Effectiveness of Defocus Incorporated Multiple Segments (DIMS) Spectacle Lenses in Retarding Myopic Shifts Among Pre-Myopic Preschoolers: Nine-Month Results of a Pilot Study

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Purpose

- To evaluate the feasibility and effectiveness of DIMS spectacle lenses in controlling pre-myopia in preschool children.

Methods

- Study Design: This pilot study was conducted at National Yang Ming Chiao Tung University Hospital and approved by the Institutional Review Board (NYCUHIRB No. 2023A015).
- Eligibility Criteria:
  - Age: 5–7 years
  - Refractive Status: Cycloplegic spherical equivalent (SE) < +1.00D and > -0.50D in the more ametropic eye
  - Astigmatism: ≤ 1.50D in both eyes
  - Anisometropia: ≤ 1.50D
  - Monocular Uncorrected Visual Acuity: 6/7.5 or better
- Exclusions: Strabismus, ocular/systemic conditions affecting vision, prior myopia control treatments (e.g., atropine).
- Intervention
  - Spectacle Design: photochromic DIMS spectacle lenses with a plano central zone.
  - Wearing Regimen: part-time wear initially (during near work at home, weekends, holidays).
  - If SE increased to ≤ -1.00D in either eye, lenses were re-prescribed to maintain 6/7.5 or better visual acuity.
  - Compliance: Logged by caregivers in daily diaries; ≥52.4% adherence to the required wearing blocks was deemed “good compliance.”
- Follow-Up Schedule: participants examined at baseline and every 3 months. Most children entered elementary school by the 9-month visit.
- Outcome Measures
  - Primary: 9-month change in cycloplegic SE.
  - Secondary: 9-month change in axial length (AXL).
  - Exploratory: Change in sub-foveal choroidal thickness(SCT), near-work behavior, and outdoor activity.
- Statistical Analysis
  - Only the eye with lower SE (more myopic/less hyperopic) was used.
  - Continuous data expressed as mean (standard deviation); categorical data as frequency (%).
  - Between-group comparisons via Independent t-test (continuous) and Pearson’s chi-square (categorical).
  - Significance set at $p < 0.05$.
  - Reference Control: A comparable cohort of 378 pre-myopic children from a separate longitudinal study with an annual SE change of -0.15D/year.

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Results

- The descriptive analyses of the 24 pre-myopic children are presented in Table 1. The average SER remained stable over nine months, shifting slightly from +0.375D (±0.319D) to +0.432D (±0.33D) ($p = 0.471$) (Figure 1), equating to +0.08D per year, compared to -0.15D per year in the pre-myopic control group (n = 378). Axial length increased significantly from 22.48 mm (±0.61 mm) to 22.64 mm (±0.63 mm) ($p < 0.01$) (Figure 2), while CCT remained stable (351.3 µm ±55.9 µm at baseline vs. 348.2 µm ±50.7 µm at nine months, $p = 0.726$) (Figure 3).
- DIMS spectacle lens adherence was high, with an average wearing rate of 74%, surpassing the target of 52%. A negative trend was observed between changes in SER and axial elongation (Figure 4). Increased wearing time showed a mild positive association with hyperopic changes in refraction, though this was not statistically significant. No significant correlation was observed between axial length and average lens-wearing time.

Table 1: Basic data of the participants

Parameters	Result
Age (mean)	5.4 ± 0.59
Sex (number)	
Male	11
Female	13
Side of eye (number)	
Right eye	16
Left eye	8
Spherical equivalent (mean)	0.28 ± 0.27
Parental myopia (number)	
None	1
One	7
Both	16
AXL (mean)	22.48 ± 0.63
Near VA with DIMS (mean)	0.995 ± 0.02

Figure 1: Box and whisker plot of SE

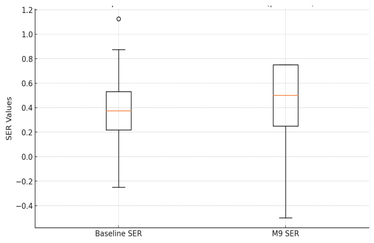


Figure 2: Box and whisker plot of AXL

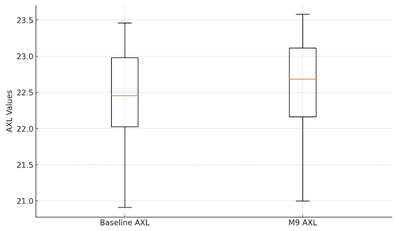


Figure 3: Box and whisker plot of SCT

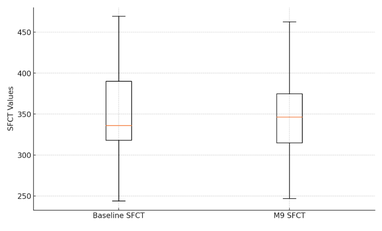
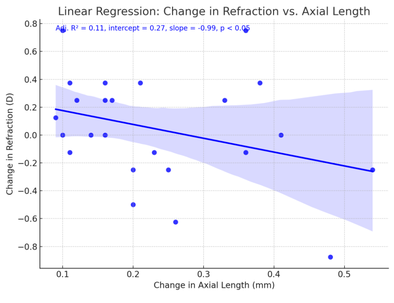


Figure 4: Linear regression of SE & AXL change



Discussion

Key Findings & Significance

- **Stable Refraction**: Over 9-month, the spherical equivalent (SE) remained essentially unchanged (+0.08D/year), compared to -0.15D/year in a comparable historical control group.
- **Minimal Myopia Onset**: Only one participant (4.2%) became myopic, underscoring DIMS spectacle lenses’ potential to delay or prevent myopia onset in high-risk children.
- **Good Acceptability**: Overall adherence (74%) exceeded the prespecified target (52%), and caregivers reported minimal visual complaints.

Factors Influencing Myopia Progression

- **Elementary School Transition**: The single case that progressed rapidly had already started elementary school, suggesting increased near-work demands and decreased outdoor time may have a role to play in the accelerated progression.
- **Parental Myopia**: Three children whose SE progressed relatively fast had ≥1 parent with high myopia, highlighting a possible genetic predisposition and underscoring the need for early intervention in such cases.

Efficacy & Comparisons

- **DIMS vs. Historical Controls**: Children wearing DIMS spectacle lenses showed nearly stable refraction, whereas the historical control group had more myopic SE progression.
- **LAMP2 Comparison**: Our younger cohort (mean age 5.4 vs. 6.8 years in LAMP 2) had much lower myopia incidence (4.2% vs. 28.4% in 0.05% atropine treatment group). This suggests DIMS spectacle lenses may offer a less invasive alternative to atropine for pre-myopic children.[1]
- **HAL Comparison**: Differences in population age, urban/rural setting, and spectacle design make direct comparisons challenging. Nonetheless, both studies highlight optical interventions as viable strategies to manage or delay myopia onset. [2]

Limitations & Future Directions

- **Pilot Study with Small Sample**: Larger studies are needed to confirm these preliminary findings and establish broader applicability.
- **Nine-month Follow-Up**: Longer-term outcomes, especially post–elementary school enrollment, require further investigation.
- **No Direct Randomized Control**: A matched historical control was used instead. A randomized trial would yield more rigorous evidence.

Conclusions

Stability in SE suggests a protective effect of DIMS spectacle lenses on refractive status. High adherence and trends in wearing time support the potential effectiveness of DIMS spectacle lenses in mitigating myopia-related parameters. Larger studies are needed to confirm these findings and evaluate the long-term impact of DIMS spectacle lenses on myopia prevention.

References

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