Adaptation and Visual Performance of CARE Spectacle Lenses: Findings from the Clinical Evaluation of MyoCare in Europe Study (5236 - B0507)

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Purpose

Effective myopia management solutions must be wearable and provide good visual performance. This study aims to compare the adaptation, and the perceived vision / visual performance of cylindrical annular refractive elements (CARE) spectacle lenses designed to slow myopia with single vision lenses (SVL) in children participating in a myopia control clinical trial.

Methods:

In an ongoing 3-year, prospective, double-masked, multi-center clinical trial (NCT05919654), 234 European children, aged 6-13 yrs with cycloplegic spherical equivalent refractive error (SE) of -0.75 D to -5.00 D, cylinder ≤-1.5D and anisometropia ≤1D were randomly assigned to CARE (n=115) and SVL (n=119).

Subjective ratings on various aspects of vision, adaptation and as well as time to adapt were evaluated via a questionnaire at dispensing, 1-week and 3-month using a Likert scale (1 to 10: 10- best/most satisfied and 1-worse/not satisfied). Peripheral (+/-20°) and central high contrast visual acuity (VA) at distance was measured at the dispensing and at the 3-month visit. Statistical significance was determined using Chi-square, Wilcoxon signed-rank, and Mann-Whitney U tests. Statistical significance was p<0.05

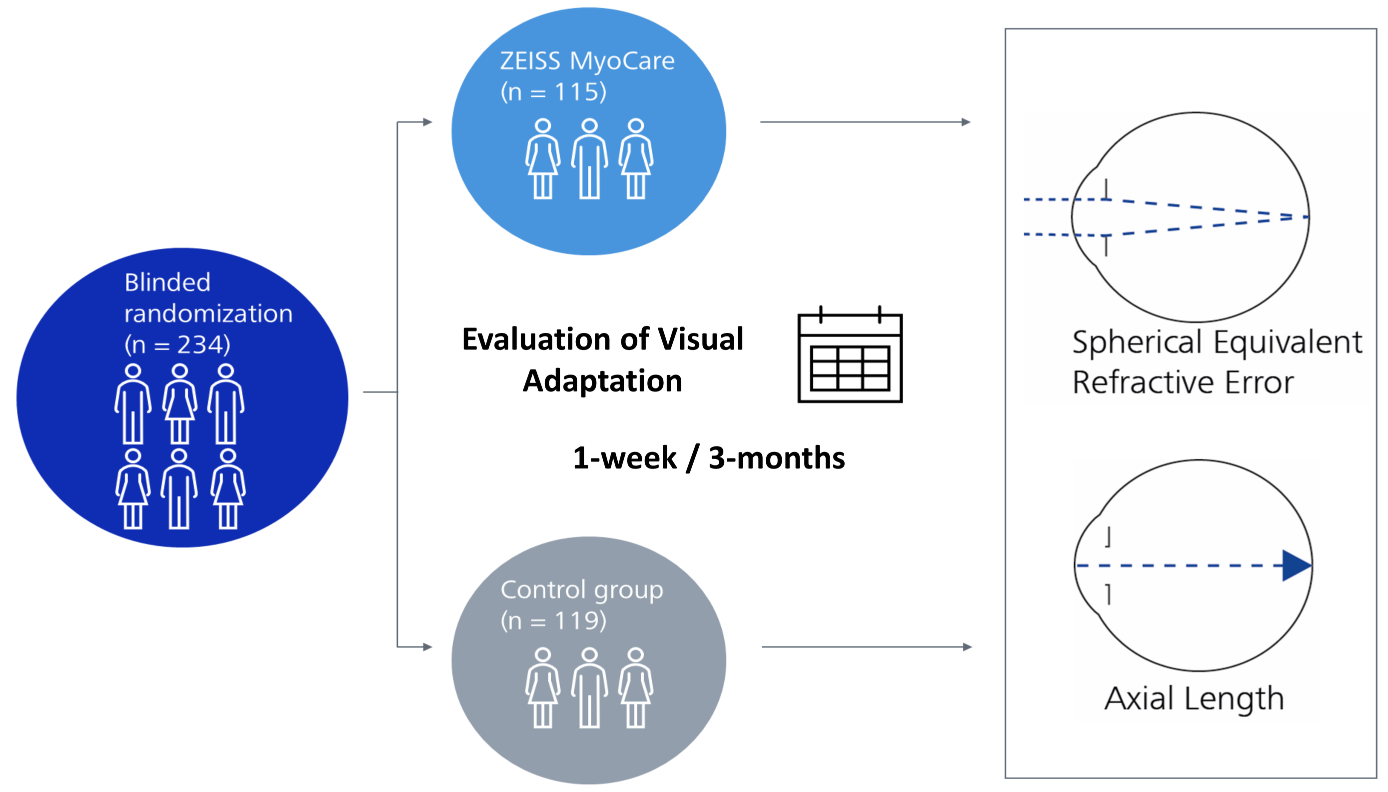

Figure 1. Overview of a randomized controlled clinical trial (RCT) to assess the safety and effectiveness of CARE lenses to manage myopia progression.

Results

Subjective ratings

Subjective impressions, based on the Likert Scale, on different aspects of vision for both groups (CARE and SVL) are presented in Table 1. Although ratings were lower for CARE at the 1-week visit, there was no difference at the 3-month visit between groups, expect for near vision. Percentages of children adapted to CARE lenses who responded "good" (Likert 8 or 9) or "very good"(Likert 10) were calculated and are presented in Figure 2.

Adaptation

At 1 week, children rated "how easy it was to adapt to the spectacles" as 7.95±2.00 and 9.41±1.15 with CARE and SVL, respectively (p<0.001). 84% adapted within 3 days.

Visual acuity

Central VA was better with CARE at the dispensing visit (Δ -0.02logMAR, p<0.001), but this is difference is not of clinical relevance, additionally, no difference was observed at the 3-month visit (Δ 0.00logMAR (p=0.379)).

For peripheral VA, differences were statistically significant and revealed clinical significance in some cases at the dispensing visit (nasal VA: Δ-0.09logMAR, temporal VA: Δ-0.08logMAR;(p<0.001)) and the 3-month visit (nasal VA:Δ-0.1logMAR and temporal: Δ-0.09logMAR(p<0.001)

Table 1. Subjective impressions to CARE and SVL

	1 Week Visit					3 Months Visit				
	CARE		SVL		p-value	CARE		SVL		p-value
	Median [CI]	Mean ±SD	Median [CI]	Mean ±SD		Median [CI]	Mean ±SD	Median [CI]	Mean ±SD	
How is your distance vision	9 [8,10]	8.67±1.43	10 [9,10]	9.17±1.31	**0.001**	9 [8,10]	8.66±1.79	9 [8,10]	8.90±1.23	0.912
How is your near vision	10 [8,10]	8.99±1.80	10 [9,10]	9.52±1.00	**0.041**	10 [8,10]	8.82±1.96	10 [10,10]	9.47±1.28	**0.003**
How is your vision walking or doing sports	9 [8,10]	8.97±1.30	10 [9,10]	9.44±0.80	**0.007**	10 [8,10]	8.89±1.69	10 [8,10]	9.13±1.42	0.332
How is your vision going up and down stairs	10 [8,10]	8.94±1.44	10 [9,10]	9.57±0.75	**<0.001**	10 [9,10]	9.05±1.70	10 [9,10]	9.41±1.14	0.172
How do you feel after wearing the spectacles all-day	10 [8,10]	8.83±1.68	10 [9,10]	9.41±0.96	**0.016**	10 [8,10]	8.88±1.93	10 [9,10]	9.28±1.34	0.123

Number of children (presented as percentage) responding with "good" (Likert 8 or 9) or "very good"(Likert 10) to questions on distance vision, near vision, ability to walk or engage in sports, and navigating stairs are as follows.

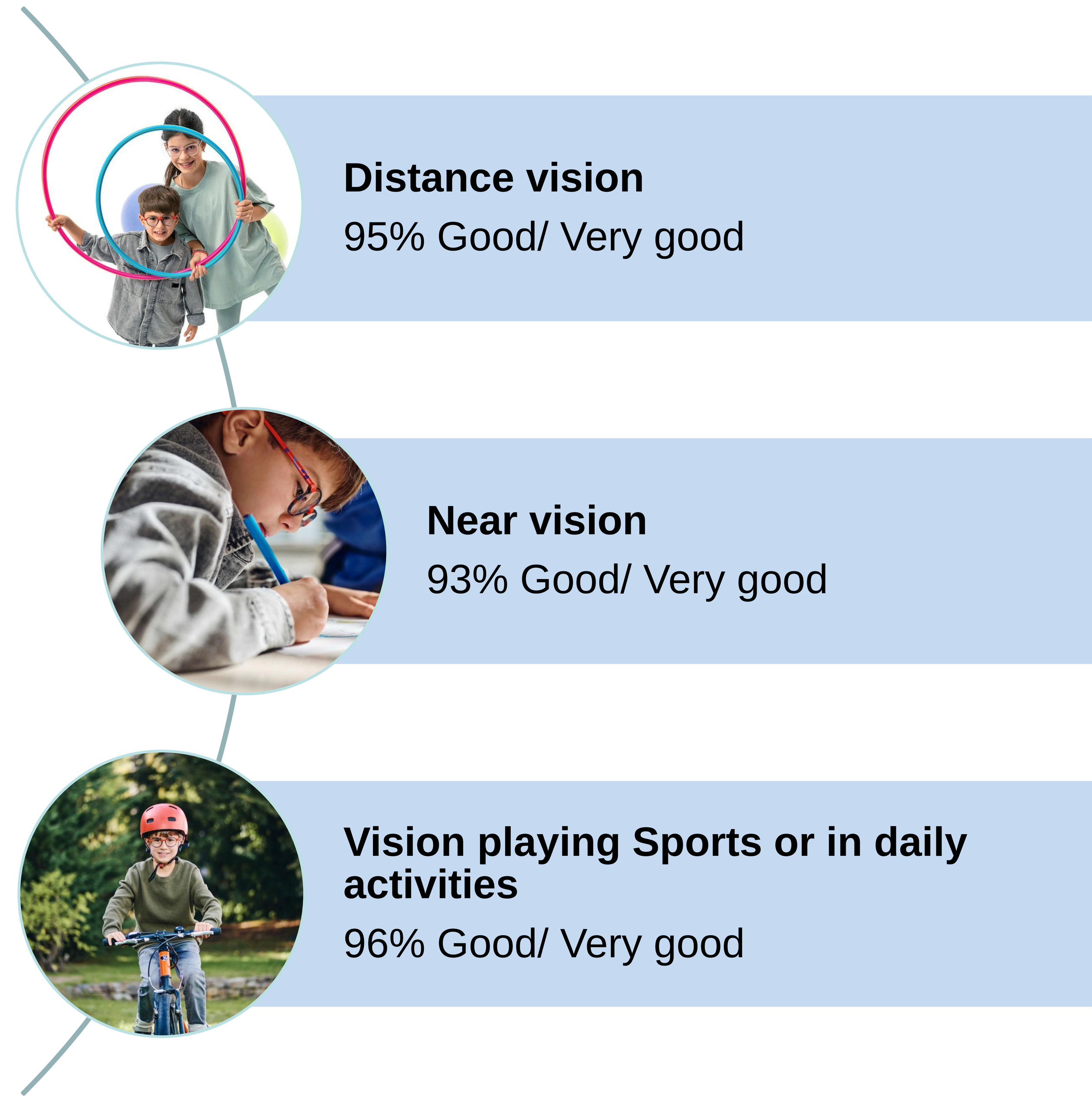

Figure 2. Positive responses to vision

Conclusions

Subjective ratings indicate that children adapted to CARE lenses and after 3 months, ratings were no different to SVL for most aspects. There were no differences in central VA, but peripheral VA was reduced by approximately 1 line

References

1. 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
2. Chen X, Wu M, Yu C, Ohlendorf A, Rifai K, Boeck-Maier C, Wahl S, Yang Y, Zhu Y, Li L, Sankaridurg P. Slowing myopia progression with cylindrical annular refractive elements (CARE) spectacle lenses-Year 1 results from a 2-year prospective, multi-centre trial. Acta Ophthalmol. 2024 Nov 15.

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