

Project Title: Improving Community Ambulation for Stroke Survivors using
Powered Hip Exoskeletons with Adaptive Environmental Controllers

NCT Number: NCT03924765

Date: September 16, 2021

Study Protocol

We utilized a lightweight autonomous powered hip exoskeleton that can provide hip flexion and extension assistance bilaterally in the sagittal plane (Gait Enhancing and Motivating System, Samsung Electronics, South Korea). The device has an additional passive joint at the hip for free abduction and adduction in the frontal plane. Overall exoskeleton system has a mass of 2.1 kg. We controlled our exoskeleton system utilizing a biological torque controller to ensure consistent and continuous assistance throughout the gait cycle. The onset and peak assistance timing of hip flexion and extension were based on the values from our previous hip exoskeleton study, which showed the largest metabolic cost reduction for able-bodied subjects. The onset timing for hip flexion and extension assistance was set to 45% and 90% of the gait cycle, respectively (defining heel strike as 0%). The peak timing for hip flexion and extension was set to 60% and 10% of the gait cycle, respectively.

The experimental protocol consisted of three sessions: 1) baseline assessment, 2) exoskeleton fitting and controller parameter tuning, and 3) exoskeleton walking trials. During Session 1, the subject's gait characteristics without wearing the exoskeleton were measured. Comfortable overground walking speed and spatiotemporal gait parameters (to calculate the subject's step length asymmetry) were measured using a 6-meter walkway (Zeno, ProtoKinetics, USA). Subjects were asked to complete 4 passes across the walkway with their self-selected walking speed. After, Subjects were asked to walk on an instrumented split-belt treadmill (Bertec, USA). The treadmill speed was set at 80% of the overground self-selected walking speed. Subjects walked on the treadmill for 1 minute. During Session 2, the subject donned and was fitted to the exoskeleton with an adjustable waist belt, thigh interface, and thigh straps. During this procedure, subjects first acclimated to the exoskeleton by walking on the treadmill with the device zero torque mode (no assistance) to ensure there was no discomfort. Following the initial familiarization phase, we provided hip assistance bilaterally by setting the assistance magnitude to a medium level (4 Nm). We utilized this magnitude to tune the assistance timing parameters for each side while the subject was walking on the treadmill. During this tuning phase, we have fixed the hip flexion and extension assistance duration to a nominal value that was shown to be effective. The hip flexion and extension onset timings were tuned based on the assessment by a clinician and the subject's verbal feedback to ensure that the exoskeleton assistance was congruent with the subject's limb movement. The hip flexion and extension onset timings for each side were set the same for all assistance magnitude conditions (2 Nm, 4 Nm, and 6 Nm) in Session 3.

In Session 3, the subject was asked to walk with the exoskeleton with 16 different combinations of assistance magnitude for both the paretic and non-paretic sides. The assistance condition was noted as level 0, 1 (low), 2 (medium), and 3 (high) with the corresponding exoskeleton magnitude set to 0 Nm, 2 Nm, 4 Nm, and 6 Nm, respectively. For example, in the NOP1 condition, the exoskeleton assistance was only provided to the paretic side with a magnitude set to 2 Nm. For each assistance condition, the subject walked on the treadmill for 1 minute. Following the treadmill trial, the subject completed 4 passes on the 6-meter walkway with the same assistance condition. Throughout

Session 3, the order of these assistance conditions was randomized. To ensure safety, all subjects wore an overhead safety harness and a handrail was mounted on the subject's non-paretic side during the entire experiment. To evaluate gait functions under different exoskeleton assistance conditions post-stroke, we recorded the subject's walking speed and step length. The subject's overground self-selected walking speed, step length, and step length asymmetry were measured and processed using the PKMAS software (Zeno, ProtoKinetics, USA). Step length asymmetry index (ASI) was calculated by dividing the paretic side step length by the sum of the paretic and non-paretic side step lengths, where an ASI of 0.5 indicates perfect symmetry between the paretic and non-paretic sides.