

Three-year myopia control efficacy of DOT spectacle lenses in young children

Deborah Laughton¹, Marcella McParland¹, Jennifer S Hill¹, Vanessa Tasso¹, Jay Neitz², Maureen Neitz², Thomas W. Chalberg¹

¹SightGlass Vision, Inc; ²University of Washington

Purpose

Despite decades of research, the exact pathogenesis of myopia is not yet fully understood. The discovery that familial high myopia is associated with abnormally high perceived retinal contrast has led to the hypothesis that managing retinal contrast could control myopia progression. To evaluate this theory, DOT spectacle lenses were designed to modulate retinal contrast. A 3-year clinical trial was conducted to evaluate the safety and effectiveness of DOT lenses in slowing myopia progression.

Methods

At 14 North American sites, in a controlled, double-masked clinical trial (CYPRESS;NCT03623074), 181 myopic children (aged 6-10 years) were randomised to wear either DOT 0.2 lenses (n=88) or standard single-vision Control (n=93) lenses. Axial Length (AL) and cycloplegic Spherical Equivalent Refraction (SER) were measured at baseline, 1, 2 and 3 years. A subgroup analysis of children aged 6-7 years at baseline was pre-planned, due to the expectation of highly progressive myopia and the paucity of efficacy data for this age group.

Results

In the overall study population, the children wearing DOT 0.2 demonstrated significantly less myopia progression than the Control group after 3 years (AL p=0.018, SER p=0.0084). Among the 6-7 year olds (n=48), mean AL and SER (\pm SE) of the Control group increased by 1.03 ± 0.07 mm and -1.73 ± 0.18 D, respectively. Compared to Control, DOT lenses significantly slowed AL (0.71 ± 0.07 mm; difference -0.32 mm; p<0.0001) and SER (-0.89 ± 0.17 D; difference 0.84 D; p<0.0001) progression. After 3 years, progression in 6-7 year olds was limited to <1.00 D in 60% of DOT lens wearers and 21% of Control lens wearers (p=0.0068). No spectacle lens related adverse events were reported.

Conclusion

The 3-year results demonstrate that DOT 0.2 spectacle lenses are safe and effective in slowing myopia progression in young children; supporting the hypothesis that managing retinal contrast can control myopia progression.