Exoskeletons: What's New?

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Objectives

- Describe the exoskeletal devices that are currently available for patient use
- Discuss the physical requirements for use of exoskeletal devices and progression of training

What is it?

- Battery operated bionic exoskeleton that enables standing and reciprocal walking, mimicking the natural gait pattern
- Weight shift activates sensors in the legs
- Motors power the hip and knee joints

Appropriate Candidates

- Near normal ROM in all leg joints
- Proficient with sitting balance and transfers
- Currently on a standing program
- Functional arm strength to manage an assistive device (triceps and grip)
- Note that there are specific leg length/ hip width/ weight limits for each device

Contraindications

- ROM restrictions
- Arm strength deficits
- Spinal instability
- Unresolved DVT
- Decreased standing tolerance/ orthostatic hypotension
- Significant osteoporosis that may increase risk of fracture
- Uncontrolled spasticity
- Uncontrolled Autonomic Dysreflexia
- Skin integrity issues
- Leg Length Discrepancy > .5”
- Cognitive impairments
- Pregnancy
- Colostomy
- Active Heterotopic Ossification or hip axis abnormalities

Not just walking

- Maintenance of bone mass
- Improved sitting balance/ activation of trunk musculature below level of injury
- Improved sleep
- Improved mental outlook, mood and motivation. Psychological benefits of being upright and walking
- Improved bowel function
- Improved bladder function and decreased incidence of UTIs
- Decreased pain
- Decreased incidence of pressure ulcers
- Reduction in fat mass and increase in lean body mass
- Improved gait parameters, gait speed with incomplete SCI and patients with CVA

Feasibility of Use

- Rewalk studies have found patients are able to acquire standing skills within 1 week and walking skills within 5 weeks of training
- Ekso studies found that patients with SCI could perform sit to stand and walk with minimal assist on average of 8 sessions and walk with close S on average of 15 sessions
- Indego study showed that patients with SCI could learn to use device in 5 sessions
- Ekso and Indego studies reported that the cardiorespiratory effort of walking to be that of light to moderate intensity. Indego case study showed that up to five times less exertion noted with use of Indego exoskeleton than KAFOs during walking tests.
- Ekso studies demonstrated that participants with CVA during inpatient rehab had a 150-200% increase in average distance walked during Ekso training sessions compared to standard PT sessions

A Quick Comparison

	ReWalk	Ekso	Indego (Parker Hannifin)
Patient Height	5’3”-6’3”	5’0”- 6’4”	5’1”-6’3”
Patient Weight	220 lb or less	220 lb or less	250 lb or less
FDA approval	SCI only; T4-T6 in clinic; T7-L5 home setting	SCI levels C7-L5; CVA Clinic use only	SCI only; C7 and below in clinic; T3 and lower home setting
Device weight	51 lb	55 lb	26 lb
Therapy use	Exercise/ training for home use	Smart Assist- adjust amount of assist at right versus left leg	Variable Assist- adjust amount of assist at each hip and knee joints individually
Cost of a home unit	$95,000 list price; some success with insurance reimbursement; rental program offered Veterans free	Home Unit not available	$98,000 list price Veterans discounted

ReWalk

- Most studied exoskeleton technology
- Small changes in the user's center of gravity is sensed by the system
- Walking mode is chosen by the user on the wrist communicator
- A forward tilt of the upper body initiates the first step. Repeated forward placement of the crutches and body shifting generates a sequence of steps which mimics a gait pattern
- Gait speed is determined by how fast the crutches are moved and forward tilt achieved
- Sit- to- stand and stand- to- sit transitions are controlled by user on the wrist communicator
- Typically used with forearm crutches only
- Can be used on Indoor/ outdoor terrain. Stair function in Europe
- Current shift towards personal systems- custom fit to each user

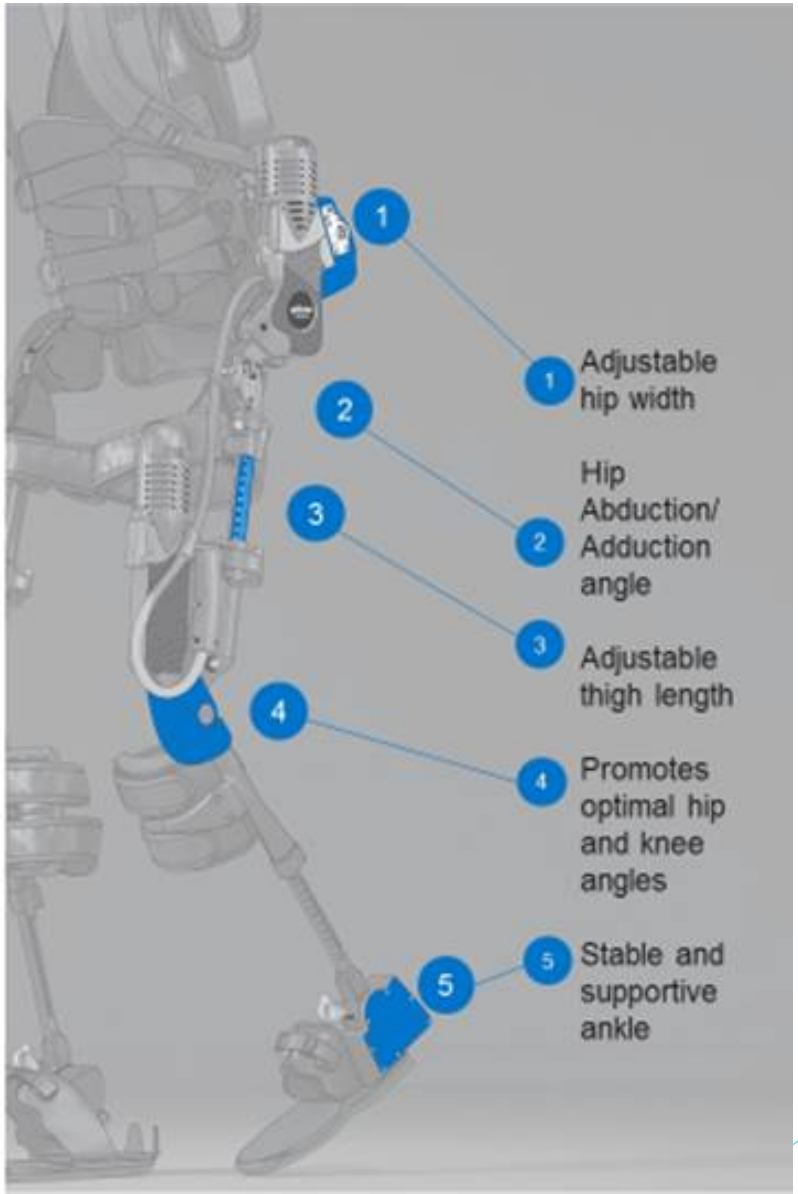
ReWalk

https://www.youtube.com/watch?v=cBzwbbTPJg0

EksoGT

Intelligent Hardware

- Powered by two sets of rechargeable **lithium ion batteries** for continuous use
- **Stores easily** by seating on a chair or hanging on a wall hook
- **Easily transported** & no need to change current facility
- Patented **load transfer** means that weight **of suit** (55 lbs.) is transferred to ground so patient bears own weight but **no additional burden**
- Materials include hand-sewn soft goods, aircraft aluminum, and carbon fiber; made in America



How does it work?

- Patient must learn how to balance and weight shift while wearing Ekso device
  - Must achieve preset lateral and forward targets with weight shift. Auditory cue when targets achieved- chirp for lateral and beep for forward
- Use with either Rolling Walker or Forearm Crutches
  - Quad cane for CVA patients

How does it work?

- First Step
  - Therapist uses push button controller to generate step after appropriate weight shift
- Active Step
  - User triggers steps using controller buttons on crutches or walker
- Pro Step
  - Step is automatically generated when the device senses that the patient has achieved appropriate weight shift
- Pro Step Plus* (for use with patients with some LE movement)
  - Step is generated once patient achieves appropriate lateral weight shift and initiates forward leg movement

Treatment Sessions (Patients with complete SCI)

- Therapist works to identify appropriate parameters to program in order to achieve optimal stepping pattern
- Goals:
  - Increase standing time
  - Increase stepping time
  - Decrease assist required for weight shift (decrease from 2 to 1 therapist assist)
  - Progress from First Step to Pro Step mode
  - Transition from walker to crutches as appropriate
  - Progress step length, swing time

Treatment Sessions (Patients with LE movement) using Smart Assist Software

- Use device for gait retraining to relearn correct stepping pattern and weight shifting
- Early mobilization with **PreGait** activities with audio feedback
  - Balance- weight shifting using visual feedback on controller
  - Stepping in place/ marching
  - Stand and Squat
  - Sidestepping with hip abduction unlocked
- Gait training using **variable assist-** provides 0-100% power to either side of the body, challenging patients to use their own power as they progress
  - Feedback on walk screen- informs the clinician and patient what area of swing is not being matched to the programmed gait path. Appears in real time. “Lift”, “Extend” or “lift and extend”
- Advanced rehab using **free gait**. Can do dual free leg walking with flexible stance support

Indego

- Most broadly indicated personal use exoskeleton in the United States
- Modular components and single hand adjustment system, which allows ease with donning/ doffing
- Slim profile compatible with most wheelchairs and can be worn while sitting in as car
- Wireless operation through an application on a mobile device allows user to change settings and capture data
- Can be used indoor and outdoor on a variety of surfaces
- Up to 4 hours of continuous use with quick charging batteries

How Does it Work?

- User controls Indego by changing his/her posture
  - Forward lean initiates transition from sit to stand
  - Hitting forward lean threshold initiates each step
  - User maintains an upright stance to stop
  - Backward lean initiates stand to sit transition
- Includes vibratory feedback for each transition and when thresholds reached
- LED indicators inform user and clinician current training mode
- Indego App allows control over gait parameters including stride length, step frequency, step height, and lean thresholds and records walking data to track progress

Variable Assist Mode

- Motion + program allows clinicians to guide patients through specific gait pattern
  - Assist-as-needed approach- level of assistance can be adjusted separately for the hip and knee joints, allowing clinicians to select settings specific for each patient's leg strength and therapy goal
  - High patient engagement - active patient participation is required as they must engage their muscle function to tolerate lower levels of assist
- Therapy + program
  - Next level of gait therapy for those with lower extremity weakness
  - Patients must initiate leg movement and Indego will support when needed
  - Active Swing mode allows clinician to provide individualized assistance to a patient at hip and knee during swing phase of gait
  - Adjustable stance support settings allows clinician to adjust amount of support required at knee joint during stance phase of walking
  - Auditory feedback allows clinician to set goals for step length to encourage symmetric gait pattern and provide patient with real time feedback on their performance

Future Directions

- Rewalk Restore - Soft suit exoskeleton intended for use in the rehab setting
  - Transmits power to key joints of the legs with cable technologies, powered with software and mechanics that are similar to the technologies used in the current ReWalk exoskeleton system
  - First commercial application will be for stroke survivors, followed by Multiple Sclerosis patients and then additional applications
- Ekso- conducting a randomized multicenter clinical trial
  - evaluate improvement in independent gait speeds of (iSCI) patients undergoing rehabilitation with the EksoGT compared to both conventional therapy and usual care control groups (including locomotor training)
- Indego
  - awaiting FDA approval for Therapy + software and use with CVA population
  - Integrated FES (electrical stimulation) with exoskeletal system in next 1-2 years

The “million” dollar question…

Is one device better than the other?

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