Title: Novel Lower-Limb Prostheses: Comparing Adherence, Perspiration, and Residual Limb Skin Health in a Hot, Humid Environment and During Activities of Daily Living

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Statistical Analysis Plan

Linear mixed effects regression was used to assess the association between outcomes and suspension system. Study participant was modeled as random. Hypothesis testing was carried out using conditional F-tests. Results are summarized as means ± standard error (SE) for each suspension system and mean differences among groups, ±SE, 95% confidence intervals and p-values to test if pairwise differences were significant using Tukey's method to adjust for multiple comparisons. Differences from the baseline measurements were not assessed. Variables with heterogeneous variances were analyzed using log transformations with mean differences back transformed into the original units and pairwise differences presented as ratios. Significance was reported with a nominal threshold of $p < 0.05$, supplemented by effect sizes (Hedges' g). Effect sizes were interpreted as small ($0.2 \leq g \leq 0.5$), moderate ($0.5 \leq g \leq 0.8$), and large ($g \geq 0.8$) (Cohen, 2013). Analyses were carried out using R 4.2.1 (Team RC, 2022), and packages tidyverse, lme4, emmeans and kableExtra (Wickham, 2019; Bates, 2015; Lenth, 2022; Zhu, 2023).

Cohen J. Statistical power analysis for the behavioral sciences. New York, NY, Academic Press, 1977.

Team RC. R: A language and environment for statistical computing [Internet]. Vienna, Austria: R Foundation for Statistical Computing; 2022. Available from: www.R-project.org

Wickham H, Averick M, Bryan J, Chang W, McGowan L, François R, et al. Welcome to the Tidyverse. J open source Softw. 2019;4(43):1686.

Bates D, Mächler M, Bolker B, Walker S. Fitting Linear Mixed-Effects Models Using lme4. J Stat Softw [Internet]. 2015 Oct 7;67(1 SE-Articles):1–48. Available from: https://www.jstatsoft.org/index.php/jss/article/view/v067i01

Lenth R V., Bolker B, Buerkner P, Giné-Vázquez I, Herve M, Jung M, et al. emmeans: Estimated Marginal Means, aka Least-Squares Means [Internet]. 2022. Available from: CRAN.R-project.org/package=emmeans

Zhu H (2023). *kableExtra: Construct Complex Table with 'kable' and Pipe Syntax*. R package version 1.3.4.9000, https://github.com/haozhu233/kableextra.