



## “Safety, Energy Efficiency, and Cost Efficacy of the C-Leg for Transfemoral Amputees”

### A Summary of the Research Article

#### Summary

A systematic literature review, entitled “*Safety, Energy Efficiency, and Cost Efficacy of the C-Leg for Transfemoral Amputees: A Review of the Literature*,” was published in *Prosthetics & Orthotics International (POI)*, 2010 Dec; 34(4): 362-77. (Highsmith, Kahle, Kaufman<sup>1</sup>).

This study is a systematic review of 18 comparative effectiveness studies published during the time range 1995-2009. The review focused on studies where C-Leg was compared to non-microprocessor-controlled prosthetic knees, and objective/quantifiable outcome measures were employed. These studies were rated for methodologic quality and risk of bias.

The goal of this review was to provide a grade recommendation — based on published, pertinent clinical studies — for the C-Leg microprocessor-controlled prosthetic knee joint in three outcome areas:

- Safety — falls, stumbles and balance
- Energy efficiency
- Cost effectiveness

The authors' conclusion:

*“Though methodologic quality varied across the selected topic areas, there was sufficient evidence to suggest that the C-Leg provided increased efficacy in safety, energy efficiency, and cost effectiveness when compared with other [non-microprocessor controlled] prosthetic knees for transfemoral amputees.” (p. 375)*

#### Background

Twenty-two percent (roughly 357, 000) of the estimated amputee population in the US has a transfemoral level amputation, with 95% attributed to vascular disease and 5% attributed to other factors, such as trauma, malignancy, or congenital conditions<sup>2</sup>.

The C-Leg microprocessor-controlled prosthetic knee joint, in use in the U.S. since 1999, is designed for use with knee disarticulation, transfemoral, hip disarticulation and

hemipelvectomy level amputees. It employs multiple sensors which provide data to an on-board microprocessor to determine joint position during the gait cycle. The microprocessor then controls the function of the knee, causing it to increase or decrease knee flexion and extension resistance in the hydraulic system.

#### Rating methods

Highsmith et al. employed quality assessment systems from internationally recognized bodies, (PEDro Scale<sup>3</sup> and SIGN 50<sup>4</sup>, and Chiou<sup>5</sup>) to rate both the methodologic quality and risk of bias for each of the 18 studies. The 18 comprised: 7 studies for safety, 8 for energy efficiency, and 3 for cost effectiveness.

#### Results

##### Safety — 7 studies

According to the article, among community level persons with lower extremity amputation, 52% had fallen in the past 12 months, 49% had a fear of falling and 65% had low balance scores. Collapse can occur whenever the amputee is suddenly faced with any situation that increases an unanticipated risk of falling.

Findings from the studies included:

- 59% of subjects reported a decreased number of stumbles and 64% reported a decreased number of falls with the C-Leg<sup>6</sup>.
- 80% of K2 subjects reported a reduced number of falls with the C-Leg<sup>7</sup>.

All studies showed improvement in some safety or surrogate safety measure with use of the C-Leg. Significantly, studies with enough information to calculate effect sizes showed large effect size for all significant outcomes with the exception of uncontrolled falls. The larger the effect size, the stronger the difference between the two options — C-Leg and non-microprocessor-controlled knees. A large effect size is important because significant differences can be demonstrated, even with a smaller sample size for the clinical study.

**Safety, continued on next page.**

Highsmith et al. note that:

*“...five of the seven studies provide consistent, statistically significant findings of improvements in self-reported reduction in stumble and fall events and improved balance.” (p. 372)*

### Energy Efficiency — 8 studies

According to the article, transfemoral amputees are less efficient ambulators and demonstrate a 27-88% increase in energy cost during walking compared to non-amputees..

Findings from the studies included:

- Using the C-Leg, 6.4% increased energy efficiency (as perceived by subjects) at typical pace and 7% at pace walking<sup>8</sup>.
- Using the C-Leg, 6-7% increased energy efficiency (as measured) at medium and slow walking speeds<sup>9</sup>.

After rating the studies, Highsmith et al. concluded there was insufficient evidence to make a recommendation. However, the authors note that:

*“...research has shown that amputees spontaneously increase their physical activity in the free living environment when using the C-Leg compared to a non-microprocessor-controlled knee. So, energy efficiency may not be of primary relevance.” (p. 375)*

### Cost Effectiveness — 3 studies

The issue: Economic evaluation is necessary to justify C-Leg, since there is a significant up-front expense for the device.

The three studies reviewed by Highsmith et al. considered full annual costs in addition to device costs (productivity loss, caretaker costs, household costs, etc.) when compared to mechanical knees. Values in the studies all demonstrated cost effectiveness in QALY (Quality Adjusted Life Years), a validated tool to measure incremental cost to incremental utility (that is, “benefit realized for every dollar spent”). The resulting cost-utility ratio provides a comparison of the impact of each intervention on overall quality of life (QOL) for the life of the prosthesis.<sup>10</sup>

- A key study (Gerzeli et al.)<sup>11</sup> showed the C-Leg resulting in a cost-utility ratio of €35,971 [US \$51,373] per QALY.
  - Various benchmarks for acceptable incremental costs per QALY have been suggested in Europe and North America; they generally range from US\$ 30,000 — \$100,000 per QALY. Assuming these thresholds, the C-Leg is a cost-effective technology.

Highsmith et al. note that:

*“All of the studies reporting societal cost-effectiveness data found that C-Leg is the dominant prosthesis strategy providing lower societal cost and a positive QALY gain from C-Leg adoption.” (p. 374)*

*“...C-Leg is cost effective and worth funding.” (p. 375)*

### Overall, the authors conclude:

*“...the grades of recommendations demonstrate that the C-Leg is a clinically significant improvement for transfemoral amputees.” (p. 376)*

1. The primary authors of the study were Jason Highsmith, DPT, CP; Jason T. Kahle, CP, School of Physical Therapy & Rehabilitation Sciences, College of Medicine, University of South Florida, Tampa, FL; and Kenton R. Kaufman, Department of Orthopedic Surgery, Mayo Clinic, Rochester, MN.

2. Dillingham TR, Pezzin LE, Mackenzie EJ. Limb amputation and limb deficiency: Epidemiology and recent trends in the United States. *South Med J* 2002;95(8):875–883.

3. Maher CG, Sherrington C, Herbert RD, Moseley AM, Elkins M. Reliability of the PEDro scale for rating quality of randomized controlled trials. *Phys Ther* 2003;83(8):713–721.

4. SIGN 50 Methodology Checklist 2: Randomised Controlled Trials. (Scottish Intercollegiate Guidelines Network). Updated January 2008.

5. Chiou CF, Hay JW, Wallace JF, Bloom BS, Neumann PJ, Sullivan SD, et al. Development and validation of a grading system for the quality of cost-effectiveness studies. *Med Care* 2003;41(1):32–44.

6. Kahle JT, Highsmith MJ, Hubbard SL. Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. *J Rehabil Res Dev* 2008;45(1):1–14.

7. Hafner BJ, Smith DG. Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. *J Rehabil Res Dev* 2009;46(3):417–433.

8. Seymour R, Engbretson B, Kott K, Ordway N, Brooks G, Crannell J, et al. Comparison between the C-leg microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic knees: A preliminary study of energy expenditure, obstacle course performance, and quality of life survey. *Prosthet Orthot Int* 2007;31(1):51–61.

9. 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. *Gait Posture* 2002;16(3):255–263.

10. A QALY (quality-adjusted life year) is the survival or treatment time corrected by the quality of life (QOL) of the patients. QOL is measured by means of validated questionnaires, the results of which can be converted into a utility index. The utility index has a range from 0 (=death) to 1 (=perfect QOL). In the Gerzeli et al. economic study the mean utility of the group using mechanical knees was 0.66 (2/3 of perfect QOL) as compared to 0.75 (3/4 of perfect QOL) in the patient group using the C-Leg.

To calculate the QALYs, the lifespan of the product (e.g., 5 years) is multiplied with the utility index. Thus, the first year of use of a mechanical knee is worth 0.66 QALY, the first year of C-Leg use is worth 0.75 QALY. For the whole lifespan it must be considered that as payers have to pay for the product at the beginning and patients “collect” benefits in the future, these future benefits (utility) have to be devalued by 5% per year (in both groups). So, over 5 years of prosthesis use, QOL sums up to 3.13 QALYs in the mechanical and 3.55 QALYs in the C-Leg group.

Thus the incremental benefit/QOL of the C-leg is 0.42 QALY in 5 years. A cost-utility analysis is based on the incremental cost for the difference of one QALY (money required to produce one additional QALY) to make different treatments in different diseases or disabilities easily comparable. In the example of Gerzeli et al., the incremental cost of the C-Leg (direct health care cost that has to be paid by the insurance) of €15,295 has to be divided by the 0.42 incremental QALY to result in a cost-utility ratio of €35,971 per QALY.

11. Gerzeli S, Torbica A, Fattore G. Cost utility analysis of knee prosthesis with complete microprocessor control (C-leg) compared with mechanical technology in trans-femoral amputees. *Eur J Health Econ* 2009;10(1):47–55.

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