

# The real-world effectiveness of defocus incorporated multiple segments and highly aspherical lenslets on myopia control: a longitudinal study from the French myopia cohort

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## ABSTRACT

**Aims** To evaluate the efficacy of myopia control by spectacle lenses in a real-world study.

**Methods** This is a longitudinal, retrospective, comparative, observational, real-world study of the French Myopia Cohort. Records of prescriptions for optical correction, gender and age were collected from 1500 opticians between 2020 and 2023. The study cohort consisted of myopic children aged 4 to 15 years who were assigned to three groups: two control groups wearing single vision lenses (SVL) and one intervention group wearing myopia control spectacles (MCS); either defocus incorporated multiple segments (DIMS, n=1786) or highly aspheric lenses (HAL, n=585). The first SVL group was matched to the MCS group for age, sex and initial refractive error (first matching), and the second SVL group was matched for the same criteria and myopia progression during the first 6 months of follow-up (second matching). The difference in myopia progression was calculated between SVL groups and the MCS group. DIMS and HAL were also compared for myopia progression.

**Results** A total of 2542 children (mean age of 9.5 years and mean spherical equivalent of -2.3 D at baseline) were included in each of the three groups. The mean progression rates for MCS were by +0.59 D (95% CI +0.57 to +0.62D; p<0.001) after the first matching and by +0.30 D (95% CI +0.28 to +0.32D; p<0.001) after the second matching, in comparison to the SVL groups. Children wearing HAL spectacles showed slightly less myopia progression (difference in progression = +0.14 D, 95% CI = +0.10 to +0.18, p<0.001) compared with the DIMS group.

**Conclusions** Although there are some limitations, including its retrospective design, the lack of lifestyle and environmental data and the use of SE rather than axial length, this study showed that in a real-world setting, both DIMS and HAL spectacles demonstrated efficacy in reducing myopia progression. While a statistically significant lower myopia progression rate was observed in the HAL group, this difference was not clinically meaningful. This study also showed that DIMS and HAL reduce myopia progression among younger children aged 4 to 6 years.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Measures to reduce the progression of myopia in children and adolescents, including glasses with defocus-incorporated multiple segments (DIMS) or highly aspherical lenslets (HAL), have previously been proven effective in recent studies on children and adolescents in Asia. It had remained unclear the effectiveness of these measures in a European population of children.

## WHAT THIS STUDY ADDS

⇒ In France, myopia control spectacles are usually prescribed to children with more rapid myopia progressions. This real-world retrospective study showed that DIMS (n=1786) and HAL (n=585) reduced myopia progression across all ages, from 4 to 15 years old. While HAL demonstrated better statistical efficacy in reducing myopia progression, this difference was not clinically meaningful.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results suggest that by either DIMS or HAL, myopia control spectacles could be beneficial to younger children.

## INTRODUCTION

The prevalence of myopia has been increasing worldwide, in particular in East and South-east Asian countries, and to a lesser degree in Western regions.<sup>1–5</sup> Besides lifestyle changes (such as promoting outdoor activities and restricting near-vision exposure), pharmacological, optical measures<sup>6 7</sup> and procedures with red light exposure<sup>8</sup> have been developed to reduce myopia progression in children and teenagers.

Defocus incorporated multiple segments spectacles (DIMS) or highly aspherical lenslets spectacles (HAL) have demonstrated

safety and efficacy in reducing myopia progression in randomised control trials (RCT), conducted primarily in Asian countries.<sup>9 10</sup> Both DIMS and HAL are spectacle lenses based on the peripheral myopic retinal defocus mechanism for myopia control. The DIMS lens developed at the Hong Kong Polytechnic University consists of a 9mm diameter central optical zone for distance refractive correction and a 33mm diameter peripheral annular zone including 400 multiple defocus segments with a relative positive power of +3.50 D.<sup>11</sup> The HAL lens developed by Essilor International comprises a central optical zone of 11 peripheral concentric rings formed by contiguous 1021 aspherical lenslets creating a volume of myopic retinal defocus.<sup>12</sup> The myopic defocus varies from 3 D on the ring closest to the centre to 5.50 D on the ring furthest from the centre. While the existence of efficient myopia control devices may render randomised trials with control groups of children untreated ethically unfeasible,<sup>13</sup> two alternative approaches may allow the assessment of the efficacy of DIMS and HAL. The first possibility includes a virtual control group based on a mathematical model of myopia progression.<sup>13</sup> The second possibility consists of real-world studies providing control groups by selection of myopic children wearing single vision lenses (SVL).<sup>14</sup> Recently, some data have emerged on the real-world efficacy of myopia control interventions in European populations. In their case series study of 40 patients, Kearney *et al* reported variable outcomes regarding the efficacy of myopia management by optical means.<sup>15</sup> Similarly, Day and Kearney observed that optical myopia interventions were successful in a minority of a UK clinic population,<sup>16</sup> both studies highlighting disparities of outcomes between real-world studies and clinical trials. In this context, we aimed to longitudinally evaluate the efficacy of two myopia control devices in a real-world cohort study, by comparing a group of children wearing myopia control spectacles (MCS) to two control groups of children wearing SVL: the first SVL group matched with MCS children on age, sex and myopia levels in spherical equivalent (SE) at baseline (first matching) and the second SVL group matched with MCS children on age, sex, SE at baseline and on the first 6-month myopia progression (second matching).

The primary objective of the study was to evaluate the effectiveness of MCS in myopia control by comparing the myopia progression between MCS group and SVL groups matched on various covariates. The secondary objective was to compare the efficacy of DIMS and HAL technologies in a real-world European population.

## MATERIALS AND METHODS

### Study design and database

The longitudinal, observational, real-world, comparative study on the French Myopia Cohort (FMC)<sup>17 18</sup> is based on a large, dynamic database of de-identified electronic optical prescription records, prospectively collected from 1500 opticians across France who voluntarily participated to enrich the dataset. All the optical stores are part of the

Krys Group network, accounting for around 10 million customers. The FMC compiles data on myopic individuals including year of birth, gender, date and type of optical correction, and measured refractive error by autorefraction after cycloplegia using cyclopentolate (Skiacol) expressed as SE. According to French legislation, no data on ethnicity were available in this cohort. In its raw state, the FMC recorded over 6.8 million individuals and more than 18 million visits between 2020 and 2023.

The study incorporated two follow-up phases: the preswitch phase, defined as the period in which all the study participants wore conventional SVL, and the postswitch phase, in which the individuals of the intervention group switched to MCS.

The study included three groups (n=2542 children per group) with similar follow-up. An intervention group of children was prescribed MCS during the follow-up and two comparison groups of children who were prescribed SVL throughout the follow-up. Among the two control groups, the first SVL group was matched with the MCS group for age, sex and baseline refractive error (first matching), while the second SVL group was matched with the MCS group for age, sex, baseline refractive error and the first 6-month myopia progression (second matching). Forming these three groups allowed testing whether conventional adjustments for age, sex and refractive error were sufficient to minimise potential selection bias and accurately estimate the effect of MCS.

Anonymised data were declared to the Conseil National Informatique et Liberté (CNIL). The study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the French Society of Ophthalmology (IRB n° 00008855). Patients or the public were not involved in the design, conduct, reporting or dissemination plans of our research.

### Participants and inclusion criteria

Inclusion criteria for the study were: children aged 4 to 15 years and a baseline refractive error of −0.5 diopters (D) or lower. The SVL group of children had to have at least three SVL prescriptions, with one prescription taken between 12 and 18 months after baseline of the study. For the MCS group, the children had to have received at least two SVL prescriptions in the preswitch phase and then having switched to MCS spectacles for the remainder of the follow-up (postswitch phase). As the decision to switch to MCS varied among the participants, the time of switch was estimated as the median of the switching times for all MCS children. To compare the effect of MCS means across age groups, we stratified the cohort of children into four age groups: 4 to 6 years, 7 to 9 years, 10 to 12 years and 13 to 15 years.

### Outcomes

Myopia progression was measured as the change in refractive error of the right eye between two prescriptions taken at least 6 months apart. For the matching process, we calculated the initial 6-month progression

rate as the change in refractive error between the baseline and second prescription. If the second prescription occurred more than 6 months after the baseline prescription, we adjusted for the time difference, assuming that myopia progressed linearly during that relatively short period of time. For the efficacy analysis, we calculated the progression rate in the pre-switch phase as the difference in refractive error between the time of switch to MCS and the baseline prescriptions. In the postswitch phase, the progression rate was the difference in refractive error between the last recorded prescription, and the refractive error measured at the time of switch to MCS. The same calculations were carried out for children of the SVL with their time of switch corresponding to the prescription taken between 12 to 18 months after study baseline.

### Statistical analysis

The children were not randomly preassigned to the groups, as the treatment plan was dependent on the patient and their physician. Therefore, we used the Mahalanobis distance matching strategy to match individuals included in the SVL group with those included in the MCS group. Mahalanobis distance matching is a subset selection method that is based on Mahalanobis distance, which accounts for the covariance structure of the data. This approach has already been used in other studies.<sup>19</sup> Mahalanobis distance matching creates a new sample in which the treatment is not confounded to the covariates, thereby making our comparison of myopia progression between the MCS and the SVL groups less subject to bias. Two matching procedures were conducted to reduce bias and achieve a 1:1 matching ratio between the MCS and the SVL groups. The first matching was adjusted for age, gender and SE at baseline, while the second matching included the initial 6-month myopia progression, in addition to the previous variables.

The treatment effectiveness was estimated using the difference in progression (DiP) approach, comparing the changes in refractive error before and after the switch between the MCS group and the SVL groups. We implemented the difference in progression as an interaction between the time variable and the treatment group variable in a regression model as follows:<sup>20</sup>

$$\text{Progression (D/phase)} = \beta_0 + \beta_1 \times \text{Phase} + \beta_2 \times \text{Group} + \beta_3 \times \text{Phase: Group} + \varepsilon$$

$$\beta_3 = (\text{postswitch}_{\text{SVL}} - \text{preswitch}_{\text{SVL}})$$

where  $-(\text{postswitch}_{\text{MCS}} - \text{preswitch}_{\text{MCS}})$  is the difference in progression between the two groups.

The approach required that the baseline trends, but not the levels of progression, were equivalent in both groups. We verified this assumption by graphically inspecting the progression trajectories in the two groups.

As a secondary analysis, we estimated the difference in myopia progression between DIMS and HAL in the MCS group, using DIMS as the reference group in the regression model.

To assess the balance between all the groups, we conducted a student t-test or Wilcoxon test for continuous variables, and a  $\chi^2$ -test for the categorical variables. Baseline characteristics and demographics were summarised with descriptive statistics, mean value and SD. The level of statistical significance was set at <0.05, and all analyses were performed using R Statistical Software (R V.4.3.2, R Core Team 2023).

## RESULTS

### Study population

Starting in March 2020, data on 22 090 myopic children were collected. The majority of children constituted the SVL group,  $n=19548$  (88.49%), and the rest of the children switched to MCS, constituting the MCS group,  $n=2542$  (11.51%). The MCS group included individuals who switched to either DIMS ( $n=1786$ ), HAL ( $n=585$ ) or both ( $n=171$ ). Among participants who changed treatments, the majority switched from DIMS to HAL ( $n=109$ ) and the minority from HAL to DIMS ( $n=62$ ). At the end of the selection and matching processes, we formed two SVL control groups and one MCS intervention, each consisting of 2542 participants (figure 1).

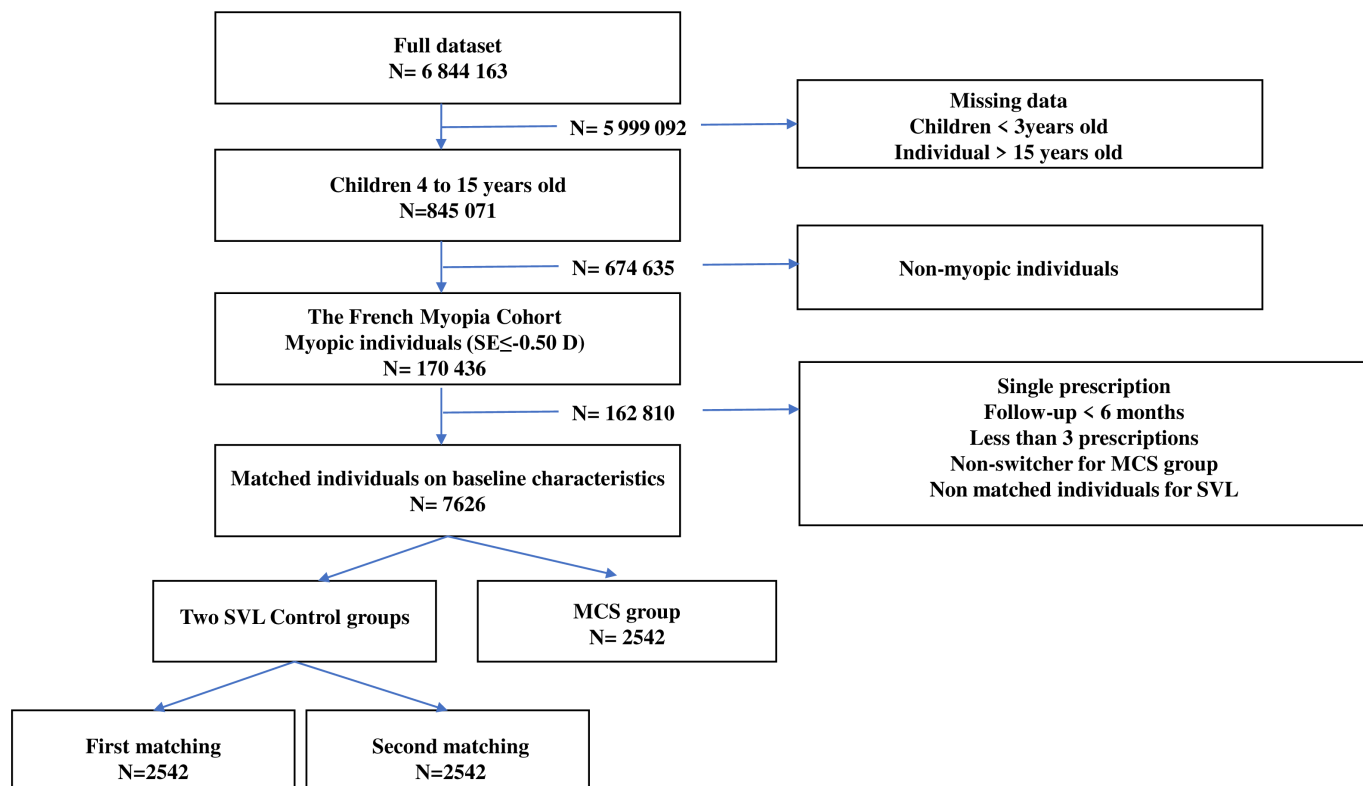
### Baseline characteristics

The youngest population in our cohort was 4 years old, with 57 children in each group. The sample size by age group is detailed in online supplemental table A. Prior to matching, there were baseline differences between the groups. The mean age was 9.51 (2.45) in the MCS groups versus 10.96 (2.97) in the SVL group ( $p<0.001$ ). The MCS participants were more myopic ( $-2.35 \text{ D} \pm 1.57$  vs  $-2.20 \text{ D} \pm 1.73$ ;  $p<0.001$ ) and had a higher rate of myopic progression than SVL participants during the initial 6 months ( $-0.36 \text{ D} \pm 0.27$  vs  $-0.16 \text{ D} \pm 0.20$ ;  $p<0.001$ ). Both groups did not differ significantly in sex (girls: 64.71% vs 64.45%;  $p=0.75$ ). After the first matching, the first 6-month myopia progression remained higher in the MCS group than in the SVL group ( $-0.36 \text{ D} \pm 0.27$  vs  $-0.17 \text{ D} \pm 0.22$ ;  $p<0.001$ ). The second matching achieved a balance between the SVL and MCS groups for all selected variables. The characteristics of the children at baseline and after the matching procedures are detailed in table 1 and online supplemental figure 1.

### Reduction in myopia progression

After the first matching, the postswitch mean progression rate was less in the MCS group than in the SVL group (difference in progression =  $+0.59 \text{ D}$ , 95% CI  $+0.5$  to  $+0.62 \text{ D}$ ;  $p<0.001$ ). The difference between both groups was found across all age groups (figure 2). Online supplemental figure 2 illustrates the time change of myopia progression in SVL and MCS individuals after first (online supplemental figure 2A) and second matching (online supplemental figure 2B). The reduction in myopia progression in the two groups and the estimated reduction effect of MCS are summarised in online supplemental table B.





**Figure 1** Flowchart of the patient population in the study. MCS, myopia control spectacles; SE, spherical equivalent; SVL, single vision lenses.

**Table 1** Baseline characteristics of myopia control spectacles and single vision lenses groups before and after the two matching procedures

	MCS	SVL	p
Full dataset			
n	2542	19 548	
Mean age (SD)	9.51 (2.45)	10.97 (2.95)	<0.001
Gender ratio (F/M) (F%)	1.83 (64.71)	1.80 (64.45)	0.75
Mean SE (SD)	-2.35 (1.57)	-2.20 (1.73)	<0.001
6-month progression mean (SD)	-0.36 (0.27)	-0.16 (0.20)	<0.001
After first matching			
n	2542	2542	
Mean age (SD)	9.51 (2.4)	9.51 (2.6)	1.00
Gender ratio (F/M) (F %)	1.83 (64.71)	1.83 (64.71)	1.00
Mean SE (SD)	-2.35 (1.57)	-2.35 (1.57)	0.99
6-month progression mean (SD)	-0.36 (0.27)	-0.17 (0.22)	<0.001
After second matching			
n	2542	2542	
Mean age (SD)	9.51 (2.45)	9.52 (2.44)	0.75
Gender ratio (F/M) (F %)	1.83 (64.71)	1.83 (64.71)	1.00
Mean SE (SD)	-2.35 (1.57)	-2.34 (1.57)	0.76
6-month progression mean (SD)	-0.36 (0.27)	-0.35 (0.26)	0.35
MCS, myopia control spectacles; SVL, single vision lenses.			

After the second matching, the postswitch mean myopia progression rate was lower in the MCS group than in the SVL group (difference in progression = +0.30 D, 95% CI +0.28 to +0.32 D;  $p < 0.001$ ; online supplemental figure 3). The reduction in myopia progression was significant across all age groups (online supplemental table B).

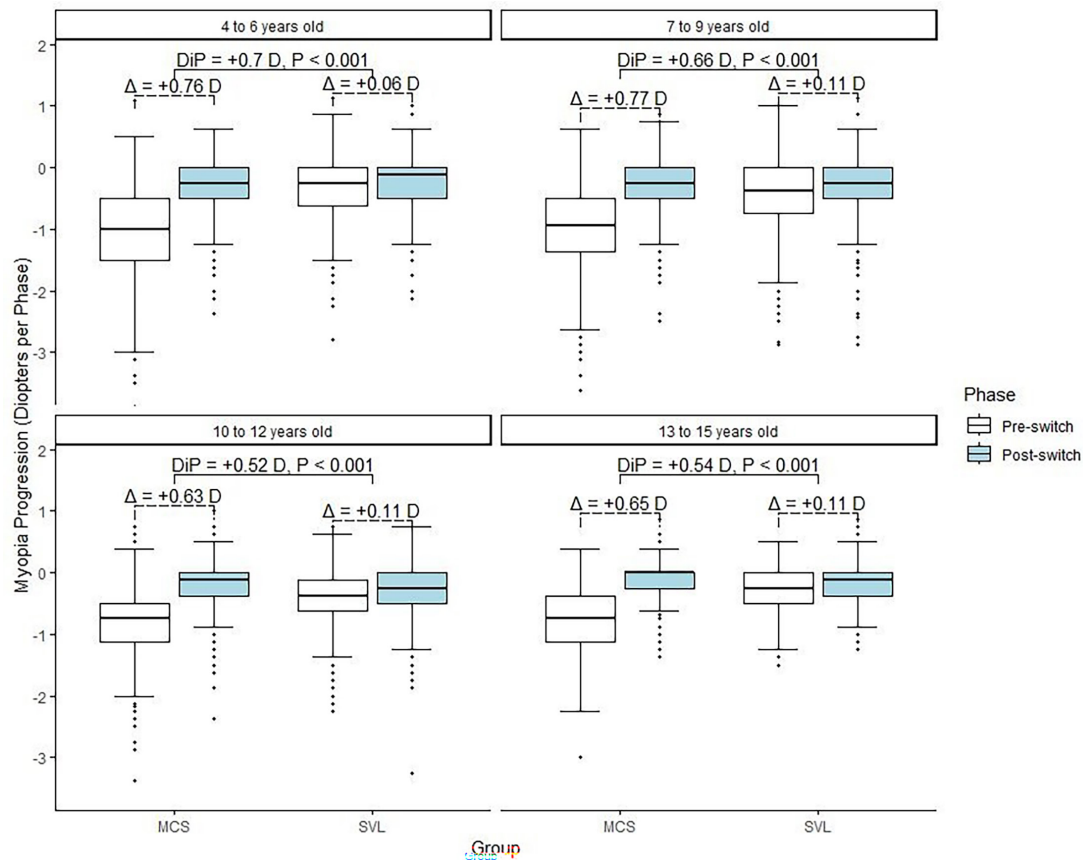
### Comparison of defocus incorporated multiple segments spectacles (DIMS) to highly aspherical lenslets spectacles (HAL)

For this analysis, we considered only individuals who switched to either DIMS or HAL, including 2371 children from the MCS group. Demographics for the DIMS and the HAL groups are presented in table 2.

Over the postswitch phase, children wearing HAL spectacles showed slightly less myopia progression than DIMS (difference in progression = +0.14 D, 95% CI +0.10 to +0.18,  $p < 0.001$ ). Online supplemental table C details the difference in progression between DIMS and HAL across all age groups. The slowing of myopia progression was slightly different in ages 7 to 9 years (difference in progression = +0.11 D, 95% CI +0.03 to +0.19,  $p = 0.01$ ) and 10 to 12 years old (difference in progression = +0.08 D, 95% CI 0 to +0.16,  $p = 0.03$ ).

### Follow-up and prescription change frequency

Among the MCS-treated patients, 86.7% ( $n = 2205$ ) had at least a 2-year follow-up, and 51.3% ( $n = 1303$ ) received their last prescription between months 30 and 36. The time window of switch ranged from 6 months ( $n = 87$ )



**Figure 2** Box plot comparing myopia progression in the pre- and post- switching phases, between the single vision lenses group from the first matching and the myopia control spectacle group. The bold line in the boxplot represents the median of myopia progression. Level. The error bars represent the upper and lower extremes. The points outside the whiskers represent the outliers. DiP, difference in progression between the groups; MCS, myopia control spectacles; SVL, single vision lenses;  $\Delta$ , difference between phases.

to 35 months ( $n=7$ ), with 56.8% ( $n=1444$ ) of children switching to MCS between 12 and 19 months (median time switch=14 months, IQR=12 to 19 months). Table 3 shows the mean duration of follow-up in the pre- and postswitch phases for the MCS individuals.

Out of 19548 patients who were prescribed SVL spectacle, 84.7% ( $n=16559$ ) were followed for at least 2

years. Among the children from the SVL group assigned to the first matching, 85.5% ( $n=2173$ ) had at least 2 years of follow-up, while among those assigned to the second matching, 85.4% ( $n=2170$ ) had at least 2 years of follow-up. The postswitch duration for the first and second SVL group was similar to that of the MCS group ( $p=0.36$  and  $p=0.22$ ).

**Table 2** Baseline characteristics of participants in defocus incorporated multiple segment highly aspherical lenslets and SVL groups

	DIMS (n=1786)	HAL (n=585)	p	SVL (n=2542)
Age mean (SD)	9.53 (2.40)	9.43 (2.55)	0.38	9.52 (2.44)
Gender ratio (F/M) (F %)	1.72 (63.33)	2.09 (67.69)	0.06	1.83 (64.71)
Spherical equivalent mean (SD)	-2.36 (1.56)	-2.31 (1.56)	0.56	-2.36 (1.57)
4 to 6 years old	-2.06 (1.53)	-1.81 (1.62)		-2.06 (1.63)
7 to 9 years old	-2.12 (1.38)	-2.12 (1.36)		-2.10 (1.35)
10 to 12 years old	-2.52 (1.63)	-2.52 (1.61)		-2.53 (1.64)
13 to 15 years old	-3.00 (1.72)	-2.90 (1.72)		-2.95 (1.70)
6-month progression mean (SD)	-0.36 (0.27)	-0.37 (0.28)	0.13	-0.35 (0.26)

DIMS, defocus incorporated multiple segments spectacles; HAL, highly aspherical lenslets spectacles ; SVL, single vision lenses.

**Table 3** Follow-up duration for myopia control spectacle and single vision lenses group

	First SVL group	Second SVL group	MCS group
Median duration in each phase (IQR)			
Pre-switch duration (months)	13 (12 to 15)	13 (12 to 15)	13.5 (12 to 18)
Post-switch duration (months)	13 (12 to 18)	14 (12 to 18)	13 (12 to 17)
No. of participants with follow-up (%)			
At least 2 years of follow-up	2173 (85.5)	2170 (85.4)	2205 (86.7)
At least 3 years of follow-up	333 (13.1)	353 (13.9)	480 (18.9)
3.5 years of follow-up	40 (1.57)	33 (1.30)	48 (1.89)
Median follow-up in months (IQR)	28 (25 to 32)	28 (25 to 32)	30 (26 to 35)
MCS, myopia control spectacles; SVL, single vision lenses.			

When comparing the frequency of visits between the matched groups of MCS and SVL, the annualised number of prescription changes was similar ( $1.46 \pm 0.33$  vs  $1.48 \pm 0.41$  prescriptions/year;  $p=0.26$ ). The annualised number of prescription changes was slightly higher among the younger children with a negative Pearson's correlation coefficient ( $r=-0.12$ ,  $p<0.001$ ).

## DISCUSSION

In our real-world based study, MCS-treated study participants as compared with the children of the SVL control group showed a significantly higher baseline progression rate ( $-0.36$  vs  $-0.16$  D;  $p<0.001$ ). It reflects the French recommendations by the official French health authority to prescribe MCS to children with confirmed myopia progression of  $-0.50$  D/year or more.<sup>21</sup> Heterogeneity between the two groups was also observed for other variables: younger age (9.5 vs 11.0 years) and more myopic refractive error ( $-2.35$  vs  $-2.20$  D) for the MCS group than in the SVL control group (table 1). We therefore additionally matched for the amount of myopia progression observed during the first 6 months of the follow-up to reduce the effect of confounding factors. The first matching was useful to compare the results of our study with other studies because up to now there has been no comparative real-world study matching the control and intervention groups with myopia progression, in addition to age, sex and myopia level at baseline. The second matching aimed to create comparable groups based on the initial myopia progression, thereby reducing bias in estimating the MCS effect.

The primary results of the efficacy analysis from first-matched children showed that myopia progression, during the 14 months of the postswitch period, was reduced by  $+0.70$  D in the 4-to-6-year age group and by  $+0.54$  D in the 13-to-15-year age group (figure 2).

This reduction of myopia progression observed in the younger group of this real-world study suggests that myopia control optical means may also be used to reduce myopia progression in children aged 4 to 6 years. Since this reduction in myopia progression might have been an effect of regression-towards-the-mean accompanied by the natural slowing of progression of myopia over time, we conducted a second matching procedure based on the myopia progression observed during the initial 6-month period. This procedure mimicked an RCT setting, in which the myopia progression rates of the individuals from SVL and MCS groups would have been equally affected by the regression-to-the-mean effect. Results from the second matching demonstrated a lower yet significant controlling effect of the MCS spectacles across all ages, with a reduction of myopia progression of  $+0.24$  D in the 4-to-6-year age group to  $+0.35$  D for the 13-to-15-year age group (online supplemental table B and online supplemental figure 3).

The preswitch duration for the MCS group was on average 2 months longer than for the SVL ( $p<0.001$ ) (table 3). Naturally, the preswitch and post-switch phases for the SVL group were not pre-determined, and therefore, we defined the time switch for the children of the SVL group as time of visit between months 12 and 18. The time window switch chosen for the SVL group was based on the quantitative calculation of the window of switch for most MCS children, which ranged from 12 to 19 months after the first prescription of the glasses (median time switch=14; IQR=12 to 19 months). Nonetheless, the children of the MCS group and SVL group had a similar post-switch duration of follow-up ( $p=0.36$ ) and frequency of prescription changes ( $p=0.26$ ), thus limiting the risk of bias.

The efficacy of myopia control by the MCS in the youngest age group with an age of 4 to 6 years had not been previously investigated, as age groups are usually 8 to 13 years in clinical trials on myopia control with optical means.<sup>12 22–24</sup> These results showed the efficiency of myopia control by DIMS or HAL in routine practice in a markedly younger population than that examined in previous investigations. A recent real-world retrospective Chinese study included 10 477 subjects aged 6 to 16 years, with 3639 children in the DIMS group and 6838 children in the SVL group.<sup>14</sup> At 1.5 years of follow-up, children wearing DIMS spectacles demonstrated an improvement of  $+0.35$  D. Our study reports the MCS efficacy of  $+0.30$  D based on the most accurate comparison from second matching. In general, the efficacy of MCS spectacles in our study, and in other non-randomised studies,<sup>14–16</sup> was reported to be weaker than those in RCT studies. Nevertheless, the reduced myopia progression is still highly important in preventing future complications.

The current study also compared the efficacy of DIMS and HAL in controlling myopia, and although we observed a lower progression rate in the HAL group than in the DIMS group, the difference was not clinically significant (difference in progression =  $+0.14$ , 95% CI

+0.10 to +0.18,  $p < 0.001$ ). In this study, there were fewer children with HAL lenses because HAL lenses were available in France in limited distribution (soft launch) from June 2021 and were more widely distributed from September 2021, while DIMS were available 1 year before, from September 2020. A recent retrospective Chinese cohort study comparing DIMS in significantly smaller study cohorts reported better myopia control in children wearing HAL than DIMS. The HAL group progressed by  $-0.34$  D and the DIMS group by  $-0.63$  D after 1 year of follow-up.<sup>25</sup> However, the authors of this study did not include in their model the degree of myopia progression at baseline, and the children of the HAL group were younger than the children of the DIMS group for a similar degree of myopia at baseline. As a general comment, studies on means of myopia control should be designed to have similar groups at baseline, for age, gender, myopia degree and also myopia progression, to avoid potential selection bias that could influence the results of the study.

When the results of our study are discussed, its limitations should be considered, which included the retrospective design of the investigation, a lack of data on environmental and lifestyle factors, a lack of data regarding the ethnicity of the children and variability in the follow-up. It is possible that the myopia progression would have been impacted by external factors such as seasonality, but given the sample size, we expected that the effect of seasonality on myopia progression would be similar for the SVL and the MCS groups. Another limitation was that clinicians might have been more inclined to recommend MCS to children showing faster progression. As a result, some of the slowing of myopia progression observed for groups from the first matching might have been due to an effect of regression to the mean. For the second matching, the groups were matched for the initial rate of myopia progression, and the MCS group still showed significantly less myopia progression, albeit lower than for the first matched groups. In this study, information on the children's socioeconomic background was not available, which was a potential factor influencing access to myopia control devices. Despite the availability of data on the opticians' locations, the socioeconomic background of the parents could not be extrapolated from the location of purchase alone. In our study, SE was the only functional outcome that reflected myopia progression. Chen *et al* have shown in their analysis a significant correlation between SE and AL ranging between  $-0.54$  and  $-0.81$  ( $r = -0.736$ ,  $p < 0.001$ ), which suggests that SE could explain the majority of the variation of axial length.<sup>26</sup> In myopia control studies, a similar trend is observed when myopia control methods are analysed for their efficacy in the two outcomes.<sup>12 14 25</sup> Indeed, in their study on atropine efficacy, Zadnik *et al* reported a correlation of  $-0.79$  (95% CI  $-0.83$  to  $-0.74$ ) between SE change and AL change from baseline.<sup>27</sup> We also acknowledge that SE to characterise a refractive error, which is widely used because of its simplicity as a scalar variable,

has some weaknesses. Indeed, SE does not include non-orthogonal oblique rays, and the same SE can reflect different refractive errors.<sup>28–30</sup>

The strengths of our study included the large sample size, the robust matching strategy and its real-world nature. Unlike a randomised controlled trial with strict inclusion criteria, our study analysed a large number of myopic children throughout France, a country in which auto-refractometry is usually conducted under cycloplegia. Indeed, the French Society of Ophthalmology recommends automatic refraction after the use of cyclopentolate (skiacol) to obtain cycloplegia for children aged 1 year or more. This method of measuring refractive errors is the most reliable.<sup>31</sup>

In conclusion, this real-world cohort study showed that MCS were effective in slowing myopia progression in European myopic children aged 4 to 15 years, including children of the age group 4–6 years. Our study also suggested that DIMS and HAL had clinically similar effects on reducing myopia progression. Further studies may compare other methods of myopia control addressing questions on the treatment effectiveness under real-world conditions.

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#### REFERENCES

- Baird PN, Saw S-M, Lanca C, et al. Myopia. *Nat Rev Dis Primers* 2020;6:99.
- Morgan IG, French AN, Ashby RS, et al. The epidemics of myopia: Aetiology and prevention. *Prog Retin Eye Res* 2018;62:134–49.
- Cumberland PM, Bountziouka V, Hammond CJ, et al. Temporal trends in frequency, type and severity of myopia and associations with key environmental risk factors in the UK: Findings from the UK Biobank Study. *PLoS One* 2022;17:e0260993.
- Williams KM, Bertelsen G, Cumberland P, et al. Increasing Prevalence of Myopia in Europe and the Impact of Education. *Ophthalmology* 2015;122:1489–97.
- Grzybowski A, Kanclerz P, Tsubota K, et al. A review on the epidemiology of myopia in school children worldwide. *BMC Ophthalmol* 2020;20:27.
- Yam JC, Jiang Y, Tang SM, et al. Low-Concentration Atropine for Myopia Progression (LAMP) Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of 0.05%, 0.025%, and 0.01% Atropine Eye Drops in Myopia Control. *Ophthalmology* 2019;126:113–24.
- Chia A, Lu QS, Tan D. Five-Year Clinical Trial on Atropine for the Treatment of Myopia 2: Myopia Control with Atropine 0.01% Eyedrops. *Ophthalmology* 2016;123:391–9.
- Chen Y, Xiong R, Chen X, et al. Efficacy Comparison of Repeated Low-Level Red Light and Low-Dose Atropine for Myopia Control: A Randomized Controlled Trial. *Transl Vis Sci Technol* 2022;11:33.
- Lam CS, Tang WC, Lee PH, et al. Myopia control effect of defocus incorporated multiple segments (DIMS) spectacle lens in Chinese children: results of a 3-year follow-up study. *Br J Ophthalmol* 2022;106:1110–4.
- Bao J, Huang Y, Li X, et al. Spectacle Lenses With Aspherical Lenslets for Myopia Control vs Single-Vision Spectacle Lenses: A Randomized Clinical Trial. *JAMA Ophthalmol* 2022;140:472–8.
- Lam CSY, Tang WC, Tse DY-Y, et al. Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial. *Br J Ophthalmol* 2020;104:363–8.
- Bao J, Yang A, Huang Y, et al. One-year myopia control efficacy of spectacle lenses with aspherical lenslets. *Br J Ophthalmol* 2022;106:1171–6.
- Bullimore MA, Brennan NA, Flitcroft DI. The future of clinical trials of myopia control. *Ophthalmic Physiol Opt* 2023;43:525–33.
- Liu J, Lu Y, Huang D, et al. The Efficacy of Defocus Incorporated Multiple Segments Lenses in Slowing Myopia Progression: Results from Diverse Clinical Circumstances. *Ophthalmology* 2023;130:542–50.
- Kearney S, Seidel D, Day M. Evaluating treatment effectiveness in a case series of myopia patients. *Optom Contact Lenses* 2022;2:108–15.
- Day M, Kearney S. Myopia optical treatments within a UK clinic population are less successful than in clinical trials. *Invest Ophthalmol Vis Sci* 2024;65:2749.
- Ducloux A, Marillet S, Ingrand P, et al. Progression of myopia in teenagers and adults: a nationwide longitudinal study of a prevalent cohort. *Br J Ophthalmol* 2023;107:644–9.
- Tricard D, Marillet S, Ingrand P, et al. Progression of myopia in children and teenagers: a nationwide longitudinal study. *Br J Ophthalmol* 2022;106:1104–9.
- Ross CJ, Ghauri S, Gilbert JB, et al. Intravitreal Antibiotics versus Early Vitrectomy Plus Intravitreal Antibiotics for Postinjection Endophthalmitis: An IRIS® (Intelligent Research in Sight Registry) Analysis. *Ophthalmol Retina* 2025;9:224–31.
- Abadie A. Semiparametric Difference-in-Differences Estimators. *Rev Econ Stud* 2005;72:1–19.
- Miyosmart. n.d. Available: [https://www.has-sante.fr/jcms/p\\_3329537/fr/](https://www.has-sante.fr/jcms/p_3329537/fr/)
- Lam CSY, Tang WC, Qi H, et al. Effect of Defocus Incorporated Multiple Segments Spectacle Lens Wear on Visual Function in Myopic Chinese Children. *Transl Vis Sci Technol* 2020;9:11.
- Nucci P, Lembo A, Schiavetti I, et al. A comparison of myopia control in European children and adolescents with defocus incorporated multiple segments (DIMS) spectacles, atropine, and combined DIMS/atropine. *PLoS One* 2023;18:e0281816.
- Lam CSY, Tang WC, Zhang HY, et al. Long-term myopia control effect and safety in children wearing DIMS spectacle lenses for 6 years. *Sci Rep* 2023;13:5475.
- Guo H, Li X, Zhang X, et al. Comparing the effects of highly aspherical lenslets versus defocus incorporated multiple segment spectacle lenses on myopia control. *Sci Rep* 2023;13:3048.
- Chen S, Liu X, Sha X, et al. Relationship between axial length and spherical equivalent refraction in Chinese children. *Adv Ophthalmol Pract Res* 2021;1:100010.
- Zadnik K, Schulman E, Flitcroft I, et al. Efficacy and Safety of 0.01% and 0.02% Atropine for the Treatment of Pediatric Myopia Progression Over 3 Years: A Randomized Clinical Trial. *JAMA Ophthalmol* 2023;141:990–9.
- Kaye SB, Rubin A, Evans T, et al. Standardised approach to the reporting and presentation of refractive data: electronic patient record. *BMJ Open Ophthalmol* 2022;7:e001015.
- Kaye SB, Surti J, Wolffsohn JS. Average paraxial power of a lens and visual acuity. *Sci Rep* 2023;13:7118.
- Kaye SB. Time to replace the spherical equivalent with the average paraxial lens power. *BMJ Open Ophthalmol* 2023;8:e001340.
- Zadnik K, Mutti DO, Adams AJ. The repeatability of measurement of the ocular components. *Invest Ophthalmol Vis Sci* 1992;33:2325–33.