PEDIATRIC INTELLIGENTLY CONTROLLED ASSISTIVE REHABILITATION ELLIPTICAL FOR WALKING AND FITNESS: PROTOTYPE DEVELOPMENT AND BIOMECHANICAL ANALYSIS

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ABSTRACT

Walking, running, and engaging in recreational activities with school peers, friends and family are central activities for many children. Yet some are not able to participate due to their physical disabilities and special healthcare needs. To improve or sustain walking and fitness, many children with physical disabilities participate in ongoing therapy sessions in pediatric clinics or through special services provided within the school system. Unfortunately, specialized pediatric rehabilitation devices that might be available for use in larger rehabilitation facilities (e.g., robotics or exoskeletons) are not likely to be available in smaller clinics and school settings due to the price. Other treatment approaches, such as body weight supported treadmill training are often too labor intensive. To address the need for effective and affordable technology that children with physical disabilities and special healthcare needs can use to improve walking and fitness, the commercially available adult ICARE (an **I**ntelligently **C**ontrolled **A**ssistive **R**ehabilitation **E**lliptical) was modified to address the needs of children as young as three years old. Select clinical and design considerations are highlighted and biomechanical findings described. Collectively, these preliminary findings suggest that a set of modifications could be integrated into the ICARE to address the rehabilitation and fitness needs of children and adults.

Keywords: child, electromyography, lower extremity, gait, exercise, physical disability

BACKGROUND

Regaining or sustaining walking capacity and cardiovascular fitness are of critical importance to many children receiving physical rehabilitation in medical and school settings. Although novel treatments such as partial body weight support treadmill training and robotic therapy are available for use across the rehabilitation continuum (Damiano, 2009; Brütsch, 2011), extensive use is limited in part due to the expense associated with purchasing the equipment and delivering the intervention.

In school settings, many devices used by typically developing children are not accessible by children with weakness, balance deficits, and/or movement control problems (U.S. Government Accountability Office, 2010). For example, as currently designed, children's elliptical trainers resist movement. They do not yet have the ability to adapt to and assist movements for children with weakness, joint pain or movement initiation problems.

In adults, the similarities observed in movement patterns and muscle demands between elliptical training and walking suggested that beyond serving as an exercise tool, elliptical trainers could help adults regain the strength and flexibility required for walking (Burnfield, 2010). Indeed, research over a three-year period, involving 110 adults with and without disabilities led to the creation of a commercially available motor-assisted elliptical (i.e., the Madonna ICARE by Sports Art) that is being used in rehabilitation settings, clinics, and medical fitness centers in the United States, Canada and Australia to address walking and fitness deficits in adults with a wide range of diagnoses including stroke, spinal cord injury, brain injury, Parkinson's disease, and multiple sclerosis (Irons, 2015; Burnfield, 2014; Nelson, 2011).

The motor-assistance helps adults repetitively advance their legs in a gait-like movement pattern (Irons, 2015). Users can train at speeds up to 65 revolutions per minute (RPM) in either the forward or reverse direction with the motor's assistance. An integrated body weight support system can further support patients with profound weakness, balance deficits, of joint pain. Step length can be adjusted between 17" and 29" to address the needs of shorter adults and those with hip flexion contractures (i.e., tissue tightness) as well as taller adults capable of taking longer steps. An electronically height adjustable seat enables ease of access and a rest location between exercise bouts. As strength improves, users are encouraged to stride faster than the speed set for the motor. This causes the motor to disengage smoothly and it no longer assists the legs to move. If the user fatigues or is no longer able to sustain the faster pace, then the motor re-engages seamlessly to assist movement as needed. As strength, endurance and movement control increase, users can select from a variety of resisted training modes to further challenge capacity.

During the initial development phase, the ICARE

was primarily designed to address the needs of adults. As such, children of shorter stature, arm length and leg length were not able to use the device safely and comfortably. For example, the 17" step length well exceeded the comfortable step length of most three year old children. Additionally, many younger children were unable to reach or see the console.

PURPOSE

To overcome barriers children with physical disabilities and special healthcare needs experience when trying to improve walking, fitness, and capacity to engage in meaningful activities in the community by creating an affordable ICARE technology for children.

METHODS

This research and development activity involved three phases. The first focused on understanding the clinicians' needs related to the proposed technology development activity. Next, a prototype pediatric ICARE device was developed and changes were made iteratively based on feedback from 3 to 12 year old children (with and without disabilities), their parents, and clinicians. Lastly, following generation of a functional prototype that addressed key end-user concerns, biomechanical research was performed to guide clinical understanding of the training opportunities provided by the technology.

Clinicians' Perceptions of Needs

Clinicians in pediatric private practice clinics, pediatric rehabilitation settings, and school settings were approached in person and through group meetings to better understand their perceived needs. Key themes that emerged included the 1) space constraints that existed within clinical settings (thus the need to limit the quantity and footprint of technology purchases); 2) need to treat children across the age spectrum, including toddlers and teenagers within one clinic/setting; and 3) need for affordable technology given budget constraints. The consistent preference was to create a device that could be adjusted to address the needs of children and adults. The one-device solution was perceived of as more cost- and space-effective than having to purchase a "pediatric" ICARE for smaller/younger children and an "adult" ICARE for larger/older children.

Assessing Prototype Pedi-Adapted ICARE Features

Clinician's preferences and initial perceptions of children's needs were translated into a functioning prototype that was iteratively assessed and refined during the study. The goals included increasing access and usability for children while ensuring safety was preserved.

Forty children with physical disabilities and/or special healthcare needs and 20 typically developing children were invited to provide feedback on the modifications. Each child was: 1) able to understand and respond to simple commands; 2) able to stand (with or without a standing frame) for at least 5 consecutive minutes; and 3) free from any orthopedic, neuromuscular or cardiac conditions that would prevent safe training on pedi-adapted ICARE. Our rationale for including typically developing children was to ensure the device would be usable by children with a range of abilities (and not hinder typically developing users' experiences), thus more likely to be adopted in school settings and other community environments. The children's parents and clinicians were also invited to offer suggestions and insights based on their knowledge of each child's needs. The initial modifications were iteratively refined based on feedback from children, parents, and clinicians.

The study was conducted in the Movement and Neurosciences Center within Madonna Rehabilitation Hospital's Institute for Rehabilitation Science and Engineering. Following Institutional Review Board approval, written informed consent was obtained from each child's parent(s) along with verbal or written assent from the child.

Seven key adaptations were developed and assessed to enable children to access and use the pedi-adapted ICARE trainer. These changes included: 1) changing minimum step length from 17" to 7" to accommodate the shorter step lengths of children (addressed by creation of an adjustable rear crank mechanism) (Nelson, 2015); 2) creating an adjustable footplate system on each elliptical that enabled the between pedal distance to be narrowed so that children's legs were aligned closer to vertical in the frontal plane compared to the initially abducted posture; 3) reducing the pedal's maximum vertical excursion during each movement cycle to more closely emulate the path of the foot during the gait cycle; 4) creating height adjustable pedals so that smaller children would still be able to interact with the console; 5) extending the reciprocally-moving handles toward the user, so that children with shorter arms could reach the moving handles; 6) modifying the electronically height adjustable seat to enable it to more closely approximate the height of a chair/wheelchair placed adjacent to the ICARE to ease children's access and reduce the need for a wheelchair platform adjacent to the motorized elliptical; and 7) integrating feedback mechanisms (e.g., automated performance-driven verbal encouragement or automated adjustment of motor-assisted training speed based on heart rate). Collectively, the modifications helped ensure children and adults with

lower extremity muscle weakness and/or reduced endurance could use the pedi-adapted ICARE to address walking and fitness goals.

Biomechanical Testing of Pedi-Adapted ICARE

It is important to understand how muscle demands vary between training conditions and people so that clinicians can adjust training parameters appropriately for each individual. We hypothesized that: 1) muscle demands would be higher during *Active Assist Plus* training compared to the *Active Assist* training when averaged across all participants (i.e., children with and without disabilities); and 2) children with disabilities would exert larger relative muscle activity when training in the *Active Assist* mode compared to typically developing children. Ten children with disabilities and 10 typically developing children participated. Inclusion criteria were similar to those described for the previous study and written informed consent was obtained from each participant's parent(s) along with verbal or written assent from each child. The diagnoses of children with disabilities and/or special healthcare needs were: autism, cerebral palsy, asthma, centronuclear myopathy, traumatic brain injury, upper extremity amputation, and obesity. All were able to walk independently or with supervision. Four used assistive devices (e.g., orthotics, walker).

To determine the impact of the Pedi-ICARE's motor assistance on lower extremity muscle demands, simultaneous recordings of electromyography (gluteus maximus, vastus lateralis, medial gastrocnemius, tibialis anterior; 1200 Hz) and elliptical trainer kinematics (12-camera motion analysis; 120 Hz) were performed as participants trained at their self-selected comfortable speed and stride length under two motor conditions: 1) *Active Assist:* motor provided adequate force to help the child's legs move at child's predetermined self-selected speed (children instructed to let the machine "guide your legs"); and 2) *Active Assist Plus:* the motor disengaged whenever a child's speed exceeded the motor's threshold speed (children asked to try to exert sufficient effort to cause the console to change from green to orange reflecting the motor had disengaged).

Training velocity (RPM) was documented from the visual display provided on the pedi-adapted ICARE. EMG data recorded during the final 1 minute of the two-minute trial were used for subsequent analysis. The gluteus maximus, vastus lateralis, gastrocnemius and tibialis anterior were selected for analysis as clinicians often focus on improving capacity of these muscles due to their role in providing controlled forward progression, stability, and limb clearance during gait. EMG data were normalized to a maximal voluntary contraction recorded for each muscle across the conditions and expressed as a percentage maximal voluntary contraction (% MVC). Reflective markers, placed on each device's footplates, defined movement cycle timing. A full movement cycle was demarcated as the period from the most anterior location of the reference limb's footplate marker to its next ipsilateral most anterior location. Ten cycles per condition were used for each participant to calculate EMG variables (peak and duration of activity).

Descriptive statistics were performed for key variables using SigmaPlot 11.0 software. Paired t-tests identified significant differences in EMG variables (peak, mean, duration) between motor conditions for all participants. Independent t-tests compared each muscle's demand during *Active Assist* training between children with and without disabilities. Nonparametric analyses were performed when assumptions of normality were violated. Bonferroni adjustments accounted for multiple comparisons.

RESULTS

Training Mode Influence on Muscle Demands at Self-Selected Comfortable Training Speed (Table 1)

Consistent with the initial hypothesis, EMG demands were higher during *Active Assist Plus* compared to *Active Assist* for three of the four muscles assessed (gluteus maximus, vastus lateralis, tibialis anterior). Medial gastrocnemius activity (peak, mean and duration) demonstrated a similar pattern of elevation during *Active Assist Plus* compared to *Active Assist*, but differences failed to achieve statistical significance.

Table 1. Influence of training mode (*Active Assist, Active Assist Plus*) on muscle activity. Surface electromyography (EMG) for children with (n=10) and without (n=10) disabilities (mean, SD).

Muscle	EMG Variable	Active Assist	Active Assist Plus	P-Value
Gluteus Maximus	Peak (% MVC)	10 (4)	33 (15)	p < 0.001
	Mean (% MVC)	10 (3)	15 (6)	p = 0.005
	Duration (% MC)	11 (3)	36 (11)	p < 0.001
Vastus Lateralis	Peak (% MVC)	24 (14)	39 (16)	p < 0.001
	Mean (% MVC)	11 (4)	18 (7)	p < 0.001
	Duration (% MC)	48 (28)	60 (21)	p = 0.014
Medial Gastroc	Peak (% MVC)	16 (7)	21 (12)	p = 0.050
	Mean (% MVC)	11 (3)	13 (5)	p = 0.155
	Duration (% MC)	18 (9)	20 (15)	p = 0.745
Tibialis Anterior	Peak (% MVC)	14 (5)	34 (11)	p < 0.001
	Mean (% MVC)	11 (3)	17 (5)	p = 0.003
	Duration (% MC)	19 (10)	46 (17)	p < 0.001

Active Assist Muscle Demand Comparison Between Children With and Without Disabilities (Table 2)

Although consistently higher for 11 of 12 comparisons, muscle demands during *Active Assist* training did not vary significantly between groups.

Table 2. *Active Assist* muscle demands (EMG) during training at self-selected comfortable speed on motor-assisted elliptical by children with (n=10) and without (n=10) disabilities (mean, SD).

Muscle	EMG Variable	With Disability	Without Disability	P-Value
Gluteus Maximus	Peak (% MVC)	23 (26)	10 (4)	p = 0.289
	Mean (% MVC)	14 (8)	9 (3)	p = 0.268
	Duration (% MC)	30 (32)	10 (5)	p = 0.183
Vastus Lateralis	Peak (% MVC)	31 (20)	24 (11)	p = 0.341
	Mean (% MVC)	14 (8)	11 (3)	p = 0.284
	Duration (% MC)	62 (33)	47 (25)	p = 0.185
Medial Gastroc	Peak (% MVC)	20 (10)	17 (8)	p = 0.659
	Mean (% MVC)	11 (3)	12 (4)	p = 0.695
	Duration (% MC)	34 (28)	16(9)	p = 0.052
Tibialis Anterior	Peak (% MVC)	17 (9)	15 (5)	p = 0.535
	Mean (% MVC)	13 (2)	10 (2)	p = 0.018
	Duration (% MC)	25 (14)	15 (5)	p = 0.098

DISCUSSION

Children with physical disabilities often face barriers to participating in school fitness programs, in part due to a lack of accessible exercise equipment that provides an appropriately challenging level of resistance to key muscles. This work highlighted the process used for seeking multiple end-users' input (e.g., clinicians, parents, and children with and without disabilities) to guide technology development. The preliminary set of modifications that emerged from the research and development efforts, as well as preliminary biomechanical data confirm the capacity to customize muscle demands across training conditions.

Pediatric clinicians and special education teachers often seek technology to use with a wide range of children to facilitate inclusion and also modulate expenses. Motor-assisted ellipticals offer a wide range of therapeutically challenging modes. *Active Assist* addresses the needs of children with greater weakness and endurance challenges. As physiologic capacity increases, children could transition to *Active Assist Plus*, and then traditional *resisted* modes. While beyond this study's scope, research with adults using the motor-assisted elliptical indicates faster speeds and reduced levels of body weight support also increase demand (Burnfield, 2014).

Although not statistically significant, children with disabilities registered greater muscle activation during *Active Assist* training than non-disabled counterparts for 11 of 12 comparisons. The most notable increase in activity related to the duration, with those in the disability group demonstrating a 32% to 200% increase in duration across muscles. During *Active Assist* training, peak muscle activity was 31% to 230% higher for those in the disability group. These data reinforce the expected differences in strength between the groups, and the need for technology that can adjust to the needs of each child so function and cardiovascular training goals are achieved.

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