

Control of myopia using contrast modulation spectacle lenses in a Chinese population: 18-month results

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PURPOSE

Contrast modulation spectacle lenses (Diffusion Optics Technology™; DOT) are designed to slow myopia progression by reducing contrast signaling in the retina. A 4-year multicenter clinical trial demonstrated DOT lenses are safe and effective at slowing the progression of myopia in North American children. The purpose of this study was to further evaluate the myopia control efficacy of DOT spectacle lenses in a Chinese population.

METHODS

The study (NCT05562622) is a 24-month, randomized (2:1 ratio), masked and controlled clinical trial across 5 Chinese hospitals, evaluating DOT spectacle lenses versus standard single vision control spectacle lenses in myopic children aged 6–13, with a planned interim analysis at 18 months (M). The primary endpoint is change from baseline in axial length (AL) and a secondary endpoint is cycloplegic spherical equivalent refraction (cSER). A linear mixed-effects model for repeated measures was fitted to the data to evaluate the treatment effect over time.

RESULTS

The modified intent-to-treat (mITT) group consist of 186 participants; 48% male; mean age 9.6 years; 128 DOT, 58 Control. Baseline average ($\pm$ SD) for AL and cSER were 24.45 mm (0.80) and -2.27 D (0.85), respectively. 171 children completed the 18M visit (123 DOT; 48 Control).

For DOT wearers, the least square (LS) means changes $\pm$ SE at 18M from baseline in AL was 0.17 ± 0.03 mm (95%CI: 0.12 to 0.22, $p < 0.0001$) and cSER was -0.20 ± 0.05 D (95%CI: -0.30 to -0.09, $p = 0.0004$). For the control group, AL was 0.51 ± 0.04 mm (95%CI: 0.44 to 0.58, $p < 0.0001$) and cSER was -0.89 ± 0.08 D (95%CI: -1.06 to -0.73, $p < 0.0001$).

Based on type 3 tests of fixed effects, estimates of the differences in AL elongation and cSER progression for DOT wearers was 0.34 mm (95%CI 0.25 to 0.42, $p < 0.0001$) and 0.70 D (95% CI 0.50 to 0.89, $p < 0.0001$) less than the control group, respectively. More than half (57%) of children wearing DOT lenses did not have clinically meaningful progression (ie 0.25 D) at 18M, compared to 15% with control.

CONCLUSIONS

Results from this ongoing trial demonstrate DOT spectacle lenses are effective at slowing axial elongation and myopia progression through to 18M in Chinese children. These results support the hypothesis that modulating retinal contrast can slow myopia progression in children from diverse populations.

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