Myopia Control
An Update…

Lyndon Jones PhD DSc FCAHS FCOptom FAAO
Professor and University Research Chair
School of Optometry & Vision Science,
Dept of Physics, Biology, Chemical Engineering & Chemistry
Director, Centre for Ocular Research & Education,
University of Waterloo, Ontario, Canada

Myopia Prevalence

Prevalence

China

- Sixty years ago
  - 10–20% of the Chinese population was myopic
- Today:
  - up to 90% of teenagers and young adults are myopic
  - almost 20% are highly myopic
  - less than 4% are emmetropic

Financial Disclosures

Over the past three years, members of CORE have received research funding and/or honoraria from the following 15 companies & 3 funding agencies:

- Alcon
- Allergan
- Contamac
- CooperVision
- GL Chemtec
- Inflamax Research
- Johnson & Johnson Vision
- Menicon
- Nature’s Way
- Novartis
- Safelens
- Santen
- Shore
- SightGlass
- Visioneering

Estimated 4.7 billion myopes

Prevalence of Myopia

- 2010
  - Nearly 28% affected by Myopia
  - Nearly 50% affected by Myopia

- 2050

Onset?

Change Over Time

- The onset of myopia is shifting to a younger age in Taiwanese school children:
  - 11 year-olds in 1983
  - 10 year-olds in 1986
  - 9 year-olds in 1990
  - 8 year-olds in 2000

10% of Singaporean children at the age of 7 are at least -6.00D myopic.

So What?

Increase in High Myopia

Impact of Myopia on Risk

Visual Impairment: Myopic Macular Degeneration

Visual Impairment: 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.

<table>
<thead>
<tr>
<th>Year</th>
<th>Visual Impairment</th>
<th>Blindness</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>10.0 million</td>
<td>3.3 million</td>
</tr>
<tr>
<td>2050</td>
<td>55.7 million</td>
<td>18.5 million</td>
</tr>
</tbody>
</table>
Myopia Control Strategies

Impact of Reducing Myopia

<table>
<thead>
<tr>
<th>Prescription</th>
<th>Retinal detachment</th>
<th>Myopic maculopathy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do nothing</td>
<td>-6.00</td>
<td>10x</td>
</tr>
<tr>
<td>Reduce by 50%</td>
<td>-3.25</td>
<td>2x</td>
</tr>
<tr>
<td>Reduce by 75%</td>
<td>-1.25</td>
<td>2x</td>
</tr>
</tbody>
</table>

Risk of visual impairment

Time Outdoors

- Recent studies have shown that time outdoors appears relevant to myopia onset
  - increased light exposure?
    - light-related release of retinal dopamine, which may be critical to regulating ocular growth
  - reduced time reading?
    - reduced accommodation
- Schools in Asia now increasing exercise and time outdoors as a public health issue

Unusual Attempts…

Reviews

1. Jones & Luensmann: The prevalence and impact of high myopia
2. Smith & Walline. Controlling myopia progression in children and adolescents
3. Gifford & Gifford. The Future of Myopia Control Contact Lenses
4. Turnbull et al. Contact Lens Methods for Clinical Myopia Control
5. Walline. Myopia Control: A Review
6. Sankaridurg: Contact lenses to slow progression of myopia
7. Kang: Optical and pharmacological strategies of myopia control
Pharmaceuticals

- Mechanism unknown
  - Atropine non-selective anti-muscarinic agent that has a high affinity to M1-M5 receptors
- Clinically significant treatment effects
- Concerns about post-treatment rebound effects and the short and long-term side effects

Myopia increase over 2 years:
- 0.49D
- 0.38D
- 0.30D
Control group: -1.20D

Low Dose Atropine Effects

- Atropine for the Treatment of Myopia 2 (ATOM2) Study
- N=400 myopic Chinese children
- Assigned to 0.5%, 0.1%, and 0.01% atropine, administered 1x nightly for 2 years
- Compared with ATOM1 study results
  - placebo vs 1% atropine for 2 years

ATOM2

- Children from ATOM2 stopped atropine treatment and followed for a further 12 months
- There was a myopic rebound after atropine was stopped
  - greater in eyes that had received 0.5% and 0.1% atropine
  - 0.01% atropine effect was more modulated and sustained

Atropine

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Concentration (%)</th>
<th>% reduction</th>
<th>Overall average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shih et al 1999</td>
<td>0.1</td>
<td>56</td>
<td>69%</td>
</tr>
<tr>
<td>Shih et al 1999</td>
<td>0.25</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Shih et al 1990</td>
<td>0.50</td>
<td>96</td>
<td></td>
</tr>
<tr>
<td>Chua et al 2006</td>
<td>1.0</td>
<td>77</td>
<td></td>
</tr>
<tr>
<td>Chia et al 2012</td>
<td>0.01</td>
<td>59</td>
<td></td>
</tr>
<tr>
<td>Chia et al 2012</td>
<td>0.10</td>
<td>68</td>
<td></td>
</tr>
<tr>
<td>Chia et al 2012</td>
<td>0.59</td>
<td>76</td>
<td></td>
</tr>
</tbody>
</table>

Atropine

- Most effective atropine concentration with fewest side effects = 0.01%
  - not commercially available (generally)
  - compounded by pharmacy
  - preserved vs unit-dose
- Concerns about side effects
  - photophobia and accommodation issues reduced with low concentration
  - long-term effect on ciliary body?
- Concerns remain about rebound effects
- Axial elongation vs myopia reduction?

Is 0.01% Atropine All Its Made Out to Be?

- Mismatch between refractive error and axial length
- 0.05% much better than 0.01%

Spectacles

Rationale
- under-correction reduces accommodative response for near vision
- animal studies
  - myopic defocus (induced by plus lenses) halts ocular elongation

Hypothesis
- under-correction slows down myopia progression

Spectacle Under Correction

Under-Correction

Spectacles (under-correction)

Under-correction of myopia with spectacle lenses enhances rather than inhibits myopia progression
Multifocals/PALs

- COMET study\(^1,2\)
  - +2D PALs vs. single vision lenses (SVLs)
  - Most of the treatment effect in year 1
  - After 3 years: -0.20D less myopia progression in PAL group
  - Statistically but NOT clinically significant

\[ \text{General: PALs & Bifocals produced only small & initial treatment effects} \]

- NEI: Routine prescription of PALs for myopia control NOT recommended\(^3\)

Gwiazda et al; IOVS 2003
Gwiazda et al; IOVS 2004
Legerton & Chou; Rev Optom 2009

Spectacles: Novel designs

- Essilor Myopilux
  - Short corridor PAL?
  - Essilor data – 62% treatment effect

- Zeiss MyoVision Pro
  - Launched October 2018 in Canada
  - central clear zone
  - peripheral defocus
  - Zeiss data – 30% treatment effect
  - more effective on young patients
  - more effective if parental history of myopia
  - further validation required
  - long term study data

Spherical RGPs

- Spectacle lens designed by Poliflex slows myopic progression by 60% and stops in 22.5% of children

A specially designed spectacle lens developed by The Hong Kong Polytechnic University POLIFLEX has been found to have slowed down myopia progression by 60% in participating children, and 22.5% of them have further slowed myopic progression. This is an effective solution to myopic children.

The Spectacle lens for vision correction children was designed by Professor D.K. Lam, Professor of the School of Optical Sciences of UPI, and Professor P. K. Chau Inc. This is the first time that the data from the study has been made public. The study includes over 3000 children from 200 to 1500 years of age. The study is designed by Dr. D.K. Lam and Dr. F. John Chau Inc. The study is being carried out in conjunction with the Optometry Centre of Hong Kong.

Further validation required
Alignment Fit RGPs

- No impact on axial growth and myopia control not demonstrated

A Randomized Trial of Rigid Gas Permeable Contact Lenses to Reduce Progression of Children's Myopia


Peripheral Defocus Concept

Hyperopic Peripheral Defocus

- Development of new spectacle and contact lens designs that correct ametropia at BOTH fovea and periphery by reducing peripheral hyperopic defocus

Hyperopic Peripheral Defocus

Eye stretches to match peripheral retina to image shell

Animal Models


Chicken model Peripheral defocus

Retinoscopy
Peripheral Defocus Correction

![Diagram showing peripheral defocus correction](image)

Peripheral Defocus SCL

Myopia & SCL with Peripheral Focus Control

Effect of Dual-Focus Soft Contact Lens Wear on Axial Myopia Progression in Children

- Walline et al. 2013

Commercially available CD MF Study

- 8-11 yr-olds
- N=40 for 2 yrs
- CD MF with +2D add
- Proclear “D”
- Compared against age-matched prior group wearing SV SCL
- Soft MF CL wear resulted in a 50% reduction in the progression of myopia and a 29% reduction in axial elongation during the 2-year treatment period

Commercially available CD Multifocals

- CooperVision
  - Biofinity D multifocal
  - Proclear D multifocal
- J&J
  - Acuvue Oasys for presbyopia
- Visioneering
  - NaturalVue Multifocal
  - Daily disposable lens

* Off label use if prescribed for myopia control purposes

Myopia & SCL with Peripheral Focus Control

- Anstice et al. 2011
- Sankaridurg et al. 2011

Correction zones: Treatment zones creating myopic defocus

Commercially Available CD MF Study

- Daily disposable
- Proclear material (omafilcon A)
- Multizone, dual-focus design
  - 2D myopic defocus
- Increasingly available
  - UK launch spring 2017
  - Canada launch Jan 2018

MiSight™ ActivControl™ Technology

- Daily disposable
- Multifocal contact lens for myopia control
  - Increasingly available
  - UK launch spring 2017
  - Canada launch Jan 2018
Seven-year clinical study

- Phase 1
  - Three years
  - Parallel group - Test and control
  - Double masked

- Phase 2
  - Three years
  - All wearers in MiSight® 1 Day
  - No masking

- Phase 3
  - One further year
  - Assessment of post-treatment effect (potential rebound)
  - No masking

MiSight® trial - 0 to 36 months

- 144 Subjects Enrolled
- 74 Subjects Dispensing Visit
- 56 Subjects 36-Month Visit

70 Subjects
53 Subjects

Age: 8-12
Randomized
Double Masked
Sites: UK; Portugal; Singapore; Canada

Change in Refractive Error (Diopters)

Change in Axial Length (mm)

Correlation

Ghosting
Seven-year clinical study

Phase 1
- Three years
- Paired with real and control
- Quit after 72 months

Phase 2
- Three years
- All wearers in MiSight® 1 Day
- No masking

Phase 3
- One further year
- Review of phase 2 results

MiSight® trial - 36 to 48 months

- 144 Subjects Enrolled
- 56 Subjects 36-Month Visit
- 53 Subjects 48-Month Visit

- ** Age 11-15 at new Baseline
- All DC within 4 weeks of fitting
- 4/5 DC were vision related
- 1 subject ineligible at 36M
- 2 decided specs were more convenient
- 1 moved away

MiSight® trial - 48 month results

- Change in Spherical Equivalent Refractive Error (D)
  - Δ 36M – 48M = -0.12D
  - Δ 36M – 48M = -0.17D

- Change in Axial Length (mm)
  - Δ 36M – 48M = 0.07mm
  - Δ 36M – 48M = 0.06mm

Summary of Phase 2 data

- Switching into MiSight® from single vision correction requires clear expectation on vision effects to maximise uptake
- Treating a child at any age is beneficial – but starting earlier is better
- Don’t be put off because of fast progression in one year

Orthokeratology
Ortho-K Lenses?

- Orthokeratology CL slow the growth of the eye by about 50%

MK & OK?

- High number reported
  - Young children – devastating results
  - Pseudomonas & Acanthamoeba
- Associated with
  - Poor fitting
  - Poor education
  - Practitioner and patient
  - Use of tap water
  - Use of low Dk materials

MK & OK?

- 1317 patients
- 640 adults (49%) and 677 children (51%)
- 2599 patient-years of wear
- Risk of MK with overnight corneal reshaping contact lenses is similar to that with other overnight modalities

OK & Rebound Effect?

- Subjects aged 8-14 yrs stopped OK after 2 yrs and resumed spec wear for 6 months
- Control group continued with OK use for 6 months
- Subjects who stopped OK had significant increase in axial length
- This was reversed if they recommenced OK wear
- “The results of this study suggest that early termination of OK treatment may not be recommended and, in case of discontinuation, it would be prudent to continue to monitor axial elongation after stopping lens wear for at least 6 months and to resume lens wear if rapid axial elongation was observed during the discontinuation period”

Summary

- Biggest impact on younger myopes
  - In particular fast progressors – greater than 0.50D per year
- Consider options/compliance
  - Contact lenses
  - Spectacles
  - Pharmaceuticals
- Manage expectations
Safety of SCL in Kids?

• Review of MK & IK in patients <18 yrs old — 19 studies
• “The overall picture is that the incidence of corneal infiltrative events in children is no higher than in adults, and in the youngest age range of 6 to 11 years, it may be markedly lower”


Risks Associated with CL Wear

Am I placing a child at risk of contact lens related infection?
Lifetime risk of Microbial Keratitis:
Daily wear (DD) 1 in 75

Am I placing a child at risk of myopia associated pathology if I do nothing different?
Lifetime risk of retinal detachment (>=-5.00D)
Retinal detachment 1 in 20

Case for offering contact lenses for myopia control outweighs the risk of allowing myopia to develop unabated


Thanks for your attention