Responders and non-responders to wear of a novel myopia control spectacle lens: A 12-month randomized, double-masked, cross-over clinical trial

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Purpose

- In a cross-over clinical trial, participants serve as their own control as they receive multiple interventions and it allows identification of individual "responders", i.e. those who respond to treatment from non-responders and additionally, helps identify risk factors if any associated with non-responders.
- A 1 yr cross-over clinical trial was conducted where participants wore both a myopia control (Test) and a single vision (SV) spectacle (SPL) to determine
  - the number of individuals with slower myopia progression with test than SV SPL (responders);
  - to identify factors if any associated with eyes that did not respond with test SPL.

Methods

- 1 year prospective, double-masked, cross-over trial (NCT06329986).
- 120 Chinese children, 6-12 years, spherical equivalent refractive error (SE) of -0.75D to -5.00D, astigmatism ≤ 1.50D, anisometropia < 1.00D.
- Randomised to Test or SV SPL for 6 months (Stage 1) and crossed over to wear the remaining lens for the second 6 months (Stage 2).
- Test SPL (also known as TAMER or ZEISS MyoEase): 7 mm central clear zone, 4 paracentral cylindrical annular elements (+4.00D mean power) extending up to 13mm from lens centre. Back surface had increasing plus power reaching a maximum of +1.30D at lens edge. Control SV SPL. Both test and control SPL from Carl Zeiss Vision Gmbh, Germany.

Fig 1: *Test lens design*

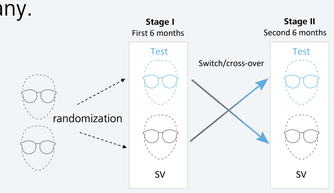

Fig 2: *Trial flow*

- Cycloplegic SE and axial length (AL) were measured every 6 months. Eyes that progressed slower with Test than SV SPL categorised as Responders and those with same or worse progression as SV SPL as Non-responders.

Statistical analysis:

- Within participant progression was assessed with paired-t test, whereas factors at baseline were compared between participants with unpaired t-test or chi-square test. For the exploration analysis of risk factors, statistical significance level was $p < 0.05$.

Results

Of the 120 children, 117 completed Stage 1 and 114 completed Stage 2.

Baseline

No significant differences between groups except for parental myopia (higher % of two myopic parents in the SV group, Table 1).

Table 1. Baseline characteristics

	SV SPL (n=60)	TEST SPL (n=60)	*p*-value
Age (years)	9.5 ± 1.4	10.0 ± 1.5	0.12
Spherical Equivalent (D)	-2.15 ± 0.97	-2.02 ± 0.91	0.44
Axial length (mm)	24.48 ± 0.85	24.32 ± 0.62	0.26
Female:Male	31:29	29:31	0.855
Parental Myopia Both: One: None	66.7: 20: 13.3	48.3: 46.7: 5.0	0.005

Treatment Response (across both stages)

Across both stages, 170 of 226 eyes (75%) had slower SE progression and 188 of 224 (84%) had slower AL progression with Test SPL. The difference in progression when wearing test versus SV SPL is illustrated in the plots below.

Fig 3: *Progression with Test vs SV SPL*

Non-Responder Analysis

- 17/120 participants progressed more with Test SPL than SV; their wearing time was less (non-responders 10.2±2.1 vs responders 11.8±2.5 hrs/day, p=0.010). Other baseline factors such as SE and AL, parental myopia, age, phoria, amplitude of accommodation or life-style factors did not differ between groups.
- At 6 months, in non-responders, overall comfort was lower with Test than SV SPL (9.2±1.2 vs 9.8±0.5, p=0.029, scale of 1-10 where 10= excellent and 1= poor) and wearing time was shorter (Test SPL: 10.2± 2.1 vs SV SPL: 11.2 ± 2.5 h/day; p = 0.06).

Discussion

- Test SPL significantly slowed myopia progression in the majority of children, consistent with results of other myopic defocus-based SPL studies.[1,2] A treatment zone that is limited to a small region surrounding the clear centre (outer edge of treatment zone was 13 mm from centre) was highly effective in slowing myopia.
- Overall, considering AL progression, 8 of 10 children progressed slower with Test SPL and this increased to 9 of 10 children when compliance of ≥ 12hrs/day was considered. This highlights a dose-dependent relationship between wearing time and treatment efficacy.
- Non-responders had a trend toward reduced wearing time and lowered comfort scores. This suggests that lens discomfort may compromise compliance, which in turn limits myopia control efficacy, consistent with previous studies.[3]
- To optimize myopia intervention outcomes, it might be beneficial to pay attention to wearing time and subjective comfort.

Conclusion

- The cross-over trial demonstrated that majority of participants responded with slower myopia progression to a Test SPL with cylindrical annular elements that imposed myopic defocus. The non-responders were few with less wearing time and lower subjective comfort being potential factors.

References

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