Financial Disclosure

I have no financial interests or relationships to disclose.
Web versus Paper
Ophthalmic PRO Assessments

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Patient-reported outcomes (PROs)

Increasingly important in clinical studies

Assessment of safety

Support of specific medical claims
Modes of administration

Paper

Electronic
Potential advantage of electronic PROs for conditions affecting vision

Images of visual aberrations

Adjusting display and formatting
Pilot
FDA/NEI Collaborative Study

Why?

Decrease resources (time, $) associated with administration of PRO instruments and

Facilitate use in device trials
Existing QoL instruments used

NEI-VFQ
  Driving
OSDI
  Symptoms
NEI-RECQ
  Near vision, Far vision, Glare, Clarity of vision,
  Symptoms, Worry, Satisfaction with correction
Study description

Web vs paper administration

Identical questions, same order

Participants completed both versions
Randomized crossover design

Subjects randomized to

Paper first, Web second (P₁)
or to
Web first, Paper second (P₂)
Analysis of agreement

![Graph showing correlation between paper score and electronic score]
Analysis of agreement

Bland-Altman approach
## Analysis of agreement

<table>
<thead>
<tr>
<th>Participant</th>
<th>Paper score</th>
<th>Electronic score</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>P₁</td>
<td>E₁</td>
<td>(P₁-E₁) = D₁</td>
</tr>
<tr>
<td>2</td>
<td>P₂</td>
<td>E₂</td>
<td>(P₂-E₂) = D₂</td>
</tr>
<tr>
<td>⋮</td>
<td>⋮</td>
<td>⋮</td>
<td>⋮</td>
</tr>
<tr>
<td>n</td>
<td>Pₙ</td>
<td>Eₙ</td>
<td>(Pₙ-Eₙ) = Dₙ</td>
</tr>
</tbody>
</table>

Mean P  Mean E  Mean D

Bias
Analysis of agreement

Multivariable logistic regression models

Outcome: Close agreement (difference between paper and web is <10% of paper score)

\[
\frac{(\text{Paper} - \text{web})}{\text{Paper}} \leq 10\%
\]
Participants

OSD patients (n=68)
Schirmer 1 ≤ 10
or TBUT ≤ 10

Controls (n=50)
Sex-matched

Age ≥18 y, near VA 20/40 or better
Study population

Controls
- Black
- White
- Other

Cases
- Black
- White
- Other

Controls
- Female
- Male

Cases
- Female
- Male
Cases were significantly older than controls.
Comparing subscale scores

- RQL Clarity
- RQL Near
- RQL Far
- RQL Glare
- RQL Sympt
- RQL Worry
- RQL Satisf.
- VFQ Driving
- OSDI Sympt

[Bar chart showing comparison between Paper (yellow) and Web (green) for each subscale]
### Comparing agreement between subgroups

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Age ≥40 vs &lt;40 yrs</th>
<th>Male vs female sex</th>
<th>OSD vs controls</th>
<th>Paper 1st vs web 1st</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarity</td>
<td>0.22</td>
<td>0.03</td>
<td>0.006</td>
<td>0.89</td>
</tr>
<tr>
<td>Near Vision</td>
<td>0.49</td>
<td>0.94</td>
<td>0.35</td>
<td>0.58</td>
</tr>
<tr>
<td>Far Vision</td>
<td>0.47</td>
<td>0.44</td>
<td>0.49</td>
<td>0.26</td>
</tr>
<tr>
<td>Glare</td>
<td>0.29</td>
<td>0.48</td>
<td>0.70</td>
<td>0.20</td>
</tr>
<tr>
<td>Symptoms</td>
<td>0.05</td>
<td>0.09</td>
<td>0.78</td>
<td>0.11</td>
</tr>
<tr>
<td>Worry</td>
<td>0.14</td>
<td>0.62</td>
<td>0.26</td>
<td>0.54</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>0.78</td>
<td>0.89</td>
<td>0.73</td>
<td>0.49</td>
</tr>
<tr>
<td>Driving</td>
<td>0.20</td>
<td>0.04</td>
<td>0.37</td>
<td>0.49</td>
</tr>
<tr>
<td>OSDI</td>
<td>0.04</td>
<td>0.72</td>
<td>0.56</td>
<td>0.98</td>
</tr>
</tbody>
</table>

*P values testing whether bias differed between groups*
Prediction of close agreement - associations with age > 40

Multivariable–adjusted analyses
Prediction of close agreement - associations with OSD (vs control)

Multivariable-adjusted analyses
Prediction of close agreement - associations with sex (male vs female)

- RQL Clarity
- RQL Near
- RQL Far
- RQL Glare
- RQL Sympt
- RQL Worry
- RQL Satisf
- VFQ Driving
- OSDI Sympt

Multivariable-adjusted analyses
Conclusion

No evidence that agreement was affected by sex

Less agreement if over age 40 (RQL Far Vision) or if had OSD (RQL Clarity of Vision) – but trends were not consistent over other subscales
Conclusion

Average score differences between paper and web versions were between 0.2 and 2.3 points – not clinically significant.

No evidence of clinically significant difference between paper and web scores for any subscales examined.
Summary

One of the first to compare web-based and paper-based versions of previously psychometrically evaluated questionnaires used in ophthalmology.
Validates computer administration of ophthalmic PRO instruments

Adds to the body of knowledge in the field of PROs