Efficacy of a next-generation design of ophthalmic lenses for myopia control: Six-month results of the CEME Study

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Purpose
Myopia and high myopia rates are increasing worldwide. There have been numerous studies on the effectiveness of myopia control treatments in the Asian population, but so far, studies on Caucasians have been limited. We aim to assess the efficacy of a new spectacle lens for myopia control in a European population.

Methods
In an ongoing 2-year, prospective, multicenter, stratified randomized clinical trial (NCT05919654), 304 Caucasian children aged between 6 and 13 were enrolled. All children were myopic with a spherical equivalent refractive error (SE) between -0.75D and -5.00D, astigmatism ≤1.50D, anisometropia ≤1.00D, and past annual progression of at least -0.50D. Children in the treatment group (n=152) were assigned spectacle lenses (SPL) incorporating cylinder annular refractive elements (CARE, MyoCare, ZEISS), and those in the control group (n=152) wore single-vision lenses (SVL). Axial Length (AL) and cycloplegic SE were measured at baseline and after 6 months of wear. Generalized linear models were constructed to estimate the changes in SE and AL, adjusted for lens type, age, and baseline SE or AL. The efficacy of CARE lenses was calculated by dividing the difference in adjusted SE or AL change between groups by the adjusted SE or AL change in the control group, then multiplying the result by 100%.

Results
88% of the children (n=138 wearing SVL and n=130 with CARE) completed the 6-month visit. There were no differences between the groups for baseline parameters. The adjusted change in SE from baseline to 6 months was -0.24±0.02D and -0.09±0.02D with SVL and CARE respectively ($p < 0.001$). The mean adjusted difference was -0.15D, with 62.5% slower progression with CARE than SVL. Similarly, the adjusted change in AL from baseline to 6 months was 0.10±0.03mm and 0.02±0.03mm with SVL and CARE respectively ($p<0.001$). The mean adjusted difference was 0.07mm, with 76.9% slower progression with CARE than the SVL SPL group.

Conclusions
Interim analysis with the next-generation myopia control spectacle lens with CARE technology from the CEME study demonstrated to be efficient over 6 months. Children will continue to be monitored after 1 and 2 years of lens wear for a more comprehensive evaluation of the long-term efficacy of the CARE spectacle lens in slowing the progression of myopia.

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