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
Analysis of the data in the Ottobock Outcome Registry* shows that self-reported outcomes: EQ-5D-5L, PLUS-M, LCI, ABC, Socket Comfort Score, and satisfaction are well suited to measure the impact of an intervention related to lower limb prosthetics.

Introduction
• Prosthetic clinics and manufactures of prosthetic components are asked to provide high quality evidence for prosthetic fitting.
• Many outcome measures have not been psychometrically tested with prosthesis users [1,2].
• The objective of this analysis is to verify that the impact of the prosthetic interventions on various dimensions is detectable with the self-reported outcome measure instruments.
• The factors significantly influencing these outcomes and correlation between them are investigated.

* In the Ottobock Outcome Registry (Registry) routine prosthetic fittings of lower limb amputees are documented with self-reported and performance based outcome measures prior and after the fitting, as well as at follow-up(s).
Methods

- The following data from the Ottobock Outcome Registry were analyzed:
  - patients already having a prosthesis prior to the intervention,
  - scores documented before and after the intervention: Prosthesis Satisfaction, Socket Comfort Score (SCS), EQ-5D-5L (German Value Set [3]), EQ-5D-5L VAS, PLUS-M and either ABC or LCI*. 
- The correlation between the outcomes and the mobility grade prior to the intervention was calculated using Pearson’s method.
- Mixed effects models were applied to analyze the contribution of the: measurement time (before/after the intervention), amputation level (HD, TF, KD, TT, PF), amputation etiology and mobility grade, on each of the outcomes.

Results

- Data from 202 fittings collected in 16 clinics in 7 countries are included:
  - 98 TT, 82 TF, 13 KD, 6 PF and 3 KD amputees; 25% female; 53% mob. grade 3.
  - Mean age: 50±18 years old.
  - The most common amputation etiology: trauma (58%), followed by diabetes (13%).
- Mixed model analysis:
  - Post-intervention scores are significantly higher that the pre-intervention ones (p=0.000 for each outcome).
  - Amputation level contributes significantly to prosthesis satisfaction (p=0.018) and SCS (p=0.031).
  - Amp. etiology contributes significantly to the prosthesis satisfaction (p=0.024), EQ-5D-5L VAS (p=0.008), and LCI (p=0.021).
  - Mobility grade contributes significantly to the EQ-5D-5L, PLUS-M and ABC Score (p=0.000 in all cases).

* In the Ottobock Outcome Registry, ABC or LCI tests are applied depending on the mobility level and they are never applied together.
Correlations between all the investigated outcomes are statistically significant ($p < 0.05$). Not the case for the mobility grade.

High correlation ($R>0.7$) between:
1) PLUS-M and ABC score;
2) SCS and prosthesis satisfaction.

Moderate correlation ($R>0.5$) between:
1) EQ-5D-5L and all other outcomes;
2) LCI and PLUS-M;
3) LCI and prosthesis satisfaction.

The correlation between mobility grade and outcomes is low, except for PLUS-M.

**Pearson correlation coefficients $R$ (first row) and statistical significance ($p$) for the analyzed correlations.**

High and moderate correlations ($R>0.5$) are indicated in bold.

<table>
<thead>
<tr>
<th></th>
<th>Prosthesis Satisfaction</th>
<th>Socket Comfort Score (SCS)</th>
<th>EQ-5D-5L (Ger.)</th>
<th>EQ-5D-5L VAS</th>
<th>PLUS-M</th>
<th>LCI</th>
<th>ABC</th>
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<tbody>
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<td>Socket Comfort Score</td>
<td>0.746</td>
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<td>EQ-5D-5L Health State Value (German)</td>
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<td>0.509</td>
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<td>EQ-5D-5L VAS</td>
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<td>PLUS-M T-Score</td>
<td>0.352</td>
<td>0.326</td>
<td>0.597</td>
<td>0.372</td>
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<td>LCI</td>
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<td>ABC</td>
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<td>Mobility Grade</td>
<td>0.076</td>
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<td>0.116</td>
<td>0.518</td>
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<td>(pre-intervention)</td>
<td>(p=0.186)</td>
<td>(p=0.051)</td>
<td>(p=0.023)</td>
<td>(p=0.020)</td>
<td>(p=0.000)</td>
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Conclusion

- The sensitivity of the self-reported outcomes documented in the Registry is sufficient to detect impact of the prosthetic intervention.
- The mobility level is not a good predictor of the intervention outcome.
- There is some correlation between all outcomes, despite different dimensions that they measure.
- There is strong dependency between the balance confidence (ABC) and the mobility (PLUS-M), as well as between socket comfort (SCS) and prosthesis satisfaction.
- The moderate correlation of the EQ-5D-5L Health State Value with all the other outcomes confirms that:
  - the dimensions measured with those outcomes are relevant for the quality of life,
  - the EQ-5D-5L despite its simple form is able to detect changes in various dimensions.

References

