Exoskeletal-Assisted Walking in MS: Can this Technology be Integrated into the Rehabilitation Setting?

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Disclosures

1. The authors have no past or current affiliation with ReWalk Robotics
2. ReWalk Robotics has invited Dr. Kozlowski to sit on an advisory board; this request is under review of the ISMMS Conflict of Interest Officer.
3. The study was approved by the Icahn School of Medicine at Mount Sinai Clinical Institutional Review Board.
4. All participants provided signed informed consent.
Acknowledgements

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2. Co-investigators:
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   Nesanet Mitiku, MD, PhD
   Michelle Fabian, MD
   Department of Rehabilitation Medicine
   Dipan Lad, BEng.

Outline

1. Background
   1. Rationale for exoskeleton use by persons with multiple sclerosis (MS)
   2. Exercise and MS
   3. Body-weight supported treadmill walking and MS
   4. Mobility and MS

2. Pilot study – Safety and feasibility of ReWalk™ with MS.
   1. Objectives
   2. Methods
   3. Outcomes
   4. Early results

3. Future of exoskeletons in rehabilitation (Discussion)
   1. Clinical intervention
   2. Fitness and wellness
   3. Community mobility
Background – Overview of SCI experience

- Powered exoskeletons provide persons with spinal cord injury (SCI) with opportunity to walk.
- Two devices currently available for clinical use: ReWalk™ and Ekso™
- Indego® clinical trials for FDA approval under way
- Evidence for feasibility and safety for persons with paraplegia:

<table>
<thead>
<tr>
<th>Device (Author Year)</th>
<th>N</th>
<th>SCI &amp; Study Characteristics</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ReWalk (Zeilig 2012)</td>
<td>6</td>
<td>T1-L1, AIS A-B 13-14 sessions</td>
<td>Walk 100 m; no adverse events</td>
</tr>
<tr>
<td>ReWalk (Esquenazi 2012)</td>
<td>12</td>
<td>T3-T12, AIS A-B 13-25 sessions</td>
<td>Walk 50-100 m in 5-10 min (0.03 – 0.45 m/s); some reported improved pain, spasticity, bowel &amp; bladder function</td>
</tr>
<tr>
<td>ReWalk (Spungen 2013)</td>
<td>7</td>
<td>T1-T11, AIS A-B 15-70 sessions</td>
<td>Walk (0.14-0.50 m/s); RPE 15±2 (1-5 sessions), 8±1 (&gt;40 sessions. Stairs (n=4) mod assist. Mild skin abrasions with early sessions.</td>
</tr>
<tr>
<td>Ekso (Kolakowsky-Hayner 2015)</td>
<td>8</td>
<td>T4-T11, AIS A 6 weekly sessions</td>
<td>Walk 28-60 min (0.14-0.42m/s). Minor skin redness anterior tibia, greater trochanter</td>
</tr>
</tbody>
</table>

Background – SCI trajectories

Patterns of recovery

- Individual variability
- Pattern of rapid recovery to plateau in +/- one year
Background – SCI trajectories

Patterns of recovery

- Varies in magnitude and rate
- Similar regardless of
  - Neurological level
  - SCI completeness

Background – MS trajectories

Recent reclassification

- Clinically Isolated Syndrome
- Relapsing-Remitting
  - Active
  - Not Active
- Secondary Progressive
- Primary Progressive
  - Active with progression
  - Active without progression
  - Not Active with progression
  - Not active without progression (stable)
- Radiologically Isolated Syndrome
  - Potential for earlier Dx
Background – MS trajectories

New perspectives in the natural history of multiple sclerosis

Helene Tremlett, PhD, Yexian Zhao, PhD, Peter Reckmann, MD and Michael Hatchiassen, MD

Variations in natural history for MS
- Relapsing-Remitting: 20-year disease course
- Secondary Progressive: onset Dx/EDSS variable – difficult to characterize
- Primary Progressive: onset to EDSS 6 – 6 to 21 years (and slowing?)

Wide variation in trajectories of progression within types

Background – Rationale for persons with MS

Mobility: wheelchair alternative?

Fitness/wellness: slow disability regardless of MS progression?
- Physical: weight gain, cardiovascular disease, diabetes
- Psychological: depression, fatigue
- Social wellbeing

Clinical Intervention
- Disease modification?
- Mechanism?

Time line
- Potential value increases with progression of disability due to MS
- Easier to learn to use with lower EDSS
- Capability to safely use exoskeleton may decline with higher EDSS
Background – Rationale for persons with MS

Clinical Evidence

Multiple sclerosis

Search date June 2008
Richard Nicholas and Jeremy Chataway

- Don’t know whether exercise reduces fatigue.
- Exercise may help to maintain
  - Strength
  - Fitness
  - Mobility
- Exercise may improve quality of life
- BUT study comparisons were difficult to make

Background – Rationale for persons with MS

Impact of Walking Impairment in Multiple Sclerosis
Perspectives of Patients and Care Partners
Nicholas G. LaRoca
National Multiple Sclerosis Society, New York, NY, USA

- 41% of people with MS reported difficulty with walking
- 13% unable to walk at least twice per week
- 70% report as the most challenging aspect of MS
- 74% report walking difficulty disrupted their daily lives
Background – Rationale for persons with MS

Physical fitness, walking performance, and gait in multiple sclerosis
Ryan M. Sandroff, Jacob J. Sosneff, Robert W. Motl

- Physiological deconditioning may contribute to walking impairments in MS
- Aerobic capacity and balance were associated with walking performance on 25 Foot Walk Test (25FWT) and 6 Minute Walk Test (6MWT)
- Multimodal exercise training interventions might improving mobility outcomes

Background – Rationale for persons with MS

Effects of Exercise Training on Fitness, Mobility, Fatigue, and Health-Related Quality of Life Among Adults With Multiple Sclerosis: A Systematic Review to Inform Guideline Development
Amy E. Latimer-Cheung, PhD; Lara A. Pluijtt, PhD; Audrey L. Hicks, PhD; Kathleen A. Martin Girls, PhD; Alyssa M. Fenuta, HBSc; K. Ann MacKibbon, PhD; Robert W. Motl, PhD

- Systematic review of 54 studies
- Strong evidence that moderate-intensity exercise twice per week increases aerobic capacity and muscular strength for persons with mild to moderate disability
- Exercise may improve mobility, fatigue, and health-related quality of life
Background – BWSTT and MS

Exercise benefits have been established for ambulatory MS patients with a relapsing-remitting disease course.
Investigated the exercise benefits for patients with progressive MS and greater impairment.
24 weeks of Body-weight supported treadmill training (BWSTT)
12 weeks of total-body recumbent stepper training
Both training modalities improved fatigue and quality of life outcomes but neither improved physical function.
Benefits of long-term BWSTT were not maintained when exercise was discontinued.

Background – BWSTT and MS

Compared effectiveness of robot-assisted BWSTT with conventional walking on gait, functional independence, and quality of life in 15 and 17 MS patients, respectively.
Some gait parameters, FIM scores, and EDSS scores improved following the treatment with no difference between the groups.
At 6 months, most gait and functional parameters had returned to baseline.
Questions

- Can exoskeletons facilitate accessibility to walking
  - For persons with greater disability?
  - For community settings?
  - In dosages that are manageable to people with
    - Moderate disability (too easy?)
    - More severe disability (too hard?)
  - For clinical applications?

Pilot Study - Objectives

- **Aim 1**: To determine the feasibility of a powered exoskeleton walking program (EWP) for persons with MS. Sub-aims are
  - accessibility
  - safety
  - tolerability of dosing parameters
  - patient acceptability
  - learnability

- **Aim 2**: To generate pilot data on secondary benefits of a powered exoskeleton exercise program on walking ability, and symptom management. Sub-aims are
  - Walking ability
  - Secondary benefits: spasticity, pain, sleep, depression and fatigue
Pilot Study - Design

- Prospective preliminary study
  - 8-week baseline
    - Weekly patient-reported outcomes
    - Timed walk and spasticity tests at 0, 4, and 8 weeks
  - 8-week walking phase
    - 3 sessions per week
    - 30 to 120 minutes per session
    - Weekly patient-reported outcomes phase
    - Timed walk and spasticity tests at 12, and 16 weeks
  - 4-week follow-up phase
    - Weekly patient-reported outcomes
    - Timed walk and spasticity tests at week 20

Pilot Study: Outcomes - Aim 1

- Accessibility:
  - Eligibility and enrollment (count/%)
  - Attendance: late/missed sessions, study drop out (count/%)

- Safety: adverse events
  - count/type

- Tolerability of dosing:
  - Session frequency and duration
  - Session intensity (BP, HR, RPE)
  - Energy expenditure in last week

- Acceptability
  - QUEST 2.0 (Quebec User Evaluation of Assistive Technology)
  - Weekly during walking phase
  - Attendance: late or missed sessions, and study drop out

- Learnability (in ReWalk)
  - Level of assistance for stand/sit and walking
  - 6MWT distance
  - 10MWT
  - Timed Up and Go test
Pilot Study: Outcomes - Aim 2 Walking ability

- 6 Minute Walk Test (6MWT)
- 25 Foot Walk Test (25FWT)
- Scored as ‘0’ if not able to perform

- Baseline Phase: mean of three trials at Weeks 0, 4, and 8
- Walking Phase: Weeks 12 and 16
  - Change and trend from baseline
  - Energy expenditure in Week 16
    - 2 trials of 6MWT
    - Mean VO₂ relative to resting VO₂

- Follow-up at Week 20

Pilot Study: Outcomes - Aim 2 Secondary Benefits

- Spasticity:
  - Modified Ashworth Scale (MAS) by physical therapist
  - Baseline Phase mean of Weeks 0, 4, 8
  - Walking Phase at Weeks 12, 16,
  - Follow-up Phase at Week 20

- Pain
  - Numeric Rating Scale (NRS) for up to three pre-existing pain locations
  - Baseline Phase weekly by NIH Assessment Center
  - Walking Phase before and after each session
  - Follow-up Phase weekly by NIH Assessment Center
  - New pains will be documented as adverse events)
Pilot Study: Outcomes - Aim 2 Secondary Benefits

Patient-Reported Outcomes via NIH Assessment Center
- Sleep disturbance (PROMIS 10-item short form)
- Depression (Neuro-QoL 8-item short form)
- Positive affect and well-being (Neuro-QoL 8-item short form)
- Fatigue
  - Neuro-QOL 8-item short form
  - Neurologic Fatigue Index for MS (NFIMS)
- Baseline Phase mean (SD) of weekly assessments Weeks 0 through 8
- Walking Phase change and trend for weekly assessments Weeks 9 through 16
- Follow-up Phase change and trend for weekly assessments Weeks 17 through 20

Study Methods: Eligibility - Inclusion

- Definitive MS diagnosis
  - relapsing-remitting
  - primary progressive
  - secondary progressive
- EDSS score 5.0 to 7.5
- Age 18 - 65
- Height 1.57 m – 1.88m
- Weight <100 kg
- Tolerate standing 30 minutes
- No weight-bearing limitations
- No medical contraindications
Study Methods: Eligibility - Exclusion

- Walking limitations attributable to another condition age, or both
- Joint contractures
  - Hip 5° extension
  - Knee 5° extension flexion
  - Ankle: neutral dorsiflexion
- Uncontrolled cardiovascular conditions (e.g., heart failure, angina, hypertension)
- Severe spasticity: Modified Ashworth Scale 4
- Osteoporosis or other risk of bone fracture from weight bearing
- Body segment length
  - Hip width >42 cm
  - Thigh >61.5 cm
  - Leg >63.5
- Pregnancy
- Limb length discrepancy
  - Thigh >1.3 cm
  - Leg >1.9 cm
- Competing inflammatory or autoimmune diagnosis
- Alternate neurologic diagnosis
- Uncontrolled cardiovascular conditions (e.g., heart failure, angina, hypertension)
- Osteoporosis or other risk of bone fracture from weight bearing
- Pregnancy
- Competing inflammatory or autoimmune diagnosis
- Alternate neurologic diagnosis
- Uncontrolled cardiovascular conditions (e.g., heart failure, angina, hypertension)
- Osteoporosis or other risk of bone fracture from weight bearing
- Pregnancy
- Competing inflammatory or autoimmune diagnosis
- Alternate neurologic diagnosis

Participant Characteristics

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Age (years)</th>
<th>EDSS score</th>
<th>Height (m)</th>
<th>Weight (kg)</th>
<th>BMI (kg/m²)</th>
</tr>
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<tr>
<td>1</td>
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<td>Median</td>
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</tbody>
</table>

Age = age at enrollment; EDSS = Expanded Disability Status Scale score; m = meters; kg = kilograms; BMI = body mass index
Outcomes: Accessibility - Enrollment (target n=12)

- **Enrolled**
  - N=10

- **Screen failed**
  - N=0
  - Medical conditions (n=0)
  - Body segment requirements (n=0)
  - Joint range of motion (n=0)
  - Spasticity (n=0)
  - Other (n=)

- **Screen passed**
  - N=7

- **Incomplete Data**
  - N=0
  - Withdrawal (n=0)
  - Other reasons (n=0)

- **Complete Data**
  - N=0

Note: study is in progress. Preliminary results are presented up to May 22, 2015

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Outcomes: Accessibility - Attendance

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Sessions</th>
<th>Sessions Missed</th>
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<tr>
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<td>Attended</td>
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<td>9</td>
<td>8</td>
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<td>3</td>
<td>In baseline</td>
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<td>In baseline</td>
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<tr>
<td>5</td>
<td>In baseline</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>In baseline</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>In baseline</td>
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</tbody>
</table>
Outcomes: Safety

- Serious Adverse Events: none to date
- Minor Adverse Events: none to date

Outcomes: Tolerability - Dosing

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Sessions</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Weeks</td>
<td>Frequency</td>
<td>Duration (mean/SD)</td>
<td>Duration (min/max)</td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>3</td>
<td>80</td>
<td>60 – 90</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>2.5</td>
<td>70</td>
<td>60 – 90</td>
</tr>
</tbody>
</table>
### Outcomes: Tolerability - Best Efforts

<table>
<thead>
<tr>
<th>ID</th>
<th>Sessions (n)</th>
<th>Longest Walk</th>
<th>6MWT</th>
<th>25FWT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Time (min)</td>
<td>Distance (m)</td>
<td>Steps</td>
</tr>
<tr>
<td>1</td>
<td>8</td>
<td>90</td>
<td>136.4</td>
<td>311</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>90</td>
<td>121.2</td>
<td>275</td>
</tr>
</tbody>
</table>

6MWT = 6 Minute Walk test; m = meters; m/s = meters per second

### Outcomes: Tolerability - Intensity

<table>
<thead>
<tr>
<th>ID</th>
<th>Sn</th>
<th>Heart Rate</th>
<th>Blood Pressure</th>
<th>Borg RPE</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Pre</td>
<td>Mid</td>
<td>Post</td>
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</tbody>
</table>

Sn = Session number
RPE = rating of perceived exertion
## Outcomes: Learnability – Level of Assistance

<table>
<thead>
<tr>
<th>ID</th>
<th>Sn</th>
<th>Stand</th>
<th>Walk</th>
<th>Sit</th>
<th>6MWT</th>
<th>TUG</th>
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<tbody>
<tr>
<td>1</td>
<td>8</td>
<td>Mod</td>
<td>Mod</td>
<td>Mod</td>
<td>Mod</td>
<td>NT</td>
</tr>
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<td>5</td>
<td>Mod</td>
<td>Min</td>
<td>Mod</td>
<td>Min</td>
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</tbody>
</table>

Sn = Session number; 6MWT = Six Minute Walk Test; TUG = Timed Up and Go
Levels of Assistance: C.S. = Close Supervision; G.C. = Contact Guard; Min = Minimal; Mod = Moderate; Max = Maximal

## Outcomes: Walking ability

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>6MWT (m)</th>
<th>25FWT (m/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (mean/SD)</td>
<td>Walking (mean/SD)</td>
</tr>
<tr>
<td>1</td>
<td>36.5 (4.5)</td>
<td>0.08 (0.02)</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
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<tr>
<td>3</td>
<td>60.0 (9.9)</td>
<td>0.21 (0.04)</td>
</tr>
<tr>
<td>4</td>
<td>10.9</td>
<td>0.15</td>
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<td>5</td>
<td>68.5</td>
<td>0.22</td>
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<tr>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>36.1</td>
<td>0.19</td>
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</table>

6MWT = Six Minute Walk Test; 25FWT = 25 Foot Walk Test
### Outcomes: Secondary Benefits

#### Spasticity (MAS) & Pain (NRS)

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Spasticity (Baseline mean/SD)</th>
<th>Spasticity (Walking mean/SD)</th>
<th>Pain (Baseline mean/SD)</th>
<th>Pain (Walking mean/SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>-</td>
<td>3.3 (2.4)</td>
<td>NR</td>
</tr>
<tr>
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<td>-</td>
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<td>1.1 (0.4)</td>
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</table>

MAS = Modified Ashworth Scale; NRS = Numeric Rating Scale

#### Sleep Quality (PROMIS) & Depression (Neuro-QoL)

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Sleep Quality (Baseline mean/SD)</th>
<th>Sleep Quality (Walking mean/SD)</th>
<th>Depression (Baseline mean/SD)</th>
<th>Depression (Walking mean/SD)</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>46.4 (3.0)</td>
<td>46.0 (0.8)</td>
<td>50.4 (2.6)</td>
<td>45.1 (3.0)</td>
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<td>2</td>
<td>39.2 (3.4)</td>
<td>37.8 (2.4)</td>
<td>40.0 (3.5)</td>
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<tr>
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<td>38.8 (3.8)</td>
<td>40.0 (3.5)</td>
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<tr>
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<td>52.2 (2.1)</td>
<td>50.2 (2.1)</td>
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<td>36.9 (0.0)</td>
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<td>7</td>
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</table>

PROMIS = Patient Reported Outcomes Measurement and Information System; Neuro-QoL = Neurological Quality of Life (T-score mean=50, SD=10)
### Outcomes: Secondary Benefits

#### Positive Affect and Well-Being (Neuro-QoL)

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Baseline (mean/SD)</th>
<th>Walking (mean/SD)</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>43.9 (4.8)</td>
<td>51.1 (1.3)</td>
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<td>65.7 (3.2)</td>
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<td>56.1 (4.3)</td>
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<td>68.0</td>
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</tr>
</tbody>
</table>

Neuro-QoL = Neurological Quality of Life (T-score mean=50, SD=10)

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#### Fatigue (NFIMS) and (Neuro-QoL)

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Fatigue (NFIMS)</th>
<th>Fatigue (Neuro-QoL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (mean/SD)</td>
<td>Walking (mean/SD)</td>
</tr>
<tr>
<td>1</td>
<td>-</td>
<td>50.6 (4.3)</td>
</tr>
<tr>
<td>2</td>
<td>-</td>
<td>45.3 (5.1)</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>31.8 (2.6)</td>
</tr>
<tr>
<td>4</td>
<td>-</td>
<td>45.2 (2.1)</td>
</tr>
<tr>
<td>5</td>
<td>-</td>
<td>51.3 (0.1)</td>
</tr>
<tr>
<td>6</td>
<td>-</td>
<td>36.6</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NFIMS = Neurologic Fatigue Index for MS (Raw score 0-30)
Neuro-QoL = Neurological Quality of Life (T-score mean=50, SD=10)
Future of Exoskeletons in Rehabilitation: Assisted walking for small sample of persons with MS

- **Accessibility:**
  - n=2
  - Age: 30-45
  - EDSS scores: 6-7

- **Learnability:** walk 121-136 m, moderate to minimal assistance, 5-8 sessions

- **Tolerability:** Borg RPE range from 10-16/20

- **Potential for exercise effects:** not yet walking for endurance
  - BP response
  - HR
  - RPE

- **Secondary benefits:** Reports for
  - Pain, spasticity, posture, sleep, fatigue
  - Psychosocial aspect: ability to walk
Future of Exoskeletons in Rehabilitation

- Accessibility: Are different devices suited to different levels of mobility disability?
  - ReWalk for lower EDSS?
  - Ekso for higher EDSS?

- Mobility: Will the technology evolve to function as a replacement for wheelchairs or scooters?

- Potential for exercise effects: Can the technology provide titrated dosage to match the frequency, intensity, and duration parameters to individual levels of ability for endurance exercise?

- Potential for secondary benefits: Will device users experience improvements to MS symptoms including pain, spasticity, sleep disturbance, and fatigue?

- Modification of MS progression: If exercise can influence systemic changes to the central nervous system, will exoskeletons facilitate such changes?

Questions and Discussion