Efficacy of a next-generation design of ophthalmic lenses for myopia control: Six-month results of the CEME Study (133 - A0433)

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Purpose

Myopia and high myopia rates are increasing worldwide.[1] 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.[2] 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 incorporating cylinder annular refractive elements (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 (figure 1). 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 MyoCare 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%.[3]

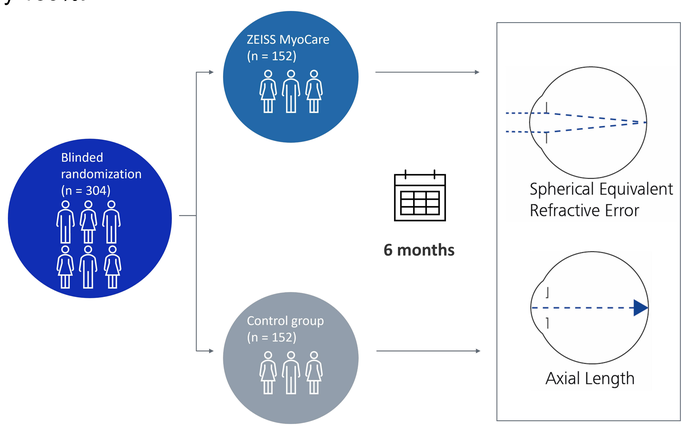

Figure 1. Overview of a randomized controlled clinical trial (RCT) to assess the safety and effectiveness of CARE lenses to manage myopia progression.

Results

Table 1 shows the baseline characteristics of the children. There were no differences between the groups for baseline parameters

88% of the children (n=138 wearing SVL and n=130 with MyoCare) had completed the 6-month visit to the date of this abstract submission.

Table 1. Baseline characteristics of the sample.

Baseline Characteristics	Total (n = 304)	MyoCare (n=152)	SVL (n = 152)
Age (Mean ± SD)	9.99 ± 1.96	10.08 ± 2.08	9.99 ± 1.85
Females (n, %)	174 (57.24)	87 (57.24)	87 (57.24)
Initial cycloplegic refraction (Mean ± SD)	−2.19 ± 1.05	−2.22 ± 1.05	−2.17 ± 1.05
Initial axial length (Mean ± SD)	24.22 ± 0.74	24.26 ± 0.75	24.18 ± 0.73

Figure 2 shows a detailed flowchart with the schedule of each visit.

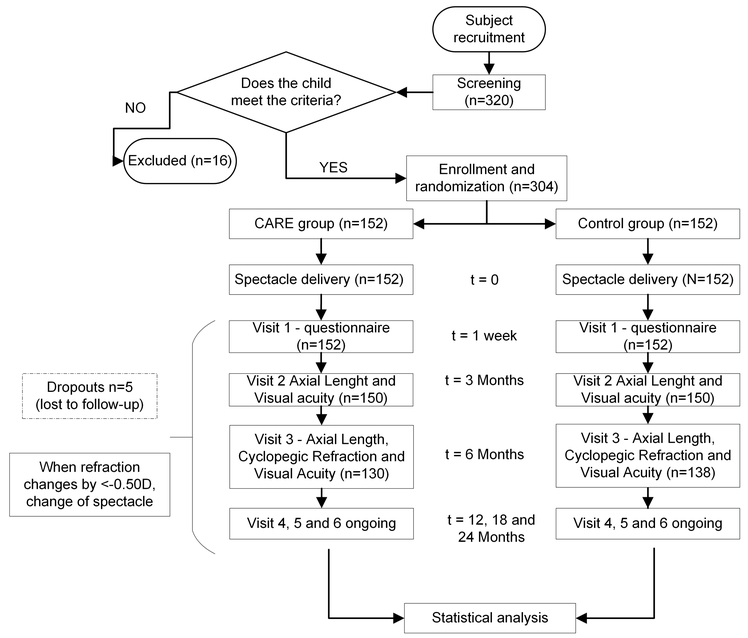

Figure 2. Flowchart with the schedule of assessments and examination items

The adjusted change in SE from baseline to 6 months was -0.24±0.02D and -0.09±0.02D with SVL and Myocare respectively (p <0.001). The mean adjusted difference was -0.15D, with 62.5% slower progression with MyoCare 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 MyoCare respectively (p<0.001). The mean adjusted difference was 0.07mm, with 76.9% slower progression with MyoCare than the SVL SPL group.

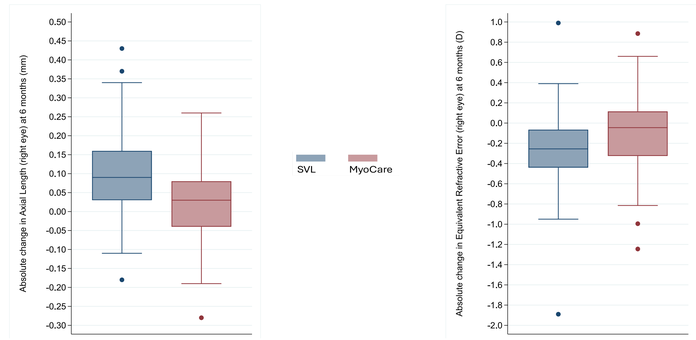

Figure 3. Absolute changes in AL an SE after 6 months of use.

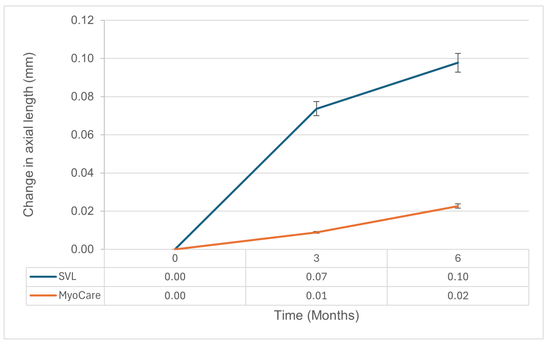

Figure 4. Changes in AL over the time

Conclusions

The interim analysis demonstrated that Zeiss MyoCare has been efficient after 6 months of wear. 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 MyoCare spectacle lens in slowing the progression of myopia.

References

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2. Németh J, Tapasztó B, Aclimandos WA, et al. Update and guidance on management of myopia. ESO in cooperation with IMI. European Journal of Ophthalmology. 2021;31(3):853-883.
3. Alvarez-Peregrina, C., Sanchez-Tena, M.A., Martinez-Perez, C. et al. Clinical Evaluation of MyoCare in Europe (CEME): study protocol for a prospective, multicenter, randomized, double-blinded, and controlled clinical trial. Trials. 2023; 24, 674.

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