“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). 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.

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 and SIGN 5) 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.
- 80% of K2 subjects reported a reduced number of falls with the C-Leg.

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

Safety, continued on next page.
Findings from the studies included: energy cost during walking compared to non-amputees. According to the article, transfemoral amputees are less efficient ambulators and demonstrate a 27-88% increase in energy efficiency — 8 studies

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 fast pace walking6.
- Using the C-Leg, 6-7% increased energy efficiency (as measured) at medium and slow walking speeds8.

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.10

- A key study (Gerzeli et al.)11 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)