The Role of Robotic Exoskeletons in SCI Rehabilitation: A Narrative Synthesis of Published Data Regarding the Safety and Efficacy of the Technology

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Background

- Robotic exoskeletons (i.e., powered lower limb orthoses) are becoming prominent tools for spinal cord injury (SCI) rehabilitation
- Exoskeletons permit individuals with sensory & motor deficits to mobilize in an upright position
- Understanding the benefits & limitations of exoskeleton technology will direct future research & aid in developing effective interventions

Objective

- Perform a narrative synthesis of exoskeleton literature to
  - 1) identify themes regarding use
  - 2) identify knowledge gaps.

Methods

1. Two search strategies performed:

Medline, Embase, Pubmed, CINAHL databases

Clinical trial databases, Websites of SCI foundations & exo-skeleton companies

2. Articles selected based on pre-defined inclusion/exclusion criteria

56 in total:
- 3 RCTs
- 35 cohort studies
- 13 case studies
- 5 reviews

3. Data extracted

(study characteristics & findings, reports of adverse events)

References
1. Forrest et al., 2012, Academy of Spinal Cord Injury Professionals.
2. Spungen et al., 2013, J Spinal Cord Med, 36 (5): 504-523.

Results

1. Four exoskeletons have been researched for safety & efficacy in current literature.

Name of System	Key Features	Requirements
ReWalk™	▪ Brace support suit containing actuating motors at the hip and knee joints ▪ Includes a rechargeable computerized control system carried by a built in backpack ▪ U.S. Food and Drug Administration approved for the use in a home and community setting	▪ Most exoskeletons are designed for paraplegic individuals with the exception of the REX™, where one's hand and shoulder function must be sufficient enough to utilize a walker or crutches in addition to the bionic suit ▪ C7-T12 Spinal Cord Injury ▪ Adequate Hip, Knee, and Ankle Range of Motion ▪ Bone and joint health and density ▪ 160 – 190 cm ▪ < 100kg/220lbs
Ekso Bionics™	▪ Robotic suit controlled by a device operator detached from the user who manages the device through a hand-held controller OR by system on forearm crutches to allow bipedal ambulation	
Indego®	▪ Exoskeleton system with no backpack mounted components or footplates ▪ Designed to be worn with a Ankle-Foot-Orthosis to stabilize the foot when taking subsequent steps ▪ First wearable exoskeleton to incorporate functional electric stimulation (FES) located at the hips and knee to aid in ambulation and neuromuscular activation	
Rex Bionics™	▪ Does not require any external aid such as crutches to provide stability, thereby allowing the user, free use of arms and hands as device is self supporting	

Table 1: Prominent Exoskeletons as listed by The National Spinal Cord Injury Association

Figure 1: Different exo-skeleton designs.

2. Four emerging themes were identified concerning the use of exoskeletons in SCI rehabilitation.

a. Examining Safety & Efficacy

- Most studies focused on evaluating the feasibility of exoskeleton gait training for individuals with SCI
- No significant adverse events reported
- Potential adverse effects were noted, including pressure sores, bruising, falls & hypertension
- Multiple studies reported that high-dosage training could result in clinically significant gains in cardiovascular status, walking ability & speed, activities of daily living & psychological health

b. Developing & Validating Relevant Clinical Measures

- Lack of valid & reliable outcome measures to assess efficacy of exoskeletons
- Primary measures used: 10meterWT, 6MinWT and Timed Up & Go
- Measures of secondary outcomes (e.g., bowel function, spasticity, aerobic capacity) are needed

c. Investigation of Neurophysiological Change with Training

- Repetitive, task-oriented locomotor training can promote neural plasticity
- No studies systematically studied neuro-physiological change with exoskeleton training
- One study reported increased muscle firing in lower leg muscles after 30 training sessions[1]
- Research on this topic is needed

d. Implementation of Technology in Home or Community Settings

- Most users reported cost as a barrier to using the technology in their daily lives
- Some participants with paraplegia showed improved performance in home/community-based skills after 45±20 sessions of supervised training with ReWalk™ [2]
- Practice of community mobility skills may be feasible with exoskeleton
- Future research warranted

Conclusions

- Literature confirms safety & efficacy of exoskeletons
- Research needed on secondary outcomes, neurophysiological change & home/community use

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