Canadian Agency for Drugs and Technologies in Health

HTA

HEALTH TECHNOLOGY INQUIRY SERVICE (HTIS)

**TITLE: Microprocessor-Controlled Prosthetic Knees (C-Leg) for Patients with Above-Knee Amputations: A Review of the Clinical- and Cost-Effectiveness**

**DATE:** 13 May 2009

## CONTEXT AND POLICY ISSUES:

A number of different prosthetic designs are available to amputees.[1] Microprocessor control to prosthetic knee mechanisms was proposed by researchers in 1989, and has been made available to the clinical application recently with the introduction of the Intelligent Knee Prosthesis in 1995 and the C-Leg prosthesis in 1999.[1] C-Leg prosthesis is a microprocessor-controlled knee prosthesis with both hydraulic stance and swing phase control that adapts to different walking speeds and provides knee stability.[1] Because of its relatively new introduction and its high cost,[1] a review of the clinical-effectiveness and cost-effectiveness of C-Leg prosthesis was requested.

## RESEARCH QUESTIONS:

1. What is the clinical-effectiveness of C-Leg prostheses for patients with above-knee amputations?
2. What is the cost-effectiveness of C-Leg prostheses for patients with above-knee amputations?
3. What are the guidelines for use of C-Leg prostheses for patients with above-knee amputations?

## METHODS:

A limited literature search was conducted on key health technology assessment resources, including Medline, Embase, the Cochrane Library (Issue 2, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles

published between 2004 and April 2009. No filters were applied to limit the retrieval by study type.

**SUMMARY OF FINDINGS:**

For the clinical-effectiveness of C-Leg prostheses, a technology assessment published in 2007 was identified.[2] Two observational studies published after the technology assessment were also included.[3,4] In addition, two economic analyses were included.[5,6]

### Clinical-effectiveness of C-Leg prostheses

A technology assessment on the clinical-effectiveness of microprocessor-controlled prosthetic knees was published in 2007.[2] The assessment, with literature search up to 2007, found four randomized controlled trials and nine non-randomized controlled trials that compared a microprocessor-controlled prosthetic knee (C-Leg or Intelligent Knee Prosthesis) to a traditional prosthetic knee (i.e., non-microprocessor prosthesis or mechanical knee). The vast majority of the patient populations are healthy, active adults with a transfemoral amputation for a non-vascular cause (usually trauma or tumor). Of the nine studies that compared C-Leg to non-microprocessor prosthesis, eight of the studies observed improvement in outcomes such as patient's balance and speed, duration and level of activity, and oxygen consumption with the use of C-Leg prosthesis.

A 2008 observational study examined the energy expenditure and activity of 15 healthy and active transfemoral amputees, with age range from 26-27 years old, using mechanical and C-Leg prosthesis.[3] Each patient was tested with mechanical knee prosthesis and retested with a C-Leg (ie, subjects served as their own controls). The users of C-Leg experienced a 2.3% decrease in oxygen consumption when walking compared to the mechanical prosthesis, which was not statistically significant ($p = 0.34$). There was also a statistically significant increase (6%; $p < 0.05$) in physical activity when amputees switched from a mechanical prosthesis to C-Leg prosthesis. Answers to a Prosthetic Evaluation Questionnaire also revealed that the amputees using C-Leg expressed better quality of life, namely on ambulation, appearance, frustration, residual limb health, social burden, sounds, utility, and well-being.

Another 2008 study compared 21 amputees' performance with a mechanical versus a C-Leg prosthesis.[4] The amputees' age range from 22 to 83 years old, and all are able to ambulate without human support. The subjects served as their own controls. Prosthesis Evaluation Questionnaire (evaluates prosthesis function and prosthesis-related quality of life) scores showed a statistically significant increase (20%, $p = 0.007$) with C-Leg use compared to mechanical prosthesis. Other evaluative measures such as stumbles, falls, and preference also favoured the C-Leg prosthesis.

### Cost-effectiveness of C-leg prostheses

A 2009 cost-utility analysis of a microprocessor-controlled knee prosthesis (C-Leg) and a traditional mechanical prosthesis in 50 trans femoral amputees was done in an Italian context.[5] Acquisition costs were €18,616 versus €3,000 for the C-Leg and mechanical prosthesis, respectively, while the costs for maintenance and repair amounted to €2,597 and €2,230 in the two groups, respectively. Given the incremental cost-effectiveness ratio (ICER) is the ratio of the difference in costs between C-leg and mechanical leg to the difference in health outcome, the analysis resulted in ICER of €35,971 per quality-adjusted life years (QALY) for C-Leg from the health care system perspective.

A cost-effectiveness analysis of C-Leg compared with a mechanical knee was performed in Sweden in 2008 based on a population sample of 20 trans femoral amputees.[6] The study showed a total cost of providing a patient with a C-Leg is €17,000 and €6,600 for a mechanical knee. The analysis resulted in a mean incremental cost for the C-Leg of €7,657 and 2.38 incremental QALY gained, yielding an ICER of €3,218.

The difference in ICER between the two studies came from many factors, in particular the differences in the cycle length of the model. The cycle length in the model of the cost-utility analysis was set to 5 years, as opposed to 1 year in the cost-effectiveness analysis. Nevertheless, considering the common threshold for willingness to pay is US$50,000, with the ICER from the 2 above studies ranging from €3,218 to €35,971, C-Leg is likely to be a cost-effective technology.

### Guidelines for use of C-Leg prostheses

The literature search did not identify any guidelines on the use of C-Leg prostheses.

## CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

A transfemoral amputation can reduce the patient's potential of living an active life. The studies identified showed that microprocessor-controlled knees may provide better quality of life to healthy and active amputees. Trials on older amputees with chronic disease are scarce and therefore it is unclear whether C-Leg prostheses would be appropriate for this patient population. In addition, no guidelines were identified and therefore no conclusions about the patient populations for use of C-Leg can be made. Given existing evidence, the microprocessor-controlled knee (C-Leg) appears to give positive health outcomes at an acceptable cost from a health care system perspective.

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