Myopia Progression Control

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Daniella Rutner, OD, MS, FAAO, FCVOVD

Why Control Myopia:

- Myopia is a common cause of vision impairment in developed countries.
  - Pathological myopia is the second most common cause of visual impairment and blindness among Chinese individuals age 40 years and above.
- Being myopic significantly increases a patient's risk of developing:
  - Glaucoma
  - Cataract
  - Retinal Detachment
  - CNV (Choroidal Neovascularization) of the macula
- Quality of life

Increasing Prevalence

The prevalence of myopia in individuals aged 12-54:
- From 1971 - 1972: 25.0% increases to 34% 1999-2004
- From 1999 - 2004: 41.6% Prevalence 66.4% higher in 1999-2004

Etiology

- Genetic
- Environmental
- Pathological

Why??

- Likely a combination of genetic and environmental factors
  - Risk of becoming myopic increases with the number of myopic parents
  - Increase in prevalence indicates that environmental factors must play a role as well
- Progression risk factor theories:
  - More time on reading and close work
  - Less outdoor time/ UV light
  - Higher education levels
  - Night lights
  - Hours of sleep
Pathological

- Aniridia
- Connective Tissues Disorders such as Marfans Stickler
- Medication induced
- Congential stationary night blindness

Work Up

- Detailed Medical History
- Detailed ADL history
- Refraction WET/DRY
- IOP GOLDMAN vs. Icare
- Retinal

Myopia Progression

- Juvenile onset myopia onset usually around 8 yrs old
- 1/6 school age children 5-17 have myopia (CLEERE)
- Typically progresses at a rate of about 0.50D/year, for 10-15 years
- Rapid progression is more commonly found with:
  - Younger age of onset
  - Higher degree of myopia at onset

Case

- 9 y/o AM presents with c/o not being able to see the Smartboard at school
- Current Spec Rx (1 year old):
  - OD: -1.00-0.25x005, 20/60
  - OS: -1.25-0.50x175, 20/60
- Manifest Refraction:
  - OD: -2.00-0.50x005, 20/20
  - OS: -2.50-0.50x175, 20/20
- Binocularity:
  - Cover Test: ortho at D, 2XP at N
  - Amps: 13D OD/OS
- Ocular Health:
  - OD: unremarkable
  - OS: 1.5DD CHRPE IT periphery

Case

- His father, who is also myopic, is concerned about the increase in Rx. Inquires about interventions...
- Options:
  A. Undercorrection
  B. Bifocal Spectacles
  C. Progressive Addition Lenses
  D. Atropine
  E. Contact Lenses: Ortho K, Soft Multifocals

UNDERCORRECTION:

Theory:
Myopes have higher accommodative lag than emmetropes
Reduced accommodation to near may cause extended periods of retinal defocus during near work → may lead to increased eye growth
Current Methods of Myopia Control: UNDERCORRECTION

Undercorrection of myopia enhances rather than inhibits myopia progression.

- **Study Design**: 2 year masked, randomized, prospective study on 94 myopes > -0.50D, with 2D or less cyl, aged 9-14 years old
- **Method**: Randomly assigned to undercorrected group (approx +0.75D, blurred to 20/40) or full correction group, followed q6m
- **Results**: Undercorrection produced more rapid myopia progression and axial elongation

**Case**

- His father, who is also myopic, is concerned about the increase in Rx. Inquires about interventions...
- **Options**:
  A. Undercorrection → No, may increase myopia!
  B. Bifocal Spectacles
  C. Progressive Addition Lenses
  D. Atropine
  E. Contact Lenses: Ortho K, Soft Multifocals

**BIFOCALS**

- **Theory**:
  Thought to work through the effect on accommodation and phoria
  Shift towards esophoria during myopia progression
  Reduced accommodation associated with near esophoria → must relax accom to reduce accommodative convergence to maintain single binocular vision → may produce hyperopic defocus during near work, which may lead to myopia axial progression

**Current Methods of Myopia Control: BIFOCALS**

- **Study Design**: 30 month randomized, masked clinical trial performed in 82 myopic children age 6-12 with near esophoria
- **Method**: Randomized to single vision glasses or +1.50BF, followed every 6 months
- **Results**: After the first 30 months, the +1.50BF group was significantly less myopic (0.25D) than the SV group. The difference in the degree of myopia was maintained but did not increase.

**CURRENT METHODS OF MYOPIA CONTROL: BIFOCALS**

- **Study Design**: Randomized clinical trial, 207 children between the ages of 6 and 15 given either DV, +1.00BF, or +2.00BF, followed for 3 years, 124 completed the study
- **Results**: Does it work? → Results were NOT statistically significant between groups. Found that subjects who entered the study at an earlier age, with a larger amount of myopia were most likely to progress.

<table>
<thead>
<tr>
<th>Single Vision Progression</th>
<th>+1.00 ADD BF Progression</th>
<th>+2.00 ADD BF Progression</th>
</tr>
</thead>
<tbody>
<tr>
<td>-0.340/yr</td>
<td>-0.360/yr</td>
<td>-0.340/yr</td>
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- **Houston Myopia Control Study** (1987, Grosvenor et al):
  - Study Design: Randomized clinical trial, 207 children between the ages of 6 and 15 given either DV, +1.00BF, or +2.00BF, followed for 3 years, 124 completed the study
  - Results: Does it work? → Results were NOT statistically significant between groups.
  - Found that subjects who entered the study at an earlier age, with a larger amount of myopia were most likely to progress.

- **Current Methods of Myopia Control: BIFOCALS**
  - 46 of these children were followed for an additional 24 months, during the last 12 months, they got to choose treatment group
  - At 54 months, the progression rate was similar to the first thirty months, with less myopia progression in the BF group. The difference in the degree of myopia was maintained but did not increase.
  - **Does it work?** → Yes, but the modest benefit needs to be weighed vs cost and attitude toward bifocals. Younger children may benefit more since they have a longer time over which progression may occur.
Current Methods of Myopia Control:

### BIFOCALS

**Study Design:** 3 year randomized clinical trial, 135 Chinese-Canadian myopes age 8-13 with a history of myopia progression

**Method:** Randomized to receive SV lenses, +1.50D executive BF, or +1.50 executive BF with 6 PD BI (in near portion); followed q6m

**Results:**

<table>
<thead>
<tr>
<th>Sph Equivalent</th>
<th>SV</th>
<th>BF</th>
<th>BF + Prism</th>
</tr>
</thead>
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<tr>
<td>2.06D</td>
<td>1.25D</td>
<td>1.01D</td>
<td></td>
</tr>
<tr>
<td>Axial Length</td>
<td>0.82mm</td>
<td>0.57mm</td>
<td>0.54mm</td>
</tr>
</tbody>
</table>

*Does it work? Yes, findings were statistically significant*

### PROGRESSIVE ADDITION LENSES

**Theory:**

Thought to work through the effect on accommodation and phoria

Provide a range of clear vision from near to far may reduce defocus and slow progression of myopia

**Case**

- His father, who is also myopic, is concerned about the increase in Rx. Inquires about interventions...

**Options:**

A. Undercorrection → No, may increase myopia

B. Bifocal Spectacles → Exception: Young Children? Executive BF?

C. Progressive Addition Lenses

D. Atropine

E. Contact Lenses: Ortho K, Soft Multifocals

### Current Methods of Myopia Control: PALs

**Study Design:** (COMET) 3 year randomized, masked clinical trial in 469 children aged 6-11 years with myopia between -1.25 and -4.50 sph equivalent

**Method:** Randomized to receive +2.00 PALs or single vision lenses

**Results:**

- Myopia progression was slowed by the use of PALs primarily in the first year
- Larger treatment effect in children with lower baseline accommodative response at near and lower amounts of myopia

*Does it work? Results were statistically significant, but not CLINICALLY significant*

### Accommodation and Phoria
Current Methods of Myopia Control:
PALs
Progressive-Addition Lenses versus Single-Vision Lenses
for Slowing Progression of Myopia in Children with High Accommodative Lag and Near Esophoria

- **Study Design**: (COMET 2) 3 year, randomized, masked clinical trial in 104 children age 8-11, spherical equivalent between -0.75 to -2.50, near esophoria >/= 2 PD, and accommodative lag >/= 1.00D
- **Method**: Randomized to +2.00PALs or single vision lenses
- **Results**:
  - Mean change in refractive error was statistically significantly lower in PAL group (-0.87D) vs single vision group (-1.15D)
  - Did not evaluate axial length
- **Does it work?** Results were statistically significant, but not clinically significant

Current Methods of Myopia Control:
Atropine

- **Study Design**: (ATOM 1) A two year, parallel-group, placebo controlled randomized, double masked study in 400 Asian children aged 6-12 with myopia of -1.00 to -6.00D evaluating the safety and efficacy of atropine in slowing myopia progression
- **Methods**: Randomized to receive 1 gtt 1% Atropine or Placebo drops administered qhs for 2 years, only one eye was chosen for treatment
- **Results**:
  - Placebo (Isoptotears): mean progression -1.20D, AL 0.38mm
  - Results similar in the non-treated eyes
  - 1% Atropine: mean progression -0.28D, AL essentially the same
- **Did it work?** Yes, results were statistically significant. However, treatment was unilateral

Current Methods of Myopia Control:
Atropine

- **Study Design**: (ATOM 2) A two year, double masked, randomized study in 400 children aged 6-12 years old with myopia of at least -2.00D to assess efficacy and safety in lower doses of atropine
- **Methods**: Randomly assigned to receive Atropine 0.5%, 0.1%, and 0.01% administered qhs OU, offered PALs or photochromic lenses if symptomatic
- **Results**:
  - 0.5% atropine: mean progression -0.30D, AL 0.27mm
  - 0.1% atropine: mean progression -0.38D, AL 0.28mm
  - 0.01% atropine: mean progression -0.49D, AL 0.41mm
  - ATOM 1: 1% Atropine: -0.28D, AL essentially the same
  - ATOM 1: placebo: -1.20D, AL 0.38mm
- **Does it work?**
  - Overall, differences between groups were small and insignificant
  - There was a statistically significant difference between the 0.01% group and the 0.5% and 0.1% groups in axial length and progression, however NOT clinically significant:
    - Difference in progression 0.19D
    - Difference in AL 0.13mm
    - Atropine 0.01% had minimal effect on accommodation and pupil size, with no effect on near VA
  - Atropine 0.01% had a better side effect profile:
    - Mean accommodation 11.8D
    - Mean pupil size was 5mm
    - Mean near vision was 0.01 logMAR (approx 20/20)
  - Atropine 0.01% seems like a safe and effective method of myopia control in children

Case
- His father, who is also myopic, is concerned about the increase in Rx. Inquires about interventions...
- **Options**:
  - A. Undercorrection → No, may increase myopia
  - B. Bifocal Spectacles → Exception: Young Children? Executive BF?
  - C. Progressive Addition Lenses → Similar to bifocals
  - D. Atropine
  - E. Contact Lenses: Ortho K, Soft Multifocals

**ATROPINE**

Non-specific muscarinic antagonist
Side effects: light sensitivity, blur at near
Initially believed to be related to accommodation, however, it has been shown to inhibit myopia in animals without accommodation

Mechanism is unknown, theories include:
May up or down regulate muscarinic receptors in the sclera and retina, which may play a role in ocular elongation
Another theory suggests it may have to do with UV exposure (from dilation) affecting the scleral collagen cross linking to limit scleral growth
Reported Adverse Events

- **ATOM 1:** (unilateral tx)
  - Allergic/ hypersensitivity reactions or discomfort (4.5% of withdrawals)
  - Glare (1.5% of withdrawals)
  - Blurred Near Vision (1% of withdrawals)

- **ATOM 2:** (bilateral)
  - Allergic conjunctivitis:
    - 4 children (1.3%), only in the 0.1 and 0.5% groups; 3 stopped tx
  - Allergy related dermatitis:
    - 4 children (1.3%), only in the 0.1 and 0.5% groups
  - Others included:
    - 0.01% group: blur (1 child), irritation (1 child)
    - 0.5% group: glare (1 child), irritation (2 children)

- Progressive lens use:
  - 70% in 0.5% group
  - 61% in 0.1% group
  - 6% in 0.01% group

Current Methods of Myopia Control: Atropine

**Study Design:** Followed the children enrolled in ATOM 1 and 2 for a 1 year washout.

**Results:**

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Atropine 1%</th>
<th>Atropine 0.5%</th>
<th>Atropine 0.1%</th>
<th>Atropine 0.01%</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 month myopia increase</td>
<td>1.20D</td>
<td>0.28D</td>
<td>-0.30D</td>
<td>-0.38D</td>
<td>-0.49D</td>
</tr>
<tr>
<td>Washout year myopia increase</td>
<td>0.88D</td>
<td>-1.16D</td>
<td>-0.87D</td>
<td>-0.68D</td>
<td>-0.26D</td>
</tr>
<tr>
<td>36 month myopia increase</td>
<td>1.34D</td>
<td>1.07D</td>
<td>-1.50D</td>
<td>-1.86D</td>
<td>-0.70D</td>
</tr>
<tr>
<td>6 month AL increase</td>
<td>0.38mm</td>
<td>0.02mm</td>
<td>0.27mm</td>
<td>0.28mm</td>
<td>0.41mm</td>
</tr>
<tr>
<td>Washout year AL increase</td>
<td>0.35mm</td>
<td>0.33mm</td>
<td>0.13mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36 month AL increase</td>
<td>0.52mm</td>
<td>0.29mm</td>
<td>0.61mm</td>
<td>0.60mm</td>
<td>0.58mm</td>
</tr>
</tbody>
</table>

**Why:**
- Rebound possibly due to tonic accommodation
- Lower doses of atropine may act at different (more anterior) site or affects different muscarinic receptors to different degrees → more modulated response?

**Take away:**
- Atropine 0.01% had:
  - Fastest recovery from side effects
  - Least myopic rebound
  - More myopia reduction → may be a safe and effective method of myopia control in children.

**AL comparison bet ATOM 1 and ATOM 2:**
- AL lower in IOL Master, difference increased for lower sph equivalents; change in AL in 0.1% does not seem significant, need placebo controlled study

**Case**

- His father, who is also myopic, is concerned about the increase in Rx. Inquires about interventions...

**Options:**

A. Undercorrection → No, may increase myopia

B. Bifocal Spectacles → Exception: Young Children? Executive BF?

C. Progressive Addition Lenses → Similar to bifocals

D. Atropine → Effective, low cost, consider lower concentration to decrease side effects, need long term, placebo controlled study

E. Contact Lenses: Ortho K, Soft Multifocals

**Leiter’s Pharmacy (compounding pharmacy)**

- Atropine 0.01% 5ML is currently listed at $38.00.

- Atropine 0.01% 10ML is currently listed at $59.50.
How do Ortho-K and Multifocal CLs work?

- **Orthokeratology:**
  - Worn overnight
  - Ortho-K lenses flatten the central cornea, and cause mid peripheral steepening
  - This corrects refractive error centrally and leaves an area of mid peripheral myopic blur

- **Multifocal Contact lenses:**
  - Typically, a center distance design is chosen
  - Thought to work by correcting myopia in the periphery with relative peripheral myopic blur

How Does it Work:

- **Orthokeratology:**
  - Worn overnight
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- **Multifocal Contact lenses:**
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Current Methods of Myopia Control: Orthokeratology

- **Study Design:** (CRAYON) A 2-year study in 40 children age 8-11 with myopia between -0.75 and -4.00D of myopia, with less than 1D of cyl

- **Methods:** Subjects were fit with corneal reshaping lenses and compared to age matched controls from a previous study. 28 children completed the study over 2 years. A-scans were performed annually.

- **Results:**
  - 55% reduction in axial growth compared to historical controls
  - 0.16mm per year

- **Does it work?** Results were clinically significant, however this was not a randomized clinical trial

**CONTACT LENS SAFETY**

- The risk of microbial keratitis with overnight corneal reshaping lens wear is similar to that of overnight extended wear soft contact lenses

- The estimated risk of microbial keratitis in children is 13.9 per 10,000 patient-years
Orthokeratology CANDIDACY

- Up to 6.00 DS*
- Up to 1.75 DC
- No age restriction
- Absence of ocular pathology
- Motivation/maturity/commitment

Best Prognosis
- Lower refractive error
- With-the-rule corneal astigmatism

Poor Prognosis
- High residual astigmatism
- Flatter K readings

Current Methods of Myopia Control:
Multifocal SCLs

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

Nicole S. Avrin, OD, FAAO, PhD, Julie E. Phillips, MD, FAAO

- Study Design: A prospective, randomized, paired eye control, masked clinical trial to compare the “Dual- Focus” lens to SV lens in myopia control
- Methods: 40 children between the age of 11 and 14 with a refraction between -1.25 and -4.00D and a history of myopia progression were randomized to receive either the Dual-Focus lens or a SV soft contact lens. Subjects were followed for 20 months.
  - For the first ten months the children wore a DF lens in one eye and a SV lens in the other; after ten months, the eyes swapped lens assignments

Current Methods of Myopia Control:
Multifocal SCLs

- Results:
  - DF lenses: -0.44D change in sph equivalent, 0.11mm change in axial length
  - SV lenses: -0.69D change in sph equivalent, 0.22mm change in axial length
    - 37% reduction in myopia progression, 49% reduction in axial length
  - In 70% of the children, myopia progression was reduced by 30% or more in the eye wearing the DF lens relative to that wearing the single vision lens.
- Does it work? Yes, however, tolerability needs to be assessed binocularly

How Does it Work:

- Orthokeratology:
  - Worn overnight
  - Ortho-K lenses flatten the central cornea, and cause mid peripheral steepening
  - This corrects refractive error centrally and leaves an area of mid peripheral myopic blur

- Soft Multifocal Contact lenses:
  - Typically, a center distance design is chosen
  - Thought to work by correcting myopia in the periphery with relative peripheral myopic blur

Current Methods of Myopia Control:
Multifocal SCLs

Dual- Focus Lens Design

- Dual- Focus lens design:
  - 3.36mm central correction zone
  - Concentric rings of treatment zones that provided 2D of myopic defocus
  - During distance (B) and near viewing with accommodation (C), the correction zones fall on the retina, and the treatment zones focal plane fall anterior to the retina
  - The children in this study were found to accommodate when wearing these lenses, and they did not use the treatment zone as an ADD.

Current Methods of Myopia Control:
Multifocal SCLs

Defocus Incorporated Soft Contact (DISC) lens slows myopia progression in Hong Kong Chinese schoolchildren: a 2-year randomised clinical trial

Eddy Su, Yi Lin, Ying Chun Yang, Dennis Yan Yin Tse,1,2 Ying Fung Tang

- Study Design: A 2 year, randomized, double blind, controlled trial to determine if the “DISC” lens (a multifocal soft contact lens) slows down myopia progression in Hong Kong schoolchildren
- Methods: 221 children between the ages of 8 and 13 with a refraction between -1.00 and -5.00 with less than or equal to 1D of cyl were randomly assigned to DISC lens or SV CLs, followed q6m for 2yrs
  - DISC Lens Design: Concentric rings with center distance correction and +2.50D ADD
- Results:
  - DISC: progressed 0.3D per year ➔ 0.59D total, AL increased 0.13mm/yr
  - SV: progressed 0.4D per year ➔ 0.80D total, AL increased 0.18mm/yr
  - Effect increased with increased wearing time ➔ slowed 50% when worn over 5hrs per day
- Does it work? Yes, statistically significant
Study Design: Prospective, matched design 2 year study to compare the progression of myopia in children wearing SV SCLs and soft multifocal SCLs

Methods: 40 children between 8 and 11 years old with Rx between -1.00D to -6.00D and less than 1D of cyl were fitted with Proclear Multifocals with a +2.00 "D" add (D center), were followed for two years and compared to age matched controls from a previous study

Results:
- SV SCLs: -1.03D of progression, axial elongation 0.41mm
- MF SCLs: -0.51D of progression, axial elongation 0.29mm
- 50% reduction in myopia progression, 29% reduction in axial elongation

Does it work? Yes, a long term randomized clinical trial is needed to confirm

Current Methods of Myopia Control:
Multifocal SCLs

Multifocal Contact Lens Myopia Control

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Contact Lens assessment in youth (CLAY)

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<th>Material</th>
<th>Care System</th>
<th>Wear Schedule</th>
<th>Years of Wear</th>
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Multifocal Soft Contact Lens Options

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- Options:
  A. Undercorrection  No, may increase myopia
  B. Bifocal Spectacles  Exception: Young Children? Executive BF?
  C. Progressive Addition Lenses  Similar to bifocals
  D. Atropine  Effective, low cost, consider lower concentration to decrease side effects, need long term, placebo controlled study
  E. Contact Lenses: Ortho K, Soft Multifocals  Effective: Consider safety, limited parameters, maturity

Clinical Takeaway

- Remember to use evidence based practice in your day to day
- Keep your eyes open for future research!