Exoskeleton variability optimization for reducing gait variability for patients with peripheral artery disease

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Study protocol

This study aims to evaluate methods for optimizing hip exoskeleton assistance to minimize gait variability. Optimization is guided by gait variability measurements quantified by the largest Lyapunov Exponent (LyE). The rationale is that this variability exponent provides a measure to track improvements in gait stability during different assistance conditions. The study is an interventional basic science study without blinding since it is not feasible to blind participants to the presence or absence of the exoskeleton or the different assistance conditions.

The protocol is performed at the Department of Biomechanics at the University of Nebraska at Omaha (UNO). Before the experiments, participants complete a health questionnaire and are fitted with an exoskeleton suit. Participants first start with a habituation session to get used to walking with the exoskeleton. Next, they proceed to the data collection session. During the optimization trials, healthy controls walk up to 20 minutes; patients with PAD walk 10x1 minutes with at least 2 minutes of rest. An algorithm prescribes the assistance profiles of the exoskeleton suit. After the optimization trials, participants will perform validation tests during which they repeat walking in the different exoskeleton and no-exoskeleton conditions (four trials of a maximum of 5 minutes for the healthy controls and two trials of a maximum of 6 minutes or until claudication onset for patients with PAD). The entire experiment will take no more than 1 hour for session 1 and 3 hours for session 2.

Hip extension and hip flexion assistance are measured using load cells (Futek Advanced Sensor Technology, Irvine, CA, USA). These load cells are connected to an exoskeleton input/output system (HuMoTech, Pittsburgh, PA, USA). To analyze the biomechanical responses to the exoskeleton assistance, three-dimensional movement data of all participants are recorded using a motion capture system (100 Hz, Vicon, Oxford, UK). The motion capture system is calibrated before data collection using a standard L-frame and a wand calibration method, following the manufacturer-recommended procedures. Reflective markers are placed on each participant's predefined anatomical landmarks according to a modified Helen Hayes marker set. Ground reaction forces are measured during walking using an instrumented force-treadmill (1000 Hz, Bertec, Columbus, OH). To remove unrealistic noise, all biomechanical signals are smoothed using a digital low-pass Butterworth filter with a cutoff frequency of 10 Hz.

Inverse dynamics analyses are conducted on the filtered biomechanical data to calculate joint moments and joint powers. These calculations are carried out using Visual3D (C-Motion, Germantown, MD). From these analyses, sagittal plane joint angles are extracted for further evaluation. To determine the torque exerted by the exoskeleton suit on the participant's hip joint, the measured forces from the load cells are multiplied by a fixed moment arm length, assumed to be 10 centimeters. The biological component of the hip joint moments is calculated by subtracting the exoskeleton-generated torque from the total joint moment computed through inverse dynamics.

Heel strikes are determined from the vertical ground reaction force signals using a threshold-based algorithm. Stride-segmented data are subsequently organized into a matrix data format within MATLAB software (MathWorks, Natick, MA, USA). Additionally, peak hip extension and flexion assistance timings are identified from the exosuit moment signals using a peak-detection algorithm. These timings are then expressed as percentages of the duration of each stride.

The primary outcome measures of this study include the peak extension timing and peak flexion timing provided by the exoskeleton suit, the time required for convergence of the optimization algorithm, and the largest Lyapunov Exponent (LyE), which is calculated as the average derived from leg joint angles.

Statistical analysis plan

Variability is quantified based on the Lyapunov Exponent. First, the optimal time lag (Tau) necessary for state-space reconstruction is estimated through the Average Mutual Information (AMI) algorithm. Tau is determined at the first local minimum of the AMI curve. Next, the optimal embedding dimension, representing the minimum number of variables required to accurately reconstruct gait dynamics, is determined using the False Nearest Neighbor (FNN) method. With these parameters (Tau and embedding dimension), the original gait time series are reconstructed into a multi-dimensional state space. LyE is computed using Wolf's algorithm, which evaluates how quickly neighboring trajectories in state-space diverge from each other. LyE is calculated individually for the hip, knee, and ankle joints.

Repeated-measures Analysis of Variance (ANOVA) is used to compare differences between conditions. The convergence of the optimization algorithm is statistically assessed by determining the number of assistance conditions after which the optimal exoskeleton settings no longer change as the convergence criterion.

Descriptive statistics are computed for all biomechanical variables, including joint angles, moments, and powers. Specifically, each biomechanical variable's mean and standard deviation are calculated across all participants for each experimental condition. These descriptive statistical values are consistently reported as mean ± standard deviation. A significance threshold for all statistical tests is set at a p-value of 0.05.