Importance of Objective Measurements of Accommodation

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Disclosure

• No Financial Relationships to Disclose
Definition of an “Accommodating IOL”

• An accommodating IOL is one that “… is designed to provide vision over a continuous range of distances by affecting a change in the vergence power of the eye resulting from the implant design that changes eye optical power or implant position in response to a stimulus.”*

* Draft ANSI standard for Accommodating Intraocular Lenses; Z80.29 Rev 019
Accommodating IOL (AIOL) Standards

- ANSI Draft Z80.29 – begun 2004
- ISO Draft 11979-7 - being revised to add AIOL
- ANSI & ISO Common Elements
  - Study design – controlled study (AIOL vs. monofocal)
  - Sample size – AIOL (min 300 eyes); Control (min 122 eyes)
  - Study Duration – 1 – 3 years
  - Performance criteria
    - ISO Safety and Performance Endpoints
    - Objective amplitude of accommodation:
      - Demonstrate avg ≥ ~1 D obj. accommodation in substudy
      - Assess stability of accommodation across study visits
    - Subjective amplitude of accommodation is optional
AIOL Standards (cont’d)

• Objective amplitude of accommodation
  – Optical methods (ISO)
  – Optical or Biometric methods (ANSI)
  – Assessed in substudy group (100 test; 50 control)
    • Minimize bias in selection of sub-group
Objective Accommodation Methods

- Optical Methods [ISO & ANSI]
  - Autorefractors
  - Wavefront aberrometry

- Biometric Methods [ANSI only]
  - Ultrasound (A-scan or UBM)
  - Optical coherence tomography (OCT)
  - Scheimpflug photography

Grand-Seiko WR5100K Autorefractor with binocular open field of view.

TRACEY iTrace ray tracing aberrometer.
Subjective Accommodation Methods

• **“Push-down” method**: Start with near chart at nose and push it away until subject can read the small letters* clearly [ANSI]

  Near Point (small letters* first clear)

• **Defocus testing**: Start with distance chart blurred with -5 D over manifest; add plus in 0.50 D increments. Note acuity at every increment [ANSI and ISO]

• **Minimum add**: add plus lenses at near until best-corrected near acuity letters first clear [ANSI]

*1 line (0.1 logMAR) larger than BCNVA
## Subjective vs. Objective Measures

<table>
<thead>
<tr>
<th>Question</th>
<th>Method</th>
<th>Yes or No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confound pseudo-accommodation with true change in dioptic power?</td>
<td>Subjective</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Objective</td>
<td>No</td>
</tr>
<tr>
<td>Affected by non-specific factors (e.g., blur interpretation, squinting, multifocality)? [Leads to overestimate of amplitude]</td>
<td>Subjective</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Objective</td>
<td>No</td>
</tr>
<tr>
<td>Affected by incomplete masking of patients?</td>
<td>Subjective</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Objective</td>
<td>No</td>
</tr>
</tbody>
</table>
Limitations of Subjective Methods -- True vs. Pseudo-accommodation: Image Quality

- True Accommodation: Maximum image contrast (and MTF) independent of working distance
- Pseudo-accommodation: Potential for reduced contrast sensitivity
Limitations of Subjective Methods -- True vs. Pseudo-accommodation: Image Quality

- True Accommodation: Light largely focused at a single plane (point focus)
- Pseudo-accommodation: Potential for visual disturbances from light focused in a different plane (potential for halos)
Limitations of Subjective Methods -- True vs. Pseudo-accommodation: Multifocality

• Many accommodating IOL designs create potential for greater unintended multifocality than conventional designs
  – Moving single optics can easily tilt
  – Dual optics can be non-parallel
  – Optics that change curvature can do so in an asymmetric manner
Limitations of Subjective Methods—Confounding factors

• Influence “when subject can read letters clearly”
  – Blur interpretation / blur adaptation,*
  – Memorization of letters
  – Squinting and pupil size affect depth of focus
  – Ocular astigmatism and higher order aberrations can create some optical multifocality
  – Subject effort and expectation** ...

Limitations of Subjective Methods—Confounding factors

- Current lenses potentially generate only small amounts of accommodation (~1 D or less)
- This greatly magnifies the significance of confounding factors
Limitations of Subjective Methods – Difficulties in masking patients

• May augment importance of confounding factors
  – Surgeon is not masked
  – Technicians often unmask the treatment through remarks to subjects
    • Many lenses have distinctive appearance at slit lamp
    • Some lenses can cause symptoms unique to the lens design, e.g., internal reflections
Limitations of Subjective Methods

• Subjective measures overestimate amplitude of accommodation (AA) by ~2 or 3 D.
  – Example*: 15 subjects with monofocal IOL
    • Subjectively measured AA:
      – Defocus method: 2.00 D mean
      – Push-Down method: ~3.5 D mean.
    • Objectively measured AA:
      – WR-5100K Autorefractor: 0.11 D mean
      – i-Trace dynamic aberrometer: 0.10 D mean

Optical versus Biometric measurement methods

• Optical methods give direct dioptric measure of accommodation
  – Are optical measurements feasible on all types of accommodating IOLs?

• Biometric methods give direct measures of IOL shape and/or position. They can be used with most lenses but may not provide accurate diopters of accommodation
  – Will biometric methods give results comparable to optical methods?
Concerns with biometric measurement methods

• Typically provide measure of optic movement or perhaps optic change in curvature

• Measured changes must be converted to dioptric changes to be meaningful
  – How much movement corresponds to 1 diopter?
  – What about dual optic lenses or other more complex designs?
Concerns with Biometric measurement methods

• Potential biases
  – Technician dependent. Alignment and positioning may be critical
  – Tested eye is blocked from fixation & accommodative stimulation
  – Either contralateral eye fixation/accommodation, or pilocarpine (perhaps also cycloplegics) are required
    • pharmacologic agents may induce larger changes than physiologic stimulation*

Concerns with biometric measurement methods

Biometric methods

• Simple conversions are not accurate
• Conversions depend on many factors*
  – Corneal curvature
  – Anterior chamber depth
  – Axial length
  – IOL power

Concerns with biometric measurement methods

- Use of biometric methods means that dioptric values are based upon theoretical models

“In theory there is no difference between theory and practice. In practice there is.”

-- Yogi Berra
Summary – Importance of objective measures

• Subjective measures:
  – Cannot distinguish true accommodation from pseudo-accommodation
  – Are affected by confounding factors (e.g., blur interpretation, squinting, unintended IOL multifocality)
  – Are subject to unavoidable biases because of difficulties in patient masking
  – Overestimate the true amplitude of accommodation

• Objective measures do not suffer from any of these disadvantages
Importance of Objective Measurements of Accommodation

Thank you