

Executive Summary

Lower limb amputation may be required due to trauma or to vascular disease, itself a result of diabetes. The former may be the most prevalent underlying cause in a younger population from the armed services, while amputations in an older population may frequently be attributable to the latter. In either case, amputation would be an important determinant of disability for VA patients.

Amputation is a life-changing event with major impacts on most activities including employment, personal relationships, self-care, and recreation. Rehabilitation of the amputee is a complex process, to which a functional prosthesis makes a significant contribution.

This technology assessment short report was produced in response to a request from VA's Rehabilitation Strategic Healthcare Group. The report combines research results from the peer reviewed medical literature with the findings of an assessment of a similar prosthesis conducted in the UK. Selected information from the manufacturer is also included. The microprocessor-controlled lower limb prosthesis (the C-LEG®) is new to the United States and is purported to be a significant improvement over the previously available mechanically-controlled prostheses.

Potential benefits of the C-LEG® include: decreased effort involved in walking; improved gait symmetry; increased confidence by the patient in the prosthesis; more natural movement, including on stairs, inclines, and uneven terrain; the perception that participation in activities such as sports is possible; and the avoidance of falls.

The published research is a small body of work. Less than 3% of published and indexed articles represent structured research, with the larger fraction of published articles being purely descriptive or frankly promotional. Most of the available structured research is based on a slightly different microprocessor-controlled prosthesis (the Intelligent

Prosthesis (IP), Blatchford, United Kingdom). The IP is associated with many of the same potential benefits as the C-LEG®.

Published studies have enrolled highly selected samples of amputees who do not have additional medical problems, whose amputations were secondary to trauma or congenital defects, and who are fit and active. These and similar characteristics have been shown to be independently predictive of successful rehabilitation or return to normal living after amputation, and may confound the results of the non-randomized, uncontrolled microprocessor-controlled prosthesis studies that have been published to date.

- Results in the highly selected patients who have participated in the available published studies may not be directly transferable to VA amputees, who are likely to have multiple additional medical problems and amputations secondary to vascular disease.
- The selective inclusion criteria for research patients noted above undoubtedly introduce bias into study results, precluding definitive attribution of improvements in gait, energy expenditure, etc. to the computerized prosthesis.

The published studies have found:

- Energy requirements of ambulation (compared to requirements with conventional prostheses) are decreased at walking speeds slower or faster than the amputee's customary speed, but are not significantly different at customary speeds.
- Results on the potentially improved ability to negotiate uneven terrain, stairs, or inclines are mixed. Such benefits, however, could be particularly important to meeting existing deficits in the reintegration of amputees to normal living, particularly those related to decreased recreation options.

- Users' perceptions of the microprocessor-controlled prosthesis are favorable. Where such decisions are recorded or reported, the vast majority of study participants choose not to return to their conventional prostheses or keep these only as back-ups to acute problems with the computerized one.
- Users' perceptions may be particularly important for evaluating a lower limb prosthesis, given the magnitude of the loss involved, along with the associated difficulty of designing and collecting objective measures of recovery or rehabilitation. However resilient the human organism or psyche, loss of a limb is unlikely to be fully compensated. A difference between prostheses sufficient to be perceived as distinctly positive to the amputee may represent the difference between coping and a level of function recognizably closer to the pre-amputation level.
- Mechanical failure is recorded in some of the studies, but seems to be rare. The manufacturer indicates that some C-LEGS® have been used for extended periods (up to 5 years) without mechanical or electrical problems.
- The UK Medical Devices Agency has conducted an evaluation of the Endolite® Intelligent Prosthesis, with generally favorable results. Recognizing constraints related to the substantial cost of the prosthesis, the UK National Health Service (NHS) makes it available to a wide range of patients, and has arranged with the manufacturer for a program to lend critical components, should these components of the prosthesis require factory repair.

Background

VA's Rehabilitation Strategic Healthcare Group requested that the VA Technology Recommendations Panel (TRP) assess a newly available microprocessor-controlled lower extremity prosthesis called the C-LEG®. As background to this request, the Group supplied the following information:

"The C-LEG® is a newly designed microprocessor-controlled lower extremity prosthesis available for distribution through the Otto Bock Orthopedic Industry,

Inc. (Minneapolis, MN). This prosthesis is one of the first microprocessor-controlled lower extremity prostheses available to the public market. The benefits of microprocessor-controlled knee movement potentially are improved stability of the knee during both the swing and stance phases of gait via continual sensing and adjustment of force and joint angle parameters throughout the gait cycle. Literature distributed by the Otto Bock Orthopedic Industry, Inc. suggests that use of the microprocessor-controlled knee will result in a more natural gait and will allow for more freedom of use on stairs, uneven terrain, or in low light conditions when visual feedback is limited (areas that are problematic for conventional prosthetic users). All of these statements appear to be justified if the limb functions as stated in the circular.

The C-LEG® and future developments could revolutionize the field of prosthetics and substantially increase the functional ability of all amputees. However, due to the relatively new technology and the precipitously higher cost of the C-LEG® compared to more standard limb applications, several questions must be answered before the VHA considers wide-spread distribution of the appliance:

What are the limits of the currently-in-progress 2-year evaluation by the FDA?

What level of residual limb function and overall physical conditioning would be required to justify purchase of this more costly and technically complex appliance? (i.e. many patients have limitations in activity or ambulation as a result of co-morbid medical illness and would not receive the higher level of benefit from the C-LEG® as compared with standard prosthesis).

Is there a reduction of energy expenditure with use of this limb compared with standard applications? If there is a reduction in energy expenditure, what objective measures of function should we set in order to rationally justify an upgrade to the computer assisted model?

The new and more complex technology may well be associated with changes in life expectancy and durability for the prosthesis. What additional costs will we accrue as a result of breakdown? What additional equipment will we need to provide for use during repairs?"

Description of the device, differences from standard prostheses

Michael (1999) notes that there are two broad functional groups of prosthetic knees: those with exclusively mechanical control properties and those that have the added versatility of microprocessor control. The latter group has only recently become clinically available in the United States. It has been available longer in Europe.

Taylor (1996) reports that conventionally-damped prosthetic limbs use a pneumatic or hydraulic damping cylinder, which is adjusted by a prosthetist, to provide optimum gait parameters at the patient's customary walking speed. If the patient walks at a different speed, he or she must compensate for the pendulum action of the prosthesis to alter stride length or step rate by tilting the pelvis, or by other maneuvers, to delay extension to ensure that the foot is in the right place for the next step. These maneuvers lead to an abnormal gait and require extra concentration and physical effort.

The "Intelligent Prosthesis" (IP) features a microprocessor-controlled knee extension damper. For this damper, a proximity switch detects step time and automatically alters knee extension level to suit walking speed. It uses a motor driven needle valve on a pneumatic cylinder (Michael 1999).

Michael (1999) also details the technical advancements of the C-LEG® (microprocessor-controlled prosthetic knee and shin system): it uses a hydraulic cylinder to provide both superior swing control and variable hydraulic stance control. Multiple sensors that gather and calculate data on, for example, amount of vertical load, sagittal plane ankle movement, and specifics of knee joint movement are integrated into the prosthetic shin structure.

Potential benefits of the device over standard lower limb prostheses

The modifications detailed above extend the knee at a rate appropriate to the walking speed, removing the need to compensate and, accordingly, reducing effort and producing improved gait symmetry (Michael 1999).

Also according to Michael, a secondary clinical benefit to those noted above would be the patient perceiving the prosthetic knee as having more consistency. The patient then develops more confidence in the prosthesis.

Additional potential benefits cited in the medical literature and in the manufacturer's product information include easier, more natural movement (including on stairs, inclines, and uneven terrain), participation in activities such as sports is perceived as possible, and improved safety (sensors allow the leg to recognize a stumble, stiffen the knee, and avoid a fall).

The extent to which the potential benefits have been documented or quantified is detailed in the Results section.

Patient selection criteria for the C-LEG®

The ability to define patient selection criteria is currently limited by the prosthesis' limited time on the market and correspondingly limited experience in a wide range, or large number, of patients. The manufacturer does not provide restrictive selection criteria and in the interest of sales promotion would not be expected to do so. As noted earlier, the patients enrolled in the published studies have generally had no medical conditions in addition to amputation, and have been fit and active.

One descriptive study (Kastner 1999; in German with English abstract) does indicate that intensive gait training is essential to full exploitation of the C-LEG's® capacity. Staros and Rubin (1991), in a general discussion of approaches to above-knee prosthetic prescription, stress the importance of patient-specific, multi-disciplinary evaluation prior to the selection of individual components from the wide range of those that are available. These authors also view the amputee's activity level and degree of physical conditioning as particularly important to prosthetic component selection. The same approach is likely to apply to selecting candidates for the C-LEG®.

Assessment Methods

On behalf of VA's TRP, the Management Decision and Research Center Technology Assessment Program (TAP) searched as described below in November, 1999 to identify published research studies addressing the assessment questions posed by the Rehabilitation Strategic Healthcare Group.

As the C-LEG® is a new product in the US, literature retrieval necessitated lengthy searches on all potentially useful databases with a variety of terms relevant to microprocessor-controlled prostheses, knee prostheses and computerized prostheses for lower limbs. TAP performed a wide array of database (Dialog®) and web searches beginning with the traditional databases: The Cochrane Library®, MEDLINE®, EMBASE®, HealthSTAR®, Science Citation Index®, Current Contents®, and BIOSIS®.

Additional searches on FDC Reports®, Pharmaceutical News Index®, DIOGENES®, Health Devices Alerts®, and the European Patents Database® augmented the information on trademarks and patents generated by the C-LEG® product in Germany, where it was developed.

Web searches collected information on the products themselves, enabling contacts with the manufacturers to elicit additional published studies or conference presentation references. The FDA web site supplied a copy of the 510K notification of intent to market the device.

Initially identified published articles were screened to identify those that appeared (in the information available from the search) to provide data resulting from attempts to objectively answer research questions relevant to VA's Rehabilitation Strategic Healthcare Group. Screening criteria were:

- An explicitly stated research question;
- An explicitly stated investigative plan to answer the research question;
- Presentation of quantitative results from the investigation.

Articles meeting screening criteria were retrieved in full text for detailed review. Reference lists of retrieved full-text articles were also reviewed to identify additional citations relevant to this review. Anecdotal reports, those apparently in awe of the technology, or frankly promotional reports were excluded by means of the screening process.

Articles meeting the screening criteria above were included in the results of this review if they met the following additional criteria:

- Reports of empirical findings of a structured comparison between the C-LEG® (or other, similar microprocessor-controlled lower limb or knee prosthesis) and a standard prosthesis.
- Analyses of factors influencing rehabilitation results, return to normal life, or level of activity for amputees.

- Articles published in English, or English abstract available

Individual studies were tabulated and then critically evaluated for the appropriateness of the study design to the research question and for the quality of the study's conduct and reporting. The results of included studies were then qualitatively combined to judge whether valid answers to critical assessment questions were obtainable from the research conducted and reported to date, as noted in the "Summary and Discussion" section.

Results

The searches detailed in the previous section generated approximately 400 citations with abstracts, of which 36 (9%) met initial screening criteria and were retrieved as full text articles. After detailed review, these 36 yielded 10 (2.5% of the originally retrieved citations) meeting the inclusion criteria. Five of these 10 were empiric comparative or analytic studies of prostheses, while five were cross-sectional analyses of factors with impacts on rehabilitation outcomes.

An overview of the volume and scope of the published empiric or analytic studies is provided in Table 1. Each row in Table 1 corresponds to one of the subsequent tables (numbers 2 through 4), as indicated in the first column.

Further detail on subjects, methods, and findings of the studies outlined in the overview will assist in drawing conclusions and are presented in Tables 2 through 4, categorized according to the research issues addressed in the studies. Kirker (1996) appears in both Tables 2 and 3, since the single publication represents a comprehensive assessment with two research questions addressed.

Table 1. Overview of the literature: 10 studies meeting inclusion criteria for this review

These 10 published reports were selected by applying screening and inclusion criteria to the 400 citations with abstracts identified in the database searches detailed in the Methods section.

Each row in Table 1 represents one of the subsequent tables (numbers 2-4), which detail individual studies.

Numbered entries in the first column correspond to those of subsequent tables.

Assessment/research question	Number of published studies identified (Total number of subjects)	Study designs represented
Empiric comparison of computerized prosthesis with standard, mechanical prosthesis		
Table 2. Energy costs of walking	3 (22)	<ul style="list-style-type: none"> • Before-and-after • Correlation study (speed of walking correlated with heart rate and oxygen uptake measures) • Cross-sectional (survey)
Table 3. Patients perceptions of subjective improvements attributable to IP	2 (40)	<ul style="list-style-type: none"> • Cross-sectional (survey) • Open crossover correlation study
Analyses of factors influencing rehabilitation results		
Table 4. Factors influencing return to normal living after amputation, level of activity/function, satisfaction with rehab information	5 (550)	All 5 studies cross-sectional (print survey or interview)

Abbreviations: IP, intelligent prosthesi

Table 2. Does a computerized prosthesis lower the energy costs of walking (compared to standard pneumatic swing-phase control prosthesis)?

Reference	Subjects/methods	Results/comments
*Kirker 1996	<p>Subjects 18 patients (amputees due to trauma or congenital abnormality), otherwise in good health:</p> <ul style="list-style-type: none"> • 29-44 years • Able to manage a free-knee prosthesis • Wore a prosthesis all day • Practiced with IP (Endolite) for 4-7 months prior to study • Regularly walked at different speeds • 6 participated in treadmill testing <p>Methods</p> <ul style="list-style-type: none"> • Testing speeds chosen from corridor walking • Practice on treadmill at testing speeds, breathing through spirometer • VO₂ measured, corrected for temperature and barometric pressure • Testing with both standard and computerized prosthesis for oxygen consumption and gait symmetry • Significance of prosthetic test order examined 	<p>Oxygen consumption</p> <ul style="list-style-type: none"> • No significant difference between knee type overall, or at any single speed, or between first knee tested and second knee • Step length significantly more symmetrical with IP, and independent of speed <p>Conclusions</p> <ul style="list-style-type: none"> • While walking at normal steady pace, IP not likely to be significantly better than conventional prostheses • IP's improved ability to swing at same rate as natural leg may be most useful in variable speed walking situations or on uneven terrain, particularly for users with strength and cardiovascular reserves to walk at different speeds <p>Gait symmetry</p> <ul style="list-style-type: none"> • Step length significantly more symmetrical with IP
Buckley 1997	<p>Subjects 3 trauma-associated amputees:</p> <ul style="list-style-type: none"> • Fit, active, regular users of conventional prostheses • Able to complete protocol in full • No alcohol or caffeine for 24 hrs prior to testing <p>Methods</p> <ul style="list-style-type: none"> • Fitting, alignment and programming of IP for range of speeds • Practice on treadmill to comfort level for treadmill speed • Analysis of expired air for average VO₂ over consecutive 30 sec intervals during periods of walking at selected test speeds 	<ul style="list-style-type: none"> • No difference between prostheses when walking at subject's normal speed • 2 of the subjects showed 5-9% reductions in energy use when walking at speeds slower or faster than usual • Third subject showed no significant change <p>Conclusion Heavier IP unit seems to lower energy costs at walking speeds different than the patient's usual speed</p>
Taylor 1996	<p>Subjects</p> <ul style="list-style-type: none"> • 1 (one of the authors) • Active 33 yo male (traumatic amputation) taking antihypertensives • At least 5 weeks experience walking on each of the 4 prostheses tested with treadmill walking for VO₂ 	<ul style="list-style-type: none"> • No significant differences in VO₂ among prostheses at slower speeds • Cadence (steps/minute) constant during each test walk, but with considerable test-retest differences • No relationship between heart rate and walking speed (possibly due to antihypertensive meds) • Full exploitation of IP adaptability may require analyses of influence of environment on range of amputee walking speeds • Energy expenditure approx. 10% lower for IP at higher speeds

Abbreviations: IP = intelligent prosthesis VO₂ = oxygen consumption

*Kirker (1996) appears here and in Table 3 because this one published article comprised two sub-studies.

Table 3. Do patients fitted with computerized prostheses experience subjective improvements over conventional prostheses?

Reference	Subjects/methods	Results/comments
Kirker 1996	<p>Subjects 18 patients (amputees due to trauma or congenital abnormality), otherwise in good health:</p> <ul style="list-style-type: none"> • 29-44 years • Able to manage a free-knee prosthesis <p>Methods</p> <ul style="list-style-type: none"> • Wore a prosthesis all day • Practiced with IP (Endolite) for 4-7 months prior to study • Regularly walked at different speeds 	<p>Subject reports:</p> <ul style="list-style-type: none"> • Significantly less effort required to walk with IP at normal and fast speeds, but improvement at slow speed was not significant • Effort reduced for walking outdoors, at work, down a slope, but not up a slope or on down stairs • Confidence that leg would not give way same for both prostheses • Strong preference for IP over conventional prosthesis
Datta and Howitt 1998	<p>Subjects 22 established unilateral transfemoral amputees</p> <ul style="list-style-type: none"> • Wearing conventional pneumatic swing phase controlled prostheses before study • Mean age 39.9 years (range: 25-76 years) • No stump problems, otherwise fit and active <p>Methods</p> <ul style="list-style-type: none"> • Received IP knee for the study • Questionnaires sent after at least 7 months of IP use 	<p>Response rate = 100% after telephone reminder</p> <ul style="list-style-type: none"> • Walking at different speeds: a lot easier or easier for 95.4% • 85% could walk further • 77% found no difference in ascending or descending stairs • 59% found walking on slopes easier • 95% felt the IP offered a more normal/symmetrical gait pattern • 64% felt the IP was more mechanically reliable • 82% adjusted to IP quickly • 100% felt the IP was an improvement over previous prosthesis • 27% made use of a spare conventional prosthesis (due to battery failure or computer breakdown; went back to IP as soon as problems corrected) • 95% did not want to return to regular use of conventional prosthesis • Wearing time for IP similar to conventional prostheses: average 14 hours/day

Abbreviations

IP, Intelligent Prosthesis

Table 4. What factors predict a return to normal living after amputation, the level of activity in amputees, successful prosthetic use, or satisfaction with information and rehabilitation?

Reference	Subjects/Methods	Results/comments
Return to normal living, level of activity, successful prosthetic use		
Helm 1986	<p>Subjects 107 amputees</p> <ul style="list-style-type: none"> 1-5 years post-amputation (68% for primary arteriosclerosis, 22% for ischemia associated with diabetes, remainder for other reasons) <p>Methods Interview assessed:</p> <ul style="list-style-type: none"> physical function (prosthesis use, other ambulation aids) pain (in phantom limb or stump), analgesic use social independence (living and domestic help arrangements) 	<p>78 survivors fitted with prostheses (80% of unilateral amputees, 50% of bilateral), but 19 did not wear or wore for cosmetic purposes only. Unfavorable associations with functional ability and social independence:</p> <ul style="list-style-type: none"> increasing age bilateral or above-knee amputation postoperative pain <p>Eight independent variables (age at operation, sex, cohabiting, preoperative independence, cause of amputation, concurrent disease, level of amputation, pain) accounted for approximately 50% of variation in function and social independence For 36% of patients, level of social independence did not change after amputation</p>
Nissen and Newman 1992	<p>Subjects 42 amputees</p> <ul style="list-style-type: none"> Average age 68 years At least 1 year beyond amputation <p>Methods Survey (demographics, medical & employment history) and return to normal living (RNL) instrument administered by telephone</p>	<p>Patients commonly had additional medical problems (high prevalence of diabetes)</p> <ul style="list-style-type: none"> More impairment in community mobility than in home or out of town mobility Only factor with significant impact on RNL score was health problems in addition to amputation Most patients who had additional health problems had multiple ones Inability to participate in recreational activities was most restricted aspect of patients' RNL profiles <p>Conclusion: better adaptive skills/substitutes for recreational activities (ambulation skills/devices for uneven ground, snow and ice) needed</p>
Medhat 1990	<p>Subjects 327 amputees</p> <ul style="list-style-type: none"> Lower extremity amputation, above or below knee Mean age = 58 years (range 24-90) No other major physical limitation <p>Methods Questionnaire and prosthetic problem inventory scale administered by mail</p> <p>Analysis</p> <ul style="list-style-type: none"> Descriptive statistics (including frequencies) Bivariate correlation t-tests for independent samples for above versus below knee amputations 	<p>Response rate = 45%</p> <ul style="list-style-type: none"> No significant differences above vs below knee amputation for daily living, sexual functioning, or athletic participation Groups did differ in yard care, shower bathing, and gardening Sewing, dusting, cooking showed the least difference between groups <p>Above knee amputation problems</p> <ul style="list-style-type: none"> Shopping Floor maintenance Dressing <p>For both above and below knee amputees, social dancing presented problems</p>
Mueller and Delitto 1985	<p>Subjects 56 amputees</p> <ul style="list-style-type: none"> Above and below knee included Amputations secondary to vascular disease Foot and bilateral amputations excluded Mean time from prescription of prosthesis = 2 years <p>Methods Survey administered by telephone as part of prosthetic clinic follow-up</p> <p>Analysis</p> <ul style="list-style-type: none"> Two-tailed chi-square test for nominal data Two-tailed t-test for ratio data P = 0.05 	<ul style="list-style-type: none"> Below knee amputees classified as successful prosthesis users significantly more often (in spite of multiple additional medical problems in that group) <p>Above knee amputee prosthesis success:</p> <ul style="list-style-type: none"> Sex (male) Age (younger) Obesity (no) Ambulation before prosthesis prescribed (yes) Strength and range of motion Compliance (keeping appointments and following recommendations) <p>Authors' conclusion: below knee geriatric amputees are more successful in prosthetic use than are above knee amputees; among the latter, compliance and medical status are important criteria for success</p>

Satisfaction with information and rehabilitation		
Watanabe 1999	<p>Subjects Patients identified from medical records at Saga Medical School Hospital, Japan</p> <ul style="list-style-type: none"> • 18 of 26 patients contacted • Lower limb amputation • Fitted with prosthesis <p>Written surveys administered by mail:</p> <ul style="list-style-type: none"> • Family and housing conditions • Use of prosthesis • Current status of patient • Patients' opinions 	<p>89% returned questionnaires:</p> <ul style="list-style-type: none"> • Mean age 60.2 years (range, 20-81) • Mean time since amputation 58.1 months (range, 14-135) <p>Satisfaction:</p> <ul style="list-style-type: none"> • Acceptable for information about reason for amputation and details about operation • Poor for advice about services, appliances, financial affairs • Mixed on duration of training during rehabilitation

Abbreviations: RNL, return to normal living

Summary and Discussion

The published research, as would be expected in the case of a relatively new device or prosthesis, is a small body of work, most of which is based on a slightly different computerized prosthesis (the Intelligent Prosthesis (IP), Blatchford, UK). The IP is associated with many of the same potential benefits as the C-LEG®.

The published studies have enrolled highly selected samples of amputees without additional medical problems, whose amputations were secondary to trauma or congenital defects, and who are fit and active. These and similar characteristics have been shown to be independently predictive of successful rehabilitation or return to normal living after amputation, and may confound results of non-randomized microprocessor-controlled prosthesis studies. Therefore, results in these selected samples may not be directly transferable to VA amputees, who are likely to have multiple additional medical problems and amputations secondary to vascular disease.

These selective inclusion criteria for research patients undoubtedly introduce bias into study results, precluding definitive attribution of improvements in gait, energy expenditure, etc. to the computerized prosthesis.

These studies have found:

- Energy requirements of ambulation (compared to requirements with conventional prostheses) are decreased at walking speeds slower or faster than the amputee's customary speed, but are not significantly different at customary speeds.

- Results on the potentially improved ability to negotiate uneven terrain, stairs, or inclines are mixed. Such benefits, however, could be particularly important to meeting existing deficits in the reintegration of amputees to normal living.
- Users' perceptions of the computerized prosthesis are favorable. Where such decisions are recorded or reported, the vast majority of study participants choose not to return to their conventional prostheses or keep these only as back-ups to acute problems with the computerized one. Mechanical failure is recorded in some of the studies, but seems to be rare.
- Users' perceptions may be particularly important for evaluating a lower limb prosthesis, given the magnitude of the loss involved in lower limb amputation, along with the associated difficulty of designing and collecting objective measures of recovery or rehabilitation. However resilient the human organism or psyche, loss of a limb is unlikely to be fully compensated. A difference between prostheses sufficient to be perceived as distinctly positive by the amputee may represent the difference between coping and a level of function recognizably closer to the pre-amputation level.

The manufacturer reports that some C-LEGs® have been used for extended periods (up to 5 years) without mechanical or electrical problems, and estimates the usual life span of the prosthesis at 2 to 5 years.

The United Kingdom National Health Service Devices Directorate has conducted an evaluation of the Intelligent Prosthesis (1994). This evaluation had generally positive results, finding that:

- The IP met safety and structural requirements for lower limb prostheses;
- Rehabilitation specialist physicians judged the IP to be a significant development in prostheses;
- Users found that they could walk greater distances with less effort than with conventional prostheses, and greater confidence in the IP at any walking speed was also reported;
- Bilateral lower limb amputees had been successfully fitted, resulting in substantial gait improvements.

The NHS offers the IP for general supply to a wide range of users, while acknowledging that the cost of the prosthesis limits the extent to which it will be prescribed.

Further components of the NHS report on the IP evaluation include discussions of warranty and service. The devices supplied to the NHS are warranted for 12 months. Since service for the microprocessor-controlled pneumatic cylinder is not available locally, the NHS has a loan agreement with the manufacturer. Under this agreement, Blatchford provides a replacement cylinder as a temporary loan while the original cylinder is under repair by the manufacturer.

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