

Title: Lower limb prostheses for individuals who carry infants, toddlers, and other loads.

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Statistical Analysis Plan

Outcome metrics: vertical GRF impulse, anterior GRF impulse, peak-to-peak range of sagittal plane whole body angular momentum (WBAM), and peak-to-peak range of frontal plane WBAM.

Linear mixed effects regression was used to assess differences in biomechanical outcomes (the dependent variable) by foot type for each load by combining all loading conditions in a single model and using a foot type by load condition interaction to estimate means and mean differences in outcomes by foot for each load separately. This model assumes a common variance in outcomes across load and foot. Thus, standard errors for the means will be similar across load and foot. Subject and foot type within subject were considered random effects. Several random effects structures were considered (from subject ID intercept only to a full subject by foot interaction model) with the best model chosen based on likelihood ratio tests. Hypothesis testing for the overall association between outcome and foot type were carried out using conditional F-tests for each load type. For comparison, the Benjamini Hochberg (BH) adjustment was also applied to the F-tests for each model across the 5 load conditions to maintain a false discovery rate of 5%. Hypothesis testing for pairwise differences across feet was carried out using Tukey's method to account for the inflation of the Type 1 error due to assessment of 10 pairwise differences for each load. Analyses were carried out using R 4.2.3 (R Foundation for Statistical Computing, Vienna, Austria) and packages tidyverse, lme4, emmeans and lmerTest.

Outcome metrics: positive net ankle joint work.

Linear mixed-effects regression was used to assess differences in biomechanical outcome (i.e., prosthetic limb joint work over the entire gait cycle as dependent variable) by prosthetic foot for each load condition. All loads were combined in a single model with a foot-by-load interaction to estimate means and mean differences in outcome by foot within each load. The model assumed a common variance, yielding similar standard errors (SE) across loads and feet. Participant and foot within participant were included as random effects. Multiple random effects structures were compared using likelihood ratio tests to select the best-fitting model. The dependent variable was transformed when residual heteroscedasticity was detected. Hypothesis testing for the overall associations between foot and outcome variables were performed using conditional F-tests for each load. For comparison, the Benjamini-Hochberg correction was also applied across the loads to control the false discovery rate at 5%. Hypothesis testing for pairwise differences across feet was performed using Tukey method to account for the inflation of the Type-1 error due to multiple testing (10 comparisons per load). All analyses were conducted in R v4.2.3 (R Foundation for Statistical Computing, Vienna, Austria) using the following packages: tidyverse, lme4, emmeans, and lmerTest.