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Six-month myopia control efficacy of five novel, spatially variant, defocus spectacles

Padmaja Sankaridurg[1,2], Linlin Du[3,4], Min Tong[3,4], Jinliuxing Yang[3,4], Jun Chen[3,4], Bo Zhang[3,4], Xinhui Huang[3,4], Nicole Liu[1], Youhua Yang[5], Arne Ohlendorf[1], Xun Xu[4], Xiangui He[3,4]

1.ZEISS Vision Care, Aalen, Germany, Carl Zeiss Vision International GmbH, Aalen, Germany; 2. School of Optometry and Vision Science, University of New South Wales, Sydney, Australia; 3. Shanghai Eye Disease Prevention and Treatment Center; Shanghai Eye Hospital, School of Medicine, Tongji University; 4. National Clinical Research Center for Eye Diseases; 5. ZEISS Vision Care, Carl Zeiss Vision (Guangzhou) Ltd., Guangzhou, P.R. China

Purpose

- Prolonged exposure to high-contrast, high-spatial-frequency patterns (for example, text) alters visual neuron sensitivity and leads to contrast adaptation[1], thus potentially influencing myopia onset and progression.
- Myopia control (MC) spectacles (SPL) with multiple optical elements can create spatially varying image quality, but the repeating patterns may generate spatially uniform or repeating blur. We therefore designed MC SPL that generate non-repetitive, spatially structured retinal signals that vary with gaze, aiming to limit adaptation and slow myopia. We report the myopia control efficacy of these novel ZEISS SPL to a single vision (SV) SPL.

Methods

- Ongoing 2-year, prospective, double-masked, multicenter clinical trial at 3 sites in Shanghai, China (NCT06563700).
- 342 Chinese children, 7-13 yrs, spherical equivalent (SE) -0.75D to -5.00D randomized to 6 groups: 1 SV and 5 test MC SPL (Carl Zeiss Vision International GMBH, Aalen, Germany).
- Test MC SPL incorporated optical elements with relative plus power; arrangement, fill factor, and power varied by design. All have 7 mm clear centre except lens IV (6 mm with a concentric ring in centre). Lens V has both cylindrical optical elements and contrast-reduction zones.

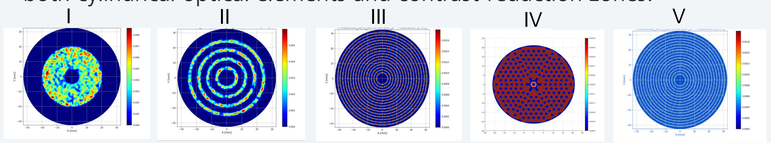


***Figure 1**. Schematic of lens designs, Lenses I to V*

- Cycloplegic SE & at baseline & 6 months (AL also at 3 months). Changes from baseline compared for each test SPL vs SV. Data adjusted for age, gender, groups, sites, baseline value and parental myopia. Statistical significance was p<0.01.
- Figure 2a-c shows an eye tracking through a SV SPL, MC SPL (ZEISS MyoCare), and test MC SPL III.
- Defocus signal is absent with SV SPL, is of uniform magnitude and repeating with MyoCare SPL and varying in magnitude and non-repetitive with test MC SPL III.

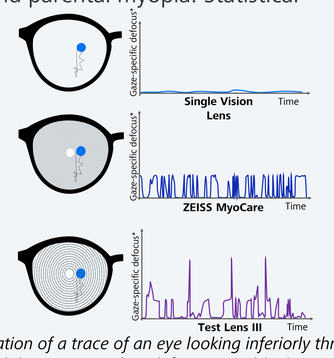
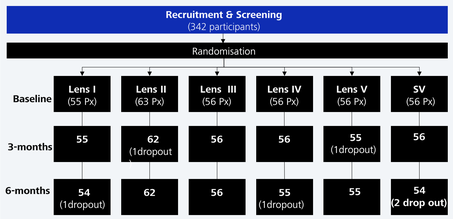


***Figure 2**. Illustration of a trace of an eye looking inferiorly through the lens (left) and the corresponding defocus signal (right panel)*

Results

Figure 3 details the trial flow. At baseline, there were no differences between the groups (Table 1)

***Figure 3:** Trial flow*



Drop outs: Lens I: fast progression (n=1, post 3- month visit); Lens II and Lens V: not willing to wear study lens (n=1 each, dispensing). Lens IV: not interested in continuing (n=1, post 3 months). SV: fast progression (n=2, after 3- month visit)

Table 1. Demographic characteristics at baseline

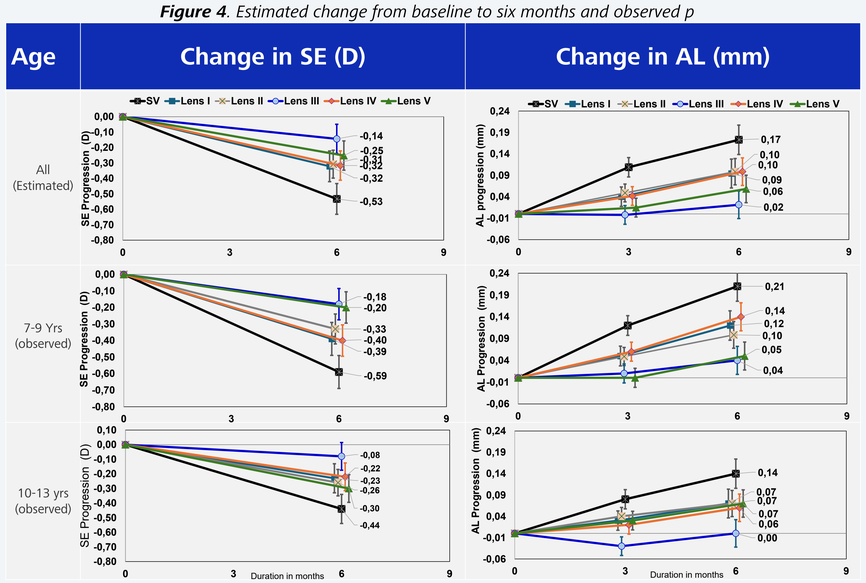
	Lens I (n=55)	Lens II (n=63)	Lens III (n=56)	Lens IV (n=56)	Lens V (n=56)	Single Vision (n=56)	p-value
SE (D)	-2.11±0.93	-1.93±0.87	-1.99±0.79	-2.14±0.85	-2.12±0.84	-2.01±0.82	0.70
AL (mm)	24.3±0.9	24.2±0.8	24.4±0.7	24.4±0.9	24.3±0.8	24.4±0.8	0.52
Age(yr)	10.4±1.8	10.0±1.6	10.0±1.7	10.4±1.7	10.0±1.5	10.3±1.9	0.37
Female: Male %	49.1:50.9	52.4:47.6	53.6:46.4	57.1:42.9	44.6:55.4	64.3: 35.7	0.40

Baseline to 6 months. All MC SPL slowed myopia (Table 2, unadjusted data). After adjusting for confounders (Figure 4), compared to SV, MC SPL slowed myopia by 0.21D to 0.39D for SE and 0.07 to 0.15mm for AL at 6 months. Differences between MC SPL and SV were observed for sphere (p<0.01) but not for cylinder (p>0.05). Of the MC SPL, Lens III slowed myopia the most.

Table 2. Unadjusted Progression by lens

	Change in SE (D): Baseline to 6 months				Change in AL (mm) : Baseline to 3 months				Change in AL (mm): Baseline to 6 months			
Group	Mean	Range	Mean diff	p-value	Mean	Range	Mean diff	p-value	Mean	Range	Mean diff	p-value
SV	-0.51±0.28	0.22 to -1.12	-		0.10±0.06	0.00 to 0.32	-		0.17±0.09	-0.01 to 0.39	-	
Lens I	-0.30±0.28	0.21 to -0.84	0.21	0.010	0.04±0.08	-0.13 to 0.24	-0.06	<0.001	0.09±0.12	-0.12 to 0.47	-0.08	0.005
Lens II	-0.30±0.34	0.34 to -1.16	0.21	0.005	0.05±0.07	-0.12 to 0.20	-0.05	0.003	0.10±0.12	-0.21 to 0.30	-0.07	0.009
Lens III	-0.13±0.34	0.67 to -0.84	0.38	<0.001	0.00±0.09	-0.26 to 0.18	-0.10	<0.001	0.02±0.11	-0.28 to 0.24	-0.15	<0.001
Lens IV	-0.30±0.37	0.84 to -1.43	0.22	0.006	0.04±0.07	-0.23 to 0.16	-0.06	<0.001	0.09±0.11	-0.23 to 0.36	-0.08	0.005
Lens V	-0.24±0.44	1.12 to -1.50	0.27	<0.001	0.01±0.10	-0.26 to 0.30	-0.08	<0.001	0.06±0.15	-0.42 to 0.52	-0.11	<0.001

***Figure 4**. Estimated change from baseline to six months and observed p*



Discussion

All MC SPL slowed myopia, with lens III & lens V (slower progression than SV by 0.39D/0.15mm and 0.28D/ 0.11mm respectively) showing the highest efficacy. The remaining MC SPL slowed myopia by 0.21D to 0.23D and 0.07 to 0.08mm. Lens III incorporates cylindrical optical elements of varying powers arranged to reduce regularity across a given meridian; lens V used cylindrical optical elements of varying powers and reduced-contrast areas.

With SV SPL, myopia progressed by -0.59/0.21mm and -0.44D/0.14mm in younger (7-9 yrs) and older children (10-13 yrs) respectively. In comparison MC SPL III slowed myopia by 0.41D /0.17mm in younger and 0.36D/0.14mm in older children. The absolute reduction was slightly greater in younger children, however, the proportional (percent) reduction was larger in the older children indicating that to obtain a realistic picture of the treatment effect, one should also consider the underlying baseline progression with SV lenses by age.

Imposed defocus produces blur that may affect information presented to retina in two ways a) attenuating retinal image contrast and b) disrupting the spatial phase.[3] Whilst there is evidence for neural adaptation for blur, it is not known if adaptation occurs for phase disruptions.[4] Future work needs to consider if the test MC SPL differed in these mechanisms.

Conclusion

After 6 months of lens wear, all MC SPL progression were observed to slow myopia progression with lens III being most effective. The MC SPL use complex patterns – lens elements, power, fill factor, arrangement and contrast changes that may act to slow myopia via contrast attenuation and/or via spatial phase disruption. The trial is ongoing for evaluation of long-term efficacy.

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Email: Padmaja.Sankaridurg@zeiss.com

Disclosures: PS (E) ZEISS Visioncare, (P) ZEISS VisionCare, Brien Holden Vision Institute; AO (E), WL (E), NL (E),