Title: Pivot-Flex Foot: Optimal Coupling Ratio Between Transverse and Sagittal-plane Motions Using a Torsionally Adaptive Prosthesis for Individuals With Lower Limb Amputation

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Statistical Analysis Plan

Linear mixed effects regression was used to test for an association between each outcome (dependent variable) by coupling ratio. Coupling ratio was the independent fixed effect (modeled as categorical using 4 dummy variables). Study participant and study participant by coupling ratio interaction were random effects. To address the variability in outcome variance among participants, maximum penalized likelihood estimation was used (Chung 2013). Hypothesis testing for the association between outcome and coupling ratio was carried out using conditional F-tests with degrees of freedom estimated using the Kenward-Roger method. Pairwise hypothesis testing was carried out with adjustments for multiple comparisons using Tukey's method. Results are summarized as outcome means (± standard error) by coupling ratio, and pairwise mean differences in outcome by coupling ratio category accompanied by standard errors and 95% confidence intervals (CI). Analyses were carried out using R 4.2.1 (Team RC, 2022), and packages tidyverse, lme4, blme and emmeans (Chung, 2013; Wickham, 2019; Bates, 2015; Lenth, 2022). Statistical analysis on satisfaction results were not performed due to the small sample size and the higher expected variances in qualitative data.

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