

EXOSKELETONS

Update on Medical Applications

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Key Takeaways

- Identify opportunities to transfer exoskeleton knowledge and technology awareness from medical applications to industrial applications.
- Describe unique considerations for ‘patients’ that are potential candidates to use exoskeletons based on medical device regulation and experience.
- Understand the state of the science in clinical use of exoskeletons as safe and effective mobility systems.
- Outline VHA approach for exoskeleton evaluation and training for Veterans.
- Discuss opportunities to utilize data sources and user feedback to support advancement of exoskeleton technologies for individuals with disabilities.

Regulatory Definition

www.accessdata.fda.gov

Powered Lower Extremity Exoskeleton (21 CFR 890.3480)

Prescription device that is composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation.

- Device Class: 2
- Current FDA 510(k) Submissions (i.e., cleared for marketing)
 - ReWalk™ (K160987) www.Rewalk.com
 - Ekso™ and Ekso GT™ (K143690 and K161443) www.eksobionics.com
 - Indego® (K152416) www.indego.com
- Based on diagnosis and level of injury, there are specific indications, limitations, and requirements for institutional and personal use in home and community environments.

Exoskeleton Candidates

- Neurologic impairment (*SCI specified levels for 3 devices, CVA for 1 device*)
- Typically utilize wheelchairs for primary mobility
- Injury onset varies from recent to longstanding
- Clinical considerations:
 - Sensation
 - Strength
 - Range of motion
 - Flexibility
 - Bone density
 - Autonomic function
 - Cognition/problem solving
 - Balance, coordination
 - Functional abilities
 - Fitness, cardiorespiratory function
 - Social support systems
 - Participation goals
 - Transportation
 - Environments:
 - > Home, work, school
community, recreation

Current Evidence

Three Recent Systematic Reviews

Fisahn C, Aach M, Janson O, Moisi M, Mayadev A, Pagarigan K, Dettori J, Schildhauer T. [The effectiveness and safety of exoskeletons as assistive and rehabilitation devices in the treatment of neurologic gait disorders in patients with spinal cord injury: a systematic review.](#) *Global Spine Journal.* 2016.6:8, 822-841.

Lajeunesse V, Vincent C, Routhier F, Careau E, Michaud F. [Exoskeletons' design and usefulness evidence according to a systematic review of lower limb exoskeletons used for functional mobility by people with spinal cord injury.](#) *Disability and Rehabilitation: Assistive Technology,* 2016. 11:7, 535-547.

Miller L, Zimmerman A, Herbert W. [Clinical Effectiveness and safety of powered exoskeleton-assisted walking in patients with spinal cord injury: systematic review with meta-analysis.](#) *Medical Devices: Evidence and Research.* 2016. 9:455-466.

Current Evidence

General Summary

- Limited longitudinal studies, small sample sizes or case studies
- Topics of inquiry:

Exoskeleton walking and impact on:

Body composition
Bone density
Bowel function
Cardiovascular fitness
Metabolic demand
Pain
Spasticity
Quality of Life
Urinary tract infections

Measures of:

Level of assistance/independence
Metabolic demand
Neurologic improvement
Perceived exertion
Walking velocity

Incidence of adverse events:

Falls
Fractures
Skin compromise
Upper limb injury

Comparisons:

Gait training approaches
Study quality and levels of evidence
Surfaces indoors and outdoors
Other orthoses (KAFO)

Diagnoses other than SCI:

CVA
Multiple Sclerosis (MS)

***Randomized Controlled Trial (RCT) in progress
at VA SCI/D Centers***

Evidence Based Practice

Rappolt, 2003

- Research Evidence
- Professional Expertise
- Client Evidence

***Integration for
Clinical Decision Making***

**Where does media
coverage fit in?**



Growing Evidence with Experience

Client Considerations

- Device limits of use
- Device fit and adjustments
- Donning and doffing
- Clothing interface and management
- Transfers sit <->stand
- Toileting
- Transportation/driving
- Companion requirements
- Device interface with wheelchair
- Access to established training centers
- Learning curve

* Unanticipated adverse events

Clinical Logistics

- Technologies highly variable
- Staffing requirements
- Scheduling/workload management
 - Number of visits
 - Length of visits
 - Frequency of visits
- Environments for training
- Additional technology needs
- Storage
- Companion requirements
- Evolving client evaluation needs
- Evolving training requirements
 - Clinicians
 - Clients

Exoskeleton Clinical Protocol

VA Spinal Cord Injury & Disorders System of Care

- VA provides exoskeleton evaluation and training. Device is potentially leased or purchased when criteria met.
- Exoskeletons cleared for personal use (2 devices) are currently limited to individuals with SCI
 - T7 to L5 level of injury for personal use with trained companion
 - Not currently cleared for personal use for diagnoses other than SCI
- VA Clinical Protocol managed by SCI/D System of Care
 - Document currently specific to one exoskeleton, first cleared by FDA
 - Protocol actively being expanded to include all current and potential future FDA cleared exoskeleton devices

Clinical Protocol

VA Spinal Cord Injury & Disorders System of Care

Detailed VA Clinical Protocol for Veterans with SCI

- Comprehensive evaluation to determine inclusion/exclusion
 - PMHX, comprehensive exam including neurologic assessment, body measures, functional skills, skin integrity, bone density, autonomic function, cognition, psychosocial profile including appropriate exoskeleton companion, environmental assessment, vision, pregnancy (contraindicated)
- Informed consent obtained from Veteran and companion
- Training and education proceeds at VA SCI/D Exoskeleton Center
 - Preliminary and advanced skills training for Veteran & companion
- Determination for home/community use under lease or purchase
- Plan for follow up and outcome measures established

Patient Safety & Exoskeletons

Signal Detection

Using Real-World Performance Data to Identify Medical Device Safety Signals

- Analyze existing data sources to ***evaluate real-world device performance*** during clinical use
- Recognize and ***communicate known use-related issues*** across the healthcare enterprise to prevent patient harm
- Provide feedback to industry so that manufacturers can ***design more resilient systems***

Important VA Data Sources (used in conjunction with external data sources)

- Patient Safety Database
 - Reporting of adverse events, sentinel events, and close calls
 - Approximately 1.5 Million case reports
- Medical Equipment Database (Computerized Maintenance Management System)
 - More than 800,000 discrete devices; hundreds of types
 - More than 14 Million device history reports

Patient Safety & Exoskeletons

The Future of Medical Device Surveillance

Improving the Safe Use of Emerging Technology

- Collaborate to detect, understand, and solve problems with complex healthcare technology
- Proactive identification of medical device safety issues
 - Unexpected or unusual events experienced with new technology
 - Increased frequency of known problems with existing technology
 - Interactions between devices
 - Human factors issues (e.g., difficult to read displays, confusing prompts)
 - End-user and patient feedback
- Contribute to the body of knowledge regarding safe device use
- Understand and incorporate the client experience

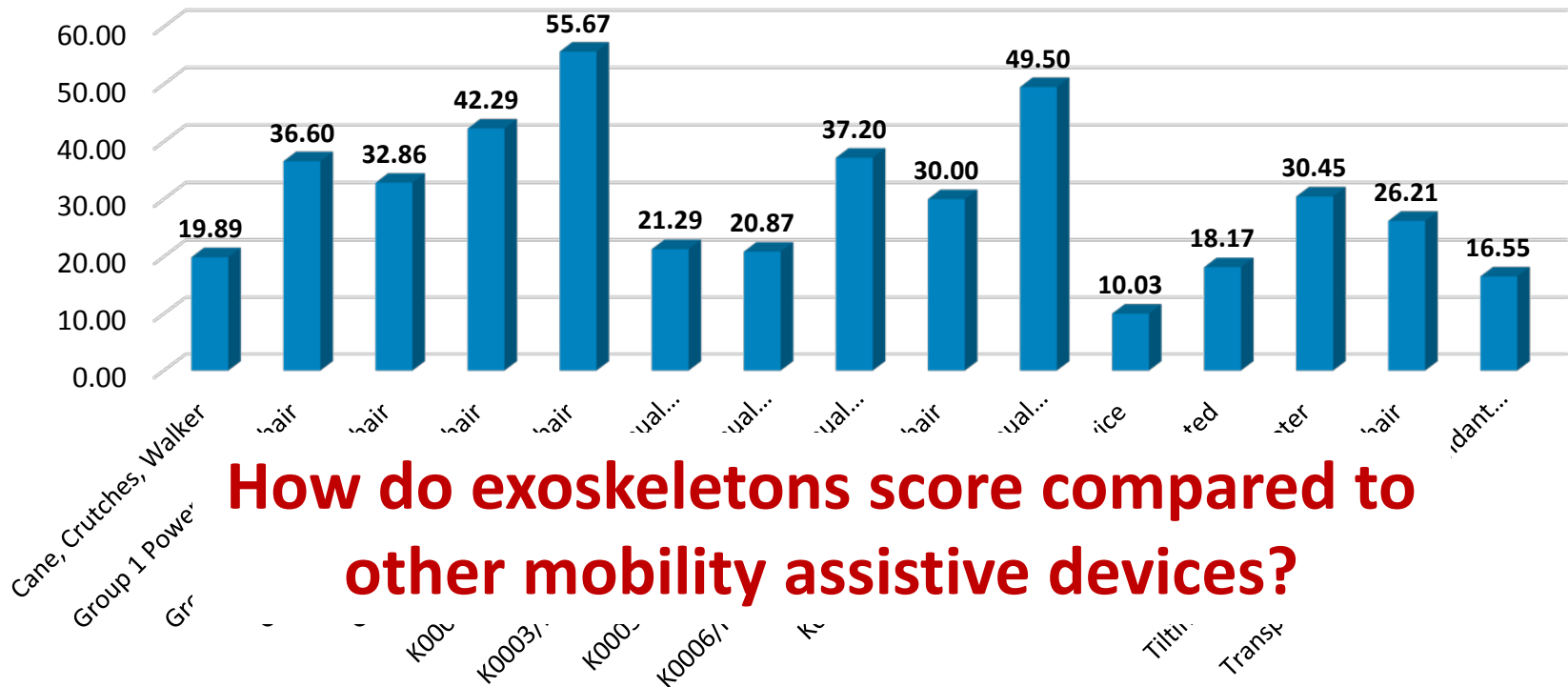
Outcome Measures & Client Experience

- **USUAL measures of exoskeleton as mobility assistive device**
 - 10 Meter Walk Test (10MWT)
 - 6 Minute Walk Test (6MWT)
 - Functional Independence Measure (FIM)
- **Client centered measure of exoskeleton as mobility assistive device**
 - Functional Mobility Assessment (FMA)
 - Uniform Data set with demographics, medical and device history
 - 6 point scale from “Strongly Disagree “ (1) to “Strongly Agree” (6)
 - 10 item inventory
 - Max 60 points
 - 6 x 10
 - 1. Daily Routine**
 - 2. Comfort Needs**
 - 3. Health Needs**
 - 4. Operate**
 - 5. Reach**
 - 6. Transfers**
 - 7. Personal Care**
 - 8. Indoor Mobility**
 - 9. Outdoor Mobility**
 - 10. Transportation**

Mobility Device Comparison with FMA Scores

with permission from University of Pittsburgh RSTCE

**Total FMA Scores by Device Type
for U.S. Rehab at Baseline (n=766)**



How do exoskeletons score compared to other mobility assistive devices?

Exoskeletons & Ethics

- **Evolving technology**
 - Current products
 - Anticipated products
 - Enhanced features
 - Enhanced performance
- **Research**
 - Current evidence
 - Active investigation
 - Needs for further study
- **Cost initial and ongoing**
 - Limited competition
 - Compared to other options
 - Care, repair & maintenance
- **Products available now**
 - FDA cleared
 - Evolving coverage criteria
 - Funding evolution
 - Replacement/upgrades

Thank You!

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