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Title

Reference values of selected self-reported and performance-based outcome measures for transfemoral and transtibial amputees

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Summary

The reference values for the selected outcome measures used in the field of lower limb prosthetics have been calculated based on the data collected in the Outcome Registry. They are consistent with the literature data and may be used as a reference especially in the daily clinical routine.

Introduction/ basics

As health care systems in many countries move toward pay for performance systems, healthcare providers are expected to provide objective evidence that a specific intervention is beneficial for patients. Therefore, more and more prosthetic clinics perform outcome measures in daily routine to support the treatment decision, but also to provide proof of the patient's benefit from the provided treatment.

One of the challenges when implementing the outcome measurement process in a daily routine of prosthetic clinic, is lack of the reference data. There are numerous publications reporting the values of different measures in the population of lower limb amputees, but they are not always consistent, as they may strongly differ depending on i.a. amputation level and mobility, but also time point of measurement. In this work we provide the typical values of selected outcome measures before and after prosthetic intervention in the population of transfemoral (TF) and (TT) transtibial amputees.

Material method; implementation/ process

The reference values have been calculated based on the data in the Outcome Registry, in which routine prosthetic fittings of lower limb amputees are documented with clinical outcome measures prior and after the fitting and at follow-up. The outcome results documented during

almost 1800 prosthetic interventions for TF and TT patients, collected in 22 clinics in 8 countries (mostly Germany and India) were considered.

Following outcome measures were included: Prosthetic Limb Users Survey of Mobility 12-Item Short From (PLUS-M), Locomotor Capabilities Index-5 (LCI), Activities-Specific Balance Confidence Scale (ABC), Timed Up and Go Test (TUG), Four Square Step Test (FSST) and Six Minute walk Test (6 MWT). The first three of them are self-reported and the remaining three are performance-based measures. The LCI and TUG data are collected in the Outcome Registry only for the limited community ambulators (MFCL K1 & K2), and ABC and FSST only for the unlimited ones (MFCL K3 & K4).

Results

The mean values have been calculated for each outcome under consideration, amputation level and measurement time points, separately for the limited and unlimited community ambulators. It was differentiated between the following measurement time points: at the delivery of the first ever prosthesis for the amputee ("Post-Initial"), at the beginning of the prosthetic intervention (e.g. new prosthesis, components change in an existing prosthesis) for the amputees already having an experience with the prosthesis ("Pre-Following") and after such an intervention ("Post-Following"). The calculated reference values and their 95% confidence intervals are presented in the Table 1. The number of data points used for the calculation of each value (n) is provided in the parentheses.

As it may been seen in the Table 1 the considered factors impact the measurement results. As it was expected, the difference in the mean scores for limited and unlimited community ambulators is clearly visible in PLUS-M and 6MWT. Also the amputation level impacts the covered distance in 6MWT (see higher values for TT than for TF). Interestingly, also the measurement time points impact the obtained scores. The highest impact is observed in the balance confidence (ABC). The lowest mean scores are observed directly after receiving the first prosthesis and they increase till the following interventions. The highest ABC score is, however, observed after the following intervention.

Discussion/ conclusion; conclusion for the practice

Our mean PLUS-M scores for limited community ambulators are similar to those of MFCL K2, and those of unlimited community ambulators to those of K3 and K4, reported by Hafner et al. [1] (45.2, 50.5, 53.8 for the MFCL K2, K3 and K4, respectively). Similarly, the 6MWT in the table 1 are comparable with those reported by Gailey et al. [2] (189.9 m for MFCL K2 and 298.4 m for K3 amputees). These examples show that the reference values that we have determined are comparable with those in the literature and therefore they may be considered as plausible. The novelty of our work, is that we distinguish between the measurement time points at the beginning and at the end of a prosthetic intervention. As shown, this distinction is relevant for some outcome measures. Therefore, we hope that these reference data may be of particular interest for the prosthetic clinics, as these are the time points when usually the outcomescores are collected in the routine practice.

References

1. Hafner, Brian J.; Gaunaurd, Ignacio A.; Morgan, Sara J.; Amtmann, Dagmar; Salem, Rana; Gailey, Robert S. (2017): Construct Validity of the Prosthetic Limb Users Survey of Mobility (PLUS-M) in Adults With Lower Limb Amputation. In Archives of physical medicine and rehabilitation 98 (2), pp. 277–285. DOI: 10.1016/j.apmr.2016.07.026.
2. Gailey, Robert S.; Roach, Kathryn E.; Applegate, E. Brooks; Cho, Brandon; Cunniffe, Bridgid; Licht, Stephanie et al. (2002): The amputee mobility predictor. An instrument to assess determinants of the lower-limb amputees ability to ambulate. In Archives of physical medicine and rehabilitation 83 (5), pp. 613–627.

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Table 1: Mean values with their 95 percent confidence interval of the selected outcome measures depending on the amputation level, mobility level ("Limited" = Limited community ambulator, "Unlimited" = Unlimited community ambulator) and measurement time point. The number of data points used for the calculation of each mean is provided in parentheses. The values with high confidence values (>20% of the respective mean) are written in italics.

OUTCOME	MES. TIME	TF, LIMITED	TT, LIMITED	TF, UNLIMITED	TT, UNLIMITED
PLUS-M	Post-Initial	43,54±2,31 (61)	43,23±1,63 (109)	50,26±1,58 (84)	51,39±0,61 (210)
	Pre-Following	41,36±2,73 (47)	42,45±2,98 (49)	53,19±1,67 (112)	53,23±1,51 (148)
	Post-Following	45,91±2,47 (46)	47,78±2,53 (53)	55,31±1,49 (112)	55,76±1,32 (153)
LCI	Post-Initial	32,06±3,36 (66)	31,32±2,49 (126)	-	-
	Pre-Following	30,30±3,76 (57)	31,74±3,86 (63)	-	-
	Post-Following	37,13±2,88 (56)	37,05±3,85 (62)	-	-
ABC	Post-Initial	-	-	66,65±3,72 (99)	58,68±2,03 (222)
	Pre-Following	-	-	71,32±3,49 (151)	71,79±3,21 (190)
	Post-Following	-	-	79,82±2,52 (156)	79,94±2,53 (195)
TUG	Post-Initial	*26,06±8,08 (9)*	*21,06±14,21 (7)*	-	-
	Pre-Following	22,98±3,57 (35)	21,84±3,04 (45)	-	-
	Post-Following	23,79±3,90 (41)	20,28±2,88 (48)	-	-
FSST	Post-Initial	-	-	17,41±3,36 (21)	10,82±1,52 (22)
	Pre-Following	-	-	14,68±1,24 (117)	12,47±0,90 (157)
	Post-Following	-	-	13,20±0,92 (141)	12,11±1,49 (171)
6MWT	Post-Initial	*156,63±48,76 (9)*	*233,60±142,89 (6)*	217,40±29,26 (21)	323,84±49,30 (20)
	Pre-Following	159,10±18,96 (31)	155,53±24,72 (35)	286,53±21,35 (97)	338,04±18,43 (134)
	Post-Following	172,52±21,53 (39)	195,17±27,17 (42)	306,75±19,88 (110)	362,16±18,00 (148)