Robotic Exoskeletons for Mobility after Spinal Cord Injury

Andrew Dolan
ReWalk

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.

- Difficulty with bowel and urinary tract function
- Osteoporosis
- Loss of lean mass/gain in fat mass
- Diabetes
- Heart disease

87% of spinal cord injury patients discharged to private, non-institutional residences

Increased healthcare costs due to paraplegia-related complications

Increased need for in-home personal device

Facts and Figures

U.S. Prevalence of SCI
273,000 people in the U.S. living with SCI
12,000 new cases of SCI annually
Age at onset: 50% are 16-30

Potential ReWalk Population

Cost
- $50,000 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
Tetraplegia: spinal cord lesion at C8 or above resulting in complete or incomplete paralysis of the arms and legs.

Paraplegia: spinal cord lesion at T1 or below resulting in complete or incomplete paralysis of the legs.

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.

Clinical / Impact SCI

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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

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

- Monozygotic Twin Data
- Intrapair difference for total body lean tissue (kg)
- Difference of an average of 7.8 kg UTM per decade of injury
- R=0.87, slope = -0.782 ±0.181, p<0.005

Spungen et al., J Appl Physiol 95:2398-2407, 2003
Diabetes and Insulin Resistance

A history of walking efforts for people with SCI

The restoration of walking in persons with paraplegia is physiologically, psychologically, and functionally desirable.

Rehab Devices

Ergys
Lokomat
EasyStand
FESBWSTT
Rehab Devices
Walking Technologies for Persons with Paraplegia

- 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.

Types of Mobility Devices

Wheelchairs

Passive Orthotics
- KAFO's
- RGO's
- SCO's

Powered Exoskeletons
- EKSO (Rehabilitation)
- ReWalk (Personal Mobility)
- Indego (Personal Mobility)
- Rex

Wheelchair Mobility

Types:
- Manual
- Power
- Power Assist
- Standing
Orthotic Technologies for Persons with Paraplegia

Knee Ankle Foot Orthosis (KAFO)

Leg Braces

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

History of...
Powered Exoskeletons for Restoring Walk

Contemporary
Powered Exoskeletons for Restoring Walk
Design Considerations

- All day use (Battery)
- Assimilation of user capabilities into the control
  - Identify & avoid obstacles
  - Select modes
  - Steer the device
  - Control the pace
- User controls the device (autonomous device)
- Natural (intuitive) gait trigger & walk
  + natural gait = minimum energy = maximum stability; acceptance; aestheticism
  - algorithm complexity: open loop trapezoidal vs. close loop arbitrary pattern; more expensive motor units

The Hardship:

- algorithm complexity: open loop trapezoidal vs. close loop arbitrary pattern; more expensive motor units
- Select modes
- Steer the device
- Control the pace
- Initiate gait & halt at will
- Manual control
- Interpret feedback & warnings signals

Structure

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 Exoskeletons 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.
Inclusion/Exclusion Criteria

Patient Qualifications

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

User Requirements:
Upper body can support crutch use
Sufficient joint motion to walk
Fair sitting posture
Stable cardiovascular and skeletal system
MD clearance to participate in walking program

Training Program - Eligibility Screening

Indications
- Lower extremity paralysis or paresis
- Fair or better upper extremity strength
- Fair or better trunk control
- Bdelum >0.5-0.8 (100-190 cm) tall or normal
- Weight <230 lbs (105 kg) or less
- Healthy bone density, no fractures
- Able to tolerate standing and gait program
- Sufficient LE ROM to allow ambulation
- Neurosensory, >2 or 0.475 crossover

Contraindications
- Uncontrolled spasticity or clonus
- Infection, Prostate cancer or OVT
- Pregnancy and/or lactating females
- Severe concurrent medical conditions
- Psychiatric or cognitive issues

*Conditions should be regularly monitored for patient compliance and appropriateness of the device by a Certified Physical Therapist. Find a list of Certified Physical Therapists in the state-by-state database located in the state of professional registration.
### Clinical Studies

<table>
<thead>
<tr>
<th>Safety and Function / Regulatory</th>
<th>Long Term Medical Benefits</th>
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<tbody>
<tr>
<td>- Multicenter study of 24 patients:</td>
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<td>- Moss Rehab (US)</td>
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<td>- Sheba Medical Center (Israel)</td>
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<td>- Villa Baretta (Italy)</td>
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<tr>
<td>- Primary Outcomes:</td>
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<td>- Safety A/E’s</td>
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<td>- Tolerance</td>
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<td>- Ease of use</td>
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<td>- Ongoing single center study of 20 patients:</td>
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<tr>
<td>- James J. Peters VA (Bronx, NY)</td>
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<td>- Primary Outcomes:</td>
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<tr>
<td>- Measure medical/clinical benefits of vertical loading and walking with exoskeleton technology:</td>
<td></td>
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<tr>
<td>- bowel function,</td>
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<tr>
<td>- urinary tract function,</td>
<td></td>
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<tr>
<td>- body composition,</td>
<td></td>
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<td>- metabolism</td>
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Further studies: Rancho (Calif.), Stoke (UK); Murneau (Germany)

### Exoskeleton Assisted Walking for Persons with Motor-Complete Paraplegia

- 7 Subjects, 45 +/– 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 for several hours after ReWalking for some patients
- Increase physical fitness (based on HR/SBP) and some reduction in body weight occurred - all subjects
vertical ground force reaction based analysis of powered exoskeleton assisted walking in persons with motor complete paraplegia

- 6 persons with thoracic motor-complete SCI (T1-T11 ASIA A/B)
- Spinal Cord Injury patients were trained to ambulate over ground using a ReWalk. vGRF was recorded using the F-Scan system (In shoe pressure mapping system).
- "A comparison peak stance average under curve (relative linear impulse) revealed that powered exoskeleton-assisted walking produced vGRF loading comparable to normal walking"

Ongoing Medical Benefits Study Experience

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

Reference:
### Health Benefits

<table>
<thead>
<tr>
<th>Total Bowel Evacuation Time per Bowel Day</th>
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<th>Bristol Stool Scale</th>
<th>Bowel Specific Medication Use</th>
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</thead>
<tbody>
<tr>
<td>1.5-2 min</td>
<td>↓ from 50 to 30 min</td>
<td>4</td>
<td>No reported change in bowel medications</td>
</tr>
<tr>
<td>3-4 min</td>
<td>↑ from 2 to 3-4x/week</td>
<td>4</td>
<td>Discontinuation of laxative (Dulcolax)</td>
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</tr>
<tr>
<td>2-3 min</td>
<td>↑ from 1 to 3-4x/week</td>
<td>4</td>
<td>Discontinuation of stool softener (Colace) and laxative (Senis)</td>
</tr>
<tr>
<td>1-2 min</td>
<td>↓ from 5 to 3-4x/week</td>
<td>4</td>
<td>Eliminated laxative use and decreased amount of additional dietary fiber supplements</td>
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### Exoskeletons - More Than Walking

**Benefits that go beyond mobility**

**Potential Benefits for the User**

- Confidence
- Relationships
- Independence
- ReWalk Community
- Inclusion
- Eye to Eye Conversations
- Access
- Inspiration
- Limited Community Walking Speed
- Natural Gait
- Vertical Ground Reaction Force
- Standing
- Exercise
- Bowel Function
- Bone Density
- Pain Management

**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
A Day in Radi’s (New) Life

The Market of Akko

WHO HELPED HER FINISH A MARATHON?

In May 2012, paraplegic Claire Lomas finished the London Marathon in 16 days using a lightweight, computer-assisted exoskeleton.