Disclosures Dr. Morgenstern

Chief Methodologist, AOA Evidence Based Optometry Committee

Co-Chair, US Centers for Medicare & Medicaid Services Ophthalmologic Disease Management Clinical Subcommittee

Subject Matter Expert, US Department of Defense/Veterans Affairs Vision Center of Excellence

Founder, PinkEye Health and Ocusolve

All information in this presentation is my opinion only based on peer reviewed information and was gained through the public domain.

I have no financial interests regarding anything discussed in this presentation.

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Man Started to Intensely Read
First Pair of Spectacles
Italy ~1250 A.D.

Invention of the Printing Press
Renaissance

Fast Forward to Today

Screen Time Recommendations
• For children younger than 18 months, avoid use of screen media other than video-chatting.
  Parents of children 18 to 24 months of age who want to introduce digital media should
  choose high-quality programming, and watch it with their children to help them understand
  what they're seeing.
• For children ages 2 to 5 years, limit screen use to 1 hour per day of high-quality programs.
  Parents should co-view media with children to help them understand what they are seeing
  and apply it to the world around them.
• For children ages 6 and older, place consistent limits on the time spent using media, and the
  types of media, and make sure media does not take the place of adequate sleep, physical
  activity and other behaviors essential to health.
• Designate media-free times together, such as dinner or driving, as well as media-free
  locations at home, such as bedrooms.
• Have ongoing communication about online citizenship and safety, including treating others
  with respect online and offline.

How Bad is the Myopia Epidemic?

<table>
<thead>
<tr>
<th>Year</th>
<th>Myopia</th>
<th>High Myopia</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>1.4 billion</td>
<td>163 million</td>
</tr>
<tr>
<td>2050</td>
<td>4.756 billion</td>
<td>938 million</td>
</tr>
</tbody>
</table>

Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050
Distribution of People Estimated to have Myopia 2000 and 2050


Wild West of Myopia Control

• Myopia onset was defined as -0.75 diopters (D) or more myopia in each principal meridian in the right eye measured by cycloplegic auto-refraction at any visit after baseline.

• Current SPHERICAL EQUIVALENT refractive error is the best single predictor of future myopia.

Predictor of Future Myopia

Pediatric Height and Weight Tables

Why Don't We Have This for Vision?

How Much Easier Would It Be to Explain Myopia Progression to the Parent?

Emmetropization of the Human Eye

What is the refraction of a 5 year old?

How Does The Eye Develop? Why Does it Matter?
Emmetropization

- The bulk of emmetropization occurs in early childhood and is largely complete by age 6.
- Therefore, refractive errors that exist at this age can be considered failures of emmetropization.
- The commonest refractive error at age 6 is hyperopia with both anisometropia and myopia being far less common at this age.
- Therefore if you have a myopic spherical equivalent in a child 5 and under, you have a very high likelihood and predictability factor that the child will be myopic in the future.

Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error (CLEERE Study Group)

- Mean spherical equivalent refraction: -4.12 D.
- 95.5% were myopic.
- Only 3.3% were emmetropic.
- 19.5% were highly myopic (> -6.00 D).

Prevalence of Myopia and High Myopia in 5,060 Chinese University Students in Shanghai

- Jing Sun, Jibo Zhou, Peiquan Zhao et al.
- Investigative Ophthalmology
- November 2012

Clinical Thinking

"Myopia Control is the same as glaucoma and keratoconus treatment… You don’t start Glaucoma treatment when you have end stage Glaucoma with 90% of the nerve lost or have hydrops and are ready for a corneal transplant"

— Morgenstern

Top Questions about Myopia Control

Who Needs It?

Who Should Offer It?

What Equipment do I Need?

Refer or Keep In-House?
What do the treatments do to the Eye?

- Goal is to slow or halt progressive axial length increase
- A pediatric individual with a progressive gain in axial length with corresponding increasing myopia absent of other ophthalmic pathology is the target demographic
- Currently Acceptable Treatment Methods
  - Ophthalmic Disease that Results in Myopia
    - Can result in progression myopia
  - Trauma
    - Can result in progression myopia
  - Ophthalmic Disease that Results in Retinal Degeneration
    - Can result in progression myopia
  - Maculopathy
    - Can result in progression myopia
  - Ectasia
    - Can result in progression myopia
  - Any pediatric patient with progressive myopia must have ophthalmologic pathology ruled out prior to the diagnosis of a refractive error as the cause

Visioneering Technologies NaturalVue® Parameters

- Multifocal
  - NaturalVue® Multifocal Contact Lenses from CooperVision
  - Designed to address the needs of the growing presbyopic population
  - Composed of Silicone Hydrogel with 30% water and available in all three powers
  - NaturalVue® Multifocal Contact Lenses are available in spherical +2.00D to +3.00D, aspheric +2.00D to +3.00D, and Toric +2.00D to +3.00D
  - NaturalVue® Multifocal Contact Lenses are available in 2 different 120° dipters on the back and front to allow the perfect fit and custom fit lens to fit the needs of each individual

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CE Mark

- The letters “CE” appear on many products traded in the extended Single Market in the European Economic Area (EEA)
- Signifies that products sold in the EEA have been assessed to meet high safety, health, and environmental protection requirements
- 1/1/2018 Visioeneering Technologies Achieves CE Mark for NaturalVue® Family of 1-Day Contact Lenses
- CE Mark includes an indication for VTR’s unique NaturalVue Multifocal (NVM) for myopic progression control (the control of progressive myopic refraction)
- CooperVision
- 2006 Cooper Multifocal CE mark for Myopia Management
- Distance Center

What Pathology Should I be Worried About?

Pathological increase in Globe Size Differential Diagnosis

Myopic Macular Degeneration

Global prevalence of visual impairment associated with myopic macular degeneration and temporal trends from 2000 through 2050: systematic review, meta-analysis and modelling

Timothy B. Prine, Monica Jones, Kevin S. Naidoo, Padma Sankaran, Thomas J Nuckels, Sult May Hui, Yien Yee Wong, Serge Resnikoff
Abstract

Background: We used systematic review and meta-analysis to identify and quantify evidence quantifying the relationship between axillary length, external ocular dimensions, and ocular tissue properties of the lamina cribrosa (LC). The aim of the study was to estimate the global prevalence of LC damage and its association with axillary length.

Methods: The systematic review and meta-analysis were conducted by searching PubMed, EMBASE, and Cochrane database, up to November 2016. Relevant studies were identified by searching titles and abstracts. Two authors independently assessed the eligibility and extracted data. Risk of bias was assessed using the Cochrane Handbook for Systematic Reviews of Interventions. All continuous outcomes were calculated as weighted mean difference (WMD) with 95% confidence interval (95% CI) and pooled effect using random effects model.

Results: We included 17 studies, comprising 771 participants. The mean difference in LC area between normal and axiale myopes was 2.1 mm². The mean difference in LC area between normal and total subjects was 2.1 mm², whereas the mean difference in normal and treated IOP subjects was 1.4 mm². The mean difference in normal and untreated IOP subjects was 1.8 mm².

Conclusion: The burden of LC damage and its association with axillary length is very significant and should be considered in future clinical trials. The findings of this systematic review and meta-analysis suggest that an axillary length ≥ 6.2 mm is associated with a higher prevalence and number of people with LC damage in each country in each decade.

Axial Length, Glaucoma and Lamina Cribosa

- In univariate and multivariate correlation analyses, a larger laminar pore area was significantly associated with longer axial length in normal and total subjects and untreated IOP in the glaucomatous subjects, whereas pore elongation index was not associated with any factors.

Advice on Eye Pediatric Myopia Control

- If you don’t have a Pentacam, Orbscan or Galilei make sure you get serial pachymetry measurements on your Myopia Control Candidates
- It is very easy to miss a pediatric keratoconus suspect
- OXL is now FDA approved and the standard of care for progressive keratoconus
- If you miss it and start Myopia Control you have possibly masked the disease
- Deformation of the cornea with contact lenses
- FDA Refractive Surgery Contact Lens Washout Protocol

Keratoconus

The Case of the GOTCHA! Myope

Axial Length, Glaucoma and Lamina Cribosa

- "In our univariate and multivariate correlation analyses, a larger laminar pore area was significantly associated with longer axial length in normal and total subjects and untreated IOP in the glaucomatous subjects, whereas pore elongation index was not associated with any factors."
FDA Refractive Surgery Contact Lens Washout Protocol

- If you wear contact lenses, it is a good idea to discontinue wearing them before your baseline evaluation.
- Contact lenses change the shape of your cornea for up to several weeks after you have stopped using them depending on the type of contact lenses you wear.
- Not wearing your contact lenses long enough for your cornea to assume its natural shape before surgery can have negative consequences.
- These consequences include inaccurate measurements and a poor surgical plan, resulting in poor vision after surgery. These measurements, which determine how much corneal tissue to remove, may need to be repeated at least a week after your initial evaluation and before surgery, just in case they have not changed, especially if you wear RGP or hard lenses.

Brien Holden Vision Institute Myopia Calculator

Evidence Based Control Rate
Controlling the Progression of Myopia: Panel 1: Selection of Trial Participants

- Refractive error range?
- How to determine refraction?
- Spherical equivalent or spherical component the best measure of myopia progression?
- Maximum astigmatism allowed to enroll?
- Maximum anisometropia allowed to enroll?

Controlling the Progression of Myopia: Panel 2: Study Design & Clinical Outcomes

- Control group?
- Primary effectiveness endpoint?
- Clinically meaningful difference for effectiveness endpoint?
- Minimum study duration?
- Stability of refractive outcomes/expected effect?
- What rate of microbial keratitis is acceptable for contact lens wear in the pediatric population?
Controlling the Progression of Myopia: Panel 3: Patient-Centric Factors & Outcomes

What patient-reported outcomes (PRO) should be collected in the clinical trial?
- Centered towards symptoms

How should PRO be collected?
- Focus groups, with parent (observable) and patient (vision)

Could patient preference studies be informative for the benefit-risk determination of myopia control medical devices?
- Yes, as ancillary study

Off-Label Use of Medical Devices: Ch. 9 Sec. 396 FD&C “Practice of Medicine”

Practitioner-patient relationship allows for off-label use of medical devices

"Health care practitioner may prescribe or administer any legally marketed device to a patient within a legitimate health care practitioner-patient relationship."

Devices cannot be marketed for off-label use

"Shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices"

FDA Classification of Contact Lenses

Class I – Low Risk
- no premarket notification

Class II – Moderate Risk (510(k))
- Daily Wear Contact Lenses

Class III – Significant Risk (PMA)
- Extended Wear Contact Lenses
- Overnight Corneal Reshaping Lenses
- Contact Lenses Indicated for Myopia Control (including Daily Wear)
Why Class III? (Significant Risk)

- New safety questions raised:
  - Increased risk for adverse events (AEs)?
  - Are induced axial length changes stable?

Off-Label Use of Medical Devices:

- Practitioner should:
  - Be well informed about the product
  - Use firm scientific rationale and sound medical evidence
  - Maintain records on use and effects

Atropine

Gross Limitation of the ATOM 2 Study
No Placebo Group!!

Low-Concentration Atropine for Myopia Progression (LAMP) Study
A Randomized, Double-Blinded, Placebo-Controlled Trial of 0.05%, 0.025%, and 0.01% Atropine Eye Drops in Myopia Control
Purpose: Low-concentration atropine is an emerging therapy for myopia progression, but its efficacy and optimal concentration remain uncertain. Our study aimed to evaluate the efficacy and safety of low-concentration atropine eye drops at 0.05%, 0.025%, and 0.01% compared with placebo over a 1-year period.

Methods: Participants: A total of 438 children aged 4 to 12 years with myopia of at least −1.0 diopter (D) and astigmatism of −2.5 D or less.

Participants were randomly assigned in a 1:1:1 ratio to receive 0.05%, 0.025%, and 0.01% atropine eye drops, or placebo eye drops, respectively, once nightly to both eyes for 1 year. Cycloplegic refraction, axial length (AL), accommodation amplitude, pupil diameter, and best-corrected visual acuity were measured at baseline, 2 weeks, 4 months, 8 months, and 12 months. Visual Function Questionnaire was administered at the 1-year visit.

Results of our LAMP study provide new evidence supporting that 0.05%, 0.025%, and 0.01% atropine reduce myopia progression along a concentration-dependent response. All concentrations of atropine were well tolerated without apparent adverse effect on the quality of life. Of the 3 concentrations used, 0.05% atropine was the most effective in controlling SE progression and axial elongation over a period of 1 year.

TAKE HOME MESSAGE

• ATROPINE REDUCES MYOPIA PROGRESSION ALONG A CONCENTRATION DEPENDANT RESPONSE

Someone Told Me I Can Double Drop 0.01%
Is That Okay?

- NOT ADVISED
  - The eye and cul-de-sac can only hold a certain amount of fluid
  - Each drop penetrates at different rates
  - Each drop concentration in the aqueous and vitreous differs
  - Theaverage cul-de-sac can hold 400µl
  - The average cul-de-sac can hold 400µl
  - Each drop concentration in the aqueous and vitreous differs
  - Weare trying to get the medication to the retina, not the cornea
  - Concentration Matters!!
What is the Theory Behind Myopic Progression and Refraction?

Who Should Offer it?

- Myopia management and myopia control is a primary care Optometric treatment.

- ALL ECP’s NEED TO OFFER IT!!!
**Keratoconus**

**Corneal Proper**

**Keratometric Measurements**

**Axial**

**Cycloplegic**

**Cycloplegic**

**Progressive**

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**What Equipment do I Need?**

- All Primary Optometric Equipment
- Ability to measure corneal curvature accurately
- Ability to differentiate from Keratoconus and other ectatic disease
- Ability to measure axial length
  - B-Scan
  - IOL Master
  - Pentacam
  - Pentacam HR and AXL

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**We Have Responsibility to Discuss with Pediatric Ophthalmology & Pediatric Optometry**

- **Myopia Control**
- **Keratoconus**

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**Michaud/Morgenstern Top Ten of Myopia Control**

1. Determine the patient’s myopia level (optique myopia unit; e.g., 6 in a standard chart: 20 and 20/20 = 6D)
2. Genetic background
3. Age (important to identify the start program (longer-term)
4. Bacteriological culture: rhodoplex (Cycloplegic Antimicrobial I)
5. Binocular vision status (e.g., 20/20)
6. Observer performance (both eyes, same, if possible, both surfaces of the cornea by fundus imaging, removing corneal impact on binocular)
7. Visual acuity, binocular vision, retest, spectacle needs, and pupil size (20/20, 20/20, 20/20, 20/20), and pupillary response (subjective, objective)
8. Visual acuity, binocular vision, retest, spectacle needs, and pupil size (20/20, 20/20, 20/20, 20/20), and pupillary response (subjective, objective)
9. Environmental conditions (ambient light, darkness, etc.)
10. Follow-up: compliance, expectations

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**My Personal Most Important Myopia Control Considerations**

- Refraction
- Corneal topography
- Myopic control
- Myopic progression
- Myopic regression
- Myopic control
- Myopic progression
- Myopic regression
- Myopic control
- Myopic progression
- Myopic regression
- Myopic control

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**Blinded List**

- Family History
- Refraction Error
- Age Table as it relates to refractive error
- Axial Length
- Method of Myopia Control: Ortho K, Soft Multifocal
- Initial evaluation with CG wavefront
- Annual CG Wavefront and evaluation
- Other ocular diseases that can mimic axial myopia
- Discord灶ure, accommodative status and how to prescribe
- When to discontinue MC