An Update in Robotics in Outpatient Rehab

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Objectives

• Be familiar with various robotic devices for both upper and lower extremities.
• Be familiar with current research on various robotic devices for both upper and lower extremities.
• Learn about advances in exoskeleton development
If a robot does “the robot”, is it still called “the robot”? Or just dancing??
• Robotics in Rehab
  – Mobility aids
  – Manipulation aids
  – Evaluation tools
  – Therapeutic aids
Robotics in Rehab

- Fewer therapists/staff
- Active participation with progression
- Reproducible
- Mental well being
Lower Extremity Robots
Upper Extremity Robots
Research

• Veterans Administration/Department of Defense, regarding UE robotics, “recommend robot-assisted movement therapy as an adjunct to conventional therapy in patients with deficits in arm function to improve motor skill” (Krebs, 2012).

• “American Heart Association suggests that robot-assisted therapy for the UE has achieved Class I level of evidence for stroke care in outpatient and chronic care setting… Class IIa for stroke care in inpatient setting” (Krebs, 2012).

• Study of 10 chronic SCI (C4-C6) participating in 6 wk study showed clinically significant improvements in aim and smoothness of movement in UE kinematics (Cortes, 2013).
Research

• RCT; Subacute (30 ± 7 days) stroke patients; showed significant improvement in Fugl-Meyer, MAS, and PROM after robot-assisted upper limb rehab tx (Sale, 2014).
  – Control group performing standard therapy also showed significant improvement in Fugl-Meyer but experimental group had higher improvement

• Single-blind RCT; children with CP improved significantly in manual dexterity assessed by Box and Block test compared with control group (Gilliaux, 2015).

• Single-blind RCT; chronic stroke patients had significant improvement in task-oriented arm training after six months (Timmermans, 2014)
<table>
<thead>
<tr>
<th>Device</th>
<th>Function</th>
<th>Cost</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARMEO</td>
<td>Intelligent arm support in 3D workspace, 6 actuated DOF, augmented feedback, provides objective data</td>
<td>$190,000</td>
<td>Pediatric option, more degrees of freedom</td>
</tr>
<tr>
<td>Reo-Go</td>
<td>3D gyro mechanism; performance feedback, collects objective data</td>
<td>$85,000</td>
<td>Mobile/easy to move; lock out specific motions</td>
</tr>
<tr>
<td>InMotion</td>
<td>2 active DOF at shoulder;</td>
<td>$110,000- ARM and Hand. Additional $90,000 for InMotion Wrist</td>
<td>Optional InMotion Hand and Wrist for combined coordination of movement. Pediatric option</td>
</tr>
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Hybrid UE Robot Research

- **MAHI-EXO II**
  - Upper extremity exoskeleton
  - 5 degrees of freedom
  - Hard stop at elbow
  - Currently conducting validation studies for patients with Stroke and SCI

MAHI-EXO II + BCI (Brain Computer Interface)
- Currently recruiting subacute and chronic stroke participants

https://clinicaltrials.gov/ct2/show/NCT01948739

Photo courtesy of www.neurogadget.com
Lower Extremity Exoskeletons

Test Centre
Walking unit mimics the design of a sea crab’s exoskeleton

Perhaps I should have warned you about only being able to walk sideways with this unit?!

Mark I Walker
Crippen
Exoskeletons

ReWalk

Ekso

Rex
Ekso

- Formerly called “E-Legs”
- Wearable bionic suit that enables user to stand and walk over ground

- Battery powered motors move limbs in reciprocal gait pattern

- Progressing walking modes
  - Training mode with audio feedback for appropriate weight shifting

- Variable assist
  - Various settings that allow range of passive to actively assisted stepping from user
    - Bilateral Max Assist
    - Adaptive Assist
    - Fixed Assist

Photo courtesy of www.prescouter.com
Research

- Clinical trials out of Kessler showing positive results from training with Ekso exoskeleton (presented at ASCIP 2012, 2014 conference by Gail Forrest, PhD)
  - Increased oxygen consumption, ventilation, and heart rate showing potential cardiovascular benefit
  - Increased muscle firing in lower leg muscles during Ekso assisted walking
  - Increase gait speed and decreased stance time on single limb with increased training
  - Increased loading on LEs
Research

- Clinical trials out of Mount Sinai (presented at ASCIP 2014 by Allan Kozlowski, PT)
  - Ekso walking is safe (no adverse events occurred)
  - Level of assistance varies
  - HR, RPE, METs comparable to light exercise
  - Secondary benefits: reports of improved pain, spasticity, posture, sleep, and bowel function
  - Psychosocial benefits
Rex Bionics

- Hands free, self supported device controlled by joystick
- Can be used by people with cervical injuries as high as C-4
- Can navigate up/down stairs and ramps
- Rehab and personal units available (UK only)
- Fast adjustability

Update:
- Clinical trials starting in early 2015
- Goal is to secure pre-market notification, 501(k) from FDA by end of second quarter of 2016 leading to at-home use late 2016.
Headley Court Demo
10/03/2014
ReWalk

- Stepping is controlled by wt shifting and subtle trunk movements that trigger tilt sensors

- Adjustability for varying levels of user (beginner – advanced)
  - Joint range, step speed, delay between steps, tilt angle, current threshold

- Battery held in backpack

- Able to ascend/descend stairs

- Used with forearm crutches

- Mode is determined by watch controller worn by user

Only FDA approved device in US for personal use
Research

- 6 Chronic SCI volunteer participants with thoracic level (T5- T12) complete injuries participated in average 13 training sessions did not show any increase in pain or adverse effects (Esquenazi, 2012)
  - One participant with chronic high-level neuropathic pain (VAS 8-9) showed repeated improvement after training (VAS 4-6).

- In a nonrandomized single intervention trial, 12 subjects with chronic thoracic level (T3-T12) motor complete SCI reported positive emotional/psychological benefits on survey (Zeilig, 2012)
  - 3/11 reported improved spasticity, 0/11 reported increase in pain, 5/11 reported improved bowel regulation
Research

- Improved bowel function in 5 motor complete SCI participating in 15-20 sessions of ReWalk exoskeleton training (Fineberg, 2012)
  - Decreased average time of evacuation
  - Reduction of dependency for manual stimulation, laxatives, or stool softeners

- Early data out of Bronx VA (Ann Spungen, presented at ASCIP 2014); 7 ReWalk users walking 1-2 hours 3 days a week
  - Improved skill level (decreased assistance, varied terrain outdoors, community mobility)
  - Potential positive lean tissue mass changes in users with lower motor partial zones of preservation
  - No changes in bone mineral density
  - Loss of fat mass
  - Report of significant improvement in bowel function
  - Increased energy expenditure but sustainable
  - Improved QOL
Case Report

- Female 27 years old; Chronic T-10 AIS-C SCI, 10 years post injury
- Goal: to walk around home with braces (KAFO/AFO)
- Previously attempted ambulation with braces and FWW
  - Subjective report: required assistance, relied heavily on UEs allowing only 5-10 ft of gait with FWW

- Measurements before ReWalk training
  - TUG: 52 sec; wearing R KAFO and L AFO in parallel bars
  - LE MMT
    - R hip flex 4-/5   L hip flex 4+/5
    - R hip ext  2-/5   L hip ext 3-/5
    - R knee ext 3-/5   L knee ext 5/5
    - R knee flex 2/5   L knee flex 3/5
  - Pain: daily nerve pain in B LEs L > R, worst 9/10 on VAS
Case Report

- Intervention
  - 2-3 days/week X 6 weeks
    - 15 sessions total; 11 ReWalk, 4 gait training with braces started after first 3 weeks

- Measurements after 6 weeks
  - TUG: 23.72 sec (52.36 sec)
  - Ambulate 77 (5-10) ft with FWW
  - LE MMT
    - R hip flex 4-/5 (4-)  L hip flex 4+/5 (4+)
    - R hip ext  2+/5 (2-)  L hip ext 3-/5 (3-)
    - R knee ext  3/5 (3-)  L knee ext 5/5
    - R knee flex 2/5 (2)  L knee flex 3+/5 (3)

- Pain: daily nerve pain in B LEs; worst 8/10 VAS (9/10)
“When using the ReWalk I could feel my abs starting to work and I hadn’t felt that before.”

“Using it definitely helped with my sitting balance”.

“Using the ReWalk has helped my trunk to get stronger with other things I do”.
Hybrid-Exoskeletons

Indego  HAL  Kinesis/H2
H2-Exo / Kinesis

- Exoskeleton developed by Technaid out of Spain

- Bilateral lower extremity equipped with active actuators at knee hinges
  - Passive elastic actuators at ankles

- EMS: PC controlled stimulator delivers biphasic current to knee ext/flex

- Can manually trigger steps

- Wearer uses walker for UE support
Research

• Pilot study; 3 motor incomplete SCI using FES hybrid exoskeleton
  – able to complete 6 minutes of walking after one day (Del Ama, May 2014)
  – After only one week of training, improved gait measures (10m and 6MWT), but also continued to improved one week after intervention.

• HYPER project
  – Recruiting for clinical trial: Subacute or chronic stroke patients
H2-Exo
Cyberdyne HAL

- Hybrid-Assistive-Limb
- “World’s First Cyborg type robot that interfaces man, machine, and information”
- Assistance triggered by EMG from surface electrodes
- Single LE, Bilateral LE, or whole body UE/LE combo
- Currently only in Japan and Germany
- Submitted application for FDA clearance in U.S.

Photo courtesy of www.cyberdyne.jp
Research

• After 16 training sessions, patients with various neurological diagnoses (Stroke, SCI) improved gait speed, number of steps, and cadence (Kubota, 2013).

• HAL was found to be safe when used for gait training in acute stroke patients (Nilsson, 2014)
  – All 7 participants improved gait measured by 10MWT
Indego

- Lightweight at only 27 lbs
- Breaks down to smaller pieces for easy travel/transportation
- Functional electrical stimulation component
- Adapts to user input with varying levels of power provided
- Requires use of AFO to be worn with device
Indego

- Slim profile that allows sitting in most standard wheelchairs
- Wireless operation through app on mobile device
- Single handed strapping
- Not yet approved by FDA
- Commercial release expected in 2016 in US

Photos courtesy of www.indego.com
Research

• Single subject case study showed exoskeleton powered locomotion to have faster gait speed and also reduced exertion compared with KAFO use (Farris, 2013).

• Single subject case study with T10 complete SCI using exoskeleton combined with FES showed 34% reduction in electrical power required at hip joints during stance phase of gait (Ha, 2012)
Research

• Preliminary data presented at ASCIP 2014
  – Potential for multiple dxs (SCI, CVA, TBI, MS, etc)
  – Easy to learn for staff and family/caregivers
  – Self report of reduced spasticity during and up to 4 hrs after
  – Reduced pain and time for bowel care

• Recruiting for multi center clinical trial
  – https://clinicaltrials.gov/show/NCT02202538
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<tr>
<th>Device</th>
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<th>Cost</th>
<th>Availability</th>
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<tr>
<td>Ekso</td>
<td>Can balance indep, Sit to stand, gait, progressing level of independence settings</td>
<td>Rehab Unit: approx-$150,000</td>
<td>Currently only rehab unit available.</td>
</tr>
<tr>
<td>Indigo</td>
<td>E-stim, sit to stand, gait, stair climbing</td>
<td>Projected estimate: approx- $30,000</td>
<td>Expecting FDA approval 2016</td>
</tr>
<tr>
<td>HAL, Cyberdyne</td>
<td>Sit to stand, gait, upper and lower limb assistance,</td>
<td>Facility contract rental agreement: $5000 initial then approx-$1400-$1600 per mo</td>
<td>Japan and Germany, has applied for FDA approval in US</td>
</tr>
<tr>
<td>ReWalk</td>
<td>Sit to stand, gait, direction change, stair climbing</td>
<td>Rehab Unit: approx-$85,000</td>
<td>Currently rehab unit available.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Personal Unit: projected approx-$65,000</td>
<td>Available for purchase. VA has covered one P unit</td>
</tr>
<tr>
<td>Rex Bionics</td>
<td>Sit to stand, gait, stairs, ramps up/down, no assistive device</td>
<td>Both rehab and personal units: $150,000</td>
<td>Rehab unit avail worldwide; Personal- UK</td>
</tr>
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3D Printing

Photo courtesy of www.dezeen.com
MindWalker Project

Photo courtesy of www.damngeeky.com
Walk Again
Criteria for Exoskeleton use

• Healthy weight

• Range of motion within normal limits

• Orthopedically stable

• Upright tolerance

• Device specific requirements

Contraindications:
- fractures, uncontrolled spasticity, pregnancy, skin breakdown, DVT, low blood pressure, psychiatric/cognitive issues, contractures
Good Physical Health is the Key!!
Considerations when choosing a device

- Patient population
- Cost
- How will it be used/ Reimbursement
- The company providing and manufacturing the device.
- Space/ceiling height in your facility
Motor Learning

- Repetition
- Specificity
- Interference
- Intensity
- Use it or Lose it
- Use it & Improve it
- Feedback
- Time
- Transference
Be Creative!

Think outside the box!
REFERENCES:

• Bishop L, Stein J, Wong CK. Robot-aided gait training in an individual with chronic spinal cord injury: a case study. JNPT. 2012;36: (138-143).


