



Myopia Control: Bringing nearsighted treatment into focus

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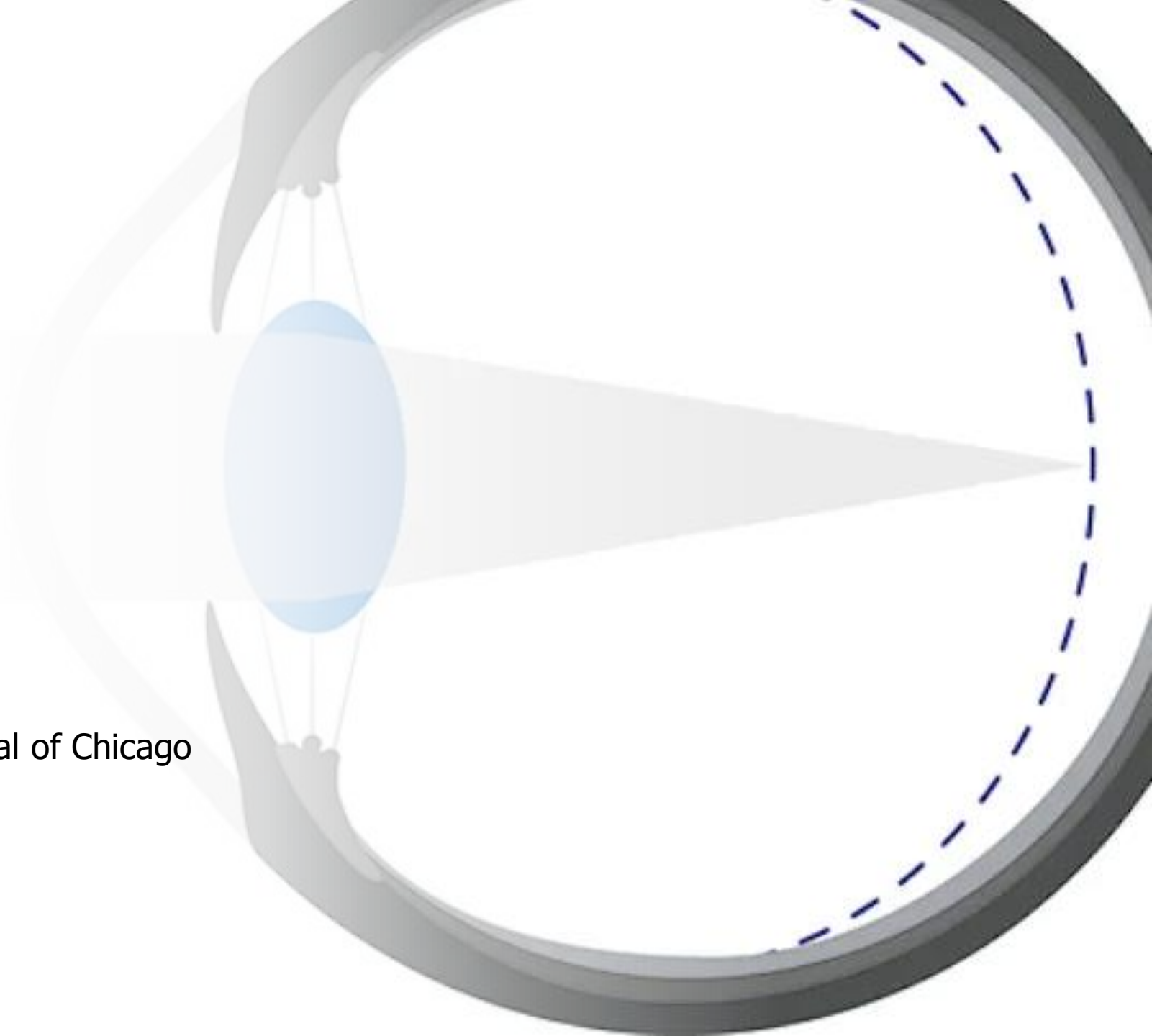
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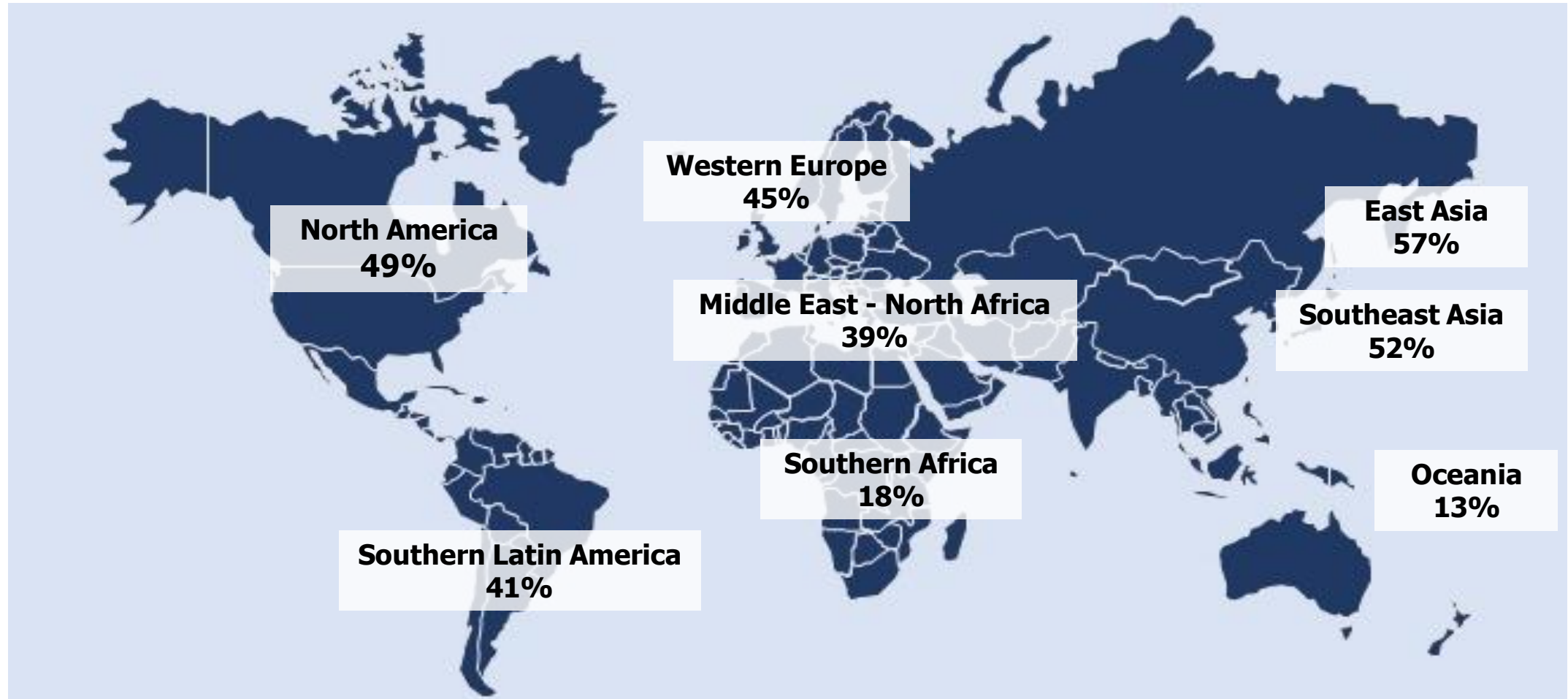
Pathogenesis of Myopia

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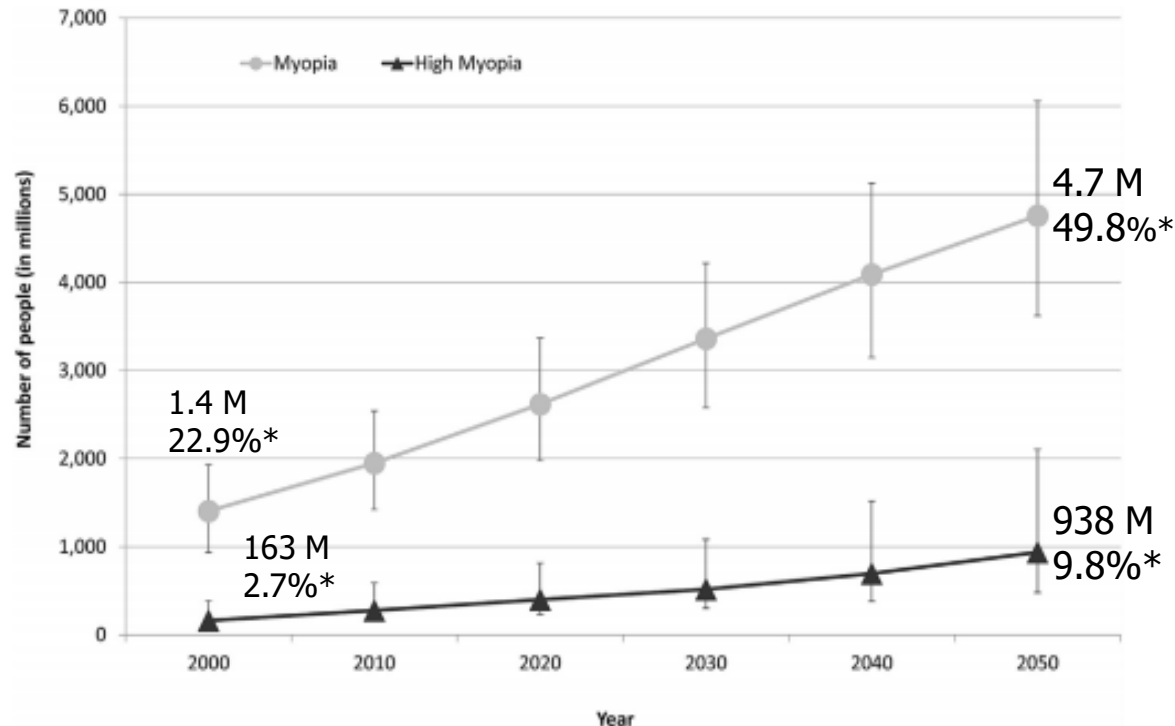
No Financial Interest



The Myopia Epidemic: Predicted Prevalence in 2030



The Myopia Boom: General Trends from 2000 to 2050 (Meta-analysis)



* Percent of the global population

Summary of original data from 145 studies

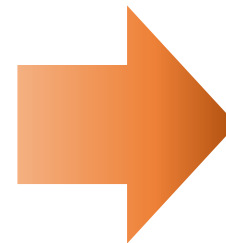
- From 2000 → 2050
- >3 billion *more* people globally with myopia
- >775 million *more* with high myopia
- Potential for increased prevalence of complications (e.g. retinal detachment, choroidal neovascularization, glaucoma)

Increase in myopia is driven by both lifestyle changes and genetics

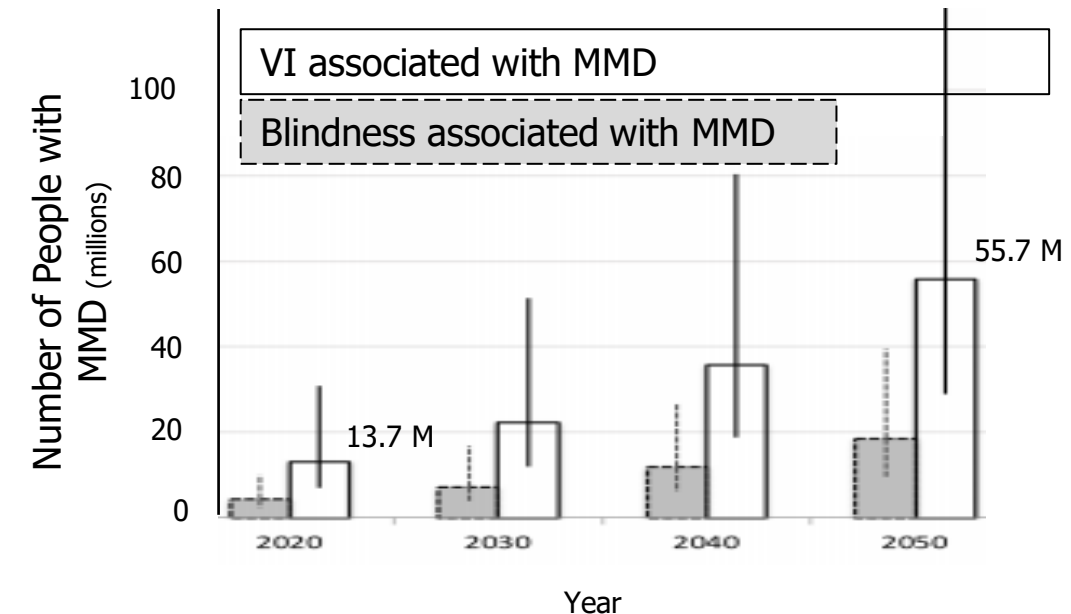
Myopia and Its Association with Visual Impairment & Blindness

Odds ratio of ocular disease relative to emmetropia

Eye Disease	-2.00 D	-4.00 D	-6.00 D	-8.00 D
Myopic Maculopathy²	2.2x higher	9.7x higher	40.6x higher	126.8x higher
Retinal Detachment³	3.1x higher	9.0x higher	21.5x higher	44.2x higher
PSC Cataract⁴	1.6x higher	3.2x higher	5.4x higher	12.3x higher
Glaucoma⁵	1.7x higher	2.5x higher	2.5x higher	N/A



Higher rates of myopic macular degeneration (MMD) lead to worsening visual impairment (VI)



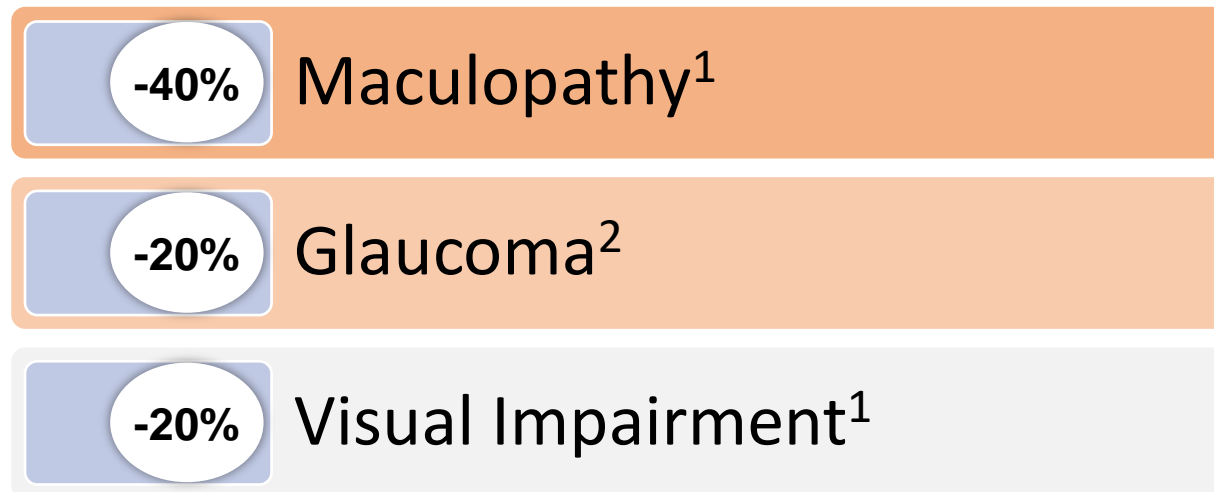
Visual Impairment and Blindness associated with Myopia is predicted to increase over the next 30 years

Impact of Reducing Myopia Over a Lifetime: “Every Diopter Matters”

Each 1-diopter *increase* in myopia is associated with an increased lifetime risk of:

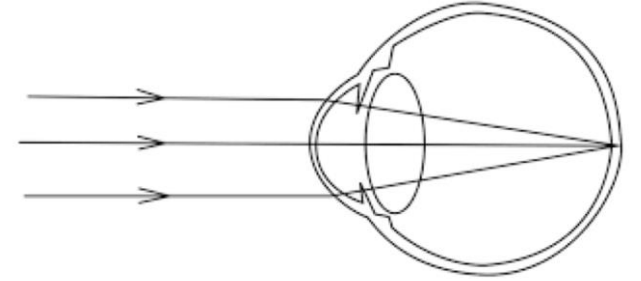
- 67% in the prevalence of **myopic maculopathy**¹
- 25% in **visual impairment**¹
- 30% in the incidence of **retinal detachment**²
- 20% in the prevalence of **glaucoma**²

Each 1-diopter *decrease* in myopia is associated with a decreased lifetime risk of:



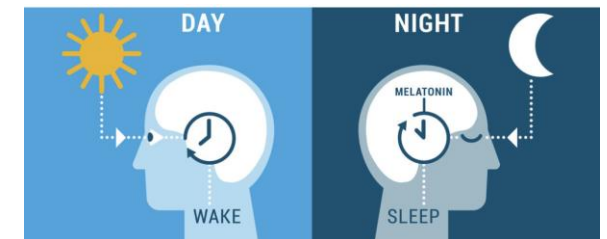
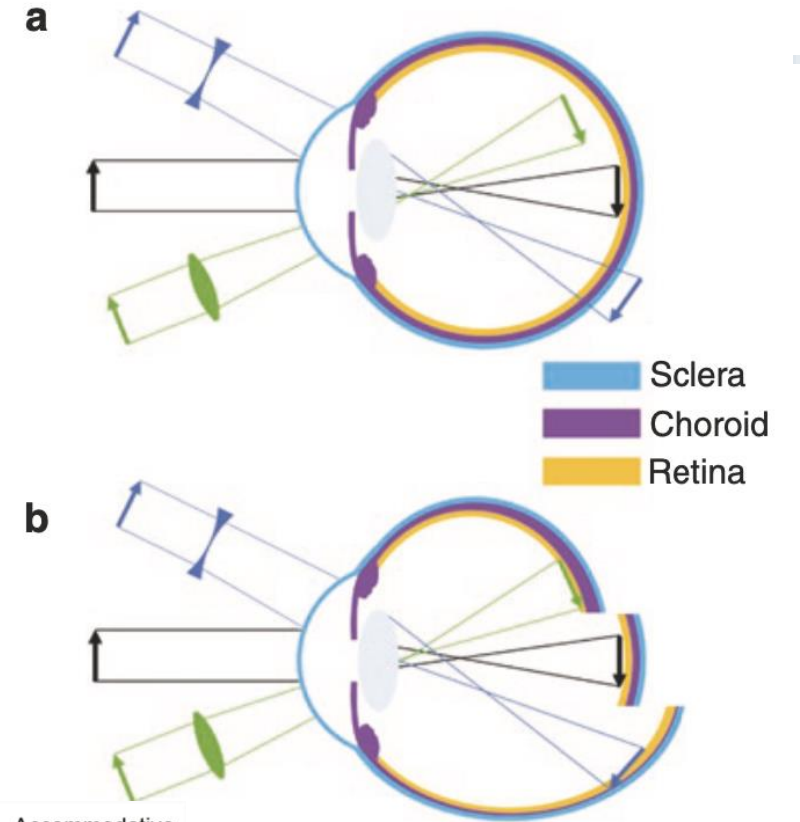
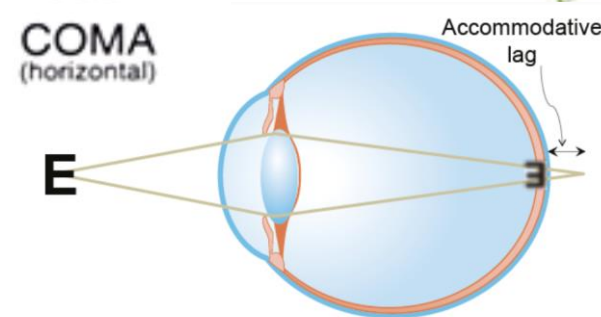
Normal Ocular Growth and Emmetropization

- Ocular growth
 - Mostly through expansion of vitreous chamber
 - Smaller changes in cornea and lens refractive power
- Emmetropization
 - Newborn: +2.00 to +4:00 with axial length ~17 mm
 - 2-5 years old: +0.50 to 1:00 with axial length ~22 mm
 - ≥ 6 years: eye growth stabilizes, with only 1-1.5 mm additional growth through teenage years



Mechanisms of Myopia

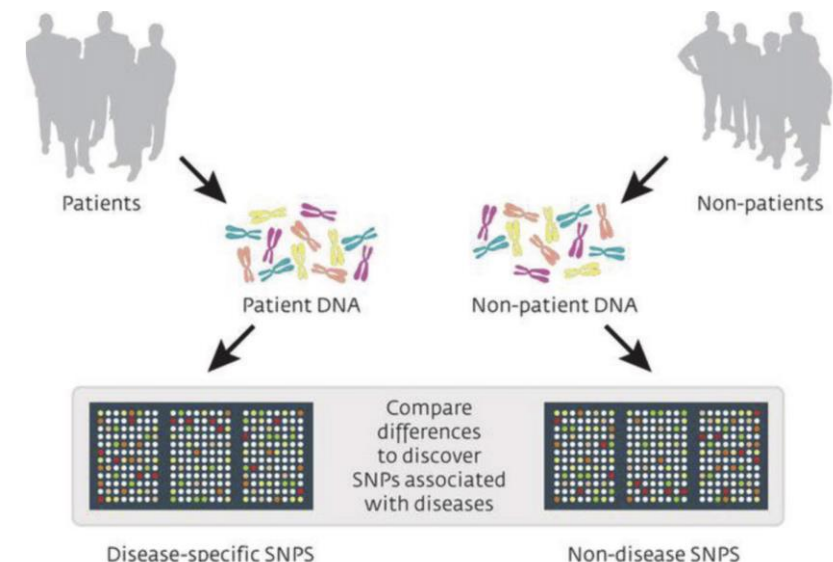
- Feedback from visual cues focused on the peripheral retina regulates emmetropization
- Peripheral hyperopic defocus drives axial growth
- Form Deprivation – Deprivation of form or pattern vision
- Lens Defocus – Hyperopic defocus
- Other factors:
 - Higher order aberrations
 - Accommodation lag
 - Circadian rhythm



Genetic Influences of Myopia

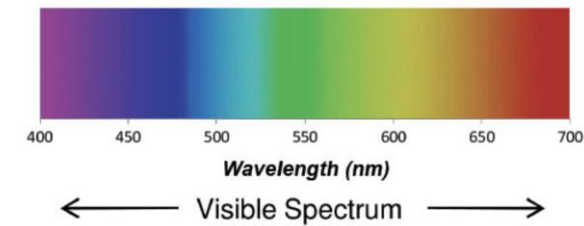


- Highly heritable, complex trait
- Syndromic Myopia - ~100 genes
 - Connective Tissue Disorders – e.g. Stickler, Marfans, Ehlers Danlos, Weill-Marchesani
 - Retinal Dystrophies – e.g. X-linked RP, Congenital Stationary Night Blindness
- Non-Syndromic Myopia
 - Genome wide association studies – 100s of potential genes
 - Molecular effects of these genes to be determined



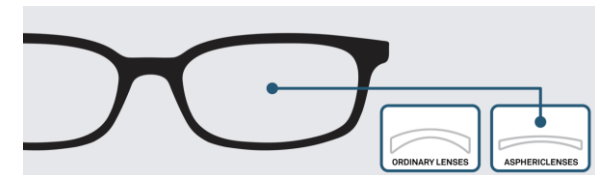
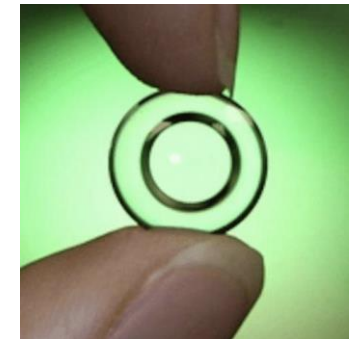
Environmental Influences of Myopia

- Near work/Digital screen time - Time and intensity
- Education - Near work, light exposure, outdoor time
- Urbanization/Population density - Education, near work, outdoor time
- Light exposure - Light intensity and exposure, light wavelengths
- Outdoor time - Light intensity and exposure



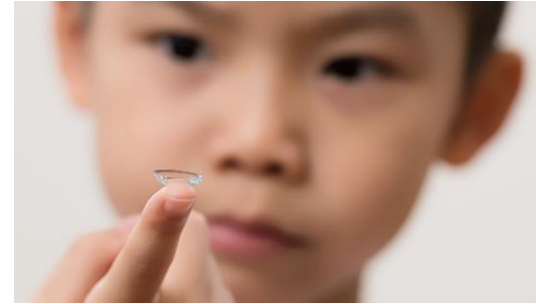
Myopia Control

- Modifying environmental factors
 - Decreased intensity and time of near work
 - Increased outdoor time
- Myopia control treatment
 - Pharmacologic - Low dose atropine
 - Refractive strategies - Soft contact lenses, orthokeratology, bifocals, aspheric spectacles



Myopia Control Considerations

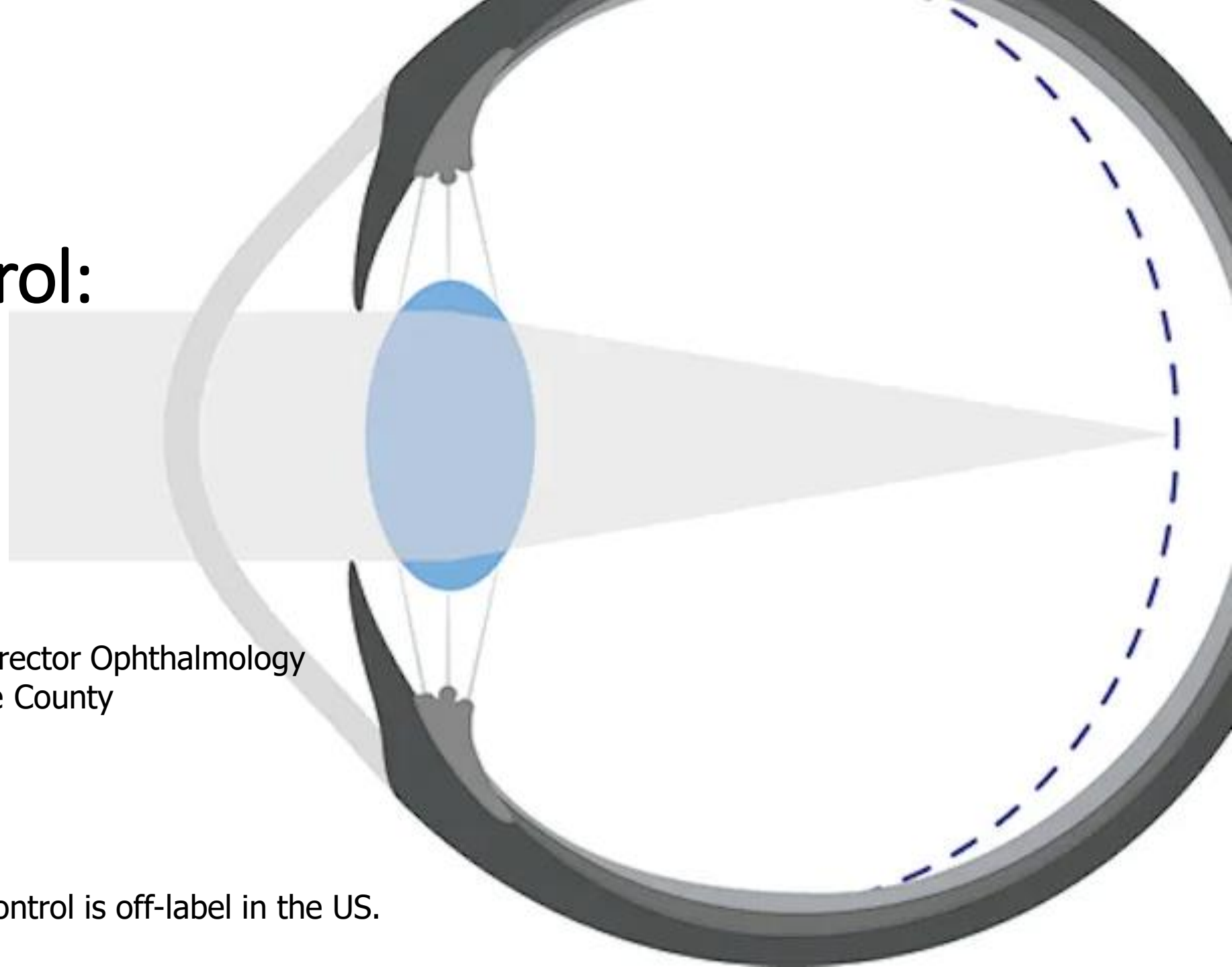
- Refractive error guidelines for starting treatment
- Choice of treatment
 - Age and cooperation
 - Refractive error
 - Activities and lifestyle
 - Cost
- Diversity, equity and inclusion considerations in myopia control treatments



Myopia Control: Low Dose Atropine

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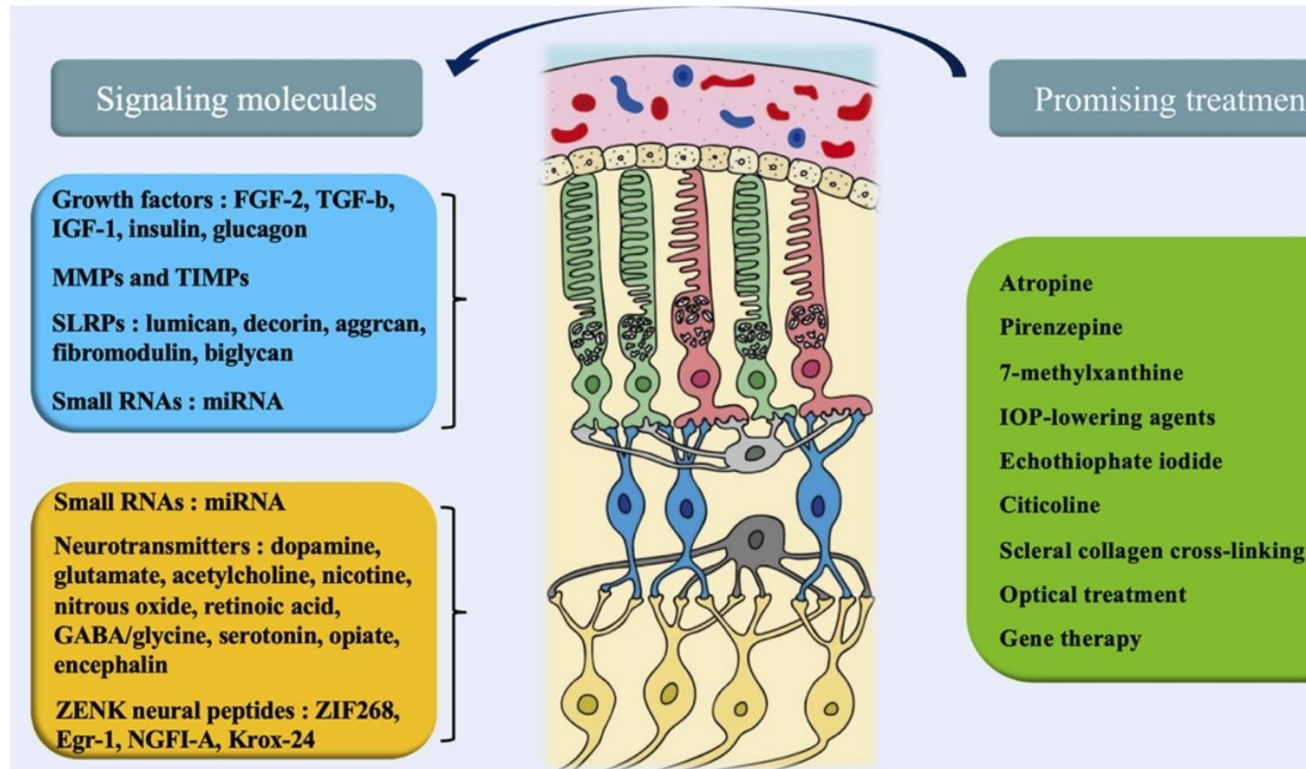
No Financial Interest
Atropine usage for myopia control is off-label in the US.



Myopia Control

- Pathophysiology of myopia involves a complex interplay of numerous environmental and genetic factors ultimately leading to progressive axial elongation.
- Despite multiple clinical trials to devise appropriate treatment strategies targeting the modifiable risk factors, no single or combination treatment modality has shown ideal results.
- In the quest of ideal treatment of Myopia, many pharmacological, optical and environmental modalities are explored.

Pharmacotherapeutic Candidates for Myopia

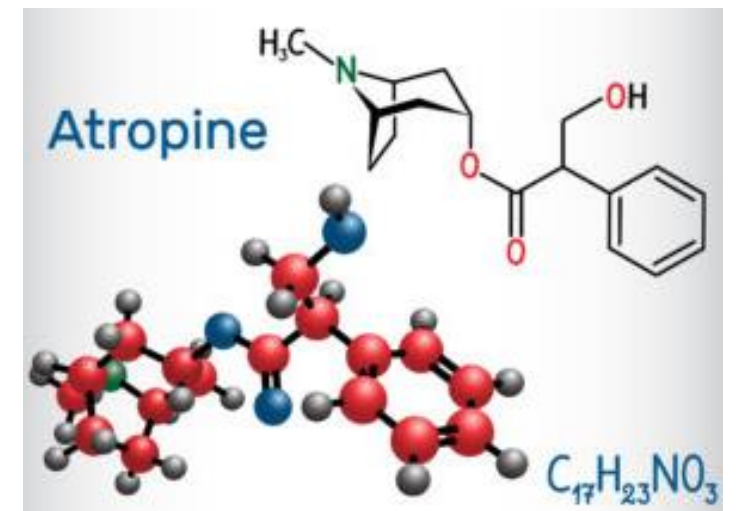


Aimed at inhibiting environmentally induced changes in visual input and subsequently in signaling pathways during myopia pathogenesis and progression

There is a lot of enthusiasm centered around pharmacotherapeutic interventions at different levels but so far only Atropine and Pirenzapine have shown benefits in retarding myopia progression in human population

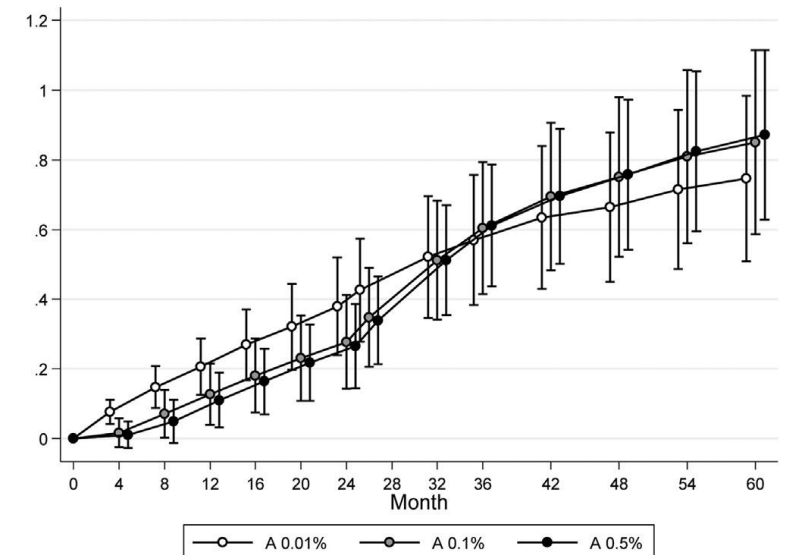
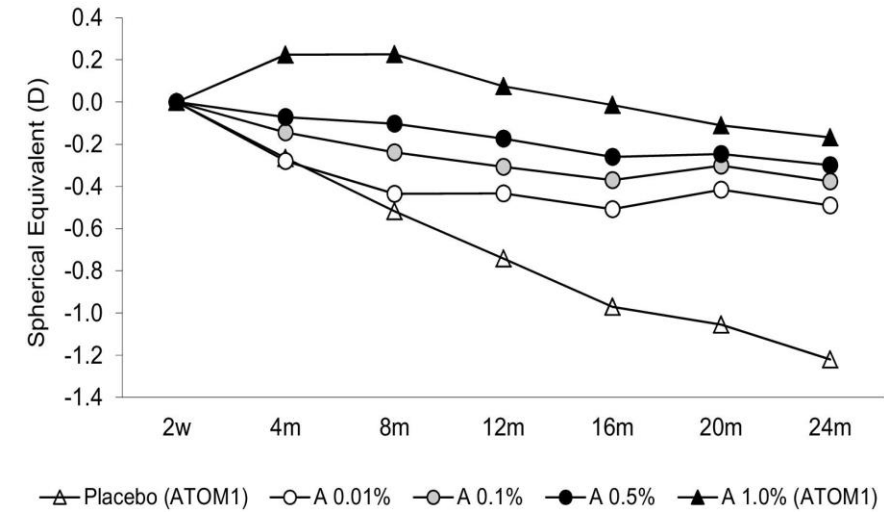
Mechanism of Atropine in Slowing Eye Growth

- Accommodative pathway
- Muscarinic receptor pathways in the retina, choroid, and sclera
- Other Receptors: α_2 -adrenergic receptors playing a role in regulating dopamine synthesis
- Multiple pathways involving both muscarinic as well as adrenergic receptors – concentration dependent



Current Evidence of Atropine on Myopia Control

- Atropine for the treatment of Myopia (ATOM1) 2003: Atropine 1% eyedrops was effective in controlling myopic progression over a 2-year period when compared to a placebo.
- Atropine for the treatment of Myopia (ATOM2 phase-1) 2012: Atropine 0.01% had minimal side effects compared with atropine 0.1% and 0.5% and retained comparable efficacy in controlling myopia progression.
- Atropine for the treatment of Myopia (ATOM2 phase-2) 2013: Washout period, showed myopic rebound after atropine was stopped which was greater for higher dosage.
- Atropine for the treatment of Myopia (ATOM2 phase-3) 2015: Over 5 years, atropine 0.01% eyedrops were more effective in slowing myopia progression with less visual side effects compared to higher doses.



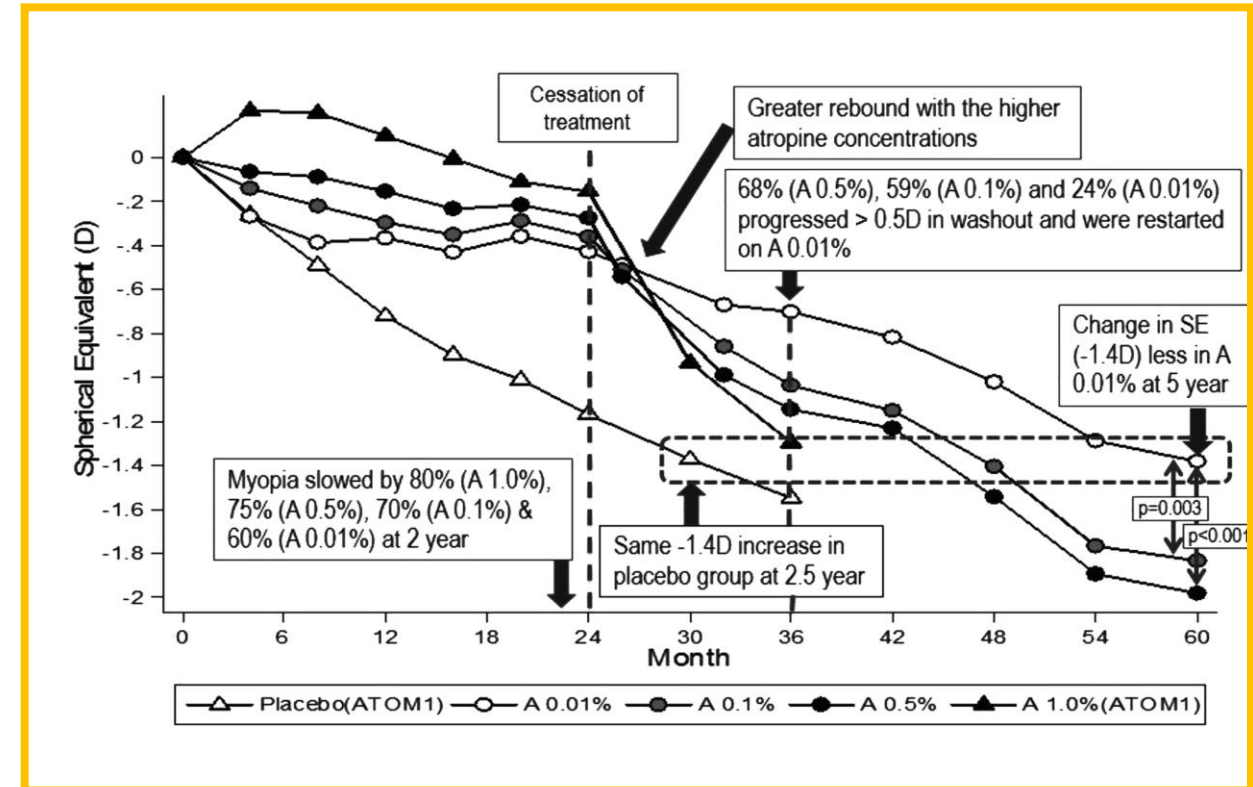
Current Evidence of Atropine on Myopia Control (ATOM Study)

Strong evidence that myopia progression can be slowed pharmacologically by using Atropine Eyedrops.

Low dose Atropine (0.01% and 0.1%) had comparable clinical efficacy to high dose Atropine for slowing Myopia progression over a 2-year period.

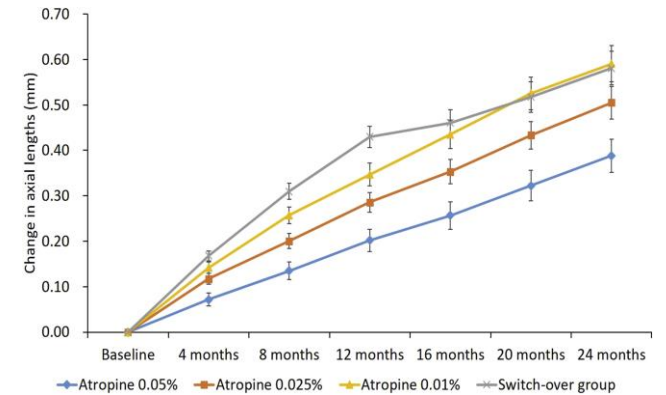
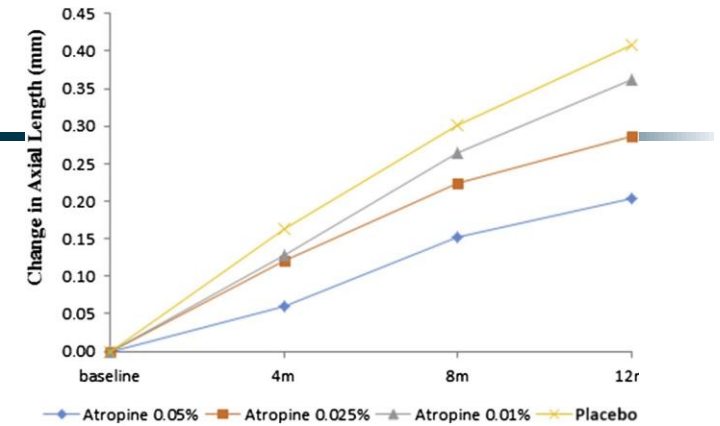
Post Cessation myopic rebound was higher in patients on higher dosage of Atropine.

Over 5 years, atropine 0.01% eyedrops were more effective in slowing myopia progression with less visual side effects compared to higher doses.

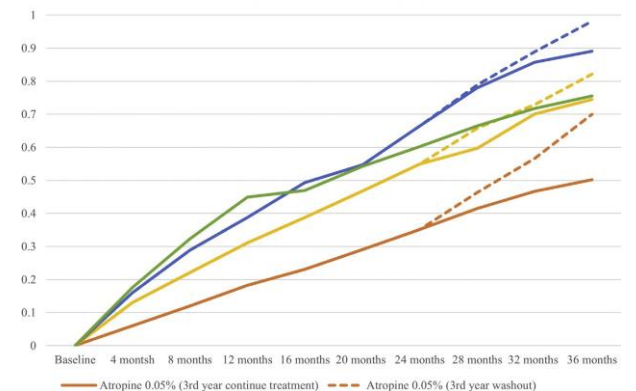


Current Evidence of Atropine on Myopia Control

- Low-Concentration Atropine for Myopia Progression phase 1 (LAMP) 2018: First Randomized placebo controlled double masked trial compared 0.05%, 0.025% and 0.01% Atropine. Showed that all 3 concentrations of atropine reduced myopia progression when compared with placebo, along with a concentration dependent response.
- LAMP phase 2 report 2020: Over 2 years, the efficacy of **0.05% atropine** was double that observed with 0.01% remaining the **optimal concentration in slowing progression of myopia**. Concentration dependent response persisted over the 2 year.
- LAMP phase 3 report 2022: 0.05% Atropine remained the optimal concentration over 3 years. Stopping treatment at an older age and lower concentration was associated with a smaller rebound.



Change in axial length (AL) in treatment groups across time.



Current Evidence of Atropine on Myopia Control (LAMP Study)

Confirmed the efficacy of Low-concentration atropine in slowing myopia progression.

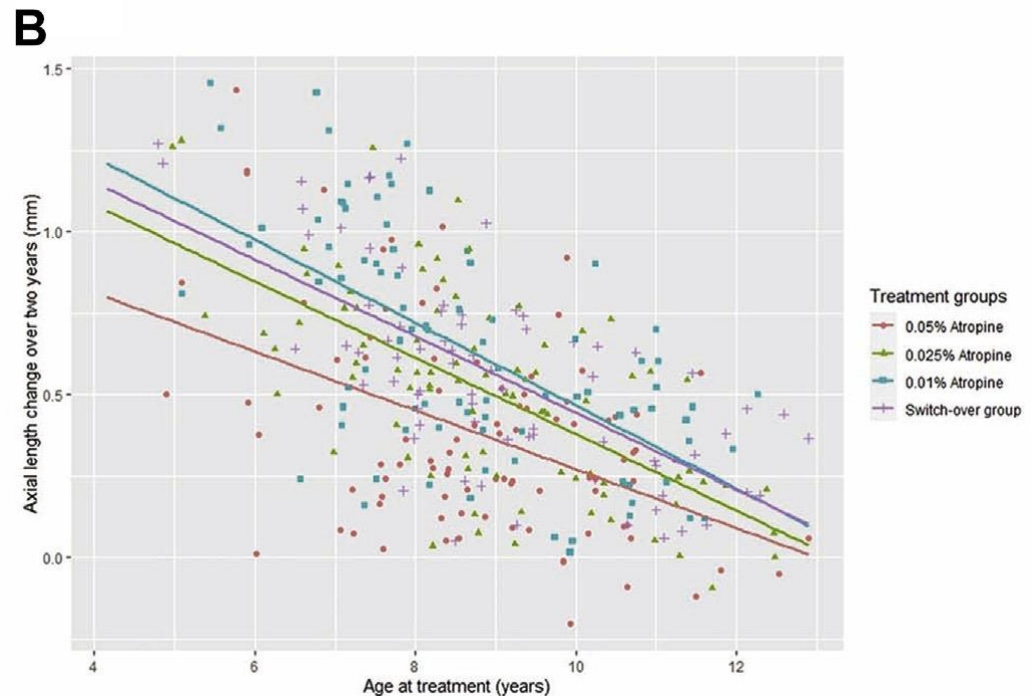
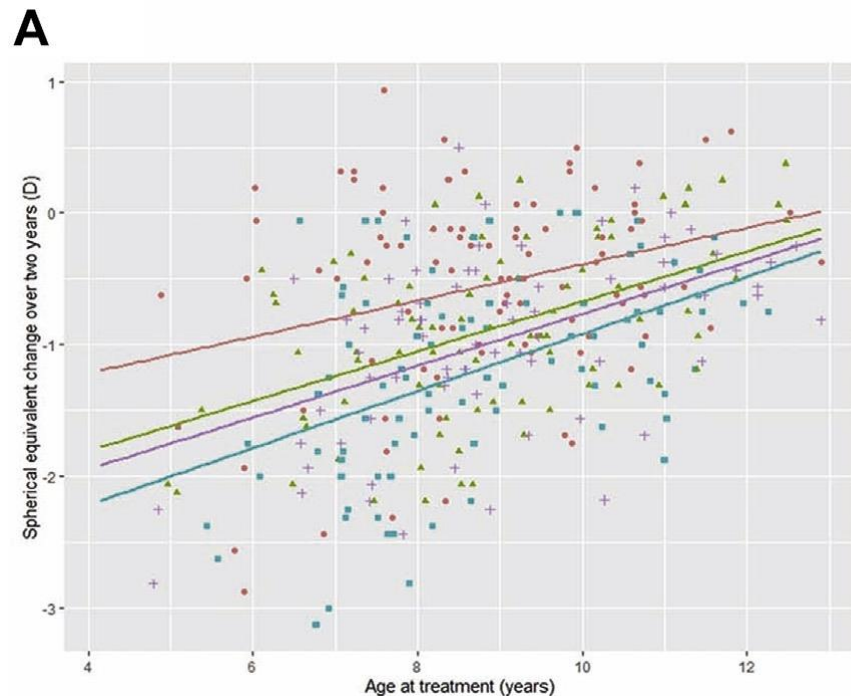
0.05% Atropine remained the optimal concentration with maximum efficacy among low dose atropine in slowing myopia progression both over 2 and 3 years.

Stopping treatment at an older age and lower concentration was associated with a smaller rebound.

Age Effect on treatment Responses to different concentrations of low dose Atropine (LAMP study). 2021

Younger Children (4-12 years) required the highest (0.05%) concentration to achieve similar reduction in myopia progression as older children receiving lower concentrations

Younger patients should be administered a higher concentration (0.05%) irrespective of the degree of myopia or parental myopia



Current Evidence of Low Dose Atropine on Myopia Control

Efficacy and Safety of 8 Atropine concentrations for Myopia Control in Children (A Network Meta-Analysis). 2022: 0.05% atropine was comparable with that of high dose atropine (1% and 0.5%)

Effect of Low Concentration Atropine in Delaying Myopia Onset

- Effect of Low-Concentration Atropine vs. Placebo on Myopia Incidence in Children (LAMP2 RCT)

Table 2. Primary Outcomes of Myopia Incidence and Participants With Fast Myopic Shift Over 2 Years

Follow-up	No./total No. (%)			P value		Difference (95% CI), %			P value ^c		
	0.05% Atropine	0.01% Atropine	Placebo	For trend ^a	For trend (adjusted) ^b	0.05% Atropine vs 0.01% atropine	0.05% Atropine vs placebo	0.01% Atropine vs placebo	0.05% Atropine vs 0.01% atropine	0.05% Atropine vs placebo	0.01% Atropine vs placebo
Cumulative myopia incidence (defined as spherical equivalent ≤ -0.50 D)											
4 mo	1/138 (0.7)	4/127 (3.1)	8/130 (6.2)	.02	.01	2.4 (-1.1 to 7.2)	5.4 (1.4 to 11.0)	3.0 (-2.5 to 8.9)	.15	.01	.25
8 mo	8/132 (6.1)	20/131 (15.3)	21/120 (17.5)	.007	.001	9.2 (1.8 to 17.1)	11.4 (3.7 to 19.9)	2.2 (-7.0 to 11.7)	.02	.004	.63
12 mo	13/136 (9.6)	35/139 (25.2)	39/128 (30.5)	<.001	<.001	15.6 (6.9 to 24.5)	20.9 (11.6 to 30.4)	5.3 (-5.4 to 16.0)	<.001	<.001	.33
16 mo	23/124 (18.5)	43/132 (32.6)	44/124 (35.5)	.004	.001	14.0 (3.4 to 24.4)	16.9 (6.0 to 27.7)	2.9 (-8.7 to 14.5)	.01	.003	.62
20 mo ^d	26/95 (27.4)	36/92 (39.1)	38/88 (43.2)	.03	.01	11.8 (-1.7 to 24.9)	15.8 (2.0 to 29.2)	4.1 (-10.3 to 18.2)	.09	.03	.58
24 mo	33/116 (28.4)	56/122 (45.9)	61/115 (53.0)	<.001	<.001	17.5 (5.2 to 29.2)	24.6 (12.0 to 36.4)	7.1 (-5.6 to 19.6)	.005	<.001	.27
Participants with fast myopic shift (defined as spherical equivalent myopic shift ≥ 0.50 D over the first 12 mo and ≥ 1.00 D over 24 mo)											
12 mo	39/136 (28.7)	68/139 (48.9)	81/128 (63.3)	<.001	<.001	20.2 (8.8 to 31.2)	34.6 (22.9 to 45.3)	14.4 (2.4 to 25.9)	<.001	<.001	.02
24 mo	29/116 (25.0)	55/122 (45.1)	62/115 (53.9)	<.001	<.001	20.1 (8.0 to 31.6)	28.9 (16.5 to 40.5)	8.8 (-3.9 to 21.3)	.001	<.001	.17

^a P values for trend were calculated via logistic regression without adjustment.

^b Adjusted P values for trend were calculated via logistic regression with adjustment of baseline age, sex, baseline spherical equivalent/axial length, outdoor time, near work time, and parental myopia.

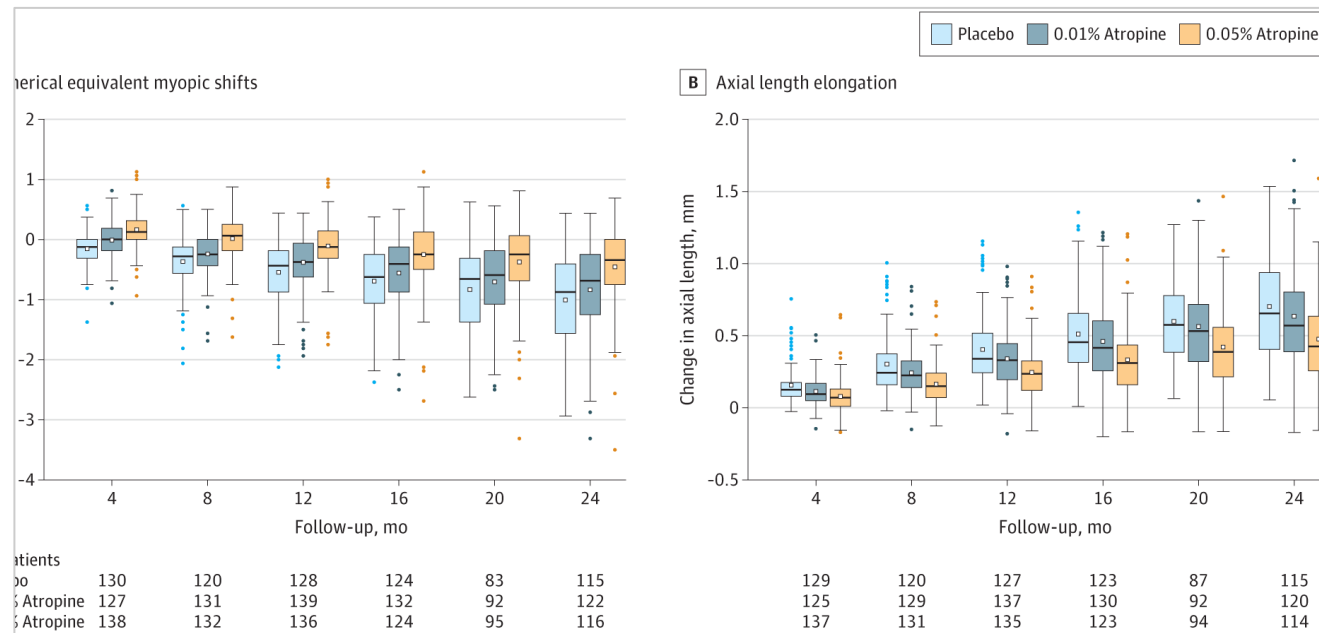
^c P values were calculated by exact unconditional methods based on the Farrington-Manning score statistic.

^d A proportion of participants did not attend the 20-month visit because of infection control restrictions during the COVID-19 pandemic.

Among children 4 to 9 years without myopia, nightly use of 0.05% atropine eyedrops compared with placebo resulted in a significantly lower incidence of myopia and lower percentage of participants with fast myopic shift at 2 years.

Effect of Low Concentration Atropine in Delaying Myopia Onset

- Effect of Low-Concentration Atropine vs. Placebo on Myopia Incidence in Children (LAMP2 RCT)

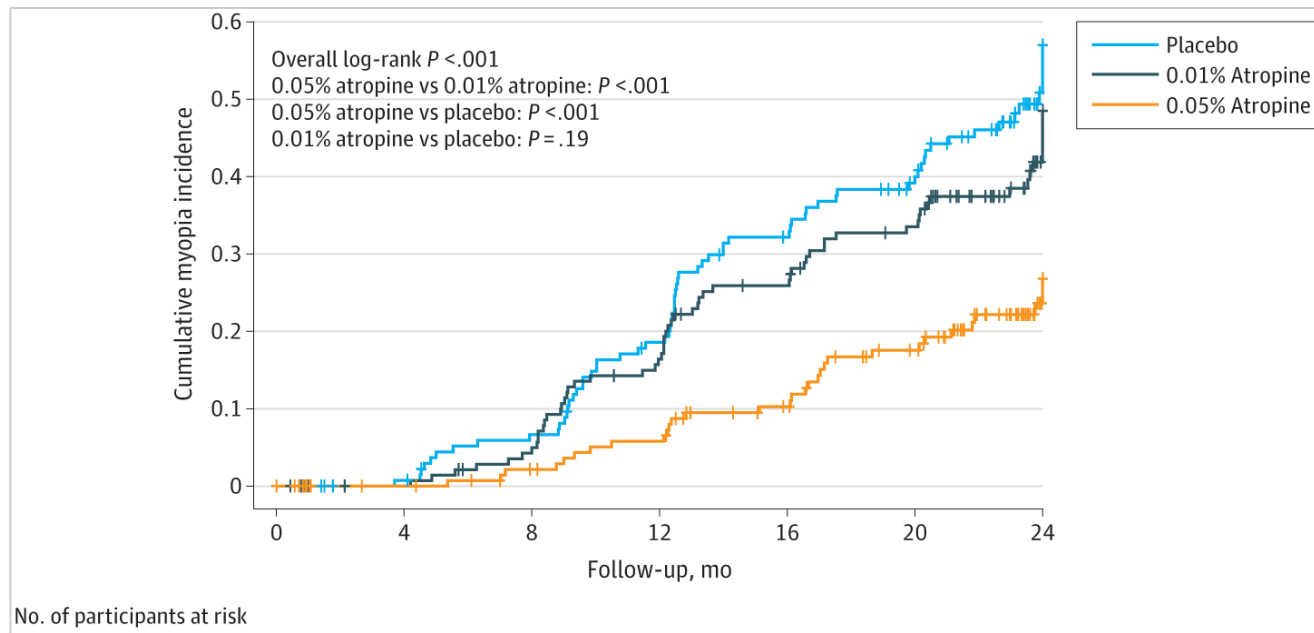


Secondary Outcome

At 2 years 0.05% atropine decreased spherical equivalent myopic shift and axial length elongation significantly more than 0.01% atropine

Effect of Low Concentration Atropine in Delaying Myopia Onset

- Effect of Low-Concentration Atropine vs. Placebo on Myopia Incidence in Children (LAMP2 RCT)

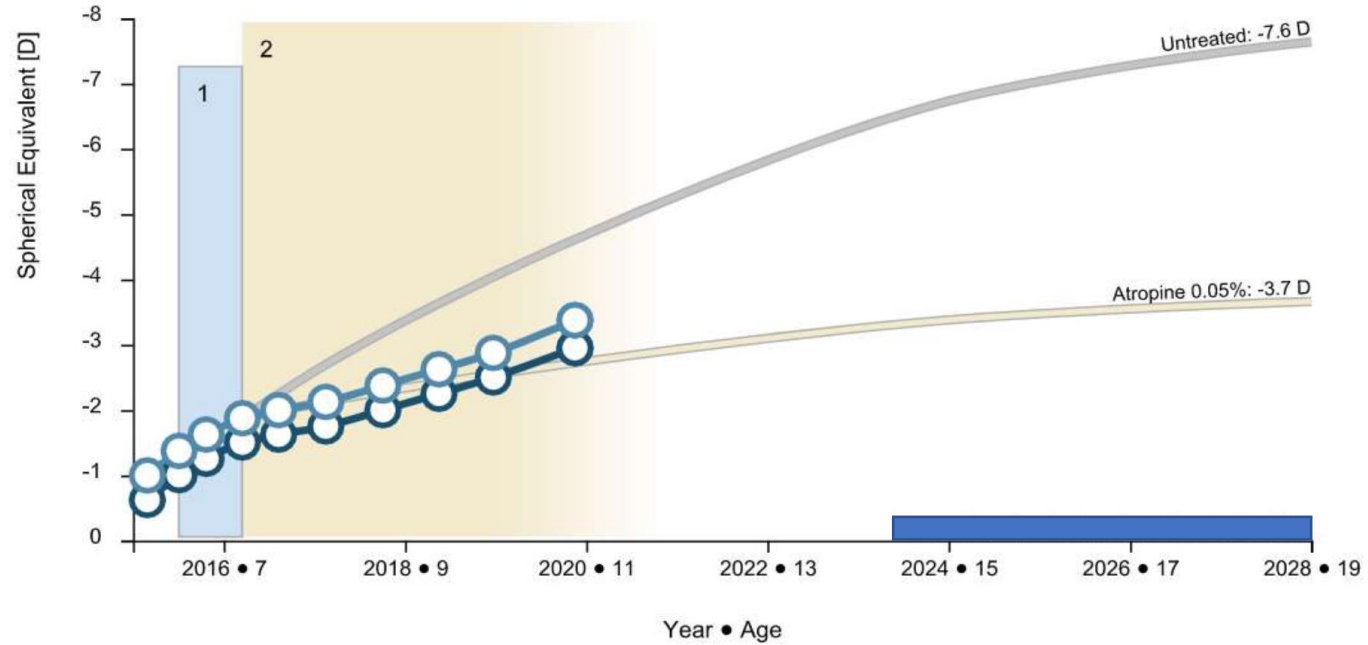


Exploratory Outcome

- Cumulative myopia incidence in the 0.05% significantly lower than that of 0.01%.
- Delay of Myopia onset in the 0.05% atropine group compared with both 0.01% and placebo.

AI- Powered Data Analytics

Refraction Progression



Treatments

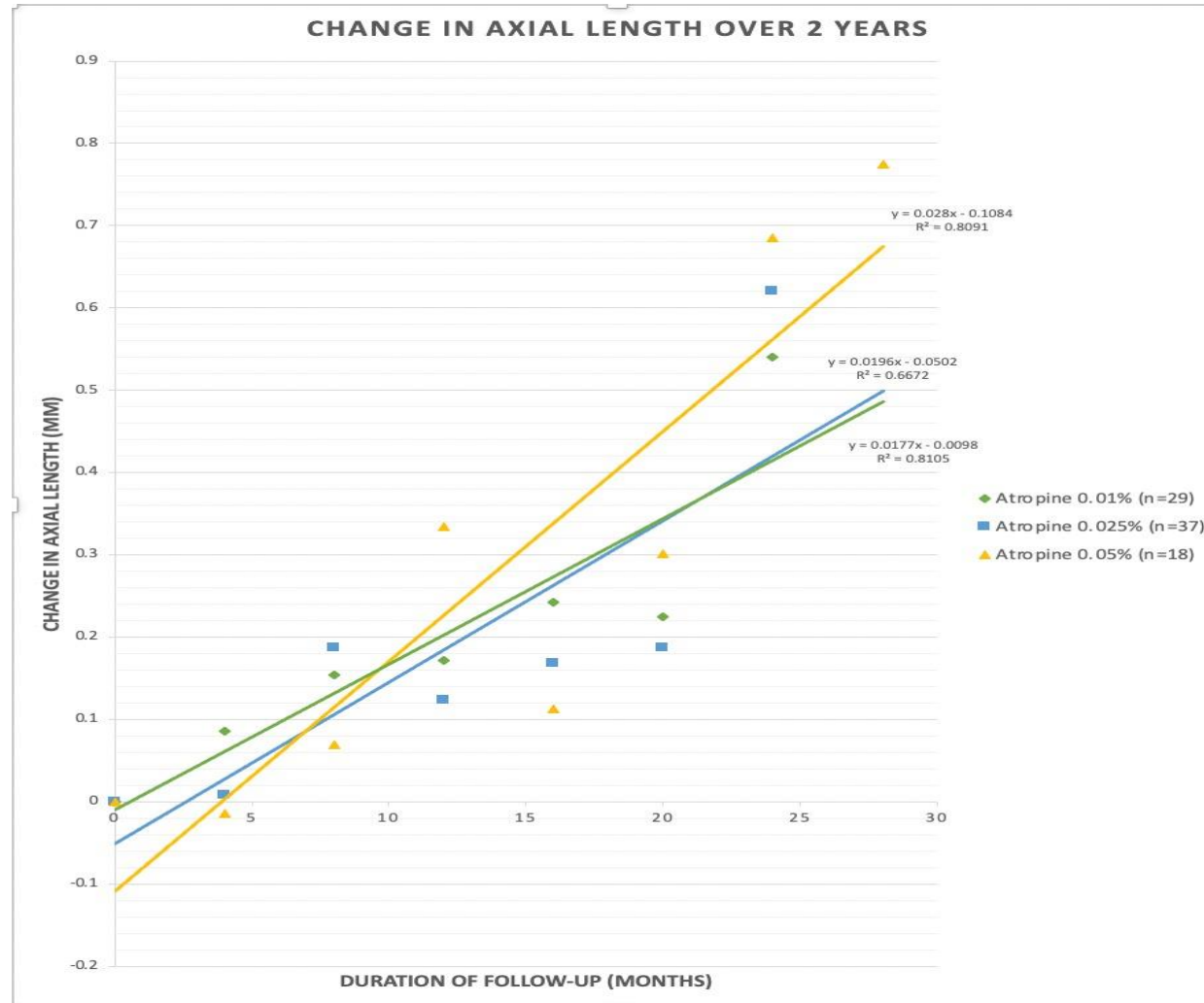
Number	Date	Label	Eyes
1	07.04.2015 – 03.15.2016	Atropine 0.02%	Both
2	03.15.2016	Atropine 0.05%	Both

Our Practice Data

	Overall	Atropine 0.01%	Atropine 0.025%	Atropine 0.05%
Number of patients	107	29	37	18
Number of males	53 (0.50%)	15 (0.52%)	17 (0.46%)	12 (0.67%)
Age	10.13 ± 2.62	8.11 ± 2.40	8.51 ± 2.45	9.67 ± 3.21
Range of age	4 to 18	4 to 18	4 to 18	4 to 18
Duration of follow-up	16.46 ± 6.13	15.92 ± 5.57	16.75 ± 6.18	16.71 ± 6.86
Change in AL (mm)	0.09 ± 0.36	0.10 ± 0.17	0.09 ± 0.49	0.08 ± 0.23
Change in SE (D)	-0.06 ± 0.36	-0.13 ± 0.36	-0.07 ± 0.14	-0.20 ± 0.40

Ethnicity	Caucasian	South Asian	Asian	Hispanic
107	19 (17.8%)	32 (29.9%)	36(33.6%)	20 (18.7%)

Our Practice Data – Axial Length Change with Atropine Dose



Clinical Guidelines for Atropine Dose

Higher Concentration Treatment reaches its maximum effect during the initial phase-

Start with a higher concentration

Better efficacy with lower concentration over time possibly due to cumulative effect over time

Switch to lower concentration after loading dose once myopia progression becomes stable

Screen All Children for Myopia

**High Risk Children Without Myopia
SE +1.00 and 0 AND at least 1 parent with SE > -3.00**

Age: Less than 4 years of Age

Discussion about Myopia with family
Discuss Increasing outdoor time
Follow up in 6 months

Age: 4 year or greater

Discussion about Myopia with family
Discuss Increasing outdoor time
Consider starting 0.05% atropine

Screen All Children for Myopia

Children With Myopia

Age: Less than 4 years of Age

Discussion about Myopia with family
Increase outdoor time
Chart baseline SE and AL
Consider starting 0.05% atropine
and/or Peripheral defocus glasses

Age: 4 year or greater

Discussion about Myopia with family
Increase outdoor time
Chart baseline SE and AL
Start 0.05% atropine
FU in 3-4 months

Algorithm for Myopia Treatment

Start with Atropine 0.05%, Baseline SE and AL

4 months

- SE shift > -0.75 D and/or AL > 0.30 mm
- Start exploring combined therapies

- SE shift < -0.75 or AL change < 0.3 mm continue 0.05% Atropine

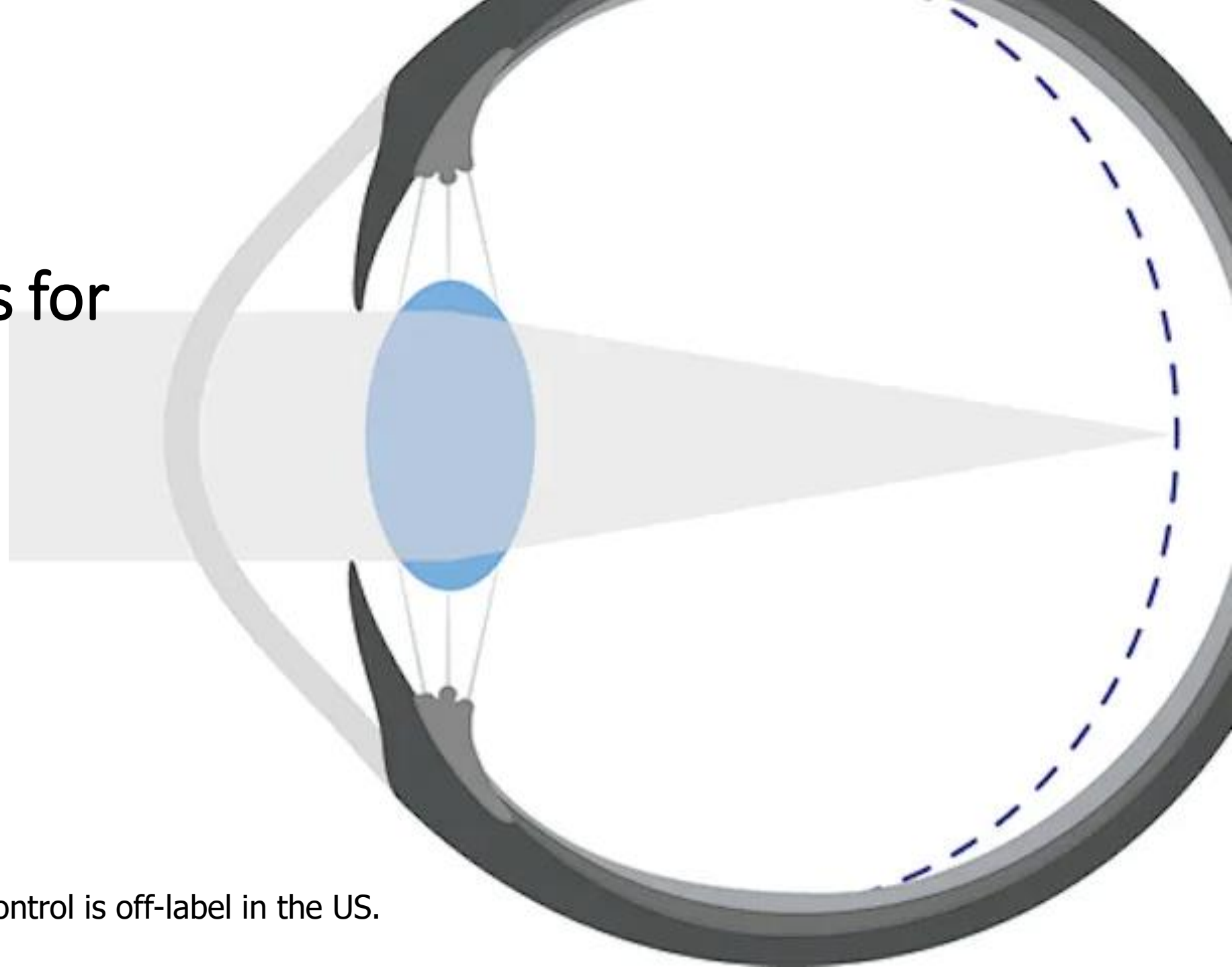
8 months

- SE shift < -0.75 or AL change < 0.3 mm after 1 year consider decreasing 0.01% Atropine

Practice Considerations for Atropine Treatment

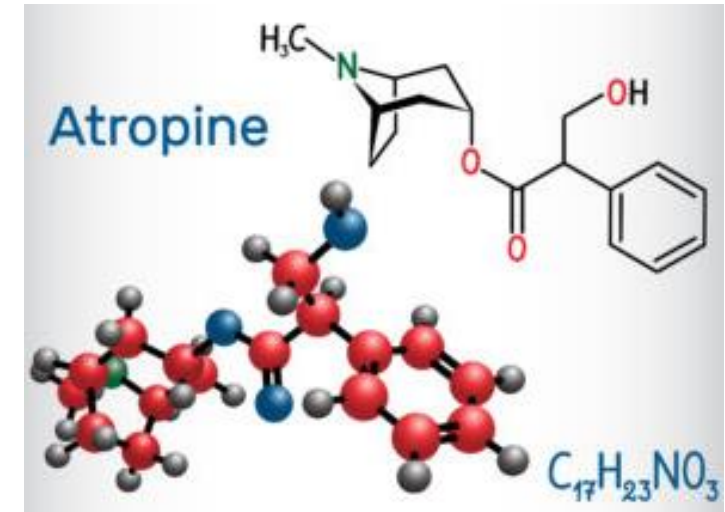
K. David Epley, MD
Pediatrix Eye Care

No Financial Interest
Atropine usage for myopia control is off-label in the US.



When Does Atropine Become Available Commercially?

- Vyluma (CHAMP) US, EU – Phase 3
 - N=576, completed Q3, 2022
 - Uses well-known excipients
 - Preservative free, daily ampules
- Sydnexis (STAAR): US, EU – Phase 3
 - N=840 , expected completion Q3, 2024
 - Uses deuterated (heavy) water known as deuterium oxide
 - Not a commonly used vehicle in topical ophthalmic products
 - Contains preservative
- Bausch / Eyenovia (CHAPARONE): US only – Phase 3
 - N= 420, expected completion Q3, 2025
 - Uses micro-dosing technology with handheld device to spray on eye
 - Contains preservative



Compounded Low Dose Atropine

- Many local compounding pharmacies are doing this.
- www.compoundingpharmacies.org has a directory of locally owned compounding pharmacies.
- Be sure to write "compounded" on your Rx; even though you discuss with families, many take the Rx to a regular pharmacy and get 1%!
- Excipients (vehicle), pH and stability can vary widely.
- Large compounding pharmacies Like Leiter's, Axis, CAPS, etc. can mail.
- Best practice: call your local compounding pharmacy and have a conversation with their head pharmacist to discuss how you are using, pH, need for a product that stays in solution for 3 months, cost, etc.
 - Keep the conversation ongoing as you get feedback from families
 - 1 10mL bottle should last 3 months and should cost <\$100.


Side Effects of Atropine


- Most common: stinging and burning
 - Putting the bottle in the refrigerator may help with this.
 - May help or hurt with longevity of the product based on excipients used.
- Blurred vision
- Photosensitivity
- Anticholinergic side effects


Anticholinergic Toxidrome


Mnemonic

Anticholinergic Side Effects

Can't SEE 

Can't PEE 

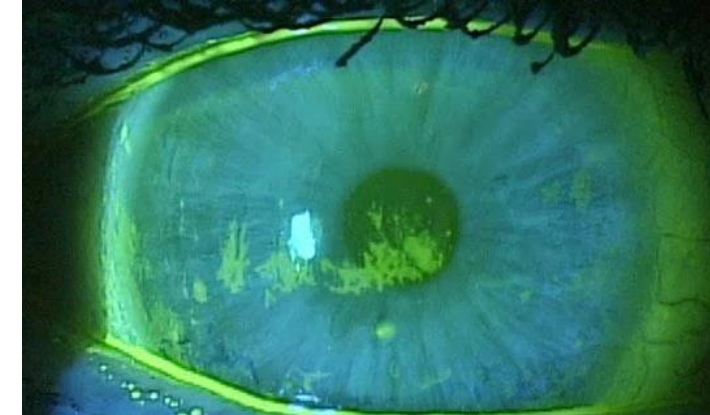
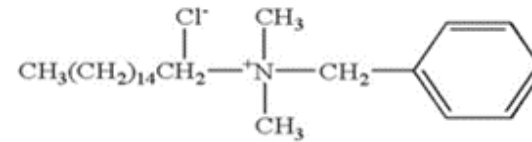
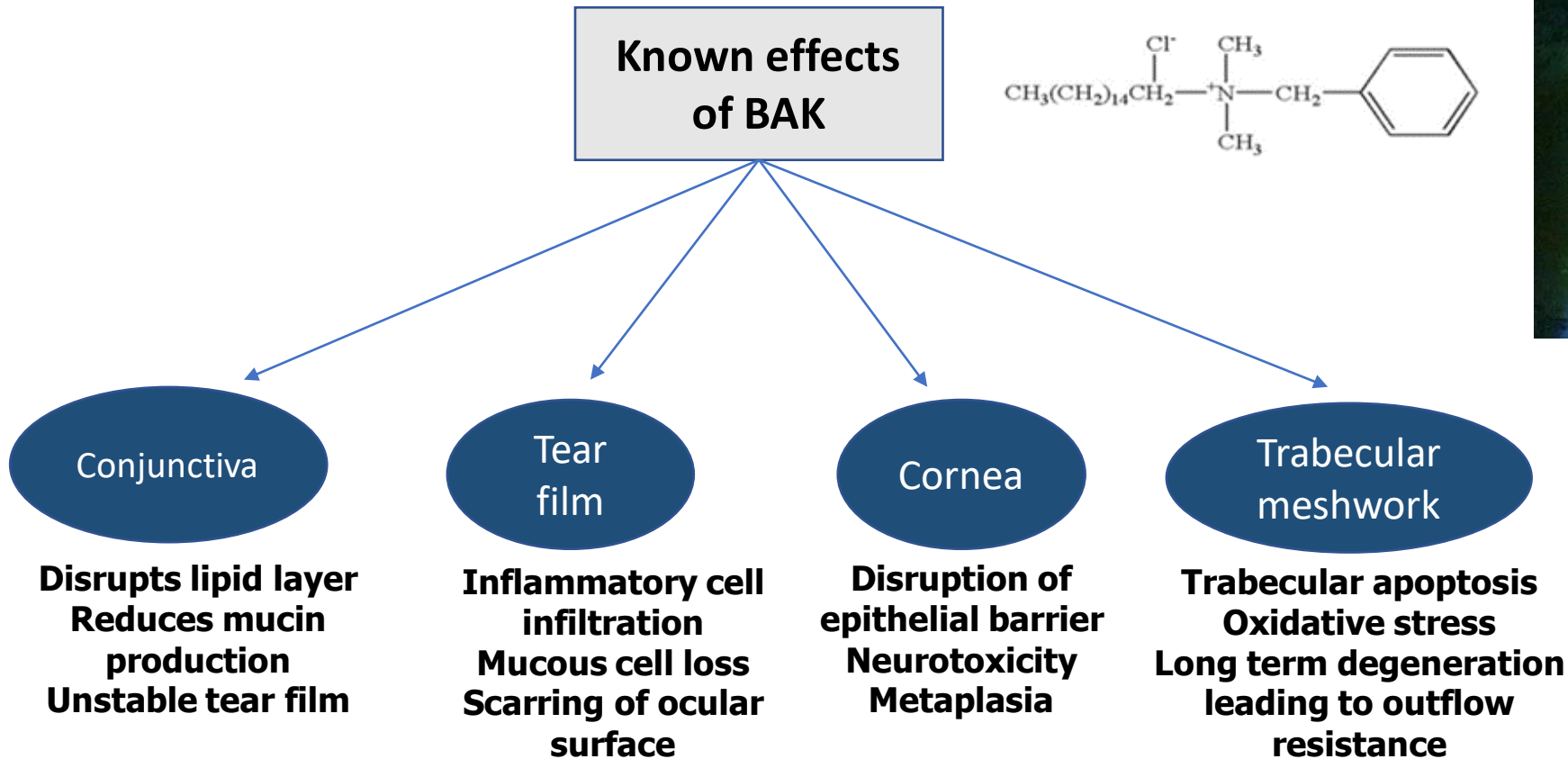
Can't SPIT 

Can't SHOT 

MEMORY PHARM™

Screenshot

Preserved vs. Non-preserved low dose atropine: risks of preservative



Topical drops with BAK stimulate an inflammatory response ~3 months that is maintained; PF drops do not.

Preservative free formulations are preferred for chronic topical medications

What About Preventing Myopia?

- Atropine for the treatment of Myopia 3 (ATOM3)
 - Estimated study completion is May of 2023.
- No other trials published demonstrating a preventive effect at this time.
- LAMP2 Study

Looking for children at risk of myopia or near/short-sightedness

- Do you have a family history of myopia?
- Do you have a child who is not yet myopic or has just turned myopic?



Children with a family history of myopia are 2-3x more likely to become myopic, and children who develop myopia early tend to develop higher myopia. We are doing a study to see if eye drops can prevent the onset or control the progression of early myopia, and thereby prevent high myopia.

ATOM 3 Clinical Trial

We are looking for children:

1. Aged 5 to 9 years old
2. No glasses or low myopia (less than -1.50D)
3. Family history of myopia (one parent with myopia more than -3.00D)

By volunteering, you can help develop treatments for myopia.

If you are interested for your child to take part and wish to know more, please contact us : 6322 4500/6322 4501

(Mon- Fri, 9am to 5 pm)

Email: ATOM3@seri.com.sg



Poster Advertisement Version 3.0 dated 8 November 2018



Ways to Prevent or Slow Myopia Progression

- Time spent outdoors
- Increase working distance
- Reduce intensity of near work
- Take reading/near work breaks (20/20/20 rule)
- Starting to sound like your nagging parents, right?

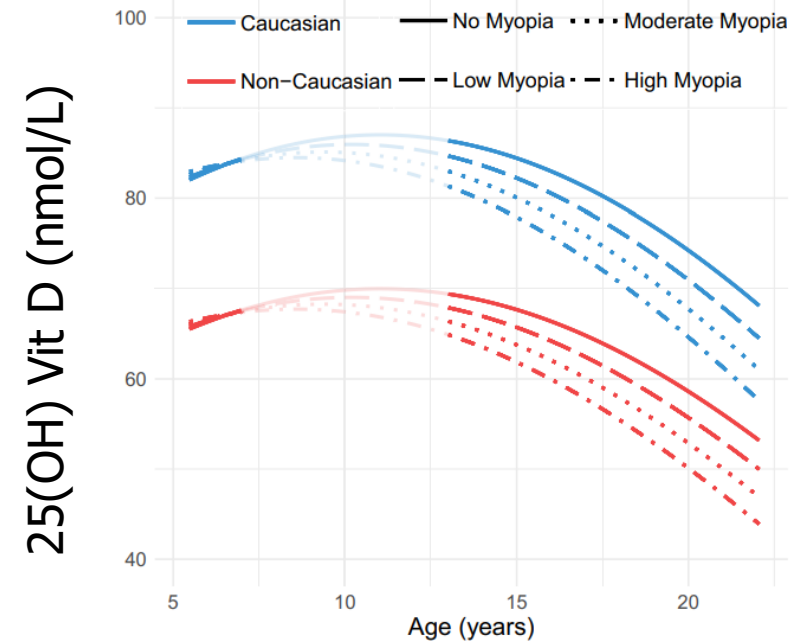
Time Spent Outdoors

A meta-analysis by Sherwin, et al demonstrated an association between the time spent outdoors and myopia in children and adolescents (N \approx 10,000)

Results

- There was a significant protective association between increasing time spent outdoors and reducing the risk of:
 - Myopia
 - Myopia progression
- **An increase** in 7 hours of **time spent outdoors** per week (**1 hr/d**) reduces the risk of myopia

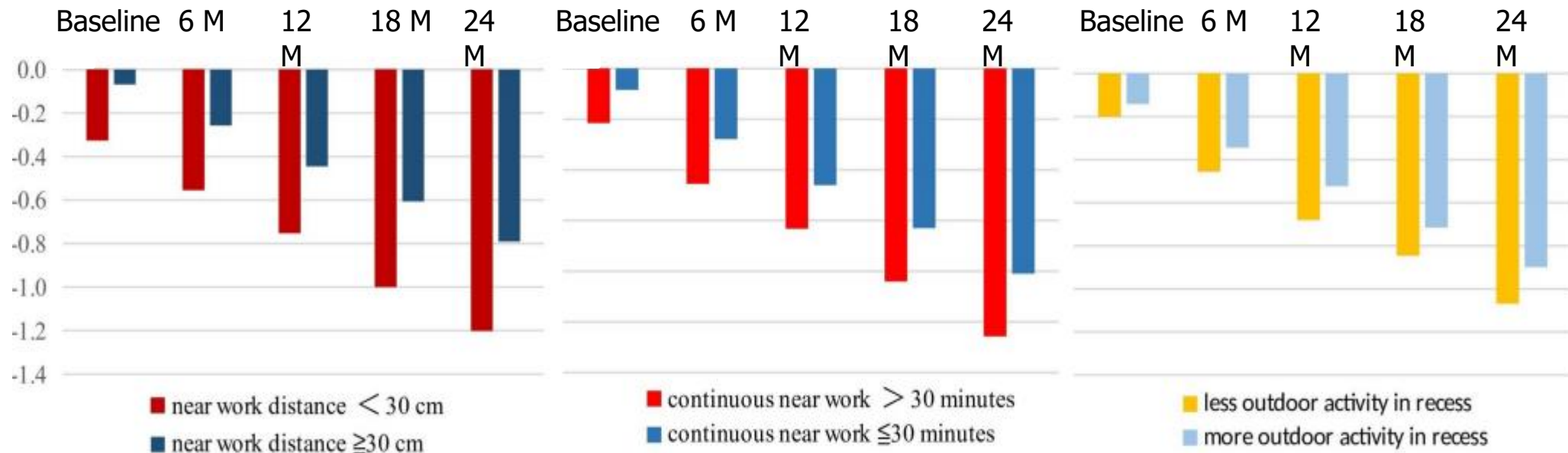
Serum 25-OH Vit D is a surrogate for time spent outdoors and impacts the risk of myopia at 20 years (N=1,344)



Serum 25-OH Vit D concentration has the potential to be a biomarker to measure a child's *time spent outdoors*

Current Behavioral Treatment Options

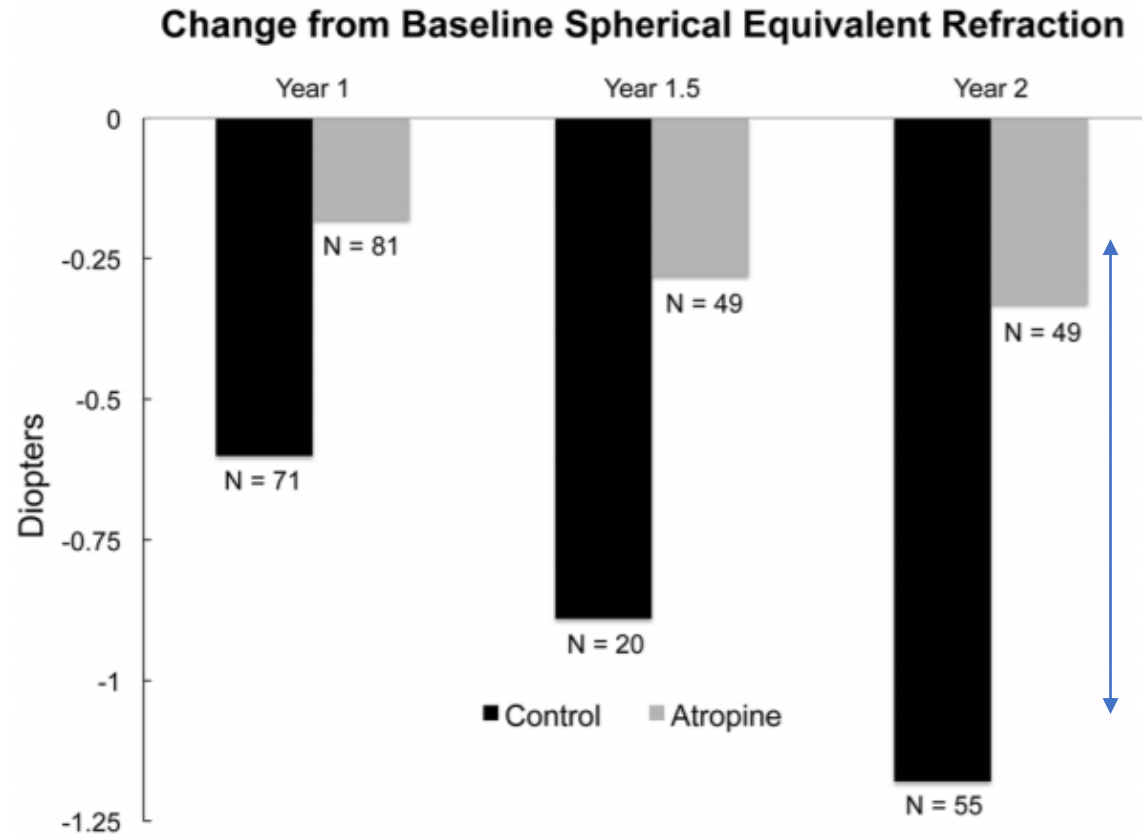
In myopic children aged around 10 years in Taipei, the following behaviors are protective in myopia prevalence and progression:



N = 10,743 students completed 2-year refraction data

Increasing reading distance, taking reading breaks, and increasing outdoor time slowed myopia progression

Study of a US Population Treated with 0.01% Atropine for Myopia Control



Retrospective case-control study of US children treated with 0.01% atropine corroborated results found in Asia

Our Data from Four US Sites

- Four Sites Across the US
 - Casey Eye Institute (Portland, OR)
 - Children's Hospital of Orange County (Orange, CA)
 - Pediatrix Eye Care (Kirkland, WA)
 - Lurie Children's Hospital of Chicago (Chicago, IL)
- Retrospective chart reviews
- At least 6 months of follow up



Children's Orange County Data

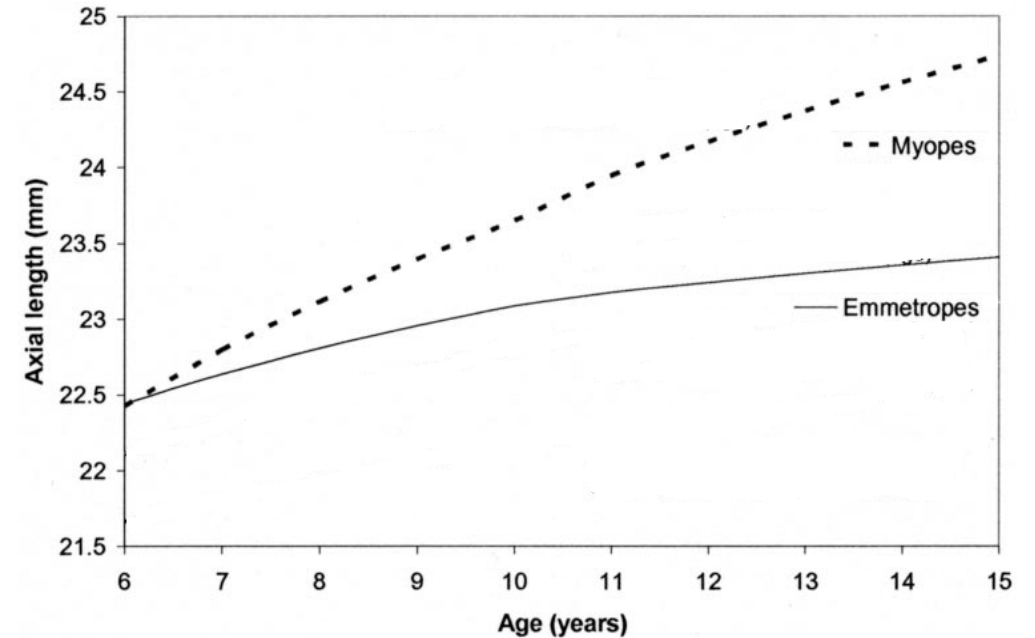
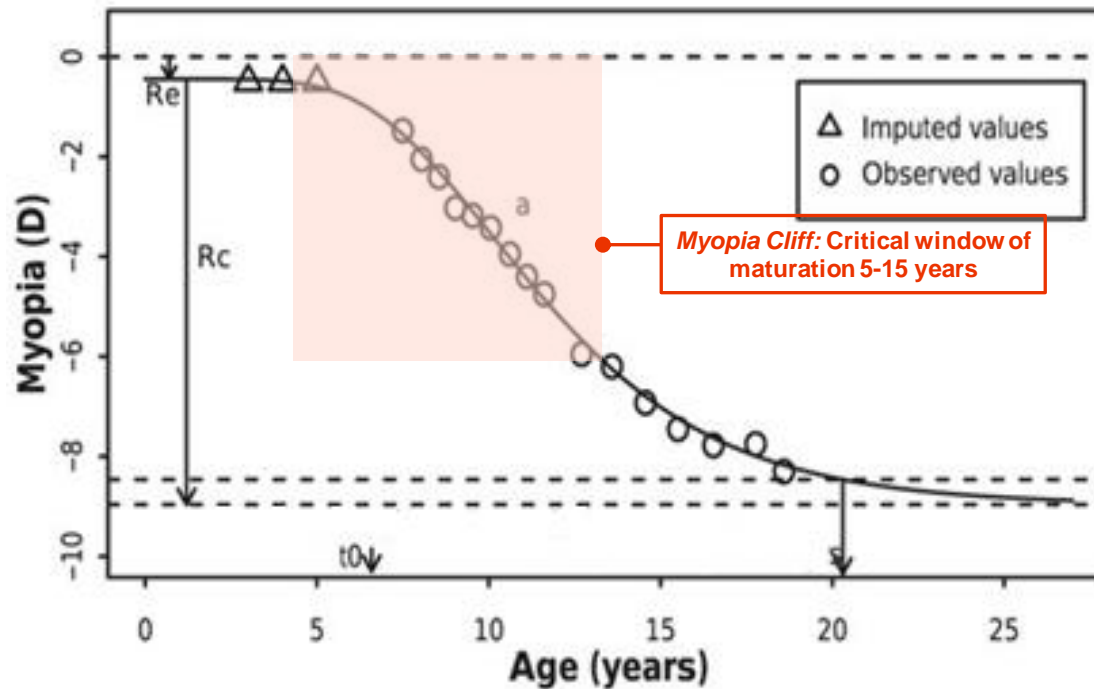
	Overall	Atropine 0.01%	Atropine 0.025%	Atropine 0.05%
Number of patients	107	29	37	18
Number of males	53 (0.50%)	15 (0.52%)	17 (0.46%)	12 (0.67%)
Age	10.13 ± 2.62	10.11 ± 2.40	10.51 ± 2.45	9.67 ± 3.21
Range of age	4 to 18	4 to 17	5 to 18	5 to 15
Duration of follow-up	6.46 ± 6.13	5.92 ± 5.57	6.75 ± 6.18	6.71 ± 6.86
Change in AL (mm)	0.09 ± 0.36	0.10 ± 0.17	0.09 ± 0.49	0.08 ± 0.23
Change in SE (D)	-0.06 ± 0.36	-0.13 ± 0.36	-0.07 ± 0.14	-0.20 ± 0.40

Lurie Children's 1-Year Atropine Data

	Overall	Atropine 0.01%	Atropine 0.05%
Number of patients	59	29	30
Number of males	30 (50.1%)	14 (48.2%)	16 (53.3%)
Age	9.2 ± 3.37	10.08 ± 3.69	8.4 ± 2.78
Range of age	2 to 23	5 to 23	2 to 14
Race/Ethnicity	Asian – 18 (31%) White – 15 (25%) Other/Hispanic – 10 (17%) Black – 8 (14%) White/Hispanic – 5 (8%) Other – 3 (5%)	White – 11 (38%) Asian – 9 (31%) Black – 5 (17%) Other/Hispanic – 2 (7%) White/Hispanic – 1 (3%) Other – 1 (3%)	Asian – 9 (30%) Other/Hispanic – 8 (27%) White/Hispanic – 4 (13%) White – (13%) Black – 3 (10%) Other – 2 (7%)
Change in SER	-0.31 ± 0.58 D	-0.51 ± 0.68 D	-0.12 ± 0.38 D

What is the Right Age to Initiate Myopia Therapies?

- Myopia may progress rapidly between ages of 5-15
- There is a time window for intervention
 - Changes in axial length are irreversible



Myopia treatment should be started as early as possible

At What Dose Should I Start?

- Variable practice patterns based on variable RCT data and practice philosophies.
- Open this up to the panel: at which dose do you usually start and when do you escalate the dose?



When to Stop Low Dose Atropine?

- Every randomized controlled clinical trial shows regression after cessation, varying by dose.
- None of these studies have data more than 5 years out.
- Anecdotally, we have independently noted that early cessation leads to resumed progression.
- Our practice patterns vary slightly, but all of us are tending to use atropine until completion of physical growth and two years of stable SER or Axial length.
 - 14-17 years of age.
- Typical myopia progression occurs over a 5-7 year period.
 - Children who start earlier may reach stability prior to the end of their physical growth.

Questions

- Dose of Atropine
- Age at onset
- AL Vs SE change
- Frequency of exams
- Duration of Atropine therapy
- When to stop

Optical Interventions for Myopia Control



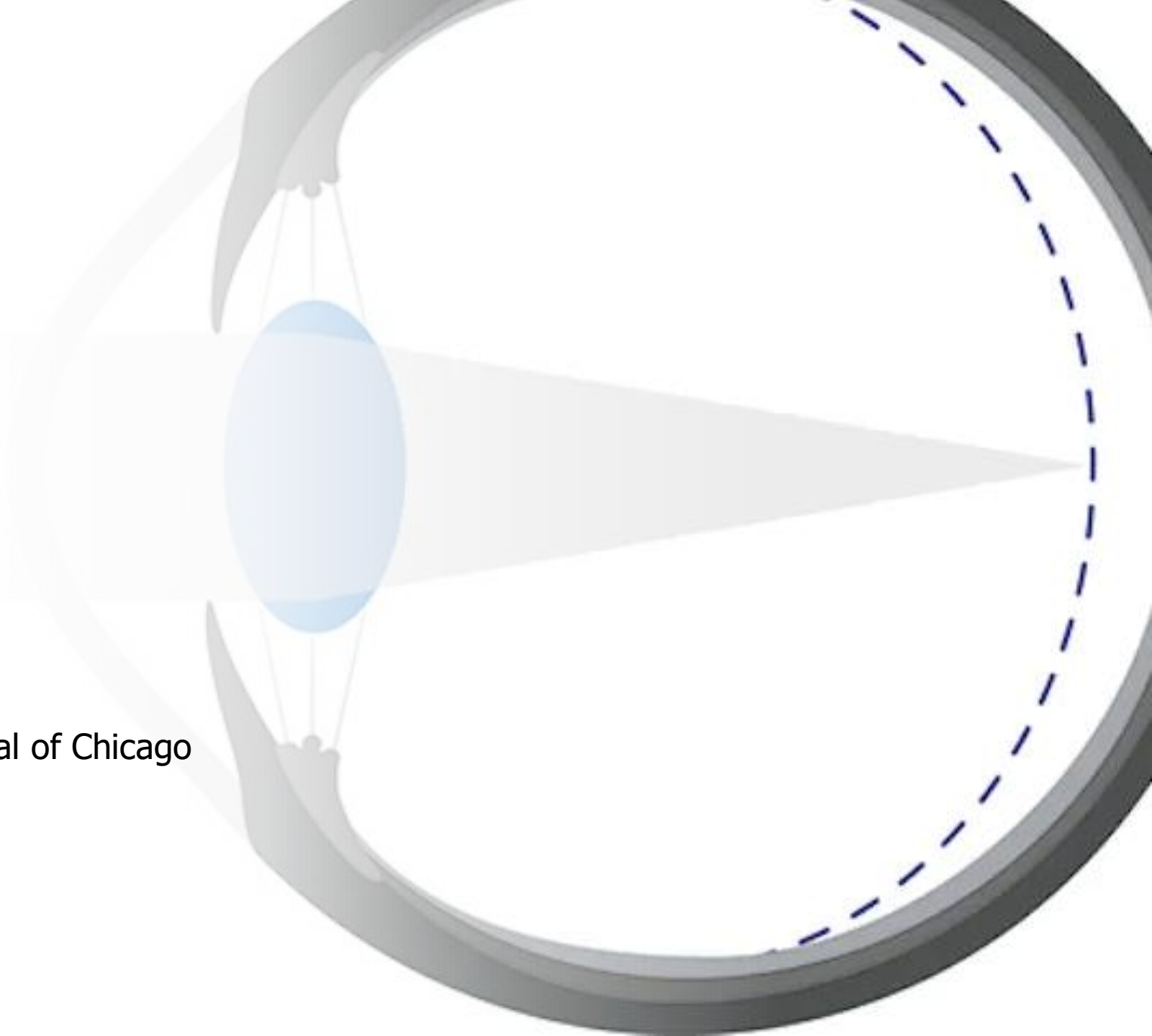
Peripheral Defocus Contact Lenses

Magdalena Stec, OD, FAAO

Assistant Professor

Ann & Robert H. Lurie Children's Hospital of Chicago

No Financial Interest

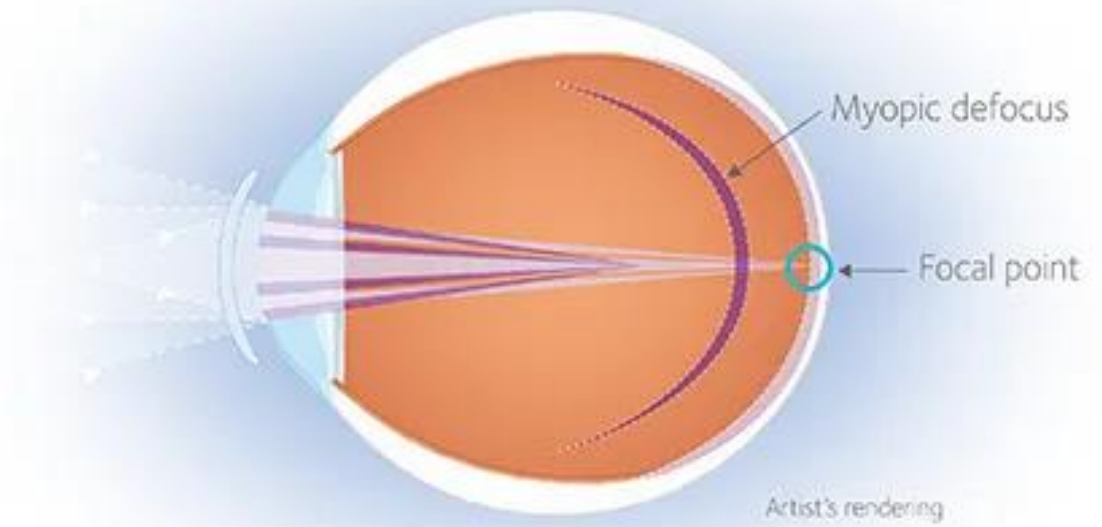


Peripheral Defocus Contact Lens (PDCL)



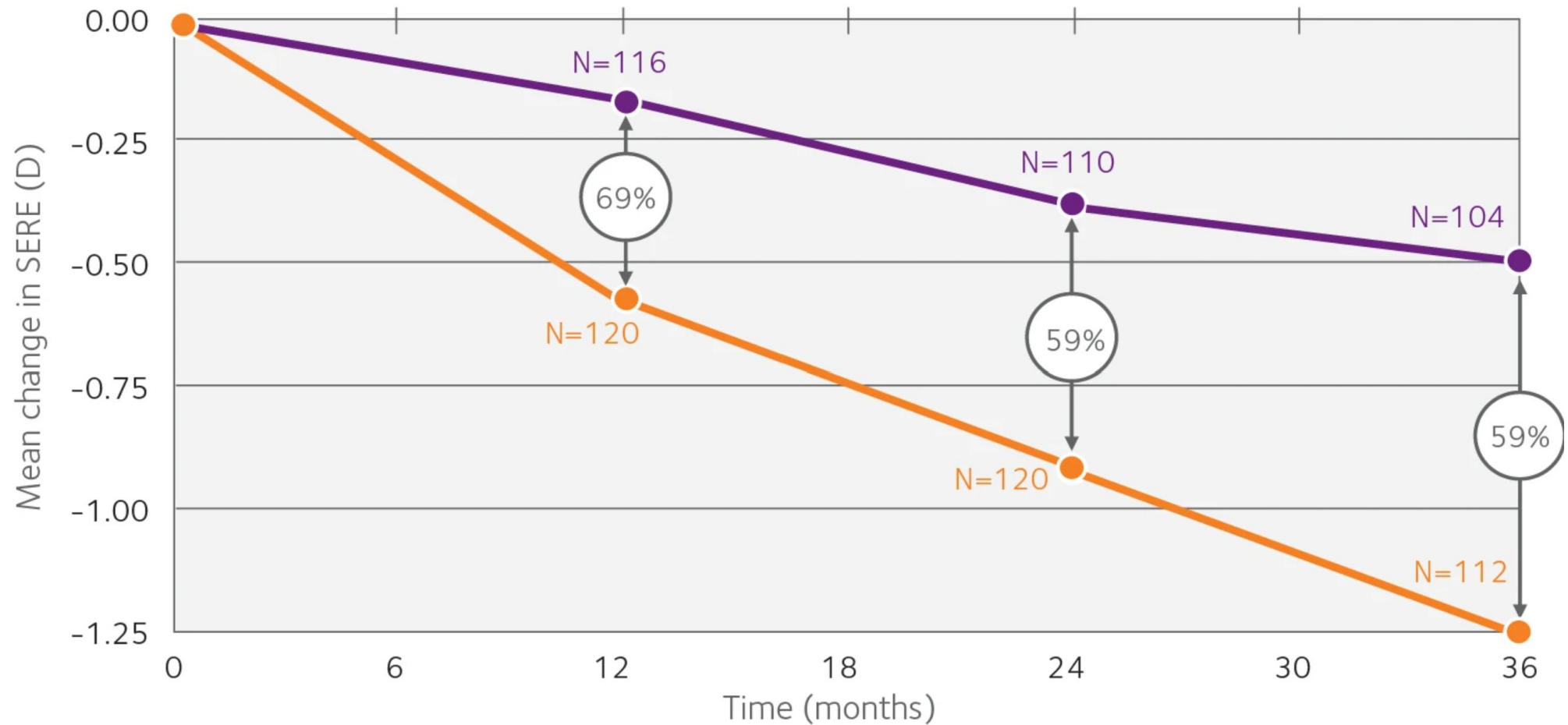
Myopic defocus

Correction zones
Treatment zones creating myopic defocus

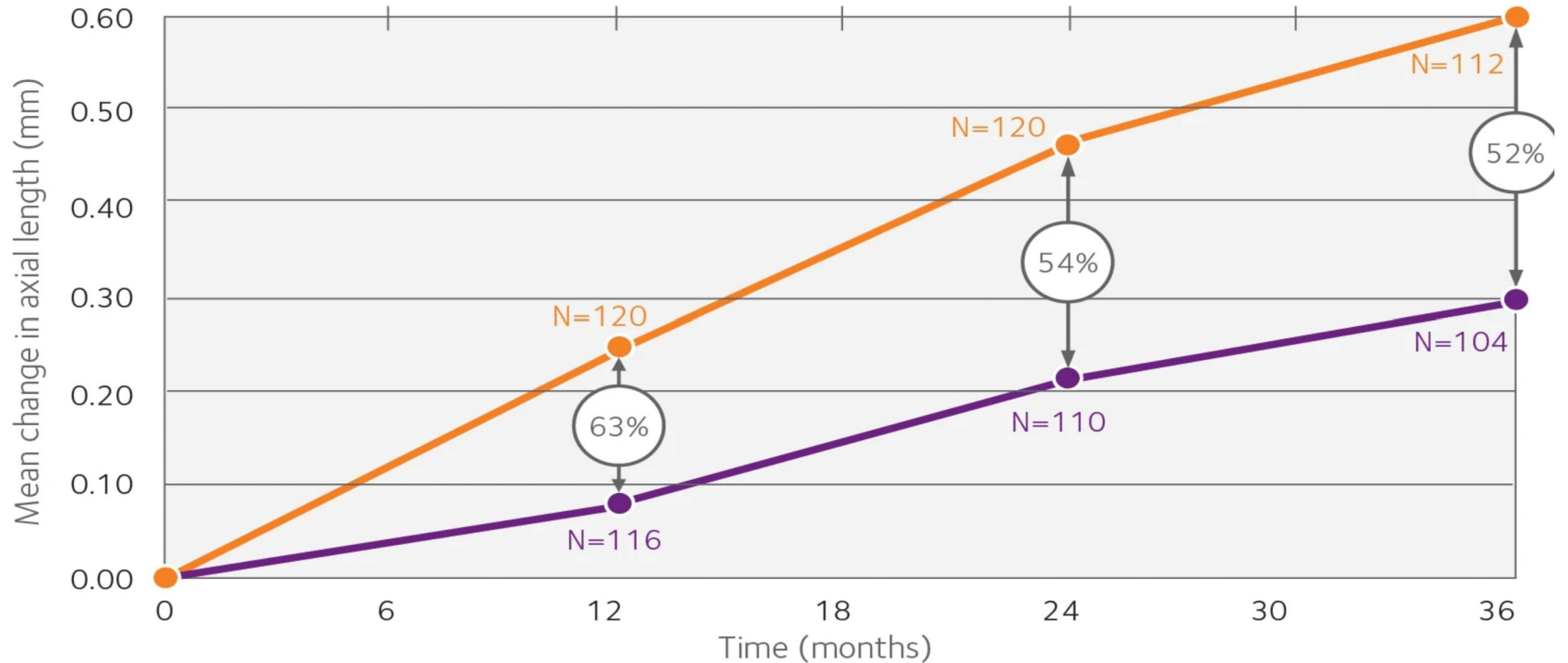


Artist's rendering

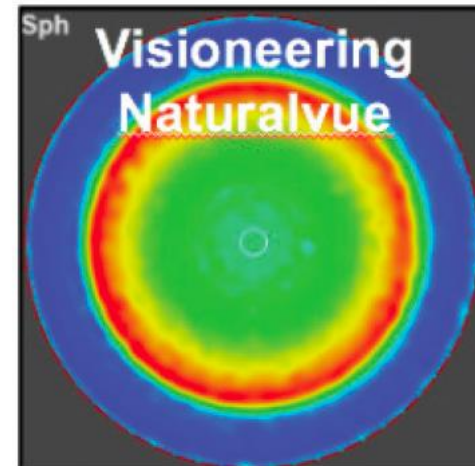
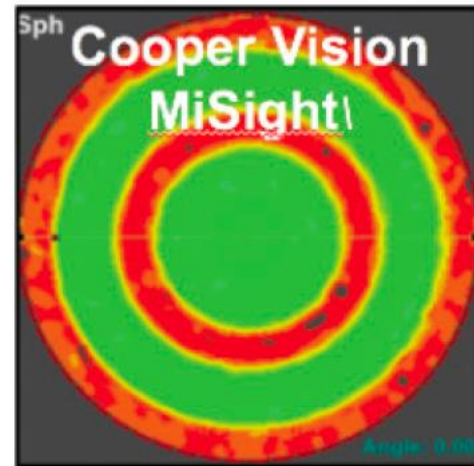
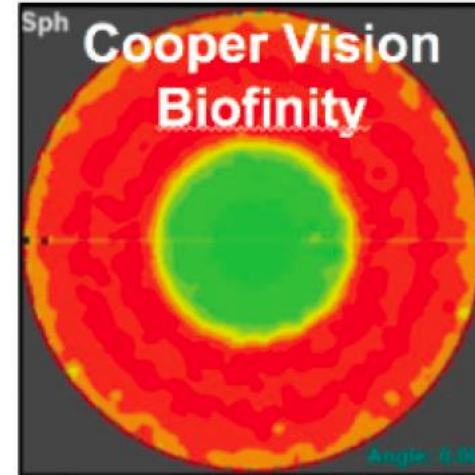
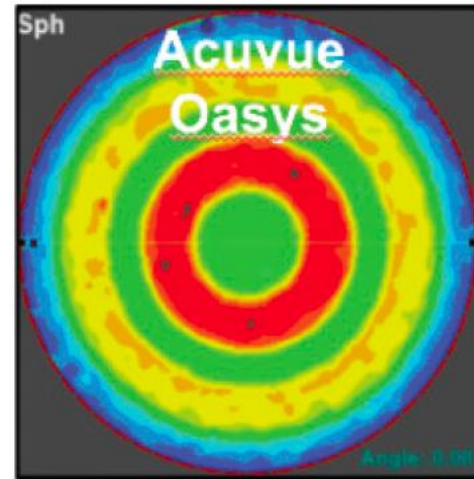
Efficacy of PDCLs vs. Spherical Lenses (Spherical Equivalent)



Efficacy of PDCLs vs. Spherical Lenses (Axial Length)



Peripheral Defocus Designs

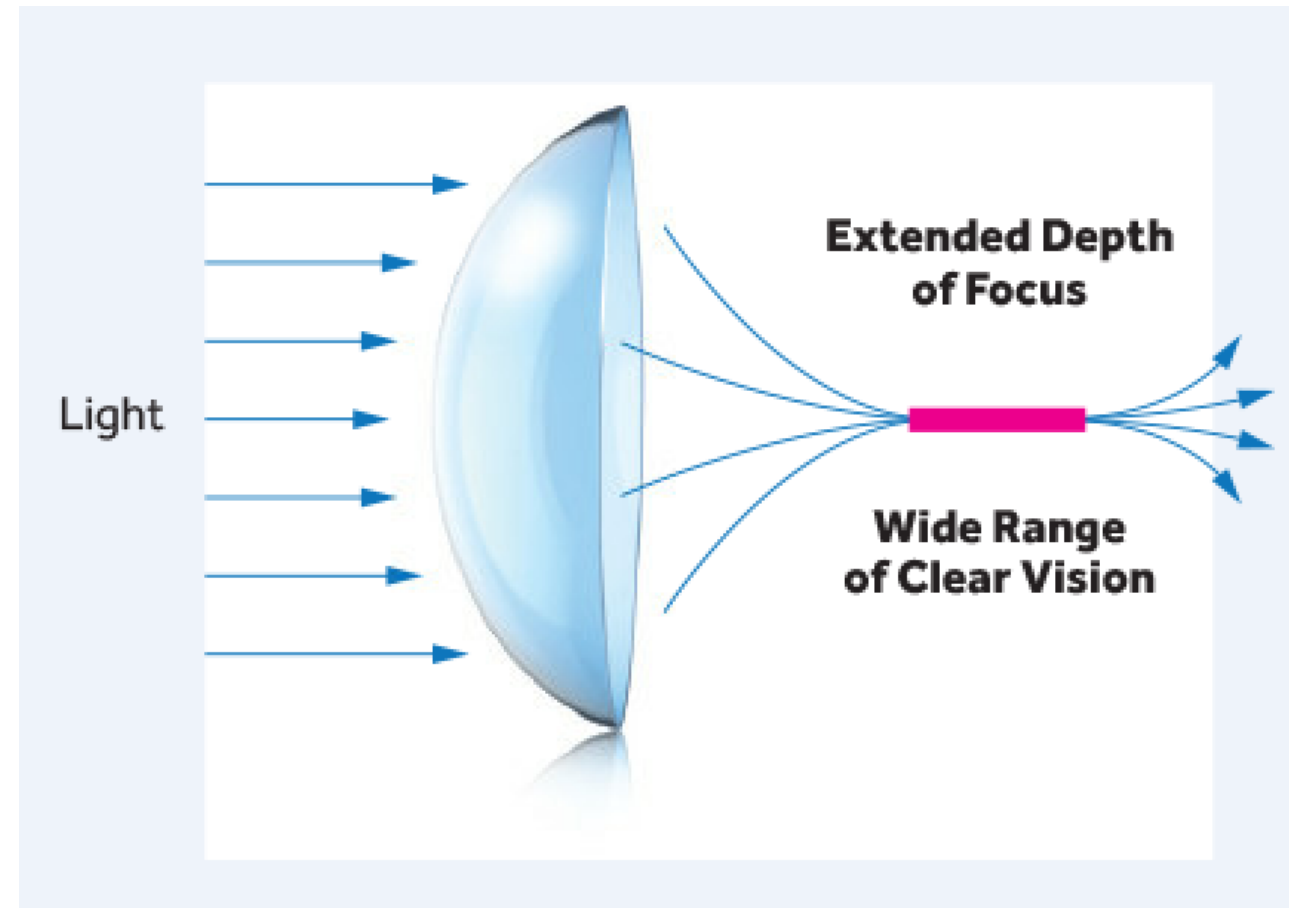
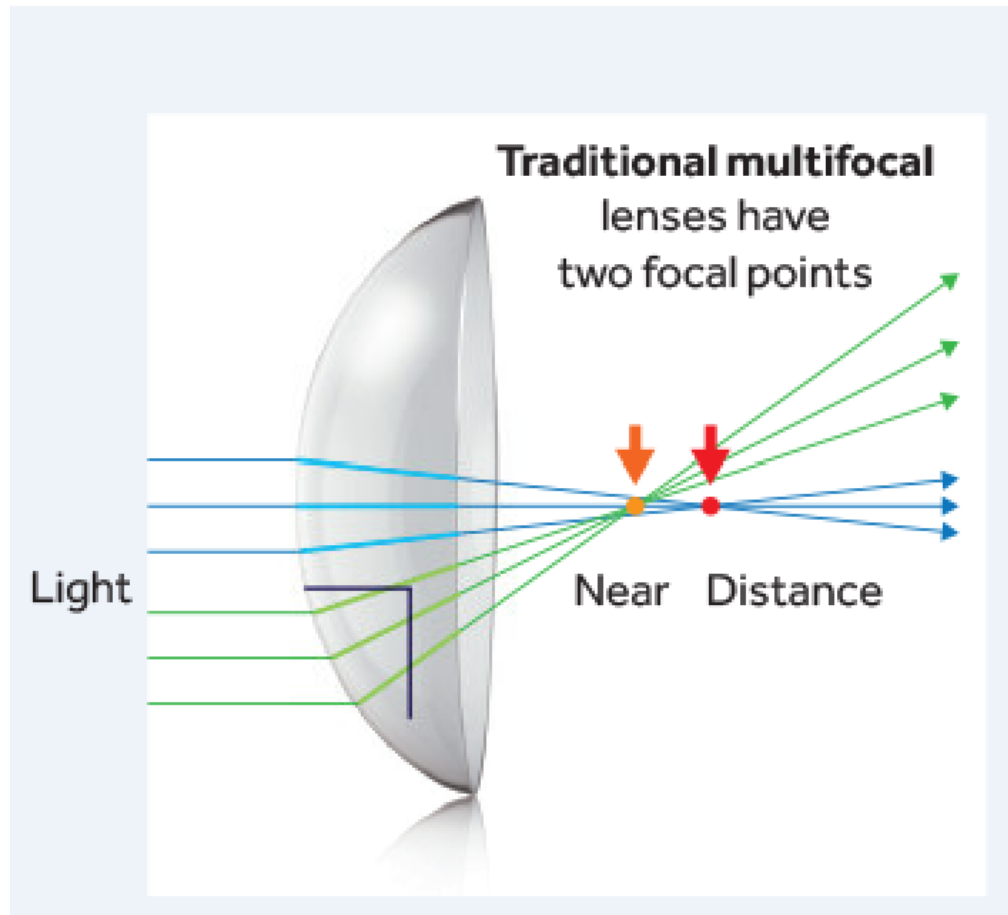


MiSight (CooperVision)

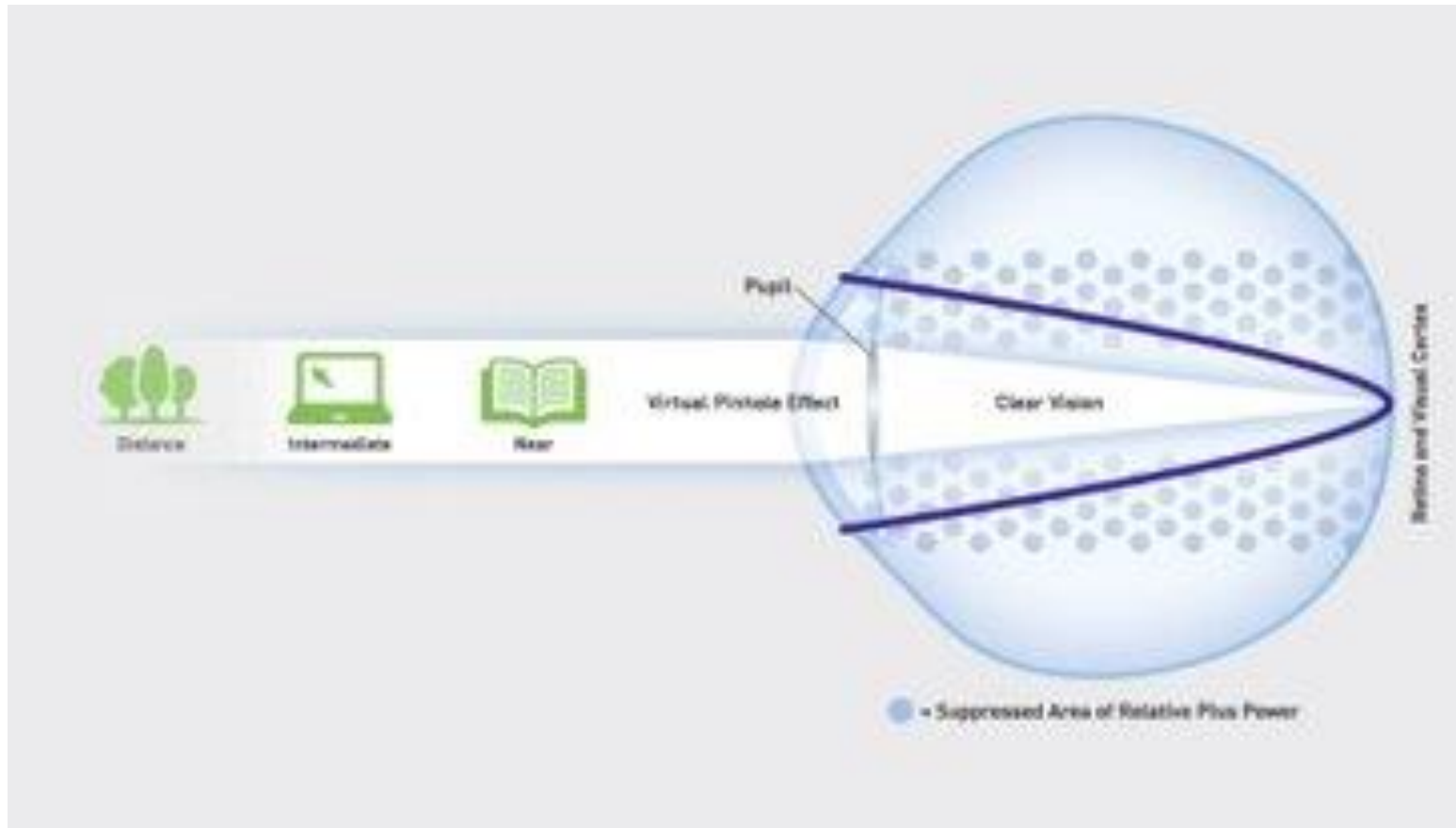
- FDA approved for Myopia CONTROL in 2019
 - Daily disposable soft contact lens
 - **59% less myopic progression** in randomized controlled study (8-12 years old; 7 year study with 1 year washout period)
 - **52% less axial length elongation**
 - **No rebound effect**
-
- **~\$1200** for a year supply
 - Power availability: **-0.50 to -7.00**



Extended Depth of Focus (EDoF) Lenses



Extended Depth of Focus (EDoF) Lenses

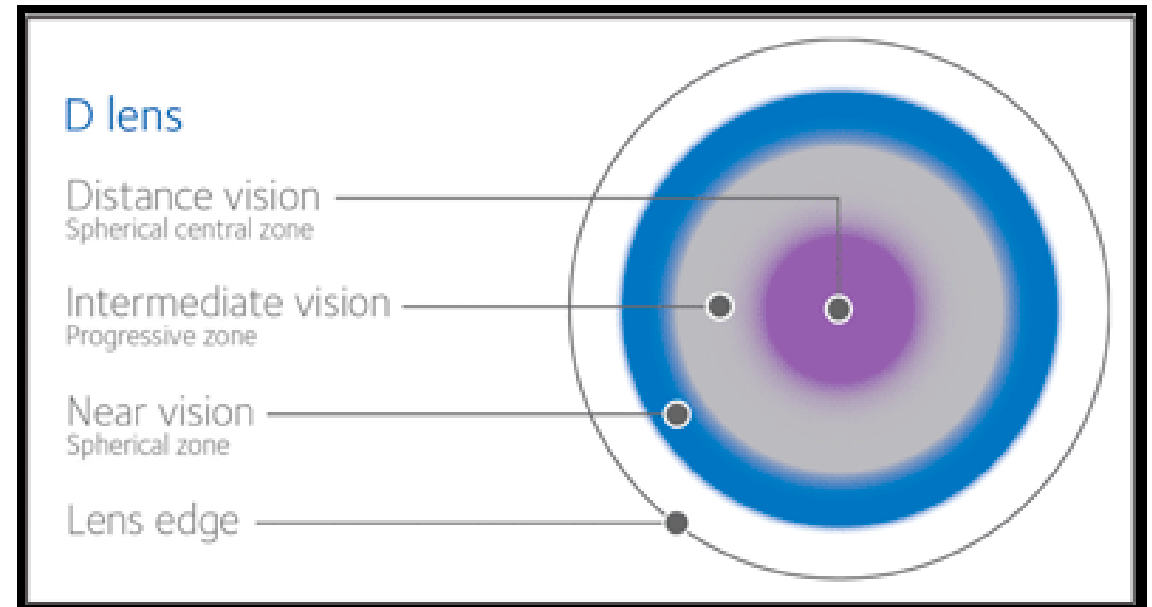


Extended Depth of Focus (EDoF) lenses

- Designed for Presbyopia – used off-label for myopia control
 - Extended depth of focus design
 - Soft daily disposable
- Randomized controlled study expected in 2025
- Retrospective case series - 196 patients; ages 6-19
 - follow up 6-24 months
 - patient's historical data used as control
- 95% of wearers showed a decrease in myopia progression
 - Average myopia progression slowed by 0.85D (85%) compared to baseline
 - Axial length measured on a subset of patients was ~0.10mm per year through 47 months of follow up
- ~\$800 for a year supply
- Power availability: +4 to -12.25

Biofinity Multifocal (CooperVision)

- Monthly contact lens with +2.50 add; Distance center lens
- BLINK study results:
 - 43% less myopic progression versus single vision in patients 7-11 years old over a 3-year period
 - 36% less axial elongation
- Patient cost:
 - \$360 for a year supply
 - \$720 for toric



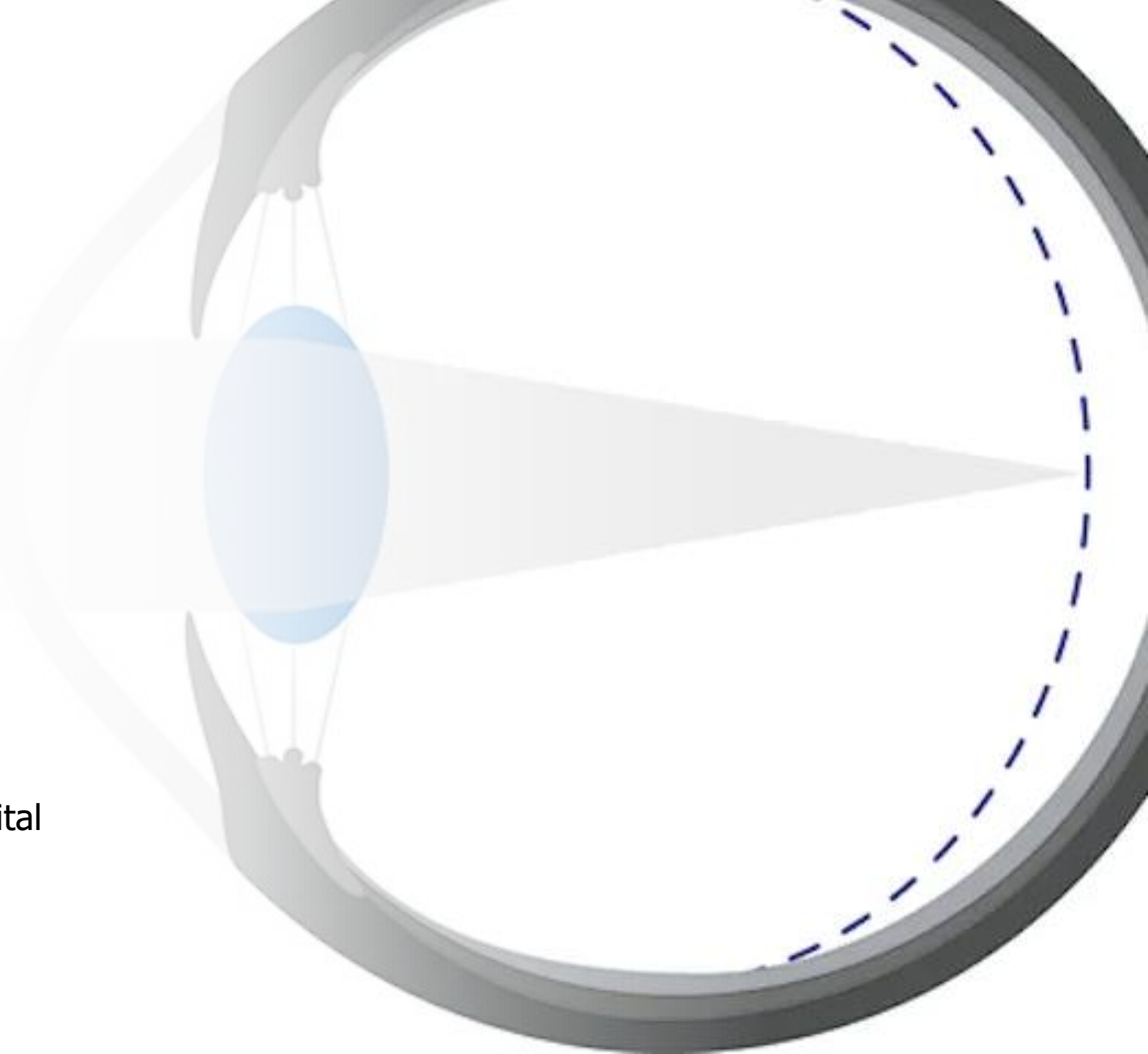
Contact Lens Comparison

	MiSight (CooperVision)	Naturalvue Multifocal (Visioneering)	Biofinity (CooperVision) Multifocal +2.50D
BC Diameter	8.6	8.3	8.6
Fit	14.2	14.5	14.0
Movement	Centered +1mm or easy push	Centered +1mm or easy push	Centered +1mm or easy push
Power	-0.50 to -7.00	+4.00 to -12.25	+6.00 to -10.00
Follow Up	4 weeks after training 6 months 12months	4 weeks after training 6 months 12months	4 weeks after training 6 months 12months
Staff Time	Optician 60 min Technician 10 min	Optician 60 min Technician 10 min	Optician 60 min Technician 10 min
Resources for Training	Training person: Optician/MA/Technician Bonus: A scan	Training person: Optician/MA/Technician Bonus: A scan	Training person: Optician/MA/Technician Bonus: A scan

Other Optical Interventions: Spectacle Lenses and OrthoK

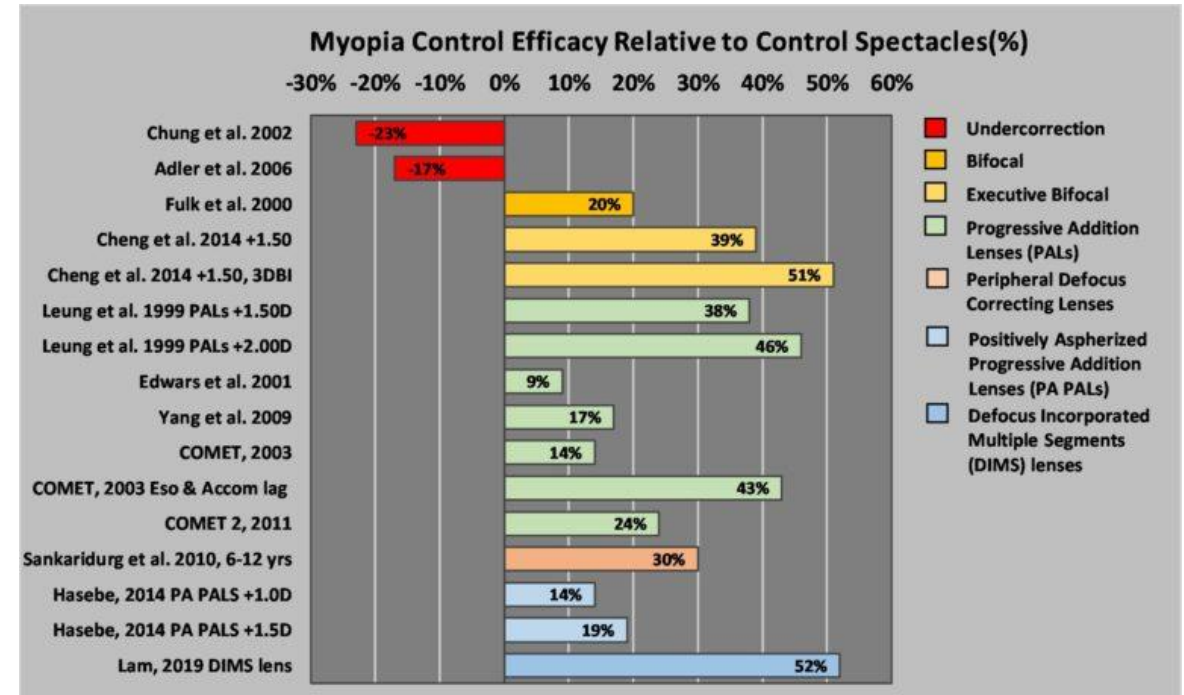
Noreen Shaikh, OD, FAAO
Ann and Robert H. Lurie Children's Hospital

No Financial Interest



Bifocal and Progressive Add (PAL) Spectacle Lenses

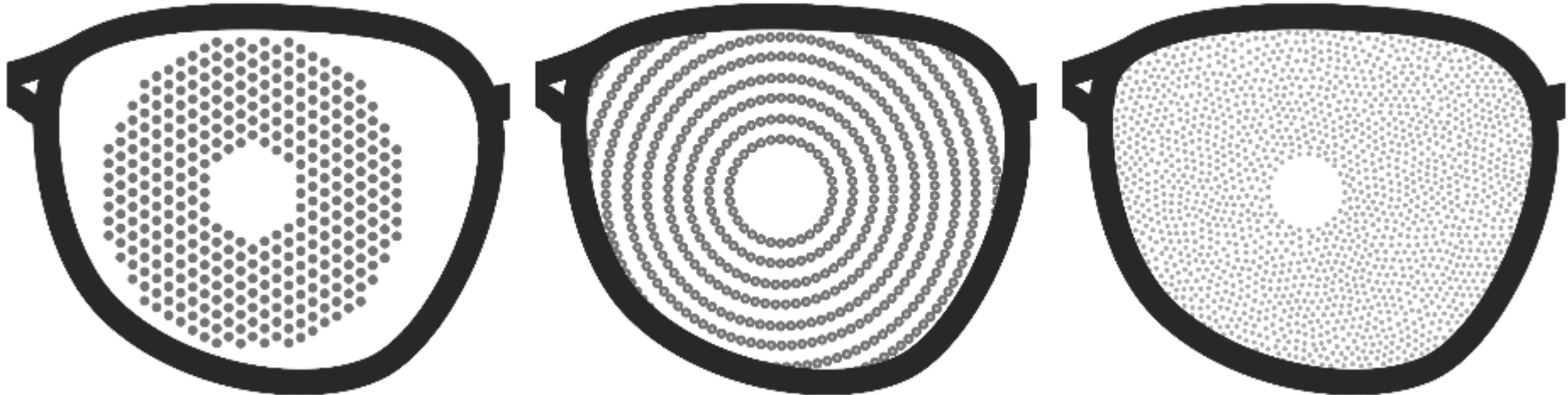
- Bifocals offer moderate myopia control
 - Effective regardless of binocularity with +1.50D Add and 3 BI Prism in each eye
 - Prismatic bifocals reduce progression by 1D (50%) over 3 years (0.50D more than bifocals alone)
- PALs offer a small myopia control effect
 - Reduce myopic progression by 0.20D over 3 years and 0.26D over 2 years
 - In patients with high accommodative lag or near esophoria, reduced myopic progression by 0.18D (24%) in a single year



<https://reviewofmm.com/current-myopia-treatment-options-part-2-spectacles-progressive-addition-multifocals-executive-bifocals-light-diffusion-technology/>

Aspheric Spectacle Lenses

New Kids on the Block



Aspheric Spectacle Lenses

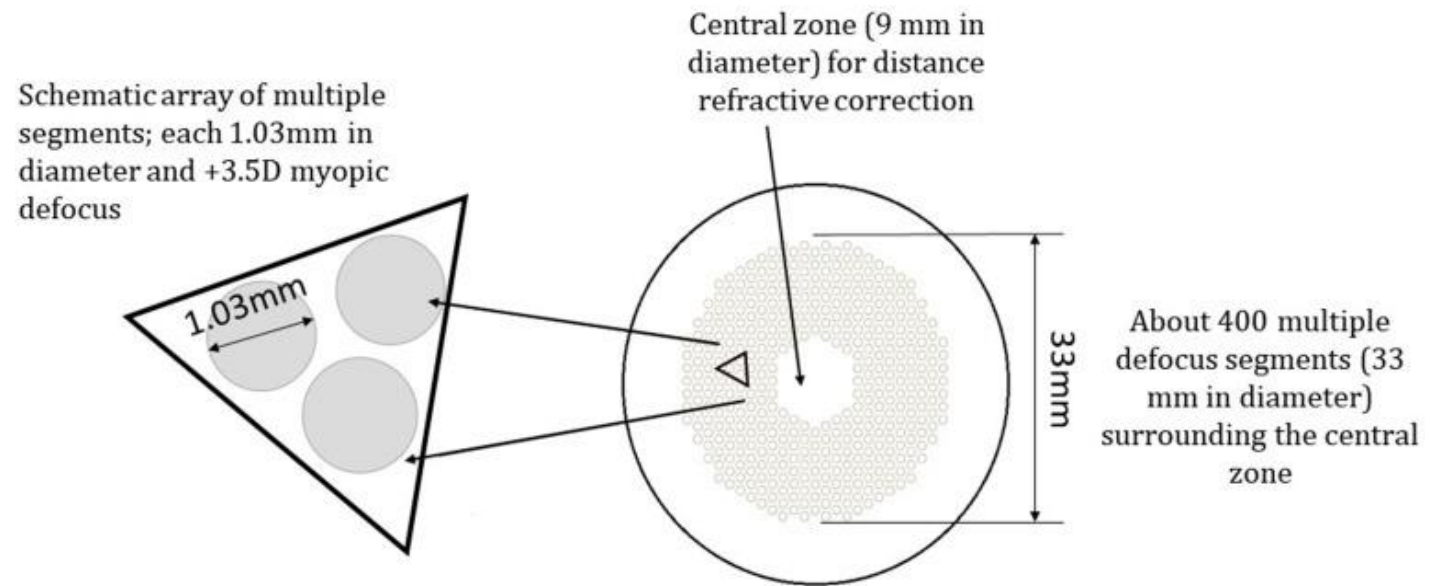
New Kids on the Block



Not currently available in the US

Defocus Incorporated Multiple Segments (DIMS)

- Central distance focus zone (9mm)
- Ring of +3.5D defocus segments with clear distance correction in between
- Two-year RCT with 8-13 yo with SER between -1.00 and -5.00D.
- SER and Axial Length change was 52% (-0.44D) and 62% less in DIMS compared to SV
- 13% continued to progress – mostly between 8-9 years old



Highly Aspherical Lenslet Target (HALT)

- 11 concentric rings of lenslets that provide an aspherical zone of defocus with clear distance vision in between
- Aspherical lenses deviate rays of light continuously in a nonlinear manner that creates a three-dimensional quantity of light in front of the retina
- Two-year RCT - 8-13 yo with -0.75 to -4.75D at baseline
- SER and AL change 55% and 51% less in HAL vs SV; 67% and 60% less if worn for 12+ hrs per day
- HAL was more effective than SAL by 37% and 33% for SER and AL respectively

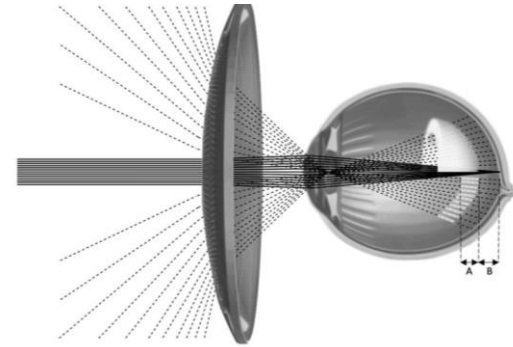
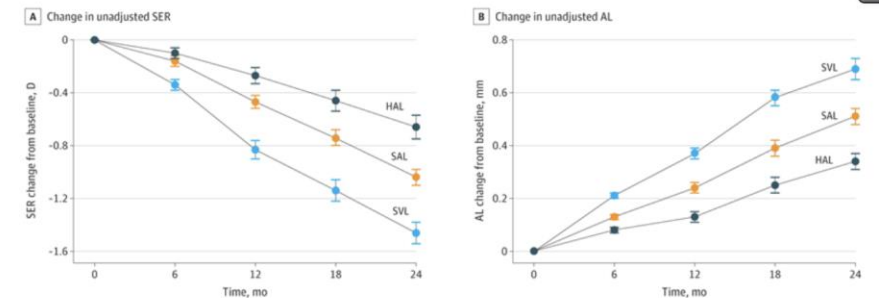


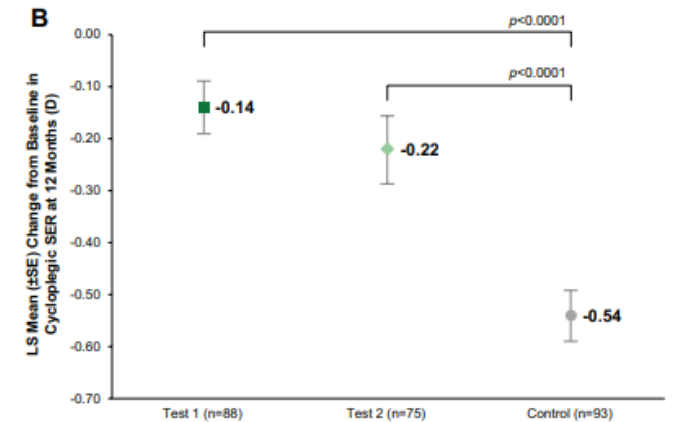
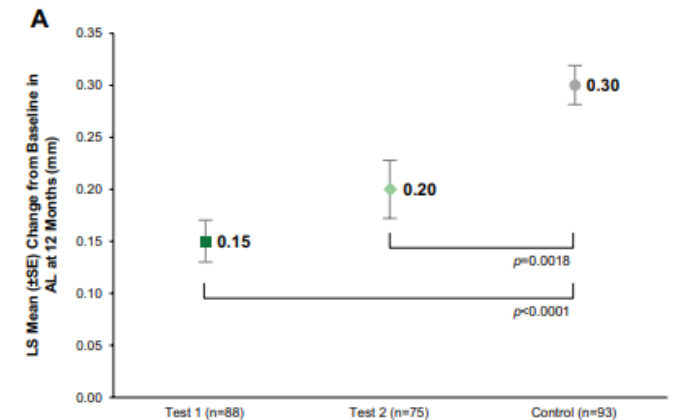
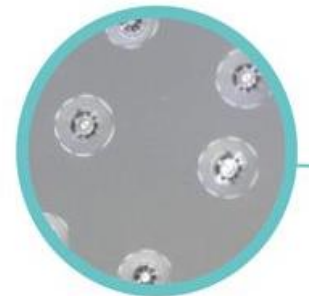
Figure 2. Change in Unadjusted Spherical Equivalent Refraction (SER) and Axial Length (AL) From Baseline to 2 Years



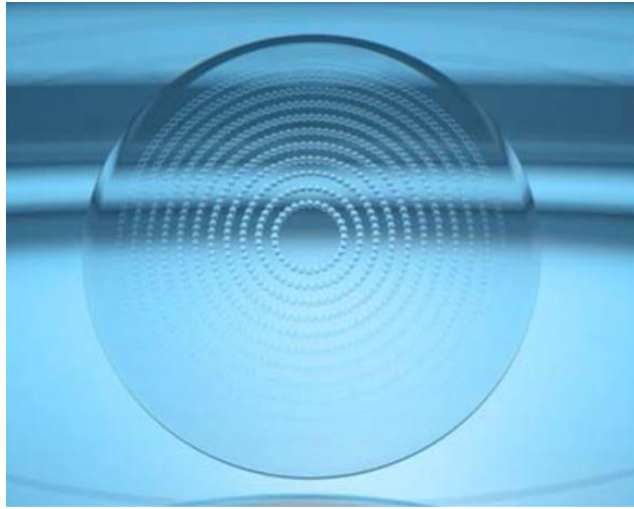
Error bars represent standard errors of the mean. HAL indicates spectacle lenses with highly aspherical lenslets; SAL, spectacle lenses with slightly aspherical lenslets; SVL, single-vision spectacle lenses.

Diffusion Optics Technology (DOT)

- Thousands of microscopic light scattering elements dispersed throughout the lens.
- High contrast environmental cues may drive axial elongation
- 12 mo results from ongoing 36-month RCT – **6 to 10 yo** with SER from -0.75 to -4.50D
- SER and AL reduction by 74% (0.4D) and 59% (0.15mm) respectively in DOT vs SV
- Effective for young – 6 to 7 yo with ave 0.56D less refractive progression versus the control group over one year
- 2 yr abstract at ARVO – 0.52 D less than control, 0.21 less axial elongation



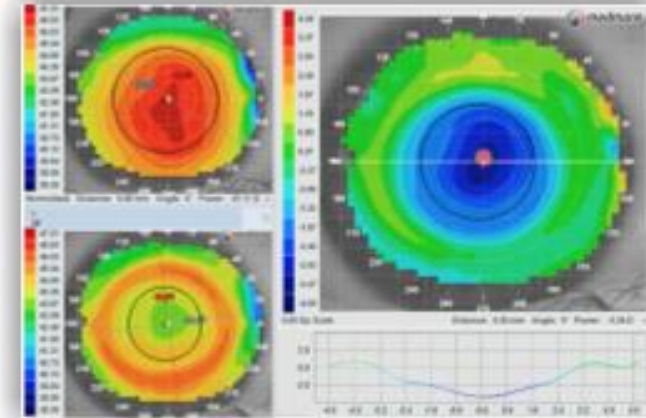
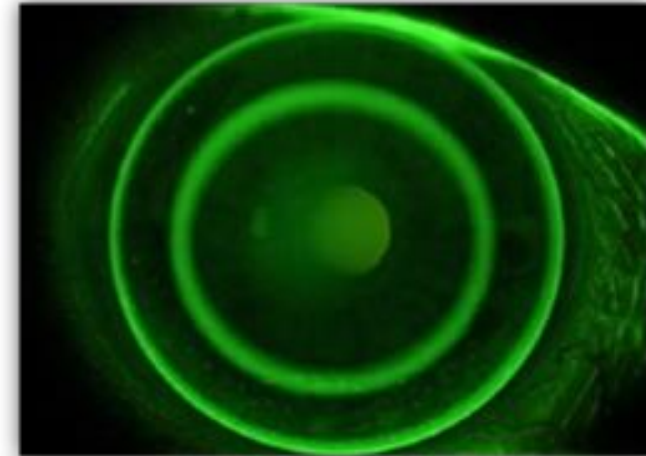
Aspheric Spectacle Lenses Summary



	Stellest (Essilor)	Miyosmart (Hoya)	Sightglass (CooperVision)
Technology	HALT	DIMS	DOT
Lens Center	Clear Single Vision Distance Zone	Clear Single Vision Distance Zone	Clear Single Vision Distance Zone
Lens Periphery	Background of Single Vision	Background of Single Vision	Background of Single Vision
Middle Zone	Lenslets 11 contiguous rings with different powers Distance vision correction between lenslets	Lenslets 1mm +3.50 lenslets Distance vision correction between lenslets	Diffusion Optics Reduced contrast signaling in periphery
Accommodation and Binocularity	No Effect	No Effect	No Data Available

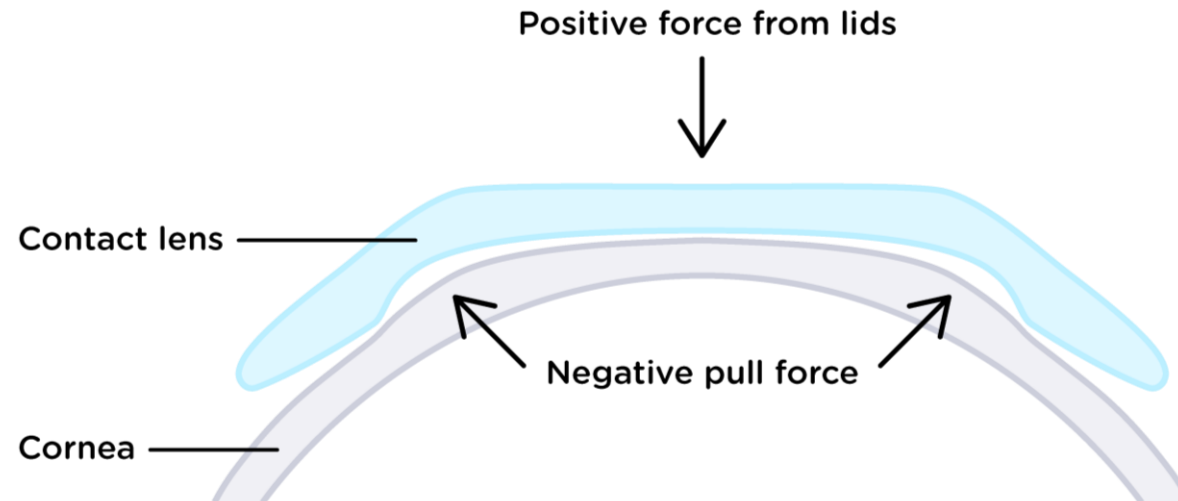
Orthokeratology

- Gas permeable lenses worn overnight to temporarily reshape the cornea to correct refractive error
- The corneal epithelium is reshaped by the fluid dynamics of the tear layer under the orthokeratology lens and positive push force.³
- The cornea returns to its original shape upon discontinuation of lens wear after 7-10 days.^{1,2}



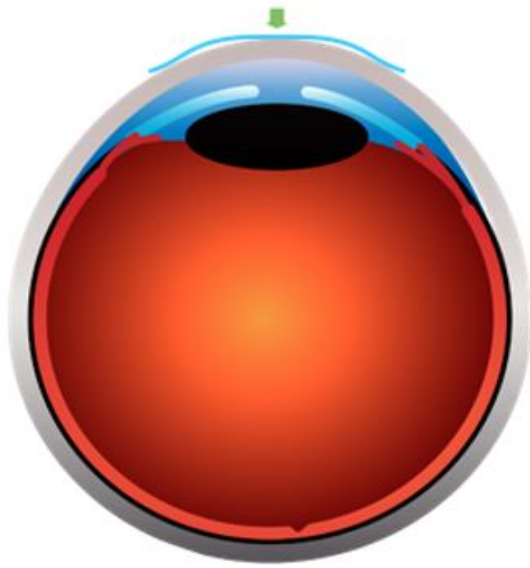
Swarbrick HA. Orthokeratology review and update. *Clin Exp Optom.* 2006;89:124-43.

Orthokeratology – How it Works

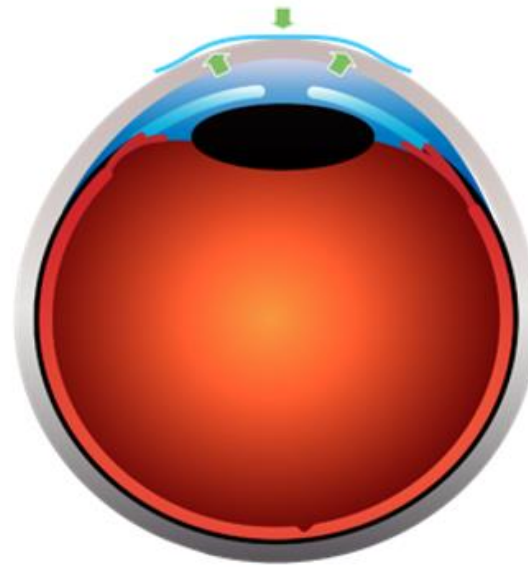


- Tear film between lens and central cornea: $1-10\mu\text{m}^1$
- Positive push force on lens by lids leaving a thin tear film below.¹
- Negative pull forces due to fluid in the reverse geometry portion of the lens creates a suction force resulting in mid peripheral steepening.¹

Orthokeratology – How it Works

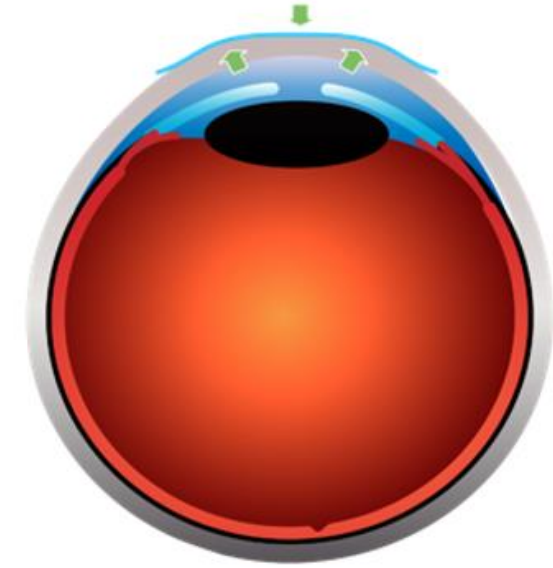


1. Place the lens on the eye overnight



2. Forces

- Central compression
- Mid-peripheral suction



3. Epithelium redistribution

- Central thinning
- Mid-peripheral thickening

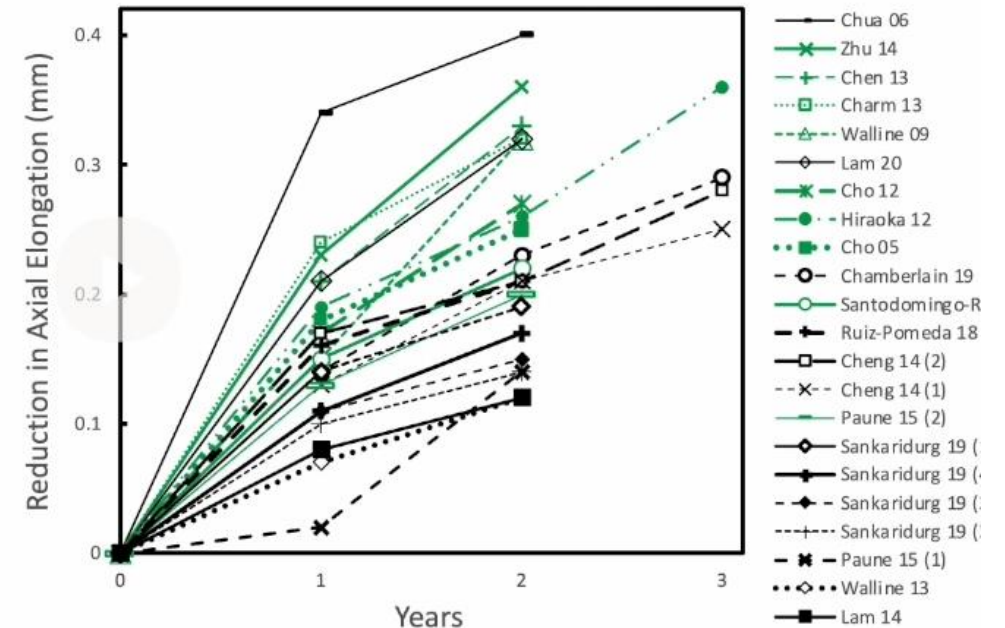
Abiliti OrthoK Lens (Johnson & Johnson)

- Received FDA approval for myopia management
- Improved safety implemented into design:
 - Reverse geometry lens design with secondary curve steeper than base curve, creating greater centration and stability
 - Software-generated lens based on topography
 - 10 microns of apical clearance
 - Fenestrations in lens to reduce risk of binding
 - High oxygen permeability (Dk = 182)
 - Air Optix Night and Day (Dk =140)



OrthoK Efficacy

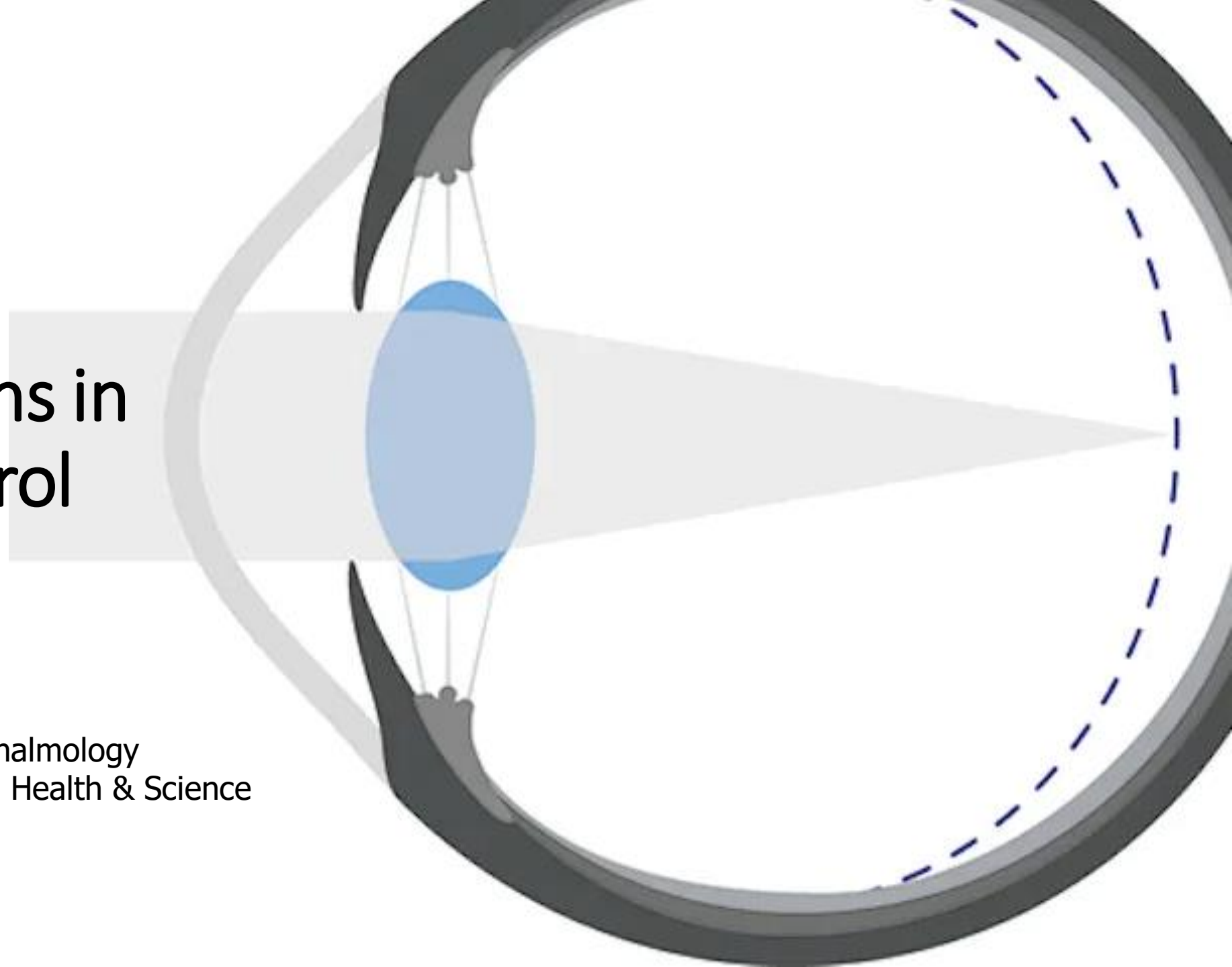
- Axial elongation
 - 2 year – 0.25mm less vs. control
 - 5 year – 0.42mm less vs. control
- CLEAR Study
 - Greatest effect in first year, then tapers
 - Greater efficacy for higher levels of myopia and Asian children vs Caucasian 0.28 vs 0.22
- Combo therapy with Atropine 0.01% is more effective for lower levels of myopia
- Smaller optical zone has greater myopia control effect



DEI Considerations in Myopia Control Treatment

Allison Summers, OD, MCR
Associate Professor of Ophthalmology
Casey Eye Institute, Oregon Health & Science

No Financial Interest



Racial & Ethnic Differences in Myopia Progression

	White	Black	Latino	South Asian	East/ Southeast Asian	Other Asian	Other/ Unknown	Total
N	1691	996	6327	215	1025	843	498	11,595
Baseline Age, yrs*	8.9 (1.6)	8.7 (1.7)	8.8 (1.6)	8.8 (1.7)	9.1 (1.4)	8.9 (1.5)	9.1 (1.5)	8.9 (1.6)
Baseline Refractive Error (RE)*	-1.9 (1.0)	-2.1 (1.0)	-2.0 (1.0)	-2.1 (1.0)	-2.2 (1.1)	-2.1 (1.0)	-2.1 (1.1)	-2.0 (1.0)
Average Yearly RE change*	-0.4 (0.4)	-0.3 (0.4)	-0.3 (0.4)	-0.5 (0.3)	-0.5 (0.4)	-0.5 (0.4)	-0.4 (0.4)	-0.4 (0.4)
Follow up, yrs*	3.2 (0.9)	3.1 (0.9)	3.1 (0.9)	3.2 (0.9)	3.2 (0.9)	3.3 (0.9)	3.1 (1)	3.1 (0.9)

Ethnic Differences in Myopia Prevalence & Ocular Biometry

- 10- and 11- Year Old Children in The Child Heart and Health Study in England (CHASE)
- Myopia prevalence in 1179 children
 - South Asian - 25.2%,
 - Black African Caribbean – 10.0%
 - White European - 3.4%
- Adjusted odds ratios of myopia compared with white European children
 - South Asian – 8.9 with 95% CI[4.0-19.4]
 - Black African Caribbean – 3.2 with 95% CI[1.4-7.2]
- Ethnic differences in the prevalence of myopia were largely accounted for by ethnic differences in axial length

Research Access & Representation

Common Exclusion Criteria	Impact on Representation in Research
Astigmatism > 1.00 diopter	Table 2 Refractive error and ethnicity in children (Kleinstei 2003) astigmatism cut off matters
Prematurity	
Baseline myopia < -6.00 D SE	

Compounding Factors in Adherence

Obstacle	Data
Uncorrected/under-corrected refraction	5 th -grade students, 1794 needed glasses, those unable to afford: 22.5% without insurance, 10.9% with Medicaid 17.6% with income <\$15,000 vs 2.7% with income \geq \$70,000 (Zhang 2012)
Delays in follow up	Visits disproportionately decreased for pediatric ophthalmology patients requiring an interpreter and self-identifying as non-White during COVID (Brettin 2022)
Less likely to receive treatment/timely refills	Among older cancer survivors, African-Americans were 2.64 X more likely and Hispanics 2.07 X more likely than whites to report cost-related medication non-adherence (Lee 2016) Gender inequality in global burden of uncorrected refractive error increases with age (Lou 2019)

Efficacy in Myopia Control: Does Race Matter?

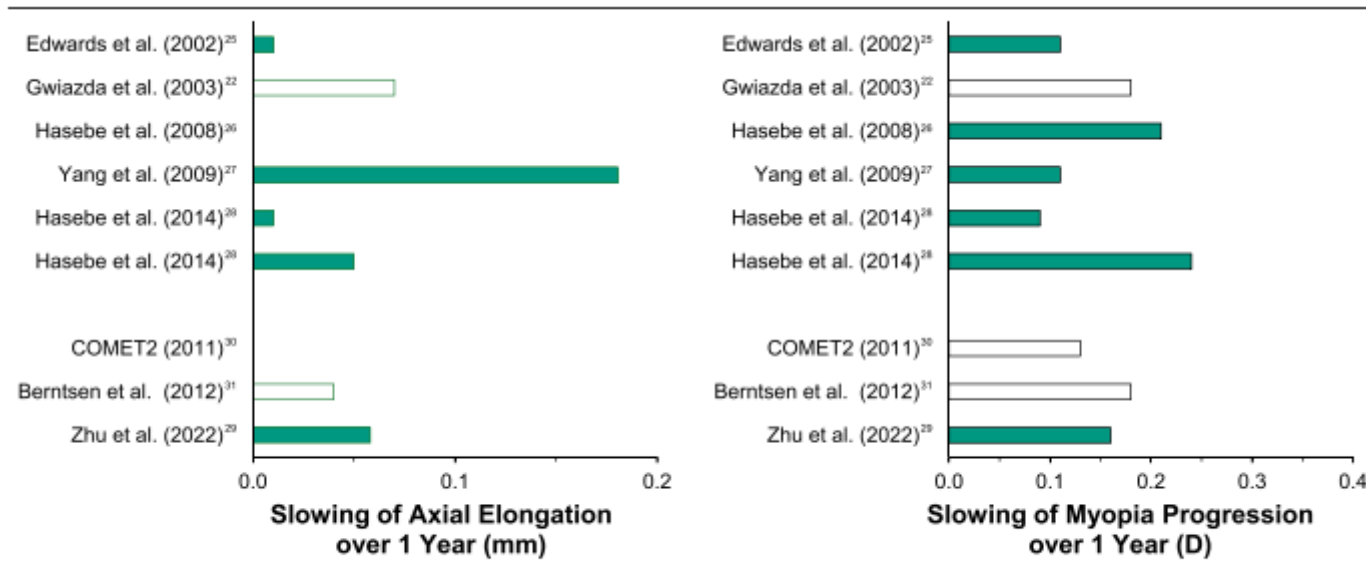


FIGURE 1. One-year slowing of axial elongation and myopia progression in randomized clinical trials of progressive addition lens. Closed bars are for East Asian children,^{25–29} and open bars are for U.S. children.^{22,30,31}

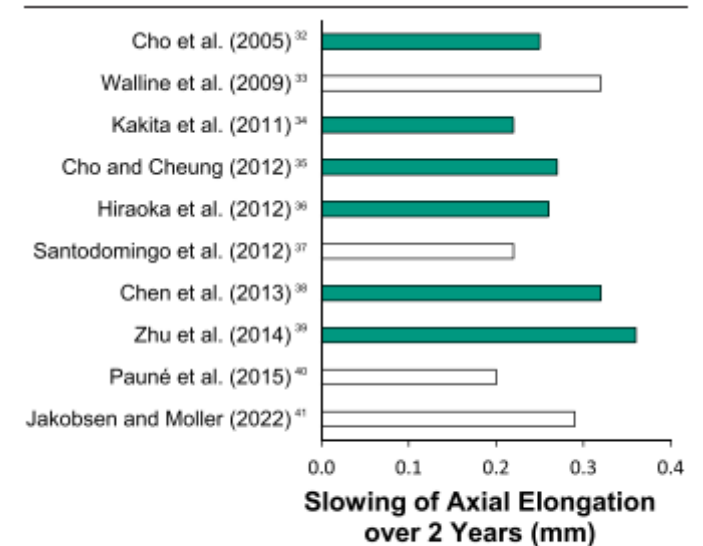


FIGURE 2. Two-year slowing of axial elongation studies of overnight orthokeratology. Closed bars are for East Asian children,^{32,34–36,38,39} and open bars are for European^{37,40,41} and U.S. children.³³

Efficacy in Myopia Control: Does Race Matter?

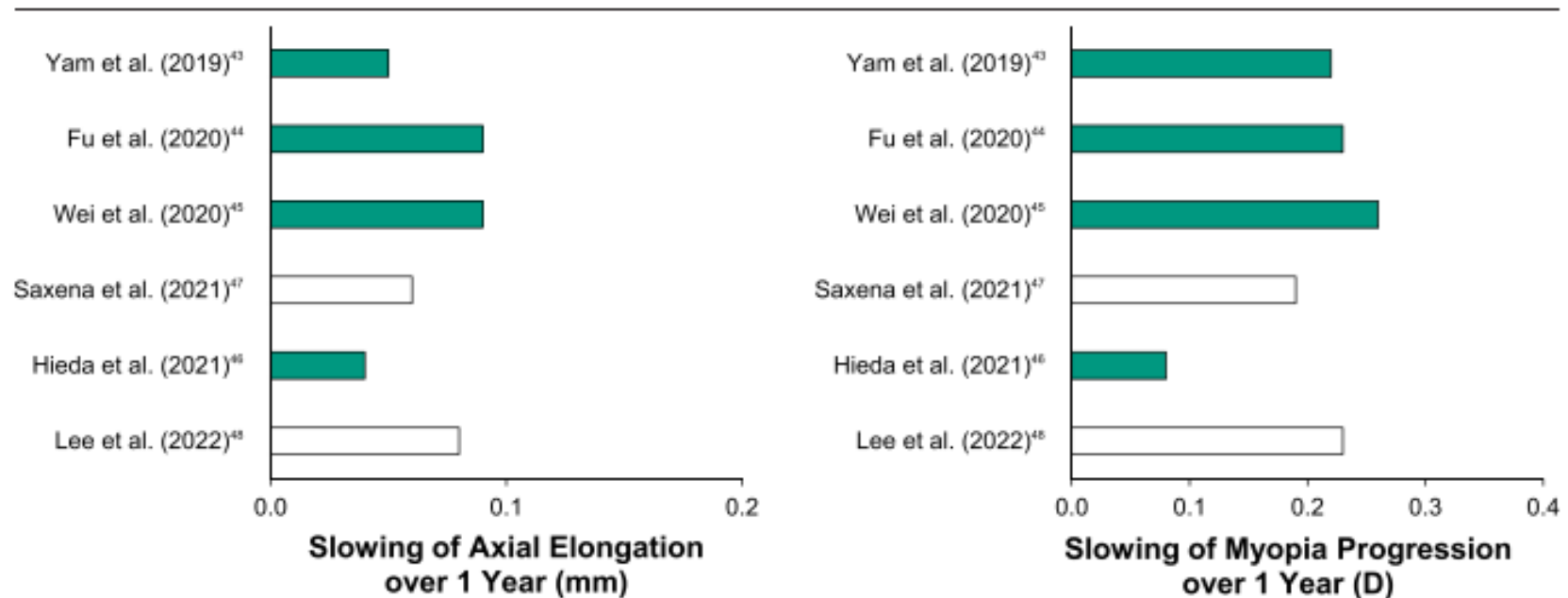
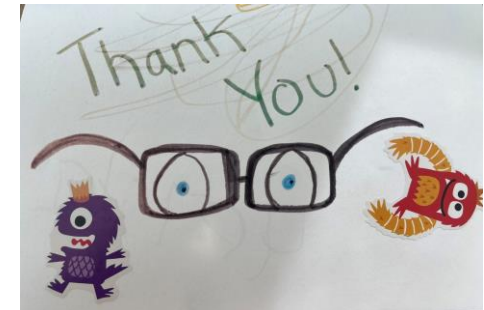


FIGURE 3. One-year slowing of axial elongation and myopia progression in randomized clinical trials of 0.01% atropine. Closed bars are for East Asian children,⁴³⁻⁴⁶ and open bars are for Indian⁴⁷ and Australian children.⁴⁸

Access to Care – Philanthropy

- Lifetime impact on vision, education, employment
- Funds for care of other eye conditions/glasses
- Clark Fund for myopia management
- Rahul's institutional fund
- Approach local service organizations



Obstacles to Treatment – Cost of Atropine

Efficacy and Safety of 1% Atropine on Retardation of Moderate Myopia Progression in Chinese School Children

Groups initially 330 each Visits every 6 months	Treatment n=262 68 dropped (21%)	Matched Controls n=308 22 dropped (7%)
Phase I: 24 months	Atropine 1% once/ m	Saline
Additional treatment	Photochromic progressive, unknown if/when discontinued	“framed glasses”
Phase II: 12 months	Atropine 1% once/ 2 m	Saline
Phase III: 12 months	No atropine	No saline?
SER Baseline	-3.82+/-0.44 D	-3.74+/-0.51 D
SER 48 months	-4.96+/-1.22 D	-7.28+/-1.26 D
SER progression 48 m	-0.41+/-0.23 D/yr	-0.75+/-0.64 D/yr
AL 48 months	25.48+/-0.29 mm	26.59+/-0.20 mm
AL progression 48 m	0.19+/-0.13 mm/yr	0.40+/-0.16 mm/yr

Obstacles to Treatment – Cost of Atropine

Obstacle to Initiating Treatment/Increased Frequency of Monitoring	Potential Methods to Address
Low health literacy, low perceived interest, medical mistrust	Helical discussion with caregiver and patient Shared decision-making Instructional handouts Links to public awareness sites
Provider expectation of prognosis based on race/ethnicity/socioeconomic status	Assess risk factors Treat based on findings Acknowledge unconscious bias Programmatic changes
Perceived ability to pay and insurance coverage	Discussion with caregiver Noncovered service forms Philanthropic funds Insurance authorizations and advocacy
Language	Documents in common languages for area In-person, video or phone interpreter services
History of poor follow up, distance from clinic, family obstacles	Telehealth, home VA monitoring, satellite Social worker or staff resource, reminders Broad clinic hours

Health Literacy/Patient Education



CHILDREN'S VISION EQUITY ALLIANCE

Patient and family educational resources

- English: [FS115-8answers-myopiaannotated.pdf \(preventblindness.org\)](https://preventblindness.org/wp-content/uploads/2011/06/FS115-8answers-myopiaannotated.pdf)
- Spanish: [ESFS115-8answers-myopiacomplete.pdf \(preventblindness.org\)](https://preventblindness.org/wp-content/uploads/2011/06/ESFS115-8answers-myopiacomplete.pdf)
- Chinese: <http://preventblindness.org/wp-content/uploads/2011/06/FS115-CHN-7answers-myopia.pdf>

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Thank you!

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