Test-Retest Reliability of a Parkinson’s Disease Monitoring System

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3. Henry Ford Health System
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Outcomes in Clinical Trials

- Clinical Assessments (UPDRS)
- Patient Diaries
- Motion Sensors

Sources of error
- Patient physical/mental condition
- Variations in testing procedure/interpretation
- Tester error
- Learning effects
Problems with Clinical Trials

- Clinical Assessments
  - Bias
  - Placebo effects
  - Limited Resolution
  - Poor intra- and inter-rater reliability

- Patient Diaries
  - Compliance
  - Recall bias
  - Poor self-assessment

- Motion Sensor Monitoring
  - Extraneous patient movements
  - Dyskinesias
  - Gravitational artifacts
  - Sensor noise
The required sample size changes as a function of the reliability of the outcome measure.

Sample size decreases as reliability increases.

Deep Brain Stimulation Tool

- Slowly modulate symptoms to simulate multiple disease states with relatively few subjects
Protocol

- 18 subjects
  - 13 male, 5 female
  - Age 44-76 years
- Tasks were performed three times each at eleven DBS stimulation amplitudes
- Videotaped for subsequent clinical rating

Rest Tremor  Postural Tremor  Finger taps
Assessment

• Unified Parkinson’s Disease Rating Scale (UPDRS)
  • Resting Tremor
  • Postural Tremor
  • Finger Tapping (Bradykinesia)

• Modified Bradykinesia Rating Scale (MBRS)
  • Finger Tapping Speed (Bradykinesia)
  • Finger Tapping Amplitude (Hypokinesia)
  • Finger Tapping Rhythm (Dysrhythmia)

• Kinesia six degree-of-freedom motion sensor
  • 0 – 4 score based on motion data
DBS Modulation

A. Finger Tapping UPDRS

B. Finger Tapping Speed

C. Finger Tapping Amplitude

D. Finger Tapping Speed

E. Finger Tapping Amplitude
Intraclass Correlation (ICC)

![Graph showing intraclass correlation (ICC) values for various tremor types.](image)

- **Kinesia** compared to **Clinicians**

- **Resting Tremor**
- **Postural Tremor**
- **Finger-Tap Speed**
- **Finger-Tap Amplitude**
- **Finger-Tap Rhythm**

- * p<0.01
- ** p<0.001
Minimal Detectable Change (MDC)

** p<0.01

** p<0.001
Sample Size Implications

<table>
<thead>
<tr>
<th></th>
<th>Clinician ICC</th>
<th>Kinesia ICC</th>
<th>Percent fewer subjects</th>
<th>Number of subjects based on Clinician</th>
<th>Number of subjects based on Kinesia</th>
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<tbody>
<tr>
<td>Rest Tremor</td>
<td>0.63</td>
<td>0.68</td>
<td>7.3</td>
<td>100</td>
<td>93</td>
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<tr>
<td>Postural Tremor</td>
<td>0.68</td>
<td>0.71</td>
<td>4.2</td>
<td>100</td>
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<tr>
<td>Speed</td>
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<td>0.94</td>
<td>38.3</td>
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<td>Amplitude</td>
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<td>0.94</td>
<td>26.6</td>
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<td>Rhythm</td>
<td>0.48</td>
<td>0.63</td>
<td>23.8</td>
<td>100</td>
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</table>
Conclusions

- Motion sensors can provide increased sensitivity and test-retest reliability over clinical assessments.
- The increased sensitivity and reliability afforded by motion sensors over clinical assessments can decrease the number of subjects, shorten the duration, and lower the costs required to detect significant outcomes in clinical trials.
- Home-based motion sensor monitoring can improve temporal resolution in addition to score resolution.
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