

Supplementary content

Title: Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomized clinical trial

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MP- myopia progression; MR- myopia reduction.

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Supplementary Methods

Other measurements at each follow-up

Distance and near visual acuity (VA), amplitude of accommodation, lag of accommodation and horizontal phoria were performed with fully correction for distance at each 6-month follow up visit. Distance and near Log MAR VA were assessed using Logarithmic 2000 series ETDRS Charts with illuminator cabinet (Precision Vision Inc.) and Mixed Contrast European-Wide Near Vision Card (at 40cm) (Precision Vision Inc.) respectively. Near horizontal phoria was measured by using the Howell near phoria card. The magnitude and direction (+ve for eso, -ve for exo) were recorded to the nearest 0.5Δ. Accommodation responses were measured using an open-field autorefractor (Shin-Nippon NVision-K5001) while subjects were viewing a letter target at 33cm with print size of 20/30. Lag of accommodation was the difference between the measured accommodative response and the actual accommodative demand (3D).

Visual performance with the experimental spectacles

Visual performance was also assessed for both groups of subjects while they were wearing their spectacles. Measurement of distance and near VA, accommodation and binocular vision tests (stereopsis and phoria tests) were carried out for the subjects when they collected their spectacles. Distance and near Log MAR VA were assessed using Logarithmic 2000 series ETDRS Charts with illuminator cabinet (Precision Vision Inc.) and Mixed Contrast European-Wide Near Vision Card (at 40cm) (Precision Vision Inc.) respectively. Near horizontal phoria was measured by using the Howell near phoria card. Monocular and binocular amplitude of accommodation (D) was measured with RAF ruler. Accommodative responses were measured using an open-field autorefractor (Shin-Nippon NVision-K5001) while subjects were viewing a letter target at 33cm with print size of 20/30. Lag of accommodation was the difference between the measured accommodative response and the actual accommodative demand (3D). Stereoacuity (second of arc) was measured with Randot Stereotest at 40 cm with Polaroid goggles.

A questionnaire (appendix in the clinical protocol) about visual performance, comfort and frequency of symptoms with lens wear was also administered to subjects. They were interviewed by the unmasked investigators during the follow-up visits. The subjective rating on visual performance included vision quality with distance, intermediate and near viewing, and stability of perceived vision at distance and at near, etc. The grading score ranged from 1 (the poorest) to 10 (excellent). Scales for rating how often the symptoms occur with the lens wear range from 1 -10 (never to always). Data of visual performance between the two groups were compared by unpaired t-tests.

Supplementary Results

eTable 1. The number of the drop-outs at different stages of the study

After the visit of	DIMS	SV	Total
Baseline data collection	9	5	14
6-month follow up	3	2	5
12-month follow up	0	0	0
18-month follow up	2	2	4
Total no. of drop-outs	14	9	23

eTable 2. Reasons of drop-outs

Main reasons	DIMS	SV	Total
Long time to wait for delivery of lenses	5	0	5
Refuse to undergo cycloplegia	2	2	4
Try other myopic control methods	5	4	9
Not willing or unable to attend follow-up	2	3	5
Total	14	9	23

eTable 3. The linear model analysis of factors and covariates and effect on slowing myopia progression

Factors	p-value
Group	0.000*
Time (visits)	0.006*
Interaction of group and time	0.408
Covariates	p-value
Gender	0.054
Age	0.004*
Baseline refraction (in SER)	0.839
Near phoria	0.267
Lag of accommodation	0.193
Parental myopia	0.346
Time spent on near works (hours per day)	0.541
Time spent at outdoors (hours per week)	0.400

*The covariates showed significant effect

eTable 4. Adjusted mean changes (standard error) in the cycloplegic spherical equivalent refraction and axial length for each experimental group

	DIMS (n=93)	SV (n=90)	Mean difference
SER changes in dioptres, mean (SE)			
6-month	-0.15 ± 0.05	-0.32 ± 0.04	-0.17 ± 0.04*
12-month	-0.08 ± 0.06	-0.18 ± 0.06	-0.10 ± 0.07*
18-month	-0.10 ± 0.05	-0.17 ± 0.05	-0.07 ± 0.07*
24-month	-0.08 ± 0.06	-0.18 ± 0.06	-0.09 ± 0.07*
Total	-0.41 ± 0.06	-0.85 ± 0.08	-0.44 ± 0.09*
Changes in AL (mm), mean (SE)			
6-month	0.05 ± 0.01	0.21 ± 0.02	0.16 ± 0.04*
12-month	0.06 ± 0.02	0.12 ± 0.02	0.06 ± 0.03*
18-month	0.04 ± 0.01	0.11 ± 0.02	0.07 ± 0.03*
24-month	0.06 ± 0.02	0.11 ± 0.02	0.05 ± 0.04*
Total	0.21 ± 0.02	0.55 ± 0.02	0.34 ± 0.04*

M= months, D = dioptres, Δ = prism dioptres, DIMS lens= Defocus Incorporated Multiple Segments spectacle lens; SV = single vision spectacle lens.

*Statistically significant difference as compared to the SV group

eTable 5. Other visual measurements with spectacle lens wear

Mean (SD)	DIMS	SV	Unpaired t-test, p-value
Distance VA, Log MAR	-0.02 ± 0.07	-0.01 ± 0.05	0.1388
Near VA, Log MAR	-0.02 ± 0.02	-0.02 ± (0.04)	0.2938
Monocular AA for right eye, D	13.7 ± 2.08	14.1 ± (2.12)	0.266
Binocular AA, D	14.8 ± 2.08	15.3 ± (2.44)	0.1243
Lag of accommodation with 3D stimulus, D	1.10 ± 0.40	1.16 ± (0.55)	0.4341
Stereopsis, second of arc	25.8 ± 4.24	29.0 ± (6.10)	*0.004

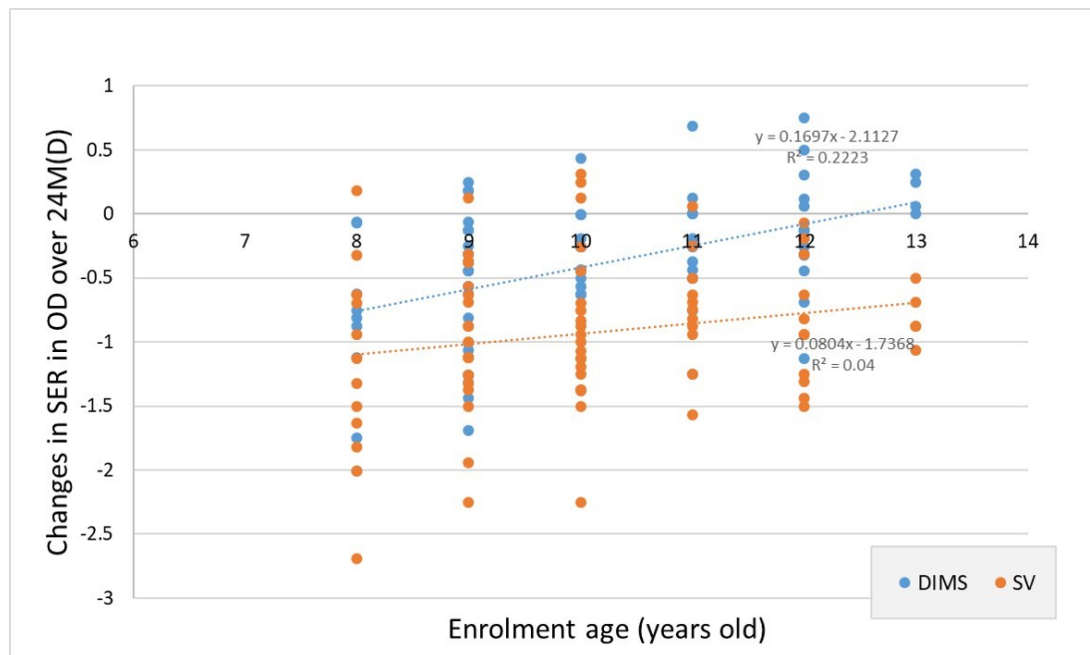
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eTable 6. A Summary of clinical studies of myopia control using optical treatment

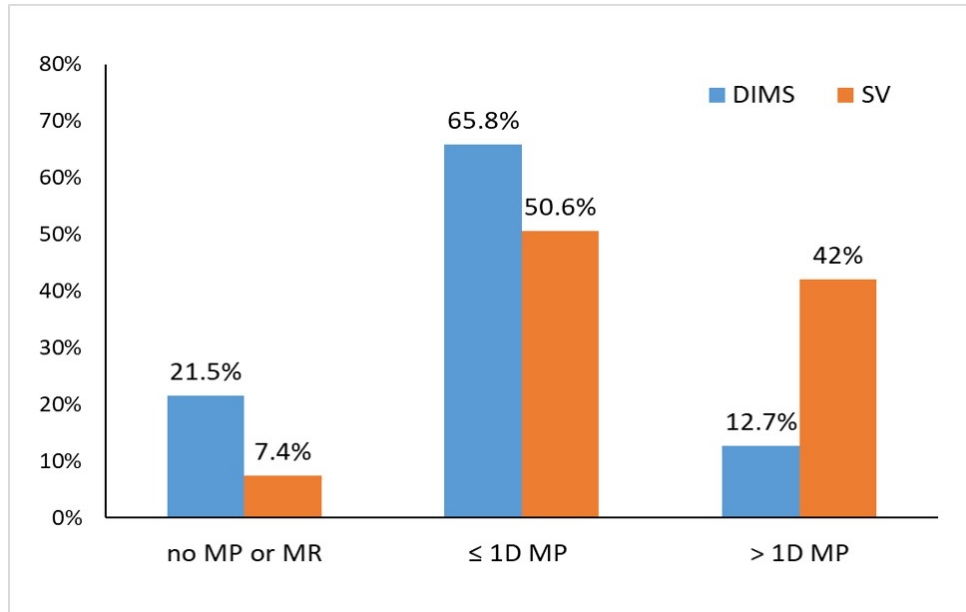
Authors (years)	Period (months)	Design	Age (years old), ethnicity	Rx (D)	Interventions and sample size (n)	Treatment effect in retarding myopia progression	
						Study period in D (%)	Per year in D
Present study	24	Randomized, double masked	8-13, Chinese	-1 to -5	SV, n=81 DIMS, n=79	0.55 (60%)	0.28
Edward et al. (2002) ²⁵	24	Randomized, double masked	7-10.5, Chinese	-1.25 to -4.5	SVL, n = 132 PAL (1.5D Add), n = 121	0.14 (11%)	0.07
Gwiazda et al. (2003) ²⁷	36	Randomized, masked	6-11, diverse ethnicity	-1.25 to -4.5	SVL, n = 233; PAL (2D Add), n= 229	0.20 (14%)	0.07
Hasbe et al. (2008) ²⁸	18	Randomized, masked, cross-over	6-12, Japanese	-1.25 to -6.	SVL, n=44; PAL (1.5D Add), n= 42	1 st period: 0.31 (18%) 2 nd period: 0.02 (2%)	1 st period: 0.2 2 nd period: 0.01
Yang et al. (2009) ²⁹	24	Randomized, masked	7-13, Chinese	-0.5 to -3	SVL, n=75 PAL (1.5D Add), n=74	0.26 (17%)	0.13
COMET2 and PEDIG (2011) ³⁰	36	Randomized, masked, multi-centre	8 to 12, diverse ethnicity	-0.75 to -2.5	SV, n=58 PAL (2D Add), n= 52	0.28 (24%)	0.09
Berntsen et al. (2012) ³⁰	12	Randomized, masked, worn SV in 2 nd year	6 to 11, diverse ethnicity	-0.75 to 4.50	SV, n=42 PAL (2D Add), n= 41	0.18 (35%)	0.18
Cheng et al. (2014) ³⁴	36	Randomized, masked	8-13, Chinese-Canadian	-1 to -5.5	SVL, n=41; BF (1.5D Add), n=48; PBF (1.5D Add, 3ΔBI), n=46	BF: 0.81 (39%) PBF: 1.05 (51%)	BF: 0.27 PBF: 0.35
Sankaridurg et al.(2010) ³²	12	Randomized	6-16, Chinese	-0.75 to -3.50	4 groups, type I, III lenses, control, n = 50 each group Type II, n =60	Type III lens (30% in subgroup of children with myopic parents)	-
Anstice and Phillips (2011) ²²	10	Randomized, paired-eye control, cross-over	11-14, diverse ethnicity	-1.25 to -4.5	SVCL, n=40 DF (2D MD), n=40	1 st period: 0.25 (37%) 2 nd period: 0.2 (54%)	1 st period: 0.3 2 nd period: 0.24
Lam et al. (2013) ²³	24	Randomized, masked	8-13, Chinese	-1 to -5	SVCL, n=65 DISC, n=63	0.21 (20%) 0.54 (58% in children with WT>7 hours)	0.26

Sankaridurg et al. (2011) ³³	12	Randomized	7-14, Chinese	-0.75 to -3.5	SVL, n=40 novel CL, n= 45	0.29 (34%)	0.29
Aller et al. (2016) ²⁴	12	Randomized, masked	8-18	-0.50 to -6.0	SVCL, n=-40 BFSCCL, n=39	0.57 (72% in children with eso fixation disparities)	0.57
Chamberlain et al. (2018) ³⁵	36	randomized, double-masked, multi-centre	8-12	-0.75 to -4.00	DF (Add +2D), n = 70 SVCL, n = 74	0.73 (59%)	0.24

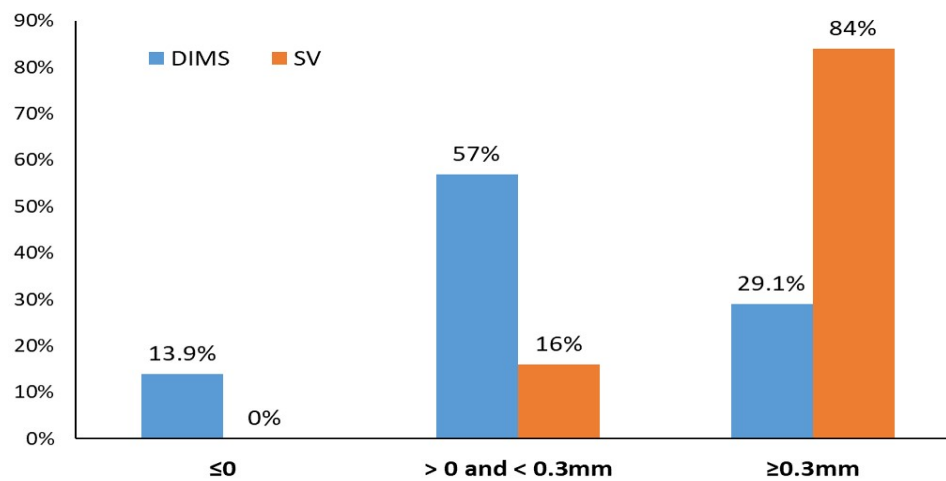
COMET2 and PEDIG = Correction of Myopia Evaluation Trial 2 Study Group and the Paediatric Eye Disease Investigator Group, SVCL = single vision contact lens, SVL = single vision spectacle lens, PAL = progressive addition lens, BF = bifocal spectacle lens, PBF = prismatic bifocal lens, DF = dual focus contact lens, MD = myopic defocus, WT = wearing time.



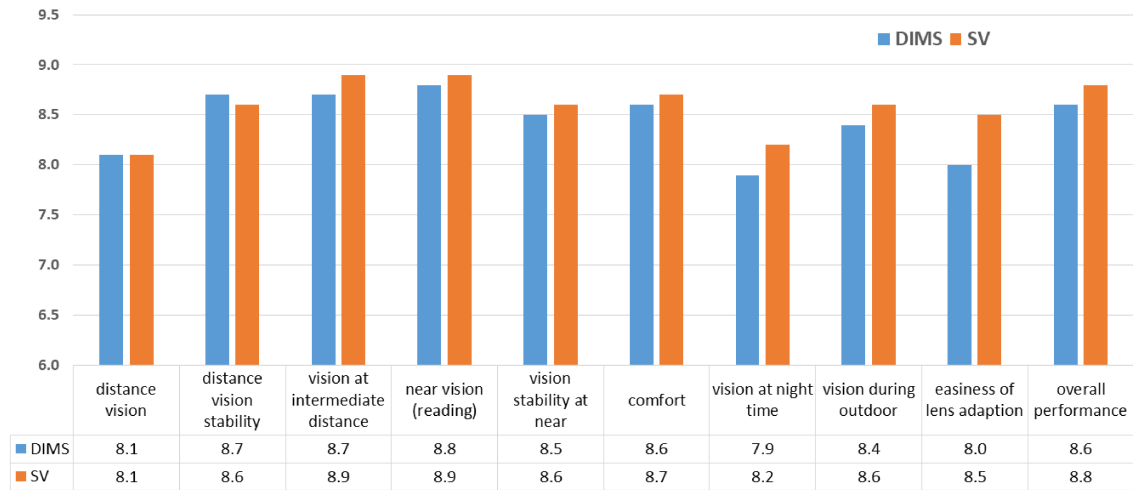
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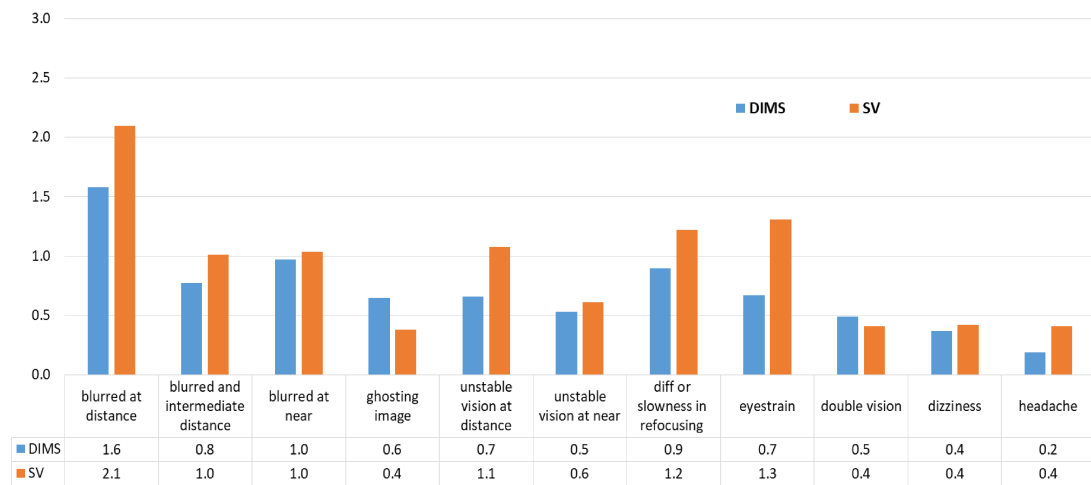
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