

INTRODUCTION

- Myopia is the most common refractive error in India, with prevalence rising from 4.4% (1999) to 21.2% (2019) and estimated to reach 50% by 2050. ¹ The burden is substantial and thus, an urgent need for interventions to reduce the progression of myopia.
- Utilising a real-world clinical setting, we aimed to explore the efficacy of myopia control spectacles (SPL) in Indian children. MyoCare SPL lenses incorporate cylindrical annular refractive elements and said to impose myopic defocus at the retina to slow eye growth. Efficacy of MyoCare has been reported from trials conducted in Caucasian ² and Chinese populations,³ but so far, its efficacy in children of Indian ethnicity remains unexplored.

PURPOSE

- To evaluate in a real-world clinical setting, the effectiveness of MyoCare SPL in slowing myopia progression as compared to matched controls wearing single vision (SV SPL) .

METHODS

- Study conducted at **Myopia Clinic, Aravind Eye Hospital, Coimbatore, India.**
- Retrospective analysis of data** from children 6-16 yrs of age prescribed with MyoCare SPL from Feb 2022 onwards. Data for eligible children from MyoCare SPL group were matched for age and baseline spherical equivalent (SE) refractive error with children that attended the same clinic during the study period and wearing single vision (SV) SPL.
- Inclusion criteria:** SE between -0.75D to -6.00 D, past annual progression of at least -0.50D and 12±1 month SPL wear with MyoCare (ZEISS Vision Care, Aalen, Germany) or SV SPL (various manufacturers).
- Data extracted** were age, sex, parental myopia, cycloplegic SE and axial length (AL) measurements (IOL Master 700,Carl Zeiss Meditec, Germany). Data of those with either missing data or lack of follow-up visits were excluded from the analysis.For AL measurements, an average of 3 values (+/-0.02 mm from each other) were considered. Change in SE & AL from baseline to 1-year was determined.
- Statistical comparisons** made using independent-t, Chi-Square, Wilcoxon rank-sum and ANCOVA adjusted for confounders. A mixed effect regression model was used to assess if SE progression was associated with age, parental myopia, baseline SE or AL.

RESULTS

Baseline:

Except for SV group being older (Table 1), there were no differences between the groups.

Table1: Baseline characteristics

	Single Vision (n=63)	Myocare (n=67)	P-value
Age, years			
Mean ±SD	13.19 ±2.29	12.01±2.56	0.007 ^a
Range	6.00 to 16.00	6.00 to 16.00	
Parental myopia, n (%)			0.441 ^b
Two	2(3.2)	1(1.5)	
One	12(19.0)	19(28.4)	
None	49(77.8)	47(70.1)	
Gender, n (%)			0.613 ^b
Male	31(49.2)	30(44.8)	
Female	32(50.8)	37(55.2)	
SE, D			0.218 ^c
Mean ±SD	-2.79 ±1.53	-2.49 ±1.34	
Median (IQR)	-2.50(-3.50 to -1.75)	-2.25(-3.00 to -1.62)	
AL, mm			0.502 ^c
Mean ±SD	24.31 ±0.80	24.41 ±0.91	
Range	22.29 to 26.29	22.82 to 27.82	

Table 2 : 1-year change in SE and AL

	Single Vision	Myocare	P-value
Change in SE (D)			
Mean ±SD	-0.28 ±0.37	-0.08 ±0.21	<0.001 ^c
Range	-1.5 to 0.0	-1.0 to 0.0	
Change in AL (mm)			
Mean ±SD	0.17 ±0.15	0.07 ±0.14	<0.001 ^c
Range	0.04 to 0.86	-0.32 to 0.51	
Annualised SE progression (D/yr)	0.30	0.09	<0.001 ^c
Annualised AL progression (mm/yr)	0.18	0.08	<0.001 ^c
Prescription changes (≥-0.25 D) n, %	33(52.4%)	10(14.9%)	<0.001 ^b
>0.50 D change (n, %)	19(15.1%)	6(4.5%)	0.004 ^b
AL Regression (n, %)	7(5.6%)	46(34.3%)	<0.001 ^b

SD=standard deviation, IQR=interquartile range, n-count, SE=spherical equivalent, AL=axial length;
a Independent -test, b Chi-square/ Fisher's exact test, c Mixed effect model, adjusted for eyes of the same patient; Changes in SE and AL were adjusted for age, family history and baseline spherical equivalent; P-value <0.05 considered statistically significant

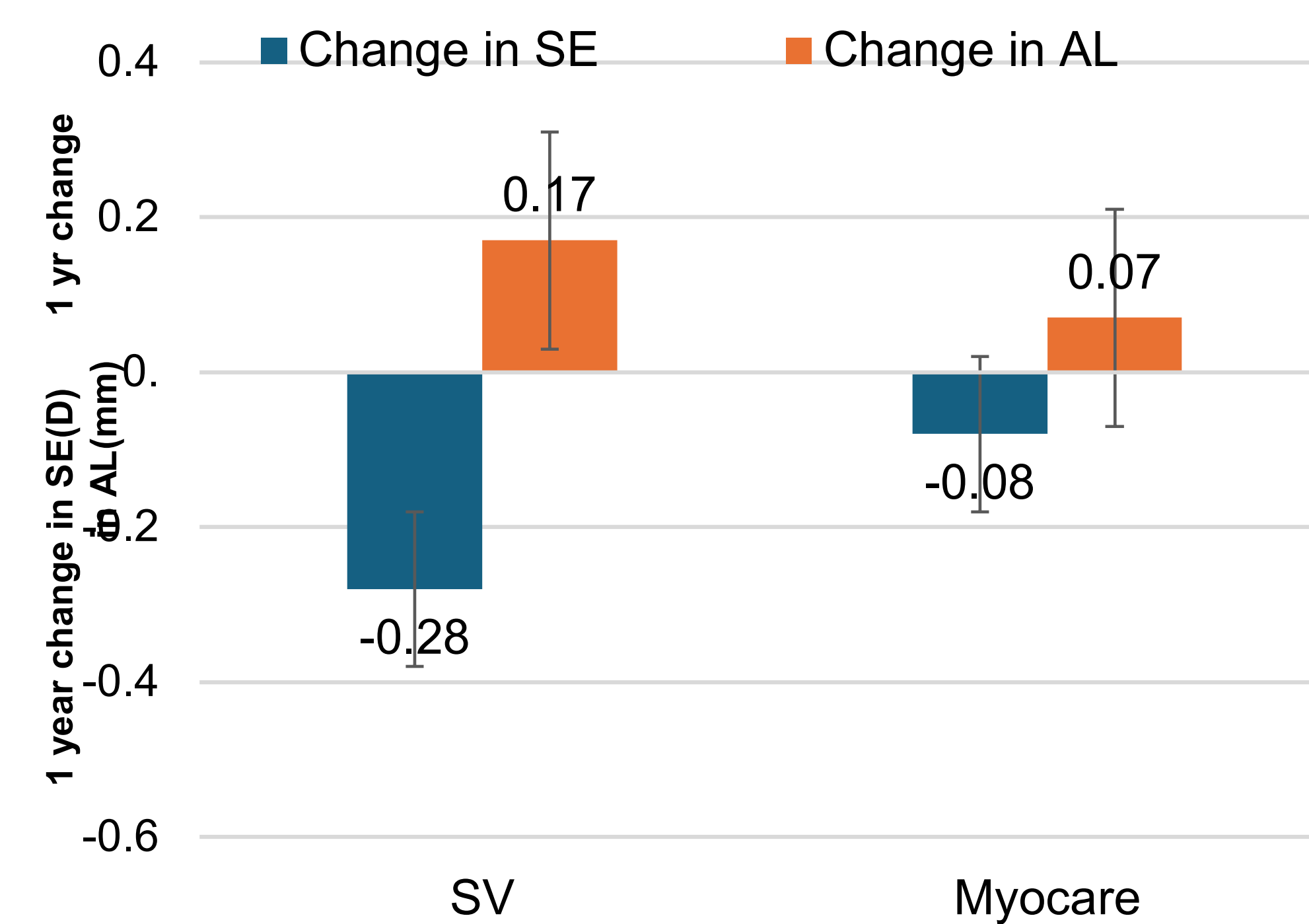


Figure2: Mean 1-year change in SE /AL for SV and Myocare

Table 3: Patient wise categorisation of SE change (based on eye exhibiting the most change)

SE change (D)	SV n (%)	Myocare n (%)	P-value
0.00	28(44.4)	55(82.0)	<0.001
>0.00 to -0.25	9(14.3)	2(3.0)	
>-0.25 to -0.50	13(20.6)	6(9.0)	
>-0.50 to -1.00	9(14.3)	4(6.0)	
>-1.00	4(6.4)	0	
Total	63	67	

Disclosures: SC: N; KN: N; RR: E -Zeiss Vision Care; MU: N; NR: N; PS: E- ZEISS VisionCare, P- ZEISS VisionCare, BHVI)
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RESULTS (contd..)

Table 3: Association of baseline factors with progression of SE (mixed effect regression model)

	Co-efficient	95% Confid interval	P-value
Age, years	-0.01	-0.02 to 0.01	0.490
Parental myopia			
None	Reference		
One	0.01	-0.09 to 0.11	0.839
Two	0.06	-0.21 to 0.33	0.678
SE (D)	0.03	-0.01 to 0.06	0.094
AL (mm)	0.03	-0.03 to 0.08	0.361

There was no association between any of the baseline factors with 1-year progression of SE.

DISCUSSION

- MyoCare SPL wearing eyes demonstrated significantly slower myopia progression, i.e. annualised difference of 0.21D/0.14mm less SE & AL compared to matched SV SPL eyes. Interestingly, the absolute difference between MyoCare and SV from this real-world setting is similar to that reported in East Asian and European populations from randomised trials.^{2,3}
- Additionally, fewer MyoCare SPL eyes demonstrated fast progression (>0.50D) and fewer eyes required prescription changes. A larger percentage of MyoCare eyes (34.3%) also demonstrated AL reversal compared SV SPL eyes (5.6%). Other than lenstype, myopia progression was not associated with individual and ocular parameters such as age, baseline SE or AL or parental myopia.
- The matched SV SPL wearers were older but there were no differences between groups for baseline SE or AL. In this group of South Indian SV wearers, mean 1-year progression was less at -0.28±0.37D than that reported in Asian eyes (approx. 0.50D for 13 year- old Asian child).⁴ However, the cohort is small needs further exploration with a larger sample.

CONCLUSIONS

- Overall, this real-world data from a cohort of myopic children attending a myopia clinic at a tertiary eye found MyoCare SPL was effective in slowing myopia compared to SV SPL. This is the first study proving efficacy of MyoCare SPL in Indian eyes. Further evaluations in lens wear are needed to determine if efficacy is sustained long-term.

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