

Project Title: *No Power Bionic Lower Extremity Prosthesis*

Document Date: 1/5/2024

NCT Number: NCT04070105

## *CAESAR Study Protocol*

### *Stiffness verification testing*

We built a Caesar foot for each participant and obtained AllPro feet based on their respective size and weight category. Due to availability, these feet were a mix of 6- and 8-inch build heights, however. We tested each foot's stiffness at loads associated with running and walking using an ISO 10328 machine at College Park Industries (Figure 1). We quantified stiffness using a linear fit to the force-displacement curve and used this to verify similarity of stiffness categories between the two experimental feet (AllPro/Caesar). We quantified both absolute difference in stiffness and percent difference ( $100 * (\text{AllPro-CAESAR}) / ((\text{AllPro} + \text{CAESAR}) / 2)$ ).

### *Experimental Protocol*

This study was a repeated measures design of three prostheses: the Caesar foot, AllPro, and participants' prescribed walking and running feet. Each foot was tested on a separate day, with the order of testing randomized. In the CAESAR and AllPro sessions, a certified prosthetist fit and aligned the prosthetic foot. The participant then walked, jogged, and walked on stairs. The prosthetist made adjustments until both the participant and prosthetist were satisfied with the fit/alignment. This process took approximately 20 - 45 minutes.

For each session, participants arrived at the lab having fasted and avoided caffeine for a minimum of 4 hr. Participants first completed metabolic testing on a treadmill. Participants remained seated for 5 minutes, while a K5 portable metabolic system (Cosmed, Rome, Italy) measured their resting metabolic rate of oxygen consumption ( $VO_2$ , mL/kg/min). Participants then ran continuously for 5 min at a self-selected speed on a treadmill. If they were uncomfortable or unable to run for 5 minutes without significant hand support, they instead walked for 8 minutes at a fixed speed based on their leg length that approximately self-selected speed in this population (Gates et al., 2013).

Participants subsequently completed a series of ambulatory tasks including walking at a fixed speed based on leg length, walking at self-selected slow, comfortable, and fast speeds, walking up and down a 3-step instrumented staircase (Bertec, Columbus, OH), and walking up

and down a 7.5° ramp at self-selected speed. After each task, participants were asked to provide feedback on their comfort and stability on a 100-mm visual analog scale. During the CAESAR session, participants completed stair and ramp walking twice, once with the foot in ‘run’ mode and then with the foot in ‘walk’ mode. We then asked which mode they preferred for that task and why.

During all tasks, we tracked the motion of 49 reflective markers at 120 Hz using a 16-camera motion capture system (Qualisys AB, Gothenburg, Sweden) for the overground tasks or a 12-camera motion capture system (Qualisys AB, Gothenburg, Sweden) for treadmill tasks. Markers were placed on body landmarks including the C7, sternum, xiphoid process, T8, and bilaterally on the acromion, iliac crest, anterior and posterior superior iliac spines, greater trochanter, lateral and medial tibial epicondyles, lateral and medial malleoli, and 2nd and 5th metatarsals. Four-marker clusters were placed bilaterally on the thighs and shanks. For the amputated side, markers were placed on the socket and shoe, so they mirrored the intact side. For the prosthetic feet with a C or J running shape, two markers were placed on the medial and lateral sides of the most acute point on the prosthesis curvature (Buckley, 2000). For standalone running blades used without a shoe, one marker was placed on the most anterior point of the foot with two additional markers on the medial and lateral edges of the foot.

### *Data Analysis*

We calculated the net  $\dot{VO_2}$  by subtracting the seated rest  $\dot{VO_2}$  from the gross  $\dot{VO_2}$  over a 2-minute period of steady-state locomotion. Visual3D filtered marker trajectories and GRF data using 4<sup>th</sup>-order low-pass Butterworth filters with cut-off frequencies of 6-Hz and 10 Hz, respectively. We then built an 8-segment model consisting of the trunk, pelvis, thighs, shanks, and feet in Visual3D (C-Motion, Germantown, MA) with segment inertial properties from (Dempster, 1955; Hanvan, 1964). The inertial properties for the prosthesis were adjusted according to (Ferris et al., 2017).

### *Statistical Analysis*

As there was variability in the type of activity performed during metabolic testing, we only report individual data and relate changes to reported minimal detectable change (MDC) values where appropriate (Davidson et al., 2016). For kinematic and kinetic measures, we first took the average across five strides for walking and 30-s for running. Due to the small sample size, we calculated effect size, as Hedge's  $g$  for these measures. These are interpreted as small for  $|g| \geq 0.2$ , medium for  $|g| \geq 0.5$ , and large for  $|g| \geq 0.8$  (Cohen 1988).