

## Appendix: Methodological Criteria

### Selection of Patients

A1, Adequacy of Description of Inclusion and Exclusion Criteria: This criterion tested whether the patient sample was sufficiently defined with the use selection criteria: such as age, gender, level of amputation, reason for amputation, activity level of the amputee, time since onset, stump condition, and comorbidity.

A2, Functional Homogeneity: The homogeneity of the study sample was assessed for all study designs. In view of clinical guideline development, at least the activity level of the included subjects should be reasonably equal. When the activity level of the patients was not described, sufficient indication of the level of amputation, the reason for amputation, and the age of the subjects were required to globally estimate the activity level of the patients. If the study sample was heterogeneous, a stratified analysis of the outcome was required to obtain a “1” score.

A3, Prognostic Comparability: As for group designs, the study groups should be comparable for possible confounding factors, such as time since onset and time since first walking with the prosthesis. In the case of a within-subjects design, this criterion was scored “1.”

A4, Randomization: In group designs, an adequate randomization procedure should have been applied. If the randomization procedure was described and the procedure reasonably excluded bias, this criterion was scored as “1.” In within-subjects designs, this criterion was applied to the sequence of interventions [1].

### Intervention and Assessment

B5, Experimental Intervention: The experimental intervention had to be given explicitly in such detail as to make performing a duplicate study as described possible.

B6, Cointerventions: This criterion tested whether cointerventions were avoided or were comparable between the study groups.

B7, Blinding: In any case, the outcome assessor had to be blinded to the intervention. In many studies investigating prosthetic components, blinding of the patients is always difficult to assure. Therefore, this type of blinding was required only for studies using subjective outcome measures.

B8, Timing of the Measurement: This criterion pertained to the moment that the outcome was assessed in relation to the time period subjects were given to adapt to the prosthetic change. An adequate adaptation period was required. According to English et al., transfemoral amputees need at least 3 weeks of walking with a new knee

mechanism to be sure that gait parameters are stable [2]. Also according to English's results and based on clinical experience [2], the amputees are assumed to need a period of at least 1 week to adapt to a new prosthetic foot or to a change in prosthetic mass.

B9, Outcome Measures: The outcome parameters should be adequate in relation to the purpose of the study, and they should have been collected with the use of a standardized protocol.

Statistical validity:

C10, Dropouts: The number of dropouts and the reason for dropping out had to be sufficiently reported. A dropout rate of more than 20% was considered as insufficient.

C11, Sample Size: The sample size ( $n$ ) in relation to the number of independent variables ( $K$ ) was adequate if the ratio  $n:K$  exceeded 10:1.

C12, Intention to Treat: Intention to treat analysis should be assessed in the case of dropouts.

C13, Data Presentation: This criterion required that adequate point estimates and measures of variability were presented for the primary outcome measures.

1. Piantadosi S. Clinical trials as experimental designs. In: Barnett V, Bardley RA, Fisher NI, Hunter S, Kadane JB, Kendall DG, et al., editors. Clinical trial: a methodological perspective. New York, Chichester, Weinheim, Brisbane, Singapore, Toronto: John Wiley & Sons, Inc; 1997. p. 61–105.

2. English RD, Hubbard WA, McElroy GK. Establishment of consistent gait after fitting of new components. J Rehabil Res Dev. 1995;2(1):32–35.