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The effects of prosthesis mass on metabolic cost of ambulation in non-vascular trans-tibial amputees

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Abstract

The effect of prosthesis mass on the metabolic cost of steady-state walking was studied in ten male non-vascular trans-tibial amputees (TTAs) and ten non-amputee controls. The subjects underwent four trials of treadmill ambulation, with each trial performed for nine minutes at level grade and 76 m/min. Twenty minutes of seated rest followed each trial. During trials numbers one and two, TTAs ambulated without mass added to their prosthesis. During the third and fourth trials, either 454 or 907 grammes mass (1 or 21bs mass respectively) were randomly assigned and added to either the prosthesis or the leg of the non-amputee control. Subjects were blinded to the amount of mass added to their limb. Within-group comparisons across the four trials showed significant differences in oxygen consumption ($VO2$) and heart rate (HR) between the two non "mass added" trials, but no effect for addition of mass. The VO_2 of TTAs was only 0.6ml/kg/min (4.7 percent) greater during walking following the addition of 907 grammes to the prosthesis than without mass addition at all, while HR averaged only 1.4 beats/min. higher under the same testing condition. Pearson-product moment correlations echoed these findings, as moderate, but in all cases, negative correlations were observed for associations among the factors of subject age, stump length, and prosthesis-shoe weight, and both VO_2 and HR. It was concluded that adding up to 907 grammes mass to a non-vascular TTA's prosthesis will not significantly increase the energy expenditure or HR at a normal walking speed, and that elevated energy cost of ambulation in repeated measures testing without mass added may reflect task familiarisation and not an added burden of prosthesis mass.

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Introduction

An estimated 105,000 to 115,000 Americans lose a lower limb to amputation each year, with approximately 30,000 trans-tibial amputations being performed (Skinner and Effeney, 1985). Although the published literature lacks consensus concerning the distribution of causes for amputation in North America, it has been estimated that 70 to 90% are the result of disease, between 10 to 20% are for traumatic reasons, approximately 4% because of tumour, and 4% are congenital (Gailey *et al,* 1994; Ganguli *et al.,* 1974; Smidt, 1990).

Previous studies have reported that the metabolic cost of ambulation in trans-tibial amputees (TTA) is 15-55% higher than that of non-amputees, while ambulation velocity is 10-40% slower (Gailey *et al,* 1994; Ganguli *et al,* 1974; Gonzalez *et al.,* 1974; Huang *et al,* 1979; Pagliarulo *et al,* 1979; Waters *et al,* 1976 and 1988) (Table 1). It has been reported that traumatic TTAs walk at a faster pace while expending greater energy than vascular TTAs (Ganguli *et al,* 1974; Pagliarulo *et al,* 1979; Waters *et al,* 1976 and 1988). By comparison

Table 1. Metabolic cost and velocity of amputee ambulation.

Author	Cause of amputation	Number of subjects	Velocity (m/min)	Rate of oxygen uptake (ml O_2/kg/min)
Gonzalez *et al.* (1974)	Trauma	n=4	71	12.9
Waters *et al.* (1976)	Trauma	n=14	71	15.5
Pagliarulo *et al.* (1979)	Trauma	n=15	71	15.5
Gailey *et al.* (1974)	Trauma	n=39	70	12.9
Gonzalez *et al.* (1974)	PVD	n=4	60	11.1
Waters *et al.* (1976)	PVD	n=13	45	11.7

non-amputee controls have an ambulation VO_2 ranging between 10.9-12.95 ml/kg/min at speeds between 60-99m/min (Blessey *et al,* 1976; Corcoran and Brengelmann, 1970; Gailey *et al,* 1994; Perry, 1992; Smidt, 1990; Waters *et al,* 1976 and 1988). (Table 2). The mean comfortable walking speed for non-amputee subjects is observed to be 76-80 m/min (Finely and Cody, 1970; Waters *et al,* 1976). In contrast the mean walking speed of TTAs is 71 m/min. approximately 10% slower than non-amputee subjects (Gailey *et al,* 1994; Pagliarulo *et al,* 1979; Waters *et al*., 1978).

Many elements contribute to altered gait mechanics, slow walking pace and elevated energy cost of ambulation in amputees. Among the most critical of these elements are: 1) the degree of displacement of the centre of mass over the base of support in all three planes of motion (Engsberg *et al,* 1990; Peizer *et al,* 1969; Saunders *et al,* 1937); 2) asymmetry of motion secondary to an imbalance of the muscle group actions of the lower limbs (Mensch and Ellis, 1986; Skinner and Effeney, 1985); 3) diminished coordinated movement between the ankle and knee joints consequent to the loss of proprioceptive feedback and musculature of the prosthetic joints (Ganguli *et al,* 1974; Mensch and Ellis, 1986; Skinner and Effeney, 1985; Waters *et al,* 1976); 4) the inability of the prosthesis to simulate the normal biomechanics and functions of the anatomical ankle and foot (Fisher and Gullickson, 1978; Radcliffe, 1961) thus altering the normal biomechanics of locomotion (Fisher and Gullickson, 1978); 5) the influence of the prosthetic design on the mechanics of gait, which may cause the amputee to deviate from a normal gait pattern and increase energy expenditure during walking (Murphy and Wilson, 1962; Radcliffe, 1955, 1957 and 1961[a,b]); 6) the loss of kinetic energy normally stored as potential energy in the anatomical limb during gait (Ehara *et al,* 1993; Ganguli *et al,* 1974; Gitter *et al,* 1991); 7) the loss of the skeletal lever arm, thus forcing proximal muscle groups acting on the remaining bone length to compensate for a longer lever arm and control the entire lower limb during the gait sequence (Ganguli *et al,* 1974; Gitter *et al,* 1991; Inman, 1967); 8) the loss of absolute amounts of contractile tissue mass, changes in insertion site, or altered functional capacity which will result in diminished potential strength (Eberhart *et al,* 1954; Ganguli *et al,* 1974; Klopsteg and Wilson, 1954; Winter and Sienko, 1988); 9) changes in body temperature regulation from loss of skin surface area which may disrupt the body's natural homeostasis

Table 2. Metabolic cost and velocity of normal ambulation

Author	Number of subjects	Velocity (m/min)	Rate of oxygen uptake (ml O_2/kg/min)
Blessey *et al.*, (1976)	n=40	82	12.95
Waters *et al.*, (1978)	n=20	82	12.95
Gailey *et al.*, (1994)	n=21	75	10.9

(Levy, 1983). Interestingly, the mass of the prosthesis is surprisingly missing from this list.

Both logic and a previous report (Inman, 1967) suggest that prosthesis mass should be included among the factors that influence energy expenditure and speed of ambulation in TTAs. However, the relationships among prosthetic mass, speed of ambulation, and energy cost of walking are not clearly defined. A recent report examined the effects of prosthesis mass on ambulation VO_2 in TTAs who used heavy prostheses operationally defined as greater than 2.27 kg and those who used light prostheses, defined as being of mass 2.27 kg or less. After controlling for stump length, age, speed of ambulation and baseline VO2, there was no significant difference in ambulation VO_2 between subjects who used high and low mass prostheses (Gailey *et al*, 1994). Additionally, no significant correlation was observed between prosthesis mass and either ambulation VO_2 or heart rate (HR), and the best predictors of the physiological responses to walking were the subjects' resting (i.e. pre-ambulation non-exercise) VO_2, HR, and stump length. It is possible, however, that the findings of this study may have been influenced by its retrospective nature and cross-sectional design. Thus, the purpose of this prospective, randomised, control-design study was two-fold: 1) to compare the VO2 and HR of TTAs and non-amputee control at a steady state walking speed of 76 m/min and 2) to determine the effects of mass on VO_2 and HR when added to the limb of TTAs and non-amputee controls.

Methods

Subjects

Subjects were ten mesomorphic males aged 24 to 52 years (x = 37.8 ± 10.4) with unilateral TTA. Ten non-amputee control subjects were matched with the TTAs for age (range = 23-51 years, x = 34.0±12.9 years), gender, and somatotype. The subjects with TTA were at least one year post-amputation from trauma or tumour but not vascular disease, while their intact limb was without injury or disability. All had a minimal stump tibial length of five centimetres and had used their current prosthesis for at least six months without skin irritation, pain, or other complication, the stump length was measured from the medial tibial plateau to the distal tibia. The prosthesis mass, both with and without the shoe, was recorded to the nearest gramme on a calibrated scale. Consent to undergo study was obtained from all subjects in accordance with the guidelines of the Institutional Medical Sciences Sub-committee for the Protection of Human Subjects. Descriptive characteristics of the subjects and their prostheses are shown in Table 3.

Ambulation trials

The subjects underwent four consecutive ambulation trials on a motorized treadmill (Trackmaster JAS Fitness System). Each trial involved ambulation at 76m/min for nine minutes at level grade followed by 20 minutes of seated rest. The first trial was conducted without addition of mass to the prosthesis, and

Table 3. Amputee demographic data

Subject	Age	Cause	Years since Amputation	Stump length (cm)	Prosthetic mass (g)
1	44	Congenital	34	2.4	1927.77
2	52	Trauma	24	2.68	2041.17
3	42	Trauma	8	1.08	1304.08
4	25	Trauma	11	4.33	1247.38
5	25	Sarcoma	10	2.26	1304.08
6	49	Trauma	44	2.07	1871.07
7	24	Trauma	1	2.56	1474.18
8	45	Trauma	17	2.56	2267.96
9	38	Trauma	6	3.35	1927.77
10	34	Trauma	4	3.54	2154.56
Mean	37.8		15.9	2.7	1752

was intended to familiarise subjects with treadmill ambulation and testing procedures. The second trial was a duplicate of the first. For the third and fourth trials, masses of either 454 or 907 grammes (1 or 2 lbs mass respectively) were added to their prosthesis in a randomly selected order. The subjects were blinded to the amount of mass added to the limb. Mass was affixed to the limb using a custom Velcro sleeve which has pockets designed to evenly distribute the added mass over the length of the intact limb or shank of the prosthesis. The sleeve was secured to the prosthesis shank of the amputee subjects, and was randomly assigned and then secured to the right or left shank for the non-TTA control subjects.

Measurements

Heart rate (HR) and oxygen uptake (VO_2) measurements were taken in the sitting position before testing. Exercise HR and VO_2 were collected very 15 seconds throughout the nine minute ambulation period with minutes 6 to 9 data averaged for the test results. Expired gases were collected in a mixing chamber from which the minute ventilation was computed by a turbine flowmeter. The fractional expired O_2 was continuously sampled from this chamber and averaged over the same 15 second period to compute the VO2. Heart rate was quantified by a Vantage Performance Monitor.[1] Oxygen uptake was measured on expired gases collected by a Hans Rudolf non-rebreathing valve[2] with assay of the gases performed on a Horizon System V Metabolic Measurements Analyzer[3] calibrated to known gas volumes and concentrations. Reliability of equipment and methodology were established by performing four trials on ten non-amputees matched with the TTAs for age, gender and somatotype.

[1] Polar Electro, Inc , Hartland, WI. USA
[2] Hans Rudolph Inc., Kansas Cily, MO, USA
[3] Sensormedics, Inc , Loma Linda, CA, USA

Data analysis

Data were analysed using a 3 x 2 x 2 design Analysis of Variance (ANOVA) for repeated measures, with main effects tested for trial (0g [first trial], 0g [second trial], 454g and 907g), sample time (resting pre-ambulation, post-ambulation) and condition (TTA vs non-TTA). Post-hoc analysis was conducted with simple effects tests. A Pearson product moment correlation was used to explore possible associations among selective descriptive characteristics (age, stump length, and prosthesis-shoe mass) and post-ambulation HR and VO_2. The criterion for statistical significant was set at the 0.05 level for all tests.

Results

All subjects reported feeling comfortable while walking on the treadmill. Between-group comparisons were significant for both HR and VO2 under all of the three testing trials (i.e. 0g, 454g and 907 g) ($p<0.05$). Oxygen consumption for TTAs was 14.3, 11.0, and 14.5 percent greater than control subjects when weighted with 0g, 454g, and 907g respectively. Likewise, HR values for TTAs were 30.8, 30.4, and 31.2 percent higher than those of control subjects when masses were added of 0, 454 and 907g respectively (Table 4). With respect to within group comparisons (i.e. the comparison of HR and VO2 across the three testing trials, each for TTA and control subjects), HR and VO_2 differed between the two trials with no added mass for amputee subjects ($p<0.05$). Otherwise, all within-group comparisons were non-significant. The VO_2 of TTAs was only 0.06

Table 4. Amputee and control group VO_2 and HR means.

Group	Means	Trial 1 (0g)	Trial 2 (0g)	Trial 3 (454g)	Trial 4 (907g)
Amputee group (n=10)	VO_2 (ml/kg/min)	13.7±2.3	12.8±2.1	13.1±2.5	13.4±2.6
	HR (bpm)	108.5±17.8	105.4±17.7	105.8±17.7	106.8±18.8
Control group (n=10)	VO_2 (ml/kg/min)	11.4±1.2	11.2±1.2	11.8±1.3	11.7±1.0
	HR (bpm)	80.6±9.3	80.6±9.3	81.1±9.1	81.4±9.2

ml/kg/min greater following the addition of 907 grammes to the prosthesis than with no added mass at all, while HR averaged only 1.4 beats/min higher. Pearson-product moment correlations showed highly positive associations between HR and VO_2 for all four ambulation trials (Table 5). Moderate, but in all cases negative, correlations were observed for associations among age, stump length, and prosthesis-shoe mass, and both HR and VO_2.

Discussion

The mass of an amputee's prosthesis has long been of concern to clinicians and amputees. Inman (1967) wrote that a prosthesis had to be of a minimum mass in order to: 1) maintain adequate momentum during the swing phase of gait; 2) carry the limb through stance; and 3) assist with push-off. Over the past two decades there has been an industry-wide movement to reduce the mass of prosthetic devices in an attempt to create ultralight prostheses. Given that the average mass of a human limb distal to

Table 5. Correlation for prosthetic mass, stump length, and age with respect to VO_2 and Heart Rate

	Trial 1 VO_2 (0g)	Trial 2 VO_2 (0g)	Trial 3 VO_2 (454g)	Trial 4 VO_2 (907g)	Trial 1 HR (0g)	Trial 2 HR (0g)	Trial 3 HR (454g)	Trial 4 HR (907g)
Trial 1 VO_2 (0g)	1							
Trial 2 VO_2 (0g)	0.959	1						
Trial 3 VO_2 (454g)	0.918	0.964	1					
Trial 4 VO_2 (907g)	0.85	0.933	0.948	1				
Trial 1 HR (0g)	0.817	0.794	0.724	0.729	1			
Trial 2 HR (0g)	0.766	0.767	0.689	0.703	0.973	1		
Trial 3 HR (454g)	0.812	0.825	0.754	0.791	0.977	0.988	1	
Trial 4 HR (907g)	0.777	0.805	0.736	0.798	0.955	0.978	0.995	1
Age	-0.295	-0.167	-0.212	-0.222	-0.366	-0.311	-0.339	-0.342
Length	-0.252	-0.47	-0.388	-0.451	-0.227	-0.303	-0.333	-0.349
Mass	-0.503	-0.442	-0.319	-0.437	-0.412	-0.44	-0.492	-0.516

the knee joint is approximately four percent of total body mass (Mensch and Ellis, 1986) an adult male of 80 kg mass ought to have a lower limb mass of 3.2 kg. By comparison, prostheses currently used by TTAs typically have a mass less than 2.3 kg.

The reduction in the mass of modern prostheses is primarily due to the increased selection of lightweight materials for fabrication, such as titanium, carbon fibre composites and copolymer plastics. Even though prostheses masses, in general, have been considerably reduced from just a decade ago, many prosthetists will often forgo the use of accessories such as rotators, shock absorption devices or durable covers to minimise the mass of the prosthesis.

The findings of this study suggest that small additional increments of mass will not significantly increase the energy cost of steady-state ambulation in TTAs, and that measured increases in this energy cost represents short-term acclimatisation to the testing conditions. With respect to the former finding, the authors have previously reported that prosthesis mass is unrelated to the energy cost of ambulation in subjects with traumatic TTA, although energy cost was influenced by the stump length when this length was stratified by long and short trans-tibial amputation (Gailey *et al,* 1994). With respect to the later finding, it is consistent with reports that observe an immediate reduction of submaximal oxygen consumption in subjects who begin an exercise training programme (Ekblom *et al,* 1968; Fox *et al,* 1975). This reduction in energy cost is attributed to motor skill familiarisation necessary to perform the exercise task and not physiological adaptation of the cardio-circulatory or muscular system (Ekblom *et al,* 1968; Fox *et al,* 1975).

The masses used for this trial were selected with the knowledge that most TTA prostheses do not vary greatly in total mass. The mean mass of the subjects prostheses was 1.77±0.43 kg. Coincidentally, the added test masses of 454 and 907 g reflected approximately one and two standard deviations above the mean, respectively, for the average prosthesis masses of the subjects. The addition of mass greater than 907 g would probably exceed the prosthesis mass a clinician might realistically encounter in practice. It is noted that the placement method for the additional mass in this study was important, as this was added throughout the entire length of the prosthesis to avoid concentrating mass at the distal end. This was accomplished by uniformly adding mass over the length of the shank to decrease the possibility of altering the swing phase momentum, and likely better represents a clinical situation in which a heavier prosthesis would not have all of the additional mass located in its distal segment.

This study tested subjects at a uniform walking speed of 76 m/min. Several studies report that the ambulation speed of non-amputees varies from 67-80 m/min (Corcoran and Brenglemann, 1970; Gailey *et al,* 1994; Pagliarulo *et al,* 1979; Peizer *et al,* 1969), while the average walking velocity of traumatic TTAs is approximately 71 m/min (Gailey *et al,* 1994; Pagliarulo *et al,* 1979). The subjects in this trial walked at a speed reflecting the average of these upper and lower limits. Ralston (1958) demonstrated that between 65-85 m/min there is no appreciable change in metabolic cost during ambulation. Moreover, none of the subjects in the trial reported feeling uncomfortable with the speed of their treadmill ambulation. The VO_2 of amputee subjects during treadmill ambulation was 13% greater than that of the non-amputee controls. This observation is consistent with prior reports of Pagliarulo *et al.* (1979) and Gailey *et al.* (1994) who reported a 16% difference in the metabolic cost of ambulation at self-selected pace, between traumatic TTA males and matched non-amputee controls.

It is important to note that the findings of this study may not be generally applicable to all amputee subjects and that the results of added mass may vary with stump length. However, stump lengths for subjects tested in this study were well within the accepted length for TTA (Epps, 190; Levy, 1983). Levy (1983) reported that 12.7-17.0 cm is the ideal TTA stump length. While most subjects in this trial had similar stump lengths (x = 15.9±5.8cm), the stump of one subject was much shorter (6.99 cm) and one much longer (27.94 cm). Nevertheless, observation suggests that the measured results for these subjects did not differ from those of other subjects. Also, young, healthy, adult male amputees who lost their limbs from non-vascular reasons were selected

for this study, as the intent was to measure the energy cost of their ambulation in the absence of confounding influences of vascular disease. In cases of vascular amputation, or procedures involving, trans-femoral or hip disarticulation amputations, the effect of prosthetic mass on energy cost may be more pronounced.

The authors have previous suggested that prosthetists have a "window of mass" in which to work when designing a prosthesis, and might use this window to fabricate limbs that include additional prosthetic components or accessories (Gailey *et al.*, 1994). This opinion is supported by the findings of this study. Prosthetic components such as rotators, mechanical ankle joints and shock absorbers may remain options for improved function and comfort without concern that the increased mass will adversely influence energy cost. Other options for prosthetic design include use of more durable covers or exoskeletal prostheses that may extend overall life of the prosthesis, and/or reduce their cost. While the findings of this study should not remove all concerns about designing heavier prosthesis, neither do they suggest that the mass of a prosthesis must reach minimum proportions to be considered "quality" or "high tech". The addition of more functional, comfortable and durable products to a prostheses, if acceptable to the amputee however, could become a greater consideration.

Conclusion

In conclusion, the addition of up to 907g of mass to the prostheses of non-vascular trans-tibial amputees does not alter the energy cost of ambulation at steady-state pace. Differences between unloaded trials result from habituation to the testing conditions. These findings suggest that prosthetists can design limbs using heavier components without significant increasing the amount of energy necessary to ambulate. The inclusion of components such as rotators, ankle joints, shock absorbers or more durable covers including exoskeletal designed limbs may allow traumatic trans-tibial amputees to improve their gait and function without compromising the energy cost of ambulation.

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Energy storage and release of prosthetic feet
Part 1: biomechanical analysis related to user benefits

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Abstract

The energy storing and releasing behaviour of 2 energy storing feet (ESF) and 2 conventional prosthetic feet (CF) were compared (ESF: Otto Bock Dynamic Pro and Hanger Quantum; CF: Otto Bock Multi Axial and Otto Bock Lager). Ten trans-tibial amputees were selected. The study was designed as a double-blind, randomised trial. For gait analysis a V1CON motion analysis system was used with 2 AMTI force platforms. A special measuring device was used for measuring energy storage and release of the foot during a simulated step.

The impulses of the anteroposterior component of the ground force showed small, statistically non-significant differences (deceleration phase: 22.7-23.4 Ns; acceleration phase: 17.0-18.4 Ns). The power storage and release phases as well as the net results also showed small differences (maximum difference in net result is 0.03 J kg). It was estimated that these differences lead to a maximum saving of 3% of metabolic energy during walking. It was considered unlikely that the subjects would notice this difference. It was concluded that during walking differences in mechanical energy expenditure of this magnitude are probably not of clinical relevance.

Ankle power, as an indicator for energy storage and release gave different results to the energy storage and release as measured with the special test device, especially during landing response. In the biomechanical model (based on inverse dynamics) used in the gait analysis the deformation of the material is not taken into consideration and hence this method of gait analysis is probably not suitable for calculation of shock absorption.

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Introduction

The general concept of energy storage and release of prosthetic feet is that they store energy during mid-stance and release the energy when it is desired, i.e. during push-off. These events are based on two major phases (Winter and Sienko, 1988) consistently seen in ankle power graphs in normal subjects. A long energy dissipation phase, A1, is thought to be a result of eccentric contraction of plantar flexors as the leg rotates forward over the flat foot, which is followed by a large energy generation phase, A2 (see Figure 4, sound side). This phase is due to concentric activity of the plantar flexors before toe-off. These parameters are calculated with the use of a biomechanical model, based on inverse dynamics.

In conventional prosthetic feet most of the stored energy is dissipated in the material. In so called energy storing feet most of the energy is said not to be dissipated in the material, but stored in the spring mechanism that should release it during push-off. Quantities of energy storage and release, as calculated from gait analysis, are not only dependent on the material

and construction of the prosthetic foot, but also on many variables concerning the user, such as walking speed and body weight. Besides, footwear has a major influence on the properties of prosthetic feet (Jaarsveld *et al,* 1990).

One of the main contributors in the calculations of energy storage and release is the ground reaction force. The pattern of the ground reaction force may be a valuable indicator, because different authors suggest that a larger energy release of the prosthetic foot, during push-off, results in an increase of the second maximum of the anteroposterior ground reaction force (Blumentritt *et al,* 1994; Wagner *et al,* 1987). This second maximum of the ground reaction force is a 'direct' measured parameter without being influenced by assumptions of a biomechanical model. However the literature is not unanimous and different authors were not able to confirm an increase in this parameter for energy storing feet (Arya *et al,* 1995; Barr and Siegel, 1992; Menard *et al,* 1992; Torburn *et al,* 1990 and 1995).

Kinematics and stride characteristics are often used to prove differences between conventional and energy storing prosthetic feet. Barr and Siegel (1992), Lehmann *et al.* (1993), Perry and Shanfield (1993) and Wagner *et al.* (1987) reported for the energy storing feet a statistically significant increase in the ankle range of motion, especially in late stance dorsiflexion. The increase in dorsiflexion range is probably dependent on the construction of the prosthetic foot. It is not clear however whether there is a relation between properties of energy storage and release and late stance dorsiflexion.

Aim of this part of the study

The aim of the study was to obtain a better understanding related to user benefits of energy storing and release behaviour of some prosthetic feet that are used regularly in patient care. It was clear that there were some subsidiary

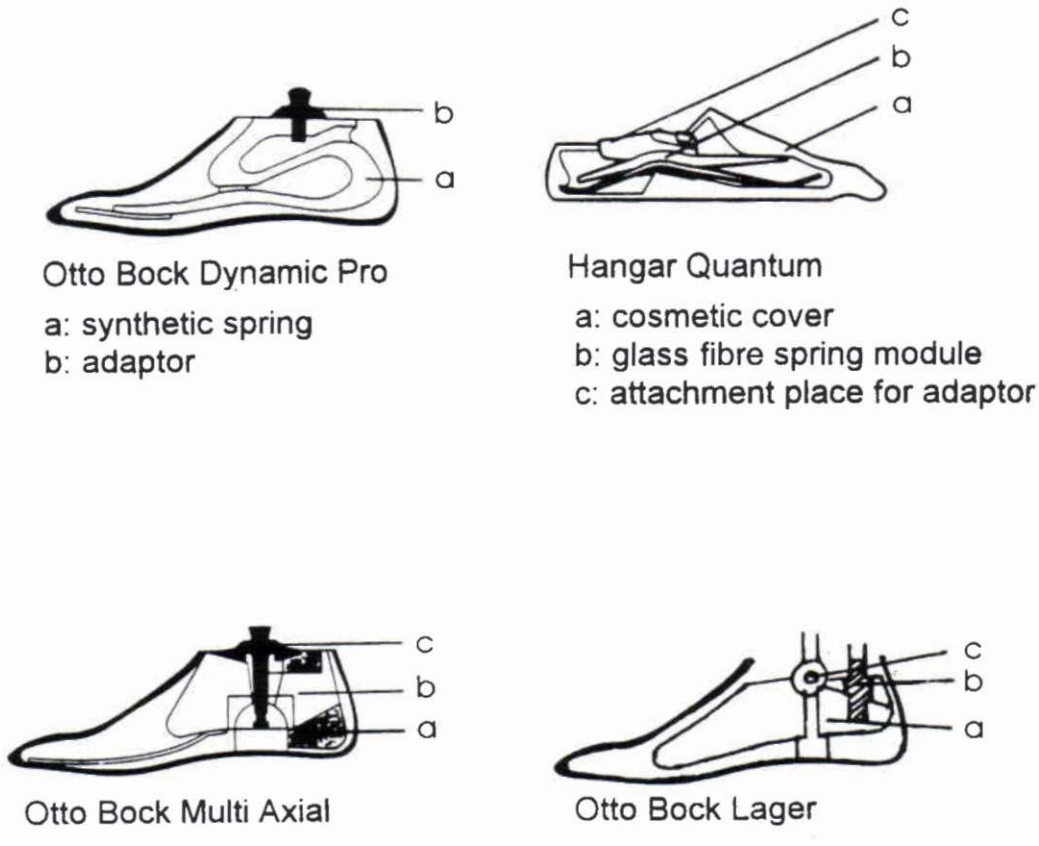


Fig 1. Basic constituents of 4 prosthetic feet.

questions which needed to be answered, such as:

- does gait analysis show differences in kinematic data and mechanical energy storage and release between so called energy storing feet and conventional feet when the feet are selected from the same price range? If differences do exist, are they clinically relevant?
- does energy storage and release as measured in a special test device (Biomedical Engineering Group of the University of Twente) with a standardized stance phase differ from the energy storage and release as calculated from the gait analysis? In other words what is the influence of the subject, in the laboratory situation, on the storage and release of energy of the prosthetic feet?

Materials and methods

Prosthetic feet

The following 4 designs of prosthetic feet were chosen, Otto Bock Multi Axial (CF1), Otto Bock Lager (CF2), Otto Bock Dynamic Pro (ESF1) and Hanger Quantum (ESF2). The first 2 are of a conventional variety and the other 2 are known to have energy storing properties. Some experienced orthopaedic technicians described the subjective characteristics of these 4 as follows:

- Otto Bock Multi Axial: stiff, mobile in sagittal and frontal plane.
- Otto Bock Lager: supple, mobile in plantar flexion direction (with ankle axis), stiff in dorsiflexion direction.
- Otto Bock Dynamic Pro: stiff in all directions.
- Hanger Quantum: very supple in all directions.

Figure 1 shows the basic constituents of the feet. The energy storing feet both show a spring mechanism while the others do not.

Since it is generally known that the properties of the shoe (e.g. stiff or supple) influence the properties of the prosthetic foot during walking all subjects were provided with the same brand of supple shoes.

Subjects

Ten trans-tibial amputees were selected. They were all active walkers who were able to walk at least 1 kilometre without any problem. None of the subjects had any stump problem. All subjects were informed in detail about the study and signed an informed consent form. Table 1 summarises the descriptions of the subjects.

Study design and data analysis

The study was designed as a double blind, randomised trial. Neither the investigator nor the subjects know which variety of foot was mounted on the prosthesis. A co-worker carried out the randomisation with the aid of a dice. The code was broken after the entire trial was completed. Every time a foot was supplied there was a habituation period of 2 weeks. The measurements were then carried out. After the measurements the foot was replaced with a different kind. Correct alignment of the prosthesis is very important because it influences the 'walking properties' of the foot and consequently the energy absorption and release. The feet were therefore always fitted and an alignment carried out by the same orthopedic technician who was not otherwise

Table 1. Description of subjects

Subject	M/F	Age (years)	Body-weight (kg)	Years since amputation	Reason for amputation	Own prosthetic foot
01	m	34	87	16	traumatic	Quantum
02	m	34	85	34-24 (reamputation)	congenital	Seattle
03	m	63	95	28	traumatic	Quantum
04	f	52	64.5	26	traumatic	Seattle
05	m	58	82	23	traumatic	1H32
06	m	66	84	46	traumatic	Endolite
07	m	50	82	20	traumatic	Endolite
08	m	43	80	23	traumatic	1D10
09	m	50	76	2	vascular	1D10
10	m	42	85	31	traumatic	1H32

involved in the trial.

Gait analysis

All the measurements were carried out at the Roessingh Research and Development Laboratory based at Het Roessingh, Centre for Rehabilitation. The gait analysis was carried out using a VICON motion analysis system (Oxford Metrics Ltd, Botley, Oxford, UK). The system consisted of 5 standard ccd cameras fitted with infrared filters linked to an Etherbox data acquisition system and a host computer (Micro VAX 3100). AMASS software for three-dimensional data collection was used for capturing kinematic data. The marker detection rate was 50 Hz. Two AMTI force platforms, operating at a sampling rate of 200 Hz, were used in conjunction to determine the ground reaction forces. VICON Clinical Manager software as used to compute walking speed, kinematic and kinetic data.

During the gait analysis 13 reflective markers were taped to both sides of the body at designated anatomical landmarks such as the sacrum, hips, upper legs, knees, lower legs, ankles and at the dorsal aspect of the metatarsal phalangeal joint II.

The subject was positioned at the end of the walkway and was asked to walk at a comfortable speed (free velocity). The distance between the force platforms was adapted, based on estimated step length of the subject, to accomplish a clean foot strike on each force platform. The walkway was 10 metres long but only a length of 4 metres in the middle of it was designated for data collection. The subjects were not informed about the use of the force platforms and they were not asked to hit them. At each session 10 trials were selected in which both feet hit the force platforms cleanly. Using the VICON Clinical Manager an average of the 10 trials was calculated. Then the kinematics and kinetic parameters were ascertained. Walking speed and cadence were measured in order to determine if differences exist which are likely to influence the ground reaction force.

The following parameters were calculated from the gait analysis:

- walking speed.
- cadence (step.min^{-1}).
- range of movement at hips, knees and ankles, with early stance plantar flexion and late stance dorsiflexion.
- impulse of deceleration and acceleration phase of the anteroposterior component of the ground reaction force. The impulse is the time-integral between the zero crossings.
- energy storage (Al phase), release (A2 phase) and final net values are calculated from the total ankle power.

Hysteresis

Hysteresis (internal friction) of the material of a prosthetic foot results in loss of energy when variable loading on the foot is applied. This loss of energy for the 4 test feet was measured using a special test device of the biomedical Engineering Group of the University of Twente, as described by Van Jaarsveld[1] *et al.* (1990), but with the difference that the foot is loaded continuously while rotating from heel to forefoot (artificial roll-off movement). All of the feet were of the same size and were mounted on the test device with the same shoe.

Energy is calculated as the integral of force with respect to displacement. The force generated by the test device was equal to the measured vertical ground reaction force as a function of the shank floor angle of a subject (amputee, good walker) of mass 80 kg. The displacement was taken as the deformation of the foot as a result of this applied force. The horizontal ground reaction force was not applied. In this study the angle between the shank and the floor was 32° at initial floor contact and 40° at toe-off.

Figure 2 shows the graph of energy storage and release as measured with the test device. It shows the amount of energy (J, Y-axis) against shank-floor angle (X-axis). Initially there is storage of energy by the hindfoot during landing (shock absorption) as indicated by the downward direction of the graph during early stance (A). The amount of energy stored (A') is a measure of the stiffness of the hindfoot. The less the energy stored the stiffer is the hindfoot. From foot-flat to mid-stance (B) some energy is returned (B'). The amount of energy which is not returned (B") is mainly dissipated although part might be transferred to the forefoot and returned during push-off. However, it is assumed that the amount of energy transferred to the forefoot in this way is negligible. After mid-stance until push-off (C) the origin of the ground reaction force shifts to the forefoot. The

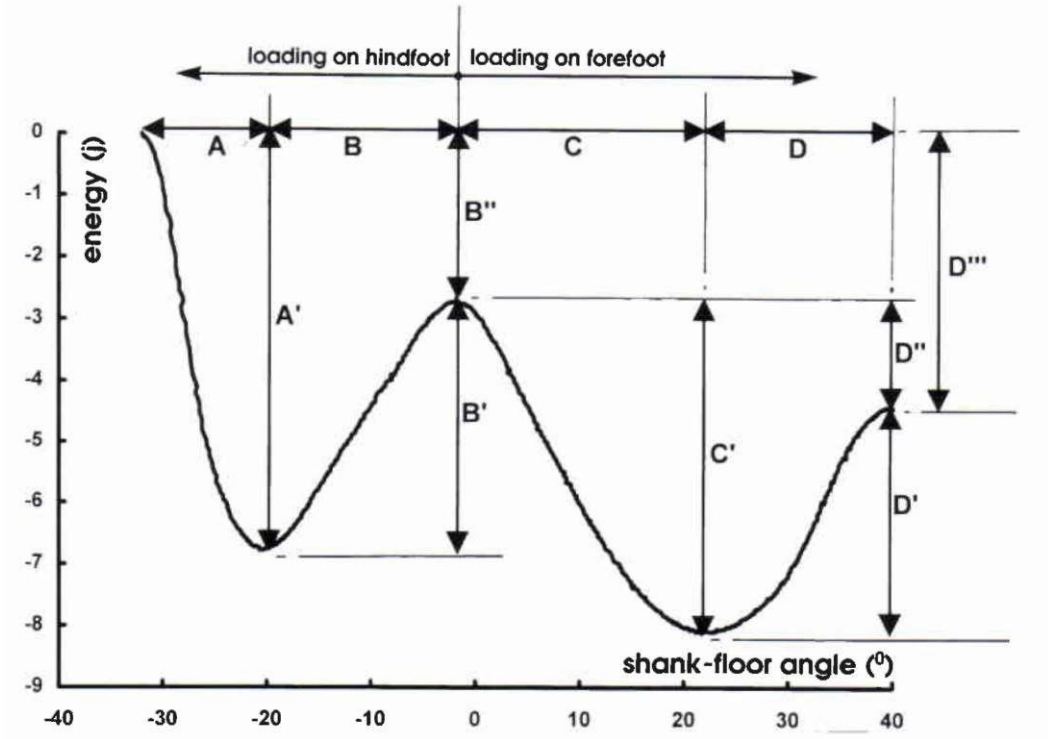


Fig. 2. Energy storage and release of a prosthetic foot, as measured with the test device (for explanation see text).

forefoot is deformed and therefore stores energy. The amount of energy stored (C) during the latter half of the stance phase (from mid-stance until push-off) is a measure of the stiffness of the forefoot. During push-off (D) part of that energy is returned (D'). The difference between the value at mid-stance and the value at toe-off (D") is the energy loss as a result of absorption of energy at the forefoot. B"+D" gives the amount of the total loss of energy, due to absorption.

Statistics

For statistical calculations multivariate analysis of variance was used with repeated measures' design with difference contrast. Thus the results for the different feet of every subject are compared within this subject, the only within subject factor was the type of prosthetic foot.

Results

One subject did not show up for the measurements with one of the feet. This resulted in a missing value. All statistical procedures, concerning the gait analysis, were performed on the results of 9 subjects.

Walking speed and kinematic data

Walking speed and kinematic data are shown in Table 2. During every session the subjects were asked to walk at a comfortable walking speed.

The mean walking speed was almost the same for the 4 feet (1.3-1.36 ms^{-1}). The mean difference between the 4 feet was 0.02m s^{-1}.

The mean cadence was almost the same for the 4 feet (0.87-0.88 steps min^{-1}). The mean difference between the 4 feet was 0.01 steps min^{-1}.

The range of motion of the hip with the CF2 was statistically significantly ($p=0.04$) larger than with the ESF1 and the CF1. The difference was less than 2°.

The range of motion of the knee showed no statistically significant differences between the 4 feet ($p=0.117$). The range of motion at the ankle with the CF2 was greater than that of the other 3 feet. The difference was statistically significant ($p=0.003$). The larger range of the

Table 2. Walking speed and kinematic data of amputated side; mean values and standard deviations.

Kinematic data	ESF1 (s.d.)	ESF2 (s.d.)	CF1 (s.d.)	CF2 (s.d.)
walking speed (m s^{-1})	1.35 (0.20)	1.34 (0.21)	1.36 (0.19)	1.34 (0.20)
cadence (steps min^{-1})	0.88 (0.07)	0.88 (0.06)	0.88 (0.05)	0.87 (0.07)
hip ROM (^{0})	46.6 (5.0)	46.7 (4.8)	45.6 (4.4)	47.3 (4.7)*
knee ROM (^{0})	65.2 (7.7)	62.4 (13.5)	58.1 (12.6)	60.0 (11.9)
ankle ROM (^{0})	16.8 (3.6)	17.2 (2.8)	17.2 (3.8)	21.2 (2.6)*
late stance dorsiflexion (^{0})	13.4 (2.9)	13.7 (2.5)	12.4 (3.0)	11.9 (2.2)
early stance plantar flexion (^{0})	3.4 (1.6)	3.2 (1.5)	5.3 (2.1)	9.4 (3.6)*

*Statistically significant.

motion with the CF2 was probably due to the ankle mechanism, which allows the foot to make a plantar flexion movement directly after heel contact. The early stance plantar flexion with the CF2 was 9.4°, while for the other feet this motion was 4 to 6° smaller (p=0.001). There was no statistically significant difference in late stance dorsiflexion for the 4 prosthetic feet (p=0.145).

Anteroposterior component of the ground reaction force

Table 3 gives the averages of the impulses of the anteroposterior component of the ground reaction force in the deceleration phase and in the acceleration phase. The measurements with the 4 prosthetic feet did not show any statistically significant difference in the impulses of the deceleration (p=0.307) or acceleration (p=0.179) phase.

Energy storage and release as calculated from the total ankle power

Table 4 gives the mean values of energy storage during phase Al and energy release during phase A2 with all prosthetic feet, calculated from the total ankle power. The mean storage of the ESF2 (0.17) was more than that of the other feet (which varied from 0.13 to 0.15 J kg^{-1}). The differences however were not statistically significant (p=0.675). The differences in the release of energy, between the 4 feet, were smaller (0.03-0.05 J kg^{-1}).

However these differences were statistically significant. The release of energy of the ESF2 was greater than that of the CF2 (p=0.026) and the release of energy of the ESF1 was greater than that of the other feet (p=0.025). The net result of the energy storage and release gives the absorption during the Al and A2 phases. There were only small differences in the net results of the energy storing and releasing phases and these differences were not statistically significant (p=0.549).

Energy storage and release as calculated with the special test device

Figure 3 gives the curves of the energy storage and release of 4 prosthetic feet (same size, same shoe). It shows the amount of energy (J, Y-axis) needed to reach a specified shank angle (X-axis). The values are given in Table 5.

Table 3. Impulses (N s) of the deceleration and acceleration phases of the anteroposterior ground reaction forces with standard deviation shown in brackets.

Phase	ESF1 (s.d.)	ESF2 (s.d.)	CF1 (s.d.)	CF2 (s.d.)
Deceleration	22.7 (4.5)	23.1 (4.2)	23.4 (4.2)	23.1 (3.9)
Acceleration	18.4 (3.9)	17.0 (3.5)	18.3 (4.1)	17.6 (4.1)

Table 4. Energy storage (A1 phase), energy release (A2 phase) and net results (A1 and A2) of the ankle in J kg^{-1} with standard deviation between brackets

Energy	ESF1 (s.d.)	ESF2 (s.d.)	CF1 (s.d.)	CF2 (s.d.)
storage (A1)	0.125 (0.03)	0.17 (0.02)	0.13 (0.06)	0.15 (0.10)
release (A2)	0.05 (0.02)	0.04 (0.02)	0.04 (0.01)	0.03 (0.02)
absorption (net result A1 and A2)	0.10 (0.02)	0.12 (0.02)	0.09 (0.05)	0.12 (0.09)

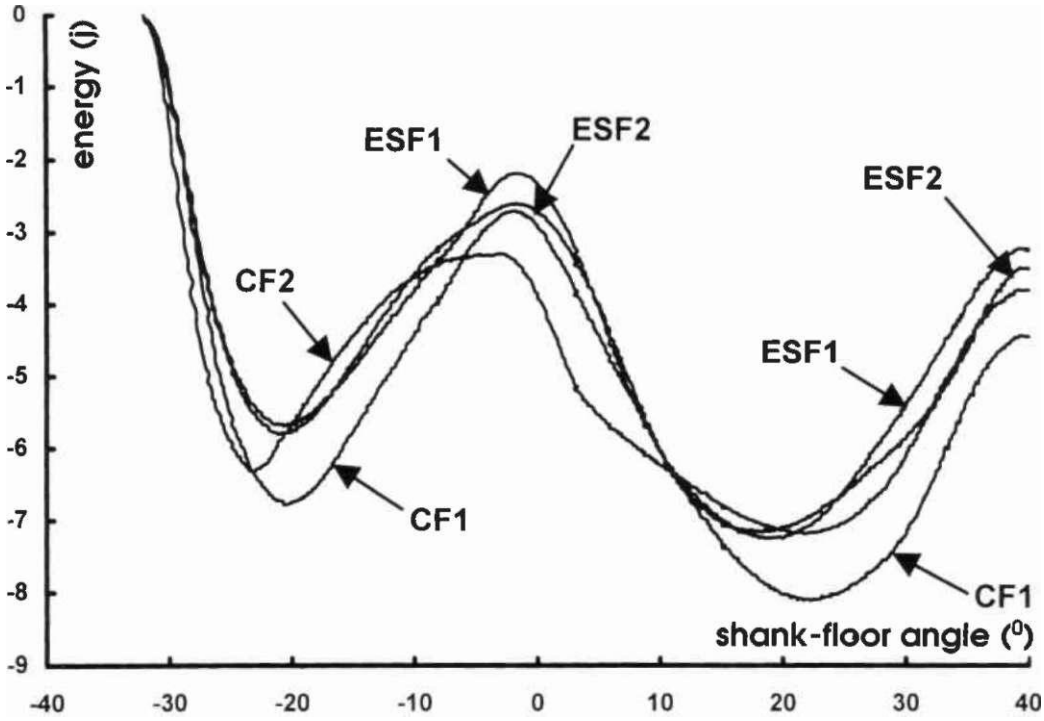


Fig. 3. Energy storage and release of 4 prosthetic feet: ESF1 (Otto Bock Dynamic Pro), ESF2 (Hanger Quantum), CF1 (Otto Bock Multi Axial), CF2 (Otto Bock Lager) as measured with the test device (J).

The results can be summarised as:

- hindfoot, energy storage (A'): the hindfoot of both non-energy storing feet store more energy.
- hindfoot, energy release (B'): most energy was released by the CF1.
- hindfoot, energy dissipation: the largest dissipation of the hindfoot, was found in the CF2. Both energy storing feet showed the lowest dissipation.
- forefoot, energy storage (C): the forefoot of the CF1 stored the most energy, while the CF2 stored the least energy.
- forefoot, energy release (D'): most energy was returned by the ESF1.
- forefoot, energy dissipation (D"): lowest dissipation was in the CF2 and highest in the CF1.
- total dissipation (B"+D"): this was lowest for the ESF1 and highest for the CF1.

Table 5. Energy storage and release as measured with the test device. The values are in J for a subject of 80 kg mass. In brackets are the values per kg body mass.

Foot	A'	B'	C'	D'	E'	F'	G"
ESF1	5.7 (0.071)	3.5 (0.044)	2.2 (0.028)	5.0 (0.063)	4.0 (0.050)	1.0 (0.013)	3.2 (0.040)
ESF2	5.8 (0.073)	3.1 (0.039)	2.7 (0.034)	4.5 (0.056)	3.7 (0.046)	0.8 (0.010)	3.5 (0.044)
CF1	6.8 (0.085)	4.0 (0.050)	2.8 (0.035)	5.3 (0.066)	3.7 (0.046)	1.6 (0.020)	4.4 (0.055)
CF2	6.3 (0.079)	3.0 (0.038)	3.3 (0.041)	3.9 (0.049)	3.4 (0.043)	0.5 (0.006)	3.8 (0.048)

A'=energy stored hindfoot
B'=energy release hindfoot
B"=dissipation hindfoot (A'-B')
C'=energy storage forefoot
D'=energy release forefoot
D"=dissipation forefoot (C'-D')
B"+D"=total dissipation

Discussion

Walking speed and kinematic data

Walking speed and cadence: in the laboratory situation the mean of the differences of walking speed and cadence were so small that it is assumed that it is unlikely these differences influenced the parameters which are based upon the ground reaction force. This is in agreement with most reports in literature.

Hip and knee range of motion: in the results reported here the CF2 showed a very small, but statistically significant (p=0.040) larger hip range of motion than the ESF1 and the CF1. The difference however was so small that it hardly could be of clinical importance. The differences of the knee range of motion were much bigger, but these differences were statistically not significant (p=0.117).

Ankle range of motion: most studies demonstrate an increase in the range of motion of the ankle of energy storing feet (Barr and Siegel, 1992; Lehmann *et al.,* 1993; Perry and Shanfield 1993; Wagner *et al.,* 1987).

The results reported here were different from these findings. It was found that the range of motion at the ankle of the CF2 was clearly and statistically significantly (p=0.003) greater than the range of motion at the ankle of the other feet. This was probably due to the ankle mechanism in this foot.

Looking at the ankle motion, the total range is the sum of motions during early stance in the plantar flexion direction, and then in late stance in dorsiflexion. The early stance plantar flexion of the CF2 was clearly and statistically significantly greater than that of the other feet (p=0.001).The early stance plantar flexion of the CF1 was greater than that of the ESF1 and the ESF2 (p=0.050). Both conventional feet (with ankle axis) showed greater early stance plantar flexion motion. The late stance dorsiflexion motion in the ankle showed no statistically significant difference (p=0.145). Various authors have reported a greater late stance dorsiflexion for energy storing feet. However, mostly the SACH foot was used as the conventional foot, while probably other conventional feet, especially those with an ankle joint, would have shown a greater range of motion at the ankle. Besides an ankle axis, the stiffness of the foot also will have an influence on the range of motion at the ankle.

Not only foot-related factors play a role in the range of motion at the ankle. Different authors hag reported that the physical condition of the amputee, traumatic amputees versus vascular amputees, is an important influence on gait parameters such as the late stance dorsiflexion and walking speed (Barth *et al.,* 1992; Casillas *et al.,* 1995; Hermodsson *et al.,* 1994; Torburn *et al.,* 1990). This means that the more active the subject, the more late dorsiflexion he needs/makes. In the authors' study the group of subjects was too small and too homogeneous (all active walkers) to enable this to be confirmed.

Importance of late stance dorsiflexion

It can be argued that the late stance dorsiflexion of the prosthetic foot is related to balance control. Balance control is, among other things, dependent on proprioceptive feedback. Proprioceptive feedback is impaired in patients suffering from polyneuropathy (i.e. due to diabetes).

An increase in late stance dorsiflexion results in an increase of knee flexion moment and thereby decreases knee stability. With poor balance control this leads to unsafe situations and therefore these amputees prefer prosthetic feet which allow only limited late stance dorsiflexion. This is in agreement with the conclusion of Casillas *et al.* (1995) that 'the vascular patient seeks easy proprioceptive support control on the amputated side - in other words, maximum safety'. Late stance dorsiflexion permits a supple roll-off movement. With limited dorsiflexion the roll-off movement will be impaired. Most active walkers do not prefer this, they prefer a supple roll-off. High level active subjects, without impairment of balance control, therefore should be provided with a prosthetic foot which allows a wide extent of dorsiflexion (Barth *et al.,* 1992).

Energy storage and release

In the literature different methods are described to assess energy storage and release of prosthetic feet. Some authors calculated an efficiency parameter from energy storage and release (Barr and Siegel, 1992; Schneider *et al.,* 1992). The energy release is expressed as a percentage of that stored. This is a relative parameter which gives information about the properties of the foot materials. However it

gives no information about the absolute quantities of energy storage and release and thus it gives no information about the amount of energy dissipation which in the authors' opinion is essential with respect to energy expenditure.

Others consider the sum of the absolute values of the Al and A2-power bursts as a measure of efficiency (Ehara *et al,* 1983; Goh *et al,* 1994). With respect to energy expenditure however this gives no clear information, because the 'same energy' is appraised twice (first during the storing phase and secondly during the releasing phase).

Sacchetti *et al* (1994) looked at both bursts (Al and A2) separately and also at the net value of both bursts as a measure of energy storing and releasing capacities of the prosthetic foot. In this way information about energy storage and release, as well as total amount of dissipation is obtained. The authors consider this is preferable and therefore used this method of describing and discussing energy storage, release and dissipation.

This study showed only little differences in energy storage, release and dissipation, despite the differences in construction of the conventional and energy storing feet. The storage during the Al phase showed no statistically significant differences between the 4 feet. The differences in energy release during the A2 phase were even smaller, however, statistically significant. The net results also did not show a statistically significant difference. It is possible that with a greater number of subjects the differences in energy storage and in the final net results also become statistically significant. Even if this were true, are differences of this size of clinical relevance? A lower leg amputee needs ± 10% more energy than a normal subject. A normal subject needs about 3.1 to 3.3 J $kg^{-1}m^{-1}$ and a lower leg amputee needs about 3.4 till 3.6 J kg m of metabolic energy to walk at a speed of 5 km h^{-1} (Corcoran 1971; Donn and Roberts, 1992). A stride, about 1.5 m long, needs 5.1 till 5.4 J kg^{-1}. The biggest difference in the net absorption between the 4 feet was 0.03 J kg per stride (mechanical energy). This means that the subject needs 0.03 J kg less for walking with the foot with the least net absorption. The power, necessary for walking, is the result of muscle activity. By a rough estimation, the efficiency of muscles is 20 to 25%. Therefore to supply 0.03 J kg^{-1} effectively for walking, the muscles have to raise 0.12 to 0.15 J kg^{-1}, which is less than 2.5 to 3% of the energy needed for 1 stride. There does not appear to be data in the literature identifying the difference in the expenditure of metabolic energy which can be noticed by subjects, while walking at comfortable speed. It is however unlikely that subjects notice such small differences during normal walking, or that a gain of this size is of clinical importance. Only at the top level of sport could differences of this size be of importance.

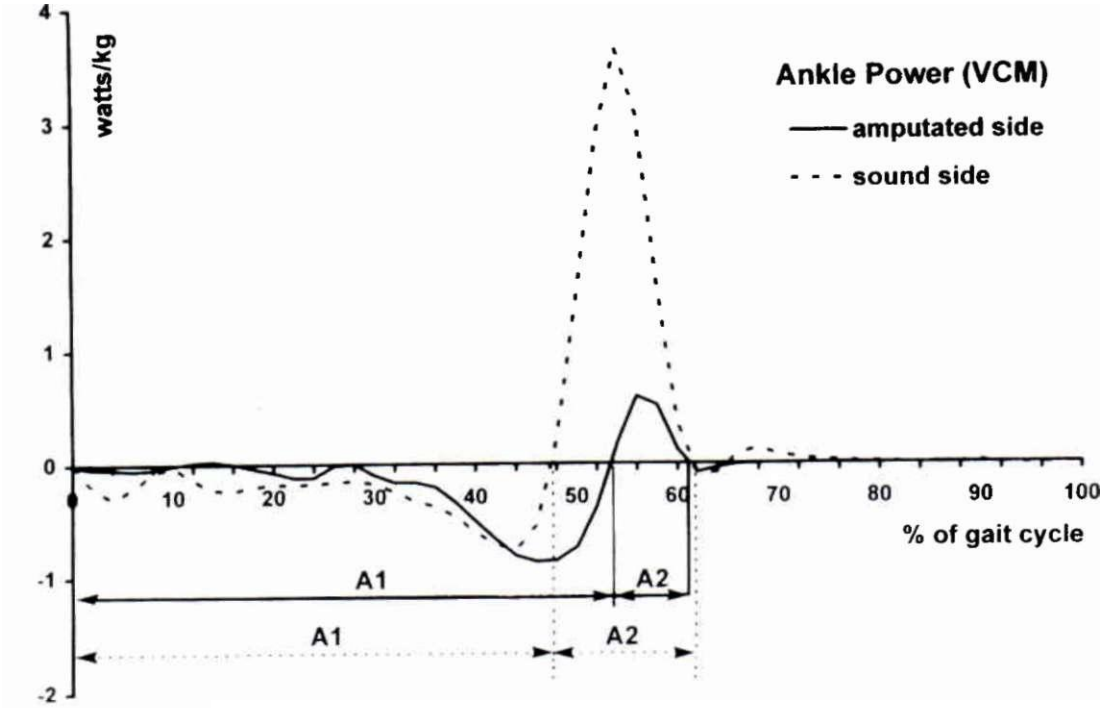
Gait analysis versus test device

A comparison of the energy storage and release of the hindfoot, as shown in the graph of the total ankle power and as shown in the graph of the test device showed some remarkable differences. Figure 3 shows the pattern of mechanical energy storage of the hindfoot, as measured with the test device. The storage takes place at heel loading. It is directly followed by a release of a part of the stored energy, until mid-stance. Although the storage of energy in the hindfoot during loading was a little larger for both conventional feet, the subjects did not experience a clear difference during heel loading. The storage and release of energy during the first part of the stance phase, as measured with the test device, was not seen in the graph of the ankle power, as is shown in Figure 4.

The reason for the observed difference of energy absorption during loading seems to be twofold. Firstly: the special test device uses for calculation forces and displacement, caused by deformation of the heel. The gait analysis uses for calculation an inverse dynamic model, based on rigid bodies approximation. This model does not take into consideration the deformation, and therefore it maybe not accurate enough to measure absorption during loading. Secondly: the accuracy of the gait analysis measuring system may be insufficient to cope with this problem.

It is concluded that the A1-power burst, as described by Winter and Sienko (1988), seems to contain only limited information about the amount of stored energy during shock absorption. Therefore it is not appropriate to consider the A1-power burst as an adequate indicator of energy storage caused by shock absorption.

The shock absorption however seems to be important in relation to comfortable walking since it has been proven that trans-tibial amputees prefer prosthetic feet which develop greater



A1=energy storage
A2=energy release

Fig.4. Total ankle power
X-axis: % gait cycle
Y-axis: Watts kg^{-1}, (pos=release; neg=storage)

damping at loading, in other words more energy dissipation (Wirta *et al,* 1991). This means that a lower net energy storage and release is not automatically related to a 'better' foot.

Both measurement systems were also compared in relation to the data of the energy storage and release of the forefoot.

The absolute data calculated from the Al and A2 phases of the ankle power and the test device showed some striking differences. The amount of storage as measured with the test device is 2 to 3 times smaller than is calculated from the Al phase, while the amount of energy release is about equal for both measurement systems. The net results, storage minus release, of the test device were about 10 times smaller than those of the Al and A2 phases.

These differences cannot be explained only by influences on the subjects such as different walking pattern, speed, non-linear weight influences etc., which are measured automatically in the gait analysis, but not with the test device. It is likely that differences in method of calculation of the 2 measurement systems and possibly differences in accuracy, are mainly responsible.

Conclusion

When comparing the 2 energy storing and the 2 conventional feet, there are no clear differences in kinematic data or in kinetic data. The range of motion at the ankle of the CF2 is bigger than that of the other feet, but this is due to the ankle mechanism and not to energy storing features.

The differences in mechanical energy storage and release (net results), as calculated from the ankle power, are small and not significant; the mean net absorption of the ESF1 is smallest. It is unlikely that differences in net dissipation of energy of the magnitude found in this study can be noticed during normal walking and therefore these differences are probably not clinically relevant.

The data of the test device (simulated stance phase) are in favour of the 2 energy storing feet. The total dissipation of energy for both ESF is less than for the CF. The size of the differences however, are again small and are unlikely to be clinically relevant.

During loading, energy is absorbed by the deformation of the foot material. This is measured with the test device (integral of force with respect to displacement) but not with the gait analysis system which uses for calculations an inverse dynamic model, based on rigid bodies approximation. Therefore this kind of gait analysis may not be suitable for calculation of energy storage due to shock absorption.

With respect to energy expenditure, in normal walking, energy storage and release of the prosthetic foot, seem only to be important when the gain in net absorption is much larger than for the energy storing feet in this study. A wooden foot would give the 'best' results (almost no energy storage, nor energy release) but would be also very uncomfortable, among other things, due to lack of energy absorption during loading and the fixed roll-off.

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Energy storage and release of prosthetic feet Part 2: subjective ratings of 2 energy storing and 2 conventional feet, user choice of foot and deciding factor

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Abstract

This paper is the second part of a study on biomechanical and functional properties of prosthetic feet. The first part dealt with a biomechanical analysis related to user benefits. This part deals with subjective ratings and deciding factors for trans-tibia] amputees using 2 energy storing feet (ESF) and 2 conventional feet (CF).

The Otto Bock Dynamic Pro and Hanger Quantum feet were used as ESF and the Otto Bock Multi Axial and Otto Bock Lager feet were used as CF. Ten trans-tibial amputees, active walkers, without stump problems, were selected (mean age: 49 years old). The study was designed as a double-blind, randomised trial and for each foot there was a habituation period of 2 weeks.

Two questionnaires were designed. (A) concerned information about the preference of the subjects and (B) concerned the order of importance of difference aspects concerning a prosthesis.

Results indicated that no clear preference for either the ESF or the CF existed and that the individual preference is not related to age. The items 'ability to walk fast' and 'no fatigue during walking', score statistically significantly worse for the CF2. With the small contrast between the ESF and CF, in relation to energy storing capacities, the subjects cannot distinguish between the ESF and CF. The 'absence of stump pain' and 'stability while walking' are ranked as most important aspects concerning a prosthesis. The perception of stability is likely to be related to the level and kind of activities the subject performs.

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Introduction

More and more leg amputations are performed mainly due to the growing number of the elderly. In the Netherlands a steady increase is seen in the number of leg amputations (SIG, 1995). Between 1991 and 1994 the incidence increased from 0.16 to 0.17 per thousand inhabitants (2,457 amputations in 1991 and 2,618 in 1994). A further increase is expected.

Up to now in the Netherlands a prosthetist and a doctor together make the total prescription for the prosthesis. But it is realised more and more that amputees have to be involved in this decision because their demands on function, comfort and cosmesis of the prosthesis ought to weigh heavily in the choice of different parts of the prosthesis. Therefore not only are rates of satisfaction about function, comfort and cosmesis of amputees required, but also an insight into which aspects concerning the prosthesis amputees rate as important.

In the literature scant attention is given to subjective ratings of various feet, personal choice of foot and deciding factors concerning that choice.

Prosthetic Profile of the Amputee (PPA) Questionnaire is a validated questionnaire about

factors potentially and actually related to prosthetic use (Grise *et al,* 1993; Gauthier-Gagnon and Grise, 1994). It gathers information about physical condition, the prosthesis itself (comfort, weight, appearance and so on), prosthetic use, environment, leisure activities and general activities. This kind of information is important for judgment and function of the prosthesis and for screening and evaluation of treatment programmes. It is not meant to give information about the rating of importance, given by the amputee, to the different factors such as function, comfort and cosmesis.

The structured questionnaires from Alaranta *et al.* (1991 and 1994) (4-point rating scale) and the 20-point rating scale of Borg as used by Macfarlane *et al.* (1991) were developed in order to gather information about functional aspects of the prosthesis.

Different studies in the literature report the preferences of the subjects involved. These preferences are based mainly on a kind of open interview. Limited reasons are given for the preferences with no insight into the order of importance of different factors (Buchold, 1991; Burgess *et al,* 1987; Lehmann *et al,* 1993; Menard *et al,* 1992; Nielsen *et al,* 1989; Sacchetti *et al,* 1994; Wirta *et al,* 1991).

Aspects of subjects and prosthetic feet which are mentioned in the literature to determine the preference of the subject are: level of activity, age, body weight, cosmetic appearance, flexibility at loading (shock absorption), plantar flexion directly after loading, dorsiflexion during stance phase, springiness of the foot at push-off phase, balance and stability (Alaranta *et al,* 1991 and 1994; Casillas *et al,* 1995; Ehara *et al,* 1993; Goh *et al,* 1984 and 1994; Macfarlane *et al,* 1991; Nielsen *et al,* 1989; Lehmann *et al,* 1993; James and Stein, 1986).

Aim of this part of the study

- What differences do the users experience between the 4 varieties of test foot?
- What is the order of importance, as given by the users of different factors concerning the prosthesis?

Materials and methods

Prosthetic feet

The following 4 designs of prosthetic feet were chosen, Otto Bock Multi Axial (CF1), Otto Bock Lager (CPF2), Otto Bock Dynamic Pro (ESI) and Hanger Quantum (ESF2). These are described in Part 1 of this study (Postema *et al,* 1997).

All subjects were provided with the same brand of supple shoes.

Subjects

Ten trans-tibial amputees were selected as described in Part 1, Table 1 of this study (Postema *et al,* 1997).

Study design and data analysis

The study was designed as a double blind, randomised trial as described in Part 1 of this study (Postema *et al,* 1997).

Questionnaires

There was no ready-made questionnaire available to address the questions in this study. Therefore 2 questionnaires were composed. The first one (A) was used to obtain information about the preference of the subjects and the second one (B) was used to get a better understanding of the order of importance to the user of different aspects of the prosthesis.

Questionnaire A

This questionnaire consisted of 27 questions that were grouped in 4 categories. After thorough discussions with some experienced rehabilitation physicians and trans-tibial amputees it was revised.

The 4 categories were:

1. stability while standing (on the level and on a slope);
2. stability while walking (on the level and on a slope);
3. functional factors (e.g. ability to walk quickly, powerful/powerless push-off, suppleness of roll-off, no fatigue during walking);
4. special activities (e.g. stair climbing, squatting).

The questions were answered in the form of a score in an increasing scale from 0 to 10 (best possible score 10). Since it is not completely known from the literature which factors are more important, all questions received the same weighting. The mean score of all questions was supposed to be the general score for a foot, and these scores were used to put the 4 feet in a ranking order. Also the ranking order for the different categories was calculated.

Table 1. Factors concerning a prosthesis, in alphabetic order.

Factors concerning a prosthesis
ability to climb the staircase
ability to walk quickly
easy turning on the prosthetic leg
feeling of firm contact with the ground
no fatigue during walking
cosmetically good walking pattern
painless stump
possibility of squatting
powerful push-off
rolling-off in a supple way
stability in stance
stability while walking

Questionnaire B

Taking into consideration literature and after extensive discussions with trans-tibial amputees and experienced rehabilitation physicians, 12 factors which were relevant for the function of a prosthesis, were selected (Table 1). The meaning of each factor was explained to the subject. The factors were then coupled to each other resulting in 66 pairs. The subjects were asked to mark the more important factor from each pair. The marked factor from each of the pairs received a score of 1.

Statistics

The results in Questionnaire A represent subjective opinions of the amputees that are likely to be dependent on characteristics of these users. For instance one subject may always score higher or lower than another subject. Therefore mean scores and standard deviations were not used for statistical calculations, but multivariate analysis of variance with repeated measures' design with difference contrast. The only within subject factor was the type of prosthetic foot.

Table 2. Mean total scores from the questionnaire for each foot, with standard deviations between brackets.

Foot	Mean total score (s.d.)
ESF1	7.4 (1.9)
ESF2	7.3 (1.5)
CF1	7.3 (1.5)
CF2	7.0 (1.8)*

(*statistically significant).

Table 3. Mean scores with standard deviations of the 4 categories of the questionnaire with standard deviations between brackets.

Category	Foot	Mean (s.d)
1. stability in stance	ESF1	7.1 (1.8)
	ESF2	7.1 (1.4)
	CF1	7.0 (1.4)
	CF2	6.9 (1.6)
2. stability while walking	ESF1	7.2 (1.9)
	ESF2	7.1 (1.3)
	CF1	7.0 (1.3)
	CF2	6.8 (1.6)
3. functional aspects	ESF1	7.9 (2.4)
	ESF2	7.7 (2.6)
	CF1	8.1 (1.9)
	CF2	7.3 (2.1)*
4. special activities	ESF1	7.3 (1.3)
	ESF2	7.1 (1.3)
	CF1	7.2 (1.0)
	CF2	6.9 (1.7)

(*statistically significant).

Questionnaire A

The mean total scores for the 4 feet showed only little differences, as shown in Table 2. The score for the CF2 was however statistically significantly lower than the scores for the other feet ($p=0.006$).

In Table 3 the categories of Questionnaire A are listed with the mean scores and standard deviations for each variety of test foot. There were no significant differences among the 4 feet for the categories 1 ($p=0.927$), 2 ($p=0.356$) and 4 ($p=0.469$). In category 3 (functional factors) the score of CF2 was statistically significantly lower than the scores of the other feet ($p=0.008$). Two factors were responsible for this, namely 'ability to walk fast' and 'no fatigue during walking'. Scores for these factors are given separately in Table 4.

Table 4. Mean scores with standard deviations between brackets for 2 factors

	Ability to walk fast	No fatigue during walking
ESF1	7.7 (2.22)	8.2 (2.6)
ESF2	7.4 (1.8)	7.7 (3.3)
CF1	7.6 (1.4)	9.0 (2.2)
CF2	6.5 (1.8)*	7.4 (2.1)*

(*statistically significant).

Ability to walk fast

The mean score of CF2 was significantly lower than that of the other feet (p=0.048). The conventional foot CF1 however scored almost best and hence it cannot be concluded that the score of the conventional feet was clearly worse than that of the energy storing feet.

Fatigue

The score of CF2 was significantly lower than the scores of CF1 and ESF1 (p=0.046). It was striking that the CF2 scored worst for 'no fatigue during walking' as well as for 'ability to walk fast'.

Each subject could rank the feet in order of choice. First choice: seven of the 10 subjects showed a preference for an energy storing foot (4 xESFl and 3 x ESF2) and only 3 subjects preferred a conventional foot (2 x CF1 and 1 x CF20. The second foot in ranking order was seen as second choice. Table 5 shows the order of choices. The mean scores for the first, second, third and fourth choice are respectively 8.2, 7.8, 7.2 and 6.5.

Questionnaire B

With this questionnaire the different factors were ranked in order of importance. The mean ranking scores, with standard error of the mean, for each factor are shown in Table 6. The minimum is 0 (not important at all) and the maximum is 11 (most important). The subjects ranked the factors 'absence of pain' and 'stability while walking' as very important, while the possibility of squatting was almost not important at all.

Table 5. Order of foot choice of the subjects (n=10),

Subject	Order of foot choice			
	1st	2nd	3rd	4th
01	ESF2	ESF1	CF2	CF1
02	ESF1	CF1	ESF2	CF2
03	ESF1	CF2	ESF2	CF1
04	ESF2	CF1	ESF1	CF2
05	CF2	ESF1	CF1	ESF2
06	CF1	ESF2	CF2	ESF1
07	ESF1	CF1	CF2	ESF2
08	ESF1	ESF2	CF2	CF1
09	ESF2	CF2	ESF1	CF1
10	CF1	CF2	ESF2	ESF1

Table 6. Ranking of importance of aspects in perception of the subjects with standard error of the mean between brackets,

Aspects	Ranking (S.E. of the mean) (maximum ranking 11)
absence of stump pain (n=9)	8.9 (0.72)
stability while walking	8.7 (0.56)
no faigue during walking	7.4 (0.67)
possibility to walk fast	7.3 (0.93)
stability in stance	6.7 (0.86)
feeling of firm contact with the ground	5.5 (0.86)
rolling-off in a supple way	5.2 (0.51)
powerful push-off	4.1 (0.80)
easy turning on prosthetic leg	3.9 (0.81)
possiblity to climb the staircase	3.5 (0.69)
cosmetically good walking pattern (n=9)	3.3 (0.96)
possibility of squatting	1.5 (0.62)

Discussion

Questionnaire A: choice of foot

Some studies show differences in foot preference according to level of activity, related to cause of amputation (traumatic versus vascular), age and weight. Young active, good walkers seem to prefer an energy storing of a flexible foot with springy push-off, while older, less active and heavily built amputees prefer a conventional foot with less flexibility (Alaranta *et al.,* 1994; Casillas *et al.,* 1995; Menard *et al,* 1992; Nielsen *et al,* 1989; Wirta *et al,* 1991).

Two important reasons are suggested in the literature about preference and acceptance of prosthetic feet. Firstly, the realistic appearance of some feet seems to be important for acceptance for both adults as well as children (Colborne *et al,* 1992; Torburn *et al,* 1990). The second aspect mentioned in the literature is a loss of proprioceptive support control, probably, more appropriate in older subjects.

Besides visual and vestibular control proprioception is an essential feedback control mechanism for maintenance of balance (Amblard *et al,* 1990). In leg amputees balance control can be trained. This indicates that a central integration of 'new' sensory input from

the amputated limb occurs, but this 'new' sensory input cannot compensate completely for the loss of normal sensory feedback (Geurts, 1992). Peripheral neuropathy results in a decrease of proprioceptive control. In older amputees especially this often is the case. Subjects with limited proprioceptive support control prefer a stable foot with a minimum flexibility because this gives more stability, in other words, maximum safety, while subjects with good proprioceptive support control do not need maximum stabilisation, and hence seem to prefer flexibility (easy roll-off) and spring push-off (Casillas *et al.,* 1995; Goh *et al.,* 1984).

This study did not display any preference in relation to age and activity level. Three arguments may be put forward for this. Firstly, the contrast between the moderately priced energy storing feet and conventional feet used in this study was probably not as big as the contrast between the feet used in other studies. Secondly, there was a small number of subjects in the study and thirdly, all the subjects were relatively young and were good walkers. The mean scores for stability in different standing and walking situations, were almost similar for all 4 feet. However, individual differences clearly did exist.

Looking at the preference of the subjects in this study, it was found that the subjects preferred the CF2 less ($p=0.006$) than the other feet. Two factors in category 3 of the questionnaire, 'ability to walk fast' ($p=0.048$) and 'no fatigue during walking' ($p=0.046$) were responsible for this detrimental statistical difference. For both the factors the CF2 scored lowest. In contrast, the CF1 scored second best and best respectively. Therefore these results do not indicate a strong preference for either type of foot.

At individual level there were clear differences. Seven subjects did prefer an ESF. If the energy storing properties of the feet were decisive in their choices, then we should also expect an ESF as a second choice. However, only 2 of those 7 who preferred an ESF as a first choice also indicated an ESF as a second choice (Table 5).

Two reasons probably play a role:

- energy storing properties of the prosthetic foot might not be decisive for the choice of the subjects and/or the contrast between the energy storing capacities of the different feet was too small to notice;
- the sample size of the study was too small to detect the differences between the energy storing factors.

In Part 1 of this study it was shown that differences in energy expenditure of the amputees during normal walking with the 4 feet should be maximally 2.5 to 3% (Postema *et al,* 1997). It was assumed that a difference of less than 3% in the amount of energy necessary for normal walking, cannot be perceived by the subject and hence is not of clinical important. No data was found in the literature about the difference in expenditure of metabolic energy while walking with comfortable speed, that could be perceived by subjects. Thus the contrast between the energy storing capacities of the different feet is probably too small to notice. In this study the energy storing capacities did not seem to be a decisive factor in itself, but other properties, such as springy push-off, flexibility, fatigue and stability could probably be derived from the energy storing capacities.

It is known that the same characteristic of a foot can affect users totally differently. For instance some people favour the Flex foot because of its springiness (Goh *et al,* 1994; Lehmann *et al,* 1993; Macfarlane *et al,* 1991), while others dislike this foot for the same reason (Menard *et al,* 1992). The difference in preference, may be explained by different personal capacities of the subject, different circumstances under which the prosthesis is used and by different demands made on the prosthesis.

It has been reported that subjects tend to prefer their own prosthetic foot, which they are used to, to those of a study (Goh *et al,* 1984). This might be due to a very short habituation period. The data in this study showed that 4 subjects had a foot that was also part of the study (2 x ESF2 and 2 x CF2). Half of this group (1 x ESF2 and 1 x CF2) preferred this foot to the other feet. On the other hand, only 2 of the 6 subjects with a totally different own prosthetic foot than those used in the study, preferred their own prosthetic foot. It, therefore, cannot be confirmed that most subjects prefer their own prosthetic foot.

Questionnaire B: ranking order of importance of different factors of prosthetic feet

Nielsen (1991) presented a study, concerning a survey of 109 amputees (leg and arm amputations at different levels), in which orders of importance were given. Fifty-two percent of the amputees rated comfort as the most important factor of the prosthesis, 38% rated function as the most important factor, 7% cosmesis and 4% rated cost as the most important factor.

The results of the questionnaire in this study suggested that more or less 2 factors were of utmost importance in order to function well with a prosthesis. First was the 'absence of stump pain' and the second was the stability of walking. One subject ranked 'absence of stump pain' as totally unimportant. However he had never experienced stump pain, and therefore, it was supposed, he underestimated the importance of the absence of it. Absence of stump pain is of course the ultimate factor of comfort. Stability while walking is a factor of functionality and it incorporates feelings of safety. Amputees with good proprioceptive control tend to describe a flexible foot as more stable (Nielsen *et al,* 1989), because most likely the flexibility of the foot allows them to keep their balance. It gives a possibility of adaptation to an uneven surface and therefore reduces the chance of falling. These subjects seem to interpret stability not as mechanical stability, but as better balance possibilities and a smaller chance of falling, in other words, as more safety. This indicates that the perception of stability is closely related to proprioceptive capacities of the subjects and to their daily activities. Two of the subjects of the study worked very often at construction sites and both described the ESF2 (most flexible foot) as most stable. Older, less active and heavily built amputees prefer a conventional foot with less flexibility (Alaranta *et al,* 1994; Casillas *et al,* 1995; Menard *et al,* 1992; Nielsen ***et*** *al,* 1989; Wirta *et al,* 1991). Probably loss of proprioceptive capacities results in worse balance control and therefore these subjects experience a conventional foot with less flexibility as more stable. The factor 'stability while walking, as experienced by the amputee' seems to be of decisive importance in the preference of prosthetic feet.

The next 4 factors (no fatigue during walking, ability to walk fast, stability in stance and feeling of firm contact with the ground) are all in the domain of functionality and make daily functioning with the prosthesis a lot easier. These factors proved to be the reason for a statistically lower ranking of the CF2, as seen previously from the results from Questionnaire A. Two factors, both, 'stability in stance' and 'feeling of firm contact with the ground', concern stability and balance. It was therefore to be expected that they were close to each other in ranking order.

The factors 'rolling-off in a supple way' and 'powerful push-off' were in the middle of the ranking order. They were clearly less important than 'absence of pain' and 'stability' (safety). The factors 'rolling-off in a supple way' and 'powerful push-off' could be prime reasons for 'no fatigue during walking' and 'possibility to walk fast'. Hence it may be reasonable that these last 2 factors ranked higher.

The last 4 items concerned special activities and cosmesis. They were clearly of less importance. However, one subject judged the factor 'cosmetically good walking pattern', as very important. This subject is probably obsessed by the fact that others can see that he is wearing a prosthesis. For individual decision making this of course is very important but it is not representative for the total group.

It is necessary to be cautious with generalising the results of this series to all amputees, because the subjects in the trial were all good walkers and relatively young. Yet, when 'absence of stump pain' is considered as a matter of comfort and 'stability while walking' as a matter of function, the results correspond with those of Nielsen *et al.* (1991).

Conclusions

The first part of this study showed that there were no clear differences between kinematic and kinetic data, either in mechanical energy storage or release, of the 2 ESF and 2 CF feet.

It is concluded that, with such small differences in energy storage and release, subjects might not be able to distinguish a clear difference in the energy storing capacities of both kinds of feet.

In the second part of the study it was shown that no foot was specially favoured by the subjects. Despite small differences, detrimental to CF2 ('ability to walk fast' and 'no fatigue

during walking'), collectively the feet were judged as being almost the same, although individually there were clear preferences.

The preference of the subject could not be related to age. In 2 subjects the kind of daily activity, working at building sites, seemed to be the reason to prefer a flexible foot (ESF1), because this offered a better safety (stability in their experience).

From the 12 factors concerning a prosthesis the absence of stump pain was ranked as the most important by the subjects, stability while walking (as experienced by the amputee) was the second while special activity such as possibility of squatting was unimportant.

It is necessary to gather this kind of information from subjects with different levels of amputation, different levels of activities, different professions etc., because it leads to a better understanding of desires and demands of amputees on their prosthesis, and therefore it can lead to a more satisfying use of the prosthesis.

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The life style of young persons after lower limb amputation caused by injury

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Abstract

In order to determine whether lower limb amputation changes the social life and free time activities of persons who were at the time of amputation young, a questionnaire was sent to 519 persons after trans-tibial or higher level of lower limb amputation who were at the time of amputation younger than 51 years, amputated because of injury, permanently resident in Slovenia and had visited the outpatient prosthetics clinic of the Rehabilitation Institute of Slovenia at least once in the last five years (1989-94).

There 228 responses, which were statistically analysed.

It was found that after amputation most persons participated less frequently in social activities, especially persons who were older at the time of amputation and also those who are older today. Changes in participation in social activities were not influenced by level of education.

Free time activities changed after amputation. Some 93 persons completely changed their free time activities and only 30 were still interested in the same activities as before. The three most frequent free time activities before amputation were cycling, team ball games and farm work. After amputation they were reading, watching television and/or listening to radio and music and housekeeping.

It is concluded that lower limb amputation severely changes the social life and free time activities of persons who were young at the time of amputation.

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Introduction

Disability following lower limb amputation is permanent and in many cases makes the individual dependent on other people (Pohjolainen *et al.,* 1989). To increase independence after lower limb amputation, there are two major goals in rehabilitation.

The first is to enable the person to walk. Although modern prostheses, with rapid incorporation of amputees into the rehabilitation programme and better therapeutic techniques, enable walking for an increasing number of persons (Pinzur *et al,* 1992), many can walk only short distances and are not able to climb stairs (Helm *et al,* 1986; Pohjolainen *et al,* 1990; Nissen and Newman, 1993; Jones *et al,* 1993; Fairhurst, 1994; Walker *et al,* 1994).

The second goal in the rehabilitation of persons after lower limit amputation is to return them into their social environment and to restore previous social contacts. However, it has been reported that many people after lower limb amputation are not able to participate in all leisure and recreational activities and have problems of reintegration into work (Nissen and Newman, 1992; Jones *et al,* 1993; Walker *et al,* 1994; Fairhurst, 1994). Decreased time spent in leisure activities and early retirements reduce the quality of life of some (Niemi *et al,* 1988; Trudel *et al,* 1984).

To achieve both goals is specially important in the rehabilitation of persons who are young at the time of amputation and in Slovenia there are many such persons. However, until now there was no data about rehabilitation outcome for

Table 1. Level of amputation.

Level	Men	Women	Total	%
Trans-tibial	95	19	114	50.0
Knee disarticulation	2	0	2	0.09
Trans-femoral	92	16	108	47.4
Hip disarticulation	2	2	4	1.8
Total	191	37	228	100.0

these persons.

Therefore, a questionnaire about mobility and social life was sent to all persons who were young at the time of amputation, to determine whether the lower limb amputation changed their social life and free time activities.

Subjects and methods

All persons after trans-tibial or higher level lower limb amputation who were at the time of amputation younger than 51 years, amputated because of injury, permanently resident in Slovenia and had visited the outpatient clinic for prosthetics of the Rehabilitation Institute of Slovenia at least once in the last five years (1989-94) were sent a questionnaire about mobility and social life. Some 519 persons were sent a questionnaire, 391 (75.3%) responded but only 228 (58.3%) filled in questions about their free time activities.

The responses were statistically analysed by SPSS programme (Statistical Package for Social Sciences). The one way analysis of variance was used.

Results

Persons who answered the questionnaire were at present on average 53.3 years (SD 15.4 years) old. At the time of amputation they were on average 24.0 years (SD 10.0 years) old. A total of 191 (83.8%) were men and 37 (16.2%) women. About half of the persons had trans-tibial and about half trans-femoral amputation, whereas the disarticulations in joints were rare (Table 1).

Lower limb amputation severely changed the life style of persons who were young at the time of amputation. Almost half of the persons who answered the questions are less frequently visiting friends and relatives after the amputation and around two thirds are less frequently visiting the cinema, theatre, sport events and going to the library, dances and shows (Table 2). Persons who are less frequently visiting friends, cinema, theatre and

Table 2. How often are persons who were young at the time of amputation participating in social life.

Social activity	Less frequently		Equal		More frequently	
	No	%	No	%	No.	%
Friends	99	46.3	103	48.1	12	5.3
Show, dance	109	67.7	48	29.5	4	2.5
Cinema, theatre	107	71.3	37	24.7	6	4.0
Library	81	59.6	39	28.7	16	11.8
Sport events	95	64.6	41	27.9	11	7.5

Table 3. The influence of age at the time of amputation on social life - mean age (years) and standard deviation (SD).

Social activity	Less frequently		Equal		More frequently		p
	Mean age (years)	SD	Mean age (years)	SD	Mean age (years)	SD	
Friends	26.4	9.5	22.4	10.1	24.8	9.2	<0.05
Show, dance	24.5	9.3	20.8	9.5	19.0	11.0	<0.05
Cinema, theatre	23.8	9.3	21.5	8.3	16.3	3.3	=0.08
Library	24.0	8.9	22.9	8.4	20.6	11.3	Non sig.
Sport events	24.2	8.8	21.4	9.7	22.1	11.5	Non sig.

Table 4. The influence of present age on social life - mean age (years) and standard deviation (SD).

Social activity	Less frequently		Equal		More frequently		p
	Mean age (years)	SD	Mean age (years)	SD	Mean age (years)	SD	
Friends	58.5	13.4	48.1	14.7	47.1	17.2	<0.0001
Show, dance	54.2	14.0	42.1	13.3	49.8	25.2	<0.0001
Cinema, theatre	52.9	14.7	43.2	13.2	44.7	22.4	<0.005
Library	52.5	15.5	46.4	13.5	44.6	15.0	<0.05
Sport events	52.1	14.5	46.3	15.6	46.3	15.5	=0.08

Table 5. The influence of level of education on social life - mean level of education and standard deviation (SD). Level of education has a number from one to seven: 1 - less than eight years, 2 - primary school (eight years), 3 - vocational school, 4 - secondary school, 5 - high school, 6 - university, 7 - MS, PhD.

Social activity	Less frequently		Equal		More frequently		p
	Mean age (years) education	SD	Mean age (years) education	SD	Mean age (years) education	SD	
Friends	3.0	1.6	3.4	1.4	2.9	1.2	Non sig.
Show, dance	3.3	1.6	3.7	1.5	2.3	1.0	Non sig.
Cinema, theatre	3.4	1.5	4.1	1.5	3.0	1.3	<0.05
Library	3.4	1.5	3.8	1.6	4.0	2.0	Non sig.
Sport events	3.4	1.6	3.6	1.3	2.4	1.0	<0.05

going to dances and shows are those who were older at the time of the amputation (Table 3) and they are also those who are six to ten years older today (Table 4). However participation in social life is not influenced significantly by the level of education (Table 5).

Table 6. Ten most often done activities in free time before the amputation,

Activity	Number of persons	
	Before amputation	After amputation
Cycling	86	25
Group games with ball	71	3+3 sitting volleyball
Farm work	67	11
Walking	61	66
Swimming	56	34
Hill walking	46	7
Dancing	46	8
Skiing	41	7
Gymnastics, recreation	30	8
Jogging	30	0

Amputation has a great influence also on free time activities. After the amputation 93 persons completely changed their free time activities and only 30 persons still take an interest in the same free time activities as before the amputation (Fig. 1). The three most frequent free time activities before amputation were cycling, team ball games and farm work (Table 6). After the amputation they were reading, watching television and/or listening to radio and music and housekeeping.

Discussion

This study shows that lower limb amputation severely changes the social life and free time activities of persons who were young at the time of amputation. It was found that one half to two thirds of persons who answered the questionnaire participated less frequently in social life (Table 1) and their free time activities were changed (Fig. 1, Tables 5 and 6).

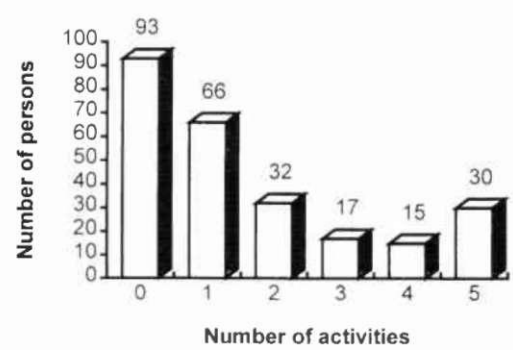

Fig. 1. Number of same free time activities the person was doing before and is still doing after the amputation.

Only 58.3% of persons who responded to the questionnaire answered the three questions about their free time activities. It is not known what the others are doing in their free time, but it is supposed that they are not very active. Some answered only what they did before the amputation and few that they have no free time.

Social activities depend on several factors. The most important are present age, age at the time of amputation and education. Present age may have a smaller direct and greater indirect influence on social activities. Directly the present age influences visiting friends and relatives, because older people may have fewer friends and relatives. An indirect influence may be through less mobility and associated diseases. Many authors (Narang *et al,* 1984; Helm *et al,* 1986; Pohjolainen *et al,* 1989; Pohjolainen *et al,* 1990; Siriwardena *et al,* 1991; Campbell *et al,* 1994; Tranter *et al,* 1995; Bond *et al,* 1995; Johnson *et al,* 1995) reported that associated diseases and advanced age diminished mobility. The same was found also by the authors in a previous study (Burger *et al,* 1995).

The influence of age at the time of amputation on social activities is small. Persons who were fairly young at the time of amputation are more frequently visiting the cinema and theatre and going to shows and dances. It may be that they were too young at the time of amputation and as they have grown up, they begin to go to these events more frequently.

The level of education influences mainly visiting cinema, theatre and sports events. The persons with the highest education are visiting these events as frequently as before the amputation and the persons with the lowest education are visiting them more frequently. It may be that the persons who are visiting the events more frequently were very young at the time of amputation and still studying. Thus their education is low.

In contrast to the authors' expectation the level of amputation has no influence on social life of persons who were at the time of the amputation young.

Many persons after lower limb amputation completely changed their free time activities (Fig. 1), probably because they were not able to participate in the sport and recreational activities they were interested in before he amputation, therefore, the free time activities after the amputation become more sedentary and less dynamic (Tables 6 and 7). The same was found by many other authors (Narang *et al,* 1984; Walker *et al,* 1994; Nissen and Newman, 1992; Fairhurst, 1994).

In conclusion, it was found that lower limb amputation severely changes the social life and free time activities of persons who were young at the time of amputation. Thus it is recommended to included a recreational therapist in the rehabilitation of young persons after lower limb amputation. The recreational therapist should inform and teach patients alternate recreational activities, advise them on adaptations to sports equipment and give them

Table 7. Eleven most often done activities in free time after the amputation.

Activity	Number of persons	
	Before amputation	After amputation
Reading	105	23
Watching TV, listening music	84	9
Housekeeping	76	18
Walking	66	61
Gardening	51	27
Needlework	48	9
Visiting friends	34	26
Swimming	34	56
Parlour games	33	9
Cycling	25	86
Rest	24	0

information about sports clubs. All this may help persons to participate in recreational activities they were interested in before amputation or help them find new activities. In clubs they may find new friends and have more fun. The result may be smaller changes in social life and leisure activities and better quality of life (Bond *et al.,* 1995).

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Lifelikeness in multilayered digital prostheses

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Abstract

The appearance of the skin is dependent on the optical properties of the various layers of tissue and the presence of pigments. In order to reproduce the lifelikeness of the skin in developing digital prostheses, a multiple layered moulding technique was utilised. The prosthesis was moulded in two coloured layers, an outer layer and an inner layer. Four combinations of multiple coloured layers and two single coloured layers varying in their optical properties and base colours were assessed. In two groups an additional intermediate layer of detailed colours was added between the two layers, to enhance the creaselines, nails, blood vessels, and other features. All prosthesis were moulded to a total thickness of 0.6 mm. This method of moulding was based on the anatomical characteristics of the epidermal and dermal layers of the skin and their optical characteristics.

The aim was to determine which combination of multiple layers gave the best outcome and made the prosthesis look lifelike in appearance. The appearance and lifelikeness of the prostheses were qualitatively assessed by a panel of assessers divided according to their vocation.

The study showed that the best combination for moulding the prosthesis in multiple layers was to have the outer layer translucent and the inner layer opaque. An intermediate layer should be incorporated to enhance the more prominent surface features and the nails. The base colour of the inner layer should be darker than the outer layer to allow the intermediate layer to have a reflective background.

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Introduction

An important consideration in developing a cosmetic prosthesis is the ability to simulate the appearance of the skin which is primarily composed of 3 layers with varying optical properties (Agache *et al,* 1989; Anderson and Parrish, 1981; Williams and Warwick, 1980; Edwards and Duntley, 1939). There is a thin and highly translucent outer layer of epidermis, a thicker and less translucent middle layer of dermis, and a highly opaque innermost layer of subcutaneous tissue immediately beneath the dermis. The colour of the skin is determined by five pigments within the three layers, namely melanin (brown), melanoid (brown) and carotene (yellow to orange), together with the haemoglobin (purple and bluish-green) and oxyhaemoglobin (red) in the vascular system. Light transmitted through the surface of the skin is either absorbed, scattered, or back-reflected (Fig. 1). The colour of the skin as perceived depends on the wavelength of the emerging light, the opacity of the skin layers, and the spectral characteristics of the pigments. The optical effect of scattering also modifies skin colour (Edwards and Duntley, 1939). The transmission of light into and eventually out of the skin layers produces the translucent appearance of the skin, with the apparent visibility of the underlying blood vessels and skin pigments imparting a dimension of depth to it.

To reproduce the visual effects of the skin in a prosthesis, its surface details, colour and the apparent dimension of depth which collectively gives it a lifelike appearance, must be reproduced (Leow, 1995; Leow *et al,* 1996).

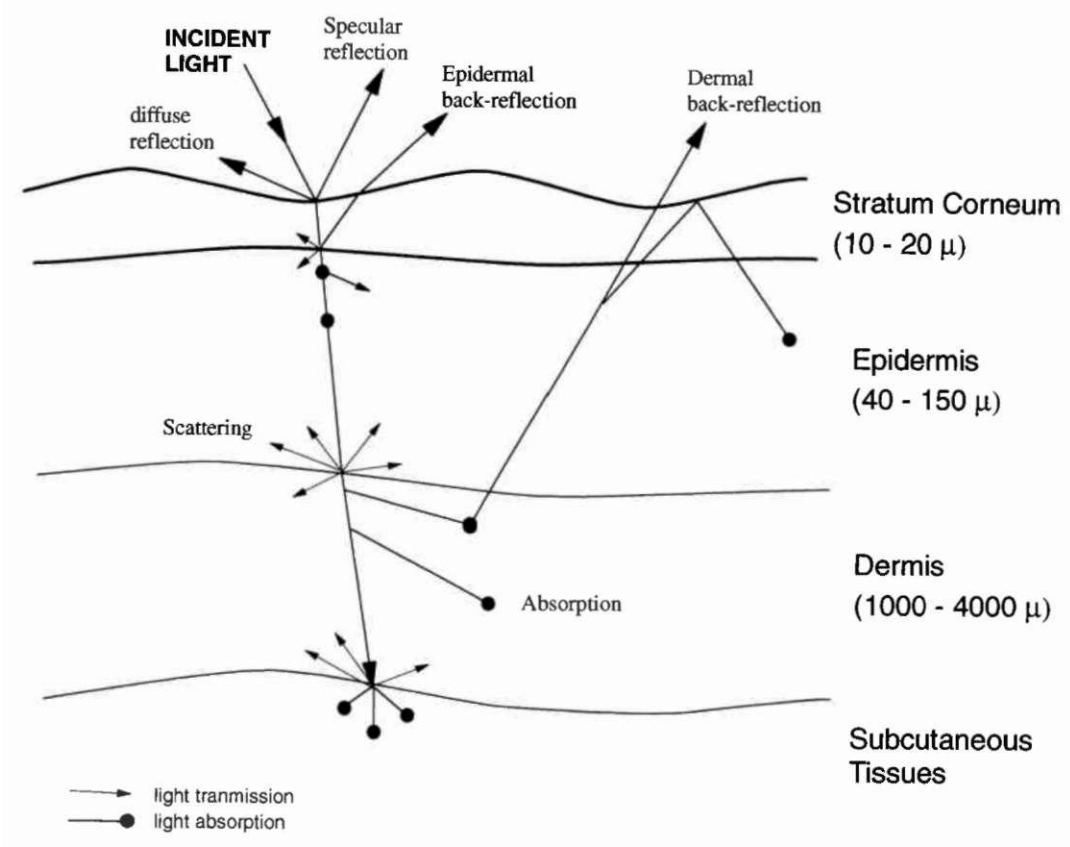

Fig. 1. Schematic diagram of the optical pathway of an incident light within the layers of skin - stratum corneum, epidermis, dermis and subcutaneous tissue layers The arrow lines indicate a transmission of light and the lines ending with a dark circle indicate light absorption.

Additionally, a tinge of surface shine due to the skin's oily secretion which gives it a healthy look should be reproduced. In producing a prosthesis for the hand, the greater pigmentation at the joints of the digits, the eponychium, the pinkish tones of the nail and the difference between the hues of the dorsal and palmar skin are important considerations.

Silicone rubber has been used to produce cosmetic prostheses for the hand (Pillet, 1983; Beasley, 1987; Alison and MacKinnon, 1992; Campbell *et al,* 1992; Leow, 1995; Leow *et al.,* 1996; Pereira *et al,* 1996). To mimic the aesthetic effects of the skin, a multilayered moulding technique has been reported by several researchers (Campbell *et al.,* 1992; Law and Dick, 1982; Leow, 1995; Leow *et al.,* 1996: Pereira *et al.,* 1996). A prosthesis moulded in multiple layers, with the layers varied in opacity and colour, helps to break up the 'solid-like' appearance and better reproduces the life-likeness of the skin. However, no reports have been published which compared the aesthetic quality of multiple layered prostheses to single layered prostheses. This study investigates and compares the aesthetic properties of six digital prostheses moulded in different combinations of coloured layers. The different layers were varied in terms of the colour and opacity. In addition, the effects of a layer of detailed colouration incorporated between the inner and outer layers to reproduce certain features like the nails, creases, vessels and skin pigmentations were also studied.

Materials and methods

Master negative impression moulds using polyvinylsiloxane dental impression material (Dent Silicone-V, Shofu Inc. Kyoto, Japan) were made from the same stone impression mould of the left index finger of Subject A (LEL). The digital prostheses were then moulded in

multiple layers (Leow, 1995) from these master negative impression moulds (Appendix). A clear commercial grade of silicone elastomer was used (KE1300T, ShinEtsu Chemical Co., Japan). Six different combinations of layers were studied, varying in the colour and opacity of the layer (Fig. 2). Colour matching of each layer was done under white light illumination, 36 watts, white light, temperature 4000°K at an intensity of 740 Lux (Phillips, Netherlands). In

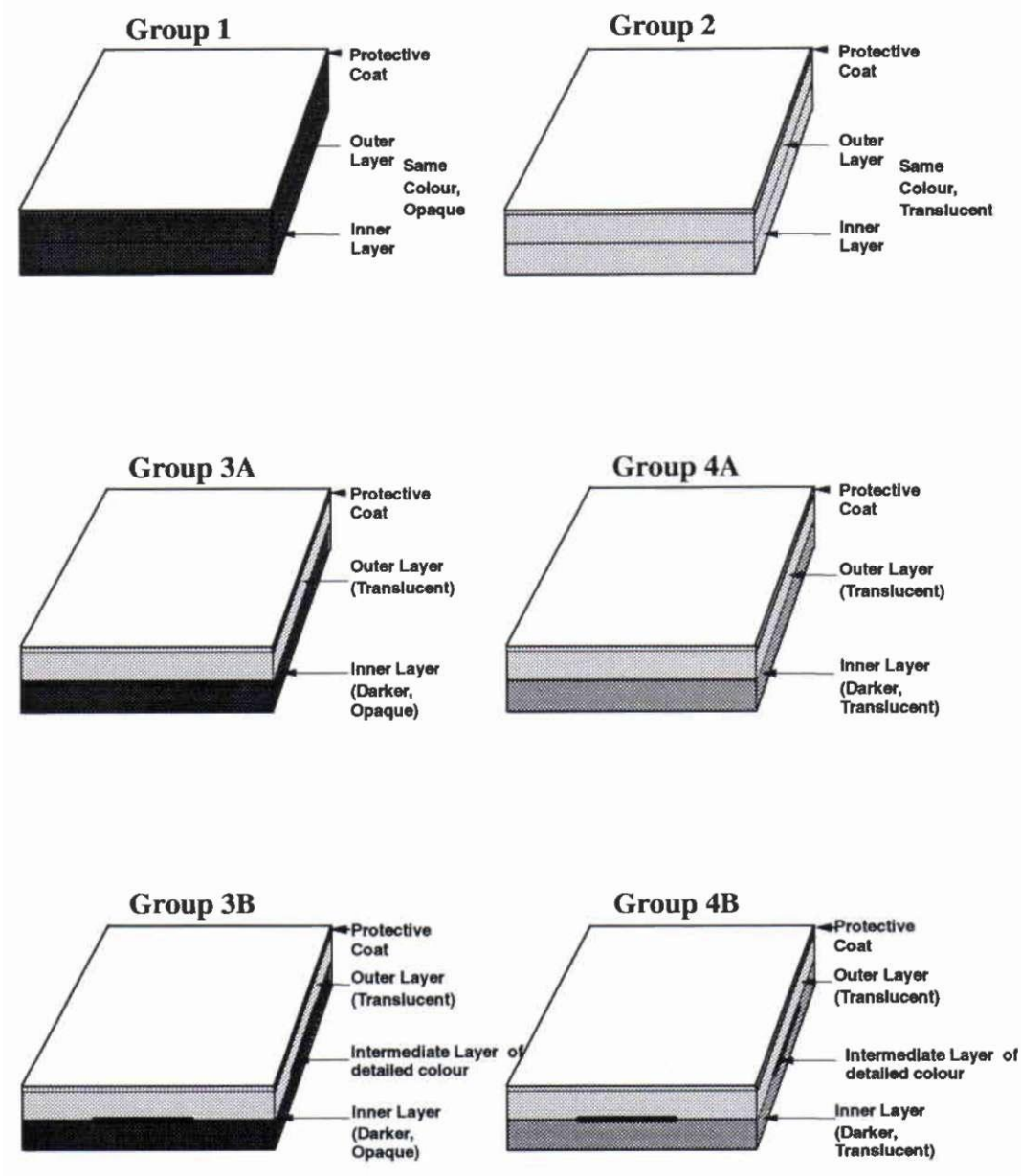

Fig 2. Schematic representation of a through thickness section of the various prostheses moulded. Each prosthesis was moulded with an inner and outer layer where the colour and opacity of each layer were varied. Prosthesis-1 and Prosthesis-2 were considered as single layer prosthesis as both layers were moulded in the same colour and opacity. Prosthesis-3 and Prosthesis-4 were moulded with both layers different in colour and opacity. Both these groups had an additional sub-group where an intermediate layer of detailed colour was included to enhance certain surface and internal features.

a preliminary study (Leow, 1995), standard silicone rubber sheets of 0.3mm thickness of the desired colour were prepared. A repetitive syringe dispenser (Nichiryo Model 8100, Tokyo, Japan) was used to quantify the amount of colour pigments (Cosmesil, Cosmedica Ltd, UK) in colouring the silicone rubber sheets. The colour hue was adjusted by varying the amount and the type of pigments used (Appendix). The colour of the silicone sheets was recorded in their *L, a* and *b* values using a tristimulus colorimeter (Chroma Meter CR-300, Minolta, Osaka, Japan). The degree of opacity of the silicone sheets was also controlled and adjusted by varying the amount of colour pigments used per l0g of silicone rubber for a 0.3 ± 0.01mm sheet thickness. For a translucent layer, the amount of pigment used was 0.15ml/10g of silicone rubber. For an opaque layer, 1.0ml/10g of silicone rubber was used. The colour contrast and opacity were measured using the tristimulus colorimeter and expressed as a contrast ratio *(CR)* defined as (Osmer, 1978):

$$CR = (Y_b / Y_w) \times 100$$

where Y_b and Y_w are the reflectance readings when the standard colour sheets of 0.3 mm thickness were measured over black and white colour standard plates respectively. The *L, a, b* values and the *CR* of the outer and inner layers used to mould the six combinations are summarised in Table 1. Prosthesis-1 and Prosthesis-2 were both moulded with both layers having the same opacity and colour. For Prosthesis-1 both layers were opaque while for Prosthesis-2 both layers were translucent. For Prosthesis-1 and Prosthesis-2, the *CR* values for the outer and inner layers in each prosthesis were not significantly different ($p>0.5$). Thus both prostheses were considered as single layered prostheses. The total thickness of both these prostheses was maintained at 0.6 mm. Prosthesis-3 had a translucent outer layer and an opaque inner layer, while Prosthesis-4 had both inner and outer layers translucent with the inner having a darker shade of colour than the outer layer. The thickness of each layer was maintained at 0.3 mm, giving a total of 0.6 mm in thickness. Prosthesis-3 and Prosthesis-4 were further divided into sub-groups A and B. Sub-group B had an intermediate layer of detailed

Table 1. L, a, b values and contrast ratio (CR) of the various prostheses assessed

Prostheses	Outer layer (thickness = 0.30 ± 0.01 mm)		Inner Layer (thickness = 0.30 ± 0.01 mm)		Remarks
	L, a, b Value	CR Value	L, a, b Value	CR Value	
Single coloured layers Prosthesis-1	L=66.22±0.02 a=14.95±0.01 b=24.92±0.02	96.75±0.68 (Opaque)	L=66.22±0.02 a=14.95±0.01 b=24.92±0.02	96.75±0.68 (Opaque)	Outer and inner layer identical in colour
Prosthesis-2	L=81.84±0.01 a= 7.91±0.02 b=25.45±0.02	47.26±0.74 (Translucent)	L=81.84±0.01 a= 7.91±0.02 b=25.45±0.02	47.26±0.74 (Translucent)	Outer and inner layer identical in colour
double coloured layers Prosthesis-3A	L=82.62±0.02 a= 4.85±0.02 b=25.55±0.02	43.98±0.65 (Translucent)	L=63.81±0.02 a=19.24±0.02 b=30.71±0.01	88.50±0.16 (Opaque)	Inner layer darker than outer layer
Prosthesis-3B (with touch-up)	L=82.62±0.02 a= 4.85±0.02 b=25.55±0.02	43.98±0.65 (Translucent)	L=63.81±0.02 a=19.24±0.02 b=30.71±0.01	88.50±0.16 (Opaque)	Outer layer and inner layer identical to Prosthesis-3A
Prosthesis-4A	L=82.62±0.02 a= 4.85±0.02 b=25.55±0.02	43.98±0.65 (Translucent)	L=80.32±0.02 a=11.13±0.02 b=27.95±0.02	47.30±0.70 (Translucent)	Inner layer darker than outer layer
Prosthesis-4B (with touch-up)	L=82.62±0.02 a= 4.85±0.02 b=25.55±0.02	43.98±0.65 (Translucent)	L+80.32±0.02 a=11.13±0.02 b=27.95±0.02	47.30±0.70 (Translucent)	Outer layer and inner layer identical to Prosthesis-4A

(Mean±Standard Deviation).

colouration to enhance and reproduce the greater pigmentation at the joints, the eponychium, the nails and the blood vessels, while sub-group A did not have any intermediate layer. The cross-sectional thickness of the intermediate layer in sub-group B was less than 0.1 mm as observed under microscope. In Prosthesis-3A and 3B, the *CR* value between the inner and outer layer were significantly different, with the inner having twice the value of the outer layer. The overall *CR* values for both Prosthesis-4A and Prosthesis-4B were not significantly different however, both prostheses had an inner layer which had a substantially higher but not a significantly different *CR* value than the outer layer.

Assessment of prostheses

The completed prostheses were assessed quantitatively using the tristimulus colorimeter (Minolta, Japan) as well as qualitatively by a panel of assessers.

Quantitative assessment of opacity and colour difference: The *L, a, b* values of the whole prosthesis (i.e. combined effect of all layers together) were measured. The contrast ratio *(CR)* was used to quantify the relative opacity of the prostheses. The total colour difference, ΔE^1 which is a measure of the size of the colour difference, was calculated by the equation:

$$\Delta E = [\ (\Delta L)^2 + (\Delta a)^2 + (\Delta b)^2\ ]$$

where, ΔL, Δa, and Δb are the differences in the *L, a,* and *b* values respectively of the prosthesis and index finger of subject A.

A small ΔE value suggests a close colour match while a larger ΔE suggests a wider difference in the colour match.

Qualitative visual assessment: The aesthetic quality of the prostheses was assessed against the actual index finger (Subject A) from which the mould was taken. Individuals from six different vocational cohorts were selected to participate in the assessment. For each cohort, a sample size of more than 10 individuals *(n* > 10) was taken, the total number of individuals involved for the six cohorts being 76 *(n* = 76). The six vocational cohorts were: doctors (n = 17); engineers *(n* = 13); artists and photographers *(n* = 11); business and marketing personnel *(n* = 12); clerical and secretarial personnel *(n* = 11); factory workers *(n* = 12). The cohorts were chosen to ensure that a general opinion was obtained.

The visual assessment was done under the same lighting conditions as in the colour-matching procedure, with the prostheses placed adjacent to the index finger of subject A for a more accurate comparison. The prostheses were evaluated using a score/questionnaire sheet addressing five specific aesthetic features. The five specific aesthetic features were: 1) how distinct the surface details (SD) were; 2) whether the prosthesis appeared to have a surface shine (SS) similar to the normal skin; 3)

Table 2. Definition of aesthetic effects: surface details, surface shine, dimension of depth, overall colour match, and lifelikeness.

Aesthetic effects	Definition
Surface details (SD)	Surface features of the prosthesis as defined by the lines, creases, and pores replicated from the finger under investigation.
Surface shine (SS)	The perception of a tinge of shine on the surface of the prosthesis as perceivable on the surface of the skin due to its oily secretion and the keratin content of the cornified epidermis, as contrasted to a dry skin.
Dimension of depth (DD)	The perception of depth as communicated by the partial vision of something underlying, such as that perceivable in the skin as imparted by the partial vision of the underlying tissues, pigmentation, and vascular system through its translucent superficial layers.
Overall colour match (OC)	The colour of the prosthesis as compared to the skin of the finger under investigation.
Lifelikeness (LL)	The perception of a healthy appearance such as that perceivable in a living tissue with adequate blood supply, as opposed to a gangrenous and cyanosed tissue.

whether the prosthesis had dimension of depth (DD) or the visual effects of an underlying layer of colours rather than the one solid layer; 4) the overall colour (OC) as compared to the subject's digit and lastly 5) the overall life-likeness (LL) of the prosthesis. These features were based on the patients' perception and on questions raised by the patients or their family members concerning the quality of the prosthesis during the course of daily use of the prosthesis. The definitions of these aesthetic parameters are described in Table 2.

Each assesser was assigned a separate score sheet and asked to score each prostheses from between 1 and 10 for each of the above aesthetic features. The statistical method used in this study was the analysis of variance (ANOVA) with the multiple range test (Bonferroni). A significance level of the null hypothesis was set at $p<0.05$.

Results

The six prostheses assessed are shown in Figure 3. The *L, a, b* values, contrast ratio, and colour difference indicator, ΔE of each prosthesis are summarised in Table 3.

The mean aggregate scores from the qualitative assessment of the five aesthetic features for the six prostheses are graphically represented in Figure 4. The mean score takes average of the total scores of the entire panel of assessers. No significant difference between each of the cohorts was noted in their visual assessment of the prostheses for the various aesthetic qualities (ANOVA, $p>0.5$).

Surface details (SD): The surface details for all six prostheses were similar as they were all made from the same mould. However, the distinctness of these details between the six prostheses and how they were perceived by the assessers differed (ANOVA, $p = 0.1$). The opaque single-layered prosthesis (Prosthesis-1) received a significantly low score (3.8) as the distinctness of the features, although accentuated by the opaque background, were over-exaggerated and did not match the subject's finger. In the other prostheses where all had a translucent outer layer, this

Table 3. L, a b values, contrast ratio, and ΔE of the overall colour of the actual index finger and the 6 types of layered moulded prostheses.

Subject	L, a, b value (colour)	Contrast ratio (opacity/translucency)	ΔE
Actual index finger	L=59.32±0.76 a=12.26±0.42 b=22.18±0.27	Not measurable due to the volume of finger	0
Prosthesis-1	L=61.07±0.05 a=12.14±0.04 b=23.26±0.05	CR=99.14±0.43	2.06
Prosthesis-2	L=60.94±0.04 a=11.76±0.07 b=22.61±0.02	CR=71.55±0.60	1.75
Prosthesis-3A	L=60.36±0.05 a=11.49±0.09 b=23.21±0.03	CR=96.53±1.83	1.62
Prosthesis-3B	L=59.80±0.52 a=12.90±0.06 b=22.54±0.48	CR=98.84±1.02	0.88
Prosthesis-4A	L=62.35±0.13 a=12.12±0.03 b=23.21±0.03	CR=67.81±0.35	3.17
Prosthesis-4B	L=58.97±0.06 a=13.09±0.15 b=21.45±0.04	CR=72.62±0.42	1.21

(Mean ± Standard Deviation)

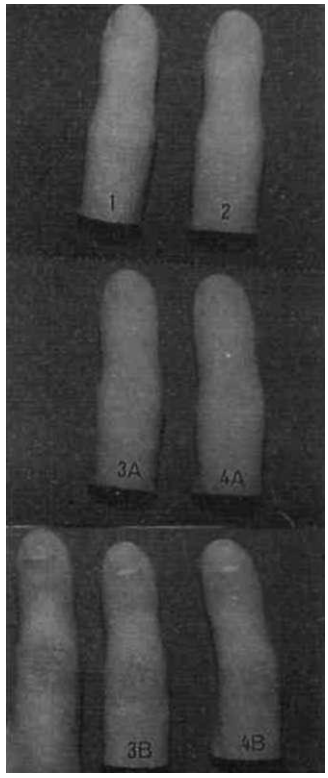

Fig. 3. The various moulded Prostheses-1, -2, -3A, -3B, -4A and -4B compared to the index finger of subject A from which the impression was taken

accentuation of the details decreased resulting in the surface details having a closer resemblance to that of the subject's finger. With an opaque inner layer and translucent outer layer (as in Prosthesis-3A). the surface details visually resembled the subject's finger highly with a mean score of 6.8. With the addition of the intermediate layer as in Prosthesis-3B, which enhanced the details, the mean score increased to 8.8. The same effect was seen in Prosthesis-4 but to a lesser extent, where both layers were translucent with the inner layer having a darker shade. With the inner layer translucent, the colour of the inner layer (Prosthesis-4A compared to Prosthesis-2) did not have any significant effect on the assessment scores for the distinctness of the surface details. With the intermediate layer detailed colour, the assessment scores were significantly higher as seen in Prosthesis-3B and 4B.

Surface shine (SS), dimension of depth (DD) and overall colour (OC): For the assessment of surface shine, dimension of depth, overall colour-match and overall lifelikeness, the prostheses which had the intermediate layer scored highest. In assessing the overall colour-match of the prostheses, the marginal colour differences as indicated by the ΔE values (Table 3) suggest a close match of the base colour of

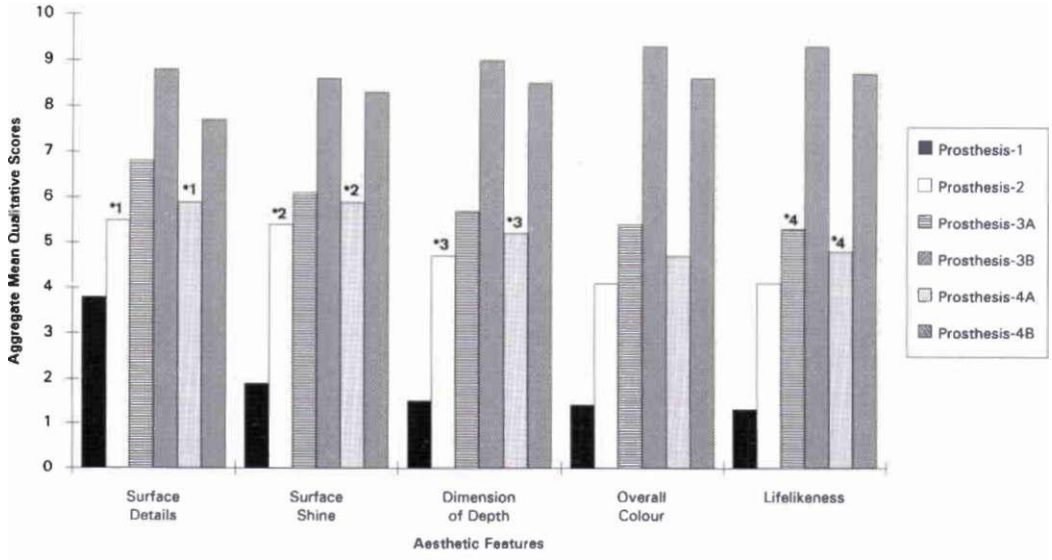

Fig. 4. Column chart summarising the aggregate mean qualitative assessment scores on the various aesthetic features for the single-layered prostheses (Prosthesis-1, Prosthesis-2) and the multi-layered prostheses (Prostheses-3A, -3B, -4A and -4B). Statistical significance (one way ANOVA) - *I:(NS, p=0.10), *2: (NS, p=0.06), *3: (NS, p=0.06), *4: (NS, p=0.10). (note: NS = not significantly different).

the sample prostheses to the subject's index finger. However, there were substantial differences in the perceived colour of the prostheses. When the inner layer was opaque (as in Prosthesis-3) as compared to one which is translucent (as in Prosthesis-4) the results of the assessment showed that the overall colour-match of the prosthesis was better with an opaque inner layer (Prosthesis-3). Between Prosthesis-2 and 4A, where the difference was that the inner layer had a darker shade of colour in the latter, the prostheses with the darker inner layer (Prosthesis-4A) scored statistically higher in its colour-match to the subject's finger. In addition, prostheses with the intermediate coloured layer gave a superior colour-match with a much higher score statistically in the visual assessment.

Discussion

Visual assessment

The primary concern in colouring a prosthesis is to achieve a close visual match to the recipient hand. The summary of assessment in Figure 4 agrees with the earlier reports (Campbell *et al,* 1992; Law and Dick, 1982; Leow, 1995; Pereira *et al,* 1995) that a prosthesis moulded in several layers of silicone rubber tinted to different shades of colour is aesthetically superior to one which is colour matched to a single shade. The study showed that the prosthesis which scored highest for the various features assessed and was considered the most life-like was Prosthesis-3B.

Light transmission and its effects on multilayered prostheses

The differences in the aesthetic effects of the prostheses can be explained using fundamental theories of light (Hunter, 1975; Rubin and Walls, 1969; Stroebel, 1980; Falk *et al,* 1986). The schematic diagram (Fig. 5) is a close-up view of the longitudinal sections though the prosthesis where the V-shape wedge models a "crease" on the surface of the prosthesis. The observed variations in the surface details between the prostheses is attributed to the visual effects of shadow formation and colour contrast

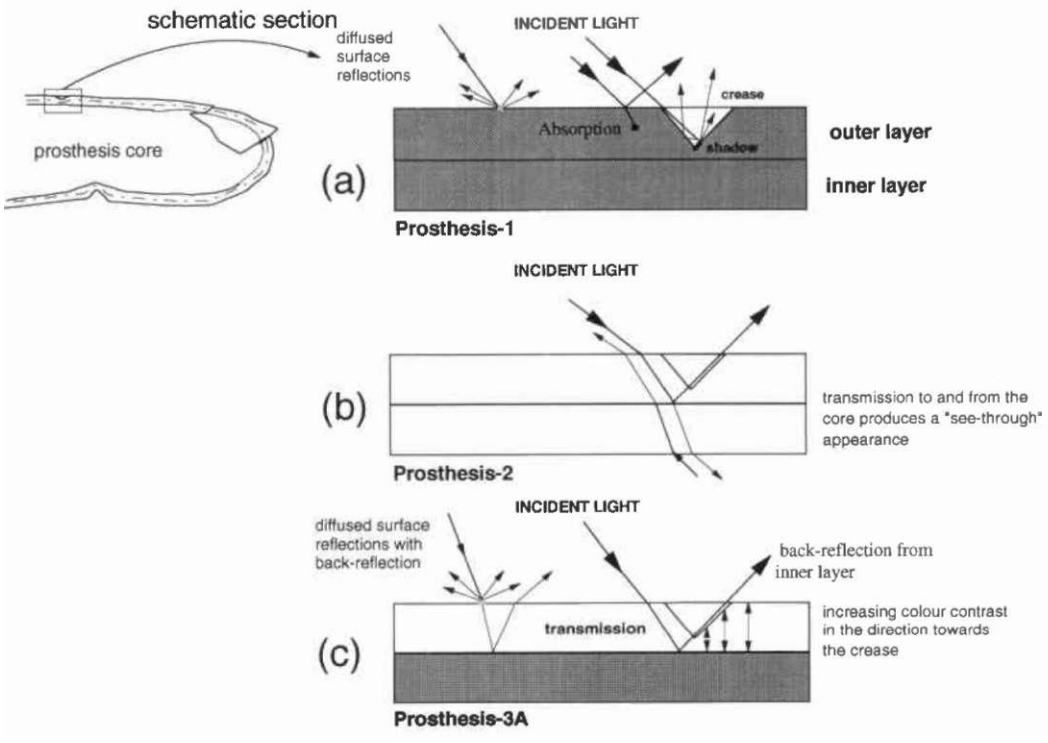

Fig. 5. Schematic diagrams of the optical pathway for an incident light on the surface of the various prostheses. A crease on the surface is also modelled to illustrate the effects it would have on the incident light in (a) Prosthesis-1, (b) Prosthesis-2 and (c) Prosthesis-3A.

interplaying in varying quantities in the different layers (Mullen and Kingdom, 1991; Falk *et al.*, 1986; Stroebel, 1980; Watt, 1991). Both these optical effects emphasise the impression of depth in the creases and interplay in different extents in the prostheses due to the differences in their layers.

Surface details (SD): In Prosthesis-1 (Fig. 5a) the highly opaque contours occlude the incident light and cast "hard" shadows on the crease. The shadow effects, strongest at the valley of the crease, create a strong visual contrast against the surface of the prosthesis at large, emphasising its depth and thus account for the grossly exaggerated surface details as observed by the assessers. In Prosthesis-2 (Fig. 5b), however, the shadow effects at the creases are diluted by light transmitted through the translucent inner layer from the core of the prosthesis thus reducing the distinctness of the surface details and giving a uniform appearance. In Prosthesis-3 (Fig. 5c) the otherwise excessive shadow at the creases is moderated by light rays transmitted through the translucent contour thus explaining the improved assessment as compared to Prosthesis-1 and Prosthesis-2.

Apart from shadow effects, colour contrast at the creases can also enhance the visual perception of surface details. This was seen for Prosthesis-3 where the outer layer is translucent and the inner layer is opaque, and also when there was an intermediate touch-up layer. Colour contrast at the creases arises as a result of the combined effect of three factors, namely, a translucent outer layer, a darker inner layer, and the surface slant at the crease. In Prosthesis-3A (Fig. 5c) the colour of the inner layer becomes increasingly visible towards the valley of the crease due to the reducing distance from the inner layer along its gradients. The resulting colour contrast at the crease against the surface of the prosthesis, strongest at the valley, has the effect of increasing its depth impression and visual perception. The appropriate tinge of colour added to the crease at the joint areas with the touch-up colouration and combined with the moderated shadow effects may account for the close match in surface details in Prosthesis-3B.

Surface shine (SS): Although there were no differences in the topography as observed under magnification for all the prostheses (Leow, 1995), there were significant differences in the manner the assessers judged the quality of the prostheses with regards to surface texture. The opaque single-layered prosthesis (Prosthesis-1) was assessed as grossly matted in appearance with the texture described as being "rough", "dry", and "powdery" in appearance. The surface texture of the prosthesis is mainly contributed to by the pattern of light reflections on its ridged topography comprising of fine lines, creases, pores, and the plateau. With the uneven microtopography, reflections on the surfaces of the prostheses are predominantly diffuse, thus producing a more matted appearance (Falk *et al.*, 1986; Burnham *et al.*, 1963; Stroebel, 1980). However, when the outer layer is opaque an overly matted appearance results because the same process of shadow formation can occur at the fine lines and pores throughout its surfaces due to the uneven topography and the opacity of the outer layer. The subtle visual effects of a mosaic of shaded and unshaded areas over the surfaces of the prosthesis can give rise to an apparent perception of a grossly matted texture. In contrast, the prostheses with a translucent outer layer were found to allow the perception of a tinge of shine from the inner layer onto the surface. This was because a translucent outer layer can modify the highly matted appearance caused by an uneven microtopography (Watt, 1991; Mullen and Kingdom, 1991). The transmission of light and thus increased brightness within the outer layer has the effect of moderating the shadow effects at the lines, creases, and pores, and this can reduce the matted appearance. In addition to this, the relatively directional emerging back-reflections from the smoother outer-inner layer interface can give rise to the apparent perception of a tinge of surface shine.

Dimension of depth (DD): In the prosthesis having a translucent outer layer, part of the incident light at the surface is transmitted through the layer (Fig. 6). The optical processes of absorption and scattering as light traverses down and its subsequent back-reflection and emergence produces the translucent appearance in the outer layer. It is the apparent vision of the inner layer through an outer translucent layer that imparts the dimension of depth to the prosthesis. Such translucent quality and depth impression are apparent in the human skin and these play an important role in the lifelike

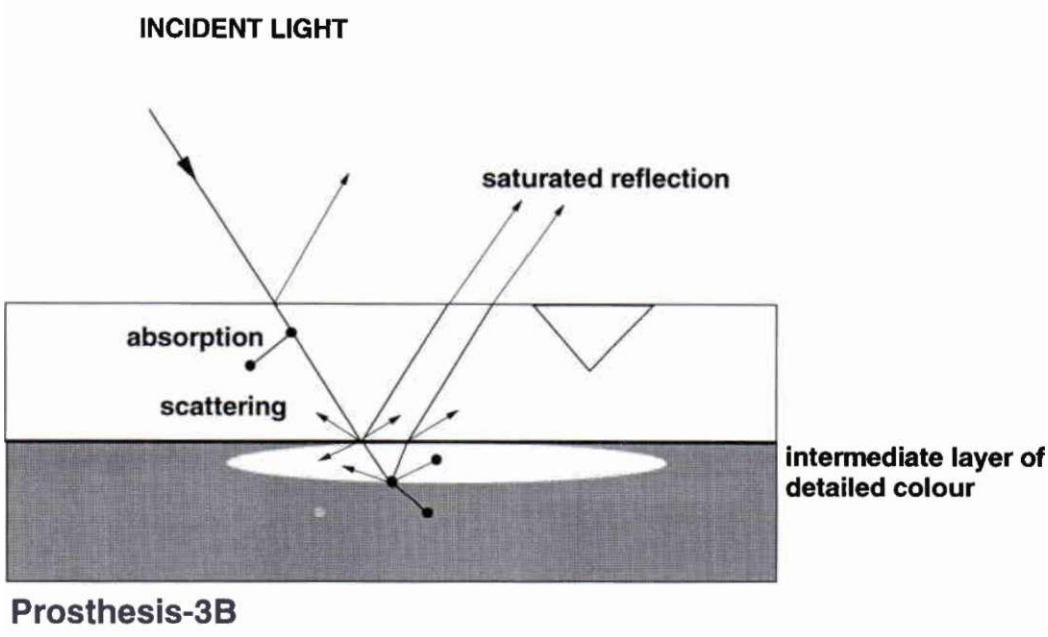

Fig. 6. Schematic diagram of the optical pathway for an incident light on a prosthesis - with an intermediate layer of detailed colour. The light transmission, absorption and scattering of the incident light on the intermediate layer through the outer layer and its subsequent back-reflection produces a dimension of depth characteristic of the prosthesis in Prosthesis-3B and Prosthesis-4B.

appearance of a prosthesis (Leow, 1995; Leow *et al.,* 1996; Fine *et al.,* 1978). In contrast, a major proportion of the light impinging on an opaque single layered prosthesis (Fig. 5a) is absorbed at a superficial level with little transmission (penetration) due to its opacity. The unabsorbed portion of the light is diffusely reflected thus producing predominantly surface visual effect. The prosthesis gives a "solid" and lifeless appearance. In the other extreme, when both layers were translucent (Fig. 5b), a portion of the light may be transmitted into the core of the prosthesis. This, together with some transmission from the core of the prosthesis in the opposite direction, produces a "see-through" appearance.

Overall colour match (OC): The differences in the perception of the colour in the prostheses can be attributed to: (i) the perceived variations in their appearance attributes such as surface details, surface shine, and dimension of depth; (ii) the modifying effects of additive colour mixing of light (Burnham *et al.,* 1963) emerging from the detailed coloured areas and non-detailed coloured areas (where the base colour was taken). The intermediate layer of detailed colour in the prosthesis reproduces the aesthetics of the skin in which light emerging from the more pigmented finger joints, eponychium, veins, arteries, etc., and the less pigmented mid-shafts enters the eye additively.

For Prosthesis 3-B, light incident at the prosthesis surface is partly reflected and partly transmitted (Fig. 6). The transmitted light traverses the outer layer and a fraction of it is reflected at the interface between the outer layer and the intermediate layer of detailed colour. The portion of light transmitted through the intermediate layer is subsequently reflected from the interface between the intermediate layer and the inner layer. The colour of the prosthesis is produced by a subtractive process (Falk *et al,* 1986; Burnham *et al,* 1963), the transmitted light becoming more saturated as part of its spectrum is selectively absorbed by the pigments within the layers. All reflected rays from different spots combined additively to give the resultant colour of the prosthesis. The colour produced depends on the spectral composition of each of the emerging reflections, which in turn, depend on the type and spectral characteristics of the colour pigments. With a highly opaque inner layer and the added intermediate colour details, a higher

concentration of pigments are involved in the light subtraction, thus the emerging reflections are theoretically more saturated, producing a saturated colour. The additive effects of light emerging from the touched-up and non-touched-up areas further modify the colour of the prosthesis towards a closer match with the skin. Thus, the colour difference between the subject's index finger and Prosthesis-3B was the smallest ($\Delta E = 0.88$, Table 3) in comparison to all groups. In Prosthesis-4B however, the emerging reflections may be relatively less saturated by reasons of the lower concentration of pigments incorporated in the translucent inner layer. The translucency of the inner layer also allows light transmission to and from the core of the prosthesis, thereby giving rise to a "see through" appearance. The relatively less saturated colour produced and the translucent appearance may have accounted for the less satisfactory colour match results as judged by the assessers.

Conclusion

Six variations of multilayered digital prosthesis were investigated to identify the combination of layers which best reproduce the aesthetic colouration and lifelike appearance of the skin. The variations were in terms of colour and opacity of the outer and the inner layer as well as the effect of incorporating an additional intermediate layer of detailed colouration to highlight certain features in the hand. Qualitative assessment of the prostheses demonstrated that the prosthesis having a translucent outer layer, an opaque inner layer plus an added intermediate layer of touch-up produced the most lifelike prosthesis of the six variations. In this prosthesis, the colour of the inner layer was also darker than the outer layer. This technique of colouring a prosthesis is based on the natural pigmentation and the optical characteristics of the human skin.

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Appendix

Moulding procedure

The liquid RTV silicone rubber (KE 1300T, ShinEtsu Chemical Co., Japan) is poured into the hollow negative mould, after which the mould is inverted to drain off the excess material, leaving behind a thin layer of the silicone adhering to inner surfaces. The silicone layer is then cured to a solid but supple and flexible state, following which it is withdrawn from the mould.

An outermost layer referred to as the protective coat was first moulded followed by the outer layer (thickness = 0.30 ± 0.01 mm). Following curing of the outer layer, the partially completed prosthesis was removed from the mould and a layer of touch-up colouration was applied extrinsically on the inner surfaces. The touch-up was then "sandwiched" with the inner layer (thickness = 0.30 ± 0.01 mm) to the final prosthesis thickness (0.78 ± 0.01 mm).

The thickness of each layer was controlled with a consistent moulding procedure by fixing the determinants of thickness i.e. silicone/solvent ratio, ambient temperature (24°C), and the angle of tilt of the mould when slush moulding.

Colour pigments

The colour pigments used for the outer layer and inner layer were basic yellow (L=68, a=10, b=26), basic brown (L=64, a=12, b=24), master sienna (L=42, a=38, b=37), master brown (L=27, a=23, b=27), master yellow (L=70, a=3, b=50), master blue (L=18, a=30, b=49) and master white (L=100, a=0, b=0). These were prepared and mixed into the silicone rubber material in different proportions to obtain standard colour mixes for the outer and inner layers (Leow, 1995). The colour of the cured silicone sheets was recorded in their *L, a* and *b* values using a tristimulus colorimeter (Chroma Meter CR-300, Minolta, Osaka, Japan). The pigments used for the intermediate layer mixed with the clear silicone rubber material were: master red (L=40, a=47, b=40), master yellow (L=70, a=3, b=50), master sienna (L=42, a=38, b=37), blue (L=18, a=30, b=49) and master

white (L=100, a=0, b=0). These were mixed in standard proportions to highlight vessels, variations in the dorsal and palmar aspects, the eponychium and digital creases. This was done under the outer layer.

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The influence of the reciprocal cable linkage in the advanced reciprocating gait orthosis on paraplegic gait performance

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Abstract

A wide variety of mechanical orthoses is available to provide ambulation to paraplegic patients. Evaluation of energy consuming walking in each of these devices has been acknowledged as an important topic in this field of research. In order to investigate the benefits of a ballistic swing on gait performance in the Advanced Reciprocating Gait Orthosis (ARGO) a study was conducted in which the ARGO was compared with an orthosis with freely swinging legs. This Non Reciprocally linked Orthosis (NRO) was obtained by removing the reciprocal linkage in the subjects' own ARGOs. Subsequently, flexion/extension limits were mounted to permit adjustment of stride length. Six male paraplegic subjects with lesions ranging from T4 to T12 were included in the study. A single case experimental design (B-A-B-A) was conducted in order to improve internal validity. Biomechanical and physiological parameters were assessed and the subjects' preference for either ARGO or NRO was determined.

It was found that large inter-individual differences produced insufficient evidence in this study to draw general conclusions about difference in energy expenditure between both orthoses. However, individual analysis of the results showed a reduction of oxygen cost (range: 4%-14%) in the NRO in T9 and T12 lesions, while oxygen cost in subjects with T4 lesions increased markedly (22% and 40%). It is concluded that patients with low level lesions could benefit in terms of oxygen lost from removing the reciprocal cable linkage in the ARGO. However, only one subject preferred the NRO for walking, whereas none of the subject chose the NRO for use in daily living activities. Removal of the reciprocal cable linkage in the ARGO may not be desirable for these patients.

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Introduction

To date, several options are available to provide ambulation to paraplegic patients. A commonly accepted classification of walking systems is that of mechanical orthoses, functional electrical stimulation and a combination of both, the so called hybrid systems (Hirokawa *et al,* 1990; Nene *et al.,* 1996). The use of mechanical orthosis has been described extensively by different authors. Well known systems are long leg braces (Huang *et al,* 1979) and various types of Hip-Knee-Ankle-Foot Orthoses (HKAFOs) including the Louisiana State University Reciprocating Gait Orthosis (RGO) (Douglas *et al,* 1983; Hirokawa *et al,* 1990), Parawalker or Hip Guidance Orthosis (HGO) (Nene and Major, 1987; Rose, 1979; Stallard and Major, 1993) and Steeper Advanced Reciprocating Gait Orthosis (ARGO) (Jefferson and Whittle, 1990).

Researchers of new walking systems have acknowledged that reducing energy expenditure during walking and improving user friendliness, e.g. with respect to donning and doffing, are important targets (Marsolais *et al,* 1988;

Bataweel and Edwards, 1995; Hirokawa *et al,* 1990). By decreasing energy expenditure one may improve the accessibility to walking systems for a larger part of the paraplegic population. Especially high level paraplegics may benefit from reduced energy cost because of their disturbed cardiovascular regulation (Glaser *et al,* 1985). Furthermore, decrease of upper body loading during walking may be worthwhile because of the high prevalence and risk of wrist and shoulder pathology (Aljure *et al.,* 1985; Gellman *et al.,* 1988).

In order to decrease energy expenditure during walking in HKAFOs, several possibilities have been described in the literature. It has been suggested to develop a system which allows knee lexion during swing phase (Bataweel and Edwards, 1995; IJzerman *et al.,* 1996). A high lateral stiffness has been described to prevent collapsing of the orthosis (Stallard and Major, 1993). Frontal alignment has been suggested in the HGO Parawalker to obtain a more efficient foot clearance with less displacements of the centre of mass of the body (Rose, 1979; IJzerman[b] *et al,* 1996). The use of a reciprocal linkage in an HKAFO was recommended for decreasing energy cost (Douglas *et al,* 1983).

Theoretical advantages of the reciprocal coupling include the transfer of energy from trunk and hip extension to contralateral hip flexion (Bowker, *et al,* 1992; Stallard and Major, 1993). Because the reciprocal linkage prevents bilateral hip flexion and extension, stance stability is improved (Douglas *et al.,* 1983). If the orthosis is well aligned, subjects are able to stand upright without using their crutches.

Disadvantage of the reciprocal cable linkage in the ARGO and RGO is the 1:1 transmission ratio between stance leg extension and contralateral hip flexion (Andrews, 1993; Yang *et al,* 1996). This 1:1 ratio imposes an unnatural walking pattern and may reduce energy efficiency during gait (Andrews, 1993). Because of the linkage, swing leg acceleration is dependent on the ability of the patient to extend the trunk rapidly. Thus, the momentum of the trunk is transferred to the swing leg.

Walking with freely swinging legs, the so-called ballistic swing, is expected to be more efficient because the movement of the leg is not limited in its natural biomechanical characteristics (Tashman *et al,* 1992). Furthermore, in order to achieve a sufficiently large stride length in the ARGO, i.e. hip flexion, the trunk has to be extended. The consecutive displacement of the centre of mass of the body to the new stance leg results in a walking pattern with alternating acceleration and deceleration of the trunk (Tashman *et al,* 1995).

In order to counter some of the above problems, Yang *et al.* (1996), developed an HKAFO allowing a 2:1 flexion/extension coupling ratio (FECR). By using a 2:1 FECR they achieved sufficient hip flexion with less contralateral hip and trunk extension in comparison with a 1:1 FECR. They compared the 1:1 with the 2:1 ratio and found lower values for the Physiological Cost Index (PCI): heart $rate_{rest}$-heart $rate_{walking}$/speed (McGregor, 1981) for the latter. Winchester *et al.* (1993) investigated the Isocentric® RGO in which a more efficient coupling of both legs was obtained. The Isocentric® RGO mainly prevents unwanted cable movement and friction, but still applies a 1:1 transmission ratio. A significant decrease in PCI was found compared with the RGO.

The present study was conducted in order to determine the influence of the reciprocal cable in the ARGO on performance of paraplegic gait. Interpretation of differences between commonly known orthoses with and without reciprocal cable linkages, e.g. (A)RGO and HGO, is difficult because of the large differences in alignment and stiffness between both devices. To investigate the influence of the cable linkage on its own, it was decided to use the ARGO both as reference as well as experimental Non Reciprocally linked Orthosis (NRO).

Physiological and biomechanical properties were assessed to analyse subjects' gait performance in both orthoses. Crutch forces during gait were measured to determine upper body load. Oxygen uptake measurements were performed to estimate energy requirements. Subjects' preference was determined as well, because of its importance with regard to future design considerations.

Methods

Subject selection

Subjects included in the study were experienced ARGO walkers, motivated to participate in a 4 week training programme

followed by an 8 week measurement period. Only paraplegic subjects with complete thoracic lesions were included, in order to obtain a homogeneous population. All subjects read and signed consent forms. The study was approved by the local ethical committee.

Study design

Single case experimental methodology was chosen in order to guarantee internal validity of the study (Barlow and Hersel, 1984). A withdrawal design (B-A-B-A) was used comprising two NRO (NRO_1 and NRO_2) and two ARGO ($ARGO_1$ and $ARGO_2$) measurements.

Single case methodology has been used to study longitudinal change when applying a specific treatment (Campbell, 1988; Hacker, 1980). The walking performance in a specific orthosis is usually a stable situation, which only requires control for measurement errors and random errors due to patient performance. Therefore, the design in this project comprised only one assessment in each phase, assuming that period effects were cancelled out.

A two week interval was used between two consecutive assessments in order to make patients accustomed to the orthosis to be measured next. Differences in patient performance due to test effects were thought unlikely to occur since all subjects had participated in previous studies and were familiar with the test procedures. An extensive training period was conducted prior to the measurement period in order to prevent bias due to training effects.

Training

The reciprocal cable in the ARGO was removed at the subjects' first visit to the unit. Subsequently, flexion/extension limits were mounted to the hip joints to permit adjustment of stride length. A 4 week training programme in the NRO was conducted in order to optimise stride length and walking technique in the NRO and to improve physical aerobic capacity. The criterion for starting the measurements was the ability to walk independently with a smooth and regular walking pattern for at least 15 minutes. Use of walking aids and crutch height were standardised for the ARGO as well as the NRO.

Measurements

The measurement protocol comprised physiological and biomechanical assessments, followed by a questionnaire. Repeated measurements of the subject took place on the same time of the day with a similar measurement sequence. Each assessment took place at the end of the two week interval between the measurements.

Physiological assessments

Subjects were asked to refrain from coffee or food for at least 2 hours prior to arrival at the unit. All subjects were non-smokers.

Breath-by-breath measurement of inspired and expired gases was conducted by using the OXYCON-alpha system (Jaeger, The Netherlands). The system was put on a trolley to be able to measure continuously during walking. Subjects were provided with a heart rate belt (Sport Tester, PE3000, Polar Electro, Finland) and a facemask with a flexible gas-tube. Measurement of rest metabolism was performed during 5 minutes, while the patient sat quietly. Subsequently, subjects were helped to stand up and when the heart rate approached a stable level, subjects were instructed to walk at a comfortable, self-selected speed during 10 minutes along a circular 125 metre pathway. The assessment ended with the analysis of the recovery period during 10 minutes (Fig. 1).

Heart rate, oxygen cost $V02$ ($ml.min^{-1}kg^{-1}$), carbon dioxide VCO_2 ($ml.min^{-1}kg^{-1}$), Respiratory Exchange Ratio (RER), tidal volume (1), breathing frequency (min^{-1}) and expiratory volume ($l.min^{-1}$) were monitored. VO_2 and VCO_2 were expressed in relation to lean body mass (kg LBM).

A delayed steady state was expected since substantial anaerobic energy contribution during walking was found in other studies (Huang *et al.*, 1979). Therefore, oxygen cost ($E02$) and PCI (McGregor, 1981) were calculated by averaging over the last 5 minute interval according to:

EO_2 ($ml.min^{-1}.kg^{-1}$) = VO_2/walking speed

PCI ($beats.m^{-1}$) = (heart $rate_{steady\ state}$ - heart rate)/v,

where v = walking speed during steady state.

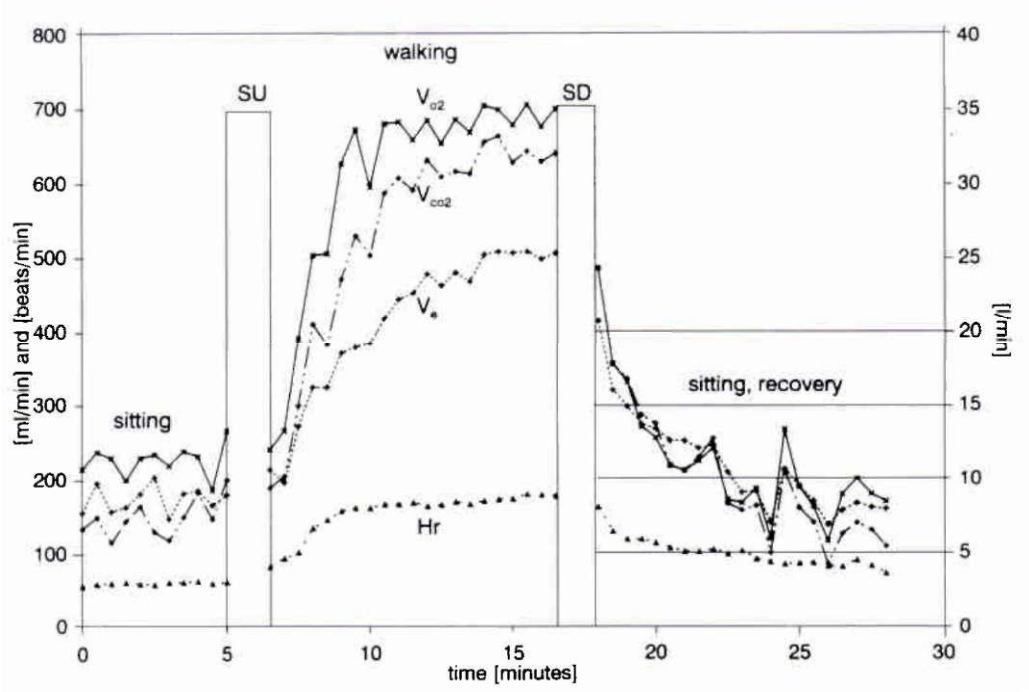

Fig. 1. Physiological measurement of one subject in ARGO. Oxygen uptake (Vo_2), carbon-dioxide (Vco_2), heart rate (Hr) and expiratory volume (V_e, right y-axis) are presented The total elapsed time is presented on the x-axis. The protocol comprises sitting, standing up (SU), walking, sitting down (SD) and sitting recovery. A delayed steady state exercise level was reached after approximately 6 minutes.

Biomechanical assessments

Kinetic and kinematic assessments were performed in the gait lab using a 5 camera 3D motion analysis system (VICON 370, Oxford Metrics, Oxford, UK). Each assessment consisted of 10 trials along a 10 metre gait lane to ensure approximately 20-30 strides for averaging. Marker positions of both ankles were sampled at a frequency of 50 Hz. Crutch forces and heel contacts were recorded simultaneously at 200 Hz using strain gauges and foot switches respectively. All data were filtered (linear phase 2nd order Butterworth, F_{-3dB} = 5 Hz) and split into gait cycle intervals using the heel strike data.

Stride length (m) and cadence (strides.min^{-1}) were calculated from the ankle marker data. Crutch Force Time Integral (CFTI) and crutch peak force (CPF) were calculated and normalised for body mass.

Questionnaire

Two questions were used to determine subjects' preferences regarding walking and general use of ARGO as well as NRO:

1. Did you like this orthosis for general use in in your home situation?
2. Did you like this orthosis to walk with?

Subjects were asked to give their opinion at each measurement day independent from the investigators. Subjects were not asked to compare the devices, since these comparisons may be subject to information bias (Sackett, 1979). Both items were scored on a 10 point scale as well as on a Visual Analogue Scale (VAS) (Price *et al,* 1983), ranging from dislike to excellent orthosis. The scores were averaged in order to obtain one general opinion about general use and about walking.

Data analysis

Box-plots, presenting median, 25% and 75% percentiles and range, were made to determine the distribution of each variable. Natural log transformations were applied to unskew the variable if necessary. Non-parametric tests were used if unskewing did not succeed.

Despite the real difference between ARGO

and NRO, a difference between ARGO and NRO can be a result of a period effect (Pocock, 1983). Period effects were separated into training effects due to improvement of walking performance in time and tests effects due to differences in measurement situation, e.g. heart rate measurement can be subject to test effects.

Training effects were tested statistically by means of a paired t-test for the difference between first and second NRO measurements (NRO and NRO_2). Systematic measurement errors and test effects were examined by comparing first and second ARGO measurements ($ARGO_1$ and $ARGO_2$).

The difference between both orthoses was estimated by calculating 95% confidence intervals for the averaged ARGO minus the averaged NRO measurements using paired t-tests. All confidence intervals are presented as relative increase or decrease with respect to the baseline ARGO. Differences in outcome on the questionnaire and in oxygen cost of more than 20% were considered clinically relevant. If the upper and lower limit of the confidence interval for the difference crossed the 20% level, it was concluded that there was insufficient evidence to draw conclusions in hypothesis testing. A p-level of 0.05 was considered significant. All analysis were done using SPSS.

Results

Six male subjects were included in the study. Two subjects had T4, three subjects T9 and one subject a T12 complete lesion (Table 1).

Cadence, oxygen cost, PCI and expiratory volume had skewed distributions. Natural log transformations yielded a log normal distributed parameter. CFT1 was negatively skewed distributed, but the natural log of (1-CFTI) appeared adequate to obtain a log normal distributed variable. Using (1-CFTI) is justified because of the expected asymptotic value of crutch force measurements.

No significant differences between $ARGO_1$ and $ARGO_2$ were found, indicating that tests effects were avoided. No significant differences in biomechanical data between NRO_1 and NRO_2 were found, indicating absence of a training effect.

The physiological reaction of walking performance was analysed in order to determine steady state exercise performance. Figure 1 shows a typical result of one subject walking in the ARGO.

Expiratory volume increased during the first six minutes of walking. VO_2 and VCO_2 were at a stable level after 4-5 minutes. Heart rate rapidly increased up to 160 beats.min^{-1} in the fourth minute.

Oxygen cost and PCI were not significantly different in the ARGO compared to NRO (Fig. 2). VO_2 and RER were not significantly higher in ARGO ($p>0.13$ and $p<0.12$ respectively) (Fig. 2). No significant differences were found in expiratory volume and heart rate. Stride length was not significantly lower in the NRO ($p<0.07$) (Fig. 3). CFTI was not significantly higher in the ARGO ($p<0.08$) (Fig. 3). No

Table 1. Subjects included in the study Weight is expressed in kilogram (kg) and kilogram lean body weight (kg LBW). Mean and standard deviation are calculated.

subject	sex/age	mass (kg/kgLBM)	lesion	walking speed ($m.s^{-1}$)	training in NRO (hours)
1	m/34	66/50	T12	0.41	16
2	m/40	67/53	T9	0.29	16
3	m/57	80/50	T9	0.09	20
4	m/44	90/67	T9	0/20	20
5	m/28	73/57	T4	0.20	14
6	m/29	79/64	T4	0.21	16
$x \pm \sigma$	38.7±10.9	75.8±9.0 56.8±7.3		0.23±0.10	17.0±2.4

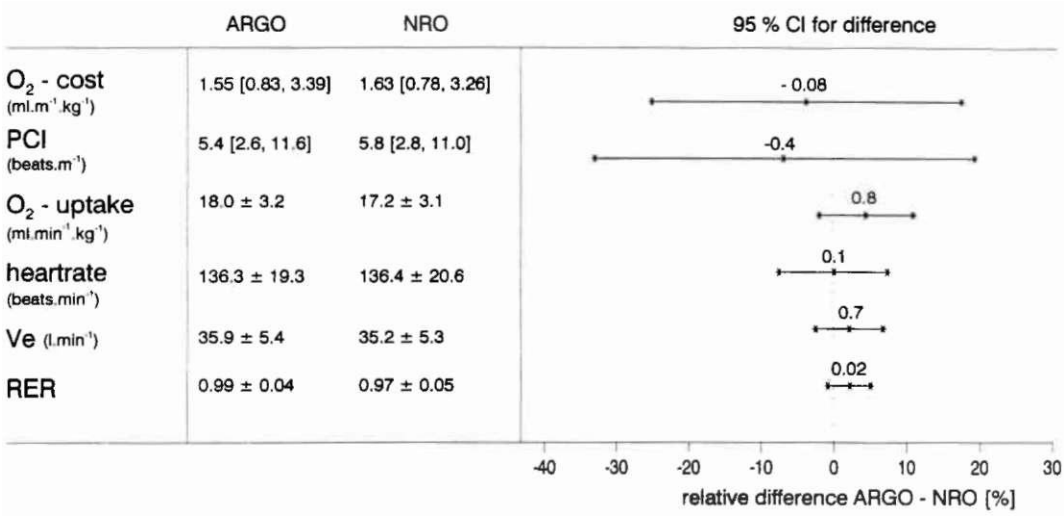

Fig. 2. Confidence intervals (95%) for estimated difference between ARGO and NRO. Mean and standard deviation of each parameter is presented for ARGO as well as NRO. The mean difference between ARGO and NRO is presented on top of the interval. The upper and lower limits of the intervals are presented as relative difference with respect to the baseline ARGO measurements. Negative value of O_2-cost and PCI indicate lower energy requirements during walking in the NRO.

differences in walking speed, cadence and CPF were found.

The scores of subjects on the VAS as well as on the 10 point scale appeared to be consistent. Analysis of the questionnaire showed that subjects preferred the ARGO for use in daily living (Fig 4). No significant difference was found with respect to walking in either the ARGO or NRO.

The large standard deviation for the differences of clinically important effect measures suggests the existence of large inter-individual differences in outcome. Subjects with T9 and T12 lesions showed consistently lower oxygen cost in the NRO (Fig. 5). Both subjects with T4 lesions showed a clinically relevant increase of oxygen cost in the NRO. Although oxygen cost was lower in the NRO in T9 and T12 subjects, only two were satisfied with walking in the NRO. Three subjects with low level lesions ultimately preferred the ARGO.

Discussion

One major concern in comparing different

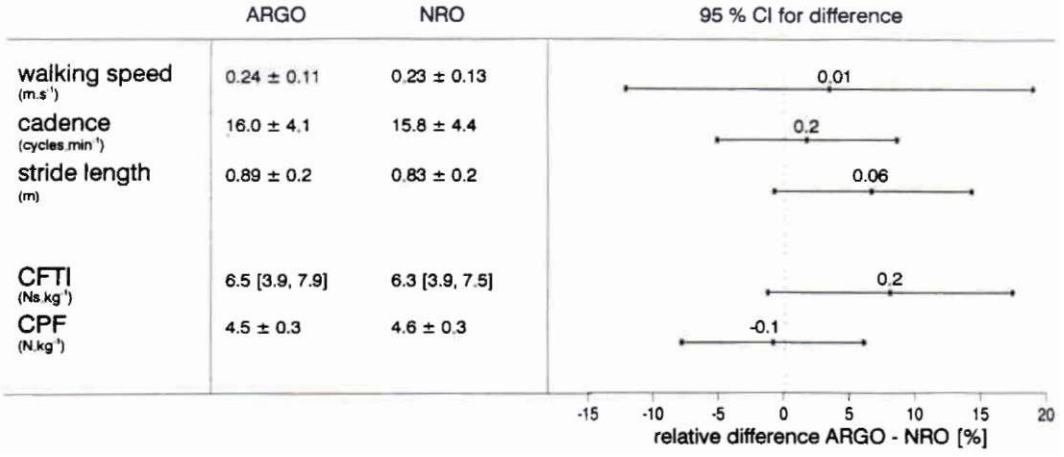

Fig. 3. Confidence interval for relative difference of biomechanical measurements. For explanation of figure see caption Figure 2.

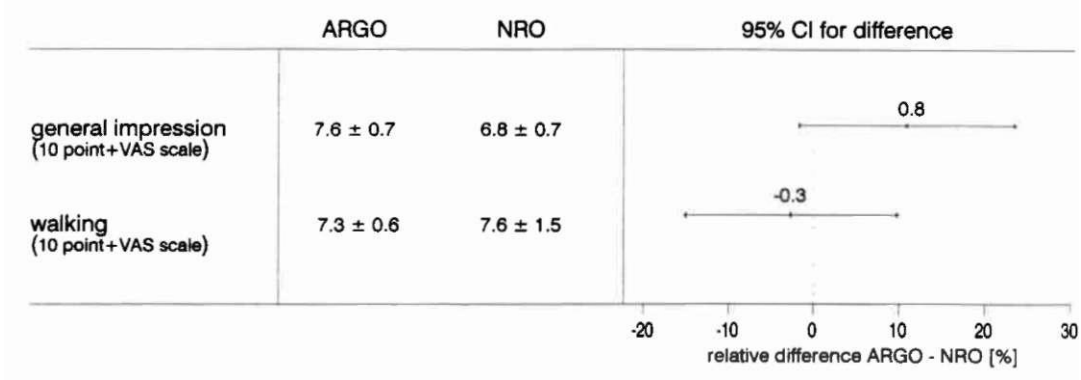

Fig. 4. Subjects' preference for either ARGO or NRO regarding general use in ADL and walking. For explanation of figure see caption Figure 2.

types of orthoses is the prescription and execution of an adequate and sufficient training programme, especially when a specific walking technique has to be learned. Whittle and Cochrane (1989) found that gait training for the Parawalker, which is a system similar to the NRO took 14.4 hours over 5 days, on average. Subjects in the study of Winchester *et al.* (1993), underwent gait training of 12 hours in the Isocentric RGO. In the current study subjects were trained in the NRO for 17.0±2.4 hours. This was thought to be sufficient in order to eliminate training effects. Comparisons of biomechanical data of both NRO measurements underline this assumption.

In the current study it was found that subjects preferred the ARGO for use in daily living. It appeared that they experienced an uncomfortable standing posture in the NRO, leaning in the flexion limit. On average,

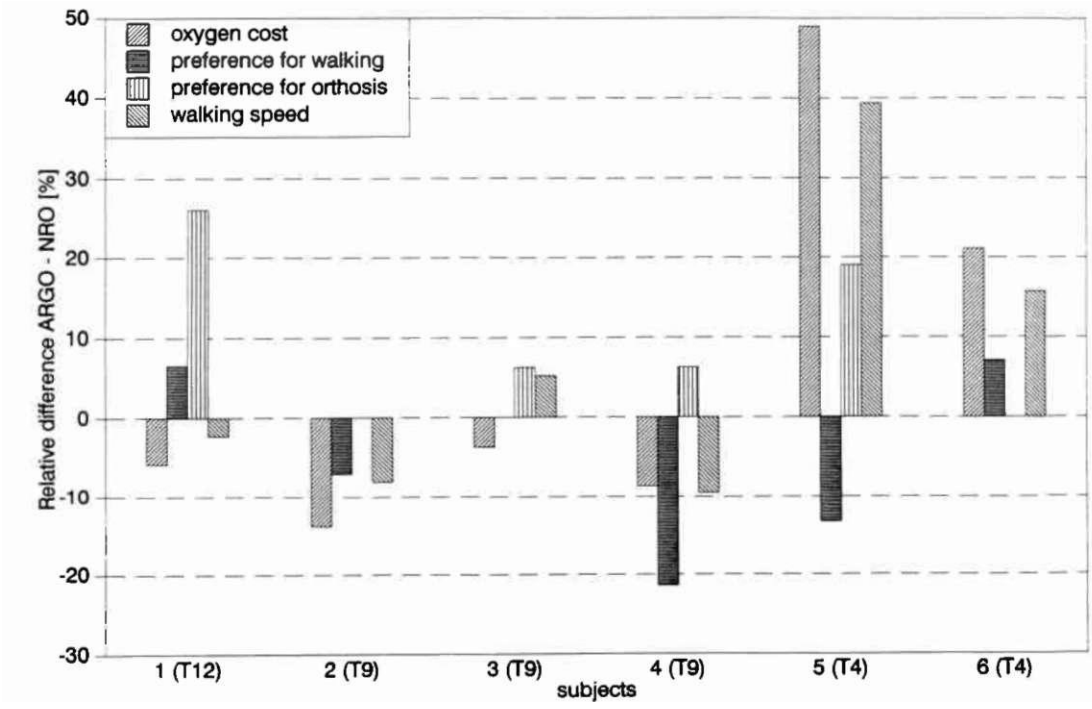

Fig. 5. Display of relative changes in oxygen cost, walking speed and subjects' opinion with respect to general use and walking in both orthoses. Positive differences indicate higher value of parameter in ARGO.

subjects did not prefer the NRO for walking (Fig. **4).** Some remarks can be made with respect to assessment of user aspects by means of a questionnaire. Whittle and Cochrane (1989) have extensively reviewed clinical and user aspects of the RGO and HGO. They noticed that there may be bias in favour of the orthoses which were assessed second in their cross-over trial. Subjects' opinions with respect to a new device may also be subject to recall bias (Sackett, 1979). The new orthosis probably gets more attention from the researchers than the baseline system, i.e. ARGO, and the recall of subjects with respect to ARGO and NRO may differ in volume and accuracy. On the other hand, subjects in the current trial may grade the NRO with respect to a well known standard with which they are very familiar. This may also lead to bias in favour of the well known standard, i.e. ARGO.

From the above, it maybe concluded that comparison of orthoses by means of patients' grading is not free of bias. Discussions with the subjects after the trials showed that their opinion was in agreement with their score on the questionnaire. The conclusion therefore can be supported that removing the reciprocal linkage in ARGO affected standing posture and did not improve the walking experiences of the subjects.

Measurement of oxygen uptake is the most reliable and valid method for estimating energy cost of walking, although several other possibilities have been used, including PCI and CFTI (Winchester *et al,* 1993; Stallard and Major, 1993; Yang, *et al,* 1996). Disadvantages of using oxygen uptake measurements have been reported, but the flexible and user friendly facemask, the small and lightweight gas-tube without valves in the device used prevented interference with the subjects' walking pattern.

Oxygen cost and PCI were calculated after the subjects had walked at least five minutes. This appeared to be a good approach, since steady state was found to be delayed. The high heart rate and respiratory exchange ratio during walking possibly indicates anaerobic energy supply during the 10 minutes walk. Therefore, calculation of energy cost from oxygen cost data was not performed, since this may underestimate energy requirements (Wasserman *et al,* 1987).

No significant difference in oxygen cost was found between the orthoses. The mean difference in oxygen cost could vary between 25% higher in NRO to 17% lower in NRO (Fig. 2). It is concluded that there is inadequate evidence to draw general conclusions for the whole group of subjects. The difference could imply a clinically relevant improvement for either the ARGO or the NRO. However, large differences between subjects were found (Fig 5). Energy requirements of both T4 lesions are up to 40% higher in NRO, whilst oxygen cost in subjects with low lesions was lower in NRO (Fig 5).

The difference in outcome between low and high level paraplegics may be explained by differences in walking speed, since walking speed in high level pearaplegics decreased (Fig. 5). Walking speed in high level paraplegics may be decreased in the NRO either because of the reduced stride length (Fig. 3) or because of a reduced cadence due to the increased effort necessary to maintain a stable posture during double stance. Stride length was reduced by means of flexion-extension limits during the training phase in order to prevent extreme step lengths. Removal of the reciprocal linkage in the ARGO resulted in an increase of flexion/extension range, which is undesirable because the subjects are not able to move the centre of gravity to the new stance leg.

Hirokawa *et al.* (1990), found that oxygen cost was lower in the HGO Parawalker than in the RGO at higher walking speeds. In an orthosis with freely swinging legs more effort is required for stabilisation during double stance. Since the double stance phase is shorter at higher walking speeds, this may explain the lower energy requirements in an orthosis with freely swinging legs.

It is assumed that high level paraplegics are not able to achieve high walking speeds, because of the irregularity of their walking pattern. Furthermore, in order to maintain stability during double stance and to prepare the next step it is expected that they need to put more effort into decelerating the body.

Oxygen cost in low level paraplegics was found to be 4% to 14% lower in NRO (Fig. 5). The observed differences in oxygen cost in the low level lesions were very small and not sufficient to consider them clinically relevant.

Furthermore, only two subjects (2 and 4) with low level lesions, preferred the NRO for

walking. Three subjects with low lesions ultimately preferred the ARGO for use in activities of daily living (Fig. 5).

As in the high level paraplegics, the authors expected the reduced stride length to cause a less efficient gait pattern. Due to removal of the reciprocal cable linkage, subjects were standing in a flexed position, leaning in the flexion limits. This flexed position of the trunk and the adjusted flexion limit prevented a full hip flexion of the swing leg. The swing leg is stopped abruptly, during swing phase, when the highest velocities of the leg are attained (Tashman *et al.,* 1995). This may result in loss of energy available for propulsion. Furthermore, the body has to be decelerated to prevent balance disturbances. Additional training of the subjects may be required to optimise the impulse given to the swing leg at toe-off.

In conclusion, it was found that large inter-individual differences with respect to oxygen cost and PCI provide insufficient evidence in this study to draw general conclusions.

However, individual analysis of the results showed that there are differences between low and high level paraplegics. Patients with low level lesions may benefit from removing the reciprocal cable linkage in ARGO, since oxygen cost was lower. However, only one subject preferred the NRO for walking, whereas none of the subjects chose the NRO for use in daily living. It is expected that the uncomfortable standing position, leaning in the flexion limits, was the major cause of this opinion.

Analysis of the results in both T4 lesions showed that oxygen cost was higher in the NRO. It is expected that high level lesions are not able to achieve a walking speed at which they can use the higher swing leg accelerations for propulsion, because of an irregular walking pattern. Removal of the reciprocal cable linkage in the ARGO may not be desirable for these patients.

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Powered wheelchairs: are we enabling or disabling?

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Abstract

Following the unsuccessful issue of three powered indoor National Health Service (NHS) wheelchairs, a survey was carried out of 40 users in a London wheelchair service to identify the problems with issue and possible areas for improvement to practice.

The survey identified improvements that were necessary both from the service and the manufacturers' booklets. The improvements include the issue of written instructions and information to complement verbal instruction given at handover. Such information should be as interesting to read as possible, make use of appropriate language and diagrams (especially in area where English is often not the first language), colour, text and print size to maximise comprehension to these severely disabled users and often their elderly relatives or carers.

The importance of the role of the rehabilitation engineer in training the user, giving instruction at handover and annual review are highlighted to ensure that the equipment remains working, suitable and up to date for the individual's needs. Training in interpersonal and communication skills and the importance of recall should also be emphasised.

The implementation of the findings should lead to increasing contact with the service by the user, reduction in repair and replacement costs, regular review, correct supply and will therefore enable users to increase their independence with appropriate equipment.

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Introduction

The development of the powered wheelchair began with the application of a car starter motor to the tubular cross frame of the wheelchair, with power derived from a car battery. With the development that subsequently followed, the cross frame of the wheelchair was removed and the space beneath the seat became available to hold equipment or the battery (Warren, 1990). Carter in London, produced motorised wheelchairs during the First World War to meet the demands of the large number of surviving paraplegics and amputees from the War (Kamenetz, 1969). With the further increase in the survival of people with physical disabilities in the 1960s and 1970s the demand for powered wheelchairs increased (Wilson, 1986). It has been said that perhaps no single piece of equipment makes a greater contribution to implementing the five basic rights for the disabled outlined by the United States of America Department of Health and Human Services. These rights are the freedom to life, to learn, of movement, to work and for independent living (Brede and Ibler, 1982).

The most obvious benefactors of powered mobility are those users who are completely dependent and who, without the equipment, are unable to move in their environment (Warren, 1990). Others also include those who are less dependent, that is, those who are unable to propel a manual wheelchair more than a few feet or those who through propelling the wheelchair are then unable to perform functional tasks with their remaining energy. Such users include those who may suffer from the following conditions: rheumatoid arthritis, osteoarthritis, cerebral vascular accident,

multiple sclerosis, upper and lower limb amputation, cerebral palsy, tetraplegia, paraplegia, cardiac conditions, motor neurone disease, cervical spondylosis, spinal degenerative diseases, poliomyelitis and muscular dystrophy.

Provision of powered wheelchairs, as with manual wheelchairs, was organised nationally in the United Kingdom (UK) through the Artificial Limb and Appliance Centres (ALAC) until 1991. Patients who were unable to manage a manual chair were referred by their general practitioner (GP) to the Department of Health and Social Security (DHSS) medical officer at the local wheelchair centre. Here an assessment would be carried out to ensure that the candidate was suitable for this equipment using a DHSS form which stated 'Conditions of Eligibility' for patients if they were:

i) suffering from a defect of the locomotor system or severe chronic lung or heart condition so that to all intents and purposes they were unable to walk;

ii) unable to propel themselves in an ordinary wheelchair;

iii) not permanently bedfast;

iv) able to derive some measure of independence in the home from using a powered indoor chair.

If it was agreed that the patient was suitable and warranted such equipment, the doctor together with the ALAC technical officer (TO) would assess the patient for a suitable model available from the NHS at the time.

In 1986, there were 8,500 users with indoor powered wheelchairs on issue from the National Health Service (NHS) within England and Wales, and 595 on issue in Scotland in 1981 (Scottish Home and Health Department, 1983). By the end of March 1992, the Department of Health reported that there were 8,907 indoor powered wheelchair users in England (Department of Health, 1983), a very small increase in the numbers over six years. The Royal College of Physicians' report on disability stated that the average GP group practice with a list of 10,000 would have 72 wheelchair users and a Health District with a population of 250,000 would therefore have approximately 1,810 persons in wheelchairs (Royal College of Physicians, 1987). A recent study indicated that the number of manual users had increased by 265% in the last 20 years (Kettle and Rowley, 1990) and today there are almost 700,000 users of NHS wheelchairs alone in England (Aldersea, 1996).

If the patient could manage to manoeuvre and handle the selected model, a home assessment would be carried out by the TO to ensure that the environment where the wheelchair was to be used was both safe and suitable. If the visit was satisfactory, the wheelchair would be delivered by the "approved repairer" and a 'hand-over' of the equipment would be completed by the TO separately. Typically the hand-over included the following: inspection of the chair and checking the model delivered was the correct one, demonstration of battery access, maintenance and charging also giving written instructions, checking of the suitability of the seating and controls for operation and use, testing the user under power, and hand-over the model handbook. A conditions of supply information sheet would also be issued. No training was routinely given regarding transfers or manoeuvres in the wheelchair. Annual checks was carried out by the TO service.

In the years prior to devolution of responsibility from central government control, the NHS indoor powered wheelchair range consisted of the following models:

i) Model 102, a heavy and slow-moving three-wheeled chair with a foot platform. The chair was not readily transportable but turned in a very limited space;

ii) Model 103, a portable, light-weight aluminium-framed and front-wheel drive chair;

iii) Models 109 and 110, both steel-framed and front wheel-drive;

iv) Model 110JX, a more advanced wheelchair which included a brake motor (Williams ***et al***, 1982).

Today, the commonly prescribed powered wheelchairs are: Bencraft's Apollo and Pioneer models, the Barrett Jewel and Gem, the Newton Badger, all of which are rear-wheel drive unlike the earlier models.

A report of the wheelchair service in Scotland stated that some of these earlier models were 'rather jerky to use' through their standard control box. Moving the joy stick would move the chair at a set speed, hence the initial jerk. However more modern proportional controls move the chair at a speed proportional to the movement of the joy stick and are therefore smoother, giving the user more control over the

speed. The report also found that there was 'a major problem with batteries for all powered wheelchairs' (Scottish Home and Health Department, 1983). The batteries that were supplied by the NHS (and continued to be supplied in some areas following the 1991 devolution) were the wet lead-acid variety. With this type of battery most of the charge (up to 80%) should be used up before they are recharged. The wet-acid batteries require regular topping up with distilled water in all of the 12 chambers, at least monthly and only after charging. If the topping up is carried out before charging, bubbling-over occurs which leads to spillage and the risk of burns to the skin, clothes and floor. Only distilled water should be used with such batteries and this is not supplied by the NHS. The six small caps on each battery have to be removed for the topping up to take place (Male and Massie, 1990). It is important to avoid overfilling the cells as this can cause spillage and burns, or underfilling which can cause corrosion of the plates and eventually a failure of the wheelchair. The safest way to refill the cells is with a special valved dispenser which should be supplied by the approved repairer with the wheelchair. It is also advised that the terminals are smeared with petroleum jelly to prevent corrosion. For safety reasons, it is recommended that the battery should only be charged in a well-ventilated room and not in the main living room or bedroom, as the gases that are given off can cause explosions, (this is the reason why services such as "dial-a-ride vehicles", ambulances, hospital transport and buses frequently refuse to take them on board). For the charging to take place, the user has to come out of the wheelchair and lift the seat canvas for access to the batteries. Charging should take place for eight hours or overnight, and if the chair is not in use it should be charged at least on a monthly basis (Department of Health/Medical Devices Directorate, 1992). The user therefore needs patience, dexterity, a fair mental ability and memory in order to carry out these tasks safely. A good command of the English language an understanding of some technical jargon is also needed to be able to follow the instructions in the booklets issued by the wheelchair manufacturer (Department of Health/Medical Devices Directorate, 1992).

Therefore prior to 1991, users were supplied with a wheelchair, instruction booklet and in most cases a distilled water bottle for topping up the battery. There was little information or detail in the booklets regarding the charging of the batteries and this varied from one sentence to a quarter of an A5 page. All modifications, repairs and necessary follow-ups at home were carried out by the TO and approved repairer. Therapists were rarely involved in powered wheelchair supply.

Following the McColl Report (1986) and the formation of the Disablement Services Authority, the wheelchair service was devolved to a district level in England in April 1991. Responsibility for prescription, supply, support, review and all the financial implications was handed over to the district therapy teams in most areas. However in some areas the service remained in the hands of the TOs (now called rehabilitation engineers), for example in the North Western Region of England.

Newham is one of the most deprived boroughs in the country. It is situated in east London and the population is both multiethnic and multicultural. The population comprises: 57% white, 13% Indian, 7% Afro-Caribbean, 6% Pakistani, 4% Bangladeshi, 3% other Asian, 1.5% other black and 0.8% Chinese. The local population therefore has special requirements, relating to, for example, verbal and written information, expectations of the NHS, problems of lower social class and low educational levels. It is a borough which has many facilities and opportunities for the disabled population. These include: day centres, specific cultural groups and centres, an under 65 physically disabled centre, learning difficulties centres, organised holidays for the disabled, outings around and out of the borough for the disabled, a community transport service as well as a council supporting the 'black cab' scheme. The area also has low-entry London Transport buses, educational courses of all types and a central sports centre which caters for the disabled.

At the time of devolution, the Regional Centre Harold Wood had 1042 powered indoor chairs on issue, 26% of the total on issue. The number of powered indoor users for each district in 1991 at devolution is not available. By 1994, the Newham population had increased from 217,000 to 226,000 (1991 Census) and there were 45 powered wheelchair users. The 39 adults and 6 children suffered with disabilities

which included: multiple sclerosis, spinal cord injuries, poliomyelitis, rheumatoid arthritis, cerebral palsy, motor neurone disease, muscular atrophy, osteoarthritis, hemiplegia, amputation and muscular dystrophy.

In Newham, at the time of the survey, users were referred to the service generally by GPs and therapists. They would be assessed for their wheelchair needs and if this included the provision of a powered indoor model, the rehabilitation engineer (RE) would become involved in both the environment check and hand-over procedure. However at this early period of the purchaser/provider split, the purchased RE sessions were limited and therapists also had to cover some of their duties.

Some 18 months after devolution and following three unsuccessful deliveries and hand-overs of indoor powered wheelchairs to new users in this district, it was decided that the area needed to be reviewed to identify problems and possible improvements to practice.

Method

In December 1993, a three part action research study was undertaken with the aim of reviewing current service to indoor powered wheelchair users. Information was sought in three areas: the past, through a review of users' experiences; the present, through the current practice of others; and finally the future, through the content of training programmes and courses.

The past - user survey

Sample group

The total number of service users on record was 45. However 5 were excluded from the study as they were either known to be abroad for some time or were recent users and would therefore be less qualified to offer assistance in the survey. The sample group of indoor powered wheelchair users was 40 (1% of the database of wheelchair users). The group consisted of 36 current users and 4 recent ex-users (i.e; chairs returned within the last 12 months as a result of changing social circumstances or an inability to use the chair).

The aim of the questionnaire was to obtain information on the following topics: detail of issue, current level of usage, therapy input before supply, general maintenance, verbal and written information offered and issued, use of the approved repairer service, wheelchair service support, additional needs unmet by the wheelchair service and ideas for improvement for the future.

Pilot study

The survey tool was tested with four established users as a pilot study. These four users were specifically selected as they were well-known to the service and known to be expressive of their views. Between them they suffered from a range of disabilities, ages and chronicity of condition. The questionnaire was semi-structured, with both open and closed format to the questions.

The sample group was also interviewed by one of the authors using a semi-structured format to gain further information about the topic area and to obtain comments on the manufacturers' booklets currently issued, namely those of the Bencraft Apollo, Newton Badger, Barrett Jewel and the two booklets given with the Bencraft Pioneer (powered and manual transit models). Comments were requested regarding: the layout/presentation, overall length, print size, paper colour, general clarity, degree of quality of the illustrations if any, and the terminology used. Colour combinations were offered from the following colours: white, pale blue, pale yellow, pale green, pale orange, and pale pink to determine the most favoured background for a booklet's readability. Courier font size 14 was used throughout.

Survey questionnaire

From the pilot study, comments were noted and the final questionnaire designed. The option of anonymity was offered as the questionnaire was not pre-coded. However if the user wished to be sent any feedback, they were asked to print their name at the end of the form. Also the option of interview either in person or over the telephone was offered but not taken up by users.

The definitive postal questionnaire was sent with a stamped, addressed return envelope and covering letter explaining the reason for the review and emphasising the importance and subsequent application of their views. The questionnaire consisted of four sections and 36 questions, in large pint on 6 pages of A4 paper (Appendix 1).

The present - wheelchair services

An open-ended letter was sent to specifically named individuals (either therapist or doctor) at 17 regional Disablement Service Centres and specific therapists at 36 district wheelchair services throughout England and Wales. (These names were available from the national wheelchair service lists and the centres were selected at random). The letter invited the therapists to give information on their local supply procedures and policies including any written information given to new powered wheelchair users.

The future - rehabilitation courses

A similar letter was sent to two Rehabilitation Course Directors and to two current course participants to establish the detail and time spent on this topic in their educational programmes, particularly concerning the user. These courses would be attended by rehabilitation engineers and therapists.

Results

The past - user survey

The response rate was 31 (78%) and 4 of these were unsuitable for analysis for the following reasons: one was poorly completed by the carer, two died after the questionnaires were sent out, and one returned the chair after three weeks. The final total analysed was therefore 27. Some 21 (78%) requested feedback.

The chair

Thirteen (48%) users had had their wheelchair less than two years and 14 (52%) longer than two years (pre-devolution). Some 15 (56%) had been seen by a member of the wheelchair service within the last 12 months and 21 (78%) were using the chair regularly. Only 21 (78%) replied that the chair was in working order and 18 (67%) said the chair was meeting their needs.

Learning to use the chair

Eighteen (67%) said they had received a home visit before the chair had been issued and 11 (41%) said they had had a trial drive of the chair. Some 20 (74%) had received no therapy training on the handling of the chair and 17 (63%) welcomed an annual therapy visit in the future. Only 17 (63%) said they had been given a contact number for the service.

Looking after the chair

Twenty-two (81%) said a relative looked after the chair and only 3 (11%) users looked after their own chairs. Some 16 (59%) said they had been taught how to look after the chair and 14 (52%) had received an information booklet about the chair. Nineteen (70%) said they knew who to contact for repairs. Regarding battery charging, 11 (41%) charged batteries every night or overnight 19 (70%). However, 4(15%) charged it for more than 24 hours. Seven (26%) checked the battery fluid correctly every two weeks, 6 (22%) monthly and 5 (19%) said they never checked the battery. One (4%) replied that they used tap water to top up the batteries.

Repairs

Seven (26%) said they called the approved repairer (AR) when they needed repairs and 13 (48%) said they contacted the service. 23 (85%) replied that they checked the chair themselves initially if there was a fault. Eight (30%) had had no repairs in the last 12 months but the remainder had had either 1 (30%), 2 or 3 (30%) or more (10%) in this period.

When asked where they stored the chair when not in use, 17 (63%) said by the bedside, 9 (33%) in the corridor/other and 1 (4%) outdoors. Six (22%) transported the chair in a car and 7 (26%) in a bus, all noting that transportation on hospital vehicles was disallowed. Some 24 (89%) said they welcomed an annual check and 25 welcomed a new information booklet about the wheelchair.

The present - wheelchair services

Regional wheelchair services

A total of 8 (47%) replies were received from the 17 DSCs, only 1 (13%) of which issued a locally devised sheet together with Her Majesty's Stationery Office (HMSO) leaflet regarding the do's and don'ts for charging batteries and also the manufacturer's booklet. Four (50%) issued the DHSS leaflet only and 3 (38%) issued the DHSS leaflet and the manufacturer's booklet.

District wheelchair services

A total of 23 (64%) replies were received from 36 district wheelchair services across England and Wales, 4 (17%) of which had locally devised an information sheet or booklet on general maintenance, 2 (9%) of these also

gave out the DHSS leaflet and the manufacturer's booklet. Ten (43%) issued the manufacturer's booklet alone, 3 (1%) issued DHSS leaflet alone and 6 (26%) issued both of these.

The future - rehabilitation courses

Both course directors replied. Courses available were:

a) a three-day postgraduate course on wheelchairs and seating; and

b) a Rehabilitation Engineering Certificate course.

The first course did not cover wheelchair maintenance in detail as it was assumed that such information would be provided by the wheelchair manufacturers/suppliers. The second course did not offer training on how to advise users but the correct procedures for battery charging were taught and the REs were also advised of their responsibility to see that patients understood the procedures.

Of the two course students questioned, one replied saying that they had received no relative written information/instruction on this topic.

Discussion

Following the NHS management inquiry in 1983 there was a proliferation of surveys in the NHS that were largely managerially led and focused on the hotel aspects of service such as quality of catering, physical amenities for inpatents or the access to health care facilities. Following the government white paper, 'Working for Patients' (The Health Service, 1989), it was envisaged that surveys would increase in seeking patients' views on information needs, interpersonal and organisational aspects of care and the value of medical treatment (Fitzpatrick, 1991).

Patient satisfaction survey results are important outcome measures and used systematically can provide feedback that offers alternative ways of organising or providing healthcare. A survey was therefore carried out in the authors' district to find out about patients' experiences with the service provided and to ascertain how procedures could be improved in the future.

Although a postal survey is less sensitive to patients' concerns and is unable to clarify ambiguities, it was the chosen method here as it held no interviewer bias, provided patient anonymity and required less staff input and costs. Ley *et al.,* (1976), in a study of medical inpatients, found that patients replying to postal questionnaires were no more likely to be satisfied than those who did not reply. The interviewing and content analysis of the individual discussions also helped in obtaining quality information.

The equipment had been on issue both pre- and post-devolution, for both more and less than two years. Typically such equipment costs approximately £1,000. Only 78% of the population surveyed were using the equipment regularly and for the same percentage it was in working order. However for only 67% was the equipment meeting their needs and only half had been seen by staff from the wheelchair service in the last 12 months. Regular reviews of this group would therefore ensure the wheelchair is meeting users' needs and remaining appropriately issued. Only half said they had had a home visit before the equipment was issued and yet this had previously been carried out by the TOs. Only 41% had had a trial before issue, thus indicating that these users had not attended the service for assessment prior to issue to see if such equipment would in fact meet their individual needs or more appropriately had a trial at home. Twelve (45%) incorrectly charged and checked wet batteries which leads to exposure of the plates in the battery and reduced battery capacity.

The quality of information given to users was poor. Some 37% said they did not have the telephone number of the service and 30% who to contact for repairs. The majority of these severely disabled users had relatives who maintained their chairs (81%) or carried out the maintenance themselves (11%) yet 41% had not been told how to use the chair and 48% had no instruction booklet that they could remember. This is in line with the findings of other surveys (Kettle *et al.,* 1992). Some were overcharging or incorrectly charging/maintaining the batteries and the majority (70%) had needed repairs to the equipment in the last 12 months. Expensive equipment that is difficult for disabled users to manage is therefore being issued with poor maintenance, without maintenance information and costing the service and the NHS money through visits, repairs and replacement of equipment (e.g. batteries).

The information given to these users was locally poor but little different from the national picture at the time. Few (5%) services had developed any local information sheets since devolution. The majority were issuing the DHS sheet with the chairs and some also the manufacturer' booklet. But as 93% of users said they wanted a new booklet, the usefulness of the current manufacturers booklet is questioned and some users interviewed said the booklets were too difficult to comprehend. The equipment issued is difficult for the disabled user and their carers (often elderly) to manage, yet few changes have been seen in its supply until the 1990s in the NHS.

Until recently, the same models of powered wheelchairs were supplied and yet problems with some aspects of the wheelchairs were identified more than 10 years ago.

Gel sealed batteries have been available in the UK for the private market for the last 30 years. They are called 'maintenance free' batteries and require no topping up. They can be charged in any room as no gases are given off and there is a special charger for them. The user can safely remain seated in the wheelchair during the charging process unlike with the wet type. The charging procedure is much the same as the lead-acid variety but it does take longer, and the user should be informed about this. This change of action often causes problems or users changing from 'wet' to sealed batteries. Transportation of this type of battery is not subject to restriction as spillage is near impossible.

Control boxes are now available that ease the charging process with front-access design for charging and with larger pin connectors.

Information

Written information has been described as frozen language, selective in its description of reality providing limited feedback but constantly available (Klug Redman, 1988). It is an efficient way to transmit information and as it is visual it can stimulate memory (Waring Rorden, 1987). It is of value only when it is used in conjunction with direct patient explanation and should never replace direct patient contact. It is a helpful form of reference and review of the information that has already been given (Goldberg, 1980; Renner and Smith, 1987). It can also act as a reinforcement of information already given as the client may remember little of what he/she has been told (Sloan, 1984). This may be due to his/her inability to concentrate through medication, advanced age or physical disorders (Waring Rorden, 1987). As written information is frozen language patients can come back to it in their own time, thus controlling their rate of comprehension. Written information is often kept and referred to more than once and by more individuals that the patients themselves, for example carers and family.

Written information is therefore a useful adjunct for the health care professional when imparting complex instructions to clients especially when their cognitive level may be reduced due to age, illness, tiredness, educational level, language problems or a lack of familiarity with the jargon.

A considerable amount of information written for patients has been found to be too difficult to read as it is at too high a level (Ley, 1989). It is also often poorly designed and many leaflets are written in language that fails the standard tests for readability (Smith, 1992). The average reading age of the British population has been found to be nine years (Greenhalgh, 1990). If written information is too complex it can be off-putting (Robertson, 1987) and if it is not presented in an interesting manner, can be boring, therefore losing the patient's attention. It can be simplified by using shorter words and sentences. Manufacturers booklets should therefore incorporate such findings to ensure the information they give to users and carers is correct, useful, comprehensible and interesting to read making maximum use of diagrams.

In 1979, Ley found that patients fail to recall much of what they are told and amongst other findings that age and intelligence are not related to recall. If patients write down in their own words what they are told, this has been found to marginally improve recall (Thompson, 1984). Ley and Spelman (1987), in a study of patients recalling outpatient statements given by doctors, found that instruction and advice were more likely to be forgotten than statements of diagnosis. A further study by Ley (1972) found that patients recall what they are told first and what they consider to be most important but they still forget far too much. Ley (1982) found that

patients remain dissatisfied with communication, often not understanding what is being said and often forgetting what they are told. Ley and Spelman (1987) argue that patients remain dissatisfied because they do not understand what they are told, are too diffident to ask questions and because they forget too much of what they are told. Therefore it is vital that the traditional powered wheelchair 'handover' is supported with written information.

Good interpersonal skills, with a demonstration of empathy, concern and respect, have also been found to improve patients' ability to recall information. It is thought that good interpersonal skills reduce the patient's anxiety, permitting better comprehension of instruction and advice (Stephens, 1967; Lazare *et al.,* 1978). The 'teacher' or person handling over such powered wheelchair maybe the 'crucial factor in the process'.

Professional jargon has been found to be either meaningless or misinterpreted by patients (Korach and Negrete, 1972; Boyle, 1970). Patients can also use jargon which may vary with age and ethnically distancing health care worker and patient. Therefore it is important that health care workers check that the information has been understood by both parties. In powered handovers, this would also include a paid or family carer.

Conclusion

The devolution of the wheelchair service has in many cases, made it more responsive to the population needs of the area, especially where local developments have taken place. The older model of NHS chairs are now being replaced by a variety of powered chairs that should meet the local needs more appropriately. Accessories, such as batteries and control boxes, are now available that are easier for the user and carer to manage and handle. The referral and assessment procedure should be more responsive to the individual with mobility needs. But such improvements are not seen all over England and improvements for powered users have been slow.

Although the sample group is only 1% of the total users of the Newham wheelchair service, they are the most severely disabled of the population. The study has identified a number of areas needing further development both within the service and from manufacturers.

There is a need for a better user information booklet, using as many diagrams as possible to cover problems of language, sight, comprehension and intellectual level. Appropriate paper, colour and font size should also be considered together with careful selection of technical language. Production in a variety of languages or with little text would also be an appropriate consideration. The booklet should include information about charging, maintenance, faults and be personalised to include local contact numbers for example to increase user ownership.

The importance of the role of the RE at handover and annual equipment review, is highlighted and their role in ensuring that these severely disabled users and their carers have equipment available to them which is up to date, easy to use and appropriate. Verbal explanation should always be complemented with written information and the RE should ensure that users understand what is being explained in their own 'language'. Annual equipment checks should include an update of the equipment to ensure that the users, often with deteriorating conditions, receive the most appropriate current equipment to alleviate their problems.

There is also a clear need for regular review and training for the REs regarding the importance of interpersonal and communication skills, recall and information giving at handover and review.

The addition of these procedures should help to ensure that local costs are kept to a minimum through: correct supply and usage, minimal repairs and replacements, fewer examples of misuse and poor maintenance and regular contact with the Service though the annual reviews. Such procedures should also ensure that the users are enabled to be as independent as possible within their environments and that the amount of help they require with the wheelchair from relatives and carers, is kept to a minimum.

The role of the therapist in the assessment for a powered chair and training users to ensure they maximise the use of the equipment and hence increase their independence were also identified. An initial assessment form used by therapists has now been developed for local use. Their role in assessment reviews should also be

highlighted (Kettle *et al,* 1992).

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Appendix 1
Electric chair user survey

Please tick boxes where you can. Ask a relative or carer to help you if you need to.

SECTION 1: Your electric chair

1. When was your chair issued to you?

in the last month ☐ in the last 6 months ☐ in the last year ☐ in the last 2 years ☐ longer ☐

2. Which District wheelchair service it come from? .....

3. When were you last seen by someone from a wheelchair service?

in the last month ☐ in the last 6 months ☐ in the last year ☐ longer ☐

4. Do you still use your chair? yes ☐ no ☐

5. Is your chair still working properly? yes ☐ no ☐

6. Does the chair still meet your needs? yes ☐ no ☐

SECTION 2: Learning to use your chair

1. Did a therapist discuss your needs with your before you were given an electric chair of your own?

yes ☐ no ☐

2. Did she see you at home? ☐ *or at a whelchair centre?* ☐

3. When your chair was delivered to you, were you or our carer taught how to look after it and charge up the batteries?

yes ☐ no ☐

4. Were you told who you could contact if you were ever unhappy with your chair?

yes ☐ no ☐

5. How many times were you visited by a therapist to help you get used to your new chair at home?

none ☐ once ☐ 2 or 3 times ☐

6. Would you welcome an annual visit by a therapist from the wheelchair service?

yes ☐ no ☐

SECTION 3: Looking after your electric chair.

1. Who looks after your electric chair and charges it up for you?

yourself ☐ relatives ☐ carer ☐ homehelp ☐ other ☐ .....

2. Was that person taught how to charge up the batteries by someone from the wheelchair service?

yes ☐ no ☐

3. Were you given an information booklet or leaflet about the chair?

yes ☐ no ☐

4. If yes, was it written in clear print? yes ☐ no ☐

was it too technical? yes ☐ no ☐

were there enough helpful pictures? yes ☐ no ☐

was there too much information? yes ☐ no ☐

5. Were you told who to contact if you needed repairs or replacement of parts to the chair?

yes ☐ no ☐

6. How often do the batteries get charged up?

every night ☐ twice a week ☐ once a week ☐ when the on/off light is flashing ☐

7.How long are the batteries left to charge up for?

less than 4 months ☐ overnight ☐ 24 hours ☐

8. Do you stay sitting in the chair whilst the batteries are being charged?

yes ☐ no ☐

9. How often are the fluid levels checked inside the batteries?

once a fortnight ☐ once a month ☐ once every 3 months ☐ once a year ☐

10. How often does your chair get checked over for worn tyres, fraying wires, loose parts, torn seat canvas, etc.?

once every 3 months ☐ once every 6 months ☐ once a year ☐ never ☐

11. What do you use to top-up the fluid in the batteries?

distilled water ☐ tap water ☐

12. Where do you keep the chair when you are not using it?

by the bed ☐ in the corridor ☐ in an outdoor shed ☐ outside ☐

13. Do you feel happy with the way your chair is looked after?

yes ☐ no ☐

14. Would you welcome an annual maintenance check for the chair?

yes ☐ no ☐

15. Do you never need to take the chair in a car?

yes ☐ no ☐

16. Do you ever need to take it in a dial-a-ride cab or transport bus?

yes ☐ no ☐

17. Please write down any problems you have had taking your electric chair on any transport.

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18. Imagine you are a new electric chair user, and you have been given an inormation booklet. What kind of things would you like the booklet to tell you?

.....

.....

SECTION 4: Getting your electric chair repaired

1. Who would you contact if your chair needed repairing or a part needed replacing?

.....

2. Have you never needed repairs or parts replacing?

yes ☐ no ☐

3. If yes, please state what kind of repairs you he had done?

.....

4. How many times have you had to call someone this year?

none ☐ once ☐ two or three times ☐ how many times ☐

5. When you think something is wrong with the chair do you bother to check anything on the chair before contacting the repairer?

yes ☐ no ☐

6. If you had an easy-to-understand booklet, would you use it to help you look after your chair?

yes ☐ no ☐

If you would like to have a copy of the new information booklet sent to you when it is finished, please print your name clearly here:

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