Current Methods for Objectively Measuring Accommodation

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Parts of the talk

• **Background**
  - Near Triad
  - Lenticular accommodative changes
  - Stimulus considerations
  - Dynamic Accommodative Response

• **Instruments for Objectively Measuring Accommodation**
  - Refractive Power Measurement
  - Biometric Measurement

• **Draft ANSI and ISO requirements**

• **Summary**
Accommodative Process - Near Triad

Near viewing involves simultaneous convergence, accommodation and pupil constriction

Dynamic Measurement of the Near Triad with a PowerRefractor

Video courtesy Dr. Adrian Glasser
Accommodative Process – Lenticular Changes

- Natural accommodation involves the following major lenticular changes:

  ➢ **Refractive changes**
    - Increase in refractive power, manifesting as ‘myopic refractive change’
    - Increase in negative spherical aberration

  ➢ **Biometric changes**
    - Increase in surface curvatures
    - Increase in thickness, also leading to reduction in anterior chamber depth
    - Decrease in lens diameter

- These attributes can be targeted for objective accommodation measurement.

Accommodation Measurement – Stimulus Considerations

• Accommodation is mainly driven by blur and proximal awareness (i.e. convergence driven)

• Binocular, real space viewing would best stimulate accommodation

• **Key considerations:**
  - High contrast fixation target
  - Free space viewing is preferable over optically presented target
  - Appropriate instructions to encourage subject participation
  - Dim room lighting to maintain large pupil needed to obtain measurements with most instruments

‘Maltese Cross’ or letter charts are typically used as fixation targets
Dynamic Accommodative Response

- Accommodation typically exhibits fluctuations
- Variations in subject attention may increase the fluctuations
- Dynamic measurements would offer a greater insight into the accommodative response

Dynamic accommodation measurements with a PowerRefractor for different stimulus magnitudes
Measurement of Refractive Power Change

**Disclaimer:**
Only a few instruments as representative examples are provided.
Accommodation measured as *myopic* refractive change

- WAM-5500 & PowerRef3 autorefractors have binocular open field of view.
- Both offer dynamic measurement of refraction and pupil size
  - WAM5500: 5 Hz; PowerRefractor: 25 Hz

Proprietary measurement principles
- WAM5500: Ring projected through 2.3 mm pupil
- PowerRefractor: light distribution across full pupil diameter

- Reflections from IOLs and small pupils can impede measurements.
Wavefront Aberrometers

- Refraction derived from wavefront aberration measurements
- Monocular open field of view (iTrace aberrometer), internal fixation target (IRX3 aberrometers) or custom target system (WASCA)
  
+ Choice of pupil diameter and advanced analysis, for example, quantification of changes in spherical aberration

- IOL reflections and edge artifacts along with small pupils can impede measurements.

![iTrace aberrometer](http://www.traceytechnologies.com)

![IRX3 aberrometer](http://www.imagine-eyes.com)

![COAS or WASCA*](http://www.wfsci.com/)

* Not commercially available
Measurement of Biometric Change

Disclaimer:
Only a few instruments as representative examples are provided.
Ultrasound (A-scan or UBM)

- **A-scan** axial biometry or **Ultrasound Biomicroscopy** for 2-D imaging of the anterior segment of the eye.

- Anterior chamber depth (ACD), lens thickness measurements at 30-50 µm resolution.
  + Advantage of imaging behind the iris.
  - Fixation target presented to the contralateral non-measured eye as the ultrasound probe would occlude the measured eye.
  - Longer measurement duration, user skill level and subject discomfort could impact measurements.

- May not be suitable for aIOLs designed to cause changes in surface curvature.

**VuMAx (Sonomed)**
http://sonomedescalon.com

**Artemis-2 (Ultralink)**
http://www.arcscan.com

**OTI Scan (Optos)**
http://www.optos.com
Scheimpflug Photography

- Photographic technique with oblique viewing to obtain in-focus image of the anterior segment of the eye
  
  + Non-contact biometry technique
  
  - ACD measurement is available for accommodation evaluation.
  
  - Advanced analysis (e.g., lens surface curvature) would require correction of optical distortions inherent in the technique.
  
  - Internal fixation target (e.g., red blinking LED) may not adequately stimulate accommodation.

Scheimpflug Imaging Principle
http://medical-dictionary.thefreedictionary.com/Scheimpflug+photography

Pentacam (Oculus)
http://www.pentacam.com

Galilei (Ziemer)
http://www.ziemergroup.com
Optical Biometry

• Interferometry based techniques provide resolution within 10 μm.
• Non-contact biometry technique
• Axial biometry or full anterior segment imaging is available.
• ACD measurement is available for accommodation evaluation. Lenstar offers lens thickness measurement also.

- Internal fixation targets may not adequately stimulate accommodation.

IOLMaster (Zeiss)  
http://www.meditec.zeiss.com/

Lenstar (Haag-Streit)  
http://www.haag-streit-usa.com/

Visante OCT (Zeiss)  
http://www.meditec.zeiss.com/
Draft Guidances for Objective Accommodation

• ISO draft guidance
  ➢ Section 6.2.3 Additional requirements for accommodating IOLs
    o “…that the accommodating IOL provides an average of at least 1 D of objective accommodation”.
  ➢ Annex E (Informative) Clinical Tests
    o “At least one objective measure of accommodation by refractive change”
    o “A measurement of a biometric change with an AIOL does not directly provide an indication of the extent of the accommodative refractive change, but may be useful to validate the intended mode of action”

• ANSI draft guidance
  ➢ Section 10.2 Clinical investigation plan requires
    o “…at least one diopter of objectively measured accommodation”
  ➢ Annex B (informative) Clinical Investigation mentions
    o “…at least one diopter of objectively-measured accommodative amplitude at 4-6 months in the Phase I AIOL subject group over the control group”
Summary

• A variety of instruments for objectively measuring accommodation are available

• Measurement of accommodation in an aIOL in a clinical study requires careful test methodology to
  – Encourage subjective effort to accommodate including use of a fixation target that will best stimulate accommodation
  – Overcome challenges arising from small pupils, convergence and IOL reflections
  – Choosing an instrument that would readily provide information to best evaluate accommodative performance of a particular aIOL design

• Both ISO and ANSI draft guidance for accommodating IOLs mention one diopter of objectively measured accommodation to confirm aIOL effectiveness.