for all personnel involved in

the provision of prosthetics and orthotics services, including primary health care staff and community health/rehabilitation workers (the education and training of primary health care staff and community health/rehabilitation workers is discussed below);

- participate in the training of primary health care professionals on prosthetics and orthotics issues;
- provide support in rehabilitation issues to the provincial level;
- develop an information package for primary health care staff and community health/rehabilitation workers outlining the prosthetics and orthotics delivery system;
- oversee the professional development of all personnel involved in the provision of prosthetics and orthotics services;
- monitor and evaluate prosthetics and orthotics services and programmes of disability prevention from a national viewpoint. It is important for all services and programmes to be evaluated in order to check whether they meet the needs of the country and to determine ways in which they may be improved and their quality can be assured.

Training of community health/rehabilitation workers

It is important to bear in mind that the community health/rehabilitation worker is neither a prosthetist/orthotist nor an orthopaedic technologist and will not be expected to fit prostheses or orthoses. He or she has a wide range of information on many different aspects of rehabilitation, of which prosthetics/orthotics is only one. Thus some prosthetics- and orthotics-related subjects need to be included in the training provided.

A syllabus to achieve this might include components on:

- disabilities that can be helped by prostheses or orthoses and how they can be helped;
- prosthetics and orthotics services available in the country and how to gain access to them;
- the range of prosthetic and orthotic devices available from district, provincial and central institutions and how the supply process works;
- fit and function of prosthetic and orthotic devices. This is important in helping to determine whether there is a problem with regard to fit and/or function of a prosthesis or orthosis;
- measures for preparing a person with disability for the fitting of prosthetic and orthotic devices, including exercises and wrapping of residual limbs;
- use, maintenance and hygiene of a prosthesis or orthosis, including exercising;
- simple repairs to prostheses and orthoses. The community health/rehabilitation worker should know what repairs can be carried out by a local craftsman and what repairs need to be referred to prosthetics/orthotics services at another level;
- construction and use of simple mobility and rehabilitation devices;
- adaptation of the environment;
- data collection. The community health/rehabilitation worker should be taught simple techniques to gather information about numbers of persons with disabilities, range of disabilities found, use of a prosthesis or orthosis, etc;
- sources of funding for prosthetic and orthotic treatment;
- integration of the person with disability into society.

Recruitment of community health/rehabilitation workers

Community health/rehabilitation workers have an important role to play in the provision of prosthetics and orthotics services. It is essential for these workers to be carefully selected and persons with disabilities, their family members and women should be encouraged to take up these posts. The following attributes are considered to be important:

- to have a good attitude to disability;
- to live in the community and be accepted and selected by it;
- to be able to read and write satisfactorily.

Education of primary health care staff

Primary health care professionals should be the trainers of the community health/rehabilitation workers. The curriculum for the training of primary health care staff in prosthetics and orthotics

should therefore include the same topics as for community health/rehabilitation workers (see "Training of community health/rehabilitation workers" above).

Education of prosthetics and orthotics personnel

In order to ensure that there is an effective relationship between the prosthetics and orthotics services and the services offered at community level, it is important for prosthetics and orthotics personnel to be made aware of the role and function of the community rehabilitation services.

A syllabus to achieve this might cover:

- the philosophy of community-based rehabilitation;
- the United Nations Standard Rules on the Equalisation of Opportunities for Persons with Disabilities;
- the national health service structure, including primary health care and community-based rehabilitation;
- community-based rehabilitation activities in the country;
- interaction of prosthetics and orthotics services, primary health care and community-based rehabilitation;
- problems of persons with disabilities in rural areas;
- adaptation of prosthetic and orthotic devices to local conditions;
- ways of providing advice in a simple and effective manner;
- basic physical therapy (exercises) before and after fitting devices.

Team approach

The foregoing sections outline the roles of the technical personnel directly involved in the provision of prostheses and orthoses: Category I and II prosthetics/orthotics professionals; non-specialised professionals, such as primary health care staff; and community health/rehabilitation workers, many of whom may be volunteers. Most people who require a prosthetic or orthotic device also require treatment from other medical and health personnel, such as surgeons and other physicians, occupational and physical therapists, and social workers. In order for those involved to work together effectively, they should be encouraged to share information with each other and, based on their respective professional and personal viewpoints, offer suggestions on measures that need to be taken to assist in the person's rehabilitation. In this respect, though not all of them meet face to face at one and the same time, the people involved in the rehabilitation process should be seen as a team. The person with disability and his or her family have an important role in this team and should be positioned at the centre of the relationship between prosthetics and orthotics services and community-based rehabilitation. For the rehabilitation services to be effective in the provision of prostheses and orthoses, an integrated approach by all the members of the team at the community level, the intermediate support levels and the specialised service level is essential.

Conclusions

A number of matters need to be addressed to enable adequate prosthetics and orthotics services to be provided in low-income countries. Some of these are set out below:

- Community, district, provincial and centralised services should all be part of the overall prosthetics and orthotics services. In order to provide an adequate prosthetics and orthotics delivery system, all services need to function in a coordinated way;
- There is a lack of trained personnel in the prosthetics and orthotics services. There is still a great need to train Category I, Category II and Category III professionals as well as training primary health care staff and community health/rehabilitation workers in subjects related to prosthetics and orthotics services;
- The training of primary health care staff and community health/rehabilitation workers should not be seen as a substitute for training professionals in prosthetics and orthotics. They are a different type of worker with completely different skills and a different job to do;
- There is a lack of financial resources. It is not possible to solve all the prosthetics and orthotics problems immediately. It is important to plan for the future and ensure that any developments are

- part of an overall plan so that resources are used effectively;
- Awareness of community-based rehabilitation and its role in prosthetics and orthotics needs to be increased. There is a need to make the public, existing prosthetics and orthotics professionals and the government aware of community-based rehabilitation and how it can be used to improve the prosthetics and orthotics care system;
 - A team approach is crucial. When possible, proper use must be made of all members of the team in order to ensure a better quality of rehabilitation.

To sum up, this document attempts to describe the relationship between prosthetics and orthotics services and community-based rehabilitation. It shows how the services offered by central, provincial and district institutions and the community can work together in helping to provide a comprehensive prosthetics and orthotics service. It should be noted that no definitive model of community-based rehabilitation in prosthetics and orthotics is available; each country should develop its own system according to its needs and the resources available.

Factors affecting wound healing after major amputation for vascular disease: a review

M. ENEROTH

Department of Orthopaedics, University Hospital, Lund, Sweden

Introduction

There has been a continuous increase in the incidence of major lower limb amputations from the beginning of the century until the mid-1980s (Table 1). This increase has been attributed to the increasing number of elderly persons, diabetics and smokers (Liedberg and Persson, 1983). During the last decade, several reports from Scandinavia have mentioned a decreased incidence of major amputations (Larsson *et al.*,

1995; Larsson and Risberg, 1988; Persson *et al.*, 1989; Pohjalainen and Alaranta, 1988; Sembo *et al.*, 1996; Wahlberg *et al.*, 1994). Others have reported a reduction in the number of major amputations (Ebskov *et al.*, 1994; Eickhoff, 1993; Lindholt *et al.*, 1994; Luther, 1994; Lääperi *et al.*, 1993; Pedersen *et al.*, 1994; Pell *et al.*, 1994; Stenström *et al.*, 1992). The reduction has been attributed to better foot care among diabetics (Gibbons *et al.*, 1993; Larsson *et al.*, 1995), and an increase and improvement in vascular surgery (Ebskov *et al.*, 1994; Eickhoff, 1993; Giddings *et al.*, 1993; Jeans *et al.*, 1994; Lindholt *et al.*, 1994; Pedersen *et al.*,

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Table 1. Incidence of major amputations.

Author(s)	Year of publication	Country	Incidence n/100,000	Period
Hanson	1964 ^a	Sweden	6-17	1947-62
Hierton and James	1973 ^a	Sweden	11-17	1947-69
Christensen	1976 ^b	Denmark	13	1961-71
Mandrup-Poulsen and Steen Jensen	1982 ^b	Denmark	30	1971-79
Liedberg and Persson	1983 ^b	Sweden	32	1979
Kald <i>et al.</i>	1989 ^b	Sweden	46	1980-82
Larsson and Risberg	1988 ^b	Sweden	38-30	1984-86
Pohjalainen and Alaranta	1988 ^a	Finland	33-28	1984-85
Jones	1990 ^a	Australia	23-24	1981, 1983-84
Lääperi <i>et al.</i>	1993 ^a	Finland	22	1989
Siitonen <i>et al.</i>	1993 ^b	Finland	27	1978-84
Wahlberg <i>et al.</i>	1994 ^a	Sweden	26-16	1987-91
Van Buskirk <i>et al.</i>	1994 ^d	USA	16	1985-87
Ebskov <i>et al.</i>	1994 ^a	Denmark	35, 25	1983, 1990
Larsson <i>et al.</i>	1995 ^c	Sweden	16-4	1982-93
Sernbo <i>et al.</i>	1996 ^b	Sweden	42, 22	1979, 1994

a = all causes of amputation included

b = peripheral vascular disease with or without diabetes

c = diabetic patients only

d = non-diabetic patients peripheral vascular disease

Relative mortality and long term survival for the non-diabetic lower limb amputee with vascular insufficiency

B. EBSKOV

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Abstract

On a well defined non-diabetic amputation group with vascular insufficiency consisting of 10,191 amputations during the period 1982 to 1992 the Standard Mortality Rate (SMR) and the long term survival (Kaplan-Meyer) were analysed. The SMR for the total group was 8.6 (8.4-8.9) times the expected mortality the first year after amputation, decreasing to 3.2 (3.3-3.4) the second year. SMR in relation to age, gender and level of amputation was analysed. In the long term survival studies the median survival time (50% survival) for the total group was 1.8 years. Significant relation was found between the long term survival and gender, age and level of amputation.

Introduction

Lower limb amputation in patients with critical ischaemia because of non-diabetic arteriosclerotic manifestations, and amputation in diabetic patients has often been analysed as one group in epidemiological studies. Together these two amputation groups constitute more than 90% of all amputations in the western world (Pohjolainen and Alaranta, 1988; Ebskov, 1991; Rommers *et al.*, 1997; Stewart and Jain, 1993; Eneroth 1997). However the causal pathway (Pecoraro *et al.*, 1990) leading to amputation in these two populations is not identical. The clinical manifestations, the treatment and the epidemiology are different in several aspects. In two recent studies on relative mortality and long term survival the author (Ebskov, 1996; Ebskov 1998) has focused on diabetic amputations. The object of this paper

was to analyse the relative mortality and survival in an isolated non-diabetic vascular insufficiency group. The survival figures from Denmark are compared to other studies. Further similarities and differences in some central epidemiological parameters between diabetic and non-diabetic amputations are discussed.

Material and methods

Since 1978 the Danish Amputation Register (DAR) has based its statistics on data from the National Patient Register. The reliability of this database has been found adequate for epidemiological studies by several authors (Andersen *et al.*, 1987; Madsen *et al.*, 1990; Schmidt *et al.*, 1989; Seidelin and Eickhoff, 1995). Diagnoses are recorded according to WHO's International Classification of Diseases (ICD). Detailed information on the infrastructure of DAR has previously been published (Ebskov, 1977; Ebskov, 1986).

Information concerning date of death from the Central Bureau of Personal Registration (CBPR), in which all Danish residents are recorded by means of a personal identification number was also used. The DAR and the CBPR have been linked using the personal identification number to identify the amputees who died during the observation period (January 1982 to December 1993).

The material includes 10,191 non-diabetes mellitus vascular insufficiency (NDMVI) primary lower limb amputations performed during the period January 1982 to December 1992.

None of the patients had suffered a major amputation before entering the study in 1982.

Definitions

Primary amputation: the first admission of a

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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. Approximates to 1.3 per patient.

Amputation levels included: transmetatarsal level or more proximal.

Assumptions

The rationale for exclusion of the toe amputations in this study is primarily that NPR data only include 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.

Data concerning previous vascular surgery are at present not available. It is assumed that about 40-50% of the amputations are performed after failed vascular reconstruction (Thomsen *et al.*, 1995).

Statistical methods

Whenever appropriate 95% confidence intervals (CI) were used. In calculating the relative mortality (Standard Mortality Ratio, SMR) the Danish population was used as the reference population. The long term survival analyses (absolute mortality) is calculated according to Kaplan-Meier statistics. Log-rank test and Cox-analysis were used when comparing survival figures. As level of significance 1% was chosen.

Results

Standard mortality ratio

The SMR for the NDMVI group ($n=10,191$) shows a mortality averaging 8.6 (95% CI 8.4-8.9) times the expected mortality in the first postoperative year. In the second year the mortality is 3.2 (95% CI 3.0-3.4) times the expected mortality. From the third year the variations are insignificant ranging from 2.9 to 3.3.

Figure 1a shows the SMR in the NDMVI group for men and women respectively. The tendency is obviously that the female group has the highest relative mortality in year 0 (9.5 with 95% CI 9.1-9.9) versus males (7.9 with 95% CI 7.6-8.2). From year 1 and in the rest of the period a high degree of accordance between the genders was found.

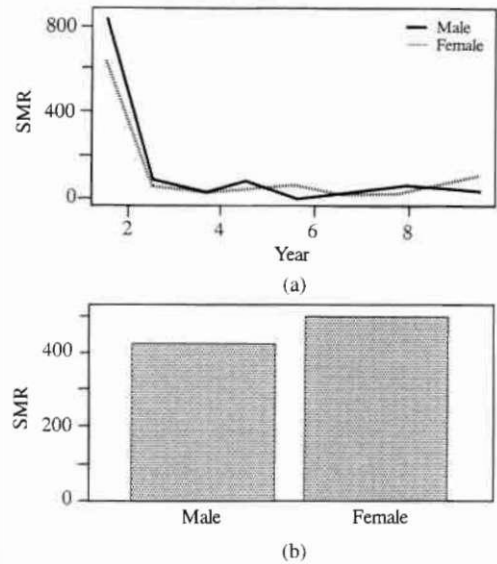


Fig. 1. (a) The relative mortality (SMR) of men and women for each year in the observation period. (b) SMR overall values for men and women.

Figure 1b shows the overall values for the period, thus emphasizing the higher SMR in the female group (500) versus the male group (425).

Figure 2a shows the SMR in the different age groups i.e. 0-59 years, 60-69 years, 70-79 years, 80 years and older. As expected there seems to

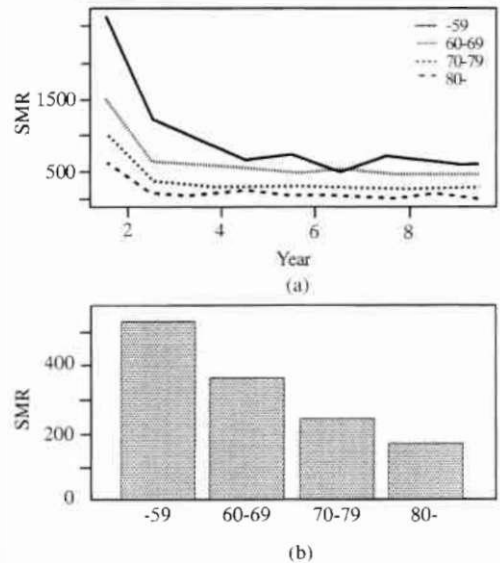


Fig. 2. (a) The relative mortality (SMR) of the age groups: ≤ 59 yrs; 60-69 yrs; 70-79 yrs and ≥ 80 yrs during the period. (b) SMR overall values for the different age groups.

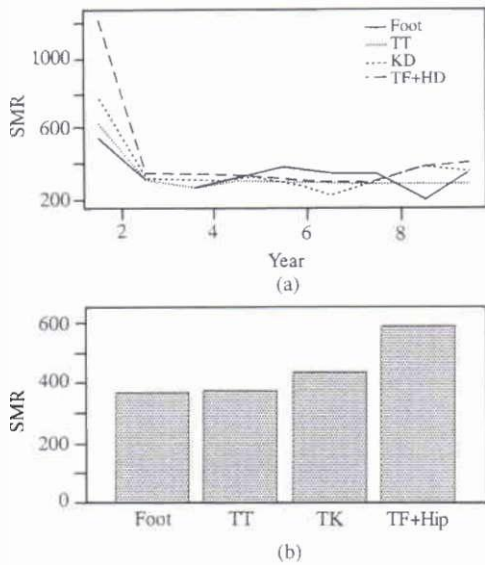


Fig. 3. (a) The relative mortality (SMR) for the level groups: foot (excl. toes); trans-tibial (TT); knee disarticulation (KD) and trans-femoral (TF) and hip disarticulation (HD). (b) SMR overall values for the level groups.

be an inverse relation between age and the SMR i.e. the youngest amputees have the highest relative mortality and the oldest amputees have the lowest relative mortality. Figure 2b shows the overall values for the period.

Figure 3a shows the relation between the relative mortality and the level of amputation. In year zero the relative mortality is significantly related to the level of amputation so that amputation at foot level implies the smallest SMR (5.5, 95% CI 4.57-6.36), trans-tibial amputation has a significantly higher relative

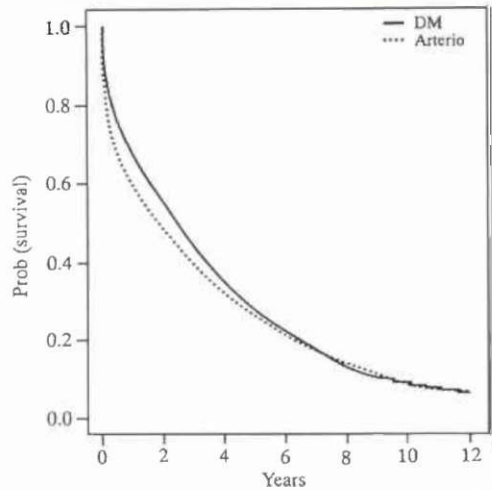


Fig 4. The long term survival (a.m. Kaplan-Meyer) with 12 years observation period for amputees with NIDDM (10,191) and DM (n=3516).

mortality (6.4, 95% CI 6.07-6.74), knee disarticulation (7.8, 95% CI 7.0-8.6) and trans-femoral amputation (including hip disarticulation) (12.2, 95% CI 11.7-12.8). This strong relation between level of amputation and SMR in year zero is much less pronounced in the remaining period. The overall values (Fig. 3b) shows the differences for the period in total.

Table 1 shows the SMR for NDMVI group compared to the figures from the DM group (Ebskov, 1996).

Long term survival

Figure 4 shows the long term survival for the NDMVI amputations (and the DM group). The median survival time (50% survival) for the non-

Table 1. The relative mortality (SMR) in relation to gender, age and level of amputation for the NIDDM group compared to the DM group.

		Year			
		0	1	2	≥3
Total material		8.6/8.4	3.2/4.1	2.9/4.3	3.1/4.3
Gender	males	7.9/7.5	3.1/3.8	2.9/3.5	3.1/3.9
	females	9.5/9.7	3.3/4.6	2.9/5.5	3.2/4.8
Age	<59	26.3/19.9	12.3/12.7	9.5/11.3	6.5/10.8
	60-69	15.2/12.4	6.3/7.2	5.9/8.5	5.1/5.5
	70-79	10.3/8.9	3.7/3.9	3.0/3.6	3.0/3.9
	≥80	6.5/6.1	2.1/2.6	1.9/2.8	1.9/2.2
Level	Foot	5.5/5.4	3.2/4.1	2.8/4.1	3.3/3.8
	TT	6.4/7.6	3.1/4.1	2.6/4.4	2.9/4.3
	KD	7.8/11.7	3.1/2.9	2.9/3.8	3.2/4.6
	TF+Hip	12.2/12	3.5/4.9	3.3/4.8	3.4/5.8

diabetic amputees is about 1.8 years. After one year about 60% of the amputees were alive, after 2 years 49%, 40% after 3 years and 26% after 5 years. In the DM group the median survival time is about 2.4 years. After one year about 68% of the amputees were alive, after 2 years 55%, 45% after 3 years and 28% after 5 years.

Analysis of the long term survival in the NDMVI group for men versus women is shown in Figure 5. The women tend to have a lower percentage of survival. According to a log-rank test the difference is significant ($p=0.008$). The median survival time for men is 2.3 years, for women 1.7 years.

There are significant ($p=0.00001$) differences between the long term survival for the different age groups as seen in Figure 6. The median survival time in the age group younger than 60 years is 6.3 years, in the age group 60-69 years the median survival is 3.2, in the age group 70-79 years the median survival is 1.85, whereas the median survival time in the age group older than 80 years is about 0.9 years.

Log-rank test applied to survival figures concerning level of amputation (Fig. 7) shows strongly significant differences between the levels of amputation ($p=0.00001$). The median survival time for the foot amputees is 3.7 years; for the TT amputees 2.6 years, for KD 2.3 years and for TF and HD amputees only 1 year.

Analysis of the survival for the patients

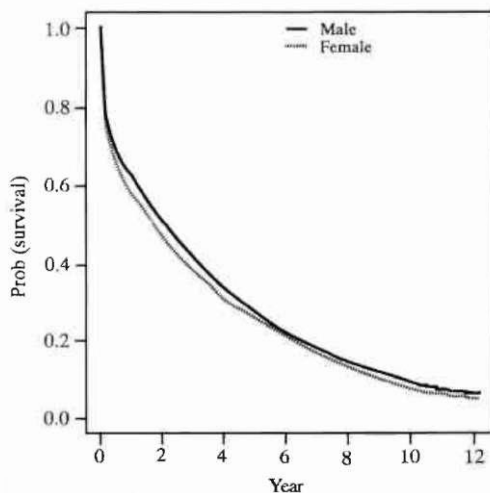


Fig. 5. The long term survival for men and women (NIDDM). Log rank test ($p=0.0001$).

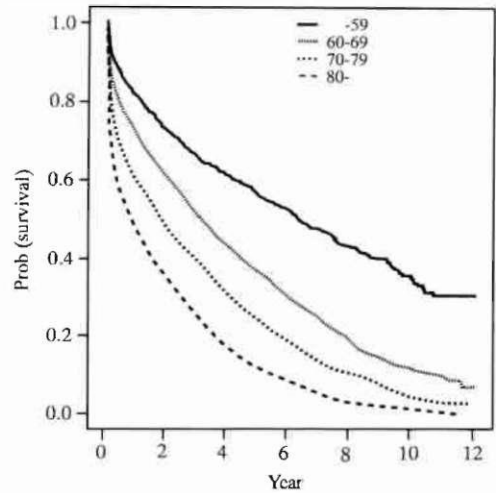


Fig. 6. The long term survival for NIDDM patients for the age groups ≤ 59 yrs; 60-69 yrs; 70-79 yrs and ≥ 80 yrs. Log rank test ($p=0.001$)

amputated in the period 1982-1987 compared to patients amputated in the period 1988-1992 (Fig. 8) showed borderline significant difference ($p=0.01$). Further it has been possible to detect significant differences ($p=0.00001$) in long term survival between the 3 different types of departments in Denmark where amputations are performed i.e. specialised orthopaedic departments, general surgical departments and

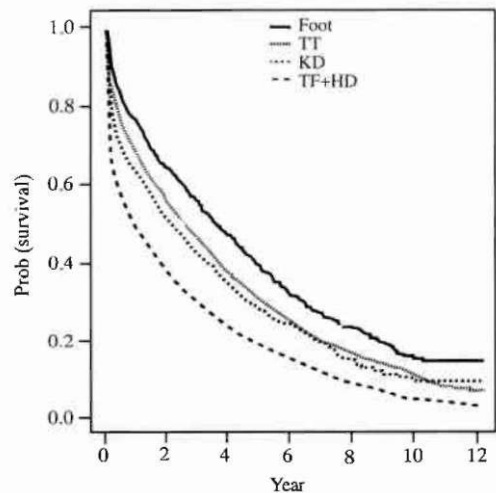


Fig. 7. The long term survival for NIDDM patients primary amputated at foot, trans-tibial level (TT), knee disarticulation (KD) and trans-femoral (TF) including hip disarticulation (HD). Log rank test ($p=0.0001$).

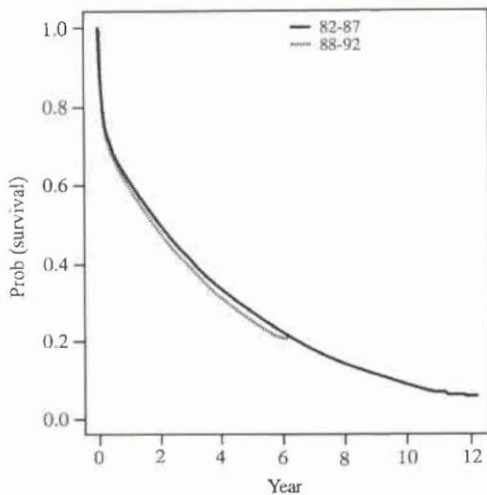


Fig. 8. The long term survival for NIDDM patients amputated in the period 1982-87 compared to patients amputated in the period 1988-92.

non-specialised departments with medicine and surgery (Fig. 9).

A Cox multivariate analysis for the isolated NDMVI group shows that when all the confounders i.e. gender, level of amputation, age, year of admission, type of department are included in the statistical calculations 3 factors i.e. the level of amputation, age and gender show significant influence on long term survival.

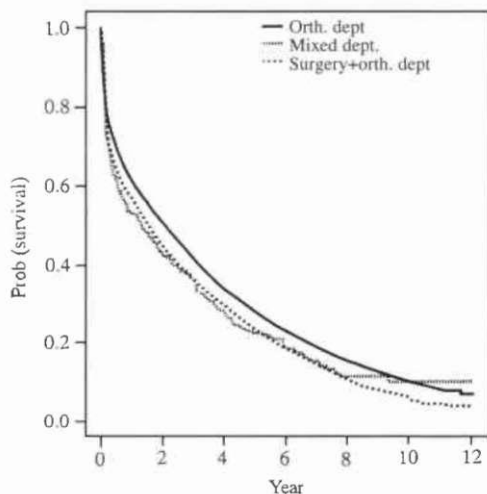


Fig. 9. The long term survival in relation to specialisation i.e. specialised orthopaedic departments versus mixed departments (internal medicine+surgery+orthopaedic surgery and surgery+orthopaedic surgery).

Discussion

The primary aim with this study was to analyse the SMR and the long term survival for the NDMVI group. The SMR (Table 1) and long term survival figures are compared with the figures from the DM group, which have been separately analysed by the author in two recent publications (Ebskov, 1996; Ebskov, 1998). It is important to emphasise that several different methods in analysing the mortality/survival have been used. As mentioned by Larsson (1994) comparison between studies with different methods is invalid. In this study two well established methods were used i.e. the SMR to analyse the relative mortality and Kaplan-Meier statistic to analyse the absolute mortality.

Some of the figures in Table 1 have to be discussed. First it should be mentioned that no significant difference between NDMVI and DM could be found when analysing total material, gender, age and level of amputation. The tendency that DM amputees have a slightly higher (but non-significant) relative mortality when analysing the total material could be because of the lower median age in the DM group (NDMVI: median age 76.1 years; DM: median age 72.9 years; Kruskal-Wallis $p=0.000001$). A very high SMR for both NDMVI and DM in the age group less than 69 years was observed especially in the first postoperative year. This may be because the expected longevity in the normal population for this age group is relatively high in combination with the fact that amputation in these relatively young patients is the result of severe arteriosclerosis with generalised manifestations. As a general rule the SMR decreases in a relatively uniform pattern with increasing age and increasing period after amputation. In the analysis of amputation level it seems that the SMR for the DM patients having a KD amputation is remarkably high compared to SMR for the NDMVI. This may be a consequence of a high complication ratio in this particular group (Baumgartner, 1983; Stirnemann and Althus, 1983).

Contrary to the SMR studies where no comparable studies have been found, it was possible to compare the long term mortality with several other authors (Larsson, 1994; Hansson, 1964; Mandrup-Poulsen and Jensen, 1982; Pohjolainen *et al.*, 1989; Cossart *et al.*, 1983;

Kolind-Sørensen, 1974; Stewart *et al.*, 1992; Helm *et al.*, 1986). Before discussing long term survival for NDMVI it is interesting to compare the curves with the normal population. For the normal population (age correlated) the median survival is about 8 years. Tibell (1971) analysed the long term survival for patients with arteriosclerosis obliterans or with DM (first admission between 1949 and 1965). The 50% survival in the arteriosclerosis obliterans group was about 2.2 years. The 50% survival in the DM group was a little higher averaging 3 years. Comparison of the 3 different conditions: the normal individual, the arteriosclerotic individual (with or without DM) and finally the amputee (with or without DM) indicates that survival/mortality after amputation is multifactorial and that the amputation as an isolated factor seems to be less important than the aetiological cause of amputation i.e. arteriosclerosis with its generalised manifestations affecting the brain, heart and kidneys.

Stewart *et al.* (1992) analysed long term survival for DM patients versus non-diabetic vascular insufficiency patients. They found a significant ($p < 0.006$) difference between the groups in favour of the non-diabetic group. The author has found the opposite with a significantly better survival for the DM group even though the curves converge after about 7 years. On the other hand the 50% survival (i.e. mean survival) found by Stewart *et al.* (1992) is much better than the survival found in this study. Actually the 50% survival for both NDMVI and DM (total materials) is less than the 50% survival among TF amputees in Dundee in the period 1970 to 1979 found by Stewart *et al.* (1992). A survival which they actually have doubled for the period 1980-89 to about 6 years. Bodily and Burgess (1983) found a 50% survival of about 3.5 years ($n=55$, combined NDMVI and DM). Rasmussen *et al.* (1982) found a 50% survival averaging 20 months ($n=58$, NDMVI). Mandrup-Poulsen and Jensen (1982) found ($n=310$, combined NDMVI and DM) a 50% survival of about 2 years and 7 months. Helm *et al.* (1986) found ($n=257$, combined material with NDMVI, DM and 7 trauma) a 50% survival of about 2 years. Larsson (1994) found a 50% survival in diabetics ($n=220$) of about 3 years (after major amputation). Hansson (1964) found a 50% survival of about 1 year (combined DM

and NDMVI).

Increase in survival over time has been analysed by Harris *et al.* (1988) who compared the period 1970-1979 (116 cases) with the period 1980-1989 (189 cases) (3 years 2 months versus 3 years 11 months) and found no statistically significant improvement, even though the tendency was positive. As mentioned above, Stewart *et al.* (1992) found an impressive improvement in long term survival. With the more limited time interval the author could not find the same positive tendency in Denmark; on the contrary it seems that the survival has been decreased.

The literature review shows a quite clear picture concerning survival after amputation. The tendency is that specialised orthopaedic centres seem to achieve better survival as compared to figures from larger areas where the data include figures from departments with less routine experience in amputation surgery. On the assumption that the materials (Dundee versus present) are comparable one of the explanations for the better survival figures is the superiority of centralisation and Stewart and Jain (1993) believed that an integrated approach to amputation and subsequent rehabilitation is obviously an advantage. This point of view is supported by the fact that a significant difference (log rank test, $p < 0.00001$) was found between the 3 types of departments which actually are engaged in amputation surgery in Denmark (Ebskov, 1992).

As indicated by the Cox analysis and the log rank test level of amputation is an important factor as regards long term survival. Level of amputation is influenced by several factors i.e. the experience of the surgeon, the possibility to perform level selection by paraclinical tests (skin perfusion etc) and the impact of vascular surgery. As regards the two first mentioned factors it seems obvious that these factors are enhanced by centralisation. The influence of vascular surgery on the epidemiology of amputations is well-documented (Holstein, 1996; Ebskov *et al.*, 1994; Eickhoff, 1993; Pedersen *et al.*, 1994; Mattes *et al.*, 1997) but the epidemiological interactions in relation to level of amputation (and long term survival) are less simple and are controversial (Burgess and Marsden, 1974; Sethia *et al.*, 1986; Tsang *et al.*, 1991; Gregg, 1985; Kazmers *et al.*, 1980; Evans *et al.*, 1990; Dardik *et al.*, 1982). Stewart *et al.*

(1993) found that 54% of the vascular cases in Dundee Limb Fitting Centre had a history of vascular surgery prior to amputation and that failed vascular surgery deteriorates the TT/TF ratio. The frequency of post revascularisation amputations is not higher than 50% in Denmark (Thomsen *et al.*, 1995). However the TT/TF ratio in the Dundee Limb Fitting Centre is more favourable (primary amputations 2.6, post-revascularisation amputations 1.8) than in the present study (total material 1.06).

The relation between long term survival and level of amputation has been described by other authors (Pohjolainen and Alaranta, 1988; Larsson, 1994; Mandrup-Poulsen and Jensen, 1982).

SMR and long term survival are important epidemiological factors. The present study demonstrates that continuous surveillance is important and should be performed to detect differences between geographical areas with different organisations. The study indicates it may be possible to improve survival after amputation in Denmark.

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Prevalence and causal conditions for amputation surgery in the third world: ten years experience at Dodoma Regional Hospital, Tanzania

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Abstract

This is a partly retrospective study of 252 major limb amputations carried out in regional hospital in Tanzania over a period of ten years mostly by the authors.

The paper reports on the aetiology and levels of amputation and identifies prevalence and sex of the amputees. The causes of amputation – classified under tumours, vascular diseases, trauma, infections, burns, animal bites, iatrogenic causes, maduromycosis and miscellanea – are discussed with particular reference to the influence of the environment, cultural habits and local customs.

Introduction

This investigation was performed at the Orthopaedic Department of Dodoma Regional Hospital, one of the few orthopaedic centres currently operating in Tanzania.

It scrutinises all the available data concerning 252 major limb amputations, which were carried out from 1983 to 1992. The paper is an epidemiological research aimed at investigating, as accurately as possible, the field of amputation surgery in a developing country.

It is a report focusing on topics which were raised or hinted at by a paper published a few years ago (Loro *et al.*, 1990), to which the readers are referred, because it offers still valid general information about the Region, the hospital, the working setting and the local facilities. When comparing the resulting data with those reported by similar studies conducted

in western countries, one can easily appreciate the peculiarities and the clear differences, mainly when consideration is given to general parameters, such as age and aetiology, or to specific ones such as amputation level.

Looking at the different aetiological groups (Table 1), one of the most interesting points concerns their classification and their relative percentages as regards the total, with tumours topping the list, followed by vascular diseases.

Traumatic injuries was the third most prevalent group, with injuries at work and a rising number of motor and train accident victims, a trend reported also by other African countries during the last years.

Finally, there was a group of causes representing almost 25% of the total number that indicate how the environment, cultural habits and local customs may play a role as cause or predisposing agents.

Materials and methods

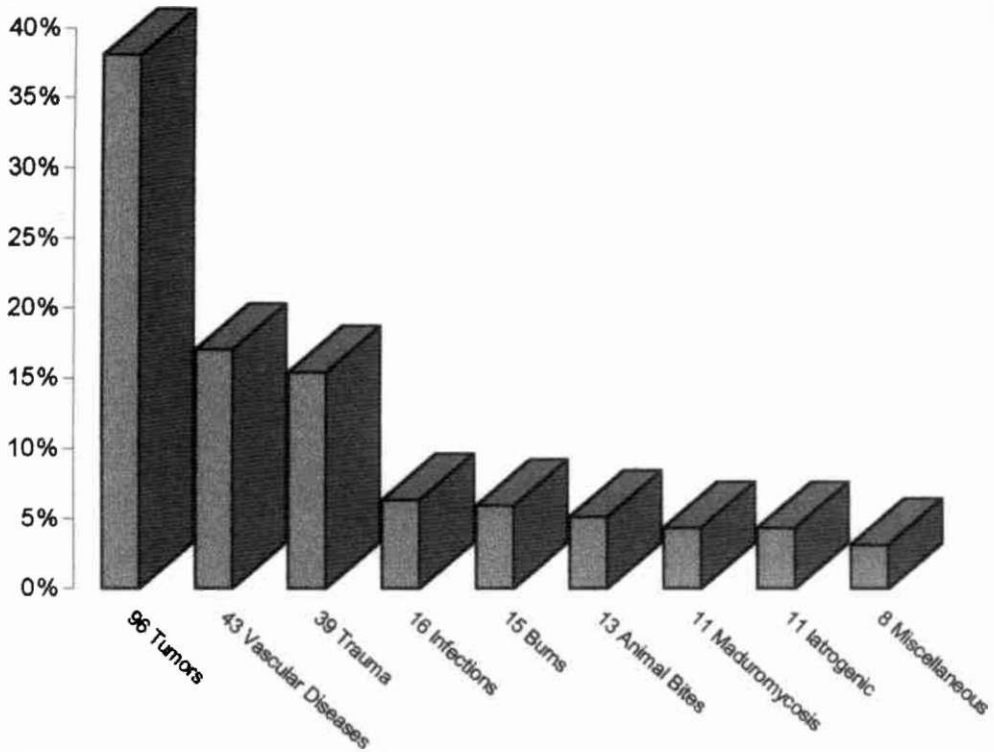
In the period under review, 241 patients underwent limb amputations of these, 8 lost two limbs while one lost all four limbs. There were 172 males and 69 females, with a mean age at the time of operation of 39.5 years (minimum 20 days, maximum 71 years). This parameter has shown great variation in relation to the specific aetiological agents.

There were 214 amputations involving the lower limbs of 207 patients (148 males and 59 females) and 38 upper limb amputations performed on 34 patients (24 males and 10 females). Table 2 shows the distribution of different types of amputation.

With the exception of a few cases, all

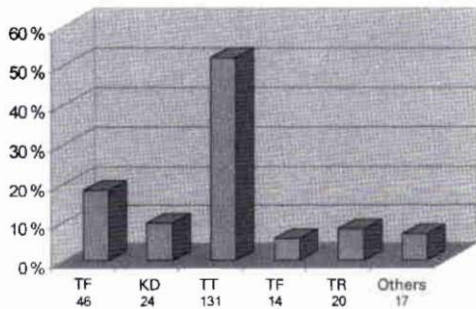
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Table 1. Prevalence of amputations by indications. There are thirty cases of unclear classification included in the vascular disease group (see text).



amputations were performed by either author, according to standardised pre-operative and post-operative protocols. Pre-operatively, only

Table 2. Prevalence of amputations by level. Note the clear prevalence of amputation at or below knee level (approximately 60% of the total). This high percentage finds its explanation in a group of causes that are specifically related to an African setting.



TF: trans-femoral
 KD: knee disarticulation
 TT: trans-tibial
 TF: trans-femoral
 TR: trans-radial

simple laboratory investigations, such as complete blood cell count, blood sugar and routine urinalysis were requested. Plain radiographs of the affected part were taken only if the investigation was judged clinically justifiable by the surgeon. When needed, specimens for histological examination were sent abroad, mainly to the Department of Surgical Pathology at the Mayo Clinic in Rochester, Minnesota, and, less frequently, to the Pathology Department of the University of Verona, Italy.

Before discharge, patients were informed about the rehabilitation programme available at the hospital, including the range of orthopaedic devices which could be provided.

Indications for amputation

Tumours

Tumours in general, were directly involved in almost 40% of the total number of amputations. Following an histological basis, they have been classified into four different groups, namely bone tumours, soft tissue sarcomas, melanomas

and squamocellular carcinomas. There were 11 cases of malignant bone tumours (7 osteosarcomas, 2 giant cell tumours, 1 Ewing's tumour and 1 Burkitt's lymphoma). As expected, all patients were young, mostly in their second decade of life. All had reported late to hospital and, when seen, were showing clinical signs and radiological features of a malignancy in an advanced stage. Except for the child treated for Burkitt's lymphoma, the prognosis was grim for all of them.

Eight patients presented with soft tissue sarcomas (3 synovial sarcomas, 1 Kaposi's, 2 fibrous hystiocytoma, 1 leiomyosarcoma and 1 schwannoma) while five patients, all females aged more than 50 years, presented with long-standing foot melanomas (Fig. 1).

All the remaining patients belonging to the tumours group were diagnosed as having squamocellular carcinomas, a rather common cancer in Tanzania. As already reported (Amir *et al.*, 1992; Lifeso *et al.*, 1990) the development of this cancer seems strictly related to long-standing ulcers, burn scars, leprotic ulcers (Awofeso, 1992) and chronic fistulae. All are regarded as predisposing factors to carcinomatous degeneration of the skin and, indeed, they were frequently recorded among the patients of this series. There were 58 males and 14 females, a male:female ratio of 4:1. Commonly, they were in their fifth or sixth decade of life when amputation was performed (mean age: 53 years).

All tumours, with the exception of three cases, involved the lower limb, particularly the distal



Fig. 1. Pathological aspect of a deeply invasive melanoma involving the hindfoot of a 60-year-old woman. Note the blackening of the calcaneal tuberosity. Amputation was employed as a palliative act. Patient died within 4 months of amputation.



Fig. 2. Extensive infiltration of the right tibia of a middle-aged man, who presented with a cancerised skin ulcer dating back 10 years. A leg amputation was performed. As in similar cases the stump healed well; the bone appears to be normally structured and spared just a few centimetres proximally to the border of the lytic area. No reamputation or revision surgery was required for local relapse of the condition.

half of the leg or the ankle joint region, with no significant difference in relation to the side.

Most of the patients were farmers, illiterate, often living alone under difficult circumstances. All had a long past medical history; tumours were, on admission, at an advanced stage, often infiltrating the bones and, in almost 50% of the cases, already spread to the regional lymph nodes. Pulmonary metastases were recorded in a few patients.

Two prevalent radiographic patterns were observed.

The first one was that of bone infiltration. Roentgenographic pictures varied from minimal indentation of the cortex to multiple lytic areas with scalloped borders (Fig. 2), from extensive resorption, leading to pathological fracture, to complete bone disappearance as is typically seen in metastatic lesions (Fig. 3).

The second one was a picture of bone

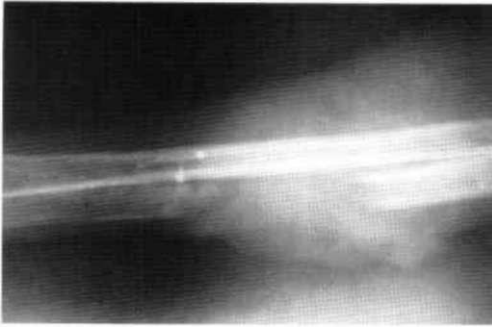


Fig. 3. Extensive ulnar defect observed in a 45-year-old man having a squamocellular carcinoma of three years duration. Cancer developed in a scar, left by a burn which had occurred ten years earlier.

“irritation”, as that seen in chronic periostitis. Radiographically, it appeared as an enlargement and deformity of both leg bones, particularly the fibula (Fig. 4). It was not uncommon to observe an involvement of the interosseous membrane, signalled by the presence of scattered, round calcifications; a picture of complete synostosis was seen in long-standing cases.

Post-operative examination of the amputated legs confirmed the radiographic findings. There were specimens characterised by extensive bone replacement by neoplastic tissue and cases where bone was spared, even if it was in close contact with the cancer. To the naked eye, at least, the cortex underlying the tumour was apparently intact.

No clear relationship was established between either bone reaction and any other parameter such as cause, site or length of the disease, sex, age, previous treatments and grade of tumour differentiation.

Vascular diseases

This is a section that had to be revised and reorganised over the years, because of the uncertainty of classification of a rather important number of vasculopathies typically seen in an African context.

The assertion that classic atherosclerosis and diabetic vasculopathy are almost unknown to Africans (Rolfe, 1990) was confirmed by the authors' study, where only three amputations were performed for diabetic complications and all three patients were belonging to the Arab or Indian communities living in the region.

It was assumed, for a long time, that Buerger's disease was to be regarded as a rare cause of

amputation in African people. But, in order to cast light on several patients who described the clinical course seen in thromboangioitis obliterans, since mid-89, specimens for histological examination were taken in any case of gangrene of dubious aetiology. Surprisingly, out of ten specimens that were sent to the USA for diagnosis clarification, six showed features typical of thromboangioitis, whereas in the remaining four the findings of “vasculitis- phlebitis” were considered highly suggestive of it. Although only a few patients among them had a history of smoking, it should be kept in mind that in Dodoma region tobacco is widely chewed and/or sniffed.

All six patients with histologically proven Buerger's disease were males, four were older than 55 years, three were smokers and one, the youngest patient in this group (35 years), was also leprotic and the only one with upper limb involvement.



Fig. 4. Radiographs of the left leg of a 63-year-old man, presenting with a skin cancer that developed in an ulcer spontaneously erupted three decades earlier. Note the fibular enlargement and deformity, coupled with a synostosis matching the involved leg segment. Usually complete synostosis is preceded by slow but progressive calcification of the interosseous membrane.

Even the four patients with findings suggestive of Buerger's were all males, three were older than 60 years and only one was an active smoker.

Open questions and doubts remain when the most consistent group included in this section is addressed, because to date there is no histological evidence to support sure classification. However, on the grounds of prevalence of Buerger's disease, records of this group of thirty patients were reviewed and, retrospectively, it was possible to separate 15 cases of probable thromboangiitis obliterans, four involving the upper limbs.

On the other hand no useful clues were found for classification of five cases of foot gangrene observed in three children aged 2 years, 2 years and 6 months and 6 years, even if a coagulation disorder was postulated. Parents denied permission for autopsy examination in all the cases.

No explanation was found for ten patients and they were included into the general group of "idiopathic peripheral gangrene" or "gangrene of unknown origin" (Barr *et al.*, 1972; Steiner and Hutt, 1972). Among them, one patient reported that his hand became necrotic after taking, three weeks earlier, a full course of chloroquine for a malaria attack, while two other patients reported a history quite similar to that described by Gelfand (1947). Furthermore in three cases histological examinations reported inconclusive findings, because the pathologist was unable to further classify the evident vasculitis or to explain the simple venous thrombosis.

Trauma

Out of 39 amputations included in this group, 10 were due to casual accidents, 4 to injuries at work, and 17 were due to motor and train accidents.

Criminal actions were responsible for 8 amputations. Among them, six occurred during cattle rustling; five were caused by pangas or axes and one by a gun-shot. One alleged thief lost both upper limbs after a rope was tied around his arms and he was left helpless for several hours in the bush (amputations were performed seven days apart).

Infections

Chronic osteomyelitis required lower limb

amputation in four patients; three of whom were children aged less than 15 years and all had been repeatedly operated on before reaching the authors' institution.

Five amputations were due to gas gangrene, all following an overlooked thorn prick injury; three to the muscles of the calf region and two to those of the forearm. All the interventions were performed as emergency procedures in rapidly evolving life-threatening conditions. Seven ablations were due to severe limb infections secondary to an inappropriately managed open injury. In six patients, all but one coming from other hospitals operating in the area, it was necessary to resort to an open type of amputation in order to eradicate the infection.

Interestingly one upper limb amputation was carried out for an extensive hand phlegmon following an improperly managed human bite that had occurred a few days earlier.

Burns

Fire and epilepsy are considered together in this section grouping 15 amputations, mostly performed in young people and sometimes in infants.

In villages, the custom to place cooking fires at floor level predisposes to burns children who crawl or play inside or around the hut, especially when they are in custody of young sisters. Besides that, there seems to be a link between fire and epilepsy, considering the relatively high number of epileptic patients who got burnt when left alone. In this series, this link was recorded in six patients.

Although there is no satisfactory explanation for this common observation, it is suggested that fire, with its changing and flashing light, could trigger epileptic crises.

On admission, the burnt limbs were all in a condition of dry gangrene or mummification, with exposed bones and joints. Furthermore, more than half of the patients were showing additional scars from previous injuries in other regions of the body, while two of them had already lost one limb some years earlier.

Animal bites

Wild animal bites were the cause of 13 amputations.

The bite of the puff adder, locally known with the name of "kifutu" (Maimu, 1982), whose venom has haemolytic properties, was the cause

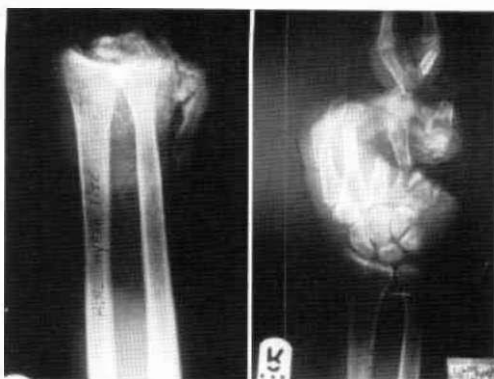


Fig. 5. A young man, attacked by a rabid(?) hyena lost both hands. He was in a group of six people going home from work, at mid-day. Only one person was left unhurt. A few weeks later, another group of four women was attacked in the same area.

of 8 amputations, mostly involving the upper limbs of young farmers.

All patients were seen late; it has often proved impossible to identify and separate natural damage from that related to human action at the accident site. Severe maiming injuries, caused by hyena attacks and involving mainly the upper limbs, were seen in 5 patients in the series (Fig 5). Because of extensive mangling of bones and soft tissues, a radical solution had to be employed in all the cases. It is well known that the hyena is provided with extremely powerful jaws.

What still needs clarification is the assertion that only rabid beasts attack human beings, as is thought by indigenous people.

Iatrogenic causes

This is a section which includes 11 amputations, all seen in children or young adults, occurring after polio surgery, fracture treatment or topical drug application on the feet.

Three lower limb amputations were performed in two polio patients a few days after an one-stage surgical correction of severe hip and knee joint contractures, while four children lost one upper limb for vascular complications in the course of treatment of simple forearm fractures (Ofiaeli, 1991; Wilson, 1991). In three cases, the plaster was applied in the out-patient clinic by untrained staff, while in one case the immobilisation was applied at village level, by means of two wooden sticks held together with a home-made bandage.

Four cases of dry gangrene were observed in male patients who had been attending the services of local healers for pain and numbness. All reported that the foot gangrene became evident after the application of a liquid substance on fresh razor cuts. It is unclear whether the gangrene was really due to the drug itself or whether the patients, all active smokers, were suffering from Buerger's disease in its early phases.

Maduromycosis

This chronic fungal infection that almost exclusively involves the foot was managed by leg amputation in 11 patients. All cases were farmers, in their mid-age. This is a condition that, if left untreated for several years, may lead to collapse of the bony architecture of the foot and, consequently, to complete loss of function (Loro and Franceschi, 1998). Although a quite rare condition in this Region, 1 case per year, it must be kept in mind and suspected at an early stage. In later phases, the foot may become really useless and troublesome, and the patient himself may demand a radical solution. That happened in four cases in this series.

Miscellanea

One amputation was due to a congenital cavernous lymphangioma seen in a child whose limb mass was 15kg.

Two ablations were done in new-borns for constriction band syndrome (Bourne and Klassen, 1987), while two were performed in children who presented with tibial total longitudinal deficiencies. According to the classification of Jones *et al.* (1978), one child had a type 1B and the other a type 2 deficiency.

Finally three amputations were carried out in two patients who were referred from an area stricken by an outbreak of meningococcal meningitis. They were showing the peripheral gangrene that is sometimes observed among the complications of purpura fulminans (Huang and Clarke, 1997) (Fig. 6).

Discussion

This clinical study on amputation surgery in a developing country offers more than one area for discussion and for further research, mainly when data concerning specific fields of investigations are compared with those coming out from researches conducted in western countries.



Fig. 6. A 31-year-old man was sent to the Department from a nearby district where an epidemic of meningococcal meningitis was going on. As known, extensive tissue necrosis may be seen in case of purpura fulminans. Bilateral leg amputation was required in this case, followed, later on, by multiple skin grafts. Patient survived and, a few months later, he was supplied with bilateral patellar-tendon-bearing prosthesis.

There are striking differences if consideration is given to specific parameters such as aetiology, age, availability of diagnostic tools and treatment options.

First of all, this study has confirmed the findings reported by other authors (Amir *et al.*, 1992), of the high prevalence of the squamocellular carcinoma, a cancer responsible for almost 30% of the total number of the reviewed amputations. There seems to be an attitude to overlook this tumour, probably because of the slow progress of the disease allowing farmers to conduct an acceptable quality of life for several years. It was quite unusual to take care of patients affected by cancer in early stages.

It is wrong to consider a chronic leg "ulcer" as a benign lesion; this tumour has to be regarded as a dangerous and debilitating neoplasm, able to spread to regional lymph nodes (more than 50% in this series) or to distant organs such as liver or lungs.

As for other malignancies, amputation was sometimes prompted by a mixture of palliative purposes and humanitarian reasons. Treating malignancies in peripheral hospitals in developing countries often presents a diagnostic task which is not balanced by available curative options.

Prevention, early diagnosis and, when possible, prompt referral should be given a decisive push, particularly in rural areas, where it is easier for skin lesions to occur and where the great majority of the population live.

Analysis of the data showed that people living in rural areas were more prone to get diseases or to sustain traumatic injuries responsible for amputation, with greater exposure to snake bites, to skin ulcers and to fungal infections. Moreover villages in rural zones are usually poorly served by public transport, so referring patients to qualified health institutions may become really difficult.

The authors' experience suggests that particular attention should be directed to lesions due to thorn pricks, to burn scars, to leprotic ulcers and to chronic sinuses. It is interesting to note that several patients admitted that the ulcer erupted in an area where, some decades earlier, a thorn prick had occurred.

Once more this research has shown that diabetes is rarely responsible for gangrene in African people perhaps because of diet (Rolfe, 1990).

On the other hand the collected data indicate that the prevalence of Buerger's disease deserves to be redefined in further studies. One may suppose that several cases diagnosed in the past as idiopathic gangrene could have been classified as thromboangiitis obliterans by a trained pathologist.

Under the general term of peripheral vascular diseases there are cases that for the time being will be included into the idiopathic gangrene group. Proper classification needs a diagnostic armamentarium which is still beyond the limited resources available to regional or district hospitals.

Clearly there is a need for different diagnostic categories, because diseases that are accounting for 90% of the total number of amputations in western countries are barely observed in epidemiological studies conducted in African regions.

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A new alignment jig for quantification and prescription of three-dimensional alignment for the patellar-tendon-bearing trans-tibial prosthesis

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Abstract

Clinically, it is hard to achieve and reproduce prosthesis alignment at will during daily prosthesis fitting. A new alignment jig was designed and developed to facilitate quantification and prescription of prosthesis alignment for patellar-tendon-bearing (PTB) trans-tibial prostheses. The alignment jig provided instantaneous readings of the three-dimensional orientation and position of the socket relative to the prosthetic foot in standardised units. The inter- and intra-tester errors of the alignment jig in measuring prosthesis alignment were evaluated and demonstrated to have good reliability. The alignment jig was recommended to be used clinically after the conventional dynamic alignment procedure to document the prosthesis alignment. Further application of the alignment jig for systematic evaluation of the effects of prosthesis alignment on gait for trans-tibial amputees is suggested.

Introduction

The sequence of providing a lower limb prosthesis includes the events of assessment and measurement, assembly of prosthesis components, alignment procedure, final finishing and fitting. Of these events, the alignment procedure is the most critical and

time-consuming process. The alignment of the prosthesis is defined as the three-dimensional orientation and position of the socket relative to the prosthetic foot. For the trans-tibial prosthesis, this refers to 6 alignment parameters, i.e. the anteroposterior (A/P) shift, A/P tilt, mediolateral (M/L) shift and M/L tilt of the socket relative to the foot, length of the prosthesis and the toe-out angle (Berne *et al.*, 1978; Zahedi *et al.*, 1986). Clinically, the alignment at which the amputee feels comfortable and the resulting gait judged by the prosthetist to be functionally acceptable is regarded as an acceptable alignment. This conventional alignment procedure is an experience dependent process and relies on both the prosthetist's subjective judgement and the amputee's feeling of the comfort level. Due to its subjective nature, the alignment achieved may not be optimal for the amputee resulting in the increased possibility of tissue or skin damage due to the resulting stress actions on the stump during functional activities.

Different alignment devices like the Berkeley Adjustable Leg®, the Winnipeg wedge disc alignment units (Foort and Hobson, 1964), the Proteor Alignment Device (distributed by Fillauer Inc.), In-built One-point Alignment (Köhler *et al.*, 1988), the Cup Connector (distributed by the United States Manufacturing Company) are commercially available. There are also commercially available jigs for prosthesis alignment duplication such as the Berkeley Horizontal Duplication Jig, the Vertical Fabrication Jig, the Otto Bock

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Balancing Apparatus, the Otto Bock Alignment Apparatus, the Otto Bock Transfer Alignment Apparatus. These alignment and duplication devices have individual measurement mechanisms for adjusting the alignment. However, they do not provide numerical documentation of the three-dimensional orientation and position of the socket relative to the prosthetic foot. Although the prosthesis alignment can be measured using a conventional plumb line method, the repeatability and accuracy are relatively low. Moreover, it is technically difficult and not reliable to prescribe an alignment using the plumb line method during the alignment procedure.

In 1978, Berme *et al.* developed a socket axis locator for defining and determining the socket axis. By digitising the three-dimensional coordinates of several reference points defined on the socket axis and the socket using a scribing block, the 6 alignment parameters were calculated with good repeatability. Evans and Evans (1994) improved the time-consuming digitisation process by using a magnetic tracking device (3SPACE Isotrak, Polhemus, Vermont, USA) and the 6 alignment parameters could be determined automatically. However, the accuracy of the measurement could easily be affected by the interference induced to the

magnetic tracking device by nearby metallic components. Moreover, prescription of prosthesis alignment using this method could only be achieved by a trial and error approach. It is therefore, the objective of this study to design and develop a simple alignment jig that can be used for measuring as well as prescribing three-dimensional prosthesis alignment with 6 degrees of freedom (Berme *et al.*, 1978; Zahedi *et al.*, 1986). As the requirements for different types of amputees are different, the current study is mainly for trans-tibial amputees who are the majority of the amputee population.

Particulars of the design

A simple mechanical alignment jig was designed and developed. The alignment jig consisted of 3 major parts, namely an alignment table, an adjustable socket mount and a socket axis locator (Fig. 1). The design of the alignment table and the socket axis locator was originated from Berme *et al.* (1978) for prosthesis alignment measurement. The alignment table was a framework structure with a pair of parallel shafts and a vertical mount. The vertical mount was used for mounting of the shank of the prosthesis to the alignment table. The adjustable socket mount consisted of 4 scaled independent manoeuvrable frames. The 4 frames were used

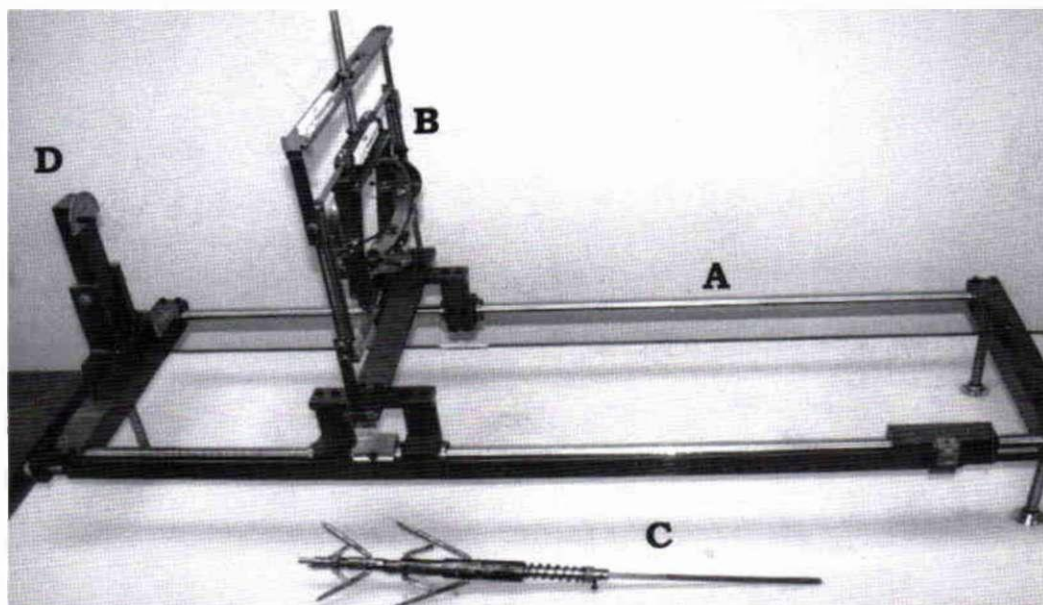


Fig. 1. The alignment jig. A – the alignment table; B – the vertical mount; C – the socket axis locator; D – the adjustable socket mount with 4 scaled independent manoeuvrable frames.

to hold the socket in space and control its position and orientation with 4 degrees of freedom (i.e. the socket tilts and shifts in A/P and M/L planes) (Fig. 2). The 5th frame of the adjustable socket mount was used to hold the 4 frames and could slide along the parallel shafts of the alignment table for controlling the height of the prosthesis. There were scales on the parallel shaft and the vertical mount for measuring the length of the prosthesis and the toe-out angle, respectively (Fig. 2).

The socket axis locator was used to define the axis of the socket (Fig. 1). It was constructed with a square central rod on which there were two sliding sub-assemblies. Both the sliding sub-assemblies consisted of 2 pairs of spring-loaded arms. The two pairs of arms were so designed that they were orthogonal to each other and there was a mechanism to permit the tips of each pair of extendible arms to be kept equidistant to the central rod.

Procedures for determining socket axis

The procedures in determining the axis of a socket using the socket axis locator are as follows. A line was firstly drawn 25mm distal and parallel to the patellar bar on the inner wall of the socket. The socket axis locator was then

put inside the socket. The position of the socket axis locator was continuously adjusted until the distal end of the central rod was in contact with the distal socket end and the tips of all the extendible arms touched the inner wall of the socket. For the proximal sliding sub-assembly of the socket axis locator, one pair of the extendible arms was positioned to be parallel to the posterior socket brim and the other pair was so positioned that the tip of its anterior arm touched the marked line. When the socket axis locator was set in such a position, the axis of the socket was defined as the central rod of the locator. Accordingly, there would be 4 points of contact between the tips of the extendible arms of the proximal sliding sub-assembly and the inner wall of the socket. By using an outside calliper, the 4 points of contact were duplicated and marked on the outer wall of the socket. They were labelled as A, P, M and L to denote the anterior, posterior, medial and lateral sides of the socket, respectively. Points P, M and L were used as reference points for determining the prosthesis alignment.

Procedures for measuring and prescribing prosthesis alignment

For a given PTB trans-tibial prosthesis, its

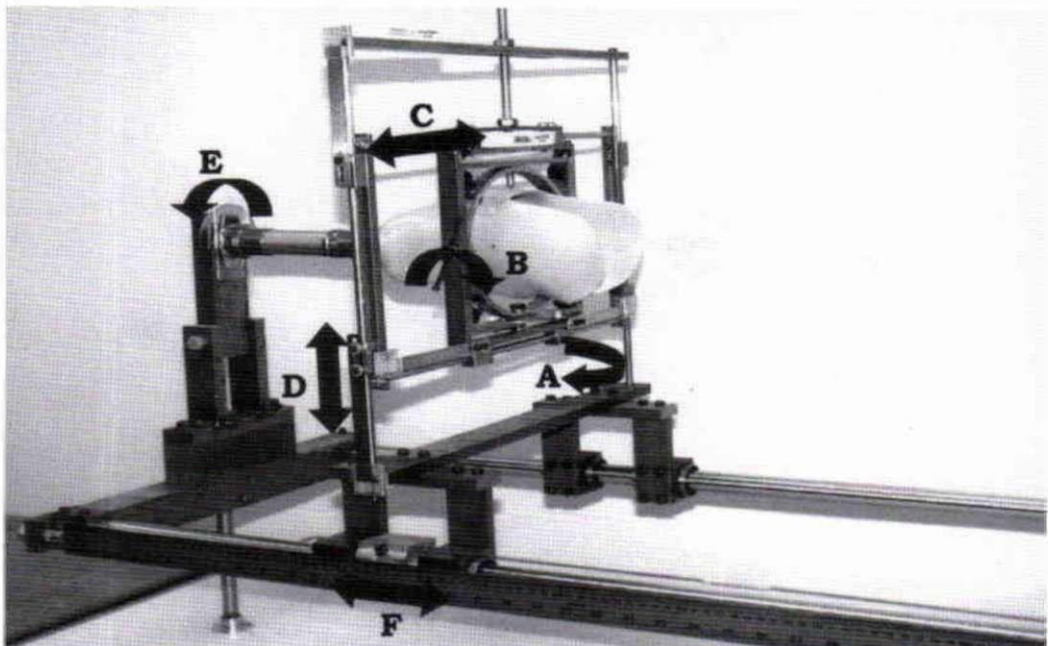


Fig. 2. The mechanisms for inputting the 6 alignment parameters. A – for M/L tilt; B – for A/P tilt; C – for M/L shift; D – for A/P shift; E – for toe-out angle; F – for prosthesis height.

alignment can be measured using the alignment jig as follows. A mark was firstly drawn on the foot adaptor to indicate the orientation of the foot. The foot was then removed. Subsequently, the axis of the socket was determining using the socket axis locator and the 3 reference points, i.e. points P, M and L, were determined. The prosthesis was then mounted onto the vertical mount at the foot adaptor using an ankle-bolt. The adjustable socket mount was adjusted manually until the tips of 3 positioning screws of the adjustable socket mount touched the 3 reference points. The 6 alignment parameters of the prosthesis were then determined directly from the scales on the vertical mount, the parallel shaft of the alignment table and the 4 manoeuvrable frames of the adjustable socket mount. It was recorded that it took less than 6 minutes for a skilled operator to complete a set of measurement.

For prescribing an alignment, the axis of the socket was firstly determined using the socket axis locator and 3 reference points were marked. The socket was then mounted onto the adjustable socket mount at the 3 reference points using the 3 positioning screws. The shank part of the prosthesis with the prosthetic foot detached was mounted separately onto the

vertical mount with the foot adaptor positioned at the required toe-out angle. The required tilts and shifts of the socket in A/P and M/L planes were input using the 4 manoeuvrable frames of the adjustable socket mount. The length of the prosthesis was determined by subtracting the total required length by the foot height and input by using the scale on the parallel shaft of the alignment table. Once all the 6 alignment parameters were confirmed, the socket and the shank were rigidly joined together using a torque wrench. If it was required to modify the alignment, the same reference points would be used and the process above would be repeated. It was also recorded that it took less than 6 minutes to complete a prescription process for a skilled operator.

Reliability study

The resolution of the scales of the alignment jig was 1° for angular and 1mm for linear measurement. The source of errors in using the alignment jig to measure prosthesis alignment may arise from the process in determining the socket axis, duplicating the reference points and measuring prosthesis alignment using the adjustable socket mount. In order to study the intra-tester and inter-tester reliability of the

Table 1. Means (SD) and ranges of the averaged alignments of the 6 prostheses measured by the two prosthetists using the new alignment jig.

Alignment parameter	Prosthetist A	Prosthetist B
Prosthesis height (mm)	352.6 (18.4)	352.7 (18.4)
	324.7 – 369.5	324.3 – 369.3
A/P tilt (degrees) ¹	6.3 (1.3)	6.4 (1.3)
	4.7 – 8.2	4.7 – 8.3
M/L tilt (degrees) ²	4.1 (0.4)	3.9 (0.7)
	3.7 – 4.5	3.0 – 4.7
A/P shift (mm) ¹	7.8 (1.6)	7.5 (1.6)
	5.5 – 9.3	5.7 – 7.5
M/L shift (mm) ²	5.3 (2.3)	5.3 (2.4)
	4.0 – 9.7	3.2 – 9.8
Toe-out angle (degrees) ³	15.1 (1.2)	15.1 (1.4)
	13.8 – 17.2	13.8 – 17.3

¹ Positive for anterior tilt/shift, negative for posterior tilt/shift

² Positive for lateral tilt/shift, negative for medial tilt/shift

³ Positive for toe-out, negative for toe-in

Table 2. Intraclass correlation coefficients, ICC(3,1), for studying the intra-tester reliability of the two prosthetists in measuring the 6 alignment parameters.

Alignment parameter	Prosthetist A		Prosthetist B	
	ICC(3,1)	p-value	ICC(3,1)	p-value
Prosthesis height	1.00	<0.001	1.00	<0.001
A/P tilt	0.86	<0.001	0.80	<0.001
M/L tilt	0.33	<0.001	0.47	<0.001
A/P shift	0.89	<0.001	0.87	<0.001
M/L shift	0.94	<0.001	0.95	<0.001
Toe-out angle	0.79	<0.001	0.85	<0.001

alignment jig, the 6 alignment parameters of 6 randomly selected PTB trans-tibial prostheses were repeatedly measured 6 times by two prosthetists. The 6 trans-tibial prostheses were currently used by the amputees of the out-patient clinic. All the amputees had a stump length longer than 10cm. For each prosthesis, its socket axis was firstly located using the socket axis locator. The 3 reference points were identified and marked using a 0.5mm pencil. The prosthesis alignment was then measured using the alignment jig. The markings of the reference points were removed after the measurement. The reliability of the measurements was assessed using the intraclass correlation coefficient (ICC) (Portney and Watkins, 1993). The ICC of model 3 (i.e. ICC(3,1)) and model 2 (i.e. ICC(2,1)), were used to reflect the intra-tester reliability of the two prosthetists and the inter-tester reliability of the measurements, respectively.

Results

For each prosthesis, the 6 alignment parameters were measured 6 times by each prosthetist. The results of the 6 trials were averaged. The means and standard deviations of the averaged prosthesis alignment for the 6 subjects measured by the two prosthetists were determined (Table 1). It was observed that the M/L tilt of the 6 prostheses used fell within a relatively narrow range.

The intra-tester reliability of the two prosthetists were quantified by the ICC(3,1) values (Table 2). It was found that all the alignment parameters, except the M/L tilt, had good intra-tester reliability with ICC(3,1) ranged from 0.79 to 1.00. The ICC(3,1) values for measuring M/L tilt were 0.33 and 0.47 for the two prosthetists.

In studying the inter-tester reliability of the measurements, only the first set of

measurements by each prosthetist was used (Table 3). It was found that all the alignment parameters, except the M/L tilt, had good inter-tester reliability with ICC(2,1) ranged from 0.74 to 1.00. The ICC(2,1) value for measuring M/L tilt was 0.26 ($p=0.301$).

Discussion

In prescribing and measuring the alignment of a trans-tibial prosthesis, the only control required is the three-dimensional position and orientation of the socket relative to the foot. There is no restriction on the relative positions of the other prosthetic components as long as they are rigidly linked together. It is therefore, independent of the types of prosthetic components to be used. In this study, a simple mechanical alignment jig was designed and developed. The alignment jig provided direct read-out of the prosthesis alignment and no numerical calculation was required. The operation of the alignment jig was simple and required only common hand tools. It was recorded that it took less than 6 minutes to prescribe or measure a prosthesis alignment for a skilled operator.

In the current study, 6 prostheses currently used by the amputees were used for the

Table 3. Intraclass correlation coefficients, ICC(2,1), for studying the intra-tester reliability of the two prosthetists in measuring the 6 alignment parameters.

Alignment parameter	ICC(2,1)	p-value
Prosthesis height	1.00	<0.001
A/P tilt	0.84	0.001
M/L tilt	0.26	0.301
A/P shift	0.94	0.001
M/L shift	0.91	0.001
Toe-out angle	0.74	0.038

reliability analysis. The alignments of these prostheses were prescribed by experienced prosthetists using conventional dynamic alignment procedures. The alignments measured using the new alignment jig were compared with the acceptable alignment ranges reported by Zahedi *et al.* (1986). It was found that A/P and M/L tilts of the 6 prostheses fell within the ranges determined by Zahedi *et al.* (1986). However, the A/P and M/L shifts and M/L tilts of the prostheses were much smaller than those reported by Zahedi *et al.* (1986) and the toe-out angles were larger than that reported by them. This might be explained by fact that the results by Zahedi *et al.* (1986) represented the extremes of the maximum acceptable alignment ranges. As there was no absolutely known prosthesis alignment available, only the reliability of the alignment jig could be studied. The intraclass correlation coefficients of the alignment jig in measuring all the alignment parameters were high except that for the M/L tilt. The low intraclass correlation coefficients for measuring M/L tilt were thought to be due to lack of variability among the M/L tilts of the prostheses used (Portney and Watkins, 1993). As the range of the measured M/L tilts was small (Table 1), it is still reasonable to conclude that the alignment jig has good intra- and inter-tester reliability for measuring all the 6 alignment parameters.

With the development of the new alignment jig, an individual's prosthesis alignment could be recorded in clinical notes for future reference and comparison and the recorded alignment could then be reproduced whenever it is necessary.

This may benefit those amputees who need to change their prosthesis frequently. Moreover, the alignment jig will be useful for both training and research purposes. As there are multiple variables related to the prosthesis alignment combinations contributing to the efficacy of prosthesis fitting, the alignment jig could provide a systematic and objective means for the control of individual prosthesis alignment and consequently to facilitate the follow-up evaluation.

It should be noted that the socket axis determined using the socket axis locator might

not represent the axis of the tibia or any skeletal structure. Therefore, further investigation is necessary to determine the correlation between the defined socket axis with the anatomical configuration of the stump so that the effects of prosthesis alignment could be systematically evaluated and compared among individual amputees. Finally, the current alignment jig design is suitable only for the PTB trans-tibial prosthesis with prosthetic foot with ankle-bolt attachment. Modification would be necessary for a prosthesis that does not have ankle-bolt attachment.

Conclusion

A simple alignment jig was designed and developed. It can provide direct read-out of the 6 alignment parameters for PTB trans-tibial prostheses without any computation. It could be used to measure and prescribe alignment for trans-tibial prostheses with good reliability.

Acknowledgement

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Effects of sagittal plane prosthetic alignment on standing trans-tibial amputee knee loads

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Abstract

The influence of sagittal plane prosthetic alignment changes on loads applied to the ipsilateral knee was investigated using 5 trans-tibial amputee subjects. The goal was to determine which prosthetic alignment results in the most energy efficient standing and also minimises stresses on knee structures during standing.

The electromyogram, the external mechanical loading of the prosthetic leg and the amputees' posture were recorded for a wide range of prosthetic alignments. The EMG of the vastus lateralis and biceps femoris muscles was measured bilaterally; the EMG of the gastrocnemius muscle was measured only on the contralateral side. The distance between the anatomical knee centre and each individual's load line, as determined by the Otto Bock "L.A.S.A.R. Posture" alignment system, was used as a measure of the mechanical load applied to the knee joint.

Prosthetic alignment has almost no influence on muscle activity of the contralateral lower limb during static standing. On the other hand, prosthetic alignment has a significant influence on the load applied to the amputee's ipsilateral knee joint. The external knee moments applied to the knee ligaments and knee muscles on the amputated side change systematically in response to different plantar flexion or dorsiflexion angles of the prosthetic ankle-foot. During standing the extensor muscles stabilise

the limb by contracting if the load line is located less than 15mm anterior to the anatomical knee centre. The biceps femoris muscle appears to have little or no protective function against hyperextension during standing even if large external knee extension moments are caused by excessive plantar flexion. Such extreme alignments significantly increase the stresses on knee ligaments and the posterior knee capsule.

When prosthetic sagittal plane alignment is altered, the trans-tibial amputee compensates by balancing the upper part of the body over the centre of pressure of the prosthetic foot.

Biomechanically optimal alignment of the trans-tibial prosthesis occurs when the individual load line is approximately 15mm anterior to the anatomical knee centre, permitting a comfortable, energy efficient standing and minimising the mechanical loading on the knee structures.

Introduction

Prosthetic alignment has long been recognised as having a substantial influence on the quality of the trans-tibial (TT) prosthesis. As a prerequisite for daily activities with his prosthesis, the TT amputee must be able to stand comfortably.

Manufacturers' guidelines for static prosthetic alignment are not individualised for each amputee. As a result, prosthetic alignment must be optimised for each individual during iterative dynamic alignment (Pinzur *et al.*, 1995; West, 1987). In current clinical practice, optimisation of prosthetic alignment is a time-consuming, subjective process requiring many years of experience combined with feedback from the amputee for the best result. It is inevitable that

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this subjective method results in a wide variation in acceptable definitive alignments. Differences in prosthetic alignment have been documented when the alignment procedure is repeated several times, such as when different prosthetists realign the same amputee using identical components (Zahedi *et al.*, 1986; Solomonidis, 1991).

A previous paper (Blumentritt, 1997) reported on the results of posture measurement and prosthetic alignment of 18 experienced TT amputees. The amputee's load line served as an objective, individual reference line. Results of this investigation included:

1. the trans-tibial anatomical knee centre was located between 8 to 40mm posterior to the load line, with a mean value of 18mm posterior to load line;
2. the distance between knee centre and load line was independent of the type of prosthetic foot;
3. definitive alignment of a trans-tibial prosthesis cannot be finalised during one fitting session using the current subjective method.

Breakey (1998) has reported his clinical experience using the Otto Bock "L.A.S.A.R. Posture" system in the alignment of definitive prostheses and has formulated a "Theory of Integrated Balance" using the load line as reference.

It is well accepted that sagittal plane alignment changes to the TT prosthesis will influence amputee comfort during standing. It may be that the acceptance or rejection of a tested prosthetic alignment by the amputee is affected by the muscular or ligamentous forces acting around the knee joint. The goal of this study is to show the results of different sagittal prosthetic alignment on the activity of knee muscles during standing and to propose guidelines for a biomechanically optimal prosthetic alignment.

Methods

The external load on the knee joint of the amputated limb was determined using the Otto Bock "L.A.S.A.R. Posture" alignment system. The posture of the amputee was also recorded using this device.

The "L.A.S.A.R. Posture" device determines the vertical component of the ground reaction forces acting on its sensing platform. When both feet are on the force platform, the patient's weight and the location of the *weight bearing*

line can be measured. If only one side, e.g. the prosthetic limb, is on the platform then the force on that leg only and the resultant *load line* will be measured. The horizontal distance between selected anatomical reference points and the load line can be determined by means of this apparatus (Blumentritt, 1997; Breakey, 1998).

The sagittal position of the anatomical centre of the ipsilateral knee was determined according to Nietert (1997), and the position transferred to the lateral side of the prosthetic socket and marked.

The electromyogram (EMG) of the biceps femoris and vastus lateralis muscles of the ipsilateral leg, and the biceps femoris, vastus lateralis and gastrocnemius muscles of the contralateral side measured by surface electrodes, were recorded using the MYOSYSTEM 2000 (Noraxon-Neurodata / Vienna, Berlin). The electrodes were located as described by Noraxon's guideline. The mean amplitude of EMG defined by the integrated EMG divided by recording time was used as a measure of myoelectric activity.

Prosthetic alignment was altered by changing the plantar flexion angle of the prosthetic foot at the ankle.

After the foot alignment was altered, the amputee stood with the prosthetic limb on the "L.A.S.A.R. Posture" force plate, with the contralateral leg standing on an adjacent compensatory block whereby both ankle joints were in the same coronal plane. The amputee was asked to load the prosthesis by half of body weight. Once this was accomplished, EMG readings were recorded for 5 seconds. Simultaneously, the sagittal distance from the load line to the ankle adapter, knee centre, greater trochanter and shoulder of the ipsilateral side were measured. The prosthetic alignment was then changed and, after a short break, the parameters were re-measured. The plantar flexion angle was varied randomly. Figure 1 illustrates these measurements.

Patients

Five (5) experienced trans-tibial amputees who had worn a prosthesis for many years and could walk a significant distance were recruited for this investigation. Consequently, amputees with circulatory impairment were not included in the study. All amputees reported their prostheses to be comfortable and that they had

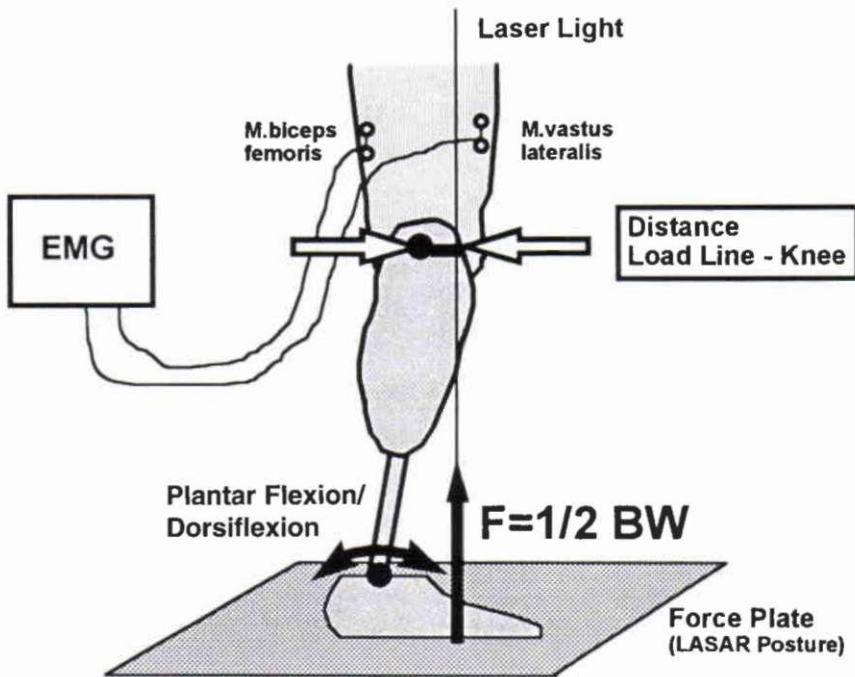


Fig. 1. Measurement principles: The prosthesis is loaded with approximately half of the body weight. By altering the plantar flexion angle of the prosthetic foot, the measured distance between the load line and anatomical knee centre is changed. The EMG of M. vastus lateralis and M. biceps femoris is recorded independently.

no joint pain or range of motion abnormalities.

All subjects wore their customary normal shoes with blocked heels during this study.

Table 1 lists each subject's individual data.

Results

Prosthetic alignment and posture of the amputees

The effect of the flexion angle of the

Table 1. Subject data

Subject	1	2	3	4	5
Age (years)	45	70	42	37	39
Body mass (kg)	83	72	105	61	101
Height (cm)	170	173	183	168	180
Time since amputation (yrs)	26	52	17	34	4
Cause	trauma	trauma	trauma	trauma	disease
Stump length	short	short	medium	long	medium
Side	right	left	right	left	right
Pain in stump	seldom	seldom	no	no	only when stressed
Additional disorders	no	no	no	no	no
Uses cane	no	no	no	no	no
Walking ability (daily)	>5km	>5km	>5km	>5km	300m-1km
Sports activities	no	cycling walking	no	no	no
Prosthesis					
Socket	PTS	PTS	PTS	PTS	PTS
Foot type Otto Bock	1D10	1D25	1D25	1D10	1D10
Size (cm)	26	26	27	24	26

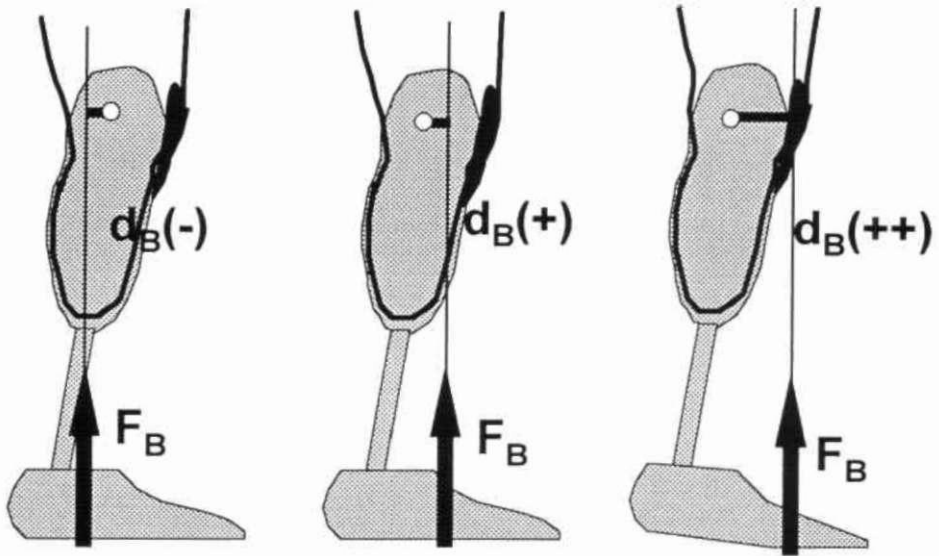


Fig. 2. Effect of plantar flexion of the foot on the mechanical loads applied to the knee joint. The acting lever arm d_B of the ground reaction force F_B changes as the ankle angle is varied (left - dorsiflexed foot, right - plantar flexed foot).

prosthetic foot on the external load on the knee joint was directly visible on all amputees by projecting the laser beam of "L.A.S.A.R. Posture" on the prosthetic side. Increasing the plantar flexion at the ankle tends to move the ground reaction force more anterior to the knee joint. Dorsiflexion of the foot shortens the acting knee lever arm as the ground reaction force falls less anterior to the knee centre. Continued dorsiflexion of the prosthetic foot eventually

results in the ground reaction forces acting posterior to the knee centre (Fig. 2). This effect is typical for all amputees tested and was very reproducible.

The amputees compensate for sagittal plane alignment changes by changing their sagittal posture so that the greater trochanter and the shoulder are balanced over the centre of pressure with constant horizontal distances. This supporting point remains almost constant when

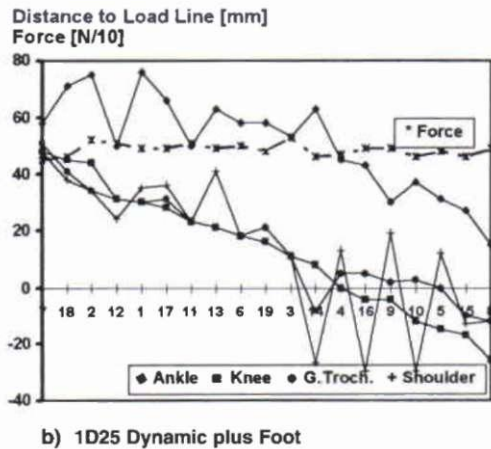
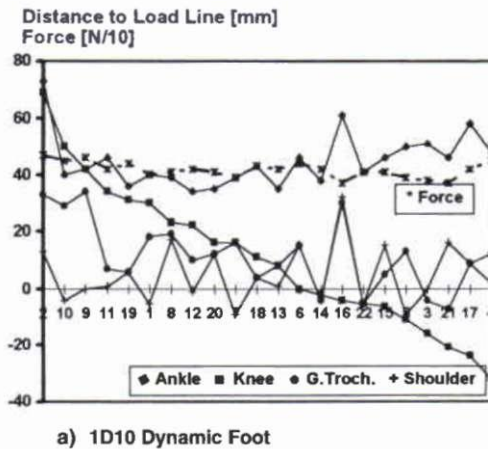


Fig. 3. Load on prosthetic limb (force): distance from ankle adaptor, knee centre, greater trochanter and shoulder to the load line; a) prosthetic foot 1D10 (Pat. 4), b) prosthetic foot 1D25 (Pat. 3). Positive distance means that the selected point is posterior to the load line; negative distance means the anatomical reference is anterior to the load line. The abscissa indicates the test number.

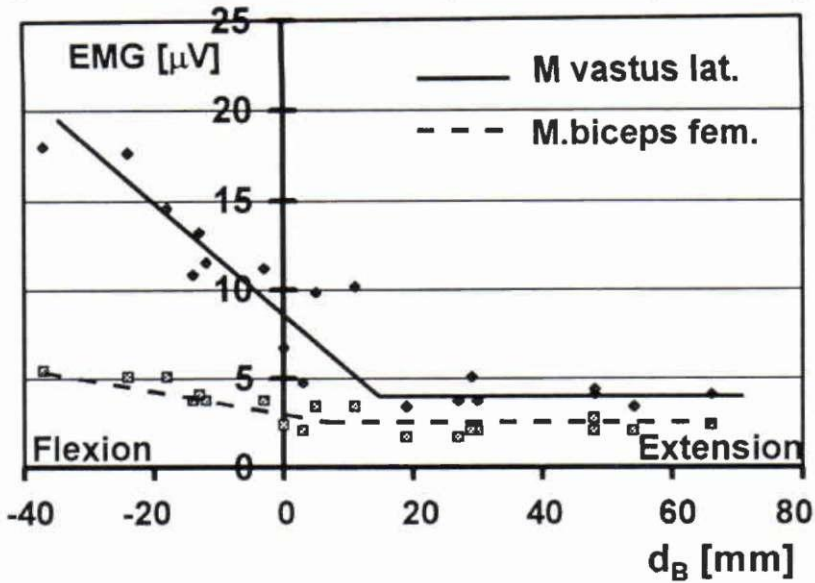


Fig. 4. Mean EMG amplitude of knee muscles on the ipsilateral side (Pat. 5) versus the knee lever arm d_B . The external moment causes knee flexion if the knee lever arm is negative. If the lever arm is positive, the knee joint is subjected to an external extension moment.

flexible keel feet such as the Otto Bock 1D10 dynamic foot are plantarflexed. The centre of pressure varies with the ankle angle for spring keel feet such as the Otto Bock 1D25 dynamic plus design, as shown in Figures 3a and 3b.

Prosthetic alignment and knee muscles' activity

During static standing, the EMG signals of knee muscles and the muscle gastrocnemius of the contralateral leg do not change when the sagittal plane prosthetic alignment is varied. In contrast, the EMG of the muscles of the knee on the amputated side is systematically affected by changes in the ankle angle.

Figure 4 illustrates the typical muscle activity

for vastus lateralis and biceps femoris related to the knee lever arm. Once the external knee extension moment is sufficient to fully stabilise the knee passively, the vastus lateralis muscle no longer fires. When the knee extension moment is less, or when the ground reaction force causes a knee flexion moment, the EMG activity of the vastus lateralis increases corresponding to this external moment.

Normally the biceps femoris muscle is inactive during standing regardless of the plantarflexion attitude of the ankle.

Figure 5 shows an overview of the innervation characteristics of the knee muscles of the ipsilateral limb. The regression curves of the

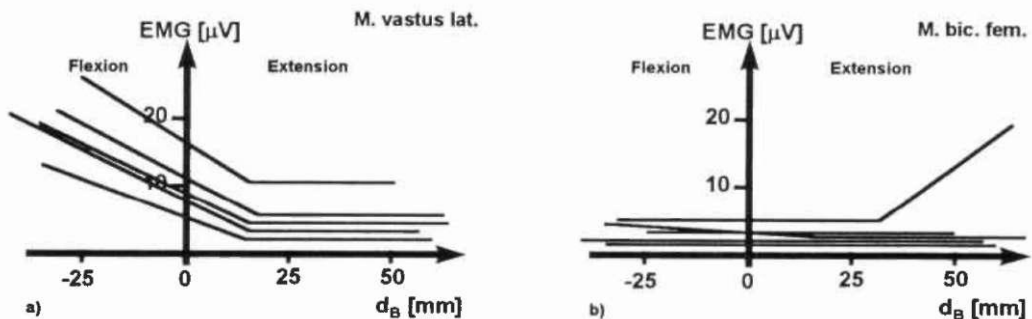


Fig. 5. Linear regression curve of the mean EMG amplitude of knee muscles of the ipsilateral limb versus the knee lever arm (all 5 investigated amputees); a) M. vastus lateralis, b) M. biceps femoris.

mean EMG amplitudes for all 5 amputees verifies that the vastus lateralis muscle is no longer activated whenever the load line is located more than approximately 15mm anterior to the knee centre. If this distance is smaller than 15mm or if the ground reaction force acts posterior to the joint centre, the EMG amplitudes of vastus lateralis increases in direct proportion to the external moment. This correlation is significant and uniform for all amputees.

The biceps femoris muscle was inactive during standing for 4 of the 5 tested amputees. In one case, extreme alignments which created a knee lever arm of more than 30mm triggered the biceps femoris.

Discussion

The importance of prosthetic alignment to the success of prosthetic fitting is well known. Current prosthetic alignment methods require many years of experience from the prosthetist and clear feedback and assessment of the functionality of the prosthesis by the amputee. Thus the procedure of prosthetic alignment is very time-consuming and subjective. Objective, reproducible and faster techniques are desirable.

Visual information about the forces and moments causing the biomechanical function of the prosthesis are one way to make prosthetic alignment more objective. Regularities in prosthetic alignment were seen in prostheses worn successfully over an extended period of time (Blumentritt, 1997). Breakey (1998) has described his extensive experience with 115 trans-tibial amputees and 42 trans-femoral amputees, reporting that when his fittings proved satisfactory over time, the discrepancy between the load line and the body weight line was less than 10mm.

This investigation suggests that the justification for prosthetic alignment can be found by defining a biomechanically sound and energy efficient static posture control.

In this study, the relationship between the electromyographic signal and muscle force produced is directly proportional, because the EMG was measured under isometric conditions. Therefore the EMG value can be replaced by the generated muscle force. The muscle and ligament forces around the knee joint are dependent on the knee lever arm and can be estimated as Figure 6 illustrates.

When the ground reaction force is acting more

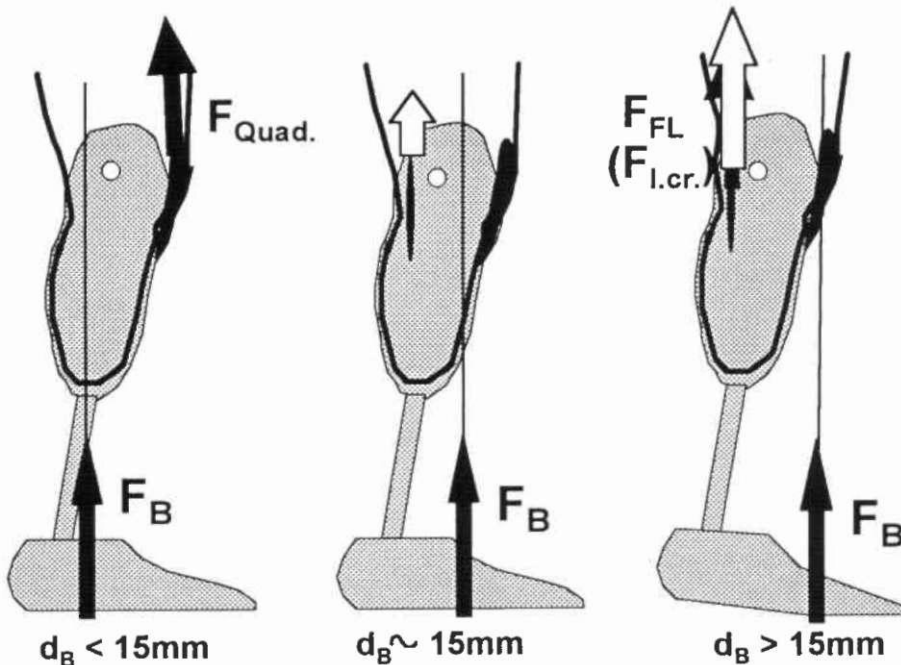


Fig. 6. Diagram illustrating sagittal plane muscle and ligament forces on the knee joint of trans-tibial amputee caused by the external knee load induced by plantar flexion of the foot (left - dorsiflexed foot, right - plantar flexed foot).

than 15mm anterior to the knee centre, knee stabilisation is provided by the ligaments. Prostheses aligned in an equinus position increase the stress on the ligaments and posterior capsule. The knee is hyperextended by such an exceptional external extending moment. This alignment error is presumably avoided in clinical practice by realignment of the prosthesis when the amputee complains. The theoretical muscular protection of the knee joint against high extension load by the muscles which flex the knee seems to be uncommon.

When the ground reaction force acts less than 15mm anterior to the knee centre, the stability of the knee joint will be controlled by using muscular activity of the quadriceps muscle group. The knee joint is extended and the more the load line falls posteriorly to the knee centre the more the knee joint will tend to be flexed. The posterior knee ligament force becomes zero. Such muscular force increases metabolic energy consumption. Stressing the passive structures of the knee joint may result in long term damage, such as that which occurs when the ankle has been fused in equinus to enable the poliomyelitis survivor the chance to walk without bracing on their paralysed leg. Thus, the optimal situation seems to be when the knee centre is located approximately 15mm behind the load line: A minimum of metabolic energy is required while

very little extension stress is applied to the ligaments and posterior capsule of the knee.

Individual differences between patients were minimal in the present investigation (Fig. 5). Previously reported individual differences during definitive fittings (Blumentritt, 1997) may have been accidental due to the subjective nature of present alignment techniques. Biomechanically optimal standing alignment can now be defined (Fig. 7).

Use of these guidelines in clinical practice has produced very good fitting results. The amputees clearly describe a noticeable increase in comfort when the prosthesis is aligned as noted above, particularly after using the prosthesis for an extended period of time. This also permits optimal alignment of the prosthesis during only one fitting session.

Of course, the linear position of the foot in the sagittal plane must also be determined. This can be done using conventional visual gait analysis. Sagittal linear alignment is optimal when the amputee slightly flexes the knee on the ipsilateral side during weight acceptance.

It should be noted that these guidelines do not apply to residual limbs with grossly abnormal structures such as occurs when genu recurvatum is present. However, the "L.A.S.A.R. Posture" system may also be useful in such difficult cases by allowing the clinician clearly to visualise the

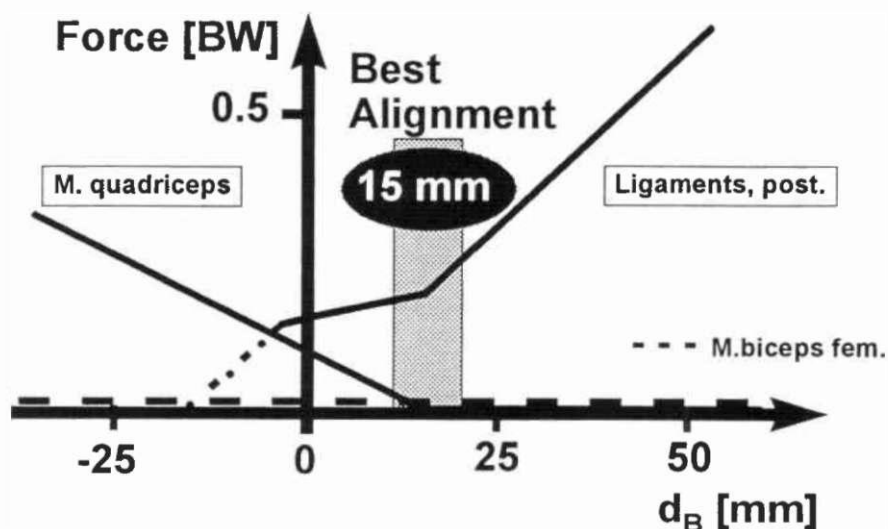


Fig. 7. Force of muscles and ligaments depending on knee lever arm (d_B) of ground reaction force: The external moment causes flexion if the lever arm is negative. If the lever arm is positive, the knee joint is loaded with an external extension moment.

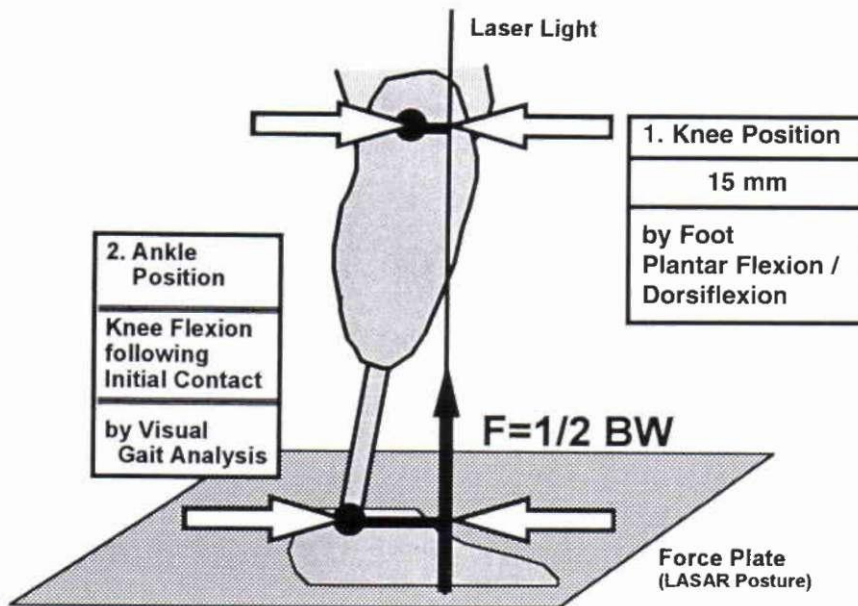


Fig. 8. Static alignment recommendations for trans-tibial prostheses.

vertical ground reaction force during standing.

Conclusions

The present investigation supports the concept that a biomechanically optimal static prosthetic alignment for trans-tibial amputees can be defined. The following principles are proposed (Fig. 8):

1. standing alignment for the trans-tibial amputee is optimal when the ipsilateral anatomical knee centre is 15mm posterior to the individual load line;
2. displacement of individual load line far anterior to the knee centre creates significant mechanical stress on the ligaments and posterior capsule of the knee;
3. when the extension moment on the anatomical knee is insufficient, or when a flexion moment is created, the quadriceps muscles fire to stabilise the joint. This consumes metabolic energy and is undesirable;
4. the static standing posture of the amputee and the activity of the contralateral leg muscles are minimally influenced by variations in the flexion angle of the prosthetic ankle.

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A survey of function in children with lower limb deficiencies

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Abstract

Function and prosthesis technical problems were surveyed in 258 experienced paediatric lower-limb prosthesis wearers. The two-part survey form consisted of the modified Prosthesis Evaluation Scale and the core module of the American Academy of Orthopaedic Surgeons/Council of Musculoskeletal Specialty Societies (AAOS/COMSS) Lower Limb Outcomes instrument. Eighty-eight percent (88%) of these paediatric subjects were able to wear their prosthesis more than 9 hours/day; only 3 subjects (1%) were not able to wear their limb at all. The average distance walked per day was reported to be 5.24 kilometres. Sixteen percent (16%) reported pain as "moderate" or worse. A majority reported not having a problem with perspiration, however, 20% had problems serious enough to limit prosthesis wearing time significantly. The most common reasons for temporary loss of limb use were pain (62 responses) and prosthesis failure (59 responses), followed by tissue breakdown (42 responses) and perspiration (30 responses). In general, the paediatric population achieves full use at a high rate, is much more active than the adult population, and experiences less limb pain

Introduction

It is widely recognised but poorly documented that children with lower limb deficiencies have distinctly different clinical outcomes with respect to surgical and prosthetic management

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than adults with comparable limb deficiencies. Demographic studies have established the preponderance of congenital amputations (approximately 2 to 1, congenital vs. acquired) and male dominance of acquired amputations (2 to 1, male to female) in the paediatric limb deficient population (Kegel *et al.*, 1978; Setoguchi and Rosenfelder, 1982; Krebs and Fishman, 1984; Ashley *et al.*, 1992). Only a few studies have considered functional or satisfaction outcomes in this group (Kegel *et al.*, 1980; Ashley *et al.*, 1992; Pruitt *et al.*, 1997). These studies, which for this comparison are limited by size or by mixing of upper and lower limb deficiencies, suggest that children are generally more active and satisfied with their circumstance than their adult counterparts.

The purpose of the current study was to evaluate the performance of prostheses, and functional status, of a large sample of children with lower limb deficiencies, who have been fitted with a prosthesis and are followed in the outpatient Limb Deficiency Clinics at the authors' institutions.

Methods

The study design was observational and cross-sectional, consisting of a two-part written survey. The first part of the survey was based on the Prosthesis Evaluation Scale (PES), originally developed for adult analyses (Fishman, 1966) and modified by the authors for paediatric use. This questionnaire considered functional issues such as time of use per day, distance walked per day, recreational/sports activities performed, days of school missed per year due to prosthetic problems, and problems related to pain, perspiration, skin breakdown, and prosthesis

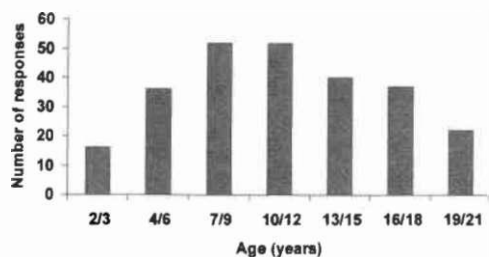


Fig. 1. Age groupings in the study.

failure. Satisfaction issues included most important goals for prosthetic use, best and worst features of the device, and what could be done to improve use of the device. The second part of the survey consisted of the core module of the AAOS/COMSS Lower Limb Outcomes Data Collection Package, Version 1.1. This validated instrument describes overall lower-limb functional status (publication pending). The responses reflected the viewpoint of the subject, although in some cases a parent or staff person made the actual notations.

Results

There were 258 subjects, 43% female and 57% male. The age groupings are shown in

Figure 1. Seventy-two percent (72%) of the subjects had limb deficiencies with a congenital etiology, 28% acquired (trauma, tumour, infection). These characteristics are closely similar to those previously observed for the paediatric population in USA (Krebs and Fishman, 1984). There were 5 cases of hip disarticulation, 95 above the knee level (30 trans-femoral, 37 proximal femoral focal deficiencies treated with ankle disarticulation and knee fusion, and 28 knee disarticulations), 194 below the knee level (80 trans-tibial amputations, 113 ankle disarticulations), and 5 partial foot deficiencies. Forty (40) subjects had bilateral deficiencies, so that there were 298 limbs total.

In much of the following data presentation, three larger subject categories are used; bilateral, above-knee and below-knee. All subjects with bilateral deficiencies are placed in the bilateral category. Subjects with a unilateral deficiency, and a prosthetic knee joint are placed in the above-knee category (hip disarticulation, trans-femoral amputation, proximal femoral focal deficiencies and knee disarticulation). Subjects with a unilateral deficiency, and a biologic joint are placed in the below-knee category (trans-

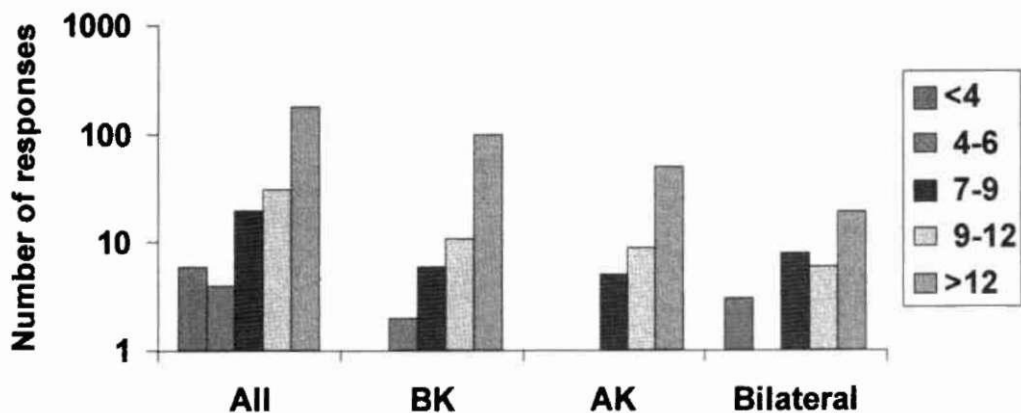


Fig. 2. Hours the prosthesis was worn per day. **All**: all respondents; **BK**: unilateral, with biologic knee; **AK**: unilateral, with prosthetic knee; **Bilateral**: all respondents with bilateral deficiency.

Table 1. Hours prosthesis worn per day (% of subjects).

Survey	none	<4	4-6	7-9	9-12	>12	average age (yrs)
Paediatric	1	2	2	8	13	75	11
Fishman (1966)	—	1	2	8	>24	>65	44
Sapp and Little (1995)	16	>7	—	—	22	44	65
Pohjolainen <i>et al.</i> (1990)	11	>5	16	—	—	60	62

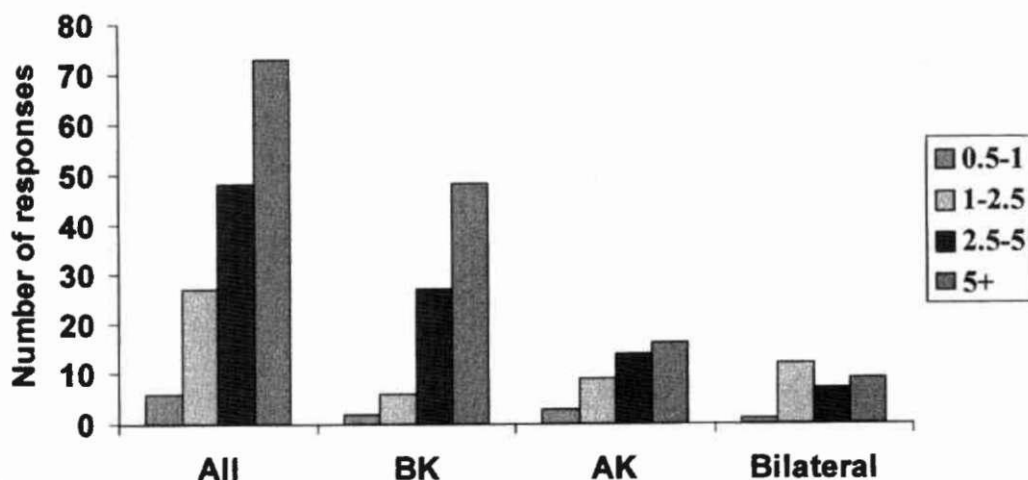


Fig. 3. Kilometres walked with the prosthesis per day. **All**: all respondents; **BK**: unilateral, with biologic knee; **AK**: unilateral, with prosthetic knee; **Bilateral**: all respondents with bilateral deficiency.

tibial amputation, ankle disarticulation and partial foot).

Eighty-eight percent (88%) of the subjects reported being able to wear their limbs 9 hours or more per day; only 3 subjects (1%) were not able to wear their limb at all (Fig. 2 and Table 1). The average distance walked per day, self-reported was 5.2 kilometres (Fig. 3). Twelve (12) subjects (5%) reported being able to walk less than one-half mile per day. Eighty-two percent (82%) missed five or less days of school per year due to their limb (Fig. 4).

On the PES, pain was reported as moderate or

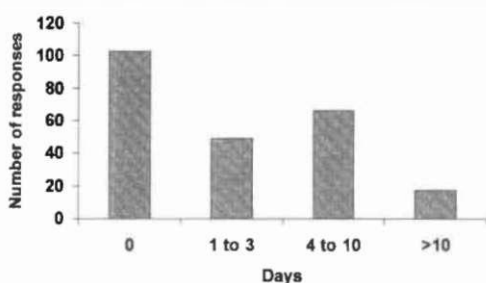


Fig. 4. Days absent from school per year, due to problems with the stump or prosthesis.

worse by 16% of children (Table 2). Similar questions on the AAOS instrument were answered in a comparable manner, with 15% reporting pain as moderate or worse. Pain was most frequently reported during strenuous activities or walking on uneven ground; and was less frequent during quiet activities. Pain while lying in bed was infrequent, with 92% reporting "no pain at all" and only 9 subjects (4%) reporting bedtime pain as moderate or worse.

A majority reported not having a problem with perspiration, however, 20% had problems serious enough to limit significantly prosthesis wearing time (Fig. 5). Perspiration data appeared to be bimodal – either the subjects had no problem with perspiration, or they had serious problems.

The most common reasons for temporary loss of limb use were pain (62 incidences reported) and prosthesis failure (59 incidences), followed by tissue breakdown (42 incidences) and perspiration (30 incidences). Feet, knees and cosmetic foam covers were the components most frequently failing. Function was the first priority with the prosthesis in the children's

Table 2. Description of level of pain (% of subjects).

Survey	none	none or mild	mild	moderate	moderate or severe	severe
Paediatric	44	84	41	10	16	6
Hoaglund <i>et al.</i> (1983)	—	46	—	36	54	18
Nielsen (1991)	—	43	—	—	57	—

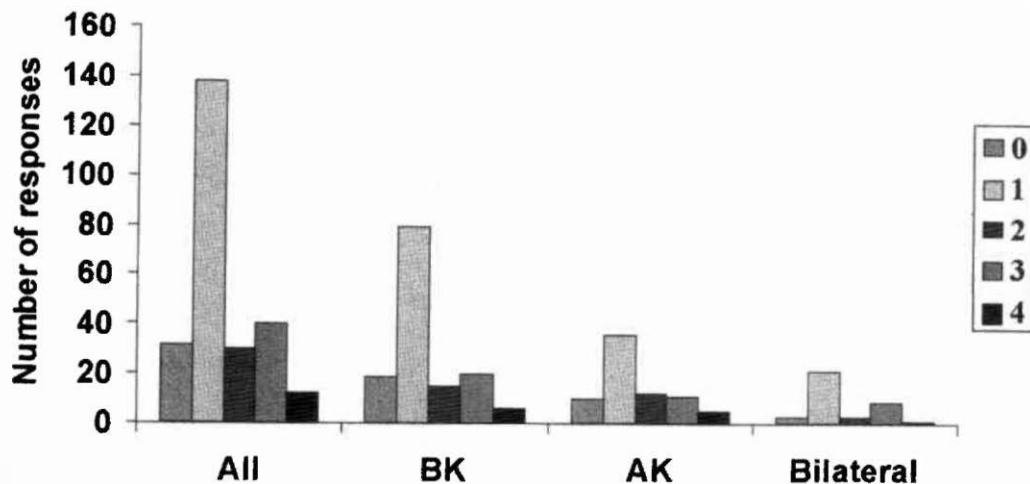


Fig. 5. Severity of perspiration-related problems. **All**: all respondents; **BK**: unilateral, with biologic knee; **AK**: unilateral with prosthetic knee; **Bilateral**: all respondents with bilateral deficiency. **0**: perspiration is "not noticeable"; **1**: "noticeable but not a problem"; **2**: "so much that it is uncomfortable"; **3**: "so much that I must occasionally remove the prosthesis"; **4**: "so much that I develop skin irritation and cannot wear the prosthesis for a significant amount of time".

minds, particularly the ability to walk (34% of subjects), play sports (20%), and go to school or work (10%). Comfort was first priority with 28%, while cosmesis was cited as the first priority only 8% of the time. This was apparently not merely a case of competing priorities, as many of the subjects reported being "very happy" (43%) or "somewhat happy" (31%) with the appearance of their prosthesis.

The most common activities, in order of declining frequency were swimming (154 responses), indoor chores (153), running (150), outdoor chores (142), bicycling (135), and basketball (108).

The scores from the AAOS instrument are given in Table 3. The slight differences in the mean scores are not statistically significant.

Table 3. AAOS/COMSS Outcomes Instrument Scores: Lower Limb Module.

Deficiency category	Score: average +/- standard deviation
hip	96.0 +/- 8.0
above-knee	91.2 +/- 9.6
PFFD	96.6 +/- 5.7
knee	93.1 +/- 12.5
below-knee	92.6 +/- 10.3
ankle	96.5 +/- 5.4
partial foot	100.0 +/- 0.0
bilateral	94.7 +/- 10.8

Comparison of these scores versus instrument norms in a future study will allow assessment of the overall lower limb functional status of the paediatric population.

The authors also examined a sub-set of the data from only those subjects who were not fully rehabilitated. Were the problems this group was having different from those of the general study population? The subjects were separated into three groups; those who reported wearing limbs 12+ hours, those between 12 and 9 hours, and those less than 9 hours. The responses for these groups were unremarkable, compared to that for all subjects, except for the obvious conclusion that perspiration problems diminished when the limb was worn less. The major problems of this sub-set were pain and skin breakdown.

Discussion

In these subjects, fitting a lower-limb prosthesis was usually a very successful treatment, resulting in high levels of rehabilitation. The reported level of use was very high. Nine (9) out of 10 subjects wore the limbs 9+ hours/day, with 3 of 4 having virtually unlimited use >12 hours/day (Table 1). These results can be compared to adult surveys, where only 60-65% reported 9+ hours/day (Fishman, 1966; Hagberg *et al.*, 1992; Hoaglund *et al.*, 1983; Moore *et al.*, 1989; Nielsen, 1991; Pohjolainen *et al.*, 1990; Sapp and Little, 1995). Only 1% of paediatric subjects was not able to

wear their limb at all, as compared to 10-15% in adult surveys. These results hold across amputation levels as opposed to adult amputees where non-use levels in trans-femoral amputees are at 40-45%. It should be noted however, that the paediatric data are very similar to those reported for a younger traumatic adult population (Fishman, 1966).

Children are also very active, walking an average of 5.2km/day (self-reported). The data include 9 bilateral amputees walking more than 5km/day. The reported distance walked, 5.2km/day, is five times that reported for adults, 0.7 to 1.3km/day (Hoagland *et al.*, 1983; Pohjolainen *et al.*, 1990). Even allowing for error and exaggeration in these self-reported data, the level of mobility implied is remarkable relative to adult experience. These results are consistent with the Ashley paediatric survey (1992), in which 95% of the children were "community ambulators"; and the paediatric study by Pruitt *et al.* (1997), where only 14% of upper and lower limb deficient subjects reported not using their prosthesis at all. Further, children report pain at a much lower rate than adults; 16% "moderate" or worse, versus 54-57% for adults (Table 2). Finally, perspiration related discomfort is also much lower in children than adults, 20% versus 70%.

Ankle-level end-bearing limbs are more common in children than in adults. Half of the limbs in this survey were ankle level; 113 (38%) ankle disarticulations with otherwise full limbs, and 37 (12%) disarticulations secondary to PFFD. The incidence in adults has been reported at 2% (Hoaglund *et al.*, 1983).

What technical improvements do children need in their prosthetic limbs? The most common reasons for temporary loss of limb use were pain and component failure, followed by tissue breakdown due to perspiration, pressure, and chafing. Pain and pressure-related tissue breakdown are functions at least partially of socket fit. Hence, improving fit may be the most relevant issue. Broken prostheses were common; with feet, knee components, and cosmetic foam covers most often reported. Perspiration-related problems do not occur in the majority of the paediatric population, but there is a significant minority (20%) in whom there are real problems. This appears to be a bimodal population with few subjects in the middle – either there is no problem, or the problem is serious.

A shortcoming of this study is that it did not separate out poor socket fits due to limb growth from poor socket fits due to other causes. Optimal socket fit in a growing child may require prosthetic adjustment or replacement as frequently as every 12-18 months, a rate that is currently not supported by third party payers in USA.

Conclusions

Children who wear lower limb prostheses achieve full use status at a higher rate than the adult population, and are much more active. Markedly fewer children than adults experience significant pain (16% versus 54-57%). Nonetheless, the most common reason for temporary loss of use of the prosthesis is pain, along with broken components. Tissue breakdown, due to pressure, chafing and perspiration was the next most common problem. The most relevant issues for research may be improving socket fit, making components with the durability necessary for paediatric use, and providing socket ventilation.

Acknowledgements

The authors wish to thank the American Academy of Orthopaedic Surgeons, and the Council of Musculoskeletal Specialty Societies, for providing the Outcomes Data Collection Instrument.

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Preliminary experiences with modified SACH feet manufactured and used in a tropical developing world setting

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Abstract

In a prospective study of polypropylene (PP) prostheses for trans-tibial amputees four different modified SACH feet were used. These are identified as:

1. BAVI from the national manufacturer of componentry in BaVi;
2. HCMC a design initiated by the International Committee of the Red Cross (ICRC) together with the Army Factory in Ho Chi Minh City;
3. HI from Handicap International;
4. VI from Veterans International, Cambodia.

Four (4) from 5 BAVI feet, 7 from 9 HCMC feet and 4 from 10 HI feet failed after about a year on average, whereas none of 10 VI feet had failed after 19 months.

Dimensional differences in the ankle part and in the height of the foot in the different designs made interchangeability impossible.

Introduction

The prosthetic foot is a known problem in the tropical part of the developing world (Day, 1995), but no results on differences between feet from clinical follow-up investigations have been published. There are different designs and fabrication methods for feet, ranging from the Jaipur rubber foot, that has a good credibility in India, to a number of SACH foot modifications manufactured locally, in the best situation at a national level (Kijkusol, 1986). The SACH foot is the most popular model in the developing world, because it is easy to make from local materials (Meanley, 1995).

In Vietnam two SACH foot modifications

have principally been in use. One is supplied by the national manufacturer of componentry in BaVi. Further to that ICRC initiated in 1989 a development of a vulcanised foot (HCMC) together with the Army Factory in Ho Chi Minh City. When the Ministry of Labour, Invalids and Social Affairs (MOLISA) in 1996 requested ISPO to undertake an evaluation of the application of polypropylene (PP) prosthetic technology for trans-tibial amputees, ISPO decided together with the German technical collaboration project, VIETCOT, the Vietnamese Education and Training Centre for Orthopaedic Technologists, that this was a good possibility of field testing these two foot modifications together with the HI foot from Handicap International which is nearly universally applied in Cambodia and the VI foot from Veterans International Cambodia, which also is somewhat used in the neighbouring country.

Patients and methods

In two communities of the Vinh Phu province west of Hanoi 32 patients with 34 trans-tibial amputations were provided with PP prostheses at the BaVi orthopaedic workshop during the period March through July 1997. The patients were nearly all veteran amputees from 1951-94 with an average age of 45 (26-73) years at follow-up. The patients were followed prospectively after 10 and 19 months, and the general results of the survey will be reported in a separate paper.

The 4 different types of feet were supplied by random selection with bilateral amputees receiving the same type of foot for each limb.

The BAVI foot has a large wooden keel, rubber forefoot and a rubber foam heel cushion.

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The components are glued together, and the sole covered with an outer textile layer.

The HCMC foot has a PP keel, rubber foam at forefoot and heel cushion, and reinforced tyre rubber for the sole. The components are vulcanised together.

The HI foot has a longer PP keel, rubber forefoot and heel cushion; and reinforced tyre rubber for the sole. The components are vulcanised together.

The VI foot is in principle identical to the HI foot, but the heel extends further towards the forefoot. This foot is also vulcanised.

At follow-up technical failures were recorded together with the reported level of daily use.

In 22 cases the patients already had an Automated Fabrication of Mobility Aids (AFMA) prosthesis provided in 1996 by the Prosthetics Outreach Foundation (POF). Partial information on the performance of the feet was available. Of these, 6 patients had a failed foot replaced at the first follow-up with a prototype, the V-M foot, developed by POF together with the BaVi factory.

Results

The overall results are displayed in Table 1,

showing that 4 out of 5 BAVI feet, 7 out of 9 HCMC feet, 4 out of 10 HI feet had broken down, whereas none of the VI feet were worn out. The VI foot performed significantly better than the other fabrications ($p < 0.02$, Student's *t*-test).

The feet failed at an average of 11 (2-19) months. The feet had been subject to intensive use in 12/15 of the failures with 14 (10-16) hours of daily use; and a walking distance of more than 2km in 11 cases. The time-related breakdown of the of the feet is shown (Fig. 1) in a Kaplan-Meier plot.

In 8 of 15 failures slipping of the keel with disruption between keel and rubber was the cause of failure. In 1 HI foot the bolt attachment had failed. In 6 of 15 cases the sole was badly worn or had cracked.

With the HCMC and HI feet only 4 out of 8 non-failures were subjected to intensive use; from the remainders only one being used at all.

The stress pattern for the VI foot did not differ from the others; 8/10 being subjected to intensive use with 14 (10-18) hours of daily use and walking distances of more than 2km for half of the patients.

With regard to the AFMA prosthesis 6 out of

Table 1 Results of prospective clinical testing of prosthetic feet for trans-tibial amputees.

	BAVI foot (n = 5)		HCMC foot (n = 9)		HI foot (n = 10)		VI foot (n = 10)
	Failure (n = 4)	OK (n = 1)	Failure (n = 7)	OK (n = 2)	Failure (n = 4)	OK (n = 6)	OK (n = 10)
Significance (p<value)	0.00005		0.00003		0.02		
Time to failure (months)	13 (2-19)		9 (4-19)		12 (8-18)		
Intensive use	3		5	1	4	3	8
Light/moderate use	1	1	2	1		3	2
Body mass, kg	51 (48-55)	52	50 (43-55)	57 (53-60)	50 (45-55)	47 (40-52)	52 (45-60)
Hours/day in use	14 (10-16)	18	14 (12-15)	16 (15-16)	15 (15-16)	17 (15-18)	14 (10-18)
<i>Walking distance</i>							
<500m			1			3	3
0.5-2km	1	1	2	1		2	2
>2km	3		4	1	4	1	5
Foot dorsiflexed	1		2			1	2
Failed bolt					1		
Failed keel	3		4		1		
Failed sole	1		3		2		
Follow-up (19 months)	4	1	5	2	3	4	9
Follow-up (10 months)			2		1	2	1
Wet rural area			1		1	2	4
Dry rural area	4	1	6	2	3	4	6

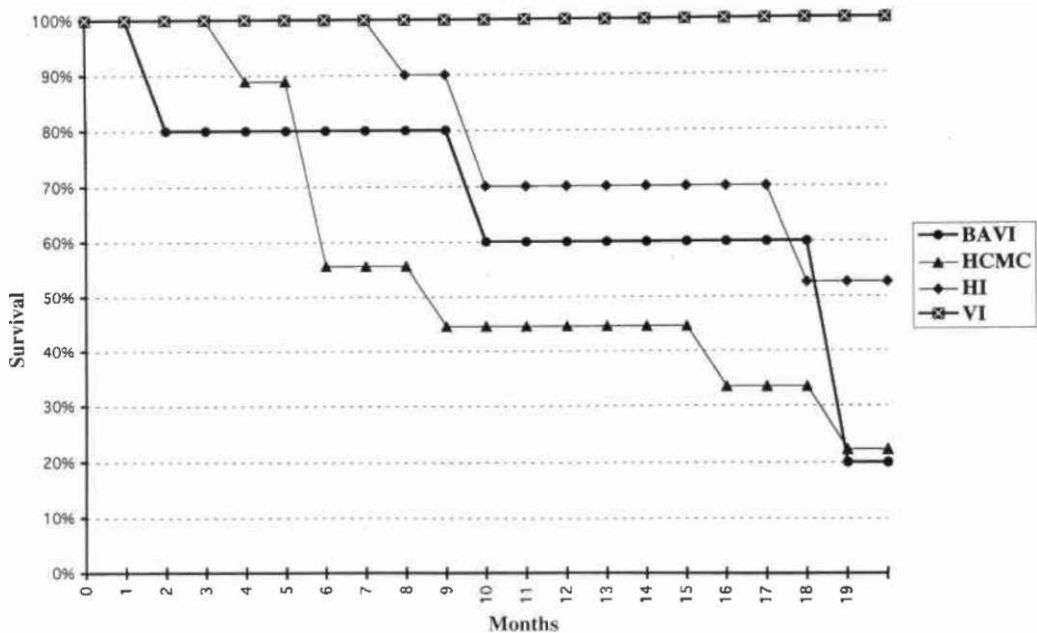


Fig. 1. Prosthetic foot failures.

19 patients reported failure of the foot within a few months; loosening from the attachment to the shank in 4 cases, and broken down in 2 cases. Three (3) prostheses had not been used because the sockets were too narrow. Only 1 prosthesis was in regular use and 2 more in light use at the time of the follow-up.

With the V-M foot only 1 patient was satisfied; whereas 2 of the 3, who disliked the new foot, had gone back to a BAVI and a HI foot, respectively. One (1) foot had broken down, and the last patient did not show up for follow-up, because he was away ill in another part of the country.

Discussion

This small study quantified the durability of modified SACH feet produced and used in a tropical area, although only a few were subjected to wet paddy field working. It showed that the vulcanised rubber foot from Veterans International in Cambodia did significantly better than any of the others in the test series, and that these feet lasted under intensive use for at least 19 months. It also showed that the durability of the different feet was longer than anticipated at the Consensus Conference on Appropriate Prosthetic Technology (Day, 1996). The life time of the foot can be the determinant

for the life time for use of that particular prosthesis, if there is not an effective service and repair system accessible.

One of the many problems in the developing world is that sustainability of local manufacture must be secured because of financial constraints limiting the import of finished goods like feet (Kijkusol, 1986). Such limitations might also apply to import of certain raw materials.

Materials and equipment can be prohibitively expensive so that their use can lead to aid dependence rather than independence (Meanley, 1995). It has been pointed out, however, that the price of some thermoplastics is not higher than natural rubber and some can be reused (Öberg, 1995), as is the case with the keel being made of recycled PP scrap in 3 of the feet included in this study. In Cambodia it has apparently been possible to convince the non-governmental organisations to use the HI foot together with PP components from ICRC (Day, 1996; Simon 1996). This was an important reason for including the HI foot in this study. The ICRC programme in Ho Chi Minh City has been self-supportive by applying the HCMC foot together with the PP technology. The BAVI foot has for many years been produced at the national component manufacturing centre.

It appears that at least 3 types of feet did not

live up to the anticipated life time of a trans-tibial prosthesis, which is supposed by MOLISA to be three years, as this is the time interval of providing renewal of limbs to Vietnamese war amputees. This problem was not realised, probably because of the lack of repair service and outreach follow-up systems. From the information collected a similar problem seems to relate to the outreach provision of POF, which also does not include any follow-up service. This problem has been previously identified (Kijkusol, 1986). It is an obvious suggestion to the country that the prosthetic provision systems should make service follow-up and repairs available.

There is currently ongoing development of new feet in different areas of the developing world. In Vietnam the HCMC foot is against the background of results of the first assessment visit in this study undergoing a radical change in design and manufacturing. The BaVi manufacturing plant is in collaboration with POF developing a new rubber foot of sandwich construction with layers of woven textile reinforcement of the midfoot. The final model is several generations younger than the V-M foot tested in the latter part of this study, is now mass produced and that latest version has been provided to a significant number of patients with AFMA prostheses.

The results of the presented study clearly show the need for independent comparative surveys of new foot devices before such are released for general use in higher numbers without any effective control and repair service. It may also be appropriate to centralise component production at a few places in a country with the application of quality control to ensure uniformity of the end product. The production of terminal devices should not be left to smaller local workshops that can not live up to such demands.

Another significant problem identified in the study was the lack of interchangeability of the different types of feet. There are considerable differences in the height of the foot device, both with and without heel height. Furthermore there

are both dimensional and geometrical differences of the ankle profile. This makes it impossible to achieve an acceptable cosmetic result when changing to a foot design different from that initially used, as we experienced with the few patients in the current series. It is recommended that these crucial dimensions should be harmonised at least among the manufacturers in a given geographical region, and absolutely within the same country. It is certainly essential if changing a worn foot should become part of the service that can be provided in a community-based rehabilitation (CBR) programme sometime in the future.

Cummings (1996) had scrutinised 33 years of technical publications before the 1995 consensus conference and reported that there were few outcome studies, and very few documented component production techniques for developing countries; that there appeared to be a significant need for durable prosthetic feet than can be manufactured in-country; and that many facilities fabrication their own components should collaborate to aid the quest for the ideal, low cost, durable, locally manufactured system. These statements still stand.

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Evaluation of use and durability of polypropylene trans-tibial prostheses

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Abstract

Forty-three (43) trans-tibial prostheses with a mean period of use of 33 months were evaluated in terms of utilisation and durability. The majority of the prostheses (80%) were worn by amputees with demanding occupations, such as farmers, fishermen and tradesmen. The prostheses were in use approximately 9 hours per day. No major or frequent breakdowns of the polypropylene prosthetic components were found. The suspension belts were the parts most frequently affected; a total of 32 needed replacement after an average 11 months of use. Eleven (11) prostheses were completely replaced, more than half at least partly because of socket-fitting problems. In all, socket-fitting problems were found in 15 prostheses, causing pain and consequently limitation of use. While the prosthetic polypropylene components were satisfactory, the rubber foot was a major cause of early breakdown. A total of 40 feet were replaced; their mean period of use before breakdown was 9 months. In practice, parts were frequently replaced at a later stage than desirable, meaning that there was frequent "overuse" of prostheses with worn parts. Measures were taken to increase the life span of the prosthesis: change in the design of the foot; issuing a spare foot with the prosthesis; strengthening the suspension belt. Additional evaluations are necessary to confirm the degree to which the findings are representative.

Introduction

The role of the International Committee of the

Red Cross (ICRC) is to assist and protect war victims. The organisation's physical rehabilitation programmes are undertaken to provide patients with assistance while at the same time setting up or strengthening structures capable of meeting the demand for repair and replacement of the orthopaedic appliances in the future. In order to achieve these two objectives, the ICRC focuses on (1) cooperation with the existing health-care system; (2) training of national staff; and (3) introduction of appropriate technology.

Since 1979, the ICRC has supported or established 49 rehabilitation centres in 25 conflict-ridden countries worldwide. Over 130,000 prostheses and over 40,000 orthoses have been produced for more than 110,000 individuals. Of the prosthetic appliances produced, the proportion of polypropylene limbs, introduced in the early nineties, is about 50%. Polypropylene has proved to be a very suitable material for projects in the countries where the ICRC operates. It is cheap, recyclable, light, and easy to transport and store. It is generally well accepted by patients and staff, especially when it has been in use for some time, even in countries with a tradition of using other imported components and materials.

The use of a prosthesis is limited in time because of the development of fitting problems or because worn parts need to be repaired/replaced. In some countries, such as Switzerland, amputees are entitled to a new prosthesis every 2-3 years. In countries in (post-) conflict situations this is often not possible for a variety of reasons: financial constraints, ignorance, problems of accessibility, priority given to fitting new patients. At the same time,

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the conditions under which the prostheses are used are often taxing, since a large proportion of the amputees are manual workers or engaged in wet or dry farming. What are the consequences for the patient? Does this mean that the prosthesis is no longer used after a relatively short period? The purpose of this paper is to answer those questions with reference to a specific region of Viet Nam covered by the Ho Chi Minh City (HCMC) Rehabilitation Centre. The centre serves an area of 53,970 sq km with an estimated population of 12,808,194. The ICRC began providing the centre with material and technical assistance, including full-time expatriate staff, in 1989. More than 13,500 amputees have been fitted with prostheses since that date. After 1995, the assistance was scaled down to short technical follow-up visits carried out 2-4 times/year by an expatriate prosthetist.

In November 1997, a retrospective study on the use and life span of prostheses among a small number of amputees was undertaken, and the main reasons for prosthetic breakdown were identified. For reasons of clarity, a distinction is made between the findings relating to the polypropylene prosthesis and those relating to

the rubber foot.

Materials and methods

The hand-casting method was practised for plaster moulding and rectification, using self-made plaster bandages (gauze and plaster of Paris powder). No brim was used and rectifications were performed according to anatomical shape. No end-bearing was provided at the distal part of the stump. For trans-tibial prostheses, a patellar-tendon-bearing (PTB) socket with a T-strap was used. The socket was made by heating a 4mm polypropylene sheet at 170° Celsius for 20 minutes and draping it on the plaster cast, covered with a stocking to facilitate suction. No soft socket was made for the trans-tibial prosthesis. A polypropylene pipe (45mm diameter x 35mm thick) with one end concave, receiving a convex disc, was attached to the end of the socket with a washer and M10 bolt. An ankle connector was attached to a rubber foot with a washer and M10 bolt. The length was adjusted by cutting the polypropylene pipe, which was later fixed with a polypropylene rod to the ankle connector. The polypropylene trans-tibial prosthesis can be seen in Figure 1. After

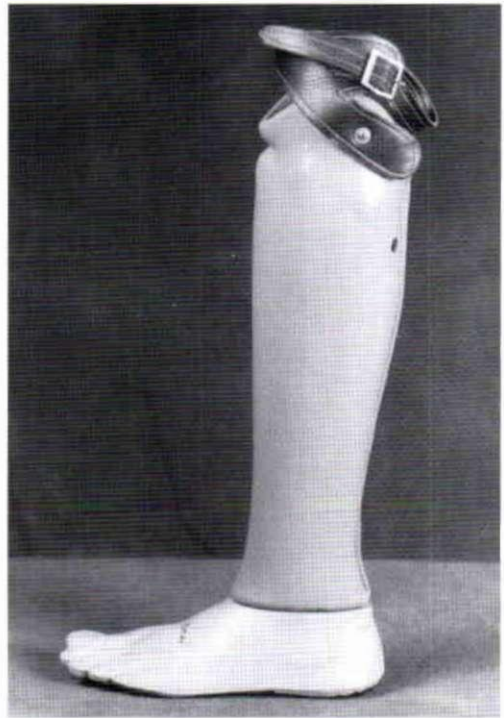
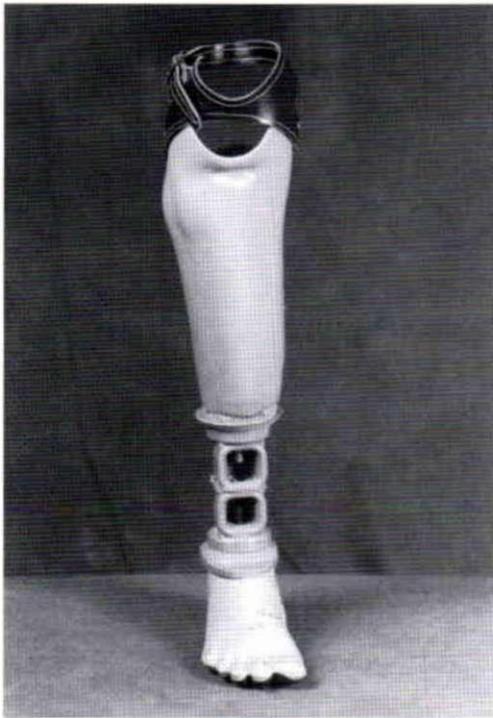


Fig. 1. The polypropylene trans-tibial prosthesis.

successful trial on the patient, the prosthesis was finished by welding all connecting component parts except for the rubber foot with a heating gun and polypropylene rod (3mm or 5mm diameter). Plaster of Paris powder was applied for cosmetic shaping. Later, another 3mm polypropylene sheet was draped over the cosmetic plaster covered with a stocking. The polypropylene cosmesis was removed by cutting both the seam and the plaster. After removal of the plaster of Paris, the cosmesis was replaced and welded with a heating gun and polypropylene rod (3mm or 5mm diameter), while the foot was attached. A PVC T-strap suspension was attached to the socket with either a copper rivet or a polypropylene rivet. Some prostheses had T-straps made of leather.

The polypropylene prosthetic components were manufactured by recycling polypropylene off-cuts. First they were placed in a crushing machine and reduced to pellets (3-5mm diameter), which were oven-heated on a Teflon sheet at 170° Celsius for about 20-30 minutes. Then they were transferred into an aluminium mould, which was preheated to 100° Celsius. Moulds of various shapes, such as concave pipes, convex discs, ankle adapters and concave cups, were placed in a press.

Essential conditions for obtaining good-quality products are consistency in the quality of the raw material, strict observance of temperatures, and avoidance of contamination of the polypropylene with dust, grease, etc.

The Ho Chi Minh Rubber Foot, made in the Z751 Army enterprise, consists of a polypropylene keel made out of pellets which were oven-heated and pressed into a mould (Fig. 2). Three different kinds of unprocessed rubber were mixed with various chemicals. The sole part is similar to the rubber of a car tyre. It is vulcanised and 8-10mm thick. For the dorsal part of the foot, a 1-2mm layer was placed in the mould. Soft foam rubber was placed between the sole, the keel and the dorsal part. The whole was placed in a mould and heated in a vulcanisation press. It is designed to be used barefoot or with slippers.

The HCMC Rehabilitation Centre employs 14 national staff, including 10 technicians, in the prosthetics section, plus 3 more in the component workshop and mechanical section. None of the staff has received training equivalent or superior to ISPO Category II. All employees have received "on-the-job" training of various durations, while some have received additional training elsewhere (3 years' training at the BaVi Orthopaedics and Rehabilitation Centre; 3 years in the former German Democratic Republic; 18 months' training by the World Rehabilitation Fund; various short seminars). The 3 employees in the component production unit have received 3 years' "on-the-job" training in addition to their basic skills as carpenters or mechanics. In 1997 the 10 technicians produced 1743 prostheses, i.e. an average of 14.5 prostheses/technician/month.

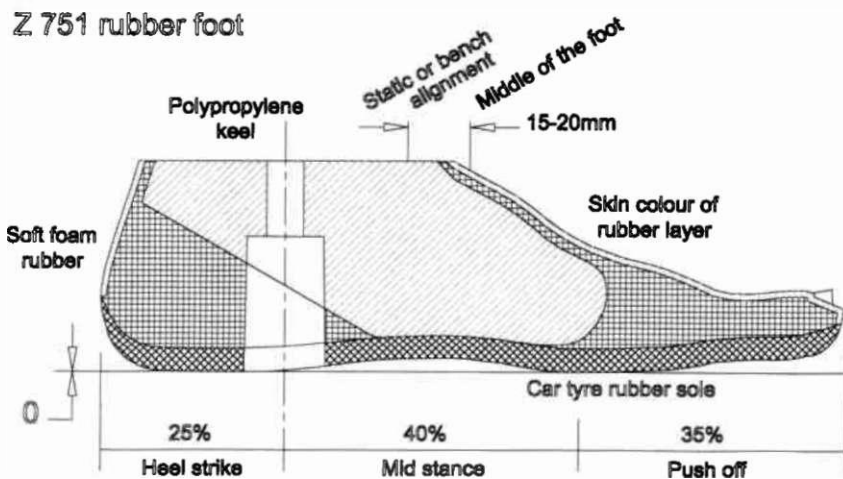


Fig. 2. Z751 Ho Chi Minh foot.

Table 1. Composition of sample group

	Sample 43 amputees	HCMC database 8,991 amputees
Mean age in years (range)	47 y (12 y-60 y)	80%: >40 y
Percentage male	81%	88%
Percentage war-wounded	95%	81%

Sample group

A random sample of 80 unilateral trans-tibial amputees who had been fitted with polypropylene prostheses at the HCMC rehabilitation centre between January 1993 and February 1996 were invited by letter in November 1997 to come to the centre for an evaluation of their prostheses. Thirty-one (31) were living in greater HCMC (8km radius) and 49 in seven surrounding provinces (100km radius). Forty-six (46) amputees (58%) replied; 16 (52%) from greater HCMC and 30 (61%) from the provinces. Of these, 7 were excluded because they came without prostheses (5) or because they were of Symes amputation level (2). Four (4) trans-tibial amputees who happened to attend the HCMC Centre for repairs were included, bringing the total to 43.

Evaluation

The amputees were questioned about their prostheses by the prosthetist and the project administrator, using a standard questionnaire. The questionnaire elicited information regarding the living conditions of the amputee, mean hours of daily use of the prosthesis, the occupation/daily activities of the patient and the repair history of the prosthesis. *Hours of daily use* indicates the average daily use at the time of the evaluation. It could vary between 0 hours, when the prosthesis was not used at all, and 12-16 hours, when it was used full-time. As an indicator of wear and tear, the daily activities of

the amputee were translated into a *load level* on the prosthesis with four possibilities: low, medium, high and very high. The amputee was asked for the repair history of the prosthesis, which was also inspected for faults. The *life span* of the prosthetic parts to be repaired/replaced was determined in consultation with the patient: this was the period between the time when the part was first used and the start of signs of wear and tear and/or cracks.

Results

Table 1 shows that the characteristics of the sample group were similar to those of the amputees registered in the ICRC database at the HCMC Rehabilitation Centre, which contained data on 8,991 amputees.

Table 2 indicates the hours of daily use in relation to the load level on the prosthesis (the load levels of 2 amputees were not classified). The table shows that the majority of the prostheses had high load levels and many hours of daily use. Eighty per cent (80%) of the prostheses were used by farmers, fishermen and merchants. Of the 8 women, one was in the medium level, 3 in the high level and three in the very high category of load level (one woman was not classified).

At the time of evaluation, the average patient was still using his/her prosthesis 9 hours per day; this figure varies little in most of the load-level sub-groups.

Table 2. Use and load levels of evaluated prostheses

Load level	Hours of daily use				Total (n)	Mean hrs/day (SD)
	0	1-5	6-11	12-16		
Low (mainly cosmetic, pensioner)	0	1	0	0	1	1 (0)
Medium (office work)	0	4	1	2	7	8 (6.0)
High (walks a lot, merchant)	0	2	1	5	8	11.3 (6.0)
Very high (farmer, fisherman)	4	5	5	11	25	9.1 (6.4)
Total	4	12	7	18	41	91.1 (6.3)

Table 3. Mean life span of prostheses and replaced parts (except feet)

	n	Mean life span in months (SD)
Replaced prostheses	11	37.3 (8.6)
Replaced parts:		
Suspension belts	32	11.0 (11.1)
Sockets (welding seams)	2	11.5 (9.2)
Sockets (fitting problems)	7	26.4 (12.7)

It was found that 9 amputees also used additional prostheses. This group used their evaluated prostheses on average 4.1 hours/day (range 1-8hrs); the additional prostheses were used 10.6 hours/day (range 7-14hrs). These additional prostheses included appliances which had been issued many years before, sometimes by a different centre if the amputee had moved to another area, and home-made prostheses (2 amputees). Frequently these amputees used the older prostheses for work, "saving" the nicer prostheses for other occasions. The majority of the amputees said they were satisfied with their prostheses, in spite of the fact that many were obviously in need of repair or replacement.

Repairs

Table 3 summarises the repairs that needed to be carried out on the prostheses, excluding the rubber feet, which are considered separately.

Eleven (11) prostheses (26%) were replaced. In the majority of these cases (64%), fitting problems were (partly) the cause. The mean life span of these replaced prostheses was 37 months. Two (2) prostheses (5%) did not need repair or replacement. These had hardly been used by the amputees (0-2 hours/day).

Of the components, it was the suspension belts

which needed by far the most repairs, with 32 replacements. In addition, two welding seams had to be repaired (both prostheses were still in use 16hrs/day), while 7 sockets were repaired or replaced because of fitting problems (average use: 2.7 hours/day).

Though a small number of prostheses had undergone previous repairs, including 5 repaired by the patients themselves, the majority of the repairs were carried out only at the time of the evaluation. Many patients had continued walking on their prostheses even when some parts were considerably worn.

Table 4 gives a more detailed breakdown of the suspension belt replacements. Although the mean life span of replaced suspension belts was about the same (11 months) in the 3 load-level sub-groups, individual variations in life span were large in all sub-groups. The small number of belts replaced precludes drawing conclusions about an association between load level and life span.

Table 5 gives a more detailed breakdown of replaced feet because of the large number of such replacements. The table shows the relation between replaced feet and load level with a high figure for hours of daily use. Of the replaced feet, 85% were being used between 6-16 hours per day. Quite a number of feet were considerably worn but still used. Three (3) prostheses had had the feet replaced twice and 3 others three times. These 6 prostheses were used on average 12.7hrs/day (SD 3.7), with a high to very high load level. The average life span of replaced feet was 8.9 months and is related more clearly to hours of daily use than to load level. Four (4) patients expressed a preference for a rocker instead of a foot for reasons of sturdiness. Twelve (12) prostheses had no history of foot

Table 4. Replaced suspension belts

Load level	Hours of daily use				Total (n)	Mean hrs/day (SD)	Mean life span in months (SD)
	0	1-5	6-11	12-16			
Low (mainly cosmetic, pensioner)	0	0	0	0	0		
Medium (office work)	0	3	1	2	6	8.8 (6.0)	8.8 (10.8)
High (walks a lot, merchant)	0	2	0	5	7	11.7 (6.3)	10.9 (9.1)
Very high (farmer, fisherman)	2	5	3	9	19	9.2 (6.3)	11.7 (12.3)
Total replaced suspension belts	2	10	4	16	32	9.7 (6.2)	11.0 (11.1)
Mean life span in months (SD)	12.5 (9.2)	6.6 (5.6)	21.0 (20.5)	11.1 (10.3)			

Table 5. Replaced feet

Load level	Hours of daily use				Total (n)	Mean hrs/day (SD)	Mean life span in months (SD)
	0	1-5	6-11	12-16			
Low (mainly cosmetic, pensioner)	0	0	0	0	0		
Medium (office work)	0	2	1	2	5	9.8 (6.3)	8.4 (3.4)
High (walks a lot, merchant)	0	2	3	7	12	11.3 (5.2)	9.4 (7.5)
Very high (farmer, fisherman)	0	2	6	15	23	12.6 (4.3)	8.7 (5.3)
Total replaced feet	0	6	10	24	40	11.8 (4.8)	8.9 (5.7)
Mean life span in months (SD)		12.3 (9.1)	11.7 (6.3)	6.8 (3.3)			

replacements; these were being used on average 1.3hrs/day (SD 1.7) at the time of the evaluation.

In 15 cases there was a poor fit between the stump and the prosthetic socket and consequently 10 of these patients complained of pain. Six (6) amputees were not using the prosthesis at all at the time of evaluation because of fitting problems. Usually such problems were caused by stump changes over the course of time, although one amputee mentioned having had pain ever since the prosthesis was first fitted.

Figure 3 summarises the various replaced parts and their mean life span.

Discussion and recommendations

The study confirmed that polypropylene parts are not a major cause of breakdown of prostheses. The rate of only 2 welding faults on

43 prostheses over an average period of more than 3 years is considered good. The welding faults were probably due to human error.

An overall limitation of this study is that the sample of 43 amputees reflects the experience of only a small number of all prosthesis users and that the response rate for the 80 patients invited to take part was only slightly over 50%. A similar evaluation should be organised for the group of non-respondents so as to determine how representative the findings relating to the respondent group is. Additional evaluations should also include trans-femoral amputees and prostheses which have been used for longer periods.

The high number of hours of daily use, the relatively high number of additional prostheses used and the frequent self-repairs indicate that

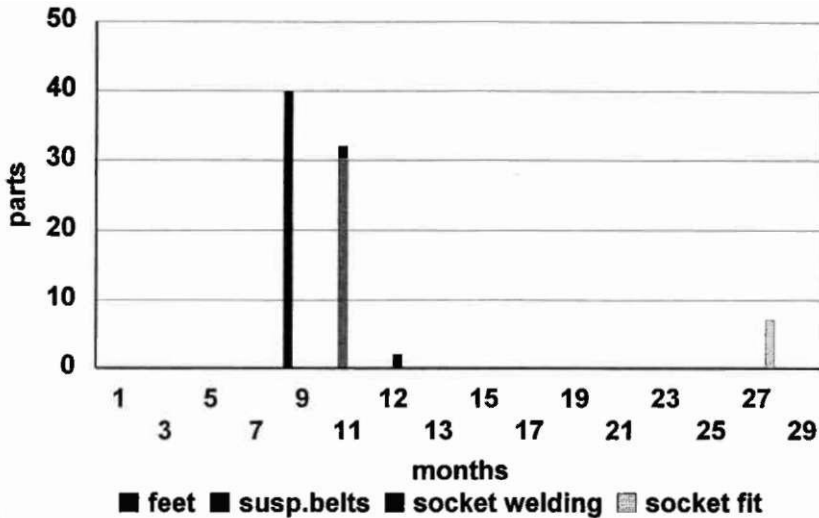


Fig. 3. Mean lifespan replaced parts in months.

the prosthesis plays an important and useful part in the daily life of an amputee. This is supported by the fact that three-quarters of the patients expressed satisfaction with their prostheses, in spite of the problems observed.

An attempt was made to cross-link *mean hours of daily use with load level*. The findings should, however, be interpreted with caution. Field conditions for individual amputees can vary widely, and furthermore both indicators depend on the ability and willingness of the patient to provide correct information. Moreover, as the hours of daily use refers to the time of the evaluation, this figure is not necessarily representative for the total period of use. It can be argued that it understates use during the total period, as prosthesis use often decreases over time owing to breakdown or pain. In general, the numbers are too small to permit conclusions being drawn about possible associations between load levels and life span. In future, stratification into a smaller number of groups which are more clearly defined may be a better option.

Although the polypropylene prosthetic parts were generally found to be sufficiently strong, the evaluation showed that some prostheses, or parts of them, were replaced too late. Only a few patients stopped using their prostheses as a consequence, most of them continuing to use prostheses with worn parts. However, the suspension belt was clearly too weak and needed strengthening (or the PTB system needed to be replaced by supracondylar suspension).

A major problem was identified with regard to the rubber foot. Its life span is considered generally too short, and although patients often continue using the prosthesis with a worn

prosthetic foot, this problem needs to be addressed. In the process of making a rubber foot, irregularities in laying the unprocessed rubber sheets can contribute to poor quality.

Apart from material problems, the fitting problems observed in about 35% of the patients are a significant cause of reduced use of the prosthesis, mainly because of discomfort and/or pain. As a consequence, six amputees were not using their prostheses at all at the time of the evaluation. The fitting problems appeared mainly due to stump changes over time and highlighted the importance of continued access to rehabilitation services.

The results of the study prompted the following decisions: to contact the foot factory, which subsequently adapted the manufacturing process to increase life span; to issue a spare foot with each prosthesis so as to allow patients living far away to do their own repairs; to use a stronger, leather suspension strap instead of the weaker plastic strap. The findings also supported the decision to develop a different and structurally more robust foot.

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Case note

The use of the shuttle lock system for problem trans-femoral suspension

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Introduction

The standard suspension for the elderly trans-femoral amputee in Dundee is the Totally Elasticated Suspension (TES) belt used in conjunction with a hand wrapped ischial containment socket.

Two patients with specific suspension problems are presented in whom an ICEROSS suspension sleeve with shuttle lock mechanism was used to resolve their difficulties.

Case 1

MG is a 61 year old arthrosclerotic amputee who, following a right popliteal by-pass graft, required a left auxiliary bifemoral by-pass. Unfortunately there was a problem with healing and the vascular graft became exposed in the left groin. The vascularity of the tissue below the transverse abdominal scar was severely compromised and on surgery, it was found there was no viable rectus muscle remaining. The abdominal skin was utilised as a trans-position flap based on the contralateral superficial inferior epigastric vessel.

The wound margin of the flap, however, underwent necrosis and further exposure at the graft and the rectus femoris muscle flap was utilised to cover the vascular implant. The wound at the right leg, however, failed to heal and amputation was required.

The result was a very tender heavily scarred abdominal wall which could not tolerate a belt of any sort (Fig. 1). Management was by way of an ICEROSS suspension sleeve with the shuttle

lock incorporated within the thigh section of the prosthesis.

The prosthesis was a hand wrapped ischial containment type thermoplastic socket attached to a Blatchford semi-automatic knee lock and multiflex foot.

The patient found this easy to apply and lock and it also gave excellent suspension and comfort resulting in no pressure on her abdomen and no pain over the grafted scarred abdominal area.



Fig. 1. Case 1 showing extensive abdominal wounds which inhibited standard waist belt suspension.

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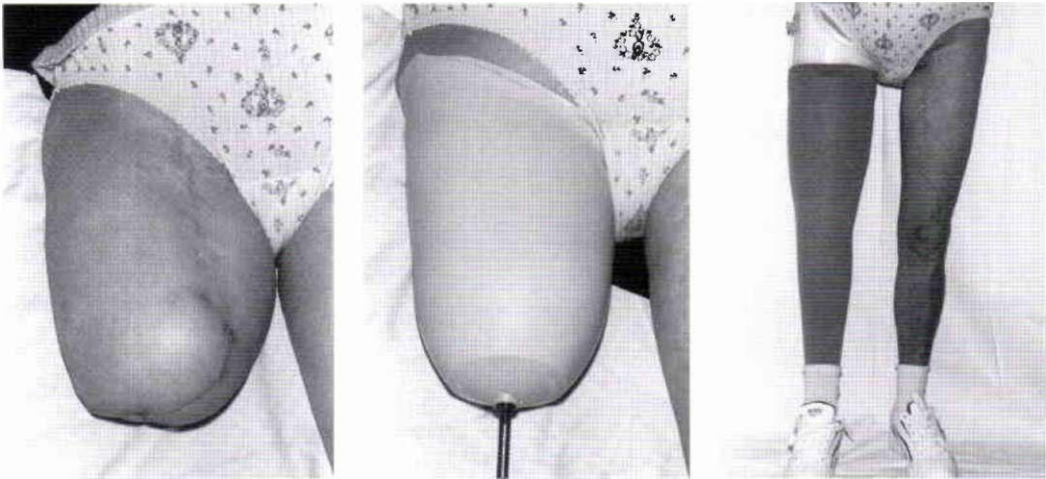


Fig. 2. Case 2: (a) stump; (b) ICEROSS fitted to the stump; (c) completed limb.

Case 2

CL is a 70-year-old arthrosclerotic trans-femoral amputee with an extremely short conical shaped stump. Suspension and stump location was considered to be difficult for a standard prosthesis with a waist belt. An ICEROSS suspension sleeve with a shuttle lock system gave her sustainable suspension when using a combination with a similar prosthetic construction to Case 1 (Fig. 2a).

Donning was initially a little difficult due to the changing volume of the stump but with practice improved and now she is completely independent.

Discussion

The TES elasticated sleeve has been used in Dundee for some years and has proved extremely popular in preference to the polypropylene waist band. Total suction sockets are not easy for elderly people to apply in the

primary situation with early loss of suction due to stump shrinkage. The shuttle lock system has proved extremely successful in these two cases, where despite some shrinkage taking place suspension has been retained. They are a little difficult to apply but with practice the patients demonstrated above have managed extremely well.

There are several shuttle lock systems on the market, each having their individual merits. In these two cases ICEROSS was used.

The use of a sleeve with shuttle lock system for the trans-femoral amputee is thus advocated for those to whom suspension is a problem, either because of the stump shape and size or the unsuitability of a waist belt or abdominal support as a result of scarring.

Pressure on auxiliary and femoral grafts by the waist belts may cause compression and compromise the limb circulation. In these circumstances this system is also recommended.

Technical note

Reduction of skin problems at the Alpha socket/skin interface

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Introduction

New interface liners, for example “Alpha” and “TEC” have been extremely successful in improving the overall comfort of amputees.

It has been observed that up to 10% of patients using the newly introduced total contact socket interfaces develop a skin eruption at the proximal edge of the liner. Other problems include the pooling of sweat and pain resulting in a rejection rate of 19% (Mullick, 1997).

The skin eruption is in the form of an erythematous eruption sometimes with an exudate.

Occasionally it is a true allergic reaction to the various materials used but in some cases it appears to be due to a mechanical problem at the top 2–3cm of the liner.

Case 1

WD is a 64-year-old man with severe atherosclerosis resulting in a dense hemiplegia as a result of a stroke 5 years prior to developing gangrene in his toes. Amputation at trans-tibial level healed well and he was initially mobilised with a patellar-tendon-bearing prosthesis.

Considerable discomfort however developed in the stump 3 months after delivery of the prosthesis. He was subsequently fitted with an Alpha Liner which he found very comfortable.

At a review clinic one month after delivery he complained of an eczematous eruption at the top of the liner. The rest of the stump was however unaffected and contact allergy to the liner was not considered a likely cause of the problem.

The scalloping of the top of the liner (Fig. 1) has resolved the problem.

It is suggested that the scalloping may reduce skin shear at the top and thus reduce skin trauma.

Case 2

JS is a 74-year-old man with diabetes mellitus related trans-tibial amputation.

His prosthetic history was complicated by the continuous presence of pain in the stump, which

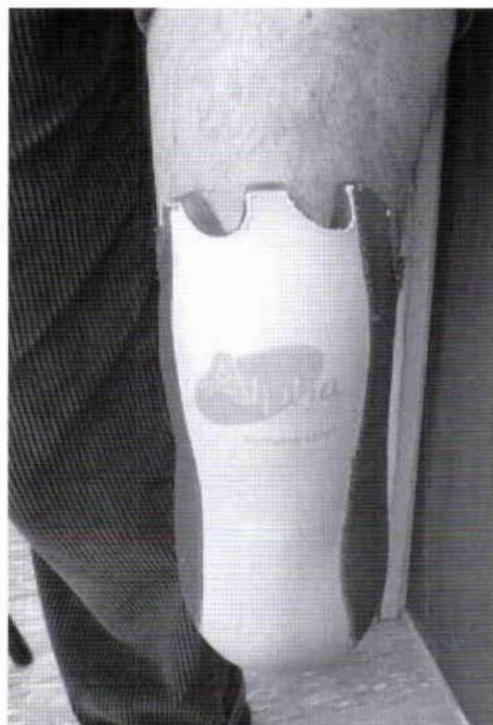


Fig 1. Scalloped edges to reduce skin shear at the top of the liner.

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repeated socket changes failed to resolve.

The provision of an Alpha Liner did help somewhat but did not completely resolve the patient's pain. He was however able to use his limb more comfortably than before. He developed a skin eruption similar to Case 1 and this was again resolved by the scalloping of the liner top.

Summary

Two cases are presented in whom the provision of an Alpha Liner relieved the patients' stump discomfort but developed a skin

eruption at the top of the liner.

This was resolved satisfactorily by cutting scallops into the top of the liner.

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Comparative trials on hybrid walking systems for people with paraplegia: an analysis of study methodology

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Abstract

A new orthosis (SEPRIX) which combines user friendliness with low energy cost of walking has been developed and will be subject to a clinical comparison with conventional hip-knee-ankle-foot orthoses. In designing such comparative trials it was considered it may be worthwhile to use previous clinical studies as practical examples. A literature search was conducted in order to select all comparative trials which have studied two walking systems (hip-knee-ankle-foot orthoses) for patients with a complete thoracic lesion. Study population, intervention, study design, outcome measurement and statistical analyses were examined. Statistical power was calculated where possible.

Of 12 selected studies, 7 were simple A-B comparisons, 2 A-B comparisons with a replication, 2 cross-over trials and 1 non-randomised parallel group design, the last of which was considered internally invalid due to severe confounding by indication. All A-B comparisons were considered internally invalid as well, since they have not taken into account that a comparison of two orthoses requires a control for aspecific effects (like test effects) which may cause a difference. Statistical power could only be examined in 4 studies and the highest statistical power achieved in one study was 47 %. It is concluded that statistical power

was too low to be able to detect differences. Even analysis through interval estimation showed that the estimation of the difference was too imprecise to be useful. Since the majority of the surveyed papers have reported small studies (of only 4-6 patients), it is assumed that lack of statistical power is a more general problem. Three possibilities are discussed in order to enhance statistical power in comparative trials, i.e. multicentre studies, statistical pooling of results and improving the efficiency of study design by means of interrupted time series designs.

Introduction

Various new developments in hybrid systems for patients with paraplegia have been reported in the last few years (Stallard and Major, 1995; Edwards and Bataweel, 1996; Ferrarin and Rabuffetti, 1996; Yang *et al.*, 1996). Beside technological improvements, two categories of clinical research can broadly be distinguished, i.e. comparisons between available clinical systems (like Reciprocating Gait Orthoses - RGO) and clinical trials on new system developments. Reduction in energy cost of locomotion is often a main goal in these reports. However, in the design of a new orthosis (Separable Reciprocator with Intelligent Knee Stabilisation - SEPRIX) the authors acknowledged user friendliness, in addition to energy cost of locomotion, to be an important target. Separability and foldability were suggested in order to improve donning / doffing and transportation respectively (Baardman *et al.*, 1997), whereas upper body load during locomotion can be reduced by aligning an

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orthosis in slight abduction (IJzerman *et al.*, 1997^b).

The effectiveness of a new walking system should be investigated in order to establish superiority of the system over another. In claiming such effectiveness, in particular when the decisions are complicated (like justification of implant technology) and the differences are small, appropriate methodology is essential (Yusuf *et al.*, 1994; Sykes *et al.*, 1996).

In designing clinical studies on effectiveness of orthoses, previous studies are often used as examples. For instance, the study of Sykes *et al.* (1996) is, with respect to the methodology, almost similar to the study of Nene and Patrick (1990). However, in designing a study on effectiveness of the new SEPRIX orthosis, some methodological problems were encountered in previously published studies and copying the methodology appears not to be a suitable approach.

The basic issues in the design stage of an experiment are usually categorised into internal validity and external validity. Internal refers to the validity of the inferences drawn in regard to the patients involved in the study and external refers to the validity of the inference in regard to the target population outside the sample (Rothman, 1986). Internal validity is a prerequisite for external validity, but external validity is not always likely to be a consequence of an internally valid study. In addition, statistical conclusion validity concerns whether the differences in the study are due to chance (Cook and Campbell, 1979; Wagenaar, 1990; Ottenbacher and Barrett, 1990). In a statistically valid study one presumes that appropriate statistical tests were used and that the study had sufficient statistical power to detect differences (Ottenbacher and Barrett, 1990).

In general, true-experimental designs are considered the most powerful method in showing treatment effectiveness (Ottenbacher, 1995). Although other designs can also be considered as true experimental (Cook and Campbell, 1979; Wagenaar, 1990), the randomised controlled trial (RCT) is uniformly accepted as the most appropriate design (Meinert, 1986; Pocock, 1983; Reilly and Findley, 1989; Pollock *et al.*, 1993). Control in this context refers to a comparison of the new therapy with a standard therapy, randomisation refers to random assignment of patients to either

a new or a standard therapy (Pocock, 1983). However, RCTs are difficult to conduct (Reilly and Findley, 1989) and, so far, no comparison of walking systems has been a randomised controlled trial. Two reasons can be put forward, i.e. (1) adequate randomisation usually requires sufficient patients in order to achieve baseline comparability of study groups (potential confounders) (Rothman, 1986; Pollock *et al.*, 1993) and (2) if only a limited number of patients can be included, an RCT is not the most efficient design, since 50 % of the patients are assigned to a standard orthosis. In contrast, cross-over trials do offer true experimentation but with a maximum statistical power since all patients are assigned to both standard as well as new therapy (Pocock, 1983; Senn, 1993). However, cross-over trials have the disadvantage that a carry-over effect may limit their internal validity.

With respect to the statistical analysis of studies, it is often found that much attention is given to proper statistical testing, but that statistical power is not addressed (Ottenbacher and Barrett, 1990). In addition, the majority of the comparative trials on paraplegic walking systems were not able to demonstrate significant differences between walking devices. Proper interpretation of the p-value (accepting H_0 when $p > \alpha$ and rejecting H_0 if $p < \alpha$) would then suggest that H_0 (no difference) is true (Barnard, 1990; Salsburg, 1990). However, this interpretation neglects the risk of a type II error (β -level). A type II error occurs if H_0 is accepted falsely or in other words there truly is a difference but the study fails to show it because of lack of statistical power (Altman, 1980; Lachin, 1981; Carpenter, 1993; Ottenbacher, 1995). Studies with lack of statistical power are unable to detect any clinically relevant difference or they provide estimates which are too imprecise to be useful (Carpenter, 1993). Conduct of such trials with *a priori* knowledge of insufficient statistical power is considered unethical, since patients and other resources are used without having a reasonable chance of drawing correct conclusions (Altman, 1980).

This study aims to support the design of clinical trials on effectiveness of (hybrid) walking systems for patients with paraplegia. A database search was carried out and the relevant literature is summarised with respect to study sample, intervention (walking system and gait

training), study design, main outcome measures and statistical analysis. The methodology will be discussed with respect to the internal validity, statistical conclusion validity and external validity. Finally, some alternative approaches for clinical evaluations of walking systems are discussed.

Methods

Literature search

A database search was performed in order to obtain all relevant publications concerning a clinical evaluation of a walking system for patients with (complete) paraplegia. Publications were searched in the Medline database in the period from January 1966 to May 1997. Search key-words included paraplegia, orthosis, walking, energy, electrical stimulation either solely or in various combinations. Current contents as well as references listed in available publications were scanned, since it is possible

that a database only partially yields the available publications (Sacks *et al.*, 1987).

Publications were included in the analyses if they had met the following conditions: (1) the comparison should be performed in adult patients suffering from complete thoracic paraplegia, (2) the comparison should comprise hip-knee-ankle-foot orthoses, either with or without electrical stimulation, (3) the trial should report a clinical comparison of two orthoses and (4) the trial should have used relevant clinical outcome measures like oxygen uptake, walking speed or crutch forces.

Summary of relevant study aspects of the selected studies

All selected studies were summarised regarding 5 different aspects, i.e. study sample, type of walking system which is compared, actual study design, outcome assessment and statistical analysis (Table 1).

Table 1. Relevant aspects along which the selected articles are judged. The five aspects include study population, intervention, study design, outcome measures and statistical analysis. Each aspect was judged on one or more criteria which are listed in third column of the table. If applicable, abbreviations to be used in Table 2, are listed in the last column. *Abbreviations:* RGO: reciprocating gait orthosis, HGO: hip guidance orthosis (parawalker), ARGO: advanced reciprocating gait orthosis, iRGO: isocentric Reciprocating Gait Orthosis, FES: Functional Electrical Stimulation, Quads: quadriceps muscles, Hams: Hamstrings, Glut: Gluteal muscles, V_{O_2} : oxygen uptake (ml/min), E_{O_2} : oxygen cost (ml/m), v: walking speed, CFTI: crutch time force intergral, CPF: crutch peak force, SD: standard deviation.

Study aspects	Criterion	Abbreviations
Study sample	A. Description of sample <ul style="list-style-type: none"> • size • gender • age • level 	– m: male ; f: female – –
	B. Previous walking experience	① yes ; ② no
Intervention	C. Standard system	
	D. New system <ul style="list-style-type: none"> • orthosis • FES application 	① RGO ; ② HGO ; ③ ARGO ; ④ iRGO a. Quads/hams ; b. Glut/hams ; c. Glut
	E. Adequate training period	① gait training described ② prior to measurements
Study design	F. Design type	① within group (AB) ② within group (AB/BA cross-over) ③ between group
	G. Measurement day	① same occasion ② different occasion
	H. Measurement sequence	① randomised ② fixed
Outcome measure	I. Main outcome measures	① V_{O_2} ; ② E_{O_2} ; ③ v ; ④ CFTI ; ⑤ CPF
	J. Assessment speed	① self-selected ; ② standardised
Statistical analysis	K. Descriptive statistics	① mean ; ② SD a. of differences ; b. for each system
	L. Inferential statistics	① parametric/non-parametric tests ② analysis of variance

With respect to the *study sample* the relevant baseline characteristics of the included subjects were of particular interest. Articles were judged on the actual sample size, level of lesion, gender, age and walking experience of the subjects included in the study.

The *walking system* being evaluated in the selected studies could be either a standard (conventional) orthosis or a new system. Four conventional orthoses are investigated frequently, i.e. the Reciprocating Gait Orthosis (RGO), Hip Guidance Orthosis (HGO), Advanced Reciprocating Gait Orthosis (ARGO) and isocentric® Reciprocating Gait Orthosis (iRGO). Three different applications of Functional Electrical Stimulation (FES) are used, i.e. (1) reciprocal electrical stimulation of quadriceps/hamstrings, (2) electrical stimulation of hamstrings / gluteal muscles on stance side and (3) electrical stimulation of gluteal muscles on stance side.

Judgement of the contents and execution of the gait training is difficult, but was considered adequate if the authors had described an extensive and adequate training schedule for the orthosis gait training, FES muscle conditioning as well as hybrid system gait training.

Judging the actual *study design* as being either experimental (randomised parallel group design) or quasi-experimental (non-randomised parallel group design) is not adequate as most authors have conducted a within patient comparison (each subject is tested in either of the two walking systems). However, within subject comparisons can be carried out differently. Methodologically most profound is a study which is conducted as a cross-over design. Randomisation of the measurement sequence (either A-B or B-A, which essentially provides a cross-over design) is considered an attempt to improve the internal validity of the A-B design. A simple A-B comparison without randomisation, i.e. all subjects are tested in the same order, is least favourable with respect to internal validity.

Measurement of the performance in either orthosis (*outcome assessment*) could have been conducted on either one or on separate days (each orthosis on a different day). This is important as the performance in the second orthosis if measured on one day may be affected by either fatigue of the subjects or decreased FES muscle performance. Though measurement

of the performance of two walking systems on different days may be superior with respect to fatigue, they are more affected by day to day variation in performance.

Important *outcome measures* are those which convey information to be used for decision making with respect to the performance of walking. Though arbitrary, important outcome measures are: oxygen uptake (oxygen uptake: V_{O_2} , oxygen cost: E_{O_2}), walking speed (v), or crutch force measures (crutch force time integral: CFTI or crutch peak force: CPF). Assessment of the walking performance could have been performed at either a standardised or a self-selected walking speed.

At least descriptive *statistics* should have been reported by the authors. The central tendency and the variation of each walking system should have been described as well as the differences between the walking systems. Statistical testing in order to draw inferences was judged with respect to the appropriateness of the tests (dependent/independent group comparisons and parametric/non-parametric) as well as the required statistical assumptions.

Post hoc statistical power calculations

All data with respect to V_{O_2} and walking speed for each orthosis in each article are summarised including the p-level reported for the difference between the systems. *Post hoc* statistical power calculations were performed using the statistical program PC-size (Dallal, 1990). As most studies were within-subject comparisons (A-B), statistical power was calculated assuming that the analysis was conducted using a paired t-test. Since this test requires the mean and standard deviation of the differences between orthoses, statistical power could only be calculated if these data were available.

Results

Selected studies

Most studies were identified while using the key-words "orthosis" and "paraplegia" separately. No search strategy could be determined to locate studies on hybrid walking systems for patients with paraplegia specifically. In addition to the papers which were excluded according to the selection criteria, papers were also excluded if they reported a case study (Phillips, 1989; Isakov *et al.*, 1992; Jefferson and Whittle, 1990; Muszkat *et al.*, 1994; Smith

et al., 1997) or if they presented results of a single system with reference to the literature (Gallien *et al.*, 1995; Saitoh *et al.*, 1996; Nene and Patrick, 1989; Nene and Jennings, 1992). The latter articles were excluded because such comparisons are often distorted by many other effects which are more related to subject selection and assessment protocols than to the differences between orthoses. A paper of Stallard and Major (1995) was excluded since a later version of the HGO with stiff hip joints was compared with historical controls, which is also considered inadequate (Pocock, 1983). If two or more publications were found which reported from the same study, only the most recent publication was included. However, two publications from the ARMOR association were included because they reported with a different scope (Thoumie *et al.*, 1995; Beillot *et al.*, 1996). After inclusion, twelve papers were available for evaluation.

Summary of relevant study aspects of the selected studies

All details with respect to study design of the selected papers are given in Table 2.

The papers showed considerable concordance in the size and characteristics of the study

population. Between 4 and 6 patients were included in the majority of the studies. Two larger studies comprised 28 and 22 patients respectively (Lotta *et al.*, 1994; Whittle and Cochrane, 1989). Mean age ranges from approximately 23 to 38. The majority of the patients were male. All studies included patients with low as well as high thoracic lesions. Two studies also reported results of patients with incomplete lesions (Sykes *et al.*, 1996; Winchester *et al.*, 1993). There were two common approaches for inclusion of patients. Either new patients were recruited and trained with two new systems (5 studies) or patients with previous walking experience were trained with a new system (6 studies).

Walking systems which are compared in the literature comprise very often the RGO. Only a few papers have been published on HGO, ARGO and iRGO.

Most authors reported extensively on the training schedules used in their study, including the stimulation equipment and parameters settings. Gait training was conducted prior to all measurements in all but one study (Whittle and Cochrane, 1989). They conducted a cross-over trial and the gait training in the second orthosis was performed after the subject had been

Table 2. Summary of the relevant study aspects of the included studies (see Table 1 for explanation).

Paper	Study sample				B	Intervention			Study design			Outcome measures		Statistical analysis	
	A					C	D	E	F	G	H	I	J	K	L
	size	gender	age	level											
Hirokawa <i>et al.</i> , 1990	6	4,2	34.7 (8.2)	T1-T10	2	1	1a	1,2	1	?	?	1,2	2	2a	-
Sykes <i>et al.</i> , 1996	5	4,1	31.8 (5.3)	C2-T9	1	1	1a	1,2	1	1	2	1,2,3	1	1a,2a ⁴	-
Petrofsky and Smith, 1991	4	?	20-35	T4-T12	3	1	1b	1,2	1	?	?	1,2,5	2	1b,2b	?
Thoumi <i>et al.</i> , 1995	6	6,0	35	T2-T10	2	1	1a	2	1	?	?	3	1	1b,2b	2
Beillot <i>et al.</i> , 1996	4	4,0	31	T7-T11	2	1	1a	2	1	1	1	1,2	2	1a,1b	1
Winchester <i>et al.</i> , 1993	4	4,0	29.8(6.1)	T5-T10 ¹	1	1	4	1,2	1 ³	2	1	1,2,3	1	1b,2b	2
Whittle and Cochrane, 1989	22	18,4	33.6(5.8)	T3-T12	2	1	2		2	2	-	1,2,3,4 ⁶	1	1a,1b	-
Lotta <i>et al.</i> , 1994	4	4,0	23.8(3.8)	T3-T12	2	2	-	1,2 ⁵	3	-	-	3	1	1a,2a ⁴	1
	11	10,1	23.5(5.8)	T3-T10	2	3	-	1,2 ⁵	-	-	-	3	1		
	13	10,3	25.3(8.6)	T3-T12	2	1	-	1,2 ⁵	-	-	-	3	1		
McClelland <i>et al.</i> , 1987	3	?	?	T4-T7	1	2	2c	1,2	1	1	?	3,4	1	1a,2a ⁴	-
Nene and Patrick, 1990	5	5,0	27.6(1.8)	T4-T7	1	2	2c	1,2	1	1	2	1,2,3	1	1a,2a ⁴	-
IJzerman <i>et al.</i> , 1997 ^a	6	6,0	38.7(11)	T4-T12	1	3	3 ²	1,2	1 ³	2	2	1,2,3,4,5	1	1a,2a ⁴	1
IJzerman <i>et al.</i> , 1997 ^b	5	4,1	36.8(6.0)	T4-T12	1	3	3 ²	1,2	2	2	-	1,2,3,4,5	1	1a,2a ⁴	1,2

¹ two incomplete paraplegic patients, ² modified ARGO, ³ replicated before-after trial, ⁴ mean and SD available from original publication, ⁵ unequal training among participating centres, ⁶ crutch peak force estimated from ground reaction force.

assessed in the first orthosis.

The majority of the studies lack detailed information on the *study design*. Out of twelve studies, only one had performed a (non-randomised) parallel group design (Lotta *et al.*, 1994). Eleven studies reported within subject comparisons. Six studies reported simple A-B comparisons without randomisation of the measurement order (Nene and Patrick, 1990; McClelland *et al.*, 1987; Sykes *et al.*, 1996; Hirokawa *et al.*, 1990; Petrofsky and Smith, 1991; Thoumie *et al.*, 1995). Only Beillot *et al.* (1996) performed an A-B comparison with randomisation of the measurement order. Two studies reported simple A-B comparisons with a replication (Winchester *et al.*, 1993; IJzerman *et al.*, 1997^a). Finally, two studies reported a cross-over design (Whittle and Cochrane, 1989; IJzerman *et al.*, 1997^b).

Four studies, which used a simple A-B comparison, have reported that all measurements took place on the same day (Beillot *et al.*, 1996; Nene and Patrick, 1990; McClelland *et al.*, 1987; Sykes *et al.*, 1996). In three of them, the (conventional) orthosis without FES was always measured as the first system.

All authors included a resting period in between the measurements. Three simple A-B comparisons did not provide information on the measurement sequence and whether assessments were performed on different occasions (Hirokawa *et al.*, 1990; Petrofsky and Smith, 1991; Thoumie *et al.*, 1995).

Two authors conducted a study with a replication of the simple A-B comparison (Winchester *et al.*, 1993; IJzerman *et al.*, 1997^a). Winchester *et al.* (1993) measured both orthoses twice on 2 separate days and has randomised the measurement order. IJzerman *et al.* (1997^a) has measured both orthoses twice on four separate days according to a BABA sequence.

Oxygen uptake (V_{O_2} : ml.min⁻¹) and oxygen cost (E_{O_2} : ml.m⁻¹) were reported as *outcome measures* in eight studies. Self-selected walking speed is presented by all but three authors. Crutch forces were measured in four studies. Conversion of oxygen uptake (ml.min⁻¹.kg⁻¹) to energy uptake equivalents (J.min⁻¹.kg⁻¹) was performed by four authors (Hirokawa *et al.*, 1990; Nene and Patrick, 1990; Beillot *et al.*, 1996; Sykes *et al.*, 1996)

Three studies performed the measurements at

a standardised walking speed imposed by means of a metronome (Hirokawa *et al.*, 1990; Petrofsky and Smith, 1991; Beillot *et al.*, 1996). All other studies have measured walking performance at a self-selected speed.

The majority of the authors have used some *statistical test* in order to conclude whether differences can be considered significant. Most tests include parametric or non-parametric paired tests and the results are reported in terms of p-values. Two publications have used confidence intervals (IJzerman *et al.*, 1997^a; IJzerman *et al.*, 1997^b). None of the authors has determined the actual statistical power of their study if a test failed to show significance.

Table 3 presents the actual data and the differences between the orthoses which were compared in the selected study including the results of the statistical tests.

Post hoc statistical power analysis was performed if the study revealed non significant results. *Post hoc* statistical power calculations in a within subject comparison (A-B) can only be calculated accurately if the mean and standard deviation of the differences are available. Since only four authors presented a standard deviation of the differences, statistical power analysis could only be conducted for those particular studies. *Post hoc* statistical power analysis showed that statistical power was only between 9% and 47% (Table 3).

Based on the actual data for these 4 studies in Table 3 it is possible to calculate a statistical power curve in which the statistical power can be estimated if the sample size is increased. Figure 1a and Figure 1b present the statistical power curve with (theoretical) increase in statistical power as a function of the sample size while using the data from the 4 studies in Table 3. Assuming that a statistical power of approximately 80% is acceptable, it can be concluded that the minimum number of subjects to be included in the comparative trial of Sykes *et al.* (1996) is 10.

Discussion

Internal validity, statistical conclusion validity and external validity are considered to be the important aspects of study design. In the remaining part of this paper, each of these items will be discussed with reference to the literature which is surveyed in the previous section.

Table 3. Summary of the results for main outcome measures oxygen uptake (V_{O_2}) and walking speed (v). Actual statistical power is reported in the last column if mean difference (δ) and standard deviation (σ) of the differences were available.

	Standard orthosis	New orthosis	Difference in V_{O_2} ($\delta(\sigma)/p$ -value)	Power	Standard orthosis	New orthosis	Difference in v ($\delta(\sigma)/p$ -value)	Power
Hirokawa <i>et al.</i> , 1990			16% (?)/?		–	–	–	
Sykes <i>et al.</i> , 1996	2.32 (0.83)	2.57 (0.67)	-0.25 (0.24) / $p < 0.08^2$	43%	0.225(0.10)	0.247 (0.12)	0.022 (0.02) / $p < 0.07^2$	47%
Petrofsky and Smith, 1991			? (?) / $p < 0.01$		–	–	–	
Thoumi <i>et al.</i> , 1995					0.21 (0.02)	0.20 (0.02)	0.01 (?) / NS	
Beillot <i>et al.</i> , 1996	0.73 (0.16)	0.86 (0.16)	-0.13 (?) / NS		–	–	–	
Winchester <i>et al.</i> , 1993	14.2 (1.8)	13.0 (1.4)	1.2 (?) / NS		0.211 (0.03)	0.225 (0.04)	-0.014 (?) / NS	
Whittle and Cochrane, 1989	618 (?)	593 (?)	25 (?) / NS		0.24 (?)	0.23 (?)	0.01 (?) / NS	
Lotta <i>et al.</i> , 1994	–	–	–		1. RGO: 0.243 (0.09) 2. HGO: 0.119(0.14) 3. ARGO: 0.186 (0.1)		1-2: $p = 0.029$ 2-3: $p = 0.022$	
McClelland <i>et al.</i> , 1987	–	–	–		15.5 (4.24)	18.1 (4.49)	-2.55 (0.91) / $p < 0.55^2$	
Nene and Patrick, 1990	2.59 (0.25)	2.50 (0.35)	0.09 (0.17) / $p < 0.31^2$	15%	0.233 (0.03)	0.24 (0.04)	-0.007 (0.02) / $p < 0.53^2$	9%
IJzerman <i>et al.</i> , 1997 ^a	18.0 (3.2)	17.2 (3.1)	0.8 (1.1) / [-0.36, 1.96] ¹	31%	0.24 (0.11)	0.23 (0.13)	0.01 (0.03) / [-0.028, 0.045] ¹	9%
IJzerman <i>et al.</i> , 1997 ^b	16.9 (3.6)	17.9 (3.2)	-1.0 (2.51) / [-4.1, 2.14] ¹	11%	0.246 (0.11)	0.274 (0.1)	-0.028 (0.03) / [-0.06, 0.005] ¹	36%

¹ Confidence intervals as presented in IJzerman *et al.*, 1997^a and 1997^b were transformed to absolute data rather than the relative difference with respect to ARGO. ² Significance calculated using presented data and paired t-test.

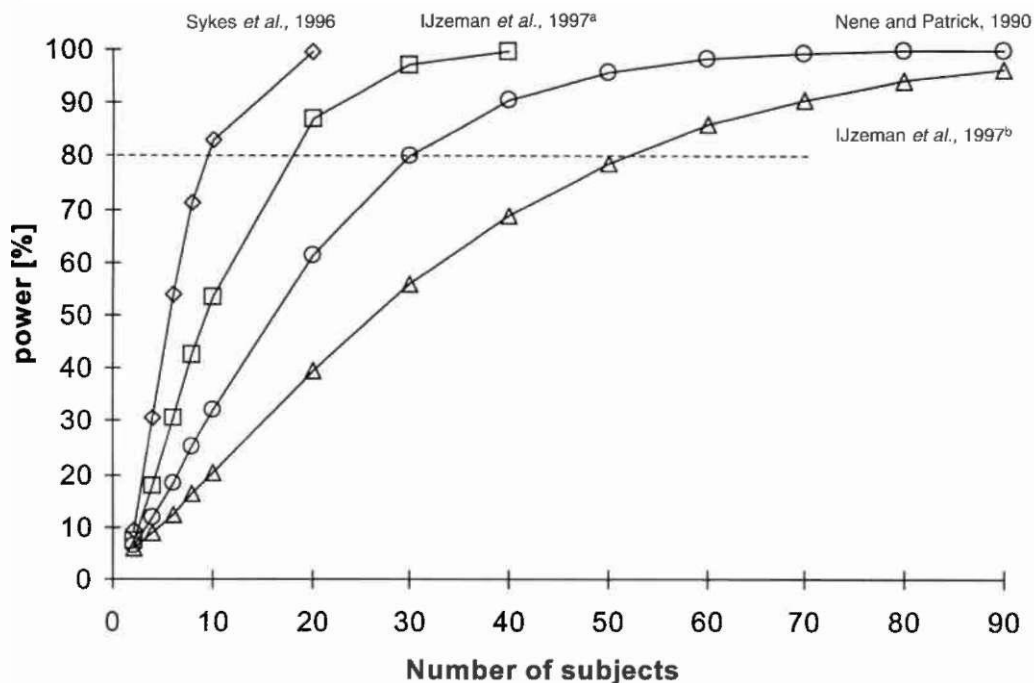


Fig. 1. (a) Statistical power of four studies (see Table 4 for actual statistical power) to detect a difference in V_{O_2} between two walking systems. The statistical power curve represents the theoretical increase in statistical power as a function of the sample size. The statistical power is calculated with the data of the indicated study and does not provide insight into the statistical power of a new trial. The data of Nene and Patrick (1990) and Sykes *et al.* (1996) were expressed in $J \cdot \text{min}^{-1} \cdot \text{kg}^{-1}$. These data were converted using the correction factor as presented in their articles.

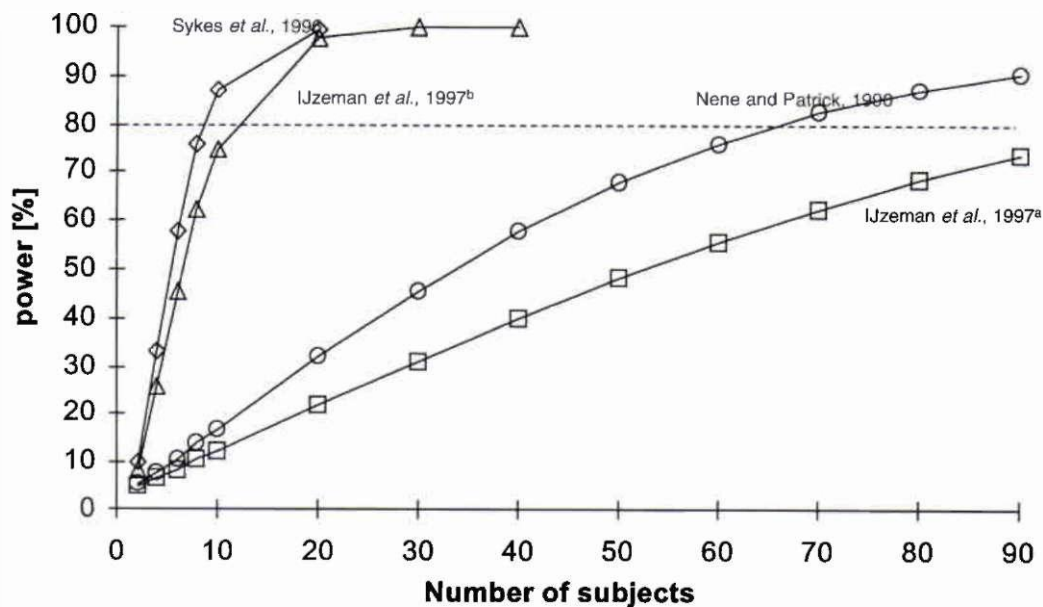


Fig. 1. (b) Statistical power curves calculated using the data of walking speed in four comparative studies. See for further explanation the text and the legends of Figure 1a.

Internal validity

Eleven (11) out of 12 studies were within patient comparisons, and one study was a between patient comparison. One major issue in judging the internal validity of parallel group trials is the baseline comparability of study groups (Meinert, 1986; Feinstein, 1985). Using randomisation an attempt is made in order to obtain baseline comparability with respect to relevant prognostic factors. However, Lotta *et al.* (1994) have not conducted a randomised controlled trial and baseline incomparability is present in their study. They allowed each of the participating centres to define their own selection criteria for each of the orthoses and subsequently, each centre executed their own training. As a result, HGO walkers (selected in only one centre) underwent less gait training than other patients in competing systems. Although Lotta *et al.* (1994) have noted that their data were not reliable, it must additionally be concluded that this comparative trial between HGO, RGO and ARGO to be internally invalid.

In judging the internal validity of a clinical trial, the trial should have acknowledged that there are specific and aspecific parts of a treatment, i.e. difference between orthoses. A control group provides a means with which the aspecific parts of the difference can be assessed. Any clinical trial which is conducted without such a control group is considered internally invalid beforehand, as the actual difference in the study between orthoses may be caused by various aspecific factors.

Aspecific effects which may be present in an A-B comparison of two orthoses are measurement errors, test-effects, history effects and regression to the mean (Cook and Campbell, 1979). *Test effects* comprise all differences which are caused by repeated use of the same testing procedures (Cook and Campbell, 1979). *History effects* are aspecific effects, caused in the period preceding the second measurement. For instance, if training in a new orthosis is conducted in between measurements, the difference can be partly explained by the level of experience with walking in general.

In a repeated measurement, a coincidental extreme (high or low) value in the first ("A") measurement is likely to be followed ("B" assessment) by a value closer to the mean. The magnitude of this regression to the mean depends on the reproducibility of the test-retest differences

(Feinstein, 1985; Cook and Campbell, 1979).

Since the seven publications which have used a simple before-after comparison did not consider the need to control for these aspecific effects which may cause a difference, they lack internal validity. The observed differences comprise specific as well as aspecific parts.

Randomisation of the measurement sequence as performed by Winchester *et al.* (1993) and Beillot *et al.* (1996) might be a solution to average out the aspecific effects. However, if randomisation of the phase order is proposed, it is more appropriate to conduct a cross-over trial which essentially offers all possibilities to control and adjust systematic differences (period-effects) and thus enhances internal validity (Senn, 1993; Pocock, 1983).

Statistical conclusion validity

Statistical power

Only two studies have reported statistically significant results. Petrofsky and Smith (1991) reported a significant decrease in V_{O_2} (normalised for walking distance) during the 1 mile walking test ($p < 0.01$) but, except for a graph, they have not presented an average effect size. Lotta *et al.* (1994) presented significant differences between RGO - HGO and ARGO - HGO, but it is argued in a previous section that this study was internally invalid due to confounding by indication. Further analysis of the data of McClelland *et al.* (1987) showed a significant increase in walking speed in the hybrid Hip Guidance Orthosis.

Interpretation of the p-values of the other studies included in this survey implies that there is no statistical evidence of a difference. Statistical power ($1 - \beta$) could only be calculated in 4 "negative" trials and appeared to be between 10 and 50%. Although actual statistical power could not be calculated for the other trials, it is expected that, with the small differences in those studies, the statistical power will not exceed 50%. Assuming that statistical power should be between 80 and 90% (Lachin, 1981; Dupont and Plummer, 1990; Carpenter, 1993), it is evident that all comparative trials lack statistical power and have an unacceptably high risk of type II errors.

Interval estimation

A number of authors have acknowledged that p-values are often erroneously interpreted as evidence of a difference, but that they do not

give insight into the effect size which may be clinically relevant. (Altman and Bland, 1995; Carpenter, 1993; Barnard, 1990; Freeman, 1993; Rothman, 1986; Bulpitt, 1987). Instead, estimation of effect sizes by means of confidence intervals are favoured since they convey a summary of the original data in original units of measurement (Gardner and Altman, 1986; Rothman, 1986; Borenstein; 1994; Smith and Bates, 1992; Bulpitt, 1987).

Interval estimation has been recommended to enhance the interpretation of statistically non-significant trials in particular (Smith and Bates, 1992; Borenstein, 1994). Whereas calculation of statistical power in such "negative" trials can sometimes be misleading, a confidence interval conveys more information required to conclude whether there was sufficient statistical power to detect clinically relevant differences (Smith and Bates, 1992).

Figures 2a and 2b display 95% confidence intervals for the difference in V_{O_2} and walking speed between two walking systems (see Table 3 for the actual data). A proper interpretation of this 95% CI is that out of 100 replicated studies, 95 will find a mean difference within this interval (Bulpitt, 1987).

The 95% CI for the mean difference in V_{O_2} in the study of IJzerman *et al.* (1997^a) suggests that V_{O_2} is higher in the orthosis without reciprocal cable (95% CI [-2, 11%]). Though this study had insufficient statistical power (31%), it is concluded that this confidence interval provides sufficient information in order to conclude that no clinically relevant differences in favour of the orthosis without reciprocal cable can be expected. This clinically relevant difference was set at 20% in this study, since removing such reciprocal cable linkage results in a highly uncomfortable standing posture.

Sykes *et al.* (1996) found an increased walking speed in the RGO+FES of 10% on average (95% CI [-21%, 1%]). Replication of this study in a different group of patients may result in either a clinically relevant (-21%) or a difference which is negligible (1%). The same interpretation holds for the confidence intervals in most other studies. In these studies, more precision is required in order to conclude meaningful differences.

External validity

Two aspects are relevant in judging the external validity of a study, i.e. the target

population of which the study population is selected and the selection criteria which are applied in order to obtain the actual study population.

In clinical studies on walking systems for people with paraplegia, the target population is considered to be "all people with paraplegia who may be appointed for prescription of a walking system".

Five studies have included patients who had no previous walking experience (Hirokawa *et al.*, 1990; Thoumie *et al.*, 1995; Beillot *et al.*, 1996; Whittle and Cochrane, 1989; Lotta *et al.*, 1994) and the other six studies (Sykes *et al.*, 1996; Winchester *et al.*, 1993; McClelland *et al.*, 1987; Nene and Patrick, 1990; IJzerman *et al.*, 1997^a; IJzerman *et al.*, 1997^b) have included subjects who already had experience with walking. Whereas the study population of the first five studies may be a representative sample of the previously defined target population, the study population of the latter six studies is in no case a representative sample. People who already have experience with walking and agree to participate in a new clinical trial are very motivated and do not represent the target population. As a consequence, external validity of at least the latter six studies is limited.

In order to obtain an internally valid study with sufficient precision, the study population is often restricted to a homogeneous population which is most likely to benefit from the orthosis. It is often not clear which selection criteria are applied to the study population. This may be explained by the fact that there are very few subjects available and that the use of narrow selection criteria will diminish the actual study population to zero.

For instance, all surveyed studies have included patients with low (T10-T12) and high thoracic lesions (T1 - T4) and none of the studies has used level of lesion as an inclusion criterion. This means that the study sample of the studies is heterogeneous. IJzerman *et al.* (1997^a) reported a study in which level of lesion caused heterogeneity of effects. Two patients with low lesions had considerably lower walking speeds in the orthosis without reciprocating cable linkage, whereas four patients with T9-T12 lesions walked faster in that orthosis. Such heterogeneity in effect results in low statistical power if group analysis is performed. However, sub-group analysis is often not feasible, as the limited number of patients per sub-group

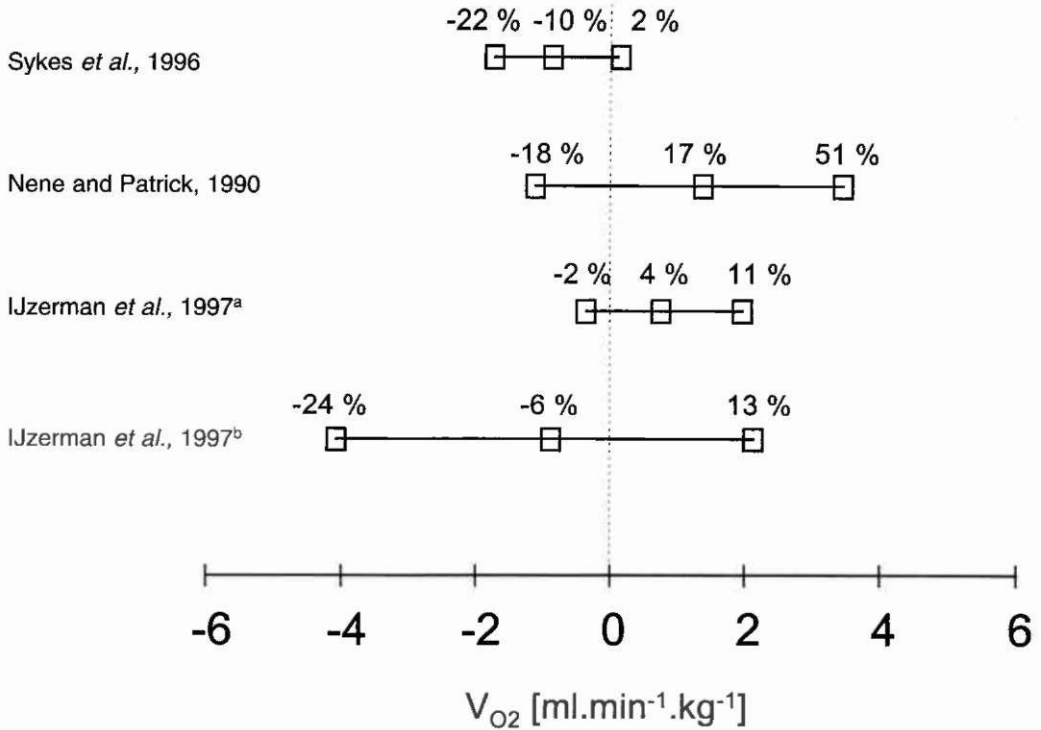


Fig. 2. (a) Estimation of difference in V_{O_2} between two walking systems by means of 95% confidence intervals. The confidence intervals are calculated with the data as given in the indicated study. Confidence interval in expressed as absolute difference (x-axis). Relative differences with respect to the standard orthosis are presented on top of each interval. The data of Nene and Patrick (1990) and Sykes *et al.* (1996) were expressed in $J \cdot \text{min}^{-1} \cdot \text{kg}^{-1}$. These data were converted using the correction factor as presented in their articles.

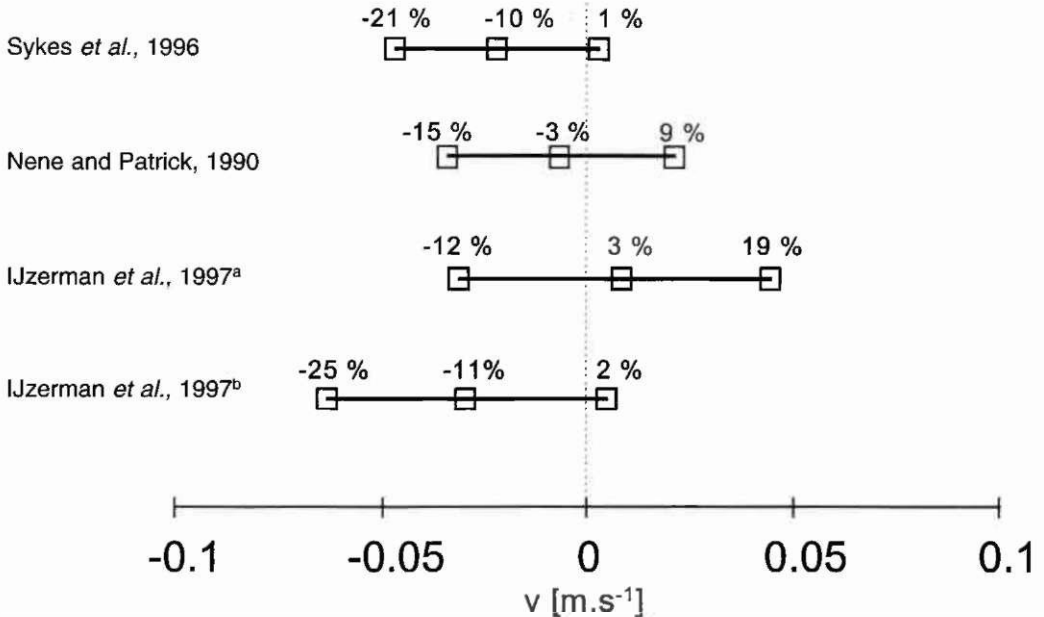


Fig. 2. (b) Estimation of difference in walking speed between two walking systems by means of 95% confidence intervals. See for further explanation the text and the caption of Figure 2a.

reduces statistical power. In general, restriction of the study population to a homogeneous group will enhance study efficiency, provided that sufficient patients can be included (Kleinbaum *et al.*, 1988; Pocock, 1983; Meinert, 1986).

One argument against restrictive selection is that it may prevent generalisation of the results to the target population (Bailey, 1994; Cook and Campbell, 1979). However, lack of generalisation in studies with a very narrow population is not always a problem. It might well be possible to generalise results achieved in a small sub-group to a target population if a plausible explanation can be given (Davis, 1994). For instance, Lehman and Stonebridge (1978) have concluded that an intelligent knee unlocking system will not be viable during paraplegic walking because of the low walking speed. Though the patients in that particular study had low level lesions, the results may also be generalised to high level paraplegics, since their walking speed is, in general, lower.

Conclusions and recommendations

Most of the studies which were included in this survey have conducted a simple within subject comparison without randomisation of the order. These designs are considered internally invalid as they do not provide the possibility to control for aspecific treatment effects. Randomisation of the measurement order, which ultimately provides a cross-over design, is considered essential in order to improve the internal validity as the aspecific effects (period-effects) can be controlled.

All studies lack statistical power due to the small sample sizes and the heterogeneity of the study population. While interval estimation may improve interpretation of (statistically) negative trials, it appeared that there still was insufficient precision to conclude whether the differences were clinically relevant. Two recommendations can be put forward, viz. include more patients and apply relevant inclusion and exclusion criteria in order to obtain a more homogeneous study sample. Though restriction of the study population prevents generalisation, it is far more important to conduct a trial which is internally valid and provides precise estimates of the differences.

Different alternatives can be advocated if it appears impossible to include more patients, including multi-centre trials, statistical pooling

of different small studies (i.e. meta-analysis) and other methodological approaches.

Though different methodological approaches should not be considered as a first choice, interrupted time series may offer some advantages. In an interrupted time series, which is essentially an extension of the AB/BA cross-over design, one obtains more statistical power because repeated measurements of the same subject are included in the analysis (Wagenaar, 1990). Moreover, because the analysis is performed on a single subject, heterogeneity of the study population is no longer affecting the statistical power.

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Technical note

Mechanical efficacy of the mobilising cervical support device (Mbrace)

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Abstract

This study evaluated the mechanical efficacy of a new "mobilising" cervical support device. This device has been developed in response to the requirements of whiplash patients to overcome the problems of heat and immobilisation which can occur in patients wearing conventional wrap-around cervical collars.

All planes of cervical range of motion of 21 volunteer subjects without current or past cervical dysfunction were measured actively and passively under two conditions (no support and with cervical support) using the cervical range of motion (CROM) instrument.

The results show that the mobilising cervical support device restricts hyperextension effectively while allowing substantial movement in other planes of motion (flexion, rotation and lateral bending). This potential mobility keeps nearly all muscles in the neck fit and problems of muscle atrophy, weakness and contraction, which can occur in patients using conventional cervical wrap around collars, can be avoided.

Regarding mechanical efficacy, the mobilising cervical support device can be useful in the (early) mobilisation phase in patients needing gentle neck support after a soft tissue hyperextension or whiplash injury.

Introduction

Recently, a cervical support device (Mbrace), especially designed for patients with a soft tissue hyperextension injury or a soft tissue whiplash associated disorder (WAD), has been introduced

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in the Netherlands. This cervical device differs from a conventional "wrap-around" cervical collar due to its "open" form, mechanical function and (front) fastening system (Fig 1).

The purpose of the cervical support device in patients with a soft tissue WAD is to provide gentle neck support, to eliminate a hyperextension re-injury and to offer substantial mobility in order to avoid the harmful affect of disuse. Up to now, the mechanical efficacy of this so called "mobilising" cervical support device has not been demonstrated. It was the authors' goal to evaluate the mechanically restrictive effect of this device in normal healthy volunteers.



Fig 1. The mobilising cervical support device.

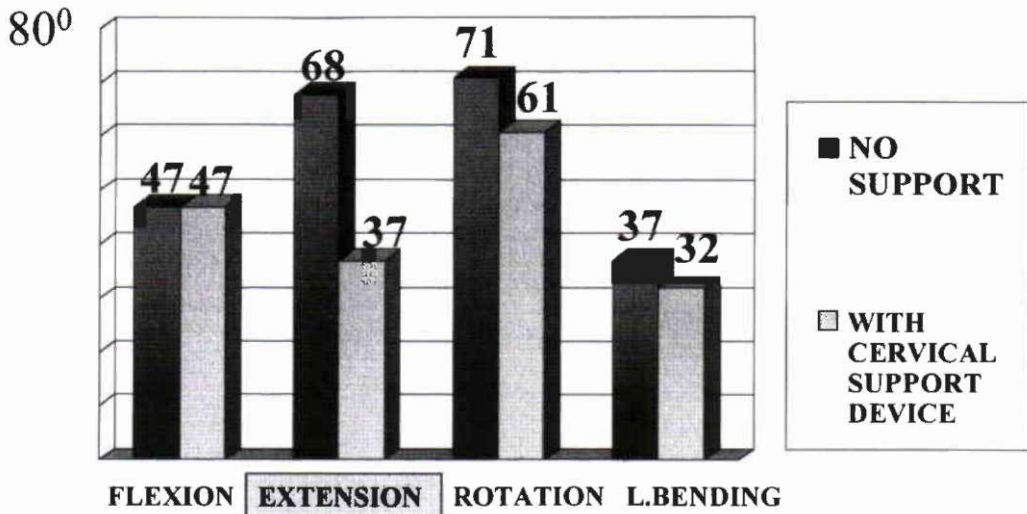


Fig 2. The mechanical efficacy of the device (active).

Material and methods

Twenty one (21) volunteer subjects (age range 15-61 years, mean age 36 years) with no history of neck abnormality were tested for neck range of motion (overall motion) using the CROM instrument. This instrument allows the collection of reliable three-dimensional motion information on the head and neck (Capuano-Pucci *et al.*, 1991). The thorax was fixed in a high chair that blocks shoulder and thoracic motion. An appropriate support (small, medium or large) was applied and properly fixed. Each volunteer was tested in and out of the cervical support device in three planes of motion. The following motion parameters were measured by the same examiner: 1) flexion, 2) extension, 3) axial rotation, and 4) lateral bending.

The maximum possible range of motion was tested using passive and active methods. For the passive test the volunteer allowed the tester to move the head and neck through the maximum range of motions without resisting. For the active tests, the volunteer was instructed to move head and neck as far as possible in all planes of motion.

The results were recorded as degrees of motion. Average range of motion using passive and active methods was then calculated for the group. The standard deviation for the four directions of motion was measured. Statistical analysis using the paired *t*-test was undertaken to assess statistical significant motion reduction.

Results

The mobilising cervical support device was fixed properly for optimal efficacy. Average unrestrained passive and active extension was respectively 70.8 ± 9.6 and 67.9 ± 9.6 (mean \pm standard deviation). Restrained passive and active extension was 40.9 ± 6.1 and 36.7 ± 6.6 .

The average reduction in motion was 29.9 ± 9.1 and 31.2 ± 9.9 . Both passive and active extension was significantly restricted by the open collar ($p < 0.05$).

Flexion, rotation and lateral bending (active and passive) were not substantially restricted.

The data are plotted in Figures 2 and 3, giving an indication of the efficacy of the mobilising cervical support device in restricting extension in normal force conditions. The performance of the device under substantial force application has not been evaluated in this study.

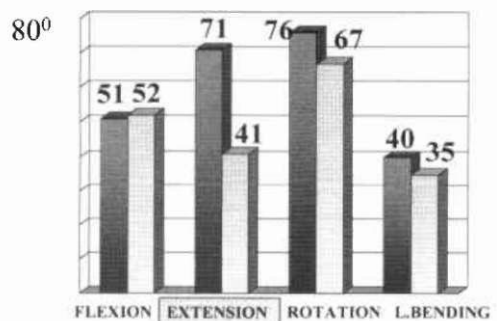


Fig 3. The mechanical efficacy of the device (passive).

Discussion

Cervical collars are often prescribed in the treatment of neck disorders of both traumatic and non-traumatic aetiology (Johnson *et al.*, 1977; Sandler *et al.*, 1996). A traumatic neck disorder that frequently occurs after a rear-end car collision is "whiplash". This term, becoming so general in contemporary society, is often described as a non-contact acceleration/deceleration injury of the neck. Although no consensus about the exact patho-physiological mechanism of whiplash exists it is postulated that hyperextension plays an important role in soft tissue damage (McKenzie and Williams 1971; MacNab, 1964). The injury frequently causes myofascial soft tissue damage with stretching and bruising of the muscles and supporting ligaments of the neck (Newman, 1990). Most neck pain developing shortly after the accident is due to myofascial soft tissue injury (Newman, 1990; Gargan and Bannister, 1990; Yeung, 1996). In many cases the patient experiences pain within a few minutes that increases progressively and is markedly aggravated by movements, especially in (hyper)extension. Consequently, patients with such an injury usually require neck support to relieve pain and to allow soft tissue healing. To provide this support, "immobilising" cervical wrap-around collars are frequently recommended.

There are a variety of cervical wrap-around collars available. Their continued widespread usage would suggest a beneficial effect. In a study on surgical collars, Naylor and Mulley (1991) found that pain was a symptom that frequently improved by wearing a soft or hard (firm) cervical collar. However, hard wrap-around collars were frequently found uncomfortable and tended to cause various problems and difficulty in daily life. Whilst soft collars were better tolerated than hard collars and caused less interference to daily activities, they were frequently found uncomfortable, too hot and irritating. Putting a wrap-around cervical collar on and fastening it at the back of the neck was sometimes also a problem, especially in patients with rheumatoid arthritis.

A well known side effect in the use of immobilising collars is that muscle atrophy, weakness and contraction may result from the use of these collars due to reduced muscular activity. In this context, previous studies show

that cervical spine immobilisation after a whiplash-type distortion gives rise to prolonged symptoms whereas more rapid improvement can be achieved by early active management and early (home) mobilisation (McKinney, 1989; McKinney *et al.*, 1989; Mealy *et al.*, 1986). Furthermore, it has recently been observed that the outcome is better for patients who are encouraged to continue their normal, pre-injury activities as usual than for patients who take sick leave from work and are immobilised in the early phase after the neck sprain injury (Borchgrevink *et al.*, 1998).

The goals of cervical bracing vary according to the patient's problem. In the (sub)acute treatment of a myofascial soft tissue WAD, the goals may be simply to provide gentle neck support, eliminate painful hyperextension and lower the risk of re-injury. In addition, one of the key aims in the treatment of soft tissue lesions is to encourage the damaged tissue to regain tensile strength as rapidly as possible (Hunter, 1994). In this study we evaluated the mechanical efficacy of a new device that is especially developed to fulfil these goals and most importantly to overcome the problems due to immobilisation. The shortcoming of the study is that the motions described are probably greater than those experienced by patients treated with the cervical support device. Nevertheless, testing on healthy individuals seems to be the best method of quantifying the ability of a cervical device to restrict cervical motion (Sharpe *et al.*, 1995).

The findings in this study indicate that the mobilising cervical support device is competent in limiting extension of the cervical spine, while allowing substantial movement in other planes of motion in normal force conditions. This implies that, regarding mechanical efficacy, this device can be useful in patients needing neck support in the (early) phase after a myofascial soft tissue WAD or a soft tissue hyperextension injury as it potentially can keep most neck muscles active and prevents hyperextension with possible re-injury. Future research should address clinical effectiveness of the cervical support device in these patients.

Due to the specific mechanical efficacy of this device one can probably use it in the prevention of a hyperextension or whiplash injury. In this context, it is possible that the neck support is capable of preventing or minimising a cervical soft tissue injury as a result of the

hyperextension mechanism in car collisions. However, further studies are needed to show the performance of the device under substantial applied forces.

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Book Review

Therapy for Amputees

B. Engstrom, C. Van de Ven (Editors)

Harcourt Brace, UK, 1999

pp 376, illustrated

ISSN 0-443-05975-6

Price: £29.50

Therapy for Amputees is the third edition of a text originally published in 1985 entitled "Physiotherapy for Amputees: the Roehampton Approach" and written by Engstrom and Van de Ven. (The second edition was published in 1993). This new edition is edited by the two original authors and includes the contributions of 11 other professionals. These contributors work either at the Nuffield Orthopaedic Centre, Oxford or Queen Mary's Hospital, Roehampton, London, and their contribution is reflected in the change of title.

The original book was intended for qualified and student physiotherapists working with amputees in both the United Kingdom (UK) and overseas. The new edition is intended for all those who work with amputees, specially qualified physiotherapists and students, occupational therapists and assistants and other health care professionals who make up the multidisciplinary clinical team. The new edition is in hard back, has three extra chapters and is 43 pages longer. The style of the publication has also changed to the division of the page in two columns as with other current Churchill Livingstone texts.

The bibliography/references for the new edition are given in a section at the end of the chapter and the references for the previous editions are given separately also at the end of each chapter. These many reference sources, although given at the end of each chapter, are rarely referenced within the text which is normal practice. Personally I feel this is an oversight by the authors and publishers in today's climate of evidence-based medicine/healthcare and intellectual copyright. This style does not help students and qualified practitioners use the

original source of the reference themselves and can lead to misinterpretation in many cases.

The new edition has updated the 'main workings of the book' in the practical approach, techniques, equipment and current healthcare organisational practice. Terminology encompasses 1999 practice (i.e. limb fitting vs prosthetic centre) and the functional activity and outcomes of rehabilitation with this group of individuals is more apparent. This edition also incorporates topics seen in other recent texts on this subject area such as psychological aspects of amputation.

A new chapter entitled 'Sport and leisure', is welcomed and reflects integration of disabled people, both young and old, into society and which is reiterated in Chapter 22 'User involvement'. The chapter 'Multiple pathology and complex cases' updates the previous chapter 'Special cases' and is well illustrated and covers both cases involving adults and children. Another new chapter also reflects current healthcare 'A different perspective: the importance of user involvement' and is written by a well respected healthcare professional and UK healthcare manager. Also the additional chapter 'Therapy service quality' gives an overview to the current National Health Service (NHS) practice of evidence-based practice (previously applied to practice as research findings), standards, audit, and quality improvement tools. Information on other English speaking countries' experience of care pathways for this group of patients would have been useful as examples for the UK audience. Many references for further investigation are given and the publications from the main two UK professional groups targeted by the book, are given.

Appendix 2 (1989) attributed to Nelham, Nichols and Pope is a checklist for complex disability cases requiring wheelchairs. Few of these would be people with amputations. This appendix also discusses the design features of modern lightweight wheelchairs but the special

problems of cushioning for these users is missing from this edition, especially for those individuals with bilateral transfemoral amputations.

This is a welcomed new edition which will be

useful to all those working in this area of clinical practice.

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Whizz-Kidz
London, UK.

Calendar of Events

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

Courses for Physicians, Surgeons and Therapists

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

Courses for Orthotists and Therapists

- NC224 Hand Trauma; 18 February, 2000

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

6- 8 January, 2000

International Conference on Rehabilitation Medicine, New Delhi, India.

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

13-14 January, 2000

14th Annual National Conference of the Orthotics and Prosthetics Society of India, Mumbai, India.

Information: OPSI Secretariat, c/o All India Institute of Physical Medicine and Rehabilitation, Haji Ali Park, Mahalaxmi, Mumbai 400 034, India.

1-4 March, 2000

ISPO Latin American Multidisciplinary Rehabilitation Congress, Curacao.

Information: ISPO Caribbean, Mauritslaan 8, Emmastad, Curacao, Neth. Antilles. Fax: (+599) 9 737 5985

15-18 March, 2000

American Academy of Orthotists and Prosthetists Annual Meeting, San Diego, USA.

Information: Diane Ragusa, AOPA, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

15-19 March, 2000

American Academy of Orthopaedic Surgeons Annual Meeting, Orlando, USA.

Information: AAOS, 6300 North River Road, Suite 727, Rosemont, IL 60018, USA.

24-26 March, 2000

6th Annual Conference of the British Association of Prosthetists and Orthotists, Glasgow, Scotland.
Information: Secretariat, BAPO, Sir James Clark Building, Abbey Mill Business Centre, Paisley PA1 1TJ, Scotland.

9-13 April, 2000

27th Annual Meeting of the International Society for the Study of the Lumbar Spine, Adelaide, Australia.

Information: Dr Marek Szpalski, Secretary, International Society for the Study of the Lumbar Spine, Sunnybrook Health Science Centre, Room MG 323, 2075 Bayview Avenue, Toronto, Canada M4N 3M5.

14-16 April, 2000

19th Southern Biomedical Engineering Conference, Virginia, USA.

Information: Carrie Sustarich, Virginia Tech, Dept. of Chemical Engineering, 133 Randolph Hall, Blacksburg, Virginia 24061, USA.

14-16 April, 2000

Scientific Meeting of the American Spinal Injury Association, Chicago, USA.

Information: Lesley M Hudson, Clinical Meeting Co-ordinator, ASIA, 2020 Peachtree Road, NW Atlanta GA 30309, USA.

1-4 May, 2000

Annual Meeting of the Pediatric Orthopaedic Society of North America, Vancouver, Canada.

Information: POSNA, 6300 North River Road, Suite 727, Rosemont, IL 60018, USA.

14-18 May, 2000

ISPO Course on Lower Limb Amputation Surgery and Related Prosthetics: Compound Fractures, Half Way House, RSA.

Information: J. Ginsberg, 8 Rosebank Medical and Dental Centre, 11 Sturdee Av., Rosebank 2196, Republic of South Africa.

30 May-2 June, 2000

Orthopaedie and Reha-Technik World Congress, Leipzig, Germany.

Information: BIV, Postfach 10 06 51, D-44006 Dortmund, Germany.

1 June -31 October, 2000

Health Futures, Expo 2000, Hanover, Germany.

Information: Ms. Monika Gehner, Office of the Director, Division of Health Promotion, Education and Communication, World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland.

2-3 June, 2000

Spinal Injury: New Horizons Conference, London, England.

Information: Spinal Injury: New Horizons, c/o The Event Organisation Company, 8 Cotswold Mews, Battersea Square, London, SW11 3RA, England.

7-10 June, 2000

50th Congress of the Nordic Orthopaedic Federation, Tampere, Finland.

Information: NOF 2000 K-Building, Room 307, Medical School, University of Tampere, PO Box 607, FI-33101 Tampere, Finland.

23-27 July, 2000

Joint Meeting of the North American Spine Society and the Japanese Spine Research Society, Hawaii.
Information: The North American Spine Society, 6300 North River Road, Suite 500, Rosemont, IL 60018-4231, USA.

23-28 July, 2000

World Congress on Medical Physics and Biomedical Engineering, Chicago, USA.
Information: Willis J Tompkins, Chicago 2000 Organising Committee, University of Wisconsin, Dept. of Elec. & Comp. Engineering, 1415 Engineering Drive, Madison, WI 53706-1691, USA.

21-30 August, 2000

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

27-30 August, 2000

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

4-7 September, 2000

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

5-7 September, 2000

46th Annual Scientific Conference of the American Paraplegia Society, Las Vegas USA.
Information: APS, 75-20 Astoria Boulevard Jackson Heights, NY 11370-1177, USA.

3-7 October, 2000

American Orthotic and Prosthetic Association Annual Assembly, Washington, USA.
Information: Diane Ragusa, AOPA, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

5-7 October, 2000

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

6-7 October, 2000

ISPO (UK) Annual Scientific Meeting, Grantham, England, UK.
Information: Mr Bill Spence, Bioengineering Unit, Wolfson Centre, University of Strathclyde, 106 Rottenrow, Glasgow G4 0NG, Scotland, UK.

2001**1-5 July, 2001**

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

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