Current Methods for Objectively Measuring Accommodation

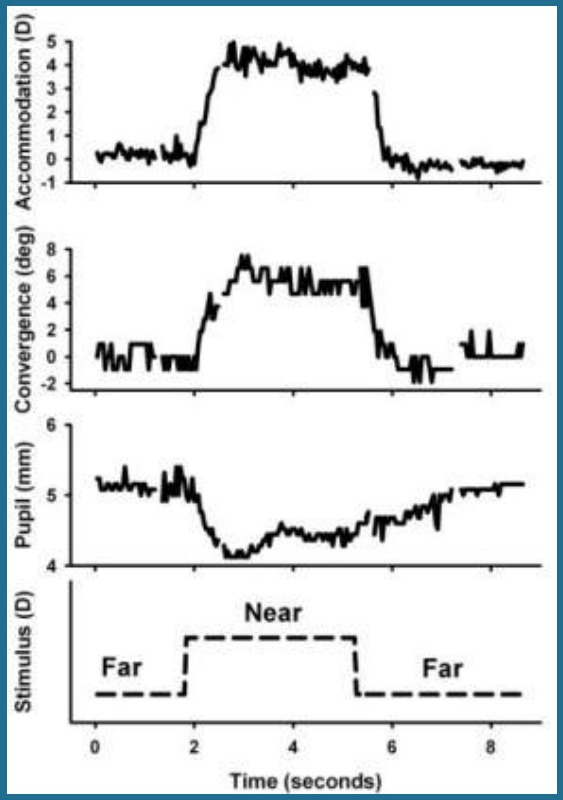
Sanjeev Kasthurirangan, PhD
Associate Research Fellow
Clinical R&D, Abbott Medical Optics

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.

"Charman WN. The eye in focus: accommodation and presbyopia. Clin Exp Optom. 2008 May;91(3):207-25"

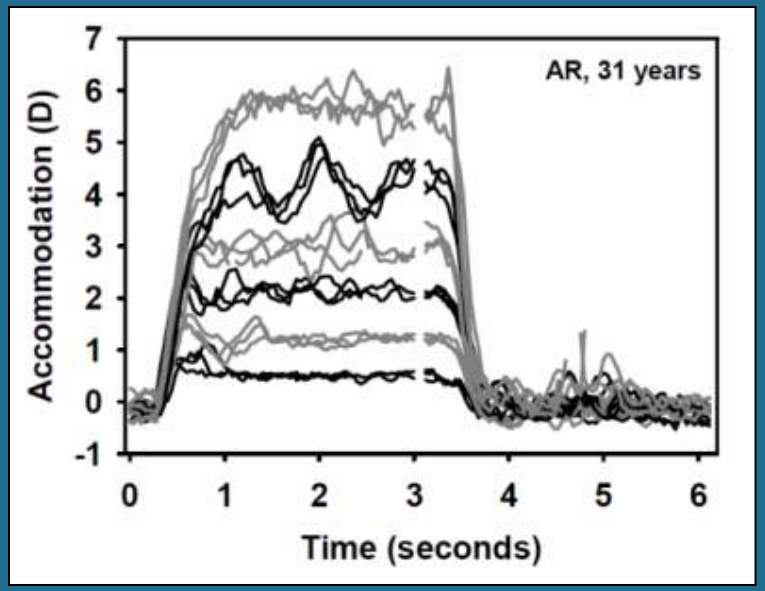
Accommodation Measurement – Stimulus Considerations

- 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.

Autorefractors

- ➢ 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
  - o WAM5500: 5 Hz; PowerRefractor: 25 Hz
- ➢ Proprietary measurement principles
  - o WAM5500: Ring projected through 2.3 mm pupil
  - o PowerRefractor: light distribution across full pupil diameter
- \- Reflections from IOLs and small pupils can impede measurements.

WAM-5500 (AIT Industries)
Green et al.J Rehabil Res Dev. 2010;47(3):183-99.

PowerRef3 (PlusOptix)
http://www.plusoptix.eu

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
http://www.traceytechnologies.com

IRX3
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)

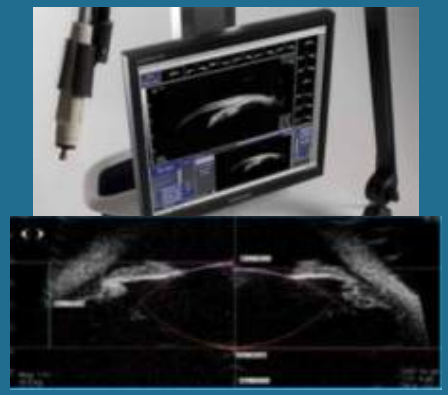
- **A-scan** axial biometry or **Ultrasound Biomicroscopy** for 2-D imaging of the anterior segment of the eye.
- Anterior chamber depth (ACD), lens thickness measurements at 30-50 µm resolution.

\+ Advantage of imaging behind the iris.

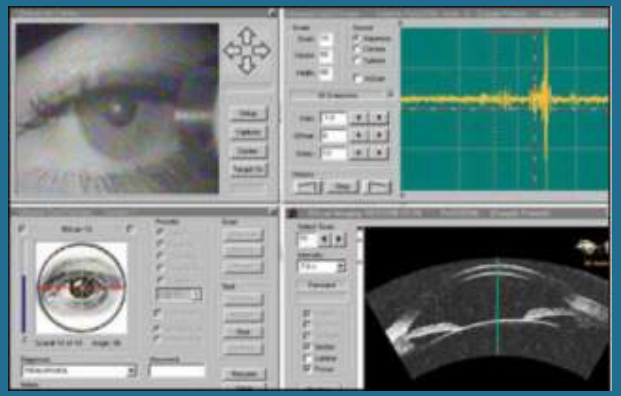
\- Fixation target presented to the contralateral non-measured eye as the ultrasound probe would occlude the measured eye.

\- 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

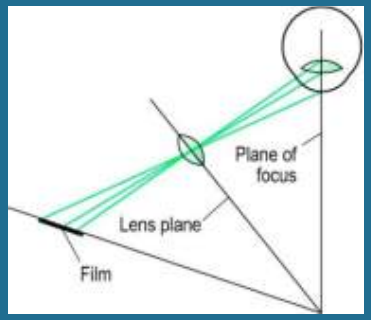


Artemis-2 (Ultralink)
http://www.arcscan.com

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 (eg: lens surface curvature) would require correction of optical distortions inherent in the technique.
- Internal fixation target (eg.: 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.