The Journal of the International Society for Prosthetics and Orthotics

Prosthetics and Orthotics International

December 1997, Vol. 21, No. 3

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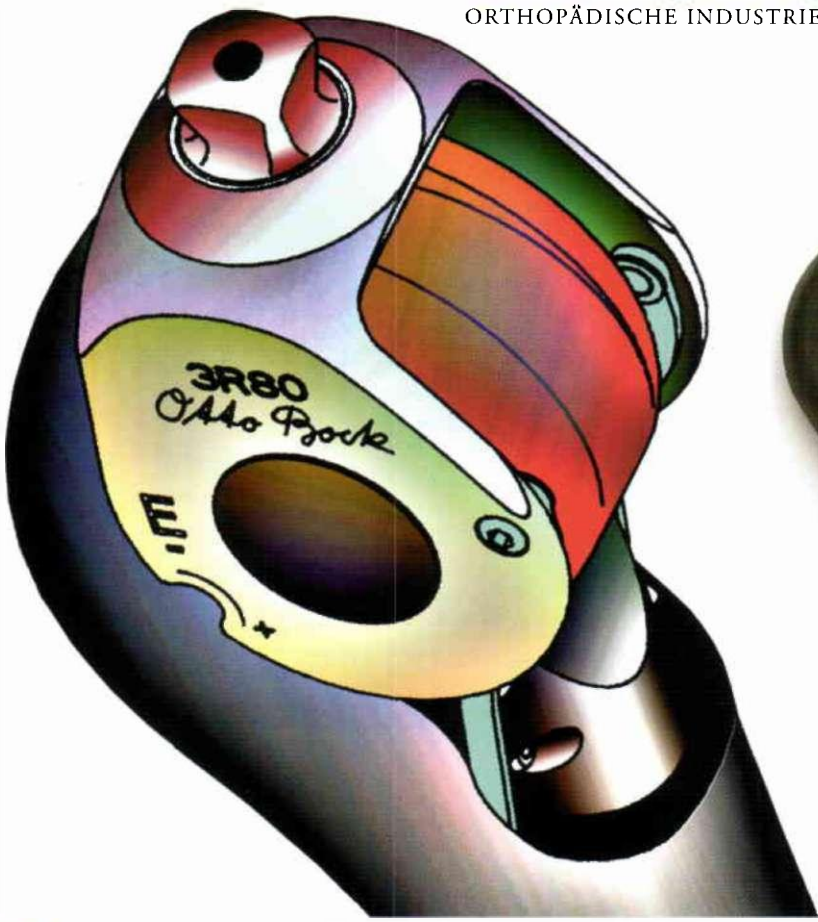

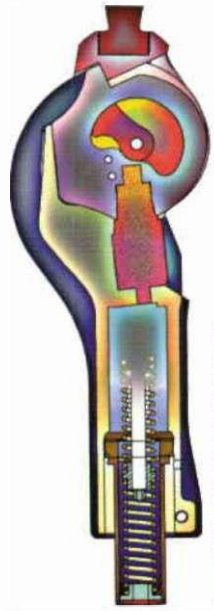

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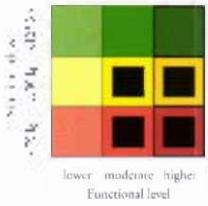

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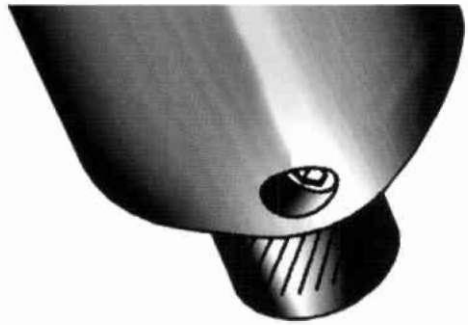

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Editorial

The suggestion to hold a consensus conference on poliomyelitis was first put to the Executive Board of ISPO about six years ago by George Murdoch and Sepp Heim. The proposal was picked up at the beginning of this triennium when the Executive Board felt that it had enough resources to underwrite such a conference.

The ISPO Consensus Conference on Poliomyelitis that was held in Hammamet, Tunisia, 16-22 November has only just ended. The purpose of the conference was to examine all aspects of the treatment of chronic poliomyelitis including the treatment of post-polio syndrome in an attempt to come to a consensus opinion as to the best surgical, orthotic and therapeutic treatment of this condition.

In order to achieve this over 100 experts in the subject from 42 countries were assembled. They represented all the major professions involved in the treatment of chronic poliomyelitis including orthopaedic surgeons, rehabilitation doctors, orthotists, physical and occupational therapists, engineers, educators and consumers.

The conference was held in collaboration with the World Health Organisation. The Ministry of Health, the Ministry of Social Welfare and the Caisse Nationale Securité Social of Tunisia also supported it especially through the staff of the Orthopaedic Hospital and the Orthopaedic Workshop in Tunis. The setting of this event in Tunisia was no accident. The efforts of the authorities in Tunisia to eradicate the onset of poliomyelitis and to treat those who have contracted it has been an example for other countries to follow.

It would not have been possible to run this conference without the help of the many organisations and agencies which have been involved in the meeting. Organisations such as Handicap International, Deutsche Geselleschaft für Technische Zusammenarbeit (GTZ) and World Orthopaedic Concern made a large contribution by supporting their own personnel to attend and other organisations, too numerous to list here, also made a significant contribution in this regard.

ISPO is indebted to those organisations that have helped sponsor this conference: Otto Bock, The Swedish National Polio Foundation, Becker Orthopedics and Proteor.

The conference was of six and a half days duration during which overview presentations, based on a critical review of the literature, were given. These presentations covered background material such as epidemiology and prevention, pathophysiology, management of the acute and sub-acute phases as well as the surgical, orthotic and therapeutic treatment of the lower limb, spine and upper limb in chronic poliomyelitis. Other topics such as national management systems, international co-operation, consumer issues and educational needs were also covered. These presentations were followed by syndicate discussions on particular aspects of the topics the reports of which were presented to plenary sessions and discussed until a consensus opinion or an identified difference of opinion had been reached. During the conference all the participants worked very hard, often until late in the evening, and agreement was reached on many of the issues discussed.

What was remarkable in the conference was the level of consensus reached during discussions especially when the number of different countries, cultures and professions is taken into account.

The information that has been gathered at the conference will be published by ISPO and widely distributed. It is the intention of the Executive Board of ISPO to examine the possibility of offering a series of courses based on the outcomes of this conference in different regions of the world. It is hoped and anticipated that this will have a positive effect on the treatment of people with chronic poliomyelitis world-wide.

Norman A. Jacobs
President-Elect

Prosthetics and Orthotics International, 1997, 21, 166-167

Report from the Executive Board

Executive Board Meeting No 53 was held in Vedbaek, Denmark, on 14 and 15 June 1997. This is a summary of points, which I think will be of interest to you.

Finance

Serious difficulties were being encountered because of late payment of membership fees to Copenhagen. Currently the deadline for payment was 1 June and it was agreed that the deadline for payment in 1998 should be 31 March in the hope that this change would relieve the problem.

Education

The Category II Information Package was approved with some amendments and additions. It was agreed that it should now be printed and distributed to interested agencies and individuals. This package will be particularly important for those interested in prosthetic/orthotic education in the developing world. It was also agreed that work should proceed on a draft Category I Information Package which would be more relevant to the industrial world at this time but would have increasing importance in the developing world over the coming years.

The recent course on Amputation Surgery and Related Prosthetics, held in Helsingborg, Sweden, had been a success. Arrangements had begun for a course on the same subject in Jaipur, Northern India on 3-7 November 1997. A draft programme had been prepared. A number of possible venues (including Angola, Vietnam and El Salvador) for future courses would be considered.

Programmes had been prepared for the ISPO Educational Seminar (30 January-1 February 1998) and the Asian Prosthetics and Orthotics Workshop (2-4 February 1998) by ISPO-Japan. The President confirmed that these events would receive funding from the Japanese Government.

Membership

A guideline on the formation of new national member societies and a standard draft constitution (in English) had been prepared to ease the process of forming a new National Member Society, particularly for countries where English is not the spoken language. This constitution could be amended to take account of local needs and the amended version would be accepted as long as it was compatible with the International Constitution. *(Any member who wishes to form a National Member Society can obtain a copy of the guideline and draft constitution from the Honorary Secretary.)*

Publications

It was agreed that the Officers of the Society should be responsible for liaising directly with the Task Officer regarding information to be included on the ISPO web page. Meanwhile, the Publications Committee would take a strategic view of the development of the web site. A guideline on submitting information for the ISPO web pages would be distributed to National Member Societies. The ISPO web page address is WWW.I-S-P-O.ORG.

Consensus Conferences, Research and Evaluation

It had been proposed that Executive Board members should be encouraged to attend Consensus Conferences and be funded to do so. There was some feeling that, to minimise costs, Executive Board members should be chosen for attendance on the basis of need. On the other hand, there was also support for the view that Executive Board members should be strongly encouraged to attend since Consensus Conferences usually lead to other activities, which may involve them after the event. The middle view that Executive Board members might be encouraged to attend if they felt that they had special interest in the event was also expressed. No agreement was reached. Thus the proposal was not accepted in its current form.

As a consequence of the consensus conference on Orthotic Management of Cerebral Palsy, a 3-day course on this topic would be hosted by Sunnybrook Health Science Centre Toronto, Canada. It was

also agreed that holding a 3-4 day course on Lower Limb Orthotics for Cerebral Palsy, associated with the Second Central and Eastern European Conference in Portorose, Slovenia (10-12 September 1998), should be considered.

It was reported that, following the consensus conference on Appropriate Prosthetic Technology for Developing Countries, a section on appropriate technology had been added to the courses on Amputation Surgery and Related Prosthetics. Also, an evaluation of the ICRC polypropylene system had been initiated in collaboration with GTZ. In the first instance, 100 prostheses from urban, rural and mountain areas of Vietnam would be evaluated. Such questions as frequency, nature and cost of repairs and manufacturing costs, problems etc would be addressed.

The next consensus conference would be on the Management of Poliomyelitis, planned for Hammamet, Tunisia on 16-22 November 1997. Over 100 individuals had been invited. Ofto Bock, Becker Orthopaedic and the Swedish Polio and Traffic Victims Association had promised sponsorship. Rotary International had also been approached. *(Since the Executive Board Meeting, Proteor has also promised sponsorship).*

Topics suggested for future consensus conferences included: Management of the Limb Deficient Child, Management of Severe Disability, Community Based Rehabilitation, Science and Practice of Shoe Fit, Management of the Child Amputee, Upper Limb Prosthetics, Foot Orthotics, The Insensate Foot, Trans-tibial Socket Design, Corsets and Spinal Orthotics, Sports Injury Orthotics and Co-ordination of Agencies Concerned with Rehabilitation. It would be necessary to identify topics for recommendation to the International Committee and the incoming Executive Board by the time of the final meeting of the present Executive Board in Amsterdam.

Quality Management

It was agreed that the proposed ISPO Workshop on Quality Management should be held in Glasgow in Spring 1998.

International Consultants

It had been agreed at the Interim Meeting of International Committee Representatives that the activities of International Consultants should be reviewed. A summary of these activities would be presented at the next meeting of the Executive Board.

International Organisations

The Society continues to enjoy good relations with the World Health Organisation (WHO), the United Nations (UN), the International Association of Prosthetists and Orthotists (INTERBOR), Rehabilitation International (RI), Handicap International (HI), the International Commission on Technology and Access (ICTA), the African Rehabilitation Institute (ARI), Internationaler Verband der Orthopädie Schutechniker (IVO), World Orthopaedic Concern (WOC), the International Committee of the Red Cross (ICRC), the World Rehabilitation Fund (WRF), the US Agency for International Development (USAID) and the International Rehabilitation Medicine Association (IRMA).

Congresses

Good progress was reported in the organisation of the IX World Congress (Amsterdam, The Netherlands: 28 June - 3 July 1998). There would be 40 instructional courses. Some 2375 square metres of the 3000 square metres of exhibition space had already been sold. The social programme was proceeding satisfactorily. Sponsorship was proceeding well. Promotional activities were adequate. There was a congress web page on the Internet.

Planning of the Xth World Congress (Glasgow, UK: 1-5 July 2001) had started. Several venues for social events were being investigated. It was hoped that a gold sponsor could be identified before the Amsterdam Congress. British Airways would be the Official Carrier and a 10% discount would be given on all classes of fare.

Germany and Argentina had expressed an interest in hosting the XIth World Congress in 2004.

Brendan McHugh
Honorary Secretary

Prosthetics and Orthotics International, 1997, 21, 168–174

Optimisation of the prescription for trans-tibial (TT) amputees

A. CORTÉS, E. VIOSCA, J. V. HOYOS, J. PRAT and J. SÁNCHEZ-LACUESTA

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Abstract

The great diversity of prosthetic mechanisms available nowadays leads to the question of which type of artificial foot would be the most advisable for a particular person. To answer correctly, it is necessary to establish, in an objective way, the performance of each type of prosthetic mechanism. This knowledge is obtained by means of the study of the subject-prosthesis interaction, both in static and dynamic conditions.

This paper, based on the analysis of 8 trans-tibial (TT) amputees, presents a quantitative method for the study of human gait which allows the determination of the influence of four different prosthetic ankle-foot mechanisms (SACH, Single-axis, Greissinger and Dynamic) on gait. To do this, 1341 gait trials at different cadences were analysed (383 with normal subjects and 958 with amputees, using the four prosthetic feet under study). From all the variables available for study only those which offered interpretable clinical information were chosen for analysis. A total of 18 variables (kinetic, kinematic and time-related) were selected. A covariance analysis (ANOVA) of these variables was made, which showed that the factors influencing TT amputee gait were, in order of importance, cadence and leg studied (sound or prosthetic), inter-individual variability and, finally, the prosthetic mechanism used. When looking at the performance during gait of the 4 prosthetic mechanisms studied it can be observed that there are similarities in the kinetic study between SACH and Dynamic feet on one hand and Single-axis and Greissinger feet on the other. These results seem to support the classification criteria of articulated and non-articulated prosthetic mechanisms.

All correspondence to be addressed to Mr Alex Cortés, Instituto de Biomecánica de Valencia, P.O. Box 199, 46980 Paterna (Valencia), Spain.

Introduction

Both the increasing demand for a better life standard on the part of the amputees, improving the functionality of gait and even taking part in sport activities, and the natural motivation of competitiveness on the part of the manufacturers are encouraging the orthopaedic industry to progress with the development of new prosthetic devices. Nowadays, the possibilities of selection (among prosthetic designs) are so many that an individual's needs can be partially satisfied by different means, which makes it difficult to select the ideal product. In general terms the basis for a correct orthopaedic prescription is suiting the features offered by a device to the user's functional needs. This demands, in the first place, a knowledge of the performance of the different prosthetic mechanisms, both in static conditions and during use; and, in the second place, it is also necessary to know the functional needs of the intended user.

Few scientific reports address the question of making comparative analyses of different prosthetic mechanisms, and those few merely compare some of their characteristics separately (Arya *et al.*, 1995; Casilla *et al.*, 1995; Ehara *et al.*, 1993; Goh *et al.*, 1984; Schneider, 1993; Wing and Hittenberger, 1989). Additionally, the parameters analysed during gait and the methods used to obtain them vary from author to author. As a consequence, the comparison of the results of different research works and, consequently, the comparison of the different prosthetic mechanisms, becomes very difficult, if not impossible. Furthermore, the objective

evaluation of the functional needs of the subject to be fitted is a question still to be solved and, maybe, a more complex matter than it seems.

If only the gait function is considered it is known that it is conditioned by numerous factors (Hoyos, 1984; Viosca, 1993):

- Individual factors: *age* (Gabell and Nayak 1984; Sudarsky, 1990), *sex* (Bhambhani and Sing, 1985; Jansen *et al.,* 1982; Zuniga and Leavitt, 1973) and *interindividual variability* (Mann, 1981; Menard *et al.,* 1992).
- Dynamics of gait: *velocity* (Murray *et al.,* 1984) or *cadence* (Ayora, 1990; Boonstra *et al.,* 1993).
- Environmental: *ground surface* or *shoe type* Jones *et al.,* 1986).
- Amputation: *etiology* (Pohjolainen *et al.,* 1989; Sulzle *et al.,* 1978), *surgical procedure* (Burgess and Moore, 1977; Murdoch, 1984; Steinbach *et al.,* 1982), or *amputation level* (Sengler, 1984; Skinner and Effeney, 1985; Waters *et al.,* 1976).
- Prosthesis: *fitting* (Meier *et al.,* 1973; Mizrahi *et al.,* 1985; Saxena and Mukhopadhyay, 1977), *alignment* (Pearson *et al.,* 1973; Radcliffe, 1962) or *prosthetic mechanism.*

It can be seen then that the solution to the problem is complex and depends on many factors, It is thus necessary to come up with a common method for the analysis of prosthetic gait which, considering the above mentioned factors, allows for the comparison of the results drawn from different research teams, and therefore, for the comparison of different prosthetic mechanisms. This would mean an important saving of effort, while it would solve many of the problems posed.

The purpose of this work is to provide solutions to some of the drawbacks mentioned, To do this, the first aim is to present an objective and quantitative method for the study of prosthetic gait, which allows for the comparison of gait patterns. This will lead to the second objective, the comparison of the dynamic behaviour of 4 prosthetic ankle-foot mechanisms used by TT amputees, through the modifications introduced in the gait parameters. Although this does not mean solving the problem of assessing the amputees' functional needs, it will give objective data about the performance of the different mechanisms and therefore mean a first approach to the solution of the prosthetic prescription in clinical practice.

Methodology

The work has been developed following an accurate experimental procedure detailed below. In order not to confuse the variability due to the prostheses with that due to the individual nature and circumstances of the amputation or the amputee, the sample for the study was selected to be as homogeneous as possible so that the only source of variability was the prosthetic mechanism.

The gait analysis was carried out in a group of 8 TT amputees and 7 non-amputees. The amputees were fitted with patellar-tendon-bearing (PTB) prostheses and they fulfilled the following requirements: male; age between 18 and 50; traumatic TT amputation at least two years prior to the experience; good shaped stump free from skin problems, suture defects or hypertrophic scars; not suffering from any concurrent illnesses and having a high or very high level of functional gait activity according to Day's scale (Day, 1981), The control group were 7 non-amputated subjects, in good health condition, with normal gait and anthropometric characteristics similar to those in the amputee group.

The data of the two groups are shown in Tables 1 and 2.

Four prosthetic feet were studied, each representative of one of the families of articular devices most commonly used in the authors' hospitals (SACH, Single-axis, Greissinger and Dynamic). These feet were mounted on a copy of the amputee's prescribed prosthesis and were interchanged at random, allowing for a two-week adaption period before measurement.

All prostheses were made by the same manufacturer, to ensure similar criteria of manufacture, fitting and alignment thus avoiding variability derived from these factors. In all cases Oxford shoes with a 25mm heel were used. The experimental sessions were carried out at the Laboratory of Human Gait and Movement Analysis at the Institute of Biomechanics of Valencia (IBV). The equipment used was:

- 12m long walkway instrumented with two DINASCAN-IBV© extensometric force plates (Sánchez-Lacuesta *et al.,* 1992).
- A system of polycentric electrogoniometry for the measurement of both limbs-hip, knee and ankle angles on the sagittal plane (Cortés *et al.,* 1992).

Table 1. Characteristics of the amputee group. m = mean, s = standard deviation.

	Age	Mass (kg)	Height (cm)	Side amp	Day
VAM	37	66.5	170	L	15
API	19	64.0	176	L	24
MLT	26	55.0	174	R	36
EPF	47	76.0	171	R	14
JGM	35	65.0	175	L	39
JUM	43	71.0	168	R	22
BFO	49	90.0	164	L	14
MCF	21	43.0	153	L	26
m/s	34.6/11.5	66.3/13.9	168/7.5		23.7/9.6

- Telemetry equipment for the transmission of signals from the electrogoniometers.
- Data acquisition and control system which combines the signals from the platforms with those from the electrogoniometers and a PC with the appropriate software for data processing.

After a period of adaption to the laboratory conditions and the equipment used, and with the purpose of studying gait in a wide range of cadences, the subject was asked to walk at free cadence and, then, faster and slower until a spectrum of cadences ranging from 60 to 140 steps per minute was obtained. No metronome was used to measure cadence since it conditioned excessively the asymmetrical gait of the amputee. Instead, the period (T) which took them to walk five steps was timed in seconds and then calculated cadence (C) C = 5x (60/T), expressed in steps/min.

A total of 1341 trials of gait were made at different cadences, 958 of which corresponded to amputees and 383 to normal subjects. From all the variables which could be studied those selected for analysis were the ones that, in the authors' opinion, gave better clinical information on gait. A total of 18 variables was selected (Figs. 1 and 2); 7 were kinetic, 10 kinematic and 1 time-related (Single Support Stance Time SST). All of them are easy to interpret and were related to mechanical or physiological events in the gait cycle.

Table 2. Characteristics of the control group. m = mean, s = standard deviation.

	Age	Mass (kg)	Height (cm)
ACF	31	67.7	167
EMV	32	64.7	167
AHF	29	65.2	170
EVH	33	74.1	171
FSL	30	53.3	165
MVM	50	78.8	166
IPS	19	67.0	183
m/s	32/9.2	67.2/8	170/61

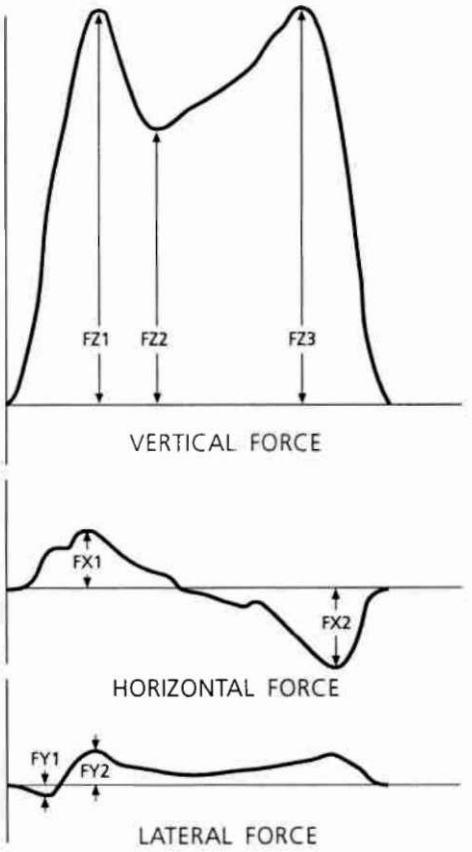

Fig. 1. Kinetic parameters.

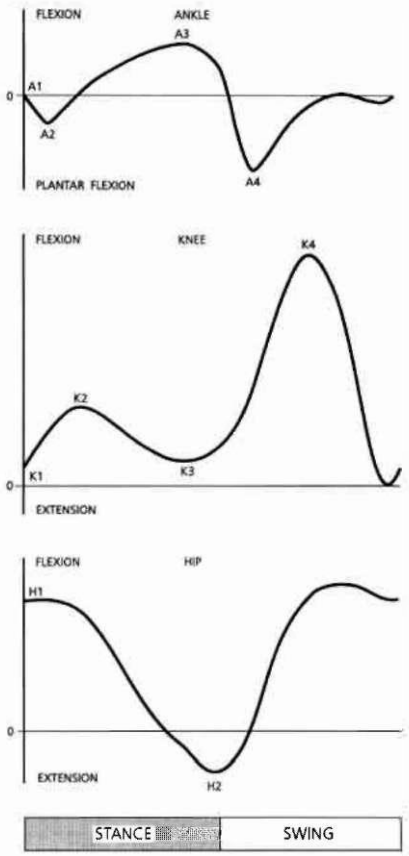

Fig. 2. Kinematic parameters.

The data were processed using BMDP Statistical Software and a co-variance analysis was done with the 18 variables selected. *Cadence* was set as covariable and *subject* (NAME), *limb considered* – sound or prosthetic – (SP) and type of *prosthetic mechanism* used (FOOTTYPE) were set as factors. The analysis of the Snedecor's F magnitude allows the controlled factors to be sorted according to their relative importance on the variable analysed.

Whenever significant differences were found a multiple linear regression analysis was performed with the purpose of adjusting evolution patterns of the dependent variables analysed as a function of cadence for each limb considered and prosthetic mechanism used. Only those graphs with a significant coefficient R of multiple correlation ($p < 0.01$) were considered.

Results and discussion

The results of the ANOVA showed that cadence, subject (NAME), limb studied (SP) and type of prosthetic mechanism used (FOOTTYPE) have a significant ($p < 0.05$) or highly significant ($p < 0.01$) influence on most of the variables analysed (Cortés, 1993). As can be seen in Table 3, the order of importance of the controlled factors with regard to the variables is, in the first place, cadence and limb studied (SP), in the second place, subject (NAME) and, in the last place, type of articular mechanism used (FOOTTYPE).

Consequently, the gait variables studied are greatly influenced by cadence. This suggests that gait trials should be performed in a wide range of cadences. Most of the experimental works reviewed (Doane and Holt, 1983; Enoka *et al.*, 1982; Hoy *et al.*, 1982; Winter and Sienko, 1988;) aim at the study of the influence of the type of prosthetic mechanism on gait although they neither consider cadence in a complete way nor the nature of the limb studied (sound or prosthetic). The results of this study show that these factors have greater influence on the dependent variables analysed than the type of articular mechanism used. This might explain the fact that the results published are not coincident.

Figure 3 depicts the relationship between kinetic variables and cadence for each type of articular mechanism. It can be observed, generally speaking, that there are similarities in behaviour of SACH and Dynamic feet, on the one hand, and of Single-axis and Greissinger on the other. This refers both to the sound limb and the prosthetic one. Therefore, from a kinetic point of view, the results suggest that the most determinant factor related to the behaviour of prosthetic feet is the presence or absence of a joint which allows for plantar flexion.

Nevertheless, it is important to point out other particular items that are not under this general rule. Single-axis and Greissinger feet show a different behaviour with respect to variable FX1 (maximum fore-aft horizontal force at heel contact). This suggests that the Greissinger foot behaves as a non-articulated foot, with values for FX1 below those of the control subjects. This pattern of kinetic behaviour is kinetically supported by Enoka *et al.*, (1982) who did not detect the expected plantar flexion corresponding to the design. On the contrary, horizontal force (FX1) in the artificial limb with the Single-axis mechanism is much higher than with the other

Table 3. Summary of the ANOVA. Arrangement of statistically significant controlled factors according to their relative importance.

Variable	1st	2nd	3rd	4th
FZ1	Cadence	SP	Name	Foottype
FZ2	Cadence	SP	Name	Foottype
FZ3	SP	Cadence	Name	Foottype
FX1	SP	Cadence	Name	Foottype
FX2	SP	Cadence	Name	Foottype
FY1	Cadence	SP	Name	Foottype
FY2	Cadence	SP	Name	
H1	Name	Cadence	Foottype	SP
H2	Cadence	Name		
K1	SP	Cadence	Name	Foottype
K2	SP	Cadence	Name	
K3	SP	Name	Foottype	
K4	Cadence	SP	Name	Foottype
A1	Name	SP	Foottype	
A2	Foottype	Name		
A3	SP	Name	Cadence	Foottype
A4	SP	Name	Cadence	Foottype
SST	Cadence	SP	Name	Foottype

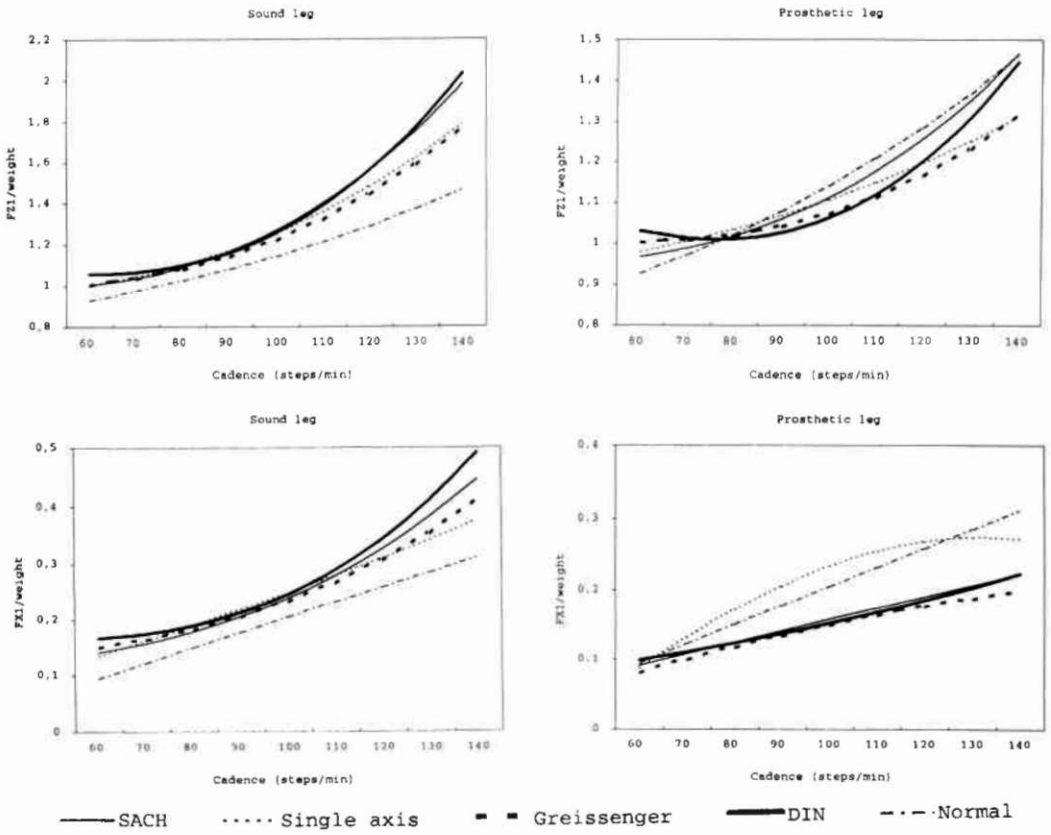

Fig. 3. FZ1 and FX1 quantitative curves as a function of cadence for each type of artificial foot in sound and prosthetic leg.

prosthetic mechanisms, and even higher than for the control group. A possible explanation is that part of the energy used during gait causes the mechanism to extend (plantarflexion), which implies that it must pivot on/around the heel and means a greater braking force. Enoka *et al.* (1982) showed that this does not occur in the Greissinger foot, probably because a higher force is needed to perform plantarflexion, which in practice behaves as a non-articulated mechanism.

Conclusions

In summary, the general conclusions of the study are as follows:

- The method presented for the study of prosthetic gait seems to be appropriate because it is objective and quantitative, allowing comparison of the results obtained with different prostheses. It could be a valid proposal as a standard method for the study of prosthetic gait.
- The factors which influence the amputee's gait can be arranged according to the following order of importance: cadence and type of limb (sound or prosthetic): subject (which accounts for individual variability) and type of prosthetic mechanism used.
- Since these factors have a significant effect, they should be considered in the experimental design; otherwise, the conclusions attained can be confusing or mistaken.
- The results of this work show similarities between the kinetic behaviour of SACH and Dynamic feet on the one hand, and Single-axis and Greissinger on the other, This fact supports the criterion for the classification of prosthetic mechanisms as articulated and non-articulated.

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The authors would like to thank Otto Bock Ibérica for supplying all prosthetic feet free of charge; Ortopedia Sotos SL for making and fitting the prostheses; Prof V. Carot (Polytechnic of Valencia UPV) for his help with statistical analysis and finally, all the subjects who generously participated in the experiment.

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Suspension effect and dynamic evaluation of the total surface bearing (TSB) trans-tibial prosthesis: a comparison with the patellar tendon bearing (PTB) trans-tibial prosthesis

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Abstract

X-ray and cineradiography measurements were used to compare the suspension effect and stability of a TSB trans-tibial prosthesis with an Icelandic Roll-On Silicone Socket (ICEROSS) system to that of a PTB trans-tibial prosthesis. The suspension effect was measured by the distance between the tibia and the socket in both suspension position and weight-bearing position in both type of prostheses. The suspension effect of the TSB prosthesis (2.53 ± 0.90cm) was superior to that of the PTB prosthesis (3.60 ± 0.56cm) ($p<0.05$) by x-ray measurement. The suspension effect of the TSB prosthesis (0.1, 0.4, 0.72cm) was superior to that of the PTB prosthesis (0.3, 0.48, 1.03cm) ($p<0.01$, $p<0.05$) by cineradiographic measurement. The stability was measured as the angle between the axis of the tibia and the prosthesis at the time of heel contact and toe off. The angle change of the TSB prosthesis was statistically smaller than that of the PTB prosthesis.

Introduction

The use of total surface-bearing (TSB) trans-tibial prosthesis with an Icelandic roll-on silicone socket (ICEROSS) (Kristinsson, 1993) has recently become popular in prosthetics. This new trans-tibial prosthesis does not require the knee cuff that is used as a suspension device in the conventional patellar tendon bearing (PTB) prosthesis. Due to the large friction between the silicone socket and skin in the TSB prosthesis, there is a reduction in the piston motion when the heel contacts the ground and an increase in the flexion angle of the knee in the swing phase (Yokogushi *et al.*, 1996; Cluitmans *et al.*, 1994; Datta *et al.*, 1996). The sense of stability and the feeling of secure attachment are also superior in the TSB prosthesis.

However, there have been no reports presenting objective measurements that confirm the superiority of the suspension and stability of the TSB prosthesis compared to those of the PTB prosthesis. Therefore, in the present study, a comparative x-ray evaluation was performed of the suspension effect between TSB and PTB prostheses, and a comparative cineradiographical evaluation was carried out of the suspension and anteroposterior stability between TSB and PTB prostheses.

Subjects

The subjects were 9 trans-tibial amputees (10 limbs), including 8 men and 1 woman aged 19 to 74 years (mean 33.9 years). The reasons for amputation were traumatic injuries in 6 cases (6 limbs), tumours in 2 cases (2 limbs), and burns in 1 case (2 limbs). The length of amputation was 13 to 29cm (mean: 19.8cm). All the subjects had previously used a PTB prosthesis for either temporary or normal walking before changing to the present TSB prosthesis for normal walking. The period of TSB prosthesis use was 6 months to 2 years and 11 months (mean: 1 year and 4 months).

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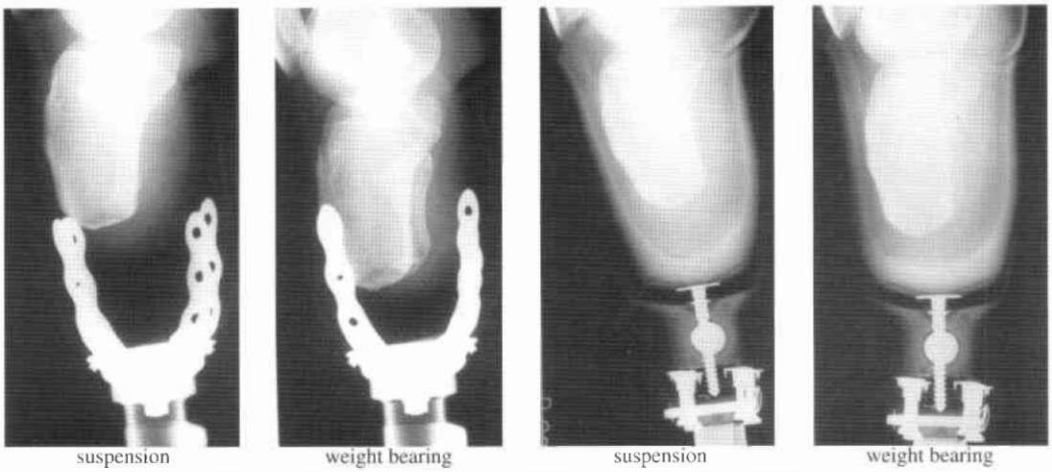

Fig. 1. Lateral view x-rays of PTB and TSB prosthesis during attachment

Methods

Comparative x-ray evaluation of the suspension

Lateral view x-rays were taken in the one leg standing position while wearing the PTB prosthesis or TSB prosthesis in the weight-bearing and suspension positions. For the suspension phase, a 5kg mass was applied to the foot of the prosthesis, and an x-ray was taken with the prosthesis suspended at a knee flexion angle of 30°. For the x-ray measurement, the distance between the tibial end and the base of the socket was measured, and the movement of the stump was calculated by subtracting the value in the weight-bearing position from the value in the suspension position (Fig. 1).

Comparative cineradiographical evaluation of the suspension

Cineradiography was taken in walking on the walking machine while wearing the PTB prosthesis or TSB prosthesis with measurements subsequently made in the foot contact phase and the swing phase. For the cineradiographical measurement, the distance between the tibial end and the base of the socket was measured and the movement of the stump was calculated by subtracting the value in the weight-bearing position from the value in the suspension position in each five times. These evaluations were done for three cases.

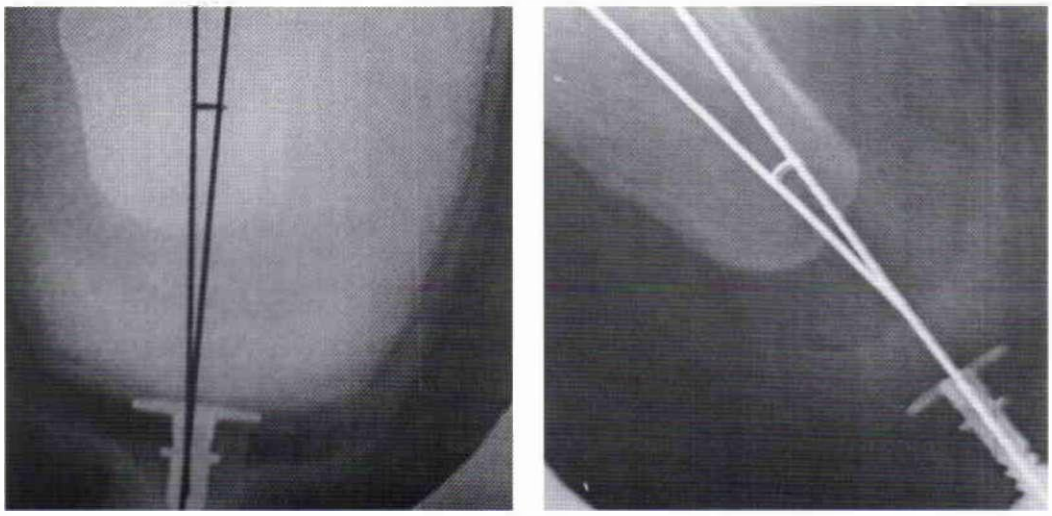

Fig. 2. Cineradiographical evaluation of tibial stability in the socket of the TSB prosthesis.

Comparative cineradiographical evaluation of the tibial stability

The angle between the tibial shaft and the axis of the prosthesis was measured. The angular change was calculated by subtracting the value at toe-off from the value at the heel contact. These evaluations were carried out on three cases and for each, five trials were completed (Fig. 2)

Results

Comparison the suspension effect by x-ray

The translation of the tibial end between the suspension position and weight-bearing phase was 2.53±0.90cm for the TSB prosthesis and 3.60±0.56cm for the PTB prosthesis. The translation for the TSB prosthesis was significantly lower ($p<0.05$) (Fig. 3) and the suspension effect of the TSB prosthesis consequently superior to that of the PTB prosthesis.

Comparison of the suspension effect by cineradiography

The stump translations on average in each of the three cases with the PTB prostheses were 0.3cm, 0.48cm and 1.03cm. For the same cases with TSB prostheses the translations were 0.1cm, 0.4cm and 0.72cm. The latter values were statistically smaller than the mean stump translation of PTB prostheses (Fig. 4). Thus, the suspension effect of the TSB prostheses was superior to that of the PTB prosthesis in walking.

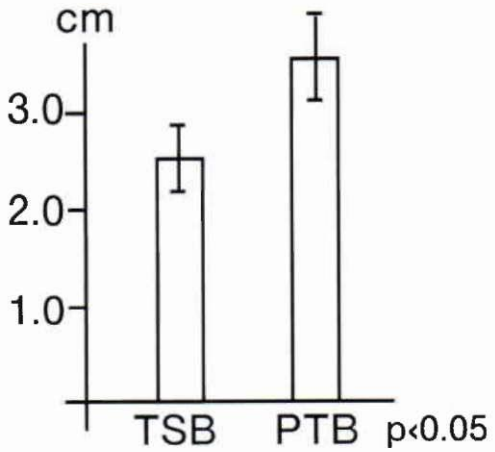

Fig. 3. Comparison of the suspension effect of TSB and PTB prostheses by x-ray.

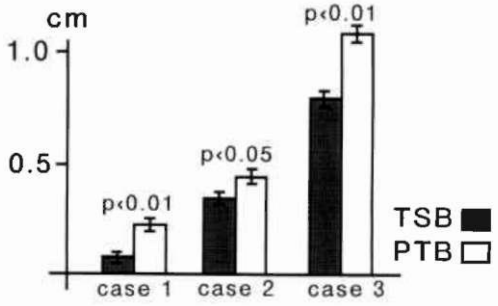

Fig. 4. Comparison of the suspension effect between TSB and PTB prostheses by cineradiography.

Comparison of the tibial stability in the socket by cineradiography

The changes of angle on average in each of the three cases with the PTB prostheses were 14.1°, 5.6° and 9.0°. On the other hand, these cases with TSB prostheses had angle changes of 2.5°, 4.0° and 6.4°. These values were statistically smaller than the mean angle change of PTB prostheses (Fig. 5). Thus, the anteroposterior stability of the TSB prosthesis was superior to that of the PTB prosthesis in the dynamic situation.

Discussion

Lilja *et al.* (1993) estimated the mean tibial movement for walking with a PTB prosthesis to be 2.8cm. This value is smaller than the result obtained by the authors (3.60 ± 0.56cm) for the PTB prosthesis with a 5kg mass applied during the swing phase to simulate the estimated centrifugal force acting on the prosthesis. However, in the present study an even smaller movement (2.53 ± 0.90cm) was obtained for the TSB prostheses with a 5kg mass applied, indicating that the TSB prosthesis has a superior suspension effect.

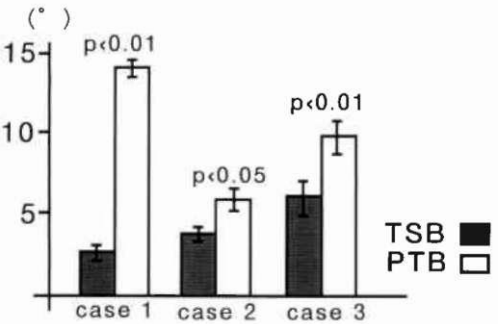

Fig. 5. Comparison of the tibial stability in the socket of TSB and PTB prostheses by cineradiography

According to Tazawa (1991), the characteristics of the suspension of a TSB prosthesis with an ICEROSS silicone socket are an improvement in the feeling of fit and lightness, which means an improvement in the feeling of stability during the stance phase and secure attachment during the swing phase. The results of the x-ray cineradiographical measurements conducted in the present study clearly show that the suspension effect of the TSB prosthesis is superior to that of the conventional PTB prosthesis, and this improved suspension effect supports the feeling of more secure attachment during the swing phase.

Satisfactory results obtained from using the TSB prosthesis with the ICEROSS silicone socket were attributed not only to the better suspension effect but also the improved stability in the stance phase compared with the PTB prosthesis.

Conclusions

1. The suspension effect of the TSB prosthesis with an ICEROSS silicone socket is superior to that of the PTB prosthesis evaluated both by static x-ray and dynamic cineradiography.
2. In dynamic evaluation by cineradiography in three cases, the changes of angle in the TSB prostheses were less than those in the PTB prostheses. Thus, anteroposterior stability of the TSB prosthesis was superior to that of the conventional PTB prosthesis.

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Calibration problems encountered while monitoring stump/socket interface pressures with force sensing resistors: techniques adopted to minimise inaccuracies

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Abstract

Force sensing resistors (FSR) have been used to measure dynamic pressures at the interface between appliance and patient. Inaccuracies using FSRs have been reported. This paper summarises both the calibration problems encountered and the techniques adopted to minimise inaccuracies.

It is considered that, by calibrating the transducers attached to the socket, and by adopting a strict test protocol, FSRs may provide a guide to the dynamic pressure distribution applied to the trans-tibial stump during gait.

Introduction

The mylar/resistive ink (9810) F-socket transducer, developed by TEKSCAN Inc. in Boston, was selected for this study. The 0.017mm thick transducer incorporates 96 individual cells, displayed in an array of 16 rows and 6 columns, covering a total sensing area of 15,500 mm^2. It is illustrated in Figure 1. This sensor was considered to be suitable for monitoring the pressure distribution during gait, between the stump tissue of a trans-tibial amputee and the prosthetic socket.

The FSR transducer detects forces applied to a cell. Pressure is force/area, and the output signal from an array of FSRs uses a common cell area to estimate the pressure of an individual cell in an array. The "threshold" load, which triggers the initial cell output, varies between the 96 FSR cells. A Tekscan equilibrium software programme balances the cell outputs at at given instant. The sensor has a maximum range of 520kPa. A 486 PC, with a 4Mb RAM, enables 750 frames to be recorded at a maximum sample rate of 165Hz. A colour coded graphic display provides an excellent illustration of pressure gradients

The advantages of the Tekscan sensor are thickness, size, sensitivity, resolution and frequency response. The disadvantages are hysteresis, drift and temperature sensitivity (Cavanagh *et al.*, 1992; Cobb and Claremont, 1995; Ferguson-Pell and Cardi, 1992; Sanders, 1995; Schaff, 1993). FSR insoles have been investigated by a number of researches (Brown *et al.*, 1996; Hayda *et al.*, 1994, Rose *et al.*, 1992; McPoil *et al.*, 1995; Woodburn and Helliwell, 1996; Young, 1993) with doubts

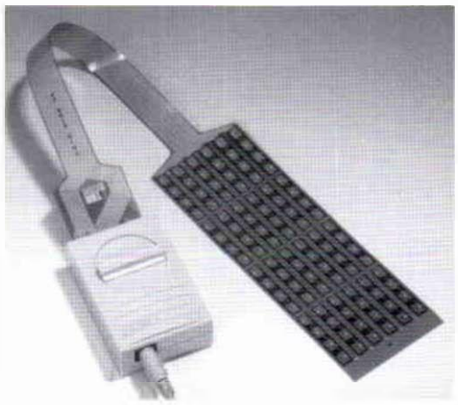

Fig. 1. TEKSCAN 9810 transducer.

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being cast on the repeatability and accuracy of FSRs. This may be influenced by both the flexibility of shoes and the compliance of the material supporting the FSR insole.

Test method

Compressive loads were applied to individual cells of the sensor, using a dynamic Instron compressive testing machine. Signal drift was investigated by applying a constant compressive load and measuring the output signal over a period of time. Flat, cylindrical and spherical matching contact surfaces were studied. Incremental compressive loads were applied to monitor the response of the FSR to the applied load. Each loading cycle lasted 10 seconds, followed immediately by 10 seconds unloaded. Individual cells were subjected to a cyclic load to investigate whether the dynamic response of the sensor output matched that of the applied load. A constant triangular wave load input was applied at various frequencies. The difference in the loading and unloading characteristics displayed the hysteresis characteristics. Cyclic drift was also studied.

A pressure rig was developed, so that all 96 sensors could be simultaneously loaded and calibrated. Figure 2 illustrates the design of a two part pressure rig. The sensor was placed on the top surface of the base plate. The small chamber, in the top plate, was pressurised with air. A 0.02mm thick mylar membrane was attached to the undersurface of the top plate and used as the loading medium. Air was introduced to the upper chamber at eight locations to ensure uniformity of loading.

The complete pressure system consists of an accurately calibrated pressure regulator connected to a valve system and hence to the upper chamber of the pressure rig. The valve system incorporates two micro valves controlled by a solenoid, which is activated by a wave input generator. The wave generator frequency controls the rate of cyclic pressure. The accuracy of the pressure rig was verified using a strain gauge pressure transducer, positioned in the air supply to the upper chamber. Alternative strain gauge transducers were positioned at the centre and edges of the pressure chamber base. These strain gauge transducers exhibited a linear calibration, with very little hysteresis. Subsequently, the air supply pressure was compared to pressure applied to the FSR and also to the pressure between the FSR and the pressure rig base. This study concentrated on the 0 – 200kPa range, which was linear for all transducers.

The following calibration procedure was adopted with the pressure rig. After 10 seconds of 100kPa static pressure, the output of all 96 cells was balanced using the equilibrium software programme. A cyclic pressure of 100kPa was applied at 0.5Hz, for a period of 60 seconds. (This is equivalent to 30 steps during gait). After a further 5 seconds of 100kPa static pressure, the FSR was calibrated at 100kPa. Having calibrated the FSR output at 100kPa, the sensor output was checked at pressure levels of 50, 75, 100, 125, 150, 200 and 100kPa.

Results

When subjected to compression tests, each individual cell has its own unique output. Maximum inter-cell variation is of the order of mean output ± 50%. At a selected applied pressure and instant, the use of the equilibrium software programme eliminates this variation.

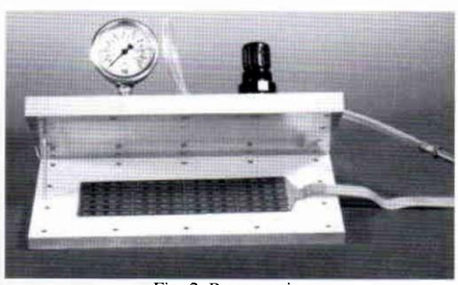

Fig. 2. Pressure rig.

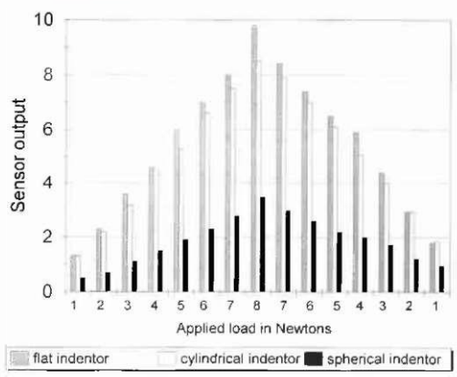

Fig. 3. Incremental loads – curvature effects.

A study of the effect of maintaining a constant load indicated an increase of sensor output with time, which can be classified as drift. Tekscan literature quotes a static drift of 5% after 10 seconds, with additional 5% increases at 10^2 and 10^3 seconds respectively. The response of the FSR to incremental loads was not satisfactory. The output of a typical cell demonstrated both a lack of repeatability and a difference between loading and unloading. Figure 3 illustrates that, when subjected to incremental loads up to 8N, cylindrical contact surfaces demonstrate these effects marginally. However, spherical or 3 dimensional curvatures will produce significant reductions in the output results.

Cyclic tests on the Instron testing machine indicated a good dynamic response between the applied load and the FSR output. Output stability was demonstrated after approximately 10 cycles. Figure 4 illustrates the FSR output for an individual cell, subjected to a triangular load wave of 1 to 8N at 1.0Hz for 20 loading cycles. Hysteresis varied with respect to the load range and frequency. The greater the load range the greater the hysteresis. A greater cyclic drift was noted at lower frequencies of 0.1 and 0.5Hz.

During pressure rig tests, good correlation was obtained between the strain gauge transducers located at the inlet, and at the centre and edges of the pressure chamber. A single Tekscan cell, positioned at random locations within the pressure chamber, indicated a consistent FSR output. Following a calibration at 100kPa, Table 1 lists the average Tekscan pressure output of 96 cells for a series of known applied pressures.

Relative to the calibration, the two subsequent studies at 100kPa indicate an

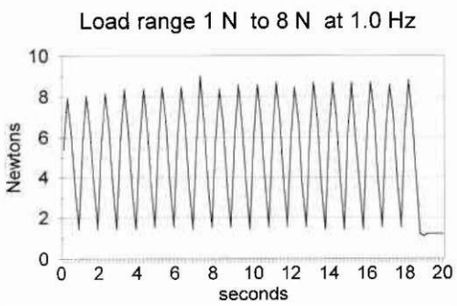

Fig. 4. Cyclic drift

Table 1.

Strain gauge pressure (kPa)	Tekscan average pressure (kPa)
50	50.1
75	76.3
100	98.7
125	123
150	145
100	102

average variation of ± 2%, with a maximum variation of ± 10% for any individual cell within the array. During cyclic tests, good correlation was noted between the calibrated FSR output and the strain gauge transducer output.

Discussion

The Tekscan equilibrium software programme ensures that, for a selected pressure, all 96 cells have the same common output. However, this common output is only valid for that selected pressure and at that particular instant.

In order to calibrate the FSR, the software programme requests the input of an applied load. An iterative method is necessary. The following procedure may be adopted. As a first approximation, multiply the total sensing area of 15,500 mm^2 by the known applied pressure. For example, if the known applied pressure is 100kPa, a load of 1550N is applied. If after 60 seconds of 100kPa cyclic pressure, the FSR sensor registers an average pressure of 90kPa, the assumed load of 1550N must be amended. This 10% "error" can be corrected by increasing the requested input load by 10%, i.e. to a value of 1705N, rather than the initial 1550N.

Random checks on a number of Tekscan 9810 sensors revealed that, occasionally, an individual cell in the sensor array may be "defective". Data from this "defective" cell must be ignored in subsequent studies.

Future clinical investigations will assess prosthetic socket fit and different casting techniques. Tekscan FSRs will be used to monitor the stump socket interface pressures. These FSRs are very thin and ideal for positioning at the interface between stump and socket. The Tekscan specification quotes an output data change of 1% per °F. Temperature

investigations suggest that there is not a significant temperature variation within a prosthetic socket, during a 10 to 15 minute gait study period.

The 3-dimensional curvatures within a prosthetic socket may introduce significant inaccuracies in FSR output data. This problem can be reduced by bonding the FSRs to the inner wall of a rigid socket and calibrating the sensors *in situ*. A gel filled "condom" is fitted in the socket, the brim of which is sealed, and the gel is pressurised to a pre-determined level. The sensors, when equilibrated and calibrated, demonstrate consistent pressures irrespective of socket curvature. This technique provides repeatable results for a total of approximately 350 cells fitted at pre-selected locations on the inner socket wall.

During socket assessments the amputee must become accustomed to the prescribed prosthesis. This involves walking for a period of time prior to recording data. The pressure sensors if fitted, will also be cyclically loaded during this period. Thus, immediately prior to calibration, the sensors are subjected to a cyclic load for the equivalent of 30 steps.

The amputee's stump tissue characteristics are not uniform. Hence, during load bearing the stump tissue loading rate may vary at different socket locations. The susceptibility of FSRs to loading rate may introduce inaccuracies.

Conclusions

The inaccuracies of FSRs must be recognised, so that the limits of their application may be identified. By selective applications and by adopting strict test protocols, it may be possible to minimise inaccuracies to such a level that a satisfactory impression of the overall pressure distribution may be recorded. However, it must be recognised that the actual pressure levels recorded are not absolute. Sensitivity to loading rates and hysteresis are two problems which still exist. In the future, development of computer software packages may minimize these effects.

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Technical note

Weight bearing and velocity in trans-tibial and trans-femoral amputees

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Abstract

The purpose of this study was to review the clinical utility of static weight bearing (SWB) and maximal self-selected ambulatory velocity as objective quantifiable measures in an outpatient lower limb prosthetic clinic.

Seventy-three (n=73) consecutive trans-tibial (TTA) and trans-femoral amputees (TFA) attending an outpatient prosthetic clinic were studied. Prosthetic weight bearing was measured on a bathroom scale (mass in kg), normalised to body mass then expressed as a percentage and labelled static weight bearing (SWB). Maximum safe self-selected ambulatory velocity over a 10 metre level walkway (m/s) was measured with a stopwatch. The SWB mean for the TTA group was 94.93% (range 77 - 100%) and 88.36% for the TFA group (range 43 - 100%). The mean ambulatory velocity was 1.70 m/s (range 0.07 - 5.75) for the TTA group and 0.78 m/s (range 0.10 - 1.54) for the TFA group. A statistically significant relationship ($p<0.05$) was found between SWB and ambulatory velocity in trans-tibial and trans-femoral amputees in this study. A ceiling effect was noted in the trans-tibial group with 42% achieving 100% SWB through their prosthetic limb so it was concluded that ambulatory velocity was the more sensitive measure in established trans-tibial prosthetic limb users. SWB may be the more appropriate quantifiable measure for use in established trans-femoral prosthesis users. Prosthetic training programmes would benefit from the objective measurement of SWB. Once optimal SWB was achieved, ambulatory velocity would be the more sensitive measure of prosthetic use.

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Introduction

Quantitative measurement in clinical practice of prosthetic gait training allows review of progress, early identification of new patient or prosthetic abnormalities, evaluation of new techniques in prosthetic rehabilitation, and external review of clinical outcomes. For quantitative measures to be used routinely in outpatient clinics, they should be quick and easy to perform and require the use of minimally sophisticated technology.

Static weight bearing in amputees has been measured and shown to quantify pressure tolerance and reflect progress in gait training (Stolov *et al.*, 1971; Gapsis *et al.*, 1982). The authors in a previous study demonstrated that static weight bearing (measured with bathroom scales) correlated closely with forces through the prosthetic limb during walking measured by a force plate (Jones *et al.*, 1997). Ambulatory velocity provides not only a direct performance indicator but an index of functional status and a predictor of rehabilitation success (Alexander, 1996). The relationship of age, gender, strength, cognitive function, activity level and specific diseases to gait has been studied extensively and summarised by Alexander's literature review.

The purpose of this study was to review the clinical utility of static weight bearing (SWB) and maximal safe self-selected ambulatory velocity as objective, quantifiable measures in an outpatient lower limb prosthetic clinic.

Table 1. Etiology grouped by amputation level.

Etiology	Trans-tibial	Trans-femoral
Vascular	23	11
Traumatic	20	10
Infection	2	2
Congenital	3	0
Neoplastic	0	2

Method

Seventy-three (n=73) consecutive trans-tibial (TTA) and trans-femoral amputees (TFA) attending an outpatient prosthetic clinic were studied. Excluded from the study were partial foot, Symes, knee and hip disarticulation and hemipelvectomy amputees. Non-ambulant amputees were also excluded. Each amputee's age, gender, level of amputation, and type of walking aid customarily used indoors were recorded. Weight bearing on the prosthesis and ambulatory velocity were measured.

Data were collected and summarised, then divided into two groups corresponding to the trans-tibial amputees (TTA) and the trans-femoral amputees (TFA) respectively. Multiple regression techniques were used for data analysis using a level of significance $p<0.05$.

Results

Forty-eight (n=48) of the participants were TTA and twenty-five (n=25) were TFA. Age ranged from 11 to 94 years in the TTA group, mean age 59.0 years (TFA mean age 61.2 years, range 32-82). The TTA group had 38 males and 10 females (TFA 19 males, 6 females). Table 1 lists amputation etiologies and corresponding levels of amputation.

Some 60% of the TTA group used no walking aid (TFA 36%), 15% of the TTA used a cane (TFA 28%), 19% TTA used a quad stick (TFA 32%), and 6% of the TTA used a frame (TFA 4%).

Static weight bearing

SWB measures ranged from 77% to 100% with a mean of 94.93% TTA (TFA mean 88.36%, range 43 - 100%). Of the TTA 42% achieved 100%, but only 8% of the TFA were able to achieve this maximal level (Fig. 1).

Safe self-selected maximal ambulatory velocity

Ambulatory velocity for TTA ranged from 0.07 - 5.75m/s, mean 1.70m/s, (TFA mean 0.78m/s, range 0.10 - 1.54m/s) (Fig. 2). Of the TTA 31% walked at a velocity of less than 1m/s (TFA 60%). Some 40% of the TTA walked 1-2m/s (TFA 40%). There were 29% TTA with velocity of more than 2m/s (TFA 0).

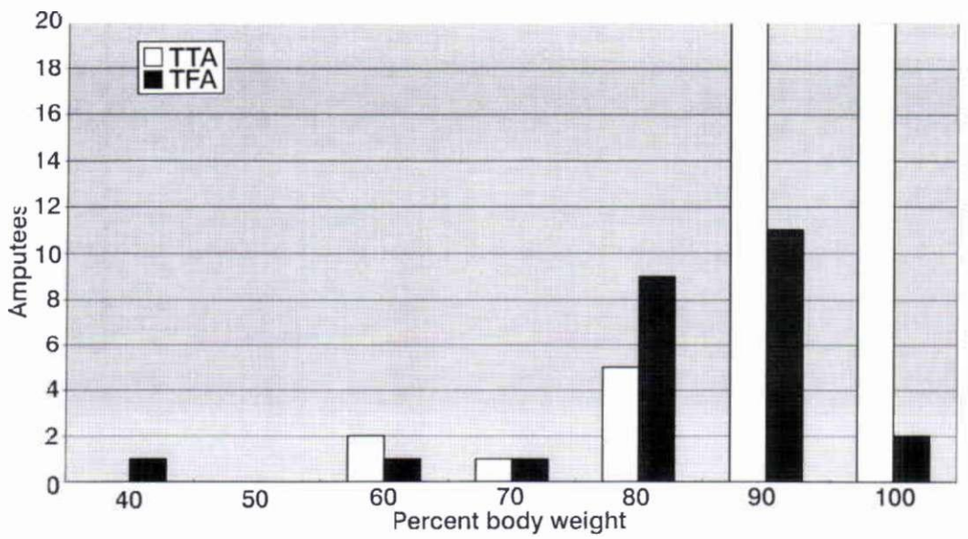

Fig. 1. Static weight bearing in TTA and TFA.

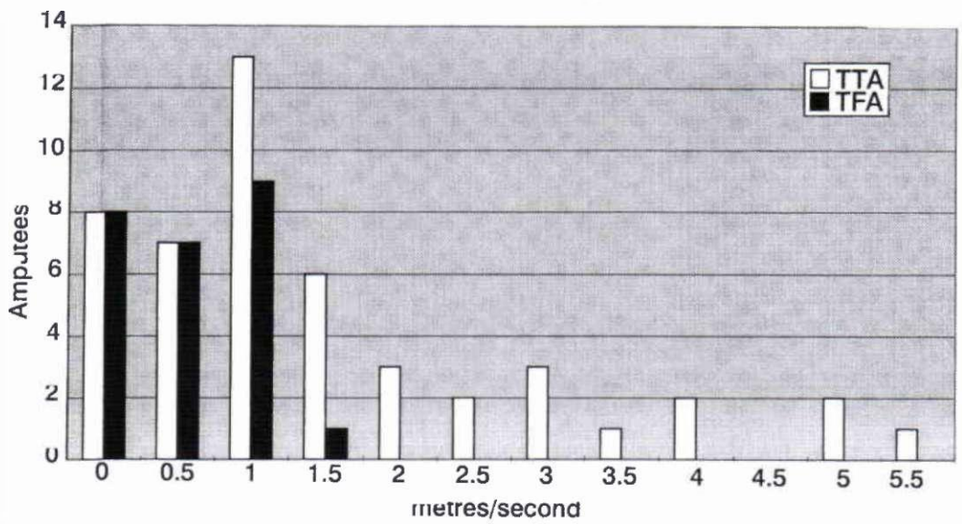

Fig. 2. Velocity in TTA and TFA.

Statistical relationships

There was a statistically significant relationship between SWB and velocity for the TTA ($F=14.3$, $p<0.05$, $df=47$) and TFA ($F=11.0$, $p<0.05$, $df=24$).

Discussion

In the context of an outpatient clinic reviewing established lower limb prosthetic users, the objective measures of static weight bearing and ambulatory velocity used are easily performed without interrupting the overall flow of the clinic.

The ceiling effect noted in SWB measurement in established TTAs limits its clinical usefulness. Once high level prosthetic users have reached 100% SWB, velocity becomes a more sensitive measure. Allowing the subjects to run, if this can be done safely, avoids a similar ceiling effect in high level users being measured for ambulatory velocity.

The SWB measure would appear to have particular potential for use in the clinical area of primary prosthetic training of both trans-tibial and trans-femoral amputees when weight transference through the new prosthesis is a major rehabilitation goal. A longitudinal study of weight bearing in this group would be recommended.

In terms of prosthetic training the provision of numerical feedback to the patients themselves is valuable as both an educational and motivational experience. In this study they took pride in their performance and gained self esteem when objective evidence of their performance in both ambulatory velocity and SWB was provided to them.

Conclusion

A statistically significant relationship was found between SWB and maximal safe self-selected ambulatory velocity in trans-tibial and trans-femoral amputees attending an outpatient prosthetic clinic. Some 42% of the established trans-tibial amputees in this study were able to statically bear 100% of their weight through their prosthetic limb. This ceiling effect made it an insensitive measure of clinical change in high level users. Ambulatory velocity would appear to be a more sensitive measure in the trans-tibial amputee group, as this group demonstrated a large range in walking velocity from 0.07m/s to 5.75m/s. However this effect was much less common for the trans-femoral amputee group. Maximal safe self-selected ambulatory velocity revealed that a large percentage of trans-femoral amputees (60%) were not able to exceed 1m/s and none was able to exceed 2m/s. This study demonstrated that objective, quantifiable measures can be undertaken quickly and easily in an outpatient prosthetic clinic.

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Case study

Am I better off with out it?: a case study of a patient having a trans-tibial amputation after 52 years of chronic lower limb ulceration and pain

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Abstract

This case study looks at a 71-year-old man who had 52 years of chronic lower limb pain and ulceration secondary to radiotherapy for an osteosarcoma. It discusses some issues surrounding amputation in such a case and raises early preoperative involvement by a multidisciplinary amputee rehabilitation team as a mandatory arm of management.

Introduction

Mr L is a 71-year-old man who underwent a right trans-tibial amputation (TTA) on 29th April 1996 at a Sydney Tertiary Referral Hospital.

Background

Mr L was born on 26/5/25 and was in good health until he developed an osteosarcoma on one of his right tarsal bones in 1943 at the age of 18 whilst serving in the Australian Army during World War II. This condition was treated at the time by excision of the cancerous bone, bone grafting and subsequent radiotherapy. The treatment was a success in the sense that the condition was cured and Mr L is alive 52 years later to tell the story. Nevertheless Mr L has had ongoing debilitating impairment over the subsequent 52 years in the form of chronic ulcers and pain in his right lower leg. This was due to the large dose of radiation Mr L received at the time and the resultant damage this caused to the tissues of his right lower limb. He cannot recall either being out of pain or the ulcers on his right leg ever healing during the subsequent 52 years.

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Despite the ulceration and pain Mr L remained relatively active and functional over the years. He was employed as pay master with a major car manufacturing company and as a penciller with a bookmaker. He was also married and has one son. He was very active in the sport of snooker. During the 1980s Mr L won the "New South Wales State Open Snooker Championships" and achieved the maximum break of 147.

During the seventies Mr L was a keen golfer, at one stage having a handicap of 5. His unrelenting condition did however take its toll, resulting in long term sleep disturbance, depression and a general and slow decrease in his avocation activities over the years. Mr L did not wear shoes for 30 years, wearing slippers even to work. He had to give up both his golf and snooker and he feels that his ulcers and pain prevented him from making more of a career out of his obvious snooker talent.

Mr L did not have the concept of "amputation" discussed or offered to him ant any time over the 52 years subsequent to his initial surgery and radiotherapy. He says that the pain and the effect of the ulceration became "so unbearable" by April 1996 that he pleaded with his surgeon to remove his leg. At that time, a right trans-tibial amputation was performed. He was not given any rehabilitation review prior to that surgery.

Outcome

Subsequent to his amputation Mr L underwent an inpatient rehabilitation programme at Lady Davidson Rehabilitation Hospital in Sydney from the 6th May 1996 until the 19th July 1996.

Mr L was discharged from Lady Davidson Hospital walking independently with a stick

utilising a right patellar tendon bearing prosthesis with modular shank, SACH foot and a suprapatellar cuff suspension. He was fully independent in all his activities of daily living and returned to live in his modified house with his wife.

He presented to the amputee clinic on 19th August 1996 "delighted" with the result of his amputation and subsequent use of the trans-tibial prosthesis. A driving assessment had been completed and Mr L was back driving his car with modifications. He had also returned to snooker. Mr L said the improvement in his overall sense of well being was remarkable. He noted that he was without pain and ulceration for the first time in 52 years and had recently been sleeping soundly for the first time in years. He openly declared that he was a "new man" with a "new lease on life".

Discussion

This case raises again the question of if and when to amputate in circumstances such as these when a patient has long term chronic ulceration, of any actiology, with little to no chance of healing (chronic osteomyelitis is another possible aetiological factor). This question is particularly vexing when chronic pain is an issue and the combination is having a significant effect on the patient's function and quality of life. It is well known that amputation does not invariably eradicate pain in such cases and this fact certainly needs to be taken into consideration.

The question has no one or easy answer. The decision always has to be made by the patient. Thanks is not forthcoming after such a major life event as having a limb amputated if the decision is thought to have been less than freely made. For this reason significant time, often many years, is needed for the patient to experience what effect the ongoing impairment is having.

The decision needs to be made with all the information at hand and may be made earlier to the overall benefit of the patient. 52 years is a long time as in the case of Mr L. He is totally convinced that he would have had this amputation years, if not decades, earlier if he "knew what he knows now". It is easy to make such a statement with the benefit of hindsight and as Mr L succinctly puts it, the decision to let someone "chop your leg off" is still the decision to let someone "chop your leg off" no matter what information is to hand.

The important concept is to manage such cases in an interdisciplinary environment. Even though the surgical side of the issue is always vital to consider it may be of no greater importance than other factors when making the decision. The medical, surgical, physical, functional, psychological, social, vocational and avocational aspects must be taken together and considered in depth. These issues must be presented to the patient in a way that he or she can synthesise and make sense of. Even enabling the patient to meet with a successful prosthesis user and see what is involved in prosthetic use can give a perspective not otherwise possible.

An early referral to an interdisciplinary rehabilitation service, that specialises in amputee management and is preferably coordinated by a rehabilitation physician, should be put in place. Such a review would only complement the surgical perspective and is appropriate preoperatively in all prospective or potential amputees, not just the "complicated and drawn out" cases such as Mr L's.

The case described, of chronic ulceration, is obviously not common in our developed society, particularly with refinements in the use of radiotherapy surgery; antibiotics etc. Nevertheless it is not unknown. Such situations though are more prevalent in third world societies including some parts of Australia, tropical climates as well as war and mine ravaged parts of the world. Unfortunately it is in these areas that the integrated rehabilitation concept is probably least known and available and this situation must be addressed.

No matter what branch of medicine or allied health is involved, the maximisation of the patients' quality of life should be paramount. A rethink of Mr L's last 52 years may help to refine practices.

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Effect on knee disarticulation on bone growth in immature rabbits

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Abstract

This study was designed by the University of Ankara Experimental and Research Laboratory for animals in 1997. In the study an anteroposterior skin flap technique was used for 20 knee disarticulation amputations and also in 20 trans-femoral amputations on immature rabbits, in order to investigate their effects on the femoral epiphyseal growth plate. The femurs of the rabbits were observed radiographically for 8 weeks. It was observed that the femurs tended to grow at a slower rate compared to the normal contralateral femur.

These studies showed that the disarticulated limb femurs grew 0.68cm shorter on average compared to the contralateral femurs and the femurs in the trans-femoral amputated limbs 3.58cm shorter on average compared to the contralateral ones. These results were found to be statistically significant.

Introduction

To date the prostheses used in knee disarticulation have never been popular, and as a consequence, this level has never gained any great prominence in the prosthetic field. Not only does the distal bulbous structure of the bone at the amputated level create problems in its doffing and donning, many other surgical and aesthetic problems occur, which altogether have disfavoured knee disarticulation as an amputation of choice. Nevertheless, from the late 1970s and onwards Burgess (1977); Jensen and Mandrup-Paulson (1983); Stirnemann *et al.* (1987) and Houghton *et al.* (1990); have all reported positive and encouraging results in favour of knee disarticulation (Atlas of Limb Prosthetics, 1992; Burgess, 1977; Lower Extremity Amputation, 1989; Amputation Surgery and Lower Limb Prosthetics, 1988).

Despite the fact that many advantages can accrue in adults by knee disarticulation (KD) compared to trans-femoral amputation (TF), such as, providing a longer lever for attachment of the prosthesis, having a lesser degree of muscular atrophy, having the ability to tolerate full end weight bearing on the stump and with good rotational control and suspension being easily acquired, it is even more advantageous in children because it protects the distal epiphyseal plate and does not result in unusual growth of the joint (Atlas of Limb Prosthetics, 1992; Donaldson, 1962; Jensen and Mandrup-Paulson, 1983; Kegel *et al.*, 1978; Mensch, 1983; Prosthetic and Orthotic Practice, 1970; Tooms, 1992).

Material and methods

The study was performed on immature, 3-week-old male New Zealand rabbits whose ossifications were yet incomplete. Ten rabbits were chosen for KD and 20 for TF amputation. The femoral growth rates of the operated legs were then compared to the contralateral intact ones.

Na Cefazol 50mg/kg was administered in all cases, 30 minutes prior to surgical intervention. The drugs used for anaesthesia were Ketalar 70mg/kg and Rompun 30mg/kg intramuscularly.

For those rabbits undergoing disarticulation, an anteroposterior flap technique defined by Batch *et al.* (1954) was used. Following the removal of hair, under surgically accepted aseptic conditions, approximately 0.5cm distal to the tibial tuberosity an anterior flap was prepared equal in length to the knee diameter

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(Atlas of Limb Prosthetics, 1992; Amputation Surgery and Lower Limb Prosthetics, 1988; Tooms 1992). The posterior flap was designed from the popliteal region and was about half the length of the anterior flap. The patellar and pes anserinus tendon were separated from the tibia as part of the anterior flap. The tibia and peroneal nerves were then clamped and cut proximal to the plane of amputation. The popliteal artery and vein were isolated and cauterized. The iliotibial band, the insertion of the biceps on the fibula and the medial and lateral heads of the gastrocnemius at the femoral condyles were then freed. Patellar excision was not done. The posterior joint capsule together with the popliteal and plantaris muscles were freed. The patellar tendon, cruciate ligament and the gastrocnemius origins were sutured to each other. Following hemostasis, the deep fascia, subcutaneous and cutaneous layers were sutured.

The procedure for TF amputation in rabbits was a follows: under surgical aseptic conditions, at the site of amputation, the anteroposterior diameter was measured and posterior and anterior flaps were made, each half the diameter in length. The incision divided the skin, the fascia and quadriceps muscle up to the bone. The femoral artery and vein were located and cauterized. The surrounding periosteum was removed and then the femur was cut in the distal one-third. The sciatic nerve was located and divided just proximal to the incision level. The posterior group of muscles were also cut in a transverse plane. Finally the distal ends of the muscles (quadriceps, adductors and hamstrings) were sutured over the distal femur cortex by nonabsorbable sutures. Following hemostasis the tissues were sutured in their respective layers.

The rabbits undergoing KD and TF amputation, were followed for femoral growth until 11 weeks old by taking radiographs every 2 weeks. Standard laboratory diet and free activity was applied to all rabbits. The results were compiled and are presented in Table Ia and Ib respectively. Prior to radiographs Ketalar 7mg/kg was administered intramuscularly, in order to achieve the same degree of extension and adduction of the hip for each of the rabbits. All films were taken at a distance of 1 metre (magnification rate: 1/1.15). Four measurements for KD length were recorded from the thickest part of the femoral condyle distally, to the widest portion of the greater trochanter proximally. Four measurements for TF amputation were recorded from the most distal portion of the amputated femur to the widest portion of the greater trochanter proximally. All results were statistically correct using *Student t test.*

Findings

Carrying out KD and TF amputations when the rabbits were 3 weeks old, the first measurements were taken at the 5th week, the second at 7th, third at 9th, and fourth at 11th weeks. Results were as shown in Tables 1 and 2. Femoral longitudinal growth continuing on both limbs. In the case of KD amputation this

Table 1. Measurements for knee disarticulated and sound femur (all measurements in cm).

Measurement			Rabbit Number																			
No.	Age	Side	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
I	5 week	KD	6.0	6.6	6.7	6.5	6.8	5.0	6.4	6.8	6.4	6.1	6.3	6.7	6.6	6.5	6.5	6.8	6.9	6.4	6.4	6.7
		S	6.2	6.6	7.0	6.5	7.1	5.1	6.6	6.9	6.6	6.4	6.4	6.9	6.9	6.5	6.7	6.8	7.0	6.6	6.6	6.8
II	7 week	KD	6.4	6.9	7.4	7.0	7.6	5.0	6.9	7.0	6.7	6.9	6.8	7.3	6.8	7.0	6.9	7.4	7.4	6.7	6.6	7.1
		S	7.3	8.2	7.5	7.5	8.0	5.3	7.0	7.3	7.1	7.2	6.9	7.5	7.3	7.1	7.0	7.5	7.6	7.1	6.9	7.5
III	9 week	KD	6.9	7.2	7.4	7.9	7.9	5.0	7.4	7.5	7.2	7.3	7.2	7.6	7.2	7.4	7.3	7.7	7.9	7.3	6.9	7.5
		S	7.7	8.9	7.6	8.3	8.4	5.6	7.7	7.9	7.6	7.7	7.6	8.0	7.9	7.7	7.6	7.9	8.1	7.6	7.4	7.9
IV	11 week	KD	7.4	7.2	8.6	8.8	9.3	5.3	8.1	8.4	8.4	7.9	7.9	8.6	8.3	8.5	8.6	8.4	8.7	8.8	7.7	8.6
		S	8.6	8.9	8.9	9.0	9.5	6.0	8.6	8.9	8.7	8.9	8.7	9.1	9.0	8.9	9.0	9.0	9.2	9.3	9.0	8.9

Table 2. Measurements for trans-femoral amputated and sound femur (all measurements in cm).

Measurement			Rabbit Number																		
No.	Age	Side	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
I	5 week	TF	2.6	2.7	3.4	3.9	2.6	2.7	2.9	3.0	3.1	2.7	3.3	3.5	3.0	3.0	3.2	3.1	2.9	2.7	3.0	3.3
		S	6.1	6.6	6.8	6.7	6.4	6.2	6.8	6.7	6.3	6.3	6.5	6.4	6.5	6.8	6.8	6.3	6.9	6.6	6.8	6.7
II	7 week	TF	3.0	3.7	3.9	4.0	3.9	3.5	3.9	3.7	3.6	3.7	4.3	4.0	3.5	3.5	3.7	3.6	3.8	3.7	3.7	4.3
		S	6.9	7.7	7.5	7.7	6.9	7.3	7.7	7.5	7.0	7.2	7.5	7.3	7.8	8.0	7.5	6.9	7.9	7.7	7.6	7.0
III	9 week	TF	3.4	3.9	4.1	4.2	4.7	3.8	4.1	4.0	3.9	4.6	4.6	4.5	3.8	3.8	4.0	3.9	4.2	4.0	3.9	4.7
		S	7.5	8.0	7.8	7.2	7.3	7.7	8.1	7.9	7.6	7.6	7.8	7.7	8.3	8.4	7.9	7.7	8.3	8.0	7.9	8.0
IV	11 week	TF	3.7	4.2	4.4	4.5	5.0	4.1	4.4	4.3	4.2	4.1	4.9	4.7	4.0	4.0	4.2	4.0	4.3	4.1	4.2	4.9
		S	7.7	8.4	8.1	7.7	7.8	8.0	8.5	8.4	7.9	8.0	8.1	8.0	8.7	8.7	8.2	8.0	8.5	8.4	8.2	8.3

produced femurs 0.15cm shorter than the contralateral one on the first measurement, 0.35cm on the second, 0.47cm on the third and 0.63cm on the fourth measurement (Table 3). The measurements for the TF amputation displayed femurs that were 3.53cm, 3.68cm, 3.73cm and 3.87cm respectively at the first to fourth measurements (Table 4).

Discussion and results

Early (1968) suggested that children who underwent knee disarticulation continued to show growth at the physis, even though at a slower rate when compared to its normal counterpart. However, to date, no such studies have been documented comparing the rate of physeal growth between patients who underwent knee disarticulation and trans-femoral amputation.

Frantz and Aitken (1960) suggested from radiographic studies, that children who underwent trans-femoral amputation, developed atrophy of the opposite pelvis, which resulted in coxa valga deformity. In the authors' studies, one of each type of surgical intervention resulted in coxa valga together with a minimal degree of opposite pelvis atrophy.

One year ago in the authors' studies, an eight-year-old who underwent knee disarticulation, had within 20 months a 3.5cm degree of shortness of the operated leg compared to the normal. Another 2-year-old child who underwent trans-femoral amputation, illustrated 0.7cm femoral growth, during a period of 8 months, which when compared to the unoperated side was very similar. In the same patient exositosis was present at the distal end of the residual femur, making the measurement

Table 3. The linear growth of knee disarticulated and sound femur.

Measurement No.	Age(week)	Side	x (cm)	Std Dev.	Min.	Max.	N
I.	5	KD	6.46	0.41	5.00	6.90	20
		S	6.61	0.43	5.10	7.10	
II.	7	KD	6.89	0.54	5.00	7.60	20
		S	7.24	0.57	5.30	8.20	
III.	9	KD	7.29	0.61	5.00	7.90	20
		S	7.76	0.62	5.60	8.90	
IV.	11	KD	8.18	0.84	5.30	9.30	20
		S	8.81	0.70	6.00	9.50	

Table 4. The linear growth of trans-femoral amputated and sound femur.

Measurement No.	Age(week)	Side	x (cm)	Std Dev.	Min.	Max.	N
I.	5	TF	3.03	0.34	2.60	3.90	20
		S	6.56	0.24	6.10	6.90	
II.	7	TF	3.75	0.29	3.00	4.30	20
		S	7.43	0.35	6.90	8.00	
III.	9	TF	4.11	0.35	3.40	4.70	20
		S	7.84	0.32	7.20	8.40	
IV.	11	TF	4.31	0.34	3.70	5.00	20
		S	8.18	0.30	7.70	8.70	

invalid (Alsancak and Korkusuz, 1996).

Growth at the distal femoral epiphyseal plate is more pronounced compared to its proximal counterpart according to research conducted by Digby (69%: 31%); (Bisgard, Gill and Abbott (70%: 30%); Green (70%: 30%) (Atlas of Prosthetics, 1992; Frantz and Aitken, 1960). In the lower limb growth is most pronounced for girls at age 14; for boys at 16. After this period growth continues at an average of 2cm annually until femoral ossification is completed (Ege and Güngör, 1980). Klein *et al.* (1994) stated that femoral linear growth of rabbits is more than 7.5 times faster than of humans. According to Pritchett (1982) of the University of Washington Orthopaedics Department, between the ages of 7 and the completion of ossification age, the average growth rate per year of the femoral distal physis was 1.3cm as obtained from radiographic studies performed on 244 normal children.

In the authors' study first measurements carried out on 20 rabbits 2 weeks after KD, showed that femurs were 0.16cm shorter, on average, compared to the contralateral one. The last measurement 8 weeks after operation revealed a 0.63cm average shortness. The difference between the lengths of the disarticulated and intact femurs on the first and second measurements were statistically significant ($p<0.05$). This difference was again found to be significant between the first and the third measurements $p<0.01$ level and between the third and the fourth measurements on $p<0.001$ level (Table 5).

Similarly 20 TF amputated rabbits' femurs were found to be 3.53cm shorter on average, than the intact ones on the first measurements

Table 5. The comparison of knee discarticulated femur to the sound femur.

Measurement No.	x (cm)	Std Dev.	Min. (cm)	Max. (cm)	N
I.	-0.16	0.11	-0.30	0.00	20
II.	-0.35	0.30	-1.30	-0.10	20
III.	-0.47	0.33	-1.70	-0.20	20
IV.	-0.63	0.40	-1.70	-0.20	20

Table 6. The comparison of trans-femoral amputated femur to the sound femur.

Measurement No.	x (cm)	Std Dev.	Min. (cm)	Max. (cm)	N
I.	-3.53	0.34	-4.00	-2.80	20
II.	-3.68	0.44	-4.50	-2.70	20
III.	-3.73	0.52	-4.60	-2.60	20
IV.	-3.87	0.49	-4.70	-2.80	20

Table 7. "t test pairs" for knee disarticulated rabbits.

Measurement No.	t	p	
I.-II.	2.64	0.016	p<0.05*
I.-III.	3.88	0.001	p<0.01*
I.-IV.	5.07	0.000	p<0.001*

Table 8. "t test pairs" for trans-femoral amputated rabbits.

Measurement No.	t	p	
I.-II.	1.63	0.120	p>0.05
I.-III.	1.89	0.074	p>0.05
I.-IV.	3.58	0.002	p<0.05*

carried out at the 2nd postoperative week, and 3.87cm on the last measurement at the 8th week. The difference between the first and the last measurements were statistically significant ($p<0.05$) while this difference was not significant between the first and the 2nd and 3rd measurements ($p>0.05$) (Table 6).

In this study although growth in length has continued at the KD and the TF amputated femurs, it is found to be not the same as that of the contralateral femurs. This result can be easily understood in the TF amputated immature rabbits whose distal femoral physeal growth is absent. Shorter growth in the KD rabbits where proximal and distal femoral physeal growth was taking place was interesting. This result may be explained by the positive effect of load stress on bone growth of intact extremities compared to the non-weight bearing limb.

Conclusion

In summary, it was possible to take radiographic measurements of 20 knee disarticulated and 20 trans-femoral amputated rabbits over a period of 8 weeks. The studies showed that the operated side of the femur on average is approximately 0.63cm shorter compared to the unoperated side for KD and this difference is statistically significant ($p<0.001$). The operated side is 3.58cm shorter compared to the unoperated side for TF amputation and is statistically significant ($p<0.05$). In addition, no complications were observed concerning bone development.

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Fungal colonisation in digital silicone rubber prostheses

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Abstract

The fungal discolouration of silicone rubber prostheses is reported in four cases. In two of the cases, the discolouration was caused by the fungus *Candida tropicalis*. In the other two cases, two different fungal organisms, namely *Trichoderma* sp. and *Scedosporium prolificans* were incriminated. The non-porous silicone rubber layers create an enclosed environment in the suction cup of the prosthesis and preclude ventilation at the prosthesis-stump interface. The moisture as a result of sweat and body warmth in the stump assists fungal growth. Residual salts from the sweat, sebum from sebaceous glands and the residues from petroleum jelly (Vaseline™) applied to facilitate donning, can adhere to the surfaces of the prosthesis and provide the nutrients for fungal growth. Prolonged continuous usages of the prosthesis, the presence of sweaty palms in the users, donning the prosthesis during manual physical activities which induce perspiration, washing of hands with the prosthesis on and warm humid climatic conditions have been identified as factors predisposing the prosthesis to fungal colonisation. The fungal growth caused a black discolouration and marred the aesthetic quality of the prostheses. As a preventative measure, daily immersion of the prostheses in denture cleaner such as benzalkonium chloride, or water at 60°C for 15 minutes, or decontamination with 70% alcohol is recommended. Prior cleaning to remove organic matter before decontamination is emphasised.

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Introduction

Silicone elastomers are widely used in the manufacture of maxillofacial and finger prostheses. One of the problems identified with the use of this material is a black discolouration caused by fungal growth (Masella *et al.*, 1975; Makila and Hopsu-Havu, 1976; Pigno *et al.*, 1994). In nasal prostheses, this has been attributed to the continual exposure to moist air and secretions that constantly pass through the nasal aperture. Although silicone digital prostheses have been prescribed to patients for over a decade (Pillet, 1983; Beasley, 1987; Alison and McKinnon, 1992; Campbell *et al.*, 1992; Leow *et al.*, 1996; Pereira *et al.*, 1996; O'Farrell *et al.*, 1996) there have been no reported incidences of fungal colonisation. However, the conditions associated with the use of the finger prostheses can make them susceptible to fungal growth.

The authors report four cases of black discolouration in finger prostheses for which a fungal cause was found.

Materials and methods

The authors have developed a custom-made digital prosthesis using a silicone elastomer (Leow *et al.*, 1996; Pereira *et al.*, 1996). The prostheses are made from a medical grade of silicone elastomer (Cosmedica Ltd, Newport, UK). Colour pigments (Cosmedica Ltd, Newport, UK) are intrinsically mixed with the silicone to match the basic colour of the patient's skin. No anti-fungal agents are

incorporated. The prostheses are moulded with layers of the silicone rubber tinted to differing shades of colour. the outer layers of the prostheses which correspond with the epidermis and superficial dermis are rendered translucent while the inner layers which correspond to the inner dermis and subcutaneous tissues are rendered opaque. This is to mimic the stratified anatomy of the skin and achieve a life-like appearance. A layer of touch-up colouration is "sandwiched" between the layers of silicone rubber at the finger joints and nail to enhance the details and colouration at these areas. The hollow part of the prosthesis which corresponds with the deficit in the segment is packed with a filler material comprising a mixture of silicone elastomer and polystyrene beads. The contact surface of the silicone polystyrene core which sits snugly on the distal stump is sealed with a layer of silicone rubber to prevent moisture from entering.

In a follow-up review of 34 cases fitted with the prostheses for over two years or more, four cases of black discolouration in the prostheses caused by fungal growth were encountered (Figs. 1 and 2). The discolouration was rough in texture (Fig. 1) and found to be extremely resistant to cleaning with 70% alcohol. Besides the black discolouration, the problems of wear and tear and a yellowing discolouration caused by exposure to sunlight was also noted.

Laboratory investigations and microscopy: Scrapings were taken from the areas affected by the black discolouration for bacteriological and myocological investigations. Transverse sections were made through the areas affected with the black discolouration for examination under the light microscope using the x10 and x40 objective lenses. Each section was examined from end to end, with particular attention to the distribution of the black discolouration.

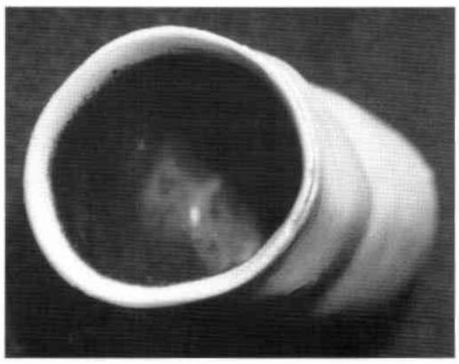

Fig 1. An affected prosthesis showing a black discolouration caused by fungal growth on the internal surfaces.

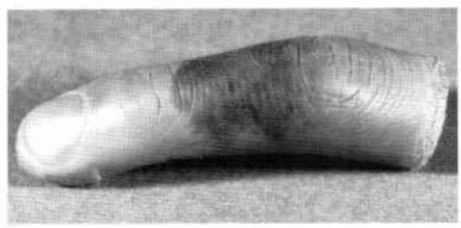

Fig 2. Another prosthesis in which the black discolouration had invaded the translucent outer layers, causing an unsightly blemish.

Results

Laboratory investigations revealed fungal growth to be responsible for the black discolouration. Brightfield microscopy showed a distinct layer of mycelial growth in the sections taken through the areas affected with the discolouration.

Laboratory investigations and microscopy: Various strains of bacteria were identified in the scrapings from the affected areas of the prostheses. These included *Straphylococcus, Micrococcus, Corynebacterium* spp., and *Flavobacterium meningosepticum.* Three fungal species were isolated from all the affected prostheses, namely *Candida tropicalis*, from two of the cases, and *Trichoderma* sp. and *Scedosporium prolificans* each from the other two cases. Investigations also reveal an invasion of the inner layers of the prostheses by fungal growth. Fungal hyphae were seen forming a distinct layer in the silicone material (Fig. 3).

The fungal discolouration was seen as black spots and patches on the inner surfaces of the prosthesis in contact with the stump, including the sealed surfaces of the silicone-polystyrene core. In all four cases, the patients reported it to have occurred between 10-18 months post-fitting. This progressed to cover a wider area and penetrated deeper into the material over a 3-4 week period with continued use (between 8-10 hours per day). As the outer layers of the prosthesis are translucent, the black discolouration became visible when the fungus penetrated through the opaque inner layers and

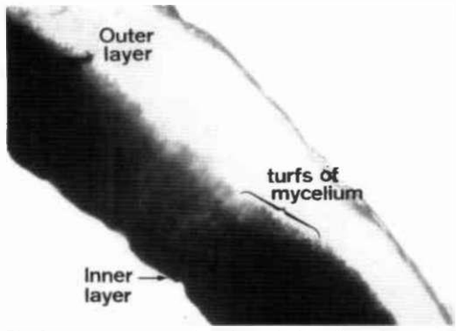

Fig 3. A transverse section through the affected areas of the prosthesis (shown in Fig. 2) as seen under Brightfield microscopy (magnification 10 x 40).

invaded the outer-inner layer interface. In one case, the black discolouration had spread to the outer layers of the prosthesis causing an unsightly blemish (Fig. 2). Brightfield microscopic observation revealed turfs of fungal hyphae (mycelia) invading the outer layers of the prosthesis (Fig. 3). The discolouration marred the aesthetic quality of the prosthesis.

The stump covered by the prosthesis was moist upon removal of the prosthesis. All patients indicated perspiration in their stump as one of the problems they encountered with the daily use of their prosthesis. No physical signs of fungal growth were observed on the stump in any of the affected cases. There were no allergic reactions in the stump in any of the four cases. However, two patients experienced discomfort due to the surface roughness (Fig. 1) created by the fungal colonisation within the suction cup.

Discussion

Various commensals are present in the skin. The types of micro-organisms and their distribution are transient and vary from time to time. Their multiplication is contained under normal use of the hand. However, if there is an increase in the level of moisture and warmth with availability of nutritional support, some fungal species may thrive. In the silicone soft lining (Silastic 390) of dentures, two fungus strains, *Candida albicans* and *Candida tropicalis* were reported to be responsible for the black discolouration often encountered with their use (Masella *et al.*, 1975). In this study, *Candida tropicalis* and two other fungal species, namely, *Trichoderma* sp. and *Scedosporium prolificans* were incriminated in the silicone rubber prostheses affected with a similar discolouration. The non-porous property of silicone rubber added to the conditions associated with the use of the prostheses provided the conditions of moisture, warmth and nutritional support for fungal growth.

Entrapped perspiration in the suction cup prosthesis: A secure prosthetic fit created an airtight seal between the non-porous prosthesis and the stump. Doffing of the prosthesis is achieved by creating an inlet for the entry of air to diffuse the vacuum effect. This same requirement for a suction cup prosthetic fit has the disadvantage of precluding cutaneous ventilation. It not only precipitates perspiration but traps the sweat on the stump when the prosthesis is donned for extended hours. The problem can be compounded by a humid tropical climate. The moisture from perspiration and body warmth of the stump provide an ideal milieu for sustaining fungal growth. An observation noted in these cases was the presence of a sweaty palm. This is a contributing factor in promoting the conditions for fungal growth.

Besides moisture and warmth, additional nutritional support is needed to sustain fungal growth. These nutrients can possibly come both extrinsically and intrinsically from the inside surface of the prosthesis. The authors have noted in this study that patches of residues composed of traces of petroleum jelly (Vaseline™) applied to facilitate donning, residual salts from sweat and sebum from the sebaceous secretions adhered to the inside surface of the prosthesis. This provided the initial extrinsic nutritional requirements for fungal growth to start with. It is also possible that the vaseline and sebaceous secretion are absorbed into the silicone material. This may provide the intrinsic source of nutrients which encouraged the fungus to penetrate into the silicone elastomer.

Of relevance was the patients' care of the prostheses. Instructions on the care of the prosthesis as advised to the patients included cleaning the inner surfaces of the prosthesis daily using a cotton-bud soaked with a mild soapy solution. As moisture encourages bacterial and fungal growth, the importance of keeping the surfaces of the prosthesis dry was emphasised. A more thorough maintenance regime thus becomes necessary when prescribing a silicone rubber prosthesis to

prevent fungal growth. Masella and coworkers (1975) showed that daily immersion of the dental prostheses in benzalkonium chloride (Zephiran, Winthrop Laboratories, New York), or water at 60°C for 15 minutes was found to be an effective measure to prevent the growth of the *Candida albicans* and *Candida tropicalis* in silicone lining on dentures. Since the black discolouration in the finger prostheses of the above patients was caused by fungal invasion, a similar preventive measure could be adopted. Cleaning the inner surfaces of the prosthesis is important to remove dirt and grease before immersing in a disinfectant, or before applying 70% alcohol for decontamination. Pigno *et al.*, (1994) also found that using an antifungal agent (Clotrimazole) incorporated into the silicone rubber elastomer was effective in inhibiting the growth of fungus *in vitro*. However, the clinical application and long term results were not investigated in this study.

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Technical note

A technique of acrylic nail fixation in multilayered silicone finger prostheses

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Abstract

A technique for the secure fixation of acrylic nails in multilayered silicone finger prostheses is described. The secure fixation of the nail to the prosthesis is achieved by a method of "sandwiching" portions of the nail between the silicone layers of the prosthesis akin to the overlapping of the nail by the anatomical nail fold and nail wall. In addition the use of a cynoacrylate adhesive ensures strong surface to surface bonding.

Introduction

The nail represents an important aesthetic feature of the hand. Its reproduction is thus an important aspect in producing a finger prosthesis for cosmetic restoration in the mutilated hand. Although silicone finger prostheses with acrylic nails are available commercially, technical information as to how the nail is securely attached to the prosthesis is not available in the literature. This is only to be expected since prosthetics for cosmetic restoration in the hand is more an enterprising endeavour than an academic exercise.

Attachment of acrylic nails on silicone prostheses is not a simple task. That silicone rubber has extremely good stain resistance is attributed to its highly inert property (Lynch, 1978; Polmanteer, 1987). This quality of silicone rubber also makes its bonding to most materials by the commonly used adhesives, a difficult challenge. Advances in material sciences have now made available new adhesives which can be used to bond acrylic to silicone surfaces. However, a secure fixation must involve more than mere surface-to-surface adhesion between acrylic resin and silicone rubber.

This paper describes a technique for a secure fixation of acrylic nails in multilayered silicone prostheses by a method of "sandwiching" portions of the nail between layers of the silicone rubber in addition to surface-to-surface adhesion between acrylic resin and silicone rubber.

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Method

Moulding, outer layer of the prosthesis

The outer layer of the prosthesis is moulded to the required thickness in translucent layers of tinted silicone rubber from a negative mould of a finger model (Leow *et al.*, 1996; Pereira *et al.*, 1996). Upon complete cure of the silicone layers, the partially completed prosthesis, with a "nail impression" replicated from the finger model, is removed from the negative mould and turned inside-out for touch-up colouration.

Nail fixation proper

After touch-up colouration at the "finger joints", the nail and the palmar aspect to match the pattern of pigmentation of the normal hand, the prosthesis is reverted to its original state and pulled over the finger model, which serves as a working base for the fixation procedure (Fig. 1a). A slit, into which a portion of the nail is to be inserted, is made along the crease of the "nail impression" of the prosthesis, excluding the distal edge (Fig. 1b). An acrylic nail of appropriate convexity is selected and trimmed to the shape of the "nail impression", in which

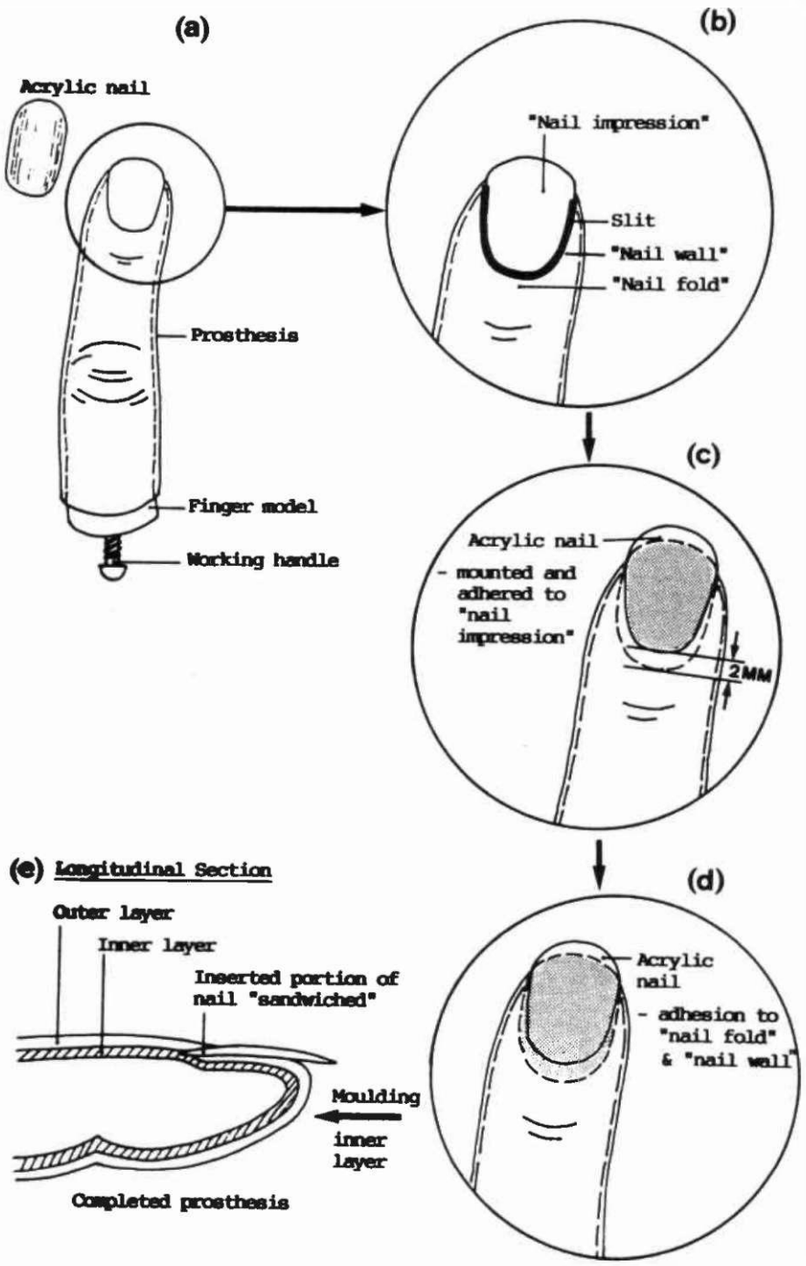

Fig. 1. Schematic illustrations of the acrylic nail fixation procedure in a multilayered silicone finger prosthesis (a) the partially completed prosthesis over the finger model, (b) a slit for nail insertion is made, separating the "nail impression" from the "nail fold" and "nail wall", (c) the acrylic is inserted, mounted and adhered to the "nail impression" (shaded area denotes adhesion) using the adhesive, (d) the acrylic nail adhered to the "nail fold" and "nail wall", (e) a logitudinal section of the completed prosthesis showing the inserted portion of the nail "sandwiched" between the silicone layers.

the acrylic nail is to be mounted and adhered. A trial mounting of the nail to establish its size and position for permanent fixation is first carried out before the actual fixation. The acrylic nail should be larger than the "nail impression" by 2mm proximally (edge-to-edge), reducing on the lateral borders to a matching size distally (Fig. 1c). The excess nail is that portion which inserts into the slit (hereafter referred to as the inserted portion of the nail).

After the size and position of the acrylic nail for permanent fixation has been established, the acrylic nail is unmounted and the "nail impression" surface is cleaned and treated with a polyolefin primer (Loctite 770, Loctite Corporation, Connecticut, USA). A cyanoacrylate adhesive (Loctite 401, Loctite Corporation, Connecticut, USA) is applied on the undersurface of the nail for bonding with the silicone surface. The "nail fold" and "nail wall" on the proximal and each collateral side of the slit is slightly lifted to allow insertion and mounting of the nail to the desired position following which it is pressed firmly against the finger model to achieve a stronger bonding to the "nail impression" (Fig. 1c). Following curing of the adhesive (45 seconds), adhesion of the inserted portion of the acrylic nail to the "nail fold", i.e., the overlying silicone layer, is effected using the same adhesive (Fig. 1d).

Moulding, inner layer of the prosthesis

Following completion of the nail fixation procedure, the prosthesis is withdrawn from the finger model for the final stage of moulding the inner layer. The inner layer of the prosthesis is moulded in opaque layers of silicone rubber pigmented such that when laminated into the outer layer, the resultant colour of the prosthesis matches the patient's skin colour. The inserted portion of the acrylic nail is thus "sandwiched" between the silicone layers and becomes securely fixed in the prosthesis (Fig. 1e).

Discussion

This technique allows a secure fixation of acrylic nails on silicone prostheses. Attempts at detaching the nail thus attached invariably resulted in the tearing of the silicone prosthesis without nail detachment. The secure attachment of the nail to the prosthesis is achieved in the technique through a method of "sandwiching" of the inserted portion of the nail between the silicone layers of the prosthesis in addition to a strong surface-to-surface bonding between acrylic resin and silicone rubber by the adhesive. The "sandwiching" method is akin to the overlapping of the nail by the anatomical nail fold and nail wall. The primer was used in conjunction with the adhesive to augment bonding of the acrylic nail to the silicone prosthesis. Further stability of the nail is obtained when the hollow prosthesis is packed with a firm filler material at the distal end for fitting. The packing, which substitutes the lost segment of the finger, reduces compression and shearing forces during the use of the prosthesis.

The achieve a life-like appearance, a custom-made highly translucent nail is used which allows the underlying pinkish touch-up colouration of the nail simulating the anatomical nail bed to show through.

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Scoliosis in Duchenne muscular dystrophy: aspects of orthotic treatment

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Abstract

The x-linked Duchenne muscular dystrophy (DMD) is the most frequent generalized muscle disorder arising from a lack of the sarcolemmic protein "dystrophin". Patients with DMD develop in the majority a progressive scoliosis when they cease walking and/or standing at the age of 10 years and become confined to a wheelchair. Increasing muscle weakness leads to a progression of the curvature, the pelvic tilt and problems in sitting. Together with the simultaneous progressive weakness of the respiratory muscles a restrictive pulmonary insufficiency will occur. Surgical stabilization of the spine (> 20° Cobb, forced vital capacity > 35%) by an adequate multisegmental instrumentation enabling early mobilization is now the treatment of choice.

However, orthotic treatment may offer an acceptable compromise in exceptional cases, if the patient rejects surgical intervention or is in the late (inoperable) stages of the disease. Such a treatment is superior to a primary sitting support provision with insufficient possibilities of correction.

The authors' experiences with 48 scoliosis orthoses made for 28 patients with DMD are reported. A "double plaster" cast has emerged as the best method to optimize adaption, especially in severe curvatures and the time taken for manufacturing the orthosis. A great deal of experience, patience and the consideration of the patients' individual demands are inevitable for a successful orthotic treatment.

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Introduction

Besides contractures and deformities of the lower limbs, scoliosis is the most important orthopaedic problem in treating patients with progressive generalized muscle disorders (Forst, 1988). The particular problem of scoliosis in muscle disorders results from the fact that lung function is restricted both by spinal curvature and muscular weakness, which also affects the respiratory muscles. In contrast to idiopathic scoliosis there is a significant decrease of vital capacity even in scoliosis with only small curvature.

Rideau (1987) could prove for example that 13-year-old patients suffering from DMD with a curvature of 23° Cobb have a forced vital capacity (FVC) of only 40%. In addition many authors (Rideau *et al.*, 1981; Jenkins, 1982; Kurz *et al.*, 1983; Rideau, 1987) showed that after an increase up to the age of 10-12 (beginning of the wheelchair stage) vital capacity in DMD develops a plateau stage. Direct conclusions concerning the type of progression (rapid/slow) of the disease can be drawn from the time of occurrence and the level of this plateau stage (Rideau, 1987). A further progressive decrease of vital capacity of an average 200ml per year follows by which the average life expectancy can be estimated (Rideau, 1987). The knowledge of this typical decrease of absolute and FVC is decisive for the correct indication of surgical stabilisation of the spine in advanced stages of DMD. The time when patients with DMD develop a scoliosis coincides with the time they lose their ability to walk and stand. Patients with DMD cease walking ability at an age of 9-12 years. Most scolioses in DMD will not occur before the beginning of the wheelchair stage. The

treatment of choice for scoliosis in DMD is nowadays the early surgical stabilization of the spine in the very beginning of the wheelchair stage, because the surgical risks arising from significant respiratory insufficiency and cardiomyopathy in later stages can be reduced. Optimal conditions are a proved progressive curvatures of more than 20° Cobb and a preserved FVC of at least 35%. The instrumentation (e.g. Luque, CD, Isola, etc.) extends from D2 down to L5 or S1 depending on the pelvic tilt and should enable an early mobilisation of the patient.

This study reports a wide experiences with patients with DMD who refused spinal stabilisation or could not be treated surgically because of their general condition in the late stages of the disease. The indications and limits of orthotic treatment as well as the particular technical features in the adaption and manufacturing of the authors' scoliosis orthoses are described.

Methods

Patients

A total of 224 patients with DMD (proved by lack of dystrophin) with an average age of 8.2 years at the first consultation in the authors' department were examined and treated comprehensively by various conservative and surgical orthopaedic procedures. Some 132 patients were still able to stand and walk independently, 92 were in the wheelchair stage. After their first examination patients were first of all regularly examined by a standardized method every six months or in case of rapid evolution every three months. If the first clinical signs of a scoliosis occur an anteroposterior and a lateral x-ray has to be taken of the total spine in sitting position. Close clinical controls have to follow three or four monthly in order to record a progression of the curvature.

At Cobb angles of more than 20° with a proved progression a "prophylactic" stabilization of the spine is recommended using the Isola system between D3 and L5 or S1 respectively depending on the extent of pelvic tilt. Patients who were inoperable or rejected an operation were treated with an orthoses (see below) and regularly examined every six months. The follow-up examinations included regular total-spine x-rays and pulmonary function tests.

Scoliosis orthosis

A thoraco-lumbo-sacral orthosis (TLSO) was made of low-pressure polyethylene and closed ventrally. Correcting pressure points have to use large pressure pads at the relevant points because of partly very thin subcutaneous adipose tissue. The extent of a possible correction is particularly determined by the rigidity of curvature, which is not great in early stages of DMD .

The plaster cast for the scoliosis orthosis is always made while sitting on a stool. After a good modelling of the pelvic contours it is important to seek the best correction of the scoliosis when fixing the plaster bandages in the trunk area. According to the rigidity of curvature manual pressure is exerted on the rib hump and is counteracted ventrally in accordance with derotation. The trunk is extended as well as possible and thus a "pre-correction" can be achieved.

There is no strict pattern for modelling the plaster positive but this has to take into account the individual patient (curvature, rigidity, etc.) An abdominal pad is not used so that ventilation is not restricted. In the abdominal area of the plaster model plaster is only slightly removed.

Fig. 1. Plaster positive modelled and corrected.

In severe lumbar scoliosis a cuneiform mass of plaster is removed so that there is enough space between the lower ribs and the iliac crest to avoid impingement. At the same time plaster is removed at the armpit and at the greater trochanter of the opposite convex side. Depending on the extent of thoracic curvature a rigid lock is not used above the sternum.

In the rare case where patients are still able to stand and walk a hyperlordosis of the lumbar spine in the orthosis has to be tolerated to balance the forward movement of the trunk, which is caused by a hip contracture so that plumb line and balance are not impaired.

It is most important that after having finished the "primary" plaster positive (Fig. 1), a pre-plaster orthosis (negative) is made (Fig. 2), cut to size and tried on the patient. A new plaster positive is produced incorporating any modifications required in the pre-plaster orthosis. Over this positive the polyethylene orthosis is made according to known techniques. The advantage of this method of "double-plaster cast" is the fact that the pre-orthosis, made of plaster, can be easily and quickly changed or even wholly renewed if this

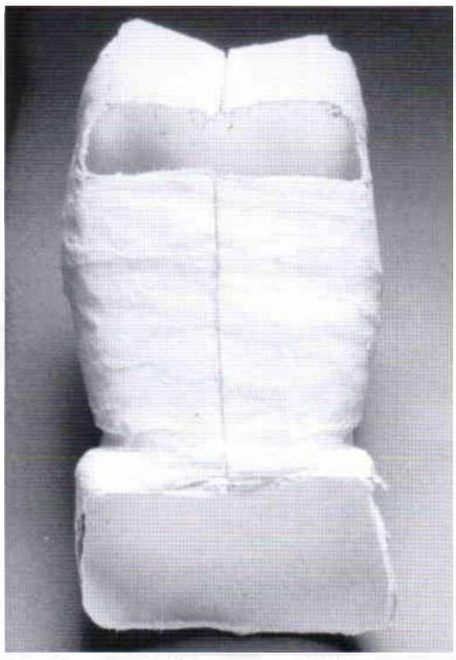

Fig. 2. Plaster orthosis pre-model (negative) to correct possible problems with fit and bruises.

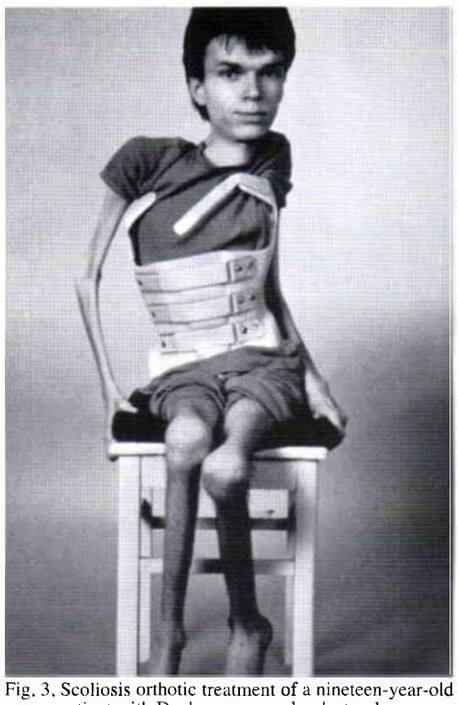

Fig. 3. Scoliosis orthotic treatment of a nineteen-year-old patient with Duchenne muscular dystrophy.

is necessary. So the treatment as an in-patient to try and produce the final orthosis can be considerably reduced, to about one week on average, even in complicated cases with severe scoliosis (Fig. 3).

The orthosis can be reshaped at those parts where it causes bruises and the places for necessary correction pressure pads marked. In a further step the orthosis is finished by fixing an elastic lock above the sternum, a leather abdominal tab, 3 straps as abdominal lock and pressure pads of soft foam rubber. For a better air circulation the polyethylene orthosis is perforated at parts that do not fit closely to the skin.

Patients suffering from DMD cannot evade correction pressure by their own muscular strength, but will sink in the orthosis after a while. For this reason the skin has to be checked every 30-60 minutes after the polyethylene orthosis has been manufactured. This is the only way to detect and thus avoid developing bruises. This part of the work will take a lot of time, and a great deal of practical experience is needed until the orthosis is finally finished

especially in patients at a late stage of their disease with severe curvatures.

Results

The age at first appearance of the scoliosis is listed in Table 1. Only those patients were included who were checked regularly before developing a scoliosis. The Cobb angles at the first detection respectively vary from 12° up to 117°. There are older patients with severe scoliosis at the first consultation. Some 81% of the patients were in the wheelchair stage when they developed scoliosis. The distribution of scoliosis to the respective parts of the spine is listed in Table 1. Regarding the main curvature 58% of the patients with muscular dystrophy showed a c-shaped thoracolumbar scoliosis with its convex side to the right. In addition to the scoliosis almost 100% had a more or less distinct pelvic tilt (0°-15°). The majority of these patients complained about pain when sitting in a wheelchair because of the one-sided load on one buttock. Some of them showed pressure sore formation and relapsing sciatic irritation. Many of the patients in advanced clinical stages had a severe restrictive pulmonary insufficiency and were in such a bad general condition of health, that the indicated

Table 1. Specific data of patients with scoliosis

No.	patient	age at detection of scoliosis		extension of scoliosis	Cobb angle	side	shape	reason for corset treatment	number of corsets	previous early lower limb surgery
		regularly checked	first examination							
1	D. J.		13	D9/L1/L4	109	R	C	reject	2	–
2	H. B.	13		D11/L1/L3	24	R	C	reject		–
3	K. M.		16	D9/D12/L3	88	R	C	reject	2	–
4	P. R.	12		D12/L3/L5	36	L	C	reject	3	+
5	S. A.		15	D6/D12/L5	93	L	C	FVC	3	–
6	S. H.		16	D10/L2/L5	86	R	C	FVC	3	–
7	S. G.	10		D11/L3/L5	59	R	C	reject	1	+
8	S. M.	11		D12/L2/L5	26	L	C	reject	1	+
9	S. F.		15	D11/L2/L4	72	L	C	reject	4	–
10	H. C.	14		D2/D6/L1 L2/L3/L5	28 36	L R	S	reject FVC	1	–
11	B. P.	12		D8/L1/L4	7(65)*	R	C	reject	1	–
12	J. T.	12		D12/L7/L5	34	L	C	reject	1	–
13	B. D.	15		D11/L2/L5	20	L	C	reject	1	–
14	D. D.		13	D9/L1/L5	44	R	C	reject	1	–
15	H. D		14	D8/L2/L5	68	R	C	FVC	3	–
16	M. M.		11	D7/D11/L4	38	R	C	reject	2	–
17	M. G.		21	D8/L1/L4	110	R	C	FVC	2	–
18	S. R.	10		D11/L3/L5	38	L	C	reject	3	–
19	S. I.		14	D9/L1/L4	60	R	C	reject	2	–
20	W. S		15	C5/D2/D9	32	L	C	reject	1	–
21	G. M.		15	D8/L1/L5	82	R	C	FVC	3	–
22	P. M.	12		D11/L3/L5	38	R	C	reject	1	–
23	R. M.		19	D8/D12/L5	103	L	C	FVC	1	–
24	R. C.	11		D5/D11/L3	58*	L	C	reject	1	–
25	H. F.	8		D12/L2/L5	18	R	C	reject	1	+
26	H. M.	13		D7/D12/L5	22	R	C	reject	1	+
27	K. T.		14	D8/D12/L5	52	L	C	reject	2	–
28	V. B.	15		D5/L1/L5	34	R	C	reject	1	+

*missed follow-up for 2 years

surgical treatment of the scoliosis was impossible, mainly because of pulmonary problems. A large majority wished to improve their sitting position by the orthotic treatment and to achieve a greater length of the trunk. Some 28 of 44 patients with scoliosis in DMD agreed to wear an orthosis either because they themselves or their parents rejected surgical intervention or because their vital capacity did not allow an operation. Sixteen patients agreed to a surgical stabilization of the spine.

Because of growth and/or changed possibilities of correction scoliosis orthoses have to be altered during treatment (Table 1). Almost all the patients accepted their orthosis after an appropriate fitting. There is no sense in classifying the Cobb angles before and after orthotic treatment because each patient wears individually manufactured orthoses and the grade of scoliosis and the age of the patients is too different.

In a great number of patients it was possible to obtain data of lung function before and after orthosis adaption. Because of the heterogeneous population (age, general condition of health, symptoms) the results of these data can only be summarized in general terms: in all cases there was no measurable reduction of vital capacity or increase of residual volume after orthosis adaption. However, only a very slight improvement of vital capacity (maximal 100ml) and just an insignificant decrease of residual volume (maximal 10%) could be achieved.

Discussion

Duchenne muscular dystrophy has a characteristic and uniform clinical course. In the first stage (up to the age of 9-10) patients are able to walk and lead a relatively normal life. At an average age of 9.35 years (Forst and Forst, 1995) they cease walking and later lose standing ability due to increasing muscle weakness and contractures of the lower limbs. The patients will be confined to a wheelchair. Almost 90% of the patients in the wheelchair stage develop a scoliosis (Wilkins *et al.*, 1976; Cambridge *et al.*, 1987; Galasko *et al.*, 1992) and 100% a marked respiratory insufficiency when they pass to the terminal stage. Even if the DMD cannot be cured it is possible to influence its clinical course by orthopaedic treatment. Operations on the lower limbs are performed when contractures begin to appear and a prolongation of walking and standing ability has been achieved later on with the aid of calipers (Forst and Forst, 1995). By keeping the orthotic assisted standing ability the formation of scoliosis, which is known to develop during the early wheelchair stage, can be delayed.

The orthopaedic treatment of DMD is a prophylaxis orientated comprehensive conception. From a therapist's point of view it is not the muscular weakness but the scoliosis which has to be seen as the most important problem. In contrast to idiopathic scoliosis, scoliosis in DMD is progressive even after the end of growth. As a consequence of the scoliosis and its resulting pelvic-tilt, patients complain about an impaired sitting position with loss of trunk stability and head control. Furthermore there is a deterioration of their angle of view and their cosmetic appearance. In particular they complain about the progressive impairment of pulmonary function.

A scoliosis treatment, especially the surgical treatment of scoliosis, aims at an increase of the quality of life by improving the sitting position and a changed respiratory condition improving nursing possibilities. In principle there are the following advantages of an early surgical treatment of scoliosis in DMD: there is less backache, less pain while sitting and no impingement of the ribs on the iliac crests. Both the cosmetic appearance and the sitting position are improved and, in addition, the handling of the wheelchair is facilitated. The prophylactic scoliosis operation, i.e. an early surgical treatment, offers an easier possibility of correction, an easier postoperative adaption, less respiratory complications as the patient has a better general condition of health at the time of operation and less blood loss. Many authors recommend the early surgical stabilisation of the spine (Jenkins *et al.*, 1982; Kurz *et al.*, 1983; Rideau *et al.*, 1987; Gibson *et al.*, 1987; Garfin *et al.*, 1988; Miller *et al.*, 1991; La Prade *et al.*, 1991; Shapiro *et al.*, 1992; Galasko *et al.*, 1992; Hopf *et al.*, 1994; Heller and Forst, 1996). A spinal stabilization in DMD is indicated at a Cobb angle of more than 20° and proved progression of the curve. An operation should be performed at a time when FVC is above 35% and with no cardiomyopathy to achieve a better postoperative performance.

Indications and limits of orthotic treatment vary. Vital capacity cannot be influenced by this

measure. A temporal improvement of pelvic-tilt, Cobb angle, comfort in sitting and of cosmetic appearance is however possible. A scoliosis orthotic treatment requires the provision of detailed information to the patients and their parents about a possible surgical treatment, which is definitely to be preferred. Both risks and limitations of orthotic treatment have to be mentioned. An orthosis should be adapted in case of a progressive scoliosis with a Cobb angle of more than 20° if both patients and parents reject a surgical intervention or if the general condition of health does not allow a surgical stabilisation of the spine.

The most important problem of orthotic treatment in DMD is the frequent formation of bruises for lack of soft tissue bolstering. Very often the orthosis has to be altered because of growth, loss or increase in weight and functional adaption. At the beginning of the treatment patients most often complain about pain at the buttocks and the iliac crest when sitting, problems in trunk control by a new regulation of the balance, problems in head control and their cosmetic appearance.

Many authors absolutely refuse orthotic treatment in muscle diseases, as they do not think there is an efficient improvement such as a positive influence on curvature or a decrease of progression. Up to now there have been only few reports on orthotic treatment of patients with muscle diseases in the international literature. These concentrate on DMD and spinal muscular atrophies (Morris *et al.,* 1961; Gibson and Wilkins, 1975; von Krüchten, 1980).

Gibson and Wilkins (1975) emphasize that in muscle diseases an orthosis can support a spine that is still rather straight much better than one that is already deformed. For this reason they recommend an early start of orthotic treatment at the beginning of the wheelchair stage before a formation of scoliosis. Gibson and Wilkins (1975) found out that a great number of patients with DMD show primary kyphosis and that only a few of them develop lumbar scoliosis. For them the "ideal" orthosis has to work most efficiently in the sitting position. In addition they demand the horizontal iliac crest and hyperextension of the spine. They use an orthosis which is closed dorsally, exactly modelled to the iliac crest and which stabilizes the pelvis as it goes down to the greater trochanter. The trunk is mainly supported at the sternum and the rib-hump. An extension of the spine is achieved by pressure pads in the area of thoracolumbar transition together with the front elements of the orthosis (3-point fixation of the spine). Spine and pelvis are supposed to build a functional unit so that changing positions of the spine cause corresponding changes of the pelvis. For the manufacturing of the orthosis a plaster cast is made in the sitting position under slight distraction with a cervical device. The iliac crest is strongly moulded with a long compress because it is the pelvic contour that mainly supports the chest in the finished orthosis. To avoid an impeding of diaphragm movements there has to be enough space in the abdominal area. The whole front part of the orthosis is left intact to exert continuous pressure on the abdominal area (liquid cylinder effect), which then effects the straightening and partly takes the load off the spine (Morris *et al.,* 1961).

Von Krüchten (1980) emphasized that the "ideal" orthosis for treating scoliosis in DMD has to avoid the development of the scoliosis. Furthermore it has to facilitate a comfortable sitting position, unrestricted respiratory function and aesthetic acceptability. The orthosis should not restrict daily life activities and must be easy to handle (dressing and undressing). The so-called "T-Orthosis", which was developed in Copenhagen, goes back to the Boston and Toronto Brace for idiopathic scoliosis (von Krüchten, 1980). It is mainly made of polypropylene and consists of a pelvic part which is inclined in the front plane and which is supposed to exert pressure on the lordotic lumbar spine. The proximal trunk parts are supported by modelling a double "T". The orthosis is closed dorsally by three straps. In this orthosis the deterioration of vital capacity is said to be far less than the reduction of respiratory function in untreated scoliosis.

Young *et al.* (1984) report about 9 patients with DMD, who did not show a scoliosis but had to use a wheelchair. They were treated with a modified metal Calot-supporting orthosis, moulded of medium dense polyethylene and an individually made "leather jacket". The orthosis fixed the lumbar area in the lordotic position that the patients were able to achieve in a short, active attempt to raise the pelvis without the orthosis when sitting. Both patients and

physicians in charge preferred the orthosis to the "leather jacket". The modified Calot-orthosis restricted lung function far less than the specially modelled "leather jacket".

Rideau *et al.* (1984) treated 10 patients with DMD by spinal orthosis or special seating in the wheelchair. In spite of these measures all their patients were unable to sit and showed severe scoliosis in the final stage of their disease. The authors concluded that in the progressive clinical situation the development of severe spinal deformation could not be avoided by a sole conservative treatment. For this reason they now recommend the prophylactic stabilisation of the spine in DMD right at the beginning of the wheelchair stage in order to avoid the appearance of advanced scoliosis.

The treatment of muscular diseases by sitting supports is also only rarely reported in the literature. In principle one can say that sitting supports should not be used in the primary treatment of scoliosis (Albrecht, 1983; Forst, 1988). Special seating can never work as a correction because of the three-dimensionality of the scoliosis. A treatment with a suitable seat may however be indicated as a palliative measure in untreated scoliosis with distinct spine and thorax deformation in very late stages (Robin, 1989).

Reports about a low acceptance of orthoses in muscle diseases (Bossingham *et al.*, 1977) have to be judged in connection with the construction features. A great number of orthoses aim to cause an extreme hyperlordosis in the lumbar region, which is difficult for the patient to tolerate in the authors' experience. For this reason the aim is a medium pelvic inclination which basically corresponds to the pelvis position in sitting.

After initial difficulties in fitting scoliosis orthoses to patients with muscle diseases the authors found that bruises at the iliac crest and of the skin could be almost completely avoided by using foam rubber as pressure pads and by supporting the pelvis at the trochanters. Patients, who even in the orthosis showed a trunk deviation because of scoliosis curvature, had to be additionally supported by lateral pressure pads in an appropriately adapted wheelchair (fixed seat, fixed back with head support). In these clinical pictures the efficiency of the orthotic treatment largely depends on the empathy of the treating team (physician, technician, physiotherapist) and on the patient's (parents') cooperation. Regular follow-up examinations every 3 to 6 months focus on an early detection and correction of changes due to growth or the underlying disease.

In most of the cases the patients felt restricted because of problems when sitting, but also because of cosmetic reasons (trunk length). Even in severe scoliosis they never complained about respiratory problems. For this reason a treatment has to be offered, that is "between" an operation and the "palliative" measure of sitting supports. Yet, patients or their parents still have to be informed that an orthosis is only a "temporary compromise", which is never as effective as an early surgical stabilisation of the spine.

Conclusion

Without doubt the early surgical treatment of scoliosis in patients with generalized muscle disorders is the most effective and thus most appropriate method, even if it has not been settled, which instrumentation gets the best results in this clinical picture with regard to stability, derotation and possible complications.

A primary treatment of children (even at the beginning of scoliosis) with sitting supports has to be rejected even in "anatomic adaption" as there is no effective approach because of the existing elements of deformation of the scoliosis (lateral deviation and rotation).

The decision in favour of a treatment with a scoliosis orthosis in muscle diseases must only be made after careful consideration. From the authors' point of view the scoliosis orthosis is only a temporary compromise with limited (but acceptable) efficiency, which should be reserved for patients who reject an operation or patients who are inoperable because of their general condition of health. If the patient has decided on an orthotic treatment the physician should always (depending on the patient's age and situation) point to the necessity or efficiency as well as the status of a surgical stabilisation of the spine. In this way it can be avoided that the surgical intervention is considered as "a last resort" after a (predictably) unsuccessful orthotic treatment with a then much worse starting position (pelvic-tilt, marked curvature, thoracic deformity).

The use of a scoliosis orthosis in muscle diseases requires wide experience and patience

on the part of both orthopaedic technician and physician to ensure the acceptance of the orthosis by the best possible wearing-comfort.

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The influence of the reciprocal hip joint link in the Advanced Reciprocating Gait Orthosis on standing performance in paraplegia

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Abstract

The effect of reciprocally linking the hip hinges of a hip-knee-ankle-foot orthosis on standing performance was studied in a comparative trial of the Advanced Reciprocating Gait Orthosis (ARGO) and an ARGO in which the Bowden cable was removed (A_GO). Six male subjects with spinal cord injury (SCI) at T4 to T12 level participated in the study, which was conducted using a single case experimental design. Standing balance, the ability to handle balance disturbances (standing stability), and the performance of a functional hand task during standing were assessed in both orthosis configurations in the order A_GO-ARGO-A_GO-ARGO.

No significant differences with respect to standing performance were found for the two orthosis configurations. However, the results indicate that the crutch force needed for maintaining balance during various tasks, especially for quiet standing with two crutches, may be much higher in the orthosis without Bowden cable. Therefore, it is very likely that the reciprocal hip joint link in the ARGO provides a substantial and clinically relevant reduction of upper body effort required for standing under functional conditions.

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Introduction

Standing is a very important activity in the daily life of persons with paraplegia. Numerous therapeutic benefits of standing upright have been discussed in the literature: muscle contracture prevention, reduction of spasticity, reduction of bone mineral loss, improvement of lower extremity blood supply, prevention of pressure sores, and improvement of bladder and bowel function (Kunkel *et al.*, 1993; Messenger *et al.*, 1989; Ogilvie *et al.*, 1993; Figoni, 1984). These preventive aspects above justify that standing is included in the rehabilitation programme for the spinal cord injured and that most paraplegics have some standing frame at home. Also, the psychological effect of being upright and able to communicate at eye level with healthy persons is very important (Nene *et al.*, 1996).

As an alternative to a standing frame, an orthosis, in thoracic spinal cord injury usually a hip-knee-ankle-foot orthosis (HKAFO), can be used. An orthosis adds to the above-mentioned therapeutic benefits the possibility of functional use in daily life activities (Douglas *et al.*, 1983; Motloch, 1992; Rose 1979; Winchester *et al.*, 1993). Besides, an orthosis offers the possibility of use outside the home environment.

It is clear that the functional characteristics of an orthosis are defined by its design. Traditionally, most attention in the design of orthoses has been directed to assistance in walking (Douglas *et al.*, 1983; Motloch, 1992; Rose, 1979; Stallard *et al.*, 1989; Stallard and

Major, 1993). As a result, the properties of an orthosis with respect to standing are a consequence rather than the objective of design choices. Since walking makes higher demands on the design of an orthosis than does standing, it is taken for granted that in well-designed walking orthoses the performance with respect to standing is of equal quality. However, functional standing, i.e. standing for the purpose of performing a (bi)manual task, imposes additional and possibly conflicting demands upon the design of an orthosis, especially with respect to stability and flexibility.

One of the important aspects related to orthosis design is energy consumption during gait (Stallard *et al.,* 1989; Nene *et al.,* 1996). Various principles and mechanisms have been described that contribute to a reduction of energy expenditure.

The alignment in the frontal plane was reported to have an impact on the lateral stability of an orthosis, and consequently on the effort required to balance the body (Rose, 1979). A similar effect was found in studies on lateral stiffness of orthoses (Stallard and Major, 1993; 1995).

An essential difference in the properties of currently prescribed HKAFOs arises from the application of a reciprocal coupling of the hip joints.

The LSU-Reciprocating Gait Orthosis (RGO) (Douglas *et al.,* 1983) and the Advanced Reciprocating Gait Orthosis (ARGO) (Hugh Steeper Ltd., London, UK) (Jefferson and Whittle, 1990) incorporate hip hinges which are reciprocally coupled via one (ARGO) or two (RGO) Bowden cables. Recently, the Isocentric® RGO was designed which incorporates a reciprocal coupling via a lever with ball bearing (Motloch, 1992; Winchester *et al.*, 1993). Though designed in the first place to provide energy transfer from the stance leg to the swing leg and vice versa during gait, a reciprocal coupling has great influence on standing as well. Since bilateral flexion or extension of the hips is made impossible, a stabilising effect results that forces the patient into an upright position, but may hinder the patient in reaching.

The Hip Guidance Orthosis or Parawalker (Rose, 1979) is mounted with free hip hinges with limited flexion and extension ranges. During gait, this hip mechanism allows the utilisation of gravity for the execution of the swing phase (Nene and Major, 1987). The other side of this favourable property with respect to energy consumption is the absence of mechanical stabilisation of the hips and trunk. Also during standing, the patient is free to flex and extend the upper body, which permits a free choice of posture, but may induce the need for substantial effort for maintaining balance. In practice two postures are applied in the Parawalker, namely the so called C-posture with extended hips, and a posture where the trunk is flexed and stopped by the hip flexion limits.

From the above it may be expected that reciprocal coupling of hip joints in an orthosis has both favourable and adverse effects on energy consumption during gait, in addition to an important effect on the functionality of standing, that is, on the applicability of standing in daily activities. In order to obtain directives for orthosis design, the authors studied these effects on both gait and standing performance. A direct comparative trial of, for example, the RGO, ARGO and Parawalker was not expected to be suitable for studying these effects, since differences between these orthoses other than the reciprocal hip joint linkage are likely to influence the results. In order to study the influence of the reciprocal hip joint link in isolation from other orthosis properties, the performance of the ARGO was compared with that of an ARGO of which the Bowden cable was removed. The results with respect to performance of gait have been reported separately (IJzerman *et al.,* 1997). This paper focuses on the effect on standing performance.

Assessment of standing performance

In literature, standing performance has been associated with three different aspects. Standing balance, most often in relation to postural control, is commonly studied by means of ground reaction force measurements during varying support and visual or cognitive task conditions (Cybulski and Jaeger, 1986; Geurts *et al.,* 1993; Goldie *et al.,* 1989; Mayagoitia and Andrews, 1989; Slobounov and Newell, 1994). From such measurements, centre of pressure diagrams can be obtained which are mostly parameterised by the excursion or amplitude, the velocity and the frequency; elaboration both in terms of circular parameters or separated

anteroposterior and mediolateral parameters have been reported. It is assumed that amplitude parameters relate reciprocally to the effectiveness of balance. Velocity parameters are commonly associated with regulatory mechanisms (Mayagoitia and Andrews, 1989). Crutch support forces are incorporated in none of the reported analyses related to paraplegic standing.

The ability to maintain balance in the presence of disturbances, or standing stability, is an aspect particularly of interest in paraplegic standing, where many of the control mechanisms used in able-bodied standing are absent. The application of closed loop functional neuromuscular stimulation (FNS) control of the knee in paraplegia was reported to support voluntary response mechanisms of the upper body (Moynahan and Chizeck, 1993). The effort necessary to maintain an upright posture after unanticipated knee flexion disturbances was assessed by measurement of vertical arm force applied to a walking frame. The effect of the disturbance was measured by the time necessary to recover to a stable posture. The possibility of performing hand tasks during standing, or standing *functionality*, is a third and very important aspect of standing performance. The assessment of the ability to free the upper limbs from support and balancing tasks in order to manipulate objects was the subject of the development of the Functional Standing Test (Triolo *et al.*, 1993). In this test 18 tasks requiring fine coordination, pushing, pulling, reaching horizontally, vertically and diagonally were included in order to allow evaluation of the effectiveness of different assistive devices for people with standing disabilities.

In the present study, an assembly of tests previously applied in comparable or related studies was made to allow comparison of functional standing performance in the ARGO with and without reciprocal hip joint link.

Methods

Subjects

Six complete thoracic spinal cord injured subjects participated in the study (Table 1). All had finished their rehabilitation programme and were well-trained and experienced ARGO users.

Informed consent was obtained from each subject prior to each measurement session. The study was approved by the local medical ethics committee.

Study design

The study was conducted using a single case experimental design. Subjects were assessed four times: two assessments of the ARGO were performed, and two of the ARGO with removed Bowden cable (hereafter referred to as A_GO) in the order A_GO - ARGO - A_GO - ARGO. A two weeks training period preceded each assessment in order to allow the subjects to get used to standing and walking in the orthosis configuration concerned.

Period effects, i.e. training and test effects, were avoided by applying a 4 weeks guided stance and gait training in the A_GO prior to the assessment phase of the study. All subjects had been previously involved in comparable studies and were well acquainted with testing equipment and procedures.

Training

At the start of the 4 weeks training programme, the Bowden cable was removed from the subject's ARGO. Flexion and extension stops were mounted to the hip hinges in the A_GO configuration and adjusted in

Table 1. Relevant subject information.

Subject	Sex	Age	Time post injury [years]	Lesion level	Weight [kg]
1	M	29	7	T4	79
2	M	40	21	T9	67
3	M	28	3	T4	73
4	M	34	5	T12	66
5	M	45	5	T9	90
6	M	57	5	T9	80

order to provide satisfactory hip angle ranges and step lengths. The training was directed at improving standing balance, obtaining unassisted, regular gait for at least 15 minutes without interruption, and improving physical aerobic capacity. If any objective had not been attained within the four weeks, the training period was prolonged.

Measurements

On each assessment day, a series of measurements was carried out in identical order and at the same time of day. Six measurements, each lasting approximately 1½ minutes including a subject installation procedure, were done for assessment of standing performance:

- 3 measurements comprising the Quiet Standing Test (dual crutch support) followed by the Balance Disturbance Test.
- 3 measurements comprising the Quiet Standing Test (single crutch support) followed by the Hand Function Test.

During the installation, subjects were positioned on a force plate (OR6-5 series, Advanced Mechanical Technology Inc., Newton, USA). The heels were aligned against a reference frame and the feet placed symmetrically with respect to the plate's centre line (Fig. 1). The lateral foot position was set using a centrally placed wedge and kept constant over all all assessments. The reference frame and the wedge were removed after the feet had been positioned.

Crutches instrumented with miniature load cells (LM-100KA, Kyowa Electronic Instruments Ltd., Tokyo, Japan) were used to measure axial crutch forces. Prior to the first assessment of each of the two orthosis configurations, the subject was asked to place the crutches in a comfortable position for prolonged standing. The crutch bottom end position was recorded and marked by a reference plate, and held identical during successive assessments of the same configuration. Different crutch positions for single and dual support were allowed. For single crutch supported standing, subjects were asked to use their non-dominant hand for support.

During all tests, the ground reaction force of the platform and axial crutch loads were sampled by a PC data acquisition setup at 50 Hz. The orientation of the crutches was identified by placing two retroreflective markers near the handle and the bottom end respectively, and measured using a 50 Hz, five camera 3-D movement analysis system (Vicon, Oxford Metrics Ltd., Oxford, UK). The crutch orientation recordings were used to calculate the normal components of the crutch ground reaction forces. All recordings were filtered off-line using a digital linear phase 2nd order Butterworth filter with cut-off frequency at 5 Hz. From the force data the centre of pressure (COP), i.e. the projection of the centre of gravity in the support plane, was calculated by weighted summation of the points of application of the normal ground reaction force components of feet and crutches.

Quiet Standing Test

This test was incorporated to assess stability during quiet standing in either orthosis with use of one or two crutches. Before the start of the 30 seconds test, the subjects were instructed to stand as still as possible and keep their eyes focused on one remote point.

The standing performance was expressed in terms of the range of the COP signal, both in mediolateral and anteroposterior directions. The support area, i.e. the area of the plane stretched by feet and crutches, was calculated from the position of the crutches and the estimated position of the feet (Fig. 1). Crutch axial forces were averaged over the test period to quantify the arm load necessary for maintaining balance.

Balance Disturbance Test

This test was performed during standing with double crutch support only. After the 30 seconds of the Quiet Standing Test had elapsed, three to four anteriorly or posteriorly directed force impulses were applied to the back tube of the subject's orthosis without warning in order to disturb standing balance. The impulses were applied in quasi-random order with 5-10 second intervals, and were generated by a nearly friction-free pneumatic cylinder with electronically operated valves in order to obtain highest possible reproduction. The levels and durations of the force impulses were set separately for anterior and posterior directions prior to the measurements, such that substantial but safe balance disturbances were obtained. Impulse settings were kept constant during all tests, for both ARGO and A_GO. The onset of

the force impluse was measured from the electronic valve actuator.

The effect of the balance disturbance was quantified by the anteroposterior and mediolateral COP ranges. The test performance was quantified by the time, T_{REC}, necessary for the subject to recover from the balance disturbance. T_{REC} for each disturbance was determined jointly by two observers during off-line visual inspection by setting markers in the combined anteroposterior position and velocity graphs of the COP. The criterion used for determining T_{REC} was that the position signal had stabilised at a value close to the value just prior to the onset of the disturbance, which could be accurately decided by simultaneous inspection of the velocity signal (Fig. 2). Visual inspection was preferred to automated calculation because the characteristics of the balance disturbance could not be determined in such a manner, that objective and subjective determinations of T_{REC} showed sufficient agreement.

Hand Function Test

This test was performed only during single crutch supported standing. Following the principles of the Jebsen Test of Hand Function, it consisted of reaching movements of the hand across the body median, while handling a heavy object (Jebsen *et al.,* 1969; Triolo *et al.,* 1993). The subject was standing in front of a table (width 80cm, depth 60cm), which was positioned at preferred workbench height and close to the body. Five cylindrical weights (1kg; height 15cm, diameter 5cm) were positioned approximately 15cm apart from left to right on the table's front end on 5 differently coloured foam circles. At the back end, identical foam circles were attached in reverse order. The subjects were instructed to move the weights–left to right–to the corresponding circle on the back end as quickly as possible, and back again from right to left. In this way, anteroposterior movements and mediolateral movements passing across the body median were combined in one test.

Prior to the series of three measurements of single crutch supported standing, the test was performed repeatedly in order to allow the subject to get used to the test. Also, for reference, the Hand Function Test was carried out three to four times by the subject while sitting in the wheelchair.

Test result was the time, necessary to complete the 10 displacements (T_{HFT}). Crutch axial force was analysed in order to obtain insight into the average and peak effort required to maintain balance during the test.

Data analysis

For each subject, all results obtained from two repeated measurements of either orthosis configuration were averaged in order to compensate for possible test effects. Variables were presented graphically in order to inspect whether their distributions deviated from a normal distribution. Differences in test results of ARGO and A_GO measurements were statistically tested by means of paired samples t-tests. For all tests, a p-value of 0.05 was considered significant. The results of the tests were expressed also in terms of 95% confidence intervals for the difference, in order to obtain better insight into the relevance of the results. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS).

Results

General

The results of the first and second ARGO assessments were compared for all subjects in order to check for test effects. Paired samples t-tests showed significant differences in one parameter of the Balance Disturbance Test (Centre of Pressure Anteroprosterior Range for anterior disturbance; $p < 0.03$) and in the reference time score for the Hand Function Test (T_{HFT} Sitting; $p = 0.02$). These differences imply that during the study, despite the measures taken in the design, some training effects were still present. The effects were reduced by averaging the results of the first and second assessment for both ARGO and A_GO.

None of the standing performance indicators showed substantial deviation from a normal distribution. Therefore, paired samples t-tests were performed on the data without prior transformations.

Further analysis of data was performed *post hoc* in order to study underlying mechanisms.

Quiet Standing Test

In the A_GO, 4 subjects preferred a standing posture in which the trunk was flexed and stabilized by the flexion stops in the hip joints.

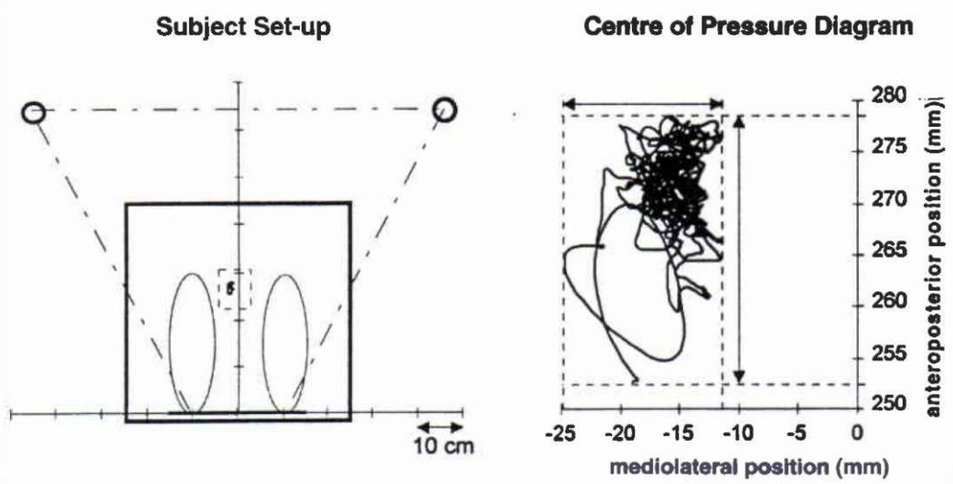

Fig. 1. Subject set-up and typical result of the Quiet Standing Test performed using two crutches. The left graph shows the position of the subject's feet (oval shapes) on the force platform (solid rectangle) and the position of the crutches (circles). The boundaries of the support area are indicated by the dash-dotted line. The small dashed rectangle near the centre of the force platform indicates the centre of pressure (COP) signal, which is presented in detail in the right graph. The right graph shows a typical 30 s recording of the mediolateral and anteroposterior position of the COP during a Quiet Standing Test with dual crutch support, taken from subject 4. Mediolateral and anteroposterior excursions are indicated by the horizontal and vertical arrows respectively.

The 2 other subjects, both having high lesion levels, preferred a C-posture with the hips extended towards the anatomical limit (Andrews *et al.*, 1989).

A typical recording of the COP during the 30s test is shown in Figure 1. The COP was located well within the base of support bound by feet and crutches, and was typically located within the support area of the feet.

Standing balance in the ARGO and the A_GO were not significantly different, as can be seen from the mediolateral and anteroposterior ranges of the COP signal of both orthoses (Tables 2 and 3). The support areas selected by the subjects did not differ significantly between orthoses.

Tables 2 and 3 show that the crutch force required for quiet standing in the A_GO

Table 2. Summarised results of the Quiet Standing Test performed with dual crutch support. Presented data are mean values and standard deviations (between brackets). The 95% confidence interval data are presented in absolute values and in values relative to the mean values of the ARGO measurements.

Quiet Standing Test			Paired samples t-test		
A. Dual crutch support	A_GO	ARGO	A_GO-ARGO	p-value	95% C.I.
COP anteroposterior range [mm]	37.94	35.22	2.72	0.74	[-16.91, 22.36]
	(8.12)	(17.38)	(18.70)		*[-48%, +63%]*
COP mediolateral range [mm]	34.53	41.72	-7.19	0.41	[-27.60, 13.21]
	(17.68)	(31.35)	(19.43)		*[-66%, +32%]*
Support area [m²]	0.34	0.34	0.00	0.94	[-0.05, 0.06]
	(0.10)	(0.11)	(0.05)		*[-16%, +17%]*
Crutch axial reaction force [N]	53.94	39.59	14.35	0.06	[-0.48, 29.18]
(averaged left and right)	(11.99)	(17.33)	(14.13)		*[-1%, +74%]*

Table 3. Summarised results of the Quiet Standing Test performed with single crutch support. Presented data are mean values and standard deviations (between brackets). The 95% confidence interval data are presented in absolute values and in values relative to the mean values of the ARGO measurements.

Quiet Standing Test			Pared samples t-test		
B. Single crutch support	A_GO	ARGO	A_GO-ARGO	p-value	95% C.I.
COP anteroposterior range [mm]	30.92	34.83	-3.91	0.64	[-24.06, 16.23]
	(7.20)	(13.58)	(19.19)		*[-69%, +47%]*
COP mediolateral range [mm]	38.04	45.92	-7.88	0.55	[-39.06, 23.31]
	(13.98)	(39.46)	(29.71)		*[-85%, +51%]*
Support area [m²]	0.09	0.08	0.01	0.32	[-0.01, 0.02]
	(0.01)	(0.02)	(0.01)		*[-9%, +24%]*
Crutch axial reaction force [N]	59.30	43.26	16.04	0.32	[-21.27, 53.35]
	(27.15)	(23.30)	(35.54)		*[-49%, +123%]*

orthosis was substantially higher than for the ARGO. Especially for double crutch support, the 95% confidence interval for the difference A_GO-ARGO, relative to ARGO, indicates that this difference can be clinically relevant (relative 95% C.I. [-1%, +74%], $p < 0.06$).

When comparing the results for single and dual crutch support, a remarkable finding was that the (averaged) force per crutch required for maintaining balance was not significantly different for quiet standing with 2 crutches and standing with 1 crutch in either orthosis configuration. For the A_GO, the mean difference was 5.35N, i.e. the force applied to the single crutch was approximately 10% higher than the averaged force for dual crutch supported standing (the relative 95% C.I. was [-35%, +55%]; $p = 0.59$). For the ARGO, the mean difference was 3.67 N, or approximately 9% (relative 95% C.I.: [-38%, +57%]; $p = 0.64$).

For the A_GO, the COP anteroposterior range for standing with 2 crutches was not significantly higher than for standing with 1 crutch (relative 95% C.I. [-19%, +56%]; $p = 0.26$). The mediolateral range for dual crutch support was not significantly smaller: relative 95% confidence interval was [-65%, +44%] ($p = 0.65$). For the ARGO, the relative 95% confidence intervals for these differences were [-41%, +43%] ($p = 0.95$), and [-88%, +67%] ($p = 0.75$), respectively.

The support area was obviously much smaller (approximately 4 times) in the single crutch supported situation than in the dual crutch supported situation ($p = 0.001$ for both A_GO and ARGO).

Balance Disturbance Test

Figure 2 shows a typical recording of the anteroposterior aspect of the COP movement during an anterior balance disturbance (push). The first seconds of the recording clearly show the anterior shift of the COP position resulting from the force impulse applied. In the second part (time > T_{REC}) the position signal has returned closely to the pre-impulse value.

Typical force impulse for anterior disturbance was 325 N during 0.2 s (ranges: 300 to 400 N; 0.1 or 0.2 s), for posterior disturbance 300 N during 0.2 s (ranges: 250 to 375 N; 0.1 or 0.2 s). Tables 4 and 5 show that during the disturbance, the anteroposterior movement was typically 3 to 4 times as much as that during the Quiet Standing Test, while the mediolateral excursion of the COP was comparable to the quiet standing situation. These findings indicate that the disturbances were applied effectively in the anteroposterior direction.

There were no significant differences found in the recovery times of ARGO and A_GO for either anterior or posterior disturbances. Recovery times tended to be slightly lower for anterior disturbances than for posterior disturbances in both orthoses, but differences were not significant (95% C.I., relative to the anterior impulse recovery time, was [-90%, +42%], $p = 0.40$, for A_GO; relative 95% C.I. [-75%, +13%]. $p = 0.13$, for ARGO).

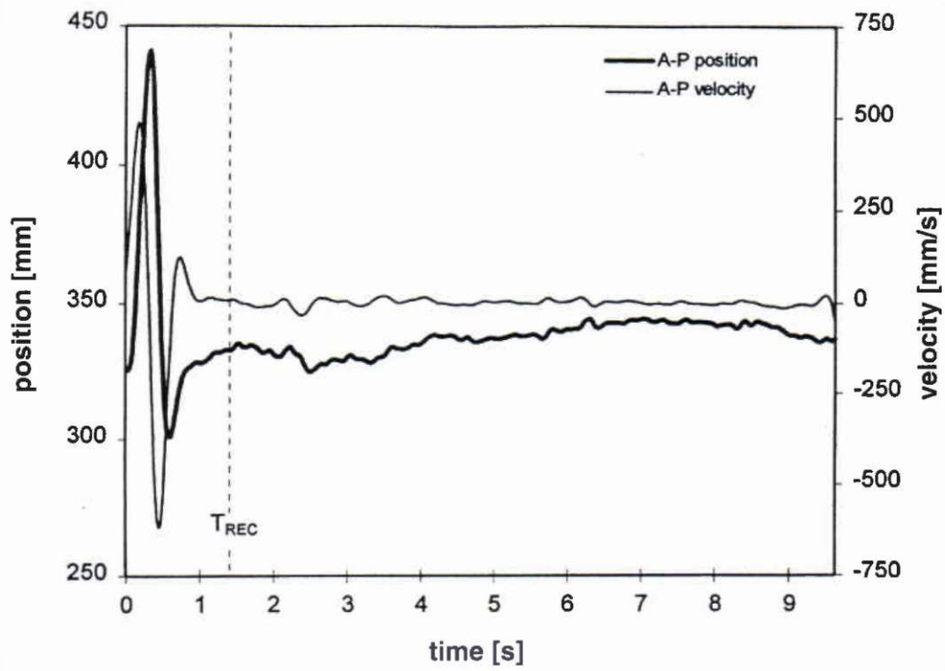

Fig. 2. Part of a centre of pressure (COP) recording measured during a Balance Disturbance Test from subject 4. The recording shown concerns an anterior disturbance with force level of 375 N and duration of 0.2 s, applied at time t=0. The bold solid line represents the anteroposterior position of the COP, the anteroposterior COP velocity is represented by the light solid line. The vertical dashed line indicates the recovery time T_{REC}, obtained from visual inspection of the COP anteroposterior amplitude and velocity signals (see text for details). For this particular case, T_{REC} was determined at 1.42 s.

Hand Function Test

Time scores were found to be higher for the standing situation than during sitting for both orthoses (Table 6). Paired samples t-tests showed that these differences were significant (A_GO: 95% confidence interval for the difference relative to T_{HFT} for sitting was [+1%, + 28%], p = 0.04; ARGO: p = 0.03, 95% confidence interval for the relative difference [+2%, +20%]).

The performance on the Hand Function Test, as indicated by T_{HFT} for stance, was not significantly different between A_GO and ARGO.

Table 4. Summarised results of the Balance Disturbance Test for anterior disturbances (push). Presented data are mean values and standard deviations (between brackets). The 95% confidence interval data are presented in absolute values and in values relative to the mean values of the ARGO measurements.

Balance Disturbance Test			Paired samples t-test		
A. Anterior disturbance (push)	A_GO	ARGO	A_GO-ARGO	p-value	95% C.I.
T_{REC} [s]	2.51	2.75	-0.23	0.55	[-1.15, 0.69]
	(1.12)	(0.89)	(0.88)		*[-42%, +25%]*
COP anteroposterior range [mm]	127.31	114.58	12.73	0.50	[-32.03, 57.49]
	(58.63)	(37.01)	(42.64)		*[-28%, +50%]*
COP mediolateral range [mm]	39.44	40.99	-1.56	0.76	[-13.46, 10.35]
	(24.30)	(17.41)	(11.34)		*[-33%, +25%]*

Table 5. Summarised results of the Balance Disturbance Test for posterior disturbances (pull). Presented data are mean values and standard deviations (between brackets). The 95% confidence interval data are presented in absolute values and in values relative to the mean values of the ARGO measurements.

Balance Disturbance Test			Paired samples t-test		
B. Posterior disturbance (pull)	A_GO	ARGO	A_GO-ARGO	p-value	95% C.I.
T_{REC} [s]	3.11	3.61	-0.49	0.48	[-2.15, 1.16]
	(0.80)	(1.29)	(1.58)		*[-60%, +32%]*
COP anteroposterior range [mm]	90.83	100.72	-9.89	0.29	[-31.10, 11.32]
	(22.84)	(21.22)	(20.20)		*[-31%, +11%]*
COP mediolateral range [mm]	38.29	43.65	-5.36	0.60	[-29.95, 19.22]
	(21.87)	(17.54)	(23.42)		*[-69%, +44%]*

Crutch forces applied were typically twice as high as during quiet standing with single crutch support, with peak values of up to 4 times as high. As was found for the Quiet Standing Test, crutch forces necessary for balancing the A_GO during the Hand Function Test tended to be higher than for the ARGO, but differences were not significant.

Discussion

Various studies have been reported which compare the performance of different orthoses, or different orthosis configurations, for persons suffering from paraplegia (Jefferson and Whittle, 1990; Whittle and Cochrane, 1989; Whittle *et al.*, 1991; Winchester *et al.*, 1993). These studies relate to walking and compare complete orthotic systems rather than specific design elements. The latter, e.g. lateral stiffness or hip transversal rotation, have been addressed in theoretical studies mainly (Stallard and Major, 1993; Ferrarin *et al.*, 1993; Ferrarin and Rabuffetti, 1996), one exception being a clinical evaluative study which shows that increased lateral stiffness in the Parawalker orthosis has a positive effect on the efficiency of paraplegic gait (Stallard and Major, 1995). It can only be speculated how the results of these studies relate to the pure influence of a component like the reciprocal hip joint coupling on the performance of standing. The present study was directed at adding a piece to this complex puzzle.

The results of this study show that in a variety of situations the presence of a reciprocal coupling of the hip joints in the ARGO has virtually no effect on the performance of standing. Standing balance, as assessed by the range of the COP during the Quiet Standing Test, was not significantly affected by removing

Table 6. Summarised results of the Hand Function Test. Presented data are mean values and standard deviations (between brackets). The 95% confidence interval data are presented in absolute values and in values relative to the mean values of the ARGO measurements.

Hand Function Test			Paired samples t-test		
	A_GO	ARGO	A_GO-ARGO	p-value	95% C.I.
T_{HFT} Sitting [s]	10.08	10.02	0.06	0.80	[-0.52, 0.65]
	(0.78)	(0.42)	(0.56)		*[-5%, +6%]*
T_{HFT} Standing [s]	11.54	11.12	0.42	0.25	[-0.40, 1.24]
	(1.73)	(1.16)	(0.78)		*[-4%, +11%]*
Crutch axial reaction force [N]	119.04	101.74	17.30	0.38	[-28.33, 62.93]
(Average)	(33.57)	(21.76)	(43.47)		*[-28%, +62%]*
Crutch axial reaction force [N]	198.00	179.75	18.25	0.40	[-32.80, 69.30]
(Peak)	(42.32)	(41.83)	(48.63)		*[-18%, +39%]*

the Bowden cable from the orthosis. The ability of maintaining balance in the presence of disturbances, i.e. standing stability, was not significantly different in the ARGO and the A_GO. The performance on the test of hand function was comparable for both orthoses.

There is, however, a strong indication that the crutch force required for maintaining balance in the ARGO was lower than in the A_GO, and that this difference may take on clinical relevance. The most likely explanation for this result is that a stable posture in the A_GO was achieved by most subjects by leaning against the flexion stops built into the orthosis' hip hinges. In this posture extra force is required for compensation of the horizontal component of gravity resulting from the forward inclination. The effect of this mechanical difference between standing in the ARGO and the A_GO may even be toned down in the results because two subjects preferred to stand in the A_GO in the so-called 'C-posture', i.e. 'leaning' against anatomical hip extension limits (Andrews *et al.,* 1989). Since the 'C-posture' is more upright than the flexed posture, the resulting horizontal component of gravity, and thus the extra arm force required for balancing, is smaller. It is clear that this inhomogeneity, as well as the low number of subjects, has an adverse influence on the statistical power of the study.

In the ARGO, the moment required for keeping the trunk erect is generated by the trunk corset, because necessary forces are transferred through the reciprocal link to the upper leg sections. Therefore, in this orthosis configuration only balancing forces have to be provided by upper body effort.

Crutch force, especially from a clinical point of view, is an important indicator in functional assessments, since shoulder and wrist problems form a major threat to the successful and prolonged application of orthotic devices in paraplegia (Gellman *et al.,* 1988). The finding that the difference in standing performance resulting from removing the reciprocal hip joint link from the ARGO lies exactly in the required upper body effort, is therefore greatly relevant.

The results of the Quiet Standing Test illustrate the mechanisms underlying the choice of posture in relation to stability. It was found that the force applied on each crutch was approximately the same for single and dual crutch supported standing. In other words, in the single crutch supported case the subjects took more weight on the feet than during double crutch support and, as a consequence, the mean position of the centre of pressure was shifted posteriorly.

This posterior shift is most likely a compensation for the changed geometry of the base of support. In single crutch supported standing, the anterior edge of the base of support extends diagonally from the front of the foot to the contralateral crutch contact point. Compared with the double crutch support situation, the distance from the anterior edge of the base of support to the COP is greatly smaller. As a consequence, the stability margin is reduced and a new optimum location of the COP must be found by posteriorly shifting weight (Karcnik *et al.,* 1995). Given this effect on stability, it is striking that the range of the COP was found not to be influenced by the number of crutches used for support. Apparently, for standing balance, the area of the base support is not relevant.

If the mechanical properties of standing in both orthoses is considered it would have been expected that differences would be found in the results of the Balance Disturbance Test for ARGO and A_GO. While quiet standing in the ARGO could be best compared with balancing an inverted pendulum, a more suitable description for the A_GO would be an inverted double pendulum. In the A_GO, four subjects chose to lean against the hip flexion stops in order to obtain a mechanically stable standing posture. It would then be expected that perturbations in anterior direction (i.e. pushes applied to the back tube of the orthosis) would cause a temporary deviation from this posture because a hip extension movement would occur. Consequently, the recovery from this change in posture would take less time than from a perturbation resulting from an indentical force impulse in the ARGO, since the inertia of the double pendulum would be lower. During the tests it was found however that, due to the high flexion moments around the hip in the A_GO, the described posture deviation did not occur at the force levels applied for balance perturbance. An analogue description holds for posterior balance disturbances applied to subjects that preferred the C-posture for standing in the A_GO. Though forces were indeed high enough to cause a temporary

flexion movement of the hips directly after the impulse, this effect did not result in significant differences in the posterior disturbance recovery time.

The results of the study lead to the conclusion that although the standing performance of ARGO and A_GO do not vary much, the reciprocal hip joint link in the Advanced Reciprocating Gait Orthosis provides a substantial and clinically relevant reduction of upper body effort necessary for maintaining a stable posture under functional conditions. Therefore, the incorporation of a reciprocal hip joint linkage, or any other mechanism providing the same stabilising properties, is highly recommendable in HKAFO design.

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Technical note

A new concept of dynamic orthosis for paraplegia: the weight bearing control (WBC) orthosis

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Abstract

A new concept of device, termed the weight-bearing control (WBC) orthosis, has been designed with three major needs in mind; a rigid frame that supports the user's body weight, a special hip joint device that reciprocally propels each leg forward, a gas powered foot device that varies the sole thickness of the device for foot/floor clearance, and control system of the orthosis.

A paraplegic (T7 level complete paraplegia, sensory evoked potential silent, response to electro-stimulation on the cortical area of the brain also silent) who has tested this WBC orthosis has been able to walk without fatigue at a high speed for a greater distance than before. In walking tests of this WBC orthosis, he achieved a maximum walking speed of 34.1 m/min for a distance of 10 metres. The walking distance reached 521 m with an average walking speed of 21.2 m/min without rest on one small tank of CO_2 liquid gas, measuring 10 cm in length and 3 cm in diameter.

Introduction

In the past, many devices have been developed to assist the paraplegic to walk, but these devices have fallen short of the paraplegic's wishes (Hahn, 1969; Scott, 1971; Rosman and Spira 1974; Silber *et al.*, 1975). Huang *et al.* (1979) examined the energy cost of orthotic gait of paraplegia. This test measured the O_2 consumption in paraplegic walking with the Craig-Scott brace. This orthosis did not provide practical assistance for walking in severe cases, so he used in this test walking a special reciprocal walker instead of the brace for paraplegia of T4 level. In the biomechanical field, many authorities have devoted effort to the design and manufacture of a walking orthosis with an external power source (Corcoran *et al.*, 1968; Nojima, 1972; Miyamoto *et al.*, 1984), but these ideas have not been realized. In most recent times, the ORLAU group, Rose (1979), Major *et al.* (1981), Butler *et al.* (1984) and Stallard *et al.* (1986) have developed the Parawalker, which to come extent, enables paraplegics to attain better walking speed and provides greater stability to protect the user's safety.

The Parawalker, like custom-made orthotic devices of the past, had no external power source, but it had several innovations; a rigid frame to support the user's walking posture, eliminating the requirement for muscle force of arm and shoulder for handling crutches, thus facilitating the swing forward that each step requires by shifting the weight of the trunk and tilting the Parawalker forward.

A special device that provides hip joint mobility, termed the hip guidance orthosis (hgo), permitted a straight swing forward and the leg braces are reinforced to protect them from damage by the force of a sudden twist or bend.

In spite of these innovations, however, the Parawalker did not fulfil the desires of paraplegics, since its basic design did not permit a more normal walking speed on account of the necessity of lateral body shift on each step.

The reciprocal gait orthosis (RGO) and the advanced type (ARGO), respectively developed by Douglas *et al.* (1983) and Beckman (1987),

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were new orthotic devices that enabled the user to walk in the following manner. During the initial stance phase, a hip joint torque provides a propulsive force to swing the limb forward; after this was accomplished, a succession of these reciprocal actions enabled the user to walk, lifting the user's weight at each step with his muscle power. Yet, despite this improvement in forward propulsion, a major problem must still be solved, the lack of sufficient foot/floor clearance for the swinging limb to move forward during walking.

Thus, the Parawalker and the RGO caused fatigue. Nene and Patrick (1990) and Phillips and Hendershot (1991) have tried to construct a hybrid orthosis using electrical stimulation of the gluteal muscles and others to produce a force to sustain an erect position of the whole body and swing the leg forward. This innovation has been useful to some extent, but the energy reduction was limited to within a few percent of the total energy needed in paraplegic walking. A better, fatigue-free, reciprocal walking orthosis still waits to be developed.

With this in mind, a new type of device, termed the weight bearing control (WBC) orthosis, has been designed.

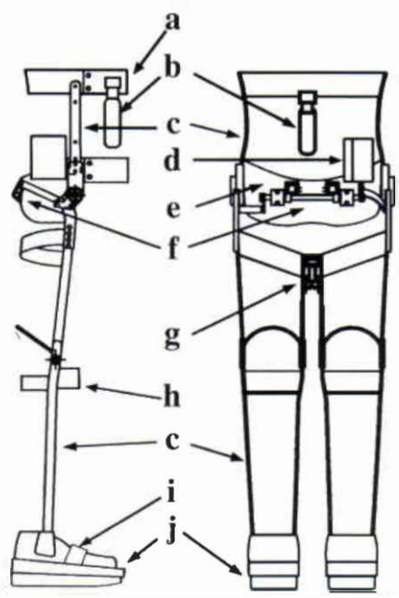

Fig. 1. Structure of the WBC orthosis
a) thoracic girdle, b) CO_2 gas tank, c) rigid exoskeletal frame, d) control box, e) pelvic girdle, f) reciprocal link system on rear pelvic girdle connected through bilateral hip joints, g) reciprocal link divide, h) bail lock device and strap for knee, i) ankle strap, j) variable sole plate.

Structure of the WBC orthosis

The WBC orthosis incorporated several major innovations in relation to the design and theory of the Parawalker and the RGO. The structure of the WBC orthosis consists of the following four main parts: 1) an exoskeletal frame with joints for supporting body weight, 2) a reciprocal link device for normal walking and for providing the optimum step length during walking, 3) a variable sole-plate for foot/floor clearance, with energy supplied from a gas tank, 4) the control system for the dynamic orthosis. Each part is described below.

1) The exoskeletal frame with joints consists of two main parts, a thoracic girdle and two long leg braces with hip and knee joints and with reciprocal connection. The thoracic and pelvic girdle are made of acrylic resin reinforced with glass-fibre, and the two long leg braces and each foot device are of duralumin and aluminium. The hip and knee joints of this exoskeletal frame are free and the ankle is fixed, but in walking, the range of hip joint motion is restricted by a locking device permitting 6° of extension and 18° of flexion, whereas the knee joint is fixed with a bail lock (Fig. 1).

2) The reciprocal joint system has two parts, one is a reciprocal link system that connects both hip joint axes through a steel bar on the back of the pelvic girdle (Fig. 2), the other is a

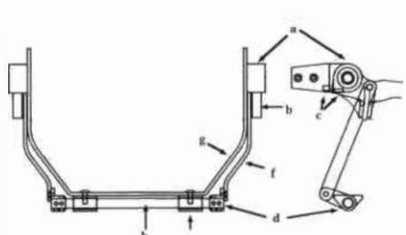

Fig. 2. The reciprocal hip joint system of pelvic rear girdle
a) hip joint axis with a radial bearing and a thrust bearing that connects leg orthosis, thoracic orthosis and pelvic girdle, b) lock device for limited motion of hip joint, c) control limits for the range of hip motion, d) reversal link device for converting the direction of hip joint rotation, e) limit switch for sensing the angular position of the hip, f) inner bar of pelvic girdle, g) lateral outer bar, h) posterior steel bar for transmitting rotational force of hip joint.

reciprocal link device that connects the medial uprights of the long leg brace at the medial proximal aspect and assists the reciprocal motion of the formerly described reciprocal link system. The level of the rotation axis of the reciprocal link device corresponds to the level of the axis of hip joint rotation of both long leg braces. This reciprocal link device reinforced the exoskeletal frame of the bilateral leg orthosis and contributed to the strength to weight ratio of the WBC orthosis (Fig. 3). The role of the reciprocal joint system is an essential feature of the reciprocal walking of the WBC orthosis. The extension force produced by the extension movement of one side produced the flexion force transmitted to the other side of the long leg brace, so that the user can swing forward the leg by the extension movement of the contralateral hip joint of the supporting leg. The user can easily achieve reciprocal swing forward of each long leg brace by the special dual design of these reciprocal joint systems.

3) Each variable sole plate consists of two metal plates at the base of each long leg brace that extend or retract by a gas powered piston supplied from a CO_2 liquid air gas tank strapped to the user's back to provide the foot and floor clearance while walking.

These sole plates can shorten by 4 cm, to allow each leg to easily swing forward in preparation for the next step without an excessive lateral body sway (Fig. 4).

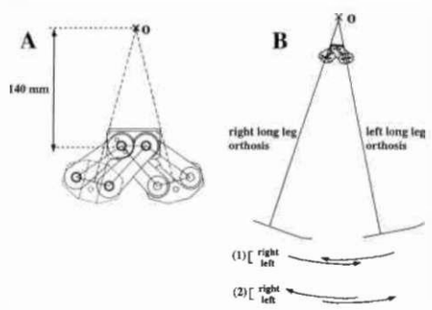

Fig. 3. The reciprocal link device
Special double link device for reverse motion of leg orthosis. It assists the role of the reciprocal hip joint and reinforces the strength of the two leg orthosis.

4) The control system consists of the hardware and software systems. The hardware consists of the following sensors which provide the control signals. The force sensor beneath the sole detects the magnitude of contact force between the sole plate and the floor. The limit switches attached to goniometers around each hip joint axis signal the angular displacement during the hip joint motion (Fig. 5). The software of the control system for the WBC

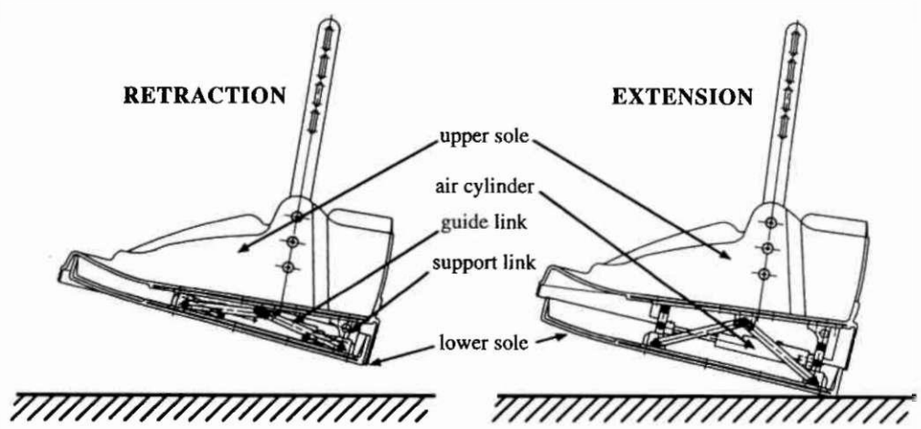

Fig. 4. Variable sole plate system
The cylindrical piston supplied CO_2 gas expands and extends the sole against gravity force by means of a linkage mechanism between the double sole plates. The signal from the control box opens the electromagnetic valve exhausting the gas from the cylinder permitting the sole to retract.

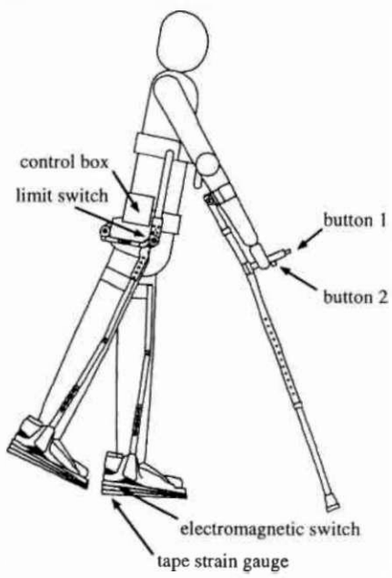

Fig. 5. The sensor system
A manual mode or automatic mode is selected by the operating button 1. In manual mode the sole plate retracts by operating button 2 and extends by releasing it. In automatic mode, pressing button 1 starts a successive retraction and extension action. The signal from the limit switch indicates the position of the leg. The limit switch actuates the electromagnetic switch on the piston thus actuating the sole mechanism. The force signals from tape strain gauge operate the fail safe programme.

orthosis contains four main programmes as follows, a) sequential operating programme, b) fail safe programme, c) buzzer system for alarm, d) count programme of step number.

The sequential programme regulates the opening or closing of exhaust gas valves by an on-off signal of an electromagnetic switch, which is on the cylindrical piston of the sole plates. Opening of exhaust gas valves results in shortening of the cylindrical piston and retraction of the double sole plate. Conversely, closing of the valve produces a lengthening of the piston due to supply of gas resulting in an extension.

The software of the sequential programme of the WBC orthosis has two modes related to the retraction and extension of the double sole plate: a manual mode and an automatic mode (Fig. 6).

The manual mode is used to initiate or to reverse the direction of walking, whereas the automatic mode is used in progressive walking. In the manual mode, retraction or extension of the sole plate thickness is done by pushing a button attached to the grip of each crutch. When the user pushes on the button of the right side crutch, the sole plate thickness is reduced on the left side of the user, and this reduction is maintained until the user releases the button. In the automatic mode, when the button is pushed on, regardless of whether the button pushed is on the left side or right side, the thickness of the sole plate starts to reduce on the required side for forward swing. However, for safety, the thickness of the sole plate does not reduce for the next phase of walking until the signals are received from the limit switch at the rotatory steel bar of the pelvic rear girdle and from the

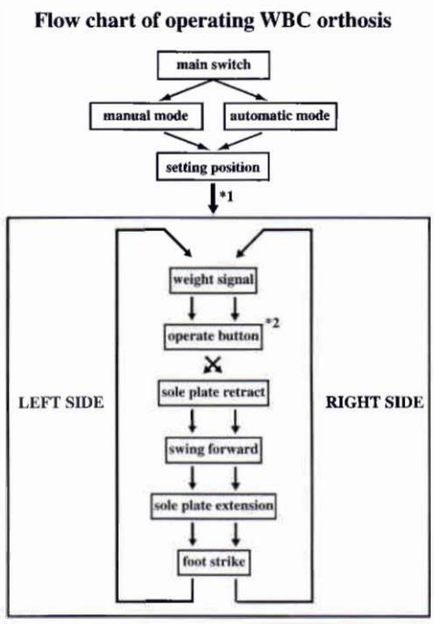

Fig. 6. Flow chart of operation of the WBC orthosis. In manual mode, the subject starts with both legs in a crossed position, for example, right leg forward and left leg backward. He moves his body weight to right forward leg (*1). He presses right button 2, causing the left sole plate to retract. Next, the left leg swings forward by extension of the right hip joint. The sole plate is extended by releasing button 2 when the angle of the left hip joint reaches the permitted flexion of about 18° producing foot strike. The second step cycle is performed by pressing left button 2, when the body weight has been transferred to left foot (*2). Automatic mode, is initiated by pressing button 1(*2).

force sensor attached under the sole plate. The signal from the limit switch provides rotatory information from the goniometer on the axis of each hip joint, about leg position with regard to forward or backward, and the signal from the force sensor indicates whether the weight on the rear leg had been reduced to under 5 kg. The fail safe programme always watches whether the sequential programme runs correctly or not. This information on gait is constantly evaluated and relayed to achieve a fast, safe progression.

The WBC orthosis gait

The walking pattern using the WBC orthosis is shown in Figure 7.

Firstly, standing erect with the orthosis and selecting manual mode, the user pushes the "on" button on the right crutch, thereby shortening the left sole plate by 4 cm, which permits the left leg to swing forward by extending the right hip joint and tilting the pelvis and trunk forward simultaneously using two crutches. On reaching an angular displacement of about 18° of flexion of the left hip joint, which is the full flexion permitted in the limited range of motion, the left sole plate extends 4 cm by releasing the button. The left leg strikes the floor, after which the user shifts his or her weight to the left leg. The user then pushes the left crutch button "on" to shorten the right sole plate 4 cm. This shortening causes the right leg to swing forward by extending the left hip joint and tilting the pelvis and trunk simultaneously as before. On reaching about 18° of flexion of the right hip joint, the right leg is extended 4 cm by releasing the left crutch button. The right leg strikes the floor. The first full step forward is thus completed.

Successive steps are a repetition of these same movements. However, after the first two or three steps, the user changes the walking mode from manual to automatic, thereby enabling a faster pace for greater distances without fatigue. It should be noted that the safety features previously described still protect the user from accidents during the automatic mode.

Results

The paraplegic subject studied is a 27 years old male, who had the injury at 23 years of age. The injury is complete paraplegia at T7 level with sensory evoked potential from the bilateral sural nerve of the foot silent and the response of magnetic electrostimulation on 23 regions of the cortical area of the brain was also silent. Voluntary EMG response was silent on the gluteal muscle group, and erector spina muscles below the T7 level. He had lost completely voluntary motion below his pelvis.

The above mentioned paraplegic subject achieved a maximum walking speed of 34.1 m/min on average for a distance of 10 metres, and a maximum walking speed of 23.5m/min on average for a distance of 50 metres.

With practice, the patient's successful walking distance of 521m was achieved with an average walking speed of 21.5 m/min without rest and on one small tank of CO_2 liquid gas, measuring 10 cm in length and 3cm in diameter.

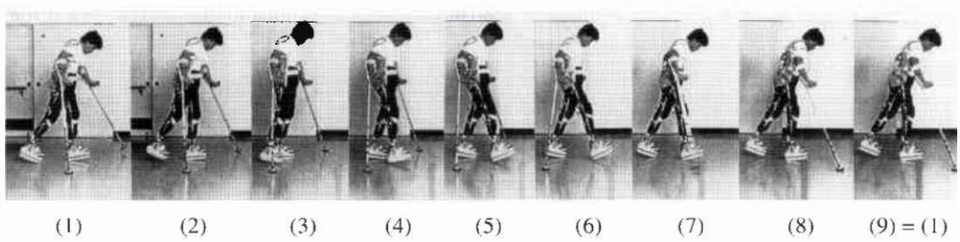

Fig. 7. Walking pattern in manual mode.
(1) The left leg is forward and the right leg backward in double support phase, (2) the right sole plate is retracted by pushing on left button 2, and swing forward of the right leg, initiated (3) and (4), the swing phase of the right leg, (5) extension of the right sole plate, (6) foot strike of right leg, (7) and (8) Moving the body weight to the right foot, (9) start of next step.
The charateristic pattern of WBC orthosis gait is seen in figure (3) to (5) where the left hip joint is fully extended after which it moves towards flexion and transmits an extension movement to the right hip joint. The subject was able to walk at high speed taking successive steps from double support phase to single support phase without losing forward momentum even when the step was long.

Table 1. Results of walking test (T7 complete paraplegia, 27yrs, male)

Parameter	WBC orthosis	Parawalker
Maximum walking speed 10m distance (m/min)	34.1	16.5
Average walking speed 50m distance (m/min)	23.5	11.5
Successive walkling distance (m)	521.0	82.0
average walking speed (m/min)	21.2	8.0
average step length (cm)	55.2	33.1
average cadence (step/min)	38.4	24.2
PCI (beat/m)	1.9	3.6

The average step length and cadence in the successful walking 521m was 55.2 cm and 38.4 steps/min respectively. The PCI as energy cost index was 1.9 (Table 1).

In spite of having a great amount of walking exercise using the Parawalker for the last two years. The results using the WBC orthosis were far better for this subject. In the course of training, achieving 12,600 steps in two months, the data showed the unexpected improvement of about fifty percent in all walking parameters.

Conclusion

The WBC orthosis proposes a new concept of dynamic orthosis for paraplegia providing the user with the low energy tool "variable sole plate" activated by supplying a small amount of CO_2 liquid energy from a gas tank as an extra-power source. The results of test walking using this WBC orthosis proved that even though the supply of external energy was small if the sequential control is adequately matched for the flexion and extension pattern of the whole body in paraplegic walking, it is able to provide power for erect reciprocal walking.

It points the way to harmonizing the provision of power and the residual biomechanical abilities of the disabled person.

Acknowledgment

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Technical note

Pressure relief characteristics in alternating pressure air cushions

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Abstract

In this study a computerised system was used which continuously measured air pressure, interface pressure and pressure-time cycle characteristics of an alternating pressure air cushion (APAC), and calculated the time the interface pressure remained below three chosen thresholds of 20,40 and 60mm Hg. Ten healthy volunteers were used to evaluate the pressure relieving characteristics of four APACs. Results indicated significant differences between products when the threshold periods were analysed, showing some devices were not capable of relieving interface pressures below 20mm Hg. Though deflation pressure decreased to nearer zero, interface pressure did not follow suit.

Introduction

Commercially available alternating pressure (dynamic) air cushions, used for the prevention and treatment of pressure sores, are documented as actively enhancing tissue perfusion by increasing and decreasing the pressures under the body seating area (Donald and Clark, 1993; Kosiak *et al.*, 1958). Consideration of seating pressure is an important aspect of comprehensive assessment when prescribing equipment for disabled persons. Recently, increased interest in the subject has led to significant improvements in seating systems and their provision (Bardsley, 1993). The hammock seat and back of a conventional wheelchair provide very little support to the pelvis and spine (Seeger and Sutherland, 1981; Medhat and Redford, 1978). Thus, unless a comfortable and functional posture is achieved with minimal risk of developing deformities and pressure sores, wheelchair users are not able to achieve their full potential during work, school or recreational activities, and therefore the provision of suitable support systems becomes a key factor in their rehabilitation.

Various support surfaces are commercially available for the management and prevention of pressure sores. These vary considerably in design, ease of use, maintenance, reliability, durability and cost (Rithalia, 1991). The majority of these support systems reduce pressure concentration on local areas by redistributing the load over as large an area as possible. Such pressure-reducing support surfaces include foam, gel and static air cushions. Other support systems operate a cyclic alteration of pressure on various parts of the body by changing the point where the subject is supported. These include alternating pressure air cushions (APACs), which achieve pressure relief by a system of cells which alternately inflate and deflate, resulting in lower interface pressure at the deflated cell during the deflation period of the cycle, thus attempting to ensure an adequate level of tissue perfusion.

The action of an APAC is time dependent and, therefore, any indicator which measures pressure relief should take the time factor into account as the effectiveness of pressure relief is related to the period of time the interface pressure remains below capillary closure pressure (McLeod *et al.*, 1994). The aim of this study was to evaluate the pressure-time-cycle characteristics of four commercially available

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APACs, with the aim of ranking each cushion according to its performance regarding pressure relief.

Methods and materials

Ten healthy adult volunteers (6 males, 4 females), whose age, weight and height ranged from 25 to 55 (mean ± SD, 31.9 ± 9.1) years,, 66 to 91 (76.1 ± 14.7)kg and 165 to 178 (169 ± 11) cm, participated in this study. The procedure for the investigation was fully explained to every volunteer and verbal consent gained before each subject took part in the study.

The four commercially available APACs investigated in this study included:

(a) Alpha Trancell – Active Pressure Relief Seat Cushion (Huntleigh Healthcare, Luton). This uses an arrangement of 9 cylindrical air cells, set transversely that alternately inflate and deflate. The cells are attached by fabric loops to a one piece plastic cover that folds over the underside and fastens in the manner of an envelope. The air is delivered by a mains powered pump via a 2-pipe system, each pipe feeding one set of cells, with an operating cycle time of 10 minutes.

(b) Bellows Air Support Equipment (B.A.S.E.) – Sequential Seating System (Talley Group Ltd, Hampshire). The cushion has eight rows of cells set transversely and each row contains six air bellows. The bellows are contained within a soft foam jacket controlling their lateral movement but allowing free up and down motion, thus not impeding the inflation and deflation pattern. A light weight pump, powered by a rechargeable nickel-cadmium battery, inflates the bellows sequentially with a cycle time of 10 minutes.

(c) Care Chair – Dynamic Posture System (British Astec, West Midlands). This consists of a complex, double-layer, interwoven single piece cell structure, with 20 transverse air cells operating in a 1-in-2 cycle over 7.5 minutes. In construction, it resembles a mattress with nearly half the cells placed on the seat and the rest covering the back-rest. The air is delivered by a mains powered pump via a 2-pipe system, each pipe feeding alternate cells.

(d) Pro-Active Seating System (Pegasus Airwave Ltd, Hants). The cushion consists of six air cells arranged longitudinally, plus a foam section in front to support the thighs. Two outer cells, one on each side, are permanently inflated while the other four cells inflate and deflate in pairs. All cells are connected to a battery powered pump with an operating cycle time of 12 minutes. They are encased in a waterproof cover and placed on to a plywood base, which can be attached directly to a wheelchair. The resulting seating system including the pump and battery weights 6.6kg.

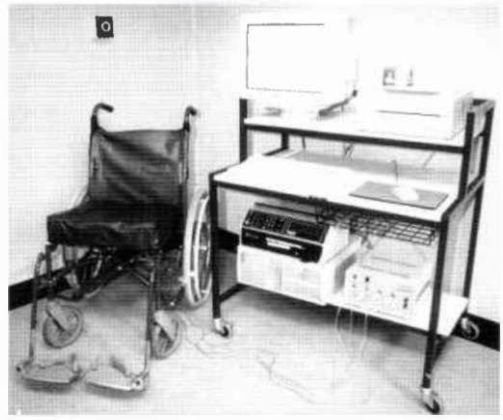

Fig. 1. Equipment used to record air pressure, interface pressure and pressure-time cycle characteristics of the cushions.

A computerised system (Fig. 1) was used to record the air pressure, interface pressure (IP) and pressure-time cycle characteristics of the APACs. Interface pressure was measured continuously using the Oxford Pressure Monitor 2 (Talley Group Ltd, Hants) and the air pressure inside cushion cells was recorded simultaneously. A graphical programming language (Lab View, National Instruments Inc, USA) is used by the monitoring system. The method employs a minimal amount of hardware and maximum flexibility by turning the computer into a data acquisition tool and its screen into a control panel. The computer interface reads the pressure sensor outputs, analyses them and then graphically represents the results. The software is developed to calculate the time IP remains below any three chosen thresholds for a chosen length of time and expresses pressure relief (PR) as a percentage of the cycle, which allows like-for-like comparisons to be made choosing any common multiple of the cycle times. For example, one hour requires six 10-minute cycles or twelve 5-minute cycles. In this investigation, for PR calculations as a percentage of the APAC cycle the IP thresholds were set at 20, 40 and 60mm Hg.

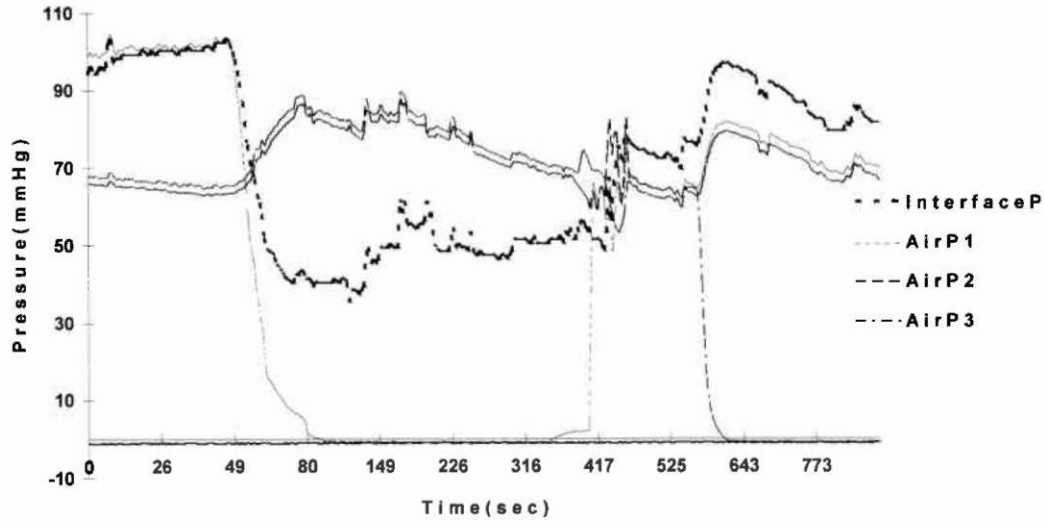

Fig. 2. Pressure-time tracings of the Pro-Active cushion showing interface and air pressures.

Subjects were seated in a standard wheelchair, with sling seat and back, in a comfortable upright position. Arm supports and foot rests were adjusted for each subject so that the hips were at right angles. For the Care Chair, measurements were taken with the subjects seated in a high seat hospital chair.

Measurements were taken at both right and left tuberosities for each subject, thus giving a set of 20 readings for each cushion in 10 volunteers. The tuberosity was palpated for location and the single sensor (20mm diameter) attached with a tape over its feeding tube. The sensor from the Oxford Pressure monitor was positioned between the centre of an inflated cell of the cushion and buttock. The duration of the readings varied between 10 and 15 minutes, depending on cycle time of each cushion, allowing an extra cycle for the subject to settle down.

From the initial data (Fig. 2) the maximum, minimum and mean interface pressures as well as the air pressure in the cushion cells were recorded or each cushion. Pressure relief characteristics were obtained as a percentage of the amount of time the interface pressure remained below the chosen thresholds throughout one cycle. This was then converted to pressure relief per hour (Table 1) as explained above.

Results

A pressure-time graph (Fig. 2) shows the experimental results obtained on a cushion regarding interface pressure and air pressure inside each cell. The mean interface pressure on inflation and deflation as well as pressure relief characteristics were then calculated and are summarised in Table 1. This showed that the Alpha Trancell had better pressure relief

Table 1. Mean interface pressure (IP), air pressure (peak) and pressure relief (PR) below 60 (A), 40 (B) and 20 (C) mm Hg in 60 minutes

Cushion	Mean (±SD) IP Inflation (mm Hg)	Mean (±SD) IP Deflation (mm Hg)	Mean (±SD) Air Pressure (mm Hg)	Mean (±SD) PR		
				(A) (min)	(B) (min)	(C) (min)
Alpha Trancell	61 (7.3)	22 (10.3)	64 (6.2)	50 (6.3)	24 (6.1)	8 (8.9)
B.A.S.E.	68 (6.2)	29 (3.1)	77 (7.1)	37 (16.6)	12 (11.9)	0
Care Chair	78 (9.3)	35 (13.9)	82 (5.1)	31 (9.6)	13 (14.4)	5 (6.8)
Pro-Active	103 (21.2)	36 (7.9)	90 (8.6)	21 (8.2)	6 (7.8)	0

characteristics than any other cushion. All cushions displayed varying degrees of pressure relief measurements below 60 and 40mm Hg, but only the Alpha Trancell and Care Chair gave relief measurements below 20mm Hg. The interface pressures and pressure relief measurement characteristics in B.A.S.E and Care Chair cushions were similar.

The maximum and minimum interface pressures were recorded when the cells were in inflation and deflation modes respectively. The Alpha Trancell recorded the lowest mean interface pressure at both inflation and deflation, while the Pro-Active recorded the highest interface pressures. However the Pro-Active gave the highest pressure differential between inflation and deflation (67mm Hg) while the Alpha and B.A.S.E. gave the lowest (37mm Hg). When the interface pressures were compared to the peak or maximum air pressure inside the cushions, only the Pro-Active gave higher readings of maximum interface pressure than the peak air pressure. The initial data also showed that on deflation the air pressure inside a cell reached a minimum of zero, but interface pressure did not.

Discussion

One commonly asked question is whether body weight affects the magnitude of the interface pressure created between the subject and support surface. Obesity can either increase or decrease the susceptibility to pressure sore development (Natow, 1983). Small quantities of adipose tissue can provide protection and cushioning for bony prominences, but due to its poor blood supply it is more vulnerable to shear forces and prolonged pressure. However, pressure alone does not cause pressure sores but, the time for which pressure is maintained above a critical level is very important (Hussain, 1953). Capillary pressure has been quoted to range from 12 to 47mm Hg (Clark, 1987) and from 32 to 60mm Hg (Wytch *et al.*, 1989). Thus, the question arises as to which thresholds to consider when evaluating pressure relief in APACs.

Over the years pneumatic cells have rendered accurate and reliable results for interface pressure measurements. One theoretical drawback is that because they conform so well to the body-support surface interface they tend to reduce the measured peak pressures (Bowker and Davidson, 1979). However at low pressures this effect is minimal and during this investigation results were only used for comparative purposes.

It could be argued that the subjects who participated in this study were all normal and healthy and would not normally be candidates for the prescription of APACs. But patients who would normally use APACs, e.g. paraplegics, are those who can least tolerate high interface pressure and would run the risk of tissue breakdown during the course of such an investigation. Thus, healthy volunteers are probably the safest.

Only 3 out of 10 subjects gave interface pressure readings below 20mm Hg for Care Chair and 5 out of 10 for the Trancell cushion. The B.A.S.E. and the Pro-Active cushion were unable to give pressure relief below 20mm Hg.

Conclusion

The B.A.S.E. and the Pro-Active cushion were unable to give pressure relief below 20mm Hg. However, there is more to prescribing a support surface for disabled persons than just interface pressure measurements. It is important to consider other factors such as age, level of activity and motivation. The optimum criteria for the design and evaluation of the APACs are inconclusive and more extensive studies are necessary. The authors are continuing the investigation in the clinical environment to assess the factors, such as, long term durability, comfort, maintenance and ease of use.

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NC221 Advances in the Orthotic Management of the Neurologically Impaired Child; 6-8 May, 1998

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

20-24 January, 1998

8th Biennial Pacific Rim Prosthetic and Orthotic Conference, Hawaii, USA.
Information: Teresa LaPorte, Pacific Rim Conference, 1621 East Fremont St., Las Vegas, NV 89101, USA.

28-30 January, 1998

2nd Australasian Biomechanics Conference, Auckland, New Zealand.
Information: Patricia Anne Hume, Sport and Exercise Science Dept., Tamaki Campus, University of Auckland, Private Bag 92019, Auckland, New Zealand.

2-6 February, 1998

10th Combined Meeting of the Orthopaedic Associations of the English Speaking World, Auckland, New Zealand.
Information: Orthopaedic Meeting, c/o Convention Management, PO Box 2009, Auckland, New Zealand.

6-8 March, 1998

4th Annual Conference and Trade Exhibition of the British Association of Prosthetists and Orthotists, Blackpool, England.
Information: Secretariat, BAPO, Sir James Clark Building, Abbey Mill Business Centre, Paisley PA1 1TJ, Scotland.

19-23 March, 1998
American Academy of Orthopaedic Surgeons Annual Convention, New Orleans, USA.
Information: AAOS, 6300 North River Rd., Rosemont, IL 60018-4226, USA.

1-4 April, 1998
AAOP Annual Meeting, Miami, USA.
Information: Annette Suriani, AAOP, 1650 King St., Suite 500, Alexandria, VA 22314, USA.

17-20 April, 1998
71st Annual Meeting of the Japanese Orthopaedic Association, Tokushima, Japan.
Information: Prof. Takaaki Ikata, Congress Chairman, Dept. of Orthopaedic Surgery, University of Tokushima, 3-18-15 Kuramoto, Tokushima 770, Japan.

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

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

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

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

4-6 June, 1998
2nd Central European Orthopaedic Congress, Budapest Hungary.
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9-13 June, 1998
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RESNA 98, Minneapolis, USA.
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28-30 June, 1998
24th Canadian Medical and Biological Engineering Conference, Edmonton Canada.
Information: CMBEC Secretariat, c/o National Research Council of Canada, Bldg. M-55, Room 382, Ottawa, Canada K1A 0R8.

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9th International Mobility Conference, Atlanta, USA.
Information: Dr. Bruce Blasch, Senior Scientist, VA Medical Center, Rehabilitation Research and Development, 1670 Clairmont Rd. (151R), Decatur, GA 30033, USA.

4 July, 1998
International Interdisciplinary Symposium on New Developments in Technical Orthopaedics.
Information: Prof. Dr. Med. G. Neff, Abtlg. für Techn. Orthop. Dysmelia und Rehabilitation, Oskar-Helene-Heim, Clayallee 229, D-14195 Berlin, Germany.

8-11 July, 1998
11th Conference of the European Society of Biomechanics, Toulouse, France.
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21-25 July, 1998
16th Symposium of the International Society of Biomechanics in Sports, Konstanz, Germany.
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3rd World Congress of Biomechanics, Sapporo, Japan.
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14-18 August, 1998
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Information: S. McGill, Dept. of Kinesiology, University of Waterloo, Waterloo, Ontario N2L 3G1, Canada.

10-12 September, 1998
2nd Central and Eastern European ISPO Conference, Portorose, Slovenia.
Information: Ela Loparic, Institute for Rehabilitation, Linhartova 51, 1112 Ljubljana, Slovenia.

15-19 September, 1998
AOPA National Assembly, Chicago, USA.
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