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Editorial

In the 1970s the World Health Organisation (WHO) introduced a new approach to disability prevention and rehabilitation known as Community-Based Rehabilitation. Its aim was to provide rehabilitation services to all people with disabilities whether they are rich or poor or whether they live in a city or in the countryside. Although this approach can be used in every country in the world it is of particular relevance in low-income countries where rehabilitation services are mostly based in the major centres of population.

This approach involves measures taken at community level to use and to build upon the resources of the community as well as making use of the services offered at district and central institutions. Thus, through community-based rehabilitation, the provision of rehabilitation services is based on a three-tiered referral system consisting of a basic home and community level; an intermediate support level (provided by the district); and a specialised service level offered centrally.

The supporting personnel of the specialised service level at the central institution and the intermediate support level at the district institution are the professionals which one would expect to be working in the rehabilitation services. The supporting personnel at the community level, however, are a new type of professional. They are likely to be local persons with minimal conventional or specialised education. They are usually referred to as community rehabilitation workers.

The success of such a referral system will be centred on the development of an integrated and coordinated programme with the activities at each level being clearly defined. It will also rest with the development of an educated and trained workforce with the role of the different types of personnel being well defined.

It has been suggested by WHO that about 70% of all rehabilitation can be carried out in the disabled persons' own community, however, about 30% of disabled persons have to be referred to other rehabilitation services outside their own community. Amongst this group are found those people requiring prostheses and orthoses. This is due to the fact that it is not realistic to believe that prosthetic and orthotic devices of an acceptable quality can be made in every single community within a country. This means that for the successful, widespread provision of prosthetics and orthotics services there should be a strong relationship between these services and community-based rehabilitation programmes.

With regard to the provision of prosthetics and orthotics services, ISPO has gone some way in defining the job descriptions and educational requirements for the different categories of professionals directly involved in this field, that is, prosthetist/orthotists (Category I), orthopaedic technologists (Category II) and prosthetics/orthotics technicians (Category III). Some consideration needs to be given with respect to the use of these categories of professionals in WHO's three-tier referral system and, in particular, to the role and training of the community rehabilitation worker in prosthetics and orthotics.

It is important to bear in mind that the community rehabilitation worker is neither a prosthetist/orthotist nor an orthopaedic technologist and will not be expected to fit prostheses or orthoses. He/she will have a wide responsibility in many different aspects of rehabilitation of which prosthetics and orthotics is only one. The role of the community rehabilitation worker in prosthetics and orthotics will include:

- acting as a link between the disabled person and the prosthetics and orthotics services;
- referring persons with disabilities to the intermediate support level or the specialised service level;
- assisting with the rehabilitation of the disabled person and adaptation to the environment;
- providing or arranging for simple maintenance and repairs to prosthetic and orthotic devices;
- providing information to intermediate support level with regard to disabilities found, numbers, and the acceptance and use of devices;
- helping persons with disabilities reintegrate into society.

It is important that ISPO becomes involved in developing the role of the community rehabilitation workers and preparing guidelines for education and training to prepare them for the specific prosthetics and orthotics aspects of their job. It is the intention of the Executive Board of ISPO to pursue this matter as a matter of priority.

Norman A. Jacobs
President

Three measures of functional outcome for lower limb amputees: a retrospective review

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Abstract

Outcome measures are becoming increasingly important in health care. Functional outcome measures are of particular importance for lower limb amputees since much of the rehabilitation process is concerned with increasing mobility and personal independence.

The Scottish Physiotherapy Amputee Research Group (SPARG) has used three measures of functional outcome: the Barthel Index, Russek's classification and the Locomotor Index. The review reported here involves 938 patients having a primary amputation at the transtibial or transfemoral level between October 1992 and July 1997. Differences in function due to age and level of amputation are well known clinically and the measures were compared by looking at their ability to detect these differences.

The Barthel Index lacked sensitivity because of ceiling effects and should not be considered as a suitable functional outcome measure for amputee patients. Russek's classification does detect significant differences but requires a large number of patients making it unsuitable for single hospital investigations. The Locomotor Index demonstrates significant differences due to age and amputation level despite fewer patients being assessed by this measure during the period covered by this paper. The range of the Locomotor Index can be extended to cover more active amputees by considering its 'advanced activities' subscale separately.

The Locomotor Index is a promising measure

and should be considered by rehabilitation teams looking for a valid, reliable and sensitive functional outcome measure for use with lower limb amputees.

Introduction

Clinicians involved in the rehabilitation of lower limb amputees increasingly need to use outcome measures to demonstrate that they are providing a clinically effective service. Functional assessment measures are of particular importance for this group of patients since much of the rehabilitation process is associated with improving mobility and personal independence.

Recognising that physiotherapy is a central component of all amputee rehabilitation programmes, the Scottish Physiotherapy Amputee Research Group (SPARG) was established in 1991 to evaluate current physiotherapy practice concerning the management of amputees and to disseminate the results (see *Physiotherapy* 79, p.649). The group comprises every senior physiotherapist in Scotland (population approximately 5.5 million) with a clinical responsibility for amputee patients; at present, 26 physiotherapists fall into this category. In addition, SPARG has members representing the British Association of Chartered Physiotherapists in Amputee Rehabilitation, the British Association of Prosthetists and Orthotists and the David Murray Foundation (a Scottish charitable organisation working with amputees). SPARG also works closely with the Scottish Vascular Audit Group whose membership comprises all consultant vascular surgeons in Scotland and with the Information and Statistics Division at the Scottish Office Department of Health.

One of SPARG's core activities is to conduct

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a regular, nationwide audit of the rehabilitation care received by lower limb amputees in Scotland (Condie *et al.*, 1996). The audit is based around a document known as a Discharge Summary Form (DSF) and custom software that allows data collected on the DSFs to be stored and subsequently analysed. The DSF was first used in October 1992 and a DSF is now completed for virtually all lower limb amputees in Scotland. Physiotherapists at ten amputating hospitals use the custom software to enter and analyse their own data. Other hospitals return their DSFs to the SPARG Coordinator where they are dealt with centrally. Analysis for the whole of Scotland is done by merging each hospital's data into a single database.

As part of this audit work, SPARG has attempted to measure the functional abilities of lower limb amputees at the time of discharge from hospital by including a functional assessment section on the DSF. This would provide an additional, standardised outcome by which to compare the rehabilitation programmes in use throughout Scotland. Since 1992, SPARG has used three outcome measures: the Barthel Index (Kullman, 1987; Mahoney and Barthel, 1965), Russek's classification (Kullman, 1987; Russek, 1961) and the 'Locomotor Index' part of the Prosthetic Profile for Amputees (Gauthier-Gagnon and Grisé, 1994; Grisé *et al.*, 1993). None of these measures was used for the whole period covered by this paper (1/10/92 - 31/7/97). The Barthel Index was used between 1/10/92 and 30/9/95, Russek's classification between 1/10/92 and 30/4/97 and the Locomotor Index from 1/10/96 onwards. As is clear from these dates, the functional assessment section of the DSF generally contained two measures. Completing the functional assessment part of the DSF took the physiotherapist less than five minutes.

The Barthel Index was originally developed as a means of assessing the level of independence in patients with neuromuscular or musculoskeletal disorders. It consists of ten items, each of which is rated in terms of whether the patient is able to perform a particular task independently (see Appendix, Table A1). Scores for the ten items are summed to give an overall score out of 100. The validity of the Barthel Index is well documented (Shah and Cooper, 1993) and the Index has also been found to be reliable (Collin *et al.*, 1988). Although not

developed for amputees, some authors (Kullman, 1987; Goldberg, 1984) have used the Barthel Index with this group of patients and found it to be a useful indicator of functional abilities and rehabilitation outcome. Further, the Barthel Index is widely used and the Royal College of Physicians (1992) and others (Wade and Collin, 1988; Shah and Cooper, 1993) recommend its use as a 'gold standard' for measuring rehabilitation outcomes. For these reasons, and because some SPARG members had used Barthel with elderly (non-amputee) patients, SPARG chose the Barthel Index as one of its functional outcome measures in 1992.

The Russek's classification, unlike the Barthel Index, was developed for use with lower limb amputees. It is a six-point scale (see Appendix, Table A2) used to assess a patient's functional abilities when using his/her prosthesis. A score of six is awarded when the prosthesis provides full restoration of function and a score of one means that the prosthesis offers no advantage to the patient. In addition to the basic six-point scale, Kullman (1987) used the positive and negative factors concerning the patient, the stump and the prosthesis listed by Russek (1961) in his original publication. The number of positive and negative factors was used to correlate walking ability (as measured by the six-point scale) with prognosis prior to receiving the prosthesis. Russek found, for example, that the presence of one negative factor usually decreased walking ability by one point on the scale. SPARG, however, was not concerned *per se* with prognosis at admission, but in assessing in a simple way functional abilities at discharge and so used only the six-point scale. Altner *et al.* (1980), for example, used Russek's classification in this way to assess the pre- and post-amputation functional abilities of blind lower limb amputees.

To the best of the authors' knowledge, there is no published work concerning the validity and reliability of Russek's classification. However, Kullman (1987) considered Russek's classification, to be a useful method of evaluating an amputee's walking abilities and, because of this, SPARG considered it worthwhile to try this measure with amputee patients in Scotland.

The Locomotor Index is part of a more detailed assessment measure known as the Prosthetic Profile for Amputees (PPA)

developed by Gauthier-Gagnon and colleagues at the University of Montreal (Gauthier-Gagnon and Grisé, 1994; Grisé *et al.*, 1993). The Locomotor Index is a self-standing 14 point measure with each item on the scale scored from zero to three according to the patient's degree of independence in performing a given activity (see Appendix, Table A3). This scoring system gives a minimum score of zero and a maximum score of 42. The index can be divided into two seven-point subscales covering basic and advanced activities. Gauthier-Gagnon *et al.* (1993) found these subscales to be clinically useful with the advanced subscale discriminating between the least and most able amputees (Gauthier-Gagnon, 1995, personal communication). The authors of the PPA have demonstrated that the measure has face and construct validity and strong test-retest agreements show the measure also to be reliable (Gauthier-Gagnon and Grisé, 1994; Grisé *et al.*, 1993).

SPARG now uses only the Locomotor Index. The aim of this paper is to review its experiences of these three measures and to explain why SPARG would now recommend the Locomotor Index as the only one of these measures that should be considered an appropriate measure of functional outcome for lower limb amputees.

Methodology

Data collected on amputees who had an amputation between 1/10/92 and 30/7/97 were reviewed. The patient group considered in this paper comprises a subgroup of 938 unilateral amputees who had an amputation at either the transtibial (74%) or transfemoral (26%) level, were fitted with a prosthesis and had their functional abilities assessed using at least one of the Barthel Index, Russek's classification or the Locomotor Index. There were 573 men and 346 women. The sex of the remaining 19 patients was not recorded but these patients are included

in the analysis since patients were not subdivided by sex. The mean age was 67 with a standard deviation of 15 years; 78% of patients were 60 or over. The dominant aetiology was peripheral vascular disease which accounted for 87% of patients, increasing to 92% for patients over 40. A third of patients with peripheral vascular disease were also recorded as being diabetic. The remaining amputations resulted from trauma (5%), tumours (2%), congenital deformities (1%) and various other causes including infection (5%).

A total of 546 patients were assessed using the Barthel Index, 772 using Russek's classification and 195 using the Locomotor Index. The different numbers of patients assessed using the three measures simply reflects the different time periods for which the measures were in use. Basic details of patients assessed using each of the three measures are given in Table 1. Many patients appear twice in Table 1 because Russek's classification was used, at different times, together with the Barthel Index and the Locomotor Index. Of the 546 Barthel Index patients, 514 were also assessed using Russek's classification while 61 of the Locomotor Index patients were also assessed using Russek's classification.

The three measures are compared here using two *a priori* predictions. Firstly, younger amputees should score significantly higher than older amputees and, secondly, transtibial amputees should score significantly higher than transfemoral amputees. The consensus view of SPARG is that a measure demonstrating both of these results is a better measure than one that does not.

Results

Summaries of median scores on the Barthel Index, Russek's classification and Locomotor Index are given in Tables 2-4. The Mann-

Table 1. Basic details of patients assessed using the Barthel Index, Russek's classification and the Locomotor Index.
PVD = peripheral vascular disease.

Patients assessed using:	Barthel Index	Russek's	Locomotor Index
Number of patients	546	772	195
% PVD	56	57	58
% diabetic + PVD	32	31	27
% transtibial	71	72	85
% male	64	62	66
Average age	66	67	67

Table 2. Median Barthel Index scores achieved by transtibial (TT) and transfemoral (TF) amputees. Amputees have been compared by level (TT v TF) and by age (e.g. TT \leq 40 v TT>40). CI = confidence interval.

	median	95% CI	n
TT	95	90 - 95	387
TF	95	90 - 100	159
TT v TF	p = 0.35		
Score by age: TT			
\leq 40	100	100 - 100	24
>40	95	90 - 95	360
TT \leq 40 v TT>40	p < 0.007		
Score by age: TF			
\leq 40	100	95 - 100	11
>40	95	95 - 100	146
TF \leq 40 v TF>40	p = 0.21		

Table 3. Median Russek's classification scores achieved by transtibial (TT) and transfemoral (TF) amputees. Amputees have been compared by level (TT v TF) and by age (eg. TT \leq 40 v TT>40). CI = confidence interval.

	median	95% CI	n
TT	4	4 - 4	554
TF	3	3 - 3	218
TT v TF	p < 0.001		
Score by age: TT			
\leq 40	5	5 - 5	35
>40	4	3 - 4	519
TT \leq 40 v TT>40	p < 0.001		
Score by age: TF			
\leq 40	5	4 - 5	17
>40	3	3 - 3	201
TF \leq 40 v TF>40	p < 0.001		

Table 4. Median Locomotor Index scores achieved by transtibial (TT) and transfemoral (TF) amputees. Amputees have been compared by level (TT v TF) and by age (TT \leq 40 v TT>40). There were too few young transfemoral amputees for a meaningful comparison of median scores for the two age groups. CI = confidence interval.

	median	95% CI	n
TT	34	31 - 35	166
TF	24	17 - 28	29
TT v TF	p = 0.002		
Score by age: TT			
\leq 40	42	40 - 42	13
>40	33	28 - 34	152
TT \leq 40 v TT>40	p < 0.001		

Whitney test has been used for significance testing as all three measures are ordinal making parametric tests inappropriate. Only the Barthel Index does not show a significant difference in median score between transtibial and transfemoral amputees. Younger (40 years old) was chosen as the cutoff; transtibial amputees score significantly higher ($p < 0.001$) than older

amputees for all three measures. Russek's classification also demonstrates a significant difference ($p < 0.001$) in median score due to age for transfemoral amputees. Unfortunately, there were too few (four) transfemoral amputees below the age of 40 assessed using the Locomotor Index and a meaningful comparison of median scores for the two age groups was not possible.

Table 5 compares median scores achieved using the full Locomotor Index with scores achieved using only the advanced activities subscale. The advanced activity subscale appears to provide the same level of sensitivity as the full Index but with median values that represent a smaller proportion of the maximum score, i.e. ceiling effects appear to be reduced. The basic activities subscale (data not shown) also shows significant differences due to age and level when considered separately but the median values obtained from this subscale represent a higher proportion of the maximum score. For example, the median basic activities score for the transtibial amputees included in Table 4 is 19 or 90% of the maximum score.

Discussion

Functional outcome measures should be valid, reliable and unidimensional (Tennant and Young, 1997). In addition to these psychometric and measurement properties, a clinically useful functional outcome measure should reflect clinical experience. A functional outcome measure for use with lower limb amputees should, at the very least, demonstrate a statistically significant difference in the scores obtained by patients who have been subdivided by age and level of amputation. A measure that does not show that transtibial amputees have more functional capacity on average than transfemoral amputees must be considered dubious since clinical observation shows that there is a very real difference. The same is true of young and old amputees. Ideally, the measure should also have a good range such that floor and ceiling effects do not adversely affect the responsiveness of the measure. Only after these basic criteria have been met can the measure be

used to investigate less obvious, and perhaps speculative, causes of variation in, functional outcome.

The Barthel Index is standardised, valid and reliable but lacks sensitivity when used with amputee patients. The data presented in Table 2 do not show a significant difference in median Barthel score between transtibial and transfemoral amputees. Further, the very high median scores are an indication that ceiling effects (i.e. a predominance of maximum scores in some items) are a significant problem. The ability of the Barthel to respond to clinically important change has been questioned by other authors (Ashburn *et al.*, 1993; Simpson and Forster, 1993; Smith, 1993) with the mobility and transfer sections receiving particular criticism. These two sections are arguably the most important for amputees as these patients generally have few problems with feeding, grooming and toileting. The feeding and grooming sections of the Index highlight the major shortcoming of the Barthel when used with amputees: it asks the wrong questions. Amputees uniformly score very high on these questions which greatly reduces the measure's sensitivity. These problems make the Barthel Index completely inappropriate for use as a functional outcome measure with lower limb amputees and SPARG stopped using it in 1995.

Russek's classification, unlike the Barthel, does show significant differences between patients of different age and level of amputation (Table 3). While these results would seem to be encouraging, the Russek's six-point scale means that large numbers of patients are required to show these differences. Annual studies conducted by SPARG (Condie *et al.*, 1996; Treweek and Condie, 1996) have generally

Table 5. Comparison of median scores achieved using the full Locomotor Index with scores achieved using only the advanced activities subscale. Amputees have been compared by level (TT v TF) and by age (TT \leq 40 v TT>40). CI = confidence interval.

	Whole locomotor index		Advanced subscale	
	median	% max score	medium	% max score
TT	34	81	14.5	69
TF	24	57	9	43
TT v TF	p = 0.002		p = 0.009	
Score by age: TT				
\leq 40	42	100	21	100
>40	33	76	13	62
TT \leq 40 v TT>40	p = 0.001		p = 0.001	

failed to replicate the results seen in Table 3. The number of patients assessed via the Russek's classification in these annual studies was around 330 which does not appear to be enough for differences due to level of amputation to reach significance. The situation for a single hospital conducting a local study of functional outcome is even worse since the number of primary lower limb amputees per year is often less than 30. The effect of age is, however, clear and has been seen in previous work (Trewick and Condie, 1996). The poor sensitivity of Russek's classification led SPARG to stop using it in 1997.

The Locomotor Index (Table 4) demonstrates significant differences due to age (for transtibial amputees) and level of amputation despite the much smaller number of patients that have currently been assessed using this measure. It is also likely that the Locomotor Index would have shown significant differences due to age with transfemoral amputees had more of these patients been available for assessment. These results suggest that the Locomotor Index is more sensitive than both the Barthel and Russek's classification. There is, however, a tendency for the median values to be at the higher end of the Locomotor Index's scale, the most striking example of this being the median score for young transtibial amputees. The original authors of the Locomotor Index calculated mean scores and obtained similar values to the medians presented here: mean Locomotor Index score of 30.7 (out of a possible 42) for 396 amputees of mixed amputation level (Gauthier-Gagnon, 1995, personal communication). Their mean score for the advanced activity subscale was 13.0 out of a possible 21.

By considering the advanced activity subscale separately, it is possible to reduce the median value as a proportion of the maximum score without losing sensitivity. This extends the use of the Locomotor Index to more active, but elderly, amputees although no improvement is seen for younger active amputees. Perhaps it is too much to expect the same functional outcome measure to be suitable for a fit, 25 year old traumatic amputee and a 75 year old amputee with peripheral vascular disease and diabetes. Although the seven-point advanced activities subscale gives similar results to the full 14-point Locomotor Index, the temptation to drop the seven items of the basic activities subscale

should be resisted since only the full measure has been validated. The use of the complete measure is the approach recommended by the original authors and should be used until the subscales are found to be valid and reliable when used alone.

Conclusion

SPARG has gained a great deal of experience with functional outcome measures during the five year period covered by this paper. Had SPARG the benefit of this experience in 1992, the Barthel Index and Russek's classification would not have been chosen as functional outcome measures. The Barthel Index has very poor sensitivity and although Russek's classification does demonstrate significant differences due to age and level of amputation, this six-point scale requires a large number of patients to achieve this. Differences in functional outcome having more subtle explanations than age and level of amputation are likely to require even more patients. Conversely, the Locomotor Index gives significant results for smaller numbers of patients and the advanced activities subscale allows the range of the measure to be increased to include some of the more active amputees.

The Locomotor Index is a promising measure of functional outcome for lower limb amputees and this is the only measure SPARG currently uses. A system of post-discharge functional assessment based around the Prosthetic Profile for Amputees and including the Locomotor Index is now being developed. This will allow monitoring of long-term functional ability and raises the prospect of being able to link elements of acute rehabilitation care to long-term functional outcome. This will provide some much needed information about long-term clinical effectiveness and give a more evidence-based foundation to some aspects of amputee rehabilitation.

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Appendix

Table A1. The Barthel Index. Patients unable to do a particular activity score zero for that activity.

	With help	Independent
1 Feeding (if food needs to be cut up = help)	5	10
2 Moving from wheelchair to bed and return (includes sitting up in bed)	5-10	15
3 Personal toilet (wash face, comb hair, shave, clean teeth)	0	5
4 Getting on and off toilet (handling clothes, wipe, flush)	5	10
5 Bathing self	0	5
6 Walking on level surface	10	15
(or if unable to walk, propel wheelchair)	0	5
7 Ascend and descend stairs	5	10
8 Dressing (includes tying shoes, fastening fasteners)	5	10
9 Controlling bowels	5	10
10 Controlling bladder	5	10

Table A2. Russek's classification. Note that some authors choose to reverse the scoring, i.e. 1 = 'Full restoration', 6 = 'Not feasible'.

Score	Characteristics
1	Not feasible (the prosthesis offers no advantage to the patient)
2	Cosmetic plus (only short distances walking indoors, insecurity, discomfort)
3	Self-care minus (help needed in varying degrees-fatigue)
4	Self-care plus (complete independence, job alterations may be necessary, regular activities)
5	Partial restoration (restriction of only certain activities-dancing, sport etc.)
6	Full restoration (not disabled by impairment)

Table A3. The Locomotor Index.

- 1 Get up from a chair
- 2 Pick up an object from the floor when standing*
- 3 Get up from the floor (e.g. if they fell)*
- 4 Walk indoors
- 5 Walk outside on even ground
- 6 Walk outside on uneven ground (e.g. grass, gravel, a slope)*
- 7 Walk outside in bad weather (e.g. rain, snow)*
- 8 Go up the stairs with a hand-rail
- 9 Go down the stairs with a hand-rail
- 10 Step up a kerb
- 11 Step down a kerb
- 12 Go up a few step without a hand-rail*
- 13 Walk down without a hand-rail*
- 14 Walk while carrying an object*

The scale is scored according to whether a patient can perform the activity:

0 = No, 1 = Yes if someone helps,

2 = Yes if someone is near, 3 = Yes alone.

Items marked with a "*" form the advanced activity subscale.

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Properties of the flexible pressure sensor under laboratory conditions simulating the internal environment of the total surface bearing socket

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Abstract

The purpose of this study was to investigate the properties of the flexible pressure sensor under laboratory conditions simulating the internal environment of the total surface bearing (TSB) socket to determine optimal conditions for measuring normal stresses on the stump. The equipment used in the study was the Pressure Distribution Sensor System for Sockets. In a climatic chamber maintained at 37°C and 70% humidity the sensor sheet was mounted on a measuring apparatus loaded with three 10 kg weights, and output from the sensor was recorded. Because of sensor creep, a sample 60 seconds after loading was adopted as the measured output. Output was greater when weight was decreased than when weight was increased because of hysteresis (paired *t*-test, $p < 0.05$). The sensor had temperature sensitivity but differences in output were not statistically significant (paired *t*-test, $0.10 > p > 0.05$). There were no significant differences in output among five sensor sheets or among five sections of four sensor sheets (two-way ANOVA, $p > 0.05$), but repeated loading on the same section of the sensor sheet increased output (two-way ANOVA, $p < 0.05$). Reproducibility and sensitivity distribution of the sensor are considered satisfactory under laboratory conditions, but measurements of rapid and repetitive movements may not be accurate and comparing subtle changes in output from a single sensor is not suitable. The reliability of

the sensor in a clinical setting for measuring normal stresses on the stump with the TSB socket should be examined.

Introduction

The patellar-tendon-bearing (PTB) prosthesis for trans-tibial amputees was developed at the University of California at Berkeley in 1957 (Radcliffe, 1961). Although the PTB socket provides a good fit for many trans-tibial amputees, some complain of excessive pressure on the patellar tendon area, limitation of knee flexion, and skin abrasions (Hachisuka *et al.*, 1995). Possible causes of these problems are that the PTB socket does not serve to suspend the prosthesis from the stump and that weight is borne mainly on an area previously considered insensitive to pressure. To resolve these problems, the total surface bearing (TSB) prosthetic socket (Staats and Hundt, 1987; Fillauer *et al.*, 1989), a type of suction socket in which weight is borne by the entire surface of the stump, has recently been used. Clinical studies have shown that the TSB socket is more comfortable and has less piston movement (Cluitmans *et al.*, 1994; Hachisuka *et al.*, 1998), most likely owing to its interface characteristics.

There are several studies on pressures at the stump-socket interface (Naeff and van Pijkeran, 1980^{ab}; Quesada and Skinner 1991; Williams *et al.*, 1992; Sanders *et al.*, 1992; Sanders *et al.*, 1993), and the localized pressures can be divided into normal stresses perpendicular to the interface and shear stresses in the plane of the interface (Sanders *et al.*, 1992; Sanders *et al.*, 1993). Excessive normal stress can interrupt blood flow (Daly *et al.*, 1976), and shear stresses and normal stresses together can cause intradermal injury or skin abrasions (Sanders *et*

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al., 1992). The authors previously found that the three factors that most affect the user's overall satisfaction with the TSB socket are comfort, ease of swinging prosthesis, and absence of piston movement during walking (Hachisuka *et al.*, 1998). Ease of swinging and piston movement may be related to suspension of the prosthesis, and comfort may be related to appropriate distribution of pressure, that is, low normal stresses on the stump. If this latter relationship could be proved, the comfort of the socket might be more objectively evaluated by measuring pressure distribution on the stump (Krouskop *et al.*, 1987).

Although transducers and strain gauges (Naef and van Pijheren, 1980^{a,b}; Quesada and Skinner, 1991; Williams *et al.*, 1992; Sanders *et al.*, 1992; Sanders *et al.*, 1993) can accurately measure normal pressures and shear stresses, a specially modified socket with spaces or holes for sensors is needed. A thin, flexible pressure sensor sheet, although no more sensitive than force transducers and unable to detect shear stresses, can be placed between the stump and the amputee's own socket and used to measure normal pressures. Such a sensor has already been used to measure foot pressure in patients with diabetes mellitus or other disorders (Lord *et al.*, 1992; Saltzman *et al.*, 1992; Albert and Rinoie, 1994). In the authors' amputation clinic, the sensor has also been used to evaluate pressure distribution on the stump during fitting of the TSB socket in trans-tibial amputees with sensory disturbances on their stump due to diabetic neuropathy and thalamic hemorrhage. However, the reliability of the sensor for measuring pressure on the stump while the TSB socket is worn has not been established. Therefore, in this study the properties of the flexible pressure sensor were investigated under laboratory conditions simulating the internal environment of the TSB socket.

Materials and methods

The Pressure Distribution Sensor System for Sockets, ^{A1} (the original model was F-Scan, and the sensor sheet was improved to increase accuracy and reliability), consists of a flexible pressure sensor sheet connected by a cable to a notebook-type personal computer, ^{B1} with analysis software. The sensor sheets evaluated in this study were 32.5 cm x 17.9 cm in size and 0.15 mm thick. Each polyester sheet

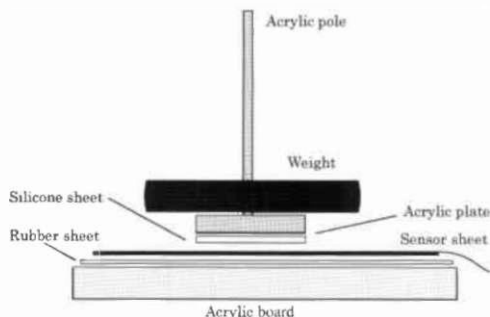


Fig. 1. Lateral view of the apparatus for testing the flexible pressure sensor. The stand for weights is placed on the sensor sheet spread on the rubber sheet covering the acrylic board.

includes a matrix of 144 sensors printed with a silver-based conductive ink. When pressure is applied to the sheet, the resulting decrease in electrical resistance is recorded and analysed with the personal computer. According to the manufacturer's instructions, the sensor can detect pressure in the range of 0.21 to 4.9 N/cm² and is accurate within 5%.

The apparatus for testing the sensor simulated the stump-socket interface (Fig. 1). A 2 mm thick rubber sheet representing the skin was placed on a 10 mm thick acrylic board, and the sensor sheet was spread on the rubber sheet. The stand for the load consisted of a 3 mm thick silicone sheet, representing the silicone inner socket, a 5 mm thick acrylic plate, representing the rigid outer socket, and an acrylic pole attached to the plate with a 6 x 6 cm square base. The stand was placed on the sensor sheet covering a matrix of 36 sensors, and one, two, or three 10 kg weights were mounted on the stand. According to the results of the preliminary study, three 10 kg weights corresponded to the highest pressure on the stump when the TSB socket is worn. Total mass, including the stand, with zero, one, two, and three 10 kg weights was 0.254 kg, 10.760 kg, 21.587 kg, and 32.372 kg, respectively, as measured with a balance ^{C1}.

- ^{A1} Nitta, 8-2-1 Ginza, Chuo-ku, Tokyo, Japan; Pressure Distribution Sensor System for Sockets (the original model was F-Scan, Tekscan Inc., Boston, USA).
- ^{B1} IBM Japan, 3-2-12 Roppongi, Minato-ku, Tokyo, Japan; Thinkpad 370C.
- ^{C1} A and D Co., 2-10-7 Doenzaka, Shibuya-ku, Tokyo, Japan, EP-12KA (0.1 g minimal measurable load).

All experiments were performed in a climatic chamber in which temperature (37°C) and humidity (70%) simulated conditions in the socket when worn (Takami *et al.*, 1985). Before each measurement, the sensor was calibrated with three 10 kg weights.

1. Creep characteristics of the sensor

Creep was defined as the increase in output with time under a given load. After calibration, one weight was mounted on the stand in the centre of the sensor sheet and output from a sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors was obtained at each sampling (two samplings per second) for 180 seconds. After a 5 minute interval, two weights were placed on the stand and were measured, and then three weights were measured after a 5 minute interval.

2. Hysteresis characteristics of the sensor

Hysteresis was defined as the difference in output under a single load between increase and decrease in weight. Five minutes after calibration, no weight was mounted on the stand in the centre of the sensor sheet, and the output 60 seconds after loading was obtained from the sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors. After 2 minutes, one weight was put on the stand and was measured. At 2 minute intervals, two additional single weights were placed on the stand and output was measured. Then, at 2 minute intervals, single weights were removed and output was again measured. This procedure was performed with five different sensor sheets. The hysteresis index was calculated with the following equation: $[\text{output with decrease in weight (g)} - \text{output with increase in weight (g)}] / \text{output with increase in weight (g)} \times 100$.

3. Error of total output

The error of total output was defined as the difference in output between the actual loaded total weight and the measured total output. Five minutes after calibration, one weight was mounted on the stand in the centre of the sensor sheet, and the total output 60 seconds after loading were recorded from a matrix of 36 sensors. After 2 minutes, output was measured with two weights on the stand, then with three

weights. This procedure was performed with five different sensor sheets. The error index was calculated with the following equation: $[\text{output (kg)} - \text{loaded weight (kg)}] / \text{loaded weight (kg)} \times 100$.

4. Reproducibility of a single sensor

Reproducibility was defined as the difference in output when the same weight was loaded repeatedly on the same section of the sensor sheet. After calibration, three weights were mounted on the stand in the centre of the sensor sheet, and the output 60 seconds after loading was obtained from the sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors. The weights were removed, then replaced 2 minutes later, after which output was again measured. This procedure was repeated five times with five different sensor sheets. The reproducibility index was calculated with the following equation: $[\text{maximal output (g/cm}^2\text{)} - \text{minimal output (g/cm}^2\text{)}] / \text{mean output (g/cm}^2\text{)} \times 100$.

5. Sensitivity distribution of a single sensor

The sensitivity distribution was defined as the difference in output when the same weight was loaded on five different sections of the sensor sheet. After calibration, three weights were mounted on the stand and the output 60 seconds after loading were obtained from the sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors. The stand with the weights was placed in turn at the five sections (proximal medial, proximal lateral, central, distal medial, and distal lateral) of four sensor sheets. The sensitivity distribution index was calculated with the following equation: $[\text{maximal output (g/cm}^2\text{)} - \text{minimal output (g/cm}^2\text{)}] / \text{mean output (g/cm}^2\text{)} \times 100$.

6. Temperature characteristics of a single sensor

The temperature characteristics were evaluated, comparing output at 37°C after calibration at 20°C and after calibration at 37°C. According to the manufacturer's instructions, output increases by about 1% with a 1°C increase in temperature. Because the sensor would be placed inside the TSB socket in a clinical setting, it is necessary to examine

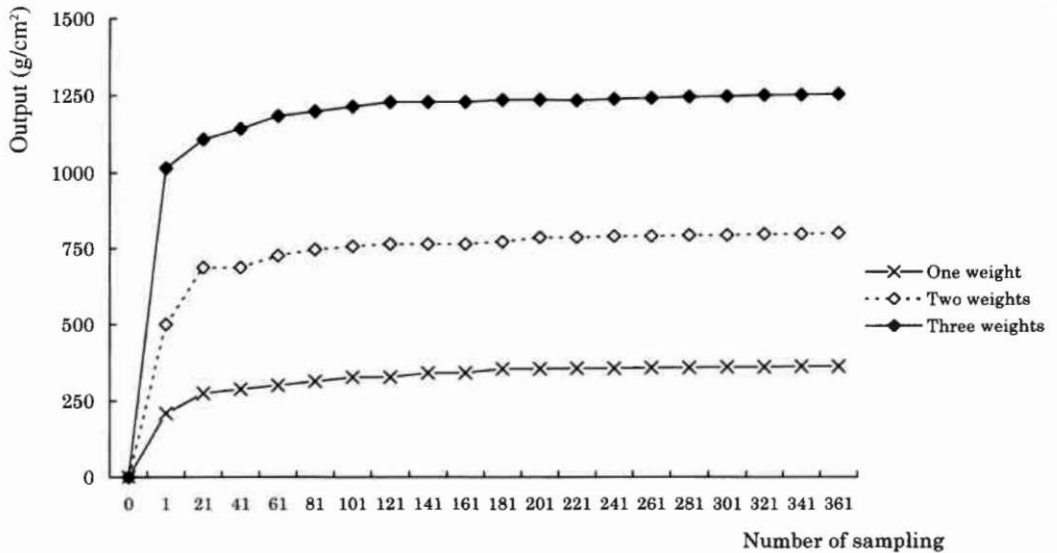


Fig. 2. Creep characteristics of the sensor. Output increased with time but increased only slightly after the 121st sampling. One weight: 10.760 kg, two weights: 21.587 kg, and three weights: 32.372 kg.

whether the sensor reaches body temperature and is calibrated. After the sensor was calibrated with three weights at 20°C, the temperature in the climatic chamber was increased to 37°C and the output with the weights was obtained from the sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors. After the sensor was calibrated again at 37°C, the output was recorded with the same weights at 37°C. This procedure was repeated with five different sensor sheets.

The above data are presented as mean \pm standard deviation, and were analysed with a commercial packaged software^{D)}. The paired *t*-test, *t*-test, and two way analysis of variance (ANOVA) were used to compare hysteresis and temperature characteristics, distribution, and reproducibility and sensitivity. Differences with a *p* value of less than 0.05 were considered significant.

Results

1. Creep characteristics of the sensor

Output increased rapidly until the 61st sampling and then increased gradually. The pattern of output was similar with different weights (Fig. 2). Output was increasing before

the 361st sampling, but the increase in output was slight after the 101st or 121st sampling. Therefore, the output at the 121st sampling (60 seconds after loading) was adopted as the measured output for the following measurements.

2. Hysteresis characteristics of the sensor

Output increased linearly in proportion to the loaded weight; however, output was significantly greater when weights were being

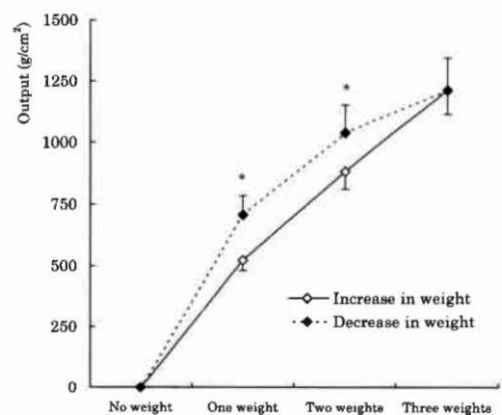


Fig. 3. Hysteresis characteristics of the sensor. Output increased linearly with the loaded weight; however, output was greater when weight was being removed. *:paired *t*-test, *p*<0.05. No weight: 0.254 kg, one weight: 10.760 kg, two weights: 21.587 kg, and three weights: 32.372 kg.

^{D)} SPSS Japan Inc. 2-2-22 Jingumae, Shibuya, Tokyo, Japan; SPSS 6.1J for Windows.

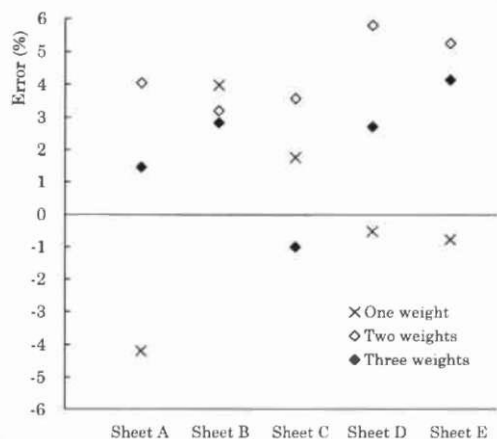


Fig. 4. Error of total output. Error indexes were calculated with the equation $[\text{output (kg)} - \text{loaded weight (kg)}] / \text{loaded weight (kg)} \times 100$, and, except two trials, were within 5%. One weight: 10.760 kg, two weights: 21.587 kg, and three weights: 32.372 kg.

removed (Fig. 3; paired *t*-test, $p < 0.05$). The hysteresis index for one weight ($36.0 \pm 16.8\%$) was significantly greater than that for 2 weights ($6.9 \pm 6.6\%$; paired *t*-test, $p < 0.05$).

3. Error of total output

The error of total output except two trials was within 5% (Fig. 4), and the average absolute error was $3.0 \pm 1.6\%$.

4. Reproducibility of a single sensor

The average output was $1,141.0 \pm 44.2 \text{ g/cm}^2$. No significant difference in output was found among the five sensor sheets, but output increased significantly with consecutive trials

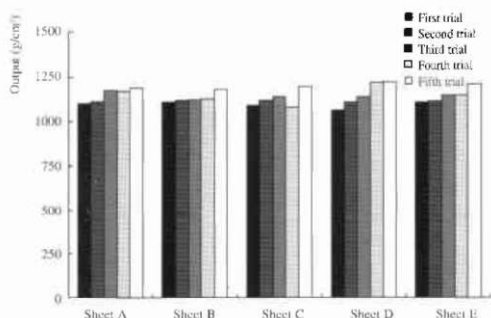


Fig. 5. Reproducibility of a single sensor. Three 10 kg weights were loaded five times in the centre of five sensor sheets. No significant differences in output were found among sensor sheets, but significant differences among trials were found (two-way ANOVA; sheet, $p > 0.05$; trial, $p < 0.05$).

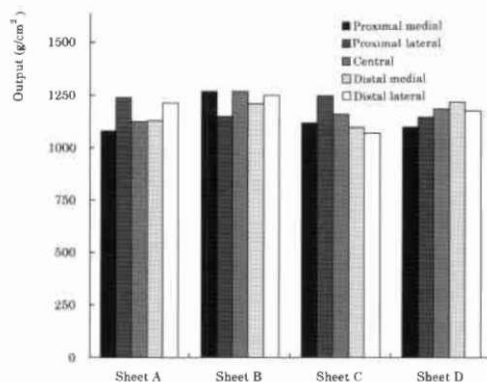


Fig. 6. Sensitivity distribution of a single sensor. Three 10 kg weights were loaded at the five sections of four sensor sheets; no significant differences in output were found (two-way ANOVA; sheet, $p > 0.05$; portion, $p > 0.05$).

(Fig. 5; two-way ANOVA; sheet, $p > 0.05$; trial, $p < 0.05$). The reproducibility index was $9.4 \pm 2.9\%$, indicating that the range of variation fell within 9.4% of the average output.

5. Sensitivity distribution of a single sensor

The average output was $1,174.6 \pm 64.0 \text{ g/cm}^2$, and there was no significant difference in output among the four sensor sheets and five sections of the sensor sheet (Fig. 6; two-way ANOVA; sheet, $p > 0.05$; portion, $p > 0.05$). The sensitivity distribution index was $12.3 \pm 2.9\%$, indicating that the range of variation fell within 12.3% of the average output. The variation in output of different sections of the same sensor sheet tended to be greater than that of repeated measurements in the same section of the sensor sheet, but the difference was not significant (*t*-test, $p < 0.05$).

6. Temperature characteristics of a single sensor

Output after calibration at 20°C was greater than that after calibration at 37°C , but the difference was not significant (Fig. 7; paired *t*-test, $0.10 > p > 0.05$).

Discussion

A flexible pressure sensor would be helpful for measuring normal stresses on the stump because it can be inserted between the stump and socket, and it does not require any modification or remake of the socket. However, before the reliability of the sensor for measuring normal stresses on the stump in a clinical setting is

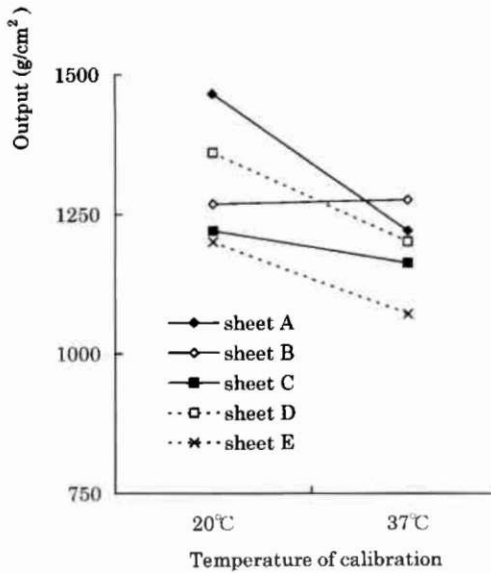


Fig. 7. Temperature characteristics of a single sensor. Calibration at 20°C tended to increase output, but the difference was not significant (paired *t*-test, $0.10 > p > 0.05$).

examined, properties of the sensor should be examined in a laboratory setting. Therefore, a measuring apparatus was devised made of the same materials as the TSB socket, and the properties of the sensor were examined in a climatic chamber simulating the environment inside the socket.

The sensor shows creep characteristics such that output from the sensor increases with time and does not reach a constant value. To improve the accuracy of measurement a sample at a constant time should be adopted as the measured output. Although samples at 30 to 60 seconds after loading may be used, a sample 60 seconds after loading was adopted on the basis of a graph of creep characteristics. The sensor shows hysteresis characteristics, for example, the output of a 21.587 kg load during a decrease in weight is 16.9% greater than that during an increase in weight. In a clinical setting, measurements should be performed from light to heavy loads.

The sensor is sensitive to temperature. When the sensor is used to measure pressure distribution of a socket, calibration at 37°C may be considered appropriate than calibration at a room temperature, considering the internal environment of the socket. However, the differences in output between after calibration at

20°C and at 37°C were not significant because the variation in output possibly reduces the variation due to temperature. Therefore, calibration at room temperature may be acceptable in a clinical setting.

The sensitivity distribution and the reproducibility of the sensor were satisfactory: the output of the sensor varied little among sections of the sensor sheet and among sheets. Although the error of the total output was less than 5% the error of single sensor output was considered more than 5% (\approx sensitivity of the distribution index / 2). When the sensor is used to measure pressure distribution of the socket, the following points must be considered. Repeated loading on the sensor sheet increased output, and the range of variation of output from a single sensor in this laboratory setting was somewhat greater than that described by the manufacturer. This variation may be explained by the sensor's own properties, that is, considerable creep and hysteresis, and the characteristics of the measuring apparatus which was made of viscoelastic materials. In a clinical setting, it is thought that measurements of rapid and repetitive movements, for example, walking and running, is not accurate and that comparing subtle changes in output from a single sensor is not suitable because of the properties of the sensor revealed in a laboratory setting.

For actual measurement of pressures on the stump in a clinical setting, the sensor should be calibrated with three 10 kg weights, although at room temperature. The sensor sheet should be trimmed to fit the contour of the stump and to allow the socket to be put on easily. So that measurements can be made with increasing weight, pressures should be measured first with the amputee standing on the intact foot (unweighted), next on the intact foot and the prosthesis, and finally only on the prosthesis. The output of the sensor should be recorded 60 seconds after loading. However, the variation in output in a clinical setting may be greater than that in a laboratory setting because some errors may arise when a stump with a trimmed sensor sheet is placed in the socket and the sensitivity and reliability of the sensor has not been established under the convex or concave surfaces.

In conclusion, it was found that the Flexible Pressure Sensor System for Sockets measures pressures reliably in a laboratory setting but has

some limitations. In the future, the authors plan to examine whether the sensor can reliably measure normal pressures of the socket in a clinical setting and the related comfort and pressure distribution.

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Conventional patellar-tendon-bearing (PTB) socket/stump interface dynamic pressure distributions recorded during the prosthetic stance phase of gait of a trans-tibial amputee.

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Abstract

Force sensing resistors (FSR) have been used to measure dynamic stump/socket interface pressures during the gait of a trans-tibial amputee. A total of 350 pressure sensor cells were attached to the inner wall of a patellar-tendon-bearing (PTB) socket. Data was sampled at 150 Hz during the approximate 0.8 seconds of prosthetic stance of gait. A total of 42,000 pressures were recorded during a single prosthetic stance. This paper describes the distribution of the pressure patterns monitored during the prosthetic stance phase of gait.

Introduction

Several researchers have reported on stump/socket interface pressures using a limited number of individual transducers. Studies such as those reported by Hulshof (1995) provide accurate pressure data for a particular local site within the socket. An overall impression of the stump/socket pressure distribution is not possible with the type of pressure transducer used by previous investigators.

Inaccuracies have been reported using FSR technology (Cavanagh *et al.*, 1992; Ferguson-Pell and Cardi, 1992; Rose *et al.*, 1992; Schaff 1993; Young 1993; Hayda *et al.*, 1994; Cobb and Claremont 1995; McPoil *et al.*, 1995; Sanders, 1995; Brown *et al.*, 1996; Pitei *et al.*, 1996; Woodburn and Helliwell, 1996). The 0.017 mm thick mylar/resistive ink (9810) F-

socket transducer developed by Tekscan Inc. in Boston provides a stump/socket pressure distribution during gait. The characteristics of this transducer, which incorporates 96 sensor cells, have been previously reported by Buis and Convery (1997).

Method

The transducers were calibrated *in situ*, while attached to the inner socket wall of the trans-tibial socket. The calibration rig, illustrated in Figure 1, consists of a frame, a socket brim

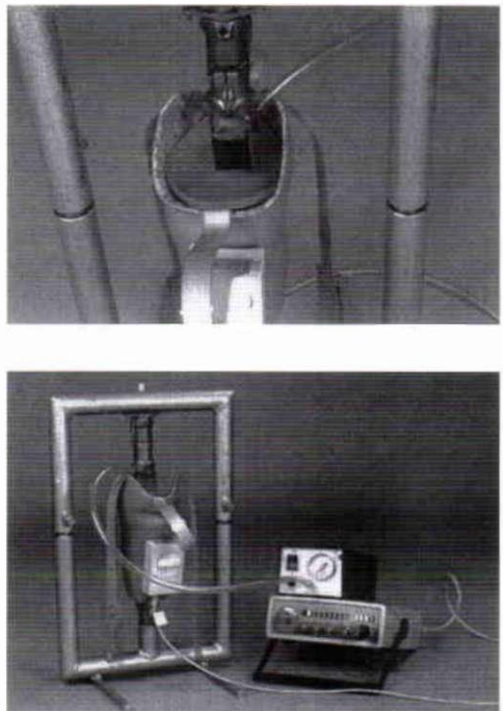


Fig. 1. Transducer calibration

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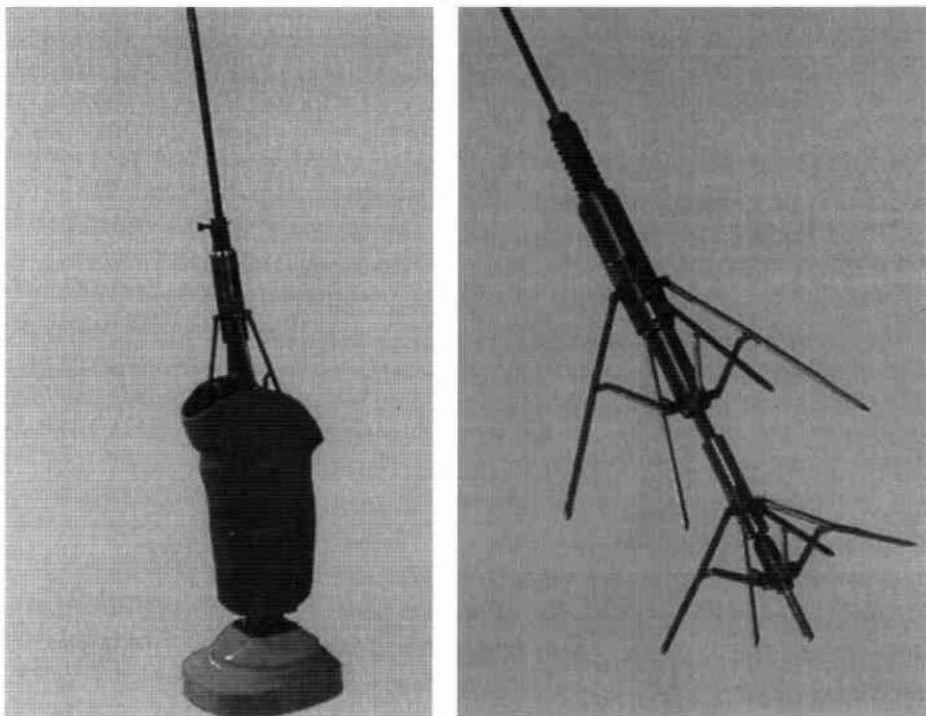


Fig. 2. Socket axis locator

template and a dynamic loading input generator. An accurate pre-selected pressure was applied to the inner socket wall via a pressurised gel filled sheath. The socket was perforated at the bottom to avoid air being trapped between the sheath and the inner socket wall during the loading cycles. By adopting a developed calibration technique and following a strict test protocol, the inaccuracies have been minimized to acceptable levels. When subjected to repeat pressures of 100 kPa the variation of the "average" pressure of a transducer was $\pm 2\%$ with a maximum variation of $\pm 10\%$ for any individual cell in the 96 sensor array.

A patient was fitted with a trans-tibial prosthesis incorporating an acrylic resin laminated PTB socket. The stump was hand cast and rectification of the cast was typical of that practised in the authors' department. The prosthesis was aligned to the satisfaction of the patient and two prosthetists. The alignment was measured using the socket axis locator illustrated in Figure 2. A duplicate prosthesis was fabricated so that the prosthesis which incorporated the transducers was used only during the pressure studies. The alignment,

measured in Figure 2, was duplicated on the instrumented prosthesis. Figure 3 illustrates the alignment of both prostheses. No socket liners were supplied with either prosthesis. A silicone sleeve was supplied for suspension of the prostheses.

A sensor reference grid was established for positioning transducers, using the socket axis locator. Four longitudinal reference lines were used to centre the four transducers.

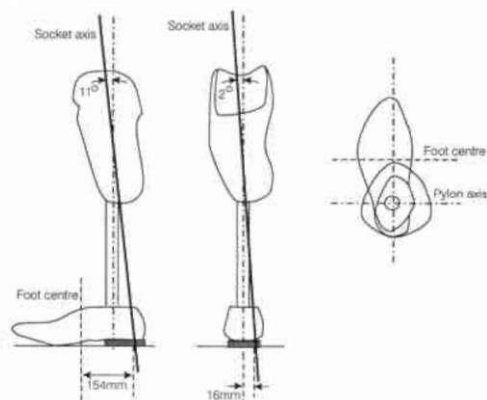


Fig. 3. Alignment of PTB prosthesis,

Circumferential lines using the bottom centre of the socket as a reference were used to locate the four transducers axially. The four transducers, with a total of approximately 350 sensor cells, were attached to the inner socket wall using non-aggressive spray adhesive. Individual cells may be positioned with an accuracy of ± 0.75 mm. The transducers were attached to the anterior, posterior, medial and lateral walls of a trans-tibial socket as shown in Figure 4. The lower posterior socket brim permitted some sensor cells from the posterior transducer to be located at the distal end of the socket.

Initial gait studies investigated the consistency of the subject's walking. This was essential because software limitations dictated that only two transducers per socket could be recorded for a particular walk. In order to obtain an overall pressure distribution using all 4 transducers, pressure data from two similar steps had to be combined. The consistency of the patient's preferred gait, with his existing prosthesis, was verified with respect to walking speed and ground reaction force (GRF). The GRF data was obtained from a force plate located in the middle of a 9 metre walkway. The statistical analysis of

15 walks, with and without a metronome, indicated that the patient demonstrated a very consistent gait with the prescribed PTB prosthesis. The patient's preference for assistance from the metronome supported the recommendation that all pressure study comparisons be undertaken at a pre-determined, metronome assisted, walking speed. This would permit future pressure studies of other socket designs to provide valid comparable data.

A strict test protocol was adopted. The patient was allocated the morning to become accustomed to the non-instrumented prosthesis. The pressure study with the prosthesis incorporating the transducers was undertaken that afternoon. A pre-conditioning sequence of taking approximately 30 steps was adopted before simultaneously recording data of walking velocity, pressure and the force plate outputs. The patient was seated for at least 3 minutes to allow the pressure sensors to recover before repeating the exercise. This procedure was repeated 15 times monitoring the two transducers attached to the anterior/posterior aspects of the socket and then 15 times monitoring the two transducers attached to the medial/lateral aspects of the socket.

Results

The selected Tekscan transducers provided a large amount of pressure data. Three hundred and fifty sensor cells sampling at 150 Hz, for approximately 0.8 seconds of the prosthetic stance of gait, resulted in 42,000 recorded pressure readings during a single step. Interpretation and presentation of the data necessitates a means of viewing all of the data to condense the results in manageable format. Particular instants of the prosthetic stance can then be selected to demonstrate pressure distributions.

Statistical analysis of force plate and pressure data for the 15x2 recorded steps revealed that there was no significant difference in the ground reaction force or the "average" pressure of the transducers. The force plate and walking speed data was reviewed and two particular steps were selected which were considered to be most representative of the patient's average gait. The pressure data from these two selected steps were combined to provide a pressure distribution from all four transducers during a "single" prosthetic stance phase of gait.



Fig. 4. Socket/sensor array.

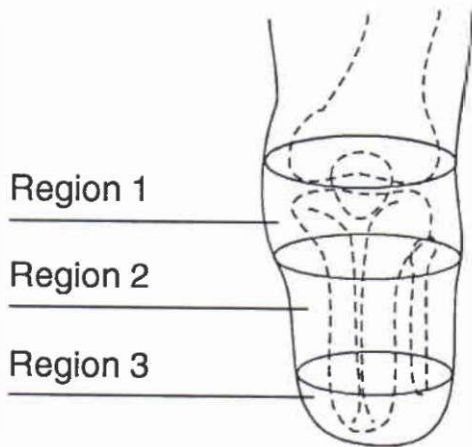


Fig. 5. Stump/socket regions.

This selected pressure and force plate data was used to develop a 3 dimensional computer model of the prosthesis. This 3D computer model permits the observer to view the output from all four transducers and hence the distribution of pressure within the socket. At any instant of gait the pressure distribution may be related to the line of action of the GRF relative to the socket.

Three axial regions within the socket may be identified, as illustrated in Figure 5. Figure 6 illustrates the typical pressure distribution of all 4 transducers displayed in a 2D configuration. The anterior, medial, posterior and lateral pressure data results are illustrated, from left to right, during an instant shortly after mid-stance. Due to the tapering of the distal socket, the medially and laterally positioned transducers have been pruned. The posterior transducer has also been pruned to accommodate the sensor cells which measure distal end bearing. During gait, some areas within the physical boundary of the transducers may be displayed in "white". The white scale merely indicates that the pressures experienced in these areas are below the minimum measurable threshold of 4 kPa. This does not imply that there is no contact between the stump tissue and socket wall in these regions.

Figure 6 demonstrates how the pressure distribution may be represented. The illustrated pressure distributions will vary throughout the stance phase of gait. A sample rate of 150 Hz for 0.8 seconds provides a total of 120 pressure distribution patterns throughout prosthetic stance.

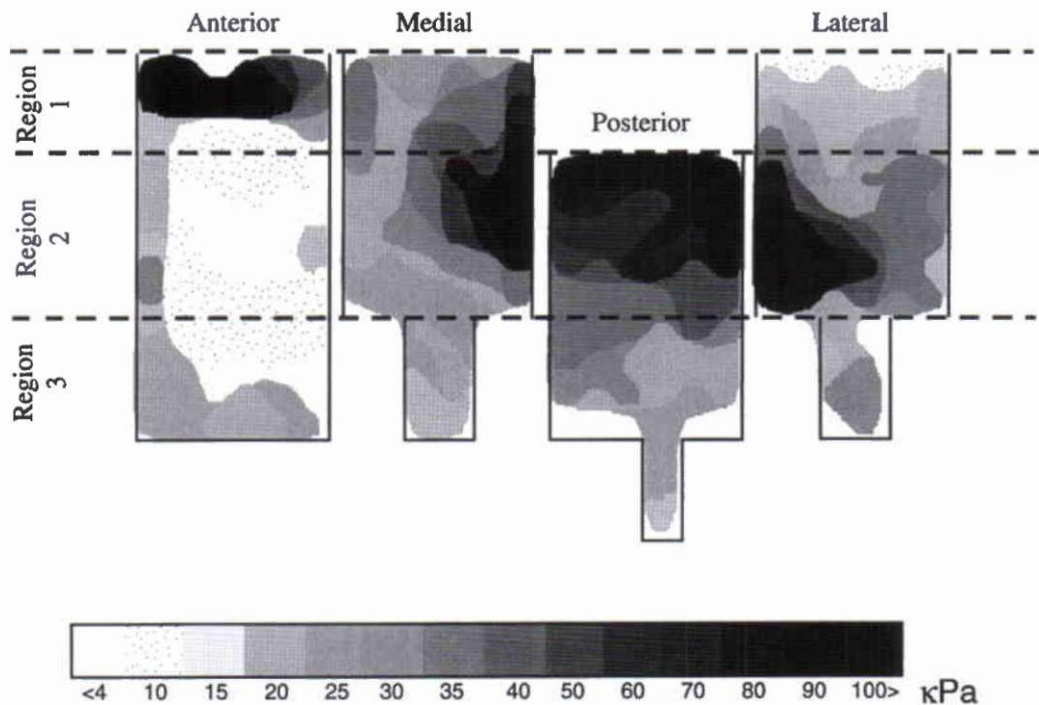


Fig. 6. Stump/socket interface pressure distribution at mid-stance.

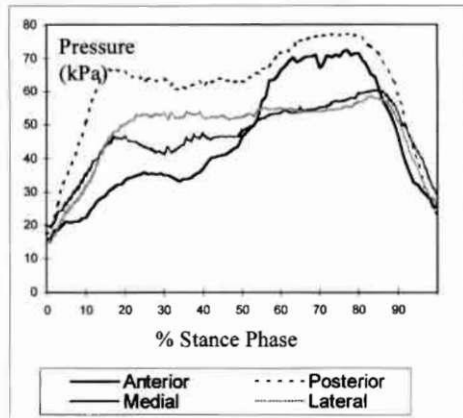


Fig. 7. "Average" pressure per transducer during prosthetic stance.

Figure 7 illustrates the variation of the "average" pressure of each of the four transducers during the stance phase of gait. However the "average" pressure reflects the mean of approximately 96 sensor cells and therefore peak pressures within the sensor array are concealed when average values are used.

Discussion

The pressure pattern (Figs. 6 and 7) will be influenced by the relationship of the line of action of the GRF to the socket during the stance phase of gait. Throughout the prosthetic stance phase of gait the line of action of the GRF always passed ahead of the socket, for this particular patient. This is not typical of trans-tibial gait.

A distinct pressure pattern was demonstrated. A ring of pressure at the patella bar level in the PTB socket was noted with no major distal end pressure. Using Tekscan software, four specific socket areas that experienced pressures in excess of 100 kPa were identified. These four areas were the patellar bar (PTB), the proximal popliteal (PP) area, the posterior medial flare (PMF) and the fibula head (FH). The variation of

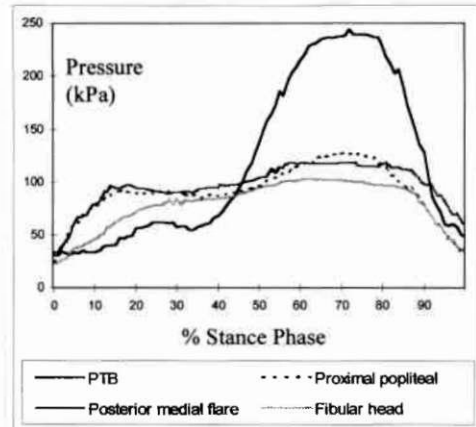


Fig. 8. Maximum "average" pressures in (>100 kPa) areas.

the average pressure in these four limited areas is illustrated in Figure 8. Table 1 highlights the number of sensor cells within these four socket areas, the maximum "average" pressure experienced and the maximum pressure experienced by an individual cell within each area.

This patient demonstrated peak pressures (>100 kPa) just after mid-stance. For example, at the patellar bar a group of 12 sensor cells recorded a maximum average pressure of 244 kPa with an individual sensor cell recording a maximum of 417 kPa. Peak pressures (>100 kPa) may be considered potentially dangerous.

Conclusions

This study highlights the capability of FSR to display stump/socket interface pressure distributions during gait. Useful pressure data may be recorded if a strict calibration procedure and test protocol is adopted.

The presentation of pressure data in this paper has been restricted to only one subject fitted with a PTB socket. A future paper will compare the pressure distribution contained in this paper with the same subject fitted with a hydrocast socket.

Table 1. Socket pressures in excess of 100 kPa.

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

Recommendations

Tekscan have improved their software system such that all four sensors may be recorded simultaneously. A series of different pressure studies may be undertaken using the improved system in the future.

A greater number of subjects must be investigated to confirm the effectiveness of different socket designs. The effect of alignment modifications on stump/socket interface pressure may be re-investigated now that the total pressure distribution within the socket may be studied rather than at "selected" localised sites. The long term variation of socket pressure distributions may be studied in conjunction with intermittently monitored patient stump volumes.

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Loads in hip disarticulation prostheses during normal daily use

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Abstract

As a result of deficiency at birth, disease or trauma, there are people who have no limbs from the hip joint downwards. These people have no possibility of locomotion without the use of other devices such as wheelchairs or hip disarticulation prostheses.

As these prostheses are used by people of all ages, people who are different in their grade of physical activities and their weights, the prostheses are subject to different stresses related to these different circumstances.

The European Level 2 Draft Standard prEN 12523: 1966 "External limb prostheses and external orthoses - requirements and test methods" contains strength requirements for lower limb prostheses. These requirements shall be verified, where appropriate, by the application of the International Standard ISO 10328 "Prosthetics – Structural testing of lower limb prostheses" and ISO/FDIS 15032 "Prosthetics: Structural testing of hip prostheses".

In order to allow the prostheses to be tested to the stresses that are experienced in real life, it is necessary to measure the stress that is induced in the prostheses while the patient is in an everyday situation, such as walking on level floor, walking on grass and/or walking on an uneven surface.

This work is concerned with the acquisition of loads generated in hip units of hip disarticulation prostheses by amputees during various

activities. More than 30 patients were tested in Germany, France, and Belgium. The measurements were carried out with financial support from the European Commission and coordinated by the secretariat of CEN TC 293.

Introduction

During walking both legs are alternately passing through two different phases: the stance phase (from the instant of heel contact to the instant of toe off) and the swing phase (from the instant of toe off to the next instant of heel contact).

The hip disarticulation prosthesis is aligned so that the load line always passes in front of the knee joint and behind the hip joint during the stance phase of walking, so that the joints are always kept in extension during load bearing and under stress.

The stress is caused by the resultant F of the gravitational force and those forces due to additional accelerations of the body and parts of it. Acting on a lever e.g. L_K or L_H (=perpendicular distance from load line to joint), this resultant creates the moment ($M=F*L$) in the joint. The position of the load line (Fig. 1) changes during the stance phase due to the changing position of the points of load application and support. When using four-bar linkage designs the load line may pass behind the knee unit without losing knee stability as long as it still passes in front of the instantaneous centre of rotation.

Nomenclature of forces and moments according to International Standards

The designation of the forces and moments generated in hip units has been carried out on the basis of ISO 10328-3:1996 although this

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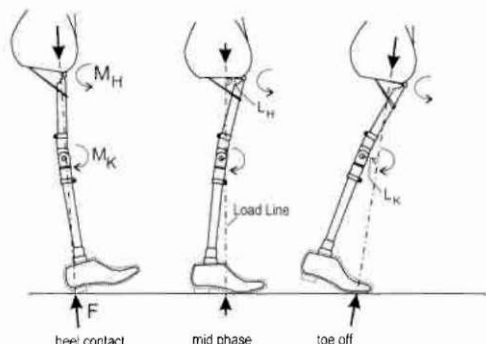


Fig. 1. Position of the load lines during the stance phase of walking.

standard excludes hip discarticulation prostheses for test purposes. In Figure 2 the application of a specific loading condition (forefoot loading) for a left-sided test sample is shown, presenting the coordinate system with $u_B=0$, with reference lines, reference points and components of internal loading generated by application of the resultant force F .

The load line passes through the knee and hip reference points P_K and P_H and the bottom and top load application points P_B and P_T . The u -axis is a line extending from the origin and passing through the effective ankle joint centre and the effective knee joint centre (ISO 10328-1:1996; ISO 10328-2:1996). Its positive direction is upwards (in the proximal direction).

Because the loading force and moments, which act in the joint centres, are vectors, these can be split into the directions f - o - u as partial vectors.

Figure 2 shows the coordinate system for a left leg, together with all positive directions of the axes, forces and moments. In order to get a

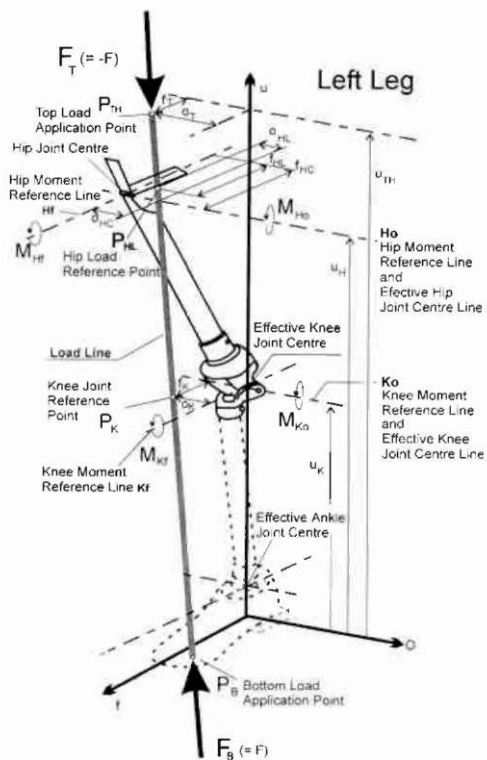


Fig. 2. Test loading condition corresponding to ISO 10328-3:1996 Annex A.

coordinate system for a right leg the system has to be reflected on the f - u plane so that the o -axis shows opposite to the original direction (ISO 10328-1:1996). As a consequence the moments M_f and M_o also turn their directions but maintain their sign and value.

NOTE: In contrast to the ankle and knee moments the cumulative hip moment M_H does not act on the u axis.

Table 1. Positive internal forces and moments with descriptions of their effects corresponding to ISO/DIS 15032:1998, Prosthetics – Structural testing of hip units.

Internal load		Anatomical description	Alternative description
Positive load tends to			
Axial force	F	compress the thigh in its longitudinal direction	
Knee moment	$M_{K_o} = \text{MKML}$	cause extension at the knee joint	straighten the knee
Knee moment	$M_{K_f} = \text{MKAP}$	cause a lateral movement at the knee relative to the hip	move the knee in an outward direction relative to the hip
Hip moment	$M_{H_o} = \text{MHML}$	cause flexion at the hip joint	move the thigh in a forward direction
Hip moment	$M_{H_f} = \text{MHAP}$	cause adduction at the hip joint	move the thigh in an inward direction
Twisting moment	$M_{u'} = \text{MHK}$	cause internal rotation of the distal end of the thigh relative to the proximal end	twist the thigh to turn the front side of the knee inwards

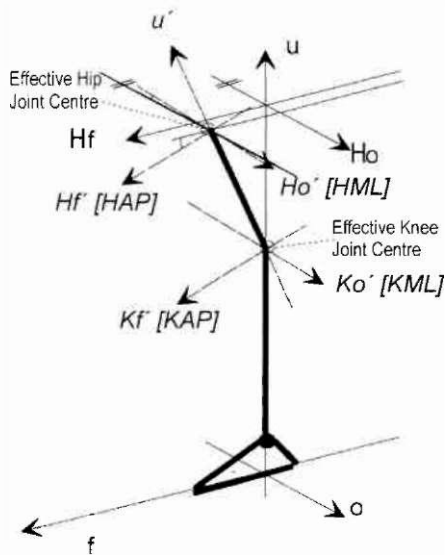


Fig. 3. Sketch of the coordinate system according to ISO/DIS 15032; f, o, u, are in accordance to ISO 10328.

Introduction of the coordinate system as specified in ISO/FDIS 15032:1998

The development of the International Standard ISO 15032 by the Working Group WG 3 of the ISO Technical Committee TC 168, was based on a new coordinate system. As this work started during the data evaluation period, the measurements were done on the basis of the

coordinate system described in ISO 10328 (Fig 2). It is necessary to transfer the values of the measurement of the pylon before comparing them with the values measured in the coordinate system [f,o,u] and their transformation into the new coordinate system [f',o',u'] related to ISO/DIS 15032. The moments M within the [f,o,u] coordinate system are designated as $M_{Ko'}$, $M_{Kf'}$ etc. (coordinate system according to ISO 10328). The designation of the moments in the ISO/DIS 15032 coordinate system are as follows: MHAP, MKML, etc. The related axes are designated as H_f or HAP, H_o or HML, K_f or KAP, K_o or KML, u' or HK. Figure 3 shows the relation between the two coordinate systems.

The internal forces and moments are indicated in Table 1 together with anatomical descriptions for their effects. It contains a list of these together with alternative descriptions for the movements which positive forces and moments tend to cause.

Measuring principle

The basis for the implemented measurements is the registration of bending moments, torsional moments, and forces by means of strain gauges. A strain gauge consists of a carrier on which there is a meandering resistance wire. If such strain gauges are glued to a bar and are wired in a Wheatstone's bridge then the detuning of the

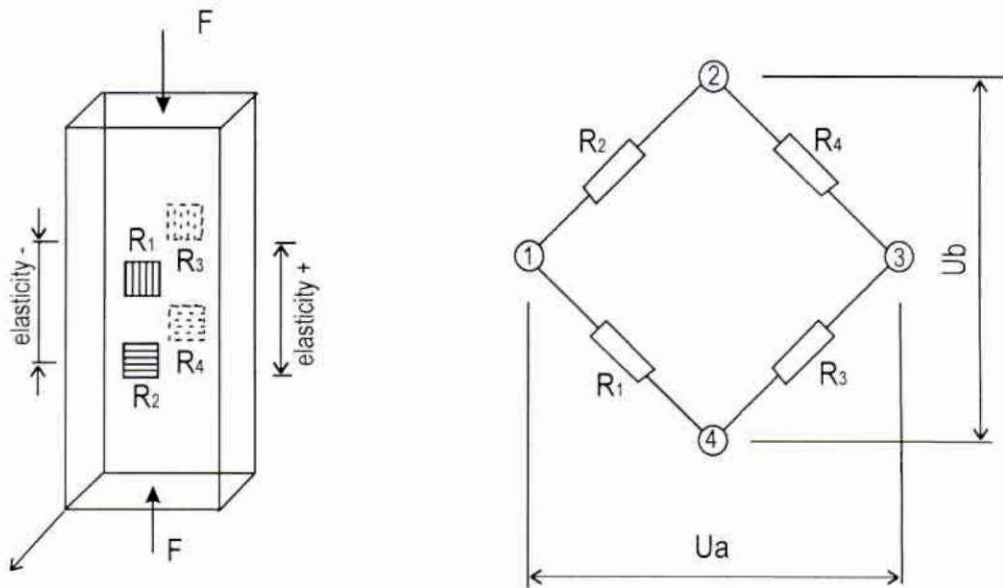


Fig. 4. Strain gauges on the bending rod and their wiring.

bridge ($=\Delta U_a$) is proportional to the appearing bending moment.

The bridge stays balanced when the rod is loaded as in Figure 4 or when the force acts along the longitudinal axis of the rod. The reason for this is that the strain gauge is glued to the rod parallel to its neutral axis. The bridge detuning only appears when the affected levers are facing forward and are acted upon by a force. In that case the elongation in the front is negative and in the rear positive and $U_a \neq 0$. When additional strain gauges are glued to the sides in the same way, bending moments in frontal (AP) and lateral (ML) directions can be measured. This principle of strain gauge measuring technology is applied to the measurement system PoMeS II used for this work.

Measuring system

The measuring system PoMeS II has been developed by the Biomechanics Laboratory of the Fachhochschule Giessen - Friedberg in collaboration with the company, Otto Bock. It consists of three basic components. The measuring pylon, the data acquisition and processing system, and the analysis software PoMGraph.

The measuring pylon consists of three parts, the basic body and two flanges a and b, which are attached to the basic body by screws (Fig. 5).

The basic pylon is equipped with strain gauges, where M1 and M2 are measuring the bending moments in the AP direction, and M4 and M6 the bending moments in the ML direction. The torsion is measured by M5 while the axial compression is measured by M3 at the measurement points.

When the bending moments are registered at the measurement points they can be converted from e.g. M1 and M2 to the bending moments at any points of the tube through application of the theorem of intersecting lines.

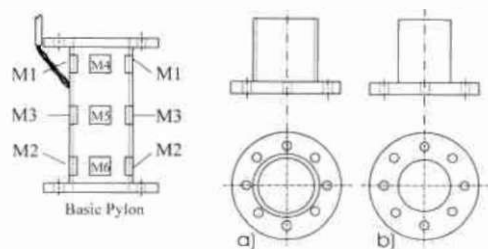


Fig. 5. Basic body of the measuring pylon and connecting flanges.

The measuring pylon can be mounted between the ankle-foot device and knee unit (Fig. 6) or between the knee and hip unit, as long as the connecting structural component between these components consists of tubes.

In order to insert the pylon into the prosthetic assembly it is necessary to shorten the tube which it will replace. The pylon is fastened by a flange (a) (Fig. 5) which is pushed over the tube and then fastened by a clamp collar or by a flange (b) which fits directly into a modular adapter and which is fastened with the clamp screw.

For the hip joint e.g. 7E7 from Otto Bock another flange had to be manufactured. This type looks like flange (b) but is specifically designed to house the extension assist mechanism of this hip unit which normally extends into the upper pylon.

The case of the portable data acquisition and processing system is fastened to the patient's body with a belt. The case of the data acquisition and processing system contains the measuring bridges to which the strain gauges of the measuring pylon are connected and also the integrated μ -processor. The measuring pylon and the data acquisition and processing system are connected by a cable.

The signals which come from the measuring bridges are to be amplified, digitised, and stored in the RAM. After the measurements have been completed the data can be transferred into a computer via a RS 232 interface, and are then ready for further usage.

The analysis software PoMGraph is a programme which runs under DOS on a PC. It takes care of several functions. It allows the communication between the PC and the data acquisition and processing system. It is able to graph the measurement values and has analysing functions such as the search for the maximal value, step coverage, and transformation of the data into WKS format. The programme was used to exploit the measured data. For a more detailed description of the programme see Kreil (1995).

Preparation of the measuring system

The calibration of the measuring pylon was checked and adjusted as needed before the measurements were started. For this purpose the measuring pylon was mounted in a calibration installation equipment.

Calibration was carried out in the AP and ML directions and also additionally in the longitudinal axis for measuring the torsional moment and the axial compression. To correct the cross-talk which occurs between the channels e.g. bending moments and axial force, it was necessary to find the correct mathematical correction factors. These were determined through calculation of the dependence of the measured value affected by the cross-talk and the value which is causing the disturbance. A 6x6 cross-sensitivity matrix was determined for each measuring pylon so that the influence of the cross-talk of the different loads to each channel could be eliminated through calculation (Nietert *et al.*, 1997).

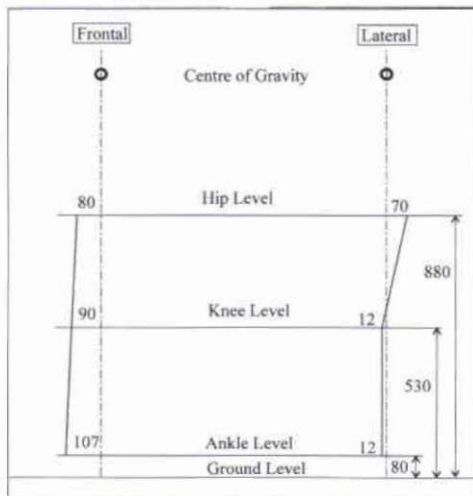


Fig. 6. Measuring pylon mounted between the ankle-foot device and knee unit and the location of the joints relative to the load line in upright stance.

The patients were checked with a LASAR measuring system of the Otto Bock Company to estimate the expected hip movements in the static alignment. This device is capable of localising the load line passing through the centre of gravity of the human body by means of a force plate and to project it on the body by means of a laser beam. Through automatically measured parallel shifting of the laser beam the perpendicular distance of any reference point from the load line and, hence, the effective lever arm by which the load is acting on any joint can be identified (Fig. 6). There has been a cover sheet drawn up for every utilised data set, containing images of a frontal and a lateral view of the patient's prosthesis, and its alignment with regard to the perpendicular distances (levers) of the joint from the load line passing through the centre of gravity recorded by the LASAR system.

The patient who was checked for the estimation was amputated on his right side and had a body mass of 65 kg. He stood with both feet on the force plate and was measured in both the frontal and lateral plane. The resulting lengths of the levers are shown in Figure 6.

The following assumptions were made to estimate the range of the hip moments:

- the centre of gravity is located at the height of the navel;
- the centre of gravity stays the same in the one legged stance position, and the force vector runs through the centre of gravity and the foot (ground).

Presentation of the data exploitation

The data was utilised with the goal to determine the size of appearing moments and forces on hip and knee joints, required for the determination of the appropriate test load level(s) of ISO/DIS 15032 and ISO/AMD 15032. A prosthesis has to withstand these test loads for at least three million cycles without cracks and deformations, otherwise the prosthesis has failed the test and the component is declared as unsafe. The test load levels A100, A80 and A60 are recommended for a body mass of up to 100, 80 or 60 kg. In the standard ISO/DIS 15032 there is nothing said about activities to indicate that a person with only 60 kg body mass but, on the other hand, very active should be fitted with a prosthesis which was tested on a higher test load level e.g. A80.

Table 2. Values of knee and hip bending moments MK and MH and test force F for AP and ML test loading conditions corresponding to ISO/DIS 15032 Table B1, B2 and ISO/AMD 15032 Table 3.

		A100	A80	A60
MKAP= M_{Kf}	Nm	60	60	60
MHAP= M_{Hf}	Nm	110	95	75
MKML= $M_{Ko'}$	Nm	80	80	65
MHML= $M_{Ho'}$	Nm	-100	-100	-100
Axial torsion= $M_{L'}$	Nm	30	30	30
Compression=F	N	1280	1050	900

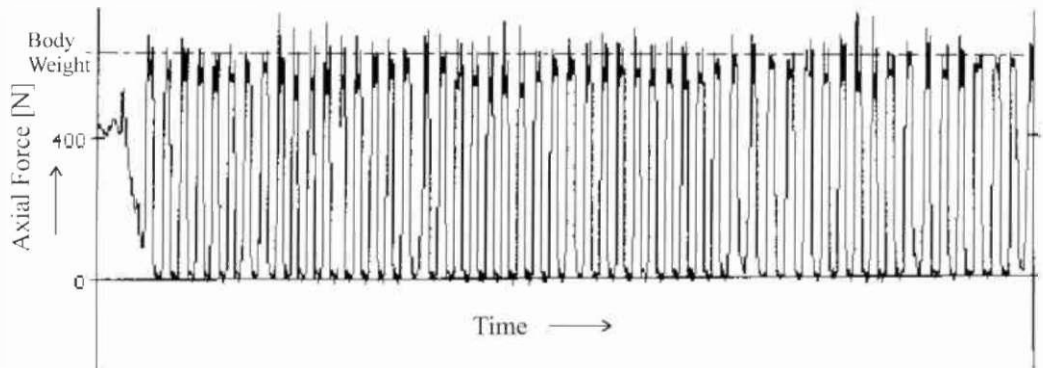


Fig. 7. Course of the axial force during normal walking.

The maximum of the different moments, the axial force and the resulting total force calculated from these were ascertained for each measurement. The steps have been superimposed and their mean with standard error was graphed, as the peak values are not representatives for all steps. The maximum moment and force have also been ascertained for the overlaying step.

The next procedure should be to look at the single steps on the screen, to register possible irregularities, as for example the application of the wrong side of amputation to the wrong side of the ML moments.

been superimposed as there were no identifiable runaways.

Visual control of the measured data

The whole file was checked for the maximum values by the programme, POMGRAPH with the special function "ANALYSIS of MAXIMA". When copying the indicated values it is necessary to make sure that the shown maximum is really part of a step, as there are often peak values appearing when the block measurement is switched off. They are to be found at the end of the file.

The graph in Figure 7 shows the axial force curve of the whole file of the patient during normal walking on level floor. The steps have

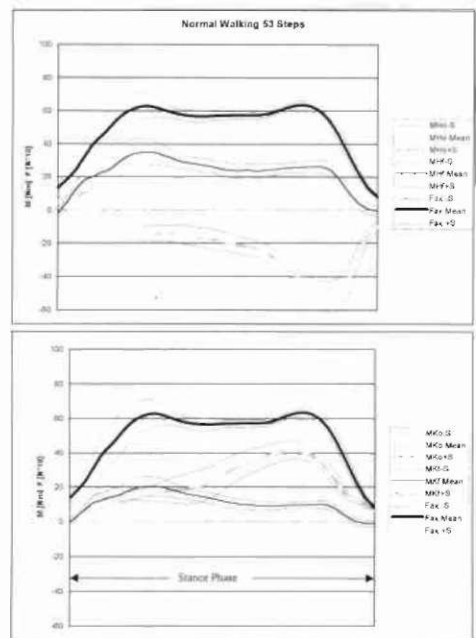


Fig. 8. Axial forces, hip and knee moments during normal walking.

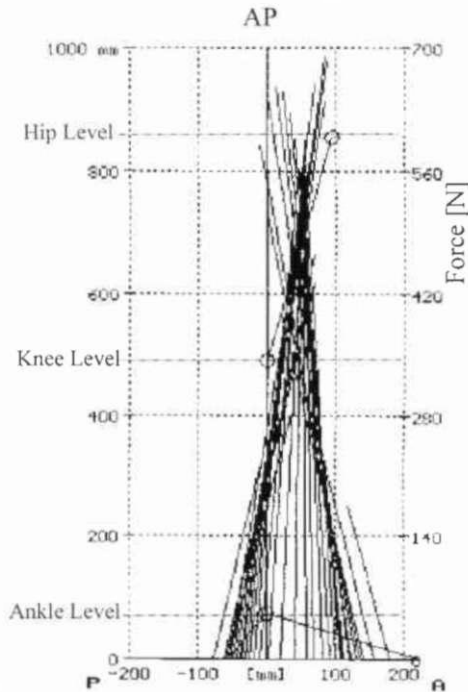


Fig. 9. Vector distribution in AP direction.

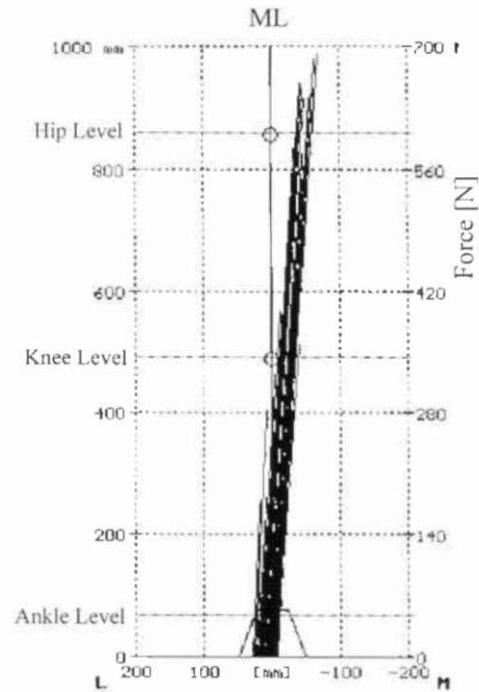


Fig. 10. Vector distribution in ML direction.

Superimposed steps

As the description of the superimposed steps with all the forces and moments and standard errors is too confusing, the knee and hip moments previously addressed have been depicted together with the related force curve and their standard deviations (Fig. 8).

Description of vector distribution

Figures 9 and 10 show the prosthesis (as a stick diagram) and the distribution of the curve

of the force vector over a step in AP and ML directions.

The density of the depicted vectors indicates that the duration of both the heel and forefoot loading by the patient is significant. The vector line is always passing in front of the knee joint and behind the hip joint so that both joints are always forced to keep their extended position during the stance phase of walking. The ML description indicates that the prosthesis is only loaded on the medial side during the step.

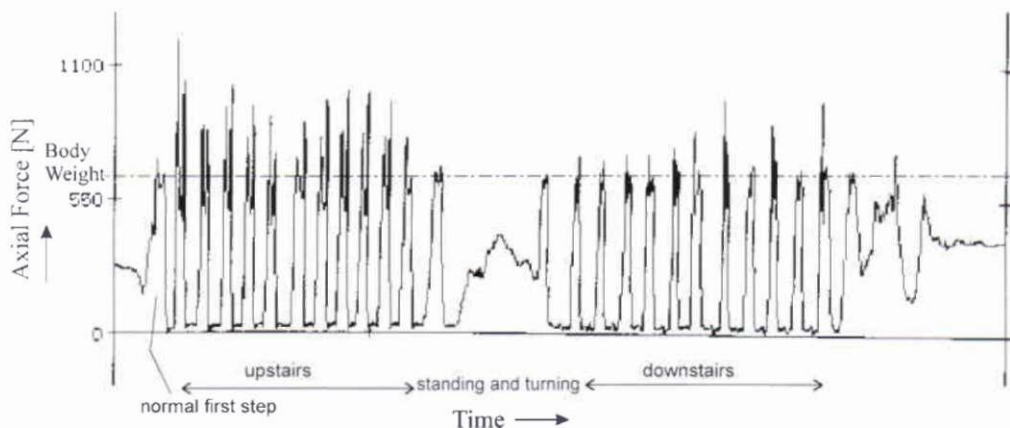


Fig. 11. Course of axial force while walking on stairs.

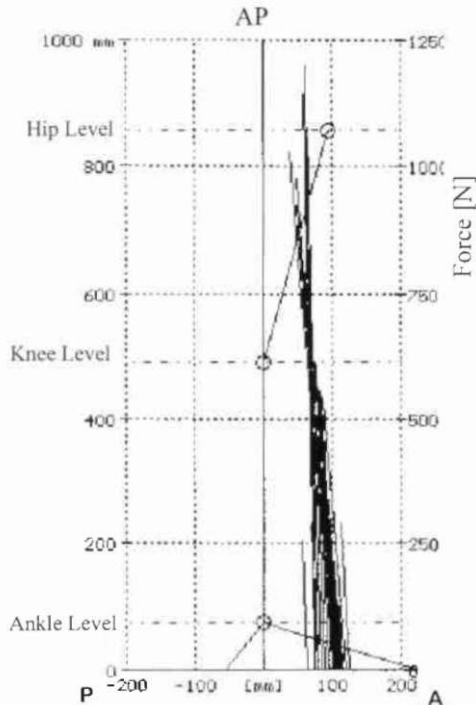


Fig. 12. Vector distribution while walking upstairs.

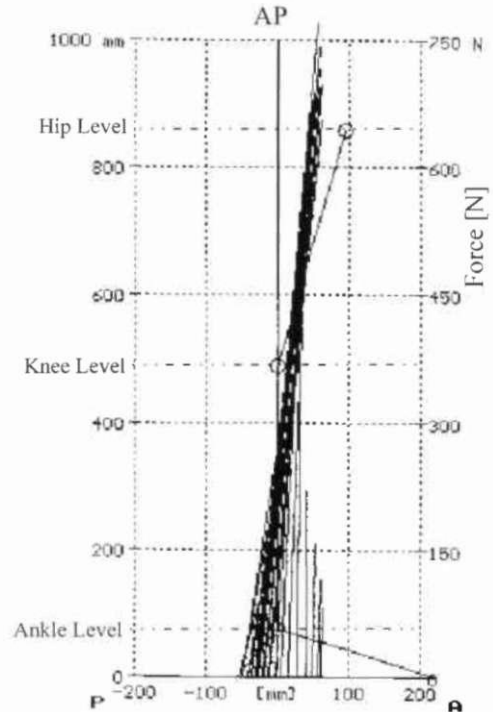


Fig. 13. Vector distribution while walking downstairs.

Walking on stairs

Figure 11 is related to walking on stairs. The first part of the curve shows the ascent and the second part the descent.

The first and second part of the file were marked to identify the maxima, and a maximum search was carried out in the 'marked region' thereafter. The steps out of the same marked regions were superimposed, graphed accordingly, and identified as 'upstairs' and 'downstairs'.

The vector distributions of 'upstairs' show that only the forefoot of the prosthesis is touching the stairs while walking upstairs and only the heel is touching the stairs while walking down.

Walking on grass and walking over a grassy hill

First the patient was walking across a meadow. Since the meadow was not very level the patient was unforeseeably/unintentionally stepping on hollows and bumps in the surface.

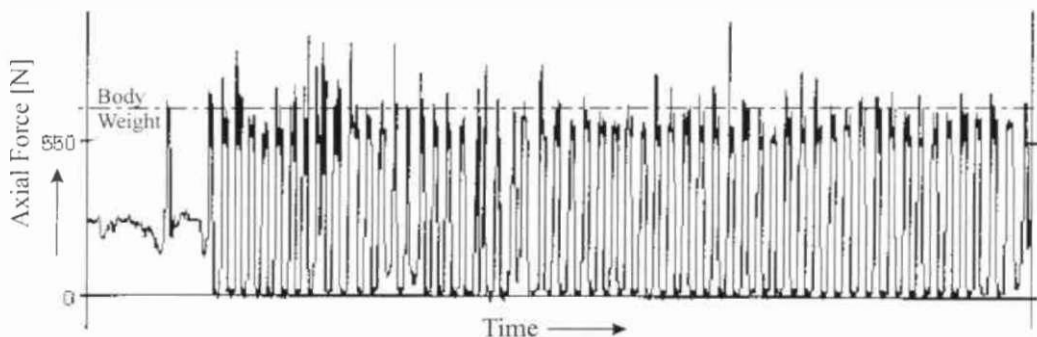


Fig. 14. Walking over a grassy hill.

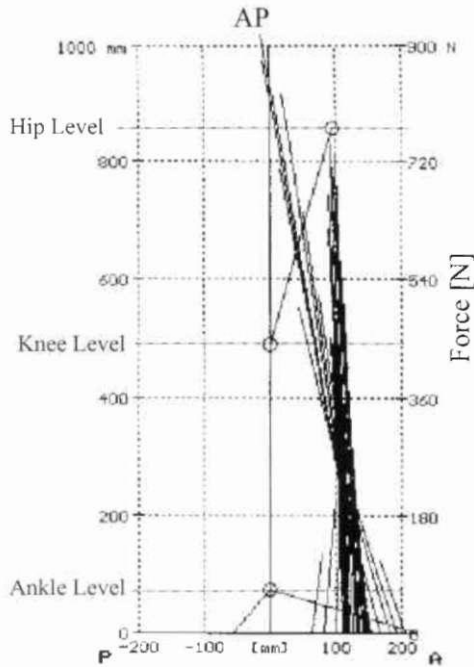


Fig. 15. Vector distribution while walking uphill.

Compared to walking on level floor the vector description shows a more even spread of the vectors over the whole foot. This more even

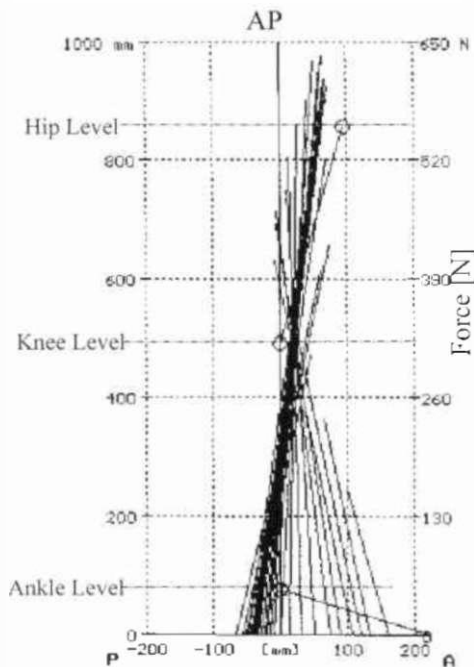


Fig. 16. Vector distribution while walking downhill.

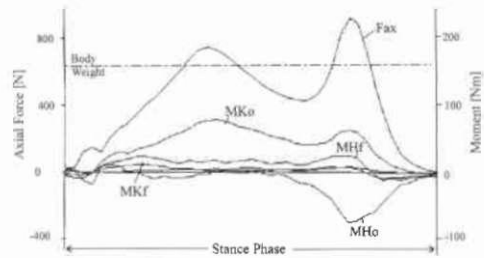


Fig. 17. Force and moments curves uphill.

spread of the vectors is (probably) related to a more careful and slower walking.

Figure 14 is representative of walking over a grassy hill which was located on the meadow used for measurements referred to in the preceding file. The steps or the procedures, respectively, are not very regular and the patient was not always walking straight up and down the hill, but instead, also ascended and descended the hill and on the meadow in a diagonal manner rather than in a straight manner. It is possible to identify the steps up and down the hill with the help of the vector description in Figures 15 and 16.

The vector distribution while walking uphill is similar to that of stair climbing. On the way up the hill only the forefoot of the prosthesis is loaded. In contrast to this, on the way down the hill mainly the heel is loaded.

The step up the hill is more distinctively powerful as can be seen on the well-defined double hump in Figure 17. In contrast to this is the step down the hill where there is almost no double hump distinguishable, because the patient has tried to load the prosthesis to the lowest possible level in order to avoid loss of stability by knee (and hip) flexion (Fig. 18).

Walking on gravel and fast walking

While walking on gravel the distribution of the vectors is similar to that of normal walking on level floor. But the patient is always looking

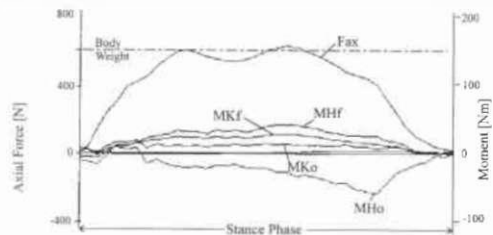


Fig. 18. Force and moments curves downhill.

for the best track. He takes the track with the least amount of stones, or tracks which have been rolled smooth by vehicles.

While walking fast the patient was running twice across a small gymnasium. When one looks at the top of the peaks, one can see a sinusoidal curve. The patient was starting slowly, accelerated then and finally decelerated at the end of the hall.

Results of the measurements

Over 30 patients between the age of 22 to 50 have been measured. The data of at least 23 patients could be used for the evaluation. The lightest weighed 51 kg, the heaviest had a weight of 95 kg. The hip offset was, related to the ankle-knee axis, within a range of 55 and 105 mm in the frontal direction, and 0 mm in the medical direction.

During the measurements the patients had to walk on different floors and with different walking speeds: level floor (normal walking), upstairs, downstairs, grass, ramp, gravel, and fast walking.

By virtue of the local conditions and the weather it was not always possible to gather all the measurements, for example in the city there was no nearby meadow for the measurements. In addition, some specific measurements could not be taken because some patients could have walked faster than they actually did, others simply refused to walk on grass, with the justification that it was impossible. However, in general the patients have been very cooperative.

To build the pylon into the prosthesis it is necessary to disconnect the foot from the prosthesis and to remove the cosmetic foam cover of the prosthesis. A prosthetist generally does this. He should also be the one who reassembles the prosthesis afterwards. The pylon should already have been roughly calibrated in the workshop so that no major corrections need to be done when the patient is wearing the prosthesis. It has also proven very helpful to ensure that all screws of the prosthesis are tightened.

After having completed the preparation of the prosthesis for measurement, the patient should test the arrangements by walking around in order to recognise the adjustments. With the built-in pylon, it is not possible to maintain the alignment and functional characteristics of the original prosthesis. The patient has to get

accustomed to the fact that the lower leg swings with a different speed due to the removal of the foam cover. The patient also recognises differences in length even when they are only a few millimetres as well as the weight of the pylon.

As soon as the patient is managing with the modified prosthesis the pylon is eventually re-fixed (the pylon with the strain gauges is aligned frontal-medial), and the geometry of the prosthesis is recorded.

Description of the force and moments generated by the body mass

The following diagrams show the forces and moments of all patients plotted against the body mass. In each diagram the maxima of the mean values of the superimposed peak values are registered, together with the peak values appearing in the related file. Since all patients did not walk on gravel, the values of walking on uneven ground, gravel and cobblestone pavement have been summarised.

Mean values with two standard deviations and peak values measured in Europe and Japan during normal walking

The force typically occurs in a double hump as seen in Figure 8 and the moments are positive with exception of M_{HO} . In the frontal view, the force vector passes medially and in front of the knee unit and behind the hip joint seen in the side view. But on the other hand the course of the moments and force are also dependent on the prosthetic alignment or when the patient is walking with walking aids. In addition several measurements were also made in Japan (ISO TC 168WG3, 1996). These data are included into the diagrams where they have been available. The diagrams include peak values as occasional event, mean values and two standard deviations (2SD).

Walking on stairs

Typical patterns of force and moments also appear while walking on stairs. During stair climbing the patient is putting the healthy leg in front and is then pulling the prosthesis behind. Many of the patients take two stairs at a time and are always using the rail. The pattern of the force shows a very well-defined double hump. The step begins with the patient setting the prosthesis on the stair. Then the patient is pulling the healthy

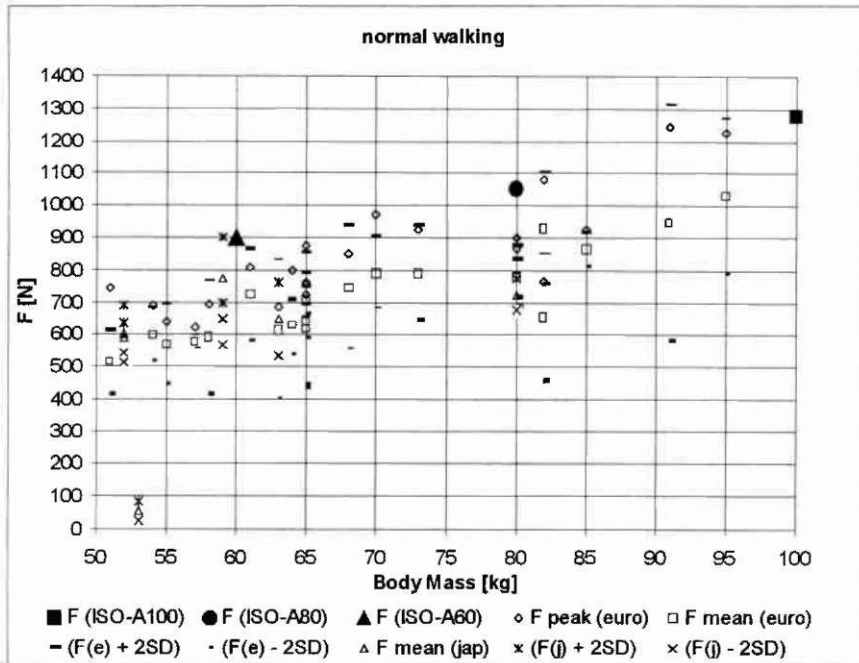


Diagram 1. Axial compression.

leg upwards to set it down one or two steps further above. The well-defined double hump is created through the swing of the leg being pulled

upwards, and the supporting pulling on the rail.

Likewise typical patterns of force and moments are found during the stair descending;

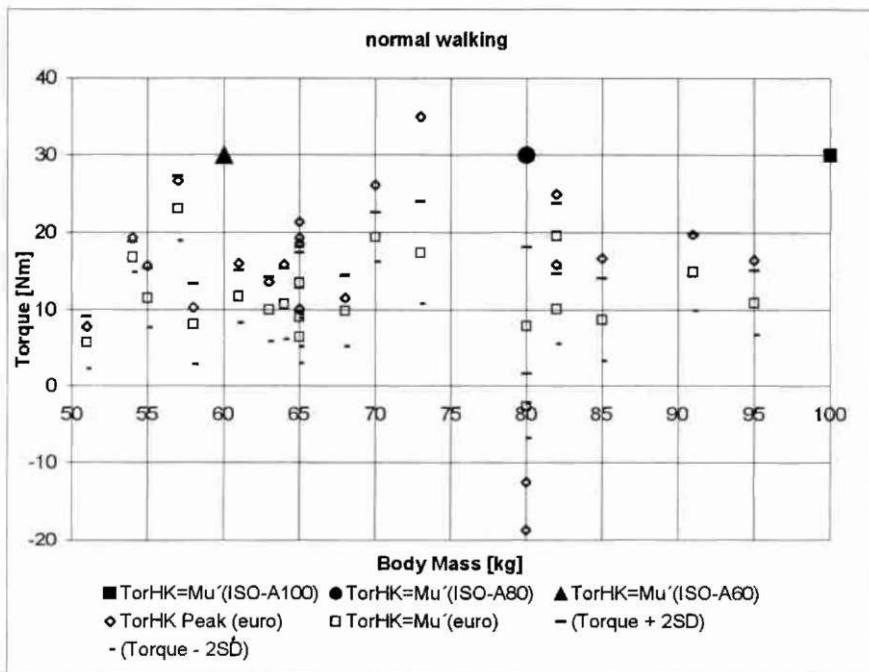


Diagram 2. Torque.

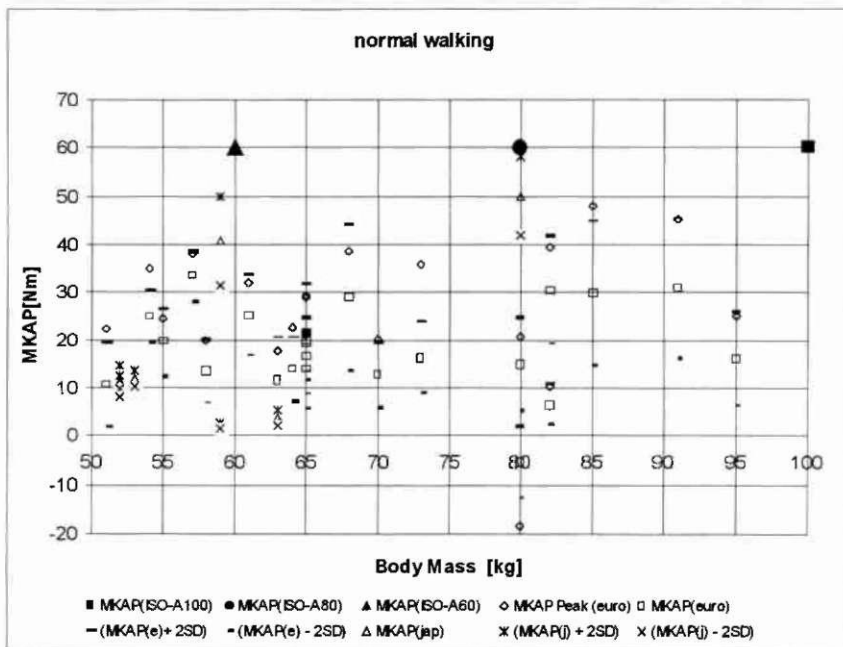


Diagram 3. Knee moments in the ML plane.

the patient first sets the prosthesis a step further down, and is then pulling the healthy leg behind. The pattern of the force shows a gradual rise without double hump. In contrast to the stair climbing here the patient is reassuring himself

through careful loading, to see the prosthesis is standing right and stable, in order to avoid tumbling.

This caution is not necessary for stair climbing since the patient is already standing securely

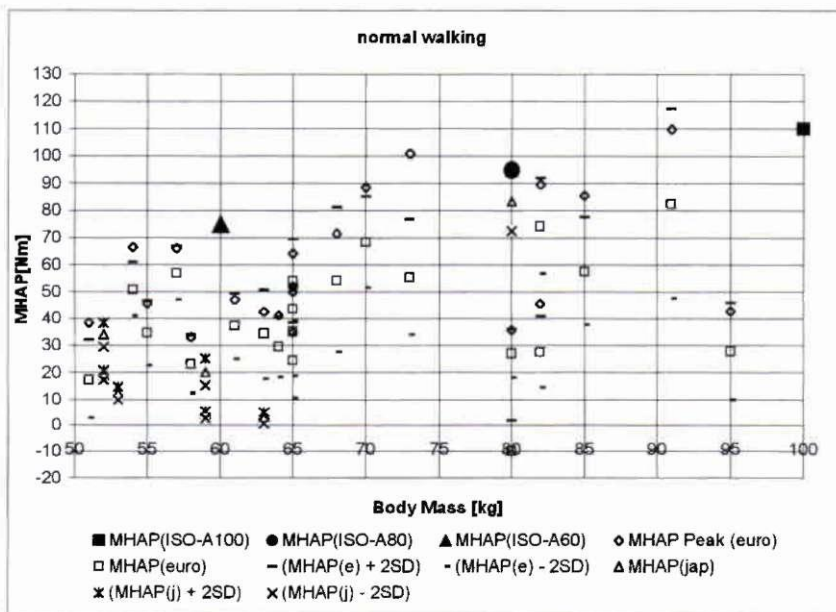


Diagram 4. Hip moments in the ML plane.

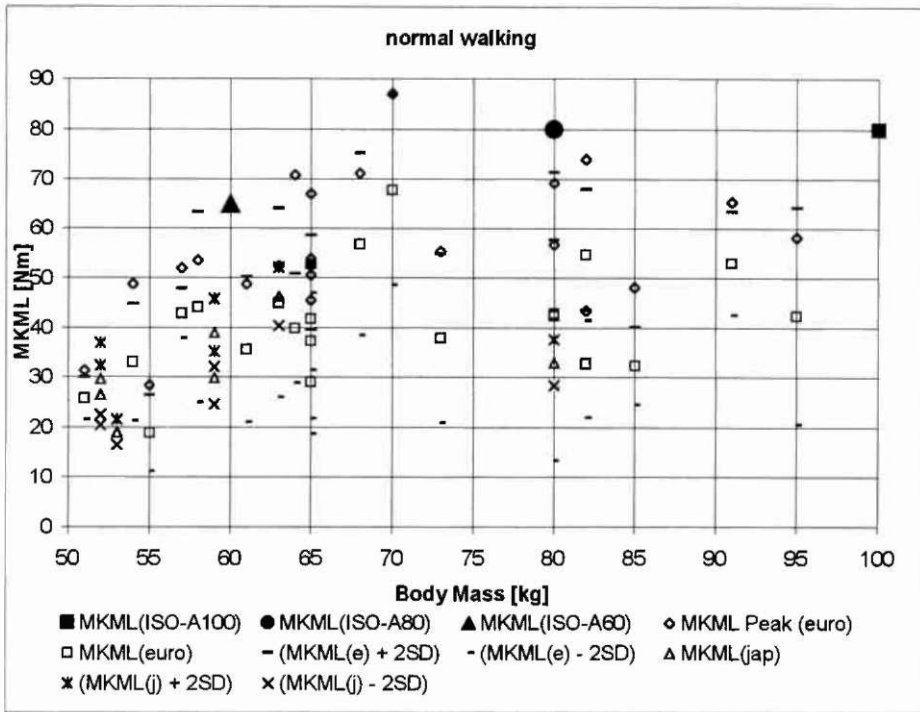


Diagram 5. Knee moments in the AP plane.

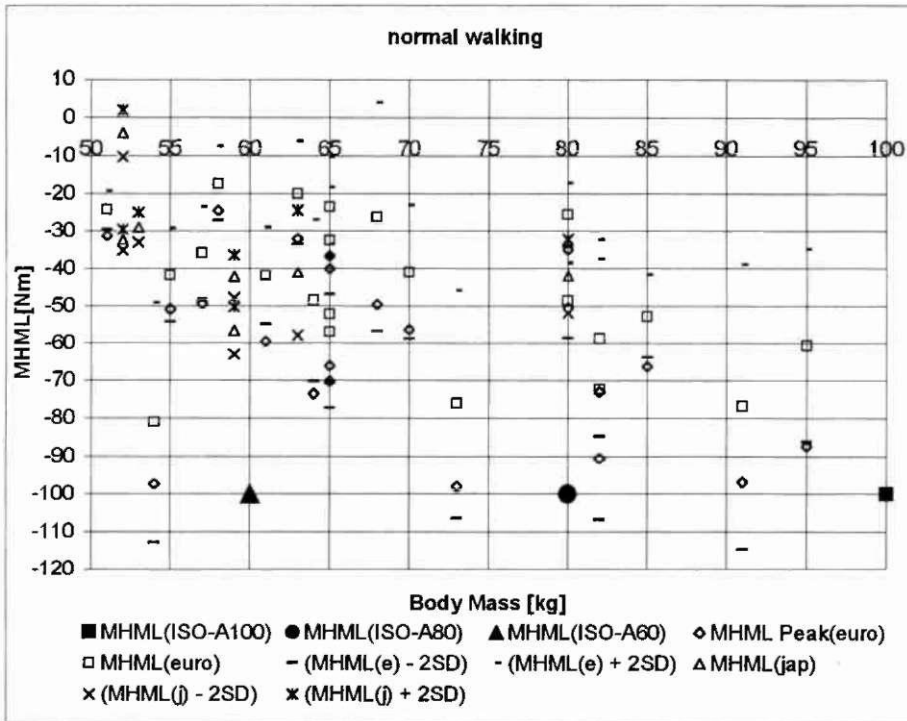


Diagram 6. Hip moments in the AP plane.

with the healthy leg, when the loading of the prosthesis begins.

There are often peaks noticeable at the beginning of the curve during stair descending. The patient is causing them through setting the prosthesis sideways on the stair while descending. As a consequence the moments in the result description are partly diverging from the expected values of these peaks.

Walking on grass

Raised first peaks in the pattern of the force are always essentially appearing while walking on grass. They are caused through the patient unintentionally stepping into hollows, which he did not recognise in the mown meadow.

The patterns of force and moments resemble those of walking on level ground, despite the raised peaks. Walking on wet grass probably would have lead to different results. However the risk of slipping on wet grass was too high for the patients.

Walking on gravel

The gravel paths used for the measurements had been rolled hard and almost even by vehicles

on the left and right. As the patients preferred to walk on the hardened ground although they had been asked to walk on gravel, there are no typical step characteristics visible. The pattern is like normal walking on level ground.

Fast walking

The values and vector patterns measured during fast walking are very similar to those of normal walking. The walking speed of the patient is limited by the minimum duration of the forward swing of the lower leg. The damping characteristics of the knee joint would have to be changed to reach maximum speed, but then the patient would have had trouble with normal walking.

Superimposed values of all data

The superimposed values of all data are shown in Figure 7 (axial compression), Figure 8 (torque), Figures 9 and 10 (knee moments), and Figures 11 and 12 (hip moments).

Discussion

Relations between the body mass and measured values of force and moment generated

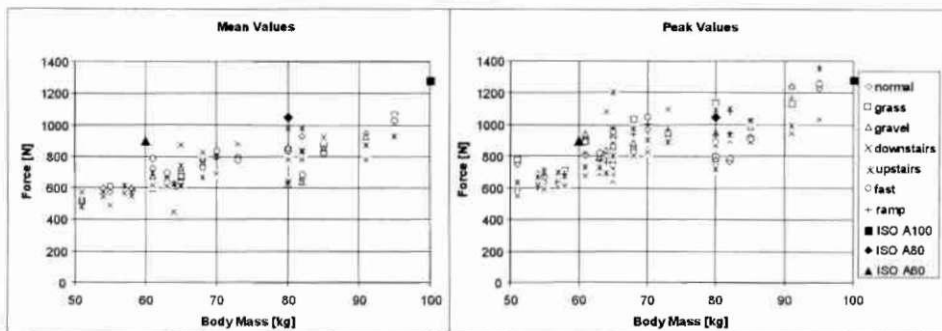


Diagram 7. Axial compression (mean and peak values) during different walking situations.

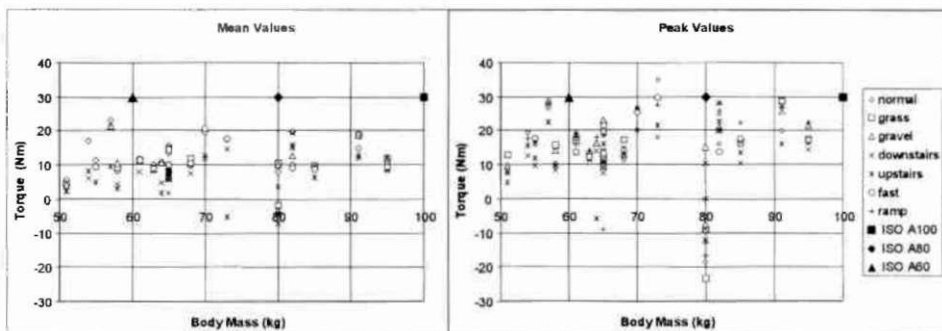


Diagram 8. Torque (mean and peak values) during different walking situations.

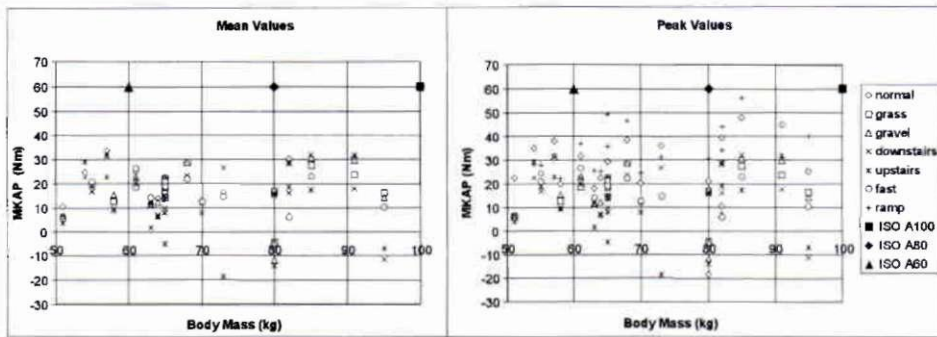


Diagram 9. Knee moment (mean and peak values) during different walking situations in ML plane.

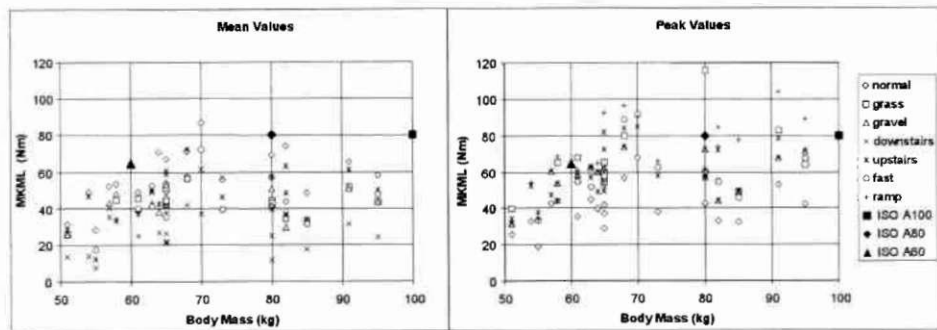


Diagram 10. Knee moment (mean and peak values) during different walking situations in AP plane.

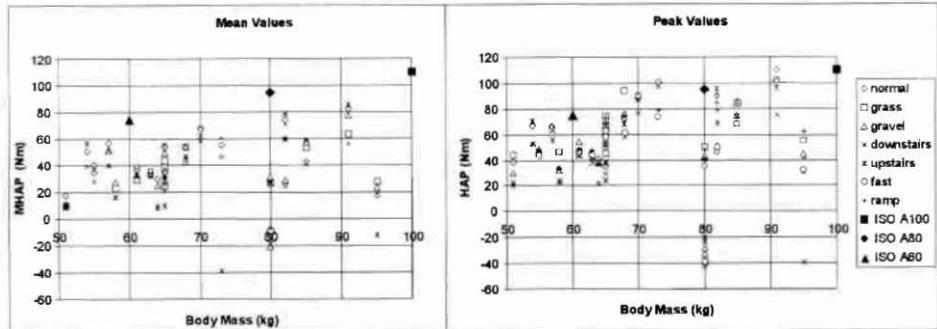


Diagram 11. Hip moment (mean and peak values) during different walking situations in ML plane.

in the prosthesis can be established considering the force F . An unambiguous linearity is not to be expected, since the measured force is not only dependent on the body mass of the patient but also on the dynamics of the gait which is different from patient to patient. The combination of the individual dynamics of the gait and the individual structure of the prosthesis is the cause that values of the moments in relation to the body mass are widely spread.

Due to the fact that the values of the moments have to be calculated from the measured data it

is necessary to consider the following comments.

None of the measured patients reached the body mass of 100 kg estimated for the standard. The patients furthermore explained that the stress on the prosthesis was very much dependent on the use during their working days. A farmer used his prosthesis for all jobs on the farm. Others indicated that they were hiking in the mountains with their prosthesis.

Most of the patients confirmed that they only leave level ground with their prosthesis when

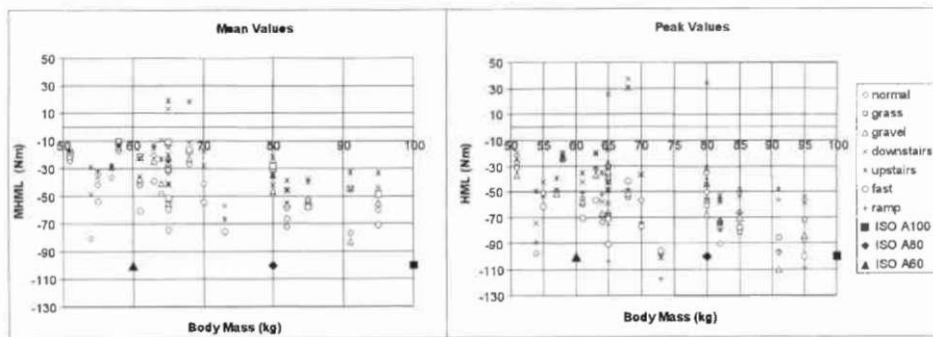


Diagram 12. Hip moment (mean and peak values) during different walking situations in AP plane.

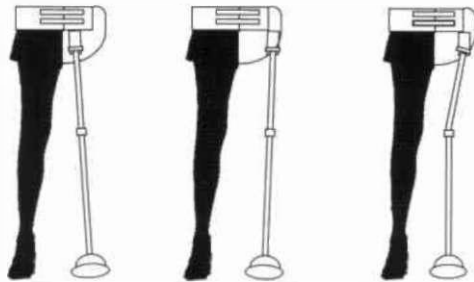


Fig. 19. Examples of prosthetic alignment.

there is no way to avoid it. This was clearly visible in their behaviour on a gravel path on which they were always looking for smooth tracks along the way. Having the alternative to walk on stairs or to take the elevator, preference was given to the latter possibility.

Another significant influence on the stress of a

prosthesis is given by the alignment of its structure.

As illustrated in Figure 19, there are different possibilities of aligning the prosthetic structure. The stresses of the single components/segments are obviously changed according to the structural alignment.

Table 3 lists the absolute ultimate mean and peak values ever reached by all patients while walking on level ground, as well as the maxima of the superimposed steps, of all patients considering all surfaces and activities. The right column contains the values of the ISO/DIS 15032 and ISO/AMD 15032.

In some cases the peak values actually appeared only once, but nevertheless they indicate that values higher than the draft values of standard for torsion, MKML, and MHML do occur. The value of the force of 1350 N is not the

Table 3. Absolute ultimate values measured with patients in comparing to the test loads of ISO/DIS 15032. Table B1, B2 and ISO/AMD 15032 Table 3.

	Normal walking on level ground			All activities		ISO/DIS 15032:1998		
	Mean values	Mean values +2SD	Peak values	Mean values	Peak values	A100	A80	A60
MKAP Nm	34 (50 jap ^{*)})	45 (58 jap ^{*)})	48	34 (normal)	57 (ramp)	60	60	60
MHAP Nm	82 (84 jap ^{*)})	117	110	83 (downstairs)	110 (normal)	110	95	75
MKML Nm	68	87	87	68 (normal)	116 (grass)	80	80	65
MHML Nm	-81	-115	-98	-82 (gravel)	-118 (ramp)	-100	-100	-100
Torsion Nm	23	27	35	23 (normal)	35 (normal)	30	30	30
Compression N	1030	1312	1243	1050 (grass)	1350 (grass)	1280	1050	900

^{*)} Japanese data (ISO/TL 168, 1996)

true value, as the amplifier of the measurement system went into overload by this patient (95 kg). The value was reached while walking on grass and downstairs by a patient whose body weight was 68 kg and whose prosthesis had no lateral offset.

Conclusions

The data clearly indicates that the determination of test values cannot be based on the supposition that the heaviest patient will automatically generate the highest stress is the prosthesis. Many factors which are dependent on the individual habit of each patient and therefore not predictable have an effect on the stress level and, hence on the lifetime of a prosthesis.

Of significant influence is the personal attitude of the patient to her/his prosthesis. Does she/he see it as an aid for locomotion or as a cosmetic device just contributing to less conspicuous appearance.

On one side it would be advisable to determine a standard alignment for the prosthesis, but on the other side it should be the goal to adapt the prosthesis optimally to the patient and not the other way round.

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Note: Standards designated ISO are published by International Standard Organisation, Geneva. Standards designated EN are published by CEN (Centre Européen de Normalisation), Brussels.

An evaluation of the use made of cosmetic and functional prostheses by unilateral upper limb amputees

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Abstract

There is currently a distinction drawn between a prosthesis considered to be provided for purely cosmetic reasons and a functional prosthesis provided to enable the amputee to achieve basic hand function. Using video analysis the study reported in this paper demonstrates that for non-manipulative actions cosmetic prostheses are actively used in the performance of everyday tasks as frequently as functional prostheses. The study provides evidence for a cosmetic prosthesis to be presented to an amputee as a realistic initial prosthesis and not as the option of last resort if a functional prosthesis is rejected. It is also recommended that training is provided in the use of cosmetic prostheses in two-handed tasks.

Introduction

Rehabilitation of upper limb amputees is usually considered successful if the amputee wears a functional prosthesis, is observed using it appropriately during clinic based training and assessment sessions, and reports wearing it for a substantial period of the day at home and in work and social situations. Wearing a prosthesis for purely cosmetic reasons can result in the wearer being classed as an unsuccessful user of a prosthesis (Roeschlein and Domholdt, 1989; Muilenburg and LeBlanc, 1989). There is little understanding of use made of cosmetic prostheses in the everyday life of the wearer or of the actual role of functional prostheses in situations other than observations made in the clinic situation and self reports from wearers.

A large number of studies have been conducted to evaluate the use made by amputees of their prostheses. Most of these studies have used postal questionnaires sent to upper limb amputees who have been identified from clinic records (Gaine *et al.*, 1997; Wright *et al.*, 1995; Burger and Marinček, 1994; Roeschlein and Domholdt, 1989; Millstein *et al.*, 1986). Some studies obtained information from upper limb amputees from questionnaires administered during structured interviews conducted in the clinic environment (Silcox *et al.*, 1993; van Lunteren *et al.*, 1983; Northmore-Ball *et al.*, 1980). All of these studies have relied on self reporting by amputees regarding the length and occasion of wear of their prostheses. From the reports, success of prosthetic use has been determined by the amount of reported wear and number of occasions when the prosthesis has been worn. Heger *et al.* (1985) and Northmore-Ball *et al.* (1980) used participants as their own retrospective controls in comparative studies of myoelectric and conventional prostheses by asking participants currently wearing myoelectric prostheses to recall their usage of the conventional prostheses which they had worn prior to the fitting of myoelectric prostheses. Retrospective accounts of usage have obvious limitations.

There are inherent problems with questionnaires that rely on self reporting and patient recall. Participants are likely to be influenced by motivational factors and give responses that they consider the generator of the questionnaire would see as desirable (Manstead and Semin, 1996). Postal questionnaires may be completed in consultation with or even by another person. This is likely to happen if questionnaires are sent to children or if

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participants have difficulty writing. The most serious threat to question reliability is ambiguity (Oppenheim, 1983), which could be particularly relevant to the use of the words "wear" and "use" when referring to prostheses (Burger and Marinček, 1994).

A few studies have assessed the use of prostheses in a more structured way in clinic situations by timing wearers performing set tasks (Datta *et al.*, 1989; Stein and Walley, 1983). It is likely that participants assessed in a clinic situation will respond and perform in a way that is expected of them from the information and training they have been given by clinic staff. This is even more likely if the tasks administered as part of the study are the same or similar to those used in training and if the tests are administered by clinic staff. Participants' behaviour in the clinic situation may not reflect their behaviour in everyday life.

Van Lunteren *et al.* (1983) visited upper limb amputees in their own home, conducting a semi-structured interview consisting of 220 questions and observing participants performing up to 50 daily living activities (ADL). Analysis of the ADL activities was undertaken by defining specific mechanical or motor functions performed by the participants. Although different sets of participants wore cosmetic, body powered or myoelectric prostheses they appear not to have performed the same ADL tasks and therefore comparison between prostheses might be unreliable. However the study did reveal that passive grasping function is sometimes used by wearers of cosmetic hands and that the use of the direct grasping function is not generally used by wearers of functional prostheses.

In order to gain more valid and relevant information regarding normal, everyday prosthetic use it was decided to conduct a video analysis of upper limb amputees wearing prostheses and performing familiar tasks in their own homes.

Method

All amputees registered with the Cambridge Disablement Services Centre in May 1996 with a unilateral absence of an upper limb were identified from clinic records. Amputees over 80 years old were excluded as a number of them were living in residential care. Children under the age of 16 were also excluded. It was

considered that amputees in both of these groups were unlikely to be routinely carrying out tasks to be used in the study. Amputees with forequarter amputations and partial hand amputations were also excluded as their prostheses were likely to be "one off" designs. All potential participants were sent a letter explaining the study and asking them if they would be willing to take part. The letter was followed by a telephone call which allowed any questions or queries to be answered and appointments to be made for the researcher to visit amputees who were willing to participate in the study. Any potential participant who could not be contacted by telephone was sent a letter asking them to contact the researcher either by telephone or letter. A stamped addressed envelope for a reply was enclosed in this communication.

All participants were visited in their own homes at a time that was convenient for them. They were asked a number of questions regarding their prosthetic history and patterns of wear. All participants were videoed performing three everyday tasks:

1. Making and serving a cup of tea or coffee.
2. Preparing a piece of toast including putting butter and jam on it and cutting the slice of toast in half.
3. Writing their name on a piece of paper, putting it into an envelope and sealing it; then after a few minutes they were asked to open the envelope and take out the letter.

These tasks were chosen as it was considered they would be regularly performed by participants and they would normally involve the use of two hands. The paper and envelope were supplied by the examiner and were identical for all participants. Participants were encouraged to use the equipment and utensils that they used daily and to wear the prosthesis and terminal device (TD) that they wore most often during the day. A small and relatively unobtrusive hand held camera was used for videoing.

Analysis of videos

A standardised category system was devised to analyse the video recordings. This system was developed using the videos from nine participants who formed a pilot group. These participants were chosen as a sample varying in level of amputation, reason for limb absence, age, gender and type of prostheses and terminal

device used. Two broad categories of actions were identified these two categories were further divided into specific descriptors.

1. Manipulative (all these actions with the exception of "change" were made by operating the functional mechanism of a TD):

Grip – open TD and close on object.

Release – open TD to release object.

Hold – hold object in TD for at least 3 seconds.

Transfer – hold object in TD and move it from one place to another.

Change – change orientation of TD.

2. Non-manipulative (All these actions are made without operating the functional mechanism of a TD):

Support – support object with TD.

Stabilise – hold an object down with the TD.

Push – push object using TD.

Pull – pull object using TD.

Wedge – hold object between body part and TD.

Balance – support self with TD.

Self grooming – touch own body part with TD.

Steadying – hold down object using part of prosthesis other than TD.

Prosthesis hold – hold object between body part and prosthesis other than TD.

Prosthesis balance – stabilise or support self with prosthesis other than TD.

Stump hold – hold object between stump and body part.

The reliability of the descriptors was assessed by an independent rater's analyses of three of the participants' videos. Agreement of 88% was found.

Analysis of the videos was done using a video cassette recorder and VDU. Each participant's video was viewed using a frame by frame analysis which allowed detailed observations of all the actions made by each participant when performing each of the three tasks. A record of each action made by each participant involving his or her prosthesis was entered on to a score sheet under the appropriate descriptor. The number of actions were then totalled for each descriptor for each participant. The computerised statistical package for social science data (SPSS) was used for the analysis.

The sample

A total of 121 potential participants was identified from clinic records. Some 66 (54%) of these agreed to take part in the study, 16 (13%) stated that they never wore their prostheses, 14 (11.5%) were unwilling to take part, and 25 (20.5%) could not be contacted and did not respond to letters sent (Table 1). Thus of the 80 contactable and relevant potential participants 82.5% participated in the study.

It is possible that potential participants who could not be contacted and who did not respond to letters were likely to be non-users. A further check of clinic records showed that 13 (52%) had no contact with the DSC over the previous 3 years. It is therefore possible to conclude that the participant group represented a higher proportion of wearers than the non-participant group.

There was no statistically significant gender differences between participants and non-participants. Amongst the male potential participants there was a significantly higher participation among amputees with a left sided absence than those with a right ($X^2 = 4.7$, $df=1$, $p<.05$).

Table 1. Potential participants by gender, age, reason and side of amputation and willingness to participate in study.

*TH=Trans-humeral; TR=Trans-radial

	Male								Female								Total
	Congenital				Acquired				Congenital				Acquired				
	Left		Right		Left		Right		Left		Right		Left		Right		
	TH	TR	TH	TR	TH	TR	TH	TR	TH	TR	TH	TR	TH	TR	TH	TR	
Participants	1	8	0	1	8	13	12	9	0	5	2	3	1	0	1	2	66
Unwilling	0	1	0	1	0	1	5	2	0	1	0	2	0	0	0	1	14
Non users	0	3	0	1	2	0	3	4	0	2	0	0	0	0	1	0	16
No contact	0	6	0	1	1	1	4	7	0	2	0	1	1	0	0	1	21
Total	1	18	0	4	11	15	24	22	0	10	2	6	2	0	2	4	121

Table 2. Average age of participants.

	Male	Female
Total potential participants (N=121)	52	46
Actual participants (N=66)	58	42
Non participants (N=55)	50	53

The age of the actual participants ranged from 16 to 79 years. Ages were recorded on the day the first contact was made by letter. Table 2 provides the average age of participants by gender. Females were on average younger than males and those females who participated in the study were on average younger than those who did not.

Fifty (76%) of participants reported that they wore their prostheses for 12 hours or more each day. Some 4 (6%) reported that they wore their prostheses for less than 1 hour a day. The average reported wearing time per day was 10 hours. There was no difference in the reported wearing time between participants who wore functional prostheses and those who wore cosmetic prostheses.

Results

For performing all three tasks, participants wore their prostheses with the TD they reported wearing most frequently. All participants completed the tasks independently. Five participants did not use their prostheses while performing any of the tasks, all of these participants had absences at trans-humeral level.

Terminal devices

Table 3 provides a list of the TDs worn by participants when performing the tasks, with the means and maximum and minimum number of actions made for each category of TD. The most worn TD was the cosmetic foam hand. Some 10 participants wore this as an integral part of a cosmetic one piece prosthesis, 3 as an integral part of an endoskeletal prostheses and 10 were fitted into the wrist unit of a standard resin prosthesis.

There was a significant difference between the categories of TDs in relation to the total number of actions made over all three tasks ($df=11$, $p<.0018$). The split hook and myoelectric hands were the most used TDs but the number of actions made with the split hooks ranged from as few as 24 actions to as many as 101 across all three tasks. This wide range in the number of actions made was observed for mechanical hands, heavy duty split hooks, cosmetic foam hands, and Steeplon hands. The maximum number of actions made with cosmetic foam hands were only slightly less than the maximum number made with myoelectric hands.

Twenty-six participants used TDs that could be considered functional i.e. the TD was capable of grasp/release action (1, 2, 3, 4, 5 in Table 3). However these TDs could only be used actively if the operating mechanisms were in place. Of the 26, 20 participants' mechanisms for operating the functional capacity of their TDs were in place, for the purpose of further analyses

Table 3. Total number of actions made for each category of TD used by participants across all three tasks for all descriptors

Terminal device	Total	Actions		
		Mean	Max.	Min.
1. Myoelectric hand	3	58.6	78	47
2. Mechanical hand	6	18.6	53	5
3. Split hook	12	58.6	101	24
4. Heavy duty split hook	4	38.0	84	4
5. Rubber hand with operating thumb	1	64.0	64	64
6. Rubber hand	1	43.0	43	43
7. Foam hand	23	24.5	71	0
8. Reinforced foam hand	3	34.6	38	28
9. Steeplon hand	8	24.5	45	5
10. Steeplon hand with spring thumb	2	7.0	14	0
11. C hook	1	21.0	21	21
12. Sack hook	2	36.0	47	25

Table 4. Mean, maximum and minimum number for all actions and non-manipulative actions only for each group of TDs

Group	Number	All actions			Non-manipulative actions		
		Mean	Max.	Min.	Mean	Max.	Min.
1. Actually functional	20	51	101	4	30	77	4
2. Potentially functional	6	30	51	9	30	51	9
3. Cosmetic	37	24	71	0	24	71	0

this group was classed as the *actually functional* group. Six participants did not have the mechanisms for operating their TD in place, this group was classed as the *potentially functional* group. Some 40 participants used TDs that had no grasp/release function. Of these 37 could be classed as cosmetic i.e. the TD was in the shape of a hand (6,7,8,9,10 in Table 3). Three could be classed as tools (11, 12 in Table 3). The numbers in these last two groups were so small that they were not included in further analysis

Actions

Overall there was a significant difference between the groups in relation to the total number of actions made across all three tasks for all descriptors ($df=2$, $p<.0005$) with the actually functional group performing more actions than the potentially functional and cosmetic groups.

Manipulative responses were virtually possible only amongst those wearing actually functional prostheses, when manipulative descriptors were removed from the analyses there was no significant difference between the three groups in relation to the number of actions made across all three tasks for non-manipulative descriptors ($df=2$, $p<.5615$) (Table 4).

As can be seen from Table 5, stabilising was the action most frequently performed by all three groups of TDs. There were no statistically significant differences between the 3 groups in relation to the number of actions made for each non-manipulative descriptor with the exception of *pull*. The cosmetic group made less pull actions ($df=2$, $p<.0138$). Pull would have been a difficult action to perform with a foam hand.

A series of ANOVAs were performed to explore the effects of level of amputation, side of amputation, reason for limb absence (acquired

Table 5. Total number of actions for each descriptor over all three tasks for actually functional, potentially functional and cosmetic TDs

	Descriptor	Act-functional TDs (20)		Pot-functional TDs (6)		Cosmetic TDs (37)	
		Total	Average	Total	Average	Total	Average
Manipulative	Grip	127	6.35				
	Release	123	6.15				
	Hold	120	6				
	Transfer	30	1.5				
	Change	21	1.05	3	0.50	1	0.02
Non-manipulative	Support	38	1.9	10	1.66	63	1.7
	Stabilise	337	16.85	105	17.5	483	13.05
	Push	86	4.3	23	3.83	99	2.67
	Pull	28	1.4	6	1.0	9	0.24
	Hold/TD	4	0.2	3	0.50	18	0.40
	Balance/TD	15	0.75	5	0.83	60	1.62
	Self grooming	43	2.15	11	1.83	34	0.91
	Steadying	8	0.4	0	0	15	0.18
	Pros. hold	27	1.35	10	1.66	63	1.7
	Pros. balance	3	0	5	0.83	13	0.35
	Stump hold	17	0.75	4	0.66	17	0.45

or congenital), gender and age on the total number of actions for all descriptors over all three tasks. There was a significant effect of level of amputation ($df=2$, $p<.000$); participants with a trans-radial (TR) absence performed significantly more actions over all three tasks than participants with trans-humeral (TH) absences. None of the other effects proved significant.

Of the 46 participants with an acquired absence, 24 (52%) had lost a dominant hand and 18% (39%) a non-dominant hand. Four (8%) considered they had been ambidextrous before their amputation. The effect of hand dominance before amputation and side of amputation on the total number on non-manipulative actions made over all three tasks for amputees for acquired amputations only was explored. No significant relationships were found.

Discussion

A number of potential participants when contacted by telephone judged they would be unsuitable for the study as they did not "use" their prostheses. When asked if they "wore" their prostheses they said yes but stated that they did not use the prostheses as they had been trained to use them. Some said they only wore their prostheses for cosmetic reasons. Most amputees expressing these views did agree to take part in the study when it was explained to them that the emphasis would be on performing everyday tasks and not demonstrating their skills in prosthetic use. Had these participants just responded to a questionnaire an accurate record of their prosthetic use may not have been obtained.

Twenty (30%) participants wore prostheses that could be activated for manipulative functional use; 4 participants in this group made no manipulative actions with their TDs. If active manipulation of a TD is seen as the determinant of good prosthetic use then the number of "good" users found in this study would be less than 25%. If involvement of the prostheses in tasks is seen as the determinant of prosthetic use then many more participants could be considered to be good users of prostheses. There was a wide range in the number of actions made by participants in all three groups. This highlights the need for a systematic review of training. The use of video to record performance of familiar tasks would be an excellent method for reviewing an amputees' use of their

prostheses. This video could be played back to the amputee as a means of providing feedback and stimulating discussion relating to the use of the prosthesis.

There was statistically no difference between groups in relation to the total number of non-manipulative actions performed. Participants who wore cosmetic prostheses used them non-manipulatively on average as frequently as participants who wore functional prostheses. The small but non-significant difference between the groups in relation to the mean for non-manipulative actions made (Table 4) could result from the fact that participants issued with functional prostheses are given training in the use of their prostheses and are likely to be reassessed when visiting the clinic. Amputees who choose to wear cosmetic prostheses do not routinely receive training in the possible use of the prostheses in performing two-handed tasks. It is more likely that this group use the postal service for repairs and replacements and therefore make fewer visits to the clinic and do not have the use of their prostheses regularly reviewed. It is not surprising that amputees who wear cosmetic prostheses unjustifiably consider themselves to be non-users.

Clearly for the small group of amputees who used the operative functions of their prostheses a level of skill had been achieved in the use of their TDs for grip, release and hold but it could be argued that these three actions are all part of a single grasping action. If this criterion had been applied to the recording of the actions made by participants using functional TDs then there would have greater similarity between the groups in relation to the total number of actions made.

Evidence from this study provides support for the prescription of a cosmetic prosthesis for an amputee's first prosthesis. It would be important that training be given and progress reviewed. If the amputee decides that they need a greater range of manipulative skills then a functional prostheses could then be considered.

This study's finding that pre-amputation hand dominance made no significant difference to the number of actions made by participants wearing a prostheses agrees with other studies (Gaine *et al.*, 1997; Roeschlein and Donnholtz, 1989). However there would appear to be evidence from this study that amputees with a left-sided absence are more likely to wear prostheses than those with a right absence. The number of amputees

registered with the Cambridge DSC with an acquired absence on the right side was higher than those with a left absence yet a significantly higher number of amputees with a left sided absence agreed to take part in the study. Interestingly it was also found that there was a significantly higher number of unilateral congenital amputees with a left-sided absence than those with a right-sided absence registered not only with the Cambridge DSCs but nationally (Fraser, 1997). It might be possible to conclude from these findings that amputees with a left absence are more likely to wear prostheses than those with a right absence. The reason for this could be that a prosthesis fulfils more satisfactorily the functions of a left or non-dominant hand than those of a right or dominant hand. An amputee expecting to perform fine motor tasks with a prosthetic device is frequently frustrated by lack of skill and speed, which can lead to the rejection of the prosthesis. More emphasis on two-handed tasks with the use of prosthetic devices for holding and stabilising and the intact hand for manipulating might be the best approach when training unilateral upper limb amputees in the use of their prostheses.

Amputees with an absence of an upper limb at trans-humeral (TH) level made less use of their prostheses when performing the tasks yet they reported wearing their prostheses on average as many hours a day as amputees with an absence at trans-radial (TR) level. It could possibly be concluded that TH amputees were more likely to be wearing their prostheses for cosmetic reasons or as "sleeve fillers". However it was found in a separate study of two amputees with an absence of an upper limb at TH that better standing balance was achieved when they were wearing a prosthesis than when they were not wearing one (Clapp, 1998). Both amputees appeared unaware of their improved balance when wearing their prostheses but both had commented that they felt "lost" without their prostheses. This finding suggests that a prosthesis has a valuable function in maintaining symmetrical balance and body posture. A comparative study between amputees who wear prostheses and those who do not in relation to posture and balance would be of interest.

Conclusion

This study has shown that prostheses that might be considered to be worn for purely

cosmetic reasons are in fact used functionally when performing everyday tasks. It would therefore seem to be important that an amputee who chooses to wear a cosmetic prosthesis is not considered to be a poor user and that a cosmetic prosthesis is presented to amputees not as an option only if functional prostheses are rejected but as a realistic alternative choice and that effective training in the use of cosmetic prostheses is routinely given.

The role the prosthesis plays in what might be considered two-handed tasks should also be reviewed in the light of this study. TDs appear to be designed primarily to reproduce aspects of fine hand function i.e. grip, release. In training amputees to use their prostheses they are frequently encouraged to practice picking up small objects with their TDs (Lake, 1997). The unilateral amputee may well demonstrate a high level of skill in the performance of these tasks in the clinic situation but is more likely to use his intact hand to execute these tasks in everyday life. He/she may become frustrated when performing such tasks with the prostheses if, as has been shown, they take longer than with the intact hand (Stein and Walley, 1983). If the role of the prostheses in supporting, stabilising, pushing, pulling, holding and facilitating balance in everyday life situations is accepted as more useful than that of manipulating small objects in the clinic situation; this could have a major influence on the design of prostheses and TDs and also influence training. A number of participants in this study were found to be using Steeplon hands. They reported that the shape of this hand was useful for pushing and pulling, and carrying things. They could lean on it to achieve balance and stabilise and support objects. Most of these participants had been issued with a foam hand to replace their Steeplon hand but they had found the foam hand did not perform the functions that the Steeplon hand did. The fingers of the foam hand could not be shaped to achieve carrying, or pushing or pulling; neither were they robust enough to lean on even when reinforced. Unlike the Steeplon hand the foam hand could not be easily cleaned, an important consideration if working in an area operating strict health and safety checks. Due to problems in manufacture the Steeplon hand is no longer available however the features of this highly "functional" if not cosmetically acceptable TD should be seen as important in the design of TDs in the future.

This study demonstrates that substantial improvements are possible in both the design and training in the use of upper limb prostheses.

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Laterality, gender and age differences in estimated frequency and actual registration of people with congenital upper limb absences

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Abstract

Initial analyses from a survey of people with unilateral upper limb congenital absence registered with the Cambridge Disablement Services Centre (DSC) indicated differences related to laterality and gender. A postal survey of all DSCs in the UK was conducted and support for these findings was provided from the analysis of the information supplied by the 25 DSCs who could provide data in the format requested. Comparing statistics for the UK population with those gained from the 25 DSCs, estimates for the number of children and adults who should be registered with DSCs in the UK are made. From these figures it is suggested that the non-registration rate for adults with a congenital absence of an upper limb could be as high as 64%.

Introduction

A number of studies have been undertaken relating to congenital limb reduction defects (Stoll *et al.*, 1996; Brown *et al.*, 1996; Froster and Baird, 1992; Rogala *et al.*, 1974). These studies have commented on the frequency of all congenital defects of the upper limbs. Comparison between studies is difficult as each study subdivides cases into subgroups differently. None of these studies focused specifically on cases that would benefit from prosthetic care although Froster and Baird (1992) did find a significant preponderance of left-sided defects within the subgroup of transverse defects at the radius/ulna level.

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McDonnell *et al.* (1988) provided estimates for the incidence of congenital upper limb deficiencies by comparing data from a number of sources. This paper focused on the number of cases that would benefit from prosthetic care but did not comment on gender. Kyberd *et al.* (1997) focused on the upper limb amputee population attending Oxford DSC. This study included both acquired and congenital upper limb absences. Although laterality and gender differences were observed amongst the clinic population with congenital upper limb absences the study did not specifically focus on these. A recent report by the Amputee Medical Rehabilitation Society (1997) provides estimates for the number of new cases per annum of upper limb congenital amputees needing prosthetic care in England. These figures are extrapolated from data from the Manchester DSC but do not give details of laterality or gender.

Cambridge DSC survey

A profile of upper limb amputees registered at Cambridge DSC was undertaken as part of a research project designed to evaluate how cosmetic and functional prostheses are used (Fraser, 1998). Analyses of the data related to congenital upper limb absences revealed significant differences between the numbers of left and right congenital absences as well as gender differences. As a result it was decided to pursue these findings further by engaging in additional enquiries.

From the Cambridge DSC records a total of 70 upper limb congenital amputees who had unilateral upper limb absences at trans-humeral or trans-radial level were identified. Some 41 were aged between 16 and 80 years in May 1996 and 29 were aged 15 years and below (Table 1).

Table 1. Congenital amputees registered with the Cambridge DSC by age, gender and side of absence.

Gender	Male		Female		
Side of absence	Left	Right	Left	Right	Total
Congenital 16 years and above	19	4	10	8	41
Congenital 15 years and below	11	10	15	3	29

There was a significant difference among the number of adults with a left limb absence and those with a right limb absence. Some 29 (71%) had a left-sided absence and 12 (29%) had a right-sided absence ($X^2 = 7$, $df = 1$, $p < .01$). Curiously this difference did not appear to exist in the younger age group. Twenty-nine congenital amputees aged 15 years and below were registered; 13 (45%) had a right-sided absence and 16 (55%) had a left-sided absence. Although there was a slight tendency for more left limb absences than right the difference was not significant.

It was possible that the laterality and gender differences observed in the Cambridge DSC population could have been an idiosyncratic feature of that population therefore it was decided to undertake a national survey of DSCs.

National DSC survey

The managers of 42 DSCs in the Directory Centres for the UK were contacted and a request made for details of the number of patients with a unilateral upper limb congenital absence who were registered at their centres, differentiated by side of absence, gender and age group (15 years and below and 16 years and above). Out of the total of 42 centres 5 did not have upper limb amputees registered with them, 4 centres did not reply and 8 centres were unable to supply data in the format requested. Thus useable data were available from 25 of the possible 37 DSCs which provide a service for upper limbs. There appeared no reason to think that the 12 centres not contributing data were systematically different from the group who did provide usable

data. From inspection they were geographically spread and from a knowledge of the centres they were equally represented in size.

Results of national survey

As can be seen in Table 2, of the 2075 patients with a congenital upper limb absence registered with the 25 participating DSCs, 363 (41%) aged 15 and below had a right limb absence and 515 (59%) had a left absence. In the 16 and above age group 467 (39%) had a right absence and 730 (61%) had a left absence. There were significantly more congenital amputees registered with the DSCs with a left absence than a right absence and this significant difference is observable in amputees aged 15 years and below ($X^2 = 25.6$, $df = 1$, $p < .000$) and those aged 16 years and above ($X^2 = 58$, $df = 1$, $p < .000$). There was a slight tendency towards a higher percentage of left congenital absences amongst the 16+ group when compared to the 15- group, but this difference was not significant ($X^2 = 3.07$, $df = 1$, $p > .05$).

If the data from the 25 DSCs are categorised by gender, there were significantly more males (54%) than females (46%) overall ($X^2 = 19.6$, $df = 1$, $p < .001$) (Table 3). If men and women were equally likely to have congenital absences of an upper limb and given that in 1995 the ratio of males to females in the UK was 1:1.04 (Population Trends 88, 1997) then it would be expected that in this sample there would be 1017 males and 1058 females. In fact there were 1118 males and 957 females. The finding of more males than female absences holds for children with right absences, children with left absences

Table 2. Congenital upper limb absences registered with 25 participating DSCs, by age group and side of absence.

Age	Left	Right	Total
16 years and above	730 (61%)	467 (39%)	1197 (100%)
15 years and below	515 (59%)	363 (41%)	878 (100%)
Total	1245 (60%)	830 (40%)	2075 (100%)

Table 3. Data from 25 DSCs divided into age groups, gender and side of absence.

	Left		Right		Total
	Male	Female	Male	Female	
16 years and above	355 (29%)	375 (31%)	276 (23%)	191 (15%)	1197 (100%)
15 years and below	284 (32%)	231 (26%)	203 (23%)	160 (18%)	878 (100%)
Total	639 (31%)	606 (29%)	479 (23%)	351 (17%)	2075 (100%)

and adults with right absences. In the case of adults with a left absence a significantly higher percentage of females is observed than would have been expected ($X^2 = 12.77$, $df = 1$, $p < .001$).

Age differences and estimates of non-registration

It might be assumed that all children (aged 15 and below) with a congenital absence of a limb who are registered with a DSC would continue to use the service at 16 years and beyond. However this would appear not to be the case. For the most recent year 1995, for which data are available, the ratio of 15- to 16+ for the UK population was 1:3.84 (Population Trends 88, 1997). There has been no significant increase in congenital upper limb absence in the last 16 years (Chappell, 1992) and if the life expectancy of people with congenital upper limb absences is similar to the general population it could be assumed that there should be 3.84 times as many adults (16 years and above) with a congenital upper limb absence as children with such a limb absence. From the 878 children registered it could be expected that 3,372 adults should be registered with the 25 DSCs. As only 1,197 adults were recorded as being registered this suggests that 64.5% of people with upper limb congenital absences who are aged 16 years and above are not registered with a prosthetic clinic and probably do not wear prostheses.

Although there is currently no central database for recording the number of people with upper limb congenital defects, attempts have been made to determine what the overall figure might be. McDonnell *et al.* (1988) reviewed various data sources for the UK and North America and suggested a figure of approximately 1:9400 for whom prosthetic provision could be considered. Kyberd *et al.* (1997) suggested that a figure of around 1:13,500 would best correspond to the upper limb congenital absence rate per year for the Oxford population who would benefit from prosthetic provision. From the report by the Amputee Medical Rehabilitation Society (AMRS) (1997) it is possible to derive a figure of 1:4,670 cases who would need prosthetic provision. A very rough estimate of the expected number of people with congenital limb absences in the UK, using the total population figure for the UK for 1995 of 58,606,000 and McDonnell's estimates would be around 6,235. If the Oxford figure was used then the number would be 4,341. If the AMRS data are used the number would be 12,307. Assuming that the 25 centres providing usable data were representative of the 37 centres in the UK who have people with congenital upper limb absences registered at their centres it could be estimated that approximately 3,071 people with congenital upper limb absences would be registered. Using the figure and comparing it with the figures gained from McDonnell, Kyberd and AMRS estimates it

Table 4. Alternative estimates of upper limb congenital absences extrapolated from different sources of observed data.

Age	Registered nos. for 25 UK DSCs	Est. registered nos. for 37 UK DSCs	Est. population from McDonnell <i>et al.</i> (1998)	Est. population from Kyberd <i>et al.</i> (1997)	Est population from AMRS (1992)
15-	878	1299	1288	897	2543
16+	1197	1772	4947	3444	9767
Total	2075	3071	6235	4341	12307

could be assumed that between 1,270 and 9,236 people with congenital upper limb absences are not registered with a prosthetic clinic (Table 4).

Again using these very rough estimates it could be assumed that slightly more than one fifth of the number of people with congenital upper limb absences derived from the McDonnell, Kyberd and AMRS figures would be aged 15 and below i.e. 1,288, 897 and 2,543 respectively. The estimated number of children 15 and below registered with the 37 UK DSCs is 1,299 which is very similar to the estimate derived from McDonnell. This figure would lead to the conclusions that, if the McDonnell figures were used then all children in the UK for whom prosthetic treatment should be considered appear to be registered with a DSC and that the discrepancy between the number of congenital upper limb absences actually registered with DSCs in the UK and the number that could be expected to be registered results entirely from the adult group.

If the Kyberd figures were to be used then it would have to be concluded that more children are registered in UK DSCs than were born with a congenital absence. The Kyberd figures were calculated for the Oxford population and may not reliably apply to the UK population as a whole. Nevertheless, also from the Kyberd figures, there would appear to be evidence for a lower number of adults registered with the Oxford DSC than might have been expected.

Using the numbers derived from both the Kyberd and McDonnell figures for the 16+ population there appears to be a non-registration of between 49% and 64% of adults with a congenital absence.

The AMRS figures appear to bear no relation to the other estimates. These figures are extrapolated from one high profile DSC which has a strong reputation for prosthetic care of children. In fact there is evidence from the data collected from the 25 DSCs to suggest that the centre has attracted twice the number of children with congenital upper limb absences who would have been expected from the catchment area. Interestingly if the AMRS estimate for children is halved it is comparable with the McDonnell figures and the estimated figure for the UK DSCs.

Discussion

A bias towards more left-sided upper limb congenital absences has been commented on in a

number of papers (Kyberd *et al.*, 1997; Froster and Baird, 1992; McDonnell *et al.*, 1988; Scotland and Galway, 1983). There appear to be no definitive explanations for this. Corballis and Morgan (1978) suggest that the developing embryo is under the influence of a left-right maturational gradient which seems to favour earlier or more rapid development on the left than on the right. Brown *et al.* (1989) raises the possibility that the asymmetric development of the cardio-vascular system leads to subtle differences in vessels serving the left and right limbs and that the most likely explanation for the mechanism of induction of unilateral limb defects may lie in the vascular supply to the limbs. These factors could be important if embryos are more likely to be exposed to negative influences earlier rather than at a slightly later stage in their development.

There is some evidence to suggest that people with a left-sided absence are more likely to wear prostheses. A slight but non-significant tendency towards a higher percentage of left absences in the 16+ age group as compared to the 15- group was observed in this study (Table 3). Dlugosz *et al.* (1988) found evidence of an apparent association between congenital limb reduction defects of the upper limb and learning difficulties. Children with learning difficulties may have problems in learning to use prostheses and this may lead to a higher rejection rate in this group. It would be interesting to explore this finding further. There was also a significantly higher number of 16+ females registered than would have been expected from the sample as a whole. Kyberd *et al.* (1997) also reports a significantly larger number of females with a left-sided congenital absence registered with the Oxford DSC. These findings might suggest that people and particularly females with a left absence are more likely to continue to use prosthetic services in their adulthood and therefore be good wearers of prostheses. Interestingly in the Cambridge study undertaken to evaluate how cosmetic and functional prostheses are used; amongst the possible participants, who included both congenital and acquired amputees, 57 (47%) had a left-sided absence and 64 (53%) had a right absence but amongst the actual participants in the study 36 (55%) had a left absence and 30 (45%) had a right absence. This might also support the idea that people with a left-sided upper limb absence

are more likely to wear prostheses than those with a right absence. McDonnell *et al.* (1988) suggests that a prosthesis would be more successful when fitted on the side that would have been dominant and as 85 per cent of the population is thought to be right hand dominant it could be expected that more people with a right-sided absence would become wearers of prostheses. From the findings reported in this paper this would not appear to be so.

Significantly more males than females were found to be registered with DSCs. This finding is supported by other studies (Jones and Lipson, 1991; Gregory-Dean, 1991; McDonnell *et al.*, 1988) but not commented on. Other studies have included amputees with an acquired absence. As higher numbers of males and a higher number of right-sided absences are seen amongst amputees with an acquired absence it could be that the laterality and gender differences amongst the congenital group have not been fully appreciated. This apparent discrepancy between the number of children and adults registered with DSCs could reflect an improvement over the last 20 years in the referral to prosthetic services of children with upper limb absences. Many adults over the age of 40 may never have been referred to a limb clinic. Before 1970 children were often only referred to a clinic when they went to school. Scotland and Galway (1983) demonstrated a dramatic increase in the acceptance rate in prosthetic wear in children fitted before two years of age. If this is the case and if as this study suggests most children with an upper limb absence are being registered with limb clinics it could be expected that as these children reach adulthood a higher number will continue to use their prostheses. There could then be a marked overall increase in the number of people using upper limb prosthetic services.

The non-registration of adults could also reflect the influence of parents who put pressure on their children to wear a prosthesis. Once in their teens they may reject their prostheses. Scotland and Galway (1983) and Brooks and Shaperman (1966) report an increase in the rejection rate amongst teenagers. Another reason for rejecting a prosthesis could be that people with a limb absence choose careers and lifestyles that minimise the need for 'two hands'. In the Cambridge study evaluating the use of cosmetic and functional prostheses, 54% of the participants reported that the choice of their

career had been influenced by their limb absence.

The wide discrepancies in the different estimates of people with congenital upper limb absences reflect the dearth of reliable sources for data collection. Drawing conclusions about the population of congenital upper limb absences by extrapolating data from one limb deficiency centre is likely to prove unreliable. It is unlikely that a reliable estimate for the number of people with upper limb deficiencies will be obtained until accurate records are available from all upper limb deficiency centres and the progress of both people who choose to use prosthetic services and those who choose not to are monitored.

Conclusions

This study has shown the need for detailed centralised records for upper limb absences in order to gain accurate and reliable information about this group. The number registered in any single clinic is small and it is only when larger numbers are used that certain patterns become apparent and significant. It will be important to monitor the numbers registered in DSCs over the next few years as children who should have benefited from early fitting of prostheses and improved follow-up become adults. Multicentre studies would provide a larger population of people with upper limb absences for study and more reliable information could emerge which would benefit both those who use prosthetic services and those who provide and plan the services

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Newly designed computer controlled knee-ankle-foot orthosis (Intelligent Orthosis)

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Abstract

The authors have developed a knee-ankle-foot orthosis with a joint unit that controls knee movements using a microcomputer (Intelligent Orthosis). The Intelligent Orthosis was applied to normal subjects and patients, and gait analysis was performed. In the gait cycle, the ratio of the stance phase to the swing phase was less in gait with the knee locked using a knee-ankle-foot orthosis than in gait without an orthosis or gait with the knee controlled by a microcomputer. The ratio of the stance phase to the swing phase between controlled gait and normal gait was similar. For normal subjects the activity of the tibialis anterior was markedly increased from the heel-off phase to the swing phase in locked gait. The muscle activities of the lower limb were lower in controlled gait than in locked gait. The ground reaction force in locked gait showed spikes immediately after heel-contact in the vertical component, and unusual patterns were observed at heel-contact in the sagittal and lateral component. Therefore, compared to locked gait, gait with the Intelligent Orthosis is smooth and close to normal gait from the viewpoint of biomechanics. Even in patients with muscle weakness of the quadriceps, control of the knee joint using the Intelligent Orthosis resulted in a more smooth gait with low muscle discharge.

Introduction

Recent advances in electronics and control engineering have been introduced into the

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medical field. In rehabilitation medicine, a walking rehabilitation robot (Siddiqi *et al.*, 1994) and a trans-femoral prosthesis in which the swing phase is controlled by a microcomputer according to the walking rate (Nakagawa *et al.*, 1985) were developed and have been put to practical use. In orthoses, joint units have been improved to control joint movements. However, in the knee-ankle-foot orthoses presently used, the support of the joint is considered to be more important than its mobility, and the knee is locked during walking. Therefore, patients generally use such an orthosis only during walking training and not in daily life.

The authors have developed a knee-ankle-foot orthosis with a metal upright containing a joint unit that controls the angle and strength of knee fixation (Intelligent Orthosis: IO). This orthosis can be used according to the degree of functional impairment in various activities of daily life.

An IO was applied to normal subjects and patients with muscle weakness of the quadriceps, and gait analysis was performed identifying, muscle activities of the lower limb, and the ground reaction force.

Constitution of IO and control method

The IO consists of a microcomputer (PC-9801NS/A, NEC Co Ltd), a brake controlling the braking power (internally expanding hub brake for wheelchairs), a servomotor as the power source of the brake (Digital AC Servo Motor-BNE006BC, Driver-DSAOS, Waco Co Ltd), a rotary encoder for detection of the angle of the knee (Micro Encoder, Microtech Laboratory Co Ltd), a heel switch (on-off type contact switch), and a knee-ankle-foot orthosis with a metal upright (KAFO). The entire orthosis weighs 4.2 kg. The microcomputer, the

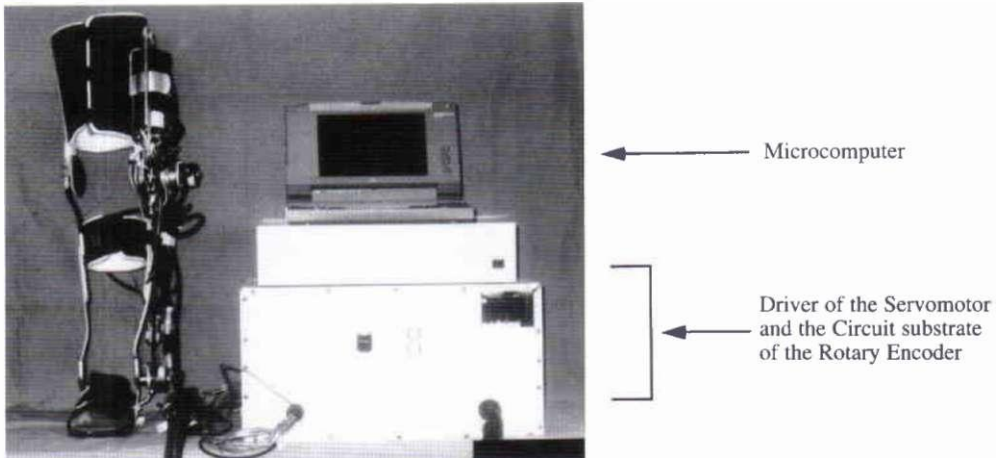


Fig. 1. Intelligent Orthosis (pat. 594050898).

driver of the servomotor and the circuit substrate of the rotary encoder were connected to the brake and the servomotor using 3 codes. The brake and the servomotor were placed on the lateral side of the femoral portion of the KAFO, the rotary encoder was placed on the lateral side of the knee and the heel switch was attached to the heel (Fig. 1). For the control of the knee, the resistance to joint movements was increased from the late swing phase so as to fix the knee at the time of heel-contact and it was decreased at the time of heel-off to release the fixation. The brake that adds resistance to the knee was controlled by inputting the knee flexion angle detected by the rotary encoder and signals from the heel switch into the microcomputer and sending commands from the microcomputer to the servomotor. The operation of the brake was initiated by signals from the rotary encoder and discontinued by signals from the heel switch (Fig. 2).

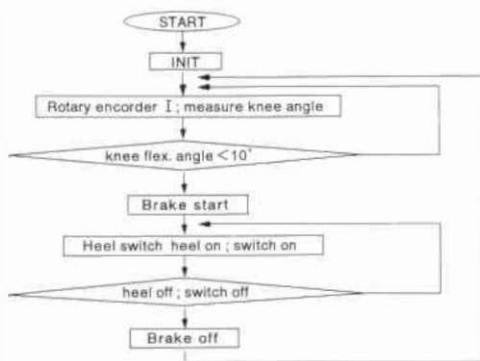


Fig. 2. Flow chart of control programme.

The brake provides braking torque when it is connected to the servomotor via the screw nut, and the servomotor rotates. To examine the characteristics of the braking torque of the brake, a weight was applied at a site 40 cm from the rotational centre in joint extension, and the maximum weight that allows maintenance of joint extension was measured. The maximum braking torque was 28.81 Nm at the extension position of the joint. A marked positive correlation ($r=0.983$, $p<0.0001$) was observed between the braking torque of the brake and the rotation rate of the servomotor (Fig. 3).

Subjects and methods

The subjects were 15 healthy adult males aged 20-35 years (mean, 26.8 ± 4.2 years). An IO was applied to the left lower limb.

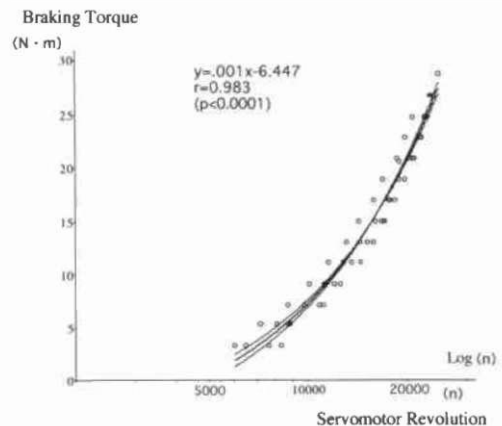


Fig. 3. The Relationship between braking torque and servomotor revolution in the experimental study.

The subjects were requested to walk: 1) without the orthosis (normal gait); 2) with an IO without knee fixation using the ring lock (braced gait); 3) with the knee fixed in extension (locked gait); and 4) with the knee controlled using a microcomputer (controlled gait). Gait analysis was performed based on measurements values in each phase of the gait cycle (Dubo *et al.*, 1976; Winter *et al.*, 1972), records of muscle activities of lower limb muscles on dynamic electromyograms (EMGs) (Bigland-Ritchie *et al.*, 1978; Bogery *et al.*, 1992; Branch *et al.*, 1989; van Lent *et al.*, 1994; Winter and Yack, 1987; Winter and Sienko, 1988), and results of the measurements of the ground reaction force (Engsberg *et al.*, 1993; Hermodsson *et al.*, 1994).

In the gait cycle, the period from heel-contact to toe-contact was defined as the early stance phase (heel-strike), that from toe-contact to heel-off as the mid-stance phase flatfoot, that from heel-off to toe-off as the late stance phase (heel-off), and that from toe-off to heel-on as the swing phase. The ratio of each phase to the gait cycle was calculated, and each gait was compared with normal gait. The events in the gait cycle were identified using a foot switch sensor system (Takei Kiki Co Ltd, T.K.K., 1901), and the foot pressure was detected at 3 sites, i.e., the heel, head of the first metatarsal bone, and the head of the fifth metatarsal bone.

Muscle activities of the lower limb were measured on the vastus medialis (Vm), rectus femoris (Rf), biceps femoris (Bf), tibialis anterior (Ta), and lateral head of the gastrocnemius (Gl) with surface electrodes using a Synafit 1000 (band pass filter 5-500 Hz, NEC San-ei Co Ltd). Surface electrodes were attached in parallel to muscle fibre arrangement with the motor point of each muscle between them (Warfel, 1974). The EMG records were analogue/digitally (A/D) converted and converted into those per gait cycle by full-wave rectification. Data for 10 steps were added and averaged. In addition, the obtained waves were integrated, and the discharge in each muscle during walking was obtained. The percentage of the muscle discharge to that during the maximum voluntary muscle contraction per unit of time in the manual muscle testing position was calculated as percent manual muscle test (%MMT) (Perry *et al.*, 1985/86). The discharge during the maximum voluntary muscle contraction in the manual muscle testing

position was measured in the sitting position at rest (hip flexion, 90°; knee flexion, 90°; ankle neutral position). Dynamic EMG records were processed (A/D conversion, full-wave rectification, averaging addition, and standardization) using a Signal Processor DP-1100 (sampling rate 5,000 points, NEC San-ei Co.Ltd). The discharge pattern of muscle activity during walking was compared using %MMT, and the amount of muscle activity using full rectified waves (Hong *et al.*, 1990; Winter, 1984; Winter, 1985).

The ground reaction force, vertical (Fz), sagittal (Fx), and lateral (Fy) components were recorded using a one-layer frame type Osaka Electro-Communication University force plate (15 cm x 33 cm) with the natural frequencies as shown in Table 1. (The measurement plane of this plate is supported by 4 struts for detection in the horizontal direction and 4 for detection in the vertical direction, and the distortion of these struts and the moment are measured.) This force plate was buried on the left side in the middle of a walking route (10 m), and ground reaction force as recorded. The obtained ground reaction force waves were normalized for body weight and the stance time, and data for 5 steps were added, averaged, and standardized (Engsberg *et al.*, 1993).

Measurement of each phase in the gait cycle and recording of dynamic EMG and ground reaction force were performed after the subject's gait became constant by practice.

Gait analysis was performed in 10 patients with decreased strength of the quadriceps muscle of the left lower limb (Table 2). With informed consent for this experiment from the patients, an IO was applied to the left lower limb. The gait cycle, muscle activities of the lower limb during walking, and ground reaction force (vertical and sagittal components) were measured. Locked gait and controlled gait were analysed.

Statistical analysis of difference was performed on Apple Macintosh system (Coppertino, California) using Microsoft Excel (Microsoft,

Table 1. The sensitivity of the force plate.

	Sensitivity	Natural frequency
Fx	30 μ / 980 N	1300 Hz
Fy	380 μ / 980 N	391 Hz
Fz	30 μ / 980 N	1300 Hz

Table 2. Patient profile.

Number	Age	Diagnosis	Operation	Post operation
1	46	Medial meniscus tear	Scopic partial menisectomy	1 week
2	21	Chondromalacia patellae	Scopic lateral release	1 week
3	23	Anterior cruciate ligament rupture	Reconstruction of ligament	1 month
4	36	Anterior cruciate ligament rupture	Reconstruction of ligament	1 month
5	22	Chondromalacia patellae	Scopic lateral release	1 week
6	32	Medial meniscus tear	Scopic partial menisectomy	1 week
7	25	Medial meniscus tear	Scopic partial menisectomy	1 week
8	67	Patellae tendon old rupture	Reconstruction of ligament	1 month
9	29	Fracture of femoral shaft	Open reduction and internal fixation	2 weeks
10	26	Fracture of femoral shaft	Open reduction and internal fixation	2 weeks

Redmont, Washington) and Statview (Abacus Concepts, Berkeley, California) software.

Results

Measurement of gait cycle

Gait analysis in terms of gait cycle was performed in 10 normal subjects in whom the gait cycle was clearly identified.

On the left side (braced leg side), the ratio of the stance phase to the gait cycle in locked gait was reduced. Significant differences were observed between normal gait and braced gait ($p<0.05$) or locked gait ($p<0.01$) but not between normal gait and controlled gait (Table 3). On the right side (non-braced leg side), the ratio of the stance phase to the gait cycle in controlled gait was increased. A significant difference was

observed between normal gait and controlled gait ($p<0.05$) but not between normal gait and braced gait or locked gait (Table 3). The ratio of the stance phase on the left side (braced leg side) to that on the right side in controlled gait was increased. A significant difference was observed between normal gait and locked gait ($p<0.05$) but not between normal gait and braced gait or controlled gait (Table 4).

Muscle activity of lower limbs as identified by dynamic EMG

The discharge pattern of the muscle (Fig.4)

Concerning the discharge pattern of the lower limb muscles in normal gait, vastus medialis (Vm) and rectus femoris(Rf) showed activity during the transition from the swing to stance

Table 3. The ratio of the stance phase in the gait cycle (10 healthy volunteers).

phase gait	Braced leg				Non-braced leg
	Heel-strike	Flat-foot	Heel-off	Stance	Stance
Normal gait	0.08±0.03	0.35±0.04	0.18±0.04	0.61±0.03 ^{a b}	0.60±0.03 ^c
Braced gait	0.10±0.03	0.32±0.05	0.20±0.05	0.62±0.03 ^a	0.60±0.03
Locked gait	0.10±0.04	0.30±0.09	0.17±0.06	0.57±0.03 ^b	0.62±0.03
Controlled gait	0.10±0.03	0.31±0.03	0.20±0.06	0.61±0.04	0.64±0.04 ^c

n = 10 (Mean±SD)

a,c: $p<0.05$

b: $p<0.01$

Wilcoxon signed-rank test

Table 4. The ratio of the stance phase of non-braced leg: comparison with the stance phase of braced leg (10 healthy volunteers).

	Normal gait	Braced gait	Locked gait	Controlled gait
Non-braced leg Stance Braced leg Stance	0.98±0.04	0.98±0.04	1.08±0.05 [*]	1.03±0.04

n = 10 (Mean±SD) * $p<0.05$

Wilcoxon signed-rank test

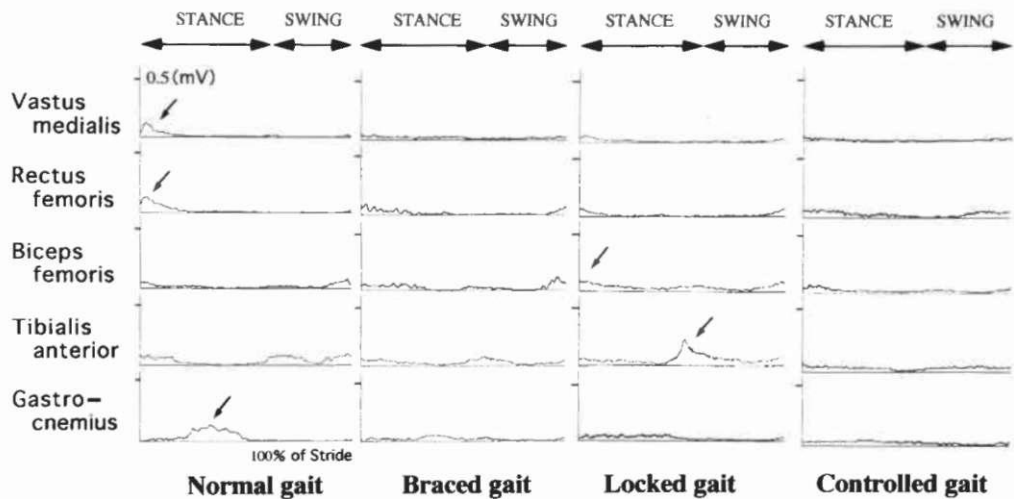


Fig. 4. Normalised fully rectified EMG of healthy volunteers.

phase and especially marked activity in the heel-strike. These findings were consistent with previous reports (Kameyama *et al.*, 1990; Kameyama *et al.*, 1994). Biceps femoris(Bf) showed activity in the bilateral leg support phase before and after heel-contact, and tibialis anterior (Ta) in each transition phase to the stance phase or to the swing phase. Lateral head of the gastrocnemius(G1) exhibited activity in the entire stance phase and especially marked activity in the heel-off phase. The state of muscle activity was compared among gait types. The activities of Vm and Rf observed in the heel-strike phase in normal

gait were decreased in braced gait, locked gait, and controlled gait. The activity of G1 observed in the heel-off phase in normal gait was also decreased in the 3 gait types. On the other hand, the activity of Ta observed from the heel-off phase to the swing phase in normal gait was markedly increased in locked gait. The activity of Bf did not markedly differ among the 4 gait types.

Muscle discharge (Fig. 5, Table 5)

The percent manual muscle test (%MMT) values for Vm, Rf, and Ta were higher in braced gait and locked gait than in normal gait, showing

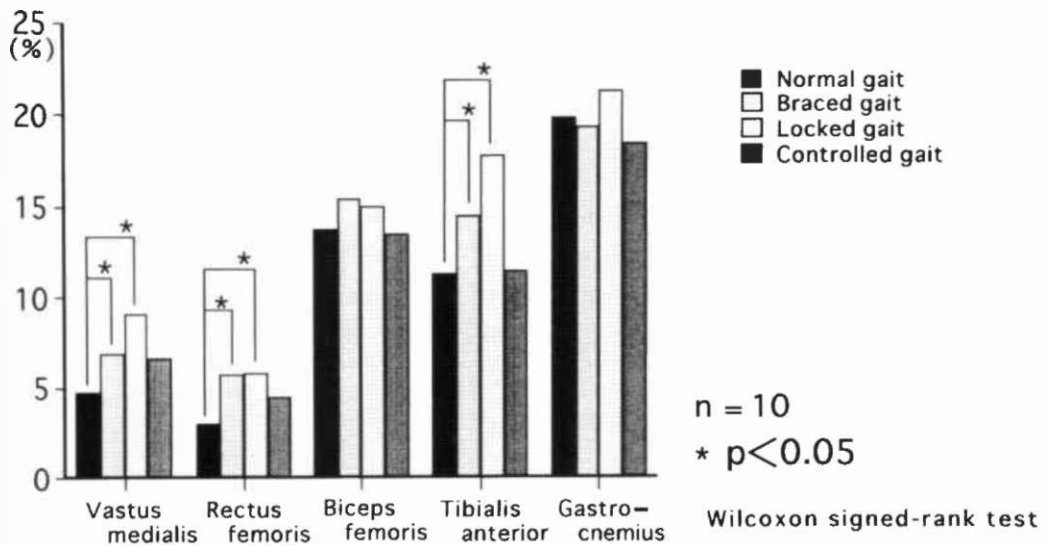


Fig. 5. %MMT of normalised fully rectified EMG (10 healthy volunteers).

Table 5. %MMT of normalised fully rectified EMG (10 healthy volunteers).

gait \ muscles	Vastus medialis	Rectus femoris	Biceps femoris	Tibialis anterior	Gastrocnemius
Normal gait	4.73±1.70 ^{a,b}	2.80±2.03 ^{c,d}	12.45±3.10	11.45±1.18 ^{e,f}	19.83±5.91
Braced gait	7.28±0.85 ^a	5.88±0.65 ^c	16.38±2.04	14.05±1.47 ^e	19.83±8.59
Locked gait	7.46±2.09 ^b	5.30±0.33 ^d	15.90±2.92	17.30±3.83 ^f	18.83±6.44
Controlled gait	5.53±1.03	4.65±0.99	14.05±4.13	9.65±2.51	18.68±5.84

n = 10 (Mean±SD)

a,b,c,d,e,f: p < 0.05

a significant difference between normal gait and braced gait ($p < 0.05$), but they did not markedly differ between controlled gait and normal gait. The %MMT values for Bf and Gl did not markedly differ between normal gait and other types of gait. All 5 muscles showed a lower %MMT in controlled gait than in braced or locked gait.

Ground reaction force

The ground reaction force waves are shown in figure 6. In normal gait, vertical component waves showed a nearly trapezoid pattern with two peaks indicating a deceleration phase and an acceleration phase. Sagittal component waves consisted of waves in a deceleration phase and those in an acceleration phase, and these waves showed similar patterns with the baseline between them. Lateral component waves

consisted of a wave indicating inward force and that indicating outward force; the former showed a positive value, and the latter, a negative value. When the types of gait were compared, the vertical component showed spikes immediately after heel-contact in locked gait but not in normal or controlled gait. In the sagittal component, the maximum value in an acceleration phase was higher, and its rise was more acute in locked gait than in normal or controlled gait. In the lateral component, a large outward wave was observed at the time of heel-contact in locked gait. The wave patterns of the sagittal and lateral components in controlled gait were similar to those in normal gait.

Clinical cases

After application of an IO to the 10 patients with muscle weakness of the quadriceps in the left

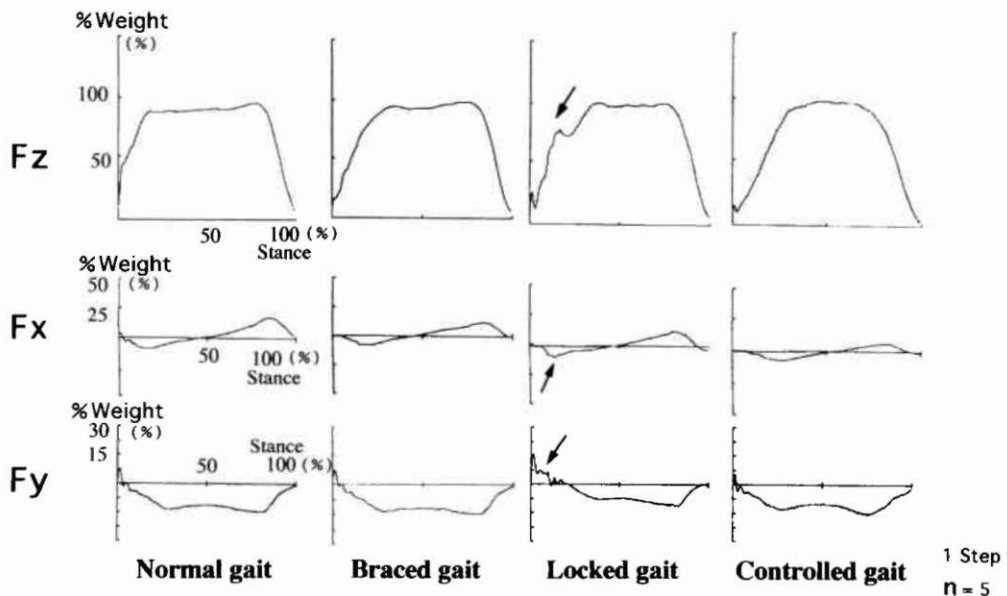


Fig. 6. Normalised ground reaction force of healthy volunteer.



Fig. 7. Walking with IO (Case 1: 46y, M, meniscus tear).

lower limb, the gait cycle, the muscle activity of the lower limb during walking, and ground reaction force (vertical and sagittal components) were measured. In all patients, walking without aid was difficult due to buckling during walking, but the use of the IO enabled safe walking. However, the patients reported that the brace is too heavy and complained of fatigue after walking for a long time (Fig. 7).

In a patient with chondromalacia patellae showing a postoperative muscle weakness of the quadriceps, the gait cycle was measured in locked gait and controlled gait. On the left side (braced side), the ratio of the stance phase to the gait cycle was shorter in locked gait than in controlled gait. The ratio of the stance phase on the right side (non-braced side) to that on the left side was increased in locked gait (Table 6).

In a patient with anterior cruciate ligament rupture showing a postoperative muscle weakness of the quadriceps, the muscle discharge was compared between locked and controlled gait. The %MMT values for Bf, Ta and G1 were lower in controlled gait than in locked gait (Fig. 8).

In a patient with meniscus tear showing a postoperative muscle weakness of the

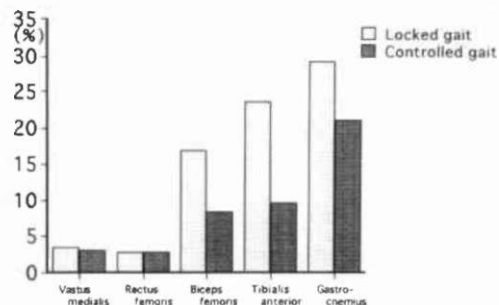


Fig. 8. %MMT of normalised fully rectified EMG of a patient (Case 3: 23y, M, ACL rupture).

quadriceps, ground reaction force waves were compared between locked gait and controlled gait. In the vertical component, spikes were observed immediately after heel-contact in locked gait. In the sagittal component, the maximum value of the deceleration phase component was higher, and its rise was more acute in locked gait than in controlled gait (Fig. 9).

Discussion

Various devices have been reported to control the mobility and support of the joint unit in limb prostheses. As a result trans-tibial prostheses in which the swing phase of the shank is controlled using a computer were developed and have been put into practical use. In the orthotic field, knee-ankle-foot orthoses with a pelvic band such as the hip guidance orthosis (HGO) or a reciprocating gait orthosis (RGO) have been developed as functional orthoses (Beckham, 1987; Douglas *et al.*, 1983; Major *et al.*, 1981; Petrofsky and Smith, 1991). However, there have been few studies on the joint unit of orthoses to control joint movements, and only a few have been put into practical use. Unlike lower limb prostheses, an affected limb is present for orthoses wearers. Therefore, the method and mechanism of the control of joint movements used in lower limb prostheses can

Table 6. The ratio of the stance phase in gait cycle of a patient (Case 2: 21y, M, chondromalacia patellae)

gait \ phase	Braced leg stance	Non-braced leg stance	Non-braced leg stance
			Braced leg stance
Locked gait	0.56±0.01	0.68±0.01	1.21
Controlled gait	0.61±0.04	0.67±0.03	1.12

(Mean±SD)

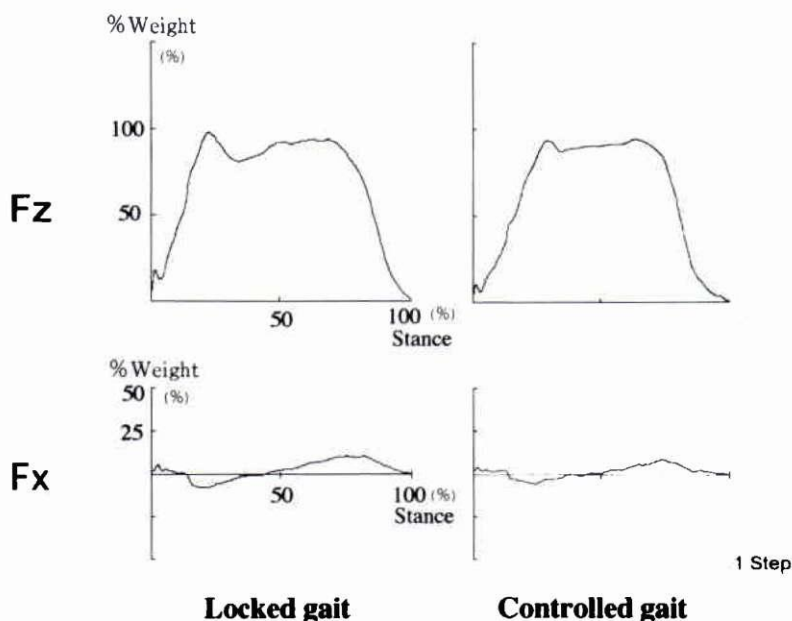


Fig. 9. Normalised ground reaction force of a patient (Case 7: 25y, M, meniscus tear).

not be applied to orthoses.

In the orthotic field, the authors developed a knee-ankle-foot orthosis with a knee unit that allows control of joint movements using a computer (IO). To evaluate the effects of the use of his IO on gait, gait analysis was performed measuring the muscle activity of the lower limb and the ground reaction force.

On the left side (braced side), the stance phase was shorter in locked gait than in normal gait. The ratio of the stance phase on the right side (non-braced side) to that on the left side was the highest in locked gait. Gait analysis showed that controlled gait is closer than locked gait to normal gait. However, on the right side, the stance phase was longer in controlled gait than in normal gait. This may be due to the weight of the IO.

In locked gait, since the knee cannot be flexed, the lower limb is abducted, resulting in circumduction gait. Therefore, from the heel-off phase to the swing phase, the ankle is dorsiflexed. Dynamic EMG showed abnormal discharge in Ta only in locked gait. In controlled gait, the activities of Vm and Rf were decreased in the heel-strike phase compared with normal gait. These decreases may be due to adequate knee fixation using the IO.

In locked gait, the lower limb swings downward from the lateral to the medial side, and the knee that absorbs the impact at the time of the heel-contact is fixed. Therefore, an acute large braking force acts on the ground at the time of heel-contact. Each component of the ground reaction force showed spikes suggesting strong impact only in locked gait. Controlled gait did not show the abnormalities observed in locked gait.

Recently, rehabilitation for various diseases such as cerebral palsy has been actively initiated in an early stage. However, since the physical function markedly changes in patients during early therapy, changes in their pathological condition cannot be promptly coped with using the present orthoses. The authors designed an Intelligent Orthosis with a joint unit that controls movements of the knee joint for the purpose of adjusting to the degree of functional impairment and changes in pathological conditions.

In the IO, the driver of the servomotor, the circuit substrate of the rotary encoder, and the microcomputer are placed outside. The output capacity of the servomotor was 60 Watt. Improvement in the material of the IO, the performance of the brake, and the output capacity can reduce the weight of the IO to make it portable.

Conclusion

1. A knee-ankle-foot orthosis was developed with a joint unit that controls knee movements using a microcomputer (Intelligent Orthosis).
2. Analysis of the gait cycle, the muscle activity of the lower limb, and the ground reaction force suggested that gait with control of knee movements using an Intelligent Orthosis is closer than knee-locked gait to normal gait in terms of the gait cycle and the state and amount of muscle activity.
3. In patients with muscle weakness of the quadriceps, the control of knee movements using an IO allowed smoother gait with lower muscle discharge than knee-locked gait.

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A review of reciprocal walking systems for paraplegic patients: factors affecting choice and economic justification

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Abstract

The prescription of treatment systems which include orthoses to enable patients with high level thoracic spinal lesions to walk reciprocally is now widely practised. It remains a clinical option for which the efficacy is frequently called into question. A broad range of experience has now been accumulated with orthoses of this type, and this is reflected in the literature. The indications for prescription and outcomes of treatment have, as a result of the reported research, become clearer. However, the length of time over which the relevant work has been published and the variety of journals in which it has appeared makes it difficult to perceive a coherent message.

This review analyses the published work in order to identify the degree to which the therapeutic benefits which can accrue from ambulatory activity produce an economically justified outcome. Provided appropriate supply procedures are observed so that good patient compliance with the treatment is achieved, there is strong evidence that fewer pressure sores and improved independence will occur at a level where real overall cost savings can be made.

Factors which affect patient compliance and on which research findings have been published are identified. Comparisons are made between different orthoses with regard to these, so that more informed choice, taking into account preferences of individual patients, can be made by clinicians.

Introduction

Reciprocal walking for patients who have no control of their lower limbs as a result of

traumatic, acquired or congenital paraplegia at level L1 or above, as proposed by Rose (1979), has now been routinely available since 1983 (Douglas *et al.*, 1983; Butler *et al.*, 1984). The objectives of such treatment systems are to provide therapeutic benefit and improvements in independence. When achieved these have important long-term financial and social implications, as well as enabling paraplegic patients who were previously unable to do so to walk in a manner which is acceptably close to normal.

There are several orthoses available to fulfil this role but confusion surrounds the justification, cost and clinical viability of these. At present the choice is most strongly influenced by the familiarity of clinicians with just one system. They are frequently overwhelmed by other clinical work and this prevents them from undertaking detailed comparisons of the efficiency of available systems. It is therefore very difficult for them to make a fully informed decision on the most suitable orthotic management of patients in their care who wish to ambulate. The increasing influence of managers within market oriented healthcare systems suggests that they should have a role in identifying the relevant health economics factors relative to walking for paraplegics, so that they can advise clinicians on the most appropriate action in the best interests of the patient, healthcare provider and purchaser.

The systems and their objectives

There are two basic types of reciprocal walking device which are routinely available:

1. Cross-linked hip joint orthoses
 - (a) Reciprocating Gait Orthosis (RGO) (Beckmann, 1987).

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- (b) Advanced Reciprocating Gait Orthosis (ARGO) (Lissons, 1992) (Fig. 1(a));

2. Freely hinged hip joint orthoses

- (a) Hip Guidance Orthosis (HGO)
(b) Parawalker (Butler and Major, 1987) (Fig. 1 (b)).

In the first group the emphasis is on close conformity of the orthosis to the patient and assuring that the hip joints are controlled to move in a fixed reciprocal pattern, whereas in the second type there is greater concentration on convenience of donning and donning and ease of clearing the swing-leg for reciprocal walking.

Major and Butler (1995) show that is not realistic to expect that any of the systems will achieve an efficiency of locomotion which approaches that of a wheelchair on flat surfaces. Their use therefore requires that the objectives be clearly identified. Anecdotal clinical experience of Carroll (1974), Rose *et al.* (1983) and Menelaus (1987) has long suggested that there are two achievable objectives from walking heavily handicapped patients:

therapeutic benefit;
improved independence.

More recently properly validated evidence to support the previous anecdotal experience has been established. Mazur *et al.* (1989) undertook a 10 year follow-up study of 36 matched pairs of paralysed spina bifida patients. One group was treated with a vigorous walking programme from the age of 2 years and the second group used only wheelchairs for mobility. From the point of view of therapeutic benefit the non-walkers had twice as many bone fractures and five times the number of pressure sores. Taking independence into account the study showed that significantly greater numbers of walkers could achieve each of a number of activities of daily living and that as teenagers 22% of the walkers were able to move about the community using cars or public transport, whereas only 6% of the non-walkers could do so.

These overall findings are further supported by the observations of Sykes *et al.* (1995). They reported that patients who used a reciprocal walking system had significantly greater feelings of well-being than those who did not.



(a)



(b)

Fig. 1. (a) RGO (b) Parawalker (Fig. 1(a) is reproduced with the kind permission of Steepers, Roehampton, UK)

The basis of choice

The anecdotal and clearly validated evidence which now exists for the benefits of walking to paralysed patients creates a more easily justifiable demand for orthotic walking systems. However, if the benefits are to be achieved patients must elect to use their expensive appliances on a regular basis. The factors which determine the degree to which this will occur are:

- ease of walking (i.e. efficiency);
- convenience of application (i.e. doffing and donning time);
- additional walking aids required (crutches or walking frames);
- reliability (lack of mechanical failures);
- cosmesis.

Overlaying those factors will be the costs of providing the treatment system, and these must be clearly understood if any form of economic analysis is to be undertaken.

Without the data necessary to make comparisons between the available systems neither clinicians nor managers can make a rational decision on choice. When these systems first became available the lack of data on performance led to inconsistencies in prescription patterns. The frequently high profile created by media attention on paraplegic patients walking with one system or another led to a broadening of interest in this area by scientific workers. As a consequence there is now much published work which addresses the individual factors identified as influencing the performance of patients and their ongoing use of walking devices.

Financial implications

There is a temptation to take a very simplistic view of the financial implications of the supply of walking orthoses and to look only at the purchase price. However, this ignores the more significant factors of:

- (a) the orthosis being only one essential element of an overall treatment system which also includes assessment, patient training, on-going routine monitoring, repair and replacement;
- (b) the long-term benefits to the patient in terms of reduced pressure sores and bone fractures, and the increase of independence in adolescence and adulthood.

As regards the cost of supply the most realistic approach is to recognise the "treatment system" concept so as to ensure that all financial implications are taken into account. Overall costings of a typical system (Parawalker) have been calculated for an average 3 year replacement cycle. On that basis the real costs are approximately five times that of the orthosis for the complete cycle. This includes the initial cost of the orthosis, additional walking aids and patient training; routine monitoring of the patient and orthosis at six monthly intervals; any repairs and the cost of any replacement parts during the 3 year period. An independent calculation by a different clinical supply centre produced figures which were very close to this (Pratt, 1991). Currently that figure amounts to approximately £8000 (GBP).

There is insufficient published data on different systems to make a direct comparison of cost. However, the training time will be a key element of any financial analysis. Lotta *et al.* (1994) did compare training times for the RGO, ARGO and Parawalker. The average times they identified are shown in Figure 2. From this it can be seen that there does appear to be some variability between the systems with the Parawalker having the lowest patient training times (or numbers of training sessions).

The benefits of a vigorous walking programme are much more difficult to assess. However, it is known that there is a high risk of pressure sores in paraplegic patients and that the cost of treating these is extremely high. McSweeney (1994) identified that there is no agreed model for assessing cost and estimates consequently do vary. Figures between £15,000 (GBP) (El Masri, 1995) and £26,000 (GBP)

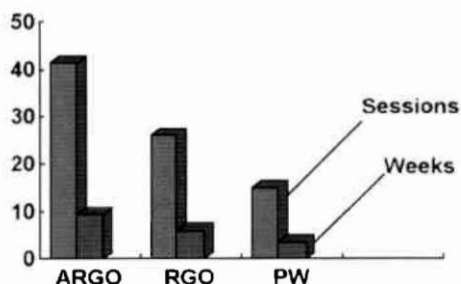


Fig. 2. Patient training times in the use of reciprocal walking orthoses (Lotta *et al.*, 1994).

(McSweeney, 1994; Dealey *et al.*, 1997) have been quoted as the average cost for each pressure sore, and Harding (1992) indicates that sores cost the UK National Health Service an estimated £600m (GBP) per annum.

If the results reported by Mazur *et al.* (1989) on the increased number of pressure sores experienced by non-walkers, the average cost of pressure sore treatment and the cost of providing ambulation with, for example, a Parawalker are taken into account then walking has the potential to make savings in the order of £50,000 (GBP) per patient over a 10 year period. These savings are large enough for the possible differences in cost between different systems not to significantly change the overall financial balance. The financial benefits of greater independence are much less easy to define. Between three and four times the number of walkers achieve independent mobility within the community as compared with non-walkers (Mazur *et al.*, 1989) and that is clearly very advantageous to those who have been given the opportunity and have elected to ambulate. Whilst such an outcome will not be directly reflected in individual healthcare departmental budgets there can be no doubt that there are potentially significant financial and social benefits to the patient and community as a whole.

The potential savings on patients who persist with their walking treatment are offset by the costs incurred on those who have been provided with an orthosis but have poor compliance. A rate of 50% of patients continuing to use their orthosis regularly still leaves scope for overall savings for the health service provider.

Performance comparisons

1. Absolute energy cost of walking

Reciprocal walking systems have been devised to reduce the energy cost of walking as compared with previously used knee-ankle-foot orthosis (KAFO) systems. Three studies of thoracic lesion patients using KAFOs have been published (Clinkingbeard *et al.*, 1964; Huang *et al.*, 1979; Merkel *et al.*, 1984). Between them these authors monitored a total of six patients with complete thoracic lesions, the average energy cost being 30.3J/kg/m. In a similar study of thoracic lesion patients using a reciprocal walking orthosis Nene and Patrick (1989) reported a significantly lower average energy cost of 16J/kg/m. These results

give a clear indication that the use of reciprocal walking systems produces a much higher level of efficiency in ambulation than that achieved in KAFO devices. This is further emphasised by the comparisons by Stallard *et al.* (1991) of the results of their study of patients using reciprocal walking orthoses with that of a similar group of patients using "conventional orthoses (KAFOs)" by Asher and Olsen (1983), on the basis of the Hoffer *et al.* (1973) classification of handicapped gait. Patients who used reciprocal walking orthoses were on average more than one category better than those using conventional orthoses. Guidera *et al.* (1993) reported that 19% of children using the RGO were community walkers and Stallard *et al.* (1991) 34% of those in the Parawalker, both considerably higher than the Asher and Olsen patients using conventional KAFOs.

Three studies of the absolute energy cost of reciprocal walking orthoses have been undertaken (Bernardi *et al.*, 1995; Hirokawa *et al.* 1990; Nene and Patrick, 1989). There is close agreement between Bernardi *et al.* and Hirokawa *et al.* on the RGO average cost at 20 and 21 J/kg/m respectively. Nene and Patrick (as reported above) show that the Parawalker has an average cost of 16 J/kg/m, slightly lower but within the same comparative range.

2. Comparable energy cost of walking

Three studies have made direct comparisons of relative energy cost between the RGO and the Parawalker (or HGO) on individual patients. Banta *et al.* (1991) used oxygen uptake techniques, Bowker *et al.* (1992) examined physiological cost index (PCI) and Whittle and Cochrane (1989) studied the peak walking aid forces required for the HGO. There is remarkable similarity of comparison in these parameters (as shown in Fig. 3), with the

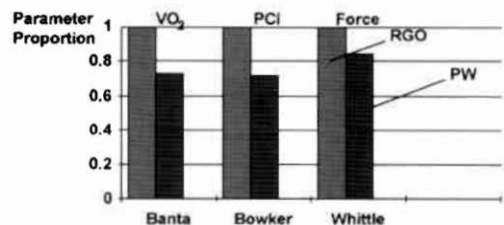


Fig. 3. Comparative energy costs in the use of the RGO and Parawalker (Banta *et al.*, 1991; Bowker *et al.*, 1992; Whittle *et al.*, 1989).

Parawalker or HGO requiring less energy in each case.

Phillips *et al.* (1995) and Jefferson and Whittle (1990) made anecdotal observations regarding ease of ambulation in comparing the HGO and the RGO, and the HGO, RGO and ARGO respectively. In the first case it was reported that heavier children with spina bifida "felt more secure in the less flexible HGO and were better able to concentrate their efforts on ambulation rather than on staying upright", and in the second it was concluded that "on the basis of the smaller pelvic movement in the HGO it would be expected that the energy cost of walking in this orthosis would be less than in either of the other two devices". Phillips *et al.* use the RGO for younger patients "because components for the HGO are not available for children under about five years of age".

3. Convenience of use

Whittle and Cochrane (1989) measured the difference in time required to independently put on and take off the RGO and the Parawalker. They showed that the Parawalker was on average 59% quicker in this respect.

Jefferson and Whittle (1990) identified that "the inclusion of a compression mechanism in the Steeper's orthosis (ARGO) made sitting and standing much easier with corresponding advantages to the patient both socially and in terms of energy expenditure at the beginning and ending of a walk", but did not provide quantitative data in this regard on differences between the three orthoses they reviewed.

4. Additional walking aids required

All of the available walking systems require additional walking aids to enable the upper limbs to generate the propulsion forces. There are two main options:

- walking frames (rollators etc);
- crutches.

The choice will affect convenience – walking frames being more cumbersome and less cosmetic. However, a walking frame does provide more inherent stability and is therefore easier to use. Orthosis design does influence the choice, though the patient will make the final decision.

Whittle and Cochrane (1989) in a cross-over trial of 22 patients using RGO and the Parawalker showed that 6% of RGO patients

used crutches whereas 69% of Parawalker patients chose to do this.

Lotta *et al.* (1994) in a review of three types of walking orthosis showed that 100% of Parawalker patients used crutches, 81.8% of ARGO patients did and 15.4% of RGO patients elected to do so.

5. Mechanical reliability

In their comparison of the RGO and HGO Whittle and Cochrane (1989) reported a repair rate of 11% for the RGO with no repairs for the HGO (i.e. 0%).

The Lotta *et al.* (1994) review of RGO, ARGO and Parawalker also reported on the numbers of repairs required on each and Fig. 4 summarises their findings in this respect. It will be seen they reported the ARGO as requiring most repairs and the Parawalker the fewest. Guidera *et al.* (1993) reported an average of three repairs per year for the RGO.

6. Cosmesis

There are two main aspects of cosmesis:

- (i) the style of walking;
 - (ii) the degree to which the orthosis can be disguised under clothing when required.
- (i) Style of walking

An objective of reciprocal walking orthoses is to mimic able bodied gait as closely as possible. Normal ambulation consists of a free flowing forward progression of the body. The more closely the patient's movements can resemble this activity the more likely is it that the ambulation style will be considered "cosmetic". Whittle and Cochrane (1989) undertook kinematic studies as part of their comparison of RGO and HGO and showed that the latter provided smooth forward translation of the trunk whereas the RGO had periods in the cycle where there was little forward

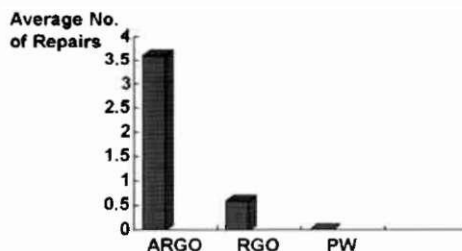


Fig. 4. Mechanical reliability of reciprocal walking orthoses (Lotta *et al.*, 1994).

translation. This difference between cross-linked and free hip hinge reciprocal walking orthoses was confirmed in a further study of three orthoses by Jefferson and Whittle (1990).

(ii) Cosmesis of the orthosis

The Whittle and Cochrane (1989) study elicited a response from patients in this regard and 75% of patients preferred the RGO to the HGO. Whilst there does not appear to be any published data on patient opinions of the ARGO, the appearance is similar enough to the RGO to suggest it would also be considered preferable to the Parawalker in this respect.

7. Weight of the orthosis

The weight of the orthosis will, theoretically, have little or no influence on patient walking performance since they are not required to lift the complete device from the ground during reciprocal walking. However, it is a factor of convenience when not being worn. The heavier the orthosis the more difficult it will be to carry and stow for transportation.

A comparison of the weight of RGO and HGO was made by Whittle and Cochrane (1989) and they reported that the RGO was on average 23% lighter.

Although no formal comparisons which include the ARGO have been published, superficial examination of the design suggests that it falls somewhere between the other two.

8. Overall comparison

Not surprisingly no orthosis is pre-eminent in all areas. As with any device or system the users have to weigh up the attributes and make a choice based on their particular needs. Sufficient information on the various elements affecting overall performance now exists for an intelligent choice to be made.

In healthcare there is an added complication in that the customer may be considered as:

- the patient;
- the clinician;
- the provider;
- the purchaser.

Within the environment it is important for managers to understand the comparisons so that they can quite properly ensure that a rational selection of treatment is made within the context of the purchaser/provider relationship and the priorities of the responsible authority.

The realisation of potential benefits

All the available evidence suggests that walking for paraplegic patients is justified. The existence of competing systems provides choice, but there is a wide divergence of experience. Wide ranging reviews of available systems have now provided data which should reduce confusion and enable choice to be more rationally decided.

A view is still expressed that it is not worth bothering to supply children because they will give it up after a short while – the implication being that the therapeutic benefits will not therefore accrue. The degree to which this happens must depend largely on the effectiveness of the treatment system and the orthosis provided. In the final analysis patient compliance will be the key to long-term benefit.

There have now been three patient compliance studies for the Parawalker (Moore and Stallard, 1991; Major *et al.*, 1997; Stallard *et al.*, 1995). In the first two studies adult traumatic patients had average compliance rates of 64% and 60% with patient's usage being approximately 3 years, whereas the third study of adult spina bifida patients showed a similar compliance rate with patient usage being 7 to 12 years. Sykes *et al.* (1995) reported compliance of children using the RGO as 29% with a mean follow-up period of 5.5 years and Guidera *et al.* (1993) as 48% for an indeterminate follow-up period which was between 0 and 6 years.

These results are greatly superior to other studies of compliance for conventional (e.g. KAFO) paraplegic walking devices (Hahn, 1974; Mikelberg and Reid, 1981; Rosman and Spira, 1974). It would be reasonable to expect a correlation between efficiency of the system, compliance and subsequent long-term benefit.

Unfortunately data on compliance of reciprocal walking systems does not appear to have been made in a coherent and directly comparable manner. However, conclusions on their likely levels could probably be inferred from comparisons of performance data. Since reciprocal walking orthoses are generically superior in walking efficiency to KAFO devices they could all be expected to have improved patient compliance. Nevertheless managers might wish to request data on individual reciprocal walking orthoses so that they can make the appropriate relevant judgements in an independent manner.

Conclusion

Great progress has been made in providing walking for the heavily disabled person since Lorber (1971) reported the disappointing outcome in which 41 spina bifida patients who had undergone 333 orthopaedic procedures were all chairbound. The prime therapeutic purpose of the extensive effort which has been made in this area has now been vindicated and there is clear evidence that provided such systems are supplied by an experienced clinic team with all the necessary resources then the compliance required to achieve those objectives can be forthcoming.

The challenge now for the healthcare managers is to reconcile the more obviously recognised costs of walking systems with the long-term and therefore less clearly defined financial savings of ambulation for high lesion paraplegic patients. To ensure they do this effectively they need to evaluate all systems so that they can promote the one which best meets the criteria of all parties – patient, clinician and finance managers.

There is no doubt that there have been disappointments and that scepticism still exists about the true value of walking systems. This is understandable when many have been provided in unsuitable clinical settings which have led to an approach in which the device is supplied without proper initial assessment and the long-term follow-up which is crucial for success. It is for managers to understand this and to ensure that appropriate arrangements for supply exist within their area of control.

Research and development will continue. In the medium term it is likely that the need for further development of purely mechanical orthoses (Stallard and Major, 1995) will lead to the evolution of better, more efficient orthotic structures. More sophisticated approaches involving electrical stimulation of paralysed muscles (Petrovsky *et al.*, 1985; Andrews, 1986; McClland *et al.*, 1987; Hermans, 1992) may produce further benefits but will demand greater investment in research and more time.

The financial implications of walking for the heavily handicapped have now become much more clearly defined. Managers need to recognise the necessity of proper professional assessment of patients, careful selection of treatment, provision of training and routine follow-up. When all that is done the published

results show that the outcome is worthwhile. Clinicians and managers alike can now provide walking for future social benefit and can do so in the knowledge that there is both therapeutic and financial justification for this. Reconciling the long-term benefits and short-term costs is therefore considerably less of a problem than once it was.

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Clinical note

Quadriceps muscle injury in trans-femoral amputees

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Abstract

Two male trans-femoral amputees using modular trans-femoral prostheses lost control and fell to the ground when their prosthetic knees gave way. The semi-automatic knee lock malfunctioned in the first case while the free knee stabilising mechanics gave way in the second case. This resulted in a high tensile force acting on the contralateral quadriceps muscle causing it to rupture. As there are a significant number of patients with both kinds of prostheses it is important to be aware of this possibility so that necessary actions can be taken to minimise its occurrence. Even with the currently available weight activated stance phase control, the prosthetic knee will give way if the knee is flexed more than 20° on weight bearing. Good power and control of hip extensors on the amputation side is needed to control the prosthetic knee joint, especially in the early stage of the walking cycle, i.e., from heel strike to mid-stance. Quadriceps muscle injury in amputees, as far as the authors are aware, has not been reported previously.

Introduction

In the elderly careful evaluation regarding balance and the ability of the stump to control a free knee should be made before prescription. It may be safer to prescribe a semiautomatic knee lock in spite of the disadvantages of a less cosmetic gait and possible increased energy consumption, in patients with poor balance, poor co-ordination or with weak muscles.

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Patients and methods

Case one

A 56 year old male patient underwent a left trans-femoral amputation 3 years earlier due to gangrene, resulting from peripheral vascular disease. In the post-amputation rehabilitation period he progressed from an automatically locked prosthetic knee joint to a weight activated "stabilised knee" stance phase control and a pneumatic swing phase control in a Blatchford endoskeletal modular Endolite prosthesis. This "free" knee joint also incorporated a manual knee lock allowing the patient to lock the knee joint if he felt unsafe to walk with the "free" knee especially outdoors, on uneven or slippery grounds. He gave a history of losing his balance because of the prosthetic knee joint giving way when he was about to start walking after getting out of his car. He reported that he had applied the knee lock, when he stood up after getting out of the car, but as he was just about to walk off with weight bearing on the prosthetic limb, the prosthetic knee joint gave way unexpectedly. This happened during the double support phase of the gait cycle when his natural right foot was still on the ground. The patient felt a very sharp pain on the anterior aspect of his lower right thigh and fell to the ground. A swelling quickly developed in the anterior aspect of his right thigh about 8 to 10 cm proximal to the upper margin of the patella. He was seen by his general practitioner who diagnosed a partial tear of the right quadriceps muscle and was treated with analgesics. An ultrasound examination 2 months later confirmed the clinical diagnosis of partial tear of the right quadriceps muscle. Clinically at this time a palpable gap in the muscle belly was still easily felt. Examination of the mechanics of the prosthetic limb revealed the

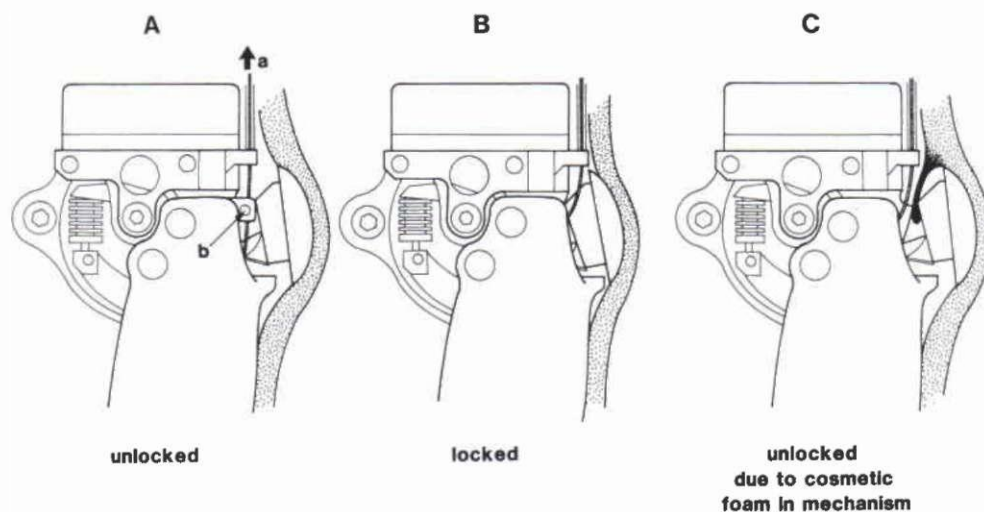


Fig. 1. The prosthetic knee in (a) unlocked (b) locked position. In (c) loose cosmetic foam is interfering with the locking mechanism of the knee lock.

cause of the malfunctioning of the manual knee lock. There was a torn piece of foam interposed in the locking mechanism, preventing the knee lock from being engaged (Fig. 1).

The patient was reviewed 6 months later, the pain and tenderness had completely resolved. Clinically he had no appreciable quadriceps weakness or extensor lag, but the patient reported that he has developed difficulty in getting up from a squatting position. Reinforcement of the foam overlying the knee joint mechanism was carried out to reduce the risks of foam tearing and thereby interfering with the knee lock mechanism. The patient was also advised that he must check properly every time he locks his knee joint that the locking has been effective. He was also strongly advised to watch out for any damage to the foam covering the prosthetic knee joint and to have it replaced or repaired regularly to reduce future risk of falls.

Case two

A 78 year old male with a left trans-femoral amputation performed 2 years previously due to critical ischaemia, fell in the physiotherapy room. When he was attending for review clinic appointment he was wearing a trans-femoral prosthesis with Blatchford Stanceflex knee with pneumatic swing phase control. While walking on level surface the prosthetic knee unexpectedly collapsed forcing him to fall to the

ground. He also complained of considerable pain in the lower anterior aspect of his right thigh. On examination, there was a palpable tender gap in the quadriceps felt at about 5 cm proximal to the superior pole of the patella. The passive range of movement of his knee joint was full, but he demonstrated an extension lag of 20° while attempting active extension. A clinical diagnosis of partial rupture of the quadriceps muscle was made, and was treated by a plaster of Paris back slab for about 3 weeks followed by a knee brace for 3 months, a programme of physiotherapy was also given. Though not performed initially, an ultrasound scan carried out 7 months after injury confirmed the clinical diagnosis of partial tear of quadriceps muscle. On enquiry, this patient gave history of two previous falls during gait training in the week prior to this fall in the physiotherapy department. As it was clear that this patient was having difficulties in controlling the "free" knee joint, his prosthesis was changed to one with a semi-automatic knee lock which meant that he could only walk with a locked knee gait, but unlocked to sit down. This gave this patient confidence to walk again and prevented further falls.

Discussion

It has been reported by some authors that quadriceps muscle or tendon can be ruptured or damaged secondary to an underlying disease

such as rheumatoid arthritis, systemic lupus erythematosus, gout, chronic renal failure, secondary hyper parathyroidism, diabetes mellitus and peripheral vascular disease (Harries *et al.*, 1995). It may occur spontaneously or secondary to injury involving a uniformly indirect force, i.e., force flexion of knee against maximum quadriceps contraction, during unexpected falls (Mann *et al.*, 1995; Brashear and Rany, 1986; Harries *et al.*, 1995; Robert *et al.*, 1970). In both patients reported here, the unexpected falls were the problem, neither suffered from diabetes or poor circulation. The first patient fell due to unexpected flexion of the prosthetic knee. The way the foam interfered with the knee locking mechanism is illustrated in Figure 1. In the authors' experience cosmetic foam getting trapped within the manual locking mechanism of this type of prosthesis has been reported by a number of patients. In the second case the inability to control the prosthetic knee due to age related lack of reflex control mechanism in the residual limb as well as general weakness of hip extensors caused the unexpected fall. In the elderly careful evaluation regarding balance and the ability of the stump to control a free knee should be made before prescription. It may be safer to prescribe a semi-automatic knee lock in spite of disadvantages of less cosmetic gait and possible increased energy consumption, in patients with poor balance, poor co-ordination or with weak muscles.

Quadriceps muscle injury in trans-femoral amputees should be suspected if an amputee patient who has fallen and complained of pain in the contralateral leg over the anterior aspect of

the thigh and present with a swelling in the muscle belly. The clinical diagnosis can be confirmed by ultrasound scanning if necessary. Treatment of quadriceps rupture is dependent on the extent of the rupture, symptoms and the level of ensuing disability. Partial ruptures are usually satisfactorily treated with analgesics, appropriate support and rest and may also need an orthosis to hold the knee in extension. Complete tears may require surgical repair (Brashear and Rany, 1986). Regular review of elderly patients is advisable, since deteriorating muscle strength compounded by poor balance may dictate change of prosthetic prescription. Clinical finding of palpable gap, local tenderness and varying degree of interference with active extension of the knee are diagnostic features.

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Clinical note

Rehabilitation of a triple amputee including a hip disarticulation

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Abstract

A multiple amputee more severe than a triple amputee is uncommon. There have been no reports on the rehabilitation outcome of a triple amputee, including hip disarticulation and trans-tibial amputation. The authors report the rehabilitation of a patient with left hip disarticulation, right trans-tibial amputation, and left trans-humeral amputation due to a train accident. He has successfully completed the rehabilitation programme and has become independent in prosthetic ambulation, activities of daily living, and driving.

Introduction

There have been few reports on the rehabilitation outcome of a multiple amputee more severe than a triple amputee (Kitowski and Leavitt, 1968; Laatsch *et al.*, 1993; Shaw *et al.*, 1977). There have been no reports on the rehabilitation outcome of a triple amputee, including a hip disarticulation and trans-tibial amputation. Multiple limb loss requires more motivation from the amputee to overcome the disability, and more cooperation and active management from the rehabilitation team to make the rehabilitation process a success. The authors treated a case where the patient underwent left hip disarticulation (HD), right trans-tibial (TT) amputation, and left trans-humeral (TH) amputation surgery secondary to a train accident. He successfully completed his rehabilitation programme to become

independent in all activities of daily living, prosthetic ambulation, and driving.

Case report

A 37-year-old man sustained multiple and severe injuries in a train accident on December 7, 1996, which resulted in left hip amputation, left forearm amputation, and multiple comminuted fractures of the right leg. In a local hospital in Seoul, Korea, he underwent a left HD, left TH amputation, and right TT amputation, and was then transferred to the Rehabilitation Hospital, Yonsei University College of Medicine, on March 15, 1997, three months after the accident.

Physical examination performed on admission revealed the left TH stump length from the acromion to be 16 cm (55%), and the right TT stump length from the medial tibial plateau to be 12 cm. The soft tissue shrinkage of the stumps was found to be relatively good, except for the left HD which showed incomplete shrinkage (Fig. 1). Muscle power of the left forearm and the right leg were slightly reduced to Grade 4 (Grade 5 being normal). On functional examination, the patient was found to be barely able to eat and wash his face independently. He could turn on his side and sit, however his balance was reduced to fair and the endurance time was 5 minutes. The X-rays did not show any bony spurs, but there was 30° angulation of the right femur shaft secondary to an old right hip fracture sustained in another accident in 1974.

After admission, his preprosthetic training began with muscle strengthening exercises including Cybex isokinetic training, stretching exercises to maintain a normal range of motion, and exercises to improve balancing ability. On April 10, 1997, the left TH prosthesis with

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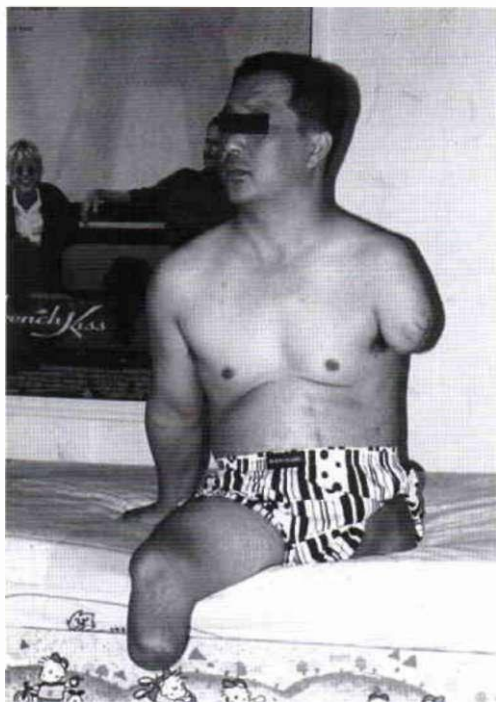


Fig. 1. Sitting without prosthesis.

standard figure-of-eight harness, Hosmer elbow unit, wrist unit of friction type, and Dorrance 8 hook was fitted. On April 15, 1997, the right TT prosthesis with a patellar-tendon-bearing (PTB) socket, cuff suspension connected with fork strap, endoskeletal shank and dynamic response foot and the left HD prosthesis with a Canadian socket, waist belt suspension, endoskeletal shank, polycentric knee joint, and dynamic response foot were fitted. The length of the prosthesis for the right lower limb was designed to be 3cm shorter than the length prior to the accident for improved stability, and the prosthesis for the left HD was designed 1cm shorter than the right side for toe clearance.

After 2 weeks of standing and weight bearing training, the patient started to practice gait training with parallel bars and progressed to gait training with a unilateral quadripod cane on a flat floor by 4 weeks. After 6 weeks, he started training on a ramp and stairs. After 8 weeks of training, he became independent in all activities of daily living including donning and doffing of his prostheses. He was able to walk about 100m, ascend and descend stairs, and climb a ramp with a quadripod cane, all independently (Fig. 2). He acquired his driver's license after 2 weeks of driving practice

with right TT prosthesis with a PTB socket, epicondyle suspension, exoskeletal shank, and SACH foot especially designed for driving.

Evaluation of his home revealed the need for several changes to facilitate his independence even without the aid of prostheses. He was unable to move into the bathtub for a shower and transfer onto the toilet without prostheses. A metal plate was specially designed to be fixed above his bathtub for showers, and portable wooden stairs were designed to facilitate transfers from the floor into the bathtub or onto the toilet seat. This allowed him to take showers and use toilet independently without prostheses. A specially designed tray with wheels was made to facilitate indoor transfers without prostheses. He practiced using an electric scooter in order to make transfers possible from his apartment to the parking lot or to nearby stores with the prostheses on. At the end of the rehabilitation programme, on June 19, 1997, he became independent in all activities of daily living including ambulation with or without prostheses as well as driving.

Discussion

There have been only a few reports on the rehabilitation outcome of multiple major



Fig. 2. Standing with prostheses.

amputees. Kitowski and Leavitt (1968) reported the rehabilitation outcome of a quadruple amputee with bilateral TT and bilateral trans-radial amputations secondary to an electrical burn. Laatsch *et al.* (1993) reported the countertransference in rehabilitation of a quadruple amputee with bilateral TT amputation and bilateral shoulder disarticulations. Shaw *et al.* (1977) reported on the psychosocial problems in rehabilitation of a patient with triple amputations including right wrist disarticulation, right trans-femoral (TF) amputation, and left ankle disarticulation amputation, as well as another patient with bilateral TH amputations and left TF amputation. The patient described in this report involves three major triple amputations including a hip disarticulation and a 30° angulated femur on the better of the two legs with TT amputation. The authors found that a more thoughtful and creative rehabilitation strategy considering the patient's physical and environmental conditions, and closer cooperation among the rehabilitation team are necessary to obtain a good functional rehabilitation outcome for a patient with multiple amputations. From this perspective, a rehabilitation team consisting of physiatrists, a prothesist, a physical therapist, an occupational therapist, a psychologist, a social worker, and rehabilitation nurses worked closely together and held weekly team meetings.

The tray with wheels for home transfers without the aid of prostheses, the metal plate installed above the bathtub for showers, and the portable stairs for transfers from the floor into the bathtub and onto the toilet were vital pieces of modified equipment that were devised after evaluation of the patient's apartment. The electric scooter was used instead of a wheelchair for short distance outdoor transfers, which was also very satisfactory in view of energy conservation. The right TT prosthesis which was fitted solely for driving, made driving possible with minimal difficulties and without any modification to a car.

Shaw *et al.* (1977) in their report on the successful rehabilitation of two triple amputees proposed that the more important factors of obtaining full physical independence are early prosthetic fitting and training, as well as prompt recognition of psychosocial needs. The authors believe the patient's confidence and positive attitude toward a successful rehabilitation outcome are more important than any other

factors, including early prosthetic fitting and training. In the beginning of the programme the patient showed a complete lack of confidence in his rehabilitation outcome. At the time, he was barely able to sit independently and the ability to stand with prostheses on was the best he could hope for. His progress was slow in the beginning and he even showed mild depression. However, as his endurance and balance in independent standing improved, his confidence also grew and, as a consequence, his motivation was reinforced. His progress became more and more rapid. The authors believe training with spinal cord-injured patients and stroke patients in the rehabilitation hospital helped him accept his disability, and to gain confidence and motivation for his rehabilitation.

One of the worries after the patient's discharge was that he might not use his prostheses often because he had become independent in all activities of daily living and indoor transfers without them. However, the assessment 3 months after discharge from the hospital assured the authors that he was using his prostheses regularly. Luckily for him, he neither had any financial nor any family problems. However, unfortunately, he still has not found a job and it is not very likely that he will find one soon as the opportunities for the disabled in Korean society are not yet bright.

As described, a patient with left HD, right TT amputation and left TH amputation secondary to a train accident became capable of performing all activities of daily living, walking, and driving independently following rehabilitation. For the successful rehabilitation outcome of a multiple major amputee, motivation and close cooperation between the patient and the rehabilitation team are necessary. Furthermore, creative consideration of the patient's functional, environmental and social disability is highly appreciated.

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Clinical note

Rehabilitation management for a patient with a radical forequarter amputation with chest wall resection.

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Abstract

Since the improvement of surgical oncological operative procedures, anaesthesiology and intensive care facilities, forequarter amputations are being performed with increasing frequency and decreasing morbidity and mortality. This clinical note reports the rehabilitation and prosthetic management of a patient with an extensive forequarter amputation including pneumectomy.

Introduction

Limb salvage procedures using combined modality therapies are gaining acceptance as a treatment choice in patients with marginal resectable soft tissue or bone sarcomas of the upper limb. For a small group of patients, an interscapulothoracic amputation or a radical forequarter amputation with chest wall resection is the only final surgical treatment with either a curative or a palliative intent (Stafford and Williams, 1958; Mansour and Powell, 1978; Ham *et al.*, 1993). A forequarter amputation is a resection of the chest wall, indicated for primary bone and soft tissue tumours, involving the shoulder girdle, axilla and chest wall, as well as for recurrent breast cancer in the axilla after irradiation (Roth *et al.*, 1984). The purpose of this report is to describe the rehabilitation management focusing on the prosthesis in a patient with an extensive radical forequarter amputation.

Case report

Medical history

A 28-year-old healthy young man known with Recklinghouse disease (neurofibromatosis) presented with pain at his left chest wall. His skin showed several typical "café au lait" spots and many little noduli.

In the medical history, the patient complained earlier of pain in his right chest wall. An x-ray of the thorax (the right side) showed some signs of a soft tissue mass. A magnetic resonance imaging (MRI) demonstrated a calcified mass with central necrosis, fixed to the right chest wall. Pre-operatively, lung function was studied using spirometry, and distant metastases were ruled out by means of computer tomography scans of the lungs and a bone scan. The tumour was curative resected "en bloc" with a part of the right chest wall. It appeared to be a malignant Schwannoma.

Half a year later, he had the same complaints of the contralateral chest wall. Again it appeared to be a malignant aggressive Schwannoma which reached far into the thorax. There were no distant metastases. Lung function and vital capacity were good. In an extensive discussion with the patient and his family, concerning the expected quality of life after surgery, a very mutilating but in design, curative operation was performed: a total resection of the tumour including pneumectomy and interthoracoscaphic amputation of the left upper limb (Figs. 1 and 2). This procedure was performed knowing that the disease-free median survival period 24 months after surgery would be somewhat more than 40% (Doorn *et al.*, 1995). After consultation with the rehabilitation team, whether it would be possible to fit such a patient with a prosthesis, surgery was planned.

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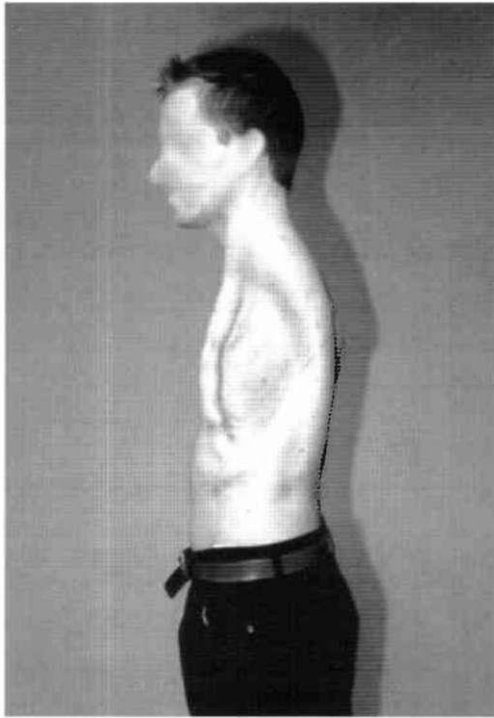


Fig. 1. Side view.

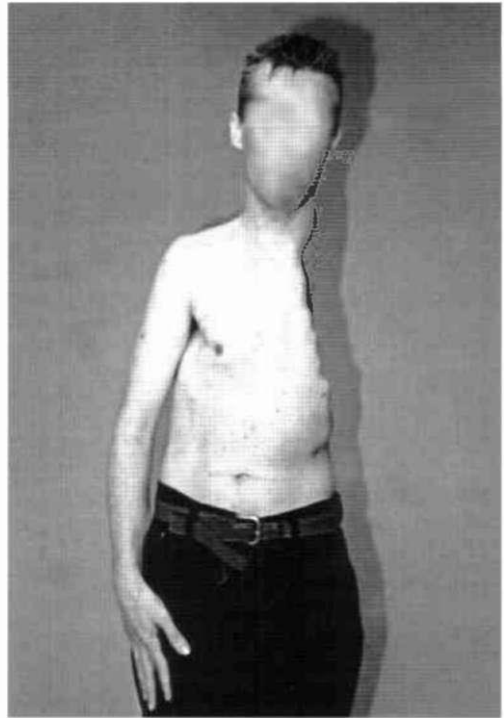


Fig. 2. Front view.

The post-operative course was uncomplicated. Despite the expected complication of a flail chest, his ventilation capacity was sufficient. Histopathological examination revealed total resection of the tumour which had also signs of a sarcoma. The patient was additionally irradiated.

Rehabilitation management

The first precautions were to start with pre- and post-operative pulmonary physical therapy. Pain management was started and the patient got a first temporary orthosis a few days after operation. The orthosis consisted of a cotton corset with at the left side a protective vitrethane perforated (ventilation) cast. The latter to protect the heart which lies just beneath the skin because of the resection of the protective chest wall. A removable shoulderdecap was moulded also. Immediate postoperative casting was not possible because of the extreme pain of the wounds, so the prosthesis was made with estimated body circumferences. Physical therapy began with mobilization, balance training, and condition training. Fourteen days after operation the patient was able to leave the

hospital. Outpatient clinic rehabilitation continued balance and condition training, and occupational therapy started with one handedness training. Furthermore, little adaptations in his house were provided. A psychologist continued to be an active member of the rehabilitation team. Six weeks after operation the patient was fitted with a definitive prosthesis which included a silicone pad at the skin. This pad was sewn in a cotton corset. This cotton corset was attached to a thin, rigid thermofac harness to protect the vital organs, lung and heart. To fill up the moulded thorax shape a polystyrene foam was used (Fig. 3). In the prosthesis a shoulder shape was moulded. Because of this extensive resection, the imbalance and posture of the patient and the possible force moments, a prosthetic arm was omitted. Later on, the silicone pad had to be removed because this was too adhesive to the skin and skin injuries were the result. As an alternative a soft polyethylene foam layer was used. The prosthesis was fitted to the body with a bandage and it was supported by the sternum and the thoracic vertebrae. The weight of the prosthesis was not more than 300 grammes. In

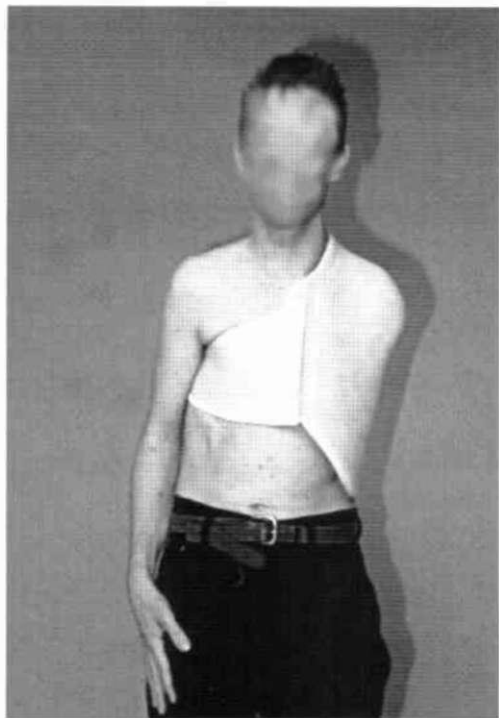


Fig. 3. Patient with prosthesis.

summary this prosthesis had a protective and a cosmetic restoring function. Because of hygienic reasons, the patient got two prostheses. The first month postoperative, the patient had phantom sensations, no phantom pain. After a few weeks phantom pain developed, all his fingers were in a flexed position, and he needed morphine. After two months vocational therapy started.

Nine months after the amputation the patient started to complain over pain in his legs and neck. Additional research revealed several metastases. Palliative therapy was started with irradiation. Unfortunately, one year after the amputation the patient died of multiple metastases.

Discussion

A radical forequarter amputation with chest wall resection is still a rare amputation. Most of these patients are seen in an university hospital. Literature search did not reveal anything about fitting a prosthesis in such a patient. This was the first patient with such mutilating amputation who was fitted with a prosthesis in the hospital. The only two studies mentioning a prosthesis for this kind of amputation were published more

than 20 years ago (Wurlitzer, 1972; Mansour and Powell, 1978). The descriptions of the prostheses in literature were of a shoulder cap, fitted six weeks after surgery (Wurlitzer, 1972; Mansour and Powell, 1978). However, the mutilation character of those amputations was less.

Although a mechanical arm and hand is the preferred prosthesis for a forequarter amputation patient, for this patient with such an extended amputation and mutilating effect, the prosthesis described earlier was prescribed. A considerable cosmetic improvement was possible by use of a one piece artificial shoulder and breast device. Fitting the prosthesis to the patient's body was difficult. The sternum and vertebrae were chosen as supporting body parts. In this way the prosthesis had to be very light. The expected postoperative flail chest was not a contraindication for wearing the prosthesis. The cosmetic appearance of the prosthesis made a considerable difference in rehabilitating this patient to his family and to society. The highly motivated patient and very understanding family and friends were instrumental in achieving successful rehabilitation following this very major and mutilating operation although the survival period was short.

Conclusion

Primary therapeutic success after a radical forequarter amputation is dependent on tumour type, grade, completeness of resection, possibilities for reconstruction and deterioration of pulmonary function. Rehabilitation is dependent on the motivation of the patient and the support of the family and rehabilitation team. Fitting a prosthesis described in this case is individually very different and difficult and is a challenge for the team. Primary function of the prosthesis is to protect heart, lung and mediastinum and secondly to give the patient a cosmetic appearance to return to society.

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Technical note

A medial linkage orthosis to assist ambulation after spinal cord injury

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Abstract

A "proof of concept" prototype of a new device to link bilateral knee-ankle-foot orthoses, the Moorong Medial Linkage Orthosis (Moorong MLO), is presented. The device consists of an arcuate sliding link centred on the hip joints with rolling element bearings to minimise friction. A single repeated-measures case study is reported in which a woman with an incomplete C6 tetraplegia ambulated over different surfaces and gradients using both the Moorong MLO and the Walkabout orthosis. Results demonstrated a slight increase in gait velocity in the Moorong MLO (between 0.36-1.02m/min faster) and a consistently lower oxygen cost across all conditions (between 18-61% reduction) compared to the Walkabout orthosis. The reduction was most noticeable on sloping surfaces. These preliminary results suggest an improved efficiency of ambulation in this new device.

Introduction

Ambulation for paraplegic individuals wearing knee-ankle-foot orthoses (KAFOs) has been recognised as impractical for all, except those with very low level or incomplete spinal cord lesions, due to the high energy costs and cardiorespiratory stresses involved (Gordon and Vanderwalde, 1956; Clinkingbeard *et al.*, 1964; Huang *et al.*, 1979; Merkel *et al.*, 1984).

Better stabilisation of the trunk and hips provided by incorporating a thoraco-lumbar

support and lateral hip joints into different types of hip-knee-ankle-foot orthoses (HKAFO) has resulted in an improvement in the mechanical efficiency of paraplegic gait, as well as a reduction in the energy cost of ambulation (Nene and Patrick, 1989; Hirokawa *et al.*, 1990; Winchester *et al.*, 1993; Bernardi *et al.*, 1995). Commonly prescribed HKAFOs have included the Hip Guidance Orthosis (HGO) (Rose, 1979), the Louisiana State University-Reciprocating Gait Orthosis (LSU-RGO) (Douglas *et al.*, 1983), the Advanced Reciprocating Gait Orthosis (ARGO) (Hugh Steeper Ltd., London, UK) (Lissens *et al.*, 1992), the modified Douglas RGO (Isakov *et al.*, 1992) and the Isocentric-RGO (I-RGO) (Motloch, 1992).

More recently, the Walkabout orthosis (Kirtley, 1992) which employs a medially-mounted hinge joint to link two KAFOs, has provided an alternative device for paraplegic ambulation. It was originally hoped that the Walkabout modular medial-linkage orthosis would be more compatible with wheelchair use and offer practical and cosmetic advantages over existing orthotic devices, which were seen as cumbersome, difficult to apply and incompatible with routine daily tasks such as transfers and toileting (Kirtley, 1992). Several recent studies, however, have questioned the functional advantages of the Walkabout orthosis (Harvey *et al.*, 1997; Middleton *et al.*, 1997).

Medial-linkage of KAFOs has been shown to significantly reduce the energy cost of ambulation compared to KAFOs alone (Cliquet *et al.*, 1989; Saitoh *et al.*, 1996). However, Harvey *et al.* (1988) found that with the Walkabout orthosis subjects ambulated

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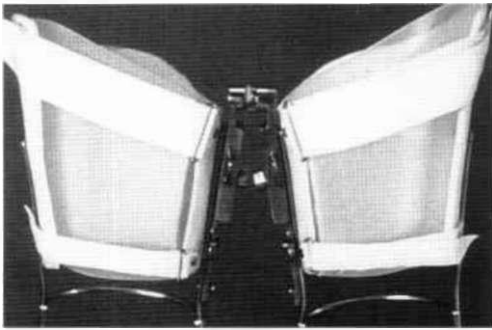


Fig. 1. The Walkabout device shown medially linking a pair of KAFOs.

significantly slower and with a $2\frac{1}{2}$ fold increase in the energy cost of a gait compared with the I-RGO.

Description of the Moorong Medial Linkage Orthosis

The Moorong Medial Linkage Orthosis (Moorong MLO) is an evolution of medial linkage orthotic devices designed to improve the function of separate KAFOs or HKAFOs. This concept was proposed by Cliquet *et al.* (1989) and realised as a device by Kirtley and McKay (1992).

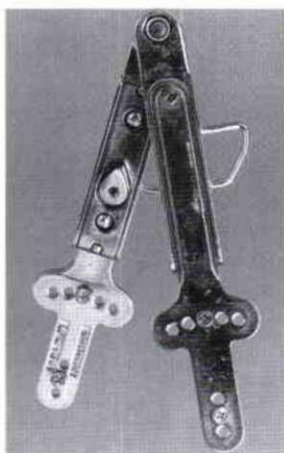
Kirtley and McKay's Walkabout device (Figs. 1 and 2a) links the medial uprights of a pair of KAFOs to control adduction and abduction of the lower limbs during ambulation. Specifically, the linkage prevents abduction of the swing-through leg while the body is tilted to create

ground clearance for the swinging leg and, at the same time, prevents abduction of the stance leg under body weight. The Walkabout orthosis employs a simple hinge mechanism which, being placed below the perineum, is not aligned with the centres of the hip joints, the discrepancy being 100 mm to 150 mm. Kirtley (1992) points out that due to the lengths of the limbs and the limited angle of hip movement required for effective ambulation, only a small amount of soft tissue distortion is needed to accommodate the discrepancy between the hip joints and the hinge axis of the Walkabout orthosis. It is the authors' contention that this discrepancy does in fact create a significant impediment to ambulation by increasing resistance to movement of the legs.

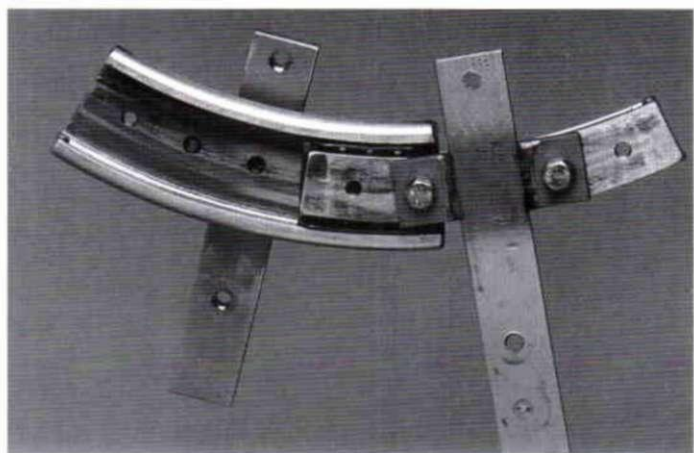
The main objective in designing an improved orthotic device was to provide controlled guidance of the legs for ambulation while minimising unnecessary constraints. To this end, it was decided to extend the MLO concept by minimising the distance between the hip joint centres and the hinge axis of the MLO. This was achieved by fabricating an arcuate sliding link centred on the hip joints and using rolling element bearings to minimise friction (Fig. 2b). The Moorong MLO is a "proof of concept" prototype and this report comprises a single repeated-measures case study.

Case history

A 25 year old woman with an incomplete C6



(a)



(b)

Fig. 2. (a) The single hinge mechanism of the Walkabout device not allowing alignment with the hip joints. (b) The Moorong MLO with an arcuate sliding linkage centred on the hip joints.

tetraplegia (ASIA Impairment Classification C with spared proprioception) was investigated whilst ambulating over several different gradients and terrain surfaces in the Walkabout orthosis and the Moorong MLO.

Her spinal cord injury resulted from a horse riding accident in July, 1991. Following vertebrectomy, bone graft and internal fixation of a burst fracture of the C5 vertebra, she underwent a multidisciplinary inpatient rehabilitation programme. This included muscle strengthening and stretching exercises, hydrotherapy, electrical stimulation of lower limb and trunk muscles and standing supported in backslab splints, in preparation for gait training. She was fitted with KAFOs and commenced gait training with the aid of a rollator frame during admission which she later continued as an outpatient using Canadian crutches.

Due to severe neurological impairment of her hip musculature (Table 1), she ambulated very slowly in unlinked KAFOs experiencing considerable difficulty swinging her legs through. Her gait improved markedly when the Walkabout device was attached to medially link the KAFOs. Several months after discharge she also tried a RGO, which she found very restricting and difficult to use. Ultimately, she preferred the Walkabout orthosis for cosmetic and functional reasons.

Over the last 5 years, the subject has regularly utilised the Walkabout orthosis, initially 3 times per week but more recently, due to the demands of full-time employment, once or twice per week. She requires some assistance to apply the orthosis and transfer from sitting to standing and *vice versa*. She describes the benefits gained from using the Walkabout as improved exercise tolerance, enhanced psychological well-being from assuming an upright posture and a reduction in time to evacuate her bowels if she had walked the previous day. When using the Walkabout orthosis, she normally walked outside the house over different surfaces and gradients.

As an experienced Walkabout user, the authors believed her to be an ideal subject to assess the new Moorong MLO.

Method

Assessment of the energy expenditure and cardiorespiratory demands of using the Moorong

Table 1. Muscle chart for subject.

Muscle group	Strength	
	Left	Right
Elbow flexors	5	4+
Wrist extensors	5-	4
Elbow extensors	2	2
Finger flexors	1	1
Finger abductors	1	1
Trunk flexors	2	2
Trunk extensors	4	4-
Hip flexors	0	0
Hip adductors	2-	2-
Hip abductors	0	0
Hip extensors	2	2
Knee extensors	4	4
Knee flexors	0	0
Ankle dorsiflexors	1	0
Ankle plantarflexors	3	3

NB. Strength graded out of a maximum of 5 according to MRC guidelines.

MLO in comparison to the Walkabout orthosis was undertaken during a continuous outdoor walk over several different gradients and terrain surfaces. The overall distance of the course was 148m comprising; (i) a 33m level concrete footpath, (ii) a 22m gentle grass-covered slope (2.5° decline, 2.3° cross-slope down to the right), (iii) a 43m downhill concrete footpath (3.7° decline), and (iv) a 50m uphill asphalt roadway (slope variable, average 4.2° incline). The subject was allowed two walking sessions to familiarise herself in the new device prior to testing. She was first tested with the Moorong MLO and then with the Walkabout orthosis. Testing was performed at the same time on two separate days. The ambient environmental conditions were unremarkable (20-26°C, 25-50% relative humidity).

Before commencement of testing, the subject sat quietly for 3 minutes to establish baseline heart rate (HR) and oxygen uptake (VO_2) measurements at rest. Energy expenditure data were collected via open circuit spirometry (KB1-C Portable Metabolic System; AeroSport Ltd, Minneapolis, USA) and heart rate was derived from chest leads to the portable system. The KB1-C portable system is carried on the front and back of the subject's chest and weighs less than 1 kilogram. The KB1-C portable system was previously validated against an open

Table 2. Data summary of heart rate and oxygen uptake at rest and during and testing over different surfaces and gradients in each device.

Condition	Orthosis	Heart rate (b/min)	O ₂ uptake (l/min)
Rest	Walkabout	78 ± 2	0.22 ± 0.01
	Moorong MLO	73 ± 1	0.17 ± 0.01
Level footpath	Walkabout	155 ± 2	0.55 ± 0.02
	Moorong MLO	164 ± 1	0.49 ± 0.02
Grass (slope -2.5°/ camber 2.3°)	Walkabout	136 ± 2	0.51 ± 0.02
	Moorong MLO	160 ± 2	0.42 ± 0.02
Footpath (slope -3.7°)	Walkabout	142 ± 2	0.52 ± 0.01
	Moorong MLO	155 ± 2	0.29 ± 0.01
Road (slope +4.2°)	Walkabout	157 ± 2	0.73 ± 0.01
	Moorong MLO	154 ± 3	0.48 ± 0.03

NB: Data are means ± SEM derived over 6 20-second measurements in steady state.

circuit laboratory system (Sensormedics 2900, Loma Linda, USA) and shown to be accurate (>96%) and reliable.

Data collected every 20 seconds during the testing period included heart rate (b/min), VO₂ (l/min), VCO₂ (l/min) and expired ventilation (l/min). An average velocity of walking (m/min) was calculated from the time taken to walk the measured distance of each section. Physical Cost Index (PCI) (MacGregor, 1981) and oxygen cost of gait (O₂ cost) were calculated by averaging the last 2 minutes of physiological data (six 20s data points) in each section of the course as follows:

$$\text{PCI (b/m)} = \frac{\text{HR}_{\text{steadystate}} - \text{HR}_{\text{rest}}}{\text{Average Velocity}}$$

$$\text{O}_2 \text{ cost (ml/min/kg)} = \frac{\text{VO}_{2\text{steadystate}} - \text{VO}_{2\text{rest}}}{\text{Average Velocity}}$$

Inspection of the raw data confirmed that a physiological steady state had been reached in the last 2 minutes of each section of the course, when measured and derived variables were collected.

Results

Heart rate and energy expenditure measurements, at rest in sitting and during gait for each test condition, are displayed for both orthotic devices in Table 2.

Walking at a self-selected pace in each device, the time to complete the total course in the Moorong MLO (22:37 minutes) was less than

with the Walkabout orthosis (24:20 minutes). In terms of velocity, ambulation with the Moorong MLO was 0.36 to 1.02m/min faster than with the Walkabout orthosis. Gait velocities for individual sections of the course in each device are shown in Figure 3a. With respect to daily function, however, the velocity of ambulation was slow in both orthoses.

The PCIs for all conditions showed little difference between orthoses, except during ambulation over the grassy cross-slope where the heart rate in the Moorong MLO was markedly higher (Fig. 3b). However, on all surfaces the calculated oxygen cost of gait was less when ambulating in the Moorong MLO by between 18-61% (mean 39%) compared with the Walkabout orthosis (Fig. 3c). This reduction was most noticeable on sloping surfaces.

Discussion

These results show lower energy expenditure with the Moorong MLO, suggesting improved overall efficiency of ambulation with this device. Visual observation of subjects ambulating in the Moorong MLO and the Walkabout orthosis suggested greater freedom and range of leg movement associated with using the Moorong MLO. It is not clear if this is due to the better alignment of orthotic and anatomical joints in the Moorong MLO or its low friction characteristics.

The subject generally ambulated somewhat faster using the Moorong MLO and with a consistently lower oxygen cost across all conditions compared to the Walkabout orthosis. It appears that, in this single case study, the

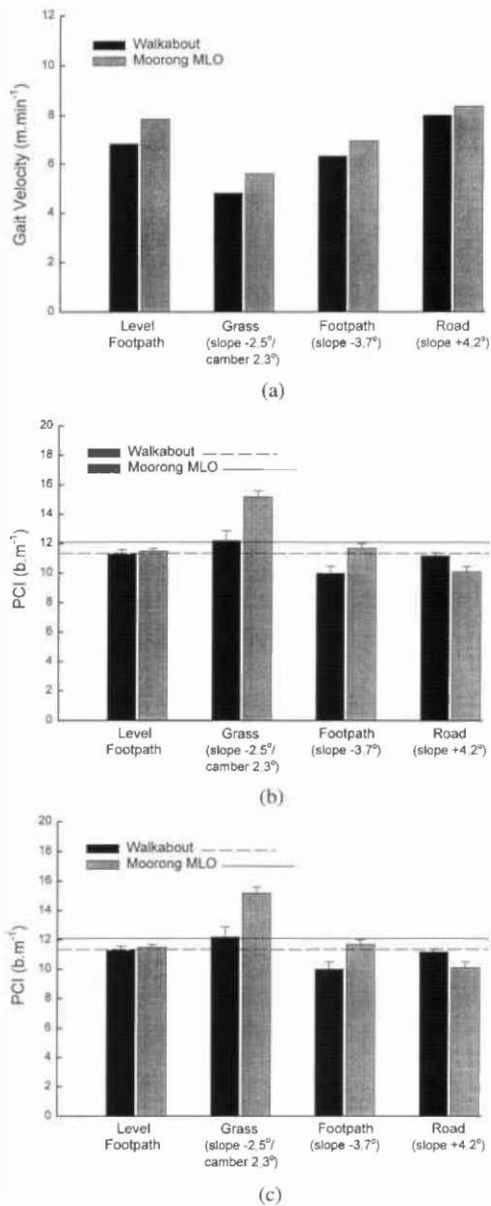


Fig. 3. Results of (a) gait velocity, (b) PCI, and (c) oxygen cost during ambulation over different surfaces and gradients in the Moorong MLO compared to the Walkabout orthosis.

speed of ambulation was not limited by energy expenditure, since it was observed that ambulation in both orthoses was fastest when negotiating a moderate incline. The subject identified a feeling of insecurity, associated with her upper limb weakness, as the major limiting

factor in her speed of ambulation. This may also help to explain why she was best able to control ambulation when ascending a slope.

An interesting and unexpected finding was that the Moorong MLO induced a marked increase in heart rate and greater PCI (compared with the Walkabout) when walking on the grassy cross-slope; the marginal increase in speed (with the Moorong MLO) seems an unlikely explanation for this finding. It seems more likely that, compared with other walking surfaces, greater upper limb forces were required on the uneven and cross-sloping grassy surface to stabilise the additional freedom of the hips provided by the Moorong MLO. The authors speculate that the additional upper limb effort required to stabilise the trunk with higher isometric muscle loading contributed to a higher heart rate without significantly elevating systemic VO_2 .

In setting up the Walkabout, a fairly wide separation of the feet (250 mm between the heels in this subject) was necessary to ensure clearance between the release knobs on the medial face of the KAFO clamps. The set-up of the Moorong MLO (which can be fitted with a smaller lateral separation of the feet than the Walkabout) was intended to duplicate that of the Walkabout orthosis, but the actual separation between the heels was a little less, about 225 mm. Medial linkage ambulatory orthoses need to be set up with a wider separation of the feet than normal in order to reduce the degree of lateral tilting necessary for ground clearance on swing through. While it seems likely that a reduction in the energy cost of ambulation could be achieved by reducing the lateral separation between the feet, this strategy is obviously limited by the need to maintain adequate ground clearance. As a strategy for reducing the energy cost of ambulation, it is likely that greater benefit would be obtained by shortening of the "leg length" in swing phase, by knee flexion or other means. This seems to have been clearly established by Yano *et al.* (1997) who used a novel powered mechanism under the foot to alter leg length and allow clearance for swing through without needing a wide gait and body tilt.

Further orthotic development planned for the Moorong MLO includes provision of some freedom for the legs to rotate about the long axis of the limb. The idea that this extra freedom may be helpful was suggested by examining wear patterns on the prototypes of the Moorong MLO

and by the authors and others trialing the Moorong MLO and the Walkabout orthosis in order to experience the sensations of freedom and constraint imposed by the orthoses. An underlying (though untested) assumption in providing this extra freedom is that it will reduce resistance to movement of the hip; in addition, loads on the orthosis may be reduced.

Conclusion

This case report comparing a new prototypic medial linkage device (an arcuate sliding joint) to the Walkabout hinge device has presented some encouraging preliminary results suggesting improved efficiency of orthosis-assisted ambulation in this new device. Further investigation is currently underway to assess the biomechanical efficiency and energy expenditure of ambulation using the Moorong MLO in comparison with the I-RGO for individuals with complete paraplegia.

Acknowledgements

This study was supported by a grant from the Northern Sydney Area Health Service (No. 94/21). The authors wish to give special thanks to Mr Kevin Brigden, Department of Orthotics, Royal North Shore Hospital, for his involvement in concept development and practical advice. The authors also thank Mr Tim Christie, Projects Engineer, Biomedical Engineering Service, NSAHS, for assistance with the design and fabrication of the Moorong MLO.

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Book Review

**Physiotherapie und Prothetik nach
Amputation der unteren Extremität
Gertrude Mensch, Wieland Kaphingst
Springer Verlag, Berlin/Heidelberg/New
York, 1998
ISBN 3-540-62769-7
DEM 78: GBP 30**

This textbook on physical therapy and prosthetics following lower limb amputation perfectly fits the ISPO philosophy. It is international, even intercontinental, and interdisciplinary.

Gertrude Mensch is, together with Patricia M. Ellis, the author of the well-known textbook on Physical Therapy Management of Lower Extremity Amputations, published for the first time in 1986 in the USA. But Gertrude is a Canadian immigrant who remained aware of her German roots. Whenever she visits her classmates in Leipzig, she cannot resist lecturing and publishing in her native language and she has become just as popular there, as she is in the New World.

Wieland Kaphingst continued his father's tradition in becoming a prosthetist. He also holds a degree in biomedical engineering from the Technical College affiliated with the University of Giessen, Germany.

He has many years of experience in orthotic/prosthetic third world cooperation and served as Director of the Federal School for Orthopaedic Technology in Germany for 5 years before moving to the United States, where he is the Vice-President of IPOS North America Inc.

Therefore, this book represents a blend of two cultures which have very much in common, except for the language. It is hence a necessity to close this language gap. Part 1 by Gertrude Mensch is an updated translation of her Manual mentioned above. Wieland Kaphingst's Part 2 is based on the state of the art in prosthetics on both sides of the Atlantic.

The first part deals with physical therapy

including the various reasons for amputation. Pre- and postoperative physical treatment is explained, followed by prosthetic gait training. Gait disorders, their reasons and how to correct them are extensively demonstrated and brilliantly illustrated. Special attention is given to the prevention and treatment of joint contractures and the conservative handling of stump problems caused by inadequate surgery, delayed wound healing and poor prosthetics. Part 1 ends with some pages on sports for amputees.

Part 2 establishes guidelines for prosthetic prescriptions depending on the patient's ability according to the 5 functional levels of the American DMERC classification. A comprehensive questionnaire has been carefully worked out. It is illustrated with some typical examples. The prosthetic components selected for these patients are limited to only three manufacturers, two German and one American.

Both parts of the book are dedicated predominantly to trans-tibial and trans-femoral amputations. It has to be admitted that most major amputations are still performed at these two levels, despite the efforts of the ISPO in 1984 to organize a seminar dedicated to through-knee amputation, and despite the progress in amputation surgery in order to preserve part of the foot instead of recommending a long trans-tibial stump. Also hip, disarticulation and hemipelvectomy should have deserved some illustrations as prosthetics and gait training are quite different from any other level.

These critical remarks are not meant to limit the outstanding practical value of this joint venture; but, on the contrary, it may be hoped that there will soon be a second edition, if possible simultaneously in German and in English, which pays equal attention to every level of amputation.

René Baumgartner,
Rumikon, Switzerland

Calendar of Events

National Centre for Training and Education in Prosthetics and Orthotics Short Term Courses 1998-99

Courses for Physicians, Surgeons and Therapists

NC 505	Lower Limb Prosthetics	11th - 15th January 1999
NC 518	Upper Limb Prosthetics	27th January 1999
NC 510	Wheelchairs and Seating	2nd - 4th March 1999
NC 514	Orthotic Management of Diabetic Foot	11th - 12th March 1999
NC 511(A)	Clinical Gait Analysis	16th - 17th March 1999
NC 506	Fracture Bracing	24th - 28th May 1999
NC 511(B)	Clinical Gait Analysis	7th - 8th September 1999

Courses for Orthotists and Therapists

NC 224	Hand Trauma	12th February 1999
NC 225	Orthoses for Brachial Plexus Injuries	26th February 1999

Courses for Orthotic Technicians

NC 604	Orthotic Technician Training	
	Module 1	7th-18th December, 1998
	Module 2	5th-15th January, 1999
	Module 3	4th-14th May, 1999
	Module 4	17th-28th May, 1999

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

4-8 February, 1999

Annual Meeting of the American Academy of Orthopaedic Surgeons, Anaheim, USA.
Information: AAOS, 6300 North River Road, Rosemont, IL60018, USA.

3-6 March, 1999

AAOP Annual Meeting, New Orleans, USA.
Information: Annette Suriani, AOPA, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

15-18 March, 1999

1st Arab Regional Conference of Rehabilitation International and 2nd Gulf Congress in Medical Rehabilitation, Kuwait.
Information: Conference Secretariat, PO Box 4070, 13041 Safat, Kuwait.

26-28 March, 1999

BAPO Annual Conference, Harrogate, England.
Information: BAPO Secretariat, Sir James Clark Building, Abbey Mill Business Centre, Paisley, Renfrewshire, PA1 1TJ, Scotland.

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