

Control of Myopia Using Diffusion Optics Spectacle Lenses: Efficacy and Safety Study (CYPRESS) 42-month results

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Purpose

The discovery that L/M opsin mutations are associated with familial high myopia led to the hypothesis that elevated contrast signalling in the retina, whether from genetic predisposition or the visual environment, plays an important role in myopia development and progression. To evaluate this theory, novel spectacle lenses (DOT lenses) were designed to modulate retinal contrast. CYPRESS evaluated the safety and efficacy of DOT lenses in reducing myopia progression.

Methods

CYPRESS part 1 (NCT03623074) was a 3-year double-masked, randomized, controlled clinical trial. Myopic children aged 6-10 years (n=256) were recruited at 14 clinical sites in North America and dispensed spectacles with one of two DOT lens designs (T1, T2) or standard single-vision control lenses. Children completing part 1 (n=200) were invited to enroll in CYPRESS part 2 (NCT04947735), in which T1 (n=35) and Control groups (n=42) continued with their original lens assignment and the T2 group (n=21) were crossed over to T1 lenses. Axial Length (AL) and cycloplegic Spherical Equivalent Refraction (SER) were measured at baseline, 12, 24, 36 and 42 months.

Results

In part 1 after 36 months, AL mean change \pm SE from baseline was 0.59 ± 0.04 mm, 0.67 ± 0.05 mm and 0.72 ± 0.04 mm, and SER mean change from baseline was -0.83 ± 0.09 D, -1.19 ± 0.11 D and -1.16 ± 0.09 D, for T1, T2 and Control, respectively. Both co-primary endpoints of AL and SER were met, with a difference between means (T1 minus Control) of -0.13 mm for AL ($p=0.018$) and 0.33 D for SER ($p=0.008$). Most of the benefit accrued within Year 1. During Years 2-3, which coincided with COVID-19, the children reported altered school routines, which likely impacted study outcomes.

In part 2, LS mean change \pm SE from 36 to 42 months in AL was 0.08 ± 0.01 mm for T1 and 0.12 ± 0.01 mm for Control ($p=0.013$) and in SER was -0.12 ± 0.03 D for T1 and -0.21 ± 0.04 D for Control ($p=0.051$). Mean AL and SER progression in part 2 was not statistically different between the original T1 group and those who crossed over from T2 to T1 (AL $p=0.28$, SER $p=0.85$).

Conclusion

DOT spectacle lenses are safe and effective at reducing myopia progression in children age 6-10, with additional benefit evident after 3-years of wear. Changes in lifestyle, behaviour and schooling during the COVID-19 pandemic may have impacted treatment efficacy in Part 1.