

MYOPIA MANAGEMENT:

The Past, The Present, and The Future

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**I HAVE NO RELEVANT FINANCIAL RELATIONSHIPS
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STATISTICS

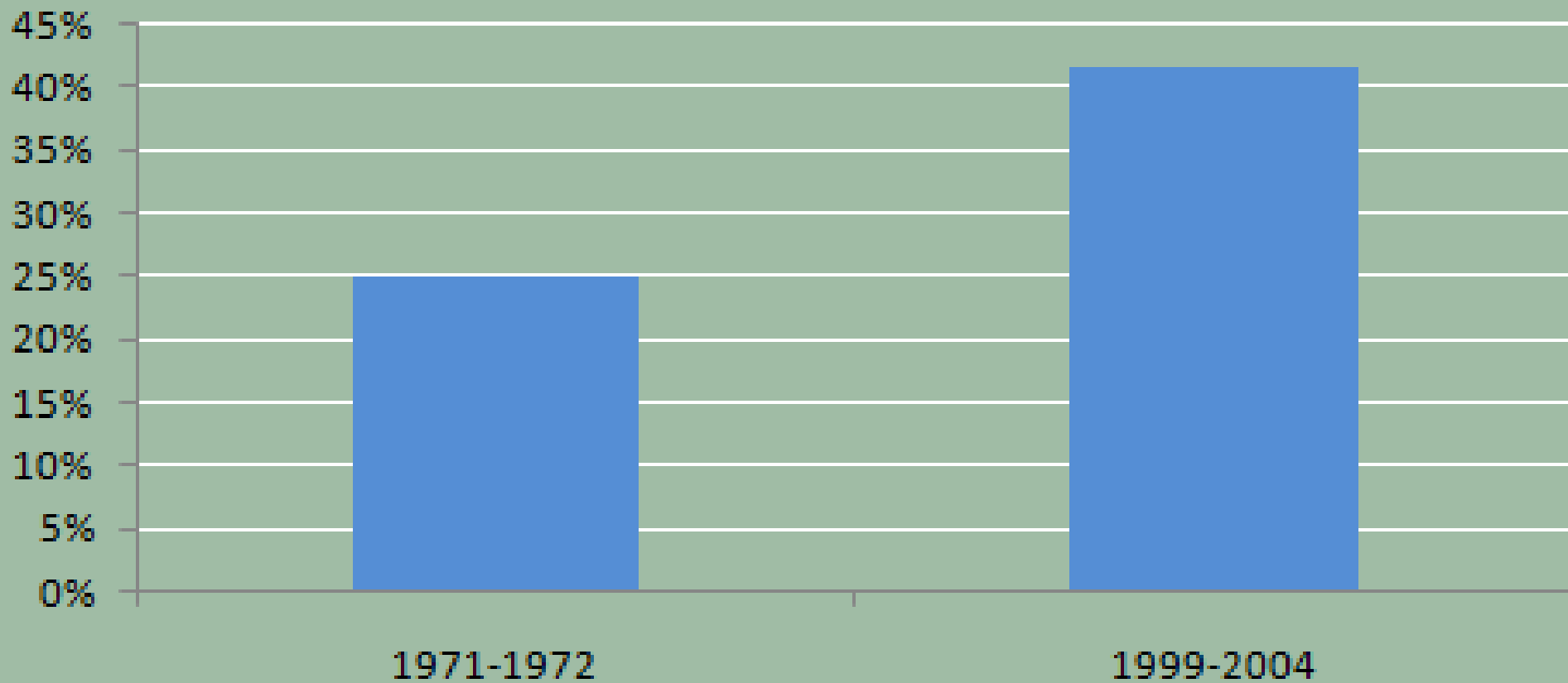
- Nearly 42% of the U.S. population (in the 12- to 54-year-old age range) are myopic (Vitale et al, 2009)
- This percentage has increased dramatically since the 1970s when only 25% of those 12- to 54 years old were myopic
- Not only has the percentage of those who have myopia increased, but the refractive error of myopic patients has also increased substantially
- Approximately 80%-90% of children and young adults in Asian countries are myopic

COURSE OBJECTIVES

- Statistics
- Implications
- Myopia Progression
- Myopia Management Strategies

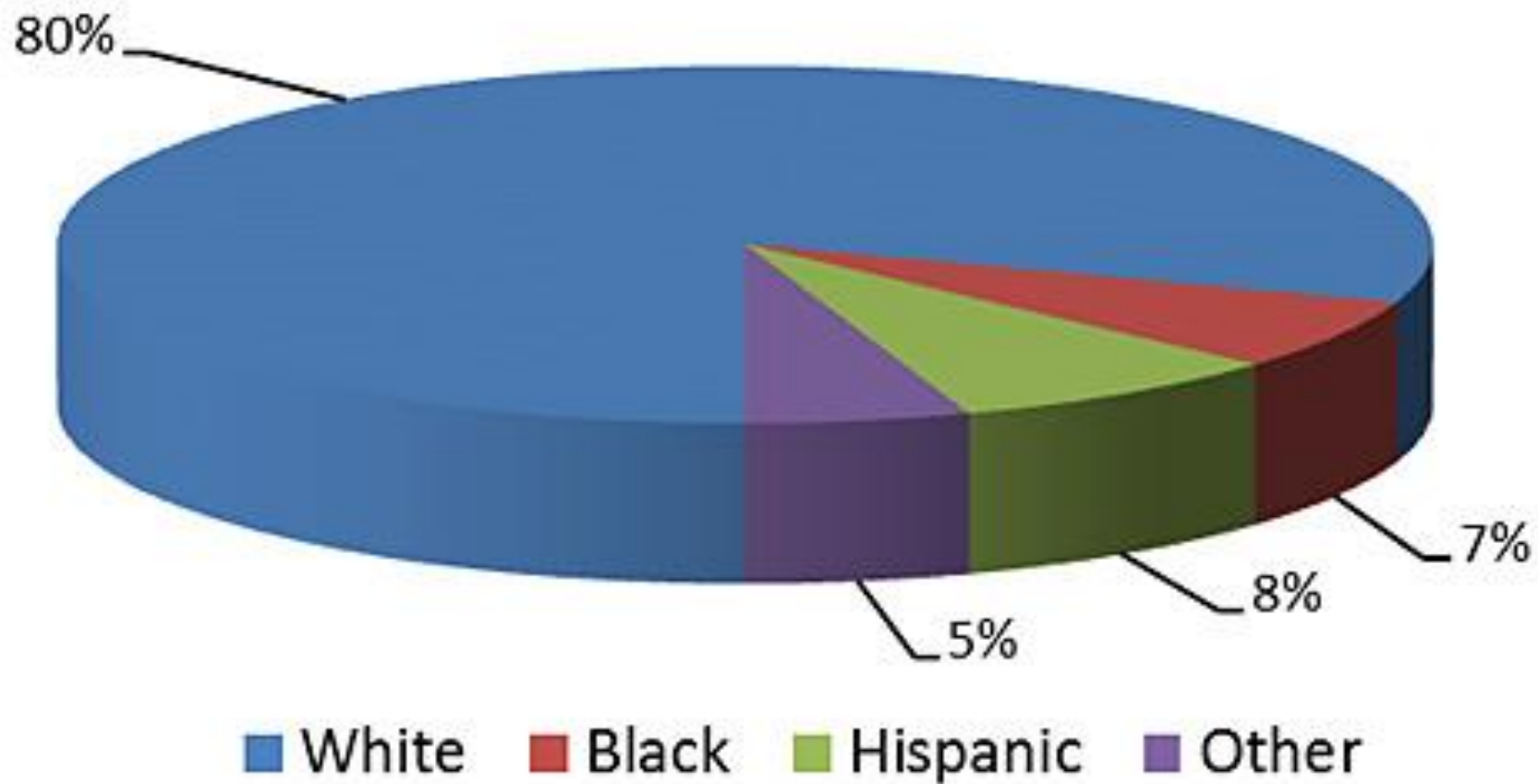


Incidence of Myopia in US ages 12-54 years

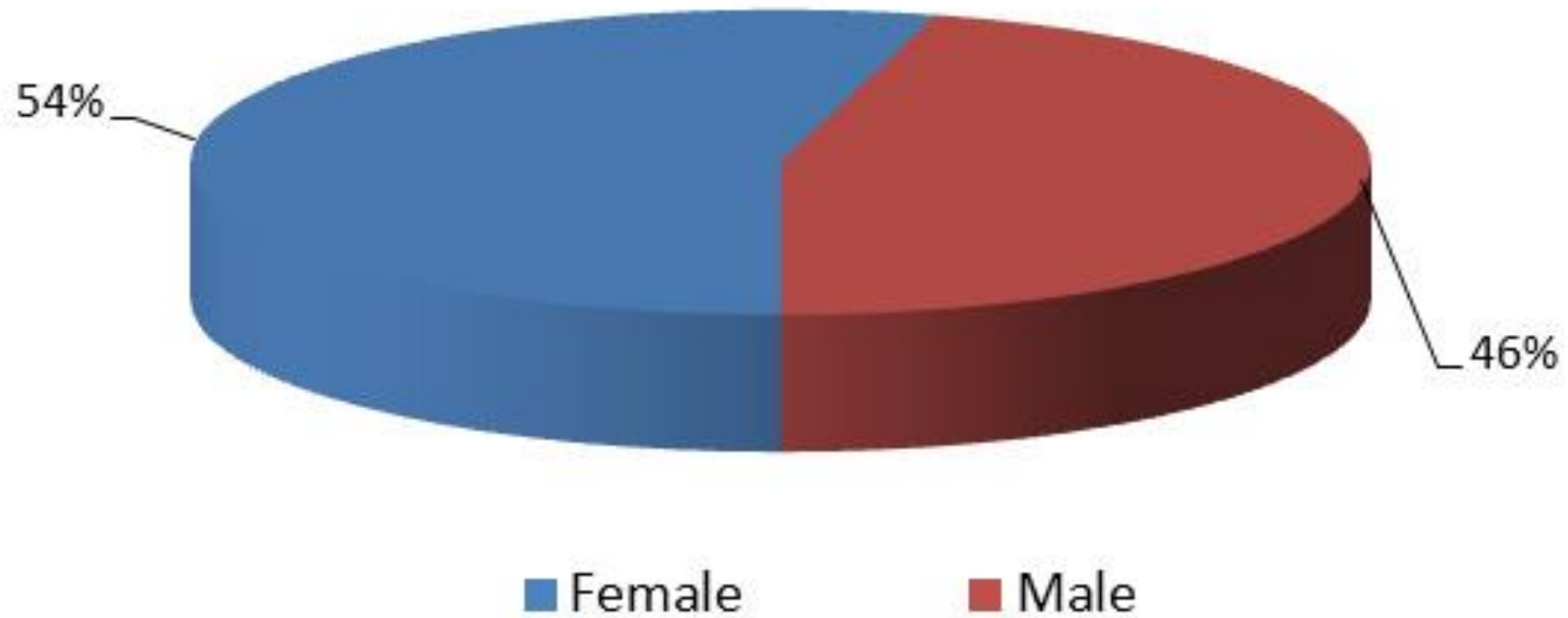


Source: S. Vitale, et al., 2009. Archives of Ophthalmology 127(12):1632-1639

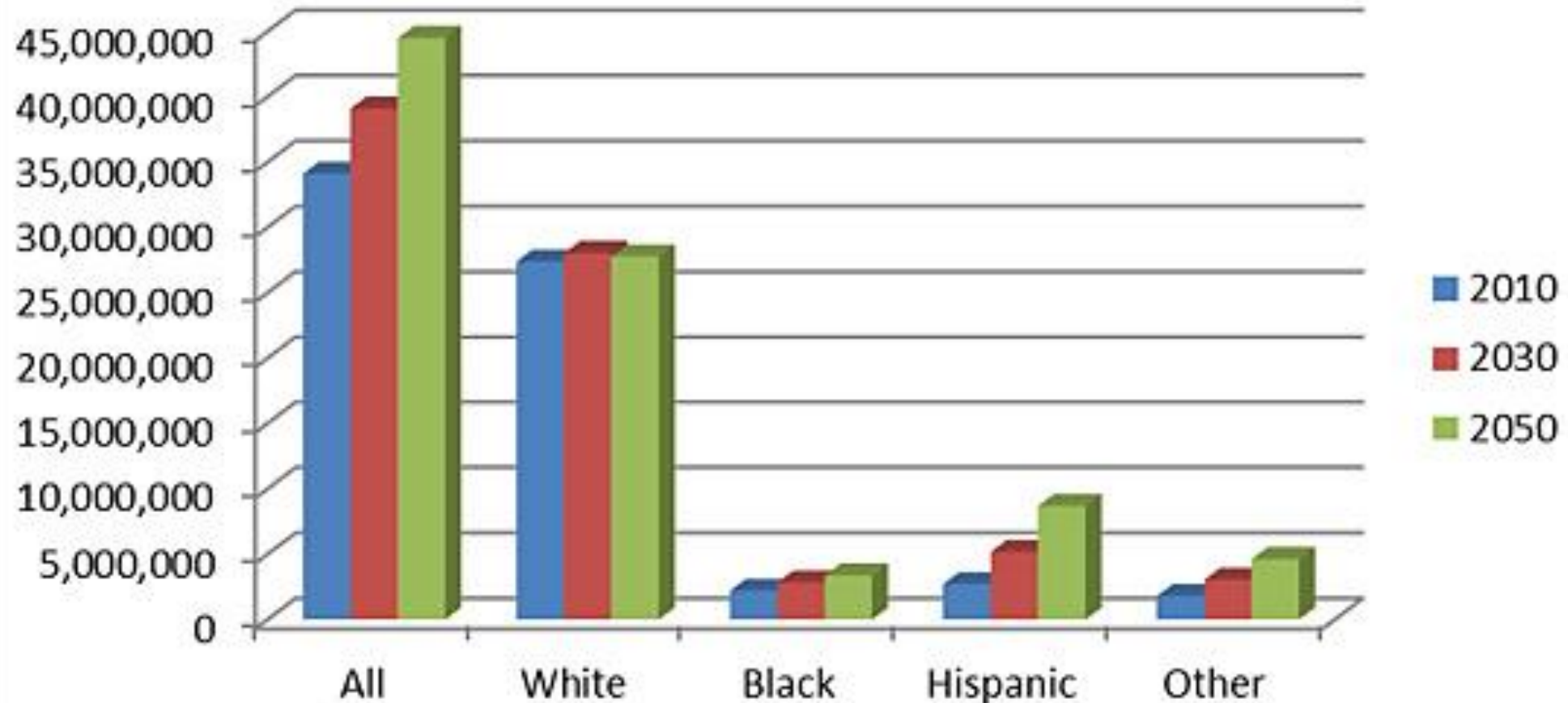
2010 U.S. Prevalent Cases Myopia

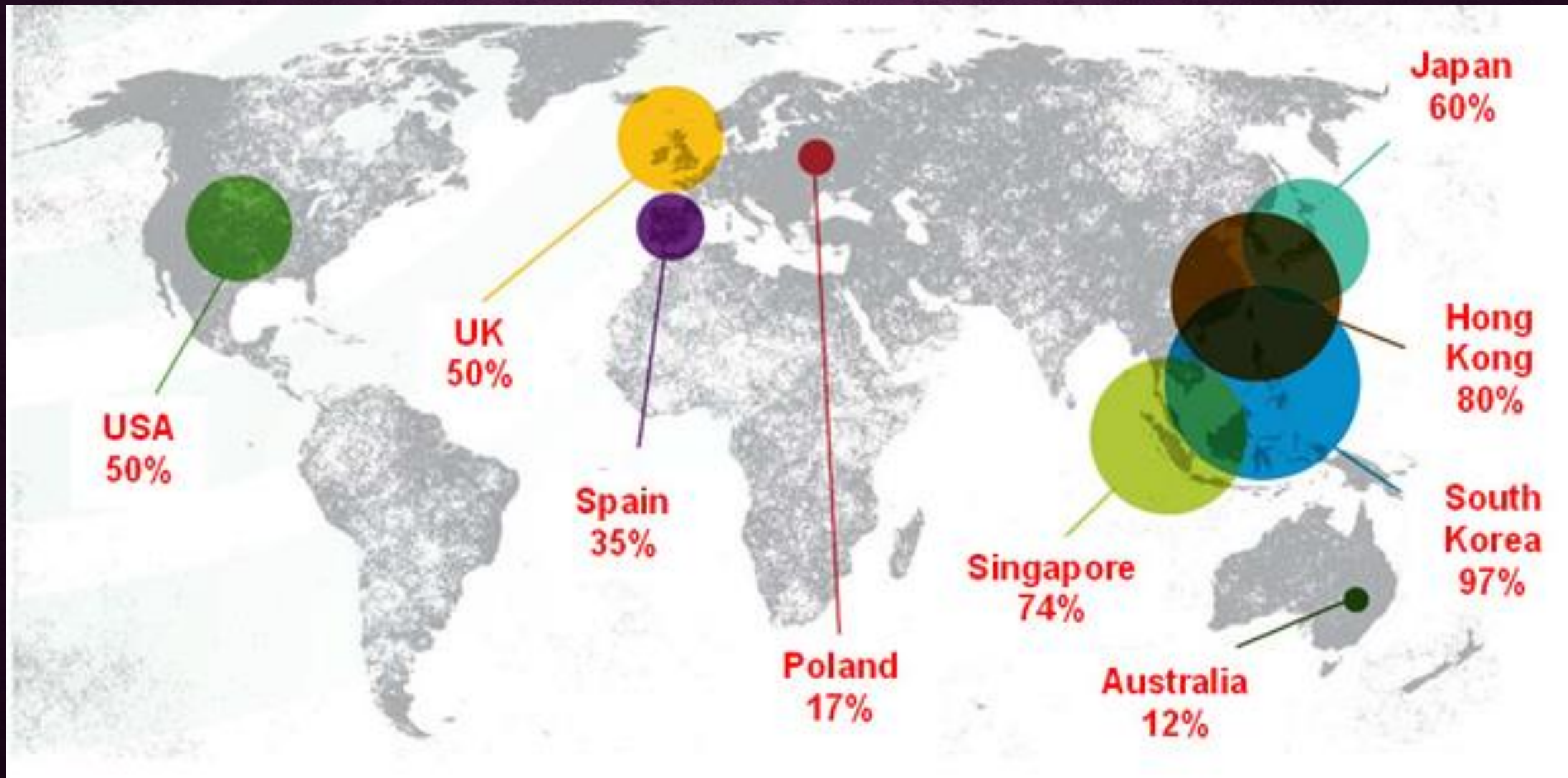


2010 U.S. Prevalent Cases of Myopia by Gender



Myopia





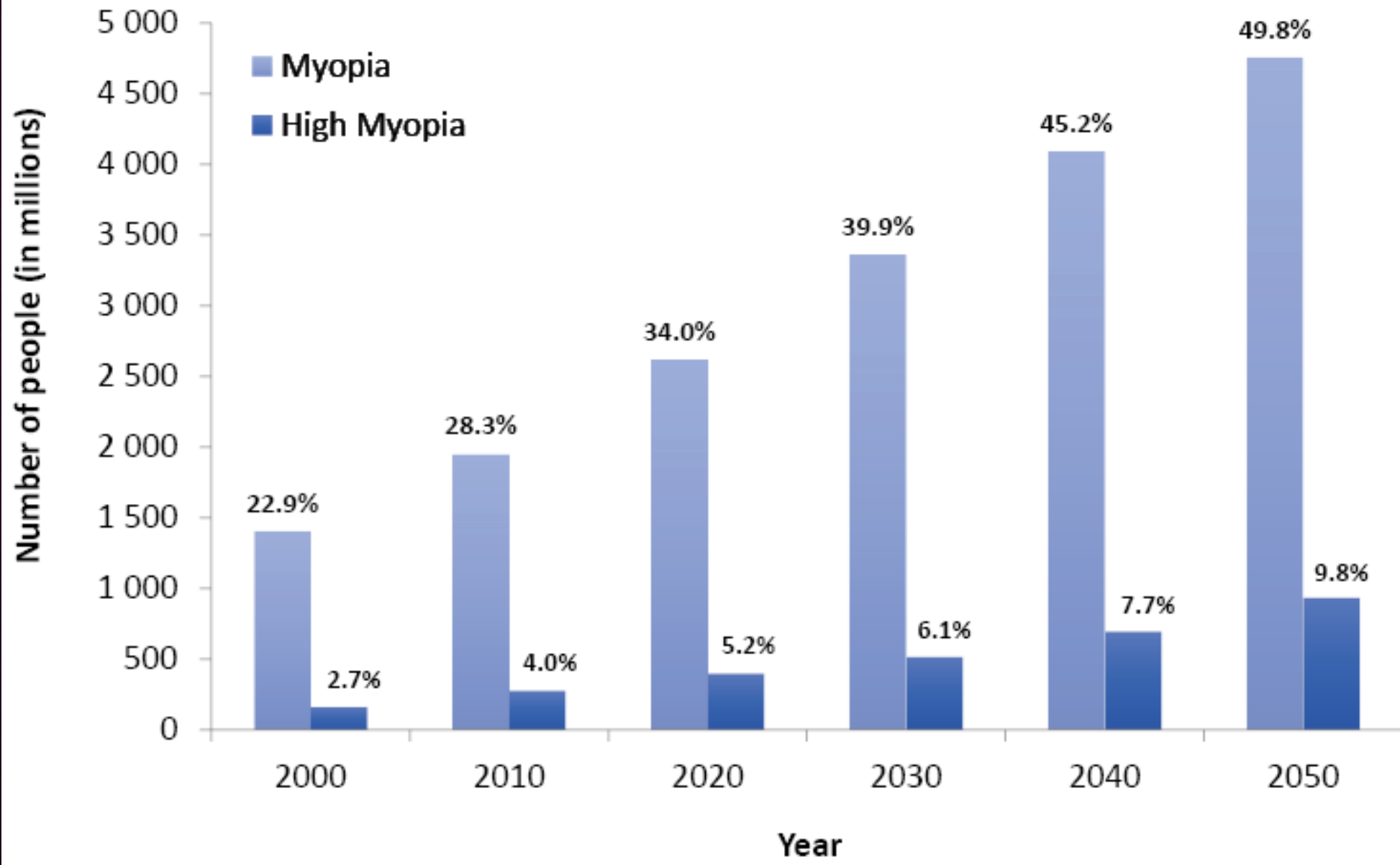
Worldwide prevalence of myopia in adolescents, 2015

IF THE CURRENT RATE OF MYOPIA PROGRESSION CONTINUES...

- **HALF OF THE WORLD'S POPULATION WILL BE MYOPIC BY 2050**
 - **10% WILL HAVE SEVERE MYOPIA BY 2050**

=

**2 billion people (2010) with the condition will grow to 2.6 billion by 2020
and 4.8 billion by 2050!!**



Holden BA, Fricke TR, Wilson DA, et al. Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. *Ophthalmology* 2016

MYOPIA CLASSIFICATION

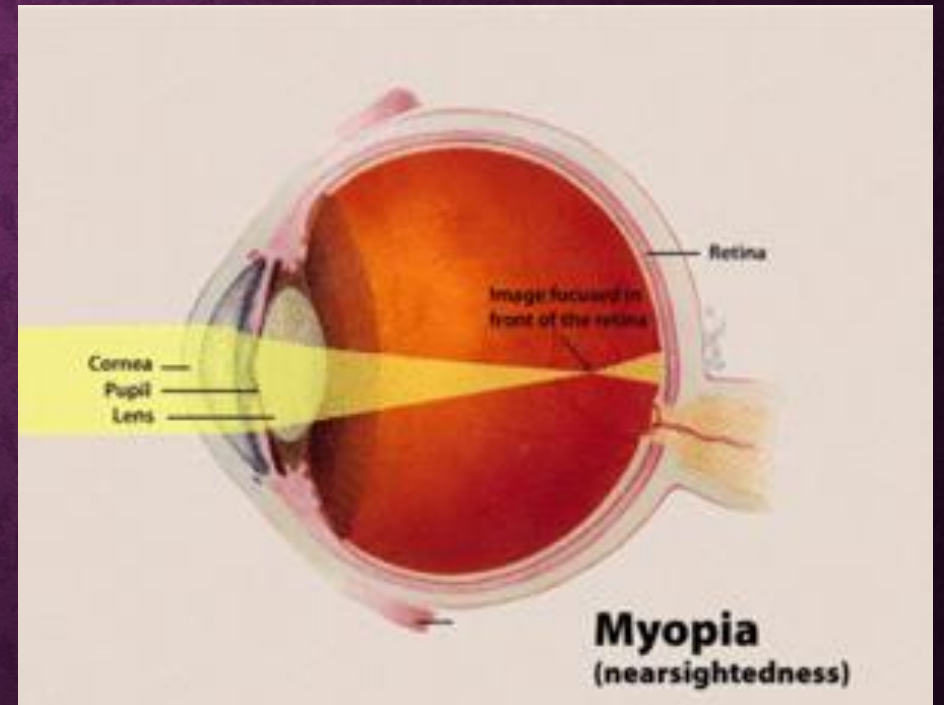
- Mild myopia: -0.25 to -3.00 D
- Moderate myopia: -3.25 to -6.00 D
- High myopia: greater than -6.00 D



**** There is no “safe” level of myopia. ****

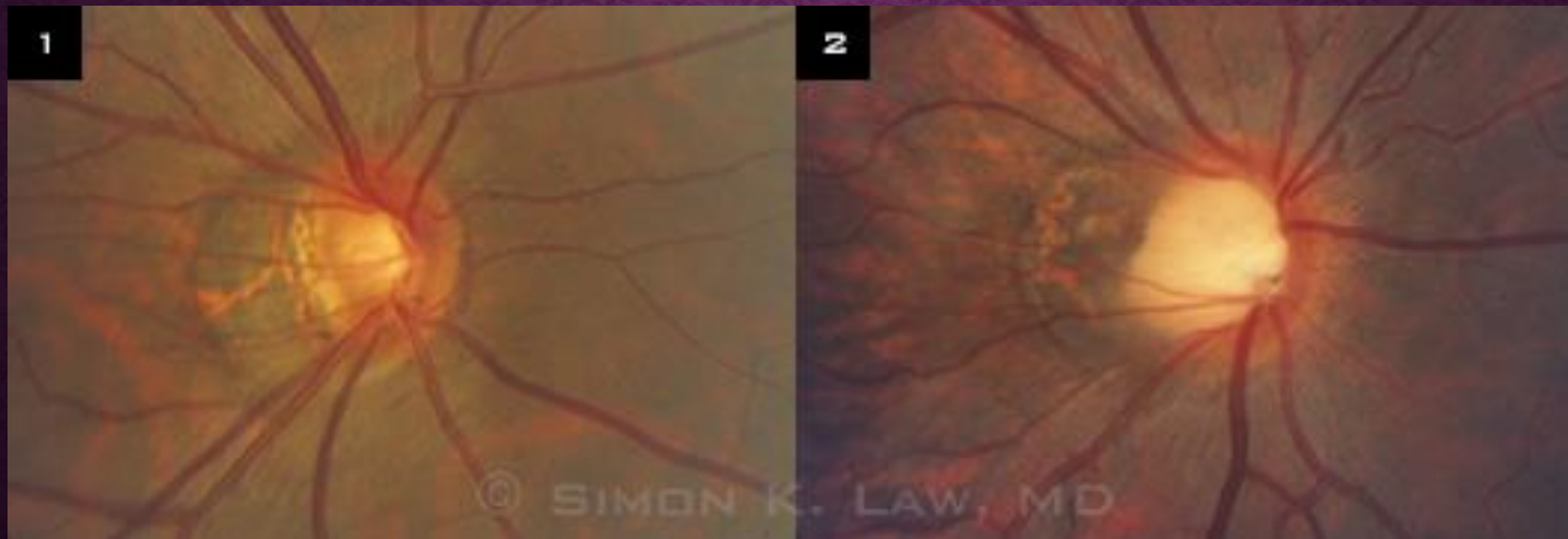
MYOPIA IMPLICATIONS

- Increased risk of:
 - Primary Open Angle Glaucoma
 - Cataracts
 - Retinal Detachment
 - Myopic Maculopathy



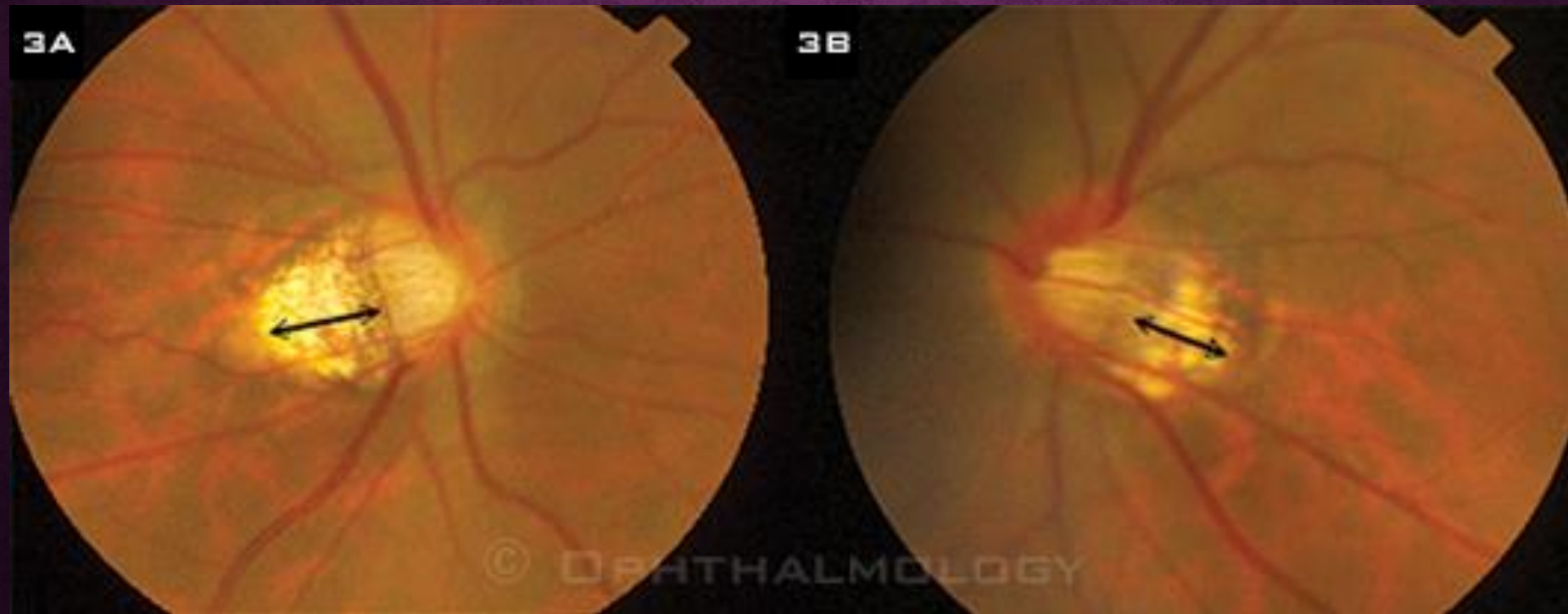
PRIMARY OPEN ANGLE GLAUCOMA

~2-3x greater risk



Optic nerve appearance of two highly myopic patients: **(1)** diagnosed with glaucoma; **(2)** without glaucoma

GLAUCOMA OR NO GLAUCOMA?



RETINAL DETACHMENT

Relative risk compared to an emmetrope:

-2.00D	-5.00D	-8.00D
3x higher	9x higher	21x higher

RETINAL DETACHMENT

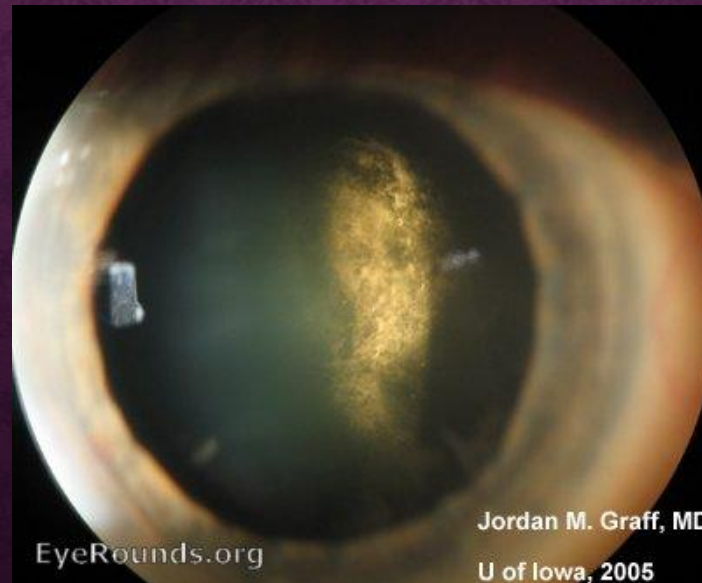
- Approximately 50% of RDs not caused by trauma are attributable to myopia
- Increased risk of RD following cataract surgery



CATARACTS

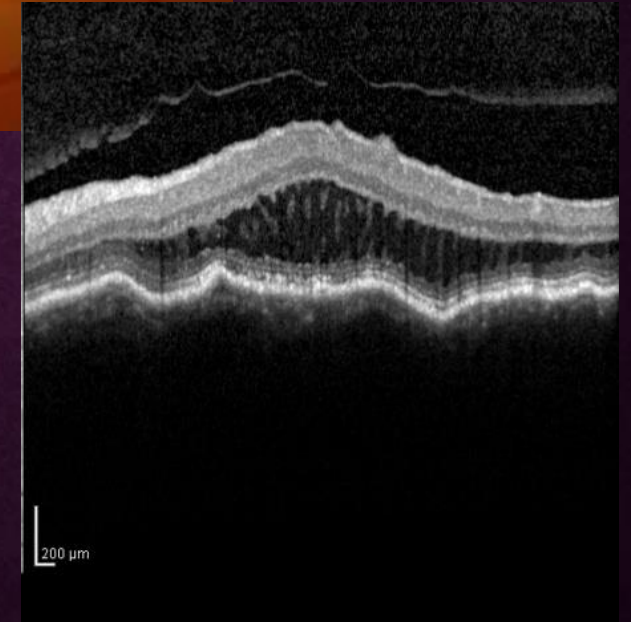
Relative risk compared to an emmetrope:

-2.00D	-5.00D	-8.00D
2x higher	3x higher	3x higher



MYOPIC MACULOPATHY

- Only disease amongst the top five causes of blindness that remains entirely untreatable
- The Blue Mountains Study reported 25.3% prevalence of myopic maculopathy in those with greater than -5.00D of myopia, increasing to more than 52.4% once beyond -9.00D



MYOPIC MACULOPATHY

Relative risk compared to an emmetrope:

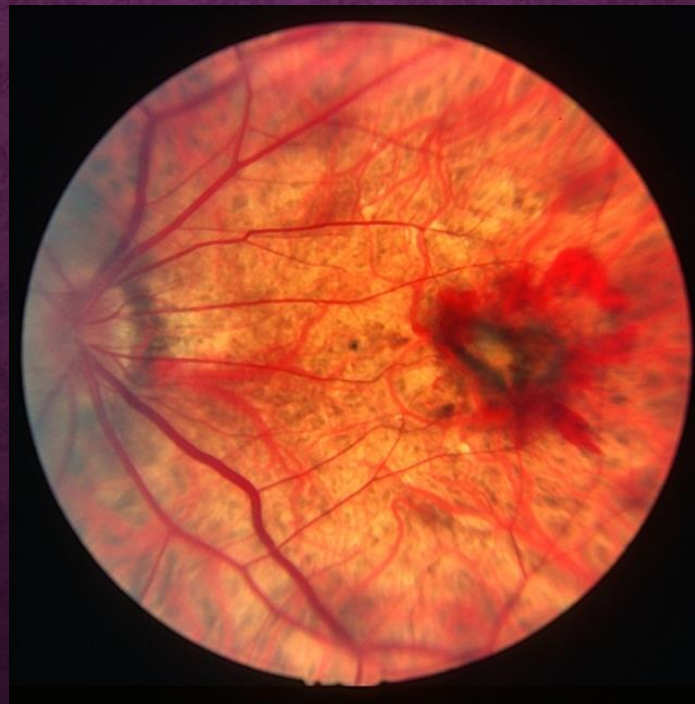
-2.00D	-5.00D	-8.00D
2x higher	41x higher	126x higher

Myopia (D)	Glaucoma	Cataract (PSCC)	Retinal detachment	Myopic maculopathy
-1.00 to -3.00	2.3	2.1	3.1	2.2
-3.00 to -5.00	3.3	3.1	9.0	9.7
-5.00 to -7.00	3.3	5.5	21.5	40.6
< -7.00	-	-	44.2	126.8
* summarized from Flitcroft (2012)				

Odds ratios of increased risk of ocular pathology with increasing levels of myopia.

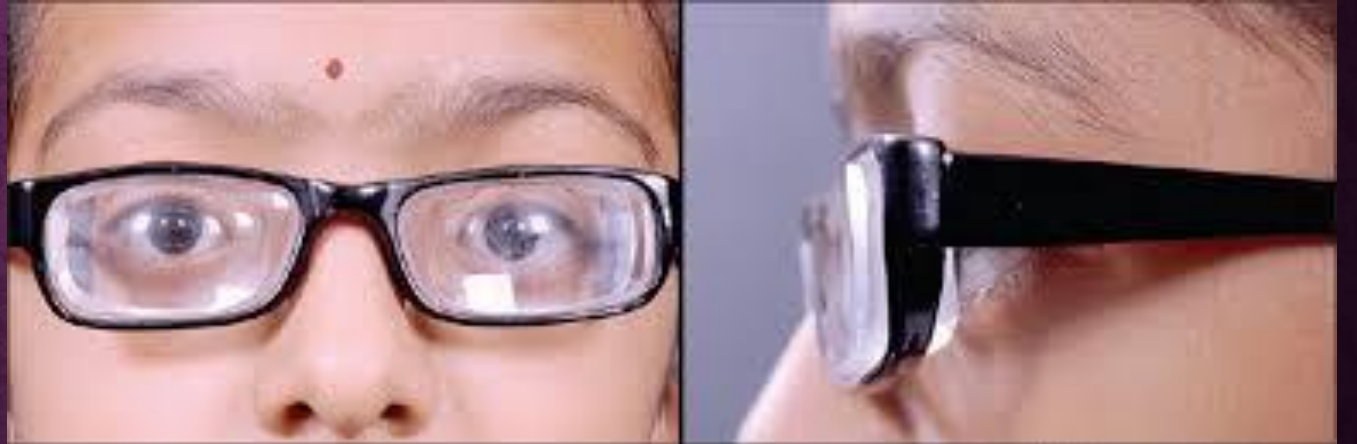
BOTTOM LINE...

With no intervention, myopia could become a leading cause of
PREVENTABLE blindness!!



MYOPIA IMPLICATIONS (CONT'D)

- Quality of Life
 - Socially
 - Economically
 - Refractive Surgery



MYOPIA FACTS

- Typically onsets between the age of 8 and 16
- Progresses rapidly at first but gradually slows down with age
- Typically increases until early to mid 20s, but varies **WIDELY**



MYOPIA PROGRESSION: HOW?

- Once myopia develops, the mean rate of progression in children 8 to 13 years of age is 0.5 D/year for Caucasian children and 0.8 D/year for Asian children.
- The earlier the onset, the longer the period of time of progression and the faster the progression.

MYOPIA PROGRESSION: WHY?

- Genetics
- Near work
- Outdoor activity



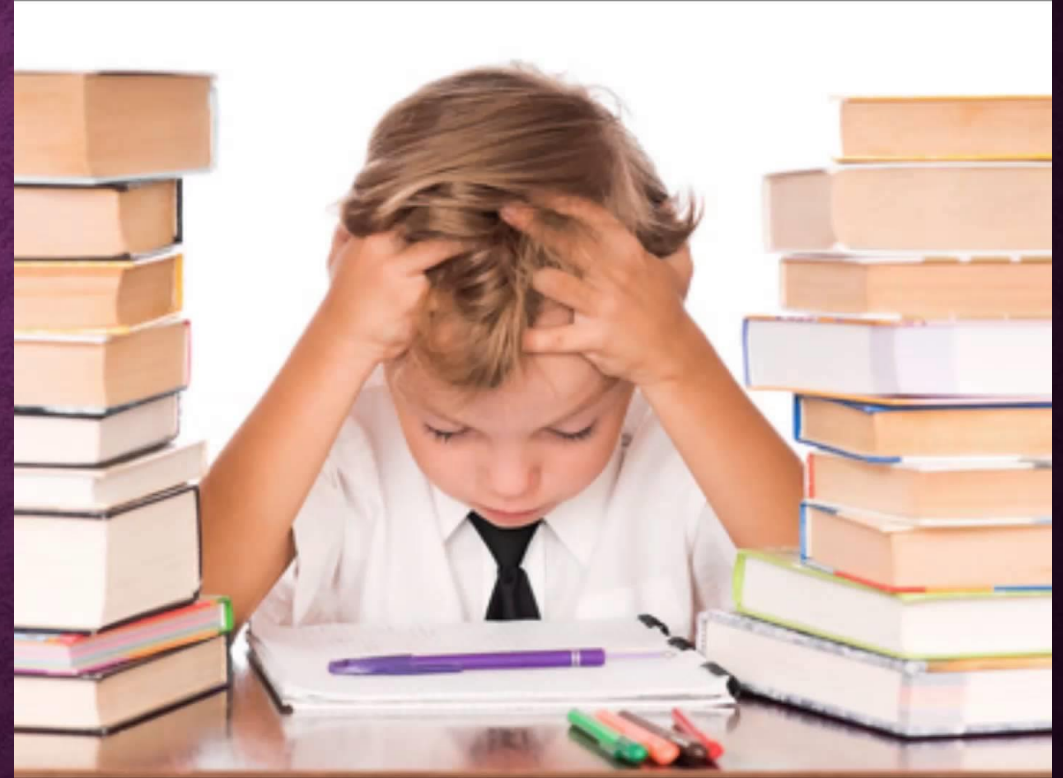
There is no consensus in literature about the true reason for myopia progression.

GENETICS

- Likely plays a role in the child's initial refractive error
- The risk of becoming myopic increases with the number of myopic parents
 - **One myopic parent – 3x greater risk of myopia development**
 - **Two myopic parents – 6x greater risk of myopia development**
 - **Two myopic parents – greater risk of progression to high myopia**
- Parents share both genetic and environmental factors with their offspring, thus, the parental relationship does not necessarily support a genetic cause.

NEAR WORK

- Myopia is more common in adults who have completed more years of schooling and who have achieved higher qualifications.
- In children, there is an almost universal pattern of increasing myopia prevalence with :
 - years of schooling
 - higher examination results,
 - academically selective schools
 - heavy school and home work loads.



NEAR WORK

- The assumption is that near vision focusing (i.e. reading and computer use) is somehow indirectly responsible for axial length elongation.
- The common thought is the constant looking at objects at 16-26 inches causes the focusing system to get stuck at the near reading or computer distance.
- **Few studies have been able to actually show a link between myopia progression and prolonged near work.**

OUTDOOR ACTIVITY

- Spending more time outdoors has been shown to decrease the likelihood of becoming myopic, but does not seem to slow down the progression of myopia.



OUTDOOR ACTIVITY

- Some schools in Taiwan were randomly assigned to encourage outdoor activities during recess, while other schools maintained their normal routine during recess.
- In the schools that encouraged more outdoor activities during recess, only 8.4% of children became myopic, compared to 17.7% in the schools that maintained their normal recess active.
- However, the myopic children who were encouraged to spend time outdoors during recess progressed in myopia at the same rate as those who maintained their typical recess activities

MYOPIA CONTROL

What must be done?

Control axial elongation (myopia progression)

-OR-

Prevent axial elongation (myopia onset)

In order to be considered clinically meaningful, a myopia control modality should slow the progression by approximately 50%, according to most myopia control grant applications.

EXAMPLE

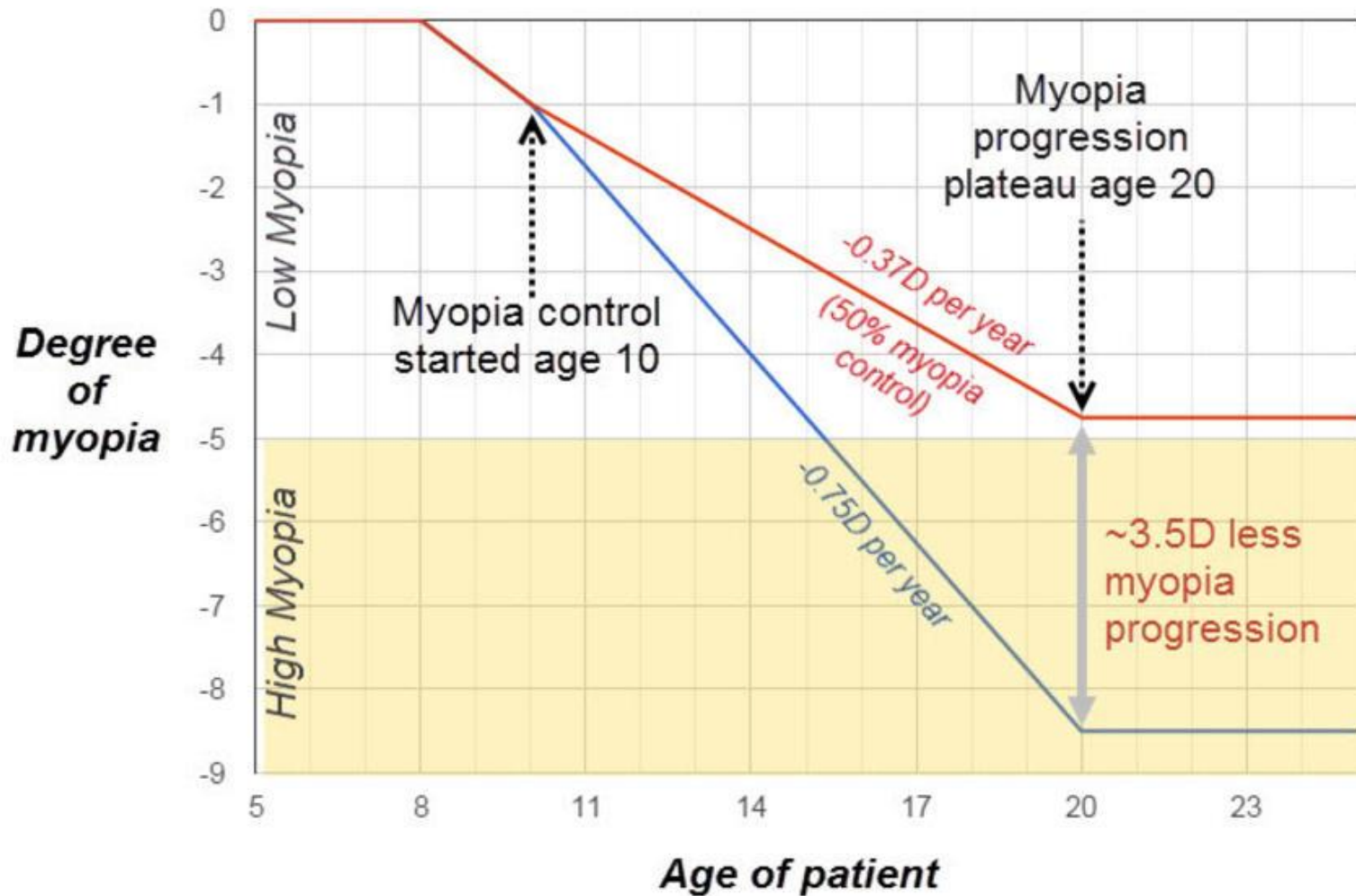
A child is diagnosed with 1.00D of myopia at the age of 8.

The expected rate of progression is 0.50D every year.

Assuming this rate of progression, by the age of 16, the patient will be a 5.00D myope.

If myopia progression is slowed by:	Final myopia would be:
0%	-5.00D
25%	-4.00D
50%	-3.00D
75%	-2.00D
100%	-1.00D

The effect of 50% myopia control on the eventual degree of myopia in a typical young patient



Patient using myopia control treatments



Patient using conventional glasses/contacts

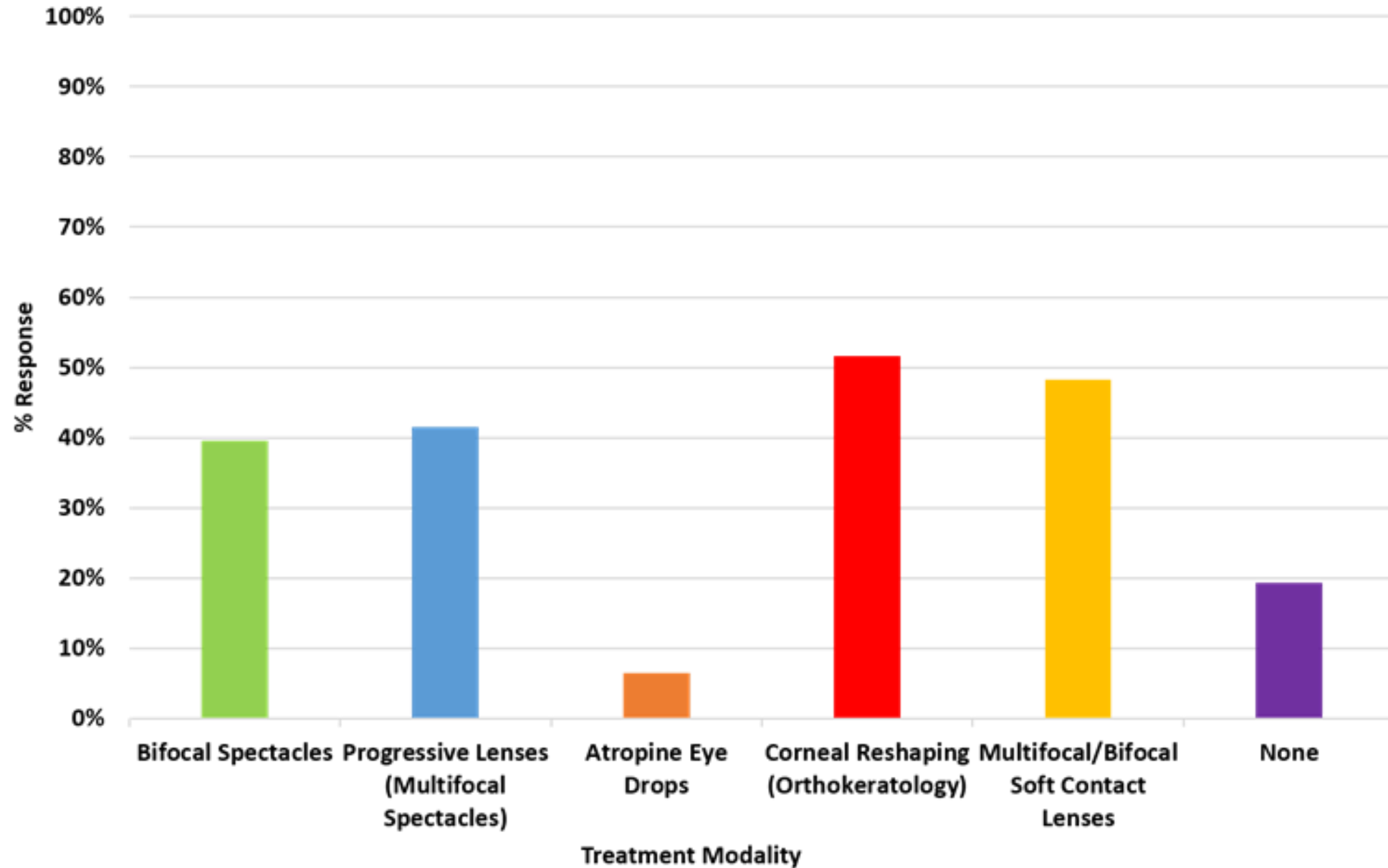
ASSESSING RISK

	Risk Factor for Developing Myopia	Risk Factor for Fast Progression of Myopia
Age	9 years old or less	9 years old or less
Refractive Error	Less hyperopic than expected for age	N/A
Current Progression	N/A	More than -1.00D/year
Ethnicity	East Asian	East Asian
Time spent outdoors	More than 1.5 hours/day	N/A
Time spent on near work	More than 2.5 hours/day	N/A

POTENTIAL APPROACHES FOR PREVENTING MYOPIA PROGRESSION

- Under-correction
- Bifocal Spectacles
- Progressive Addition Lenses (PALs)
- Soft Multi-focal Contact Lenses*
- Orthokeratology*
- Pharmaceutical Therapy*

Myopia Control Treatment Options Prescribed Between 2011 - 2013



IMPORTANT NOTE

There is no method of myopia control that is currently FDA approved.

Thus, all methods are off-label use and patients and parents should be informed of this before proceeding with treatment.



UNDER-CORRECTION

- Theory:
 - Myopic patients have a higher accommodative lag than emmetropic patients.
 - The lag of accommodation focuses light behind the retina during near work, potentially acting as a cue for increased myopia progression.
 - Under-correction of myopia reduces accommodative effort and accommodative lag and is thought to slow myopia progression.



UNDER-CORRECTION

- Adler and Millodot found that under-correction of myopia by approximately 0.50 D **did not significantly affect myopia progression** in 6- to 15-year-old myopic children wearing full myopic correction over 18 months. (2006)
- Chung et al. found that myopia progressed an average of -1.00 D for 9- to 14-year-old myopes under-corrected by approximately 0.75 D, compared with -0.77 D for fully corrected myopes of the same age range. (2002)

UNDER-CORRECTION

- Truth:
 - Under-correcting a child's refractive error by 0.50D to 0.75D either increases or has no effect on myopia progression.

May have to dispel the myth with child's parents that updating or increasing the child's prescription will weaken their child's eyes

BIFOCAL SPECTACLES

- Theory:
 - The add may control myopia progression by reducing or eliminating the accommodative effort or error associated with myopia.
 - This may be especially beneficial for esophoric myopes since they tend to have a more significant accommodative lag



BIFOCAL SPECTACLES

- The largest randomized clinical trial reported that children wearing multifocal spectacles **progressed 0.20 D less** than children wearing single vision spectacles over a 3 year period. (Gwiazda J. et al, 2003)
- A clinical trial randomly assigned children to wear single vision, executive bifocal, or executive bifocal with 3D base-in prism spectacles. **The prism had no effect on myopia progression, but the executive bifocal slowed myopia progression from -2.06 D for single vision wearers to -1.25 D for the executive bifocal group over three years (39% reduction).** (Cheng et al, 2014)

BIFOCAL SPECTACLES

- Truth:
 - Studies vary from 20% reduction to up to 45% reduction in myopia progression.
 - These results are more favorable than under-correction or single vision lenses.
 - May be most beneficial for esophoric myopes (~30%).
 - An executive bifocal **MAY** be the most effective lens design.

*Although these results are statistically significant, they are not considered **CLINICALLY** significant.*



PROGRESSIVE ADDITION LENSES (PALS)

- Theory:
 - Same basic idea of bifocal spectacles with the added advantage of improved cosmetic appearance.
- Truth:
 - Most studies found minimal myopia control. COMET study concluded that the significant increased cost of PALs doesn't warrant usage of them over single vision distance spectacles.

BIFOCALS AND PALS (CONT'D)

Conclusions:

- Bifocals (and PALS) are better options than under-correction and single vision spectacles.
- Reserve for patients who are not contact lens candidates (i.e. astigmatism)



3 OPTIONS FOR MOST EFFECTIVE MYOPIA CONTROL



Pharmaceutical Therapy

Soft Multi-Focal Contact Lenses

Orthokeratology



PHARMACEUTICAL THERAPY

- Anti-muscarinic eye drops that are used in routine eye care to dilate the pupil and reduce or eliminate accommodation
- Atropine is a broad spectrum anti-muscarinic agent.
 - Ocular side effects include temporary sensitivity to light and blurry near vision
 - Systemic side effects include decreased lacrimation, allergic reaction, tachycardia, restlessness, and dryness of the mouth, throat, and skin

PHARMACEUTICAL THERAPY

- Theory:
 - Researchers do not know exactly why and how atropine works to slow myopia
 - Initially, it was believed that temporarily paralyzing the ciliary muscle thus preventing active accommodation would halt myopia progression.
 - Now, it is believed that atropine has an unknown anti-myopic effect on the retina and sclera



PHARMACEUTICAL THERAPY

- Myopic children were randomly assigned to 1 nightly drop of either 0.01%, 0.1%, or 0.5% atropine and compared with children randomly assigned to either 1.0% atropine or placebo eye drops. (Chia, A. 2012)
- The most effective myopia control over 2 years was exhibited by children using 1.0% atropine. There was not a significant difference in myopia progression between the three lower concentrations.

PHARMACEUTICAL THERAPY

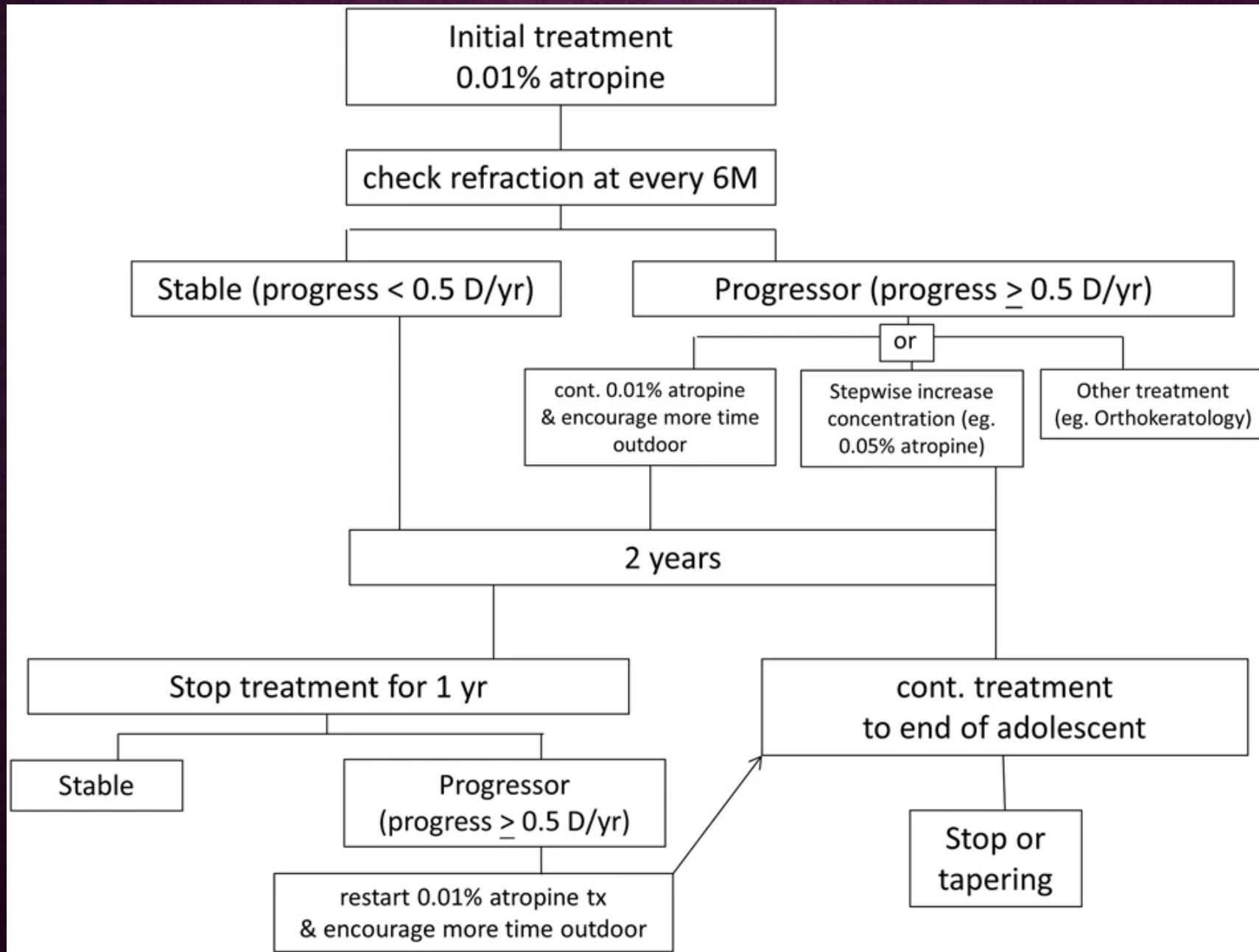
- Truth:
 - The most effective method of myopia control after one year of therapy (76% to 96%).



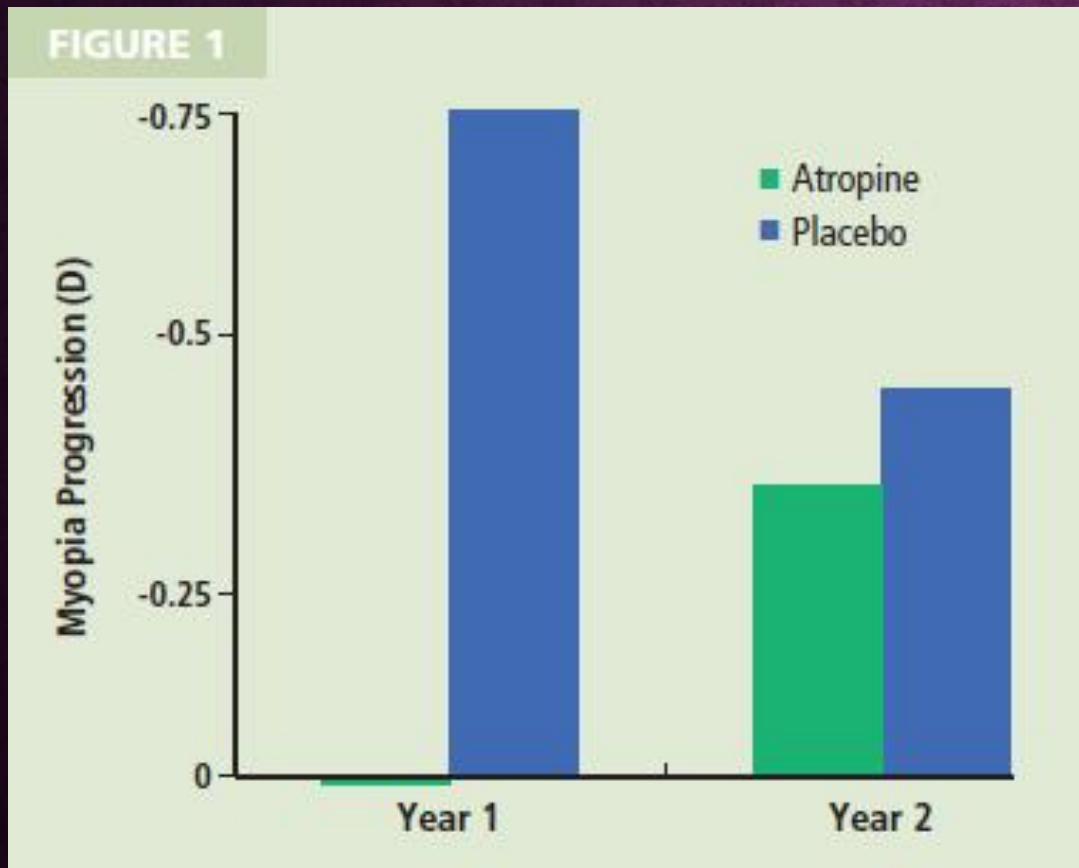
PHARMACEUTICAL THERAPY

- Although it is the most effective method of myopia control, atropine is rarely utilized in clinical practice because of the ocular and systemic side effects.
- Note: Some recent studies have shown that lower concentrations of atropine (0.01%) provides effective myopia control without the side effects.





PHARMACEUTICAL THERAPY



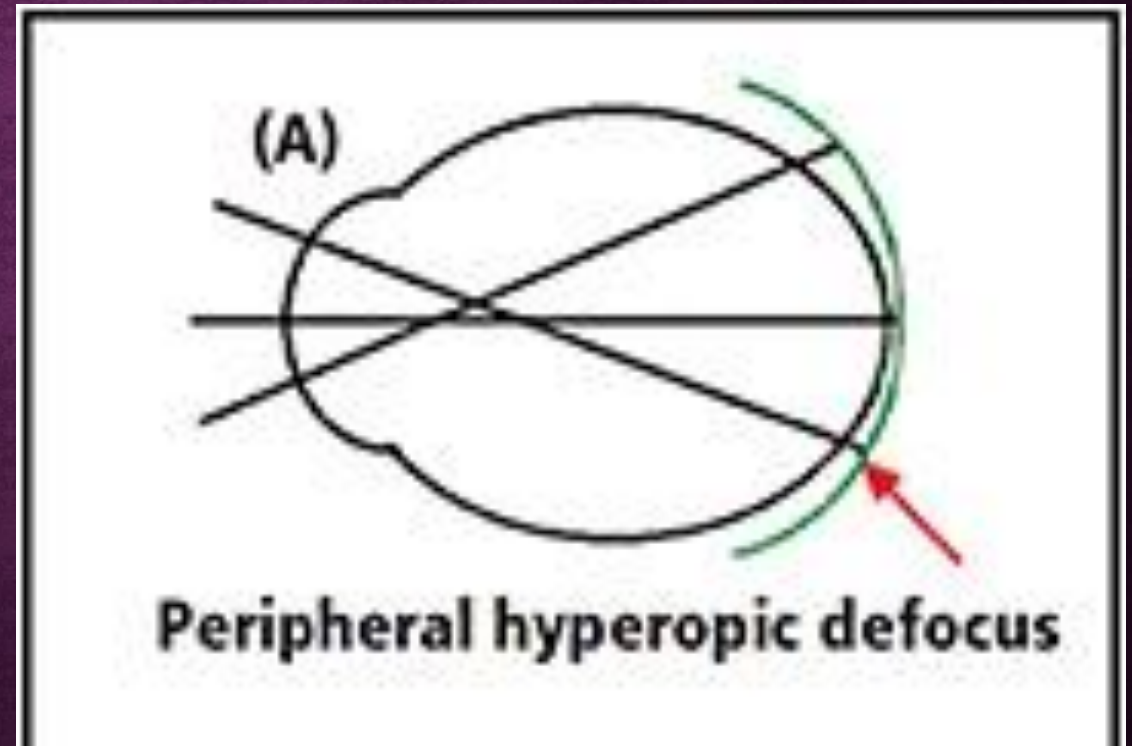
- There is evidence that the accrual of a treatment effect from atropine does not continue after the first year and short-term use of atropine may NOT lead to a permanent treatment effect.

HOW DO CONTACT LENSES INDUCE MYOPIA CONTROL?

- Initial studies concluded that the fovea was a contributing factor to axial elongation.
- Now, we know that the peripheral retina is responsible for axial elongation and thus refractive error.
- Peripheral myopic defocus has been shown to slow axial elongation, whereas the opposite occurs with peripheral hyperopic defocus.

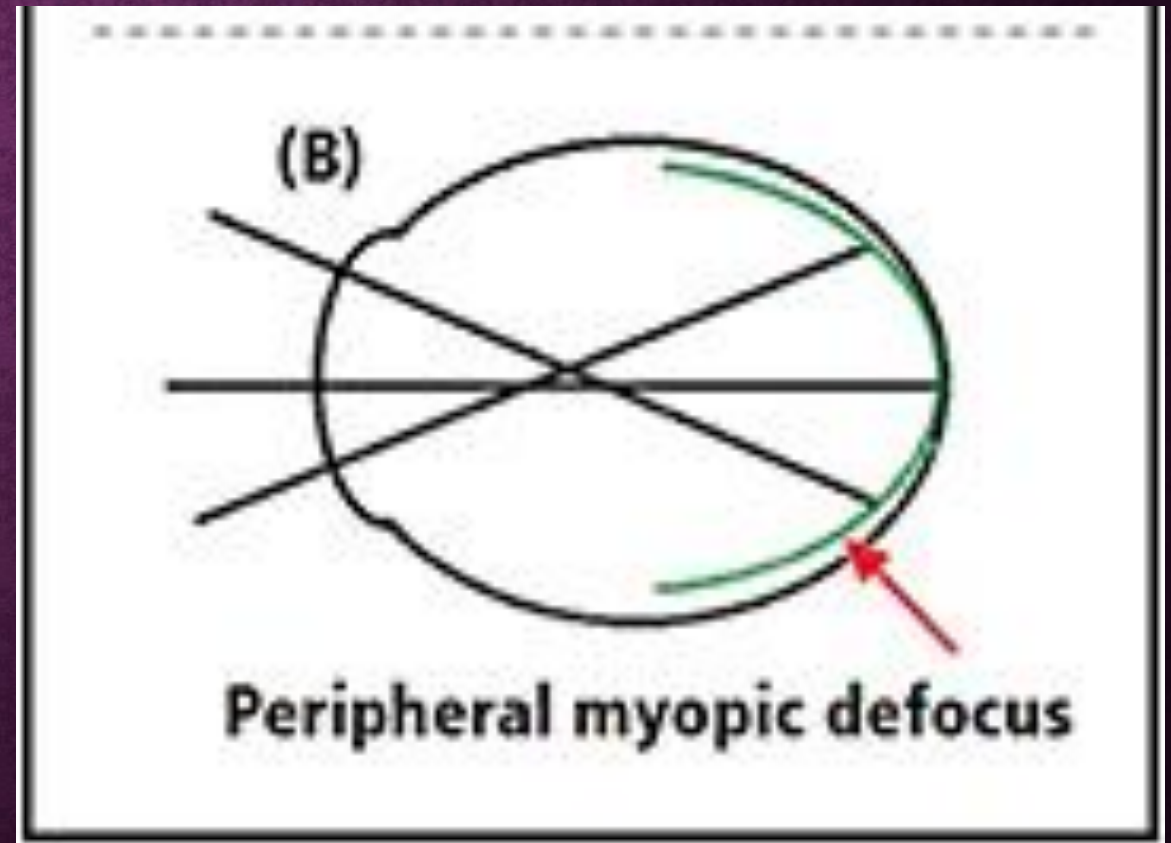
HOW DO CONTACT LENSES INDUCE MYOPIA CONTROL? (CONT'D)

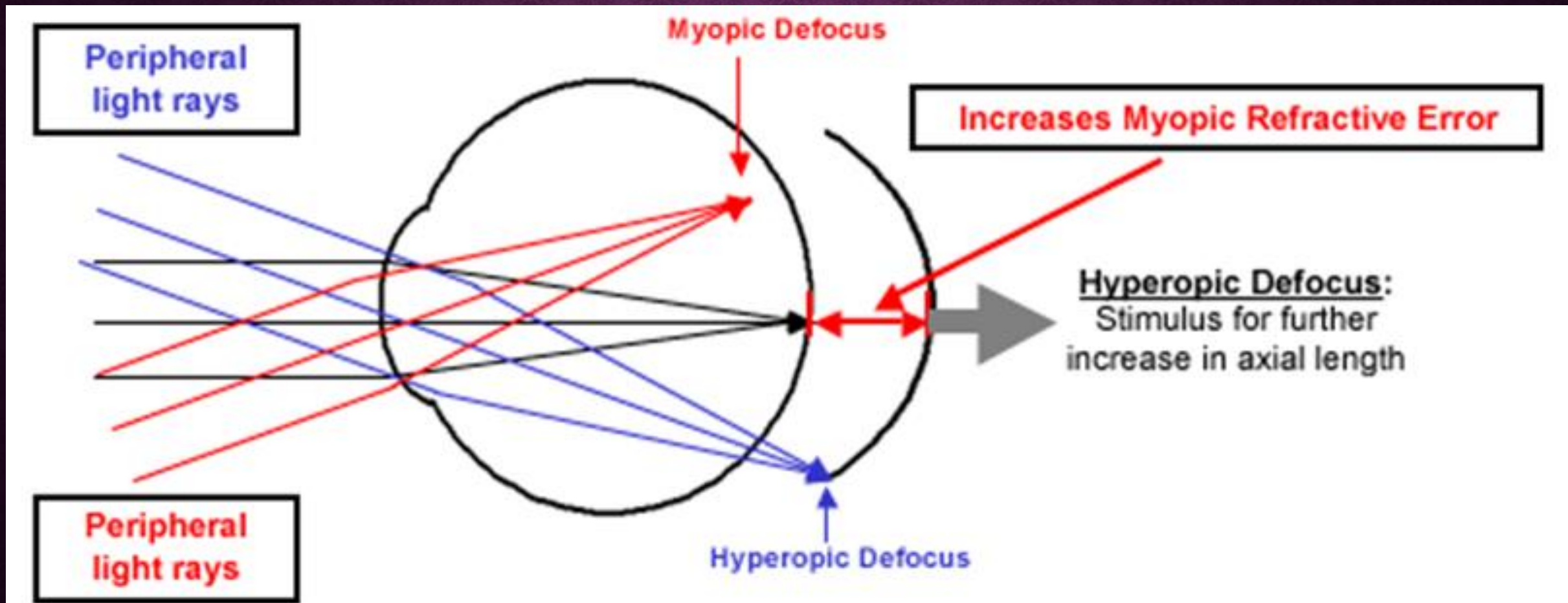
- When a patient wears single-vision spectacles or contact lenses, central light rays focus on the retina (macula) while peripheral light rays focus behind the retina, creating a peripheral hyperopic defocus.



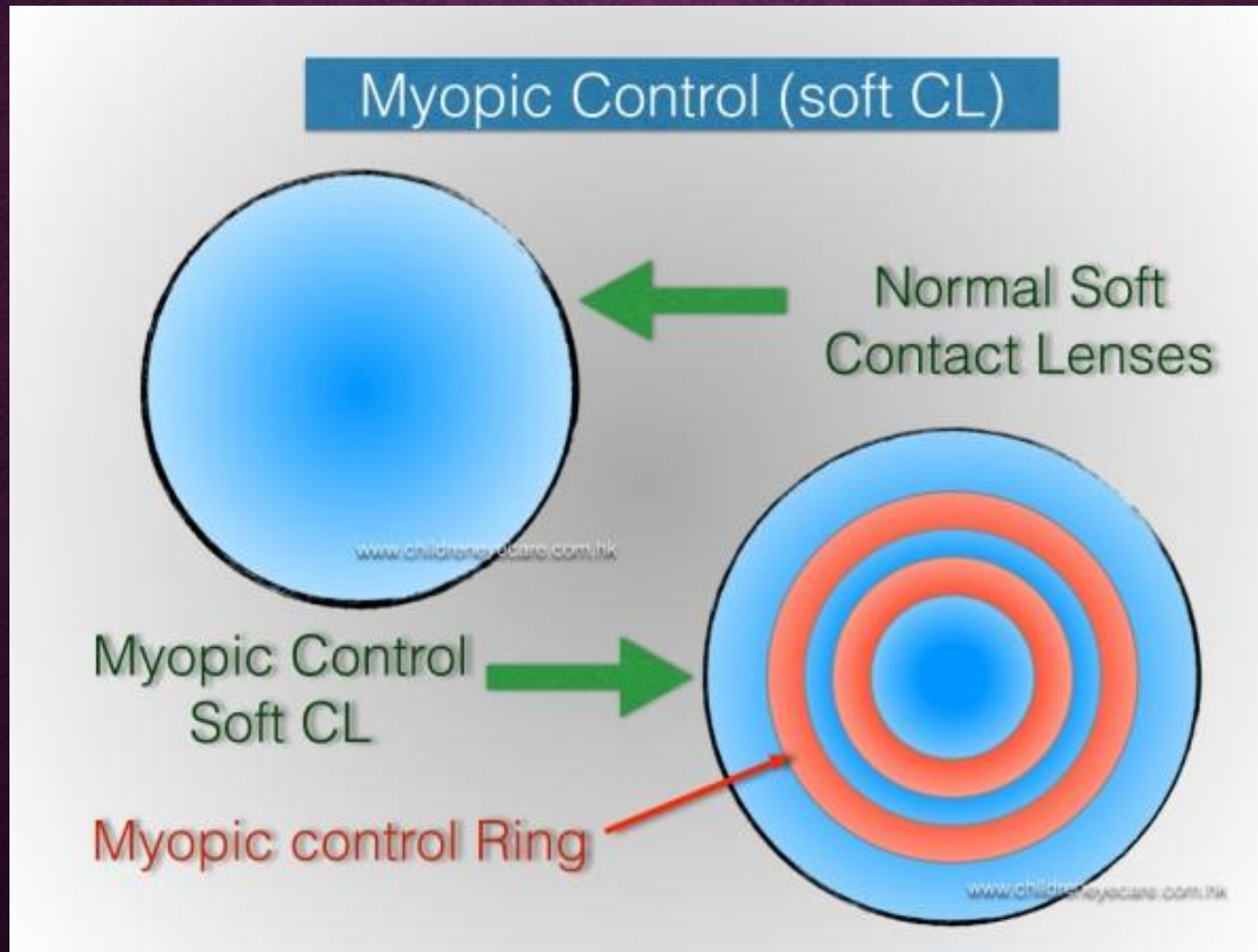
HOW DO CONTACT LENSES INDUCE MYOPIA CONTROL? (CONT'D)

- When a patient wears center-distance soft multifocal lenses or corneal reshaping lenses, central light rays still focus on the retina to provide a clear image while there is peripheral myopic defocus from peripheral light rays.





SOFT MULTIFOCAL CONTACT LENSES



SOFT MULTIFOCAL CONTACT LENSES

- Center distance designs are the only design that have been shown to provide effective myopia control
- At this time, there is no consensus on most effective add power. Some studies support using the highest add power the patient can tolerate.
- Can be beneficial for patients who are not candidates for orthokeratology either because of choice or prescription parameters.
- Best option for patients with a significant amount of astigmatism.

SOFT MULTIFOCAL CONTACT LENSES

The effect of slowing myopia progression became obvious when children wore the lenses for five hours a day, and the improvement increased if they wore them for seven hours a day or more, according to the study published in the January 2014 issue of the *British Journal of Ophthalmology*.

SOFT MULTIFOCAL CONTACT LENSES

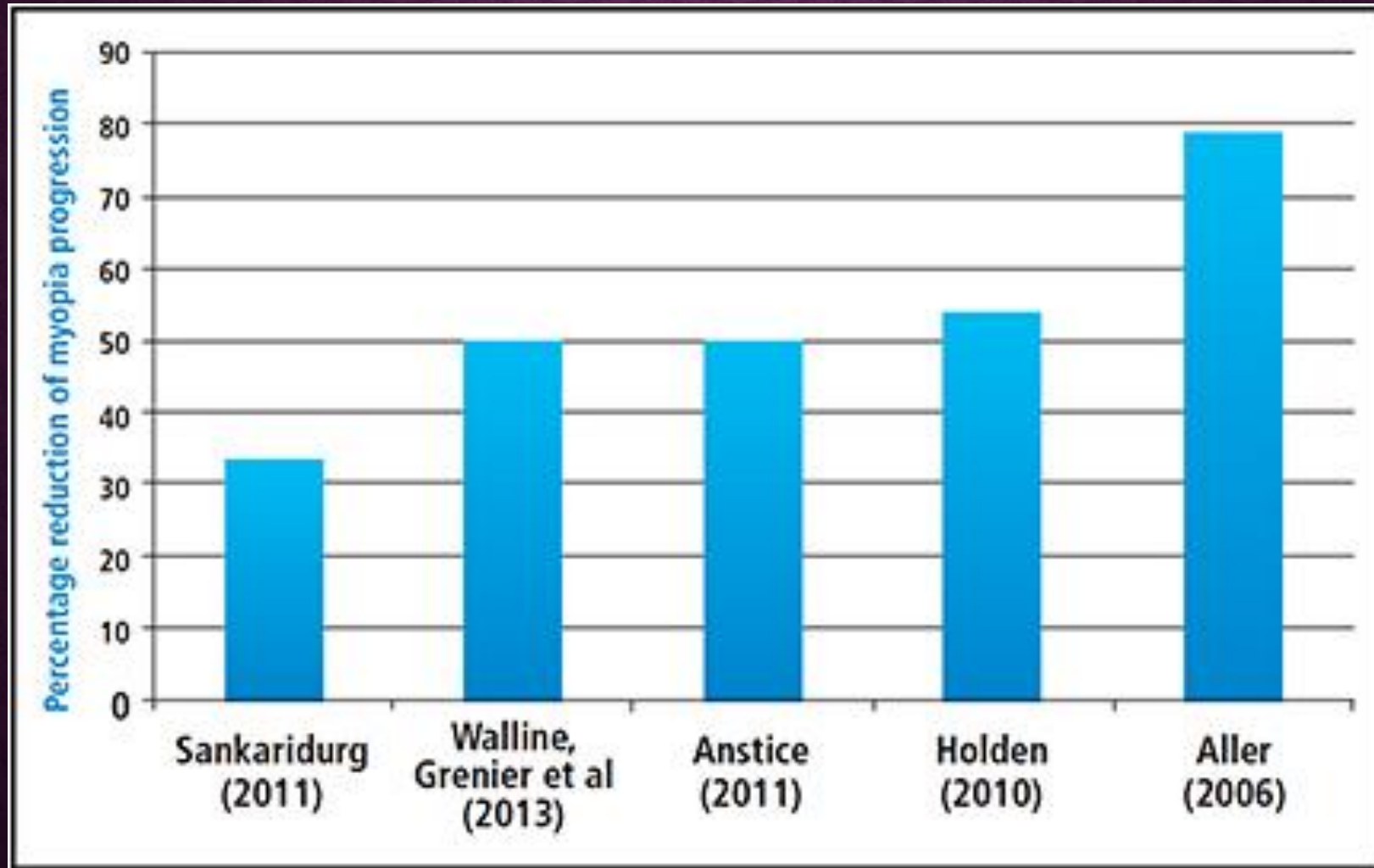
Advantages

- Less adaptation time
- Less expensive (?)
- Can accommodate more prescription parameters

Disadvantages

- Possibility of decentered optics throughout the day
- Typical soft contact lens issues
 - Dryness, irritation, slightly higher risk of infection
- Quality of vision

SOFT MULTIFOCALS



34%-79% reduction in myopia. (Avg. 46%)

SOFT MULTIFOCAL OPTIONS

Proclear MF (D lens)

Proclear MF Toric (D lens)

Biofinity MF (D lens)

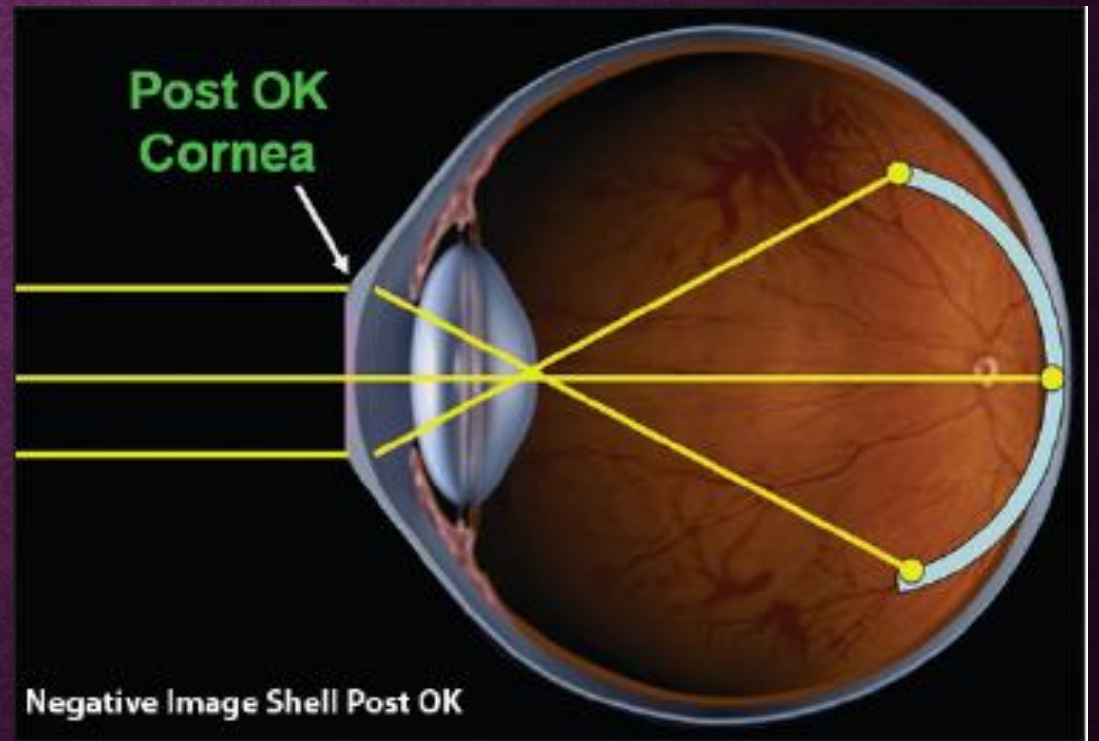
Acuvue Oasys for Presbyopia

SpecialEyes

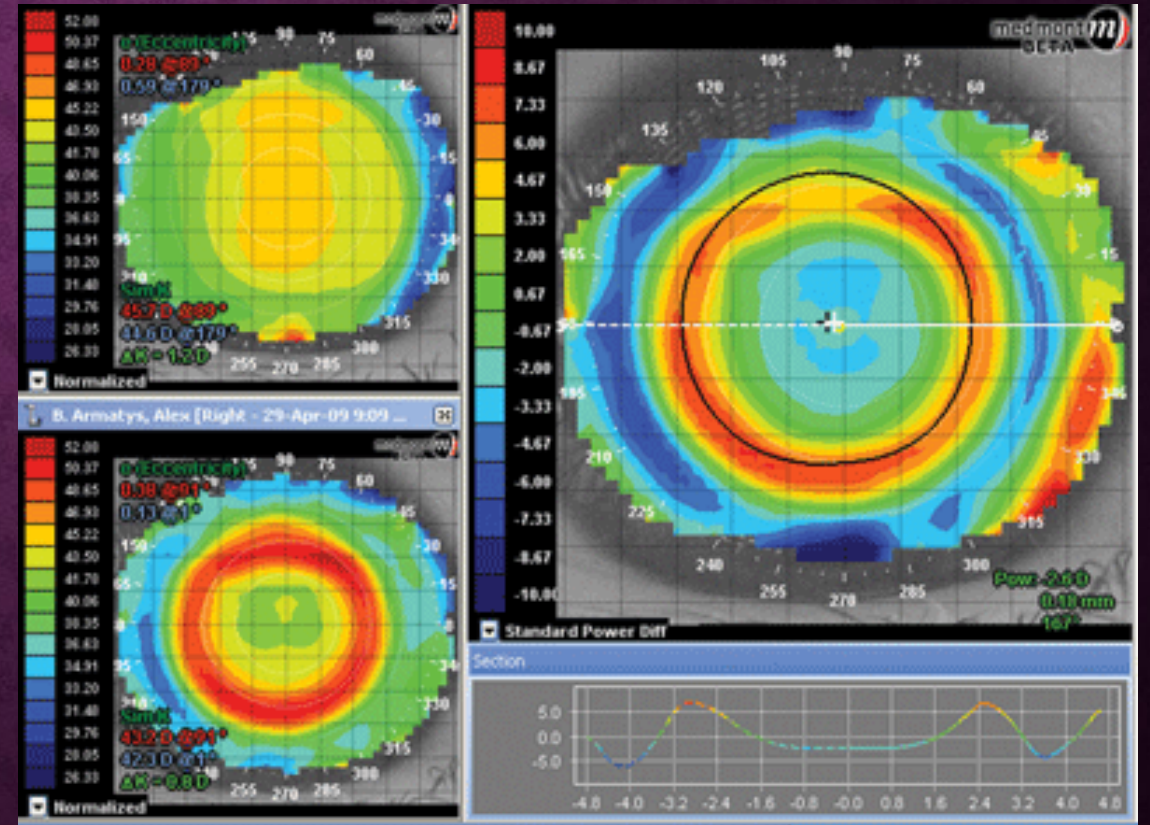
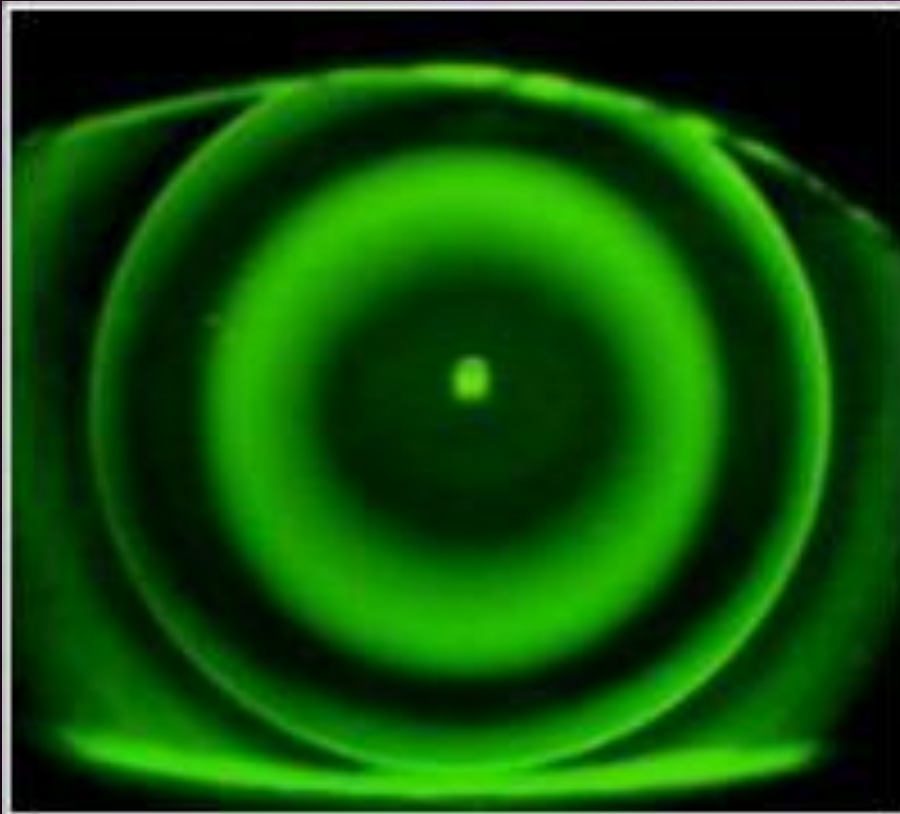
NaturalVue MF

ORTHOKERATOLOGY

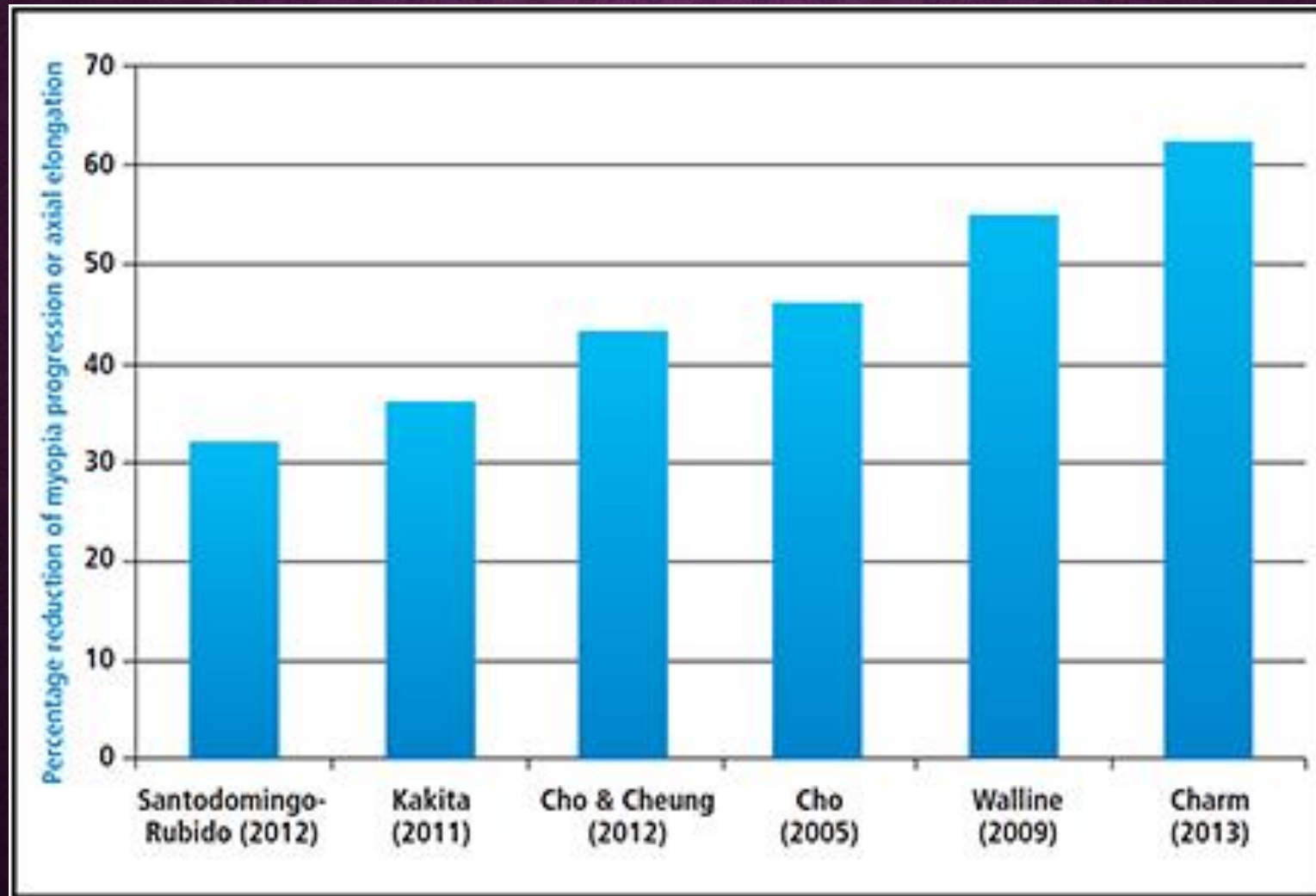
- Contact lenses are worn overnight to flatten the central cornea and temporarily reduce the amount of myopia.
- Contact lenses provide clear vision without the need for vision correction during the day and they also reduce myopic progression.



ORTHOKERATOLOGY



ORTHOKERATOLOGY



32% to 62% reduction in myopia. (Avg. 43%)

ORTHOKERATOLOGY

Advantages

- Freedom from day time contact lens wear
- Centered optics all day long

Disadvantages

- Prescription limitations
 - FDA approval up to -6.00D sphere and -2.00 cylinder
- Risk of infection with overnight wear
- Adaptation time
- Cost
- Vision implications for large pupils

WHEN IS THE IDEAL TIME TO START TREATMENT

Pre-myopic child with myopic parents?

-OR-

At the time of onset?

There is some debate on whether orthokeratology has equal effect on both low and moderate myopes.

May want to consider starting with soft multi-focals.

CHILDREN AND CONTACT LENSES: BOTTOM LINE

- Optometrists traditionally do not fit children in contact lenses until about 12 years old
- Current evidence suggests that we can be confident in fitting soft, rigid and orthokeratology lenses from 8 years of age
- Pre-teens report contact lens wear to improve their physical appearance, athletic competence and social acceptance compared to glasses



Walline J. et al, 2007

QUESTIONS TO CONSIDER WHEN DECIDING BETWEEN ORTHOKERATOLOGY AND SOFT MULTI-FOCAL CONTACT LENSES?

- What visual demands does the child have while at school or during extracurricular activities?
- Do the parents feel comfortable with the child wearing a contact lens overnight?
- Do the parents prefer to not have to worry about the child having issues at school or at other activities while wearing lenses during the day?
- Do the parents want the child to wear the same contact lens modality as them?
- What price point are the parents comfortable with?

POTENTIAL APPROACHES TO PREVENT AXIAL ELONGATION

- Outdoor Time
- Low Dose Atropine



OUTDOOR TIME

- Exact mechanism of action is unknown at this time
 - Theorized that Dopamine release may be stimulated by bright outdoor light, inhibiting eye growth
- Many studies have confirmed that outdoor time can prevent the onset of myopia BUT has no effect on preventing progression
- The effect has no correlation with engagement in sports

Time outdoors and the prevention of myopia, French, A. et al, 2013

LOW DOSE ATROPINE

- Children between the ages of 6 and 12 years with +1.00 D and -1.00 D spherical equivalent, cycloplegic refractive error were followed for at least 12 months and included in a retrospective comparison of children who received 0.025% atropine and those who did not.
- 21% of the children receiving atropine became myopic
- 54% of the children not receiving atropine became myopic
- Refractive error progression was also less for those on atropine than for those not on atropine.

Fang PC, Chung MY, Yu HJ, et al. Prevention of myopia onset with 0.025% atropine in premyopic children. *J Ocul Pharmacol Ther* 2010;26: 341–345

THE CLEERE STUDY

Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error,
(CLEERE) Study, K. Zadnik et al, 2015

**Determined ONE simple test that can predict whether a child will
become myopic...**

THE CLEERE STUDY



Early Refractive Error

Exhibiting less than 0.50D of manifest hyperopia at age 6 to 7 years is the most significant risk factor for future myopia.

OTHER PREDICTORS OF MYOPIA...

- Emmetropic children are at risk of becoming myopic when their axial length is greater than 23.5mm (Mutti et al, 2007).
- The ratio between axial length and corneal radius (in mm) seems to be a better predictor of myopia onset if it is > 3 mm in children aged 6 to 12 (He et al, 2015).

OTHER RECOMMENDATIONS

- Outdoor activity minimum of 45 minutes/day
- Reduce exposure to technology at near working distance
- Increase working distance at near



THE FUTURE, THE UNKNOWN

- What are the effects of discontinuing myopia control?
 - Will the patient return to their original Rx?
 - Will the Rx catch-up despite controlling it over time?
 - Will the patient's accommodative system be affected after wearing a soft multi-focal?
 - Will the patient's cornea be permanently altered?
- How much myopic blur is actually necessary to prevent progression?
- Is there a specific demographic that treatment will be most effective?

WHAT'S ON THE HORIZON?

- Orthokeratology
 - Customized lenses to induce more myopic defocus in the peripheral retina
- Multi-focal soft contact lenses
 - Designs that induce more myopic defocus but don't reduce visual acuity
- Peripheral defocus spectacles
- Scleral reinforcement procedures
- Caffeine eye drops
- Circadian rhythm manipulation

QUESTIONS?

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