Translating tracked activity into outcomes, interventions, and surveillance for peripheral artery disease...

Challenges, opportunities, and gaps

Matthew A. Corriere MD, MS
Frankel Professor of Cardiovascular Surgery
Department of Surgery, Section of Vascular Surgery
• AIM Specialty Health (Vascular expert advisory panel)
• I am a vascular surgeon
• I am not an advanced coder a computer scientist
• Data from recent randomized crossover study will be presented, but group-wise outcomes by intervention will be omitted
  – (presented yesterday)
<table>
<thead>
<tr>
<th>Day</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wed</td>
<td>4,245</td>
</tr>
<tr>
<td>Tue</td>
<td>3,110</td>
</tr>
<tr>
<td>Mon</td>
<td>3,177</td>
</tr>
<tr>
<td>Sun</td>
<td>2,837</td>
</tr>
<tr>
<td><strong>Total This Week</strong></td>
<td><strong>14,418 steps</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sat</td>
<td>5,283</td>
</tr>
<tr>
<td>Fri</td>
<td>3,221</td>
</tr>
<tr>
<td>3/14</td>
<td>2,819</td>
</tr>
<tr>
<td>3/13</td>
<td>2,277</td>
</tr>
<tr>
<td>3/12</td>
<td>3,088</td>
</tr>
<tr>
<td>3/11</td>
<td>2,142</td>
</tr>
<tr>
<td>3/10</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Last Week</strong></td>
<td><strong>18,830 steps</strong></td>
</tr>
</tbody>
</table>

**Mar 3 – 9**

| | | | | |
Activity Tracking

- Embraced by consumers for wellness and physical fitness
- Not widely adopted for disease or treatment outcome assessment
- Research data collection concentrated on devices designed for researchers, not consumers or patients
Structured Exercise Programs for PAD: Definitions

Supervised exercise program (COR I, LOE A)
- Program takes place in a hospital or outpatient facility.
- Program uses intermittent walking exercise as the treatment modality.
- Program can be standalone or within a cardiac rehabilitation program.
- Program is directly supervised by qualified healthcare provider(s).
- Training is performed for a minimum of 30–45 min/session; sessions are performed at least 3 times/wk for a minimum of 12 wk.
- Training involves intermittent bouts of walking to moderate-to-maximum claudication, alternating with periods of rest.
- Warm-up and cool-down periods precede and follow each session of walking.

Structured community- or home-based exercise program (COR IIa, LOE A)
- Program takes place in the personal setting of the patient rather than in a clinical setting.
- Program is self-directed with guidance of healthcare providers.
- Healthcare providers prescribe an exercise regimen similar to that of a supervised program.
- Patient counseling ensures understanding of how to begin and maintain the program and how to progress the difficulty of the walking (by increasing distance or speed).
- Program may incorporate behavioral change techniques, such as health coaching or use of activity monitors.
Ways to track walking for clinical research

- **Devices**
  - Treadmill
  - Digital video (GoPro)
  - Tablet
  - Smartphone
  - Wearable
    - Misfit
    - Fitbit
    - Pedometer
  - Paper and Pencil
  - Stopwatch
  - Telephone

- **Formats**
  - Analog
  - Web-based
    - Redcap
    - Qualtrics
    - Google Forms
    - Sawtooth
    - Custom
  - EMR
  - Hybrid
Low Tech

**Pros**
- Inexpensive
- Little/no equipment
- In-person or at-home
- Physical copy
- Electronic storage possible

**Cons**
- Error prone
- Cannot force formatting
- Requires manual recoding for database entry/analysis
- Requires postage for remote completion
- Physical loss=data loss
- Need to physically meet the patient or get their address
High tech

- **Pros**
  - Remote completion
  - Repeat completion
  - Can force data formats
  - Metadata available
  - Real time data capture analysis
  - Adaptable
  - Conducive to gamification
  - No postage needed

- **Cons**
  - Need a device
  - Need access to internet
  - Battery dependent
  - Potential device loss
  - Opportunities for technical failure
  - Lots of decisions to make
  - Training may be needed
  - Regulatory considerations
  - Availability
## Smartphone vs. wearable head-to-head

<table>
<thead>
<tr>
<th>Pros:</th>
<th>Cons:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seldom forgotten</td>
<td>Expensive</td>
</tr>
<tr>
<td>Interactive</td>
<td>Battery</td>
</tr>
<tr>
<td>Multimedia capability</td>
<td>Sometimes forgotten</td>
</tr>
<tr>
<td>Tailored notifications</td>
<td>Battery</td>
</tr>
<tr>
<td></td>
<td>Less expensive</td>
</tr>
</tbody>
</table>

|                      | Less interactive            |
|                      | Potential data loss          |
|                      | Not multimedia               |
Is this a medical device?

FDA-Cleared, Medical-Grade Wearables

Our medical-grade wearable solutions have been deployed in dozens of pharmaceutical drug trials to capture real-world patient measures relating to physical activity, mobility, and sleep behavior. ActiGraph is ISO-13485:2016 certified, and our activity monitors are FDA 510(k) cleared Class II medical devices in the U.S. and adhere to regulatory standards worldwide.

Learn more ›
CENTREPOINT Insight Watch
Medical-Grade Actigraphy Monitoring, Redefined

The compact and stylish CentrePoint Insight Watch captures and records continuous high-resolution raw acceleration data to provide objective, real-world physical activity, mobility, and sleep measures, in near real time.

U.S. federal law restricts this device to sale by or on the order of a physician.
Walking outcome, intervention, or both?

- Tracking walking is different for patients with PAD
  - Walking *causes symptoms*
  - Walking exercise *is a treatment* for the disease
  - Walking (and walking impairment) are *outcomes*
Challenges: Analysis and Reporting
Traditional walking analysis and reporting

- Patient self-report
  - Verbal
    - Reps
    - Distance
  - Written
- Tests done at medical facility
  - Treadmill walking
  - 6 Minute Walk Test
## Traditional walking assessments

<table>
<thead>
<tr>
<th>Test</th>
<th>Authors (Year)</th>
<th>Measurement</th>
<th>Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graded treadmill test</td>
<td>Hiatt et al (1988), Hiatt et al (2014)</td>
<td>Claudication onset time/distance; peak walking time/distance</td>
<td>3-min stages 2 mph/0% grade, increase grade by 3.5%</td>
</tr>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Gardner et al (1991)</td>
<td>Claudication onset time/distance; peak walking time/distance</td>
<td>2-min stages 2 mph/0% grade increase grade by 2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patients unable to walk at 2 mph start at 0.5 mph and increase walking speed by 0.5 mph every 2 min until 2 mph, after which the regular Gardner et al protocol is followed</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Treat-Jacobson et al (2009)</td>
<td>Claudication onset time/distance; peak walking time/distance</td>
<td>3-min stages 2 mph/0% grade, increase grade by 3.5% until 10.5% and then increase speed by 0.5 mph keeping 10.5% grade</td>
</tr>
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<td></td>
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<tr>
<td>6-min walk test</td>
<td>Montgomery and Gardner (1998), McDermott et al (2014)</td>
<td>Distance walked over ground in 6 min</td>
<td>A 100-ft corridor is needed; a shorter (50 or 75 ft) corridor is acceptable if necessary, but validation of this test in patients with PAD has been done with a 100-ft corridor Patients walk back and forth for 6 min after scripted instructions that advise them to walk as far as they can in 6 min</td>
</tr>
</tbody>
</table>
On your mark...6MWT
Tracked walking activity is different...!

- Patient without an audience, appointment, or monitor chooses:
  - Where
  - When
  - Frequency/Intervals
  - Duration
  - Distance
  - Speed

- Outcomes
  - Intervals
  - Steps
  - Duration
  - Speed
  - Cadence

- Sampling can span longer intervals of time
The Magic of 10,000 Steps

https://blog.fitbit.com/the-magic-of-10000-steps/
10,000 steps

- The Japanese first started using the 10,000 steps a day number, as part of a marketing campaign (!) to help sell pedometers.
- Since that initial campaign however, medical experts around the world have agreed that 10,000 is a healthy number for which to aim.
- 10,000 steps a day is a rough equivalent to the Surgeon General’s recommendation to accumulate 30 minutes of activity most days of the week.

How much do patients with PAD walk in a day?
Is 10,000 steps an achievable goal for your average PAD patient?

https://blog.fitbit.com/the-magic-of-10000-steps/
The University of Michigan Cardiovascular Center seeks PAD patients for a research study

**Project VOICE:** Vascular Outcomes Improvement through Collection of PatiEnt Reported Data

Principal Investigator: Matthew A. Corriere, MD, MS
IRB Approval: HUM00142561

**Time Requirements:** 9 weeks of active participation, including 2-3 research visits. Followed by a 6 month post-study survey.

**Compensation:** Complimentary Fitbit Flex 2

You may be eligible to participate if you:
- Are 21 years or older
- Have a diagnosis of Peripheral Arterial Disease with symptoms of claudication (i.e. thigh and/or calf pain while walking)
- Have home WiFi access (for use of Fitbit and study iPad)
- Study visits will take place at the University of Michigan Cardiovascular Center

For more information, please contact the study coordinator at (734) 764-4679

Wake Forest School of Medicine

Michigan Medicine

UNIVERSITY OF MICHIGAN
Exploring tracked walking activity over a month or longer...

- >1800 participant days with tracked walking
- 27,922 walks
  - ~35 daily walking intervals per participant

- Only 324 responses to claudication question within digital health platform
  - “Have you walked until you experienced leg pain within the last 2 days?”
Walks categorized by interval (minutes)
Intervals dichotomized by 6-minute cut-point

N = 25041
N = 2882

<6 minutes  > 6 minutes
Challenge: Scale (one size doesn’t fit all)

Participant 16025574
• 178 days with tracked walking
• 1990 intervals
• 6,655 steps per day
• 10.7 minutes per interval
• 0.33 miles per interval
• 1.1 mph

Participant 16439922
• 539 days with tracked walking
• 8,991 intervals
• 4,486 steps per day
• 4.4 minutes per interval
• 0.1 miles per interval
• 0.8 mph
Challenge: Feasibility (tracking isn’t for all)

Participant 19889858
- 1 day with tracked walking
- 14 intervals
- 2400 steps per day
- 3.3 minutes per interval
- 0.05 miles per interval
- 0.7 mph
Summary and Conclusions
(Where do we go from here?)
Decisions to make for walking activity study

- Device- Phone versus wearable?
- Outcome, intervention, or both?
  - Start with a hypothesis
- Control intervention?
- Instruct patients clearly and consistently
  - Wear continuously versus only during walking.
  - While sleeping?
  - Can it get wet?
- Plan on how to control for “noise”
  - Minimum cadence, distance, duration
  - Patient report (if you can get it)
- Think about how to identify symptoms
  - Text message (passive or active)
- Prepare for what to do when technical issues arise
  - Interface crashes
  - Device loss
  - Pursue “radio silence” actively
Barriers that must be overcome

• Appropriate metrics
  – Traditional metrics modeled through activity tracking
  – New endpoints spanning longer intervals of continuous data collection
  – Tailoring to the individual patient

• Identifying the right (and wrong) patient

• Clinicians need to learn how to interpret this information
Summary

- Activity tracking expands our ability to evaluate walking
- Sometimes less is more, depending on the patient and data
- Persistence, patience, and flexibility are valuable
- Ask around to avoid mistakes discovered by others
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