WorkSafe™

WORKERS' COMPENSATION BOARD OF BC

Evidence Based Practice Group (EBPG)

November 27, 2003

A REVIEW OF MICROPROCESSOR-CONTROLLED KNEE PROSTHESES

The Workers' Compensation Board of British Columbia's Evidence Based Practice Group (EBPG) has undertaken a review of microprocessor controlled above-knee prosthetic limbs, the topic of this document.

After discussion with the EBPG Steering Committee, it has been determined that the WCB will accept responsibility for Physical Medicine and Rehabilitation specialist prescribed microprocessor controlled lower limb prostheses using the parameters and guidelines developed by the U.S. Department of Veteran Affairs.

C.W. Martin, MD
Senior Medical Advisor
Chair, Evidence Based Practice Group

Location:
6951 Westminster Highway
Richmond BC V7C 1C6

Telephone:
(604) 273 2266
1 888 967 5377
Fax: (604) 279-7898

Mailing Address:
PO Box 5350
Vancouver BC V6B 5L5

Otto Bock C-leg®:
A review of its effectiveness

For Special Care Services

by
WCB Evidence Based Group
Dr. Craig W. Martin, Senior Medical Advisor

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WorkSafe WORKERS' COMPENSATION BOARD OF BC Compensation and Rehabilitation Services Division

TABLE OF CONTENTS **Page**

Otto Bock C-leg®: A review of its effectiveness

Background

A number of different prosthetic designs and bio-engineered products are available to amputees. Which one may be the most appropriate depends on many factors including the limb affected, level of amputation, physical and psychological co-morbid conditions, prior level of functioning and patient preference, to name a few. With regard to above knee amputees, selection of an appropriate prosthetic knee mechanism is one very critical component in the overall rehabilitation of the patient. The current available prosthetic technology, in general, has improved remarkably during the past decades(1). Recently, Special Care Services (SCS) at the WCB of BC has noted an increasing number of requests for C-leg®, a microprocessor controlled type of above knee prosthetic limb, produced by Otto Bock Orthopaedic Industry Inc. This particular ‘high tech’ above knee prosthetic device is relatively new, particularly in North America, and relatively costly. Thus, the SCS at the WCB of BC requested the Evidence Based Practice Group (EBPG) to evaluate what the world literature, to date, has to say about this new technology.

<u>Above knee prosthetics (knee prosthetics)</u>

There are different prosthetic designs and supplements available to amputees depending on the amputation level. With regard to the above knee amputees, the simplest and least expensive type of prosthetic device are those which have a single axis hinge that allows the knee to flex and extend(2,3). An optional adjustable friction cell may provide some dampening of swing phase motion by pressing against the knee axle. An additional spring loaded or elastic extension device helps limit heel rise and extends the ankle before heel strike(2,3). Because proper knee swinging occurs at a fixed cadence, this particular design overly restricts many patients that would like to participate in various sport activities.

The addition of fluid control units to a knee frame helps to control the swing phase. The pneumatic or hydraulic fluid-controlled knee prosthesis has pistons that adjust the swing phase resistance as gait changes. Pneumatic control cylinders contain compressible air, and hydraulic dampers contain silicone oil to control cadence(3). Because knee resistance responds automatically to changing walking speeds, the amputee is able to engage in a range of activities.

Many prosthetic knees include built-in stance phase stability. The rarely used manual locking knee product provides the greatest amount of stability but results in a stiff legged gait requiring the most effort(2). Other types, such as the stance control or safety knees, use the amputee's body weight to engage a friction brake to stop knee motion. The spring loaded brake binds when loaded during stance and releases during swing. Thus, when an amputee applies little or no weight to the prosthesis, the stance control knee prosthesis will swing freely. However, it has been noted that brake stability interferes with the initiation of knee flexion during pre-swing at a normal walking speed(2,3).

Another commonly used design is the polycentric knee or 4-bar knee(3). The 4-bar knee prosthesis has 4 points of rotation connected by a linkage bar. An inverse relationship exists between knee flexion and prosthesis length. As a result, this design offers greater toe clearance at mid-swing. Additional benefits of the 4-bar knee include an improved cosmetic appearance as well as stance stability(2,3). This complicated polycentric design weighs more than the more simple designs. Hybrid polycentric knee prostheses also offer fluid swing phase controls. The 4-bar knee is best suited for walking at moderate or faster speed(2).

Microprocessor-controlled knee prosthetics and C-leg®

Although proposed by Kobe Steel researchers in 1989(12), the clinical application of microprocessor control to prosthetic knee mechanism is a recent development. Two microprocessor controlled pneumatic knee prosthesis using the Kobe technology are available: the Endolite Intelligent Prosthesis (Blatchford and Sons, London, UK) and the Seattle Limb Systems Power Knee (Seattle Limb Systems, Seattle, WA) [2]. Intelligent Prosthesis was first developed in 1993 and an improved version was further introduced in 1995 (Intelligent Prosthesis Plus) and 1998 (Adaptive Prosthesis)[4].

The Adaptive Prosthesis uses 2 microprocessor-controlled motor valves to control a hybrid hydraulic and pneumatic system. The hydraulic system controls stance, flexion and terminal impact. The pneumatic portion of the system control both swing phase and knee extension. The Adaptive Prosthesis also offers a voluntary locking mechanism for extended standing and a stumble control that responds to prevent knee buckling. The Adaptive Prosthesis has batteries that power the system for several months and a software design that prevents memory loss during battery replacement[4,5,6].

The C-leg was first introduced in 1997 during the World Congress on orthopaedics in Nuremberg. Otto Bock Orthopaedic Industry manufactured the 3C100 (a.k.a. C-leg) in 1999. C-leg® is a microprocessor controlled knee prosthesis with both hydraulic stance and swing phase control[7]. It has force sensors in the shin that use heel, toe and axial loading data to determine stance phase stability. A knee angle sensor provides data for control of swing phase, angle, velocity and direction of the moment created by the knee. Sensor technology adapts to movement by measuring angles and moments 50 times per second. The unit transfers information to the hydraulic valve allowing reaction to changing conditions. This mechanism results in an individual's gait that resembles natural walking on many different types of terrain. The C-leg® uses a rechargeable battery that lasts 25 to 30 hours. When the battery drains of power, the knee goes into safety mode[7]. The C-leg® was cleared by the US FDA in July 1999 based on its 510(k) application[8]. In this patent application, Otto Bock stated that the C-leg® (3C100) is a microprocessor-controlled knee joint system with hydraulic stance and swing phase control. The company claims that C-leg® immediately adapts to different walking speeds and provides knee stability. Further, the company stated that C-leg® is recommended for lower limb amputees weighing up to 110 kg (220 pounds) who have a moderate (level 2 or

3, i.e. AADL Functional Levels Prosthetic Lower Limb) functional level[8]. The FDA cleared C-leg® based on substantial equivalence to a predicate device that was on the market prior to the enactment of the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act. As such, Otto Bock was not required to provide efficacy data that would be required for pre-market approval.

Objectives of this Review

1. To conduct a systematic review on the effectiveness of C-leg® as compared to mechanical prosthetics or other brands of computer-controlled prosthetics;
2. To identify the characteristics of above knee amputees that may benefit most from the use of C-leg®;
3. To provide a cost analysis among WCB of BC claimants with C-leg® and mechanical above knee prosthetics; and
4. To make recommendations to the Evidence Based Practice Group Steering Committee.

Materials and methods

Literature review on C-leg® and other prosthetics

- Literature searches were undertaken on medical literature databases including PubMed, Cochrane Library, ACP Journal Club, Clinical Evidence, Bandolier, the US Agency for Healthcare Research and Quality and the NHS Centre for Reviews and Dissemination at the University of York.; websites of members of the International Network of Agencies for Health Technologies Assessment (including Canada, the US, Great Britain, New Zealand, Australia, Sweden and Denmark); websites of BC, Alberta and the Quebec Office of Health Technology Assessment; websites of other WCB's in Canada (including Yukon and Northwest Territories, Alberta, Saskatchewan, Manitoba, Nova Scotia, Newfoundland, PEI, Quebec and Ontario) and in the US (Washington State, Colorado, California and Oregon); private health insurance companies (including Aetna, Blue Cross Blue Shields, Humana, Permanente Medical group, Tuft and Western Health Advantage); websites of physical therapies and orthopaedics association including the US, the UK, Canada, Australia and other agencies including Health Canada, the US FDA, the US NIH, the US Department of Veterans Affairs and the Otto Bock company itself.

- Searches were undertaken in two steps:
  1) The first search was done in order to identify available reviews (systematic or non-systematic). This search was done by employing a combination of medical subject heading and keywords of; (above knee amputee or above knee amputation or transfemoral amputee or transfemoral amputation) and (mechanical prosthetics or hydraulic prosthetics or pneumatic prosthetics or computer controlled prosthetics or computerized prosthetics or electronic prosthetics or micro processor controlled prosthetics or C-leg® or Otto Bock) and (review or systematic review or meta analysis).
  2) The second search was done in order to identify the published literature on the subject of above knee prosthetics to up-date any reviews on the subject. This search was done by employing a combination of medical subject heading and keywords of; (above knee amputee or above knee amputation or transfemoral amputee or transfemoral amputation) and (mechanical prosthetics or hydraulic prosthetics or pneumatic prosthetics or computer controlled prosthetics or computerized prosthetics or electronic prosthetics or micro processor controlled prosthetics or C-leg® or Otto Bock).
- *Inclusion criteria:* publications were selected if they involved human subjects with no restriction to age, sex, ethnicity or cause of the amputations. There was no restriction placed on the year of publication. Publications were restricted to those where at least the abstract was available in English.
- *Exclusion criteria:* for the review or systematic review the publications were excluded if the methodology used to evaluate the quality of the primary studies were not apparent.

Cost analysis on C-leg® and mechanical above knee amputees among the WCB of BC claimants

- Data source

There were three data sources used in this analysis. The data was obtained from the amputee unit within Special Care Services, pension data from disability Awards and payment systems available through the WCB of BC mainframe information system.

In order to provide accurate information, the amputee unit within the SCS attempted to create a database of all active amputee claimants at the WCB of BC. For the same purpose, Disability Awards maintains a database of active claimants that have been awarded long term disability. The Amputee Unit provided the name and claim numbers of 13 claimants that have received C-leg® prostheses (12 patients already have C-leg® and 1 is waiting for installation as of October 2003) to Disability Awards. Both databases (Special Care Services and Disability Awards) complemented each other and, along with the payment database, a financial analysis was undertaken.

- Analysis

The Amputee Unit maintains their database on a Microsoft Excel spreadsheet. Disability Awards maintains a Microsoft Access database. Therefore, the data from these two databases had to be translated into an SPSS format for further analysis. The mainframe payment system at the WCB of BC is a DB2 type of database. Crystal Report was employed to download this data. The 1999 to August 2003 payment data were downloaded as a text file which was then translated into SPSS format for further analysis.

There were 1253 claimants registered in the Amputee unit spreadsheet. Of these, 18 claimants were entered twice, as such there were approximately 1235 claimants in the amputee database (7 claimants did not have any claim numbers and apparently the unit has not completed data entry at the time this report was written). Of the 13 claimants on C-leg® provided separately by the Amputee Unit, three were not registered on this spreadsheet. Above knee amputees were identified from the injury description that was available on the spreadsheet. Specific information on the lower limb injury was then verified with the information available on the claim's E-file if the claim was an E-file claim. A total of 118 above knee amputees were ultimately identified from the Amputee Unit spreadsheet.

Of the numerous variables collected in the pension database by Disability Awards, injury description and percentage of total disability were employed as potential markers in order to identify all patients with above knee amputations. By employing criteria of injury description and percentage of total disability including; lower extremity with total disability > 50%; both leg with 100% disability; amputated leg at hip; hip amputation; knee amputation with >50% total disability; leg at hip; and, upper half with 100% total disability, 13 more above knee amputees were identified. The claimant's E-file was used to verify this information.

Thus, overall, there were 131 above knee amputees accounted for, 12 of these patients had been fitted for a C-leg® and these patients were used in the cost analysis. Four non C-leg amputees matched on sex and age (± 5 years) were selected as a comparison for each C-leg case. Thus, there were 60 claimants (12 cases and 48 'controls') included in the cost analysis.

Results of literature review

Literature on C-leg® available from the Otto Bock website

With regard to C-leg, there are three studies available at the Otto Bock website[9-11]. These three studies are case series types of analyses (Evidence level 4). It should be note that these studies have never been published in any peer reviewed journal.

1. **Schmalz T, Blumentritt S, Tsikishiro K et al. Energy efficiency of tranfemoral amputees walking on computer controlled prosthetic knee joint 'C-leg'[9]**

   Six trans-femoral amputees participated in this 'cross over' study. The study compared the energy expenditure of amputees fitted with mechanical 3C1 knee followed by C-leg. The energy expenditure was measured by O_2 consumption (VO_2), CO_2 emission (VCO_2), respiratory quotient (RQ i.e. ratio of O_2 consumption over CO_2 emission) and heart rate. The authors did not mention the participant selection criteria nor did they provide the actual energy consumption data on each participant. The authors stated that there was a significant reduction of oxygen consumption between 4% to 7% when the C-leg was used. However, one should note that any difference that is < 5% is considered to be within normal variation for sub-maximal exercise for most people. Given the data provided in the manuscript, readers could not evaluate the numbers of participants that truly had a significant reduction in O_2 consumption. The authors stated that reduction of energy expenditure with C-leg was more pronounced when walking slowly rather than walking at a fast speed.

2. Kastner J, Nimmervoll R, Kristen H, Wagner P. What are the benefits of the C-leg? A comparative gait analysis of the C-leg, the 3R45 and the 3R80 prosthetic knee joints[10]

Ten unilateral above knee amputees (5 males and 5 females) participated in this study. The participants were between 32 and 64 years old and weighed 112 lbs to 160 lbs. The amputations took place between 2 and 37 years prior to the study.

The inclusion criterion necessitated the ability to perform tests with all 3 different models of knee joints. Exclusion criterion included significant pain in the residual limb or the healthy leg. Thus, this study only included 'good walkers' without residual limb problems.

After receiving 10 minutes to accustom themselves to the joints, each patient underwent 4 tests including: i) stance phase load; ii) swing phase; iii) uphill-downhill; and iv) 1000 m ground tests.

This study found that the differences in all parameters of the <u>stance load</u> findings were statistically not significant.

In the <u>swing phase test</u>, the differences in cycle time, cycle length as well as swing and stance phase time were not statistically significant. Further, it was found that the maximum flexion angle in the knee was not significantly different between the three prosthetic joints when compared to their own, healthy leg.

During the uphill and downhill treadmill test, the pulse curves followed the same level in all three prosthetic joints. However, when going downhill, some of the test subjects reported problems and or felt insecure with the C-leg, particularly when initiating swing phase.

On the <u>1000 meter level ground test</u>, all 10 participants achieved their fastest time with the C-leg.

3. C-Leg fitting statistics (abstract) [11]

In this abstract, Otto Bock collected extensive information on 108 randomly selected patients (of 150 amputees). 90 participants were from Germany while 18 were from Austria.

Participants included 87 males and 21 females aged between 19 and 79 years (mean age 42 years). 86 of the amputations were due to trauma. Participants had been using C-legs for an average of 9.6 months (range 1 to 31 months). 76 of the participants stated they did not have any activity limitations due to the amputation. All participants were highly mobile individuals. 70% of the participants were employed while 14% were retired.

In this company sponsored review only 7 of the 108 patients reviewed felt the C-leg offered them no advantage over less expensive, conventional prostheses.

<u>Published literature on C-leg®</u>

1. **Stinus H. Biomechanics and evaluation of the microprocessor-controlled C-leg exoprosthesis knee joint (article in German)[14]** (Evidence level 4)

Stinus presented a series of 15 patients with C-leg prostheses that were observed for 6 to 14 months. The author concluded that from the perspective of the prosthetists and the patients, C-leg was rated highly and was felt to be an improvement from the previous, purely mechanical prosthetic fitting.

The EBPG could not comment further on this article as the original article was written in German.

2. **Schmalz T, Blumentritt S, Jarasch R. Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components**[15] (Evidence level 4)

The purpose of this study was to investigate the influence of different prosthetic alignment and components on patients' oxygen consumption and to investigate the important biomechanical characteristics of normal gait pattern of leg amputees.

Fifteen trans-tibial and 12 trans-femoral amputees participated in this study. All participants were able to walk at least 5 km daily. Those with cardiovascular disorders were excluded. Of the 12 trans-femoral amputees, six participated in the measurement of oxygen consumption and biomechanical gait parameters using Otto Bock 3R80 mechanical knee prosthetic. The other six trans-femoral amputees participated in the measurement of oxygen consumption wearing hydraulic knee joint (Otto Bock 3C1) and C-leg while the prosthetic alignment was optimized.

In comparing the O_2 consumption among six trans-femoral amputees wearing mechanical and C-leg prostheses, the authors reported that walking with the C-leg reduced the net O_2 consumption at low and medium walking speeds by 6% – 7%. The net O_2 consumption was not found to be significantly different between mechanical knee prosthetic or C-leg devises at high speed walking. However, it should be noted that metabolic energy consumption is highly dependent on the amputee's physical condition and many other variables that were unaccounted for in the study.

The authors have pointed out the importance of systematic prosthetic alignment among trans-femoral amputees and how this may impact significantly on the patient's oxygen consumption. This study suggests that prosthetic alignment has a higher metabolic impact among trans-femoral amputees compared to trans-tibial amputees.

3. **Lemaire ED and Fawcett JA. Using NetMeeting for remote configuration of the Otto Bock C-leg: technical considerations**(16) (Evidence level 4)

Lemaire and Fawcett demonstrated the ability of prosthetists to remotely configure the C-leg by employing Microsoft NetMeeting software. The authors examined various types of computer remote connection speed and applied it to one study participant.

The authors report that remote configuration of C-leg could be done through computer with a connection speed of at least 56Kbs.

4. **Seymour R, Ordway N, Cannella P et al. A comparison of the 3C100 C-leg prosthetic knee joint to conventional hydraulic prosthetic knees: a pilot study (abstract presented at the World Confederation for Physical Therapy 14th Congress 7-12 June, 2003 in Barcelona)** [17] (Evidence level 4)

The purpose of this study was to compare the temporal, kinematic and kinetic energy expenditure as well as functional outcomes of C-leg with hydraulic prosthetics use among four amputees. The average age of the participants was 36 years (range 30 – 45 years).

Temporal data showed decreased step length for all four participants using C-leg at regular speed. Cadence was greater for C-leg at regular and high speed in all four participants. Kinematics results varied for the hip, knee and ankle. In all participants, the use of the C-leg resulted in a decreased heart rate and O_2 consumption at steady state. Peak power and moments varied on the intact leg when using the C-leg at initial contact. Functional outcome as measured by the SF-36 questionnaire showed variable results for the physical component measures.

The authors concluded that the results seen with the C-leg showed positive benefits to patients. As the full manuscript is not available, we are unable to critically evaluate these conclusions.

Systematic review on C-leg® and other microprocessor controlled above knee prosthetics (Evidence level 1)

1. **The US Department of Veteran Affairs Technology Assessment Program. Computerized Lower Limb Prostheses [18]**

The US Department of Veteran Affairs Health Services Research and Development Management Decision and Research Center conducted a systematic review on computerized lower limb prostheses in March 2000. The technology assessment short report was produced in response to a request from Veteran Affairs Rehabilitation Strategic Healthcare Group. Specific questions that the Department of Veterans Affairs posed were:

- Did a computerized prosthesis lower the energy costs of walking compared to standard pneumatic swing-phase control prosthesis?
- Did computerized prosthesis improve ability to negotiate uneven terrain, stairs or incline?
- Did patients fitted with computerized prosthesis experience subjective improvements over conventional prostheses?

The VA Technology Assessment Program (VATAP) exhaustively searched various databases including the Cochrane Library, Medline, Embase, HealthSTAR, Science Citation Index, Current Content, BIOSIS, FDC Reports, Pharmaceutical News Index, DIOGENES, Health Devices Alerts and European Patents Database, up to November 1999. The VATAP also did searches on the World Wide Web, conference presentations and the US FDA.

The screening criteria were: an explicitly stated research question and explicitly stated investigative plan to answer the research question and presentation of quantitative results from the investigation. Articles meeting screening criteria were retrieved in full text for detailed review. Reference lists of retrieved articles were also reviewed for additional citations relevant for the systematic review being conducted. Anecdotal reports or promotional reports were excluded during this screening process.

Articles meeting the screening criteria were included in the review if they met the following additional criteria. These criteria included reports of empirical findings of a structured comparison between 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 and articles published in English or English abstract available. These individual studies were then tabulated and critically appraised according to the standard protocol of critical appraisal of the literature in medicine.

Four hundred articles were identified. Thirty six (9%) of these met the initial screening criteria and were retrieved. Only 10 articles (2.5% of the originally identified articles) met the additional inclusion criteria. Five of these 10 were empiric comparative or analytic studies of prostheses (the microprocessor controlled knee prosthesis in these studies was Intelligent Prosthesis instead of C-leg®), while the other five were cross sectional analyses of factors with impacts on rehabilitation outcomes.

This systematic review found that (Evidence level 1):

- Energy requirements of ambulation (compared to requirements with conventional prostheses) were decreased at walking speed both slower and faster than the amputee's customary speed, but were not significantly different at customary speed.
- Results on the potentially improved ability to negotiate uneven terrain, stairs, or inclines were inconclusive.
- User's perceptions of the computerized prosthesis were favourable. The vast majority of the study participants choose not to return to their mechanical prosthesis. It should be noted that participants on these studies were relatively healthy and led an active lifestyle prior to amputation.

- Mechanical failure of microprocessor controlled knee prosthesis (in this case was Intelligent Prosthesis) was recorded in some of the studies although it happened rarely.
- Otto Bock reported that some of the C-leg devices have been used for 5 years without mechanical or electrical problems (no definitive numbers were provided). Otto Bock estimated the life span of C-legs at 2-5 years.
- The UK National health Services offers the Intelligent Prosthesis 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.

2. State of Washington Department of Labor and Industries (SWDLI). Microprocessor-controlled Prosthetic Knees (19)

The State of Washington Department of Labor and Industries conducted this systematic review in August 2002. The report available to the EBPG does not specify the methodology employed by the SWDLI on this review. However, the SWDLI identified and appraised the same articles as that done by the Veterans review. There is, however, one additional article that is covered in the Washington State report. The article by Heller, Datta and Howitt(20) compared the cognitive demand of transfemoral amputees using Intelligent Prosthesis® with mechanical knee prosthesis (this article is appraised by the EBPG and presented in the next section).

Washington Department of Labour and Industries concluded that evidence of microprocessor-controlled prosthetic knee's ability to facilitate walking on uneven ground and stairs was mixed. Computerized knees may reduce energy expenditure but may not reduce cognitive effort required for walking. Due to the small number of studies and study participants, evidence of the broad effectiveness of microprocessor-controlled prosthetic knees remained inconclusive.

Additional literature

The purpose of this section is to up-date the two systematic reviews reported in the previous section with new research, if any, and to introduce research that is relevant in evaluating prosthetic knees.

1. **Heller BW, Datta D and Howitt J. A pilot study comparing the cognitive demand of walking for transfemoral amputees using the Intelligent Prosthesis with that using conventionally damped knees**[20] (Evidence level 4)

   The purpose of this study was to compare the cognitive demand of walking when using mechanical knee prosthesis with that using the Intelligent Prosthesis®.

   Ten unilateral transfemoral amputees participated in this 'cross over' study. The study suggested there was no significant difference in cognitive demand between patients using the mechanical device and those using the microprocessor-controlled knee prostheses.

2. **Chin T, Sawamura S, Shiba R et al. Effect of an Intelligent Prosthesis (IP) on the walking ability of young transfemoral amputees**[21] (Evidence level 4)

   The main purpose of this study was to compare the energy expenditure during walking between able-bodied people and young Intelligent Prosthesis® users.

   Eight transfemoral amputees (mean age 22.5 years, SD 3.3 years) and fourteen able-bodied persons participated in this study. This study suggested that by using the Intelligent Prosthesis®, properly rehabilitated young amputees were able to walk at the normal speeds of able-bodied persons with only about a 24% increase in energy expenditure.

3. **Cutson TM and Bongiorni DR. Rehabilitation of the older lower limb amputee: a brief review**(22)

This article is not a systematic review; however, the authors had undertaken a comprehensive review of the literature at that time. In this review, the authors concluded that age alone should not determine prosthetic rehabilitation. Co-morbidities and general health were important determinants in the outcome of prosthetic rehabilitation among older amputees.

4. **Legro MW, Reiber G, del Aguilla M et al. Issues of importance reported by persons with lower limb amputations and prostheses**(23)

This is an interesting paper undertaken by the researchers at the US Department of Veterans Affairs between 1995 and 1997. The purpose of this research was to investigate prosthesis related issues of importance that were identified by a diverse group of persons living with lower limb amputations and prostheses. Two instruments were used to answer the research question. These instruments were Prosthesis Evaluation Questionnaire and the SF-36. The study had an 81% response rate.

Of 7 domains measured in the Prosthesis Evaluation Questionnaire (PEQ), several items have been identified to be most important (score above 90 of max 100). These items included fit of prosthesis, not feeling off balance while using prosthesis, comfort while standing when using prosthesis, avoidance of blisters or sores on the residual limb, avoidance of rashes on residual limb, ability to walk with prosthesis, ability to walk on sidewalks and streets with prosthesis, ability to walk down stairs with prosthesis and ability to walk up stairs with prosthesis. The last two items (ability to walk up or down stairs) were the least important among these 9 items. Interestingly, items with lower scores tended to have higher standard deviations indicating diverse opinions on this topic.

In the open-ended questions included in the PEQ, four themes were identified. These themes were interpreted as: the fit of the socket with residual limb; persons with transfemoral amputations were particularly interested in knees that would lock and unlock reliably in more than one or two positions; appropriate 'weight' of the device and having a good prosthetist to work with – all of these issues were identified as very important to amputee patients.

Reimbursement status of C-leg®

1. The US Department of Veterans Affairs.

The following guidelines and parameters are used by this administration in addressing requests for microprocessor-controlled knee prostheses.

Prescription for any computer-controlled lower limb prosthesis is limited to patients with documented evidence of the following[24]:

- Patients with adequate cardiovascular reserve and cognitive learning ability to master the higher level of technology and to allow for faster than normal walking speed;
- Patients must demonstrate the ability to ambulate at a faster than baseline rate using a standard prosthesis application with a swing and stance control knee;
- Demonstrated patient need for long distance ambulation at variable rates (> 400 yards) on a daily basis. Use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over standard limb applications; and
- Demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs. Use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application.

In addition, all prescribing services are mandated to:

- Complete a multi-disciplinary assessment of each anticipated user including Prosthetic, Physician, and therapy personnel evaluations. The assessment must objectively document that all of the above criteria have been evaluated and meet the assigned parameters;

- Complete two 2-minute timed ambulating trials of the patient using a standard prosthesis and then repeat the trials with the computerized limb once training is completed. One trial will be done on indoor/smooth surfaces, the second outdoors on uneven terrain. Total distance will be recorded for each trial and submitted to the Rehabilitation Strategic Healthcare group (SHG) in Headquarters; and
- A similar 2-minute timed stair climbing trial will also be completed using both standard and computerized limb applications. Data are forwarded to the Rehabilitation SHG.

Currently, The US Department of Veterans Affairs in Seattle is conducting a controlled trial evaluating C-leg. The result of this study is expected in late 2004[(25)].

2. State of Washington Department of Labor and Industries

In general, Workers' Compensation in Washington State does not purchase microprocessor-controlled knee prosthesis, such as the Otto Bock C-leg®, Endolite Intelligent Prosthesis® or Endolite Adaptive Prosthesis®[(26)]. However, the Workers' Compensation may authorize purchase of a microprocessor-controlled knee prosthesis for the following exceptions:

- The patient's documented need for the computerized prosthesis relates to maintaining or enhancing work-related function:
    - The patient may require greater ability to ambulate long distance (> 400 yards) at variable rates on a daily basis at work. Use of the limb at home or for basic community ambulation does not justify provision of the computerized limb over standard applications; **OR**
    - The patient may require greater ability to ambulate on uneven terrain or on stairs at work. Use of the limb for limited stair climbing in the home or basic community does not justify provision of the computerized limb over standard applications.

- **AND** the patient has previously mastered the use of an advanced stance and swing control hydraulic unit (e.g. Mauch, CaTech or 3R80) as demonstrated by the ability to ambulate at a faster than baseline rate.
- **AND** the patient is unilateral, transfemoral amputee weighing up to 220 lbs and has a moderate or higher functional level. In addition, the patient has an adequate cardiovascular reserve to allow for faster than normal walking speed.

3. Aetna

Based on the systematic review on microprocessor-controlled knee prosthesis conducted by the VATAP, Aetna does not provide coverage for C-leg® because of "lack of sufficient evidence in the published peer-reviewed medical literature substantiating its effectiveness"[(27)].

4. Blue Cross Blue Shield of Iowa and South Dakota

BCBS of Iowa and South Dakota provide coverage for C-leg® when the following criteria are met[(28)]:

- For person with existing prosthesis, gait analysis must be performed by an independent certified orthopaedic gait lab facility using the patient's standard prosthetic application with a swing and stance control knee;
- The subject's gait analysis must demonstrate improved functional, safety and performance using C-leg vs. conventional hydraulic swing stance prosthesis as stated on the Gait Analysis medical policy (#Med39);
- The subject should not have any major cardiovascular, musculoskeletal or neuromuscular problems;
- The patient must be an amputee who has successfully utilized a hydraulic knee system for at least two years;

- The request for C-leg must meet orthotic and prosthetic guidelines; and
- Second opinion is required for the early replacement of the prosthesis.

5. **Blue Cross Blue Shield of North Carolina (BCBSNC)**.

   BCBSNC does not cover prosthetic appliances with microprocessor because the modification is generally not required for standard, daily activities[29].

Results of cost analysis

A more comprehensive cost analysis is in progress but preliminary results suggest the following:

- The vast majority of workers with amputations, have below knee amputations; therefore, C-leg prostheses are not appropriate for them.
- Each year the WCB accepts approximately 15 new claims for amputations. Perhaps two of these would benefit from and meet the criteria outlined by the US Veterans Affairs and Washington State Labour and Industry.
- A C-leg costs approximately $45,000. This is in contrast to a more conventional prosthesis that costs approximately $20,000.

Summary and recommendations

- To date, the published research on computerized knee prosthesis is very limited. Less than 3% of published and indexed research represents structured research. Most published articles are purely descriptive or promotional in nature.
- Most of the available structured research is based on a slightly different microprocessor controlled prosthesis (Blatchford's Intelligent Prosthesis®). However, this prosthesis is associated with many of the same potential benefits as the C-leg®.
- Published studies enrolled highly selected sample of amputees who did not have additional medical problems and who were fit and active. These characteristics have been shown to be independently predictive of successful rehabilitation or return to 'normal' living after amputation. Thus, these variables are most likely to confound the results of the non-randomized, uncontrolled studies on microprocessor controlled knee prosthesis that have been published to date.
- At present, the small number of studies on computerized knee prostheses does not conclusively show the effectiveness of the prostheses in (Evidence level 1):
    - reducing energy expenditure particularly in normal speed walking
    - improving ability to walk on uneven terrain
    - improving ability to climb and descend stairs
    - increasing walking distance
- Given the nature of the evidence to date, the EBPG has outlined various options to its Steering Committee. The option accepted is as follows:
    - The WCB will accept responsibility for Physical Medicine and Rehabilitation specialist prescribed microprocessor-controlled knee prostheses using the parameters and guidelines developed by the U.S. Department of Veterans Affairs.

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