Energy-Harvesting Knee Prosthesis:
Assist-Knee

NCT04023045
Protocol # 7826-01

Revision Date: 09/06/2022

Grant PI:
Sarah Chang, PhD

Orthocare Innovations, LLC
123 Second Avenue South, Suite 220
Edmonds, WA 98020 USA

Statistical Analysis Plan

In this small pilot trial of three participants, we calculated and reported descriptive statistics (means and standard deviations) with the different conditions (Habitual and Assist-Knee) to determine ranges of values for the following measures:
- Time to complete sit-to-stand
- Time to complete stand-to-sit
- Timed Up and Go Test
- Percentage of Body Weight on Contralateral Side at 65 degrees knee flexion

Due to the small sample size, the use of parametric statistical analyses such as Analysis of Variance (ANOVA) and averaging as a single group are not appropriate. Instead, each participant served as their own control since each user's prosthesis is unique, and we analyzed these values and the extremes (e.g., how fast or slow the sit-to-stand or stand-to-sit times were), to better understand the effect of our investigational device and inform sample size calculations in future research.