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Outcome of fitting an ICEROSS prosthesis: views of trans-tibial amputees

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Abstract

A report of the outcome of fitting ICEROSS prostheses to trans-tibial amputees from a sub-regional amputee rehabilitation centre is presented. This work has mainly concentrated on obtaining patients' own views to judge advantages and disadvantages of ICEROSS compared to their previous patellar-tendon-bearing (PTB) prostheses. Sixty-nine patients were entered for this study, but the results of the study are based on 54 patients who responded. Fifteen patients (27.7%) had rejected their ICEROSS prosthesis at the time of the study. Provision of ICEROSS prostheses did not improve indoor and outdoor walking abilities in terms of distance or use of other walking aids, nor were they more comfortable to wear. An increase in sweating in the first 3 months of wearing ICEROSS was significant, but settled afterwards. The amputees considered that the rate of stump skin breakdown with ICEROSS compared to their PTB prostheses was significantly less. Walking up and down stairs was more comfortable and in a general overall rating of ICEROSS prostheses they were scored significantly higher by the amputees themselves. It is concluded that appropriate patient selection is vital and in certain cases ICEROSS will provide considerable benefits to the amputees.

Introduction

The use of the Icelandic roll on silicone socket (ICEROSS) as a prefabricated socket for lower limb amputees began in 1986, though custom made silicone sockets began several years earlier (Kristinsson, 1993; Fillauer *et al.*, 1989). It is suggested that the main advantage of the ICEROSS is improved suspension and that it also considerably improves the weight bearing capabilities of the prosthesis and the interface between the stump and the prosthesis (Kristinsson, 1993).

Published reports of clinical experience and outcome of fitting ICEROSS prostheses by independent researchers are limited. The experience of using the ICEROSS system for trans-tibial amputees by a team from the Netherlands has been encouraging (Cluitmans *et al.*, 1994). There has also been a report of an audit of 89 trans-tibial amputees fitted with ICEROSS sockets in Birmingham, England (Panagamuwa *et al.*, 1994).

Following appropriate training of the prosthetists, ICEROSS for trans-tibial amputees was formally introduced in April 1993 in a sub-regional rehabilitation centre in Sheffield. The additional financial cost of hardware , as well as the extra time required of the prosthetic staff, necessitates convincing evidence of both short and long term benefits for the amputees. Apart from the professionals' own experience of use of the new system, it was felt equally important to consider the users, i.e. the amputees' own views and opinions when outcomes are considered. In this project the main concentration has been on the trans-tibial amputees' views of the ICEROSS systems. They were all previously using PTB prostheses, thus allowing a comparison between PTB and ICEROSS prostheses.

Materials and method

Between April 1993 and October 1994, 69 unilateral trans-tibial amputees were provided

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with ICEROSS sockets on Endolite* prostheses with multiflex ankle joints. An ICEROSS roll on silicone sleeve was used in all cases in conjunction with a polypropylene outer socket and they were connected to each other by means of a "shuttle lock" mechanism. In all cases a thin stump sock was worn between the silicone sleeve and the outer hard socket. All these patients were previously using Endolite prostheses with mutliflex ankle joints and polypropylene PTB sockets with inner Pelite liners. The decision to change to an ICEROSS for these patients was taken in the prosthetic clinics by the rehabilitation physician in conjunction with the prosthetist, with full discussion with the amputee. In some cases the amputee had enquired about the ICEROSS system, having seen a commercial advertisement. An ICEROSS system was not provided to amputees with poor hand function or to patients who could not reach their stump with both hands due to major restriction of joint movements or other reasons.

A composite questionnaire was devised after an initial pilot excercise to ascertain users' views. The three page questionnaire included direct questions e.g. "how many hours per day do you wear your prosthesis on average", some 2 or 3 point response closed questions, e.g. Yes/No or Same/More/Less and some questions with response on a digital score of 0-5 (0 = very poor, 5 = very good). The questionnaire also included 3 open questions inviting comments on users' own perceived advantages and disadvantages and their own ideas for possible areas of improvement of the ICEROSS system. In all but the 3 open questions, patients' response for both ICEROSS and PTB were specifically required so that a comparison could be made.

The main indications for changing over to the ICEROSS system were, problems with suspension, skin problems e.g. skin grafts or very scarred stumps vulnerable to frequent breakdown. In 13 patients ICEROSS was prescribed for young active amputees where it was felt that improved weight bearing tolerance of the ICEROSS and possible reduction of the shear forces to the skin of the stump could be beneficial. Statistical analyses of the responses to questionnaires were done by using *t*-tests for parametric data. McNemar test and Wilcoxon matched pairs signed ranks test were used for statistical analysis of non-parametric data.

Results

Out of 69 amputees who were sent the questionnaire, 54 returned their questionnaires giving a response rate of 78.26%. Out of these 54 patients amputation had been carried out due to trauma in 27, vascular disease and/or diabetes mellitus in 11, congenital limb deficiency in 6 and other miscellaneous causes in 10 patients. The PTB prostheses for these 54 patients prior to the supply of ICEROSS were suspended by leather cuff suspension in 31, self-suspending supracondylar sockets in 21 and by elasticated sleeve suspension in 2 patients.

All analyses of results are from these 54 returned questionnaires. The questionnaires were incomplete in some instances and these were taken into account in presenting the results and analyses.

The average age of the amputees was 48.35 years (range 22-80 years). At the time of the questionnaire, 15 out of 54 were not using the ICEROSS and reverted back to their old PTB prostheses. Of these 15 patients, 10 had stopped using the ICEROSS due to the development of skin problems e.g. marked skin rash, blisters, sometimes associated with excessive sweating, 4 patients had stopped due to pain and discomfort at the distal end of the stump and 1 patient felt insecure with the ICEROSS system as he missed the mediolateral knee joint support of a supracondylar PTB socket.

The respondents had worn their ICEROSS systems for between 2 and 104 weeks (mean 21.22 weeks). A comparison was made between PTB and ICEROSS of the number of hours the limb was said to be worn per day. An average use of 12.26 hours per day for PTB and 10.42 hours per day for ICEROSS was not significantly different (*t*-test, $p = 0.074$). Similarly a comparison between the two types of prostheses of distance said to be walked per day was not significant (*t*-test, $p = 0.776$).

Trans-tibial amputees who were provided with ICEROSS prostheses did not wear them longer, did not walk longer distances, did not find walking on rough ground any easier and did not use walking aids any less compared to their PTB prostheses. Sweating of stump was significantly increased in the first three weeks of using ICEROSS, but settled after 3 weeks. Skin breakdown tended to be less and walking

*Trade name of Blatchford modular, carbon fibre endoskeletal prosthesis.

Table 1. Analysis of response to questions requiring direct Yes/No answers

Information from questionnaire	Number of respondents	With PTB	With ICEROSS	p value	Statistical significance
Use of walking aids, indoors	49	11	6	0.2168#	NS*
Use of walking aids, outdoors	51	25	26	0.6875#	NS*
Use of walking aids on rough ground and bad weather	45	24	22	1.0000#	NS*
Presence of pain in the stump	46	10	8	0.8145#	NS*
Presence of skin breakdown of the stump	47	32	28	0.1153#	NS*

*NS – Not significant # – McNemar test

up and down stairs was significantly improved compared to the PTB prosthesis. The amputees rated ICEROSS significantly higher than the PTB prosthesis in the overall rating.

Responses and detailed analyses of the questions are presented on Tables 1, 2 and 3.

The response to the open ended questions could not be analysed statistically and many did not comment on these questions. Some mentioned, as expected, more than one advantage, disadvantage or suggestion. These responses have been collated to individual grouping and are presented in Tables 4 and 5.

Discussions

This study is based on the amputees' own experience of using the ICEROSS system. As all patients in this study were established PTB prosthesis users, this provides an opportunity to make a comparison of amputees' subjective opinion between the two types of prosthesis. Though the responses are generally subjective in nature, they appear to coincide with clinical observation, as the patients were regularly and routinely reviewed in the clinic by the same team. It is therefore felt that the responses and comments given by the amputees are a generally accurate reflection of their perceptions.

Following the introduction of the ICEROSS system in the clinic, all members of the team are on a learning curve in respect of identifying

Table 2. Analysis of response to questions with 3 response choices

Information from questionnaire	Number of respondents	Same	Less	more	p value	Statistical significance
Rate of skin breakdown with ICEROSS compared to PTB	49	10	26	13	0.0376#	Some significance
Rate of sweating in first 3 weeks with ICEROSS compared to PTB	52	8	4	40	0.0003#	Strong significance
Rate of sweating with ICEROSS after 3 weeks compared to PTB	49	14	15	20	0.3954#	No significance

– McNemar test

Table 3. Analysis of information derived from questions using a digital scale (range 0-5; 0=Very poor, 5=Very good)

Information from questionnaire	ICEROSS		PTB		p value	Statistical significance
	Number of respondents	Mean score	Number of respondents	Mean more		
Comfort of wearing	52	3.50	51	2.82	0.679#	NS*
Comfort of walking for long distances	51	3.06	50	2.66	0.2976#	NS*
Ease of donning and doffing	52	3.63	51	3.25	0.2399#	NS*
Comfort of walking over rough terrain	51	3.00	50	2.52	0.1157#	NS*
Ease of maintenance of prosthesis	50	3.86	50	3.36	0.0546#	NS*
Comfort of climbing stairs	51	3.55	50	2.82	0.0230#	Some significance
Comfort of coming down stairs	51	3.43	50	2.90	0.0390#	Some significance
Overall rating	49	3.82	49	3.12	0.0182#	Some significance

*NS - Not Significant # – Wilcoxon matched pairs signed ranks test

indications, and contra-indications, casting methods and fabrication. The "success rate" may therefore improve by more appropriate patient selection and the application of improved technical expertise.

The rejection of the ICEROSS by 15 patients is of some concern. In 10 of these 15 patients, the ICEROSS was rejected because of skin rash, blisters, irritation and marked sweating, singularly or in combination. The above problems continued for a prolonged period and the decision to reject was taken after an adequate trial in all cases. Two of the 15 found the tightness of the sleeve at the distal end of the stump was too painful to be able to continue wearing their ICEROSS.

In some cases this problem could now be resolved as a greater range of silicone sleeve

Table 4. Responses to open questions regarding advantages of ICEROSS prosthesis

Advantages mentioned	Number of respondents
Better comfort	14
Better donning and doffing	12
Less friction/less skin problems	8
Secure/better suspension	8
Better movement of knee	5
Better cosmesis	2
Better control	2
No more cuffs and straps leading to less wear and tear of clothes	2
Feels part of human body	1
ICEROSS is the only prosthesis which is good	1

Table 5. Responses to open questions regarding disadvantages of ICEROSS prosthesis

Disadvantages mentioned	Number of respondents
Skin ulceration/itching/rash/sweating	20
Difficulty in donning and doffing	7
Connection at bottom of stump	4
Discomfort/feels the socket is hard	3
Needs washing frequently	2
Prosthesis feels insecure/rotates	2
Wool sock gets stuck in lock	1
Sleeve gets damaged	1
Prosthesis feels heavier	1
Constriction at top of sleeve	1

sizes is now available where previously some patients fell between two sizes. The team believes that for patients who have marked tenderness and hypersensitivity, especially at the distal end of the stump, the ICEROSS system is likely to fail. One blind patient, who is an insulin dependent diabetic and who felt very comfortable with the ICEROSS and liked its improved suspension, developed a deep ulceration over the head of the fibula. It is believed that this is because of a marked increase in the use of her prosthesis because of its advantages. This patient, however, has diabetic neuropathy and a non-sensate stump and was unable to feel or see the results of increased pressure over the head of the fibula – before the ulceration developed.

The finding of significant increase in sweating for about the first 3 weeks of use of the ICEROSS and the difference in sweating after this period compared to the PTB prostheses becomes non-significant, corroborating clinical experience.

The observation of some significant reduction of skin breakdown is worthy of note. The tendency had been to provide the ICEROSS to patients who were troubled with vulnerable stump skin, e.g. split skin grafts, adherent scarring resulting in frequent stump breakdowns from PTB prostheses. So, it is possible that the rate of skin breakdown might have been even lower if patients had not been pre-selected for these reasons. The case of major skin breakdown in the diabetic patient, reported above is something which the professionals and amputees must be aware and vigilant.

It is believed that comfort in climbing and descending stairs is due to the improved suspension of the ICEROSS system and both these activities were significantly easier according to the amputees. Patients are concerned about increased sweating when using the ICEROSS. They should be informed that for most patients this increased sweating settles after the first 3 weeks. Twenty patients felt that sweating, itching and skin rash were the main disadvantages of ICEROSS system. Some patients commented that it was easier to wash the silicone liner and wipe it dry and that the ability to wear the limb immediately was an advantage over the traditional Pelite liner for the PTB sockets. The increased weight of the ICEROSS prrostheses compared to the PTB prostheses did not appear to cause any difficulties for any of the patients. It would appear that the improved suspension of the ICEROSS negated the theoretical problem of the increased weight of the prostheses.

Improved suspension, reduction of skin breakdown and better overall rating of the ICEROSS compared to the PTB by amputees are important observations to be taken into account when selecting the type of prosthesis for the trans-tibial amputee. From the writers' experience and from the literature, there is no convincing clinical evidence to suggest that any significant gains could be achieved by considering ICEROSS as a "standard" prosthesis for all trans-tibial amputees. Rejection of ICEROSS by 15 amputees in this study suggests that ICEROSS sockets may not be suitable as standard prostheses for all amputees. Panagamuwa *et al.* (1994) also reported that 36% of patients provided with ICEROSS prostheses did not have a satisfactory outcome. Improving technique in fitting, improved availability of sizes and types of silicone sleeves and appropriate patient selection should decrease failure or rejection rate. In the light of this current limited and short term experience the authors reserve ICEROSS sockets for trans-tibial amputees who are having, or are likely to have, significant problems with suspension and stump skin breakdown. Appropriate selection of the type of prosthesis for an individual amputee can only be determined by a thorough and complete assessment of the patient, combined with knowledge, expertise and the availability of appropriate prosthetic technology.

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