• Meta-Analysis •

# Myopia control efficacy of peripheral defocus modifying spectacle lenses in children and adolescents: a Metaanalysis

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# Abstract

• **AIM:** To evaluate the effects of microlens design of peripheral defocus modifying spectacle lenses (PDMSLs) and non-microlens design of PDMSLs on controlling myopia progression in children and adolescents.

• **METHODS:** A systematic search was carried out in the PubMed, Cochrane Library, Embase, CNKI, and Web of Science databases. The search targeted randomized controlled trials (RCTs) and cohort studies (CTs) that explored the effects of PDMSLs on myopia control among children and adolescents. The Cochrane risk-of-bias tool and the Newcastle-Ottawa Scale were employed to evaluate the risk of bias in the included studies. The published biases of the included studies were evaluated using Egger's test.

• **RESULTS:** Nine studies (7 RCTs, 2 CTs) were included, involving 4332 participants in the PDMSLs group and 7317 participants in the single vision lenses (SVLs) group. Metaanalysis showed that PDMSLs with microlens design had lower change in spherical equivalent refraction (SER) than SVLs at 6, 12, 18, and 24mo after wearing glasses, with reductions of 0.19 D (95%Cl: 0.14 to 0.24, *P*<0.00001), 0.36 D (95%Cl: 0.25 to 0.46, *P*<0.00001), 0.43 D (95%Cl: 0.32 to 0.55, *P*<0.00001), and 0.51 D (95%Cl: 0.33 to 0.69, *P*<0.00001), respectively. The changes in axial length (AL) were also lower in PDMSLs compared to SVLs, with reductions of -0.09 mm (95%Cl: -0.13 to -0.04, *P*=0.0002), -0.15 mm (95%Cl: -0.21 to -0.08, *P*<0.00001), -0.27 mm (95%Cl: -0.34 to -0.20, *P*<0.00001), and -0.29 mm (95%Cl: -0.38 to -0.20, *P*<0.00001), respectively. There was no significant difference between the non-microlens group and SVLs in controlling the changes of SER and AL in myopia (both *P*>0.05).

• **CONCLUSION:** The synthesized evidence indicates superior myopia management outcomes with microlens design of PDMSLs compared to both SVLs and non-microlens design of PDMSLs in children and adolescents.

• **KEYWORDS:** peripheral defocus; spectacle lenses; myopia; axial length; Meta-analysis

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# **INTRODUCTION**

M yopia, which affects 1.406 billion people worldwide, accounting for 22.9% of the global population<sup>[1]</sup>, is a significant issue that cannot be ignored due to its impact on human eye health. Research has shown that the occurrence and progression of myopia were closely linked to factors such as insufficient outdoor activities<sup>[2:4]</sup>, excessive use of closerange vision<sup>[5-6]</sup>, changes in lighting methods<sup>[7]</sup>, and inadequate sleep<sup>[8]</sup>. In today's society, the use of digital technology and changes in entertainment methods have contributed to an increasing myopia rate year after year, not only in East Asia but also in Europe and North America, particularly among children and adolescents<sup>[9-11]</sup>. It is estimated that by 2050, there will be 4.758 billion myopia patients worldwide, accounting for 49.8% of the total population<sup>[1]</sup>.

In 1971, Hoogerheide *et al*<sup>[12]</sup> reported on the relationship between peripheral retinal defocus and myopia, and since then, the role of peripheral retinal diopter has been widely discussed. Subsequent studies have demonstrated that the sign, degree, and retinal distribution of peripheral retinal defocus significantly affect eye growth, suggesting that eyes with a higher degree of hyperopic defocus in the peripheral retina are more susceptible to myopia<sup>[13-16]</sup>. These findings implied that improving peripheral retinal hyperopic defocus may be a method to prevent the occurrence and progression of myopia in adolescents<sup>[17-18]</sup>. Conventional spectacle lenses, which are the most commonly used, primarily corrected refractive errors in the foveal area but failed to consider the influence of peripheral retinal defocus<sup>[19]</sup>.

Peripheral defocus modifying spectacle lenses (PDMSLs), designed based on the theory of peripheral retinal defocus, have been used for many years to control the development of myopia in children and adolescents. However, there is still controversy regarding whether they can provide a better myopia control effect<sup>[16,20-22]</sup>. Additionally, previous Meta-analyses of PDMSLs had not included some new designs of this type of lens in recent years<sup>[23-24]</sup>. The objective of this study is to conduct a Meta-analysis comparing the differences between PDMSLs and single vision lenses (SVLs) in controlling the increase of diopter and axial length (AL) of myopia in children and adolescents. This analysis aims to provide a basis for the selection and application of lenses to control the development of myopia.

# MATERIALS AND METHODS

This evidence synthesis was methodologically aligned with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) framework<sup>[25]</sup> with prior registration completed in International Prospective Register of Systematic Reviews (PROSPERO) under identifier CRD42023475928.

**Search Strategy** Two researchers searched the following databases including PubMed, the Cochrane Library, Embase, CNKI, and Web of Science databases to collect relevant studies on the effects of PDMSLs for myopia control in children and adolescents. The search was conducted from the inception of the databases until October 31, 2023, and included studies in the English language. The English search terms utilized were peripheral defocus, spectacles, myopia, and single vision. The search strategy was adapted for different databases. Besides the initially identified studies and relevant systematic reviews, further studies were incorporated through screening the reference lists of related studies and systematic reviews.

**Study Selection, Inclusion, and Exclusion Criteria** Studies were eligible for inclusion if they met the following criteria:

1) Study design: randomized controlled trials (RCTs) and cohort studies (CTs). 2) Participants: The refractive error range comprised myopia from -0.50 to -8.00 D and astigmatism <1.00 D; Age range: 8-18y; No significant differences in preintervention best-corrected visual acuity (BCVA), spherical equivalent refraction (SER), or AL were observed between the PDMSLs and SVLs groups; Exclusion of studies with patients who had other eye diseases wore other spectacles or contact lenses with myopia control effects or used drugs or other myopia control methods while wearing lenses. 3) Intervention: PDMSLs; 4) Control intervention: SVLs; 5) Follow-up period: Studies have shown a time effect of PDMSLs on myopia control. Therefore, the outcome measures of all studies were grouped according to the follow-up time. 6) Outcome measures: changes in SER and AL before and after intervention. Studies were excluded based on these factors: 1) Non-compliance with inclusion criteria; 2) Unavailable full texts or incomplete data extraction; 3) Duplicate publications; 4) Non-English language reports.

**Data Extraction** Two independent reviewers abstracted study data using standardized extraction forms, with verification of accuracy and consistency by a third reviewer. After extracting relevant information from the literature, the data were entered into a standardized table, which included such as the first author's name, publication year, country and region, study type, duration, baseline characteristics of the study population, and primary outcome measures. Missing data were supplemented through supplementary literature retrieval or correspondence with original investigators. All extracted data were systematically organized in evidence tables.

**Risk of Bias Assessment** Two reviewers independently evaluated methodological quality using design-specific assessment tools. RCTs were appraised through the Cochrane Risk of Bias tool, which examines randomization procedures, allocation concealment, blinding (participants/personnel and outcome assessors), completeness of outcome data, and selective reporting. CTs were assessed using the Newcastle-Ottawa Scale (NOS), with evaluation domains covering participant selection, group comparability, and exposure ascertainment. Studies achieving NOS scores  $\geq$ 7 were classified as high-quality. Discrepancies between reviewers were resolved through consensus discussions with a third methodologist.

**Statistical Analysis** Statistical analysis was conducted using Review Manager 5.4 software, where treatment outcomes for SER and AL were expressed as mean difference (MD) accompanied by 95% confidence interval (CI), derived from reported means and standard deviations (SD). Between-study variability was quantified through  $I^2$  test. Some studies<sup>[20,26-27]</sup> have shown that PDMSLs with different designs have varying effects on myopia control. Therefore, this study is divided

into two subgroups based on the design of defocus lenses: the microlens group and the non-microlens group. A fixed-effect model was applied for Meta-analysis when study heterogeneity was nonsignificant ( $I^2 < 50\%$ ); otherwise, a random-effects model was implemented. Subgroup and sensitivity analyses were conducted to investigate heterogeneity sources and result robustness. Publication bias was evaluated using Egger's regression test.

# RESULTS

**Search Strategy** Systematic screening identified 680 studies, with 278 proceeding to title/abstract review after duplicate removal. This phase excluded 256 records, leaving 22 articles for full-text evaluation. Thirteen studies were subsequently excluded for not meeting inclusion criteria. Ultimately, 9 studies (7 RCTs and 2 cohort studies) were included in the Meta-analysis<sup>[16,20-22,27-31]</sup>. The study selection process was shown in a PRISMA flow diagram (Figure 1).

Study Characteristics and Risk of Bias Assessment Among the included myopic children aged 6 to 18, there were 4332 cases in the PDMSLs group and 7317 cases in the SVLs group. The studies were conducted in the following countries or regions: China (n=5), Hong Kong, China (n=1), Japan (n=1), Italy (n=1), and Vietnam (n=1). In these studies, Bao *et al*<sup>[20,27]</sup> included PDMSLs of two different designs, namely highly aspherical lenslets (HAL) and slightly aspherical lenslets (SAL). Sankaridurg *et al*<sup>[21]</sup> included PDMSLs of three different designs (types 1, 2, and 3). Among the RCTs, only two had a low risk of bias, while the others had different degrees of risk of bias. The cohort studies were generally of high quality, with scores of at least 8 out of 9 (Figure 2, Tables 1-2).

#### **Meta-analysis Results**

**Comparison of PDMSLs and SVLs groups on the changes in SER** Among the included studies, nine studies reported the changes in SER as the primary outcome and compared the differences between the PDMSLs and the SVLs.

Meta-analysis showed the changes of SER between the microlens design of PDMSLs and the SVLs interventions were not heterogeneous at 6mo (P=0.15,  $I^2=38\%$ ), but heterogeneous at 12mo (P=0.0003,  $I^2=79\%$ ), 18mo (P=0.06,  $I^2=60\%$ ) and 24mo (P=0.002,  $I^2=80\%$ ). The difference in the changes of SER between the microlens group and the SVLs group was 0.19 D (95%CI: 0.14, 0.24; P<0.00001), 0.36 D (95%CI: 0.25, 0.46; P<0.00001), 0.43 D (95%CI: 0.32, 0.55; P<0.00001), and 0.51 D (95%CI: 0.33, 0.69; P<0.00001) during the 6, 12, 18, and 24mo follow-up periods, respectively. The changes of SER between the non-microlens design of PDMSLs and the SVLs interventions were not heterogeneous at 6mo (P=0.56,  $I^2=0$ ) and 12mo (P=0.62,  $I^2=0$ ), and there was no statistically significant difference in the changes of SER



Figure 1 PRISMA flow diagram of the study selection process.



Figure 2 Risk-of-bias assessments of the included studies A: Risk of bias graph; B: Risk of bias summary.

between the non-microlens group and the SVLs group during the 6mo (P=0.55) and 12mo (P=0.60) follow-up periods (Figures 3-6).

**Comparison of PDMSLs and SVLs groups on the changes in AL** Among the included studies, nine studies reported the changes in AL as the primary outcome and compared the differences between the PDMSLs and the SVLs.

Meta-analysis showed the changes of AL between the microlens design of PDMSLs and the SVLs interventions were heterogeneous at 6mo (P<0.00001,  $I^2$ =89%), 12mo (P=0.0003,  $I^2$ =81%), 18mo (P=0.06,  $I^2$ =65%) and 24mo (P=0.05,  $I^2$ =66%). The difference in the changes of AL between the microlens group and the SVLs group was -0.09 mm (95%CI: -0.13, -0.04; P=0.0002), -0.15 mm (95%CI: -0.21, -0.08;



Figure 3 Forest plot of the change in SER after 6mo of spectacle wear After 6mo of spectacle wear, the microlens group of PDMSLs showed a lower SER increment compared to the SVLs group (0.19 D), while there was no significant difference in SER changes between the non-microlens group of PDMSLs and the SVLs group. PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; SER: Spherical equivalent refraction.

Tabl	e 1	Character	istics of	the studies	include	ed in t	the I	Meta-ana	lysi	is
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Study	Country or	Study		SI c docign		Sampla ciza	Follow-up	Base	Outcomos		
(author, y)	area	design	PDIVI	SES DESIGN	Age (y)	Sample Size	duration	SER (D)	AL (mm)	Outcomes	
Bao 2022 <sup>[27]</sup>	China	RCT	HAL/SAL	Microlens design	HAL: 10.7±1.47; SAL: 10.1±1.48; SVLs: 10.4±1.44	HAL: 54; SAL: 55; SVLs: 52	6 and 12mo	HAL: -2.70±1.03; SAL: -2.31±0.96; SVLs: -2.46±0.87	HAL: 24.76±0.66; SAL: 24.43±0.74; SVLs: 24.77±0.65	SER, AL	
Bao 2022 <sup>[20]</sup>	China	RCT	HAL/SAL	Microlens design	HAL: 10.6±1.47; SAL: 10.2±1.46; SVLs: 10.4±1.40	HAL: 54; SAL:53; SVLs: 50	18 and 24mo	HAL: -2.70±1.03; SAL: -2.28±0.95; SVLs: -2.44±0.85	HAL: 24.76±0.66; SAL: 24.44±0.73; SVLs: 24.77±0.64	SER, AL	
Kanda 2018 <sup>[26]</sup>	Japan	RCT	MyoVision (Type 3)	Non-microlens design	Type 3: 9.58±1.51; SVLs: 9.76±1.38	Type 3: 102; SVLs: 103	6, 12, 18, and 24mo	Type 3: -3.18±0.91; SVLs: -3.36±0.92	Type 3: 24.6±0.69; SVLs: 24.7±0.72	SER, AL	
Lam 2020 <sup>[22]</sup>	Hong Kong, China	RCT	DIMS	Microlens design	DIMS: 10.20±1.47; SVLs: 10.00±1.45	DIMS: 79; SVLs: 81	6, 12, 18, and 24mo	DIMS: -2.97±0.97; SVLs: -2.76±0.96	DIMS: 24.70±0.82; SVLs: 24.60±0.83	SER, AL	
Liu 2023 <sup>[31]</sup>	China	СТ	DIMS	Microlens design	DIMS: 10.31±2.36; SVLs: 11.40±2.54	DIMS: 2472; SVLs: 3501	12, 18, and 24mo	DIMS: -2.93±1.69; SVLs: -2.70±1.76	-	SER	
Liu 2023 <sup>[30]</sup>	China	RCT	CARE	Microlens design	CARE: 10.1±1.0; SVLs: 10.0±1.1	CARE: 52; SVLs: 44	6 and 12mo	CARE: -2.67±0.69; SVLs: -2.56±0.75	CARE: 24.65±0.67; SVLs: 24.66±0.63	SER, AL	
Nucci 2023 <sup>[29]</sup>	Italy	СТ	DIMS	Microlens design	DIMS: 11.34±3.96; SVLs: 13.37±2.22	DIMS: 30; SVLs: 32	6 and 12mo	DIMS: -1.54±0.74; SVLs: -1.97±0.68	DIMS: 24.64±0.78; SVLs: 24.85±0.70	SER, AL	
Sankaridurg 2010 <sup>[21]</sup>	China	RCT	MyoVision (Type 1/2/3)	Non-microlens design	Type 1: 10.7±2.4; type 2: 11.1±2.2; type 3: 11.4±2.3; SVLs: 10.8±2.5	Type 1: 50; type 2: 59; type 3: 49; SVLs: 50	6 and 12mo	Type 1: -1.82±0.62; type 2: -1.81±0.67; type 3: -1.82±0.66; SVLs: -1.87±0.68	Type 1: 24.33±0.66; type 2: 24.47±0.70; type 3: 24.51±0.63; SVLs: 24.55±0.77	SER, AL	
Sankaridurg 2023 <sup>[28]</sup>	Vietnam	RCT	DIMS	Microlens design	DIMS: 11.2±1.6; SVLs: 10.9±1.7	DIMS: 54; SVLs: 65	6mo	DIMS: -3.47±1.16; SVLs: -3.37±1.22	DIMS: 25.1±0.8; SVLs: 24.9±0.8	SER, AL	

PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; HAL: Highly aspherical lenslets; SAL: Slightly aspherical lenslets; DIMS: Defocus incorporated multiple segments; CARE: Cylindrical annular refractive element; SER: Spherical equivalent refraction; AL: Axial length; RCT: Randomized controlled trial; CT: Cohort study.

Study		Selecti	on		Comparability of		NOS		
	Exposed cohort representative	Non-exposed cohort selection	Exposure ascertainment	Outcome not present at start	cohorts	Assessment	Follow-up length	Follow-up Adequacy	score
Liu 2023 <sup>[31]</sup>	1	1	1	1	2	1	1	1	9
Nucci 2023 <sup>[29]</sup>	1	1	1	1	1	1	1	1	8

*P*<0.00001), -0.27 mm (95%CI: -0.34, -0.20; *P*<0.00001), and -0.29 mm (95%CI: -0.38, -0.20; *P*<0.00001) during the 6, 12, 18, and 24mo follow-up periods, respectively.

The changes in AL between the non-microlens design of PDMSLs and the SVLs interventions were not heterogeneous

at 6mo (P=0.37,  $I^2=5\%$ ) and 12mo (P=0.20,  $I^2=35\%$ ), and there was no statistically significant difference in the changes of AL between the non-microlens group and the SVLs group during the 6mo (P=0.63) and 12mo (P=0.60) follow-up periods (Figures 7-10).



**Figure 4 Forest plot of the change in SER after 12mo of spectacle wear** After 12mo of spectacle wear, the microlens group of PDMSLs showed a lower SER increment compared to the SVLs group (0.36 D), while there was no significant difference in SER changes between the non-microlens group of PDMSLs and the SVLs group. PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; SER: Spherical equivalent refraction.



Figure 5 Forest plot of the change in SER after 18mo of spectacle wear After 18mo of spectacle wear, the microlens group of PDMSLs showed a lower SER increment compared to the SVLs group (0.43 D). PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; SER: Spherical equivalent refraction.



**Figure 6 Forest plot of the change in SER after 24mo of spectacle wear** After 24mo of spectacle wear, the microlens group of PDMSLs showed a lower SER increment compared to the SVLs group (0.51 D). PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; SER: Spherical equivalent refraction.

**Sensitivity Analysis and Publication Bias Analysis** Sensitivity testing was conducted by iteratively removing individual studies, complemented by Egger's regression analysis for publication bias assessment. The outcomes indicated that the combined effect of SER and AL each time after intervention was the same before and after eliminating the literature, suggesting that the combined effect of the above two results had good stability. Egger's test results provided

	PI	MSLs	;	:	SVLs			Mean Difference	Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV. Random, 95% CI	
2.1.1 Microlens design										
Bao 2022.8-HAL	0.08	0.07	54	0.2	0.07	52	10.7%	-0.12 [-0.15, -0.09]	+	
Bao 2022.8-SAL	0.14	0.07	55	0.2	0.07	52	10.7%	-0.06 [-0.09, -0.03]	-	
Lam 2020.3	0.03	0.09	79	0.2	0.09	81	10.6%	-0.17 [-0.20, -0.14]	+	
Liu 2023.9	0.19	0.12	52	0.23	0.12	44	9.7%	-0.04 [-0.09, 0.01]		
Nucci 2023.2	0.09	0.11	30	0.13	0.11	32	9.3%	-0.04 [-0.09, 0.01]		
Sankaridurg 2023.3	0.06	0.15	54	0.13	0.15	65	9.4%	-0.07 [-0.12, -0.02]	-	
Subtotal (95% CI)			324			326	60.5%	-0.09 [-0.13, -0.04]	◆	
Heterogeneity: Tau <sup>2</sup> = 0.00; C	hi² = 46	81, df	= 5 (P	< 0.000	01); l²	= 89%				
Test for overall effect: Z = 3.7	7 (P = 0	0002)								
2.1.2 Non-microlens design										
Kanda 2018.9	0.22	0.1	102	0.21	0.1	103	10.7%	0.01 [-0.02, 0.04]	+	
Sankaridurg 2010.9- Type 1	0.24	0.13	50	0.25	0.13	50	9.6%	-0.01 [-0.06, 0.04]	+	
Sankaridurg 2010.9- Type 2	0.24	0.13	59	0.25	0.13	50	9.7%	-0.01 [-0.06, 0.04]	-	
Sankaridurg 2010.9- Type 3	0.21	0.12	49	0.25	0.13	50	9.7%	-0.04 [-0.09, 0.01]		
Subtotal (95% CI)			260			253	39.5%	-0.01 [-0.03, 0.02]	<b>+</b>	
Heterogeneity: Tau <sup>2</sup> = 0.00; C	2hi² = 3.1	7. df =	3 (P =	0.37);	² = 5%					
Test for overall effect: Z = 0.48 (P = 0.63)										
Total (95% CI)			584			579	100.0%	-0.06 [-0.10, -0.01]	•	
Hotorogonoity: $Tou^2 = 0.00$ : C	bi2 - 11	1 20 4	f = 0 /E	~ 0.00	001)-1	2 - 0.20		-0.00[-0.10, -0.01]		
Test for everall effect: $7 = 2.6$	7 (D = 0	000	i – 9 (P	~ 0.00	001); 1	- 927	0		-0.5 -0.25 0 0.25 0.5	
Test for subgroup differences	Test for overall effect: $2 = 2.07$ (P = 0.000) Favours [PDMSLs] Favours [SVLs]									
Test for subaroup differences	: Chi² = '	10.41.	df = 1 (	P = 0.0	01). I <sup>2</sup>	= 90.49	%			

**Figure 7 Forest plot of the change in AL after 6mo of spectacle wear** After 6mo of spectacle wear, the microlens group of PDMSLs showed a lower AL increment compared to the SVLs group (-0.09 mm), while there was no significant difference in AL changes between the non-microlens group of PDMSLs and the SVLs group. PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; AL: Axial length.



**Figure 8 Forest plot of the change in AL after 12mo of spectacle wear** After 12mo of spectacle wear, the microlens group of PDMSLs showed a lower AL increment compared to the SVLs group (-0.15 mm), while there was no significant difference in AL changes between the non-microlens group of PDMSLs and the SVLs group. PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; AL: Axial length.



**Figure 9 Forest plot of the change in AL after 18mo of spectacle wear** After 18mo of spectacle wear, the microlens group of PDMSLs showed a lower AL increment compared to the SVLs group (-0.27 mm). PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; AL: Axial length.

no indication of publication bias among the analyzed studies (Table 3).

#### DISCUSSION

Due to changes in the social environment and the impact of

the global COVID-19 pandemic, children and adolescents are increasingly exposed to electronic devices, leading to a decline in outdoor activities<sup>[32-33]</sup>. The prevalence of myopia, primarily in East Asia, is steadily rising as a result of AL



Figure 10 Forest plot of the change in AL after 24mo of spectacle wear After 24mo of spectacle wear, the microlens group of PDMSLs showed a lower AL increment compared to the SVLs group (-0.29 mm). PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; AL: Axial length.

elongation<sup>[34-35]</sup>. AL abnormalities are significant risk factors for various myopia-related pathological changes, including myopic maculopathy<sup>[36]</sup>, scleral staphyloma<sup>[37]</sup>, and retinal detachment<sup>[38]</sup>. Studies have shown that slowing myopia by 1 diopter should reduce the likelihood of a patient developing myopic maculopathy by 40%<sup>[39]</sup>. Reducing the progression of myopia is crucial in preventing the development of myopiarelated diseases, regardless of the severity of myopia<sup>[38,40-41]</sup>, thereby alleviating the public health and economic burden associated with myopia<sup>[1,18]</sup>.

Currently, clinical interventions for myopia primarily focus on three main approaches: behavioral interventions, optical interventions, and drug interventions<sup>[42-44]</sup>. Optical interventions commonly used include PDMSLs, orthokeratology, peripheral defocus soft contact lenses and others. The design of these optical intervention products is primarily based on the theory of peripheral retinal defocus. Previous studies have demonstrated a negative correlation between the degree of peripheral myopic defocus and AL<sup>[27,45]</sup>. Stimulation of retinal neurons by hyperopic defocus images can promote an increase in axial length, whereas myopic defocus signals can inhibit this increase<sup>[46-47]</sup>. In the human eye, the peripheral retina has a lower density of neurons compared to the macular region, but an overall higher number of neurons<sup>[47]</sup>. Therefore, changes in myopia are more closely associated with peripheral refraction. This viewpoint has been extensively validated in animal studies involving chicks<sup>[48-50]</sup>, guinea pigs<sup>[51]</sup>, and macaques<sup>[52]</sup>. The early designs of PDMSLs were non-microlens designs, which included rotationally symmetrical design or asymmetric design<sup>[16,21]</sup>. These designs consisted of a central optical zone and a defocused zone formed by changing the curvature of the lens surface. However, there is some controversy surrounding the effectiveness of this type of lens design. A study<sup>[21]</sup> found that type 3 lenses (asymmetric design) have a positive effect on children with myopic parents. Kanda et al's study<sup>[16]</sup> showed that no significant difference was in myopia control between type 3 lenses and SVLs. Our research showed that there was no significant difference between PDMSLs with non-microlens design and SVLs in controlling myopia in children and adolescents, which is similar to the conclusion of Kanda *et al*'s study<sup>[16]</sup>.

In recent years, researchers have proposed to improve the design of PDMSLs by microlens<sup>[22,27,30]</sup>. PDMSLs with microlens design are also composed of a central optical area and a peripheral defocus area. Based on the differences in microlens designs, there are mainly three design forms: concentric ring configurations, honeycomb configurations, and annular micro-cylinder arrays. The concentric ring design is represented by SAL and HAL, the honeycomb design by defocus incorporated multiple segments (DIMS), and the annular micro-cylinder design by cylindrical annular refractive element (CARE). Current research suggests that PDMSLs with microlens designs achieve better myopia control compared to SVLs<sup>[20,22,27-31]</sup>. A study<sup>[27]</sup> found that 20% of HAL wearers experienced a hyperopic shift, and 24% experienced a decrease in AL, while this phenomenon was not observed in the SVLs group. Another study showed that short-term changes in SER and AL may be associated with changes in choroidal thickness<sup>[53-54]</sup>. Zhang et al's research<sup>[55]</sup> demonstrated symmetrical peripheral myopic defocus between the nasal and temporal retina in the DIMS group, whereas asymmetrical changes were observed in the SVLs group. Therefore, Zhang et al<sup>[55]</sup> speculated that DIMS control of myopia development may be related to peripheral refraction profile and relative peripheral refraction changes.

Our results also demonstrated the effectiveness of PDMSLs designed with microlenses in controlling myopia. However, it is important to note that there is heterogeneity within the subgroups of microlens designs, which may be attributed to variations in their optical performance. This speculation is

# Table 3 Sensitivity analysis and publication bias analysis

Meta-analysis	Follow-up				Sensitivity analysis			Publication
indicators	duration	Subgroup	Study exclusion -	MD	95%CI	Ζ	Р	<ul> <li>bias, Egger's test (P)</li> </ul>
Comparison of	6mo	Microlens design	Bao 2022.8-HAL	0.18	0.13, 0.23	6.80	<0.00001	0.0699
PDIVISES and SVES			Bao 2022.8-SAL	0.20	0.14, 0.25	7.40	<0.00001	
change in SER			Lam 2020.3	0.18	0.12, 0.23	6.47	<0.00001	
			Liu 2023.9	0.20	0.15, 0.25	8.01	<0.00001	
			Nucci 2023.2	0.18	0.13, 0.23	6.67	< 0.00001	
			Sankaridurg 2023.3	0.21	0.16, 0.26	8.14	<0.00001	
		Non-microlens design	Kanda 2018.9	0.02	-0.05, 0.10	0.60	0.55	0.9478
			Sankaridurg 2010.9-type 1	0.01	-0.06, 0.09	0.36	0.72	
			Sankaridurg 2010.9-type 2	0.05	-0.03, 0.12	1.15	0.25	
			Sankaridurg 2010.9-type 3	-0.00	-0.08, 0.08	0.05	0.96	
	12mo	Microlens design	Bao 2022.8-HAL	0.32	0.23, 0.42	6.70	<0.00001	0.6335
		-	Bao 2022.8-SAL	0.36	0.24, 0.48	5.87	< 0.00001	
			Lam 2020.3	0.35	0.23. 0.47	5.63	<0.00001	
			Liu 2023.5	0.38	0.26. 0.50	6.13	< 0.00001	
			Liu 2023.9	0.39	0.28. 0.50	6.82	<0.00001	
			Nucci 2023.2	0.33	0.23, 0.43	6.40	< 0.00001	
		Non-microlens design	Kanda 2018.9	0.02	-0.09. 0.13	0.38	0.71	0.8145
			Sankaridurg 2010 9-type 1	0.05	-0.07.0.16	0.81	0.42	0.0110
			Sankaridurg 2010.9 type 1	0.05	-0.07.0.16	0.82	0.41	
			Sankaridurg 2010.9 type 2	-0.01	-0.12.0.10	0.02	0.87	
	18mo	Microlens design	Bao 2022 5-HAI	0.01	0.32 0.42	13 95	<0.0001	0 2303
	10110	Wile Diens design	Bao 2022.5-MAL	0.57	0.32, 0.42	5 7/	<0.00001	0.2355
			Lam 2020 3	0.45	0.30, 0.01	5 10	<0.00001	
				0.40	0.28, 0.05	5.10	<0.00001	
	24mo	Microlons dosign		0.40	0.32, 0.05	5.60	<0.00001	0 1969
	24110	Where the set of the s	Bao 2022.5-HAL	0.42	0.29, 0.35	4.40	<0.00001	0.1808
			Bd0 2022.5-SAL	0.54	0.30, 0.78	4.40	<0.0001	
			LdIII 2020.3	0.50	0.20, 0.75	4.03	<0.0001	
Comparison of	6		LIU 2023.5	0.58	0.39, 0.77	5.87	<0.00001	0 4 0 4 5
PDMSLs and SVLs	6M0	Microlens design	Bao 2022.8-HAL	-0.08	-0.14, -0.02	2.65	0.008	0.1815
groups on the			Bao 2022.8-SAL	-0.09	-0.14, -0.04	3.53	0.0004	
change in AL			Lam 2020.3	-0.07	-0.10, -0.03	3.96	< 0.00001	
			Liu 2023.9	-0.09	-0.14, -0.05	3.84	0.0001	
			Nucci 2023.2	-0.09	-0.14, -0.05	3.81	0.0001	
			Sankaridurg 2023.3	-0.09	-0.14, -0.04	3.44	0.0006	
		Non-microlens design	Kanda 2018.9	-0.02	-0.05, 0.01	1.38	0.17	0.2792
			Sankaridurg 2010.9-type 1	-0.01	-0.04, 0.02	0.51	0.61	
			Sankaridurg 2010.9-type 2	-0.01	-0.04, 0.02	0.50	0.61	
			Sankaridurg 2010.9-type 3	0.00	-0.02, 0.02	0.23	0.82	
	12mo	Microlens design	Bao 2022.8-HAL	-0.12	-0.19, -0.06	3.80	0.0001	0.1566
			Bao 2022.8-SAL	-0.15	-0.23, -0.08	3.93	<0.00001	
			Lam 2020.3	-0.13	-0.20, -0.05	3.38	0.0007	
			Liu 2023.9	-0.16	-0.23, -0.08	4.14	<0.00001	
			Nucci 2023.2	-0.16	-0.23, -0.10	4.91	<0.00001	
		Non-microlens design	Kanda 2018.9	-0.02	-0.05, 0.01	1.33	0.18	0.2601
			Sankaridurg 2010.9-type 1	-0.01	-0.06, 0.03	0.49	0.62	
			Sankaridurg 2010.9-type 2	-0.01	-0.05, 0.04	0.33	0.74	
			Sankaridurg 2010.9-type 3	0.01	-0.02, 0.04	0.34	0.73	
	18mo	Microlens design	Bao 2022.5-HAL	-0.24	-0.33, 0.15	5.38	<0.00001	0.8856
			Bao 2022.5-SAL	-0.30	-0.34, -0.25	12.53	<0.00001	
			Lam 2020.3	-0.26	-0.40, -0.12	3.72	0.0002	
	24mo	Microlens design	Bao 2022.5-HAL	-0.26	-0.39, -0.12	3.68	0.0002	0.5559
			Bao 2022.5-SAL	-0.33	-0.39, -0.27	11.30	< 0.00001	
			Lam 2020.3	-0.27	-0.43, -0.10	3.14	0.002	

PDMSLs: Peripheral defocus modifying spectacle lenses; SVLs: Single vision lenses; HAL: Highly aspherical lenslets; SAL: Slightly aspherical lenslets; SER: Spherical equivalent refraction; AL: Axial length; MD: Mean difference; CI: Confidence interval.

supported by other research results. Li et al's study<sup>[56]</sup> has shown that HAL and DIMS lenses can lead to decreased contrast sensitivity and visual acuity. HAL lenses have better modulation transfer function compared to DIMS, indicating better optical performance, which may be attributed to diffraction effects caused by differences in microlens diameters between HAL lenses and DIMS lenses<sup>[56-57]</sup>. A recent study indicates that the HAL lens possesses a larger functional zone for inducing peripheral myopic defocus compared to the DIMS lens, potentially leading to more effective myopia control<sup>[26]</sup>. However, this study has certain limitations as it does not further discuss the impact of confounding factors such as outdoor activity time, near work time, parental myopia status, and daily wearing time of spectacles. Sng et al's study<sup>[58]</sup> conducted in Singapore demonstrated differences in peripheral refractive power among myopic individuals with different degrees of myopia. Additionally, Liu et al's study<sup>[31]</sup> demonstrated that the effectiveness of myopia control provided by DIMS lenses gradually decreases as the degree of myopia increases. Therefore, further verification is needed to determine whether there are differences in myopia control between HAL lenses and DIMS lenses.

The difference in optical performance between PDMSLs and SVLs results in changes in visual quality. When children choose to use DIMS lenses at a younger age, they can adapt to the changes in visual quality brought about by wearing glasses for a shorter time<sup>[59]</sup>. However, studies have shown that wearing PDMSLs or SVLs does not affect the wearer's heterophoria, accommodative response, or accommodative amplitude<sup>[60-61]</sup>. For children with intermittent exotropia wearing HAL lenses can still maintain good fusion function<sup>[60]</sup>. Two three-year follow-up studies have demonstrated the longterm effectiveness of PDMSLs with microlens designs in myopia control<sup>[62-63]</sup>. Additionally, emphasizing good wearing habits during the wearing process and improving compliance can also improve myopia control efficiency<sup>[30]</sup>. This has been confirmed in related studies on defocus soft contact lenses<sup>[64]</sup>. Nucci et al<sup>[29]</sup> believed that PDMSLs combined with lowconcentration atropine can achieve a better myopia control effect. However, low-concentration atropine not only shows a good myopia control effect but also brings about a withdrawal rebound effect, which should be paid full attention by ophthalmologists or optometrists<sup>[65-66]</sup>. Some researchers suggested that gradually reducing the dosage of the drug can

suggested that gradually reducing the dosage of the drug can help avoid the rebound effect of atropine<sup>[67]</sup>. In comparison, controlling myopia by improving peripheral retinal optical defocus signals is less likely to cause rebound effects after discontinuation<sup>[29,68]</sup>. This has been supported by evidence in the myopia control effects of peripheral defocus soft contact lenses<sup>[69]</sup>. In the case of PDMSLs, Sankaridurg *et al*'s study<sup>[28]</sup> showed that there was no rebound in the myopia diopter of children after discontinuing the use of PDMSLs.

Huang *et al*'s study<sup>[23]</sup>, through a network Meta-analysis, showed PDMSLs had a weaker myopia control effect than SVLs. Intervention PDMSLs reduced the SER and AL by 0.12 D/y (95%CI: -0.24, 0.47) and -0.05 mm/y (95%CI: -0.15, 0.05), respectively. Ma et al's study<sup>[24]</sup> indicated that children wearing PDMSLs had a decrease in SER progression of 0.20 D/y (95%CI: 0.05, 0.35) and a reduction in AL elongation of -0.08 mm/y (95%CI: -0.18, 0.01) compared to those wearing SVLs. On the contrary, our research shows that the effect of PDMSLs designed by microlens on controlling SER and AL of children and adolescents increases by 0.36 D/y (95%CI: 0.25, 0.46) and -0.15 mm/y (95%CI: -0.21, -0.08), respectively, which is better than Huang et al's study<sup>[23]</sup>. Considering that Huang *et al*'s study<sup>[23]</sup> was published in 2016, the differences between our study and theirs may be attributed to the changes in the PDMSLs' design in recent years and the publication of more new research. In addition, we considered the peripheral refraction and defocus design characteristics of PDMSLs and divided them into two subgroups: microlens design and non-microlens design. Through this classification, we found that PDMSLs with micro-lens design included in our study had a superior effect in myopia control compared to PDMSLs without micro-lens design. On the other hand, Ma et *al*'s study<sup>[24]</sup> categorized subgroups based on the study regions, without considering the differences in lens design, which may explain the differences in results between our study and theirs.

This study has some limitations: 1) This study only searches English databases, which may lead to language bias. 2) Most of the follow-up period included in the study was less than 12mo, and there was no study on the influence of long-term wearing lenses on myopia control. 3) This study only compared the effects of PDMSLs and SVLs on myopia control, excluding other myopia control methods.

In summary, the synthesized evidence indicates superior myopia management outcomes with microlens design of PDMSLs compared to both SVLs and non-microlens design of PDMSLs in children and adolescents.

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