

TITLE

Control of myopia using contrast modulation spectacle lenses in a Chinese population: 12-month results.

PURPOSE

Diffusion Optics Technology (DOT) lenses are designed to slow myopia progression by reducing contrast signaling in the retina. A recent 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 research was to evaluate the safety and efficacy of DOT spectacle lenses in a Chinese population, where the prevalence and severity of myopia is even greater.

METHODS

The study (NCT05562622) is a 24-month, randomized and controlled clinical trial across 5 Chinese hospital sites, evaluating DOT spectacle lenses versus control standard single vision spectacle lenses in myopic children aged 6–13, with a planned interim analysis at 12 months (M). The primary endpoints are change from baseline in axial length (AL) and cycloplegic spherical equivalent refraction (cSER).

RESULTS

A total of 195 participants were enrolled, ranging from 30 to 51 at each of the 5 sites. There were 9 non lens related discontinuations prior to 12M (2 DOT, 7 control). Participants were dispensed study lenses in a 2:1 ratio. 186 children completed the 12M visit (48% male; mean age at screening 9.6 years; 128 DOT, 58 Control). Baseline average (\pm SD) AL and cSER were 24.45 mm (0.80) and -2.27 D (0.85), respectively.

For DOT wearers, the mean changes \pm SE at 12M from baseline in AL and cSER were not significant, with AL being 0.09 ± 0.10 mm (95%CI: -0.10 to 0.29 , $p=0.34$) and cSER being -0.17 ± 0.11 D (95%CI: -0.38 to 0.05 , $p=0.13$). For the control group, the mean changes at 12M from baseline were significant; AL 0.35 ± 0.16 mm (95%CI: -0.66 to -0.04 , $p=0.03$) and cSER -0.64 ± 0.16 D (95%CI: -0.96 to -0.32 , $p=0.0001$).

The difference in AL progression for DOT versus control at 12M was significant (0.26 mm, $p<0.0001$), representing a 74% reduction compared to control. The difference in cSER progression for DOT versus control was also significant (-0.48 D, $p<0.0001$), representing a 75% reduction.

CONCLUSIONS

12M results from this ongoing trial demonstrate the safety and effectiveness of DOT contrast modulating spectacles for reducing myopic progression in Chinese children. These findings support the year one results from North American research and demonstrate DOT lenses can significantly slow myopia in children from diverse populations.