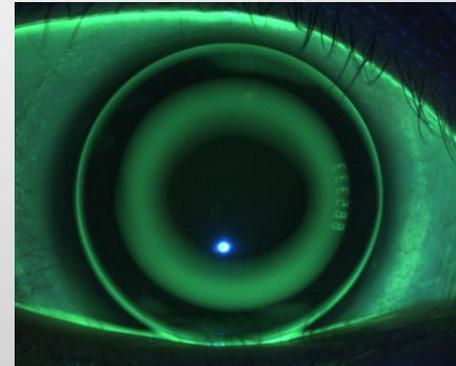


MYOPIA MANAGEMENT IN 2025

JULIE DEKINDER, O.D. FAAO, FSLS

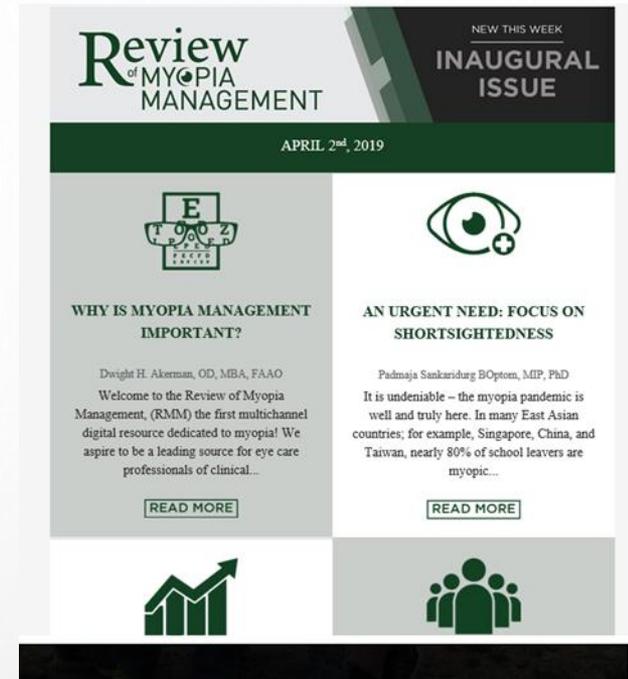
DIPLOMATE, CCLRT

CLINICAL PROFESSOR



OVERVIEW

- MYOPIA
- EVIDENCE BASED RESEARCH
- APPLYING EVIDENCE BASED RESEARCH IN CLINICAL PRACTICE



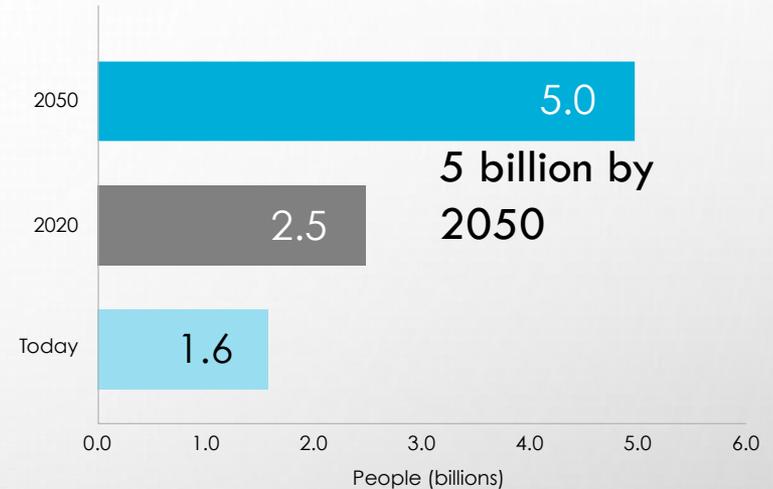
PRACTICE WHAT YOU PREACH

- MY DAUGHTER
 - WORE SMF FOR 2+ YEARS
 - WEARS ORTHOKERATOLOGY
 - 5 YEARS
 - NO CHANGE IN LENS PARAMETERS
 - NO CHANGE IN RX



MYOPIA

Myopia prevalence projections³



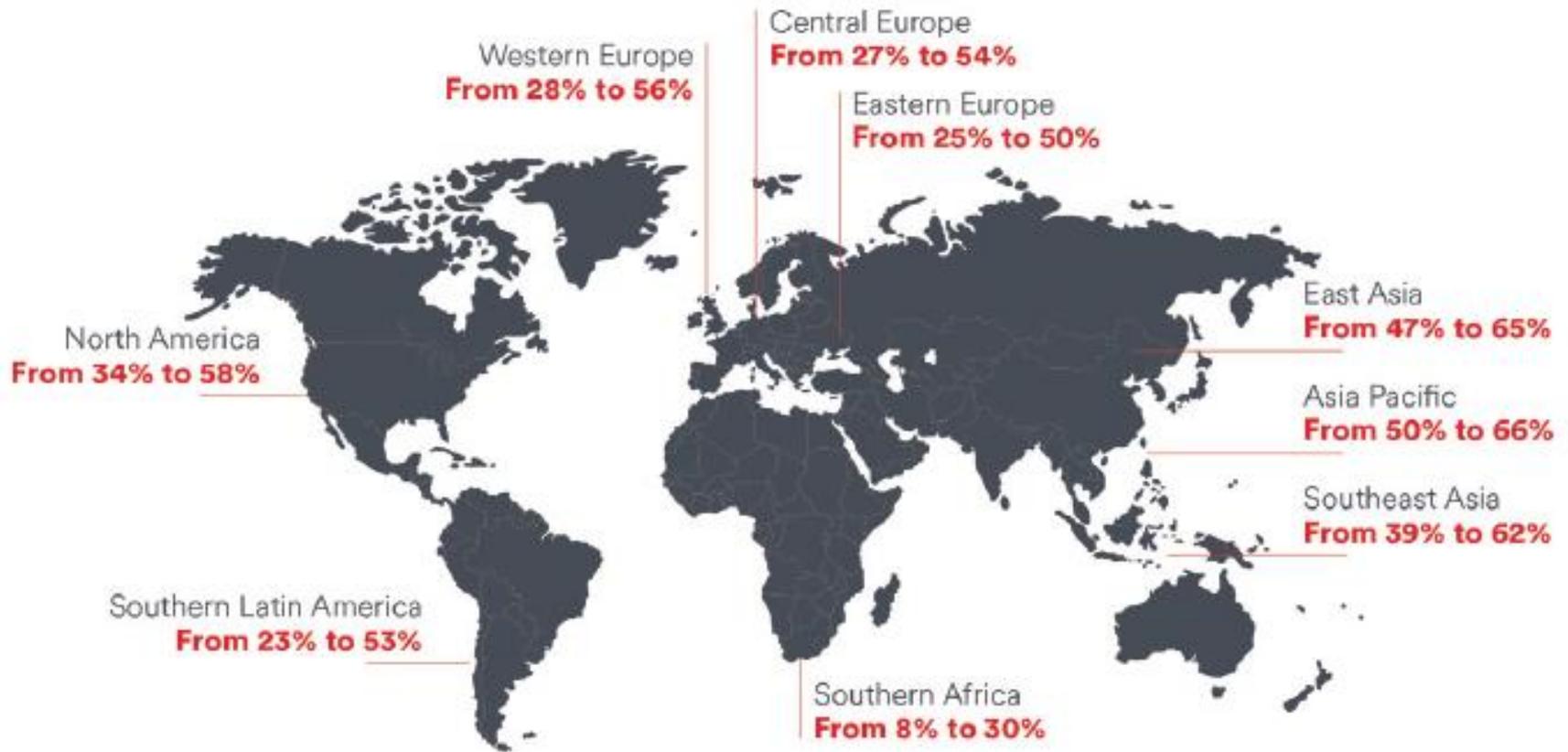
Holden, B. A., et al. (2016). Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. *Ophthalmology*. 123(5): 1036-1042.

- 300+ MILLION PEOPLE IN US
 - INCREASING IN PREVALENCE
 - 25% TO 42%

33.9% current world population
2.64 billion people are myopic

- MORE PREVALENT:
 - INDUSTRIALIZED COUNTRIES
 - CITIES VS RURAL

GLOBAL SNAPSHOT



Reported myopia prevalence current and projected 2050.

Johnson & Johnson Vision and Holden BA, Fricke TR, Wilson DA, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. Ophthalmology. 2016;123(5):1036-1042.)

THE DREAM STUDY

MYOPIA PROGRESSION FROM WEARING FIRST GLASSES TO ADULT AGE

N=2555

- MYOPIA PROGRESSES THROUGH CHILDHOOD:
 - SLOWS DOWN WITH AGE,
 - STABILIZES AROUND 21 YEARS OF AGE.
- MEDIAN PROGRESSION:
 - -0.50D/YEAR AT 10 YEARS OF AGE GRADUALLY DECREASED
- GREATER PROGRESSION AND HIGHER MYOPIA IF:
 - FIRST RX BEFORE AGE 10

All individuals with
SER **-3.00D or more**
at 10 developed
high myopia by **25**
years of age.

THE REFRACTIVE AND AXIAL LENGTH DEFINITION OF MYOPIA AND EMMETROPIA

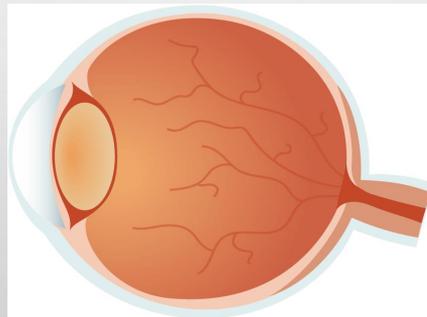
MYOPIA IS AN ABNORMAL PROCESS THAT BREAKS EMMETROPIZATION.

	Refraction	Axial Length
Normal Emmetropia		
Birth	+2.00D	18mm
Age 2	+1.00D	23mm
Age 18	Emmetropia	24mm
Myopia	> -0.50D	>24 mm
High Myopia	> -6.00D	>26mm

9 yo
 -10.50-2.00 26.67mm
 -11.50-0.75 26.53mm

MYOPIA

****PROGRESSION IS DUE TO ELONGATION OF THE AXIAL LENGTH, WHICH IS PRIMARILY DUE TO THE ELONGATION OF THE VITREOUS CHAMBER DEPTH OF THE EYE****



MYOPIA

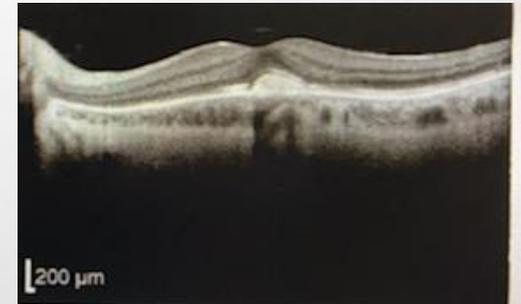
SIGHT-THREATENING COMPLICATIONS ASSOCIATED WITH HIGH MYOPIA

Ocular condition	Risk for $-5.00D$ or worse	Reference
Cataract	$>3.3 X$	Younan et al. 2002 (Blue Mountains Eye Study)
Glaucoma	$>3.3 X$	Mitchell et al. 1999 (Blue Mountains Eye Study)
Retinal detachment	$>9 X$	Ogawa & Tanaka, 1988
Myopic macular degeneration	$>40 X$	Vongphanit et al. 2002 (Blue Mountains Eye Study)

Projected to be the leading cause of permanent blindness in the world by 2050

CLINICAL IMPLICATIONS

- GIFFORD AND GIFFORD SUGGEST:
 - IF A MYOPIC CHILD COULD BE KEPT FROM PROGRESSING FROM A -1.00D TO -3.00D
 - DECREASE THE RISK:
 - MYOPIC MACULOPATHY BY 4 TO 5 TIMES
 - RETINAL DETACHMENT BY 3 TIMES
 - POSTERIOR SUBCAPSULAR CATARACT BY 1.5 TIMES



MYOPIA

Control Progression

Decrease the rate of eye growth

During Development

- Pharmacological, environmental, and optical interventions

Delay of Onset

Low concentration Atropine

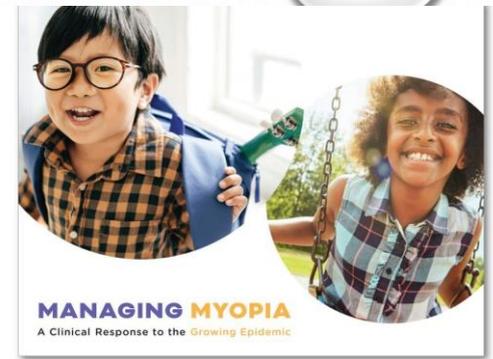
Time outdoors

MYOPIA

- COLLABORATIVE LONGITUDINAL EVALUATION OF ETHNICITY AND REFRACTIVE EFFORT (CLEERE) STUDY
 - IF A CHILD IS LESS HYPEROPIC THAN +0.75D BY FIRST GRADE, THE CHILD IS AT AN INCREASED RISK TO DEVELOP MYOPIA.
- 6 YOM OD: +.25 OS +0.50
- 6YOF OD: +0.25 OS PL



MYOPIA



The best predictor for myopia onset is cycloplegic spherical equivalent refractive error at a given age

Refractive error predicts myopia onset

Numerous risk factors can help predict myopia onset, but the best predictor is cycloplegic spherical equivalent refractive error at a given age. A child with low hypermetropic refraction for a given

age (Table 3) has greater than an 80% likelihood of myopia onset by age 13.⁵ This approach provides a simple clinical method to evaluate risk of myopia onset that is just as accurate as more complex algorithms.

Table 3: Cycloplegic spherical equivalent autorefraction threshold by age, for children at high risk of becoming myopic by 8th grade⁵

AGE	6	7-8	9-10	11
REFRACTIVE ERROR	< +0.75 D	≤ +0.50 D	≤ +0.25 D	≤ +0.00 D

If less hyperopic >80% likelihood of myopia by the age of 13.5

MYOPIA

- RISK FACTORS FOR MYOPIA DEVELOPMENT
 - PARENTAL MYOPIA
 - EXCESSIVE NEAR WORK AT CLOSE DISTANCES
 - REDUCED TIME OUTDOORS
 - ETHNICITY WITH EAST ASIAN CHILDREN AT GREATER RISK
 - **LESS THAN AGE-EXPECTED HYPEROPIA**
 - FEMALE GENDER

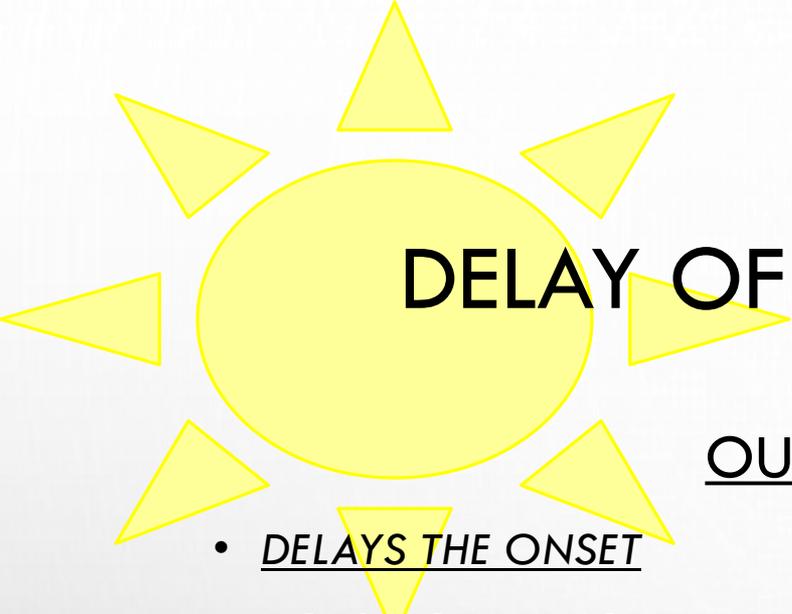


#screenagers

MYOPIA

WHAT CAN WE DO TO DELAY THE ONSET OF MYOPIA?





DELAY OF MYOPIA ONSET

OUTDOOR TIME

- DELAYS THE ONSET
- DOES NOT REDUCE THE PROGRESSION OF MYOPIC REFRACTIVE ERROR.
 - DESPITE HIGH AMOUNTS OF NEAR WORK OR PARENTAL MYOPIA
 - BOTH THE INTENSITY AND DURATION OF THE LIGHT EXPOSURE AFFECT THE PROTECTIVE EFFECT OF OUTDOOR TIME.
- LIGHT LEVELS OUTDOORS ARE HIGHER THAN INDOORS AND ABOVE THE THRESHOLD ILLUMINANCE FOR MYOPIA PREVENTION EVEN WITH ADEQUATE SUN-PROTECTIVE MEASURES.

DELAY OF MYOPIA ONSET

OUTDOOR TIME

- CLINICAL RECOMMENDATIONS:

- PRESCRIBE OUTDOOR TIME 10-14 HOURS
- PRESCRIBE SUN-PROTECTIVE MEASURES
- ENCOURAGE DURING THE WINTER MONTHS
 - THERE IS A SLOWER PROGRESSION OF MYOPIA IN THE SUMMER, LIKELY RELATED TO CHILDREN SPENDING MORE TIME OUTDOORS, FEWER HOURS IN SCHOOL.



-The effects of Different outdoor environments, sunglasses and hats on light levels: implications for myopia prevention <https://tvst.arvojournals.org/article.aspx?articleid=2738326>

-Gwiazda, J., Deng, L., Manny, R., & Norton, T. T. (2014). Seasonal variations in the progression of myopia in children enrolled in the correction of myopia evaluation trial. *Investigative Ophthalmology & Visual Science*, 55(2), 752-758



DELAY OF MYOPIA ONSET

NEAR WORK

- TAKE BREAKS EVERY 20 MINUTES BY LOOKING ACROSS THE ROOM FOR 20 SECONDS WHEN USING A DIGITAL DEVICE OR READING AND SPEND A MINIMUM OF TWO HOURS PER DAY OUTDOORS — [20-20-2 RULE](#).
- CHILDREN SHOULD NOT SPEND MORE THAN THREE HOURS A DAY — IN ADDITION TO SCHOOL TIME — ON CLOSE WORK SUCH AS READING, HOMEWORK, OR SCREEN TIME.
- READING AND DIGITAL DEVICE USAGE SHOULD BE PERFORMED AT A DISTANCE OF AT LEAST 12 INCHES (30 CM.)

DELAY OF MYOPIA ONSET

Low Dose Atropine

Prev of Myopia

No treatment vs
0.025% atropine
qdhs

- 21% atropine treated became myopic
- 54% not receiving atropine became myopic

LAMP 2

- Nightly use of 0.05%, 0.01% and placebo
- 2 year cumulative incidence of myopia:

• 0.05%	28.4%
• 0.01%	45.9%
• Placebo	53.0%

ATOM3 study

- Phase three – The Use of Atropine 0.01% in the Prevention and Control of Myopia

Recommend: 0.05% Atropine at bedtime daily to delay the onset of Myopia

Fang PC, et al. Prevention of myopia onset with 0.025% atropine in premyopic children. J Ocul Pharmacol Ther 2010; 26:341-45.

Yam JC, Zhang XJ, Zhang Y, et al. Effect of Low-Concentration Atropine Eyedrops vs Placebo on Myopia Incidence in Children: The LAMP2 Randomized Clinical Trial. JAMA. 2023;329(6):472-481.

DELAY OF MYOPIA ONSET

- *SYSTEMIC REVIEW AND META-ANALYSIS*
 - *4 STUDIES; 644 CHILDREN (4YO-12YO) PREMYOPIC*
 - *0.01% TO 0.05% ATROPINE*
 - LOWER MYOPIA INCIDENCE
 - REDUCTION IN RAPID MYOPIA SHIFT (≥ 0.5 D/1 Y)
 - SPHERICAL EQUIVALENT AND AXIAL LENGTH EXHIBITED ATTENUATED PROGRESSION IN THE ATROPINE GROUP.
 - NO MAJOR ADVERSE EVENTS

MYOPIA – DELAYING THE ONSET

1. ENCOURAGE OUTDOOR TIME
2. LIMIT NEAR WORK
3. RX LOW DOSE ATROPINE



MYOPIA

HOW DO WE CONTROL
PROGRESSION?



What do we know about myopia progression

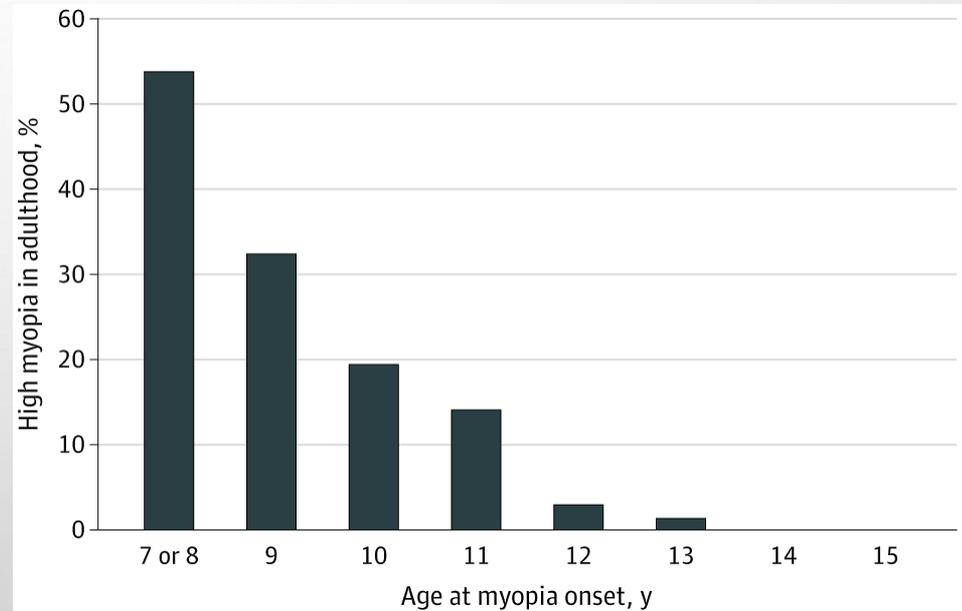
MYOPIA

- **Progresses faster**
 - winter months vs summer months
 - in younger children
 - Dependent on baseline age
 - decreasing progression with age
- **Ethnicity**
 - Myopic children in Asian countries progress faster than children in western countries
- Increased **near work** increases progression

MYOPIA

- TWINS AGED 7 TO 15 FOLLOWED ANNUALLY FOR 12 YEARS.
 - AMONG ALL 443 PARTICIPANTS 54 (12.2%) HAD HIGH MYOPIA IN ADULTHOOD

Age at myopia onset	>6.00D myopia	percentage
7/8 year olds	14/26	53.9%
9 year olds	12/37	32.4%
10 year olds	14/72	19.4%
11 year olds	11/78	14.1%
12 and older	3/230	1.3%

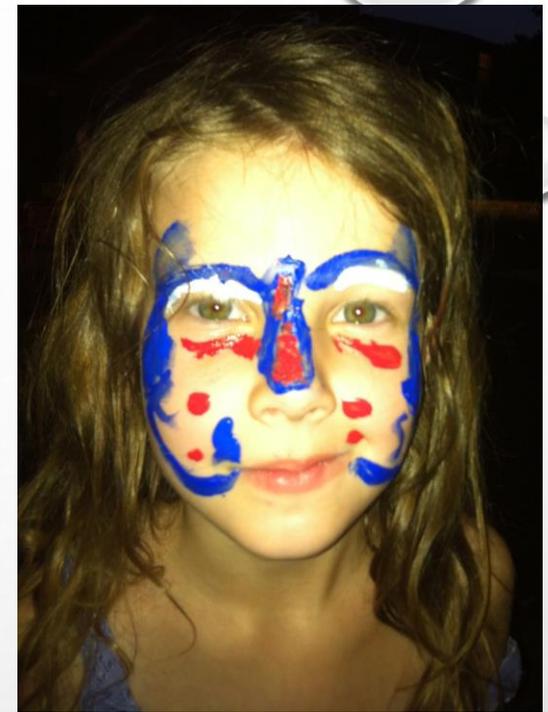


Hu Y, Ding X et al. Association of Age at Myopia Onset with risk of high myopia in adulthood in a 12-year follow-up of a Chinese cohort.

MYOPIA

MEAN PROGRESSION RATE:

- 0.55D/YEAR CAUCASIAN
- 0.63D/YEAR HONG KONG CHINESE
 - 0.82D/YEAR ASIAN
- 0.80D/ YEAR FEMALES (COMBINED ETHNICITIES)
- 0.71D/ YEAR MALES (COMBINED ETHNICITIES)



MYOPIA

16 YEARS = AVERAGE AGE FOR STABILIZATION OF CHILDHOOD MYOPIA

- PROGRESSION PAST AGE 20: YOUNG ADULT PROGRESSION
- RECENT ENVIRONMENTAL CHANGES HAVE RESULTED IN SHARP INCREASE IN MYOPIA AND INCREASE IN THE AGE OF PROGRESSION, OVERALL MAGNITUDE.



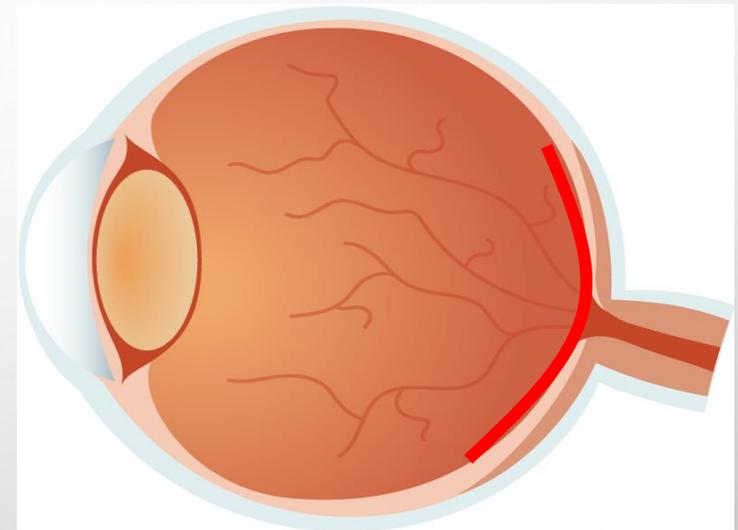
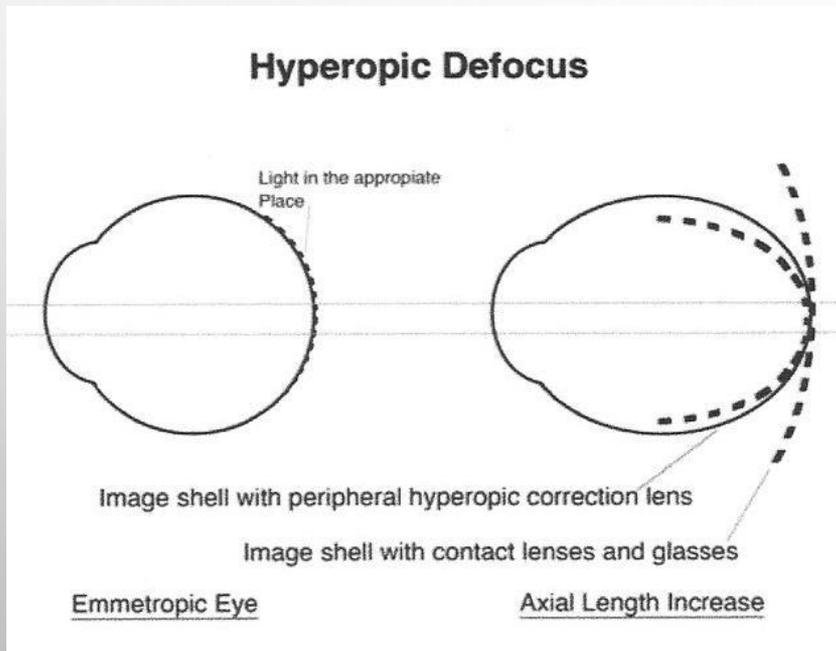
MYOPIA

Question Is home confinement due to coronavirus disease 2019 associated with the burden of myopia?

Findings In this cross-sectional study that included 194 904 photoscreening tests conducted in 123 535 children, a substantial myopic shift (-0.3 diopters) was noted after home confinement due to coronavirus disease 2019 for children aged 6 to 8 years. The prevalence of myopia increased 1.4 to 3 times in 2020 compared with the previous 5 years.

MYOPIA

HYPEROPIC PERIPHERAL DEFOCUS SIGNAL FOR OCULAR ELONGATION



Changing hyperopic defocus to myopic defocus

Fig 3. Current status on the dev & tx of myopia; Cooper, et al

MYOPIA

- *HOW DO WE TREAT MYOPIC PROGRESSION*
 - *REDUCING THE LAG OF ACCOMMODATION*
 - *REDUCING BOTH CENTRAL AND PERIPHERAL DEFOCUS*
 - *BLOCKING MYOPIAGENIC SIGNALING IN THE EYE*
- *WHEN INITIATE MYOPIA MANAGEMENT?*
 - *INITIATE TREATMENT WHEN MYOPIA IS FIRST DIAGNOSED WITH*
CYCLOPLEGIC SPHERICAL EQUIVALENT REFRACTION OF -0.50D

EFFICACY IN MYOPIA CONTROL

- ISSUES WITH EFFICACY: DISSIMILARITY IN ENDPOINTS, STUDY DURATION, DEMOGRAPHICS OF STUDY POPULATIONS AND REPORTING PROTOCOLS RENDER GENUINE COMPARISON BETWEEN TREATMENTS DIFFICULT
- HIGH MYOPES: CAUTION SHOULD BE EXERCISED WHEN APPLYING MYOPIA CONTROL RESEARCH TO THOSE WITH LONGER AXIAL LENGTH – AS THIS POPULATION HAS NOT BEEN STUDIED.

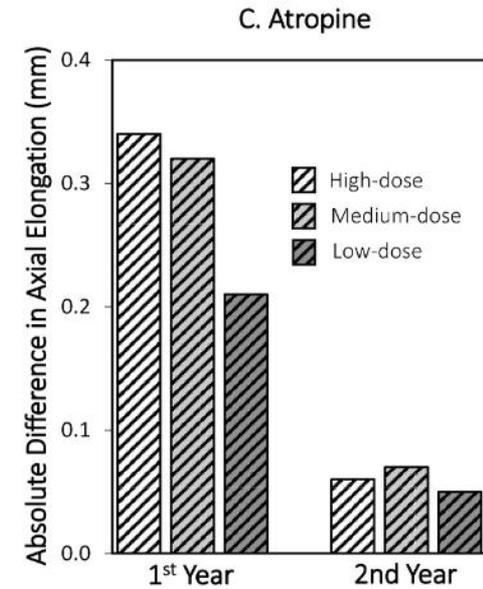
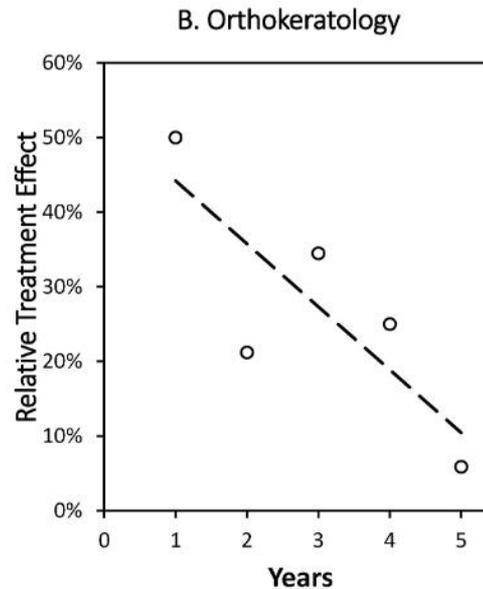
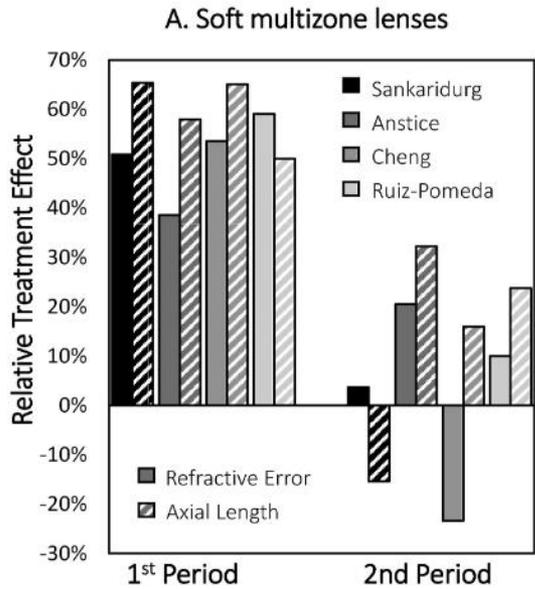
EFFICACY IN MYOPIA CONTROL

- REQUIRE 0.11 MM (0.25D) REDUCTION IN AXIAL ELONGATION ELONGATION TO BE INCLUDED IN REVIEW.
 - STUDIES OF SMCLS MOST OFTEN CONFORM TO BEST SCIENTIFIC PRACTICE IN TERMS OF STUDY DESIGN
 - FEW ORTHOKERATOLOGY STUDIES EMPLOYED RANDOMIZATION DESPITE THE CONSIDERABLE NUMBER OF PUBLICATIONS ON THIS TOPIC
 - RELATIVELY FEW STUDIES OF SPECTACLES AND PHARMACEUTICALS MET INCLUSION CRITERIA TO DETERMINE EFFICACY.

EFFICACY IN MYOPIA CONTROL

N.A. Brennan et al.

Progress in Retinal and Eye Research xxx (xxxx) xxx



Reduction in treatment effect over time with all treatment methods

EFFICACY IN MYOPIA CONTROL

- TAKE HOME POINTS:

- AXIAL LENGTH IS THE PREFERRED METHOD FOR TRACKING MYOPIA PROGRESSION
- INSUFFICIENT EVIDENCE THAT FASTER PROGRESSION OR YOUNGER MYOPES EXPERIENCE GREATER TREATMENT EFFICACY
- THERE IS A REDUCTION IN TREATMENT EFFECT OVER TIME WITH ALL TREATMENT METHODS
- NO SINGLE METHOD OF TREATMENT SHOWS CLEAR SUPERIORITY

EFFICACY IN MYOPIA CONTROL

- TAKE HOME POINTS:
 - DESPITE ALL THE CONCERNS ABOUT EFFICACY
 - MYOPIA CONTROL TREATMENT SHOULD BE CONSIDERED FOR ALL YOUNG MYOPES
- CONSIDERING THE MODEST EFFECT SIZE EXPECTED FOR CURRENT TREATMENTS – PRACTITIONERS SHOULD BE BOLD IN IMPLEMENTING MYOPIA CONTROL THERAPY
 - USE THE MOST POWERFUL TREATMENTS, COMBINATION TREATMENT, BEHAVIORAL MODIFICATIONS, BEGIN AT AN EARLY AGE, AND CONTINUE FOR SEVERAL YEARS, WHILE ENCOURAGING COMPLIANCE.

THE STUDIED OPTIONS FOR CONTROL OF MYOPIC PROGRESSION

- UNDERCORRECTION
- SOFT SPHERICAL
- GP'S
- BIFOCAL/PAL
- SPECTACLES
- ORTHOKERATOLOGY
- SOFT CL BIFOCAL
- ATROPINE



UNDERCORRECTION

- DON'T DO IT!
- 2 STUDIES:
 - AN INCREASE IN THE PROGRESSION OF MYOPIA
 - NO CHANGE AS COMPARED TO FULLY CORRECTED CONTROLS
- ASSOCIATED WITH FASTER PROGRESSION OF MYOPIA

CLINICAL AND EXPERIMENTAL
OPTOMETRY

ORIGINAL PAPER

The possible effect of undercorrection on myopic progression in children

Clin Exp Optom 2006; 89: 5: 315–321

DOI:10.1111/j.1444-0938.2006.00055.x

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E-mail: millodot@btinternet.com

Background: Undercorrection has recently been found to enhance the rate of progression of myopia. This result was thought to be controversial as it contrasted with expectations based on animal studies, as well as the results found wearing progressive addition lenses. The aim of the present study was to again determine the effect of undercorrection on the progression of myopia in a random population of children who are known to be very susceptible to myopia.

Methods: A cohort of 48 myopic children, aged six to 15 years was randomly assigned to either a fully corrected group (n = 23) or to an undercorrected group (n = 25). The subjects in the latter group were blurred by +0.50 D. The prospective study extended over a period of 18 months. Optometric examinations were carried out at the beginning of the study, then at six-month, 12-month and 18-month follow-up.

Results: Undercorrection produced a slight but not statistically significant increase in myopic progression over the 18-month period equal to 0.17 D, compared to full correc-

N=48; 23 fully corrected; 23 under corrected by +0.50D

GP CONTACT LENSES

- CONTACT LENS AND MYOPIA PROGRESSION (CLAMP) STUDY
 - REFRACTIVE CHANGES MOST LIKELY DUE TO CORNEAL FLATTENING (TEMPORARY) FROM GP LENS WEAR; DID NOT REPRESENT A TRUE SLOWING OF MYOPIA
- GP WEAR VS SPECTACLE WEAR
 - NO SIGNIFICANT DIFFERENCE IN REFRACTIVE ERROR
- GP'S DO NOT REDUCE THE PROGRESSION OF MYOPIA

META-ANALYSIS: SPECTACLES, SCL, ORTHOKERATOLOGY

- TREATMENT EFFECTS ARE THE LARGEST DURING THE FIRST 12 MONTHS OF TREATMENT
 - SHORTENING OF AL; TRANSIENT CHOROIDAL THICKENING
 - PROGRESSION SLOWING WITH AGE
- BASELINE REFRACTION MAGNITUDE HAS A TREATMENT EFFECT WITH PERIPHERAL BLUR SPECTACLE ONLY
 - HIGHER BASELINE, GREATER TREATMENT EFFECT FOR MYOPIA CONTROL

BIFOCAL/MULTIFOCAL SPECTACLES

- RATIONALE:
 - *IF ACCOMMODATION CAUSED AN INCREASE IN MYOPIA, THE BIFOCALS/MULTIFOCALS WOULD REDUCE THE ACCOMMODATIVE RESPONSE AND SLOW MYOPIA PROGRESSION*
 - *MYOPIC CHILDREN DO NOT ACCOMMODATE AS WELL AS EMMETROPIC CHILDREN.*

BIFOCAL/MULTIFOCAL SPECTACLES

Researcher	Methods/Finding	Esophoric
Goss	+0.75D to +1.25D BF add SV specs No statistically sig diff	0.32D/year vs 0.54D year
Grosvenor	+1.00, +2.00 BF SV specs No statistically sig diff	Goss re-analyzed 0.20D/ year less progression vs SV
Fulk	+1.50 BF All esophoric children	20% reduction in progression for eso BF vs SV
COMET	+2.00D PAL SV specs Sig at 3 year, not at 5 years	

MYOPIA MANAGEMENT - OPTICAL BIFOCAL/MULTIFOCAL SPECTACLES

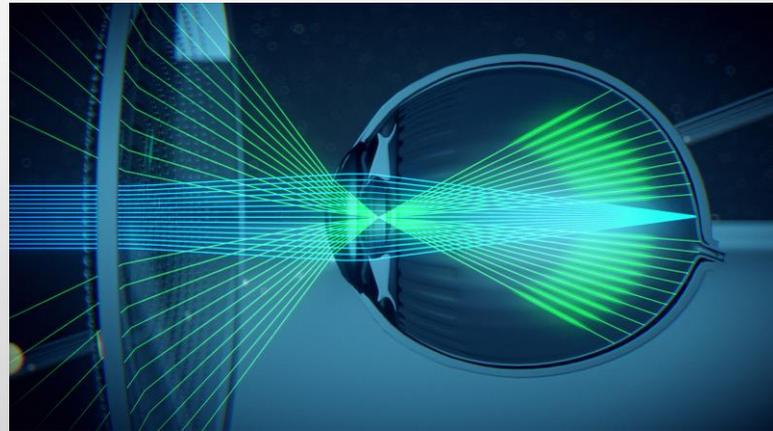
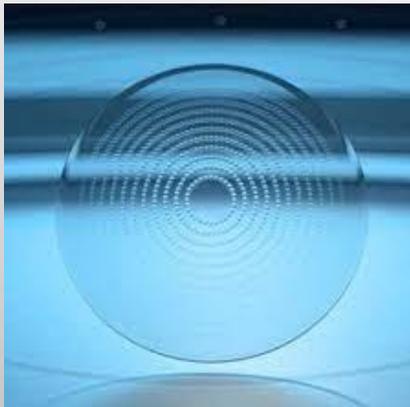
- *MAY BE EFFECTIVE FOR CHILDREN THAT ARE ESOPHORIC AT NEAR AND HAVE HIGH ACCOMMODATIVE LAGS.*
- MOST SIGNIFICANT RESULTS UTILIZE:
 - BASE-IN PRISM WITH +1.50D BF, EXECUTIVE DESIGN
- RESEARCH ONGOING FOR EXECUTIVE DESIGNS WITH BASE-IN PRISM
 - BI PRISM – DESIGNED TO BALANCE ACCOMMODATION AND VERGENCE SYSTEMS, NOT REDUCE THE RESPONSE OF EITHER

MYOPIA MANAGEMENT SPECTACLES

At 24 months, they reduced spherical equivalent refraction by 71% and eye elongation by 53%.

STELLEST WITH H.A.L.T. TECHNOLOGY

- HIGHLY ASPHERIC LENSLET TARGET (HALT) DESIGN
- 11 CONCENTRIC RINGS OF SMALL ASPHERIC LENSLETS; CLEAR CENTRAL ZONE OF 9 MM DIAMETER



MYOPIA MANAGEMENT - OPTICAL SPECTACLES

STELLEST WITH H.A.L.T. TECHNOLOGY

- HIGHLY ASPHERIC LENSLET TARGET (HALT) DESIGN
- SLOWED REFRACTION 57% (1.95D) AND AL BY 52% (0.81MM) COMPARED TO SV SPECTACLES – 6 YEAR FOLLOW-UP
- COMPRISING A CONSTELLATION OF 11 CONCENTRIC RINGS OF SMALL ASPHERIC LENSLETS RADIATING OUT PERIPHERALLY FROM A CLEAR CENTRAL ZONE OF 9 MM DIAMETER



STELLEST

Key Frame Requirements for Stellest Lenses

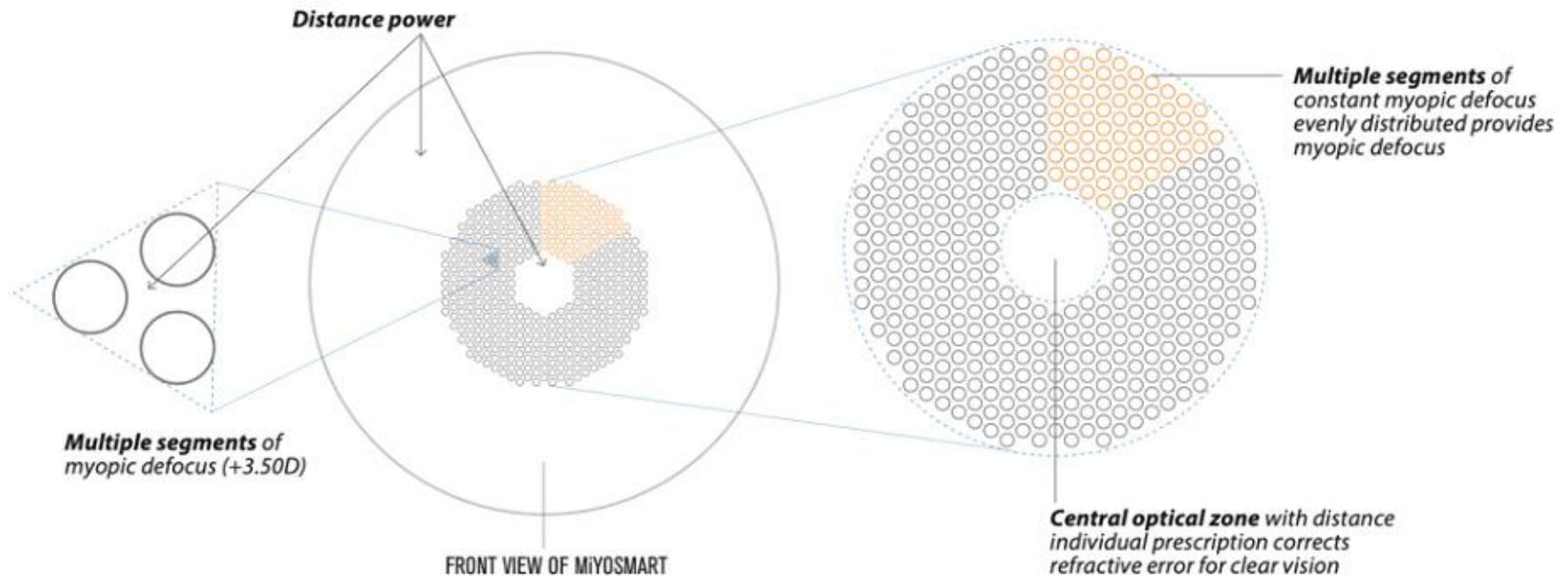
- **Secure Fit:** The frame must sit securely on the face to prevent slipping, as the clear zone of the lens needs to stay aligned with the center of the eye.
- **Adjustable Nose Pads:** Frames with adjustable nose pads are beneficial for achieving a secure fit and preventing the glasses from slipping.
- **Correct Temple Length:** The temple arms should be long enough to bend over the ear comfortably without being too long.
- **Pupil Placement:** The frame must be chosen and fitted so the pupil is centrally located within the clear central zone of the Stellest lens, with at least 12mm between the top of the frame and the pupil.

MYOPIA MANAGEMENT - OPTICAL SPECTACLES

MIYOSMART WITH D.I.M.S. (HOYA)

- DEFOCUS INCORPORATED MULTIPLE SEGMENTS
- SLOWED REFRACTION BY 52% AND AL BY 63% COMPARED TO SV SPECTACLES
- CLEAR CENTRAL ZONE THAT IS 9 MM IN DIAMETER
 - CORRECTS THE PATIENT'S REFRACTIVE ERROR
- MID-PERIPHERAL PORTION CONSISTS OF A HONEYCOMB-LIKE SECTION OF TINY OPTICAL SEGMENTS
 - APPROXIMATELY 1 MM DIAMETER
 - EACH OF +3.50D POWER

MYOPIA MANAGEMENT - OPTICAL SPECTACLES



MYOPIA MANAGEMENT - OPTICAL SPECTACLES

MIYOSMART WITH D.I.M.S.

3 YEAR FOLLOW-UP

TO DETERMINE MYOPIA PROGRESSION IN CHILDREN WHO CONTINUED TO WEAR THE DEFOCUS INCORPORATED MULTIPLE SEGMENTS (DIMS) LENSES OR SWITCHED FROM SINGLE VISION (SV) TO DIMS LENSES FOR A 1-YEAR PERIOD FOLLOWING A 2-YEAR MYOPIA CONTROL TRIAL.

CONCLUSIONS: MYOPIA CONTROL EFFECT WAS SUSTAINED IN THE THIRD YEAR IN CHILDREN WHO HAD USED THE DIMS SPECTACLES IN THE PREVIOUS 2 YEARS AND WAS ALSO SHOWN IN THE CHILDREN SWITCHING FROM SV TO DIMS LENSES.

MYOPIA MANAGEMENT - OPTICAL SPECTACLES

SIGHTGLASS WITH D.O.T. TECHNOLOGY

- DIFFUSION OPTICS TECHNOLOGY (DOT)
- INCORPORATES THOUSANDS OF MICROSCOPIC LIGHT-SCATTERING ELEMENTS POSITIONED THROUGH THE LENS, SPARING A SMALL CENTRAL CLEAR ZONE
- USES NON-VERGENCE OPTICS TO ACHIEVE A CONTRAST REDUCTION AT THE RETINA BETWEEN ADJACENT PHOTORECEPTORS,
- DEVIATES FROM THE PERIPHERAL RETINAL DEFOCUS HYPOTHESIS

MYOPIA MANAGEMENT - OPTICAL SPECTACLES

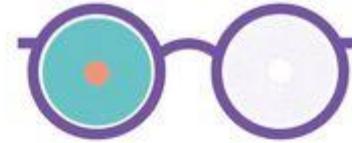
Received Breakthrough Device designation from The FDA

SIGHTGLASS WITH D.O.T. TECHNOLOGY

- “LIGHT DIFFUSION TECHNOLOGY”
 - REDUCE THE PERIPHERAL RETINAL CONTRAST BY AT LEAST ONE-THIRD TO HALF
- HYPOTHESIS:
 - THAT HIGH CONTRAST SIGNALS AT RETINAL PHOTORECEPTORS INDUCE THE EYE TO GROW AND LOW CONTRAST INDUCE THE EYE TO SLOW THE AXIAL GROWTH

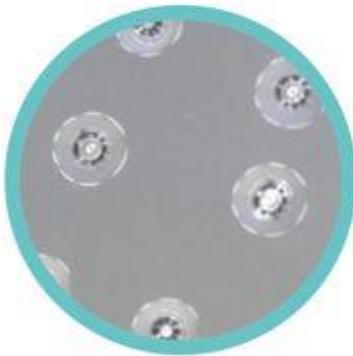
Aperture

Treatment zone



Clear aperture aligned with patient's pupil

5 mm



Thousands of micro-dots that softly scatter light to slightly reduce contrast on the retina^{7,8}



MYOPIA MANAGEMENT - OPTICAL SPECTACLES

- 18 MONTH DATA
- 57% HAD NO CLINICALLY MEANINGFUL MYOPIA PROGRESSION
- COMPARED TO 15% PROGRESSION IN THE CONTROL GROUP
- 0.34MM LESS AXIAL ELONGATION
- 0.70D LESS REFRACTIVE CHANGE

• VISUAL IMPACT:

Study	Study Design and Population	Control	On-axis Distance Visual Acuity	Off-axis Distance Visual Acuity	On-axis Contrast Sensitivity or Contrast Sensitivity Function	Off-axis Contrast Sensitivity or Contrast Sensitivity Function	Impact on Binocular Function	Impact on Subjective Performance
MiYOSMART (DIMS)								
Kaymak et al. (2022) [13]	Non-dispensing; Adult	SV^	No significant difference	3-6 letter reduction^^	No significant difference	0.02 logCS worse	-	-
Lam et al. (2020)[11]	Dispensing; Children	SV^	No significant difference	-	No significant difference	-	Stereo acuity worse by 5 sec. arc.	Initial awareness of mid-peripheral blur
Lu et al. (2020)[3]	Dispensing; Children and adults	SV^	No significant difference	2-3 letter reduction (children), 3-8 letter reduction (adults)*	-	-	-	Initial awareness of mid-peripheral blur (children & adults), Eyestrain, headaches, nausea, necessity to adjust frame (adults)
Stellest (HALT)								
Bao et al. (2021)[8]	Dispensing; Children	SV^	No significant difference	-	-	-	-	No significant impacts reported after 3 days of wear
Bao et al. (2022)[9]	Dispensing; Children	SV^	No significant difference	-	-	-	-	-
Li et al. (2021)[14]	Non-dispensing; Children	SV^	-	3-4 letters	-	Significant lower AULCSF** at high spatial frequencies	-	-
SightGlass (DOT)								
Rappon et al. (2022) [15]~	Dispensing; Children	SV^	No significant difference	-	-	-	-	-

^SV = single vision spectacles
 ^^In high and low illumination conditions
 *In high and low illumination and high and low contrast conditions
 ** AULCSF = the area under the log contrast sensitivity function
 ~ Interim data presented at ARVO 2022

SPECTACLES

- BENEFITS: LOW RISK OF COMPLICATIONS OR ADVERSE SIDE EFFECTS, EARLY STUDIES SHOW EFFICACY
- DISADVANTAGES: POOR LONG-TERM DATA



CONTACT LENSES AND ATROPINE

ORTHOKERATOLOGY - SOFT MULTIFOCAL CL - ATROPINE

- THE AVERAGE MYOPIA CONTROL TREATMENT EFFECT FOR INDIVIDUAL THERAPIES OVER A 2- TO 3- YEAR PERIOD 0.30MM REDUCTION IN ELONGATION (ABOUT 0.75D)
- RE-EVALUATION OF CURRENT TREATMENT MODALITY SHOULD BE CONSIDERED WITH
 - >0.50D INCREASE IN REFRACTION IN ONE YEAR OR LESS OR
 - .0.2MM INCREASE IN AXIAL LENGTH

CONTACT LENS OPTIONS

ORTHOKERATOLOGY - SOFT MULTIFOCAL CL

- RETROSPECTIVE ANALYSIS, PUBLISHED MAY 2023:
 - REAL-WORLD CLINIC DATA SHOWED NO DIFFERENCE IN AXIAL LENGTH ELONGATION BETWEEN ORTHOKERATOLOGY AND PERIPHERAL DEFOCUS CONTACT LENSES.
 - AXIAL LENGTH PROGRESSION IN THIS CLINICAL SETTING IS CONSISTENT WITH THAT REPORTED IN RANDOMIZED CLINICAL TRIALS



SOFT MULTIFOCAL CONTACT LENSES

SOFT BIFOCAL CONTACT LENSES

Anstice NS, Phillips JR. **Effect of dual-focus soft contact lens wear on axial myopia progression in children. Ophthalmol 2011**

Cooper J, O'Connor B, Aller T, Dillehay SM, Weibel K, Benoit D. [Reduction of Myopic Progression Using a Multifocal Soft Contact Lens: A Retrospective Cohort Study](#). Clin Ophthalmol. 2022 Jul 4;16:2145-2155. doi: 10.2147/OPHTH.S370041. PMID: 35814919; PMCID: PMC9270009.

Walline JJ, Greiner KL, et al. Multifocal Contact Lens Myopia Control. OVS 2013

Cooper J et al. **Case Series Analysis of Myopic Progression Control With a Unique Extended Depth of Focus Multifocal Contact Lens Eye Cont Lens 2018**

Sankaridurg P. et al. Decrease in rate of myopia progression with a contact lens designed to reduce relative peripheral hyperopia. Inv Oph vis sci 2011

Holden BA, Sankaridurg P et al. decreasing peripheral hyperopia with distance-center relatively-plus powered periphery contact lenses reduced the rate of progress of myopia: a 5 year vision crc study IOVS 2012

SOFT MULTIFOCAL CONTACT LENSES

- *IF HYPEROPIC DEFOCUS STIMULATED EYE GROWTH*
- *SOFT BIFOCAL CL THAT RESULT IN A MYOPIC SHIFT IN DEFOCUS:
POTENTIALLY SLOW MYOPIA PROGRESSION*
- *WHILE STILL PROVIDING CLEAR CENTRAL VISION*
 - **ALL CENTER-DISTANCE DESIGNS**
 - **CONCENTRIC RINGS AND PROGRESSIVE POWER DESIGNS**

SOFT MULTIFOCAL CONTACT LENSES

SOFT MULTIFOCAL LENS ARE AN **OFF-LABEL** APPLICATION FOR SLOWING THE PROGRESSION OF MYOPIA, EXCEPT MISIGHT

FDA NEWS RELEASE

FDA approves first contact lens indicated to slow the progression of nearsightedness in children

[f Share](#) [t Tweet](#) [in LinkedIn](#) [✉ Email](#) [🖨 Print](#)

For Immediate Release: November 15, 2019

The U.S. Food and Drug Administration today approved the first contact lens indicated to slow the progression of myopia (nearsightedness) in children between the ages of 8 and 12 years old at the initiation of treatment. The MiSight contact lens is a single use, disposable,

November 15, 2019

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-contact-lens-indicated-slow-progression-nearsightedness-children>

UMSL | Optometry
University of Missouri—St. Louis

SAFETY CONCERNS

Healthy Soft Contact Lens Habits

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Congratulations on your new soft contact lenses!

To ensure continued success with your soft lenses, review these healthy lens habits.

1. Wash your hands thoroughly with soap, rinse and dry them before handling your lenses.^{1,2} 
2.  Do not use tap water to clean or handle your lenses or to clean the case.³⁻⁷
3. Your solution has been chosen specifically for your type of lens. Do not change without discussing this with your eye doctor.⁸⁻¹¹
Your chosen solution is _____.
4. To maintain comfortable lens wear, rub your lenses with the prescribed solution to remove protein, oil and make-up.^{12,13} 
5. Store brand solutions are often old formulations of solutions and may not be compatible with your type of lens.¹⁴⁻¹⁷
6. Always recap your solution bottle.^{1,18} 
7.  Do you want to nap or sleep with your lenses? Ask your doctor if your lenses are designed for that.^{19,20}
8. Never share your contact lenses with anyone.²¹⁻²³
9. Before using any type of eye drop (medication or artificial tear), ask your doctor if the lenses need to be removed.²⁴⁻²⁶ 
10. Clean the case with your prescribed solution and let air dry completely, uncapped and upside down, on a paper towel. It is recommended to replace your case at least every 3 months.^{2,27-30} 
11. Empty completely the solution in the lens case every day. Never add more solution if there is solution already there.^{12,28,31} 
12. Healthy lens wear should not induce redness, discomfort or visual disturbance. If you have any concerns, consult your eye care professional.
13. Your eye doctor has selected a wearing and replacement schedule for you. These are important to be followed.^{32,33}

Your next contact lens checkup is:

Your contact lenses must be replaced every:

- day 2 weeks month

Association of Optometric Contact Lens Educators
www.aocle.org



Warning: Use this form at your own risk. The AOCL, its officers, and members are not responsible for any loss, injury, or damage resulting from using this form.

es in Children

This review collates data from a range of events and microbial keratitis, in patients

. A broad range of studies are summarized ns, hospital-based case series, long- and

19-year-olds include safety outcomes. In soft contact lens wear in patients 8 to 14 ata from a large retrospective study show (based on 411 patient years of wear) and). None of the prospective studies report

orneal infiltrative events
the youngest age range

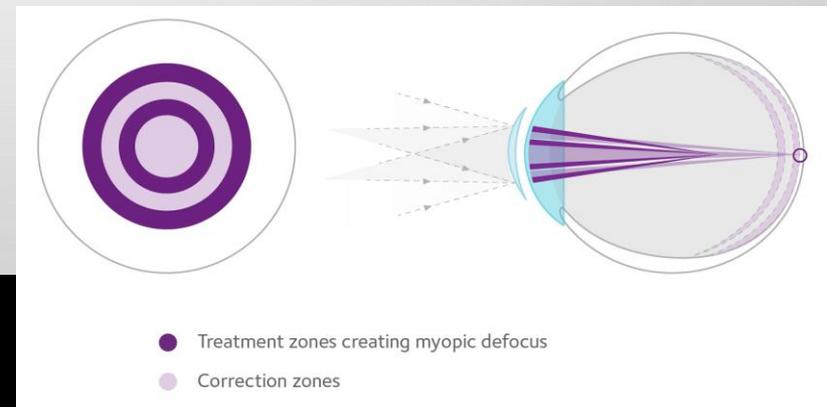
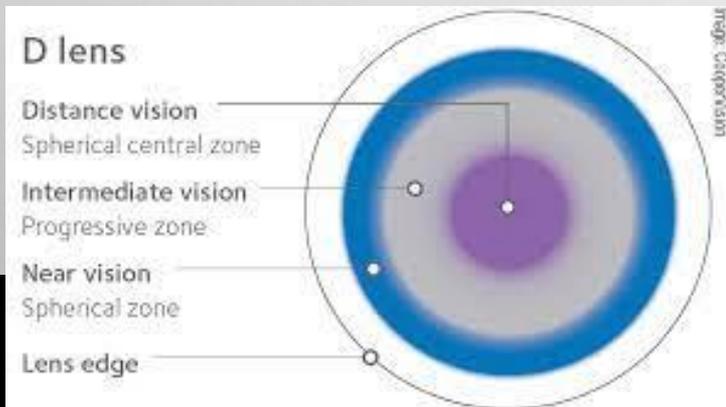
SOFT MULTIFOCAL CONTACT LENSES

LENS DESIGN

MULTIFOCAL LENS THAT IS A

CENTER DISTANCE DESIGN

HIGHEST ADD POWER ACCEPTABLE TO THE CHILD WITHOUT
COMPROMISING DISTANCE VISION



SOFT MULTIFOCAL CONTACT LENSES

Replacement Schedule	Company	Brand	Distance Powers	Add power options
Monthly	Coopervision	*Biofinity Multifocal "D" <i>*also available in MF toric design</i>	+6.00 to -10.00	+1.00, +1.50, +2.00, +2.50
Daily Disposable	Visioneering Technologies, Inc	NaturalVue (daily disposable)	-0.25 to -12.25D in 0.25D steps	1 Universal ADD power, effective up to +3.00D
	CooperVision	MiSight <i>FDA approved design</i>	-0.25D to -10.00D	1 ADD power (+2.00D)
Quarterly	Special Eyes	54 Bifocal and Multifocal	PI +/- 25.00	Up to +4.00

The above designs are center Distance soft multifocal contact lenses with moderate to high add powers, commercially available in the US.

MISIGHT 7 YEAR RESULTS

Year 7: all participants were transitioned from MiSight to Proclear spherical 1 day lens

- **DO WE HAVE ANY SIGNS OF REBOUND?**
 - THERE IS NO EVIDENCE OF LOSS IN TREATMENT.
- **DO THE EYES GO BACK TO THEIR AGE-NORMAL EYE GROWTH?**
 - YES. THE EYES DO GO BACK TO AGE-NORMAL EYE GROWTH.
- **CAN WE STILL HAVE MYOPIA CONTROL EFFECT EVEN WHEN MISIGHT IS NOT BEING WORN?**
 - THERE WAS A SLIGHT INCREASE IN AXIAL LENGTH GROWTH AFTER STOPPING MISIGHT
 - WHEN YOU STOP WEARING MISIGHT, YOU DO NOT GET ANY MORE MYOPIA CONTROL EFFECT.
- **DOES THE LENGTH OF PRIOR TREATMENT AFFECT THE POST-TREATMENT EFFECT?**
 - THE LENGTH OF PRIOR TREATMENT HAS NOT AFFECTED THE POST-TREATMENT MYOPIA CONTROL EFFECT.
- **TWO IMPORTANT POINTS:**
 - ONE IS THAT OLDER KIDS WILL BENEFIT FROM MISIGHT
 - TWO IS THAT IT'S NEVER TOO LATE TO START MYOPIA MANAGEMENT ON THE RIGHT CANDIDATES.

MISIGHT –AFTER DISCONTINUATION

- THE STUDY FOLLOWED SUBJECTS WHO HAD COMPLETED THE SIX-YEAR MISIGHT 1 DAY CLINICAL TRIAL —
 - BOTH THE COHORT WHO WORE MISIGHT 1 DAY FOR ALL SIX YEARS AND THE COHORT THAT SWITCHED FROM THE SINGLE VISION TO THE MISIGHT 1 DAY LENS FOR THE FINAL THREE YEARS — FOR AN ADDITIONAL YEAR FOLLOWING TREATMENT CESSATION.¹
- THE RESULTS: NO REBOUND EFFECT WITH MISIGHT 1 DAY CONTACT LENSES.
- AFTER TREATMENT CESSATION, EYE GROWTH RETURNED TO AGE-EXPECTED LEVELS AND
- THE ACCUMULATED MYOPIA CONTROL TREATMENT GAINS WERE RETAINED OVER THE 12 MONTHS AFTER TREATMENT CEASED.

SOFT MULTIFOCAL CONTACT LENSES

- CLINICAL FITTING PROTOCOL
 - INITIAL LENS SELECTION BASED ON CYCLOPLEGIC SPHERICAL EQUIVALENT REFRACTIVE ERROR
 - CENTER DISTANCE DESIGN
 - HIGHEST ADD POWER ACCEPTABLE TO THE CHILD WITHOUT COMPROMISING DISTANCE VISION
 - +2.00D OR GREATER

- *EXAMPLE: MR -2.00 SPH*

INITIAL LENS SELECTION: -2.00/+2.50 ADD "D" LENS OR MISIGHT -2.00

SOFT MULTIFOCAL CONTACT LENSES

- BLINK RANDOMIZED CLINICAL TRIAL
 - *DOES A HIGH ADD POWER SMF (+2.50D) SLOW MYOPIA PROGRESSION MORE THAN MEDIUM (+1.50D) ADD POWER LENSES*
 - 292 PARTICIPANTS; MEAN AGE 10.3 YEARS
 - 3 YEAR MYOPIC PROGRESSION:

• +2.50D ADD	-0.60D	0.42MM
• +1.50D ADD	-0.89D	0.58MM
• SINGLE VISION	-1.05D	0.66MM
 - *TREATMENT WITH HIGH ADD POWER MF SIGNIFICANTLY REDUCED THE RATE OF MYOPIA PROGRESSION OVER 3 YEARS OVER MEDIUM ADD POWER AND SINGLE VISION.*

Walline J, Walker M, Mutti D, et al. Effect of High Add Power, Medium Add Power, or Single Vision Contact Lenses on Myopia Progression in Children.

SOFT MULTIFOCAL CONTACT LENSES

- QUESTIONS YOU MIGHT HAVE:
 - *DO I REALLY NEED TO USE THAT HIGH OF AN ADD POWER?*
 - *WHAT IF THE CHILD CAN'T SEE WELL WITH THAT HIGH OF AN ADD POWER?*
 - *WHAT IF I GET A DISTANCE OVER-REFRACTION FOR BEST VISION, WON'T OVER-MINUSING THE KID CAUSE INCREASED PROGRESSION?*

SOFT MULTIFOCAL CONTACT LENSES

- BLINK RANDOMIZED CLINICAL TRIAL
 - *DOES A HIGH ADD POWER SMF (+2.50D) SLOW MYOPIA PROGRESSION MORE THAN MEDIUM (+1.50D) ADD POWER LENSES*
 - 292 PARTICIPANTS; MEAN AGE 10.3 YEARS; 3 YEAR MYOPIC PROGRESSION
- *TREATMENT WITH HIGH ADD POWER MF SIGNIFICANTLY REDUCED THE RATE OF MYOPIA PROGRESSION OVER 3 YEARS OVER MEDIUM ADD POWER AND SINGLE VISION.*

Walline J, Walker M, Mutti D, et al. Effect of High Add Power, Medium Add Power, or Single Vision Contact Lenses on Myopia Progression in Children.

SOFT MULTIFOCAL CONTACT LENSES

- WHAT IF CHILD CAN NOT SEE WELL WITH +2.50 ADD?
 - INITIATE A BUILD-UP PERIOD
 - BEGIN WITH +1.50 OR +2.00 ADD
 - WEAR FOR 1 MONTH
 - CHANGE TO NEXT STEP UP
 - WEAR FOR 1 MONTH
 - INCORPORATE DISTANCE OVER-REFRACTION



SOFT MULTIFOCAL CONTACT LENSES

- BLINK STUDY GROUP
 - *TO DETERMINE THE SPHERICAL OVER-REFRACTION NECESSARY TO OBTAIN BCVA WHEN FITTING MYOPIC CHILDREN WITH CENTER DISTANCE MFCL.*
 - CHILDREN TYPICALLY REQUIRE -0.50D TO -0.75D SOR TO ACHIEVE BCVA
 - WITH +2.50 ADD IN MFCL

SOFT MULTIFOCAL CONTACT LENSES

- BLINK STUDY GROUP – QUALITY OF LIFE
 - USED THE PEDIATRIC REFRACTIVE ERROR PROFILE 2 (PREP2) SUBSCALE
 - KEYS POINTS WITH **+2.50D ADD**
 - MAY HAVE A TRIVIAL NEGATIVE EFFECT ON THE VISION- RELATED QUALITY OF LIFE
 - MAY REPORT SLIGHTLY LOWER QUALITY OF VISION, THEY DID NOT EXPERIENCE A SIGNIFICANT DIFFERENCE IN SYMPTOMS, ACTIVITIES OR OVERALL QUALITY OF LIFE.
 - THE PEDIATRIC REFRACTIVE ERROR PROFILE 2 PROVIDES A VALID ASSESSMENT OF SUBJECTIVE ISSUES RELATED TO SOFT MULTIFOCAL CONTACT LENS MYOPIA CONTROL.

SOFT MULTIFOCAL CONTACT LENSES

- CLINICAL FITTING PROTOCOL
 - CYCLOPLEGIC SPHERICAL EQUIVALENT REFRACTIVE ERROR
 - HIGHEST ADD POWER ACCEPTABLE TO THE CHILD WITHOUT COMPROMISING DISTANCE VISION
 - ADJUST DISTANCE POWER WITH OVER-REFRACTION FOR IMPROVED DISTANCE VISUAL ACUITY.
 - WEAR TIME FOR ADEQUATE MYOPIA MANAGEMENT IS EIGHT OR MORE HOURS EACH DAY



SOFT MULTIFOCAL CONTACT LENSES

- CLINICAL FITTING PROTOCOL
 - CONSIDERING THAT MISIGHT IS A +2.00 ADD AND HAS EVIDENCE OF MYOPIA CONTROL
 - BLINK STUDY DETERMINED THAT +2.50 ADD IS BEST, COMPARED TO LOWER ADD POWERS
- *PRACTITIONERS SHOULD FEEL COMFORTABLE WITH A CHILD WEARING EITHER A +2.00 OR HIGHER ADD FOR MYOPIA CONTROL, BUT NOT A LOWER ADD POWER.*

SOFT MULTIFOCAL CL

- CLINICAL APPOINTMENT SCHEDULE:
 - 1 WEEK, 1 MONTH, 6 MONTHS
- FOLLOW-UP CLINICAL PROTOCOL
 - A SCAN
 - LENS FIT EVALUATION/SLE
 - VAS, OR AND MANIFEST REFRACTION



SOFT MULTIFOCAL CL



BLINK 2 STUDY: AXIAL GROWTH AND MYOPIA PROGRESSION AFTER DISCONTINUING SOFT MULTIFOCAL CL WEAR

Question Does axial eye growth increase after discontinuing soft multifocal contact lenses for myopia control?

Findings In this cohort study, children with myopia randomly assigned to wear either single-vision or multifocal soft contact lenses for 3 years in the BLINK Study all wore high-add multifocal contact lenses for the next 2 years and on average had no difference in rate of eye elongation. When children then switched to single-vision contact lenses for 1 year, axial elongation increased to age-normal growth.

Meaning Faster but age-expected eye growth with no loss of the accumulated treatment effect was noted after discontinuing soft multifocal contact lens wear.

SOFT MULTIFOCAL CL

- 11 YEAR OLD FEMALE
- OD: -1.00 OS: -0.75
 - FIT INTO BIOFINITY MF “D” LENSES
 - OD: -1.00/+2.00D 20/25- OS: -0.75/+2.00D 20/25-
 - OR: -0.25 OD, OS
- -1.25 / +2.00D -1.00/+2.00D X 1 MONTH
- -1.25 / +2.50D -1.00 / +2.50D FINALIZED

SOFT MULTIFOCAL CL

- 1 YEAR FOLLOW-UP
- 12 YEAR OLD FEMALE
- OD: -1.00 OS: -0.75 -0.50 X 175
BIOFINITY MF CENTER D – CONTINUE WITH SAME:
- -1.25 / +2.50D -1.00 / +2.50D FINALIZED
- WORE GLASSES X 1 YEAR
- NOW 17 YEAR OLD, WEARING ORTHO-K FOR 4 YEARS
 - **OD: -1.75 AND OS: -1.50**

SOFT MULTIFOCAL CL

- CLINICAL CONSIDERATIONS
 - CHECK REFRACTION EVERY 6 MONTHS AND AXIAL LENGTH ELONGATION
 - IF CHILD HAS PROGRESSED **LESS THAN** 0.5D/YEAR
 - CONTINUE WITH SMF
 - IF CHILD HAS PROGRESSED **MORE THAN** 0.5D/YEAR
 - CONSIDER ADDING LOW DOSE ATROPINE TO SMF THERAPY

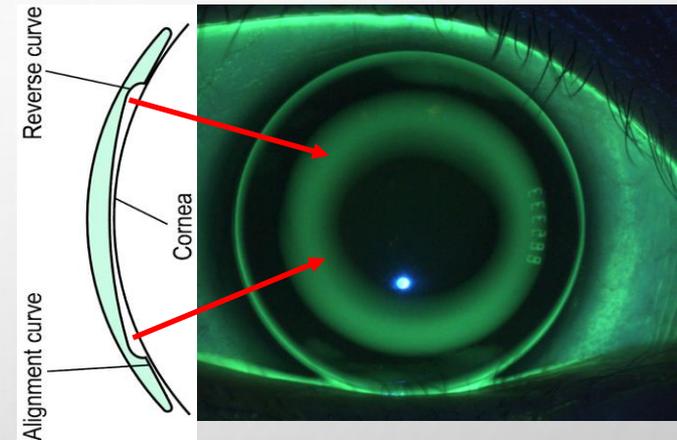


ORTHOKERATOLOGY

ORTHOKERATOLOGY (OK)

OrthoK is FDA approved for overnight wear and indicated for the correction of myopia and astigmatism in patients of all ages. There is currently no FDA approval for any OrthoK lens design in the U.S. for the indication of “slowing the progression of myopia.”

- REVERSE GEOMETRY GAS PERMEABLE LENS
- FLATTEN CENTRAL CORNEA TO CORRECT FOR MYOPIA
- MID-PERIPHERAL STEEPENING
 - CREATES LESS PERIPHERAL DEFOCUS VERSUS SINGLE PLANE CORRECTION
 - THEORETICALLY CORRECTS HYPEROPIC PERIPHERAL DEFOCUS



NUMEROUS STUDIES

- KANG P, SWARBRICK H. PERIPHERAL REFRACTION IN MYOPIC CHILDREN WEARING ORTHOKERATOLOGY AND GP LENSES. OVS 2011
- REIM TR, ET AL. ORTHOKERATOLOGY AND ADOLESCENT MYOPIA CONTROL. CL SPECTRUM 2003
- WALLINE JJ, RAH MJ, JONES LA. THE CHILDREN'S OVERNIGHT ORTHOKERATOLOGY INVESTIGATION PILOT STUDY. OVS 2004
- CHO P, CHEUNG SW, EDWARDS M. THE LONGITUDINAL ORTHOKERATOLOGY RESEARCH IN CHILDREN IN HONG KONG: A PILOT STUDY ON REFRACTIVE CHANGE AND MYOPIC CONTROL CURR EYE RES. 2005
- WALLINE JJ. CORNEAL RESHAPING AND YEARLY OBSERVATION OF NEARSIGHTEDNESS (CRAYON) STUDY 2007
- KAKITA T ET AL. INFLUENCE OF OVERNIGHT ORTHOKERATOLOGY ON AXIAL ELONGATION IN CHILDHOOD MYOPIA. CLIN AND EPI RES 2011
- SANTODOMINGO-RUBIDO J ET AL. MYOPIA CONTROL WITH ORTHOKERATOLOGY CONTACT LENSES IN SPAIN: REFRACTIVE AND BIOMETRIC CHANGES. INV OPH VIS SCI 2012
- KWOK-HEI MOK A, SIN-TING CHUNG C. SEVEN-YEAR RETROSPECTIVE ANALYSIS OF THE MYOPIC CONTROL EFFECT OF ORTHOKERATOLOGY IN CHILDREN: A PILOT STUDY. CLIN OPTOM 2011;3:1-4
- LONG-TERM EFFECT OF OVERNIGHT ORTHOKERATOLOGY ON AXIAL LENGTH ELONGATION IN CHILDHOOD MYOPIA: A 5-YEAR FOLLOW-UP STUDY.
- HIRAOKA T, KAKITA T, OKAMOTO F, TAKAHASHI H, OSHIKA T INVEST OPHTHALMOL VIS SCI. 2012 JUN 22; 53(7):3913-9
- CHO P, CHEUNG SW. RETARDATION OF MYOPIA IN ORTHOKERATOLOGY (ROMIO) STUDY: A 2-YEAR RANDOMIZED CLINICAL TRIAL

NUMEROUS STUDIES

- BIGGEST TAKE HOME POINTS
 - YOUNGER PROGRESS FASTER
 - GREATER AXIAL LENGTH ELONGATION WITH YOUNGER CHILDREN
 - EFFECT OF ORTHOKERATOLOGY ON MYOPIA MANAGEMENT DECREASE WITH TIME
 - SEE DIMINISHED RESULTS AROUND YEAR 3 IN TWO DIFFERENT STUDIES
 - EXPECTED TO SLOW MYOPIA PROGRESSION BY 30% TO 60%
 - AXIAL LENGTH BEST MEASUREMENT FOR MONITORING PROGRESSION
 - NEWER DESIGNS MODIFICATIONS FOR MYOPIA MANAGEMENT
 - SMALLER OPTIC ZONE SIZE
 - HYPERDK MATERIALS

ORTHOKERATOLOGY (OK)

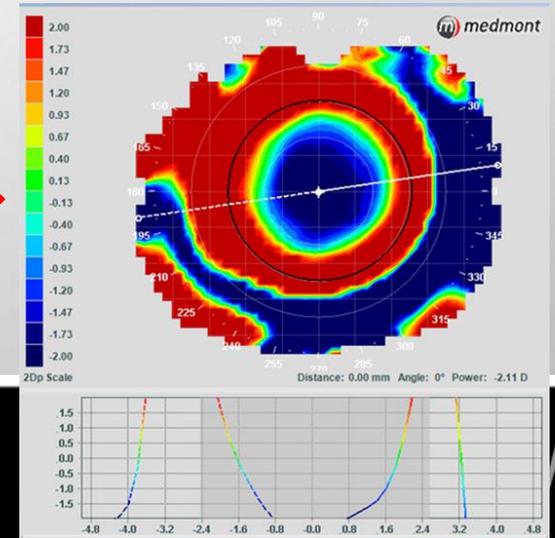
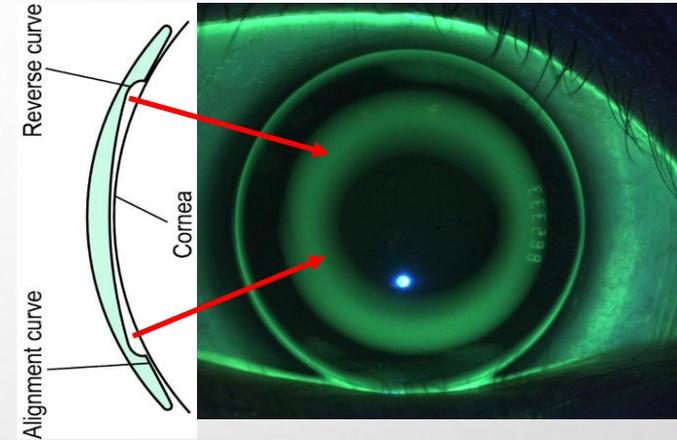
- HOW DOES IT WORK FOR MYOPIA MANAGEMENT:

- REVERSE GEOMETRY GAS PERMEABLE LENS

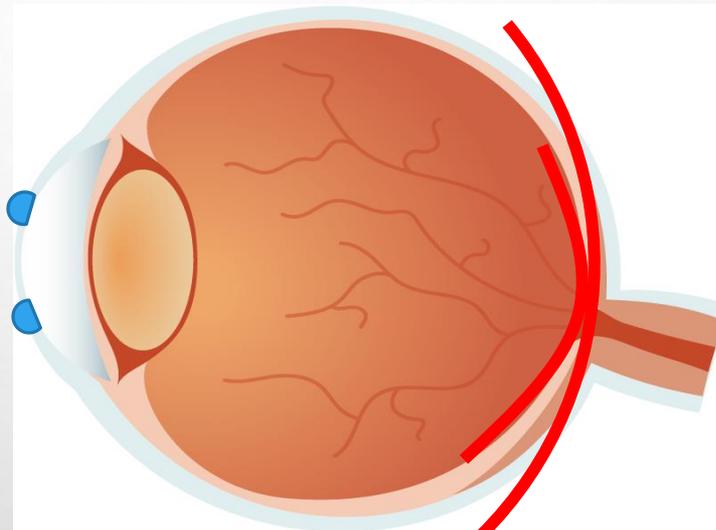
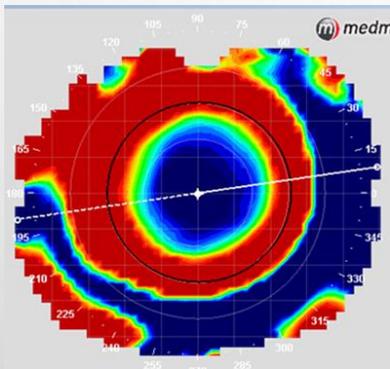
- FLATTEN CENTRAL CORNEA TO CORRECT FOR MYOPIA

- MID-PERIPHERAL STEEPENING

- THEORETICALLY CORRECTS HYPEROPIC PERIPHERAL DEFOCUS



HOW DOES ORTHOK WORK?



Changing hyperopic defocus to myopic defocus

PATIENT SELECTION

- FDA APPROVAL FOR CRT (CORNEAL REFRACTIVE THERAPY)
 - UP TO -6.00 D OF MYOPIA
 - UP TO -1.75 D OF ASTIGMATISM
 - NO AGE LIMITATIONS
- FDA APPROVAL FOR VST (VISION SHAPING TREATMENT)
 - -1.00 TO -5.00 D OF MYOPIA
 - UP TO -1.50 D OF ASTIGMATISM
 - NO AGE LIMITATIONS

My rules for patient selection:

More successful:

Up to -4.00D myopia
Up to -1.75 WTR astigmatism
Up to -1.00 ATR astigmatism

Less Successful:

Up to -6.00D myopia
Up to -1.75 astigmatism

ORTHOK - SAFETY CONCERNS?

REVIEW ARTICLE

OPEN

The Safety of Orthokeratology—A Systematic Review

Yue M. Liu, OD, Ph.D., MPH and Peiyang Xie, MD, Ph.D.

Objective: The aim of this review is to evaluate the ocular safety of orthokeratology (OrthoK) treatment of myopia correction and retardation.

Data Sources: Clinical studies published in English and Chinese were identified from MEDLINE, EMBASE, CNKI, CQVIP, and WANFANG DATA (all from 1980 to April 2015). The reference lists of the studies and the Science Citation Index were also searched.

Selection Criteria: Relevant clinical studies including case series, case reports, patient/practitioner surveys, retrospective and prospective cohort

centric curves surrounding a central base curve fitting in alignment with the central cornea, the modern reverse geometry designs for myopia correction are characterized by a central base curve, that is, fitted significantly flatter relative to the central corneal curvature and one or more surrounding steeper secondary or "reverse" curves that enable a smooth transitioning from the flat-fitting base curve to the alignment-fitting landing curve. The unique reverse geometry design significantly improves the

“There is sufficient evidence to suggest that OrthoK is a safe option for myopia correction and retardation. Long-term success of OrthoK treatment requires a combination of proper lens fitting, rigorous compliance to lens care regimen, good adherence to routine follow-ups, and timely treatment of complications.”

Liu and Xie, [Eye Contact Lens](#). 2016 Jan; 42(1): 35–42

Healthy Corneal Reshaping Gas Permeable Contact Lens Habits

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Congratulations on your new corneal reshaping GP contact lenses!
To ensure continued success with your reshaping contact lenses, review these healthy contact lens habits.

1. Wash your hands thoroughly with soap, rinse and dry them before handling your contact lenses.^{1,2}
2. Do not use tap water to clean, handle or store your contact lenses or to clean the contact lens case.^{3,8}
3. Your care regimen has been prescribed specifically for your contact lens type. Do not change your regimen without consulting your eye care provider.¹ Using improper contact lens care products may impact the quality of your contact lenses, your eye health or overall contact lens wearing experience.
Storage, disinfecting, cleaning solution(s): _____
Daily Cleaner (if recommended): _____
Additional Cleaner (if recommended): _____
Every _____ weeks
Rewetting drops: _____
4. Generic "store brand" solutions are often formulations of older solutions and may not be compatible with your type of contact lenses.
5. To maintain comfortable lens wear, rub and rinse your contact lenses in the palm of your hand with the prescribed solution to remove debris, as directed.^{9,11}
6. Always recap your solution bottle.^{2,12}
7. Proper care of your contact lens case
 - a. Completely empty the solution in the contact lens case every day.
 - b. Clean the contact lens case and any accessories with your prescribed solution.




- c. Completely wipe dry your contact lens case¹¹, leave the case uncapped and place your contact lens case upside down on a clean surface.¹¹
- d. Replace your contact lens case and accessories periodically as recommended by your doctor.^{14,15}

Replacement frequency for cases and accessories: _____
Cleaner for contact lens case: _____

8. Never add more solution to the left over solution in the case; no "topping off."^{10,13,16}
9. You should store a spare pair of contact lenses dry in a contact lens case until needed. Then prior to use, clean the contact lens(es) and soak in disinfecting solution per manufacturers recommendation prior to application.
10. Be sure that your contact lenses are freely moving on your eye before removing them. You can place a rewetting drop in each eye prior to contact lens removal.
11. Discontinue contact lens wear immediately if you experience redness, discomfort, or visual disturbance and call your eye care professional.
12. It is important to follow your doctor's instructions on the wear and care of your contact lens. As with any contact lens wear, there is an inherent risk for contact lens complications.^{10,21}
13. ALWAYS bring your contact lenses to every follow up visit.
14. Your follow up schedule is the following:

1-day 1-week 1-month 3-months 6-months

Association of Optometric Contact Lens Educators
www.aocle.org



Warning: Use this form at your own risk. The AOCL, its officers, and members are not responsible for any loss, injury, or damage resulting from using this form.

Orthokeratology for Myopia Management is OFF-label

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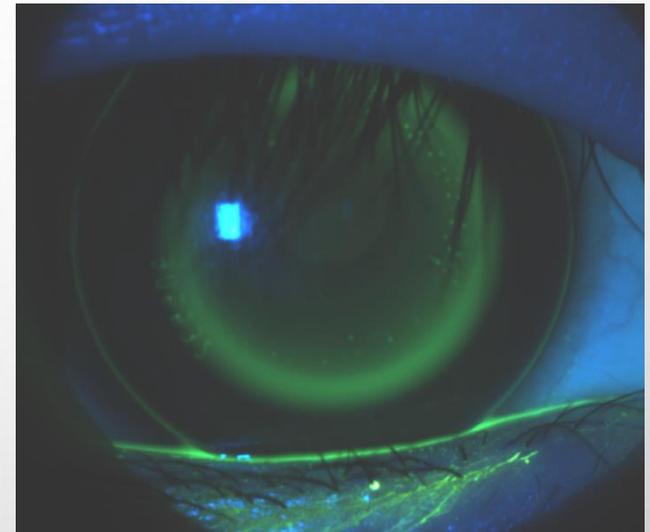
ORTHOKERATOLOGY

- TECHNOLOGY NEEDED:
 - A SCAN
 - BASELINE, EVERY 6 MONTHS
 - TOPOGRAPHER
 - BASELINE, EVERY FOLLOW-UP APPOINTMENT
 - MONITORS
 - LENS POSITIONING
 - PROGRESSION OF TREATMENT
 - DETERMINING THE PROBLEM SOLVING APPROACH



PATIENT SELECTION

- IN-OFFICE SCREENING:
 - MANIFEST REFRACTION
 - SLIT-LAMP EXAMINATION
 - MEASUREMENT OF CORNEAL HVID
 - PUPIL SIZE MEASUREMENT
 - BASELINE CORNEAL TOPOGRAPHY
 - BASELINE A SCAN
 - DISCUSSION OF PATIENT MOTIVATION AND EXPECTATIONS



FITTING OPTIONS

- DIAGNOSTIC SET

- LENS SELECTION FROM FLAT K(TOPOGRAPHY) AND REFRACTION
- MORE HANDS-ON FOR DOCTOR; HIGHER START UP COSTS
- EXAMPLE: PARAGON CRT

- TOPOGRAPHY DESIGNED

- HVID, TOPOGRAPHY, AND MANIFEST REFRACTION
- EXAMPLES: BE RETAINER, WAVE, EYESPACE, ARISE

- LABORATORY/FITTING SOFTWARE DESIGNED

- HVID, TOPOGRAPHY, AND MANIFEST REFRACTION
- EXAMPLES: EUCLID EMERALD, CONTEX, MOONLENS

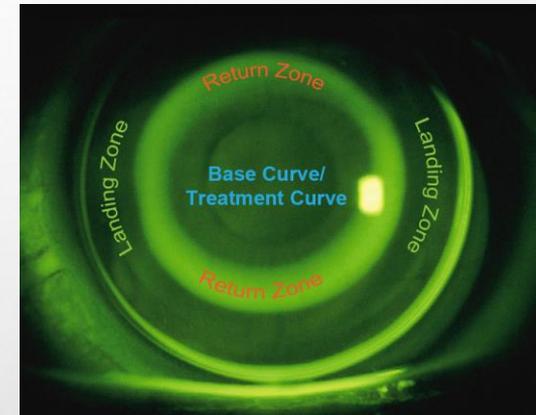


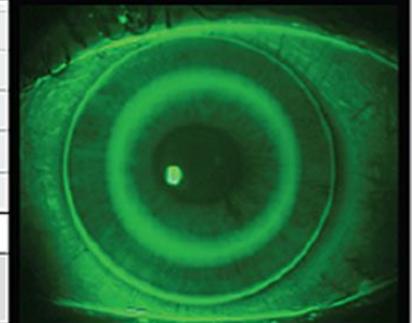
Image courtesy of paragon vision sciences

ORTHOKERATOLOGY

Myopia Control Design

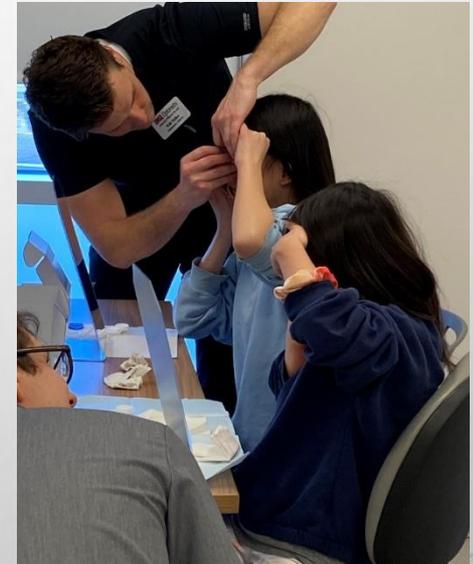


Adult Design

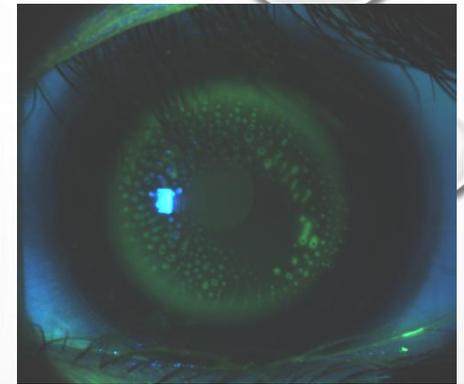


ORTHOKERATOLOGY

- IDEAL RX: **-2.00D UP TO -6.00D**
- LENS CARE: HYDROGEN PEROXIDE SOLUTION
- HELPFUL TO ORDER LENSES IN TWO DIFFERENT COLORS
 - RED – RIGHT EYE BLUE – LEFT EYE
 - GREEN – RIGHT EYE YELLOW – LEFT EYE
- FOLLOW UP SCHEDULE
 - 1 WEEK VS 1 DAY FOLLOW-UP APPOINTMENT
 - 2 WEEK FOLLOW-UP APPOINTMENT
 - 1 MONTH FOLLOW-UP APPOINTMENT
 - 6 MONTH FOLLOW-UP APPOINTMENT



ORTHOKERATOLOGY

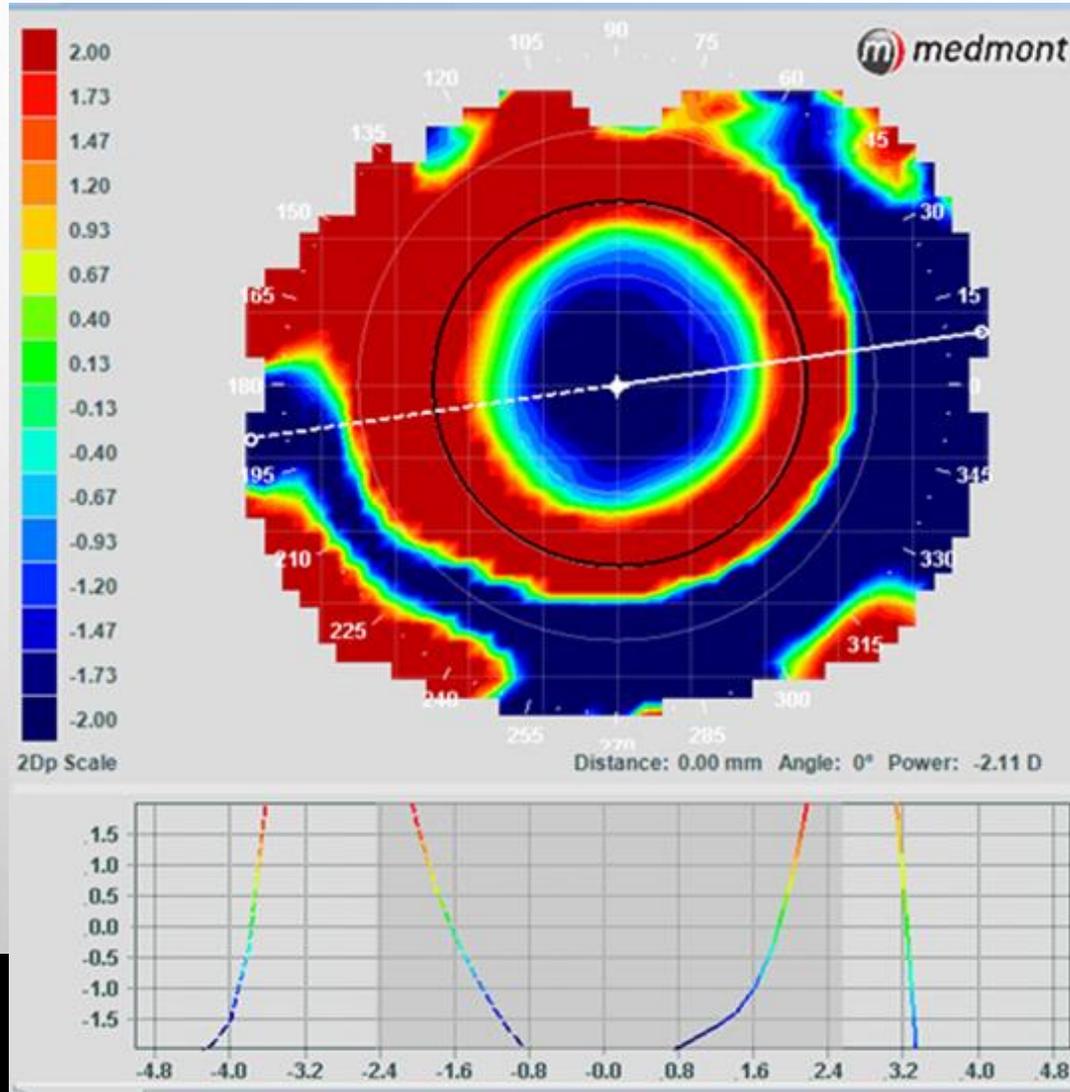


- ADJUSTMENT OF COMPRESSION OR JESSEN FACTOR
 - SEVERAL SHORT TERM STUDIES SHOW THE COMPRESSION FACTOR CAN BE INCREASED
 - DOES NOT AFFECT LENS FITTING OR OCULAR HEALTH
 - RESULTED IN MORE RAPID REFRACTIVE ERROR CORRECTION
 - NEW 2 YEAR STUDY
 - **MODERATE MYOPIA** (-3.00 TO -5.00D) WITH AN INCREASED (+1.75) COMPRESSION FACTOR HAD LESS AL ELONGATION VS STANDARD (+0.75) COMPRESSION FACTOR
 - **NO DIFFERENCE WITH LOW MYOPIA** (-1.00 TO -2.75D)

ORTHOKERATOLOGY - REFRACTION

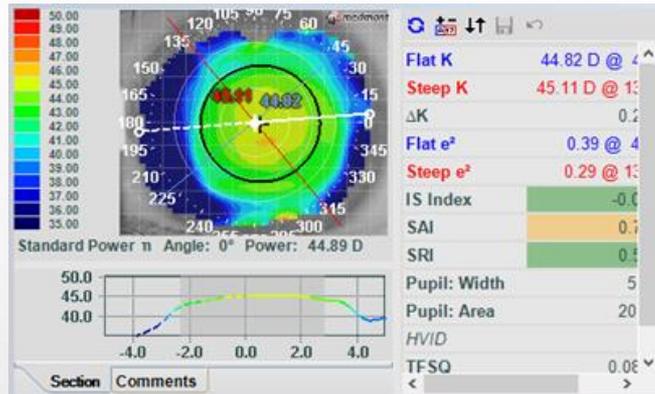
- REFRACTIVE ERROR AFTER LENS WEAR SHOULD BE CLOSE TO PLANO.
 - SCENARIOS TO CONSIDER:
 - 8AM REFRACTION LOW PLUS -- WONDERFUL, DO NOTHING
 - NOON REFRACTION PL TO -0.25 -- NO PROBLEM, DO NOTHING
 - 3PM REFRACTION -0.50 -- CAUTIOUSLY OPTIMISTIC
 - NOON REFRACTION -1.00 -- MODIFY LENS PARAMETERS TO IMPROVE VISUAL OUTCOME; WILL ALSO NEED AN OR WITH LENS ON THE EYE.
 - LENS OVER-REFRACTION
 - THE OR SHOULD BE LOW, MOST LIKELY +0.50
 - THE OR SHOULD MIMIC THE “POWER OF THE LENS”
 - THE LENS POWER WILL BE SLIGHTLY HYPEROPIC

ORTHOKERATOLOGY - TOPOGRAPHY

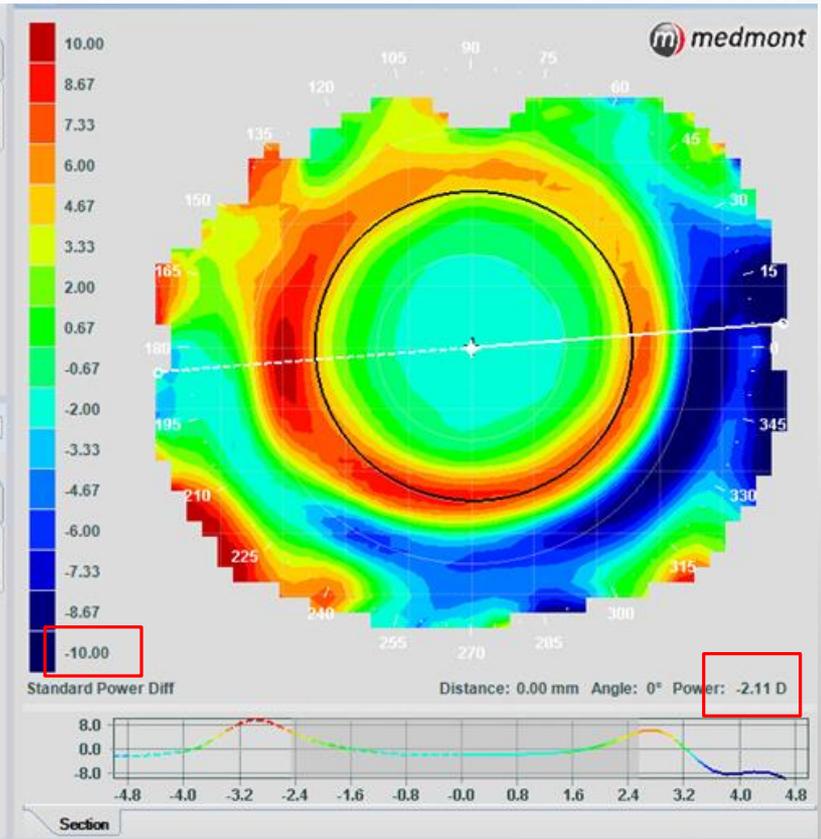
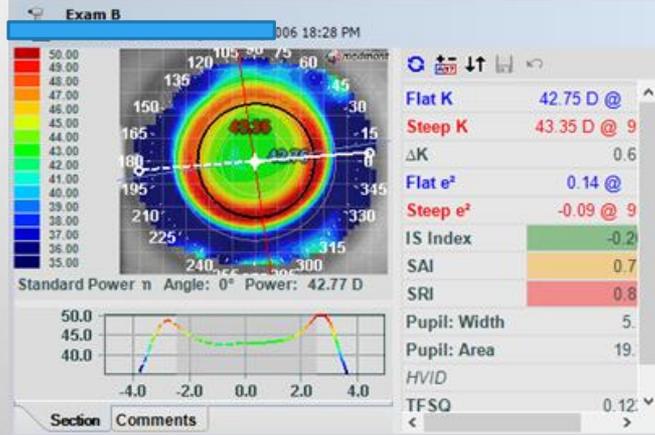


ORTHOKERATOLOGY - TOPOGRAPHY

Baseline

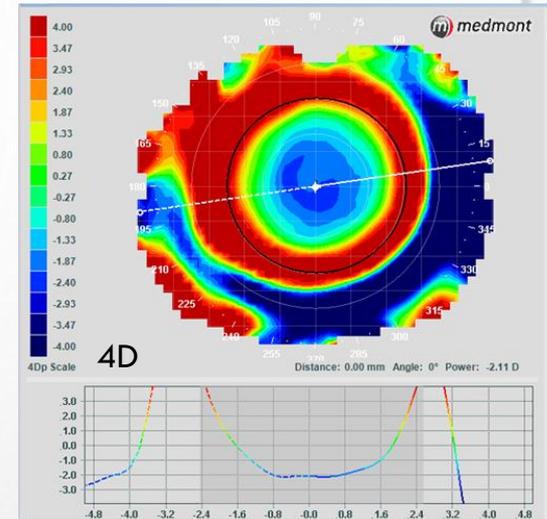
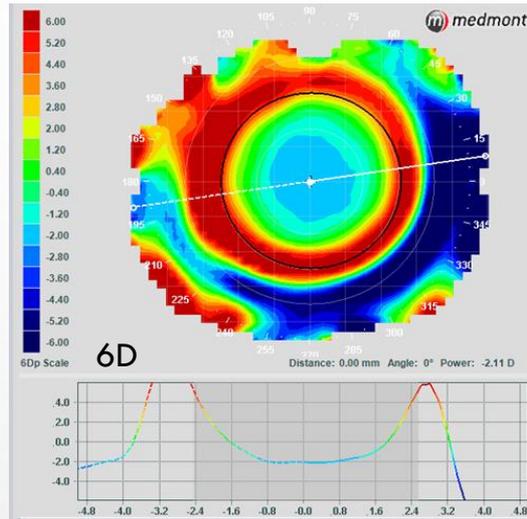
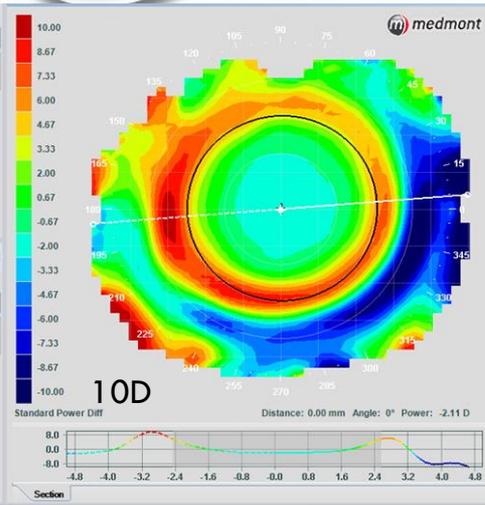


Post wear

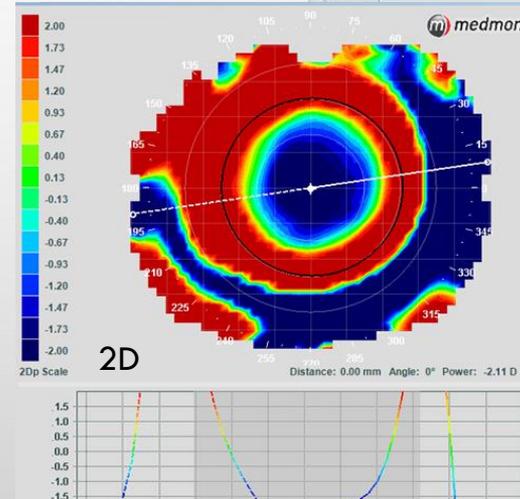
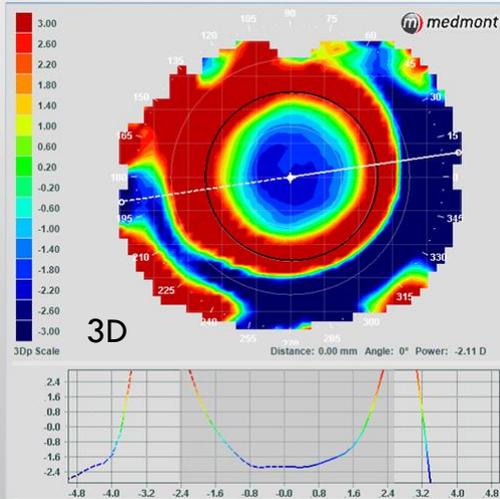


Subtractive or Difference Map; Tangential Power Map

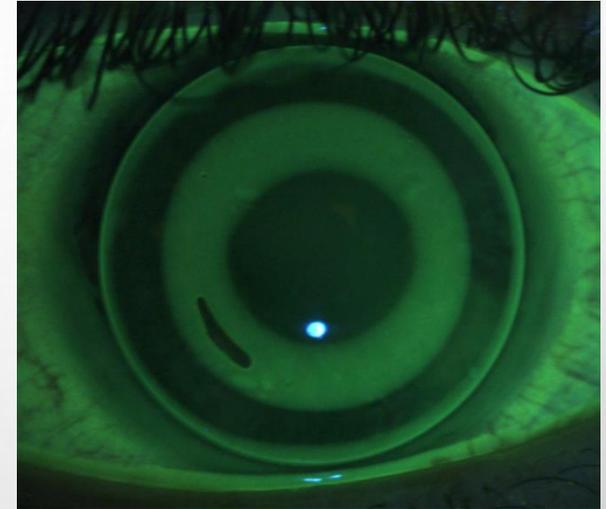
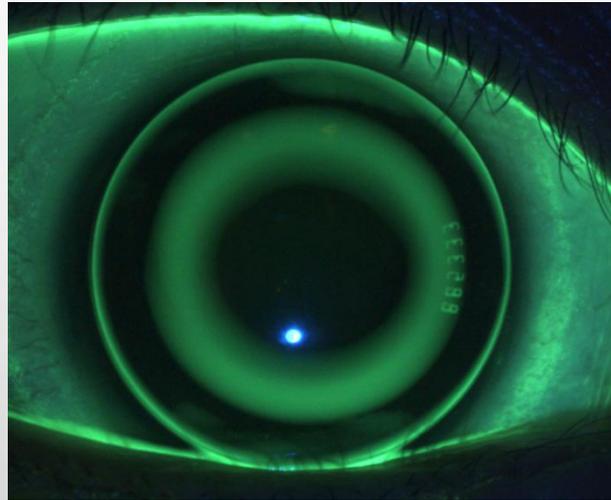
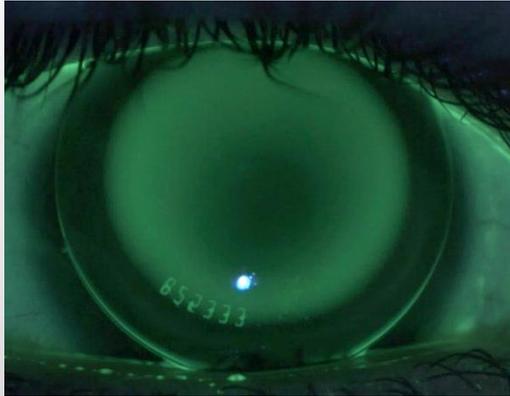
ORTHOKERATOLOGY - TOPOGRAPHY



Dioptric scale comparison on subtractive map



ORTHOKERATOLOGY – LENS EVALUATION



ORTHOKERATOLOGY – LENS EVALUATION



ORTHO K – SEASONAL IMPACT

- RETROSPECTIVE STUDY; 600 CHILDREN; AGED 7 TO 13 YEARS WEARING ORTHOK;
MINIMUM OF ONE YEAR.
 - FOLLOW-UP VISITS EVERY THREE MONTHS DURING ORTHOK TREATMENT
 - SPHERICAL EQUIVALENT OF THE SUBJECTS RANGED FROM -0.75 TO -5.00D, AND WITH
ASTIGMATISM <1.50D.
- PROGRESSION: **0.07 ± 0.09MM IN SUMMER AND 0.12 ± 0.09 MM IN WINTER**
- AGE IMPACT:
 - 7 TO 12 YEARS WERE FOUND TO HAVE SLOWER RATES OF AL ELONGATION IN THE SUMMER COMPARED TO
THE WINTER. NEVERTHELESS
 - STUDY FOUND LITTLE SEASONAL-BASED IMPACTS IN CHILDREN AGED 13 YEARS.

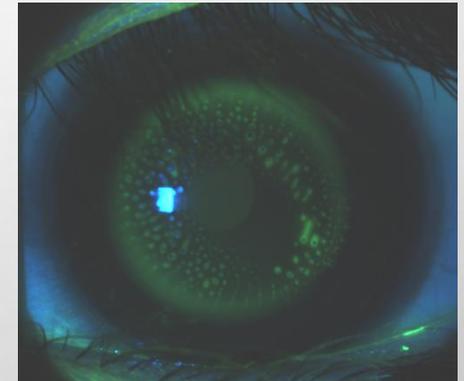
Seasonal Variation in Axial Elongation in Children with Orthokeratology Treatment

Wenzhi Ding, Chenpei Zhao, Xiaoxiao Li, Weicong Lu, Dongdong
Jiang, Yuyin Tian, Lin Leng

ORTHOKERATOLOGY – CLINICAL PROTOCOL

MONITORING FOR ONGOING SUCCESS

- IF AT 6 MONTH FOLLOW- UP OR 1 YEAR FOLLOW-UP
 - REFRACTION CHANGE $>0.50D$ OR
 - AXIAL LENGTH ELONGATION >0.2
 - PATIENT MYOPIA HAS LIKELY PROGRESSED.
 - CHANGE LENS PARAMETERS TO IMPROVE VISION



HYBRID MULTIFOCAL CL

- SYNERGEYES EXTENDED DEPTH OF FOCUS (EDOF)
MULTIFOCAL HYBRID LENS
 - CENTER DISTANCE DESIGN
 - NO RESEARCH, EXCEPT FOR EDOF SOFT LENS

PHARMACOLOGICAL INTERVENTIONS



ATROPINE MOA

- ACCOMMODATIVE MECHANISM OF ACTION?
 - NONSELECTIVE MUSCARINIC ANTAGONIST
 - COMPETES FOR BINDING SITES ON ALL MUSCARINIC RECEPTORS
 - THEORY: EXCESSIVE ACCOMMODATIVE EFFORT CAUSED MYOPIA AND ATROPINE ABOLISHED THE ACCOMMODATIVE FUNCTION
- ATROPINE INHIBITED MYOPIA IN CHICKS THAT LACK MUSCARINIC RECEPTORS IN THE CILIARY MUSCLE, AND ADDITIONALLY, MYOPIA COULD BE INDUCED IN SPECIES THAT HAD NO FUNCTIONAL ACCOMMODATIVE SYSTEM.
- CHICKEN MUSCLES ONLY CONTAIN NICOTINIC RECEPTORS

1. Leech EM, Cottrill CL, McBrien NA. Pirenzepine prevents form deprivation myopia in a dose dependent manner. *Ophthalmic Physiol Opt* 1995;15(5):351-6. [published Online First: 1995/09/01]
2. McBrien NA, Moghaddam HO, Reeder AP. Atropine reduces experimental myopia and eye enlargement via a nonaccommodative mechanism. *Invest Ophthalmol Vis Sci* 1993;34(1):205-15. [published Online First: 1993/01/01]

ATROPINE MOA

- NON-ACCOMMODATIVE MECHANISM OF ACTION
 - MOA IS UNCLEAR
 - MAY BE EXERTING ITS EFFECT BY MORE THAN ONE PATHWAY
 - INCLUDING RETINAL, CHOROIDAL, SCLERAL & OTHER EYE PATHWAYS

ATROPINE SIDE EFFECTS:

- PUPILLARY DILATION AND CYCLOPLEGIA
 - GLARE, PHOTOPHOBIA, AND NEAR VISION BLUR
- HOT AND DRY SKIN
- FACIAL FLUSHING
- DRYNESS OF THE NOSE
- LOSS OF TASTE
- CONSTIPATION
- DIFFICULTY SWALLOWING
- DIFFICULTY SLEEPING
- DROWSINESS
- EXCITEMENT
- CHANGES IN HEARTBEAT
- HALLUCINATIONS
- FEVER
- HEADACHE
- DIZZINESS
- NERVOUSNESS
- NAUSEA
- VOMITING
- ALLERGIC REACTIONS

ATROPINE

- ATOM 1 – 1% ATROPINE IN 400 CHILDREN
 - VS PLACEBO
 - CONTROL EYE PROGRESSED 0.6D/YEAR
 - ATROPINE TREATED EYE WAS 0.14D/YEAR
 - 77% REDUCTION IN THE PROGRESSION

ATROPINE

- ATOM 2

- **0.5%, 0.1%, AND 0.01%**
- THE MEAN INCREASE IN AXIAL LENGTH
 - 0.27±0.25 MM 0.5%
 - 0.28±0.28 MM 0.1%
 - 0.41±0.32 MM 0.01%

- AXIAL LENGTH COMPARISON

- *NO STATISTICAL DIFFERENCE IN AL ELONGATION BETWEEN THE PLACEBO AND ATROPINE 0.01% GROUP.*

ATROPINE

- IMPORTANT FOR TWO REASONS:
 - PRIMARY PURPOSE OF SLOWING MYOPIA PROGRESSION IS TO REDUCE THE AXIAL ELONGATION WHICH IN TURN DECREASE FUTURE RETINAL COMPLICATIONS.
 - MINIMAL DIFFERENCE BETWEEN PLACEBO AND 0.01% AL CHANGES, WITH SIGNIFICANT REFRACTIVE CHANGES SHOULD MAKE THE CLINICIAN QUESTION THE TRUE EFFECT OF ATROPINE 0.01%

ATROPINE

LOW-DOSE ATROPINE EYEDROPS NO BETTER THAN PLACEBO FOR SLOWING MYOPIA PROGRESSION

- 2 YEAR STUDY, 187 CHILDREN, AGES 5 TO 12
 - LOW TO MODERATE BILATERAL MYOPIA (-1.00D TO -6.00D)
 - **0.01%** ATROPINE VS PLACEBO
 - **NO SIGNIFICANT DIFFERENCES** IN AXIAL LENGTH WITHIN THE TWO GROUPS WHEN COMPARED WITH BASELINE
 - AFTER THE TWO YEAR TREATMENT PERIOD AND AN ADDITIONAL 6 MONTHS OF OBSERVATION

ATROPINE

- LAMP STUDY (1 YEAR)
 - **0.05%, 0.025%, AND 0.01%** ATROPINE DROPS
 - CONCLUSIONS: THE ATROPINE DROPS REDUCED MYOPIA PROGRESSION ALONG A CONCENTRATION-DEPENDENT RESPONSE.
 - ALL CONCENTRATIONS WERE WELL TOLERATED WITHOUT AN ADVERSE EFFECT ON VISION-RELATED QUALITY OF LIFE
 - **0.05% ATROPINE WAS MOST EFFECTIVE IN CONTROLLING PROGRESSION AND AL ELONGATION**

ATROPINE

- LAMP STUDY PHASE 2 (2 YEARS)
 - **0.05%, 0.025%, AND 0.01%** ATROPINE DROPS
 - INITIAL PLACEBO GROUP SWITCHED TO 0.05%
 - CONCLUSIONS: 0.05% AND 0.025% ATROPINE REMAINED SIMILAR, 0.01% IMPROVED MILDLY.
 - THE EFFICACY OF 0.05% ATROPINE OBSERVED WAS DOUBLE THAT OBSERVED WITH 0.01% ATROPINE.
 - **0.05% REMAINED THE OPTIMAL CONCENTRATION AMONG STUDIED ATROPINE CONCENTRATIONS**
 - **0.05% CONTINUED TO BE OPTIMAL CONCENTRATION IN PHASE 3**

Yam JC, Jiang Y, et al. Two year clinical trial of the Low-Concentration Atropine for Myopia Progression (LAMP) study

ATROPINE

SE = Spherical equivalent

- LAMP STUDY PHASE 3 (3 YEARS)
 - CHILDREN IN EACH GROUP WERE RANDOMIZED AT A 1:1 RATIO TO CONTINUED TREATMENT AND WASHOUT SUBGROUPS.
 - SE PROGRESSION AND AL ELONGATION WERE FASTER IN THE WASHOUT SUBGROUPS VS THE CONTINUED TREATMENT
 - OLDER AGE AND LOWER CONCENTRATION WERE ASSOCIATED WITH SMALLER REBOUND EFFECTS IN BOTH SE PROGRESSION AND AL ELONGATION
 - CONTINUED TREATMENT ACHIEVE A BETTER EFFECT ACROSS ALL CONCENTRATIONS IN THE THIRD YEAR
 - **0.05% REMAINS THE OPTIMAL CONCENTRATION**

ATROPINE

- LAMP STUDY PHASE 4 (5 YEARS)
 - *THE RESEARCHERS CONCLUDED THAT OVER FIVE YEARS:*
 - *THE CONTINUED 0.05% ATROPINE TREATMENT DEMONSTRATED GOOD EFFICACY FOR MYOPIA CONTROL.*
 - *MOST CHILDREN NEEDED TO RESTART TREATMENT AFTER ATROPINE CESSATION AT YEAR THREE.*
 - *RESTARTED TREATMENT WITH 0.05% ATROPINE ACHIEVED SIMILAR EFFICACY AS CONTINUED TREATMENT.*
 - *CHILDREN SHOULD BE CONSIDERED FOR RETREATMENT IF MYOPIA PROGRESSES AFTER TREATMENT CESSATION.*
 - **0.05% REMAINS THE OPTIMAL CONCENTRATION**

ATROPINE

RECOMMENDATIONS FOR TAPERING AND PRESCRIBING OF LOW-DOSE ATROPINE

- ATOM 2 STUDY
 - TWO YEARS OF INITIAL TREATMENT FOLLOWED BY A ONE-YEAR WASHOUT PERIOD WITH MONITORING
 - HALF OF THE PARTICIPANTS WERE REQUIRED TO BE RE-TREATED; TREATED FOR AN OVERALL FOUR YEARS.
 - A HIGHER PERCENTAGE OF YOUNGER CHILDREN (6-8YO) REQUIRED RE-TREATMENT AT THE END OF THE WASHOUT YEAR IN COMPARISON

ATROPINE

Question Do low-dose atropine, 0.01%, eye drops delivered nightly over 2 years slow the progression of myopia in children aged 5 to 12 years in the US?

Finding In this randomized clinical trial including 187 children, atropine, 0.01%, eye drops did not slow myopia progression or axial elongation.

Meaning Results do not support the use of atropine, 0.01%, eye drops nightly to slow progression of myopia in US children; future studies of myopia control should test stronger concentrations of atropine or optical and environmental approaches to reduce myopia progression, which may reduce the risk of adult myopic macular degeneration and retinal detachment.

ATROPINE

RECOMMENDATIONS FOR TAPERING AND PRESCRIBING OF LOW-DOSE ATROPINE

- TREATMENT SHOULD BE STARTED EARLY AND CONTINUE UNTIL LATE ADOLESCENCE (15-18YO)
- BEGIN **TAPERING AFTER A CERTAIN AGE** RATHER THAN THE PERIOD OF TREATMENT

ATROPINE

- 1%
 - GREATER SIDE EFFECTS; TAPERED WHEN DISCONTINUED
- LOW DOSE 0.05%
 - FEWER SIDE EFFECTS
- PRESCRIBE FOR AT LEAST 2 YEARS OR UNTIL THE AGE OF 15

ATROPINE

WILL NEED TO USE A COMPOUNDING PHARMACY
COST CAN VARY \$80-\$135 FOR 15ML BOTTLE

RECOMMEND: ATROPINE 0.05% QDHS

[HTTPS://WWW.OSRXPHARMACEUTICALS.COM/](https://www.osrxpharmaceuticals.com/)



OSRX

Atropine+

Available Via Rx

50% LESS BAK

Use **RMM23** to get a special \$39 per bottle price

Low-Dose Atropine **Plus Soothing Lubricant**
0.01% • 0.025% • 0.05%



			
Atropine Sulfate 0.01% Sterile Ophthalmic Solution	3.5 mL Atropine Sulfate 0.025% Sterile Ophthalmic Solution	3.5 mL Atropine Sulfate 0.05% Sterile Ophthalmic Solution	3.5 mL
Potential Contraindications	Potential Contraindications	Potential Contraindications	
MYOPIA DROPS	MYOPIA DROPS	MYOPIA DROPS	

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ATROPINE

- **CONCERNS ABOUT COMPOUNDING ATROPINE**
 - *LABELING PRACTICES, CONCENTRATION OF ATROPINE AND DEGRADANT PRODUCT TROPIC ACID, PH, OSMOLARITY, VISCOSITY, AND EXCIPIENTS IN 0.01% ATROPINE SAMPLES OBTAINED FROM NINE US COMPOUNDING PHARMACIES*
 - AN INCONSISTENT AND WIDE VARIETY OF FORMULATION AND LABELING PRACTICES EXIST FOR COMPOUNDING 0.01% ATROPINE PRESCRIBED TO SLOW PEDIATRIC MYOPIA PROGRESSION
 - ONE QUARTER OF SAMPLES WERE UNDER THE 90% MINIMUM TARGET CONCENTRATION OF 0.01%.

ATROPINE

- CHAMP STUDY – VYLUMA
 - PRESERVATIVE FREE, LOW DOSE ATROPINE **0.01% AND 0.02%**
 - 4 YEAR DATA, FDA APPROVAL PENDING
 - **0.01%**
 - 30% OF CHILDREN USING 0.01%
 - DID NOT PROGRESS MORE THAN -0.50D AT THE END OF 36 MONTHS.
 - 40% OF THE CHILDREN USING 0.01%
 - DID NOT PROGRESS MORE THAN -0.75D OVER THAT TIME.

ATROPINE



- SYDNEXIS (STAR) SYD-101, A PROPRIETARY 0.01% ATROPINE
 - DENIED FDA APPROVAL IN OCTOBER 2025
- *THE FDA WROTE IN ITS COMPLETE RESPONSE LETTER THAT ALTHOUGH THE DRUG MET ITS PRIMARY EFFICACY ENDPOINT IN A PHASE 3 STUDY, AND NO SAFETY OR QUALITY DEFICIENCIES WERE NOTED, THE DATA DID NOT SUPPORT THE EFFECTIVENESS OF LOW-DOSE ATROPINE IN PEDIATRIC MYOPIA*

COMBINATION THERAPY



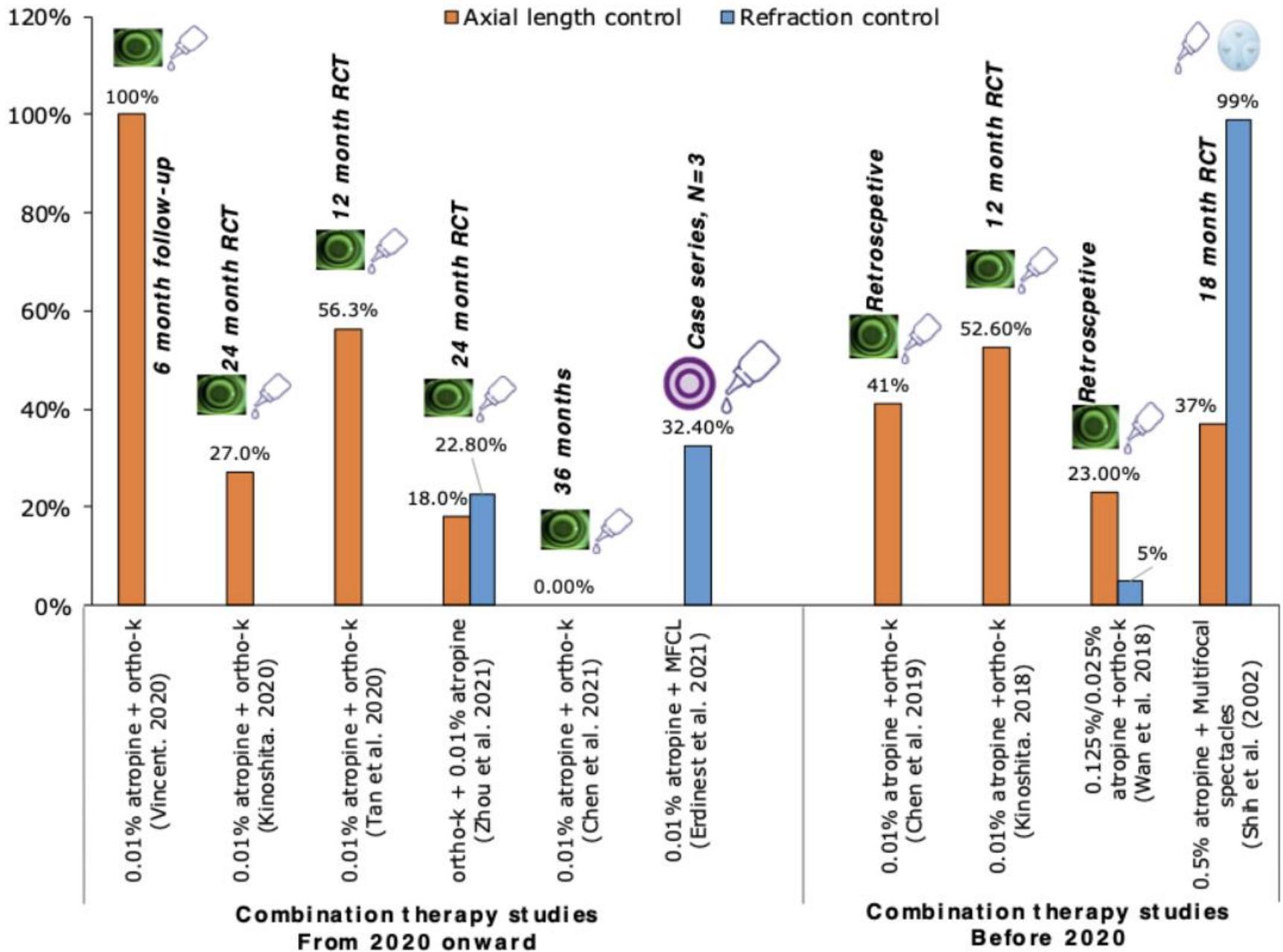
Not all interventions will demonstrate the intended therapeutic effect in all individuals

There will be:

non-responders

Slow responders

In those cases combination treatment should be considered



COMBINATION THERAPY

- ORTHOKERATOLOGY IN COMBINATION WITH ATROPINE
 - MORE EFFECTIVE THAN MONOTHERAPY
- SOFT MULTIFOCAL WITH ATROPINE
 - LIMITED EVIDENCE
 - *LOW-CONCENTRATION ATROPINE MONOTHERAPY VS. COMBINED WITH MISIGHT 1 DAY CONTACT LENSES FOR MYOPIA MANAGEMENT: **COMBINATION TREATMENT DID NOT PRESENT AN ADVANTAGE OVER MONOTHERAPY***
- NEXT-GENERATION MYOPIA MANAGEMENT SPECTACLES AND ATROPINE
 - LIMITED EVIDENCE

NEW RESEARCH



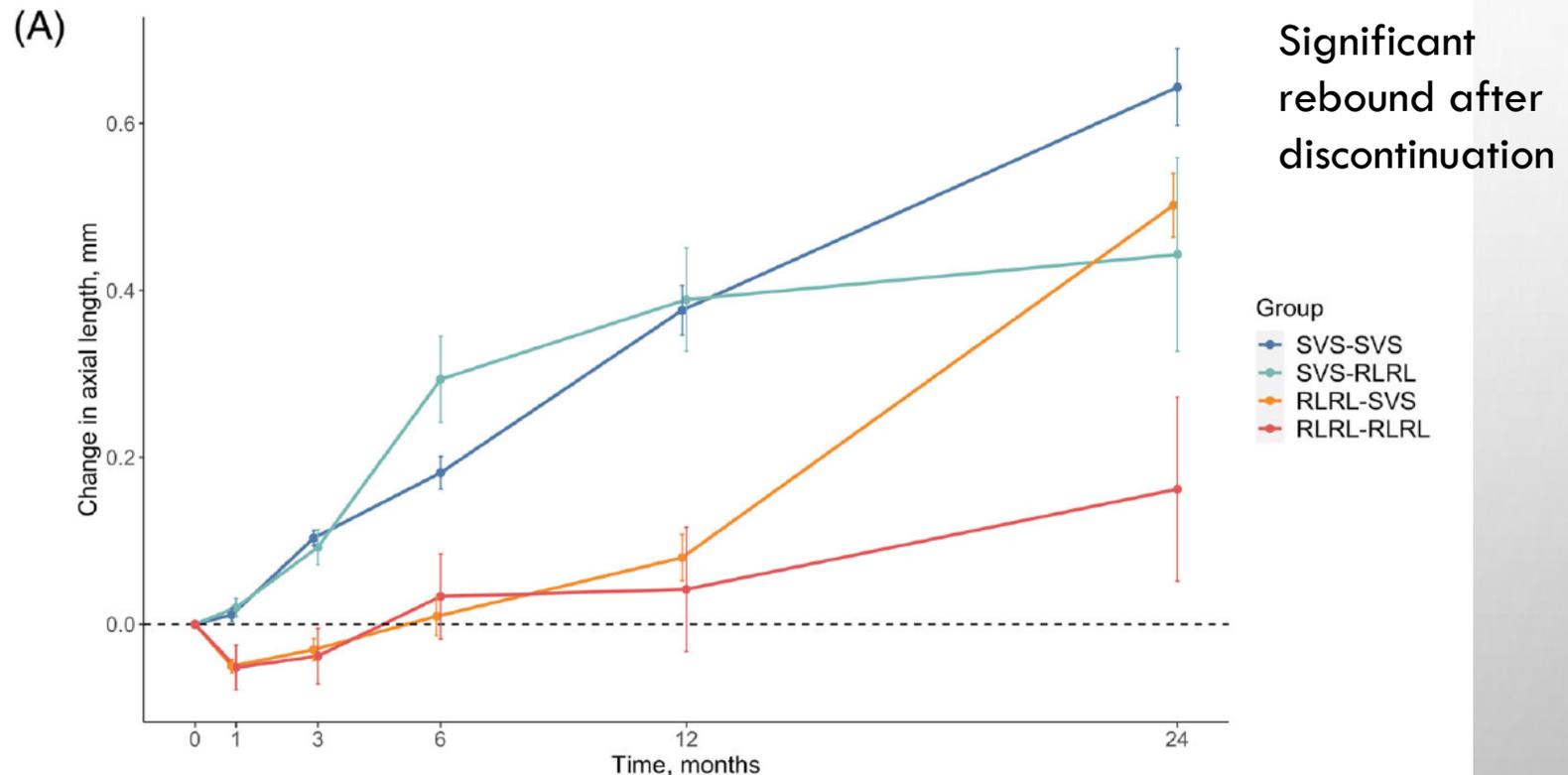
- LIGHT THERAPY (NO, SERIOUSLY)
 - LOW-LEVEL, RED LIGHT THERAPY
 - 650NM WAVELENGTH WITH A DESKTOP LIGHT THERAPY DEVICE
 - EMITTED RED LIGHT OF 1,600 LUX FOR 3 MINUTES, 2 X TIMES FOR 5 DAYS EACH WEEK FOR 12 MONTHS
 - AXIAL ELONGATION: TREATMENT GROUP: 0.13MM; CONTROL GROUP: 0.38MM
 - VIOLET LIGHT (360–400 NM) – NOT SIGNIFICANT RESULTS
 - CHICKEN MODELS, SHOWS SLOWING OF PROGRESSION OF MYOPIA
 - VIOLET LIGHT TRANSMITTING CL SUPPRESSED AL ELONGATION IN CHILDREN

-Torii H, Kurihara T, et al. Violet Light Exposure Can Be a Preventive Strategy Against Myopia Progression. EBioMedicine. 2017 Feb;15:210-219.

-Jiang Y, Zhu Z, et al. Effect of Repeated Low-Level Red-Light Therapy for Myopia Control in Children: A Multicenter Randomized Controlled Trial. Ophthalmology. 2022 May;129(5):509-

519. photo: Credit: Chen Y, Xiong R, Chen X, et al. Efficacy comparison of repeated low-level red light and low-dose atropine for myopia control: a randomized controlled trial. Trans Vis Sci Technol.

RED LIGHT THERAPY – 2 YEAR RESULTS



Ruilin X, Zhuoting Z, Yu J, Xiangbin K Sustained and rebound effect of repeated low-level red-light therapy on myopia control: A 2-year post-trial follow-up study Experiment Ophthalmol. 2022;50:1013–1024.

RED LIGHT THERAPY

- LIGHT THERAPY
- TO DATE, MORE THAN 20 CLINICAL STUDIES HAVE BEEN CONDUCTED IN CHINA ON THIS TOPIC
 - RESULTS SHOWING THAT THE THERAPY SLOWS THE PROGRESSION OF MYOPIA IN CHILDREN.
 - SUCCESSFUL IN DELAYING THE ONSET OF MYOPIA IN PRE-MYOPIC CHILDREN.
 - WHILE THERE ARE DIFFERENCES IN THE STUDY DESIGN, DURATION, AND AGE OF THE PARTICIPANTS AMONG THE STUDIES, THE CONSISTENT FINDING IS THAT THE TREATMENT SIGNIFICANTLY SLOWS THE AXIAL ELONGATION RATE, WITH SOME STUDIES EVEN SHOWING REGRESSION.

-Torii H, Kurihara T, et al. Violet Light Exposure Can Be a Preventive Strategy Against Myopia Progression. *EBioMedicine*. 2017 Feb;15:210-219.

-Jiang Y, Zhu Z, et al. Effect of Repeated Low-Level Red-Light Therapy for Myopia Control in Children: A Multicenter Randomized Controlled Trial. *Ophthalmology*. 2022 May;129(5):509-519.

RED LIGHT THERAPY

- 12 YO GIRL REDUCED VISION X 2 WEEKS FOLLOWING 5 MONTHS OF RLRL – FOVEAL DAMAGE AND MACULAR HYPOAUTOFLUORESCENCE WITHOUT INFLAMMATION BCVA AFTER 20/25
- POSSIBLE MOA IN SLOWING MYOPIA PROGRESSION: CHOROIDAL THICKENING
 - EVIDENCE RIGHT NOW IS LOW CERTAINTY AND REBOUND EFFECT SEEMS LARGE AFTER DISCONTINUATION

RED LIGHT THERAPY

- COMBINATION WITH ORTHO K WEAR
 - 47, 8-13 YEAR OLD CHILDREN.
 - RLRL 2X DAILY FOR 3 MINUTES.
- AT 12 MONTHS CHILDREN WEARING OK AND RECEIVING RLRL HAD LESS AL CHANGES VS OK ONLY GROUP.
 - NEED ADDITIONAL LONG TERM STUDIES TO CONFIRM RESULTS.

MYOPIA CONTROL CLINICAL PROTOCOL

- 1ST GRADE, REFRACTION MORE MYOPIC THAN +0.75D, BUT STILL HYPEROPIC
 - EDUCATE PARENTS ABOUT ATROPINE AND SPENDING TIME OUTDOORS; RX ATROPINE LOW DOSE IF PARENTS ARE WILLING TO DELAY ONSET
- AGE 6-11
 - MONITOR FOR MYOPIC DEVELOPMENT INITIATE TREATMENT WHEN MR > -0.50D OR IF PARENT UNWILLING
 - ENCOURAGE TREATMENT WHEN PROGRESSION IS > 0.50D/YEAR
 - ORTHOKERATOLOGY, SOFT MULTIFOCALS, ATROPINE

MYOPIA CONTROL CLINICAL PROTOCOL

- AFTER TREATMENT INITIATED:
 - MONITOR EVERY SIX MONTH
 - REFRACTION
 - A SCAN
- IF SMF, OK, ATROPINE PROGRESSION $<0.50D/YEAR$
 - MONITOR WITH 6 MONTH REFRACTION CHECKS/AXIAL LENGTH ELONGATION

MYOPIA CONTROL CLINICAL PROTOCOL

- IF SMF OR ORTHOKERATOLOGY OR ATROPINE
 - > 0.50D/YEAR PROGRESSION AND AXIAL LENGTH ELONGATION
 - CONSIDER A COMBINATION TREATMENT
 - ADD ATROPINE IF USING CONTACT LENS TREATMENT
 - ADD CONTACT LENS TREATMENT IF USING ATROPINE

SUMMARY

- EDUCATE PARENTS
- DISCUSS ALL THE OPTIONS AND LET THE FAMILY DETERMINE WHICH METHOD WILL WORK BEST FOR THEM
 - BOTH SOFT BIFOCAL CONTACT LENSES AND ORTHOKERATOLOGY CAN REDUCE MYOPIA PROGRESSION
 - CAN BE EASILY FIT ON YOUNG PATIENTS
 - COMPOUNDED LOW DOSE ATROPINE (0.05%)
- MONITOR ON A REGULAR BASIS
- USE A SCAN TO DETERMINE CONTROL

THANK YOU

