

Conventional versus microchip controlled pneumatic swing phase control for trans-femoral amputees: user's verdict

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Abstract

A questionnaire survey of 22 selected trans-femoral amputees who were switched from pneumatic swing phase control knee joints (PSPC) to microprocessor controlled intelligent knee joints (IP) is presented. On overall rating all respondents considered the IP to be an improvement or a great improvement compared to the PSPC and none decided to revert back or wished to use their previous PSPC prosthesis on a regular basis. However the IP was not rated to be superior in every area of the questionnaire. Walking at different speeds, walking further, reduction of energy consumption were the main areas where subjective improvements were perceived by the amputees themselves. It is strongly believed that patients' own views should be an important and integral part of the evaluation of new prosthetic technology.

Introduction

The microprocessor controlled pneumatic swing phase knee joint for trans-femoral amputees was first demonstrated in Japan in 1989. The license for this technology was obtained by Chas A. Blatchford, UK who developed and then marketed the first commercially available product in 1993 as the intelligent prosthesis (IP) (Zahedi, 1993).

The IP provides a varying damping action for flexion/extension of the knee joint depending on the amputee's gait speed. This is in contrast to a conventional pneumatically dampened knee mechanism (pneumatic swing phase control or (PSPC) which is adjusted by the prosthetist to

one particular gait speed as judged 'optimum' or 'preferred' for an individual amputee.

The IP is claimed to provide a number of benefits including reduction of energy cost of gait, increased range of walking speed and more natural gait (Zahedi, 1993).

The authors designed a study to compare and evaluate the benefits or otherwise of the IP for trans-femoral amputees compared to the usual and common practice of using PSPC. Results of the energy consumption tested, gait analysis and cognitive demands will be published separately. In this paper the authors report the results of the questionnaire survey to gain knowledge of the patient's own views of the IP compared to the previously used PSPC. The authors feel it is mandatory to obtain patients' own views when evaluating prosthetic components as well as obtaining the more objective outcome measures.

Methods

Twenty-two established unilateral trans-femoral amputees who were wearing Endolite prostheses with PSPC, were recruited from the clinic for this study. This was a selected sample of patients who had no stump problems were otherwise fit and were generally fairly active.

The profile of the study group is presented in Table 1.

All patients were fitted with a new PSPC knee unit, multiflex ankle joint and new cosmetic foam and were changed to a new knee unit of IP, new multiflex ankle and a new cosmetic foam 8-10 weeks later. Socket adjustments, alignment alterations or knee joint readjustments were carried out, if necessary, 3 weeks after the initial fitting and delivery of both types of prosthesis. The original comfortable sockets were retained in use for all prosthesis for all the patients

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Table 1. Profile of the study group (N = 22)

Male: 14	Female: 8
Age (range):	39.9 yrs (25 yrs - 76 yrs)
Side of amputation:	Right: 11 Left: 11
Aetiology of amputation:	Trauma: 16
	Malignancy: 5
	Osteomyelitis: 1
	Occupation:
Occupation:	Employed: 16
	Student: 2
	Housewife: 2
	Unemployed: 2
Mean time since amputation (range):	19.2 yrs (5 yrs - 53 yrs)
Prostheses used prior to change to IP:	Endolite* with ESK and PSPC and multiflex ankle
Mean time since provision of IP (range):	17.4 months (7 months - 41 months)

*Endolite - is the trade name of a modular prosthesis manufactured by Chas A. Blatchford UK.
ESK = Endolite Stabilised Knee.
PSPC = Pneumatic swing phase control.

throughout the stages of the study.

All prosthesis were fitted by one prosthetist (JH). Local ethical committee approval was obtained prior to the commencement of the study. All participants in the trial had the research protocol explained and signed consents were obtained.

Users' views were obtained by a carefully constructed semi-structured questionnaire (Appendix 1). Most of the questions were 'closed' with 5 possible responses. Two questions were 'open' inviting users' own comments and opinions.

The anonymous questionnaires were sent out after at least 7 months of acclimatisation with IP, 18 out of 22 questionnaires were returned promptly. A telephone reminder was given to all patients 3 weeks later, to return the questionnaires if they had not already done so.

Results

All 22 questionnaires were returned (100% response). Compilation of responses for the closed questions are presented in Table 2. Answers to the questions are related to their IP compared to their previously used PSPC.

Walking at different speeds: 95.4% (21/22) found this a lot easier or easier; 14 out of these

21 found this a 'lot easier'.

Walking distance: 81.8% (18/22) said they could walk further or a lot further; only 5 out of the 18 however felt they could walk 'a lot further'.

Ascending stairs: 77.2% (17/22) found no difference in ascending stairs with their IP.

Descending stairs: 77.2% (17/22) found no difference in descending stairs.

Walking on slopes and hills: 59% (13/22) found this a lot easier.

Walking on rough/uneven ground: 63.6% (14/22) found this easier though 12 out of these 14 felt this was easier rather than a lot easier.

Energy level: 95.4% (21/22) found walking with IP or a lot less tiring, only one did not feel any difference.

Gait pattern: 95.4% (21/22) felt that their walking was more normal. There was almost an even split between more normal and much more normal.

Mechanical reliability: 63.6% (14/22) thought their IP prosthetic limb was mechanically more reliable.

Learning to walk: 81.8% (18/22) felt that they adjusted to their IP within a short time or found it easy with no problems at all. Only 3 out of 22 found some initial problems to adjust to walking with their IP.

Gait pattern - comments by others: 86.3% (19/22) commented that they have received very positive or favourable comments on their gait pattern.

Overall comment: all 22 (100%) felt that the IP was improved or much improved compared to their PSPC. 72.7% (16/22) felt that this was much improved.

Use of spare limb with PSPC after provision of IP: all patients were in possession of a spare limb with PSPC. Six out of 22 (27%) did also make use of their spare prosthesis. This was due to battery failure in 3, computer breakdown in 1 and socket discomfort in 1 patient. The cause of using the spare prosthesis in 1 patient was not clear. As soon as the problems were rectified they reverted back to IP.

Twenty-one out of 22 patients (95.4%) did not want to return to wearing a prosthesis with PSPC on a regular basis.

The wearing time for the IP did not alter for the study group compared to PSPC. Average time wearing the IP was 14.38 hours/day (range 6-18 hrs/day).

Table 2. Compilation of total number of responses of questionnaire survey.

<p>Q. A. Walking at different speed A lot easier = 14 Easier = 7 No difference = 0 Difficult = 1 A lot more difficult = 0</p>	<p>Q. H. Walking style Much more normal = 11 More normal = 10 No difference = 1 less normal = 0 A lot less normal = 0</p>
<p>Q. B. How far can you walk? A lot further = 5 Further = 13 No difference = 3 Less than before = 1 A lot less than before = 0</p>	<p>Q. I. Mechanical reliability Much increased = 7 Increased = 7 No difference = 7 Less reliable = 1 A lot less reliable = 0</p>
<p>Q. C. Ascending stairs A lot easier = 0 Easier = 5 No difference = 17 Difficult = 0 A lot more difficult = 0</p>	<p>Q. J. Learning to walk Easy = 10 Adjusted within a short time = 8 No difference = 0 Initial problems = 3 Very difficult = 0</p>
<p>Q. D. Descending stairs A lot easier = 2 Easier = 3 No difference = 17 Difficult = 0 A lot more difficult = 0</p>	<p>Q. K. Comments by others re: walking style Very positive = 11 Favourable = 8 No comments = 3 Unfavourable comments = 0 Very negative comments = 0</p>
<p>Q. E. Negotiating slopes and hills A lot easier = 6 Easier = 7 No difference = 8 Difficult = 1 A lot more difficult = 0</p>	<p>Q. L. Overall rating Much improved = 16 Improved = 6 No different = 0 Performed worse = 0 A lot worse = 0</p>
<p>Q. F. Walking on rough uneven roads Much improved = 2 Improved = 12 No difference = 7 Worse = 1 A lot worse = 0</p>	<p>Q. M. Use of prosthesis with PSPC since delivery of IP Yes = 6 No = 16</p>
<p>Q. G. Energy level on walking Lot less tiring = 8 Less tiring = 13 No difference = 1 More tiring = 0 A lot more tiring = 0</p>	<p>Q. N. Would they be happy to wear PSPC again regularly? Yes = 1 No = 21</p>
	<p>Q. O. Was programming for IP difficult? Yes = 1 No = 10 Indifference = 1</p>

Some of the comments given by the amputees in the questionnaire are given in Table 3.

Discussions

The study was undertaken in a specialised rehabilitation centre, servicing a sizeable amputee population. The intelligent knee joint is the first commercial application of microcomputers in lower limb prosthetic technology. The results of some research work evaluating the IP have been published in peer reviewed journals but these have mainly concentrated on the effects on oxygen consumption or gait parameters. (Buckley *et al.*, 1996; Taylor *et al.*, 1996; Kirker *et al.*, 1996).

The Medical Devices Agency in England carried out a questionnaire evaluations of 85 units of IP in 24 centres in the UK and published their results in their own MDA evaluation report (Medical Devices Agency, 1994). While these results were compiled from the patients' opinion about the IP – no information is available as to the type of knee joints or types of prosthesis they were wearing previously or indeed any other conditions which might make any comparative evaluation more satisfactory. Kirker *et al.* (1996) however in their assessment of IP also included a questionnaire using a visual analogue response scale and their research methodology was more explicit.

Though this study was carried out in a selected group of patients it was felt this allowed a more valid comparison of patients' views as by selection it was possible to eliminate any other patient and stump condition which might affect the outcome. By giving the patients new knee units, ankle joints and new cosmetic foam, it was also possible to reduce the number of variables which might have affected the outcome.

The patients overwhelmingly favoured their IP and *all* of them wished to continue wearing their IP on a regular basis. This is felt to be significant as all these patients were doing extremely well, active, mostly in employment or full-time students with their previous prosthesis with PSpC. Contrary to the usual experience where it is found difficult for established amputees to change to a different type of prosthetic component, unless they have problems, the study group quickly adjusted to the IP and did not wish to revert back to PSpC.

The authors are aware of the subjective nature of questionnaire surveys and the bias that might have been introduced to a patient by the publicity of this actively marketed prosthetic technology. However, it is believed that in this study patients' perceptions are genuine as 77.2% of the patients did not find negotiating stairs any easier and responses to walking on slopes, hills and on rough and uneven ground were much less

Table 3. Some of the comments made by the patient on their questionnaire.

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|---|
| <p>"IP has made a tremendous difference in 95% of daily movements."</p> <p>"I was perfectly happy with the PSpC, but IP is superior."</p> <p>"Lot easier, less tiring, more natural."</p> <p>"Quality of life has improved greatly."</p> <p>"Some difficulty in reaching faster speed – as had been previously unable to walk fast."</p> <p>"I am an amputee for the last 30 years ... I had some difficulty in accepting/realising that I could vary speed."</p> <p>"Backache has improved."</p> <p>"Backache has improved dramatically though hip has become painful."</p> <p>"Easier to walk and feels more natural."</p> <p>"Slight problem on uneven grounds."</p> <p>"Less physical discomfort in the groin."</p> <p>"IP knee almost feels elastic – no matter what the walking speed – the leg always follows through at the right speed."</p> <p>"Pleasure to experience the walk at ground level – but on uneven ground – this is a problem as it gives you a 'false sense of security' – with the old type of limb you gave it a resounding kick forward automatically."</p> <p>"IP is the best thing that happened to me."</p> <p>"Cosmetic foam lets the leg down."</p> <p>"Less tired after a round of golf and thus we were able to enjoy the 19th hole!"</p> |
|---|

enthusiastic. Biased views or placebo effect would have been expected to produce general blanket praise response for IP. This was not the case, suggesting a genuine and critical appraisal by the subjects in this study.

The response to gait pattern as perceived by patients as well as by others (friends, relatives, etc.) were reported to have improved. The improvements however were not at all obvious when 9 of these patients when video recorded in a laboratory environment on a separate section of the study reported elsewhere (Datta *et al.*, 1997). This discrepancy may be possibly explained by the fact walking in daily living activities may be different from walking in artificial laboratory conditions. The perception of better walking may be related also to ease of walking by spending less physical and cognitive efforts thus making walking more enjoyable.

The patients have shown a strong preference for the IP when compared to PSpC in a survey by questionnaires, in a controlled study. None of the patients were given any specific gait re-education physiotherapy programme for their IP, though some advice was given by the prosthetist during the time of fitting and readjustment. The main benefits from this subjective study for the IP appears to be ability to walk at various speeds, reduction of effort of walking and patients' perception of improvement of walking pattern. Whether patients do walk further, walk at different speeds, have reduced cognitive effort, have improved gait as measured by sophisticated gait analyses and have any reduction on oxygen consumption are addressed as objective measures and are to be reported separately. Nevertheless, the authors feel, that irrespective of the results of the objective outcome measures, users' own

views are also vital in the evaluation of a new prosthetic product.

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Appendix 1

INTELLIGENT PROSTHESIS (IP) QUESTIONNAIRE

Circle appropriate answer that corresponds as close as possible with your views/observations (i.e. circle 1, 2, 3, 4 or 5)

- A.** How would you compare walking at different speeds with your IP when compared with your previous knee joint?
1. A lot easier
 2. Easier
 3. No difference
 4. Difficult
 5. A lot more difficult
- B.** How far can you walk with your IP compared with your previous knee joint?
1. A lot further
 2. Further
 3. No difference
 4. Less than before
 5. A lot less than before
- C.** Is ascending stairs, steps, etc. any different with your IP compared with the previous knee joint?
1. A lot easier
 2. Easier
 3. No difference
 4. Difficult
 5. A lot more difficult
- D.** Is descending stairs, steps, etc. any different with your IP compared with the previous knee joint?
1. A lot easier
 2. Easier
 3. No difference
 4. Difficult
 5. A lot more difficult
- E.** Is negotiating slopes and hills any different with your IP compared with the previous knee joint?
1. A lot easier
 2. Easier
 3. No difference
 4. Difficult
 5. A lot more difficult
- F.** When walking over rough or uneven ground, how does your IP perform compared to the previous knee joint?
1. Much improved performance
 2. Improved performance
 3. No difference
 4. Performs worse
 5. A lot worse performance
- G.** How does you rate your energy levels when walking with the IP compared to the previous joint?
1. A lot less tiring
 2. Less tiring
 3. No difference
 4. More tiring
 5. A lot more tiring
- H.** Do you think that your walking style has improved since you have been using the IP?
1. Much more normal
 2. More normal
 3. No difference
 4. Less normal
 5. A lot less normal
- I.** Assess the mechanical reliability of your IP compared to your previous knee joint?
1. Much increased reliability
 2. Increased reliability
 3. No difference
 4. Less reliability
 5. A lot less reliability
- J.** What are your views regarding learning to walk with the IP after using the previous knee joint?
1. Easy, not considered a problem
 2. Adjusted within a short time
 3. Noticed no real difference
 4. Initial problems
 5. Very difficult with lots of problems
- K.** Since having your IP have you had any comments from other people (i.e. family, friends, etc) about the way you walk with the IP compared to your previous knee joint?
1. Very positive comments
 2. Favourable comments
 3. No comments at all
 4. Unfavourable comments
 5. Very negative comments
- L.** Overall how do you rate your IP compared to your previous knee joint?
1. Much improved
 2. Improved
 3. No difference
 4. Performs worse
 5. A lot worse performance
- Please answer the following questions along with your observations and views (please circle numbers appropriate to you)

INTELLIGENT PROSTHESIS (IP) QUESTIONNAIRE

M. Have you used your prosthesis with the previous knee joint since taking delivery of your IP?

1. Yes 2. No

If the answer to the above is Yes

Number of days approximately using previous knee joint =

or number of weeks approximately using previous knee joint =

Please state reasons for using previous knee joint.

N. How many hours on average per day do you wear your IP? =

How many hours on average per day did you, or still do, wear your prosthesis with the previous knee joint? =

O. Would you be happy to wear your prosthesis with the previous knee joint on a regular basis again?

1. Yes 2. No 3. Indifferent

Please add some comments if required.

P. Have you had any major problems using the IP since taking delivery?

Please comment accordingly.

Q. Did you find the programming of the IP at the fitting stage, difficult or complicated, in being able to give the prosthetist good feedback about different walking speeds, etc.

1. Yes 2. No 3. Indifferent

Please add some comments if required.

R. Have any of the problems associated with being an amputee improved or got worse since you took delivery of your IP?

(i.e. socket/stump comfort, backache, vaulting with good foot, etc)

S. What general comments do you have about IP?

(i.e. areas for improvement, good/bad points etc)

Some questions about yourself

1. Age 2. Weight 3. Sex

4. Marital status

5. Occupation

6. Sports/hobbies etc

7. Reason for amputation

8. Date of amputation (approx)

9. Length of time wearing prosthesis

10. Indicate your average activity level

A. Number of hours standing per day? =

B. Number of hours walking per day? =

11. Do you have any other medical conditions?

12. Any other comments