Evaluation of Functional Walking Assessment Algorithms for Post-Stroke and K-level applications

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Purpose of Functional Walking Assessment Post-Stroke

- Determine level of walking recovery
- Allow consistent method of measuring patient progress across continuum of care
Why Consider Community Ambulation Measures?

- *Improvement in real-world performance is the ultimate goal of stroke rehabilitation.*
  - 75% (97 post-stroke subjects) stated that “getting out and about in the community” was essential or very important¹

- Limitations of considering only clinical measures
  - Capacity tests are limited in their ability to reflect real-world performance
    - Gait speed – explained 42% of steps per day variance²
    - Six-Minute Walk Test – explained 46% of steps per day variance²
Self-reported Community Ambulation

• Important but can be ambiguous because people have a difference interpretation of active.

• A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review (Prince et al. 2008)
The most appropriate activity monitor will depend on the level of impairment of the patient.

<table>
<thead>
<tr>
<th>Step Counter</th>
<th>Approximate Accuracy</th>
<th>Approximate Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-walking impaired (walking speed at 40 m/min or 1.5 miles/hour)</td>
<td>Patients with post-stroke or hip fracture</td>
</tr>
<tr>
<td>StepWatch 3 (SW)</td>
<td>100%[^1]</td>
<td>97.4% - 98.5%[^2,^3] 92.7%[^3]</td>
</tr>
<tr>
<td>activPAL (PAL)</td>
<td>98%[^1]</td>
<td>59%[^4] 46.6%[^4]</td>
</tr>
<tr>
<td>ActiGraph (AG7164)</td>
<td>80%[^1]</td>
<td>-</td>
</tr>
<tr>
<td>Actical (AC)</td>
<td>65%[^1]</td>
<td>-</td>
</tr>
<tr>
<td>Digi-Walker SW-200 (DW)</td>
<td>60%[^1]</td>
<td>-</td>
</tr>
<tr>
<td>ActiGraph (GT3X)</td>
<td>40%[^1]</td>
<td>-</td>
</tr>
<tr>
<td>ActiGraph (GT1M)</td>
<td>40%[^1]</td>
<td>-</td>
</tr>
</tbody>
</table>

StepWatch Use

- High accuracy in post-stroke applications
- Metrics of steps and cadence more intuitive than raw acceleration values
Methods

- Enrolling Post-stroke patients at initial outpatient PT visit
  - Criteria
    - Receiving outpatient physical therapy as a result of experiencing a stroke
    - Able to ambulate 50 feet with at most moderate assistance from another person
    - Limited walking ability is one of the subject’s primary activity restrictions as determined by the treating physical therapist
    - Improving walking ability is one of the subject’s primary goals for physical therapy
    - Age greater than or equal to 21 years of age
    - Montreal Cognitive Assessment score >21
## Methods

### Table 1 - Flow of Data Collection

<table>
<thead>
<tr>
<th>Tasks</th>
<th>1\textsuperscript{st} Session</th>
<th>2\textsuperscript{nd} or 3\textsuperscript{rd} Session</th>
<th>Every 10\textsuperscript{th} Session</th>
<th>Discharge Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gait Speed, Berg Balance Scale, Functional Gait Assessment</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SAM (s) Download / Review</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>SAM (s) Attachment to ankle</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Community Walking

Steps per Day

Subject 1

Initial: 0.21 m/s, BBS=26, CN
Visit 10: 0.32 m/s, BBS=31, CN
Discharge: 0.81 m/s, BBS=55, CK

Subject 2

Initial: 0.43 m/s, BBS=27, CN
Discharge: 0.45 m/s, BBS=42, CM

Subject 3

Initial: 0.78 m/s, BBS=55, CK
Discharge: 0.28 m/s, BBS=30, CN

Subject 1

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Community Walking

Minutes per day above 30 steps/min

Subject 1
Initial: 0.21 m/s, BBS=26, CN
Discharge: 0.28 m/s, BBS=30, CN

Subject 2
Initial: 0.43 m/s, BBS=27, CN
Visit 10: 0.32 m/s, BBS=31, CN
Discharge: 0.45 m/s, BBS=42, CM

Subject 3
Initial: 0.78 m/s, BBS=55, CJ
Discharge: 0.81 m/s, BBS=55, CK

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Percent Difference Between Discharge and Initial Visit Scores

<table>
<thead>
<tr>
<th>Subject #</th>
<th>Clinical Measures</th>
<th>Community Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gait Speed</td>
<td>Steps Per Day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minutes per Day at Medium to High Cadence</td>
</tr>
<tr>
<td>Subject 1</td>
<td>+25%</td>
<td>+60%</td>
</tr>
<tr>
<td></td>
<td>+13%</td>
<td>+93%</td>
</tr>
<tr>
<td>Subject 2</td>
<td>+4%</td>
<td>-4%</td>
</tr>
<tr>
<td></td>
<td>0%</td>
<td>-3%</td>
</tr>
<tr>
<td>Subject 3</td>
<td>+4%</td>
<td>-24%</td>
</tr>
<tr>
<td></td>
<td>+36%</td>
<td>-15%</td>
</tr>
</tbody>
</table>

Clinical and community measures appear unique
Interpretation

- Clinical capacity and community ambulation measures provide unique information about the patient's function.
- What does it mean when clinical and community ambulation measures disagree?
  - Lack of motivation?
  - Environmental barriers to being active?
  - Deconditioned?
<table>
<thead>
<tr>
<th>Subject 1</th>
<th>Initial Visit</th>
<th>Visit #2 w/ StepWatch Data</th>
<th>Discharge Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CM (80% - 100% impaired)</td>
<td>CN (100% impaired) 1537 steps/day</td>
<td>CN (100% impaired) 3831 steps/day</td>
</tr>
<tr>
<td>Subject 2</td>
<td>CK (40% – 60% impaired)</td>
<td>CJ (20% - 40% impaired) 8109 steps/day</td>
<td>CK (40% - 60% impaired) 7801 steps/day</td>
</tr>
<tr>
<td>Subject 3</td>
<td>CN (100% impaired)</td>
<td>CN (100% impaired) 3234 steps/day</td>
<td>CM (80% - 100% impaired) 2607 steps/day</td>
</tr>
</tbody>
</table>

Severity modifier interpretation is not intuitive.
Community Walking

- **Subject 1**
  - Initial: 0.21m/s, BBS=26, CN
  - Visit 10: 0.32m/s, BBS=31, CN
  - Discharge: 0.81m/s, BBS=55, CK

- **Subject 2**
  - Initial: 0.78m/s, BBS=55, CJ
  - Discharge: 0.28m/s, BBS=30, CN

- **Subject 3**
  - Initial: 0.43m/s, BBS=27, CN
  - Visit 20: 0.34m/s, BBS=31, CN
  - Discharge: 0.45m/s, BBS=42, CM

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G-code Severity Modifier
Walking Impairment

- Clinic in Potsdam, New York
  - 100% impairment must mean walking below the ability of non-impaired adults
  - Patient demonstrating 4 weeks at ~5,000 steps per day was still considered 100% impaired (max walking speed = 0.34 m/s (0.76 mi/hr)).

- Clinic in Chicago, Illinois
  - 100% impairment means not able to take one step without assistance of another person.
How to Bridge the Gap

- Objective measures give transparency to debate G-code severity modifier interpretation
  - What does 100% walking impairment mean?

- Using clinical capacity measures and community ambulation are important in the severity selection.

- Methods are needed that provide consistent interpretation of G-code Severity Modifiers.
Severity Modifier
Interpretation

- What can be used to improve consistency of interpretation?
  - Perry et al. 1995 – Classification of Walking [Ability] in Stroke Population
Six-Tier Classification

1. Physiological walker – CN 100% impairment
   - Walks for exercise only either at home or in parallel bars during physical therapy
   - Uses a wheelchair for both bathroom and bedroom use

2. Limited household walker – CM 80 – 100% impairment
   - Relies on walking to some extent for home activities
   - Requires assistance for some walking activities, uses a wheelchair, or is unable to perform others
   - If a wheelchair is needed for either bedroom or bathroom mobility, the other activity can be performed with supervision only
Six-Tier Classification

3. Unlimited household walker – CL 60 – 80% impairment
   • **Able to use walking for all household activities without any reliance on a wheelchair**
   • Can perform bathroom mobility without assistance (may need supervision)
   • If supervision is required for both bedroom and bathroom mobility, then can enter/exit the home without a wheelchair.
   • Encounters difficulty with stairs and uneven terrain
   • **Needs at least supervision for both entering/Exiting the house and managing curbs**
Six-Tier Classification

4. Most-limited community walker – CK 40 – 60% impairment

- Independent (without supervision) in either entering/exiting the home or managing curbs
- Can manage both entering/exiting the home and curbs without assistance
- Requires some assistance in both local store and uncrowded shopping centers
Six-Tier Classification

5. Least-limited community walker – CJ 20 – 40% impairment

- Can perform all moderate community activities without use of the wheelchair
- **Needs at least some assistance with a crowded shopping center**
- Can perform without assistance (but may need supervision) in one of the following: local stores or uncrowded shopping centers
Six-Tier Classification

6. Community walker – CI 1 – 20% impairment
   • Independent in all home and moderate community activities
   • Can accept uneven terrain
   • Can negotiate a crowded shopping center with supervision only
CH – 0% Impaired, Limited, or Restricted

7. Unlimited Community walker
   - Can negotiate a crowded shopping center without supervision
   - Walking characteristics similar to age-matched healthy people
# Functional K-Level Assessment

Table 1 - The MFCL definitions for each K-level.

<table>
<thead>
<tr>
<th>K-level</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>K-level 0</td>
<td>Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance quality of life or mobility.</td>
</tr>
<tr>
<td>K-level 1</td>
<td>Has the ability or potential to use a prosthesis for transfers or ambulation in level surfaces at a fixed cadence. Typical of the limited and unlimited household ambulator.</td>
</tr>
<tr>
<td>K-level 2</td>
<td>Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.</td>
</tr>
<tr>
<td>K-level 3</td>
<td>Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.</td>
</tr>
<tr>
<td>K-level 4</td>
<td>Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.</td>
</tr>
</tbody>
</table>
Functional K-Level Assessment

- No gold standard for objectively defining K-levels
- Difficult to understanding how each clinician uses his/her judgment to classify a patient’s K-level.
- Patient self-report of activity adds another layer of uncertainty¹

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Case Series

- Developing a “Reference K-Level” for assessing validity of common measures to classify K-level objectively.
Preliminary Thresholds for Consistence Interpretation

<table>
<thead>
<tr>
<th>K-Level</th>
<th>Steps per Day¹</th>
<th>Peak Steps per Day</th>
<th>Fastest 1-Min Cadence²</th>
</tr>
</thead>
<tbody>
<tr>
<td>K1</td>
<td>&lt; 100</td>
<td>NA</td>
<td>&lt; 60 steps/min</td>
</tr>
<tr>
<td>K2</td>
<td>≥100</td>
<td>NA</td>
<td>≥ 60 steps/min</td>
</tr>
<tr>
<td>K3</td>
<td>≥ 2500</td>
<td>2 days ≥ 5000 Or 1 day ≥ 7500</td>
<td>≥ 80 steps/min</td>
</tr>
<tr>
<td>K4</td>
<td>≥ 5000</td>
<td>2 days ≥ 7500 Or 1 day ≥ 10000</td>
<td>≥ 100 steps/min</td>
</tr>
</tbody>
</table>

Not to take place of clinical judgment. Only contribute and add transparency.

Subject 1 – K1
Subject 2 – K3
Subject 3 – K4
## Results

<table>
<thead>
<tr>
<th>Subjects (Clinical Judgment)</th>
<th>Average Steps per Day</th>
<th>Peak Steps per Day</th>
<th>Fastest 1-min Cadence (steps/min)</th>
<th>K-Level Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject 1 (K1)</td>
<td>184 ± 108</td>
<td>1) 354 2) 272</td>
<td>50</td>
<td>K1 to K2</td>
</tr>
<tr>
<td>Subject 2 (K3)</td>
<td>3695 ± 1865</td>
<td>1) 5998 2) 5968</td>
<td>96</td>
<td>K3</td>
</tr>
<tr>
<td>Subject 3 (K4)</td>
<td>7009 ± 3959</td>
<td>1) 14028 2) 12788</td>
<td>114</td>
<td>K4</td>
</tr>
</tbody>
</table>
Next Steps

• Improve “Reference K-Level”

• Add GPS to enrich understanding of ambulation outside of the home and barrier traversed
# GPS

<table>
<thead>
<tr>
<th>K-level</th>
<th>Ambulation in Community</th>
<th>Environmental Barriers (curbs, stairs, dirt trails, and/or hills)</th>
</tr>
</thead>
<tbody>
<tr>
<td>K1</td>
<td>&lt; 14 steps per community outing</td>
<td>None</td>
</tr>
<tr>
<td>K2</td>
<td>≥ 14 steps per community outing</td>
<td>≥ 1 environmental barrier</td>
</tr>
<tr>
<td>K3</td>
<td>&gt; 1000 steps per community outing</td>
<td>≥ 1 environmental barrier</td>
</tr>
<tr>
<td>K4</td>
<td>&gt; 1000 steps per community outing</td>
<td>≥ 1 environmental barrier</td>
</tr>
</tbody>
</table>
Points to Consider

- A transparent reference K-level is needed to validate clinically feasible functional measures for K-level differentiation.
  - Previous studies use clinician expertise without explanation

- Transparency facilitates healthy debate on what each K-level represents

- A better understanding of patient function can only improve our ability to serve the patient
# Study Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical K-level determined</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6MWT</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMPPRO</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply StepWatch &amp; GPS device</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Download / Analysis StepWatch &amp; GPS data</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Reference K-level determined</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Retrieve Galileo K-level</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Remove GPS device</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Apply StepWatch</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Remove Stepwatch</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Analysis

- Results of Galileo FLAS, 6MWT, and AMPPRO will be grouped based on the reference K-Level category
  - Use paired t-test to differentiate (adjust for multiple comparisons)
    - K1 to K2
    - K2 to K3
    - K3 to K4
- ROC analysis: sensitivity and specificity
  - AMPPRO
  - Galileo FLAS
  - Medical record K-level without use of community data
Thank you for your Time

- VA Team and University of Utah Team
  - Bradeigh Godfrey, DO (PI)
  - Jeffery Berdan, DO (investigator)
  - Robert Engelen, DO (investigator)
  - Bryson Garbett, MSIV (investigator)
  - Teri Chou, PhD (investigator)

- Clarkson University
  - George Fulk, PhD, PT (PI)
  - Teri Chou, PhD (investigator)