Robotic Exoskeletons for Mobility after Spinal Cord Injury

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Today’s Objectives

1. Review clinical and social impact of spinal cord injuries.
2. Outline of the history of mobility technologies for Spinal cord injuries
3. Defining the technical and functional design goals and current exoskeletons available for medical applications
4. Outline the current research evidence and the clinical applications of this emerging industry

The Problem...

Wheelchair confinement can cause severe physical and psychological deterioration, resulting in bad health, poor quality of life, low self-esteem and significant medical expenses

Secondary medical consequences of paralysis:
- Difficulty with bowel and bladder function
- Osteoporosis
- Loss of lean mass / gain in fat mass
- Insulin resistance
- Diabetes
- Heart disease

Increased healthcare costs due to paraplegia-related complications

Increased need for in-home personal devices

87% of spinal cord injury patients discharged to private, non-institutional residences
U.S. Prevalence of SCI

273,000 people in the U.S. living with SCI
An estimated 218,000 (or ~80%) are candidates for ReWalk.
12,000 new cases of SCI annually
Age at onset: 50% are 16-30

Potential ReWalk Population

Cost
- $510,000 the first year
- $77,000 annually
- 1.5-2.5 million lifetime

Re-Hospitalization
- 30% hospitalized 1 or more times per year
- Average stay ≤ 23 days
- Primary cause: Genitourinary, digestive and skin

Potential ReWalk Candidates 80%
273,000 Individuals with SCI in U.S.

Facts and Figures

The Impact of a Spinal Cord Injury....

“the pathetic [paralyzed] patient lying long in a bed, the urine leaking from his distended bladder, the lime leaking from his bones, the blood clotting in his veins, the flesh rotting from his seat, the scybala stacking up in his colon, the spirit draining from his soul”.... British Medical Journal; ii:967-8, 1947.

Dr. Richard Alan J. Asher, an eminent British Endocrinologist and Hematologist during the 20th Century
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Secondary Medical Consequences of Paralysis

Difficulty with Bowel Evacuation
- Osteoporosis
- Loss of Lean Mass
- Gain in Fat Mass
- Insulin Resistance
- Diabetes
- Heart Disease

Bowel Dysfunction
- Difficulty with evacuation, especially constipation and impaction, is common after spinal cord injury (SCI).
- Bowel care requires regular use of laxatives, enemas, suppositories, and manual digit extraction.
- Bowel care is often time-consuming and labor intensive.
- Smartpill data for total gut transit time:
  - AB (n=10) 1.0±0.7 vs. SCI (n=20) 3.3±2.5 days (P<0.001)

Osteoporosis

- SCI is a non-weight bearing condition
- Bone is lost rapidly with acute SCI; goal is to preserve bone architecture and mass
- Bone continues to be lost years after SCI; goal is to replace bone mass

Normal Bone

Osteoporotic Bone

Total Body Lean Tissue Loss with Duration of Injury in the SCI Twins

Monozygotic Twin Data

<table>
<thead>
<tr>
<th>Duration of Injury (y)</th>
<th>Total Body Lean Tissue Loss (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-1</td>
</tr>
<tr>
<td>5</td>
<td>-4</td>
</tr>
<tr>
<td>10</td>
<td>-7</td>
</tr>
<tr>
<td>15</td>
<td>-10</td>
</tr>
<tr>
<td>20</td>
<td>-13</td>
</tr>
<tr>
<td>25</td>
<td>-16</td>
</tr>
<tr>
<td>30</td>
<td>-19</td>
</tr>
</tbody>
</table>

R = 0.87, slope = -0.782 ± 0.181, p<0.005

Spungen et al., J Appl Physiol 95:2398-2407, 2003

A history of walking efforts for people with SCI

The restoration of walking in persons with paraplegia is physiologically, psychologically, and functionally desirable.
• Locomotor training with partial body weight support (BWS) over a treadmill has been shown to ameliorate some of the secondary medical consequences and show improvement in measures of quality of life.
• Studies that have used BWS treadmill training in motor complete SCI have shown improvements in
  • cardiovascular regulation
  • muscle activation, which increases metabolic demand
  • improvements in subjective well-being
• Yet, most of these benefits were lost once the walking program was discontinued.
Wheelchair Mobility

Types:
- Manual
- Power
- Power Assist
- Standing

Orthotics

PASSIVE

POWERED

Walking Technologies for Persons with Paraplegia

Leg Braces

Knee Ankle Foot Orthosis (KAFO)

Reciprocating Gait Orthosis (RGO)
Orthotics Limitations

KAFOs induce gait deviations:
- Hip hiking
- Vaulting
- Circumduction
- Pelvic retraction
- Change in center of gravity

Clinical Implications:
- Increased metabolic demand
- Falls
- Low Back Pain
- Compliance is often poor

Exoskeleton Development

Exoskeletons for Augmenting Human Abilities
Design Considerations (1/2)

- All day use
- Assimilation of user capabilities into the control
  - Identify & avoid obstacles
  - Select modes
  - Steer the device
  - Control the pace
  - Initiate gait & halt at will
  - Apply judgment in hazardous situations
  - Manual control
  - Interpret feedback & warnings signals
- User controls the device (autonomous device)
- Natural (intuitive) gait trigger & walk
  - natural gait = minimum energy = maximum stability; acceptance; aestheticism
- The Hardship:
  - algorithm complexity: open loop trapezoidal vs. close loop arbitrary pattern; more expensive motor units
Design Considerations (2/2)

- Stability & safety: crutches
- No FES: muscles’ fatigue, practicality, reliability
- User supports his/her own weight
- Device carries its own weight
- Safety

Structure

- Batteries & Controller Pack
- Wireless Remote Control
- Pelvic Support
- Manual Buttons
- Actuation Unit
- Crutches

All Day Use Because it Needs Only “Normal” Energy Requirements (Heart, Calories)

VA Bronx, New York, Interim Data, Medical Benefits Study 2012
What’s the Added Value? (1/2)

- Independent Up-right mobility
  - Walking... sit-to-stand...stairs...slopes...reclining
- User in full control of the device
- Improved Health, Safety & Efficacy
  - Proved by multi-center clinical studies
- Dignity...Self-Esteem...Independence
- Inclusion
- Significantly less fatigue
  - than any other gait-restoration devices or wheelchairs
- Easier getting in/out a car

What’s the Added Value? (2/2)

- All day use
- Natural (intuitive) gait trigger & walk
- Acceptance
  - (enthusiastically received by users)
- User in full control of the device
- Device carries its own weight
- Works in multiple environments

Robotic Exoskeletons
Exoskeleton Regulatory Update

What is the Regulatory status of the ReWalk and Ekso devices in the EU?
Both the ReWalk and Ekso have been classified as class IIa devices by their respective Notified Bodies. This classification is applied to moderate risk devices.

What is the Regulatory status of the ReWalk device in the USA?
ReWalk Rehabilitation and ReWalk Personal are the only exoskeletons that have been cleared by the FDA per the recently issued Powered Exoskeleton regulation 21 CFR 890.3480. This regulation defines these category of devices as class II devices. Class II devices require review by the FDA prior to them being placed on the market in the USA.

Does this apply to devices used in a rehabilitation center?
Yes, the regulation does not define where the devices can be used. It applies to both rehabilitation centers as well for home use.
The ReWalk Solution

ReWalk Personal and ReWalk Rehabilitation designed to fundamentally change the health and life expectancies of users

- Enables walking in multiple environments, as well as ability to sit, stand, turn, and, in some cases, climb and descend stairs.
- Light, wearable exoskeleton designed for all-day use.
- User-initiated walking, powered by patented tilt-sensor technology.
- Supports its own weight; user does not expend unnecessary energy while walking.
- Rechargeable battery power.

Published clinical studies demonstrate ReWalk’s ability to mimic a natural gait and deliver functional walking speed.

Ekso

Ekso Demo
Patient Qualifications

*Indicated for SCI, T4 and below, all ASIA classifications

User Requirements:
- Upper body can support crutch use
- Fair or better upper extremity strength
- Fair or better trunk control
- Between ~5'3" - 6'2" (~160-188 cm) tall
- Weighs 220 lbs (100 kg) or less
- Healthy bone density, no fractures
- Able to tolerate standing and gait program
- Sufficient LE ROM to allow ambulation
- Normal ankle, hip and knee, level I-II contracture

Contraindications:
- Uncontrolled spasticity or clonus
- Infection. Pressure sores or DVT
- Pregnancy and/or lactating females
- Severe concurrent medical conditions
- Psychiatric or cognitive issues

Training Program - Eligibility Screening

Indications:
- Lower extremity paraplegia or paraparesis
- Fair or better upper extremity strength
- Fair or better trunk control
- Between ~5'3" - 6'2" (~160-188 cm) tall
- Weighs 220 lbs (100 kg) or less
- Healthy bone density, no fractures
- Able to tolerate standing and gait program
- Sufficient LE ROM to allow ambulation
- Normal ankle, hip and knee, level I-II contracture

Contraindications:
- Uncontrolled spasticity or clonus
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Training Program - Basic Skills Inventory

ReWalk Basic Skills Inventory

<table>
<thead>
<tr>
<th>Skill</th>
<th>Note</th>
<th>User Score</th>
<th>Companion Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Walk</td>
<td>Note</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic Stand</td>
<td>Note</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic Sit</td>
<td>Note</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic Heel</td>
<td>Note</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic Cuff</td>
<td>Note</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic Wheelchair</td>
<td>Note</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I certify that all skills have been completed successfully by both User and Companion.
<table>
<thead>
<tr>
<th>Safety and Function / Regulatory</th>
<th>Long Term Medical Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multicenter study of 24 patients:</td>
<td>Ongoing single center study of 20 patients:</td>
</tr>
<tr>
<td>• Moss Rehab. (US)</td>
<td>• James J. Peters VA (Bronx, NY)</td>
</tr>
<tr>
<td>• Shabba Medical Center (Israel)</td>
<td>• Primary Outcomes:</td>
</tr>
<tr>
<td>• Villa Baretta (Italy)</td>
<td>○ Measure medical/clinical benefits of vertical loading and walking with exoskeleton technology:</td>
</tr>
<tr>
<td>• Primary Outcomes:</td>
<td>• bowel function,</td>
</tr>
<tr>
<td>• Safety A/E’s</td>
<td>• urinary tract function,</td>
</tr>
<tr>
<td>• Tolerance</td>
<td>• body composition,</td>
</tr>
<tr>
<td>• Ease of use</td>
<td>• metabolism</td>
</tr>
</tbody>
</table>

Further studies: Rancho (Calif.), Stroke (UK), Murneau (Germany)
Exoskeleton Assisted Walking for Persons with Motor-Complete Paraplegia

- 7 Subjects, 45 +/-2 1-2 Hour Sessions
- All 7 learned to perform sit-stand, stand to sit and to walk 50-160mm in 6 minutes (4 accomplished this with no assistance, 3 with varying levels of assistance)
- 4/7 learned to ascend and descend >5 stairs with assistance. Same 4 also achieved some outdoor-specific walking skills
- No study related serious adverse events
- “These preliminary results suggest that exoskeleton-assisted walking and other mobility skills can be performed independently by persons with motor-complete SCI.”

More Experience = Faster, Longer Distances

Multi-Center Trial Outcome Measures

- Safety
- User satisfaction survey
- 6 minute walk w/o assistance
- 10 meter walk w/o assistance
- Sit to stand and stand to sit abilities
- Instrumented gait analysis
- Adverse effects
- Subject satisfaction
- Equipment performance
Multi-Center Trial Adverse Effects

- Superficial skin abrasions - 4 subjects, padding solved
- One subject had orthostatic hypotension improved by elastic stockings and abdominal binder
- Two subjects had lower limb edema controlled with knee height elastic stockings
- No falls or fractures
- No equipment failures

Conclusions: Excellent & Supports FDA Endpoints

- All the trained persons with complete motor thoracic-level SCI could safely transfer and ambulate short distances independently
- Pain and spasticity were reduced with majority for several hours after ReWalking
- Some patients gained PROM in lower limbs
- Increase physical fitness (based on HR/SBP) and some reduction in body weight occurred - all subjects

Reference: Zeilig, G., Weing...
Ongoing Medical Benefits Study Experience

AAPM&R Presentation of VA Clinical Trial

1. 4 subjects had change in level of injury; 3 in LEMS
2. Increased HR/VO2 consistent at a level sustainable for regular use—potential to improve adverse health conditions
3. Improvements in SF-36 scores
4. Decreased bladder complications
5. Improved bowel function
6. Improved sleep and less fatigue reported
7. 9/9 showed decrease in regional fat tissue mass
8. Significantly improved dynamic seated balance

### Health Benefits

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Changes</th>
<th>Total Bowel Evacuation Time per Bowel Day</th>
<th>Bowel Evacuation (Frequency per week)</th>
<th>Bowel Specific Medication Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>↓ from 90 to 30 min, ↑ from 1-2 to 3-4x/week</td>
<td>↓ from 3 to 4</td>
<td>No reported change in bowel medications</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>↓ from 60 to 30 min, ↑ from 2-3 to 3-4x/week</td>
<td>↓ from 3 to 4</td>
<td>Discontinuation of laxative (Dulcolax)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>↓ from 90 to &lt;30 min, ↑ from 2-3 to 3-4x/week</td>
<td>↓ from 3 to 4</td>
<td>Discontinuation of the use of a stool softener (Colace) and laxative (Senna)</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>↓ from 90 to &lt;30 min, ↑ from 2-3 to 3-4x/week</td>
<td>↓ from 3 to 4</td>
<td>Reduction in use of a stool softener (Colace) and/or a laxative (Senna) from weekly to ≤1x/month</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>↓ from 120 to 45 min</td>
<td>↓ from 3 to 4</td>
<td>Eliminated laxative use and decreased amount of additional dietary fiber supplements</td>
<td></td>
</tr>
</tbody>
</table>

VA Bronx, New York, Interim Data, Medical Benefits Study 2012
Exoskeletons- More Than Walking
Benefits that go beyond mobility

Potential Benefits for the User

- Psychological
  - Confidence
  - Relationships
  - Independence
  - Reengagement
  - ReWalker community

- Social
  - Inclusion
  - Eye to Eye Conversations
  - Access
  - Inspiration
  - Limited Community Walking Speed

- Health Benefits Currently Being Evaluated
  - Natural Gait
  - Vertical Ground Reaction Force
  - Standing
  - Exercise
  - Bowel Function
  - Bone Density
  - Pain Management

Gain, maintain and expand these benefits with use at home

Potential Benefits for the Payer

- Reduction rate of re-hospitalizations
- Lower medication costs
- Decreased prevalence of secondary complications
  - Pressure sores
  - Diabetes
  - Heart Disease
  - Bowel and Bladder
  - Osteoporosis

Gain, maintain and expand these benefits by using at home

A Day in Radi’s (New) Life

The Market of Akko
Exoskeletons in News

Otto Bock

Thank You