Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees: A review of the literature


Products

C-Leg vs NMPKs vs other MPKs

Major Findings

With C-Leg compared to NMPKs:

- Improved safety
  - Reduced stumbles and falls
  - Improved safety

- Increased physical activity

- Trend for increased energy efficiency

- Cost effective and therefore worth funding

Reduced stumble and fall events with C-Leg

7 articles discussing stumble and fall events as well as balance were reviewed. 5 of them showed reduced stumble and fall events and improved balance with C-Leg.

Population

Subjects: 440 for safety, 56 for energy efficiency, 146 for cost effectiveness

Previous prosthesis: not reported

Amputation causes: 56% trauma, 23% others, 17% disvascular, 4.4% disvascular, 4.4% disvascular, 4.4% not reported

Mean age: 54 yrs for safety, 43 yrs for energy efficiency, 45 yrs for cost effectiveness

Mean time since amputation: not reported

MFCL: not reported
Results

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<th>Activities</th>
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<th>Results for C-Leg</th>
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<tr>
<td>Level walking</td>
<td>Gas analysis at controlled walking conditions</td>
<td>Energy efficiency tended to be increased compared to Intelligent Prosthesis.</td>
<td>Chin 2006</td>
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<td>Stairs</td>
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<td>Energy efficiency tended to be decreased compared to Rheo Knee.</td>
<td>Johansson 2005</td>
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<td>Ramps, Hills</td>
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<td>Energy efficiency increased compared to NMPK when walking at medium and fast velocities.</td>
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<td>Uneven ground, Obstacles</td>
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<td>Energy efficiency increased compared to NMPK when walking at medium and slow velocities.</td>
<td>Schmalz 2002</td>
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Summary

2 of 8 studies showed increased energy efficiency.
4 of 8 studies and one case report showed a trend for increased energy efficiency. 2 of these studies did show increased self-selected walking speed and increased total daily energy expenditure associated with increased physical activity.

Safety

| Safety and surrogate safety related outcomes | Reduction in number of stumbles by 59% and reduction in number of falls by 64%. | Kahle 2008 |
| K2 subjects: 15.8% reduction in frequency of stumbles. 4.5% reduction in frequency of uncontrolled falls. 80% reduction in number of uncontrolled falls. | Hafner & Smith 2009 |
| K3 subjects: 31% reduction in frequency of stumbles. | |

Balance and balance confidence

| Improved balance performance measured by improved composite | Kaufman 2008 |
There was sufficient evidence to suggest increased efficacy of the C-Leg in the areas of safety, energy efficiency and cost when compared with other prosthetic knees for transfemoral amputees. Regarding safety, available evidence supports a grade “B” recommendation that following accommodation with a C-Leg, users will experience a reduction in stumble and fall events and have improved balance. Use of the C-Leg for the purpose of improving energy efficiency is supported by a grade “D” recommendation. However, 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. Finally, evidence supports a grade “B” recommendation that the C-Leg is cost effective and worth funding. Based on standardized review criteria, methodologic quality could be improved and the risk of bias minimized with improved study design, decreased attrition, and use of double blinding for micro-
processor-controlled knee prosthetic studies. While these are worthwhile goals, the practicality of some of these methodological changes in prosthetic research is currently unrealistic. Specifically, patients recognize differing prosthetic components and the different prosthetic knees need to be aligned differently, which makes it unrealistic to conduct double-blind studies. So, given these constraints, the grades of recommendations demonstrate that the C-Leg is a clinically significant improvement for transfemoral amputees.” (Highsmith et al. 2010)