Atropine and Spectacle lens Combination Treatment (ASPECT): 12-month results of a randomised controlled trial for myopia control using a combination of Defocus Incorporated Multiple Segments (DIMS) lenses and 0.025% atropine

Guemes-Villahoz, Noemi^{1,2}; Talavero-Gonzalez, Paula¹; Porras-Angel, Paloma^{2,4}; Bella-Gala, Rafael⁴; Ruiz-Pomeda, Alicia⁴; Martin-Gonzalez, Beatriz⁴; Hernandez-Garcia, Elena¹; Gomez-de-Liano, Carmen Nunila³; Shah, Rakhee^{5,6}; Garcia-Feijoo, Julian^{1,2,3}; Gomez-de-Liano, Rosario^{1,2,3}

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1.Department of Ophthalmology, Hospital Clinico San Carlos, San Carlos, San Carlos Health Research Institute, Madrid, Spain. 3.Department of Immunology, Ophthalmology and Otorhinolaryngology, Medical school, Complutense University, Madrid, Spain. 4.Optometry and Vision Department of Immunology, Ophthalmology and Otorhinolaryngology, Medical school, Complutense University, Madrid, Spain. 5.Department of Optometry and Vision Care, Amsterdam, the Netherlands

noemiguemes@gmail.com

Purpose

Defocus Incorporated Multiple Segments (DIMS) spectacle lenses and atropine have proven standalone efficacy in controlling myopia progression in children. However, there is a scarcity of evidence of their efficacy when used in combination. This is the first randomised controlled trial (RCT) that evaluates and compares the efficacy of combination treatment using 0.025% atropine and DIMS spectacle lenses to 0.025% atropine and single vision (SV) spectacle lenses in slowing myopia progression in myopic children.

Methods

Children aged 4-16 years with myopia between -1.00D and -6.00D and astigmatism ≤2.00D were recruited and randomly allocated in two groups: 0.025% atropine and SV spectacle lenses treatment group (group A) or 0.025% atropine and DIMS spectacle lenses treatment group (group B).

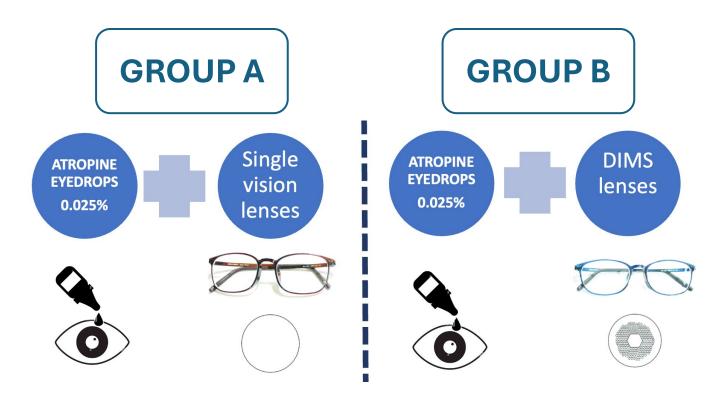


Figure 1. Study treatment groups

Cycloplegic spherical equivalent refraction (SER) and axial length (AL) were measured at baseline, 6 and 12 months. Statistical analyses using independent sample t-test or the non-parametric Mann-Whitney U test, as appropriate, were performed to test for significance between the two groups.

Results

102 patients completed the 12-month follow-up: n=49 in group A, mean age 9.50±2.78 years, and n=53 in group B, mean age 9.90±2.47 years.

At 12 months, mean AL \pm SD change was 0.18 \pm 0.16mm in group A and 0.07 \pm 0.16mm in group B (mean difference: 0.11, 95% CI: 0.05 to 0.17; p=<0.001).

Mean SER ±SD progression was -0.19±0.42D and -0.09±0.35D in group A and B at 12 months, respectively (p=0.13).

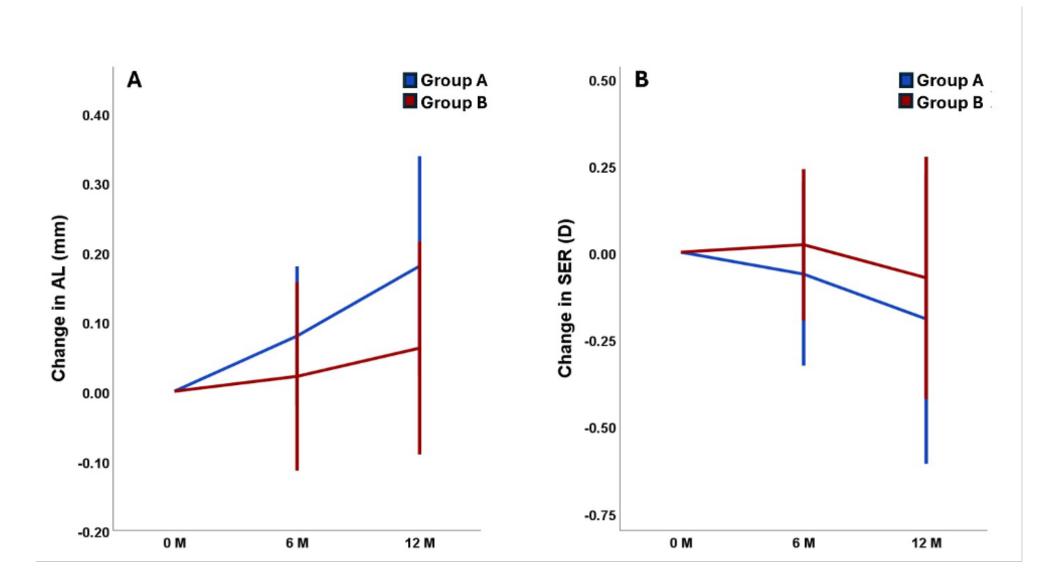


Figure 2. Changes in axial length (AL) and spherical equivalent refraction (SER) over 1 year in group A (blue) and group B (red).

39.6% of children in group B had no axial elongation over 12 months, compared to 12.2% of the children in group A (p=0.002).

Discussion

According to the Age-Matched Myopia Control (AMMC) system data, most patients treated with a combination of 0.025% atropine eye drops and DIMS spectacle lenses achieve comparable axial elongation to age-matched emmetropes during the first year of treatment. This suggests that combined therapy is a promising management strategy, especially for younger children with increased AL.

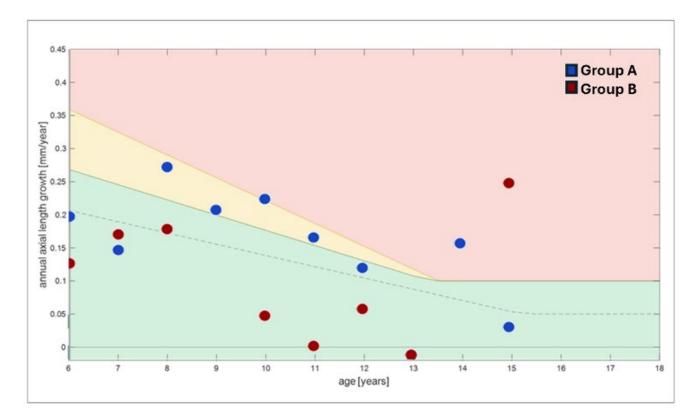


Figure 3. Axial length growth in groups A and B, plotted in the AMMC system. For each age, the mean annual AL growth value is plotted within the color-coded zones: "green" corresponds to the physiological AL growth rate, "yellow" corresponds to a moderately excessive AL growth rate (+25% but less than +50% of the average physiological AL growth rate), "red" reflects a highly excessive AL growth rate (more than 50% above the physiological AL growth rate). Each point represents the mean AL value for a given age.

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. Myopic children treated with combination treatment achieved emmetropic agematched axial length growth over 12 months, and approximately 4 out 10 children had no axial elongation over 12 months, suggesting a promising approach for myopia management.

References

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Acknowledgments / Disclosures

