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Title

Effects of mobility grade, age and etiology on functional benefit and safety of subjects evaluated in 1200+ C-Leg trial fittings in Germany

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Summary

Trial fittings prove highly efficient for identifying responders for C-Leg and C-Leg compact.

Responder rates range above 80%. The supply with the technology influences mobility grade rating. Mobility grade, age and/or etiology do not possess diagnostic power. Trial fittings remain required¹.

Introduction

Trial fitting is a standard procedure conducted prior to the prescription of microprocessor controlled prosthetic knee components . In Germany approval requires demonstration of the utilization functional benefits offered by C-Leg² . It is generally accepted that unrestricted community ambulators and outdoor walkers with rigorous demands may benefit. It is still discussed to which extent subjects classified as restricted community ambulatory may utilize functional benefits. This is of significant importance specifically in countries where the indications of such devices depend on mobility grade rating as this may inappropriately inhibit access to state-of-the art technology.

Methods

A retrospective, cross sectional analysis of a cohort that underwent a C-Leg or C-Leg compact trial fitting is conducted. Data were retrieved on standardized questionnaires from 445 prosthetic fitting centers. Utilization of functional benefits as assessed by both subjects and their practitioners was obtained on either 5-point Likert scales or corresponding measures. Correlations of functional benefits with age, mobility grade and amputation etiology were tested. Responders were defined as subjects receiving ratings within the top 40% of the respective scale. A logistic multiple regression model was used to calculate effect sizes.

Results

Data on 1223 subjects mean age 55.6, predominantly male (83%), were investigated. In 88% the trial fittings were conducted in a single day. The cohort was stratified based on age (21-40 yrs: 13.7%; 41-60yrs: 44.1%; > 60 yrs 38.2%) mobility grade (MOBIS:MG2: 38.4%, MG3: 39.2%, MG4: 6.5%) and amputation etiology (vascular disease including diabetes: 24%, other 76%). Subjects showed a high potential to change mobility grade after having been fitted with a C-Leg (MG2-MG3 50%, MG3-MG4: 22%). The number of reported falls reported was high: 82% reported at least one fall in the past 12 month, 49% reported multiple falling in this period. The utilization of functional benefit (responsiveness) was related to safety (83%), relief of sound limb (95%), capability to divide attention (94%), gait pattern harmonization (95%), variation of gait speed (93%), overall reduction in walking effort (88%) and reduction in walking aids (23%). Kendal's tau detected either none or weak correlations of functional benefit with age, mobility grade or amputation etiology. The multiple regression model calculated predictive power of the stratifiers to range between 0.7% and 9%.

Conclusion

The general responder rate is high. Responders are not limited to specific age groups, mobility grades or amputation etiologies. The utilization of functional benefits is not correlated with age, mobility grade or etiology of the amputation nor do any of these factors possess any relevant predictive power. Rather, the responsiveness is highly independent of age, mobility grade and amputation etiology. Further, it seems that technology itself substantially influences mobility grade rating. Therefore we find it important that the potential benefits of an MPK are assessed on an individual basis. The present study suggests that a prediction of an individual's capability to utilize the functional benefits of C-Leg solely on grounds of the above cited factors or their interdependencies is hard to argue.

References

1. Hahn, A., Lang, M. (2015). Effects of Mobility Grade, Age, and Etiology on functional benefit and safety of subjects evaluated in over 1200 C-Leg trial fittings in Germany. *Journal of Prosthetics & Orthotics*, 27(3), 86–94

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