Control of Myopia using Diffusion Optics Technology Spectacle Lenses

Purpose:
4-year Results It has been well-established that eye growth and refractive development is a visually-guided process and that manipulation of retinal image quality with optical defocus or contrast modulation can change the course of refractive development. To investigate the impact of slightly lowering retinal contrast on myopia progression, novel spectacle lenses (DOT lenses) were designed and evaluated over a 4-year period.

Methods:
CYPRESS part 1 (NCT03623074) was a 3-year randomized controlled trial comparing two DOT lens designs (T1, T2) and standard single-vision control lenses in 256 myopic children aged 6-10 years at 14 North America clinical sites. 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 (DOT 0.2) lenses. Children were classified as full-time wearers if they wore their study spectacles for near vision activities, as reported by parental questionnaires. Axial Length (AL), cycloplegic Spherical Equivalent Refraction (cSER) and Visual Acuity (high contrast, low contrast and peripheral VA) were measured at baseline, 12, 24, 36 and 48 months.

Results:
T1 spectacle lenses demonstrated superiority to Control in terms of both co-primary endpoints after 4 years: with a difference between means ± SE (T1 minus Control) of -0.20 ± 0.09 mm for AL (p=0.033) and 0.52 ± 0.22 D for cSER (p=0.017). Children wearing their spectacles full-time (T1 n=26, Control n=31) showed substantial clinical benefit, with a difference between means of -0.35 ± 0.15 mm in AL (p=0.006) and 0.81 ± 0.30 D (p=0.008) in cSER. During Years 2-3, which coincided with COVID-19 restrictions, the children reported altered school routines, which likely impacted study outcomes. Mean binocular high contrast LogMAR VA measurements were clinically stable and similar between groups at distance (48 month VA ± SD: T1 -0.09 ± 0.08, Control -0.07 ± 0.06) and near (T1 -0.03 ± 0.14, Control -0.04 ± 0.10). Mean monocular low contrast (10%) distance VA showed an improvement over the course of the study (mean change from baseline: T1 0.05 ± 0.12, Control 0.07 ± 0.11). Mean peripheral VA improved or remained similar in all quadrants, with no significant differences between treatment groups (48 month VA Superior Temporal T1 0.96 ± 0.28, Control 0.94 ± 0.32; Superior Nasal T1 0.92 ± 0.32, Control 0.88 ± 0.25; Inferior Temporal T1 0.93 ± 0.28, Control 0.92 ± 0.32; Inferior Nasal T1 1.03 ± 0.28, Control 1.02 ± 0.31).

Conclusion:
After 4-years of wear, the children wearing DOT spectacle lenses demonstrated significantly less myopia progression than the Control group. DOT spectacle lenses provided good all-round visual performance and were well tolerated for the study duration. This study was funded by SightGlass Vision, Inc

Disclaimers:

Deborah Laughton is a SightGlass Vision employee. Marcella McParland is a SightGlass Vision employee. Jennifer S Hill is a SightGlass Vision employee. Vanessa Tasso is a SightGlass Vision employee and has investment interests. Jay Neitz have patent and investment interests. Maureen Neitz has been provided research funding and has patent and investment interests. Thomas W Chalberg is a consultant with patent and investment interests.

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