Wearables and Application Solutions for Parkinson’s Disease: An Overview

Joseph P. Giuffrida, PhD
President & Principal Investigator
<table>
<thead>
<tr>
<th>Topic</th>
<th>Duration</th>
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<tbody>
<tr>
<td>Parkinson’s Disease: Challenges and Opportunities</td>
<td>5 min</td>
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<tr>
<td>Wearable Technology Space &amp; Big Data</td>
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<tr>
<td>Wearables Road Map</td>
<td>10 min</td>
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<tr>
<td>Clinical Validation of Wearables</td>
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<td>Targeted Applications within Targeted Applications</td>
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<td>Closing the Clinical Workflow</td>
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<td>Closing the Business Case</td>
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<td>Closing the Patient Perspective</td>
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<tr>
<td>Questions</td>
<td>5 min</td>
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Parkinson’s Disease: Challenges and Opportunities
Parkinson’s is Very Difficult

SYMPTOMS
- Tremor
- Dyskinesias
- Bradykinesia
- Rigidity
- Gait
- Non-Motor et al.

TREATMENTS
- Levodopa
- Rasagiline
- Duodopa
- DBS
- Exercise
- Neuroprotection?

DEMOGRAPHICS
- Over 60
- Growing Incidence
- Neurodegeneration
- Medicare
- VA
- Access to Care
Advanced Parkinson’s
Wearable Technology Space & Big Data
A Wearable Monitor for Movement Disorders in Parkinson's Disease

Statement of Problem

- Difficulty in monitoring patients remotely
- Need for continuous and real-time data collection

Description of Work to Date

- Developed a wearable sensor system
- Integrated with mobile devices for data transmission

Proposed Solution

- Wearable wireless sensor platform
- Continuous monitoring of gait, balance, and tremor

Proposed Work

- Expand the sensor system
- Incorporate machine learning algorithms

Europeans developing automatic monitoring for Parkinson’s

Sensitivity, Validity, and Reliable Outcome Measures

With over 100 universities and hospitals using this system worldwide, Mobility Lab™ is the most trusted sensor-based gait and balance system on the market.

Mobility Lab™ makes it easy for you to collect, analyze, and store outcome measures. Simply strap sensors on to your subject, instruct them to perform a standardized test, and when they are finished a report is automatically generated to compare against normative values. Beginning to end takes less than 5 minutes.

Postural Sway
- Sway Area
- Sway Speed
- Sway Distance
- Sway Path
- Center of Mass Motion

Postural Transitions
- Turn Duration
- Turn Speed

Upper Limb
- Arm Swing Speed
- Arm Range of Motion
- Arm Swing Variability
- Arm Swing Asymmetry
- Trunk Range of Motion

Lower Limb
- Gait Speed
- Stride Length

Adaptive auditory cuing system
Intel, Michael J. Fox and Big Data: Fighting Parkinson's Disease

By Virginia Backaitis | Aug 13, 2014

Featured Webinar: Why You Can't Afford Your Homegrown CMS

You've been there. In the doctor's office that is. You're not feeling well and you want to tell the doc all about it, but he wants to ask you questions like: How would you rate the pain on a scale of 1 to 10? When did this start? How long does it last? How would you rate your sleep 1 to 10?

You answer the questions with what is, at best, a guess. And the doctor makes assessments based upon your answers. But is what he calls an "8" the same thing you call an 8? And what does "sleeping well" actually mean? (And, yes, we know there's information like heart rate, blood pressure, lab work data to consider, but we're putting that aside for the moment.)

Now forget about yourself and think of a Parkinson's patient. Michael J. Fox or Intel's Andy Grove may be the ones we "know" best, unless there's someone in our personal lives who has been affected. Their doctors probably include some
Apple ResearchKit Turns iPhones Into Medical Diagnostic Devices

Posted Mar 9, 2015 by Josh Constine (@joshconstine)

3,737 SHARED

Medical research is plagued by small sample sizes and inconsistent data.

Parkinson mPower study app
By Sage Bionetworks, a Not-For-Profit Research Organization

Open iTunes to buy and download apps.

Description
How can we together better manage the symptoms of Parkinson disease?

Living with Parkinson disease means coping with symptoms that change daily. Yet these daily changes are not

Sage Bionetworks, a Not-For-Profit Research Organization Web Site » Parkinson mPower study
app Support »

iPhone Screenshot

Welcome to mPower
A Parkinson Disease Research Study
TURNS OUT, YOU CAN MEASURE DESIRE.
As part of an effort by Biogen idec to explore ways to use wearables with MS patients to help physicians quantify patient activity, it recently completed a study of 250 patients in collaboration with PatientsLikeMe, Naomi Fried, vice president of medical information and innovation at Biogen, referenced the study as part of a keynote presentation on digital health at the MidAmerica Healthcare Venture Forum in Chicago this week.

This is the problem that Biogen idec wants to solve. Impaired mobility affects more than 90 percent of people with MS, but the quantified assessment of their walking ability tends to be limited to clinical settings. Sensors could give physicians a more accurate assessment of the level of activity of these patients if they were willing to wear activity trackers between appointments.

The study of 250 people with MS sought an answer to the questions: Would patients actually use wearables as part of their daily lives and be willing to share that information with physicians?

The initial takeaway from the study is that it needs to use devices with more sophisticated sensors to quantify movement accurately and consistently. “Current technology is not built to provide consistent and validated data in MS. We are early in the process, but hope to have progress in the coming months,” according to an emailed statement about the study from Biogen. It also noted that it was encouraged by the “overwhelming positive participation” from MS patients. It took the response as a sign of encouragement as it explores using wearables in the future.
Agile Development: Systems, Algorithms, and Applications
Clinical Validation and Publications

**NIH Funding**
Over $25 Million in SBIR Funding
- National Institute of Health, US
- State of Ohio Commercialization Programs

**Collaborators**
Over 30 Collaborating Institutions
- Clinical Testing
- Research Collaboration
- Commercialization Partners
- Controlled Database with over 1,000 Patients

**Publications**
Over 75 Peer-Reviewed & Presentations
- Tremor, Bradykinesia & Dyskinesia Assessment
- Parkinson’s Telemedicine
- Deep Brain Stimulation Programming
- Clinical Trials
Quality and Regulatory

**FDA Clearance to Market**
- 510k Clearance to Market
- Intended Use
  - Kinesia is intended to monitor physical motion and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired.

**ISO, CE Mark, Health Canada, and TGA**
- ISO 13485:2003
- European Medical Device Directive 93/42/EEC
- Canadian Medical Device Conformity Assessment System
- EMERGO EUROPE: Authorized Agent

**Standards and Testing**
- Tested to IEC 60601 Standards
- Complies with FCC Part 15 Rules
- HIPAA Compliant
Wearables Roadmap
Context

Environment
Would I Use Wearables?
I Want My Doctor to See...
A Road Map for Parkinson’s Wearables

- What Symptoms are You Trying to Measure?
- Detection or Severity?
- Are Symptoms Voluntary or Involuntary?
- Context of Daily Life?
- Patient Environment and Confounding Factors?
Clinical Validation of Wearables
Clinical Validation Workflow

- Start with Controlled Environment
- Include Broad Range of Severities
- Compare Versus Traditional Gold Standard (Video)
- Demonstrate Correlations, Sensitivity, and Test-Retest Reliability
- Move to Unconstrained Environment and Tasks That Mask or Mimic Symptoms
Objective Quantification

Kinematic features are highly correlated to clinician MBRS scores

Published

Heldman, DA; Giuffrida, JP; Chen, R; Payne, M; Mazzella, F; Duker, AP; Sahay, A; Kim, SJ; Revilla, FJ; Espay, AJ. The Modified Bradykinesia Rating Scale for Parkinson’s disease: Reliability and Comparison with Kinematic Measures. Movement Disorders. 2011.
Mera, TO, Burack, MA, and Giuffrida, JP. “Quantitative Assessment of Levodopa Induced Dyskinesia Using Automated Motion Sensing Technology”, IEEE-EMBS Proceedings 2012.
Discrete Gait and Balance Assessment

Test-Retest Reliability: Intra Class Correlations

- Rest tremor
- Postural tremor
- Finger-tap speed
- Finger-tap amplitude
- Dyskinesia

Kinesia ICC
Clinicians ICC
Sensitivity: Minimum Detectable Changes, % of Full Scale

- Rest tremor
- Postural tremor
- Finger-tap speed
- Finger-tap amplitude
- Dyskinesia

Kinesia % MDC
Clinicians % MDC
Targeted Applications
Objective Sensor

Mobile App

Web Portal and Reports

Arms Extended

Time Remaining

15

Start

Kinesia™one
### Task-Based Motor Assessments

<table>
<thead>
<tr>
<th>Time</th>
<th>Rest Tremor</th>
<th>Postural Tremor</th>
<th>Finger Taps Speed</th>
<th>Finger Taps Amplitude</th>
<th>Finger Taps Rhythm</th>
<th>Dyskinesia</th>
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</table>

**Mean Fluctuation**
- Fluctuation: 0.4, 0.5, 0.5, 0.4, 0.5
- Mean: 1.3, 1.6, 1.4, 1.5, 1.6

**Increase dose by 200mg. Dose interval unchanged**

**Decrease dose by 100mg. Decrease dose interval by 2 hours**
Sensitivity of Data Versus Patient Burden
Continuous Tremor Assessment

Continuous Dyskinesia Assessment

- **Hair Brushing**: R = 0.88, RMSE = 0.35
- **Cutting Food**: R = 0.91, RMSE = 0.37
- **Drinking from a Cup**: R = 0.85, RMSE = 0.41
- **Bagging Groceries**: R = 0.91, RMSE = 0.37
- **Dressing**: R = 0.89, RMSE = 0.39

Wearable Sensors

Mobile App

Start Test to begin

Kinesia360

Start Test

My Diary

Symbol faces up

Next

Place both sensors on the charge pad and press next.

Start

Attach sensors to the wrist and ankle of your more affected side.

Tablet establishing connection

Sensors connected. Press Start
**Continuous Parkinson’s Monitoring**

### Summary Data

**Total Wear Time:** 9:52 HR

#### Tremor Summary Data

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<thead>
<tr>
<th>Time Rnd (TremorScore)</th>
<th>Time</th>
<th>Percent Wear Time</th>
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<td>Average (Tremor Score)</td>
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<td>Standard Dev (Tremor Score)</td>
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#### Mobility Data Summary

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<th>Percent Wear Time</th>
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<td>Total Time Rest</td>
<td>0:25</td>
<td>4.3</td>
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<tr>
<td>Total Time Active (Non-Gait)</td>
<td>2:14</td>
<td>22.7</td>
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<tr>
<td>Total Time Gait</td>
<td>7:12</td>
<td>73</td>
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<tr>
<td>Total Active Time</td>
<td>9:26</td>
<td>95.7</td>
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<tr>
<td>Wear Time Steps</td>
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<td>% Arm Swing During Gait</td>
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#### Dyskinesia Data Summary

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<th>Percent Wear Time</th>
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<td>84.5</td>
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<tr>
<td>Total Time DysDetect=1</td>
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<td>15.5</td>
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<td>78</td>
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<tr>
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#### Subject Reported Diary

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<th>Percent Day</th>
<th>Percent Waking Day</th>
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<td>OFF</td>
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<td>58.6</td>
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<td>ON</td>
<td>1:30</td>
<td>6.3</td>
<td>10.3</td>
</tr>
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<td>ON with Non-Troublesome Dys</td>
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<td>8.3</td>
<td>13.8</td>
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<td>ON with Troublesome Dys</td>
<td>2:30</td>
<td>10.4</td>
<td>17.2</td>
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</table>
Continuous Parkinson’s Monitoring
Patient Perspective

The sensor was easy to put on

The sensor is comfortable
Deep Brain Stimulation: Outpatient Programming
Objective

Sensor

Wireless Ring Sensor

DBS Programming Map

Amplitude Configuration
0 mA A

Stim Settings

Kinesia Tasks
Postural Tremor
Rest Tremor
Gait

Manual Tasks
Gait
Rigidity

Side Effects
None

End Session
Back

Amplitude (mA): 1.3
Scores: 5.3

Web Portal

UPDATE MAP
Set Threshold
Assign Final Settings

Kinesia Tasks
Postural Tremor
Rest Tremor
Bradykinesia
Patient Tags
Speed
Amplitude
Rhythm

Manual Tasks

Change the way you see PD

Kinesia ProView™
Closing The Clinical Workflow
Rest Tremor DBS Tuning Maps

Subject A

Subject B

Subject C

Amplitude (V)

Contact

Amplitude (V)

Contact

Amplitude (V)

Contact

Subject A

Subject B

Subject C

Contact

0 1 2 3

Contact

0 1 2 3

Contact

0 1 2 3

0 1 2 3
Potential Solution for DBS Programming

Can a Computerized Sensing System...

1. Find DBS Settings that Improve Motor Outcomes Compared to Clinicians?
2. Find DBS Settings that Provide Similar Motor Outcomes at Lower Amplitude?
3. Automatically Guide a Programming Session to Improve Motor Outcomes?
Post Hoc Comparisons to Clinicians

DBS Parameter Selection

Contact vs. Amplitude (V) for different contacts and amplitudes.
Optimization Algorithms for Tremor & Bradykinesia

Optimization of Therapeutic Benefit (n = 16)

- Total Motor Score
  - p < 0.0001

- Stimulation Amplitude (V)
  - p = 0.003

Post Hoc Comparisons to Clinicians
Optimization Algorithms for Tremor & Bradykinesia

Optimization of Therapeutic Benefit (n = 16)

- Total Motor Score
  - OFF
  - ON-Clinician
  - ON-Algorithm

Optimization of Battery Life (n = 6)

- Stimulation Amplitude (V)
  - OFF
  - ON-Clinician
  - ON-Algorithm

Post Hoc Comparisons to Clinicians
### Algorithm Settings

<table>
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<tr>
<th>Subject</th>
<th>Contact / Polarity</th>
<th>Amplitude (mA)</th>
<th>Pulse Width (μs)</th>
<th>Frequency (Hz)</th>
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*p = 0.01
Closing The Business Case
Reimbursement
Reimbursement

Delivery Models

DARN IT! - WE'RE NOT IN ANYBODY'S DELIVERY AREA!
Reimbursement

Delivery Models

Business Models

EHR Integration

“All this talk about EMRs and EHRs is just a fad - like the Internet thing.”
Closing The Patient Perspective
I, Myself, Want to See...
Wearables are Important Because...
<table>
<thead>
<tr>
<th>Site</th>
<th>Location</th>
<th>Collaborator(s)</th>
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<tr>
<td>Baylor College of Medicine</td>
<td>Houston, TX</td>
<td>Dr. Joseph Jankovic</td>
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<tr>
<td>Cleveland Clinic</td>
<td>Cleveland, OH</td>
<td>Dr. Hubert Fernandez;</td>
<td>Bradykinesia Assessment</td>
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<td>Henry Ford Health System</td>
<td>Detroit, MI</td>
<td>Dr. Peter LeWitt</td>
<td>Quantitative PD Assessment, Neuroprotection</td>
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<td>Kent State University</td>
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<td>Dr. Espay, Dr. Revilla, and Dr. Duker</td>
<td>Quantitative Assessments, Home Monitoring, Deep Brain Stimulation</td>
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Questions?

Joseph P. Giuffrida, PhD
President & Principal Investigator

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216-619-5904