

C - Leg[®]

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Workers' Compensation Board of BC

Clinical Services

Evidence Based Practice Group

The Evidence Based Practice Group:

Since January 2001

- Was assembled to address 'front line' medical medical issues
- Includes representatives from Clinical Services, Policy & Practice and Compensation Management

- Mandate is/was to apply established techniques of critical appraisal and evidence based reviews of topics topics that are solicited from Board Staff and other other interested parties
- Aim to make all these reviews ‘practical’ with front line front line staff receiving clarification on policy and and practice issues based on up-to-date medical evidence
- Our poster:
“Developing an Evidence-Based Process for Validation of Health Care Practices and Technologies within a Workers’ Compensation Setting”

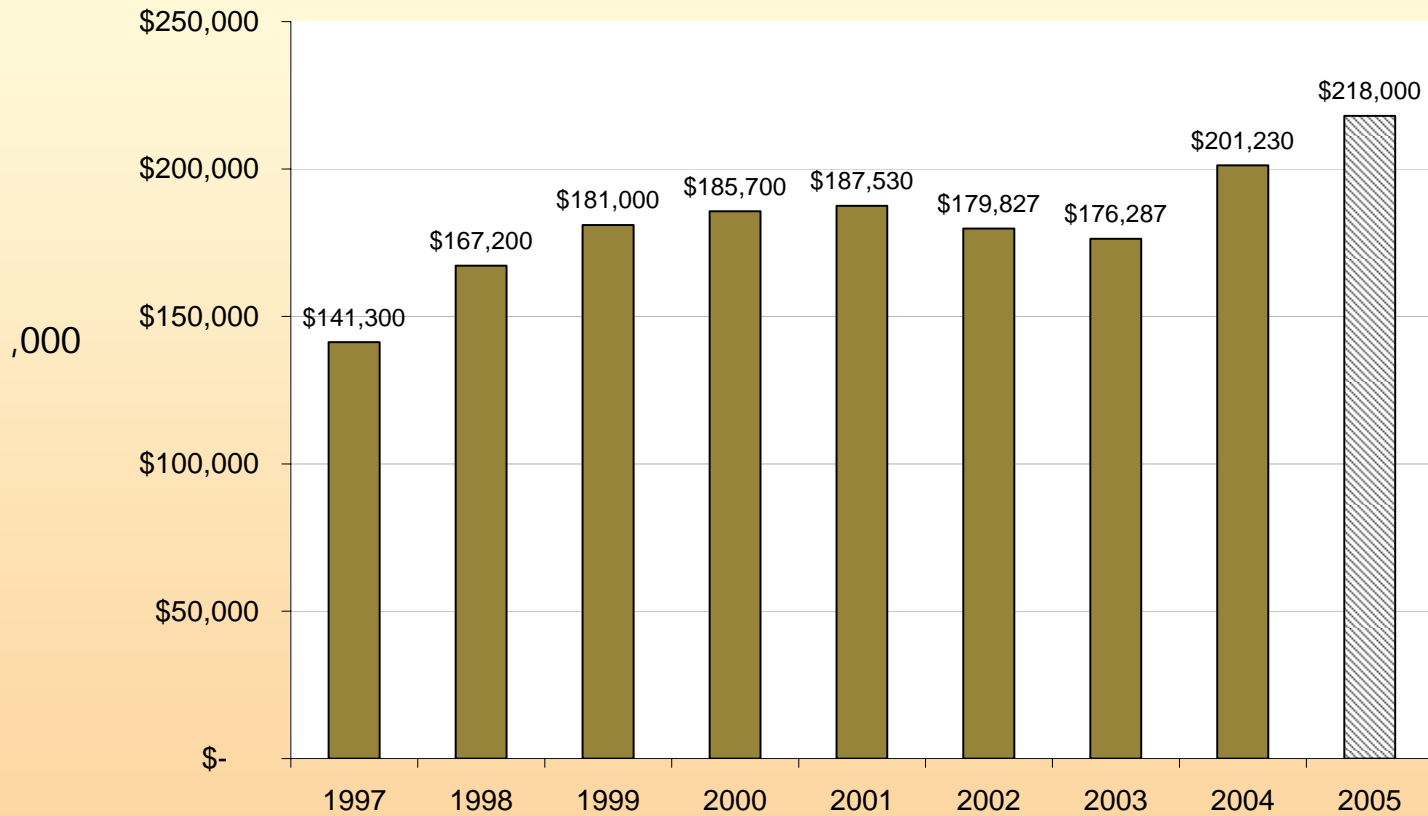
Outline:

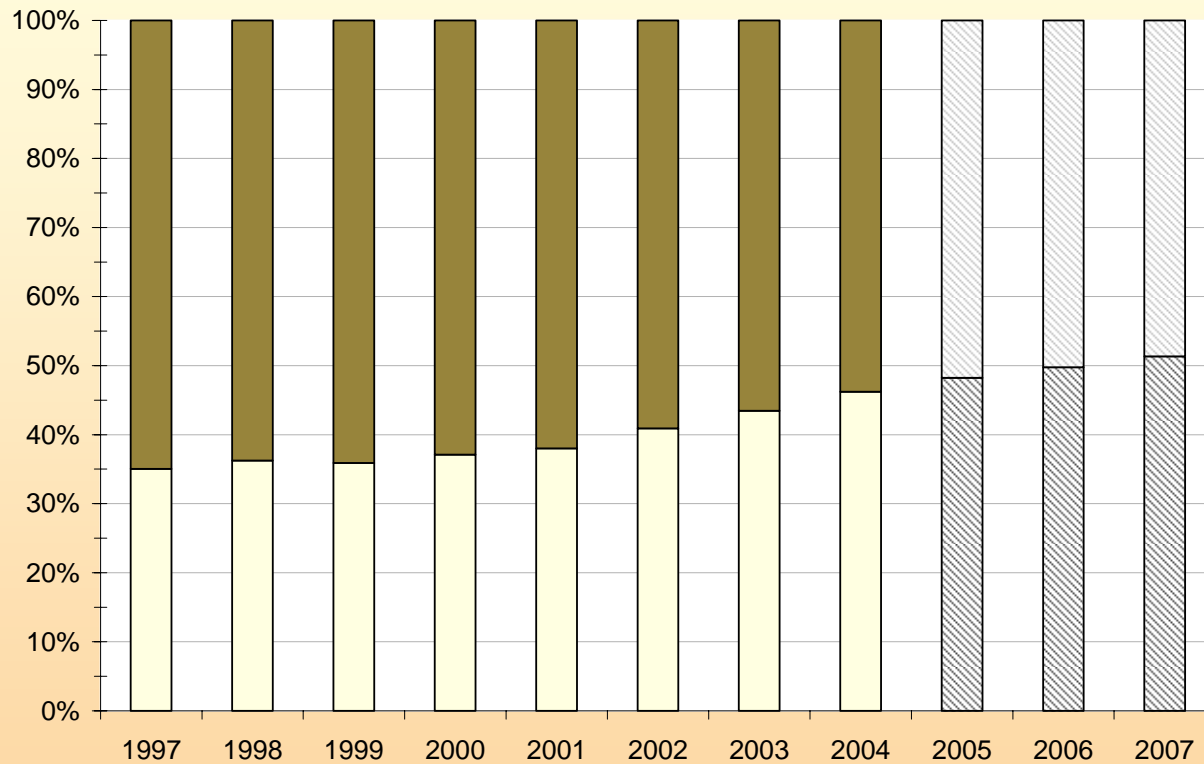
- Background.
 - WorkSafeBC mandate
 - Health care costs at WorkSafeBC
 - Why did we need to review C-leg[®] ?
 - What is C-leg[®] ?
- Objectives.
- Methods.
- Results.
- Search update.
- WorkSafeBC conclusions.

Background:

- The mandate of the Workers' Compensation Board of BC includes:
 -
 - Rehabilitate those who are injured and provide timely return to work
 - Ensure sound financial management for a viable workers' compensation system
 -

Health care related cost at WorkSafeBC





By 2007, it is predicted that the health care costs will exceed short term disability award costs.

- Many prosthetic designs available for amputee amputee patients
- Many factors, such as the limb affected, level level of amputation, physical and psychological co-morbid conditions, prior level level of functioning and patient preference, have an impact on the overall rehabilitation of rehabilitation of the patients

- The issue:
 - Increasing numbers of requests received by the Special Care Services for microprocessor controlled type of above knee prosthetic limb called called C-Leg[®]
 - This device was relatively new (particularly in North North America) and relatively costly

- C-Leg[®]:



- ‘old’ prostheses (wood, hydraulic etc):



hydraulic

Endolite®

Wooden c. 1965

- Microprocessor controlled knee prostheses was a recent development.
- Kobe technology based:
 - Endolite Intelligent Prosthesis[®] (UK)
 - Seattle Limb Systems Power Knee (US)
- C-leg[®]:
 - Is a microprocessor controlled knee prosthesis with both hydraulic stance and swing phase control
 - Introduced in 1997
 - Manufactured in 1999 by Otto Bock Orthopaedic Industry Industry
 - Uses a rechargeable battery that lasts 25 to 30 hours. When the battery drains of power, the knee goes into safety safety mode

- Cleared by the US FDA in July 1999 based on a 510(k) application
 - as a microprocessor-controlled knee joint system with hydraulic stance and swing phase control
 - C-leg[®] immediately adapts to different walking speeds and provides knee stability
 - C-leg[®] is recommended for lower limb amputees weighing up to 110 kg who have a moderate “functional” level
 - FDA approved 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.
 - Thus, Otto Bock was not required to provide efficacy data that would be required for pre-market approval

Objectives:

- conduct a systematic review on the effectiveness of C-leg[®] in transfemoral amputees
- identify those patient characteristics that suggest a patient may benefit
- provide a cost analysis among WorkSafe BC BC claimants with C-leg[®] and mechanical above knee prosthetics *(not presented)*
- make recommendations to the Steering Committee

Outline:

- Background.
- Objectives.
- **Methods.**
 - Search date
 - Inclusion/exclusion criteria
 - Keywords
 - Sources
- Results.
- Search update.
- WorkSafeBC conclusions.

Methods:

- **Timeline:**
Inception date up to week 1 October 2003
- **Inclusion:**
 - Human, English language (at least the abstract)
 - Any age, sex, ethnicity, cause of amputations or year of year of publication
- **Exclusion:**
 - Review method not apparent
- **2 step search:**
 1. Identifying review articles (systematic or non systematic systematic)
 2. Updating available review articles

- Keywords:

1. Identifying review articles:

- (above knee amputee OR above knee amputation OR OR transfemoral amputee OR transfemoral amputation) amputation) AND (mechanical prosthetics OR hydraulic 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) Bock) AND (review OR systematic review OR meta analysis)

2. Updating review articles:

- Same with above but without (review OR systematic review OR meta analysis)

- Sources:
 - OVID[®] Gateway Databases :
 - ACP[®] Journal Club, BIOSIS[®], CINAHL[®], EMBASE[®], OVID[®] Medline
 - Cochrane Library:
 - Cochrane Database of Systematic Review, Cochrane Central Trial registry, DARE
 - INAHTA and its member countries:
 - CCOHTA, AHFMR, Aetmis, VATAP, NCCHTA, MSAC, MSAC, NZHTA, SBU, DACEHTA and GR

- Other workers' compensation boards:
 - Canada: Yukon and Northwest Territories, Alberta, Saskatchewan, Manitoba, Nova Scotia, Newfoundland, Newfoundland, PEI, Quebec and Ontario
 - US: Washington State Department of Labor and Industries, Colorado Department of Labor and Employment, California State Compensation Insurance Insurance Fund and Oregon Workers' Compensation Insurance
- Health insurance providers:
 - AETNA, Medicare-Medicaid, Regence group, Blue Cross Cross Blue Shields, Humana, Permanente Medical group, group, Tuft and Western Health Advantage

- Websites of physical therapy and orthopaedics associations:
 - in the US, the UK, Canada and Australia
- Federal agencies websites:
 - Health Canada, the US FDA and the US NIH
- The Otto Bock company websites (Canada branch) branch) (<http://www.ottobock.ca/>)

Outline:

- Background.
- Objectives.
- Methods.
- Results.
 - 2 systematic reviews
 - The US VATAP
 - State of Washington Department of Labor and Industry
 - 6 primary research papers to update the systematic reviews
 - Reimbursement guidelines
- Search update.
- WorkSafeBC conclusions.

Results:

- 2 systematic reviews:
 1. Computerized Lower Limb Prostheses. The US VATAP
 - Published in March 2000 (search was done up to November 1999)
 - Attempted to answer whether computerized prostheses : prostheses :
 - Lower the energy costs of walking compared to standard standard pneumatic swing-phase control prostheses
 - Improve patients' ability to negotiate uneven terrain, stairs stairs or inclines
 - Allow patients to experience subjective improvements over over conventional prostheses
 - Is a comprehensive and high quality systematic review review

- Conclusions from the US VATAP review:
 - Energy requirements of ambulation 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 prostheses were favourable. Participants on these studies were relatively healthy and led an active lifestyle prior to amputation.
 - Mechanical failure of microprocessor controlled knee prostheses was recorded in some of the studies although it although it happened rarely.
 - Otto Bock reported that some of the C-leg® devices have 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- at 2-5 years.

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

- Published August 2002
- Used primary research as per VATAP
- 1 additional primary research article on comparison of of the cognitive demand in transfemoral amputees using using Intelligent Prosthesis[®] with mechanical knee prostheses

- Conclusions from the SWDLI review:
 - Evidence on ability to facilitate walking on uneven ground and stairs was mixed
 - Computerized knees may reduce energy expenditure but but may not reduce cognitive effort required for walking walking
 - Evidence of the broad effectiveness of microprocessor-controlled prosthetic knees remained inconclusive

- 6 relevant published primary research papers
papers were found to update these 2
reviews:

1. *Heller BW, Datta D and Howitt J. A pilot study comparing the comparing the cognitive demand of walking for transfemoral transfemoral amputees using the Intelligent Prosthesis with with that using conventionally damped knees. Clinical Rehabilitation. 2000;14:518-522.*

- Purpose: to compare the cognitive demand of walking when when using mechanical knee prostheses with using the Intelligent Prosthesis®.
- 10 unilateral transfemoral amputees participated in this ‘cross ‘cross over’ study.
- Results: there was no significant difference in cognitive demand demand between patients using the mechanical device and those using the Intelligent Prosthesis®.

2. *Chin T, Sawamura S, Shiba R et al. Effect of an Intelligent Intelligent Prosthesis (IP) on the walking ability of young young transfemoral amputees. American Journal of Physical Physical Medicine and Rehabilitation. 2003 Jun;82(6):447-Jun;82(6):447-51*

- Purpose: to compare the energy expenditure during walking walking between able-bodied people and young Intelligent Prosthesis[®] users
- 8 transfemoral amputees and 14 able-bodied persons
- This study suggested that by using the Intelligent Prosthesis[®], Prosthesis[®], properly rehabilitated young amputees were able able to walk at the similar speeds of able-bodied persons with with only a 24% increase in energy expenditure

3. *Stinus H. Biomechanics and evaluation of the microprocessor-controlled C-leg exoprosthesis knee joint joint (article in German). Z Orthop Ihre Grenzgeb. May-Jun May-Jun 2000;138(3):278-282.*
- Case series of 15 patients with C-leg[®] prostheses that were observed for 6 to 14 months.
 - The author concluded that from the perspective of both prosthetists and patients, C-leg[®] was rated highly and was felt to be an improvement from the previous, purely mechanical prosthetic fitting.

4. *Schmalz T, Blumentritt S, Jarasch R. Energy expenditure expenditure and biomechanical characteristics of lower limb limb amputee gait: the influence of prosthetic alignment and alignment and different prosthetic components. Gait and and Posture. 2002;16:255-263.*

- Purpose:
 - to investigate the influence of different prosthetic alignment and and components on patients' oxygen consumption
 - to investigate the important biomechanical characteristics of normal gait pattern of leg amputees
- 15 trans-tibial and 12 trans-femoral amputees participated. All participated. All participants were able to walk at least 5 km km daily. Those with cardiovascular disorders were excluded. excluded.
- This study suggested that prosthetic alignment had a higher higher metabolic impact among trans-femoral amputees compared to trans-tibial amputees

5. Lemaire ED and Fawcett JA. Using NetMeeting for remote remote configuration of the Otto Bock C-leg: technical considerations. Prosthetics and Orthotics International. 2002;26:154-158.
- The authors demonstrated the ability of prosthetists to remotely remotely configure the C-leg[®] by employing Microsoft NetMeeting software.
 - The authors reported that remote configuration of C-leg could could be done through computer with a connection speed of at of at least 56Kbs.

6. *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 Physical Therapy 14th Congress 7-12 June, 2003 2003 in Barcelona.*

- Purpose: to compare the temporal, kinematic and kinetic kinetic energy expenditure as well as functional outcomes of C-leg with hydraulic prosthetics.
- 4 amputees with mean age of 36 years (range 30–45 45 years).
- The authors concluded that the results seen with the C-C-leg[®] showed positive benefits to patients.

- Guidelines for reimbursement of microprocessor controlled knee prostheses:
 1. The US Department of Veterans Affairs:
 - Patients with adequate cardiovascular reserve and cognitive learning ability to master the higher level of technology and to allow for faster than normal walking walking speed
 - Patients must demonstrate the ability to ambulate at a faster than baseline rate using a standard prostheses application with a swing and stance control knee
 - Demonstrated patient need for long distance ambulation at ambulation at variable rates (> 400 yards) on a daily basis basis
 - Demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs

2. State of Washington Department of Labor and Industries Industries

- In general does not purchase microprocessor-controlled knee knee prostheses, such as the Otto Bock C-leg®
- Exceptions:
 - The patient's documented need to maintain or enhance work-related function:
 - The patient may require greater ability to ambulate long distance (> 400 yards) at variable rates on a daily basis at work; **OR**
 - The patient may require greater ability to ambulate on uneven terrain or on stairs at work;
 - **AND** the patient has previously mastered the use of an advanced stance and swing control hydraulic unit;
 - **AND** the patient is unilateral, transfemoral amputee weighing up to 220 lbs and has a moderate or higher functional level;
 - **AND** the patient has an adequate cardiovascular reserve to allow for faster than normal walking speed.

3. Blue Cross Blue Shield of Iowa and South Dakota:

- For persons with existing prostheses, gait analysis must be performed using the patient's standard prosthetic application application with a swing and stance control knee
- The gait analysis must demonstrate improved functional, safety safety and performance using C-leg® vs. conventional hydraulic hydraulic swing stance prostheses
- The person should not have any major cardiovascular, musculoskeletal or neuromuscular problems
- The person must be an amputee who has successfully utilized 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 the prostheses

4. Blue Cross Blue Shield of North Carolina as well as Aetna[®] do not reimburse microprocessor-controlled knee prostheses
- Aetna's policy was based on the US VATAP systematic review
 - Aetna[®] considers microprocessor-controlled knee prostheses as experimental

Outline:

- Background.
- Objectives.
- Methods.
- Results.
- Search update.
 - 3 new published primary research papers
- WorkSafeBC conclusions.

Search update:

- Done November 10, 2005
- Same methods as before
- 3 new articles:
 1. Hofstad C, Van der Linde H, Van Limbeek J, Postema K. Prescription of prosthetic ankle-foot mechanisms after lower limb amputation. *The Cochrane Database of Systematic Reviews* 2004, Issue 1. Art. No.: CD003978. DOI: 10.1002/14651858.CD003978.pub2
 2. Willingham LL, Buell NC, Allyn KJ et al. Measurement of knee center alignment trends in a national sample of established users of the Otto Bock C-Leg microprocessor-controlled knee unit. *Journal of Prosthetics and Orthotics*. 2004 Jul; 16(3): 72-7.

3. Johansson JL, Sherrill DM, Riley PO et al. A clinical comparison of variable-damping and mechanically passive passive prosthetic knee devices. *American Journal of Physical Medicine & Rehabilitation*. 2005; 84(8): 563-575. 563-575.

- These did not add new data or change the previous conclusions available from the 2 systematic reviews

WorkSafeBC conclusions:

- Limited published research
- Highly selective sample
- Fit and active amputee more likely to return to return to normal activity
- Inconclusive evidence on its effectiveness

- Limitations of WorkSafeBC Review:
 - lack of hand searching
 - unpublished materials not reviewed
 - non-English articles not reviewed

- Complete review document is available at:

http://www.worksafebc.com/health_care_providers/Assets/PDF/Otto_Bock_Cleg.pdf

Current WorkSafeBC policy:

- Accept responsibility for prescribed microprocessor-controlled knee prostheses:
prostheses:
 - Prescribed by Physical Medicine and Rehabilitation specialist
 - Within the parameters and guidelines developed developed by the U.S. Department of Veterans Veterans Affairs

THANK YOU.

Questions ?

[http://www.worksafebc.com/for health care providers/related information/evidence based medicine/default.asp](http://www.worksafebc.com/for_health_care_providers/related_information/evidence_based_medicine/default.asp)

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