

Effectiveness of Defocus Incorporated Multiple Segments (DIMS) Lens in Slowing Myopia Progression among Malay Schoolchildren

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ABSTRACT

INTRODUCTION: Defocus Incorporated Multiple Segments (DIMS) lens imposes simultaneous myopic defocus for myopia control and has been proven to be effective in controlling myopia progression in children. However, the effectiveness of the DIMS lens may vary between different ethnicity due to different retinal profiles among children. This study aims to determine the effectiveness of DIMS lens in controlling myopia progression among myopic Malay schoolchildren. **MATERIALS AND METHODS:** This is a randomized control trial and was conducted as a single-site study where forty-two myopic Malay schoolchildren, (mean age of 9.53 ± 1.50 years old) were recruited. The effectiveness of the DIMS lens was measured via changes in spherical equivalent refraction and axial length elongation for 12 months, and findings were compared with children wearing single vision (SV) lens. Data was analysed using repeated analysis of variance (ANOVA), between-within with Bonferroni correction, and $p < 0.05$ indicated a significant difference. **RESULTS:** After 12 months, 38 subjects completed the study, with 20 subjects in the DIMS group and 18 subjects in the SV group. The DIMS group showed a significantly lower myopia progression; with 0.07 ± 0.10 mm increment in axial length elongation and -0.16 ± 0.30 D in spherical equivalent refraction increment compared to the SV group. The main effect comparing the changes in axial length elongation and spherical equivalent refraction increment between the DIMS group and the SV group was significant, ($F=7.61$, $p < 0.05$) and ($F=3.23$, $p < 0.05$), respectively. **CONCLUSIONS:** Full time wear of the DIMS lens is significantly effective in slowing myopia progression compared to SV lens in myopic Malay schoolchildren.

Keywords

Myopia progression, DIMS lens, Myopic Malay schoolchildren

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INTRODUCTION

Myopia prevalence is rising significantly worldwide,^{1,2} especially in developed Asian countries such as China, Hong Kong, Taiwan and Singapore.³⁻⁵ This is disconcerting because of the increased risk to visual impairment and blindness including cataract, glaucoma, retinal detachment and other chorio-retinal abnormalities.

⁶⁻⁸ Current interventions, including low dose atropine, dual-focus contact lenses, and orthokeratology, have shown promise in mitigating myopia progression among schoolchildren.⁹ However, their invasive nature and associated risks pose challenges, especially concerning

their implementation in younger children.¹⁰ Therefore, the preferred myopia control strategy for younger children should be simple and minimally invasive, which makes spectacle lenses an appealing and ideal alternative option for them.

Myopia is associated with excessive axial eye growth and disproportionately high corneal power. Animal studies have shown that myopic defocus can impede eye growth while hyperopic defocus drives eye elongation.^{11,12} Observations on animal studies also showed that when

the eye was presented with equal amounts of competing defocus, myopic defocus produced a stronger effect than hyperopic defocus.¹³ Nowadays, myopic defocus theory has been established and already underlaid several current myopia control strategies, such as in orthokeratology and multifocal soft contact lenses.

In 2020, a research team from The Hong Kong Polytechnic University designed a novel spectacle lens based on the myopic defocus theory for myopia control, known as Defocus Incorporated Multiple Segments (DIMS) spectacle lens. This lens provides a simultaneous myopic defocus and have shown to significantly slow myopia progression in schoolchildren by 52% over 2 years in spherical equivalent increment and 62% in axial elongation when compared to the single vision (SV) lens.¹⁴ DIMS lens is safe and has no effect on children's binocular vision.¹⁵ In addition, a six-years study on the effectiveness of DIMS lens showed no rebound effect, and annual increment in axial length is maintained at 0.12 mm.¹⁶ The effectiveness of DIMS lens during COVID-19 related lockdown measures in schoolchildren were also proven to be superior to SV lens¹⁷ as well as in the large scale or diverse clinical circumstances study on myopic children.¹⁸

However, previous randomized control trial¹⁴ recruited only homogenous Hong Kong Chinese schoolchildren and not evaluated on another ethnicity. Epidemiological evidence¹⁹ have shown major differences between ethnic groups in the prevalence of myopia even though detail analysis suggests that these differences may be mediated by environmental exposures.²⁰ To the best of the authors' knowledge, there is no other randomized clinical trial that study the effectiveness of DIMS lens in other ethnicity; which may limit the generalizability of its results.

Malaysia is a multi-ethnic country with a population of almost thirty-five million. The largest ethnicity is made up of Malays accounting for over half of the country's population besides Chinese and Indian. Although Chinese ethnicity has the highest prevalence of myopia among schoolchildren in Malaysia, the quadruplet increment of myopic schoolchildren in Malay is worrying.²¹ This present study therefore aims to investigate if the

DIMS lenses can effectively slow down the myopia progression in myopic Malays schoolchildren by comparing the change in spherical equivalent of cycloplegic autorefraction (SER) and axial length between DIMS and single-vision spectacle lenses. This study also reports the best-corrected visual acuity (BCVA) and lens performance between both groups.

MATERIALS AND METHODS

Study design

This was a prospective, randomised, double-masked clinical trial and a single site study, conducted at Optometry Clinic, Faculty of Health Science, Universiti Kebangsaan Malaysia. The subjects were randomly allocated to two groups: the treatment group (DIMS lens) and the control group (SV lens). Changes in spherical equivalent refraction (SER) and axial length were used to determine the efficacy of the DIMS lens. Each parameter was measured at baseline and every 3-months for 12 months, and the changes in SER and axial length between two groups were compared over the study period. Three months follow-up regime were designed to determine the pattern of the myopia control in shorter interval. This study adhered to the tenets of the Declaration of Helsinki and approval was obtained from the institutional ethics committee (UKM PPI/111/8/JEP-2020-667). Detailed explanation about the research was given to both parents and subjects including its potential risks and benefits before consent was obtained in this study. The subjects were free to withdraw from the clinical research at any time.

Subjects

Subjects were selected based on specific inclusion criteria, which required them to be schoolchildren aged 7 to 12 years with a spherical refractive component ranging from -0.50D to -5.00D and astigmatism and anisometropia of less than 1.50D. They should demonstrate a monocular best-corrected visual acuity (BCVA) of 0.00 log MAR (6/6) or better. They were also required to commit to participating in multiple follow-up sessions for data collection and agree to randomized group allocation as part of a masked study design.

This study recruited only myopic Malay schoolchildren. The Malay ethnicity of the subjects was contained to at least a minimum of three tiers of Malay descendants. Subjects were excluded if they have any strabismus and binocular vision abnormalities, ocular and systemic abnormalities and had prior experience with any myopia control program. The inclusion and exclusion criteria were developed from the recommendations by the International Myopia Institute to reduce bias and variability, and to maximize generalizability for easier comparison with myopia control studies elsewhere.^{22,23}

Subjects were instructed to wear the spectacles during the whole waking hours, except during shower. Wearing time compliance was asserted at every follow-up appointment. The final distance prescription was determined using cycloplegic subjective refraction and the lenses were replaced with an updated prescription when the change of SER was more than 0.50D.

Intervention and control

All subjects were supplied with spectacle lenses that were made of polycarbonate. The children in the treatment group wore the DIMS spectacle lenses while those in the control group wore SV spectacle lenses. Each DIMS lens comprises a central optical zone of 9 mm in diameter and contains multiple lenslets, each lenslet with a relative positive power of +3.50D. The optical principles and designs of the DIMS lens were described in detail by Lam et al.¹⁴

Sample size

The sample size required in this study was calculated using statistical package G*Power version 3.1.9.4 for analysis of variance (ANOVA) between and within interaction of the two groups. With a total of 5 visits for a complete data collection, a total of 24 subjects were required in this study to achieve an 85% study strength with an alpha level of 0.05 (2-tailed). Attrition rate was initially set at 10% but was revised and increased to 25% to safeguard the subject enrolment since the unprecedented emergence of COVID-19 outbreak and prolonged movement control order during the data collection phase. Therefore, with a higher

attrition rate estimation, a total of 32 subjects were required in this study.

Masking and randomisation

To adhere to the double-blinded research protocol, a designated investigator who was not associated with the masking process undertook responsibilities including group allocation, dispensation, spectacle delivery, and record-keeping. Both children and parents remained unaware of the group assignments, ensuring the integrity of the blinding procedure. Block randomisations were used in this study by using the $f(x)=\text{ran}()$ function available in the Microsoft Excel. Block randomisations were chosen to achieve a balanced subject distribution between groups, minimizing potential biases and enhancing the validity of the study results. Subsequently, eligible subjects were allocated to either the treatment or control group based on the sequence generated by Excel. Detailed instructions were provided during the spectacle delivery, emphasizing on full-time wear. Rigorous monitoring of wearing hours compliance was executed through regular face-to-face interviews during follow-up sessions and via comprehensive questionnaires.

Outcome variables

Three primary research outcomes were observed at baseline and at 3-month intervals for 12 months in this study. The primary outcome was myopia progression, which was the difference between the mean axial length at the baseline and the subsequent axial length recorded at every visit throughout the study period. The secondary outcome was the change in the SER.

In this study, axial length was measured using optical biometry (Lenstar 900, Haag-Streit, USA) while an autorefractor (Grand Seiko WAM-5100, Hiroshima, Japan) was used to measure the cycloplegic SER. Average of five measurements of axial length and autorefraction for each eye were obtained for analysis. Prior to the autorefractor measurement, two drops of cyclopentolate hydrochloride 1%, (Cyclogyl, Alcon) were instilled at five-minute intervals between each drop to achieve the cycloplegic effect. Cycloplegia was confirmed by

measuring the amplitude of accommodation via push-up method when accommodation was 2D or less.

The third outcome was the BCVA and was observed at baseline. In this third outcome, variables comprised the changes in BCVA throughout the study period including the high contrast VA (HCVA) and low contrast VA (LCVA) for both distance and near visual acuity. HCVA at distance was measured using Logarithmic 2000 series Early Treatment Diabetic Retinopathy Charts while Low Contrast Early Treatment Diabetic Retinopathy Charts at 4m (Precision Vision Inc., Woodstock IL, USA) were used to measure the LCVA at distance. HCVA and LCVA at near were measured using the Mixed Contrast European-Wide Near Vision Card (Precision Vision Inc.) All VA measurements were conducted monocularly and binocularly under standardized room illumination of 500 cd/m².

Statistical Analysis

Data from all subjects who completed with the 12 months follow-up were analysed. Data analyses were conducted using per-protocol without employing imputation to account for missing data or dropouts. The change in parameters was defined as the difference between baseline and corresponding follow-up measurements. Data from the right eye will be used for data analysis if high correlation was found between the two eyes. Statistical analyses were conducted using a commercial software (SPSS version 23.0; SPSS, Inc., Chicago, IL).

The distribution of the measured variables for univariate analysis was estimated by the Shapiro-Wilk test meanwhile Cook's Distance was used for multivariate analysis. Parametric tests were chosen for normally distributed data, while non-parametric tests were used if normality were breached. Baseline demographic, refractive and biometric measurements such as age, gender ratio, corneal curvature, lag of accommodation, axial length and SER between DIMS treatment group and SV group were compared using unpaired t-test. Changes in SER and axial length elongation at different time points relative to the baseline were calculated. Repeated measure ANOVA was used to compare the changes in SER and axial length

elongation between DIMS group and SV group during the experimental period, with the assumption in the homogeneity of variance. Post-hoc tests were conducted by Bonferroni correction. Pearson correlations were used to analyse the relationship between age, SER and axial length elongation. P-values of less than 0.05 were considered as statistically significant.

RESULTS

Subject profile

Forty-two myopic Malay schoolchildren, mean age of 9.50 ± 1.48 years old, were randomised and included in this study. However, at the end of the study duration, only 38 subjects completed their data collection for the final data analysis. The drop-out cases were unrelated to the study protocols. Specifically, the parents of two children opted to withdraw their children from the study due to concerns about the ongoing COVID-19 pandemic during the study duration. Two participants were counselled-out for not able to cooperate during the data collection phase. Fig. 1 provides a visual representation depicting the number of subjects screened and enrolled in this study. Even with the stringent limitations and restrictions policies during the COVID-19 pandemic, 38 subjects managed to complete the study, which yielded a study strength of more than 95% when calculated via G*Power of post-hoc statistical test for ANOVA.

In general, both groups showed an overall good compliance and were able to wear the spectacles full time. The mean daily lens-wearing time in the DIMS group and SV group was 15.85 ± 1.62 and 15.94 ± 1.57 hours, respectively, and the difference was not statistically significant ($p < 0.05$). Preliminary analysis of the data found both eyes to be highly correlated (correlation between eyes for SER, $r = 0.93$, $p < 0.001$, and correlation between eyes for axial length, $r = 0.97$, $p < 0.001$). Therefore, only data of right eyes were used for further analysis.

Baseline characteristics

The mean SER in the DIMS group was $-2.81 \pm 1.25D$ and the mean SER in the SV group was $-3.05 \pm 1.32D$ at the baseline. Meanwhile, the mean AL in the DIMS and

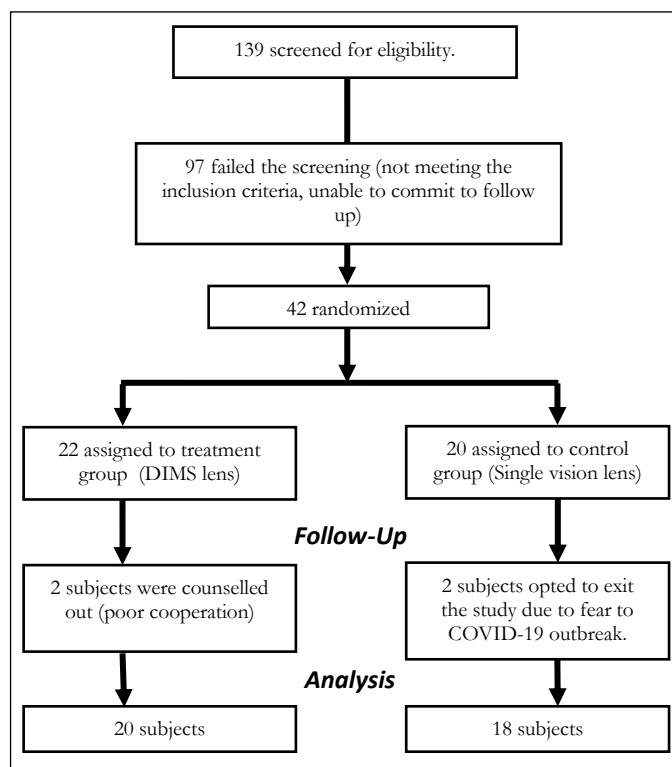


Fig. 1 A flow diagram of the subject enrolment. DIMS, Defocus Incorporated Multiple Segments spectacle lens; SV, single vision spectacle lens.

SV groups was $24.48 \pm 0.98\text{mm}$ and $24.31 \pm 0.85\text{ mm}$, respectively. In this cohort, thirty-three subjects have at least one or both myopic parents. The baseline characteristics of each treatment group for all participants who completed the 12 months follow-up are shown in Table I.

Table I Baseline characteristics of participants who completed the 12 months follow-up in each treatment group.

	DIMS (n=20)	SV (n=18)	p-value
Age at enrolment (years)	9.55 (1.61)	9.50 (1.43)	0.92
Gender ; Female, % (n)	75.0% (15)	44.5% (8)	0.05
Distance High Contrast VA	0.01 (0.03)	0.00 (0.04)	0.58
Distance Low Contrast VA	0.13 (0.06)	0.13 (0.06)	0.85
Near High Contrast VA	0.02 (0.04)	0.02 (0.03)	0.73
Near Low Contrast VA	0.15 (0.07)	0.14 (0.04)	0.60
Cycloplegic Autorefraction, SER (D)	-2.81 (1.25)	-3.05 (1.32)	0.58
Axial length (mm)	24.48 (0.98)	24.31 (0.85)	0.57
Corneal power at flat meridian (D)	43.60 (1.50)	43.96 (1.31)	0.43
Distance phoria, Δ	-0.25 (1.68)	-0.67 (2.25)	0.53
Near phoria, Δ	-1.35 (1.84)	-0.56 (1.20)	0.31
Accommodation lag (D)	1.18 (0.34)	1.07 (0.32)	0.31

Note: Data are presented as Mean (Standard Deviation, SD), $p < 0.05$ is considered significant (Independent paired t-test)

Abbreviation: Δ , prism dioptres; AL, axial length; D, dioptres; DIMS, Defocus Incorporated Multiple Segments; SV, Single Vision; -ve phoria indicate exophoria

Changes in SER

In general, both groups showed an increment in SER after 12 months of the observation. The mean SER progression in the SV group was statistically higher ($-0.44 \pm 0.36\text{D}$) compared to the increment in the DIMS group ($-0.16 \pm 0.30\text{D}$).

Repeated measure ANOVA with Bonferroni correction showed a significant main effect for time $F=5.72$, $p=0.003$, $\eta_p^2=0.14$ and significant main effect for type of lens used $F=3.97$, $p=0.05$, $\eta_p^2=0.01$. The main effect comparing the changes in the SER in DIMS and SV groups was also significant $F=3.23$, $p=0.038$, $\eta_p^2=0.08$. These statistical analysis findings confirming that there was significant effect of DIMS lens on SER over 12 months in myopic Malay schoolchildren. Children wearing DIMS lens had significantly less SER increment by 63.6%, with mean difference of $-0.29 \pm 0.36\text{D}$, $p < 0.0125$ (Fig. 2). Pearson correlation analysis showed that the changes in SER was not correlated with the age of enrolment in both groups ($p > 0.05$).

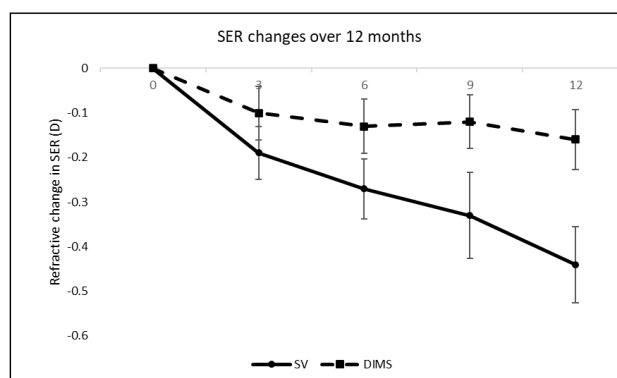


Fig. 2 SER from baseline to 12 months. Error bar denotes SEM

Changes in axial length elongation

Similarly to SER, both groups also showed an increment in axial length elongation after 12 months of the study period. The total axial length elongation over 12 months was $0.07 \pm 0.10\text{ mm}$ and $0.20 \pm 0.13\text{ mm}$ in the DIMS and SV groups, respectively. Children wearing DIMS lens had significantly less axial length elongation by 65.0%, with mean difference of $0.13 \pm 0.04\text{mm}$, $p < 0.0125$ (Fig. 3).

Repeated measure ANOVA with Bonferroni correction showed a significant main effect for time $F=22.96$,

$p < 0.001$, $\eta^2 = 0.39$ and significant main effect for type of lens used $F = 11.60$, $p = 0.002$ $\eta^2 = 0.24$. The main effect comparing the changes in the axial length elongation between the DIMS group and SV groups was also significant $F = 7.61$, $p = 0.003$, $\eta^2 = 0.18$. These statistical analysis findings confirmed that there were significant effect of DIMS lens on axial length elongation over 12 months in myopic Malay schoolchildren. Pearson correlation analysis showed that the changes in axial length elongation was not correlated with the age of enrolment in both groups ($p > 0.05$).

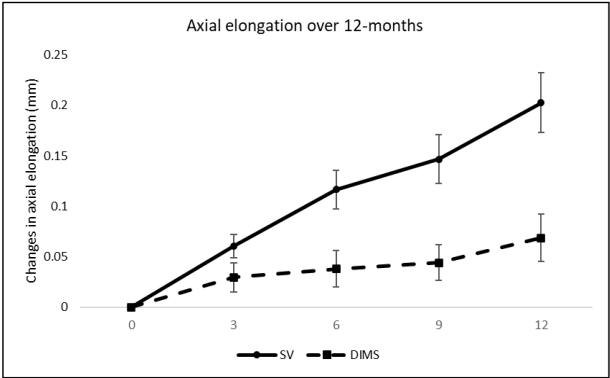


Fig. 3 Mean and SE of axial length elongation from baseline to 12 months. Error bar denotes SEM.

Changes in visual acuity performance

Both groups showed good and stable VA at both distance and near acuity measurements throughout 12 months of study duration with no significant difference noted. Details of the visual acuity performance is shown in Table II.

Table II Changes in VA between DIMS group and SV group for 12 months

	Baseline		3 rd month		6 th month		9 th month		12 th month	
	DIMS	SV	DIMS	SV	DIMS	SV	DIMS	SV	DIMS	SV
HCV A (Distance)	0.01 (0.04)	0.01 (0.03)	-0.01 (0.05)	-0.01 (0.06)	-0.02 (0.04)	-0.04 (0.05)	-0.05 (0.05)	-0.05 (0.06)	-0.04 (0.05)	-0.06 (0.05)
LCVA (Distance)	0.13 (0.06)	0.14 (0.06)	0.11 (0.06)	0.12 (0.09)	0.07 (0.05)	0.10 (0.05)	0.07 (0.05)	0.10 (0.05)	0.07 (0.05)	0.10 (0.05)
HCV A (Near)	0.02 (0.04)	0.02 (0.03)	0.00 (0.07)	0.02 (0.06)	-0.02 (0.06)	0.00 (0.02)	0.00 (0.02)	-0.01 (0.04)	-0.01 (0.04)	-0.02 (0.03)
LCVA (Near)	0.15 (0.07)	0.14 (0.06)	0.13 (0.07)	0.12 (0.06)	0.12 (0.06)	0.10 (0.04)	0.09 (0.04)	0.09 (0.04)	0.09 (0.05)	0.08 (0.04)

Note: Data is presented as Mean (Standard Deviation, SD)
No significant difference between group at all visual acuity measurements
Repeated measure ANOVA (between-within subject analysis of variance) with Bonferroni correction, $p > 0.005$, $\eta^2 < 0.03$
Abbreviations: DIMS, Defocus Incorporated Multiple Segments; SV, Single Vision;
HCVA, High Contrast Visual Acuity ; LCVA, Low Contrast Visual Acuity
-ve notation indicate better acuity than the Log MAR 0.00

In addition, all VA elements showed improvement towards the end of the study. This observation is possibly contributIn addition, all VA elements showed improvement towards the end of the study. This

observation is possibly contributed by subjects getting more experienced with data collection techniques and better adaptation to the spectacles. Both groups also recorded about 1.5 line poorer in LCVA than the HCVA. This finding is expected as the HCVA and LCVA are usually reduced by two lines at distance for normal subjects.²⁴

Lens performance

Direct information on lens performance acquired via questionnaires demonstrated that DIMS and SV gave a comparable performance. On the last question regarding subjects’ feedback on the overall lens performance, the DIMS group scored only 0.1 point less than the SV group (Fig. 4). No treatment-related adverse events were reported throughout the study period from any of the group.

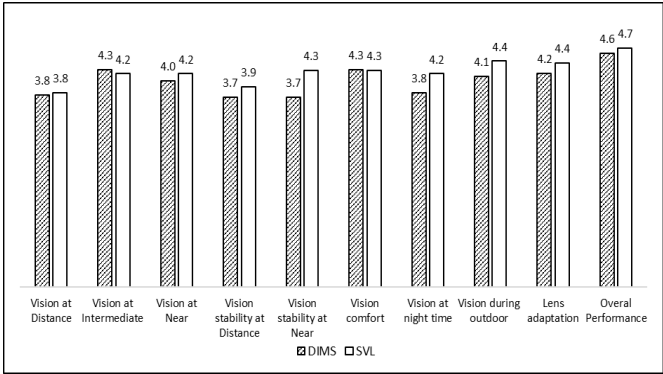


Fig. 4 Subjects’ response to lens performance. (Score: 1-Poorest to 5-Excellent).

DISCUSSION

DIMS lens has been established as an effective treatment option for controlling myopia progression in Chinese population.^{14–18} More reports on the effectiveness of DIMS lens in controlling myopia progression were also being established in other ethnic population.^{25,26} This study hereby showed that the simultaneous myopic defocus provided by the DIMS lens was also effective in controlling myopia in myopic Malay schoolchildren and ascertained the effectiveness of DIMS lens in another ethnicity.

Myopia is a multifactorial condition, and even though ethnicity was not considered as a major risk factor for myopia as opposed to education and time spent outdoor,

ethnicity may affect the genetic determination in human. Various epidemiological evidence shows major differences between ethnic groups in the prevalence of myopia,^{27,28} even though these prevalence differences are probably mediated by environmental exposures as well. In this cohort, the 12 months cumulative absolute reduction in axial length elongation was 0.07mm with the standard error of 0.03mm and comparable with result by Lam et al.,¹⁴ which reported the 12 months cumulative absolute reduction in axial length elongation of 0.11mm with the standard error of 0.02mm. Axial length is more sensitive in monitoring myopia progression and has been recommended as a gold standard in monitoring myopia progression in clinical studies.^{22,29} However, the smaller effect size noted in the interaction analysis of SER increment between the two groups observed in this study probably contributed by varied residual accommodation which may affect the final measurement of SER especially in dark-irided/pigmented children³⁰ like the Malays.

Another important observation in this study was the treatment effect. The treatment effect in terms of axial length elongation was greatest at the first nine months of the study with the relative efficacy of up to 73% and reduced to 65% at the end of 12th-month. Brennan et al.²⁹ calculated an approximately 31%-40% of the projected treatment efficacy of optical interventions to control myopia occurred in the first 6th-month of the study period and suggested one of the possible factors to this short treatment effect may attributed by transient choroidal thickening in the retina in response to simultaneous myopic defocus induced by the optical lens. Recent research has already proposed that the choroid is an important biomarker of eye growth in the human eye and prompted further research in human for better understanding in signals and pathways regulating the eye growth.³¹

In addition, study on human eye has already documented quick retinal response in the human eye and the retina can detect and response to sign of blur (defocus) within minutes.^{32,33} Therefore, caution must be applied in generalizing or postulating the short-term treatment study

efficacy for the long-term myopia management for every myopic child.

No treatment-related adverse events were reported during these 12 months of observation. Information acquired via questionnaire also showed a comparable score in terms of lens performance demonstrated in both group suggesting the stability and comfort of using the DIMS lens for myopia control in children.

Limitation in this study must be addressed for better research design in the future. The SER range in this cohort was limited to -5.00D with anisometropia and astigmatism of not more than 1.5D. It is then suggested that future RCT should extend the SER inclusion criteria to a higher degree of myopia. Meta regression analysis by Sarkar et al.³⁴ showed baseline SER having a significant impact on the treatment effect where treatment effect was larger with higher magnitude of baseline SER. This study also recruited subjects from a large age group even when many established research has established a greater risk of myopia progression in early onset myopia.²⁰ It is thus recommended that future studies have younger age groups in mind, preferably children less than 9 years old. Small sample size is always a concern, but as mentioned previously, the small sample size is justified with the study strength of more than 95% when recomputed again from the post-hoc statistical test for ANOVA upon the study completion.

CONCLUSION

In conclusion, full time daily wear of the DIMS lens can effectively control myopia progression and axial elongation in myopic Malay schoolchildren when compared to children wearing SV lens. DIMS lens also provides stable and good vision at both to distance and near. This intervention is straightforward, and the least invasive method compared to pharmacological or contact lens treatments. Spectacle correction using the DIMS lens would be a strategic approach to reduce myopia progression in younger schoolchildren.

FUNDING

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CONFLICT OF INTEREST

All authors declare no conflicts of interest.

INSTITUTIONAL REVIEW BOARD (ETHICS COMMITTEE)

This study adhered to the tenets of the Declaration of Helsinki, and approval was obtained from the institutional ethics committee (UKM PPI/111/8/JEP-2020-667).

CONSENT TO PARTICIPATE

All individual participants in this study provided informed consent. The parents and participants were provided with a comprehensive explanation of the research, including the potential risks and benefits, prior to giving their consent to participate in this study. Participants had the autonomy to discontinue their involvement from this study at any given moment.

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