

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

M. Jason Highsmith^{1,2}, Jason T. Kahle^{1,3}, Dennis R. Bongiorno⁴, Bryce S. Sutton², Shirley Groer^{2,5}, & Kenton R. Kaufman⁶

¹School of Physical Therapy & Rehabilitation Sciences, College of Medicine, University of South Florida, Tampa, Florida,

²HSRD/RR&D Center of Excellence, James A. Haley Veterans' Administration Hospital, Tampa, Florida,

³Westcoast Brace & Limb, Tampa, Florida,

⁴Department of Physical Medicine & Rehabilitation, Durham Veterans' Administration Medical Center, Durham, North Carolina,

⁵College of Nursing, University of South Florida, Tampa, Florida, and

⁶Department of Orthopedic Surgery, Mayo Clinic, Rochester, Minnesota, USA

Abstract

The purpose of this paper was to review the literature through a structured literature review and provide a grade of recommendation for patient safety, gait energy efficiency, and cost effectiveness of the C-Leg microprocessor-controlled prosthetic knee for transfemoral amputees. Medline (Ovid) and CINAHL (EBSCO) data bases were searched to identify potentially pertinent studies within the 1995–2009 time range. Studies were screened and sorted. Pertinent studies were rated for methodologic quality and for risk of bias. Following assessment of methodologic quality and bias risk, the level of evidence and a grade of recommendation was determined for each of three categories: Safety, energy efficiency, and cost effectiveness. A total of 18 articles were determined to be pertinent: seven for safety, eight for energy efficiency, and three for cost effectiveness. Methodologic quality was low with a moderate risk of bias in the safety and energy effectiveness categories. Studies in cost effectiveness received high scores for methodologic quality. Though methodologic quality varied across the selected topics, 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.

Conclusion

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 microprocessor-controlled knee prosthetic studies. While these are worthwhile goals, the practicality of some of these methodological changes in prosthetic research is currently unrealistic.^{38,39} 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.³⁸ So, given these constraints, the grades of recommendations demonstrate that the C-Leg is a clinically significant improvement for transfemoral amputees.

PMID: 20969495 [PubMed - indexed for MEDLINE]