THE NEED TO CONTROL SPEED; A NOVEL APPROACH TO EXOSKELETON – ENABLED WALKING

PVA Summit 2018
August 30
Dallas, Texas

Clare Hartigan, PT, MPT
M. Taylor Jones, MS, NSCA-CSCS
DISCLOSURES

Presenters have the following interest to disclose:

• Parker Hannifin, manufacturer of the exoskeleton used in this study, sponsored the IRB approved research.

• Presenters have no financial interest to disclose.

This continuing education activity is managed and accredited by Professional Education Services Group in cooperation with Paralyzed Veterans of America. PESG, PVS, and all accrediting organization do not support or endorse any product or service mentioned in this activity.
LEARNING OUTCOMES

At the conclusion of this activity, the participant will be able to:

1. Recognize the importance of speed and being able to control one’s speed when using an exoskeleton.
2. Explain a newly proposed walking outcome measure, a 40 Meter Walk Test.
3. Describe speed controllability factors which influence exoskeleton walking.
4. Know how to locate the VA Memorandum regarding Exoskeletons.
EXOSKELETONS: PERSONAL USE

• FDA has approved two exoskeleton devices for Personal Use
  • ReWalk™ for T7 SCI and lower
  • Indego® for T3 SCI and lower

• FDA Stipulations for Personal Use
  • Personal Use Teams (User and identified Companion) must successfully complete the respective company approved Personal Use Training Program (approximately 40 hrs of training).
  • The trained Companion must be with the User at all times.
VA MEMORANDUM: JUNE 07, 2018

From: Deputy Under Secretary for Health Operations Management

Subject: Revised Clinical Protocol for Issuance of Powered Exoskeleton Device to Veterans with SCI

What Does This Mean?

• VA has provided a protocol for veterans with SCI, who qualify to use an exoskeleton of their choice for home use (ReWalk T7 and lower, Indego T3 and lower).

• Veterans may receive training at either a VA site or a Civilian site – with prior approval as some VA sites may or may not have the device the veteran has chosen on which to train.

• Must also train support person/companion as required by FDA

Go To http://vaww.sci.va.gov for all details
OBJECTIVES OF THIS STUDY

To present an exoskeleton control method that enables functional community walking speeds and improved speed control; thus being able to speed up or slow down at the User’s discretion without having to stop and change device settings.

To introduce a newly developed clinical assessment tool to quantify maximum walking speed, speed range, and speed control.
WHY IS CONTROL OF WALKING SPEED IMPORTANT WHEN USING AN EXOSKELETON?

• Personal Use:
  • Provides option to speed up or slow down as able bodied persons do - **without having to stop and change parameter settings** on a software mechanism.
  • Achieve speeds compatible with functional community ambulation for personal users.

• Clinical Setting:
  • Enhance gait re-training in a clinical environment where challenges can be optimized in terms of dosage/steps in a single session.
EXOSKELETON USED FOR THIS STUDY

Indego® Personal (26 lbs or 12 kg)
- SCI T3 and lower for personal use
- Support person is required
- 5 components (Sm /Med / Large)
- Don/ doff / fits in most wheelchairs
LITERATURE: WALKING SPEED POST SCI\textsuperscript{1-4}

- Indoor walking = 0.2 m/s (0.45 mph)
- Outdoor/limited community walking = 0.2 m/s - 0.4 m/s (0.89 mph)
- Outdoor community = 0.4 m/s – 0.8 m/s (1.79 mph)
- To cross a 2 way street 0.6 m/s (1.34 mph)

* Normal walking speed able bodied adults = 1.0 to 1.6 m/s (2.24 to 3.58 mph)


WHAT DO WALKING SPEEDS LOOK LIKE?

C4 AIS C with LEMS 1/50
Walking ~ 0.2 m/s

T7 AIS A with LEMS 0/50
Walking ~ 0.2 m/s
WHAT DO WALKING SPEEDS LOOK LIKE?

L1 AIS C with LEMS 12/50

Walking ~ 0.6 m/s
DESIGN

- New software controller developed to safely improve rate and control of walking speed
  - Controller was named “Advanced Gait” (AG)
- 5 persons with motor complete T7 – T11 SCI
  - Experienced walkers with “standard gait” control settings
  - Consented and enrolled in IRB approved protocol.
- New Outcome Measure
  - 40 Meter Walk Test
  - User’s asked to increase walking speed at 5 meter increments to demonstrate ability to gradually increase speed based on postural control (not having to stop) to transition from “Standard Gait into/out of Advanced Gait”
WHAT EXACTLY IS ADVANCED GAIT?
Software suite option which allows Users to walk with a more continuous stepping motion.

A posture based “lean forward walk forward” approach to trigger steps remains, but the pause between steps as in Standard Gait is eliminated.

WHO QUALIFIES TO USE ADVANCED GAIT?
Persons who have mastered walking in Standard Gait and want to achieve faster walking speeds.
STANDARD GAIT

ADVANCED GAIT
GRAPHICAL COMPARISON OF ADVANCED GAIT AND STANDARD GAIT TRAJECTORIES AT THE A) HIP JOINT AND B) KNEE JOINT.
METHODS

• Subjects each received approximately 3 sessions to learn how to transition from Standard Gait to Advanced Gait and vice-versa.
• Subjects were asked to walk along a 40 Meter Track with markers placed every 5 Meters.
  • 40 Meter Walk Test was repeated 3 times with verbal cues to start…
  • “Begin walking at a very slow speed and then increase walking speed gradually at each marker along the 40 meter track”
  • “Manage your speed such that your fastest speed would take place during the final 5 meter section of the 40 meter track”
• Walking speeds were calculated for each 5 meter section
• FIM score assigned to reflect level of assistance/independence
TRANSITION INTO (A) AND OUT OF (B) ADVANCED GAIT VIA HIP POSITION

A) B)

Upper Leg Angle (Trailing Leg, Terminal Stance)
Advanced Gait Threshold (Generalized)
WIRELESS IPOD APP CONTROLLER
BLUE TOOTH CONNECTION
STANDARD GAIT CONTROLLER

To emulate and enable walking, the Indego employs a finite state controller which cycles through alternating single support and double support states in response to the user’s input (i.e. volitional changes in CoP). As entered from the standing state, these cyclic walking states are as follows: right step (single support), right forward (double support), left step (single support), and left forward (double support). In single support states, one leg is in swing while the other is in stance, with the stance foot on the ground. In double support states both feet are on the ground.

Typically, at lower speeds, the user triggers subsequent steps by leaning forward during double support, while the device is at rest.
ESTABLISH STANDARD GAIT FIRST

Step Transition
- Forward Lean Threshold
- Dynamic Gait

Step Settings
- Speed
- Length
- Height

Stand Transition
- Delay

---

Shepherd Center
STANDARD GAIT VIDEO

T12 AIS A

Forward Lean: Med Low
Dynamic Gait: Low
Step Speed: Med
Step Length: Med
Step Height: Low
Stand Transition: Med
ADVANCED GAIT CONTROLLER

The AG controller presented herein alters how steps are triggered and executed based on step frequency to enable continuous joint motion. That is, the user must intentionally restrain forward progression of CoP prior to stepping, when the device is in motion, to arrest subsequent steps. Essentially, as step frequency increases, the control paradigm shifts from the assumption that the user wants to rest after each step (until prompted to move), to the assumption that the user wants to move after every step (until prompted to rest). By determining user intent during the previous step, as opposed to between steps, continuous joint motion is made possible.
THEN ESTABLISH ADVANCED GAIT SETTINGS

- Swing to Stance
  - Early Hip Extension
- Stance to Swing
  - Early Knee Flexion
- Step Speed
  - Boost Level
    - Boost Onset
    - Off, Low, High, Gradual, Immediate
AG: EARLY HIP EXTENSION

- Early Hip Extension Threshold: 100
  - Enable: On

- Early Knee Flexion Threshold: 50
  - Enable: On

- Step Speed
  - Boost Level: High
  - Boost Onset: Gradual
AG: EARLY KNEE FLEXION

- Swing to Stance
- Early Hip Extension Threshold
- Enable
- Stance to Swing
- Early Knee Flexion Threshold
- Enable
- Step Speed
- Boost Level
  - Off
  - Low
  - High
- Boost Onset
  - Gradual
  - Immediate
AG: BOOST LEVELS

Boost Level: Swing Speed
- Low = ½ swing speed increase
- High = full swing speed increase

Boost Onset: Timing of the Boost Level
- Gradual = after 2 steps of AG
- Immediate = first AG step
ADVANCED GAIT VIDEO       L1 AIS C 15/50 LEMS

Early Hip Extension: 30
Early Knee Flexion: 50
Boost Speed: High
Boost Onset: Immediate

Walking speed ~ 0.82 m/s
PUTTING IT ALL TOGETHER: SG → AG → SG

T10 AIS A with LEMS 0/50

SG to AG at Picture Frames

AG to SG in preparation to stop
PUTTING IT ALL TOGETHER: FOREARM CRUTCHES
TRANSITION FROM STANDARD TO ADVANCED GAIT

T7 AIS B with 0/50 LEMS

MAS 2 for BLEs
MEASURES

Did not use 10 MWT

Though standard assessment tools such as the 10MWT exist and are widely used to measure straight-line walking speeds (i.e. self-selected or fast), no test or metric has been developed to evaluate speed range or control.

Propose NEW measure 40 MWT A new assessment tool is proposed here which has been developed to quantify speed control by capturing the range of speeds which a user can command (from minimum to maximum) and producing a controllability metric to indicate how well that range of speeds was controlled. The authors have named this test the Forty-Meter-Walk-Test (40MWT), and the accompanying controllability metric, the Speed Control Factor (SCF).

The 40MWT results in 8 raw data points: time (in seconds) corresponding to each of the eight 5-meter walking segments from the 40 meter walkway. The data is processed by dividing the distance of each segment (i.e. 5 m) by the associated walking time to obtain walking speeds (m/s) from each segment.
SPEED CONTROLLABILITY FACTOR (SCF)

To obtain the Speed Control Factor, the eight data points are plotted graphically with distance (m) on the independent axis and speed (m/s) on the dependent axis. A linear best-fit line is then generated for the data and the $R^2$ value for quality of the fit is recorded. The Speed Control Factor is then calculated by:

$$SCF = SR \times R^2$$

where $SR$ is the speed range, calculated by subtracting the minimum recorded speed from the maximum recorded speed. The importance of the $R^2$ factor in the calculation is that it provides an objective measure of the user’s ability to modulate gait speeds over the recorded distances. A perfect linear fit results in an $R^2$ value of 1, and would indicate that a user was able to control speed increases in a perfectly linear fashion across the 40-meter walk. Any nonlinear deviation results in an $R^2$ value of less than 1 and thus reduces the SCF. In this manner the SCF considers not only the total range of speeds the user demonstrates, but also the ability of the user to incrementally control speed over that range.
TESTING PROCEDURE

Testing was performed at Shepherd Center in Atlanta, GA under Institutional Review Board approval and the supervision of one or more trained clinicians.

Once selected, gait settings were held constant as each subject performed three 40MWTs and data was collected.

FIM (Functional Independence Measure) gait score associated with each 5-meter walking portion of each test. To capture the qualitative level of effort required of the subjects during the tests, each subject was asked to assign a rating of perceived exertion (using the Borg Rating of Perceived Exertion scale) for the eight segments of the 40MWT.
## RESULTS

Subject Demographic Data

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>SCI Level</th>
<th>ASIA Score</th>
<th>Age (years)</th>
<th>Years Since Injury</th>
<th>Height (cm)</th>
<th>Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>T11</td>
<td>A</td>
<td>34</td>
<td>4</td>
<td>180</td>
<td>66</td>
</tr>
<tr>
<td>2</td>
<td>T10</td>
<td>A</td>
<td>47</td>
<td>15</td>
<td>185</td>
<td>78</td>
</tr>
<tr>
<td>3</td>
<td>T7</td>
<td>A</td>
<td>20</td>
<td>4</td>
<td>178</td>
<td>55</td>
</tr>
<tr>
<td>4</td>
<td>T7</td>
<td>A</td>
<td>31</td>
<td>7</td>
<td>180</td>
<td>66</td>
</tr>
<tr>
<td>5</td>
<td>T7</td>
<td>B</td>
<td>23</td>
<td>6</td>
<td>175</td>
<td>61</td>
</tr>
</tbody>
</table>
40 MWT Speeds, All Subjects, All Trials

\[ y = 0.0117x + 0.1157 \]

\[ R^2 = 0.9604 \]
# BEST TRIAL SUMMARY DATA

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>SCI/AIS</th>
<th>Speed (Min)</th>
<th>Speed (Max)</th>
<th>SR</th>
<th>R²</th>
<th>SCF</th>
<th>Borg (Low/High)</th>
<th>FIM</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>T11/A</td>
<td>0.24</td>
<td>0.78</td>
<td>0.55</td>
<td>0.94</td>
<td>0.52</td>
<td>9/12</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>T10/A</td>
<td>0.13</td>
<td>0.57</td>
<td>0.44</td>
<td>0.91</td>
<td>0.40</td>
<td>7/9</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>T7/A</td>
<td>0.16</td>
<td>0.68</td>
<td>0.52</td>
<td>0.95</td>
<td>0.50</td>
<td>8/11</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>T7/A</td>
<td>0.19</td>
<td>0.52</td>
<td>0.33</td>
<td>0.94</td>
<td>0.31</td>
<td>10/14*</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>T7/B</td>
<td>0.21</td>
<td>0.67</td>
<td>0.46</td>
<td>0.91</td>
<td>0.42</td>
<td>8/11</td>
<td>4</td>
</tr>
</tbody>
</table>
40MWT Speeds, All Subjects, Best* Trials

*As determined by (SCF = SR x R²)

Filled markers indicate blended steps
OUTCOMES DISCUSSION

• All 5 subjects achieved speeds above the limited community threshold (0.40 m/s)

• 3 of 5 subjects achieved speeds within a standard deviation of the average speed associated with full community ambulation (0.62 m/s).

• Almost all speeds attained above the most-limited community threshold were associated with blended steps, and were therefore enabled by features specific to the control method presented herein.
OUTCOMES

Indego Gait Speeds

- Community
- Limited Community
- Household

STANDARD GAIT

ADVANCED GAIT
CONCLUSIONS

Researchers have described the importance of increased walking speed and speed control in the context of exoskeleton enabled gait.

A novel exoskeleton control method that features continuous joint motion was developed and implemented for research using a commercially-available exoskeleton system.

To evaluate this, and other future control methods, a new clinical assessment tool was proposed—the 40MWT. As such, no other speed controllability data can be compared to the current controller using 40 MWT outcomes.

Subjects had limited training sessions and still achieved higher walking speeds than is currently seen in the literature. With continued training, walking speeds would be expected to be in excess of 1.0 m/s conducive to community ambulation.
REFERENCES


