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**Title**

Clinical predictors for improvement in outcomes after lower limb prosthetic fittings

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**Summary**

In a retrospective chart review including over 900 lower limb prosthetic fittings, lower mobility level, shorter time post-amputation and bilateral amputation were found to be associated with a greater proportion of patients showing clinical improvement.

**Introduction**

Documentation of improvements in clinical outcomes after routine prosthetic fittings in an O&P clinic is possible when assessments are taken at both baseline and follow-up. Recently, a retrospective study including 279 LL amputees undergoing prosthetic fittings reported that 50% of subjects improved in at least one outcome and that K-Level (=German activity class) was the only predictor for clinical improvement (1). The aim of this research was to seek predictors for clinically meaningful changes in outcomes in a larger cohort of subjects.

**Methods**

Outcome measures routinely administered at three clinic sites included the following: Fast Walking Speed (FWS), Self-selected Walking Speed (SSWS), 2-minute Walk Test (2MWT), Timed Up and Go (TUG) (K1/K2 only), Four-Square Step Test (FSST) (K3/K4 only), Amputee Mobility Predictor (AMP), Activity-specific Balance Confidence (ABC), Socket Comfort Score (SCS), Prosthetic Limb User Survey of Mobility (PLUS-M), and Quality of Life (EQ-5D).

Outcomes were assessed at baseline, initial follow up typically 2-3 weeks after the fitting, 6 months, and annually. Cutoffs for clinically meaningful changes were established. Statistical significance for predictors of clinical improvement was tested using the Fisher's exact test for 2x2 matrices and the Pearson's Chi-square test for the others (SPSS).

## Results

Outcomes data at baseline and follow-up were collected from 907 fittings in 680 lower limb amputees. The average age was  $56.8 \pm 16$  yrs (3-93) and 186 (27%) were female. 190 (28%) were above the knee (AK), 473 (70%) below (BK), 15 (2%) bilateral mixed AK/BK, and 1 unknown. There were 76 (11%) bilaterals. 25% of amputations were due to trauma, 50% dysvascular/infection, 4% cancer, and 16% unknown.

The proportion of fittings that resulted in a clinically meaningful change by outcome is shown in Table 1.

Factors were tested as predictors for clinical improvement, including amputation level and cause (traumatic, dysvascular), K-level, bilateral, age (5 bins), gender, follow-up (4 bins), time since amputation (3 bins) and insurance (5 categories).

Significant factors were bilateral amputation ( $p=.046$ ), K level ( $p<.001$ ), insurance ( $p=.022$ ), time since amputation ( $p<.001$ ), follow-up time ( $p<.001$ ) and age ( $p=.005$ ).

The percentage of prosthetic fittings resulting in improvement in patient-reported and performance-based outcomes by K-Level are shown in Figure 1. Overall, lower K-Level, shorter time since amputation, bilateral amputation, and shorter follow-up were associated with better outcomes. Insurance, mobility level and age may be related.

## Conclusion

This study confirms previous findings that amputees with lower K-Level (=German activity class) appear more likely to experience clinically meaningful improvements in the outcomes tested. Other factors also appear to predict outcomes in the larger dataset. Additional analyses in process will assess the relationships between factors and whether component selection also predicts outcomes.

The routine collection of outcome measures is feasible and may highlight the type of patients more likely to show meaningful clinical benefit from prosthetic intervention.

## References

1. Lundstrom, R, et al, 2018 AOPA National Assembly Proceedings.

Image: Predictors\_Graphic\_2542.PNG

Outcome	n	Δ Cutoff	% ↑	% -	% ↓
FWS <sup>1</sup>	253	+0.1 m/s	25%	44%	31%
SSWS <sup>1</sup>	308	+0.1 m/s	28%	47%	25%
2MWT <sup>1</sup>	65	+17 m	18%	46%	35%
TUG <sup>1</sup>	164	-3 s	26%	60%	14%
FSST <sup>1</sup>	74	-3 s	15%	70%	15%
AMP <sup>1</sup>	269	+4 (~10%)	17%	76%	7%
ABC <sup>2</sup>	259	+15%	33%	47%	19%
PLUS-M <sup>2</sup>	578	+4 (~10%)	44%	39%	17%
SCS <sup>2</sup>	82	+1	40%	33%	27%
EQ5D <sup>2</sup>	205	+10	38%	50%	12%

Table 1. % of fittings resulting in improvement, no change or decline by outcome. Overall, 51% of fittings resulted in an improvement in one outcome. <sup>1</sup> patient-reported outcomes, <sup>2</sup> performance-based.

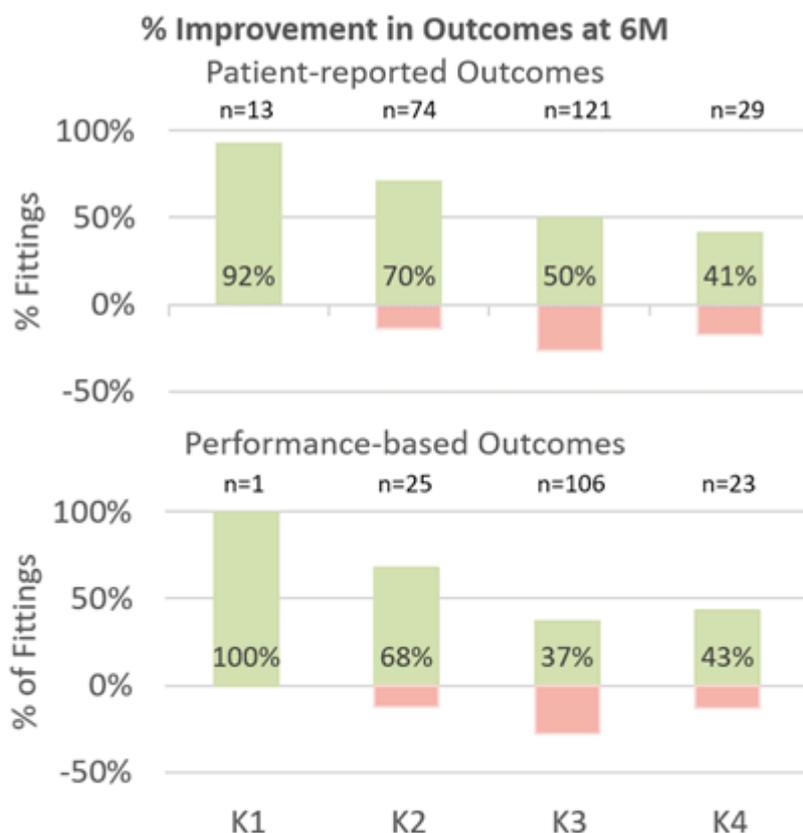


Figure 1. % of subjects showing clinically meaningful improvement by outcome type and K-Level. Green = Improvement; Red = Decline. Socket replacements, toes/partial feet and liners excluded.