Official Title: Intelligent and Adaptive Control Applied to Powered Walkers

NCT05465239

STUDY PROTOCOL

Brief Summary/Abstract

Barron Associates, Inc. (BAI) has teamed with the University of Virginia's (UVA's) Motion Analysis and Motor Performance (MAMP) laboratory to propose development of an advanced control and computer learning strategy that will intelligently drive a powered walker for people with walking disabilities. The aim of the control strategy is to provide powered assistance that optimally reduces the metabolic cost of walking. The goal of the proposed intelligent walker is to reduce the workload of walking, keeping this population walking longer, providing critical exercise, continued muscle development and improved quality of life.

Background

1. Provide the scientific background, rationale and relevance of this project.

Fig. 1. Typical Unpowered Walkers

Many individuals with walking disorders due to neuromuscular disabilities, such as cerebral palsy (CP), use walkers or crutches to aid their mobility unless impairment is so severe as to require the use of a wheel chair. United Cerebral Palsy (UCP) reports that an estimated 764,000 individuals in the United States have one or more symptoms of CP, and a recent multisite UCP study of school-age children found that 24.8% of these individuals use walkers [1] and it is estimated that more than 10,000 pediatric walkers are sold each year in the U.S. Walkers are often equipped with four wheels of varying diameters, which can be mounted on fixed axles or can swivel on casters. Anterior walkers are configured to have the main cross frame in front of the user, whereas posterior walkers position this frame behind the user. Yet both configurations generally "surround" the user with supporting frames. Fig. 1 shows some typical, commercially available anterior and posterior unpowered walkers. Walking requires mechanical work to lift/lower and accelerate/decelerate the center of mass (CoM) of the body. The energy recovered as a result of exchange between potential energy (PE) and kinetic energy (KE) is the main energy saving mechanism of walking, minimizing metabolic expenditure in healthy individuals [2]. However, in individuals with walking disabilities, valuable energy is lost at each gait cycle due to the misappropriation of KE and PE during movement of the CoM. The net result is that energy recovery is substantially reduced and walking becomes a high workload activity – even with typical walkers or crutches. In children with CP, the metabolic cost of walking can be up to *ten* times that of children with typical development, due to poor energy recovery when walking [3-5]. Bennett et al. [6] found mechanical work performed by children with CP to be more than double that of children with typical development, in part due to the fact that children with CP were only able to recover 44% of the available energy, in contrast to 66% recovered by unimpaired children.
Individuals with CP or other disabilities can have compromised motor control, impaired balance, and weakness, all of which can make ambulating difficult — even with a walker. Studies of walker use by children with CP have focused on the kinetics, kinematics, and tradeoffs regarding walker configurations [7-,12]. This research has shown that the use of current walkers does not alter the relatively large effort required for these children to walk; as a result, fatigue itself may limit their participation in activities. The walker is fundamentally used for balance, or "something to hold on to" while walking, not to reduce the workload of walking. Exacerbating the problem is the fact that most of these walkers are designed to be large and heavy to meet the requirements for stability/balance. Further, some walker configurations have no wheels or have fixed wheels that do not turn. Thus, the walker has to be dragged or picked up during turning, which is an essential part of moving during everyday activities [13]. These difficulties with walking and the use of cumbersome walker designs often result in this population eventually using wheelchairs, which reduces their mobility and ability to fully

participate in many social settings. Studies have reported up to 79% of children with CP to be ambulatory at six years of age, (the rest already requiring wheelchairs). However, among adults with CP, 63% reported owning and using one or more wheelchairs and only 21% reported never using a wheelchair. The majority (59%) reported decreased walking ability before reaching 34 years of age; by age 44 the percentage was 90%. [14]
It is important to keep individuals with these types of walking disabilities ambulatory for as long as possible. The significance of this effort is to provide a walker that reduces the workload of walking, keeping this population walking longer, providing critical exercise and continued muscle development. This will help the individual stay active longer, and perhaps prevent the use of a wheelchair. This will greatly improve their quality of life, gaining key physiological, mental, and social benefits.

Hypothesis to be Tested

Hypothesis: A powered posterior walker will have a significant effect on A) the mobility and B) the efficiency of the gait patterns for typically developed individuals and those of children with cerebral palsy

1. Hypothesis: An adaptive learning control algorithm can be implemented for a powered walker to develop optimal movement and efficiency in the gait patterns of typically developed individuals and those of children with cerebral palsy

Study Design: Biomedical

1. Will controls be used? Yes

►IF YES, explain the kind of controls to be used.

Matching gait analysis will be conducted on typically developed individuals with and without the walker

2. What is the study design?

This study design is a repeated measures crossover study. Repeated measures ANOVA will be performed to determine any global effects of the powered walker on the efficiency Kinematics, and force loads applied during walking.

3. **Does the study involve a placebo?** No

4.

Human Participants

Ages: 5-30
Sex: Male and female
Race: Any
Subjects- see below

1. **Provide target # of subjects (at all sites) needed to complete protocol.**
   48 subjects total, 24 individuals with CP and 24 typically developed subjects.

2. **Describe expected rate of screen failure/ dropouts/withdrawals from all sites.** 2

3. **How many subjects will be enrolled at all sites?** 50

4. **How many subjects will sign a consent form under this UVa protocol?** 50

5. **Provide an estimated time line for the study.**
   48 subjects were recruited in year 2.

Inclusion/Exclusion Criteria

1. List the criteria for inclusion

Typically developed subjects;	No walking disabilities
Subjects with CP;	Diagnosed with spastic CP GMFCS level II-III Ages 5-25 inclusive No surgeries in last 6 months Able to ambulate 40ft unaided (excluding walker) Understand and follow commands

2. List the criteria for exclusion

Typically developed subjects;	Observed intramuscular pathology
Subjects with CP;	Mental retardation Severe uncontrolled seizures Leg or foot surgery in last 12 months Surgery or significant injury in last 6 months affecting walking ability Inability to ambulate unassisted (other than walker) 40ft without stopping to rest Inability to understand or follow commands

3. List any restrictions on use of other drugs or treatments. None

Statistical Considerations

1. **Is stratification/randomization involved? No**

2. What are the statistical considerations for the protocol?

BAI and UVA will work together to prepare the trial results for statistical analysis. The analysis shall include testing for within-subject differences of oxygen consumption, walking speed, and device acceptance scores based on participant's use of the baseline (unpowered) and powered walkers. Past experience by the BAI/UVA team gives us the qualifications to complete statistical analyses in-house. Success will be defined by the controlled/powered walker significantly reducing oxygen consumption, increasing walking speed, and having superior device acceptance compared to the unpowered walker.

3. Provide a justification for the sample size used in this protocol.

Table 1. Detectable Differences in Powered Minus Unpowered Walker Outcomes.

Outcome Measure	Standard Deviation of Paired Differences	Paired Data Correlation	Detectable Difference (Δ)	Detectable Effect Size
Oxygen Consumption	4.61 mL/kg/min	0.256	–3.0 mL/kg/min	0.65
Walking Speed	4.16 m/min	0.963	3.5 m/min	0.85
Device Acceptance	2.26 units	–0.019	1.3 units	0.58

Power analysis: Assuming a significance level of $\alpha=0.05$, based on the standard deviations of paired differences listed in column 2 of Table 1 and the empirical measurement correlations in column 3 of Table 1, a one-sided paired t-test achieve 80% power to detect a mean of the paired differences listed in column 4 of Table 1. These represent medium-to-large effect sizes (column 5 of Table 1), but magnitudes that we would expect to achieve under the alternative hypothesis.

4. What is your plan for primary variable analysis?

Include a sketch of the analysis to assess primary study objectives.

Each patient will provide one trial of unpowered walker data and two trials of powered walker data. Thus, a total of two *difference* combinations *(i.e., powered minus unpowered outcomes)* for each of 10 patients will yield 20 difference (Δ) values for *each* outcome measure: $\Delta_{\text{oxygen consumption}}$, $\Delta_{\text{walking speed}}$, and $\Delta_{\text{device acceptance}}$. To assess the unpowered to powered walker changes in outcomes based on each set of 20 pooled Δ values, a one-sided paired t-test will be used to test the following null hypothesis: H_o: $\Delta_{\text{oxygen consumption}} = 0$ versus the alternative hypothesis H_a: $\Delta_{\text{oxygen consumption}} < 0$; H_o: $\Delta_{\text{walking speed}} = 0$ versus the alternative hypothesis H_a: $\Delta_{\text{walking speed}} > 0$; and H_o: $\Delta_{\text{device acceptance}} = 0$ versus the alternative hypothesis H_a: $\Delta_{\text{device acceptance}} > 0$.

5. What is your plan for secondary variable analysis? NA

6. Have you been working with a statistician in designing this protocol? No

7. Will data from multiple sites be combined during analysis? No