Two-year evolution of Cylindrical Annular Refractive Elements (CARE) lens efficacy (1233 - 1003)

Alvarez-Peregrina, Cristina[1]; Sanchez-Tena, Miguel Angel[1,2]; Fernandez-Fernandez, Victor[1] ;Liu, Nicole[3], Li, Wayne[4]; Padmaja, Sankaridurg[3,5]; Ohlendorf, Arne[3]

1. Universidad Complutense de Madrid, Spain; 2. ISEC Lisboa, Portugal; 3. ZEISS Vision Care, Aalen, Germany; 4. ZEISS Vision Care, Carl Zeiss Vision Ltd., Guangzhou, China; 5. School of Optometry and Vision Science, University of New South Wales, Sydney, Australia

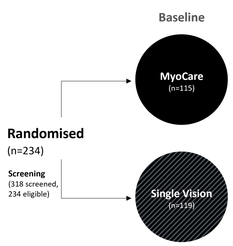
Purpose

The effectiveness of various myopia control treatments is well established in Asian populations, but studies in European populations have been limited. This study aims to quantify changes in spherical equivalent (SE) and axial length (AL) over two years of wear with ZEISS MyoCare (Carl Zeiss Vision GmbH, Aalen, Germany) spectacle lenses (SPL) versus single-vision lenses (SVL).

Methods:

A 24-month interim analysis was conducted as part of an ongoing 3-year, multi-center, randomized, double-masked, controlled clinical trial (NCT05919654). 234 European children (6–13 years; SE -0.75 to -5.00 D) were randomized to either ZEISS MyoCare (CARE technology - Cylinder Annular Refractive Elements, ZEISS MyoCare, Carl Zeiss Vision GmbH, Aalen) or SVL.

208 participants (MyoCare: 105; SVL: 103) completed the 24-month follow-up. AL and SE were measured every 6 months. Treatment dynamics were evaluated using a repeated-measures General Linear Model (GLM) to assess the interaction between time (Year 1 vs. Year 2) and treatment group. Analysis was performed using SPSS v.31 (α=0.05).



Dispensing	1 week	3 months	6 months	12 months	18 months	24 months
N=115	113 completed *(2 drop outs)*	111 completed *(2 drop outs)*	111 completed	109 completed *(2 drop outs)*	108 completed *(1 drop out)*	105 completed *(3 drop outs)*
N=119	119 completed	118 completed *(1 drop out)*	118 completed	117 completed *(1 drop out)*	106 completed *(11 drop outs)*	103 completed *(3 drop outs)*

Reasons for drop out:
- **MyoCare**: Lost to follow up – 6; switched to contact lenses – 1; discomfort – 2; non-compliant – 1.
- **Single Vision**: lost to follow-up – 4; switched to contact lenses – 7; family relocation – 3; switched to atropine – 2.

Figure 1. Flowchart with the schedule of assessments and examination items

Results

Adjusted change in SE over the 24 months was −0.32 D (95% CI −0.36 to −0.28) with ZEISS MyoCare versus −0.69 D (95% CI −0.73 to −0.66) with SVL (p<0.001). Corresponding adjusted AL change was 0.21 mm (95% CI 0.19–0.23) in ZEISS MyoCare versus 0.43 mm (95% CI 0.41–0.45) in SVL (p<0.001) (Fig. 2). A repeated-measures GLM revealed a significant interaction effect between time and treatment group (F1,204 = 10.89, p=0.001,n2p = 0.051), illustrating divergent growth dynamics (Fig. 3). SVL exhibited a typical age-related deceleration in axial growth, significantly decreasing from Year 1 (0.235±0.01mm) to Year 2 (0.192 ±0.01 mm, p=0.002). ZEISS MyoCare demonstrated an immediate and deep suppression of axial elongation in Year 1 (0.093 ±0.01 mm) and maintained a stable, near-physiological trajectory through Year 2 (0.115 ±0.01 mm, p=0.111). Younger children showed greater slowing of progression in Year 2 (p<0.001).

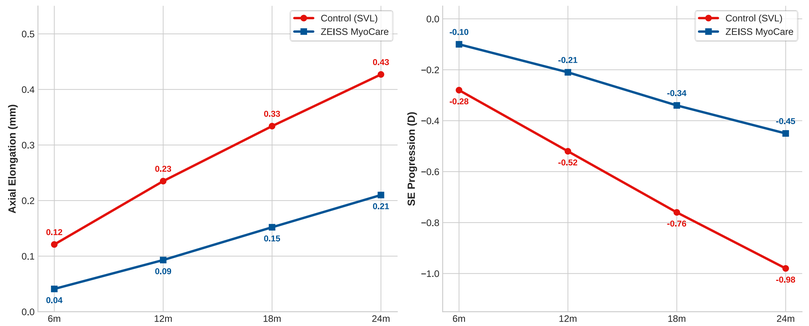


Figure 2. Adjusted changes in AL and SE over time

Discussion

The 24-month efficacy of ZEISS MyoCare is consistent with results reported for other microstructured spectacle lenses, such as DIMS and HAL. Similar to these treatments, the difference in growth between groups was smaller in the second year than in the first.

However, our interaction analysis (p=0.001) suggests that this pattern reflects a clear shift in growth dynamics. While the SVL group followed a natural age-related slowing, ZEISS MyoCare maintained axial elongation at low, stable levels throughout the second year. This suggests that the lenses bring axial growth close to normal physiological limits very early in the treatment process. Once this "stabilization effect" is reached, the treatment focus changes from actively slowing down the eye to maintaining this healthy, slow growth rate over time. This explains why the year-over-year change in the MyoCare group is stable (p=0.111), whereas the control group continues to slow down significantly as the children get older (p=0.002). This continued benefit confirms that ZEISS MyoCare is a reliable and effective option for long-term myopia management in European children

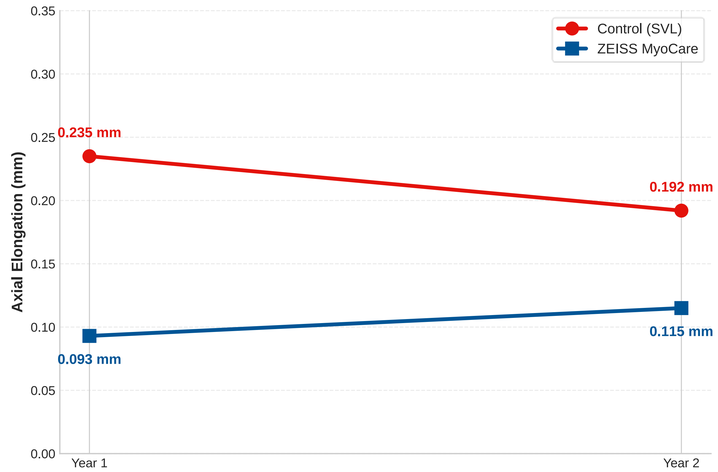


Figure 3. Interaction plot of axial elongation rates. Note the rapid stabilization in the ZEISS MyoCare group compared to the natural age-related deceleration in the control group.

Conclusions

ZEISS MyoCare spectacle lenses provide a robust and sustained myopia control effect over 24 months in European children. The significant interaction effect serves as the study's primary novel finding, proving that ZEISS MyoCare does not merely follow natural growth trends but fundamentally alters the axial elongation trajectory. While the control group shows a gradual natural slowing, ZEISS MyoCare induces a rapid stabilization of the eye, keeping axial growth consistently low throughout the 24-month period. This evidence supports the use of ZEISS MyoCare technology for long-term stabilization of myopia in pediatric populations

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Corresponding Author - Cristina Alvarez-Peregrina – cristina_alvarez@ucm.es

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