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

NOEMI GUEMES-VILLAHOZ^{*1,2}, Paula Talavero-Gonzalez¹, Paloma Porras-Angel^{1,2}, Rafel Bella-Gala³, Alicia Ruiz-Pomeda³, Beatriz Martin-Gonzalez³, Elena Hernandez-Garcia¹, Carmen Nunila gomez-de-liano³, Rakhee Shah^{4,5}, Julian Garcia-Feijoo^{1,2}, Rosario Gomezde-liano^{1,2}

¹Ophthalmology, Hospital Clinico San Carlos, Madrid, Comunidad de Madrid, Spain; ²Complutense University of Madrid, Ramón Castroviejo Institute for Ophthalmological Research, Madrid, Spain; ³Universidad Complutense de Madrid, Madrid, Spain; ⁴Department of Optometry and Visual Sciences, City St George's, University of London, London, London, United Kingdom; ⁵Hoya Vision Care, Amsterdam, Amsterdam, Netherlands

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). 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±SD change was 0.18 ± 0.16 mm in group A and 0.07 ± 0.16 mm 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). 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).

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 therapy achieved emmetropic age-matched 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.

Layman Abstract (optional): Provide a 50-200 word description of your work that nonscientists can understand. Describe the big picture and the implications of your findings, not the study itself and the associated details.

Myopia has become a major global public health problem, recently classified as a disease by the National Academies of Sciences, Engineering, and Medicine. Therefore, controlling myopia progression is crucial to reduce the risk of myopia-related ocular complications. Atropine eyedrops and Defocus Incorporated Multiple Segments (DIMS) spectacle lenses have shown efficacy in slowing myopia progression in children. However, there is limited evidence on the efficacy of combining these two treatments. This is the first randomised controlled trial to assess the efficacy and safety of combined treatment with atropine eye drops and Defocus Incorporated Multiple Segments (DIMS) spectacle lenses in Europe and, to the best of our knowledge, worldwide. This study demonstrates that the combination of atropine (0.025%) eyedrops and DIMS spectacle lenses was more effective in controlling axial elongation than atropine with single vision lenses. Additionally, approximately 4 out 10 children had no axial elongation over 12 months, suggesting that combination treatment is a promising approach for myopia management.