Defocus Incorporated Multiple Segments Spectacle lenses and 0.025% atropine for myopia control in European children: 12-month results of a Randomized Clinical Trial

Noemi Guemes Villahoz[1-3], Paula Talavero-Gonzalez[1], Rafael Bella-Gala[2], Paloma Porras-Angel[2,3], Elena Hernandez-Garcia[1], Beatriz Martin-Garcia[2], Alicia Ruiz-Pomeda[2], C Nunila Gomez-de-Liano[2],Rakhee Shah[4,5], Julian Garcia Feijoo[1-3], Rosario Gomez-de-Liano[1-3]

Affilations: *1. Ophthalmology Service, Hospital Clinico San Carlos, Madrid, Spain. 2. San Carlos Health Research Institute (IdISSC), Madrid, Spain 3. Complutense University of Madrid, Spain 4. Centre of Applied Vision Research, Optometry & Visual Sciences, City St George's, University of London. 5. HOYA Vision Care, Amsterdam, The Netherlands*

noemiguemes@gmail.com

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BACKGROUND

Defocus Incorporated Multiple Segments (DIMS) spectacle lenses and atropine have proven standalone efficacy in controlling myopia progression in children.[1,2]

There is a scarcity of evidence of their efficacy when used in combination.[3,4]

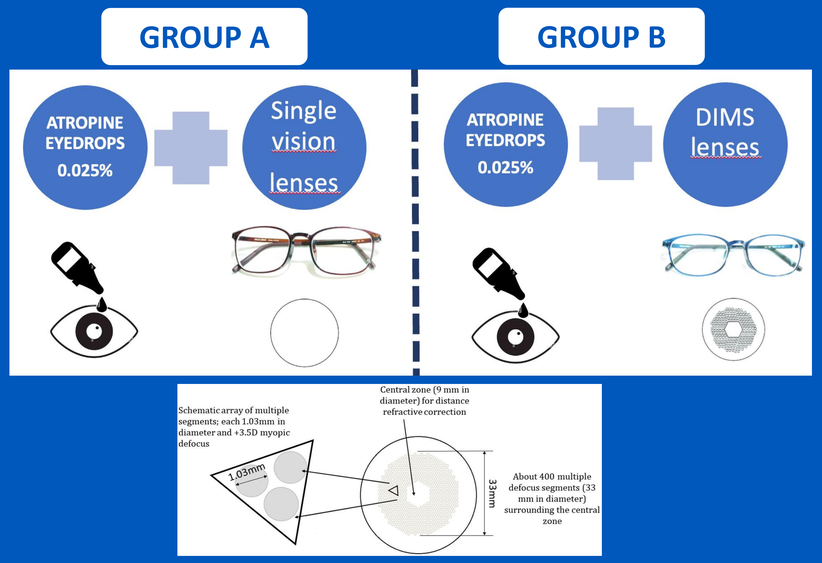
PURPOSE: This **randomized controlled trial (RCT)** aims to evaluate and compare the **efficacy** of **combination treatment** using **0.025% atropine and DIMS spectacle lenses** compared to **0.025% atropine and single vision (SV) lenses** in slowing myopia progression in European myopic children.

METHODS

RCT conducted on children aged 4-16 years with myopia between -1.00 and -6.00D and astigmatism ≤2.00D.

Random allocation:

0.025% atropine and SV lenses treatment group (group A) **or** 0.025% atropine and DIMS lenses treatment group (group B).



Cycloplegic spherical equivalent refraction (SER) and axial length (AL) were measured at baseline, 6 and 12 months.

Statistical analyses (Mann-Whitney U-test or Chi-squared test) were performed to test for significance between the two groups.

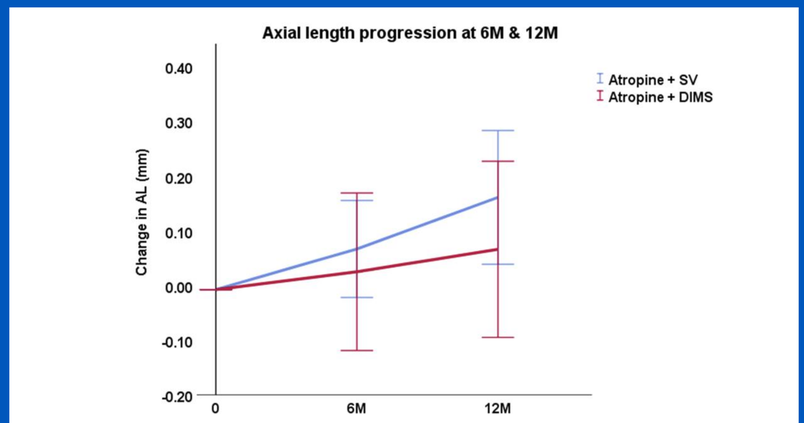
RESULTS

79 patients completed the 12 month-follow-up:

Group A: n=38 (48.1%), 47.4% female, mean age of 9.00 ±2.74 years

Group B: n=41 (51. 9%), 46.3% female, mean age of 9.68±2.65 years

No significant differences in gender (p = 0.93) or age (p = 0.26) between the groups.



AXIAL LENGTH

At 6 months, mean AL ±SD change was 0.08±0.09 mm in group A and 0.03±0.15 mm in group B. Group B had significantly less axial elongation than group A, with a mean difference of 0.04 (SE: 0.03)mm (95% CI -0.01 to 0.10, p=0.13).

At 12 months, mean AL ±SD change was 0.18±0.13 mm in group A and 0.08±0.16 mm in group B. Group B had significantly less axial elongation than group A, with a mean difference of 0.10 (SE: 0.03)mm (95% CI 0.03 to 0.16, p=0.005).

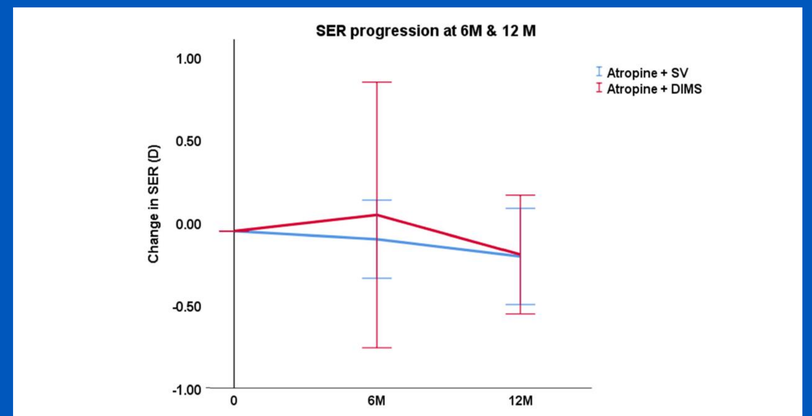
36.6% of the children in Group B had no axial elongation over 12 months, compared to 7.9% of the children in group A (p=0.002).

RESULTS

SER:

At 6 months, mean SER ±SD progression was -0.05±0.25 D (Group A) and 0.10±0.85 D (Group B), mean difference -0.16 (SE: 0.14) D (95% CI -0.3 to 0.12, p=0.27).

At 12 months, mean SER ±SD progression was -0.16±0.31 D and -0.15±0.38 D, respectively, mean difference -0.01 (SE: 0.08) D (95% CI -0.17 to 0.14, p=0.87).



CONCLUSIONS

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

The differences in SER between the groups were not significant.

The AL increase in group B was less than that previously reported with DIMS spectacle lenses alone in Asian and European children over 12 months.

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 between the two treatments.

References

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