27th EVER CONGRESS
3 - 5 November 2024
Valencia

Defocus Incorporated Multiple Segment (DIMS) spectacle lenses and 0.025% Atropine for myopia control in a European population: 12-month results of a randomized clinical trial

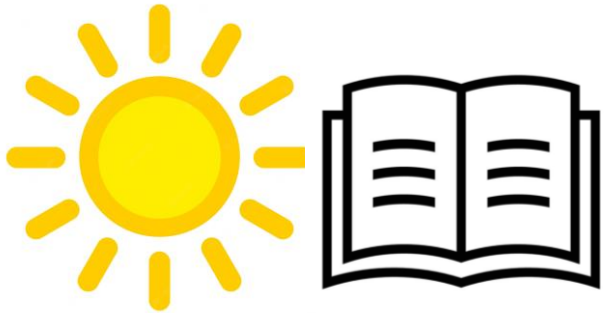
Noemi Guemes Villahoz, Paula Talavero-Gonzalez, Rafael Bella-Gala, Paloma Porras-Angel,Elena Hernandez-Garcia, Beatriz Martin-Garcia, Alicia Ruiz-Pomeda, C Nunila Gomez-de-Liano, Rakhee Shah, Julian Garcia Feijoo, Rosario Gomez-de-Liano

CONFLICTS OF INTEREST

Financial disclosure: Outside consultant to HOYA Corporation

This study is a collaborative research project supported by HOYA Corporation

MYOPIA MANAGEMENT



ENVIROMENTAL RISK FACTORS

PHARMACEUTICAL INTERVENTIONS (Atropine Eyedrops)

OPTICAL INTERVENTIONS

Repeated Low-level Red Light (RLRL)

Atropine in Combination with Optical Interventions

1. Atropine + Ortho-K
2. Atropine + Soft Contact Lenses (*different designs*)
3. Atropine + Spectacle Lenses (*different designs*)

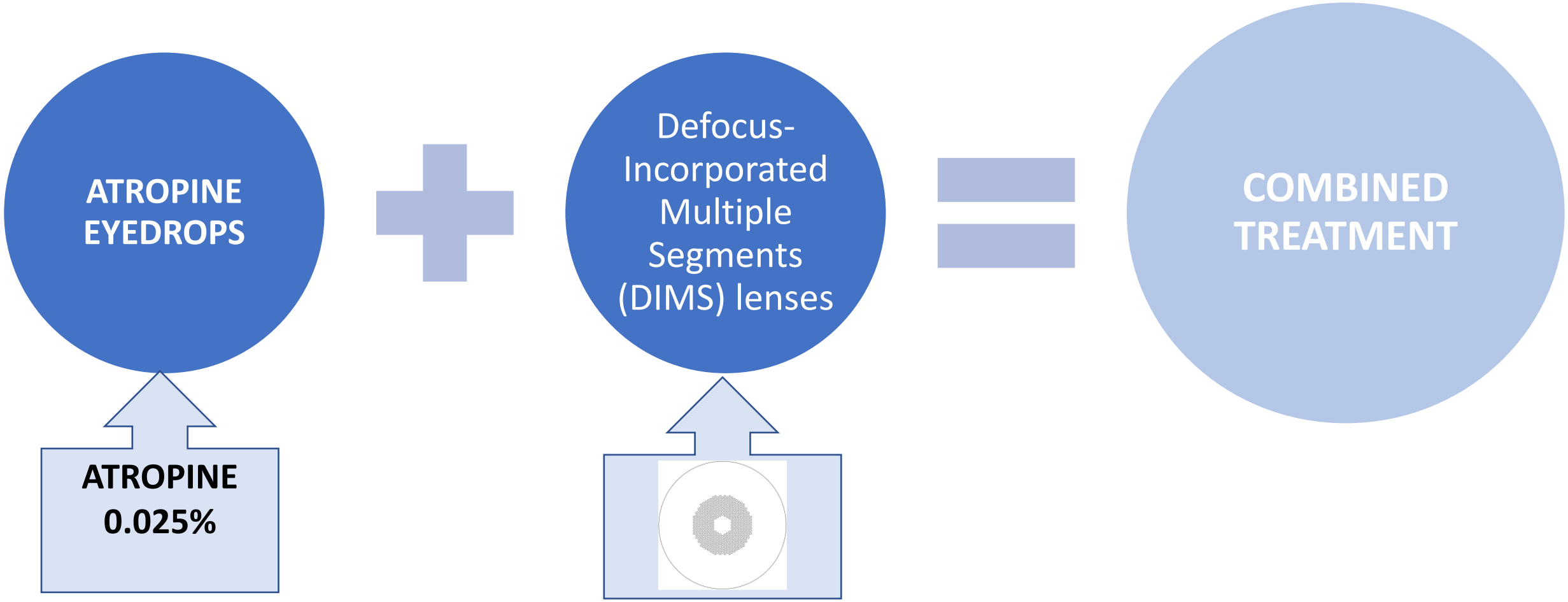
- *Xu S et al Effect of atropine, orthokeratology and combined treatments for myopia control: a 2-year stratified RCT. Br J Ophthalmol. 2023*
- *Erdinest N et al.Low-Concentration Atropine Monotherapy vs. Combined with MiSight 1 Day Contact Lenses for Myopia Management. Vision (Basel). 2022*
- *Erdinest N et al. Treatment of Rapid Progression of Myopia: Topical Atropine 0.05% and MF60 Contact Lenses. Vision. 2024.*
- *Nucci P, et al. A comparison of myopia control in European children and adolescents with defocus incorporated multiple segments (DIMS) spectacles, atropine, and combined DIMS/atropine. PLoS One. 2023.*
- *Huang Z et al. Synergistic effects of defocus-incorporated multiple segments and atropine in slowing the progression of myopia. Sci Rep. 2022*

Atropine in Combination with Optical Interventions

1. Atropine + Ortho-K
2. Atropine + Soft Contact lenses (*different designs*)
3. **Atropine + spectacle lenses (*different designs*)**

- *Xu S et al Effect of atropine, orthokeratology and combined treatments for myopia control: a 2-year stratified RCT. Br J Ophthalmol. 2023*
- *Erdinest N et al.Low-Concentration Atropine Monotherapy vs. Combined with MiSight 1 Day Contact Lenses for Myopia Management. Vision (Basel). 2022*
- *Erdinest N et al. Treatment of Rapid Progression of Myopia: Topical Atropine 0.05% and MF60 Contact Lenses. Vision. 2024.*
- *Nucci P, et al. A comparison of myopia control in European children and adolescents with defocus incorporated multiple segments (DIMS) spectacles, atropine, and combined DIMS/atropine. PLoS One. 2023.*
- *Huang Z et al. Synergistic effects of defocus-incorporated multiple segments and atropine in slowing the progression of myopia. Sci Rep. 2022*

Defocus Incorporated Multiple Segment (DIMS) spectacle lenses and 0.025% atropine for myopia control: 12-month results of a Randomized Controlled Trial



METHODS

Cycloplegic Spherical Equivalent Refraction (SER)

Axial Length (Biometry)

Choroidal Thickness Optical Coherence Tomography (OCT)

Visual Related Quality of Life (VR-QoL)

Primary Outcomes

Secondary Outcomes

INTERVENTIONS

1 Atropine 0.025%

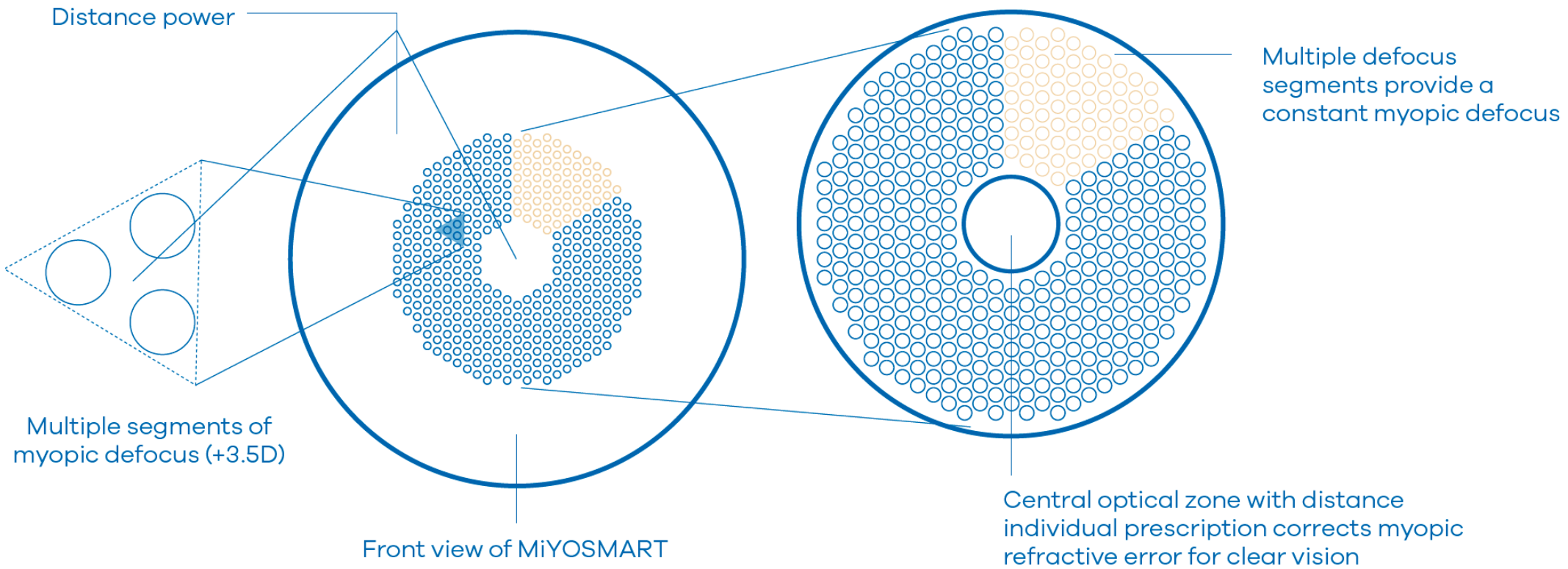
Atropine sulfate at 0.025% concentration

- Compounded Atropine→*not commercially available in Europe.*

All eyedrops came from the same compounding Pharmacy specialized in the preparation of individualized medications

- *Goverment regulated→ Drug Quality and Security Act*

2 Defocus-Incorporated Multiple Segments (DIMS) spectacle lenses



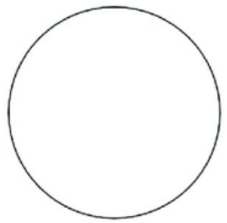
Randomized Controlled Trial (RCT) aims to evaluate and compare the efficacy of combination treatment using 0.025% atropine and DIMS spectacle lenses compared to 0.025% atropine and single vision (SV) lenses in slowing myopia progression

Group A

ATROPINE EYEDROPS
0.025%

+

Single vision lenses

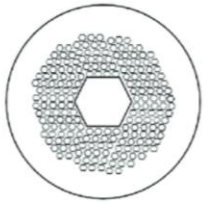


Group B

ATROPINE EYEDROPS
0.025%

+

DIMS spectacle lenses



METHODS

EU Clinical Trials Register

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

agencia española de medicamentos y productos sanitarios

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

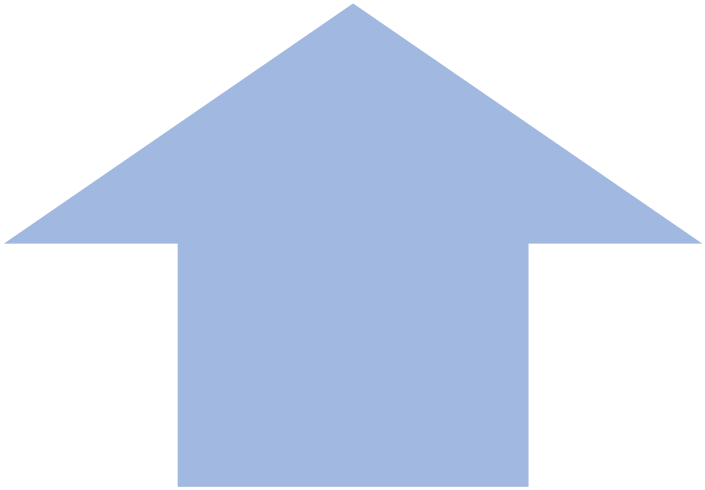
Combination therapy vs. Monotherapy

Atropine 0.025% eyedrops

+

DIMS spectacle lenses

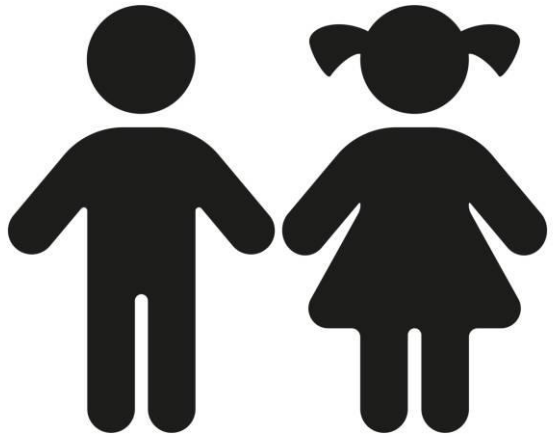
12 month Preliminary Data



RESULTS: Demographic Data

- 79 patients completed the 12 month-follow-up to date

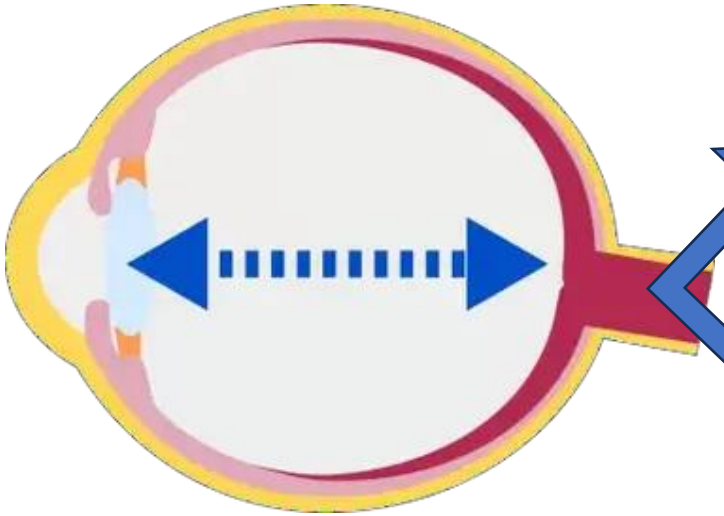
Group A	Group B
• **n=38 (48.1%)** • Mean Age 9.00 ±2.74years • Female 47.4%	• **n=41 (51.9%)** • Mean Age 9.68±2.65 years • Female 46.3%



All p>0.05

There was no significant association between group and sex (p = 0.93) or the difference in age between the groups (p = 0.26).

RESULTS: Mean AL ±SD change over 12 months



Group A

0.18±0.13 mm

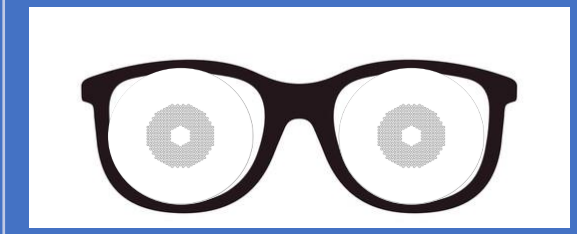
Group B

0.08±0.16 mm

Combined treatment group (B) had significantly less axial elongation than group A

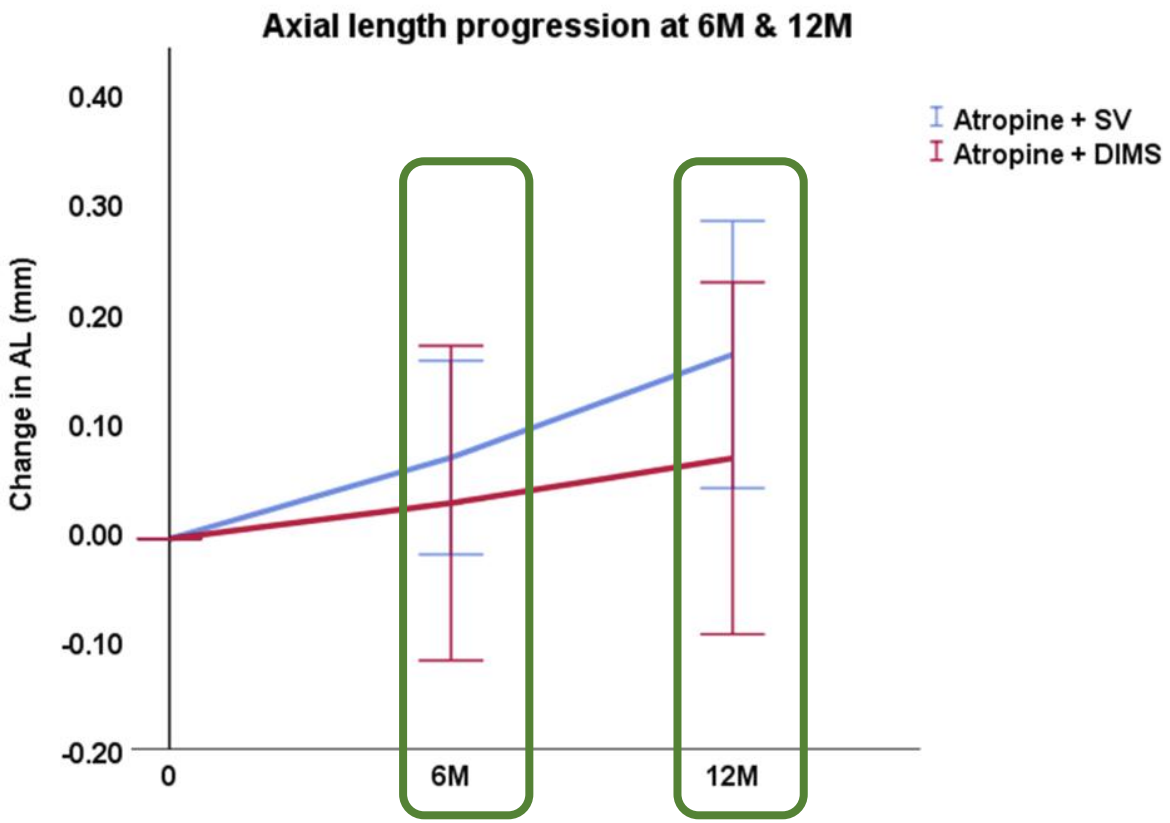
mean difference of 0.10 (SE: 0.03)mm (95% CI 0.03 to 0.16, p=0.005).

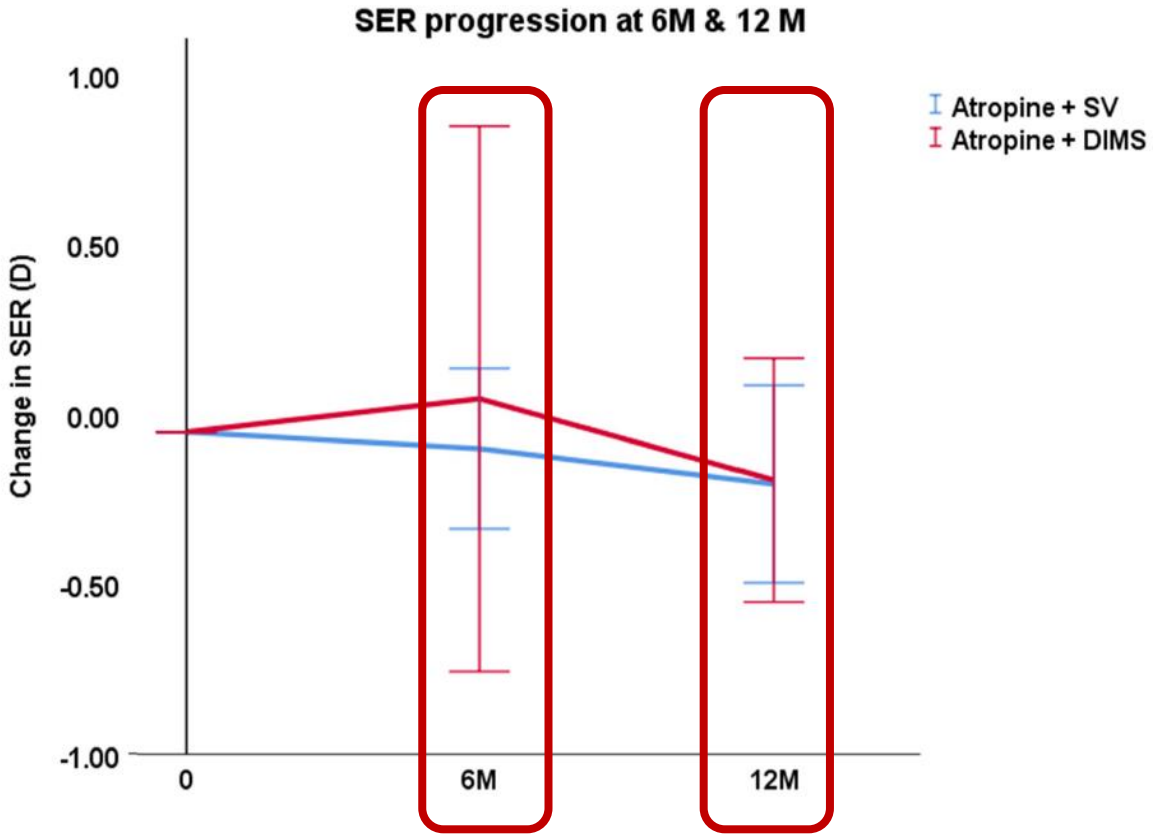
RESULTS: Mean SER ±SD progression over 12 months

Group A	Group B
0.16±0.31 D	0.15±0.38 D
	

mean difference -0.01D (SE: 0.08, 95% CI -0.17 to 0.14, p=0.87).

RESULTS: Mean AL and SER over 12 months





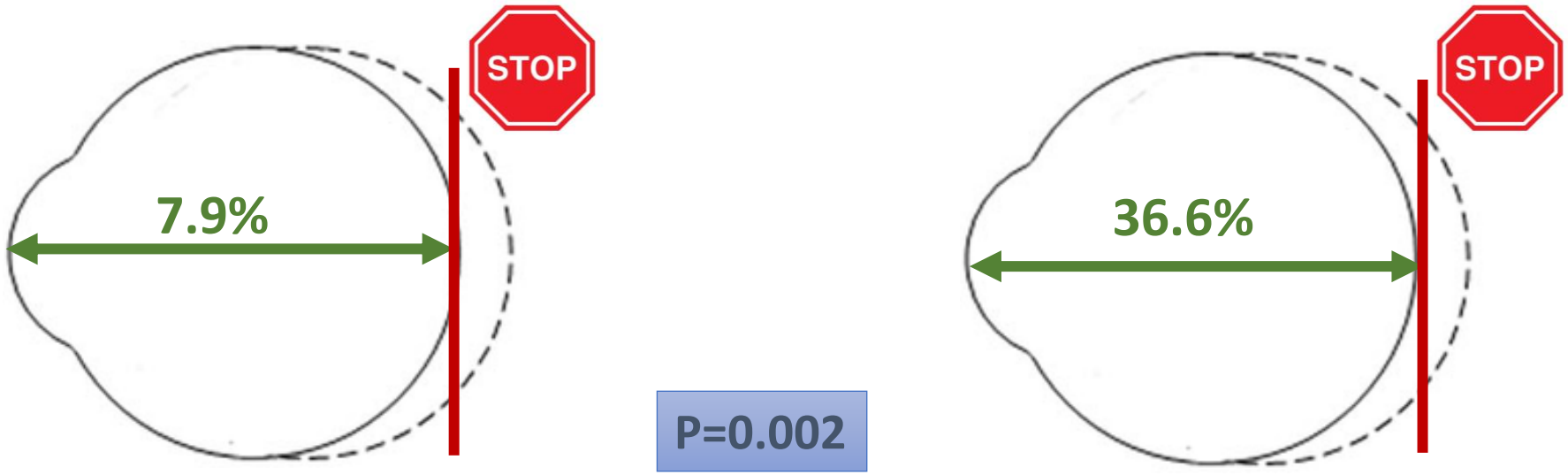
RESULTS: No axial elongation over 12 months

Group A

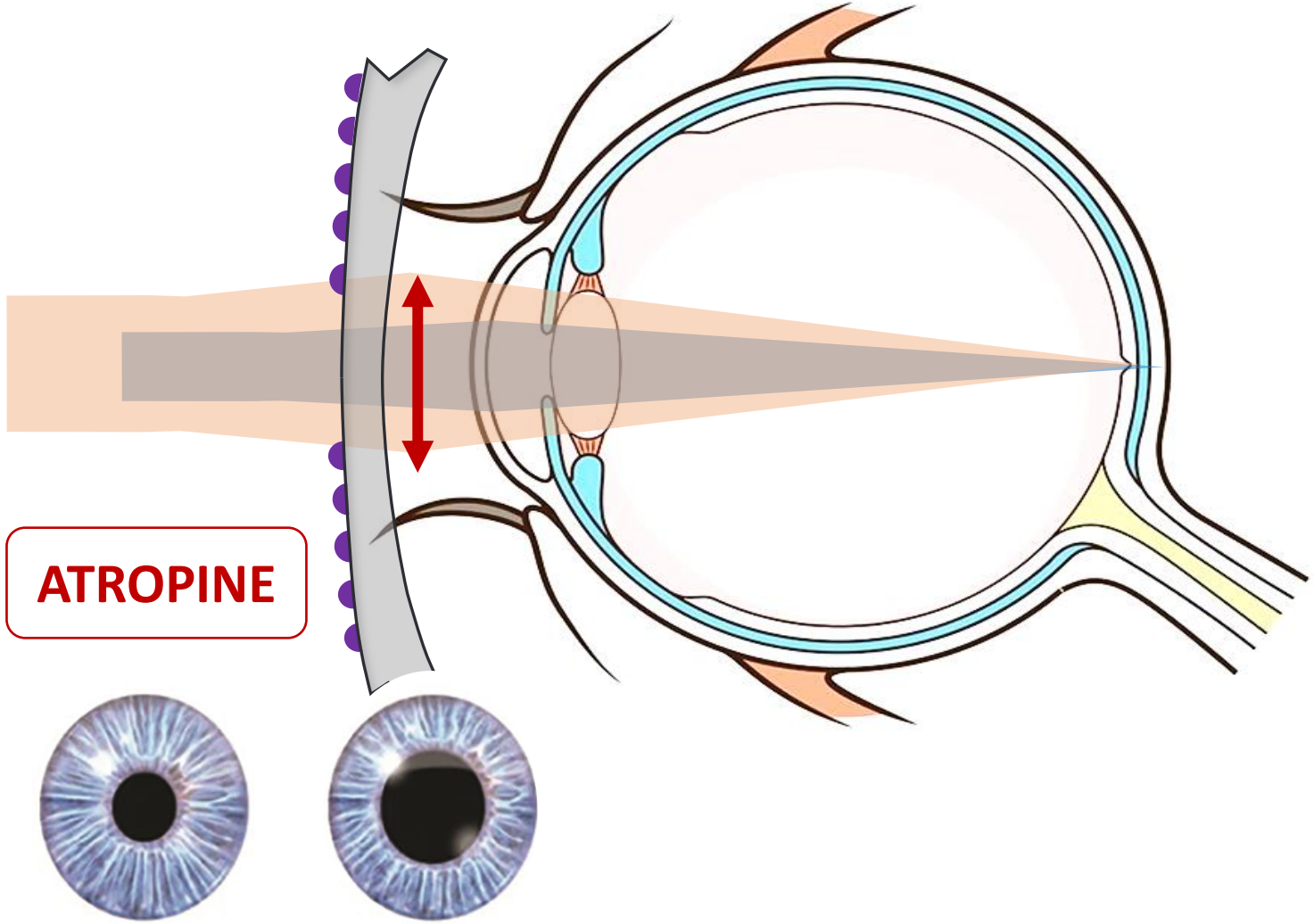
- **7.9%** of the children in had no axial elongation over 12 months

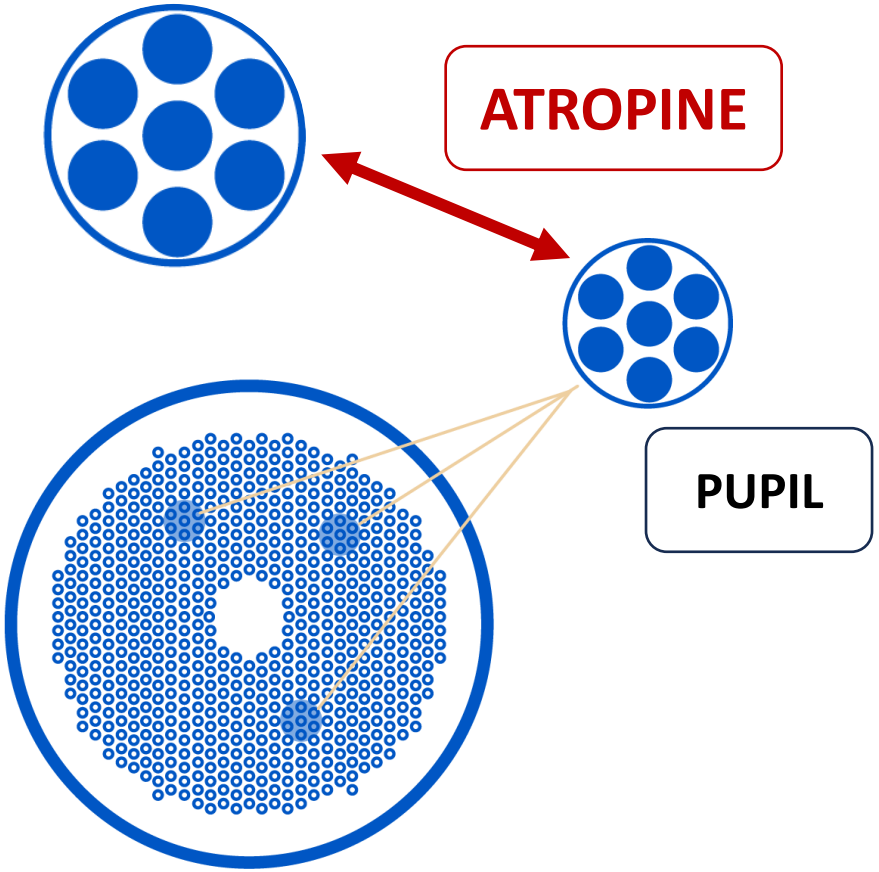
Group B

- 36.6% had no axial elongation over 12 months



DISCUSSION: Possible mechanisms: Atropine + DIMS lenses





COMBINED TREATMENT: Atropine + DIMS Spectacle Lenses

› Sci Rep. 2022 Dec 24;12(1):22311. doi: 10.1038/s41598-022-25599-z.

Asian

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

Zhu Huang [1 2], Xu-Fei Chen [2], Ting He [2], Yun Tang [2], Chi-Xin Du [3 4]

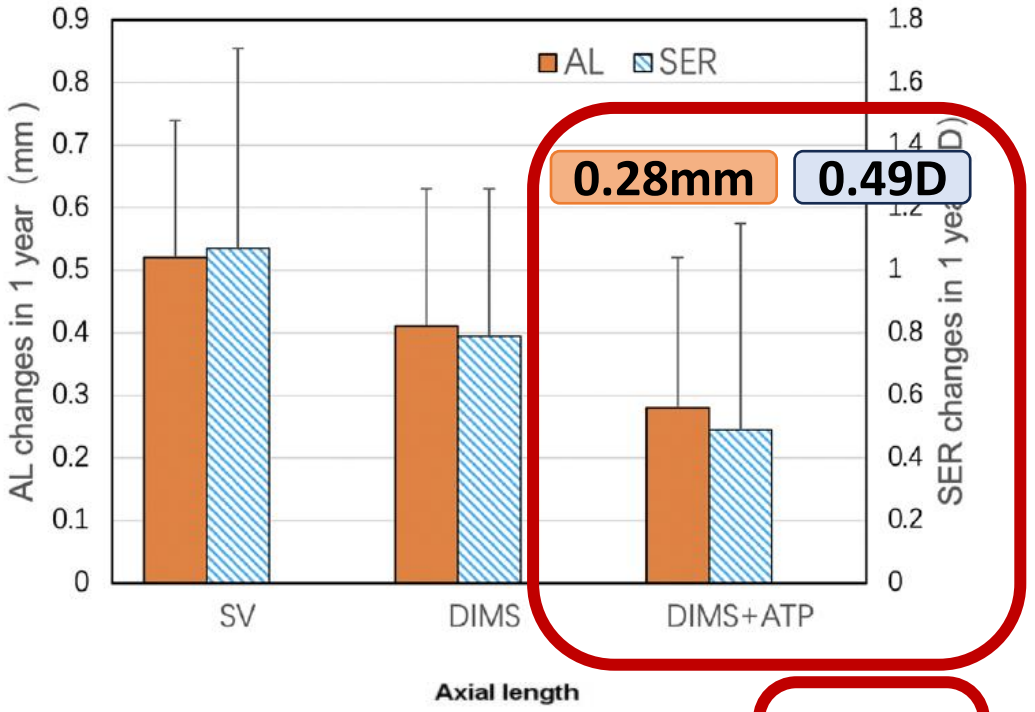
Observational Study › PLoS One. 2023 Feb 16;18(2):e0281816. doi: 10.1371/journal.pone.0281816. eCollection 2023.

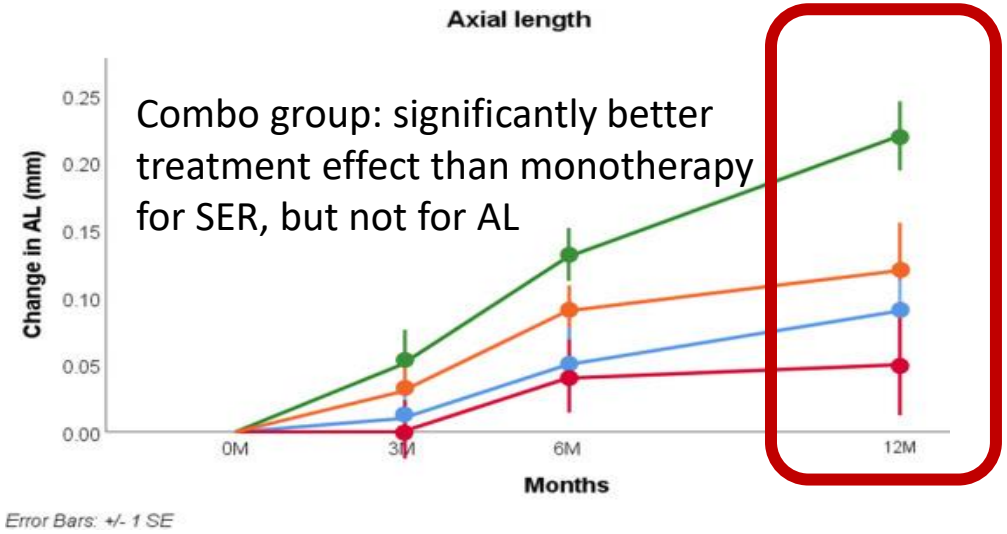
European

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]

ATROPINE 0.01% + **DIMS Spectacle Lenses**





Combo group: significantly better treatment effect than monotherapy for SER, but not for AL

CONCLUSIONS

1. **Combination treatment with 0.025% atropine and DIMS spectacle lenses is more effective in controlling axial elongation** than 0.025% atropine with SV lenses

2. The **differences in SER** between the groups were **not significant**

CONCLUSIONS

3 **The AL increase in group B** (0.07mm/year) **was less than that previously reported with DIMS lenses alone** in Asian (0.11mm/year) and European children (0.18mm/year) over 12 months

4 These findings suggest that other factors, such as pupil size, **may enhance the efficacy of DIMS lenses in controlling axial elongation**, supporting a possible synergistic effect of the two treatments.

Lam CSY et al. Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial. Br J Ophthalmol. 2020
McCullough Set al. 2-Year Multi-Site Observational Study of MiYOSMART myopia control spectacle lenses in UK children: 1-year results. Invest. Ophthalmol. Vis. Sci. 2023

CONCLUSIONS

Combined 0.025% atropine and DIMS spectacle lens treatment is more effective in controlling axial elongation than 0.025% atropine with SV lenses

Preliminary data
12-month results→Long-term results
Atropine concentration
Rebound effect

27th EVER CONGRESS

3 - 5 November 2024
Valencia

THANKS
MUCHAS GRACIAS