AASAP ZOT

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Methods of myopia control

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II. List of abbreviations

ACD	anterior chamber depth
AL	axial length
AMMC	age matched myopia control system
AOK	atropine + orthokeratology
AULCSF	area under the log contrast sensitivity function
BCVA	best-corrected visual acuity
CARE	cylindrical annular refractive element
cpd	cycles per degree
CC	corneal curvature
CDVA	corrected distance visual acuity
CS	contrast sensitivity
DF	dual focus
DIMS	defocus incorporated multiple segments
DOT	diffusion optics technology
EE	enhancing efficacy
EV	enhancing vision
FrACT	Freiburg Acuity and Contrast Test
HAL	highly aspherical lenslets
HC	honeycomb configuration
ITT	intention-to-treat
LDA	low dose atropine
LLLT	low-level laser therapy
LSM	least-square mean
MTF	modulation transfer function
MTFa	MTF area
OK	orthokeratology
PP	per protocol
RL	red light
RLRL	repeated low-level red-light
SAL	slightly aspherical lenslets
SFChT	subfoveal choroidal thickness
SE	spherical equivalent
SER	spherical equivalent refraction (sphere plus half of cylinder)
SV	single vision
SVS	single vision spectacles
UCVA	uncorrected visual acuity
VA	visual acuity
VoMD	volume of myopic defocus
WTW	white-to-white corneal diameter

1. Contact Lenses

Myopia Control via CL

Aim

- quantify the effectiveness of MiSight daily disposable soft contact lens in slowing the progression of juvenile-onset myopia

Method

- 3-year, double-masked, randomized, multicentered clinical trial in four countries (PRT (n = 21), UK (n =28), SGP (n = 31), CAN (n = 64))
- Subjects: n=109 (start: 144, 75.5 % completed clinical trial); 55 % White, 23,5 % East Asian, 8 % West Asian; age: 8-12 years, spherical equivalent refraction (SER): −0.75 to −4.00 D; astigmatism: < 1.00 D, no prior contact lens experience
- 2 groups:
  - Test: MiSight 1-day contact lens, n = 53
  - Control: Proclear 1-day, n = 56
  - Both: soft CL, omalficon A material, identical lens overall geometry (CooperVision, Inc.)
- Measurements:
  - change in cycloplegic SER & axial length (AL)
  - follow-up visits at 1 week, 1 month, and 6, 18, 24, 30, and 36 months
  - questionnaires at each follow-up visit (comfort, vision, and overall satisfaction)

Results

- Unadjusted change in cycloplegic SER: −0.73 D (59 %) less at 36 months in the test group (0.40 D less at 12 months; 0.54 D less at 24 months) than in the control group (−0.51 ± 0.64 vs. −1.24 ± 0.61 D, P < 0.001)
- Mean change in AL: 0.32 mm (52%) less in the test group at 36 months (0.15 mm less growth at 12 months, 0.24 mm at 24 months) than in the control group (0.30 ± 0.27 vs. 0.62 ± 0.30 mm, P < .001)
- Changes in SER and AL were highly correlated (r = −0.90, P < .001 at 36 months; r = -0.77 at 12 months, r = -0.86 at 24 months)
- No difference between study groups in questionnaire about CL-insertion, -removal and satisfaction
- No difference in myopia progression as a function of ethnicity, interaction of lens type with ethnicity or lens type with site when assessing SER and AL progression was not significant

→ MiSight daily disposable soft contact lens are effective in slowing myopia progression by reducing the rate of axial growth (highest in first year but continued to accrue across the period of observation)

→ Similar findings in Ruiz-Pomeda et al. MiSight Assessment Study Spain (MASS). A 2-Year Randomized Clinical Trial. Graefes Arch Clin Exp Ophthalmol 2018;256:1011–21.

CLINICAL TRIALS

A 3-year Randomized Clinical Trial of MiSight Lenses for Myopia Control

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Author Information

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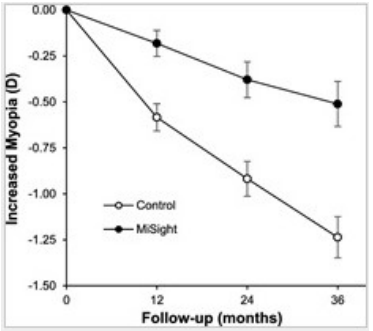

Fig. 01: Mean unadjusted changes in SER (D) for the test (MiSight) and control (Proclear 1-day) study groups. The mean unadjusted differences were 0.40 D less with MiSight at 12 months, 0.54 D less at 24 months, and 0.73 D less at 36 months.

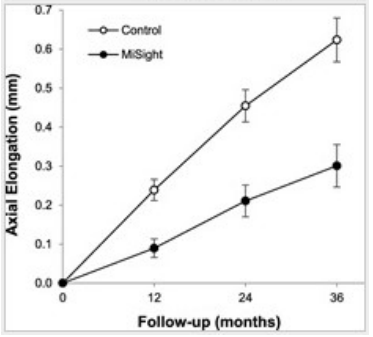

Fig. 02: Mean unadjusted changes in AL (mm) for the test (MiSight) and control (Proclear 1-day) study groups. The mean unadjusted differences were 0.15 mm less with MiSight at 12 months, 0.24 mm less at 24 months, and 0.32 mm less at 36 months.

Myopia Control via CL

Aim

- compare effects of higher add power (+2.50 D) vs. lower add power (+1.50 D) soft multifocal CL vs single vision (SV)-CL on myopia progression at 3 years in children aged 7 to 11 years with myopia

Method

- 3-year, double-masked randomized clinical trial
- Subjects: n = 287 (97.6 % of 294), American (26 % Hispanic or Latino, 68 % White), age: 7-11 years, SER: −0.75 D to −5.00 D, astigmatism: ≤ 1.00 D
- Groups:
  - High add power: soft Multifocal D CL with +2.50 D add power (Biofinity, CooperVision), n = 98
  - Medium add power: soft Multifocal D CL with +1.50 D add power (Biofinity, CooperVision), n = 98
  - SV-CL: (Biofinity, CooperVision), n = 98
- Measurements: cycloplegic spherical equivalent (SE) autorefraction (mean of 10 measurements), AL, visual acuity (VA)

Results

- Adjusted myopia progression: high add power: −0.60 D, medium add power: -0.89 D, SV: -1.05 D
  - → Statistically significant between high add and medium add power & high add power and SV-CL over 3 years
  - → Progress of ≥ -1.00 D: 16.8 % in high add power, 36.5 % in medium add power, 51.0 % in SV
- Adjusted AL growth: high add power: 0.42 mm, medium add power: 0.58 mm, SV: 0.66 mm
  - Progress of ≥ 0.36 mm: 47.4 % in high add power, 61.5 % in medium add power, 80.2 % in SV
- mean low-contrast logMAR distance VA statistically significantly better for SV group than for high add power (p = 0.04) and medium add power group (p = 0.01)

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Effect of High Add Power, Medium Add Power, or Single-Vision Contact Lenses on Myopia Progression in Children

The BLINK Randomized Clinical Trial

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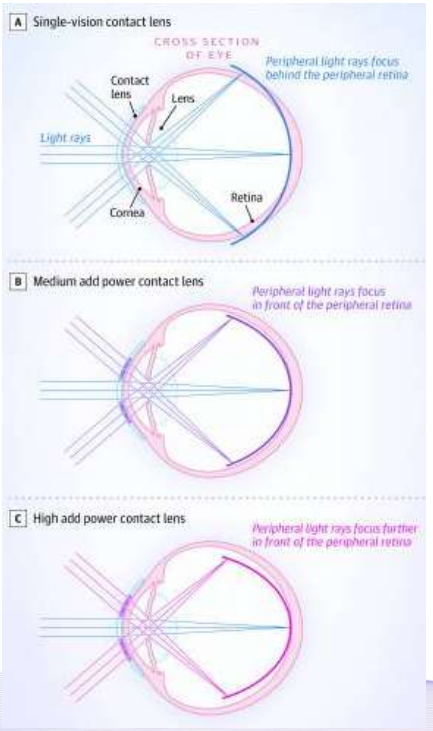

Fig. 03: Theoretical model: peripheral rays through the distance portion of the SV-CL focus behind the peripheral retina. The peripheral rays through the medium and high add portion of the multifocal CL focus in front of the retina, acting as a cue to slow myopia progression and eye growth. The high add focuses further in front of the retina than the medium add, potentially acting as a stronger signal to slow eye growth.

Myopia Control via CL

Aim

- evaluate efficacy and vision with 2 prototype myopia control soft CL with noncoaxial ring-focus designs (for enhancing efficacy [EE] and enhancing vision[EV]) compared with dual-focus (DF) and SV designs

Method

- Multicenter (CAN, CHN, US), prospective, randomized, controlled, double-masked clinical trial over 6 months
- Subjects: n = 185 (start: 199), 52% Asian, 43% White, age: 7-12 years, SER: -0.75 to -4.50 D
- Groups:
  - EE: soft prototype CL with multizone, concentric annulus, noncoaxial ring-focus design to enhance efficacy, n = 44
  - EV: soft prototype CL with multizone, concentric annulus, noncoaxial ring-focus design to enhance vision, n = 49
  - DF: soft standard DF design with +2.5 D coaxial plus power, n = 45
  - SV: soft control lens, n = 47
- Measurements: cycloplegic AL & SE autorefraction at baseline and AL without cycloplegia at baseline, 1, 4, 13, and 26 weeks

Results

- SE: only EE had statistically significantly less (−0.12 [0.27] D) progression of myopia than SV (−0.35 [0.33] D)
  - →least-square mean (LSM) difference: 0.22 D [0.09, 0.35, $p < 0.05$]
- AL:
  - EE, EV, and DF all had statistically significantly less elongation than SV after 26 weeks
    - LSM difference compared to SV → EE: −0.105 (−0.149, −0.062), EV: −0.063 (−0.106, −0.020), and DF: −0.056 (−0.100, −0.013)
  - EE had statistically significantly less axial elongation than DF (LSM:−0.049 mm [−0.093, −0.004], $p < 0.05$)
- EE and DF groups have similar reports of halos but more than EV and SV
- Asians associated with more axial elongation ($P < 0.0001$) and myopia progression ($P = 0.005$)

→ EE more efficacious in slowing axial elongation than DF with comparable vision performance

→ EV produced comparable efficacy to DF with similar vision performance to SV

Myopia Control via CL

Aim

- evaluate the effectiveness of multifocal CL in halting progression of myopia in children aged between 13 and 15 years in Kuala Lumpur
- compare the progression of myopia and axial elongation of children prescribed with two commercially available distance–center soft multifocal CL (Multistage +1.50D and Proclear +3.00D multifocal CL) to SV-CL
- outcome of these multifocal contact lenses on myopia progression and AL elongation over 18 months

Method

- experimental longitudinal, prospective, randomized, double-masked study over 18 months
- Subjects: n = 30 (start: 37), Malaysian, age: 13-15 years, SER: −2.00 to −6.00 D, astigmatism: ≤−1.00 D
- Groups:
  - Multistage +1.50 D: Multifocal CL (SEED, Japan), n = 11
  - Proclear +3.00 D: Multifocal CL (CooperVision, NY, USA), n = 9
  - SV-CL: control group (2-week Pure- SEED), n = 10
- Measurements: Cycloplegic refraction, corneal curvature (CC), AL

Results

- Myopia progression: significant difference between SV and Proclear +3.00 D group ($P < 0.001$) at 18 months, significant difference between Multistage +1.50 D and Proclear +3.00 D at 6,12,18 months ($P = 0.02$, $P = 0.05$, and $P = 0.41$), no significant difference between Multistage +1.50 D and SV ($P = 0.06$)
  - control: 38.6 % in Multistage + 1.50 D group and 66.6 % in Proclear +3.00 D group in comparison to SV
- AL reduction: 31.1 % in in Multistage + 1.50 D group and 63.2 % in Proclear +3.00 D group in comparison to SV
- No statistical significant difference in CC between baseline and last visits in all 3 groups (SV: $P = 0.90$; Multistage + 1.50: $P = 0.78$, and Proclear + 3.00: $P = 0.05$) → no impact on changing the CC, no flattening of the cornea

→ Proclear +3.00 D was revealed to cause slow development of myopia and axial elongation among myopic children

→ Multicocal CL with higher add powers could be more effective on myopia progression in comparison with moderate add powers

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PMCID: PMC9266467 | PMID: 35814985

Myopia control with soft multifocal contact lenses: 18-month follow-up

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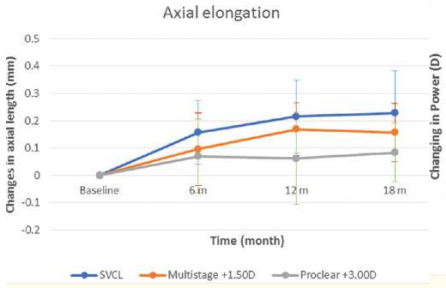

Fig. 04: Relative axial elongation changes during 6-, 12-, and 18-month follow-up visits for myopic children.

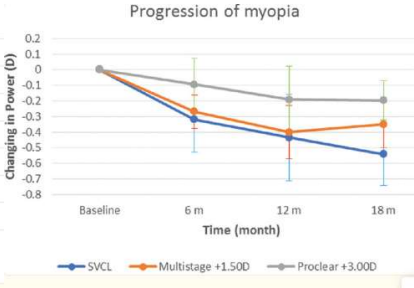

Fig. 05: Relative myopia progression changes during 6-, 12-, and 18-month follow-up visits for myopic schoolchildren.

2. Orthokeratology

Myopia Control via Orthokeratology

Aim

- investigate long-term ocular clinical safety and myopia control efficacy of an orthokeratology (OK) lens in Chinese school-aged children relative to SV spectacle lens treatment
- Monitor tear proteome using SWATH-MS quantitation for an up to 1-year period after start of lens wear

Method

- 2-year randomized, parallel-group, single-blind clinical trial combining clinical and tear proteomics data
- Subjects: n = 71 (start: 91), Chinese, age: 8-12 years, SER: −1.00 to −4.00 D, astigmatism half of SER
- Groups:
  - OK: n = 43, Breath-O-Correct OK lens
  - SV: n = 28, spectacle lens treatment
- Measurements: AL, cycloplegic SE, quantitative tear proteomics via tear samples (Schirmer's strip) at 6-months intervals

Results

- Mean AL elongations significant: OK: 0.37 ± 0.37 mm, SV: 0.60 ± 0.41 mm (p = 0.03) at 24-months
- OK-mediated myopia control efficacy was 52.3 % at 12-months & 37.1 % at 24-months
- Only one significant difference in clinical safety parameters of both groups: thinner central corneal thickness in the OK group (p = 0.01)
- Proteomics: modest OK lens-mediated effects on immune response proteins
  - increased abundance of haptoglobin at 6 and 12 months
  - decreased abundance of two proteins (neutrophil defensin 3 and histone 4) at 6 months

J Clin Med. 2023 May; 12(9): 3210. Published online 2023 Apr 29. doi: 10.3390/jcm12093210

PMCID: PMC10179394 | PMID: 37176650

Myopia Control Efficacy and Long-Term Safety of a Novel Orthokeratology Lens (MESOK Study)—A Randomized Controlled Clinical Trial Combining Clinical and Tear Proteomics Data

Kai Yip Choi,[1,†] Jimmy K. W. Cheung,[2,†] Gigi T. K. Wong,[1] Peter H. Li,[2] Sonia S. H. Chan,[1] Thomas C. Lam,[1,2,3,*] and Henry H. L. Chan[1,2,3,*]

Paulo Fernandes, Academic Editor and Andrzej Grzybowski, Academic Editor

Myopia Control via Ortho-K

Aim

- investigate efficacy of myopia control defined by axial elongation & safety of OK lenses in a Scandinavian (Danish) population over 18 months

Method

- 18-months randomized clinical trial
- Subjects: n = 47 (start: 60), Danish, age: 6-12 years, SER: 0.5 to 4.75 D, astigmatism: ≤ 2.5 D
- Groups:
  - OK: n = 19 (30), Dreamlite® (Procornea, LZ Eerbeek, NL)
  - SV: n = 28 (30), SV spectacles
- Measurements: AL every 6 months

Results

- no fast progressors (> 0.75 D/year) in the OK group during the follow-up period in contrast to 22 % in the SV group
- average AL elongation in the OK group was 0.24 mm smaller as compared to the SV group
- OK lenses reduced AL elongation in myopic Scandinavian children by 59 %, with no treatment-requiring or vision-threatening adverse events
- 30 % dropout in OK factors: time from referral to baseline < 75 days, handout during dark season (Nov. – March)

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Original Article | Open Access

Control of myopia using orthokeratology lenses in Scandinavian children aged 6 to 12 years. Eighteen-month data from the Danish Randomized Study: Clinical study Of Near-sightedness; TReatment with Orthokeratology Lenses (CONTROL study)

Trine Moldrup Jakobsen | Flemming Møller

First published: 07 July 2021
https://doi.org/10.1111/aos.14911

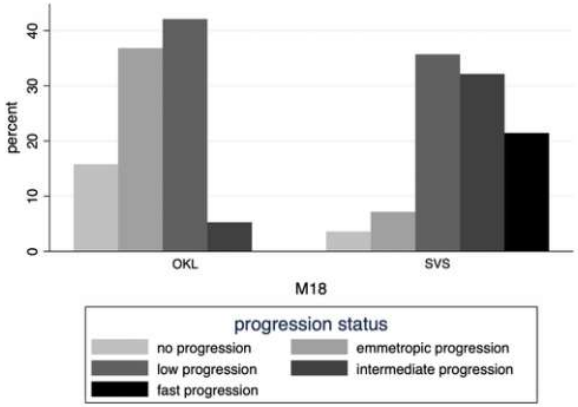

Fig. 06: Progression status at 18-month follow-up for OK and SV groups. No progression: ≤0 mm; emmetropic progression (0 D/year): >0–0.22 mm; low progression (<0.5 D/year): >0.22-0.41 mm; intermediate progression (>0.5 < 0.75D/year): >0.41-0.62 mm; fast progression (>0.75D/year): >0.62 mm.

Quality of life with Orthokeratology

Aim

- assess the satisfaction, compliance, and side effects among long-term OK users in Taiwan and analyze side effects and related risk factors

Methods

- Multiple-index questionnaire about background information, wear and care behaviors, daily activities, satisfaction, and related concerns, comparison with clinical data (refractive data, side effects), guardians helped children with some answers (e.g. time for near-work) and answered questions about reasons & concerns for using OK, 5-point frequency/ severity scale for each symptom in the last 6 months
- Subjects: n = 305, East Asian, age: 6-18 years (average: 13.13 ± 3.39 years), average wearing period: 17.1 ± 8.1 months, all lenses were fitted by the same practitioner

Results

- Children:
  - Over 83 % had clear daytime vision all day
  - 66 % say it is easy or very easy to wear the lenses
  - around 88 % felt satisfied or very satisfied with the results
  - 98 % exhibited a willingness to continue wearing the Ortho-K lenses
  - Leading side effects within the previous 6 months: lens binding (34.8 %), lens decentration (15.4 %), and punctate keratitis (7.9 %)
  - Leading discomfort symptoms within the previous 6 months: secretion (37 %), lens binding (35 %), and itching (32 %) → severity: mild (1.46 – 1.95 of 5)
  - The regular follow-up rate decreased from 97 % in primary school users to 77 % in senior high school users
- Guardians:
  - 83 % were pleased with the controlling effect of myopic progression
  - 65 % think the lenses were a little expensive
  - main reasons for using Ortho-K: effectiveness (95 %), safety (73 %), and practicality (65 %)
  - major concerns: discomfort (86 %), harmful to the eyes (80 %), and no effect (76 %)
- Comparison with clinical data:
  - Initial SE and regular cleaning of the lens protein significantly correlated with clear day vision ($p < 0.001$ and 0.038, respectively)
  - Wearing Ortho-k > 6 days/week correlated with less risk of lens binding compared with wearing them ≤ 5 days/week ($p = 0.044$)

→ High degree of satisfaction with OK use

→ A comprehensive care program could improve compliance among Ortho-K users (parental compliance with scheduled follow-up visits may correlate with whether they were informed of AL changes during the consultation)

Assessment of Satisfaction, Compliance and Side Effects among Long-Term Orthokeratology Wearers

by Shang-Yen Wu [1], Jen-Hung Wang [2] and Cheng-Jen Chiu [1,3,*]

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3. Atropine eye drops

Myopia Control via atropine

Aim

- evaluate efficacy and safety of 0.01 % atropine eye drops in controlling myopia progression over 5 years

Method

- Experimental, analytical, prospective, randomized, and longitudinal study over 5 years
- Subjects: n = 361 right eyes, Spanish, age: 6.68 ± 1.93 years, SE -1.00 to -4.00 D, astigmatism ≤ 1.50 D, myopia increase of 0.50 D in the 6 months before the start of the study
- Groups:
  - Control group: n = 177, no treatment, no placebo
  - Treatment group: n = 184, 0.01 % atropine eye drops once a day
- Measurements: cycloplegic SER, AL, keratometry, anterior chamber depth (ACD), anterior & posterior pole examination, follow-up every 6 months

Results

- Treatment group: SER increased −0.63 ± 0.42 D, AL 0.26 ± 0.28 mm after 5 years
- Control group: SER increased −0.92 ± 0.56 D, AL 0.49 ± 0.34 mm after 5 years
- ACD and keratometry: insignificant changes between groups
- No side effects

→ efficacy was 31.5 % ($p < 0.001$) regarding SER and 46.9 % ($p < 0.001$) regarding AL after 5 years

Clinical science

Five-year results of atropine 0.01% efficacy in the myopia control in a European population

Manuel Moriche-Carretero,[1,2] Remedios Revilla-Amores,[1] Ana Gutiérrez-Blanco,[3] Francisco Javier Moreno-Morillo,[1] Clara Martinez-Perez,[4] Miguel Ángel Sánchez-Tena ,[4,5] Cristina Alvarez-Peregrina [5]

Myopia Control via atropine

Aim

- compare the efficacy of continued and stopping treatment for atropine eye drops at 0.05 %, 0.025 %, and 0.01 % during the third year
- Evaluate efficacy of continued treatment over 3 years
- investigate the rebound phenomenon and its determinants after stopping treatment

Method

- Randomized, double-masked, extended trial over 3 years
- Subjects: n = 326 (start year 1: 438, start year 3: 350),Chinese, age: 4-12 years at beginning, SE ≥ -1.0 D, astigmatism ≤ -2.5 D
- Groups:
  - 0.05 % atropine: n = 90
  - 0.025 % atropine: n = 78
  - 0.01 % atropine: n = 86

  Each divided in half into continue and washout group
  - Control: : 1st year placebo eyedrop, 2nd year switch to 0.05 % atropine, n = 72
- Measurements: cycloplegic SER, AL at 4-months intervals

Results

- During the third year, continued atropine treatment achieved a better effect across all concentrations compared with the washout regimen → less SE progression & AL elongation in continued treatment
- rebound SE progressions during washout were concentration dependent, but their differences were clinically small (P = 0.15)
- Older age and lower concentration associated with smaller rebound effects in both SE progression (P < 0.001) and AL elongation (P < 0.001)
- 0.05% atropine remained the optimal concentration over 3 years in Chinese children

Three-Year Clinical Trial of Low-Concentration Atropine for Myopia Progression (LAMP) Study: Continued Versus Washout

Phase 3 Report

Jason C. Yam, FCOphthHK, FRCSEd(Edin) • Xiu Juan Zhang, PhD • Yuzhou Zhang, MSc •

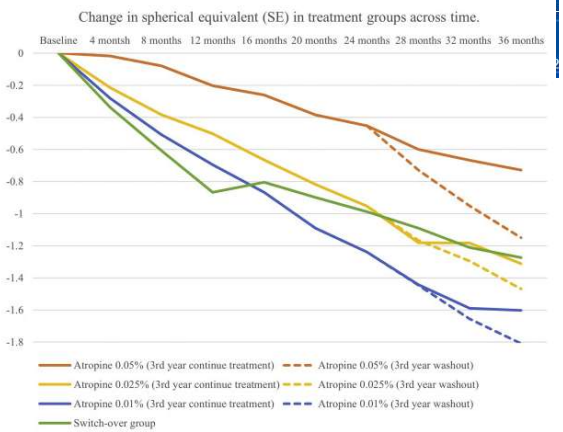


Fig. 07: Changes in spherical equivalent (SE) progression for treatment groups over time.

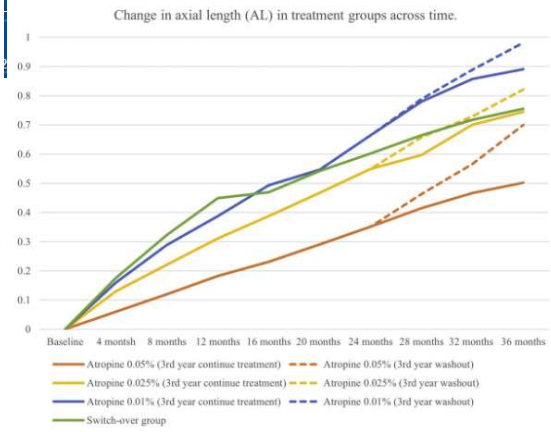


Fig. 08: Changes in axial length elongation for treatment groups over time.

Table 01: Change in ophthalmic parameters over 3 years in the atropine groups.

	0.05% Atropine (n=90)		0.025% Atropine (n=78)		0.01% Atropine (n=86)		P values
	Continue	Washout	Continue	Washout	Continue	Washout	
SE change over 3 years [D]	–0.73 ± 1.04	–1.15 ± 1.13	–1.31 ± 0.92	–1.47 ± 0.77	–1.60 ± 1.32	–1.81 ± 1.10	**Continue: 0.001** **Washout: 0.03**
SE change in year 3 [D]	–0.28 ± 0.42	–0.68 ± 0.49	–0.35 ± 0.37	–0.57 ± 0.38	0.38 ± 0.49	–0.56 ± 0.40	Continue: 0.65 Washout: 0.15
AL change over 3 years [mm]	0.50 ± 0.40	0.70 ± 0.47	0.74 ± 0.41	0.82 ± 0.37	0.89 ± 0.53	0.98 ± 0.48	**Continue: <0.001** **Washout: 0.04**
AL change in year 3 [mm]	0.17 ± 0.14	0.33 ± 0.17	0.20 ± 0.15	0.29 ± 0.14	0.24 ± 0.18	0.29 ± 0.15	Continue: 0.19 **Washout: 0.003**

Myopia Control via atropine

Aim

- investigate the effect of age at treatment and other factors on treatment response to atropine in the 2-year LAMP Study (previous slide)

Method

- Secondary analysis from a 2-year, randomized, double-masked controlled trial
- Subjects: n = 350 (79,9 % of 438), Chinese, age: 4-12 years, SER ≥ 1.0 D, astigmatism ≤ -2.5 D, myopic progression of ≥ 0.5 D in past year
- Groups (stratified by age 4-6, 7-9, 10-12 years):
  - 0.05 % atropine: n = 93
  - 0.025 % atropine: n = 86
  - 0.01 % atropine: n = 91
  - Switch-over: 1st year placebo eyedrop, 2nd year switch to 0.05 % atropine group, n = 80
- Evaluation of potential predictive factors in SE and AL: age at treatment, gender, baseline refraction, parental myopia, time outdoors, diopter hours of near work, and treatment compliance

Results

- In 0.05 %, 0.025 %, and 0.01 % atropine groups, younger age was the only factor associated with SE progression and AL elongation over 2 years, other factors e.g. parental myopia had no effects
  - For each year of younger age, mean change of SE at 2 years was 0.14 D larger (i.e., more myopic) in 0.05 % group, 0.15 D larger in 0.025 % group, and 0.20 D larger in 0.01 % group over 2 years
  - For each year of younger age, mean change of AL was -0.10 larger in 0.05 % group, -0.11 in 0.025 % group, and -0.12 in 0.01 % group

  → the younger the age, the poorer the efficacy
- At each year of age from 4 to 12 years across the treatment groups, higher-concentration atropine showed a better treatment response, following a concentration-dependent effect (P < 0.05 for each age group)

  → Younger children required the highest 0.05% concentration (6 years, -0.90 D) to achieve similar reduction in myopic progression as older children with lower concentrations (8 years, 0.025% atropine, -0.89 D; 10 years, 0.01 % atropine, -0.92 D)

AMERICAN ACADEMY OF OPHTHALMOLOGY

Age Effect on Treatment Responses to 0.05%, 0.025%, and 0.01% Atropine

Low-Concentration Atropine for Myopia Progression Study

Fen Fen Li, PhD,[1] Yuzhou Zhang, MSc,[1] Xiujuan Zhang, PhD,[1] Benjamin Hon Kei Yip, PhD,[2] Shu Min Tang, PhD,[1,3] Ka Wai Kam, FCOphthHK, FHKAM(Ophthalmology),[1,4] Alvin L. Young, FRCSI,[1,4] Li Jia Chen, FCOphthHK, PhD,[1,4,5] Clement C. Tham, FCOphthHK, FRCOphth,[1,4,5,6] Chi Pui Pang, DPhil,[1,6] Jason C. Yam, FCOphthHK, FRCS(Edin)[1,4,5,6,7]

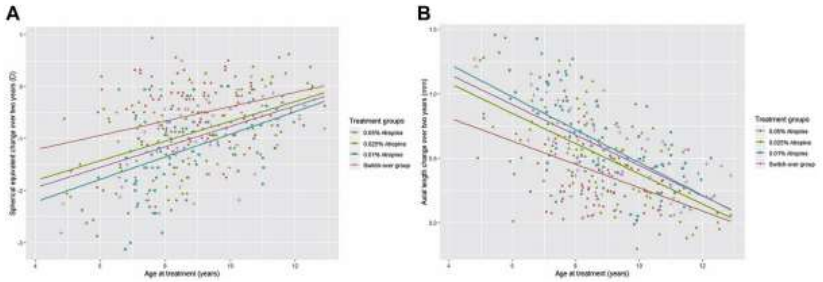


Fig. 09: Scatterplot showing A. change in SE and B. change in AL over 2 years with age in the 0.05 %, 0.025 %, and 0.01 % atropine groups and the switch-over group (placebo group during the first year, which was switched over to the 0.05 % atropine group at the beginning of the second year).

Quality of life with atropine

Aim

- evaluate the influence of low dose atropine (LDA) myopia control on the quality of life in patients with myopia
- Assess the clinical symptoms (photophobia and difficulties with near work) and psyche of adolescent patients with regard to their functioning in the peer group

Methods

- self-constructed questionnaire (8 questions, collected separately for boys and girls) given after 1 year of 0.01 % atropine application, divided into 2 subsections:
  - influence of LDA on visual functions
  - influence of LDA on self-esteem
- Subjects: boys: n = 18, girls: n = 22 (all n = 40), age: boys: median: 12.5 years, range: 9–15 years; girls: median: 13.5 years, range: 10–16 years
- Evaluation: questions rated between 1-10 points (1: no problems/ most satisfied, 10: many problems, no satisfaction), comparison of the responses considering the SE and myopia progression rate, measurement of cycloplegic autorefraction, best-corrected visual acuity (BCVA) and AL

Results

- Ophthalmological: all BCVA: 0.00 logMAR or better, median SE: boys: −2.88 (−12.25 to −1.50) D, girls: −3.12 (−8.5 to −1.25) D
- Girls:
  - reported more issues with near activities (but median values equal for both groups, only a few significant problems were reported) and pupil size (suggested that appearance is more important to them than to boys)
  - with lower progression rates reported more issues with near work, sun glare and less trust in LDA therapy's effectiveness than girls with a higher progression rate
  - recommended LDA therapy more often than boys, especially when the progression rate was low (despite their complaints), talking about refractive error and its ongoing therapy may improve adolescents' position among friends
- Boys:
  - no statistically significant difference in answer scores between groups with different myopia progression rates ≥ −0.25 D/year and −0.50/year
- Boys and girls:
  - complained regarding the sun glare
  - high level of certainty about the efficacy of LDA therapy
  - little improvement in self-esteem
  - no statistically significant correlation between SE and the total answer score (boys: r = −0.98; p = 0.696, girls: r = 0.257; p = 0.248), but results suggest that boys are less concerned about LDA when SE is less myopic and girls tend to have the opposite reaction
    - → boys more concerned about refractive error value, don't complain when myopia is low
    - → Girls accept eventual LDA side effects when refractive error is high, otherwise they tend to complain more
- → no reports of significant problems caused by LDA therapy during pharmacological myopia control
- → Children & adolescents were convinced about LDA efficacy, had greater self-esteem, and (especially girls) recommended it to peers
- → Positive impact of LDA on subject's psyche is an important factor that should favor early initiation in subjects with nearsightedness progression

J Clin Med. 2020 Dec; 9(12): 3920. Published online 2020 Dec 3.
doi: 10.3390/jcm9123920

PMCID: PMC7761740 | PMID: 33287174

Pharmacological Myopia Control Influence on Quality of Life and Psyche among Adolescents

Andrzej Michalski,[1,*] Małgorzata Rogaczewska,[1] Magdalena Maleszka-Kurpiel,[2,3] and Marcin Stopa[1]

4. Red-light therapy

Myopia Control via red light

Aim

- assess the efficacy and safety of repeated low-level red-light (RLRL) therapy in myopia control in children

Methods

- Prospective, multicenter, randomized, parallel-group, single-blind clinical trial over 12 months
- Subjects: n = 246 (93.2% of 264), Chinese, age: 8-13 years, SER: –1.00 to –5.00 D, ast.: ≤ 2.50 D, anisometropia: ≤ 1.50D, BCVA: 0.0 logMAR or more
- Groups:
  - RLRL: RLRL treatment (desktop light therapy device (Eyerising, Suzhou Xuanjia Optoelectronics Technology), emits red light (RL) of 650 nm wavelength, illuminance level of approx. 1600 lux, power of 0.29 mW for a 4 mm pupil (class I classification)) in 3 min sessions, twice daily with minimum interval of 4h, 5 days/week (automated diary function recorded date & time of sessions) + single vision spectacles (SVS), n = 117
  - SV: control group, SVS, n = 129
- Measurements: AL, cyclopegic SER (autorefractor), ACD, CC, and white-to-white (WTW) corneal diameter and choroidal thickness (optional, RLRL: n = 72; SV: n = 90) at 1-, 3-, 6-, and 12-month follow-up visits

Results (of right eyes):

- Adjusted axial elongation: RLRL: 0.13 mm, SV: 0.38 mm → difference: 0.26 mm (95 % CI, 0.20–0.31 mm) → 69.4 % reduction
- Significant AL shortening of > 0.05 mm of 39.8 % in RLRL group after 1 month, 29.2 % at 3 months, 32.9 % at 6 months, and 21.6 % at 12 months
- Adjusted SER progression: RLRL: –0.20 D, SV: –0.79 D → diff.: –0.59D (95 % CI, –0.72 to –0.46 D) → 76.6 % reduction
- SER regression (worsened myopia of > 0.25 D) in RLRL group were 15.1 %, 17.9 %, 15.8 %, and 18.9 % at the 1-, 3-, 6-, and 12-month follow-up visits, respectively
- UCVA improved by at least 2 lines: significantly greater in RLRL than in SV group (21.8 % vs. 7.9 %; P < 0.001)
- Mean change in choroidal thickness: RLRL: 12.1 µm (95% CI, 6.1–18.1 µm), SV: –9.5 µm (95 % CI, –15.6 to –3.5 µm)
- Similar changes in RLRL and SV group in ocular biometric parameters (ACD, CC, and WTW corneal diameter)
- No adverse events (sudden vision loss ≥ 2 lines or scotoma), functional visual loss, structural damage on OCT scans
- Median treatment compliance in the RLRL group was 75 %; improvements in treatment compliance from < 50 % to > 75 %, efficacy increased from 44.6 % to 76.8 % in reducing axial elongation and from 41.7 % to 87.7 % in controlling SER progression
  → significant association between treatment compliance and myopia progression

doi: 10.1016/j.ophtha.2021.11.023. Epub 2021 Dec 1.

Effect of Repeated Low-Level Red-Light Therapy for Myopia Control in Children: A Multicenter Randomized Controlled Trial

Yu Jiang [1], Zhuoting Zhu [1], Xingping Tan [2], Xiangbin Kong [3], Hui Zhong [4], Jian Zhang [1], Ruilin Xiong [1], Yixiong Yuan [1], Junwen Zeng [5], Ian G Morgan [6], Mingguang He [7]

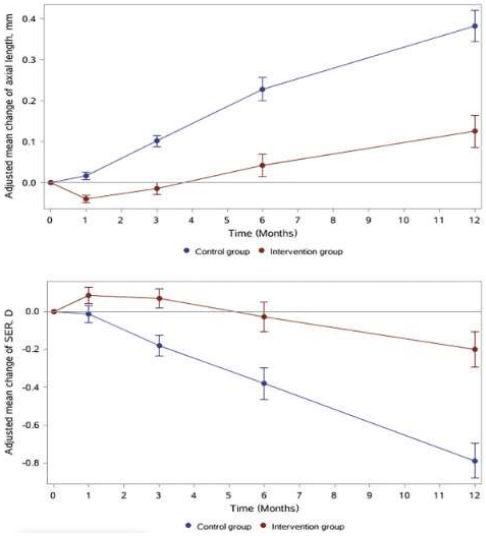


Fig. 10: adjusted mean changes in (A) AL and (B) cycloplegic SER from baseline to 12 months at each time point between the RLRL group and SV spectacle group.

Myopia Control via red light

Aim

- evaluate the long-term efficacy and safety of continued repeated RLRL therapy on myopia control over 2 years, and the potential rebound effect after treatment cessation

Methods

- Follow-up of a 12-month RCT study (previous slide)
- Subjects: n = 114 (57.3 % of starting original study (n = 199); n = 138 (69.3 %) started this follow-up), Chinese, age: 8-13 years, SER: -1.00 to -5.00 D, astigmatism: ≤ 2.5D, anisometropia ≤ 1.50D, BCVA: 0 logMAR
- Groups:
  - RLRL-RLRL: continued RLRL-therapy, n = 11
  - RLRL-SVS: stopped RLRL and switched to SV spectacles in the second year, n = 52
  - SVS-RLRL: started additional RLRL therapy, n = 10
  - SVS-SVS: continued wearing SV spectacles, n = 41
- Measurements: AL, cycloplegic SER, ACD, CC, Choroidal thickness

Results (of right eyes):

- 2nd year AL mean changes: SVS-SVS: 0.28 ± 0.14 mm, SVS-RLRL: 0.05 ± 0.24 mm, RLRL-SVS: 0.42 ± 0.20 mm and RLRL-RLRL: 0.12 ± 0.16 mm ($p < 0.001$) → significant reduction in SVS-RLRL compared to SVS-SVS group ($p = 0.005$)
- 2nd year SER mean changes: SVS-SVS: −0.54 ± 0.39 D, SVS-RLRL: −0.09 ± 0.55 D, RLRL-SVS: −0.91 ± 0.48 D, and and RLRL-RLRL: −0.20 ± 0.56 D ($p < 0.001$)
- Comparison between 1st year and 2nd year
  - → AL and SER significantly decreased for the SVS-RLRL group (axial elongation: $p = 0.002$, SER progression: $p = 0.014$)
  - → AL and SER significantly increased after cessation of RLRL treatment in 2nd year (all $p < 0.001$)
- 2-year period changes: smallest in RLRL-RLRL group (AL: 0.16 ± 0.37 mm; SER: −0.31 ± 0.79 D), followed by SVS-RLRL (AL: 0.44 ± 0.37 mm; SER: −0.96 ± 0.70 D), RLRL-SVS (AL: 0.50 ± 0.28 mm; SER: −1.07 ± 0.69 D) and SVS-SVS group (AL: 0.64 ± 0.29 mm; SER: −1.24 ± 0.63 D)
  - → efficacy of myopia control regarding axial elongation relative to SVS-SVS group: 75.0 % in RLRL-RLRL, 31.3 % in SVS-RLRL and 21.9 % in RLRL-SVS group
  - → efficacy of myopia control regarding SER progression relative to SVS-SVS group: 75.0 % in RLRL-RLRL, 22.6 % in SVS-RLRL and 13.7 % in RLRL-SVS group
- Choroidal thickness: improvements during 2nd year in SVS-RLRL (8.25 ± 25.01 µm) and RLRL-RLRL (12.34 ± 18.78 µm), reductions in RLRL-SVS (−18.23 ± 23.14 µm) and SVS-SVS (−7.46 ± 14.78 µm) groups
  - increased over the 2 years on average by 21.49 ± 36.21 µm in RLRL-RLRL, while thinning was noted in the other three groups

→ Continued RLRL therapy sustained promising efficacy (75 %) and safety in slowing myopia progression over 2 years

→ 2nd year progression in SVS-RLRL (AL: 0.05 mm, SER: −0.09 D) similar to 1st year progression in RLRL-RLRL (AL: 0.04 mm, SER: −0.11 D) and RLRL-SVS (AL: 0.08 mm, SER: −0.19 D) groups

→ modest rebound effect was noted after RLRL treatment cessation

› Clin Exp Ophthalmol. 2022 Dec;50(9):1013-1024. doi: 10.1111/ceo.14149. Epub 2022 Sep 7.

Sustained and rebound effect of repeated low-level red-light therapy on myopia control: A 2-year post-trial follow-up study

Ruilin Xiong [1], Zhuoting Zhu [1 2 3], Yu Jiang [1], Xiangbin Kong [4], Jian Zhang [1], Wei Wang [1], Katerina Kiburg [2], Yixiong Yuan [1], Yanping Chen [1], Shiran Zhang [1], Meng Xuan [1], Junwen Zeng [1], Ian G Morgan [5], Mingguang He [1 2 3]

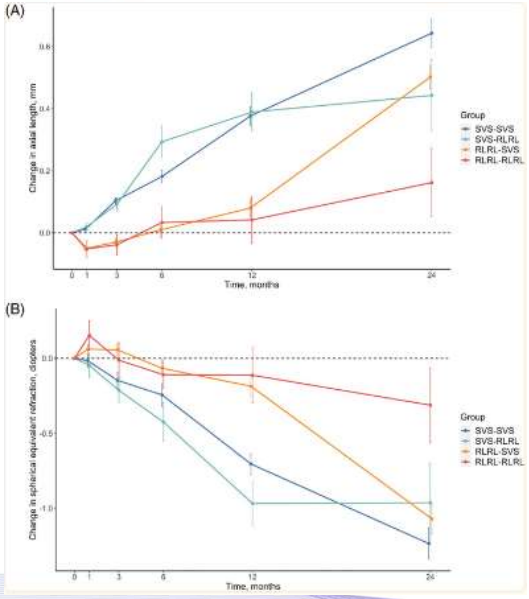


Fig. 11: Mean changes in AL and cycloplegic SER from baseline to 24 months. (A) For axial elongation; (B) for myopia progression.

Myopia Control via red light

Aim

- assess the efficacy and safety of RLRL intervention in preventing incident myopia among children with premyopia

Methods

- parallel-group, multicenter, school-based randomized (by grade) clinical trial over 12 months (masked outcome assessors and statisticians)
- Subjects: n = 248 (89.2 % of 278), Chinese, age: 6-11 years, SER: −0.50 to 0.50 D (premyopia) in the more myopic eye, ast. and anisometropia: ≤1.50 D, have at least 1 parent with SER ≤−3.00 D
- Groups:
  - RLRL: 3 min sessions, twice daily with minimum interval of 4h, 5 days/week (650 nm desktop device (Eyerising, Suzhou Xuanjia Optoelectronics Technology)), n = 126
  - Control group, n = 122
  - Subdivided into intention-to-treat (participants in both groups at baseline) and per-protocol (participants in control group and those in RLRL group who were able to continue the treatment without interruption by the COVID-19 pandemic(n = 32))
- Measurements: cycloplegic SER, AL, uncorrected visual acuity (UCVA), BCVA, OCT scans and choroidal thickness at baseline, 3-, 6-, 9-, and 12-month follow-ups (half of both groups did not attend the 9-month follow-up due to COVID-19)

Results

- 12-month incidence of myopia
  - 40.8 % (49 of 120) in RLRL group and 61.3 % (68 of 111) in the control group → mean difference 20.4 % (p = 0.003) → relative 33.4 % reduction in incidence
  - 28.1 % (9 of 32) in per-protocol group (continued treatment) in RLRL group → mean difference 33.2 % → relative 54.1 % reduction in incidence
- Significant reduction of myopic shifts in SER and AL in RLRL group compared to control group
  - Mean AL: RLRL: 0.30 [0.27] mm vs. control: 0.47 [0.25] mm → difference: 0.17 mm [95 % CI, 0.11-0.23 mm, P < .001] → 36.2 % reduction in AL changes
    → per-protocol group: 0.24 mm → 48.9 % efficacy in lowing AL compared to control group
  - Mean SER: RLRL: –0.35 [0.54] D vs. control: –0.76 [0.60] D → difference:, –0.41 D [95 % CI, –0.56 to –0.26 D, P < .001] →53.9 % reduction in SER shift
    → per protocol group: -0.18 D → 73.6 % efficacy achieved in slowing SER compared to control group
- UCVA decreased by at least 2 lines: significantly greater in control (32 %) than in RLRL (17.5 %) group
- Mean change in choroidal thickness: RLRL: 3.0 µm, control group: -9.2 µm (p = 0.001)
- No VA or structural damage noted on OCT scans
- Better efficacy observed among children with SER of 0.01 to 0.50 D than among those with an SER of −0.50 to 0.00 D (relative efficacy: 64.0 % vs. 14.0 %; SER changes: 69.0 % vs 39.8 %; AL changes: 45.7 % vs 23.4 %), no significant differences in different age groups

→ efficacy of a 33.4% to 54.1% relative reduction in incidence if myopia should be interpreted carefully due to decreased outdoor time during COVID-19

→ prophylactic effect was much lower in subjects with SER very close to -0.50 D (cutoff for myopia) because the intervention was introduced too late

Effect of Repeated Low-level Red Light on Myopia Prevention Among Children in China With Premyopia

A Randomized Clinical Trial

Xiangui He, PhD[1,2]; Jingjing Wang, PhD[1]; Zhuoting Zhu, PhD[3,4,5]; et al

» Author Affiliations | Article Information

JAMA Netw Open. 2023;6(4):e239612. doi:10.1001/jamanetworkopen.2023.9612

Myopia Control via red light & ortho-k

Aim

- verify the hypothesis that low-level laser therapy (LLLT) treatment could control myopia progression
- comparing the abilities of OK lenses and LLLT to control the progression of myopia

Methods

- Clinical 6-month follow-up
- Subjects: n = 229 (start: 300), Chinese, age: 6-16 years, SER: ≤ −0.50 D, noncontact intraocular pressure: 10 to 21 mmHg
- Groups:
  - OK: at least 7h every night (Euclid Systems Ortho-k, USA), n = 81
  - LLLT: 3 min sessions, twice daily with minimum interval of 4h (power: 2 ± 0.5 mW; wavelength: 650 nm; Ya Kun Optoelectronic Co., Ltd., Wuhan, China) + SVS, n = 74
  - SVS: control group, n = 74
- Measurements: SER, AL, subfoveal choroidal thickness (SFChT) at 1,3 and 6 months

Results

- SER changes: SVS: -0.50 ± 0.24 D, LLLT: 0.21 ± 0.34 D → significantly more myopic in SVS group
- AL changes: SVS: 0.23 ± 0.06 mm, OK: 0.06 ± 0.15 mm, LLLT: −0.06 ± 0.15 mm → significantly shorter AL in LLLT
  - Increases significantly associated with age at LLLT at 6 months ($p < 0.001$)
  - Changes significantly correlated with baseline SER in OK ($p = 0.007$) and LLLT ($p = 0.006$) groups
- SFChT changes: SVS: −16.84 ± 7.85 µm, OK: 14.98 ± 22.50 µm, LLLT: 35.30 ± 31.75 µm → In LLLT and OK group significantly thicker compared to SVS
  - Increases positively associated with age at enrolment in OK group at 6 months ($p = 0.022$)

→ Axial elongation decelerated in OK and LLLT group at 6 months, better myopia control in LLLT group

› Biomed Res Int. 2021 Jan 27:2021:8915867. doi: 10.1155/2021/8915867. eCollection 2021.

Orthokeratology and Low-Intensity Laser Therapy for Slowing the Progression of Myopia in Children

Fen Xiong [1], Tian Mao [1], Hongfei Liao [1], Xiaoqin Hu [1], Lei Shang [1], Li Yu [1], Nana Lin [1], Liang Huang [1], Yunmin Yi [1], Rui Zhou [1], Xueyun Zhou [1], Jinglin Yi [1]

5. DIMS

Functionality of DIMS

- Myopic defocus on retina (focus in front of retina) induced by plus lenses reduces eye length growth
- A) uncorrected myopia (image plane is in the center in front of the retina)
- B) Correction with minus lens: shift of the focal plane or image plane of distant objects in the center into the macula, but in the perifoveal and peripheral retinal sections the focal plane then remains behind the retina → hyperopic defocus (increased eye length growth)
- C) DIMS: central area of the image plane is in the retina & small DIMS lenses create additional individual focal points in front of the retina (no second contiguous image plane) → Systematic myopic defocusing in the periphery can slow down length growth & effectively prevent myopia progression

OPEN ACCESS 08.07.2021 | Atropin | Das diagnostische und therapeutische Prinzip

Myopietherapie und Prophylaxe mit „Defocus Incorporated Multiple Segments“-Brillengläsern

verfasst von: Dr. med. Hakan Kaymak, Birte Graff, Kai Neller, Achim Langenbucher, Berthold Seitz, Hartmut Schwahn

Erschienen in: Die Ophthalmologie | Ausgabe 12/2021

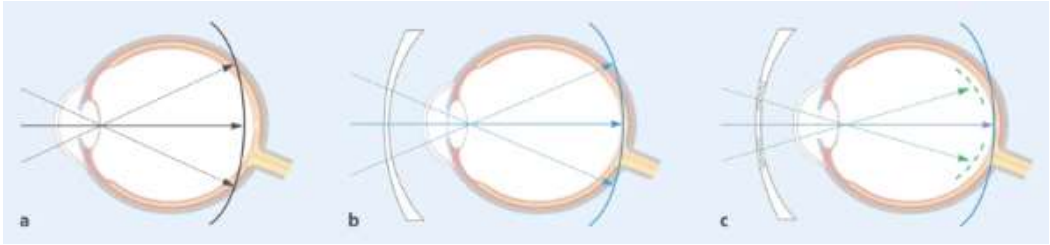


Fig. 12: myopic defocus in a) uncorrected myopia b) with minus lens and c) with DIMS.

Myopia Control via DIMS

Aim:

- Investigation of effectiveness of DIMS spectacle lens in controlling the progression of myopia in Chinese children
- Comparison of the changes in progression of myopia and axial length between DIMS group and SV group over a period of two years

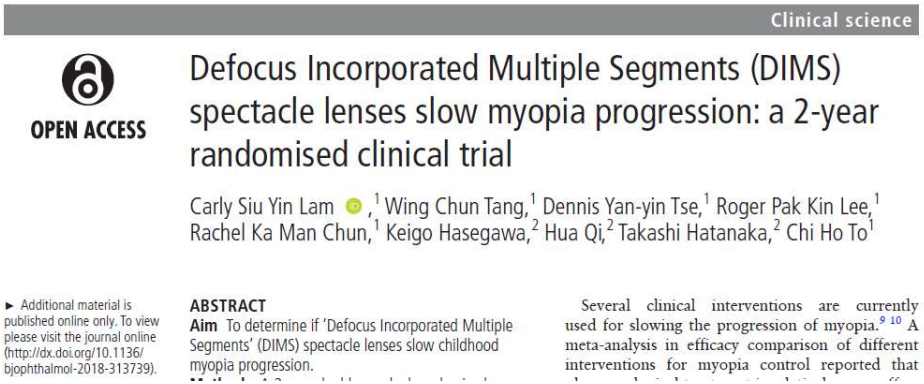
Methods

- Subjects: n = 160 (87 % of 183), Chinese, age: 8-13 years, SER: -1.00 to -5.00 D, astigmatism & anisometropia ≤ 1.50 D
- 2-year double-masked randomized controlled trial
- Groups:
  - DIMS: Hoya MiYOSMART, n = 93
  - SV: n = 90
- Measurements: SER and AL at baseline + every 6 months → lens replacement at SER change of more than 0.50 D, only right eyes used for analysis
- DIMS lens design: central optical zone (⌀ 9 mm), surrounded by multiple focal zones (⌀ 33 mm) with ~400 defocus segments of +3.50 D (segment- ⌀: 1.03 mm)

Results

- Average myopic progression over 2 years: DIMS: -0,41 ± 0.06 D, SV: -0.85 ± 0.08 D → progression with DIMS 52 % slower than SV over 2 years
- No myopic progression over 2 years DIMS: 21,5 %, SV: 7,4 %
- Mean axial elongation DIMS: 0,21 ± 0,02 mm, SV: -0.55 ± 0.02 mm → 62 % less axial elongation than SV over 2 years
- No axial elongation over 2 years DIMS: 14%, SV: 0%

→ Daily wear of the DIMS lenses significantly slowed down the progression of myopia & axial elongation in myopic children compared to wearing single-vision lenses



Clinical science

OPEN ACCESS

Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial

Carly Siu Yin Lam ,[1] Wing Chun Tang,[1] Dennis Yan-yin Tse,[1] Roger Pak Kin Lee,[1] Rachel Ka Man Chun,[1] Keigo Hasegawa,[2] Hua Qi,[2] Takashi Hatanaka,[2] Chi Ho To[1]

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bjophthalmol-2018-313739).

ABSTRACT

Aim To determine if 'Defocus Incorporated Multiple Segments' (DIMS) spectacle lenses slow childhood myopia progression.

Several clinical interventions are currently used for slowing the progression of myopia.[9 10] A meta-analysis in efficacy comparison of different interventions for myopia control reported that

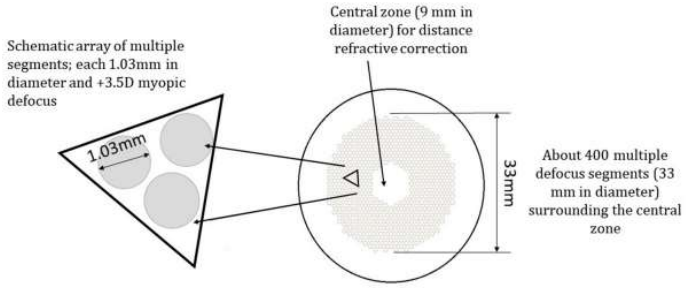


Fig. 13: Design of the DIMS spectacle lens-

Myopia Control via DIMS

Aim:

- Determine if myopia deceleration, as measured by changes in SER and AL, persists through the third year of DIMS (Hoya MiYOSMART) lens wear
- Investigate whether there is a delay in myopia in the original SV control group during the first year of DIMS lens wear

Methods:

- Follow-up study of 2-year randomized trial on effectiveness of DIMS spectacle lenses (previous slide)
- Subjects: n = 120 (start of third year: 128), Chinese children
- Groups
  - DIMS: continued to wear DIMS for the third year, n = 65
  - 2 control groups:

  1. Control-to-DIMS: previous SV-group during 2-year study switched to DIMS, n = 55
  2. new historical control group: to assess effectiveness of myopia control, n = 76

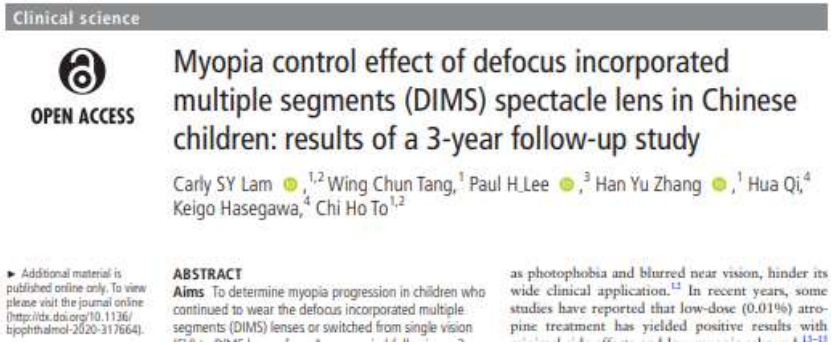
  → Comparison of baseline data (age, sex, SER, AL) of historical group with both DIMS groups
- measurements of SER (cycloplegic autorefraction) and axial length (partial coherence interferometry) at 6-months interval

Results:

- DIMS: mean SER difference: -0.52 ± 0.69 D & mean AL difference: 0.31 ± 0.26 mm over 3 years → no significant change over time
- Control-to-DIMS-group: mean difference in SER -0.04 ± 0.38 D & AL 0.08 ± 0.12 mm were significantly less then first and second year changes
- SER & AL changes in both DIMS goups were significantly less than in the historical control group (DIMS vs. historical: mean difference: −0,18 ± 0,42 D, p = 0.012; 0.08 ± 0.15 mm, p = 0.001; Control-to-DIMS vs. historical: adjusted mean difference: −0.30 ± 0.42 D, p < 0.001)

→ Myopia control effect was sustained in the third year in children who had used DIMS in the previous 2 years and was also shown in the children switching from SV to DIMS

→ even when children started wearing DIMS lenses at an older age, they still experienced a significant reduction in myopia progression and axial elongation (80 % of the Control-to-DIMS group had myopia progression less than 0.5 D, approx. 70 % showed progression less than 0.25 D)



Clinical science

OPEN ACCESS

Myopia control effect of defocus incorporated multiple segments (DIMS) spectacle lens in Chinese children: results of a 3-year follow-up study

Carly SY Lam ,[1,2] Wing Chun Tang,[1] Paul H Lee ,[3] Han Yu Zhang ,[1] Hua Qi,[4] Keigo Hasegawa,[4] Chi Ho To[1,2]

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bjophthalmol-2020-317664).

ABSTRACT

Aims To determine myopia progression in children who continued to wear the defocus incorporated multiple segments (DIMS) lenses or switched from single vision

as photophobia and blurred near vision, hinder its wide clinical application.[1,2] In recent years, some studies have reported that low-dose (0.01%) atropine treatment has yielded positive results with

Myopia Control via DIMS

Aim

- Evaluate long-term myopia control effect and safety in children wearing DIMS (Hoya MiYOSMART) for 6 years
- Determine effect of stopping DIMS lens wear & changes in refractive error and axial growth in those children who reverted to SV
- Evaluation of any rebound effects after discontinuation of DIMS wear

Methods:

- Follow-up study of children who completed both the 2-year RCT and the 3rd year study of DIMS lenses (previous 2 slides)
- Subjects: n = 90 (start of 6-year follow-up: 92), Chinese children
- Groups:
  - Group 1: wore DIMS for the entire 6 years of the study, n = 36
  - Group 2: wore DIMS for the first 3,5 years and then switched to SV afterwards, n = 14
  - Group 3: wore SV for the first 2 years and switched to DIMS afterward, n = 22
  - Group 4: wore SV for the first 2 years, switched to DIMS for 1,5 years and switched back to SV again, n = 18
- Analysis of changes in SER and AL over 6 years (no regular six-month measurements due to COVID)

Results:

- Group 1:
  - myopia progression: − 0.92 D (− 0.15 D/year), axial elongation: 0.60 mm (0.10 mm/year) over six years
  - no significant differences in myopia progression (− 0.52 ± 0.66 vs. − 0.40 ± 0.72 D) and AL (0.32 ± 0.26 vs. 0.28 ± 0.28 mm, both $p > 0.05$) between the first and the following 3 years
- Less myopia progression and axial elongation in the last 2,5 years of the study in the DIMS groups (groups 1 & 3) than the SV groups (groups 2 & 4), Group 3 had a significantly slower change in AL than group 1
- no rebound effect after DIMS wear has ended (group 2 & 4) → no faster progression in SV wear history in the last 2,5 years compared with the DIMS wearing years → treatment effect from DIMS lens was sustained
- Post-wear visual functions in all groups within norms

→ DIMS lenses provided sustained myopia control without adverse effects over the 6-year study period

Myopia Control via DIMS

Aim

- Reassess first-year AL data from the study by Lam et al. (2020) using the age matched myopia control (AMMC) system since it is unknown whether AL growth is sufficiently inhibited by DIMS to achieve the treatment goal of physiological AL growth
- Review method of AMMC by means of already published data to allow direct comparison between different methods to evaluate effectiveness of myopia treatments

Methods

- Re-evaluation of data collected by Lam et al. (2020) according to the age-matched myopia control system
- Evaluation: plot individual AL growth after first year of treatment of each eye against corresponding age of the same time point (Epidemiological data from Truckenbrod et al. (2021) and own data collection (Kaymak et al. 2022)) → conclusion about effectiveness of current treatment: uncritical, moderately excessive and highly excessive AL growth rate) , treatment groups were subdivided based on age (younger/ older than 10 years) & baseline AL

Results

- 65 % of eyes with DIMS lenses and 16 % of eyes with SV are within range of physiological AL growth rate
- 28 & of eyes in DIMS group and 79 % in SV group showed highly excessive AL growth
- Median AL growth rate and age of eyes with DIMS lenses is within range of physiological growth
- In all subgroups eyes with DIMS were also superior to the ones with SV regarding physiological AL growth
- SV group: older children and children with high baseline AL were least likely to achieve physiological AL growth rate

→ DIMS can bring AL growth rate of myopic children to the level of physiological AL growth rate, indicating 100% reduction of excessive myopic AL growth, independent of age and baseline AL

→ Older children and children with high AL have the risk of having increased AL growth without treatment

→ AMMC is a chance to quantify treatment success, help decisions as to whether treatment should be continued or internalized

Age-matched analysis of axial length growth in myopic children wearing defocus incorporated multiple segments spectacle lenses

Birte Graff [1,2] Carly S Y Lam [3,4] Natalia Vlasak [5] Hakan Kaymak [1,2]

Myopia Control via DIMS

Aim

- assess the effectiveness of DIMS (Hoya MiYOSMART) lenses in attenuating myopia progression within a European pediatric cohort
- Special focus on impact of baseline optic parameters and parental myopia on efficacy of DIMS

Method

- retrospective observational study, no comparable control group of evolutive myopes treated with SVS was available →compared with AL data from myopic subset (n = 187) of larger cohort in LIFE Child Study (Truckerbrod et al. 2021)
- Subjects: n = 62, Caucasian, age: 4-17 years (mean: 10.21 ± 2.70 years); SER: range −0.88 to −8.25 D, mean: −3.73 ± 1.56 D, coupled with astigmatism up to −3.25 D cylindrical
- Measurements: cycloplegic SER, AL at baseline, 6 and 12 months, questionnaire, record of parental myopic dioptre

Results

- Myopia progression (mean: −0.40 ± 0.05 D) mirrors findings from prior European DIMS studies, but 50 % of patients show no progression at 12 months
- baseline astigmatism (≥ -0.5 D cylinder) and younger age (< 10 years) adversely affected therapy outcomes in both SER and AL, while severe maternal myopia (≥ 9 D) led to greater SER progression
- Comparison group: young age but not astigmatism was associated with AL increase → suggesting that efficacy of DIMS may be diminished in the presence of astigmatism
- excellent long-term overall acceptance of the DIMS spectacles

→ astigmatism, young age, and severe myopia are risk factors for suboptimal outcomes in DIMS therapy in European children and adolescents

Astigmatism and maternal myopia as important factors affecting success rate of DIMS lens treatment

Patricia Domsa,[1,2] Éva M Bankó ,[3] Judit Körtvélyes,[1,4] Christof Meigen,[5] Rita Széchey,[1,6] Krisztina Lantos,[2] Zoltán Zsolt Nagy,[7] Adrienne Csutak[2]

Myopia Control via DIMS in lockdown

Aim

- analyze the association of COVID–19–related lockdown measures with myopia progression in schoolchildren
- compare the performance of DIMS with SV lens treatment in reducing myopia progression

Method

- exploratory, prespecified, comparison of 2 independent longitudinal studies
- Subjects: n = 171, age: 7-13 years, Chinese children
- Groups:
  - Study 1: DIMS lens for 18 months, n = 115
    - Less lockdown time: n = 57, more lockdown: n = 58
  - Study 2: SVS for 24 months, n = 56 (control group in study 2)
    - Less lockdown: n = 28, more lockdown: n = 28
  - Subjects in SVS group were approx. half a year older (mean age: 10.3 [1.5] years vs. 10.8 [1.5] years) and had milder myopia (mean SER: −2.99 [1.06] D vs. −4.02 [1.46] D) than DIMS group at baseline
- Measurements: cycloplegic SER, AL
- Change from baseline in AL & SER were proportionally adjusted and normalized to 12-month change due to COVID restrictions → comparison between DIMS and SV lens groups

Results

- DIMS have significantly 46 % less myopia progression (−0.31 D vs. -0.57 D, p = 0.001)) and 34 % less axial elongation (0.19 mm vs. 0.30 mm, p < 0.001) compared with SV lens treatment after 12 months
- more lockdown time was associated with significantly more SER (−0.54 D vs. -0.34 D; p = 0.01) and AL (0.29 mm vs. 0.20 mm, p = 0.001) compared with less lockdown time
- More lockdown time subpopulation: DIMS significantly 52 % less SER (-0.35 vs. -0.73 D) and 37 % less AL (0.22 mm vs. 0.35 mm) 12-month progression than SV

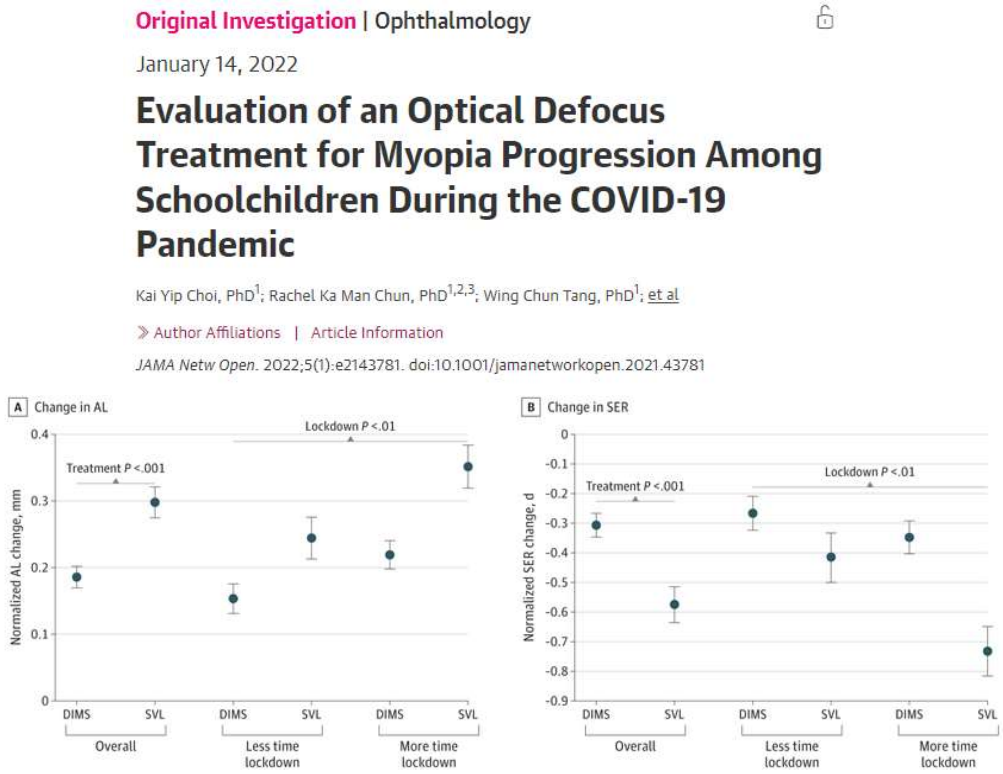


Fig. 14: Covariate-adjusted mean 12-month normalized change of AL and SER by lockdown severity in children wearing DIMS (Study 1) and SV lens (Study 2).

Myopia Control via DIMS after non-response to atropine

Aim

- assess the effect of DIMS (Hoya MiYOSMART lenses on myopic progression in children not responding to low-concentration atropine (0.01 %) eye drops

Methods

- single-arm, non-randomized, prospective, interventional study over 1 year
- Subjects: n = 10, Indian, mean age: 8.4 ± 2.1 years, had no response to 0.01 % atropine over at least 1 year (progressing −0.5 D per year or 0.3 mm AL per year) → add DIMS ((MiYOSMART, Hoya) as a complementary treatment to 0.01 % atropine
- Measurements: SER, AL at baseline and 1 year

Results

- 8 of 10 children showed a reduction in the progression of myopia:
  - → Pre-atropine progression: -0.76 ± 0.4 D/ year, 0.32 ± 0.1 mm the year before atropine started
  - → Pre-DIMS progression: −0.68 D ± 0.3 D, 0.28 ± 0.3 mm
    - → In 8 children: post-DIMS progression by −0.24 ± 0.2 D, 0.16 ± 0.2 mm over 1 year
    - → In 2 children: post-DIMS progression by −0.57 ± 0.4 D, 0.24 ± 0.2 mm over 1 year
      - → Mean progression for all 10 children: −0.39 ± 0.5 D
      - → Peripheral mean refraction: 20° temporal: -3.1 ± 2.4 D, central: -3.9 ± 2.3 D, 20° nasal: -3.2 ± 3.1 D

→ DIMS lens shows initial promise in reducing progression of myopia even in children not responding to 0.01% atropine eye drops when given in conjunction with atropine eye drops

Effect of defocus incorporated multiple segments lenses on halting myopia progression not responding to low-concentration atropine (0.01%) eye drops

Jethani, Jitendra

Author Information

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Adaptability & acceptance via DIMS

Aim

- Investigate adaptability and acceptance of DIMS (Hoya MiYOSMART) in Chinese youth

Method

- prospective, cross-over study
- Subjects: Chinese, SER: 0.50 0 to 6.00 D; astigmatism of ≤ 1.50 D; interocular anisometropia of ≤ 1.25 D, BCVA: 0.2 logMAR
- Groups:
  - children group (n = 20): 7–15 years, mean age: 10.80 ± 2.55 years; SER 3.03 ± 1.73 D
  - adult group (n = 19): 18–30 years, mean age: 25.60 ± 2.01 years; SER 3.38 ± 1.44 D
- Wear DIMS & SV for a week with random assignment which lens type to wear first
- Measurements:
  - high and low contrast central distant VA
  - high contrast mid-peripheral near VA (at 40 cm distance in 20° away from horizontal visual axis)
    → Both at 500 lux and 50 lux ambient illuminance after 30 minutes and a week
  - Questionnaire to evaluate the visual discomfort at the 1-week visit (scala 0 to 4: 0 = none (0 times/ day) to 4 = complete (> 7 times/day))

Results

- Central VA: not affected by DIMS lens compared with SV lens in all circumstances (all P > 0.05)
- mid-peripheral near VA: reduced by approx. 0.06 logMAR in 2 of 4 quadrants (500 lux; P < 0.05) and in 3 quadrants (50 lux; P < 0.05) for DIMS (4 quadrants: inferior, superior, nasal, temporal)
- No improvement was detected in the 1-week visit
- Main visual complaint: midperipheral blurred vision, noticed only once or twice a day
- significantly more complaints about the DIMS were reported by adults
- After being informed about antimyopic efficacy: 90 % of children and 70 % of adults would wear DIMS,

→ Mid-peripheral vision through DIMS lenses was slightly affected compared with SV lenses

→ DIMS received good tolerance and acceptance in children, adults less tolerant

ELSEVIER

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Original Article

The Adaptation and Acceptance of Defocus Incorporated Multiple Segment Lens for Chinese Children

Yiqiu Lu [a], Zhenghua Lin [a], Longbo Wen [a], Wenyu Gao [a c], Lun Pan [a c], Xiaoning Li [a b c], Zhikuan Yang [a b c], Weizhong Lan [a b c]

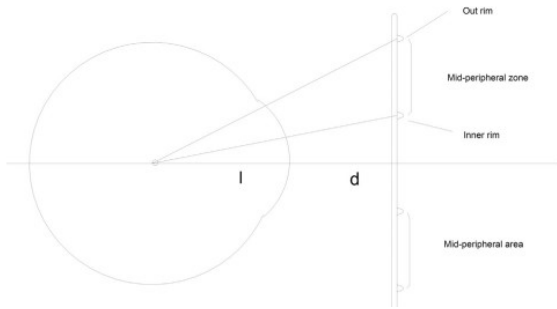

Fig. 15: Rotation angle of the eyeball related to rims of the mid-peripheral zone of DIMS. The line of central sight through the mid-peripheral zone was approx. 8-28.°

VA & CS via DIMS

Aim

- investigate parameters relevant to vision and road safety of DIMS spectacle lenses in combination therapy with 0.01 % atropine

Methods

- Retrospective pilot study
- Subjects: n = 12, age: 24-45 (30,1 ± 5,7) years, SER: − 8.13 to + 1.13 D (− 2.84 ± 2.35 D)
- Subjects wore corrective CL to achieve emmetropia + DIMS (MiYOSMART, Hoya Lens, Thailand) without any additional vision enhancement + used 0.01 % atropine
- Measurements: corrected distance visual acuity, (CDVA, via FrACT (Freiburg Acuity and Contrast Test) on right eye) with and without glare, contrast sensitivity (CS, via FrACT with and without glare on right eye; via Visual Function Analyzer (Stereo Optical, USA) under mesopic and photopic conditions, in each case with and without glare on both eyes), mesopic vision and glare sensitivity before (0h) and at 1h after administration of atropine; scotopic & photopic pupil size at 0, 1,4 and 8h after atropine installation

Results

- Pupil dynamic under atropine influence: 0h: 2.59 ± 0.52 mm, 1h: 1.97 ± 1.08 mm ($p < 0.05$), 4h: 1.35 ± 0.83 mm ($p < 0.001$), 8h: 1.81 ± 0.69 mm ($p < 0.01$)
- Distance VA:
  - Without glare: significant reduction in DCVA without atropine (0.24 logMAR, $p < 0.001$) and with atropine (0.27 logMAR, $p < 0.001$) looking through DIMS area compared to central area
  - With glare: significant reduction in DCVA without atropine (0.25 logMAR, $p < 0.001$) and with atropine (0.17 logMAR, $p < 0.001$) looking through DIMS area compared to central area
  - Through central area:
    - No significant decrease due to influence of atropine
    - influence of glare and atropine leads to a reduction of CDVA by 0.10 logMAR ($p < 0.01$)
  - Through DIMS area (nasal peripheral):
    - reduced by 0.09 logMAR ($p < 0.05$) due to the influence of atropine in the absence of glare
    - No significant reduction of VA in the presence of glare under influence of atropine
- CS: not altered by the effects of atropine looking through central of DIMS area at spatial frequencies of 3 and 6 cycles per degree (cpd); tendency for CS to icrease under mesopic conditions with & without glare
- Glare sensitivity with DIMS: no visual impairment that would be relevant to vision and road safety, not affected by additional atropinization

→ DIMS lenses safe for participation in road traffic, no clinically relevant impairment of traffic safety either alone or under acute influence of 0.01 % atropine

→ VA is generally reduced looking through DIMS area but no impairment to CS at spatial frequencies of 3 & 6 cpd (necessary in order to roughly recognize objects & safety-relevant vision in regard to road safety)

Klin Monbl Augenheilkd. 2022 Oct; 239(10): 1197–1205. Published online 2022 Oct 18. doi: 10.1055/a-1930-7116

PMCID: PMC9578763 | PMID: 36008055

Safety of DIMS Spectacle Lenses and Atropine as Combination Therapy for Myopia Progression

Hakan Kaymak, Ann-Isabel Mattern, Birte Graff, Kai Neller, Achim Langenbucher, Berthold Seitz, and Hartmut Schwahn

VA & CS via DIMS vs. Multi-CL

Aim

- investigate the short-term tolerability and visual performance of the DIMS lenses and compared it to known SV spectacle lenses, monofocal CL and multifocal CL

Methods

- Pilot study
- Subjects: n = 8, mean age: 28,1 ± 3.0 years, SER: -1.0 to 7.0 D, astigmatism: < 1.0 D, all long used to wear CL & spectacles
- Lenses:
  - DIMS (MiYOSMART, Hoya Lens)
  - SV (Hoya SV spectacle lenses)
  - Multi-CL (Dailies Total 1 multifocal-medium centre-near add(+2 dpt.), Alcon)
  - CL (Dailies Total 1 monofocal, Alcon)
- Measurements:
  - Examination after 1h of initial short-term wear on 4 consecutive days, order of optical design and tests were randomly selected
  - VA (Landolt C) & CS (contrast C) at 3 different gaze points (−22° nasal, +22° temporal and 0° central) after short-term wear via FrACT; CS (photopic & mesopic conditions) with and without glare using sinusoidal gratings at 1.5, 3, 6, 12 and 18 cpd

Results

- Multi-CL: general decrease in VA & CS compared with SV
- DIMS:
  - Central zone: no reduction of VA or CS, visual performance corresponds to SV
  - Temporal & nasal:
    - VA decreased by 0.23±0.19 logMAR (similar level as Multi-CL) compared to SV; decreased by about 0.3 logMAR compared to central VA → corresponds to defocus of less than about 0.5 D
    - CS decreased nasal by −0.12±0.20 and temporal by −0.18 ± 0.20 logCS compared to SV → correspond to defocus of about 0.5 D
- SV, DIMS and CL did not differ in visual quality at CS test with and without glare under photopic & mesopic conditions, Multi-CL had a decrease in CS at higher spatial frequencies, most prominent in mesopic conditions and/or with glare

→ under artificial adverse conditions no significant impact on visual performance by DIMS

→ Even looking constantly sideways & through the annular DIMS area the reduction in visual quality is not significantly higher than in Multi-CL

Vision tests on spectacle lenses and contact lenses for optical myopia correction: a pilot study

Hakan Kaymak,[1] Kai Neller,[1] Saskia Schütz,[2] Birte Graff,[1] Wolfgang Sickenberger,[2] Achim Langenbucher,[1] Berthold Seitz,[3] Hartmut Schwahn[1]

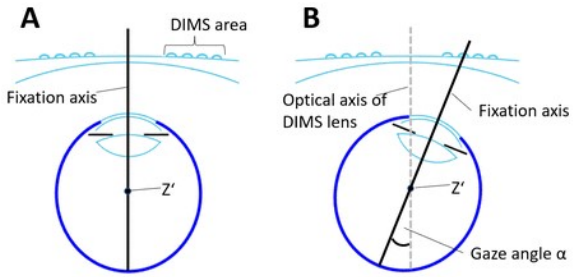

Fig. 16: Eye in central (A) and nasal or temporal (B) gaze position, Z' is the centre of rotation of the eye, gaze angle α is 22°.

Operating principle DIMS vs. Multi-CL

- central and peripheral paths of a bundle of rays passing through 2 myopia correcting lenses
- A: DIMS technology: small positive lenslets embedded in SV spectacle lens → producing plurality of myopic defoci on level of retina
- B: Multi-CL: concentric arrangement of near zone and far zone in the lens, forms two distinct focal planes → near focus forms blur point on retina that overlays sharp far point image
- Difference: DIMS has no second focal plane like Multi-CL, each lenslet forms its separate focal point and its separate blur point → resulting image of DIMS area on level of retina as sharp far point image overlaid by plurality of nearby and small blur points
- Zoomed in pictures: foci of ray bundles in the region of the retina

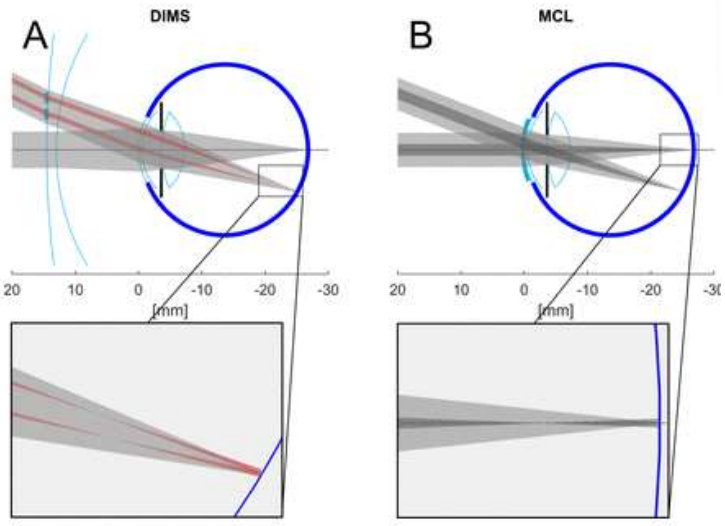

Fig. 17: Schematic ray tracing through a myopic eye with A) DIMS and B) Multi-CL.

Eye fatigue with DIMS

Aim

- determine whether DIMS lenses (compared to SV lenses) impact eye fatigue and visual performance in a demanding visual search task, comparing two different age cohorts

Methods

- Subjects (all Korean):
  - adults: n = 20, mean age: 24.85 ± 3.68 years, right eye SE: -3.59 ± 2.37, left eye SE: -3.21 ± 2.38
  - adolescents: n = 22, mean age: 14.64 ± 0.58 years, right eye SE: -3.69 ± 2.10, left eye SE: -3.57 ± 1.75
- "Finding Wally" in 20 visual search puzzles (7x7 grids, 4 different sets á 5 pictures, each containing 2 difficulty levels: easy & difficult, based on number of distinct human characters in one grid square) while wearing standard SV and DIMS (Hoya) lenses, adaptation time for DIMS: at least 14 days
- Measurements: response time to find the grid containing "Wally", fatigue/ eye strain assessment with self-report questionnaire after each stimulus (5 levels; 1: not/ very little fatigued, 5: very much fatigued, very difficult to concentrate), half of the participants in each age group watched the first 2 sets with SV lenses and then switched to DIMS, the other half did the opposite

Results

- Discomfort caused by wearing DIMS disappeared after max. 7 days (adults: 6.45 ± 2.89 days, adolescents: 5.23 ± 2.14 days)
- Accuracy: adults have an average of 10 % higher accuracy than adolescents in "Finding Wally"
- Response time: adults had a slightly faster average response time (p = 0.04), easy images (mean response time: 69.88 s) were around 18 s faster to solve than difficult images (mean response time: 88.31 s)
- Eye fatigue:
  - higher for difficult (mean: 2.70) than for easy (mean: 2.53) images
  - Significantly reduced on average by 23 % wearing DIMS (SV: mean = 2.94; DIMS: mean = 2.28); both age groups fatigue levels were reduced considerably by DIMS (SV: Adolescents: 2.72, adults: 3.17; DIMS: adolescents: 2.22, adults: 2.35)
  - Degree of fatigue levels and response time increase as the number of tests increases, but fatigue levels for DIMS stay continuously lower than SV levels across all tests, whereas response times are similar across lens type
  - → age and difficulty did not result in significant differences in eye fatigue
  - → clear reduction of fatigue levels in both age groups when wearing the correcting lenses

→ additional accommodation of DIMS lenses may result in less strain in a task requiring sustained eye movements at near viewing distances

Myopia-correcting lenses decrease eye fatigue in a visual search task for both adolescents and adults

Hyeongsuk Ryu, Uijong Ju, Christian Wallraven

Published: October 13, 2021 • https://doi.org/10.1371/journal.pone.0258441

Quality of life with DIMS

Aim

- assess the impact of DIMS spectacle lenses on the quality of life of children using it

Methods

- Snapshot (cross-sectional) qualitative study
- Separate in-depth interviews with children using DIMS for at least 1 month & their parents on prepared guides → transcribition and identification of themes by using inductive & deductive coding methods → categorization & fitting into 4 domains of the WHO Quality of Life (social relationships, physical, psychological & environmental health)
- Subjects: Indian, n = 29 → children: n = 15 (mean age: 12.47 ± 2.13 years, mean SER: −2.25 D to −9.00 D, BCVA: 0.18 logMAR); parents: n = 14

Results

- Total of generated codes: 63
  - social relationships: 2 codes
    - Children: no impact on relationships with friends or team activities like sports
  - Physical health: 28 codes
    - Children: symptoms like peripheral blurred vision, eyestrain, dizziness, headache, image jump, haloes, shaking of objects, uneasiness and magnified view during the adaptation period, faded away with time (2 days to 1 month)
    - Parents: thought their child was too young to handle CLs (less safe & cumbersome), did not opt for atropine drops because of invasive nature
    - Both: preferred DIMS over other methods, children who used atropine before complained about headaches & eye irritations from the eye drops
  - Psychological health: 17 codes
    - Children: no influence on body image and appearance, liked the “normal look”
    - Parents: “normal look” of the lenses → no bullying in school, were satisfied if children’s myopic power got stable/ disappointed if not
  - environmental health: 16 codes
    - Parents: concerned about scratches, repair and replacement (DIMS lenses not available in all opticians in all the cities), high costs (lower costs would make them more accessible), no photochromic features available
    - Children: are still participating in all kinds of sport, no problems with bicycles

→ Satisfaction with most of the facets of social relationships, physical and psychological health domains

→ children & parents prefer DIMS over atropine and CL in myopia control

→ few facets such as quality, accessibility and finance of the environmental health domain need improvement

Paediatric Ophthalmology
Original research

Impact of defocus incorporated multiple segments (DIMS) spectacle lenses for myopia control on quality of life of the children: a qualitative study

Mobashir Fatimah [1], Sumita Agarkar [2], Anuradha Narayanan [1]

Myopia Control via DIMS, atropine, Ortho-K, Multi-CL

Aim:

- Comparison of DIMS with other myopia therapy methods

Method:

- Creation of an eye length growth curve for emmetropic children from epidemiological growth data by Truckenbrod et al. (2021) & verification using epidemiological surveys of German schoolchildren (Kaymak et al. 2021)
- Acquisition and inclusion of mean growth rates from current study data in the curve:
  - Effect of DIMS (Lam et al. 2021)
  - Effect of atropine eye drops (Yam et al. 2020)
  - Effect of OK lenses (Cho et al. 2012)
  - Effect of Multi-CL (Walline et al. 2020)

Results:

- Suggested check-ups: every six months, measurement of SER and AL → Plot in percentile curves from Tideman et al. (2018) or Truckerbrod et al.(2021) → Determination of current myopia risk progression & efficacy of therapy
- Suggested therapy goal:
  - up to 13 years: AL growth ≤ 25 % above growth of a corresponding emmetropic eye
  - From the age of 13 years.: AL growth ≤ 0.1 mm/year
  - → Myopia increase up to adulthood only approx. 1.0-1.5 D

→ Only DIMS completely fulfill the presented therapy criterion in the observation period, therapy with 0.05% atropine, OK therapy and high add CL still achieve tolerable therapy performance (descending)

→ 0.05% atropine concentration is critical due to side effects (Joachimsen et al. 2021), but lower doses are significantly less effective

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Angenommen: 16. Juni 2021
Online publiziert: 8. Juli 2021

Myopietherapie und Prophylaxe mit „Defocus Incorporated Multiple Segments“-Brillengläsern

Hakan Kaymak[1,2] · Birte Graff[1,2] · Kai Neller[1,2] · Achim Langenbucher[2] · Berthold Seitz[3] · Hartmut Schwahn[1]

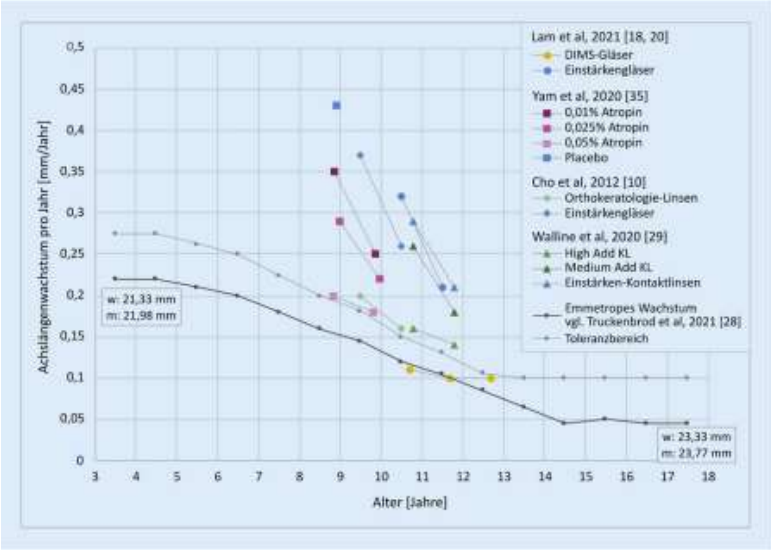

Fig. 18: Comparison of studies: Annual eye length growth as a function of age in different patient groups.

Myopia Control via HAL & SAL

Aim

- Evaluate whether spectacle lenses with higher lens asphericity are more effective in controlling myopia than SV lenses over 2 years

Methods:

- Subjects: n = 157 (start: 170), Chinese children, age: 8-13 years, SER: −0.75 D to −4.75 D, astigmatism ≤ 1.50 D, anisometropia ≤ 1.00 D
- 2-year double-masked randomized clinical trial
- HAL & SAL lens design:
  - spherical front surface with 11 concentric rings formed by contiguous aspherical lenslets (⌀ 1.1 mm)
  - geometry of aspherical lenslets generates volume of myopic defocus (VoMD) in front of the retina at any eccentricity, serving as a myopia control signal
  - center: distance correction
- Groups:
  - highly aspherical lenslets (HAL) spectacle lenses: n = 54
  - slightly aspherical lenslets (SAL) spectacle lenses: n = 53
  - SV spectacle lenses: n = 50
- Measurement of two-year changes in SER and AL & differences between the groups at 6-months intervals

Results:

- Mean myopia progression over 2 years: HAL: −0.66 ± 0.09 D, SAL: −1.04 ± 0.06 D, SV: -1.46 ± 0.09 D
  - Baseline age was significantly associated with SER progression (p = 0.04)
- Mean increase AL over 2 years: HAL: 0.34 ± 0.03 mm, SAL: 0.51 ± 0.04 mm, SV: 0.69 ± 0.04 mm
  - Baseline age (p = 0.002) and age at myopia onset (p = 0.02) were significantly associated with AL elongation
- During 2nd year: HAL still slowed SER and AL progression compared to SV, but no significant differences were observed between SAL and SV groups
  - SAL slowed myopia progression mainly during the first year
- HAL daily wear-time ≥ 12h: change in SER was slowed by 0.99 ± 0.12 D, and increase in AL slowed by 0.41 ± 0.05 mm compared to SV
  - For part time wearers only 0.54 ± 0.15 for SER and 0.26 ± 0.07 mm in AL compared to SV
- HAL slowed myopia progression by 0.80 D (55 %, p < 0.001) and increased AL by 0.35 mm (51 %, p < 0.001) compared with SV
- HAL slowed myopia progression by 0.38 D (37 %, p = 0.002) and AL by 0.17 mm (33 %, p = 0.002) compared with SAL

→ HAL and SAL reduced the rate of myopia progression and axial elongation throughout 2 years, with higher efficacy for HAL

→ Longer wearing hours resulted in better myopia control efficacy for HAL

JAMA Ophthalmology | Original Investigation

Spectacle Lenses With Aspherical Lenslets for Myopia Control vs Single-Vision Spectacle Lenses
A Randomized Clinical Trial

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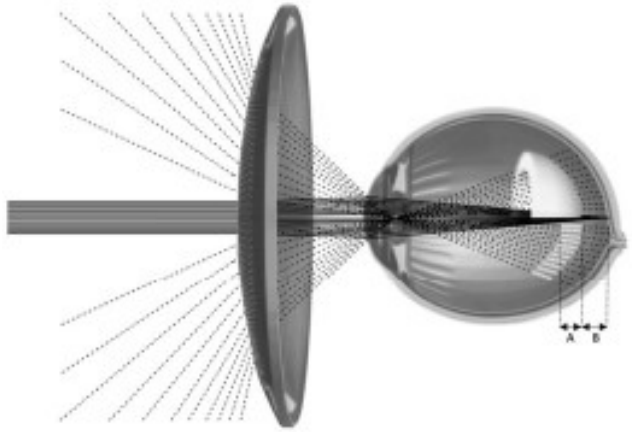

Fig. 19: Study lens providing a VoMD (white shell) in front of the retina through 11 concentric rings of contiguous lenslets (A: depth of VoMD and B: distance from the retina).

Myopia Control via HAL

Aim

- investigate myopia control efficacy in children who continued wearing HAL or switched from SAL or SV lenses to HAL for 1 year after a 2-year myopia control trial

Method

- 1-year non-blinded extension of a 2-year, randomized, double-blind clinical trial (Bao et al., 2022; previous slide)
- Subjects: n = 191 (start of year 3: 207), Chinese, age: 10-15 years,
- Groups:
  - HAL1: had already worn HAL for 2 years, n = 51
  - HAL2: had originally worn SAL, switch to HAL for year 3, n = 50
  - HAL3: had originally worn SV lens, switch to HAL for year 3, n = 42
  - nSVL: new control group wearing SV lenses, inclusion criteria based on HAL3 group (original control group), n = 48
- Measurements: SER & AL every 6 months in year 3

Results

- SER: nSVL: -0.56 D → less in HAL1 (−0.38 D, p = 0.02), HAL2 (−0.36D, p = 0.01) and HAL3 (−0.33 D, p = 0.005)
- AL elongation: nSVL: 0.28 mm → less in HAL1 (0.17 mm, p < 0.001), HAL2 (0.18 mm, p < 0.001), and HAL3 (0.14 mm, p < 0.001)
- Myopia progression and axial elongation comparable in all 3 HAL groups (all P > 0.05) in year 3

→ Myopia control efficacy remained in children who wore HAL in the previous two years
  - mean changes in SER and AL were −0.99 ± 0.11 D and 0.49 ± 0.05 mm over 3 years
  - annual rate of myopia progression was similar in each of the 3 years
  - Axial elongation in 3rd year significantly faster than in 1st year (mean diff. of 0.06 ± 0.02 mm, p = 0.02) but similar to 2nd year (mean diff. of −0.03 ± 0.02 mm, p = 0.13)

→ Children who switched from SAL or SV to HAL in year 3 had slower myopia progression & axial elongation than control group
  - → SAL/HAL2: mean SER similar in each of the 3 years (p = 0.05), AL elongation less in 3rd year than in 1st and 2nd year (p = 0.02)
  - → SVL/HAL3: mean SER and AL changes in 3rd year less than in 1st and 2nd year (all p < 0.001) → indicating that HAL is efficacious in older children (10-15 years) wearing HAL for the first time

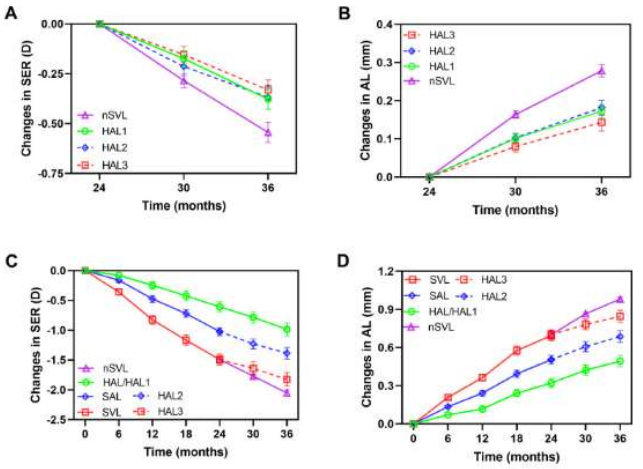

Fig. 20: The 3rd year changes in SER (A) and AL (B) in the HAL1, HAL2, HAL3 and nSVL groups, and changes in SER (C) and AL (D) from baseline to 36 months.

Myopia Control via HAL, SAL, HC

Aim

- evaluate short-term visual performance & optical quality of 3 different lenslet configurations on myopia control spectacle lenses compared with SV

Method

- Cross-over design
- Subjects & measurements:
  - VA: n = 50 (age: 10-15, mean 12.7 ± 1.7; SER: -6.50 to -0.38 D, mean: −3.22 ± 1.57 D)
  - CS: n = 36 (age:10-16, mean 13.2 ± 1.2; SER: −7.25 to −0.75 D, mean:−3.20 ± 1.67 D)

  } To determine subjective visual quality
  - Optical quality determined by modulation transfer function (MTF) & MTF area (MTFa)
  - Each test: 4 spectacle lenses in random order (1-min break in between)
    - SV, HAL, SAL & honeycomb configuration (HC) of spherical lenslets
    - Only view through lenslet zone: central clear zone + area beyond distance of 12 mm were patched up with non-light-permeable tapes
  - Monocularly R with full correction, L was occluded

Results

- HAL and SAL had larger MTFa than HC
- VA:
  - in lenses with lenslets significantly reduced compared to SV (all $p < 0.01$)
  - reduction worse with HC than with SAL ($p = 0.02$) & HAL ($p = 0.03$), no effect of lenslet asphericity ($p>0.05$)
  - changes induced by lenslets showed no correlation with SER, weakly positively associated with age for SAL (, $p = 0.01$) and HC ($p = 0.03$), but not for HAL ($p = 0.30$)
- area under the log contrast sensitivity function (AULCSF) decreased significantly with HAL and HC (all $p < 0.001$) in all illumination levels, was higher with HAL than HC in photopic condition (1.17 ± 0.10 vs. 1.10 ± 0.13, $p = 0.0004$)
- CS:
  - 3 cpd: no effect
  - 6-18 cpd: significantly reduced by HAL and HC (all $p < 0.05$), but not SAL ($p > 0.05$) compared to SV
  - high spatial frequencies (> 12 cpd): both SAL and HAL reduced CS significantly less than HC (all $p < 0.01$)

→ Short-term visual performance was minimally impaired by looking through the lenslet structure

→ Concentric rings with aspherical lenslets had a significantly lower impact on both VA and CS than honeycomb structure

Influence of Lenslet Configuration on Short-Term Visual Performance in Myopia Control Spectacle Lenses

Xue Li[1,2,3†], Chenglu Ding[1,2†], Yuhao Li[1,2], Ee Woon Lim[3,4], Yi Gao[3,4], Bruno Fermigier[5], Adeline Yang[3,4], Hao Chen[1,2,3] and Jinhua Bao[1,2,3*]*

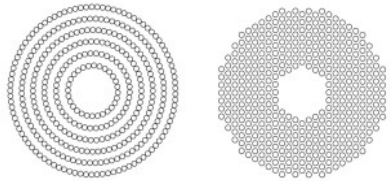

Fig. 21: Pictorial representation of concentric rings (left) in HAL & SAL and HC (right) configurations of lenslets.

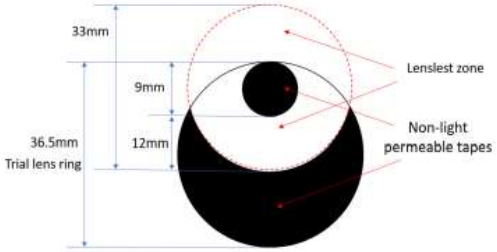

Fig. 22: Representation of patched lenses. Large solid circle of ⌀ 36.5 mm: actual edged lens (trial lens), small black circle of ⌀ 9 mm: patched central clear zone of the original lens, and black crescent-shaped area: patched peripheral clear zone of the original lens. All four lenses were patched in identical ways.

Myopia Control via HAL vs. OK

Aim

- compare one-year efficacy of myopia prevention & control using 3 optical intervention methods – SV lens, HAL, and OK lens – in children with low myopia

Methods

- prospective non-randomized controlled study over one year
- Subjects: n = 150, Chinese, age: 7-13 years, SER: ≥ 3.00 D, difference between eyes < 1.50 D, VA: 0.8 or better
- Groups:
  - SV: n = 50
  - HAL: n = 50 (Stellest, Essilor)
  - Ortho-K: n = 50
- Measurements: AL, SER, flat and steep keratometry, ACD, WTW, non-contact tonometry at baseline, AL and SER after 1 year

Results

- No statistically significant baseline differences in age, BCVA, SER, AL, non-contact tonometry, ACD, corneal curvature, and corneal size among all groups (all $p > 0.05$)
- AL growth rate: HAL group (0.163 ± 0.113 mm) < OK lens group (0.280 ± 0.170 mm) < SVL group (0.516 ± 0.190 mm) → statistically significant disparities (all $p < 0.05$)
- HAL group had a higher 1-year AL growth control rate at 68.41 % than OK at 45.74 % ($p < 0.001$)
- SER progression in SV (−1.225 ± 0.467 D) and HAL (−0.304 ± 0.249 D) → significant difference ($p < 0.001$)
- Age- AL growth correlation: negative correlation in SV group ($p < 0.001$), not statistically significant in HAL ($p = 0.135$) or OK ($p = 0.191$) groups

→ HAL and OK lens are more effective than SV lenses in controlling axial growth in mild myopia

→ HAL group demonstrated most effective control in children with low myopia

Three optical intervention methods for low myopia control in children: a one-year follow-up study

Weixia Lai[1†], Chunli Diao[1†], Haiping Li[1], Yuyi Zhang[1], Yiyue Jia[1] and Xixi Wu[1*]

Myopia Control via DIMS vs. HAL

Aim

- compare spectacle lenses with HAL vs. DIMS on myopia progression control in 1 year

Methods

- 1-year, retrospective cohort study
- Subjects: n = 135 (start: 257), Chinese, mean age at baseline: HAL: 9.57 ± 0.16 years, DIMS: 10.29 ± 0.26 years
- Groups:
  - HAL: n = 102
  - DIMS: n = 33
- Measurements: SER, AL at baseline & 1 year

Results

- Adjusted 1-year changes in SER: HAL: − 0.34 (0.04) D, DIMS: − 0.63 (0.07) D → HAL reduced myopia progression by 0.29 D at 1 year compared to DIMS ($p < 0.001$)
- Adjusted mean AL increase: 0.17 ± 0.02 in HAL and 0.28 ± 0.04 mm in DIMS group → HAL group had 0.11 mm less AL elongation than DIMS group ($p = 0.02$)
- Age at baseline significantly negatively associated with AL elongation
  → standardized AL showed 0.02 mm less increase with 1 year older at baseline ($p = 0.03$)

→ Children with HAL spectacle lenses had less myopia progression and axial elongation than those with DIMS

→ older children had slower axial elongations but showed similar SER changes compared to younger children

Comparing the effects of highly aspherical lenslets versus defocus incorporated multiple segment spectacle lenses on myopia control

Hui Guo, Xianfang Li, Xiaoxiao Zhang, Haizhao Wang & Jianhua Li

Scientific Reports **13**, Article number: 3048 (2023) | Cite this article

Myopia Control via DOT

Aim

- Diffusion optics technology (DOT) lenses are designed to reduce contrast signaling in the retina and slow myopia progression
- Evaluate changes after 12 months in AL, SER and safety (best-corrected VA, device deficiencies, adverse events)

Methods:

- 36-month, multicentre, randomised, controlled, double-masked trial, this paper contains results of planned interim analysis at 12 months
- Subjects: n = 226 (start: 256), North American, age: 6-10, SER −0.75 to −4.50 D, 0.10 logMAR, astigmatism ≤ 1.25 D, anisometropia ≤ 1.50 D
- Lens design:
  - contains light scattering centers that disperse light → reduce contrast → reduce lower signal differences between L & M cones while maintaining excellent VA and functional peripheral vision
  - light scattering features are integrated across the entire lens except for a small clear aperture aligned with the pupillary axis
  - Translucent microscopic diffusers, irregularly shaped (⌀ approx. 0.14 mm, height approx. 0.2 mm); irregular radial curvature that, steeper on the sides and flattened across the top
  - Base lens n = 1.53, diffusers n = 1.50
- 3 groups (n =256), balanced for age, sex, and race:
  - Control: standard SV, green tint → transmission reduction ~5% → no impact on myopia progression, n = 91
  - Test 1: diffusers with 0.365 mm spacing across entire lens, except for ~5 mm center (wearer's pupils), n = 79
  - Test 2: diffusers with 0.240 mm spacing across entire lens, except for ~5 mm center (wearer's pupils), n = 56
- Measurements of AL and SER and lens replacement every 6 months

Results:

- Baseline averages: AL: 24.02 ± 0.77mm, SER (manifest refraction): −2.01 ± 0.9 D, SER (cycloplegic autorefraction): −1.94 ± 1.0 D
- 12-month interim analysis:
  - mean diff. in SER progression: test 1 vs. control: −0.40 D (p < 0.0001) (→74 % reduction), test 2 vs. control: −0.32 D (p < 0.0001) (→ 59 % reduction)
  - Age 6-7 SER changes: test 1: −0.19 ± 0.47 D, test 2: −0.33 ± 0.63 D, control: −0.75 ± 0.51 D
  - Age 8-10 SER changes: test 1: −0.12 ± 0.34 D, test 2: −0.19 ± 0.43 D, control: −0.44 ± 0.41 D
  - < 1.00 D of cycloplegic SER myopia progression: 99 % test 1, 93 % test 2, 86 % control → only significant for test 1 vs control
  - Diff. in AL progression: test 1 vs. control: 0.15 mm (p < 0.0001)(→50% reduction), test 2 vs. control: 0.10 mm (p = 0.0018)(→33 % reduction)
  - No serious adverse events due to lens wearing were reported

  → both test group lenses significantly slowed the progression of myopia vs. standard spectacle lenses

OPEN ACCESS

Control of myopia using diffusion optics spectacle lenses: 12-month results of a randomised controlled, efficacy and safety study (CYPRESS)

Joe Rappon [1], Carol Chung,[2] Graeme Young,[3] Christopher Hunt,[3] Jay Neitz,[4] Maureen Neitz,[4] Thomas Chalberg[1]

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/bjo-2021-321005).

ABSTRACT

Background Mutations in the L/M cone opsin gene array cause abnormally high perceived retinal contrast and the development of myopia. Environmental factors may also lead to high visual contrast and cause myopia. Diffusion optics technology (DOT) lenses are designed to

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Myopia, a significant public health issue affecting billions of people worldwide, is known to increase the risk of visual impairment and blindness. Recent research in patients with an

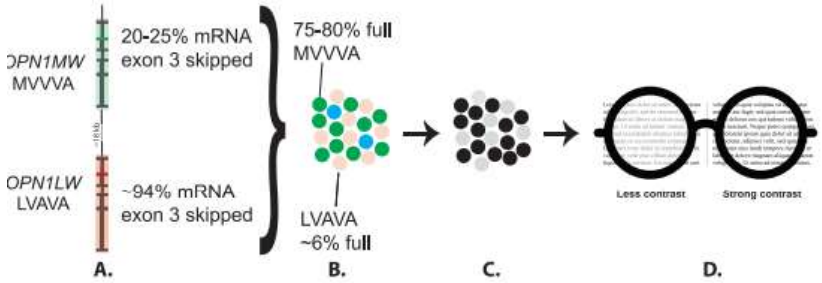

Fig. 23: Contrast hypothesis of myopia and development of DOT lens
A)L causes exon 3 to be skipped in pre-mRNA splicing → only ~6% of mRNA is full length
B) L and M cones have dramatically different photopigment OD because of mis-splicing. S cones are blue
(C) Retina signals high contrast even under uniform white light because of OD differences. Activity of L cones (grey) is low, activity of M and S cones (black) is high. Hypothese: constitutive contrast signals due to photopigment OD differences stimulates axial elongation of the eye → causes myopia
(D) → development of DOT that reduces contrast (L) vs. standard lens (R).

Myopia Control via CARE

Aim

- evaluate the 1-year myopia control efficacy of a spectacle lens with annular cylindrical microstructures
- Assess safety of the lenses by monitoring the occurrence of adverse events

Method

- 2-year randomized controlled clinical trial, planned interim analysis after 1 year
- Subjects: n = 96 (81.4%, start: 118), Chinese, age: 8-12 years (mea: 10.4 ± 0.6), SER: -1.00 to -4.00 D (mean: -2.67 ± 0.66 D), astigmatism: < 1.50 D, anisometropia: <1.00 D, BCVA ≥ +0.1logMAR, mean AL: 24.75 ± 0.77 mm
- 2 groups (randomly assigned):
  - Cylindrical annular refractive element (CARE) spectacle lenses: n = 61
  - SVS: n = 57
- Lens design:
  - central clear aperture (⌀ 9.4 mm), peripheral side-vision zone is covered by annular micro-cylinder array
  - Annular micro-cylinders are concentrically patterned with constant radial intervals of 1.2 mm
  - Along radial direction: filling factor of the micro-cylinders is 60% in each period
  - Power: unoccupied areas between adjacent micro-cylinders: same as central clear aperture base power, micro-cylinders: bring addition of +8.00 D cylinder power to base power of occupied areas
- Measurements
  - SER, AL, adaptation & compliance questionnaires at baseline + 6-month intervals

Results

- Adjusted 1-year myopia progression: CARE: −0.56 D, SVS: −0.71 D → difference: 0.14 D (95% CI, −0.04 to 0.32)
- Adjusted 1-year eye growth: CARE: 0.27 mm, SVS: 0.35 mm → difference: 0.09 mm (95% CI, −0.15 to −0.02)
- no reported adverse events, complaints, or discomfort

→ Treatment with CARE significantly reduced rate of axial elongation over 1 year compared with SV

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ORIGINAL ARTICLE

Acta Ophthalmologica

One-year myopia control efficacy of cylindrical annular refractive element spectacle lenses

Xinting Liu | Pengqi Wang | Zhu Xie | Muhan Sun | Minfeng Chen | Jiefang Wang | Jing Huang | Siyun Chen | Zhaohe Chen | Yanli Wang | Yiyu Li | Jia Qu | Xinjie Mao

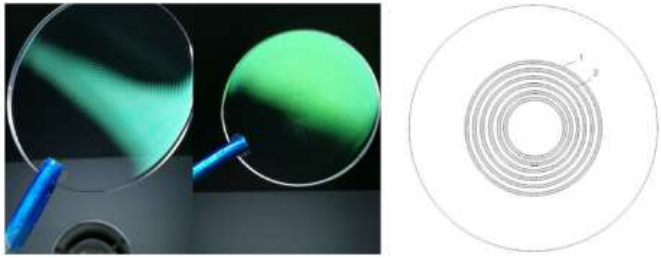

Fig. 24: Within the specific aperture range of the lens, the annular micro-cylinder array is centered on the geometric center of the lens (1-the occupied area with annular micro-cylinders, and 2-the spacing of two adjacent micro-cylinders).

6. Combination therapy

Myopia Control via OK & atropine combination

Aim

- investigate the adjunctive effect of OK and low-dose atropine eye drops on AL elongation in fast-progressing myopic children

Methods

- 2-year retrospective study
- Subjects: Experimental group: n = 60 and historical control group: n = 24, Chinese, age: 5.6 – 11.6 years, SER: -1.00 to -5.00 D, all were fast progressors (annual axial elongation rate faster than 0.25 mm/year undergoing OK treatment for 1 year)
- Groups:
  - Experimental group:
    - Phase 1: first year of OK (Euclid, USA) treatment (all had AL elongation rate faster than 0.25 mm/year)
    - Phase 2: OK + nightly 0.01% atropine (30 min before OK lens insertion)
    - Subdivided by age:
      - younger (7.5 ± 1.2 years), n = 28
      - older (9.0 ± 1.4 years), n = 32
  - Historical control group: fast progressors of a previous 2-year study (Zhong et al. 2015), wearing only OK, n = 24
- Measurements: AL every 6 months

Results (right eye only)

- Phase 1: mean axial elongation rate was 0.46 ± 0.16 mm/year, significantly faster in younger (7.5 ± 1.2 years) than in older (9.0 ± 1.4 years) children ($P < 0.001$)
- Phase 2: annual axial elongation rate significantly decreased to 0.14 ± 0.14 mm/year ($p < 0.001$), faster AL progressors in Phase 1 had greater reduction in AL elongation during Phase 2 ($p < 0.001$), but no correlation to age ($p = 0.920$) or SER ($p = 0.261$)
- Control group: axial elongation faster in first (0.35 ± 0.11 mm) than in second year (0.25 ± 0.08 mm)

  → Reduction in elongation from first to second year more significant in experimental group (−0.31 ± 0.20 mm) compared to control group (−0.10 ± 0.06 mm; $p < 0.001$)

→ AL elongation faster in younger children during OK treatment (phase 1)

→ Fast myopia progressors: low dose atropine may significantly slow AL elongation in addition to OK's treatment effect compared to OK monotherapy, regardless of SER and age

Adjunctive effect of orthokeratology and low dose atropine on axial elongation in fast-progressing myopic children—A preliminary retrospective study

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https://doi.org/10.1016/j.clae.2018.10.026

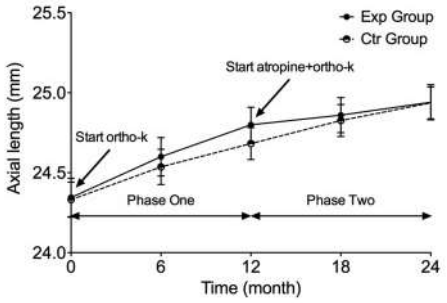

Fig. 25: Two-year axial growth of the subjects.

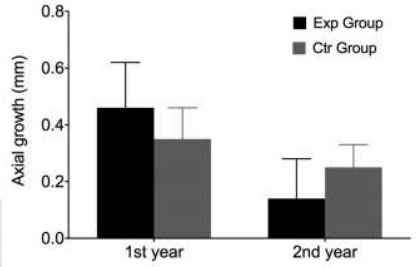

Fig. 26: Comparison of 1st year and 2nd year axial growth in the experimental and the control group.

Myopia Control via OK and atropine combination thearpy

Aim

- investigate whether combining 0.01% atropine with OK (AOK) has a better effect in retarding axial elongation, compared with OK alone over two years

Methods

- interventional, single-masked, randomized study over 2 years
- Subjects: n = 69 (start: 96), Chinese, age: 6 to < 11 years, SER: -1.00 to -4.00 D, myopic progression in SER of at least 0.50 D in last year
- Groups:
  - AOK: preservative-free 0.01% atropine, 10 min before nightly wear of OK (KATT BE Free Lens, Precision Technology Services, Vancouver, B.C., Canada), n = 34
  - OK: same OK as AOK group at night, n = 35
  - No 0.01 % atropine only group because it failed to retard myopic progression in terms of axial elongation in several studies
  - Analysis for intention-to-treat (ITT, including all subjects who received randomization) and per-protocol (PP, subjects who completed 2-year study)
- Measurements: AL, pupil size, choroidal thickness, UCVA and BCVA at baseline, at 1-month and 6-monthly intervals

Results

- statistically slower mean axial elongation in atropine + OK (0.17 ± 0.19 mm) than OK (0.35 ± 0.20 mm, $P < 0.001$) over 2 years in both ITT and PP analyses
- AOK had larger increase in mesopic (0.70 ± 0.09 mm vs 0.31 ± 0.09 mm, $p = 0.003$) and photopic pupil size (0.78 ± 0.07 mm vs 0.23 ± 0.07 mm, $p < 0.001$) than OK group, no difference between ITT and PP
- greater thickening of the choroid in AOK than OK group (22.6 ± 3.5 µm vs −9.0 ± 3.5 µm, $P < 0.001$), no difference between ITT and PP
- Slower axial elongation was associated with a larger increase in the photopic pupil size and a greater thickening in the choroid in the AOK group
- higher incidence of photophobia in the AOK group ($P = 0.006$), no differences in other symptoms or adverse events
- no significant between-group differences in UVA, BCVA, or changes in the amplitude of accommodation (all $P > 0.05$)

→ Slower axial elongation (by 0.18 mm) following 2-year AOK treatment may result from increased pupil dilation and a thickening in the choroid observed in the AOK group

Randomized Controlled Trial > Cont Lens Anterior Eye. 2023 Feb;46(1):101723.
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Combined 0.01% atropine with orthokeratology in childhood myopia control (AOK) study: A 2-year randomized clinical trial

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Myopia control via atropine, OK & combined therapy

Aim

- investigate 2-year efficacy of atropine, OK and combined treatment (AOK) on myopia and factors influencing the efficacy

Method

- 2-year age-stratified RCT study to provide more solid evidence of the age effect, blinded patient allocations
- Subjects: n = 164 (80.4 %, start: 129), Chinese, age: 8-12 years, SER:−1.00 to −6.00 D, astigmatism and anisometropia ≤ 1.50 D
- Groups: separated into 2 age subgroups (8-10, n = 81 vs. 11-12, n = 83) and 2 SER subgroups (−1.00 to −3.00 D vs. −3.01 to −6.00 D), randomized into:
  - Atropine: 0.01 % atropine once a day + spectacles, n = 31
  - Ortho-K: OK (Euclid Systems OK) + placebo drops (0.9 % sodium chloride), n = 34
  - AOK: OK + 0.01% atropine once a day, n = 34
  - Control: Placebo drops + spectacles, n = 30
- Measurements: AL at baseline, 6, 12, 18, 24 months

Results

- All interventions significantly reduce axial elongation at all visits (all $p < 0.05$)
- 2-year axial elongation was significantly reduced in combined (0.31 ± 0.23 mm) than in monotherapies (atropine: 0.42 ± 0.23 mm, p = 0.036; OK: 0.43 ± 0.22 mm, p = 0.034)
  → elongation slower by 63.4 % in AOK, 47.5 % in OK & 48.7 % in atropine compared with control group
- Subgroup aged 8–10: AL significantly reduced in AOK (0.42 ± 0.20 mm) than in atropine (0.55 ± 0.16mm), p = 0.021; insignificant difference between AOK and OK (p = 0.106)
- subgroup aged 10–12: AL significantly reduced in AOK (0.18 ± 0.19 mm) than in OK (0.37 ± 0.23 mm), p = 0.029; insignificant difference between AOK and atropine (p = 0.121)
- significant age-dependent effect:
  - OK group vs control group (p for interaction age x treatment = 0.013)
  - OK group vs atropine group (p for interaction age x treatment = 0.035)
  - → Indication that OK can achieve better efficacy in younger children

→ Atropine combined with OK treatment can improve the efficacy of myopia control compared with monotherapy in children aged 8–12; when using monotherapy younger children might benefit more from OK

Effect of atropine, orthokeratology and combined treatments for myopia control: a 2-year stratified randomised clinical trial

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Myopia Control via CL & atropine Combi

Aim

- investigate whether combining 0.01% atropine and soft multifocal CL with +2.50-D add power leads to greater slowing of myopia progression and axial elongation than soft Multi-CL alone

Methods

- Non-randomized ancillary study of the BLINK Study (Walline et al. 2020), double-masked, randomized clinical trial
- Subjects: n = 138 (new: n = 46 (start: 49, 93.9 %), BLINK (Subsets of age-matched groups (7-9 vs. 10-11 years): n = 92), 67 % White, age: 7-11 years, SER: −0.75 to −5.00 D, astigmatism: ≤ 1.00 D, anisometropia: ≤ 2.00 D
- Groups:
  - Combi: soft multifocal CL with +2.50 D (Biofinity "D") & 0.01 % atropine eye drops, n = 46
  - Multi-CL: soft multifocal CL with +2.50 D (Biofinity "D"), n = 46
  - SV: single-vision CL, n = 46
- Measurements: cycloplegic SER, AL (annual), high & low contrast in distance & near logMAR VA (annual)

Results

- 3- year adjusted mean myopia progression: : Combi: −0.52 D, Multi-CL: −0.55 D, SV: −1.09 D
  - Difference in progression: 0.03 D in Combi vs. Multi-CL, 0.57 D in Combi vs. SV
  - Progress of ≥ -1.00 D over 3 years: Combi: 17.4 %, Multi-CL: 15.2 %, SV: 47.8 % → only significant between Combi and SV (p = 0.002), not between Combi and Multi-CL (p = 0.67)
- 3-year adjusted axial elongation: Combi: 0.31 mm, Multi-CL: 0.39 mm, SV: 0.68 mm
  - Difference in elongation: -0.08 mm in Combi vs. Multi-CL, -0.37 mm in Combi vs. SV
  - Elongation of ≥ 0.36 mm over 3 years: Combi: 39.1 %, Multi-CL: 50 %, SV: 84.8 % → only significant between Combi & SV (p < 0.01), not between Combi and Multi-CL (p = 0.35)
- high-contrast distance & high-contrast near logMAR VA for both the Combi group (−0.06 & -0.13) and the SV group (−0.06 & -0.11) was significantly better than the Multi-CL (−0.03 & -0.07), but the difference was no more than 2 & 3 letters
- low-contrast distance logMAR VA significantly better for SV (0.07) than both Combi (0.12) and Multi-CL (0.11) group, but differences were less than 3 letters

→ Adding 0.01% atropine to soft multifocal CL with +2.50-D add power failed to demonstrate better myopia control than CL-monotherapy

› Optom Vis Sci. 2022 May 1;99(5):434-442.
doi: 10.1097/OPX.0000000000001884. Epub 2022 Feb 25.

Effect of Combining 0.01% Atropine with Soft Multifocal Contact Lenses on Myopia Progression in Children

Jenny Huang Jones, Donald O Mutti [1], Lisa A Jones-Jordan [1], Jeffrey J Walline [1]

Myopia Control via DIMS, atropine & combination

Aim

- evaluate the efficacy of DIMS at slowing progression of myopia in a population of European children in comparison with 0.01% atropine and combined DIMS and atropine

Method

- 1-year non-randomised experimenter-masked prospective controlled observational study
- Subjects: n = 146, Italian/ European, age 6-18 years (mean: 10.3y ± 3.2), European, SER: -0.50 D to 4.00 D, astigmatism ≤ 2.50 D, anisometropia < 1.25 D
- 4 groups (selected by patient):
  - 0.01% atropine eyedrops (n = 53)
  - DIMS (Hoya® MiyoSmart®) spectacles (n = 30)
  - combined atropine + DIMS (n = 31)
  - SV (control group, n = 32)
- Measurements:
  - SER, AL, VA at baseline and after 3, 6, 12 months

Results

- SER:
  - at each stage all treatment groups had significantly reduced progression compared with SV ($p < 0.016$)
  - At 12 months: atropine + DIMS group had significantly reduced progression (-2.002 ± 0.028 D) compared with the DIMS only (-2.153 ± 0.029 D) and atropine only groups (-2.165 ± 0.022 D; all $p < 0.001$)
- AL: at 6 & 12 months, all treatment groups had significantly less progression than the control group ($p < 0.005$)
  - Combi: 24.851 ± 0.014 mm, DIMS: 24.883 ± 0.015 mm, atropine: 24.887 ± 0.011 mm → no significance between groups
- VA: deterioration at 6 & 12 months significantly less in each treatment group than in control group

→ DIMS and atropine are effective at reducing myopia progression and axial elongation in progressing myopia

→ most successful at reducing myopia progression when used in combination

A comparison of myopia control in European children and adolescents with defocus incorporated multiple segments (DIMS) spectacles, atropine, and combined DIMS/ atropine

Paolo Nucci[1], Andrea Lembo[2], Irene Schiavetti[3], Rakhee Shah[4,5], David Francis Edgar[4,5], Bruce John William Evans[4,5]*

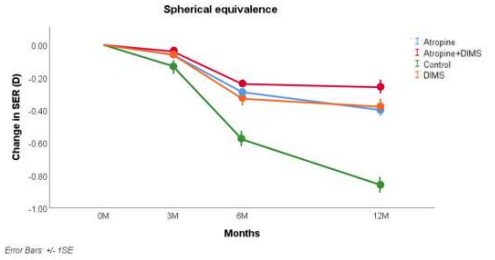

Fig. 27: Model-adjusted mean and SE of myopia progression (SER) from baseline to 12 months.

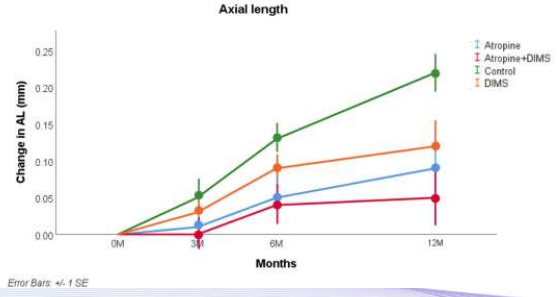

Fig. 28: Model-adjusted mean and SE of change in axial length from baseline to 12 months.

Myopia Control via DIMS, atropine & combination

Aim

- determine whether the combination of DIMS lenses & 0.01% atropine can slow the progression of myopia compared with DIMS lenses or SV lenses alone

Method

- retrospective cohort study
- Subjects: n = 107 (start: 136), Chinese, age: 7-12 years, SER: − 1.00 to − 5.00 D, astigmatism & anisometropia: ≤ 1.50 D, baseline AL: 23-26 mm
- Groups:
  - Combi: DIMS (Hoya MiyoSmart) and 0.01% atropine combination, n = 30
  - DIMS: DIMS monotherapy (Hoya MiyoSmart), n = 38
  - SVS: control group, n = 39
- Measurements: AL, SER at baseline, 6 and 12 months

Results

- AL elongation : Combi: 0.28 ± 0.24 mm, DIMS: 0.41 ± 0.22 mm, SV: 0.52 ± 0.22 mm
  - Both Combi ($p < 0.001$) and DIMS ($p = 0.009$) group showed a significant effect compared to SV
- SER increase: Combi: 0.49 ± 0.66 D, DIMS: 0.79 ± 0.47 D, SV: 1.07 ± 0.64 D
  - Both Combi ($p < 0.001$) and DIMS ($p = 0.020$) group had a significant effect compared to SV
- Age at intervention had significant effect on AL change ($p = 0.0003$) and SER change ($p = 0.022$)

→ Combi group showed a significant reduction in AL by 54 % and myopia progression by 46 % than the DIMS and SV groups (DIMS group: AL by 26 % and myopia progression by 21 % compared to SV)

→ combination treatment with DIMS and 0.01% ATP might be a better choice for children with myopia

Article | Open access | Published: 24 December 2022

Synergistic effects of defocus-incorporated multiple segments and atropine in slowing the progression of myopia

Zhu Huang, Xu-Fei Chen, Ting He, Yun Tang & Chi-Xin Du

Scientific Reports **12**, Article number: 22311 (2022) | Cite this article

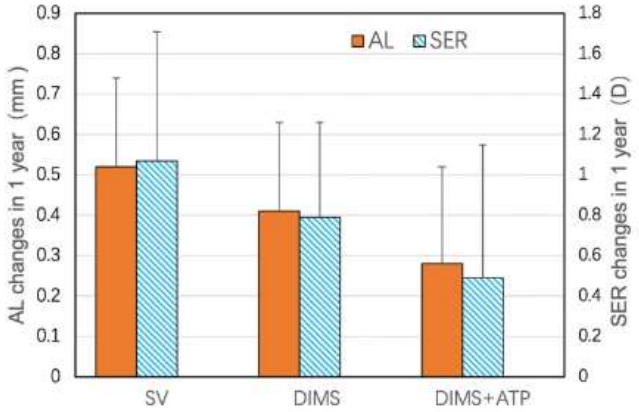

Fig. 29: Changes in AL and SER over 1 year in the DIMS and 0.01% ATP combination group, DIMS monotherapy group, and SV group.

Myopia Control via DIMS and OK

Aim

- compare the efficiency of OK and DIMS lenses in myopia control in children with divergent refractive error status

Methods

- 1-year prospective study
- Subjects: n = 496 (92 %, start: 540), Chinese, age: 7-14 years, SER: −0.50 to −5.00 D (mean: −2.45 ± 1.30 D), astigmatism & anisometropia ≤ 1.50 D, BCVA: 20/20 or better,
- Groups:
  - DIMS: n = 165 (Hoya Inc, Tokyo, Japan)
  - OK: n = 171 (Euclid Inc, Charlotte, NC)
  - SV: control group, n = 160 (aspheric design, Chemilens Inc, Zhejiang, China)

  → after one year follow-up subdivision into:
    - LM: low myopia degree subgroup, -0.50 D to -1.50 D
    - MM: moderate myopia degree subgroup, -1.50 D to -3.00 D
    - HM: high myopia degree subgroup, -3.00 D to -5.00 D
- Measurements: AL at baseline, 6 months and 12 months

Results

- Mean AL changes: OK: 0.20 ± 0.18 mm, DIMS: 0.30 ± 0.22 mm, SV: 0.38 ± 0.19 mm ($p < 0.001$)
- Subgroups:
  - LM: OK and DIMS groups had similar AL changes, but both exhibited significantly slower changes than the SV group ($p = 0.001$)
  - MM: OK group had the shortest AL elongation ($p < 0.05$), better than DIMS group ($p < 0.05$)
  - HM: OK had shortest AL elongation ($p < 0.05$) but no significant differences between DIMS and SVS groups ($p > 0.05$)
  - DIMS showed no significant difference among the subgroups ($p = 0.099$); Ortho-K and SV had lowest increase in AL elongation in HM subgroup, no statistical differences in MM and LM subgroups
- AL change was associated with age ($p = 0.005$), initial AL ($p = 0.011$), initial SE ($p = 0.007$), and interventions using OK ($p = 0.020$) and DIMS ($p = 0.020$)

→ OK and DIMS can significantly retard AL elongation compared with SV

→ OK were more effective than DIMS in controlling AL in subjects with higher degree myopia

Different efficacy in myopia control: Comparison between orthokeratology and defocus-incorporated multiple segment lenses

Weicong Lu [a b c], Rongyuan Ji [a b c], Dongdong Jiang [a b c], Lin Shi [a b c], Wenzhi Ding [a b c], Yuyin Tian [a b c], Chenpei Zhao [a b c], Lin Leng [a b c]

Myopia Control via DIMS, OK & combination with atropine

Aim

- evaluate the efficacy of OK, DIMS lens, combined OK/atropine, and combined DIMS/ atropine for myopia control in children

Methods

- 1-year retrospective clinical study
- Subjects: n = 167, Chinese, age: 6-14 years, SER: −0.75 to −4.00 D, astigmatism and anisometropia: ≤ 1.50 D, BCVA: ≤ 0.10 logMAR
- Groups:
  - OK (Euclid Inc, Charlotte, NC): n = 41
  - AOK: combined OK group (Euclid Inc, Charlotte, NC)/ 0.01 % atropine (at least 15 min before Ortho-K lens wear), n = 43
  - DIMS: n = 41
  - DIMSA: combined DIMS/ 0.01 % atropine, n = 42
- Measurements: AL at baseline and at 3, 6, 9, and 12 months

Results

- AL change after 1 year: OK: 0.20 ± 0.12 mm, AOK: 0.12 ± 0.14 mm, DIMS: 0.22 ± 0.14 mm, and DIMSA: 0.15 ± 0.15 mm
  - → Significant change between OK & AOK (p = 0.042), DIMS & AOK (p = 0.008) and DIMS & DIMSA (p = 0.039), no significant change between OK & DIMS and AOK & DIMSA
  - → AOK and DIMSA significantly slowed axial elongation compared to OK and DIMS monotherapy, slower by 0.08 mm in AOK than OK and by 0.07 mm in DIMSA than DIMS
  - → After stratifcation by age:
    - → subgroup aged 6–10 years: significant difference in AL change between AOK and DIMS (p = 0.013), no significant difference between other groups
    - → subgroup aged 10–14 years: difference between AOK and DIMS became insignificant (p = 0.237), and the difference between OK and AOK (p = 0.046), OK and DIMSA (0.005), DIMS and DIMSA (p = 0.040) became significant
  - → axial length elongation ≤ 0.15 mm in 53.33 % AOK, 47.06 % DIMSA, 43.75 % DIMS, and in 37.93 % OK subjects
- → OK and DIMS lenses show similar reductions in myopia progression among children with low initial myopia
- → Atropine can significantly improve the efficacy of myopia control of both OK and DIMS lenses, and this add-on effect is better in older children
- → OK combined with atropine achieved the best efficiency of myopia control over 1 year of treatment

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Comparison of the long-term effects of atropine in combination with Orthokeratology and defocus incorporated multiple segment lenses for myopia control in Chinese children and adolescents

Tao Tang, Yuchang Lu, Xuewei Li, Heng Zhao, Kai Wang, Yan Li & Mingwei Zhao

Eye **38**, 1660–1667 (2024) | Cite this article

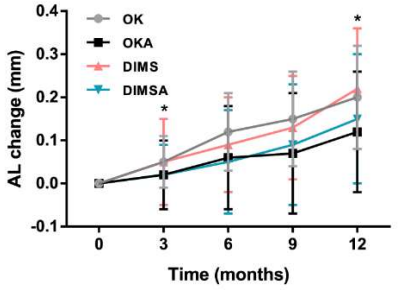


Fig. 30: Change in AL for 1 year in the four treatment groups.

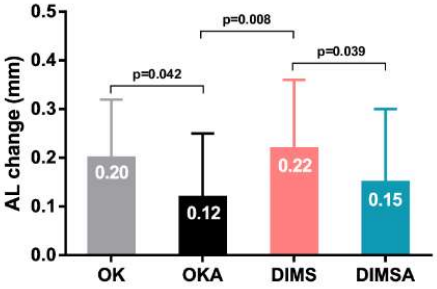
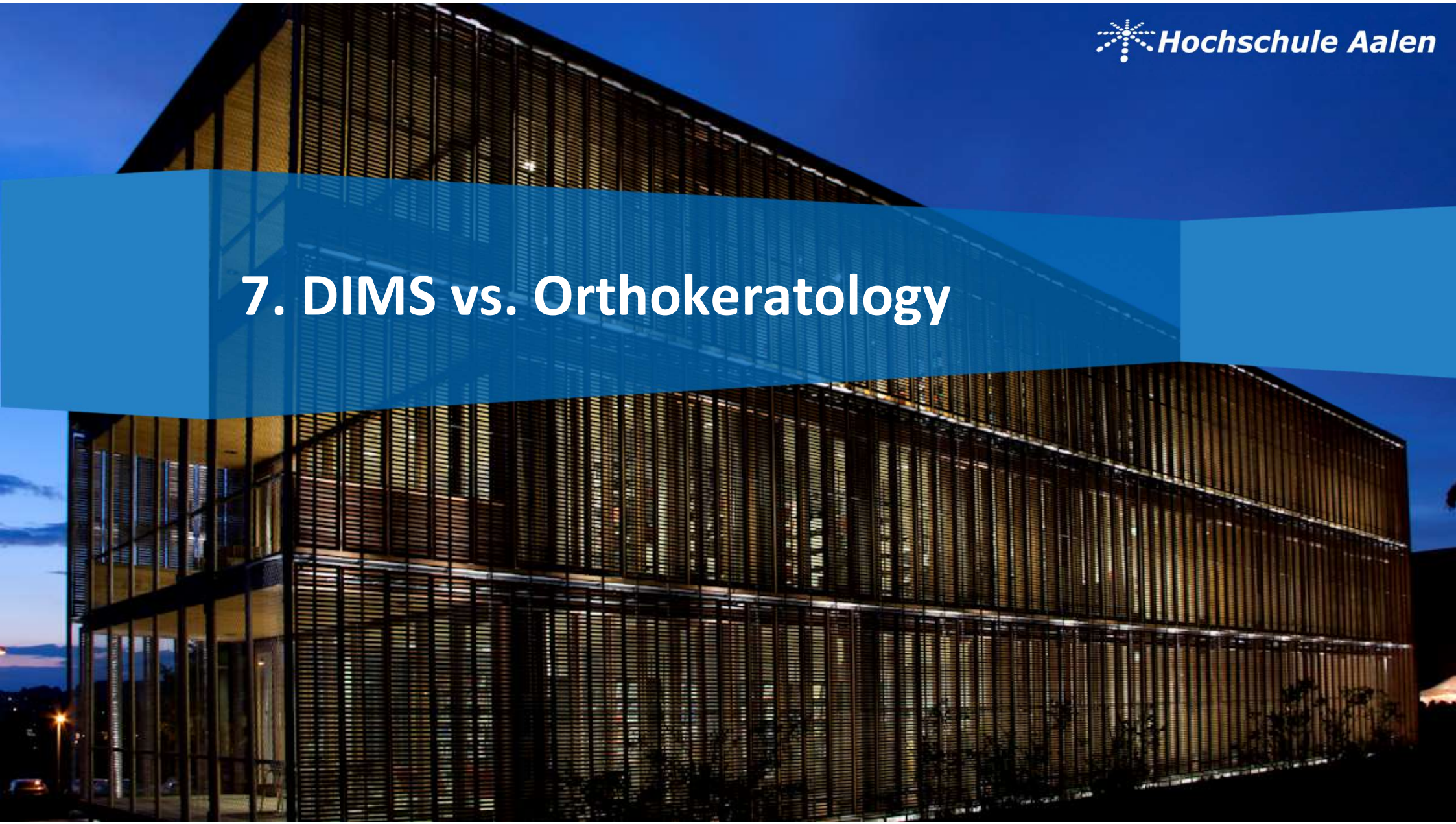


Fig. 31: 1-year AL elongation in the four treatment groups.



7. DIMS vs. Orthokeratology

Effectiveness in combination therapies

- **Multifocal-CL + 0.01 % atropine:** no better myopia control than with CL-monotherapy
- **OK + 0.01 % atropine:** significantly slower axial elongation than with monotherapies by 0.08 – 0.18 mm
- **DIMS + 0.01 % atropine:**
  - Nucci, P. et al. (2023): Significantly less progression in SER by 0.151 D compared to DIMS and by 0.163 D compared to atropine at 12 months therapy, only less AL growth progression compared to control group
  - Huang, Z. et al. (2022): significantly less SER progression by 0.3 D and significantly less axial growth by 0.13 mm compared to DIMS
  - Tang, T. et al. (2024): significant less axial growth by 0.07 mm compared to DIMS

  → DIMS most successful at reducing myopia progression when used in combination with 0.01 % atropine

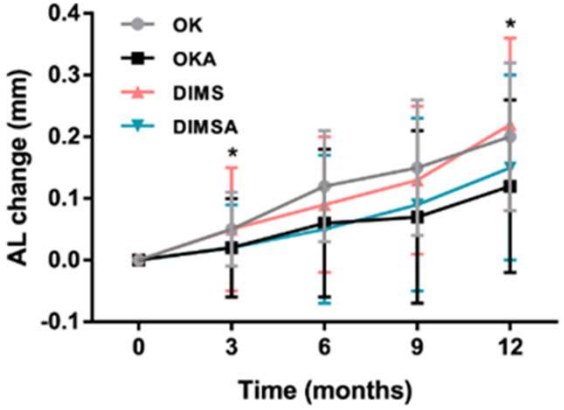
  → OK + atropine and DIMS + atropine most effective, lets compare those treatment options

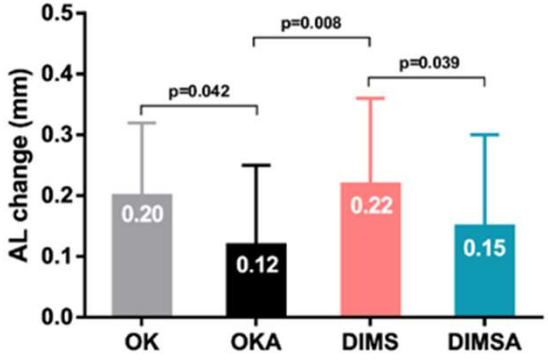
DIMS vs. Orthokeratology

- Lu, W. et al. (2024): 0.10 mm less mean AL change with OK than with DIMS therapy, OK more effective than DIMS in higher degree myopia
- Tang, T.et al. (2024):
  - Significant less AL change by 0.10 mm in AOK than in DIMS group
  - No significant changes between OK & DIMS and AOK & DIMSA
  - AOK and DIMSA significantly slowed axial elongation compared to OK and DIMS monotherapy

→Atropine can significantly improve the efficacy of myopia control of both OK and DIMS lenses, effect is better in older children

→AOK achieved best efficacy in myopia control over 1 year





DIMS vs. Orthokeratology

Why might OK have performed better than DIMS?

- Lu, W. et al. (2024):
  - DIMS lenses have fixed defocus power of +3.50 D; OK defocus power is based on individual refractive error
  - Range of defocus area could also play a role
- Tang, T.et al. (2024):
  - differences in the retinal profile or peripheral refraction
  - initial age important

→Larger peripheral retinal myopic defocus & smaller defocus zone in OK

DIMS summary & outlook

- **DIMS main messages:**

1. Effective non-invasive technology in myopia control
2. Lenslets induce myopic defocus in retina to slow down eye growth
3. Most successful at reducing myopia progression when used in combination with atropine

→Technology is continually evolving
→High hope in combination therapies
→fewer control groups for single vision, as this is ethically questionable as every year wasted contributes to eyes getting longer and developing diseases

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