Slowing myopia progression with cylindrical annular refractive elements (CARE) – 12-month interim results from a 2-year prospective multi-center trial

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Purpose

Myopia imposes a significant health and socio-economic burden especially in countries such as China where the prevalence is high.[1, 2] Higher levels of myopia are associated with a greater burden.[3] Thus, there is a need for interventions to slow or reduce the progression of myopia.

This study evaluated the myopia control efficacy of 12 months of spectacle lens (SPL) wear with two SPL incorporating cylindrical annular refractive elements (CARE) which introduce simultaneous myopic defocus at the retina as compared to a single vision SPL.

Methods

- Ongoing 2-year prospective, double-masked, multi-center clinical trial at 3 sites in China (Tianjin Eye Hospital Optometric Center, Tianjin, Shenyang He Eye Hospital, Shenyang, and Beijing Tongren Hospital, Beijing) (NCT05288335; Figure 1)

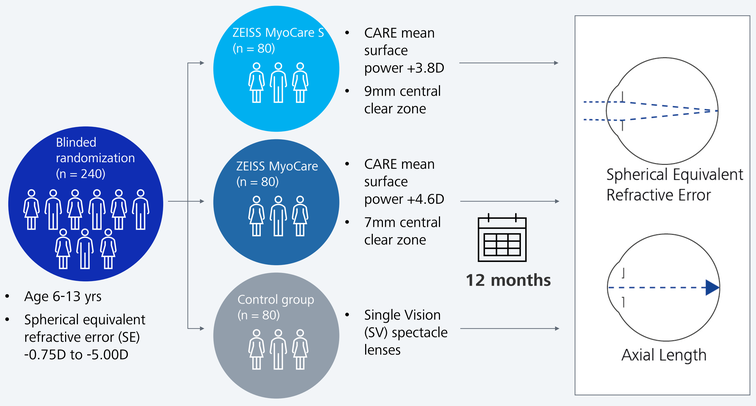

Figure 1. Overview of the randomized controlled clinical trial.

- Cycloplegic SE and axial length (AL) measured at six-monthly intervals. Change in SE and AL from baseline determined at 6 and 12 months (M).

- An intent to treat analysis conducted for change in SE and AL at 12 M between groups with linear mixed models after adjusting for relevant confounders selected based on the Aikaike information criterion. Statistical significance maintained at $p < 0.05$.

Results

- There were no differences in the baseline characteristics between groups (Table 1). A total of 78, 78 and 77 participants in MyoCare, MyoCare S and SV SPL completed 12M in the trial (Figure 2).

Table 1. Baseline characteristics

Characteristic	MyoCare	MyoCare S	Single Vision	p-value
Age (yrs)	9.9 ± 1.7	9.8 ± 1.7	9.8 ± 1.6	0.2148
Gender (Male/	45 (36.6%) /	39 (31.7%) /	39 (31.7%) /	0.5486
Female)	35 (29.9%)	41 (35.0%)	41 (35.0%)	
Parental Myopia				
None	14(20.5%)	21 (31.3%)	18(26.9%)	0.713
One	26 (38.2%)	23 (34.3%)	23(34.3%)	
Both	28 (41.2%)	23 (34.3%)	26(38.8%)	
Cycloplegic SE (D)	-2.23±0.98	-2.30±1.06	-2.31±1.01	0.902
AL (mm) RE	24.44±0.73	24.34±0.74	24.43±0.73	0.870

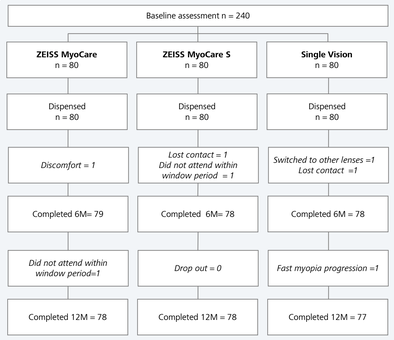

Figure 2. Trial flow over 12 months.

- There was reduced change in SE and AL with MyoCare and MyoCare S compared to SV (p=0.001 & <0.001 at 6M; <0.001 at 12M for SE & AL; Table 2 and Figure 3).
- At 12M, absolute difference in SE and AL between MyoCare and SV was 0.31D (48%) and 0.13mm (41%) and between MyoCare S and SV was 0.29D (45%) and 0.11mms (34%).
- Post hoc analysis indicated that both test SPL were different to SV (p<0.05) but not different to each other (p>0.05 for both SE and AL at 6 and 12M).

Table 2. Observed change in SE and AL at 6 and 12M.

Observed change in SE/AL	6 months	12 months
SV	-0.29±0.33D/0.17±0.09mms	-0.65±0.40D/0.32±0.17mms
MyoCare	-0.10±0.32D/0.10±0.10mms	-0.37±0.39D/0.20±0.16mms
MyoCare S	-0.13±0.27D/0.11±0.11mms	-0.38±0.38D/0.22±0.15mms

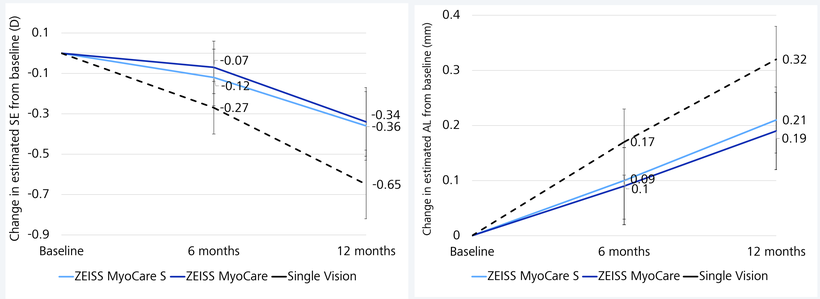

Figure 3. Estimated change in SE and AL over 12 months

Discussion

- Compared to SV SPL, both MyoCare and MyoCare S SPL slowed progression of myopia. Difference in progression compared to SV SPL was significant at both 6 and 12M. After adjusting for confounders, difference in progression with MyoCare compared to SV was 0.31D and 0.14mm and with MyoCare S was 0.29D and 0.11mm.

- Both the test lenses were effective in slowing progression of myopia; although MyoCare had slightly better efficacy, the differences were negligible. With the cylindrical annular refractive elements, light directed through the elements results in one of the focal planes in myopic defocus at the retina. Combined with the alternating zones that correct for the distance refractive error or the distance optic, they result in overlapping areas that result in an elongated zone of myopic defocus in front of the retina.

- The strengths include the multi-center nature of the trial, allowing for greater confidence in the generalisability of the data to the wider population. There were also few discontinuations over the 12-month period. The limitations of the trial is that although the trial was prospective and double-masked, due to the visibility of the lens features, masking may not have been possible. However, this is unlikely to have affected the trial outcome as the discontinuation rate was low .

Conclusion

The interim 1- year results from a multi-center clinical trial demonstrate the efficacy of MyoCare spectacle lenses in slowing myopia. The differences are both statistically and clinically relevant with >0.25D difference in SE and >0.10mm difference in AL in comparison to single vision spectacle lenses.

References

1. Holden BA, Fricke TR, Wilson DA, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. Ophthalmology. 2016;123:1036–42.
2. Thorn F, Chen J, Li C, et al. Refractive status and prevalence of myopia among Chinese primary school students. Clin Exp Optom 2020;103:177–83.
3. Naidoo KS, Fricke TR, Frick KD, et al. Potential lost productivity resulting from the global burden of myopia: systematic review, meta-analysis, and modeling. Ophthalmology 2019;126:338–46.

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