

Defocus Incorporated Multiple Segment lenses and 0.025% atropine for myopia control in European children: 12-month results of a randomized clinical trial

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

Methods: A 12-month RCT was carried out on myopic children aged 4-16 years with myopia between -1.00 and -6.00D and astigmatism ≤ 2.00 D. Children were randomly assigned to the 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: n=38 (48.1%) in group A (47.4% female), mean age of 9.00 ± 2.74 years and n=41 (51.9%) in group B (46.3% female), mean age of 9.68 ± 2.65 years. There was no significant association between group and sex ($p = 0.93$) or the difference in age between the groups ($p = 0.26$). At 6 months, mean AL \pm SD change was 0.07 ± 0.10 mm in group A and 0.03 ± 0.13 mm in group B. Group B had significantly less axial elongation than group A, with a mean difference of 0.04 ± 0.02 mm (95% CI 0.01 to 0.08, $p=0.007$). At 12 months, mean AL \pm SD change was 0.16 ± 0.13 mm in group A and 0.09 ± 0.16 mm in group B. Group B had significantly less axial elongation than group A, with a mean difference of 0.07 ± 0.02 mm (95% CI 0.03 to 0.12, $p < 0.001$). Mean SER \pm SD progression was -0.05 ± 0.25 D and -0.05 ± 0.27 D, and -

0.16±0.31 D and -0.16±0.36 D in group A and B at 6 and 12 months, respectively (p=0.61). 39.5% of the children in Group B had no axial elongation over 12 months, compared to 14.5% of the children in group A (p<0.001).

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 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.