

Clinical Outcome Measures: Applicability of Current Instruments to Differentiate Functionalities of Prosthetic Components

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Background

Clinical Outcome Measures (OM) represent performance-based or self-reported tests that assess the quality of execution of everyday movements, functional mobility, balance or quality of life [1,2]. Besides the use of OM to rate patients' functional capacity they can be used to document the progress of therapy and rehabilitation and might be useful to evaluate the benefit of a prosthetic component compared to another (figure 1). Despite a huge amount of existing OM, their usage in amputees seems to be limited and a gold standard is still missing [1,3].

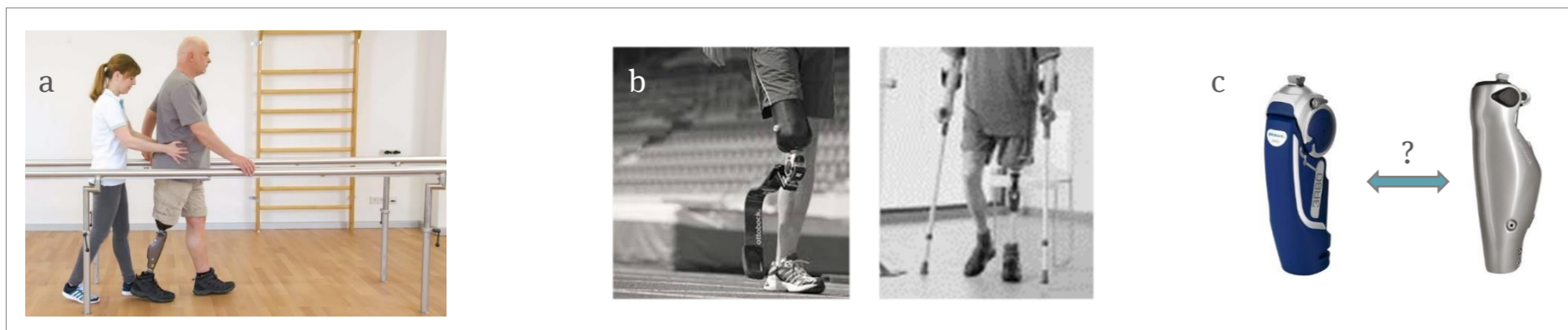


Figure 1: Potential fields of application of OM: a) documentation of progress in therapy and rehabilitation; b) classification of e.g., performance, mobility grade; c) differentiation of prosthetic components

Aim

The purpose of the study was to investigate the usability of established clinical OM to display the benefits of different functional prosthetic knee joints in transfemoral and prosthetic feet in transtibial amputees, respectively.

Method(s)

Ten transfemoral amputees (54±6 years, 76±13 kg, 178± 8cm) and ten transtibial amputees (52±11 years, 84±11 kg, 177± 8cm) with MFCL 3 and 4 were enrolled in the study to perform a set of performance-based OM. This set included the Amputee Mobility Predictor (AMPPro), Dynamic Gait Index (DGI), Stair Assessment Index (SAI), Hill Assessment Index (HAI), Timed Up and Go Test (TUG), L-Test, Four Square Step Test (FSST), 6-Minute Walk Test (6MWT) and Narrowing Beam Walking Test (NBWT). All OM were conducted with three knee joints (C-Leg4 – microprocessor-controlled (MPK), 3R80 – conventional controlled hydraulics and 3R92 – brake knee; Ottobock, Germany) by the transfemoral amputees and three feet (Triton – energy storage and return (ESR), Trias – ESR, SACH – Non-ESR; Ottobock, Germany) by the transtibial amputees.

Result(s)

Regarding the evaluation of prosthetic foot functionalities, none of the OM scores showed significant differences (table 1). In contrast, significant differences between the three prosthetic knee joints were detected for the time- and distance-based OM as well as for ascending stairs and the ramp. Even though, those findings are diminished when considering the minimal detectable change (MDC) given for a population of lower limb amputees additionally. The differences measured by the AMPPro did not exceed the MDC [4] for any subject. For between zero and three subjects, the MDC was exceeded for the TUG, L-Test and 6MWT [4,5] for most knee joint comparisons. When comparing the MPK and the brake knee, for seven subjects the MDC was exceeded for the L-Test and 6MWT.

Table 1: Results of prosthetic knee joint and foot comparison

Outcome Measure	C-Leg vs. 3R80	C-Leg vs. 3R92	3R80 vs. 3R92	Triton vs. Trias	Triton vs. SACH	Trias vs. SACH
AMPPro	-	sig (†)	-	-	-	-
DGI	-	-	-	-	-	-
SAI up	-	-	-	-	-	-
SAI down	sig (†)	sig (†)	sig (†)	-	-	-
HAI	-	sig (†)	sig (†)	-	-	-
FSST	sig (†)	sig (†)	-	-	-	-
TUG	sig (0)	sig (2)	sig (1)	-	-	-
L-Test	sig (3)	sig (7)	sig (3)	-	-	-
6MWT	sig (3)	sig (7)	sig (3)	-	-	-
NBWT	-	-	-	-	-	-

„-“: no significant difference; „sig“: significant difference; value in parentheses: number of subjects (out of ten), for which the value exceeded the MDC; „†“ no MDC available for a population of amputees

Discussion & Conclusion

A reason for the limited applicability of the investigated OM might be that many of those commonly used OM originate from unrelated disciplines (e.g., neuro-rehabilitation) [1,3,4]. This might lead to OM items that are not designed for the specific needs of amputees and therefore are not sensitive enough to display functional differences of prosthetic components. Furthermore, amputee-specific OM (such as the AMPPro) do not seem to be necessarily specific enough for this application. Therefore, further research regarding a specific adaption of available OM as well as psychometric data gathered with a population of amputees is necessary.

References

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