

Tina Graff, Patrick Caroline, Eef van der Worp, Randy Kojima

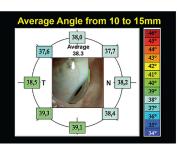
Candidates Fitting Process Troubleshooting Candidates Fitting Process Troubleshooting Candidates Fitting Process Troubleshooting Candidates Fitting Process Troubleshooting

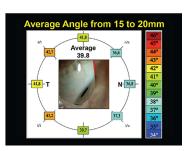
Scleral Shape Plot

(Quantitative)

Axis (Degrees)

16 mm Diameter





Beyond the Limbus: Scleral Peripheral Curves and Their Modifications

Candidates Fitting Process Troubleshooting

5.7% spherical — spherical landing zone

28.6% toric-regular — toric landing zone

40.7% asymmetric

25% periodicity different from 180° —

65.7% with a quadrant-specific/custom design.

Scleral shape and its correlations with corneal astigmatism

Alejandra Consejo, MSc PhD,1,2 and Jos J. Rozema, MSc PhD1,3

¹ Department of Ophthalmology, Antwerp University Hospital, Edegem, Belgium ² Department of Biomedical Engineering, Wroclaw University of Science and Technology, Wroclaw, Poland ³ Department of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium

ABSTRACT

Scleral Elevation Map

(Qualitative)

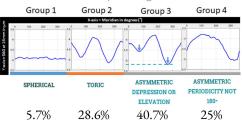
 $\textbf{Purpose} \hbox{:}\ To\ assess\ the\ correlation\ between\ scleral\ shape\ and\ corneal\ astigmatism.}$

Methods: Twenty-two participants (11 non-astignatic and 11 astignatic) aged from 19 to 36 years and with no previous outlaw surgeries were included in this study. Three-dimensional (3D) corneo-scleral maps from both eyes (44 eyes) were acquired using a corneo-scleral topographer (Eye Surface Profilel). Each 3D may awa spilt up in 13 concentric annuli, each 0.5 mm-wide, staring at 1.0 mm radius from the corneal apex to the scleral periphery at 7.5 mm from the apex. Each ring was stifted to a quadratic function of the radial distance to the apex, to calculate the elevation difference between the raw data and the fitting surface ring, to a sum off gate is function. Determined the surface is a sum off gate is function. Determined from the insolidal fit were analyzed and compared between non-astignatic and astignatic groups.

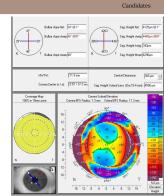
Results: In astignatic eyes corneal and scleral asymmetry are highly correlated, while both appear independent from each other in non-astignatic eyes. No significant difference between astignatic and non-astignatic eyes was found for decentration term (p > 0.05/[N] (Bonferroni)), while for the astignatic component the differences were statistically significant (p < 0.05/[N] (Bonferroni)).

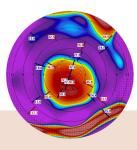
Conclusion: Corneal and scleral shape are correlated in astigmatic eyes, suggesting that astigmatism is not restricted to the cornea, but should rather be considered a property of the entire eye globe.





Candidates Fitting Process Troubleshooting



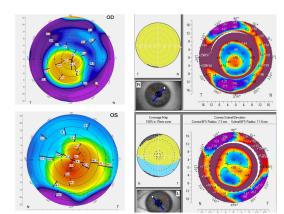


"When considering lens design, eyes that exhibit central_ectasia have scleral shapes that are similar to normal eyes and would, on average, be best fitted with a scleral lens that has a toric landing zone.

Eyes that have <u>peripheral</u> ectasia would, on average, require a scleral lens with a more customized landing zone design, such as a quadrant-specific or a free-form design."

"This difference is higher if the apex of the ectasia is ≥ 1.25 mm from the corneal center"

DeNaeyer, Gregory, et al. "Correlation of corneal and scleral topography in cases with ectasias and normal corneas." Journal of Contact lens Research and Science 3.1 (2019): e10-e2

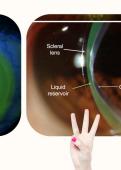


A few rules of

More likely to need toric peripheral curves if

- > 15 mm scleral lens
- Corneal astigmatism

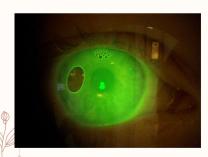
FLOWER INSERTION METHOD

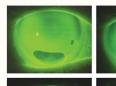


Fitting Process Troubleshooting





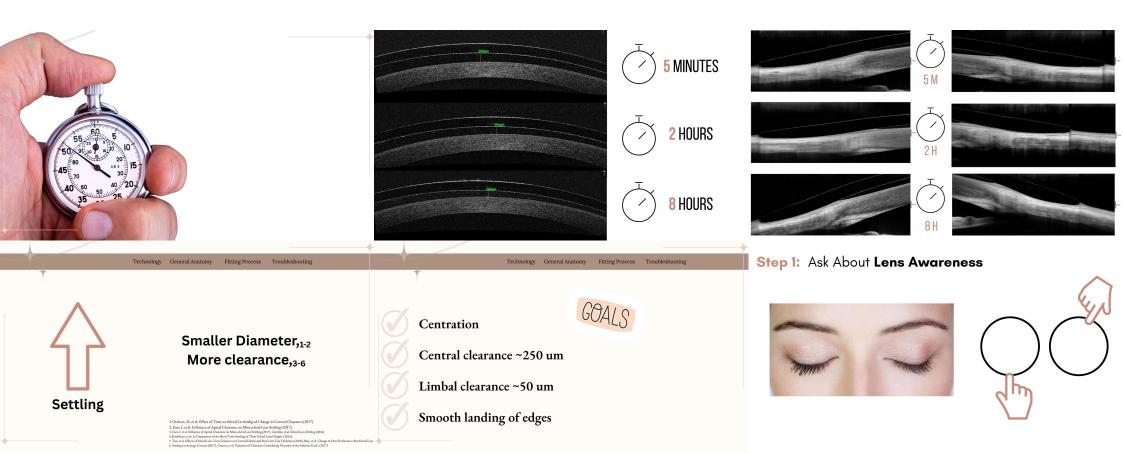




Technology General Anatomy **Fitting Process** Troubleshooting







Step 2: Diffuse clearance throughout lens



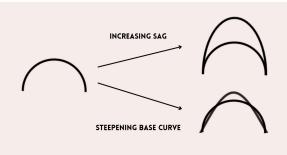
SLIT LAMP

Diffuse beam Blue Light Wratten Filter Low Mag

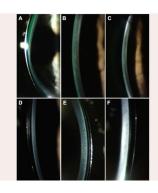
LOOKING FOR

Any areas of bearing?
Centration?

Step 3: Appropriate **Central Clearance?**



Step 3: Appropriate Central Clearance?



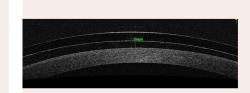
SLIT LAMP

Optic section White Light High Mag

LOOKING FOR

Clearance

Step 3: Appropriate **Central Clearance?**



SLIT LAMP

Optic section White Light High Mag

LOOKING FOR

Clearance

Step 4: Appropriate **Limbal Clearance?**



SLIT LAMP

Optic section White Light High Mag

LOOKING FOR

Areas of touch?
Areas of excess clearance?
Centration?

Step 5: Aligned Edges?



SLIT LAMP

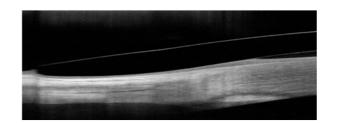
Diffuse Beam White Light Low Mag

LOOKING FOR

Blanching? Impingement? Healing? Lift?

Flat Edges

Step 4: Aligned Edges?



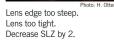








If SLZ is too tight (too steep) decrease the SLZ number (flatten)





Blanching. Lens too tight. Decrease SLZ by 4.



Extreme edge tightening around entire lens. Decrease SLZ by 6 in both meridians.



If SLZ is too loose (too flat) increase the SLZ number (steepen)



Excessive edge lift in flat meridian. Increase SLZ by 2 in flat meridian. Increase SLZ In both meridians.



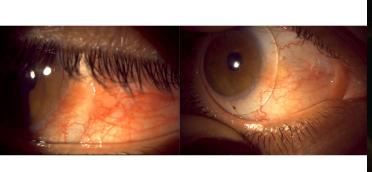
Excessive edge lift in both meridians.





Microvault Notching Custom-mold Scleral Topography Based

THE FIX









Candidates Fitting Process **Troubleshooting** Candidates Fitting Process **Troubleshoot**

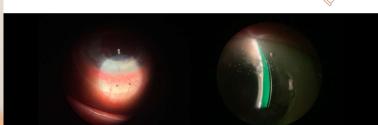
Questions at follow-up:

- <u>WTT/AWT</u> (Wear Time Today/Average Wear Time):
- Solutions:
- Comfort?
- Ease of insertion/removal?
- Redness?
- Vision throughout day?

Difficulty with removal...follow-up questions:

- Is it difficult to remove regardless of how long it's been on?
- Do drops help?
- Where is the plunger being applied?
- Watch them take it out







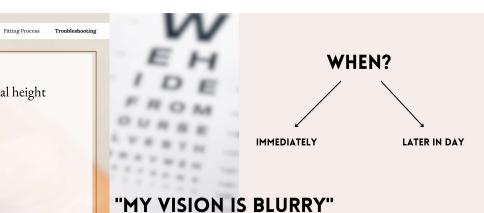
IMMEDIATE

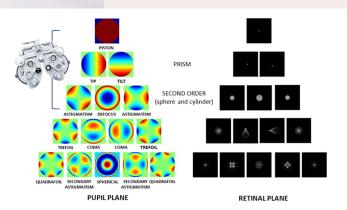


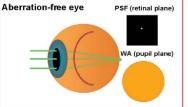
Difficulty with removal solutions Ensure alignment of edge, limbus, saggital height Adjust diameter/edge design

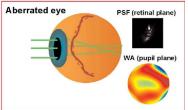
• Add fenestrations/smart channels

Perform auto-refractor (AR) over scleral lens -1.00-1.75x090 Auto-Ks Auto-Ks 49.00/49.00@180 49.00/50.75@90 **Check for centration Check for Flexure:** & rotational stability • Aligned Edges? Not stable? • Thin lens? Add spherical-Add -1.00-1.75x180 equivalent over-refraction Refine fit

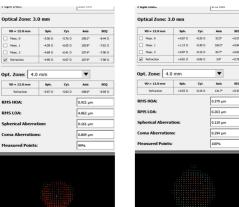


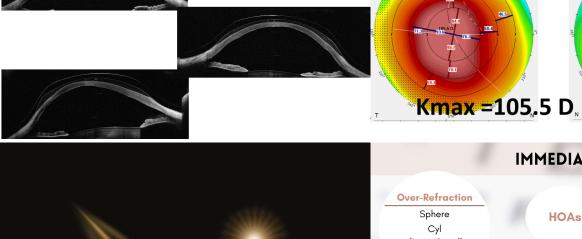






Glare/haloes/Starbursts Shadowing/smearing Monocular diplopia Ghost images Reduction in CS Distorted night vision





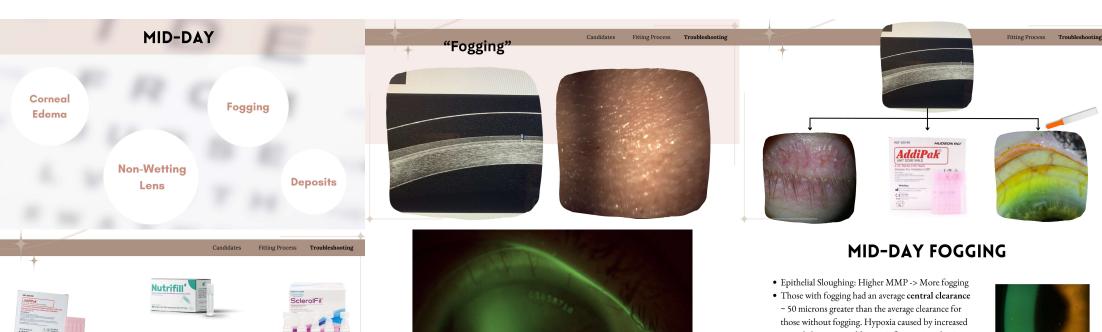
Spherical Aberration

Coma

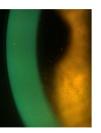


OD

os

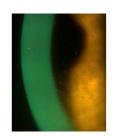


- central clearance could cause inflammation that in turn causes midday fogging.
- The study found that 80% of the participants with fogging had tightly fitting lenses, compared to 40% of the wearers without interrupted wear. Interestingly, the tear exchange rate measured by fluorophotometry was the same in the two groups



MID-DAY FOGGING

- 1. Align Edges
- 2. Treat OSD
- 3. Ensure proper insertion
- 4. Ensure proper filling solution
- 5. Minimize central clearance
- 6. Add viscous PFAT (Celluvisc, Optase Intense, etc)

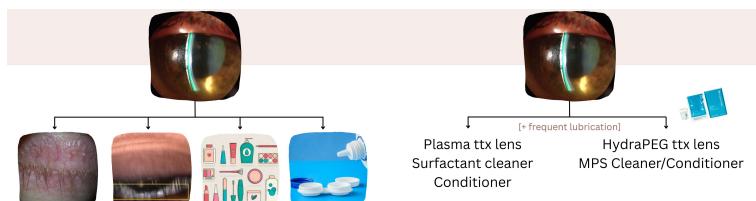


r, Jennifer Swingle, "Midday Fogging of Scleral Contact Lenses: Current Prespectives," Clinical Optometry (2021): 219-219

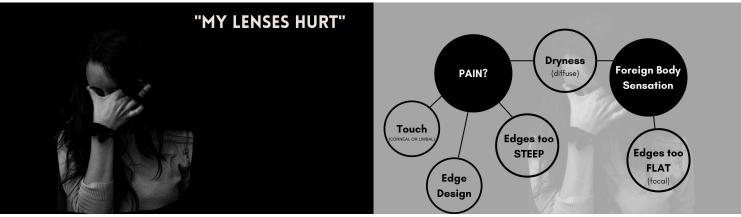
DEPOSITS

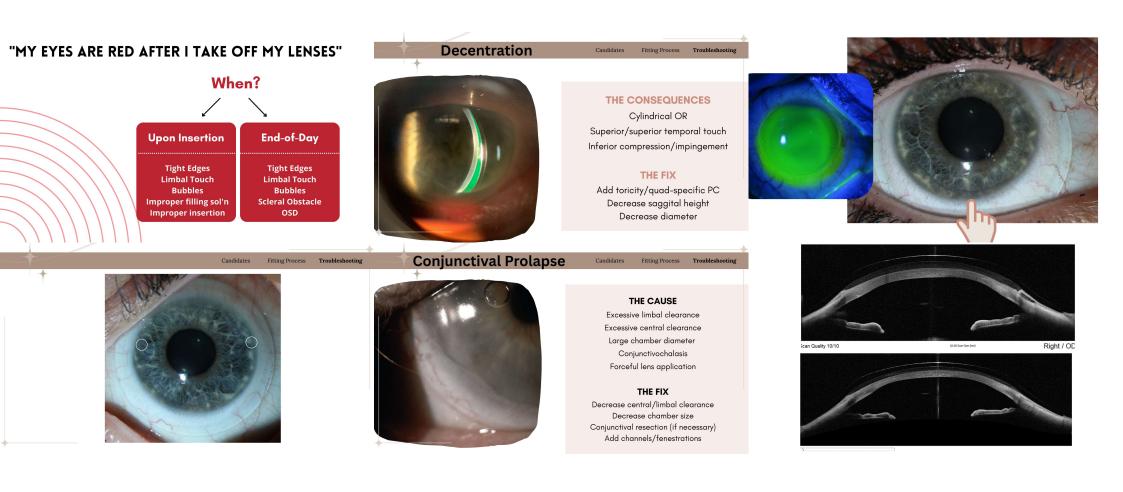
- 1. Abrasive nightly cleaners
- 2. Mechanical rubbing
- 3. Protein remover
- 4. Progent treatment
- 5. Frequent lubrication throughout day

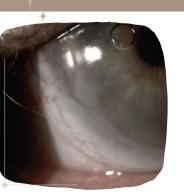




Reverse piggyback?







THE RISK

Fitting Process Troubleshooting

- · Localized vascularization,
- Conjunctivalization (fibrovascular pannus)
- Impaired stem cell function.



THE CAUSE

Fitting Process Troubleshooting

Excessive limbal clearance
Decreased oxygen transmission
Bearing on limbus
Chronic conjunctival prolapse

THE FIX

Decrease limbal clearance Improve scleral lens alignment

THE CAUSE
Overwear

Sleeping in lenses

Compromised cornea

Excessive central clearance
CL too thick

. 100 11110

Low dK

Fitting Philosophies While some practitioners strive for maximum lens material oxygen permeability and minimum reservoir and lens thickness to minimize corneal hypoxia, is this always necessary? Recent laboratory-based studies of young, healthy eyes have provided further insights into the effect of manipulating these variables on corneal edema (Figure 3). Dhallu and colleagues²² demonstrated that increasing the lens oxygen permeability beyond a Dk of 100 provided no further reduction in corneal edema, and Fisher and coworkers²³ highlighted that minimizing the fluid reservoir thickness (Dk of ~80) provided a greater reduction (~two times greater) in corneal edema than similar modifications for lens thickness values (Dk of 141).

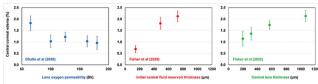


Figure 3. Mean (± standard error) scleral lens-induced central corneal edema as a function of lens oxygen permeability (blue), inlitial central fluid reservoir thickness (red), and central scleral lens thickness (green). For other lens and fitting parameters refer to Dhallu et al (2020), Fisher et al (2020), and Fisher et al (2020), and







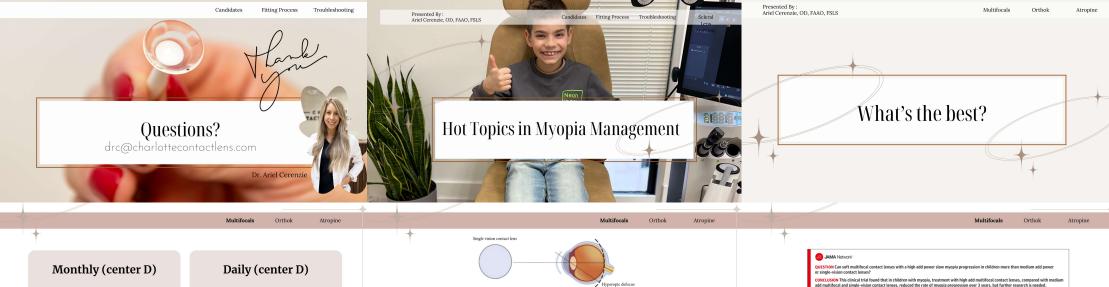
CORNEAL EDEMA







Fitting Process Troubleshooting



Biofinity MF SiHy: Sphere: Up to -10.00 D

Cyl: Up to -5.75

Proclear MF Hydrogel:

Sphere: Up to -20.00 D Cyl: Up to -5.75

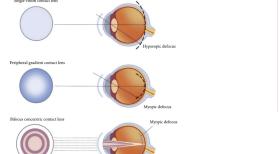
MiSight:

+2.00 Concentric Rings

Sphere: Up to -7.00 D Cyl: Up to -0.75

<u>Aspheric</u>

Sphere: Up to -12.25 D



-0.60 D (95% CI, -0.72 D to -0.47 D)

Medium add power contact lenses −0.89 D (95% CI, −1.01 D to −0.77 D)

1.05 D (95% CI, −1.17 D to −0.93 D)

 $\begin{array}{c} \mbox{High add vs single-vision:} & 0.46 \ \mbox{(0.28-0.63);} \ \mbox{$P\!\!<\!.}\ \mbox{.000} \\ \mbox{Medium add vs single-vision:} & 0.16 \ \mbox{$(-0.01$ to 0.33);} \ \mbox{$P\!\!<\!.}\ \mbox{$1$} \\ \mbox{High vs medium add:} & 0.30 \ \mbox{$(0.13-0.47)$;} \ \mbox{$P\!\!<\!.}\ \mbox{$0.40$ to 0.30$;} \\ \mbox{$(-0.13-0.47)$;} \ \mbox{$P\!\!<\!.}\ \mbox{$(-0.13-0.47)$;} \ \mbox{$P\!\!<\!.}\ \mbox{$(-0.13-0.47)$;} \ \mbox{$P\!\!<\!.}\ \mbox{$(-0.13-0.47)$;} \ \mbox{$P\!\!<\>.}\ \mbox{$(-0.13-0.47)$;} \ \mbox{$(-0.13-0.47)$;} \ \mbox{$P\!\!<\>.}\ \mbox{$(-0.13-0.47)$;} \ \mbox{$(-0.13-0.47)$;} \$

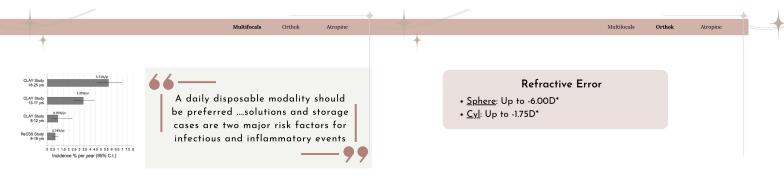


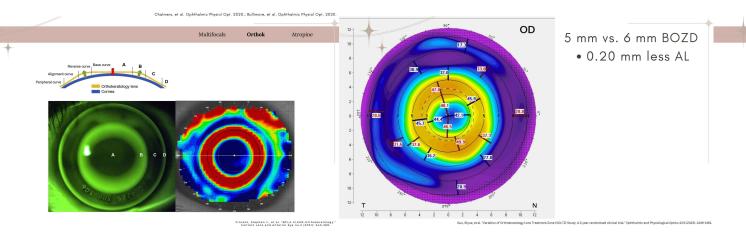
Study Time (Months)

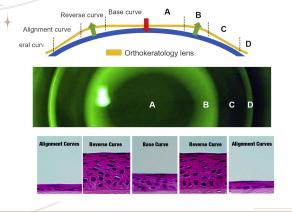
Chamberlain P et al. Myapia Progression in Children on Cessation of Dual-Facus Contact Lens Wear; MiSight 1-day 7-year findings AAO November 2021

Incidence % per year (95% C.I.)

Chalmers, et al. Ophthalmic Physiol Opt. 2020.; Bullimore, et al. Ophthalmic Physiol Opt. 2020







AXIAL ELONGATION

 $\sim\!50\%$ Ranging from 41-45% in most meta-analyses.

Multifocals

Atropine



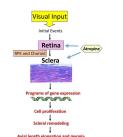
Non-selective antagonist of muscarinic acetylcholine receptors

Muscarinic ACh Receptors are found in the:

<u>Retina</u>: The layer involved in transferring the signaling cascade toward the choroid and/or the sclera. Atropine boosts dopamine release from cellular stores, which then controls eye growth.

<u>Choroid</u>: Atropine results in rapid and transient choroidal thickening and inhibited eye growth. Suggested that the choroidal thickening and eye growth may be linked. Atropine was found to inhibit choroidal thinning induced by hyperopic defocus.

Sclera: Blocks the proliferation of scleral fibroblasts and consequent axial elongation



Refractive Error

No Limit!

Liu, Yue M., and Peiying Xie. "The safety of orthokeratology—a systematic review." Eye & contact lens 42.1 (2016)

Multifocals Orthok Atropine Multifocals Orthok Atropine

	ATOM 2			LAMP		
Atropine Dosage	0.5%	0.1%	0.01%	0.05%	0.025%	0.01%
Refractive Efficiency	75%	68%	59%	66%	43%	27%
Axial Efficiency	29%	25%	-8%	51%	29%	12%

0.05% atropine remained the optimal concentration over 3 years

The difference in rebound effects were clinically small across all three studied atropine concentrations.

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

What's in a Bottle

A Survey of 26 pharmacies across 19 US states

- Diluted from 1% atropine gtts or atropine powder
- · Preservatives may vary: BAK commonly used
- Atropine is an unstable compound
 - Susceptible to hydrolysis influenced by pH and carriers/preservatives/diluting agents
 - Analysis found the actual concentration compared to the prescribed concentration
 was:
 - As low as 70% and a quarter of all samples were under the 90% minimum target concentration.
 - More neutral pH = more degradation

Richdale K, Tomiyama ES, Novack GD, Bullimore MA. Compounding of Low-Concentration Atropine for Myopia Control. Eye Contact Lens 2022;48:48

+	0.05% Atropine	0.025% Atropine	0.01% Atropine	Placebo
Photopic pupil size (+mm)	1.03	0.76	0.80	0.13
Photophobia, 2 weeks	31.2%	18.5%	5.5%	12.6%
Photophobia, 1 year	7.8%	6.6%	2.1%	4.3%
Photochromic Lenses	30.3%	34.3%	30%	39.6%
Accommodative Amp (D), 4 mo	-2.38	-1.34	-0.50	-0.35
Accommodative Amp (D), 1 yr	-1.98	-1.61	-0.26	-0.32
PALS	0.96%	0%	1.8%	0.9%

Randomized Controlled Trial > Optom Vis Sci. 2023 Aug 1:100(8):550-556.

Effect of Low-dose Atropine on Binocular Vision and Accommodation in Children Aged 6 to 17 Years

"Pupil size was significantly enlarged by 0.01%, 0.03%, and 0.05% atropine in both dim and bright illumination with more effect at 60 minutes after application. However, low dose atropine eye drops have no effect on binocular vision measurements.

Thus, in respect to binocular vision, it is relatively safe to use low-dose atropine to treat myopia progression in children aged 6 to 17 years."

Which one is better?

Consider

- o Kid's/Parent's preference
 - Previous CL experience
 - FDA approval
 - Wary of "drugs"
- Hygiene
- Maturity
- o Concerns of compliance

4. Gauging

Success

- Extracurricular activity involvement
- BV issues?

WORKING?

S





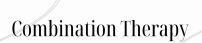


Which one is better?

- Esophoria and accommodative lag: Likely to be improved in orthokeratology wear. 1,2
- Multifocal contact lenses can potentially cause small exophoric shift and/or increase in accommodative lag.3,4
- The MiSight/dual focus concentric contact lens design does not appear to alter accommodation or phoria.5,6

Atropine + Orthok Atropine + Soft CLs







Orthokeratology + 0.01% Atropine

2-years RCT: - combination ttx significantly slowed axial elongation compared to ortho-k alone - 0.17 mm vs. 0.34 mm

• Additive effect was particularly **pronounced in the first six months** of treatment, suggesting that the combination is most effective in the early stages.¹

<u>2-years retrospective study</u>: Combination ttx reduced axial elongation by 36% compared to ortho-k alone - 0.28 mm vs. 0.44 mm.²

• Additive effect was more pronounced in younger children, indicating that early intervention may provide greater long-term benefits.

The Latest on Combination Therapy

Orthokeratology + 0.05% Atropine

1 year retrospective study - Children using ortho-k combined with 0.05% atropine experienced significantly less axial elongation over a year compared to those using ortho-k alone (0.14 mm vs. 0.27 mm).

• Effect appeared to diminish slightly in the second half of the year, suggesting a potential adaptation period.1

Some studies suggest that the effectiveness of atropine in combination therapy may plateau after 1.5 years.2

The Latest on Combination Therapy

MiSight + 0.01% Atropine

3- year retrospective study - myopia progression in children using 0.01% atropine alone, 0.01% atropine plus MiSight 1 Day, and a control group wearing single-vision spectacles. Children treated with 0.01% atropine alone showed significantly less myopia progression than the single vision group, with 0.44 D in year 1 and 0.51 D in year 2. The combined MiSight + 0.01% atropine group exhibited the lowest myopia progression, with 0.35 D in year 1 and 0.44 D in year 2.

Conclusion: No clear additive effect was observed in one study of MiSight 1 Day and 0.01% atropine, but study limitations prevent a definitive conclusion.

Atropine + Orthok Atropine + Soft CLs

The Latest on Combination Therapy

Biofinity + 0.01% Atropine

3-year RCT - Myopia progression was -0.52 D in the combination group, -0.55 D in the SMCL group, and -1.09 D in the SV group, indicating no significant added benefit of atropine when combined with SMCL. Axial elongation was also similar between the combination and SMCL groups (0.31 mm vs. 0.39 mm).

Conclusion: adding 0.01% atropine to SMCL does not provide a meaningful additional benefit.

The Latest on Combination Therapy

RLRL + Orthok

Repeated low-level red-light therapy (RLRL)

- 12 month RCT
- 8-13 yo fast progressors
- RLRL + Orthok: -0.02 mm
- Orthok only: 0.27 mm

"These results suggest that RLRL therapy significantly enhances the myopia control effect of orthokeratologyin children with fast axial elongation. The treatment was well tolerated, with no serious adverse events reported" 14



Myopia structural changes: Choroidal thinning and reduced blood flow --> hypoxia.

Unpublished reports indicate potential benefits:

- Increased choroidal thickness
- · Improved blood flow
- Stabilization of axial elongation.

Potentially could reduce scleral hypoxia and reduce risk of development/progression of myopia



Eyerising International indicates that the RLRL device has approximately 70,000-80,000 daily users in China

DOSE

650±10nm at a laser power of 0.29mW going through a 4-mm pupil and is used for **180 seconds at a time twice a** day for 5 days per week **Participants:** n= 264 children randomly assigned to the intervention group [RLRL treatment plus single vision spectacle (SVS)] and control group (SVS).

• 12 months

TTX: desktop light therapy device (red light of 650 nm wavelength with illuminance level of \sim 1600 lux and a power of 0.29 mW for a 4-mm pupil.

• At home under the supervision of parents, three minutes per session, twice per day with a minimum interval of four hours, five days per week.

Outcome: RLRL treatment slowed axial elongation by 0.26 mm and SER progression by 0.59D compared with SVS

• 69.4% and 76.6% slowing axial elongation and myopic refraction progression.

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(c) Multifued decharating-para plats, right car

(d) Multifued decharating-para plats, right car

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(a) Walthack decorating are place felt for yellow a record (CPT(D)) of the felt (CPT) (CPT

12 year old female with bilateral vision loss after 5-month use of RLRL laser exposure

The Data

Safety

Vision: BCVA declined from 20/20 to 20/30 OU

Ocular Health Findings:

Mechanism

- Darkened foveae with hypoautofluorescent
- plaque in autofluorescence images
 Foveal ellipsoid zone disruption, OU
- · Interdigitation zone discontinuity
- ERG: moderately reduced response in macula

3 months later:

Bilateral outer retinal damage partially recovered

BCVA improved to 20/25 OU

The study examined two LLRL devices — the Sky-at 2018 and the Future Vision measured their optical covers using an integrating sphere radiometer through a sperium. The refinal spot sizes of the options are dominated using a mobel very

Low-Level Red Light Therapy: Safety Concerns Continue

BA, FAAO, FBCLA, FIACLE



,

use of **low-level red light** (LLRL) thorapy has gained popularity as a treatment for myopia hidden, especially in China. However, concerns have been raised about the safety of these lone, as their output may exceed the recommended safety firms. A recent study conducted Las Ostrin and Alexander Schill aimed to characterize the output of two LLRL devices and minim their thermal and photochemical maximum premisebble exposure (LMPL) for myopia The published case report cited several possibilities for this adverse outcome, such as the device's light power stability, extended exposure, or the patient's light sensitivity.16

"Data supplied by Eyerising International indicates that the RLRL device has approximately 70,000-80,000 daily users in China: of those, these 5 cases

are the only adverse events that have been reported to the company's sideeffect reporting centre, constituting a rare side effect rate of 0.0067%.17

The Data

The device does include a stringent control system whereby users must log in with specific credentials, and the system regulates the duration of light exposure, making prolonged exposure virtually impossible. A possible reason for adverse outcomes may be sensitivity to phototoxicity.

While determining those that may be susceptible to this could be difficult, Eyerising International recommends that **children who notice an afterimage persisting longer than 5 minutes should cease use and contact their clinician for further advice***



Risk Factors Outdoor Time Atropine Impact Risk Factors Outdoor Time Atropine Impact

RISK FACTORS FOR DEVELOPING MYOPIA

- · Lower baseline hyperopia than expected for their age
- · A family history of myopia
- · Visual environment factors which increase risk of myopia, such as reduced time spent outdoors and intensive near work habits.

Age (years)	Refraction cut point		
6	<+0.75		
7 to 8	<+0.50		
9 to 10	<+0.25		
11	< 0.00		

Protective Effect of outdoor time on reducing onset of myopia:

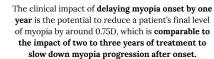
- 1 hr/day or 7 hr/week = **Reduction of incident** myopia by 45%.
- · Aiming for at least 2 hrs/day or 13 hours per week places children out of the highest risk category
- Recent research has shown this effect is most powerful in children aged 3 to 9 years, to reduce onset of myopia between ages 10 to 15

Risk Factors Outdoor Time Atropine Impact Risk Factors Outdoor Time Atropine Impact



- · Randomised clinical trial
- 474 Hong Kong Chinese children
- 4-9 (mean 6.8) years
- Does atropine 0.05% and 0.01% delay myopia onset?
 Nightly use of 0.05% atropine eye drops significantly reduced the 2-year cumulative incidence of myopia to 28.4%, and fast myopic shift to 25.0%
- · Nightly use of 0.01% atropine group showed no significant difference from
- placebo, with a myopia incidence of 45.9% and a fast myopic shift of 45.1%.

 Conclusion: 0.05% atropine as effective in preventing early myopia onset.7



Presented By : Ariel Cerenzie, OD, FAAO, FSLS

Candidates Fitting Process Troubleshooting





Frequency of Progression of At Least -0.75D (%) Baseline Age (v)

48.2 (40/83)

35.3 (36/102) 25 - 30

20 - 25

35 - 40

27.3 (18/66) 30 - 35 25.0 (10/40)

35.7 (104/291)

SPAN (Study of Progression of Adult Nearsightedness) Study
The highest risk factor for progression
in adults was extensive near work

Consensus between these studies that one-fifth of myopes in their 20s will experience significant progression of at least 1D.





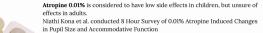


drc@charlottecontactlens.com

Age at myopia stabilization



CONSIDER TREATMENT SIDE EFFECTS OF TREATMENTS



- ~50% young adult subjects found their accommodation was most impaired at the 8 hour mark after instillation.
- Along with adults night driving and frequently having high visual demands as university students and/or in screen based work - this could mean that
- adults may not tolerate atropine as well as children. Orthokeratology may be effective in adult myopia stabilization

Two small studies:

- 1. Orthokeratology (OK) wear in 18-29 year old myopes stabilized refraction and axial length.
- 2. Paper reported similar results in a case series of three adults wearing OK over
- three years.
 3. Two studies are small and present limited data there are no randomized controlled trials for any type of myopia control treatment in young adults.