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TWO-YEAR EFFECTIVENESS OF A NOVEL MYOPIA MANAGEMENT SPECTACLE LENS WITH FULL-TIME WEARERS

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Abstract

Purpose : New therapies are urgently needed to slow or stop myopia progression in children, and therefore reduce the risk of long-term, sight-threatening complications from myopia. The discovery that polymorphisms at the myopia genetic locus, MYP1, are associated with splicing-defective cone opsin genes (*OPN1LW* and *OPN1MW*) led to the hypothesis that contrast signaling in the retina plays an important role in myopia development and progression. This hypothesis predicted that reducing the contrast of images on the retina could slow myopia progression. Novel spectacle lenses (DOT lenses) were developed to evaluate this hypothesis, and a multi-center, double-masked, randomized, controlled clinical trial was initiated.

Methods : CYPRESS (NCT03623074) evaluated two investigational spectacle lenses (Test 1, Test 2) designed to slightly reduce contrast compared to control spectacle lenses for the ability to reduce myopia progression in children 6-10 years of age over a period of 3 years. Two hundred and fifty-six (256) eligible myopic subjects were randomized and dispensed spectacles at 14 clinical sites in North America. Subjects were asked to wear the study spectacles constantly, except for activities in which standard spectacle wear would be inappropriate, such as contact sports and swimming. “Full time wearers” were defined as those subjects whose parents reported that they did not remove the study spectacles for near vision activities. Axial length (AL) and cycloplegic autorefraction (SER) were measured at baseline and annual follow-up visits, now through 24-months.

Results : Approximately two-thirds of study subjects (61, 45, and 66 in Test 1, Test 2, and Control, respectively) met criteria for “full-time wearers”. After 24-months, the mean (± SD) change from baseline in AL was 0.33 ± 0.23, 0.34 ± 0.39, and 0.53 ± 0.33 mm for Test 1, Test 2, and Control respectively. The mean change from baseline in SER after 24-months of usage was -0.36 ± 0.54, -0.48 ± 0.85, and -0.88 ± 0.77 D for Test 1, Test 2, and Control, respectively. The difference in means (Test 1 minus Control) for change from baseline of AL (-0.21 mm) and SER (0.52 D) were statistically significant ($p<0.0001$).

Conclusions : DOT spectacle lenses were designed to reduce retinal contrast to slow the progression of myopia. After 24-months of usage, subjects who wore DOT lenses full-time had less myopia progression than control subjects.

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