One-year results of the CEME Study: Efficacy of Myocare for myopia control in a European Population

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Purpose

Optical interventions are crucial in controlling myopia to prevent the development of high myopia[1]. MyoCare is one of the ophthalmic solutions for managing myopia, but its effectiveness has not been evaluated in the European population. This study aims to assess the efficacy of MyoCare in a European population after a year of follow-up.

Methods

An ongoing ongoing 2-year, prospective, multicenter, stratified randomized clinical trial (NCT05919654), is being carried out to study the efficacy of spectacle lenses incorporating cylinder annular refractive elements (CARE, MyoCare, ZEISS Vision) compared to single-vision lenses (SVL) in European children aged 6 to 13 years[2]. The two-year trial has enrolled 296 children who meet the inclusion criteria of having a cycloplegic spherical equivalent refractive error (SE) between -0.50D and -5.00D, astigmatism ≤1.50D, anisometropia ≤1.00D, and a past annual progression of at least -0.50D. The children were randomly assigned to the treatment or control group. The study's primary outcomes are the axial length (AL) and SE, measured at the beginning of the trial and after 6 and 12 months of wearing the assigned lenses. 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 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 and then multiplying the result by 100%.

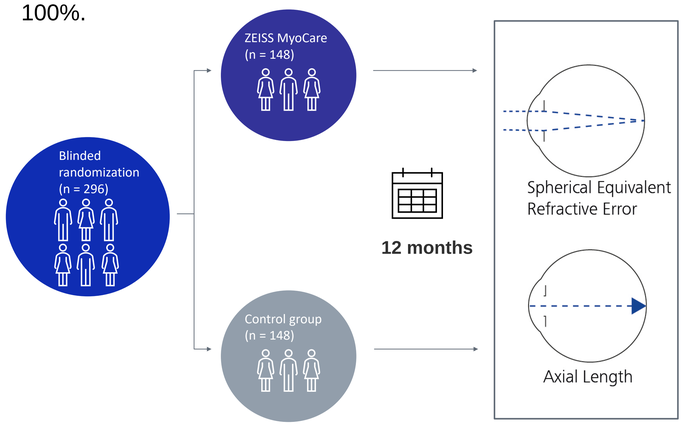

Figure 1. Overview of a randomized controlled clinical trial (RCT) to assess the safety and effectiveness of CARE lenses to manage myopia progression.

Results

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

Table 1. Baseline characteristics of the sample.

Baseline Characteristics	MyoCare (n=148)	SVL (n = 148)
Age (Mean ± SD)	10.14 ± 2.01	9.87 ± 1.86
Females (n, %)	86 (58.11)	86 (58.11)
Initial cycloplegic refraction (Mean ± SD)	−2.25 ± 1.03	−2.21 ± 1.02
Initial axial length (Mean ± SD)	24.28 ± 0.74	24.19 ± 0.73

The adjusted change in SE from baseline to 6 months was -0.23±0.02D and -0.09±0.02D with SVL and MyoCare respectively. This change was -0.37±0.08D and -0.19±0.09D with SVL and MyoCare from baseline to 12 months, respectively (p <0.001). The mean adjusted difference at 6 months was -0.14D, indicating that MyoCare had 60.8% slower progression than SVL. Similarly, at 12 months, the mean adjusted difference was -0.18D, indicating that MyoCare had a 49.2% slower progression.

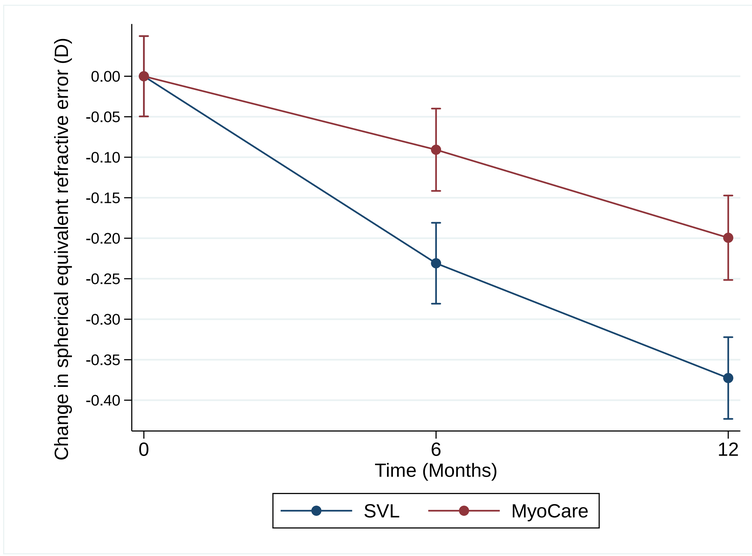

Figure 2. Changes in SE over the time.

Furthermore, the adjusted change in AL from baseline to 6 months was 0.10±0.03mm and 0.03±0.03mm for SVL and MyoCare, respectively. From baseline to 12 months, this change was 0.21±0.05mm and 0.10±0.06mm for SVL and MyoCare, respectively (p<0.001). The mean adjusted difference at 6 months was 0.07mm, indicating that MyoCare had 73.2% slower progression than the SVL group at 6 months. Similarly, at 12 months, the mean adjusted difference was 0.11mm, indicating that MyoCare had a 53.3% slower progression.

These calculations has been done with the 85% of the 12-month visits completed.

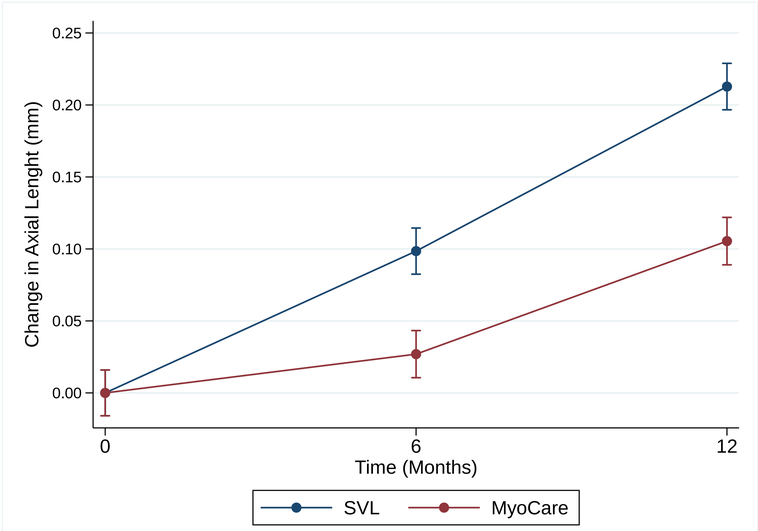

Figure 3. Changes in AL over the time

Conclusions

The interim analysis conducted over one year has shown that MyoCare is effective in managing myopia. The children participating in the CEME study will be monitored for an additional two years to provide a more comprehensive evaluation of MyoCare's long-term effectiveness in slowing down the progression of myopia.

References

1. Logan, N.S., Bullimore, M.A. Optical interventions for myopia control. Eye 38, 455–463 (2024)..
2. Alvarez-Peregrina, 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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