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**Title**

Analysis of sensitivity and correlation of selected self-reported clinical outcomes in lower-limb prosthetic application based on real world data

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**Summary**

The analysis of the data from the Outcome Registry has shown that the following self-reported outcomes: EQ-5D-5L, PLUS-M, LCI, ABC Scale, Socket Comfort Score, and satisfaction are well suited to measure the impact of an intervention related to lower limb prosthetics.

**Introduction**

As health care systems in many countries move toward pay for performance systems, amputation research is transitioning to examining patient-oriented outcomes [1]. Prosthetic clinics and manufactures of prosthetic components are asked to provide high quality evidence that a specific prosthetic fitting is beneficial for patients. However, many outcome measures suitable for use in clinical care and research have not been psychometrically tested with prosthesis users [2].

In the Outcome Registry (Registry) prosthetic fittings of lower limb amputees are documented with self-reported and performance based outcome measures prior and after the fitting and at follow-up. The objective of this analysis is to verify if the impact of the prosthetic interventions on various dimensions is detectable with the self-reported outcome measures instruments included in the Registry. Further, the factors significantly influencing these outcomes and correlation between them should be investigated.

**Methods**

Only data for the patients already having a prosthesis before the intervention have been analyzed. The interventions were included for which all of the following scores have been documented both before and after the intervention: Prosthesis Satisfaction, Socket Comfort Score, EQ-5D-5L Health State Value (Using German Value Set [3]), EQ-5D-5L VAS, PLUS-M

and either ABC or LCI. In the Registry, ABC or LCI tests are applied depending on the mobility level and they are never applied together.

The correlation between all the outcomes and the mobility grade at the time of pre-fitting was calculated using Pearson's method. Afterwards, mixed effects models were applied to analyze the contribution of the following factors: measurement time (before and after the intervention), amputation level (HD, TF, KD, TT, PF), amputation etiology and mobility grade, on each of the outcomes. Post-hoc analyses were performed with Tukey's pairwise comparisons.

### **Results**

Data from 202 fittings collected in 16 clinics from 7 countries were included. There were 98 TT, 82 TF, 13 KD, 6 PF and 3 KD amputees; among them 25% female and 53% mobility grade 3. Mean age:  $50 \pm 18$  years old. The most common amputation etiology was trauma (58%), followed by diabetes (13%).

Correlations between all the investigated outcomes were statistically significant (see table). High correlation ( $R > 0.7$ ) were observed between PLUS-M and ABC score, as well as socket comfort score and prosthesis satisfaction. Moderate correlation ( $R > 0.5$ ) was also observed for Health State Value and all the other outcomes, LCI and PLUS-M, as well as LCI and prosthesis satisfaction. The correlation between Mobility Grade and outcomes was low, except for the PLUS-M instrument.

Mixed model analysis have shown that the post-fitting scores for each outcome are significantly higher than the pre-fitting ones ( $p = 0.000$  in all cases). The contribution of the amputation level to the mixed effects model was significant for prosthesis satisfaction ( $p = 0.018$ ) and socket comfort score ( $p = 0.031$ ). Amputation etiology contributed significantly to the prosthesis satisfaction ( $p = 0.024$ ), EQ-5D-5L VAS ( $p = 0.008$ ), and LCI ( $p = 0.021$ ). Mobility grade at pre-fitting contributed significantly to the Health State Value, PLUS-M and ABC Score ( $p = 0.000$  in all cases).

### **Conclusion**

Our analysis has shown that the sensitivity of each of the self-reported outcome measures used in the Registry is sufficient to detect impact of the prosthetic intervention, and that the mobility level is not a good predictor of the intervention outcome.

Although, the considered outcomes measure different dimensions, the correlation analysis have shown that there is some correlation between all of them. The strongest correlation is between the balance confidence and the mobility measured with the PLUS-M instrument, and between socket comfort and prosthesis satisfaction. This indicates strong dependences between those dimensions.

The moderate correlation of the quality-of-life-related Health State Value with all the other outcomes under consideration confirms on the one hand that the dimensions measured with those outcomes are relevant for the quality of life, and on the other hand, that the EQ-5D-5L despite its simple form is able to detect changes in various dimensions.

### **References**

1. Hawkins, Alexander T.; Henry, Antonia J.; Crandell, David M.; Nguyen, Louis L. (2014): A systematic review of functional and quality of life assessment after major lower extremity amputation. In *Annals of vascular surgery* 28 (3), pp. 763–780. DOI: 10.1016/j.avsg.2013.07.011.
2. Hafner, Brian J.; Morgan, Sara J.; Askew, Robert L.; Salem, Rana (2016): Psychometric evaluation of self-report outcome measures for prosthetic applications. In *Journal of rehabilitation research and development* 53 (6), pp. 797–812. DOI: 10.1682/JRRD.2015.12.0228.
3. Ludwig, Kristina; Graf von der Schulenburg, J.-Matthias; Greiner, Wolfgang (2018): German Value Set for the EQ-5D-5L. In *PharmacoEconomics* 36 (6), pp. 663–674. DOI: 10.1007/s40273-018-0615-8.

**Image:** Correlation\_2522.PNG

	Prosthesis Satisfaction	Socket Comfort Score	EQ-5D-5L Health State Value (Ger.)	EQ-5D-5L VAS	PLUS-M	LCI	ABC
Socket Comfort Score	<b>0.746</b> (p=0.000)						
EQ-5D-5L Health State Value (German)	<b>0.531</b> (p=0.000)	<b>0.509</b> (p=0.000)					
EQ-5D-5L VAS	0.351 (p=0.000)	0.310 (p=0.000)	<b>0.510</b> (p=0.000)				
PLUS-M T-Score	0.352 (p=0.000)	0.326 (p=0.000)	<b>0.597</b> (p=0.000)	0.372 (p=0.000)			
LCI	<b>0.527</b> (p=0.000)	0.474 (p=0.000)	<b>0.688</b> (p=0.000)	0.377 (p=0.000)	<b>0.686</b> (p=0.000)		
ABC	0.379 (p=0.000)	0.406 (p=0.000)	<b>0.595</b> (p=0.000)	0.404 (p=0.000)	<b>0.801</b> (p=0.000)		
Mobility Grade (@pre-fitting)	0.076 (p=0.186)	0.112 (p=0.051)	0.131 (p=0.023)	0.116 (p=0.020)	<b>0.518</b> (p=0.000)	0.334 (p=0.001)	0.269 (p=0.000)