



One-Year Efficacy and Tolerance of Myofix Defocus Spectacles for Control of Myopia Progression

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ABSTRACT

Introduction: To report the 1-year efficacy of Myofix Defocus spectacles, designed to control the progression of myopia in childhood.

Methods: A total of 47 children with myopia aged 7–15 years were enrolled. Cycloplegic objective refraction (spherical equivalent

refraction, SE) and axial length (AL) were measured at baseline, 6 months, and 12 months. Linear regression models were used to identify risk factors of 12-month changes in SE and AL. For comparison, two virtual control groups of children were included. Tolerance was assessed through a questionnaire at each follow-up visit.

Results: Of the initial cohort, 11 participants were lost to follow-up after 6 months due to reasons unrelated to lens design (77.1% retention rate). Over 12 months, the mean SE change in all eyes was -0.21 ± 0.30 D, and AL change was 0.19 ± 0.13 mm. Progression was significantly different in participants who reported good compared to poor compliance ($p < 0.001$). At the 12-month follow-up, participants with good compliance had a mean SE progression of -0.12 ± 0.25 D and a mean AL change of 0.17 ± 0.11 mm. In virtual controls, the mean annual SE progression was -0.47 ± 0.36 D, and

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AL change was 0.26 ± 0.17 mm (both $p < 0.001$). In compliant participants, Myofix Defocus lens demonstrated a 75% reduction in SE and 37% reduction in AL compared to virtual controls.

Conclusions: After 1 year, Myofix Defocus spectacles slowed myopia progression in children, demonstrating comparable efficacy to other defocus-incorporated spectacle designs. Greater compliance resulted in better treatment effect. Further long-term studies are warranted to confirm these findings.

Trial Registration: ClinicalTrials.gov identifier: NCT07092072. Registered retrospectively on July 29, 2025.

Keywords: Myopia control spectacles; Full-field defocus design; Tolerance; Efficacy

Key Summary Points

Why carry out this study?

To evaluate the efficacy of a full-field peripheral defocus spectacle lens (Myofix, Novar) for myopia control.

The study tested the hypothesis that this new lens would be as effective as other commercially available options developed for myopia control.

What was learned from the study?

After 12 months of prospective follow-up, full-field defocus spectacles were effective in reducing myopia progression.

The straightforward design and demonstrated effectiveness of this lens suggest that it represents a practical option for managing myopia.

INTRODUCTION

Refractive errors are considered the second leading cause of visual impairment worldwide [1]. Highly educated populations tend to have higher rates of myopic refractive errors [2, 3], highlighting the need to develop effective treatments to ensure that the next generations can pursue advanced education without an increased risk of developing myopia. In 2001, Saw et al. [4], reported a marked increase in the prevalence of myopia among Singapore conscripts within a single generation, suggesting that environmental rather than genetic factors were primarily responsible for this rapid rise [2]. Since then, a myopia epidemic has clearly emerged in East and Southeast Asia. Numerous studies have confirmed this trend, with alarming projections for the development of high myopia in large segments of the population [5–7]. In contrast, Latin-American countries such as Brazil and Argentina have reported myopia prevalence rates of approximately 15–30% in adults [8], with urban youth populations reaching up to one-third affected [9]. Despite the relatively low prevalence among adults in the city of Buenos Aires, it is important to acknowledge that myopia progression can lead to pathological changes in ocular structures such as the retina, choroid and macula, being the leading cause of legal blindness in large urban settings [10, 11]. These degenerative changes are among the leading causes of irreversible vision loss and blindness, particularly in individuals with refractive error exceeding -5.00 to -6.00 diopters [6, 12]. In Buenos Aires, a study conducted among office workers at the beginning of this century reported a prevalence of high myopia less than 2% [13], yet despite its low prevalence, it remains a leading cause of visual impairment in the region [10].

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Low-dose atropine (0.01–0.05%) has been used as a first-line treatment to slow myopia progression [14–17]. However, despite its low concentration, some pediatric ophthalmologists remain concerned about the potential long-term effects of daily use over several years. Therefore, there is growing interest in developing less invasive therapeutic methods for myopia control [14, 18]. Recent randomized controlled trials have demonstrated promising outcomes with various designs of peripheral defocus or contrast modulation spectacles and contact lenses [19]. These specially designed spectacles may serve as alternative spectacles to standard single-vision lenses for children with myopia, as these may promote myopia progression by imposing peripheral hyperopic defocus [20]. This study investigated compliance and myopia progression over a 1-year period using a new defocus spectacle design (Myofix, Novar) [21].

METHODS

The Myofix Defocus Study was a longitudinal, prospective, interventional, non-randomized research study developed to evaluate the tolerability, compliance, safety, and effectiveness of specially designed spectacles for myopia control in children. Baseline data and methods have been published previously [21]. This study included children aged 7–15 years who voluntarily agreed to use the Defocus spectacles for 1 year. Eligible participants were a consecutive series of children diagnosed with myopia, attending accredited private practice ophthalmology clinics across Argentina. Inclusion criteria were the absence of ocular pathology other than myopia, with spherical equivalent ($SE = \text{sphere} + [\text{cylinder}/2]$) between ≤ -0.50 D and -5.00 D, astigmatism less than -2.00 D, anisometropia less than -1.00 D, and keratometry less than 47.00 D in the steepest meridian. The corrected distance visual acuity based on subjective refraction was required to be 0.1 log-MAR (20/25 Feet Snellen) or better in each eye. Exclusion criteria included myopia with onset before the age of 6 years, any genetic syndromes, or current medical treatment for myopia other

than single vision spectacle correction. Subjects who had previously undergone any form of myopia control treatment were excluded.

At the baseline visit, all participants underwent a comprehensive ophthalmological evaluation, including subjective refraction and cycloplegic refraction [21]. Cycloplegia was induced with two drops of 1% cyclopentolate, instilled 5 min apart, and the refractive assessment was performed 45 min after the first drop. Cycloplegic refraction and axial length (AL) measurements (using optical biometry) were conducted at baseline, 6 months, and 12 months. A detailed questionnaire was administered to collect data on lifestyle habits and family history, including reading and outdoor exposure, hours of schooling, age of first prescription, and family history of high myopia. Besides, bedtime use of smartphones, and use of inverted contrast in electronic devices were also explored. Compliance with spectacle use was assessed through two methods at the 6- and 12-month visits. First, a structured questionnaire administered during follow-up visits asked whether the child wore the spectacles full-time or only part of the day (morning or afternoon), and whether they used them at home, outdoors, or both. The questionnaire also included a question on tolerance, asking whether the spectacles were well accepted. In addition, at both follow-up visits, children were asked three specific questions to assess tolerance: whether they experienced any discomfort or difficulty when moving their head while reading, walking, or during lateral gaze. Second, the ophthalmologist independently evaluated and recorded overall compliance as 'good' or 'poor' in the clinical history, providing explanatory comments in the 'observations' section.

All participants received a pair of spectacles (Myofix, Novar, USA) with frames (Usual, Argentina) at no cost for the duration of the 1-year study. Children were instructed to wear the spectacles every day full-time and were evaluated at 6-month intervals. The Myofix lens design consists of a 9-mm central optical zone for distance correction, surrounded by a peripheral zone providing approximately $+3.50$ D of additional power to induce peripheral myopic defocus (Fig. 1). A preliminary questionnaire taken by 45 children who were fitted for 1 month with

these spectacles at La Pirámide Optics (Mendoza, Argentina) reported good tolerance in 80% of cases [21]. While most participants experienced some initial adaptation difficulties during the first 2 days, tolerance improved markedly thereafter.

Participants were recruited from 13 optical centers and 15 ophthalmological institutions. These institutions were included after confirming that their affiliated pediatric ophthalmologists were equipped to perform standard myopia assessments, including cycloplegic autorefraction and AL measurements using the Lenstar (Haag Streit), Aladdin (Zeiss), or Myah (Topcon) biometers. Both ophthalmologists and opticians received 6 h of training to ensure standardized adherence to the study protocol, including the procedures for refraction, biometry, and fitting of Myofix spectacles. Training also covered data entry using a secure, encrypted online platform developed by Novar, which was used to record clinical information. Opticians received additional online instructions focused on accurate

centration of the lenses and the selection of appropriate frames to ensure proper positioning of the peripheral treatment zone around the visual axis.

Reference Data

For the virtual control group, data were obtained from 114 children followed with cycloplegic refractions by the Pandemic Study Group during 2018–2019 [22]. In addition, another virtual control group was derived from a U.S.-based randomized clinical trial that publicly reported cycloplegic refraction and biometry data in a comparable sample of children with myopia. The untreated arm in that study served as the control group for evaluating the effect of low-dose atropine [23]. As both control datasets included younger participants, only those aged 7 years or older at baseline were selected for this analysis to match the age distribution of the current study cohort. This resulted in the inclusion

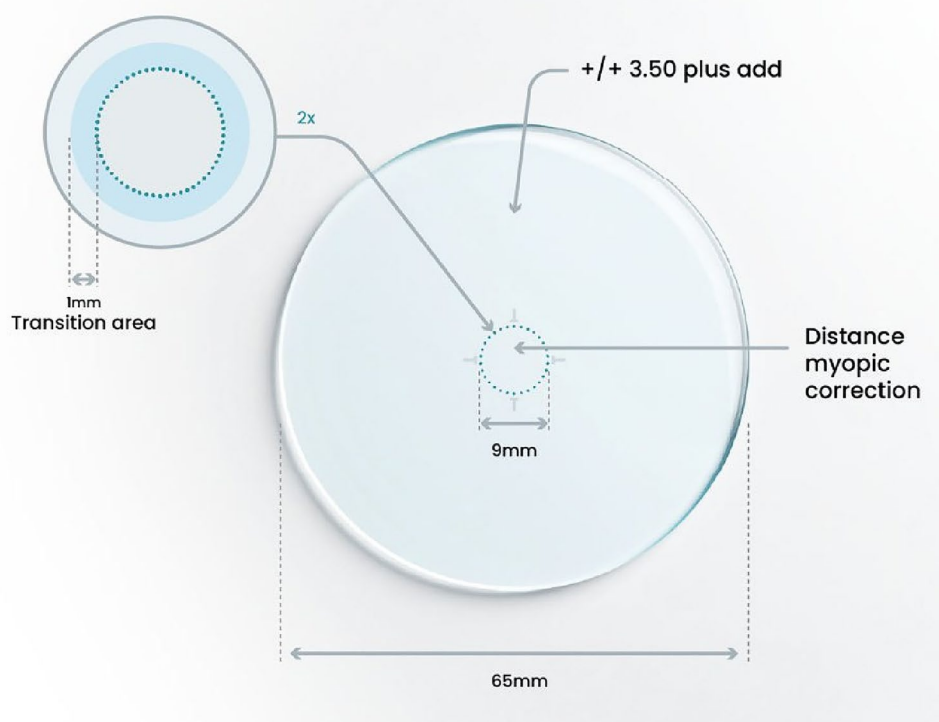


Fig. 1 Myofix design with a 9-mm central zone for distance myopic correction and peripheral add

of 70 children for the Pandemic Study (Argentina) [22] and 41 children from the U.S.-based study [23]. Additionally, AL growth in our study cohort was compared to recently published emmetropic growth curves from age-matched white children [24].

Ethics

The study protocol was approved by the Ethics Committee of the Argentine Society of Ophthalmology and the Government of Buenos Aires City (March 2023; Registration No. 8638). The study was also registered with the ClinicalTrials.gov Identifier Number: NCT07092072. <https://clinicaltrials.gov/study/NCT07092072?cond=myofix&rank=1>

Patients who exhibited a myopia progression of -0.50 D or more within 6 months were excluded from further follow-up. As recommended by the ethics committee, these participants were transitioned to treatment with low-dose atropine. The study was conducted in accordance with the Declaration of Helsinki and its amendments, Good Clinical Practice (GCP) guidelines, and Resolution 1480/11 of the Argentine Ministry of Health. Both parents were verbally informed about the study objectives, and written informed consent was obtained from both parents and children. Participant anonymity was strictly preserved, with all identifying information removed from the dataset prior to statistical analysis.

Statistical Analysis

Continuous variables are presented as mean $\pm$ standard deviation, and categorical variables are reported as absolute frequencies and percentages. The sample size was estimated at 40 participants [21] based on detecting a mean difference of 0.25 D in myopia progression compared with virtual controls, assuming a standard deviation of 0.50 D, an α level of 0.05, and a statistical power of 80%. This calculation resulted in a minimum of 31 subjects required. Considering a potential 20% loss to follow-up, the target sample size was increased to 38–40 participants. The final sample included 36 participants. There

was a strong correlation between SE values of the right and left eyes at baseline ($R=0.875$, $p<0.001$), with no significant difference between them (paired t test, $p=0.085$). The statistical analysis was based on the average change in SE or AL across both eyes following similar methods in a previous atropine trial [25]. This approach was supported by similar correlations between the two eyes observed for AL at baseline and for changes in SE and AL during follow-up (data not shown). Differences in myopia progression (SE and AL) between the study group and virtual control groups were analyzed using Student's t test. To identify predictors of 12-month change in SE and AL, multiple linear regression models were constructed, adjusting for relevant covariates including age, sex, baseline SE, AL, compliance, and parental history of high myopia. To reduce the risk of overfitting due to the relatively small sample size, the number of predictors in each model were limited and progressively simplified in the models across three steps: Model 1 included five predictors: parental history of myopia, age at baseline, sex, mean baseline SE (for the SE model) or mean baseline AL (for the AL model), and treatment compliance at 12 months; Model 2 excluded parental history of myopia for the SE model and mean baseline AL for AL model, retaining four predictors. Model 3 further excluded variables based on statistical insignificance or model fit criteria, leaving three core predictors: mean baseline SE, sex, compliance at 12 months for the SE model, parental history of myopia, age at baseline, and compliance at 12 months for the AL model. A $p<0.05$ was used to determine statistical significance. Statistical analyses were conducted using Microsoft Excel (Microsoft Corp., Redmond, WA, USA), SPSS Statistics version 25 (IBM Corp., Armonk, NY, USA), and R (R Foundation for Statistical Computing, Vienna, Austria) for data visualization.

RESULTS

A total of 47 patients were enrolled between June 2023 and April 2024, with a planned follow-up duration of 1 year. By the 6-month visit, 11 children were lost to follow-up (77.1% retention rate). Of these, four discontinued

their participation due to personal reasons or relocation to another city or country. Among the remaining seven, one child discontinued use of the spectacles for esthetic reasons, specifically dissatisfaction with the frames, and did not return for replacement. The other six were young children with low baseline myopia (-0.50 to -1.00 D), who were not regular spectacle users and did not wear the study spectacles at all. These children showed a myopic progression of -0.50 D over the first 6 months and, in accordance with the Ethics Committee's guidance, were withdrawn from the study. They were prescribed standard single-vision spectacles and initiated low-dose atropine. This subgroup represented 12.5% of non-users at the 6-month follow-up. The flow chart is shown in Fig. 2.

The baseline characteristics of the 36 included children are given in Table 1. Among participants, 5 had mothers with high myopia and 4 had fathers with high myopia. Most children (23/36; 63.9%) attended school for only 4 h per day. Half of the children (18/36, 50.0%) lived in houses with gardens, while the remainder resided in homes without gardens or high-rise buildings. Seven children attended extracurricular tutorial classes (19.4%). The baseline characteristics of the two virtual control groups (Pandemic [22] and US atropine group [23]) were 10.8 ± 2.0 and 10.7 ± 1.4 years of age, and a SE of -2.17 ± 1.38 D and -2.87 ± 1.01 D, respectively.

Daily screen time with tablets or smartphones averaged 2.41 ± 0.79 h per day. Regarding bedtime habits, 17 out of 33 children (51.5%) reported going to bed with their mobile phone, and 13 (39.4%) reported using inverted contrast settings on their devices (dark mode).

The mean change in SE from baseline to 12 months was -0.21 ± 0.30 diopters, and the mean AL change was 0.19 ± 0.13 mm. SE progression was significantly different in participants with good compliance compared with children with poor compliance (Student's *t* test, $p < 0.001$, Fig. 3). In the good compliance group, children had a mean SE progression of -0.12 ± 0.25 D and a mean AL change of 0.17 ± 0.11 mm over 12 months. No significant differences were found in SE progression for sex, family history of high myopia, schooling, type of housing, reading at night with smartphones, age at baseline,

or tutorial classes in the univariate analysis. Children who used inverted contrast settings on electronic devices showed a trend for lower SE progression compared to those using standard contrast settings, although this difference did not reach statistical significance (Student's *t* test, $p = 0.214$; -0.11 D vs. -0.23 D, respectively, see Supplementary Fig. 1). When participants were divided into two age groups (≤ 11 years and ≥ 12 years), no significant difference was found in the proportion of children who reported going to bed with their smartphones (40.0% vs. 69.2%, $\chi^2 = 2.69$, $p = 0.101$). There was also a trend for lower SE progression in children who used spectacles the whole day vs. half a day (Student's *t* test, $p = 0.127$; -0.10 vs. -0.25 D, respectively).

Among the 36 children who completed the 12-month follow-up, there were 11 children classified as having poor compliance with spectacle use. To further explore compliance, we compared questionnaire responses regarding spectacle tolerance with reported compliance levels. Notably, 77.8% of children classified as having poor compliance still reported that they tolerated the lenses well (93.8% of the whole sample tolerated the spectacles well). Overall, 75.4% of children reported no difficulties while walking around or moving their head when reading. When asked about wearing habits, seven children (18.9%) indicated that they did not use the spectacles at home, and eleven (29.7%) reported they were not wearing them outdoors. Reported reasons for non-compliance at the 12-month follow-up ($n = 11$) included esthetical concerns in two female children who switched to their previous frames, lost or breakage of spectacles in two children who felt embarrassed to request a replacement and reverted to use their previous prescription, and two children who independently chose to wear standard contact lenses (not designed for myopia control), using the Myofix spectacles only few hours per day. The remaining cases of poor compliance involved children with low levels of myopia and irregular spectacle use.

Supplementary Figures S2–S4 illustrate the mean changes in SE, AL and AL/corneal curvature over 12 months in children wearing Myofix defocus spectacles compared to a virtual control group from Repka et al. [23] At

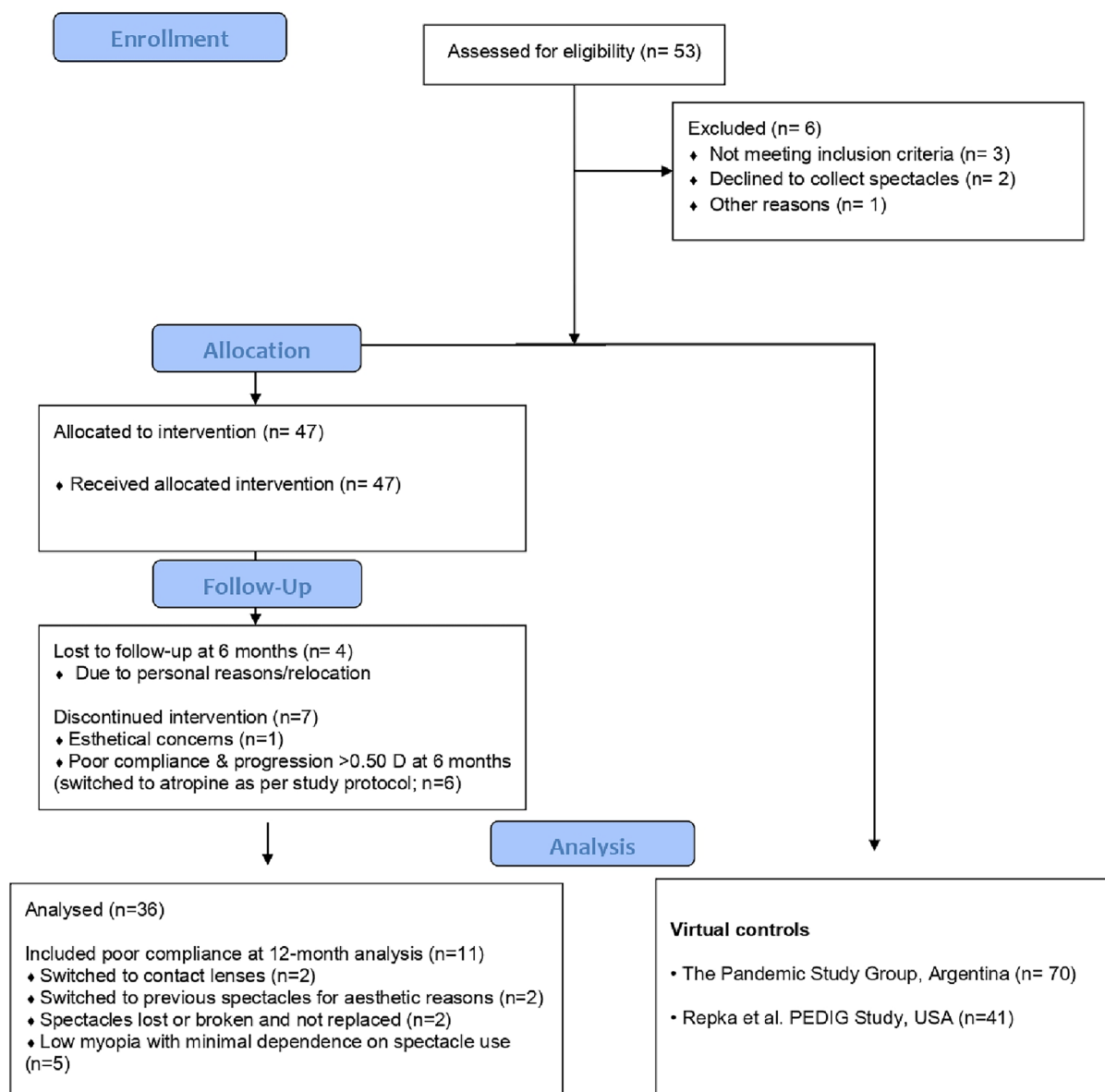


Fig. 2 Flowchart of the Myofix spectacles for the control of myopia progression study

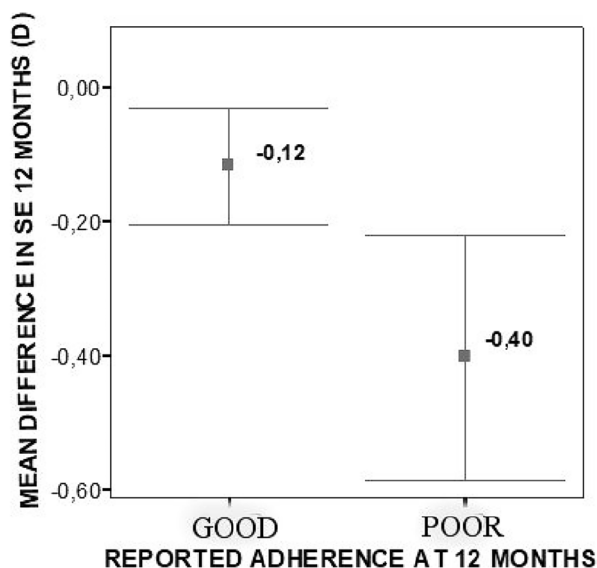
12 months, the mean SE progression in the Myofix group was -0.21 D, substantially lower than the -0.47 D observed in the control group ($p < 0.001$, Fig. S2a). A clear divergence in SE progression emerged after the 6-month mark, with the Myofix group showing consistently slower progression throughout the follow-up period. Similarly, the mean axial elongation in the Myofix group was 0.19 mm at 12 months, compared to 0.26 mm in the US control group ($p < 0.01$,

Fig. S2b). Although the difference in AL progression was less pronounced than that observed for SE, the trend also significantly favored the Myofix group.

Figure 4 shows individual trajectories of SE (diopters) plotted against age (years) for two study groups: the US atropine study control group and in the Myofix-treated group (similar data for the Pandemic Study control group and Myofix-treated group are provided

Table 1 Descriptive statistics of the 36 included participants

Mean age (SD) (years)	10.9 ± 1.9
Sex (female/male; <i>n</i>)	18/18
Mean interval 6 months follow-up (days)	182 ± 30
Mean interval 12 months follow-up (days)	375 ± 33
Mean spherical equivalent at baseline (diopter)	-2.72 ± 1.02
Median spherical equivalent at baseline (diopter)	-2.72
Mean keratometry at baseline (diopter)	43.37 ± 1.08
Mean axial length at baseline (mm)	24.57 ± 0.75
Mean age of first spectacle prescription (years)	7.58 ± 1.86
Time per day spent on homework (h/day)	1.31 ± 0.68
Time per week spent outdoors (h/day)	20.06 ± 6.55

**Fig. 3** Mean spherical equivalent progression in 12 months of participants with good or poor compliance. Whiskers represent the 95% confidence intervals

in Supplementary Figure S5). In the control group (left panel), most children showed a clear trend toward increasing myopia over the

12-month follow-up, with relatively consistent rates of progression across individuals. In contrast, the Myofix-treated group (right panel) demonstrated more varied responses over 12 months. While some children experienced minimal progression, others, particularly those with poor compliance (indicated by dotted lines), exhibited greater myopic shifts. These findings suggest that Myofix lenses may help slow myopia progression, especially when worn consistently.

Figure 5 shows the individual axial growth trajectories of boys and girls compared to recently developed emmetropic axial growth curves for European children. These curves were designed to facilitate comparison of the slopes of axial growth between normal, compensated axial growth, and myopic progression in studies lacking control groups.

The results of the multiple linear regression are shown in Table 2. Across all three models, treatment adherence at 12 months was consistently associated with significant changes in both SE and AL. Poor compliance was linked to a greater AL elongation and a more myopic SE, indicating worse myopia control. Age at baseline showed a negative association with AL change, suggesting that younger age was linked to greater axial elongation. Other variables, including parental history of high myopia, sex, and baseline SE or AL, were not significantly associated with SE or AL changes in any of the models.

DISCUSSION

The Myofix Defocus Study was designed to evaluate the tolerance and effectiveness of a novel design of full-field peripheral defocus spectacles developed in Argentina. These findings show promising outcomes, with good tolerance reported among children under the age of 15 years (an age group known for its great neural plasticity and adaptability when receiving anisometropic or high astigmatic prescriptions in pediatric ophthalmology practice). In the present trial, children with good compliance (whole day users) and a mean age of 11 years showed minimal progression of

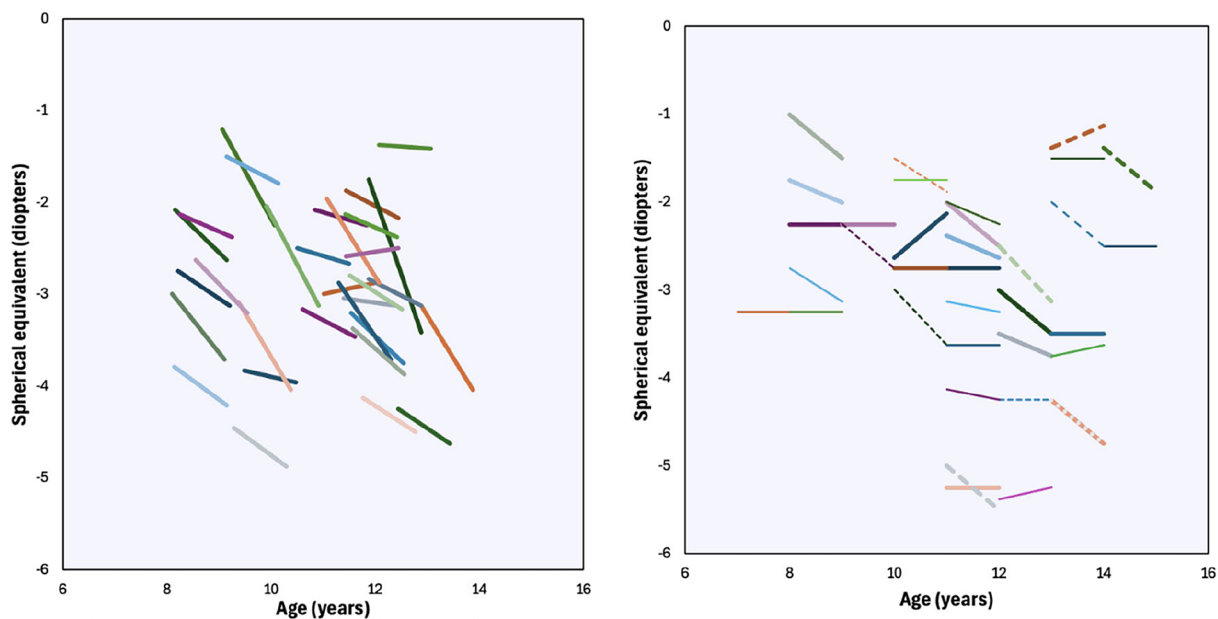


Fig. 4 Individual trajectories of spherical equivalent refractive error (diopters) plotted against age (years) for two study groups. *Left panel:* Control group from the USA atropine study, with each *solid line* representing one partici-

part's refractive change from baseline to 12 months. *Right panel:* Myofix-treated group over 12 months. *Solid lines* represent children with good compliance, while *dotted lines* indicate children with poor compliance

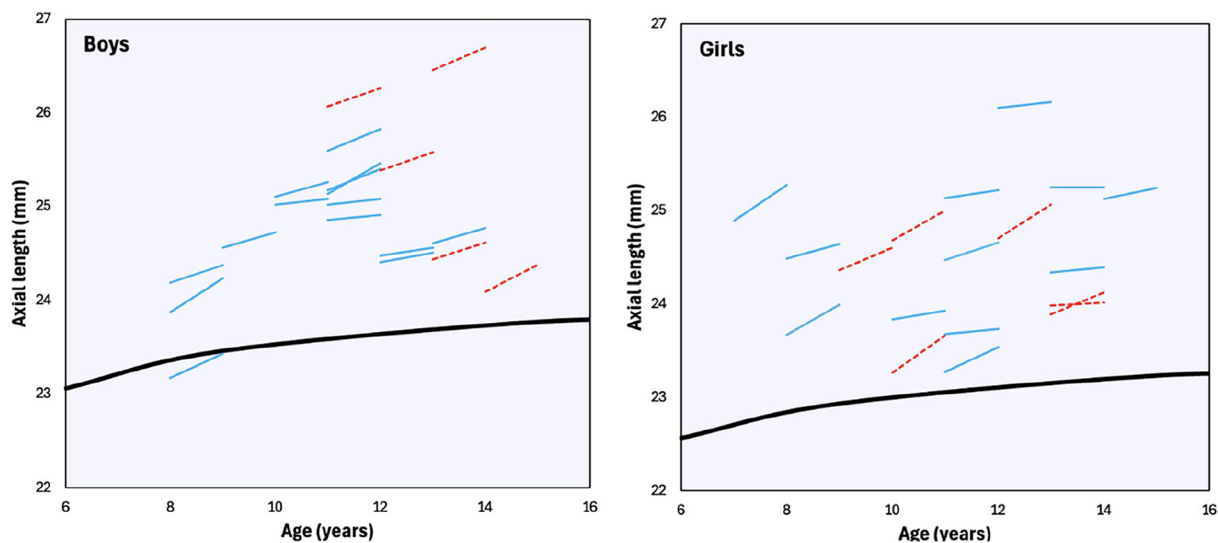


Fig. 5 Individual trajectories of axial length growth (mm) in children using Myofix spectacles, for boys and girls, plotted against age (years). The full line represents the emmetropic compensated normal growth slope [24] for compari-

son with the slopes of the individual trajectories. *Solid lines* represent children with good compliance, while *dotted lines* indicate children with poor compliance

Table 2 Regression coefficients (B), 95% confidence intervals, and *p* values for predictors of 12-month change in spherical equivalent (SE) and axial length (AL) across three linear regression models

Variables	Mean difference SE (D) at 12 months			Mean difference AL (mm) at 12 months				
	Coef. (B)	95% CI Lower	95% CI Upper	p value	Coef. (B)	95% CI Lower	95% CI Upper	p value
Model 1								
Parental HM	0.023	-0.167	0.213	0.804	-0.026	-0.101	0.051	0.498
Age at baseline	0.017	-0.029	0.063	0.457	-0.030	-0.048	-0.011	0.003
Mean baseline SE	-0.033	-0.109	0.042	0.373	-	-	-	-
Mean baseline AL	-	-	-	-	-0.013	-0.061	0.043	0.576
Sex	0.061	-0.100	0.222	0.444	0.020	-0.047	0.087	0.897
Compliance at 12 months	-0.295	-0.481	-0.109	0.003	0.123	0.049	0.197	0.002
Model 2								
Parental HM	-	-	-	-	-0.030	-0.103	0.043	0.405
Age at baseline	0.017	-0.028	0.062	0.444	-0.031	-0.049	-0.013	0.001
Mean baseline SE	-0.035	-0.108	0.038	0.335	-	-	-	-
Sex	0.062	-0.096	0.220	0.429	0.014	-0.049	0.077	0.652
Compliance at 12 months	-0.297	-0.479	-0.115	0.002	0.123	0.050	0.195	0.002
Model 3								
Parental HM	-	-	-	-	-0.029	-0.101	0.043	0.413
Age at baseline	-	-	-	-	-0.031	-0.048	-0.013	0.001
Mean baseline SE	-0.038	-0.110	0.033	0.285	-	-	-	-

Table 2 continued

Variables	Mean difference SE (D) at 12 months			Mean difference AL (mm) at 12 months		
	Coef. (B)	95% CI Lower	95% CI Upper	Coef. (B)	95% CI Lower	95% CI Upper
Sex	0.064	- 0.093	0.221	-	-	-
Compliance at 12 months	- 0.274	- 0.445	- 0.103	0.122	0.050	0.193

Bold values indicate the statistical significance ($p < 0.05$)

- 0.12 D over 12 months. These findings highlight the critical role of adherence in influencing the efficacy of the myopia control intervention over 12 months. As shown in Table 3, when compared with other published studies, this progression rate ranks among the lowest reported in similarly aged cohorts over 1 year.

Comparison with Previous Studies and Virtual Control Data

Conducting randomized controlled trials with untreated control groups in myopia research has become increasingly challenging due to ethical concerns and loss of follow-up [26]. As low-dose atropine (e.g., 0.01%) is now widely recognized and endorsed by clinical guidelines as a first-line intervention, withholding treatment in control groups is no longer considered acceptable in many settings [16, 17]. Consequently, studies employing natural history control groups often experience high dropout rates, as participants or their guardians seek available therapeutic options to slow myopia progression at nearby ophthalmology centers. This trend reflects an evolving standard of care and highlights the need for alternative control strategies in future research, such as the use of virtual control groups and normative emmetropic growth curves [24, 27, 28]. For comparison, two virtual control groups were used instead. First, a pre-pandemic cohort of 70 Argentine children, with a mean age of 11 years and myopia less than - 4.00 D, which were followed with cycloplegic refractions between 2018 and 2019. In this group, the mean one-year progression was -0.48 ± 0.52 D [22]. Moreover, a well-characterized control group that received no treatment from a U.S.-based randomized clinical trial on atropine treatment in similarly-aged children [23] was used as it provided publicly available data on cycloplegic spherical equivalent and biometric changes over 1 year. These two cohorts represent some of the best-documented examples of untreated myopia progression and were thus selected for comparison. The present study compares its outcomes against one of these groups, showing the change in SE over

Table 3 Change in spherical equivalent (SE) and axial length (AL) at 12 months in different studies and virtual control groups

	First author	Mean baseline age	Baseline SER	Change in SE 12 months	Baseline AL	Change in AL 12 months
<i>Studies with treated groups</i>						
Myofix trial (only good compliance group)	Iribarren	11.0	− 2.86	− 0.12	24.64	0.16
Dot spectacles (USA) treated group [29]	Rappon	8.1	− 2.00	− 0.14	24.09	0.15
Indian Atom Study (INDIA) (Atropine Group) [30]	Saxena	10.8	− 3.50	− 0.16	–	0.22
Myosmart trial treated group (China) [31]	Lam	10.2	− 2.97	− 0.17	24.60	0.11
Myofix trial of all included participants (Argentina)	Iribarren	11.0	− 2.86	− 0.21	24.64	0.19
Myocare Treated Group (Spain) [32]	Alvarez	10.0	− 2.17	− 0.20	24.34	0.09
Stellest Trial Treated Group (China) [33]	Bao	8.7	− 2.70	− 0.27	24.76	0.13
Lamp Study Atropina 0.05% (China) [25]	Yam	8.5	− 3.98	− 0.27	24.85	0.20
Iranian Atropine Study Treated Group (Iran) [30]	Nangia	9.6	− 4.32	− 0.31	–	0.29
Mycon Lenses Treated Group (Russia) [34]	Tarutta	–	–	− 0.33	–	–
Shamir Lenses Treated Group (Israel) [35]	Cohen	9.9	− 2.53	− 0.48	24.27	0.21
<i>Studies with control groups</i>						
Myocare Control Group (Spain) [32]	Alvarez	10.0	− 1.90	− 0.41	24.17	0.23
Atropine study control group (USA) [23]	Repka	10.7	− 2.87	− 0.47	24.57	0.26
Pandemia control group (Argentina) [22]	Picotti	9.5	− 2.17	− 0.48	–	–
Mycon Control Group (Russia) [34]	Tarutta	–	–	− 0.53	–	–
Dot Lenses Control Group (USA) [29]	Rappon	8.1	− 1.95	− 0.54	24.03	0.30
Myosmart Lenses Control Group (China) [31]	Lam	10.0	− 2.76	− 0.55	24.70	0.32
Myocare Control Group (China) [36]	Liu	8.5	− 2.67	− 0.56	24.65	0.26

Table 3 continued

	First author	Mean baseline age	Baseline SER	Change in SE 12 months	Baseline AL	Change in AL 12 months
Lamp Study Control Group (China) [25]	Yam	8.4	− 3.85	− 0.59	24.82	0.36
Shamir Lenses Control Group (Israel) [35]	Cohen	9.9	− 2.74	− 0.64	24.39	0.32
Stellest Controls (China) [33]	Bao	8.7	− 2.46	− 0.81	24.77	0.36
Myovison Controls (Japan) [37]	Kanda	9.8	− 3.36	− 0.96	24.70	0.39

12 months between our treated cohort and the U.S. control group. The second control group exhibited similar, but slightly higher, SE progression at 12 months, suggesting that our results would have appeared more favorable if that group had been used for comparison.

Table 3 summarizes the outcomes of several comparable studies conducted in Asia, allowing for comparison of age ranges and progression in both SE and AL. Our study was intentionally benchmarked against trials with the lowest reported progression rates in untreated control groups of similarly aged children. Despite this conservative comparison, the Myofix lens demonstrated a 75% reduction in SE change (− 0.35 D less progression) and a 37% reduction in axial elongation (98 μ m less elongation) among children with good compliance, relative to the natural history control group reported by Repka et al. [23]. Notably, the Myofix lens differs from other myopia control spectacles in its simplicity of design and manufacturing. Unlike lenses that require pre-molded treatment zones or proprietary blocks, the Myofix design can be digitally carved using standard equipment and locally sourced lens blanks in any digital lab. This makes it a scalable and accessible option for widespread implementation across countries without the need for complex imports.

The myopia progression rate observed in the Argentine Pandemic Study cohort (− 0.48 D per year) [22] closely aligns with that reported in the control group of the U.S.-based Repka trial (− 0.47 D) [23], which served as a benchmark for comparison in the present study. These

progression rates, observed in children aged 10–11 years, are consistent with the values reported in International Myopia Institute (IMI) publications for similarly-aged groups [14, 38]. Notably, this rate of progression is lower than that typically observed in East Asian populations, which may be partly explained by higher levels of outdoor activity among Argentine children. Previous research conducted in the same region has shown that children spend, on average, more than 20 h per week outdoors, similar to the children included in the present study [39]. However, in our current regression analysis, no significant association was found between individual differences in outdoor exposure and the rate of myopia progression within the study group.

Additional Factors Potentially Influencing Treatment Outcomes

Interestingly, none of the commonly recognized risk factors were significantly associated with myopia progression in this treatment group. In this prospective study, myopia progression was studied in relation to the habit of going to bed with a smartphone in darkness and the use of inverted contrast settings on electronic devices. While recent research has indicated that reading with defocus spectacles in dark environments may fail to trigger a choroidal thickening response [40], a signal associated with slowed eye growth, the lack of a clear effect on progression in our study underscores the need for further investigation in this area. Notably, a small

but non-significant trend toward reduced myopia progression was observed in children who used inverted contrast. This preliminary finding supports the rationale for future clinical trials investigating the impact of visual contrast polarity [41] or red-in-focus strategies [42, 43], which have already shown promising outcomes inducing short-term choroidal thickening in experimental settings over the past several years [44, 45].

When considering compliance and potential adverse effects of myopia control strategies, spectacle-based interventions with peripheral defocus zones offer a non-invasive alternative that avoids the long-term ocular exposure to pharmacological agents, such as atropine, which may be required daily over many years. In the present study, treatment was limited to children aged 7 and older, with myopia onset after age 6 years, to exclude those with very early onset who are at highest risk for rapid progression to high myopia. Despite this criterion, the mean age of first spectacle prescription was 7 years, suggesting that the cohort may still include many children with a predisposition to rapid progression. It remains unclear whether genetically driven early-onset myopia (onset before 6 years) is responsive to environmental interventions such as increased outdoor exposure. In this sense, outdoor exposure was notably high in our sample, averaging 20 h per week. Children with onset at 3–5 years likely represent genetically determined cases who may require more intensive or combined treatment strategies. Several studies in East Asian populations have included children with early-onset myopia and reported less favorable outcomes in these subgroups, in contrast to the more encouraging results observed in our present study.

In both the present and previous studies, myopia control appeared more effective when measured by changes in SE than by changes in AL. This relative stability in refractive error, despite continued axial elongation, suggests a possible compensatory mechanism involving lens power loss, a phenomenon that remains largely unexplored. The underlying biological basis for how myopia control strategies, such as defocus spectacles or low-dose atropine, might influence crystalline lens power is not well

understood. To date, one study from India [46] has reported increased lens power loss in atropine-treated children, which may have partially offset axial elongation and contributed to refractive stability in that group. It is possible that defocus lenses and atropine exert their effects by modulating retinal signaling pathways that regulate ocular growth [44]. It is well established that myopic eyes tend to have lower crystalline lens power compared to emmetropic eyes [47], and that progressing myopic eyes often exhibit an accelerated loss of lens power at myopia onset [48]. This reduction in power has been linked to both increased zonular tension and internal remodeling of the lens. Axial lens thickness during growth is maintained by a delicate balance between the addition of new fibers at the surface and the compaction of older fibers in the deeper layers [47]. These structural changes can influence the gradient index profile of the lens. Specifically, a slower-growing lens undergoing constant age-related compaction may develop a steeper gradient index, as has been predicted in optical models. [47]

A recent *in vivo* study assessing the elastic modulus of the crystalline lens in myopic and emmetropic eyes confirmed that myopic lenses exhibit a steeper gradient of increasing stiffness [49]. This suggests that the growing, compacting lens in myopic eyes may possess a form of biomechanical inertia that limits its ability to adapt to changes in axial elongation. Consequently, increased lens power loss could partially compensate for axial elongation, particularly during the first year of treatment with interventions such as defocus spectacles or low-dose atropine. This may be the reason why some studies have reported better outcomes in the first year. Future myopia control studies should consider including calculations of lens power loss as part of their evaluation metrics. Unfortunately, this was not possible in the present study because the biometers used did not measure anterior chamber depth or lens thickness.

Recent evidence suggests that Defocus Incorporated Multiple Segments (DIMS) spectacles reduce myopia progression by decreasing the detection of high spatial frequency contrast in the perifoveal region [50–52]. Similarly, studies have shown that both positive [53] and negative

defocus lenslets [31] in specially designed spectacles can slow ocular growth, likely through a shared mechanism involving contrast modulation rather than the simple direction of defocus [50]. This shifts the prevailing theory away from the idea that positive defocus alone mimics the effects of plus lenses in animal models, and toward the notion that reduced contrast sensitivity of high frequencies may be key to signaling growth arrest [54]. By limiting high-frequency input, these lenses may leave the perifoveal zone more responsive to low-frequency cues, which are thought to be critical for defocus detection and ocular growth regulation. Interestingly, the Myofix lens design appears to incorporate both mechanisms: it reduces high-frequency contrast through peripheral blur and introduces a low-level full-field positive defocus, with a 9-mm central zone dedicated to clear distance correction, as if it were a positive lens with a central hole in front of the eye [55–57].

Limitations

This study has several important limitations. First, the absence of a randomized control group limits the strength of causal inferences. However, this study is among the first to adopt the use of virtual control groups in regions where ethical guidelines no longer permit untreated children to follow the natural course of myopia progression. In settings where short-term observational control periods are still permitted, future trials could consider randomization. Notably, the Myofix lens has an aesthetically conventional appearance because the peripheral positive add carving produces less myopic peripheral correction and a thinner lens structure with less frame margin prismatic effects, making it difficult to distinguish from standard spectacles, an advantage in minimizing potential bias in a masked trial. To support lens identification in clinical settings, simple verification methods were developed, for instance, viewing the lens against an Amsler grid or showing the shadow produced when a beam of light is directed towards the spectacle, which clearly reveal the distinct distance and peripheral treatment zones. Future research should aim to evaluate

the non-inferiority of Myofix lenses in comparison with established myopia control interventions such as atropine or orthokeratology.

Another limitation of this study is the lack of investigator masking; researchers knew that participants were using a treatment lens. Nevertheless, the use of objective outcome measures, cycloplegic autorefraction, and optical biometry helps to mitigate this potential bias. Additionally, the marked difference in progression between children with good versus poor compliance further reinforces the likely treatment efficacy of the Myofix lenses. Further limitations are a small sample size with drop-outs and the inclusion of several ophthalmological centers with different biometers. However, each participant was measured with the same biometer at different time points.

The sample size was determined based on a power calculation conducted before recruitment, which indicated that 31 participants would be sufficient to detect a statistically significant difference in myopia progression between the treated and control groups. The main reason for the small sample size in this study is that Argentina has one of the lowest prevalences of myopia worldwide, making it challenging for eye care practitioners to recruit children with early-onset myopia. This subgroup, which is more likely to develop high myopia in adulthood, represents less than 2% of the pediatric population. For this reason, multiple centers were involved, each contributing a small number of participants, which inevitably reduced the overall statistical power of the study.

Another important limitation is the retrospective registration of the study in an international clinical trials database. Although the registration was completed retrospectively, ethical approval had been obtained from the Ethics Committee of the Argentine Society of Ophthalmology and the Government of Buenos Aires City prior to the start of recruitment. Therefore, all study procedures were conducted in accordance with approved ethical standards.

In our setting, the average annual myopia progression among 10-year-old children is approximately -0.48 D, meaning that a

progression of -0.50 D over 6 months would represent roughly twice the expected rate. Such rapid progressors are uncommon in our clinical practice, therefore, we believe this criterion did not introduce bias, as the enrolled sample accurately reflects the characteristics of the local pediatric myopic population.

CONCLUSIONS

In conclusion, Myofix lenses demonstrated good tolerability and effectiveness in controlling myopia progression in white children over 1 year. Among those with good compliance, most were able to continue using the same spectacles throughout the study duration. Importantly, non-compliance was not attributed to the spectacle design, indicating that the lens was generally well accepted by the pediatric population.

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are available at a reasonable request by contacting the corresponding author.

Declarations

Conflict of Interest. Abel Szeps, Martin de Tomas, Gabriel Martín and Rafael Iribarren are consultants of NOVAR and OPULENS. Jos Rozema is a consultant for Cooper Vision. Carla Lanca reports a relationship with Eyerising that includes consulting and advisory.

Ethical Approval. The study protocol was approved by the Ethics Committee of the Argentine Society of Ophthalmology and the Government of Buenos Aires City (March 2023; Registration No. 8638). The study was also registered with the ClinicalTrials.gov Identifier Number: NCT07092072. <https://clinicaltrials.gov/study/NCT07092072?cond=myofix&rank=1>. Patients who exhibited a myopia progression of -0.50 D or more within 6 months were excluded from further follow-up. As recommended by the ethics committee, these participants were transitioned to treatment with low-dose atropine. The study was conducted in accordance with the Declaration of Helsinki and its amendments, Good Clinical Practice (GCP) guidelines, and Resolution 1480/11 of the Argentine Ministry of Health. Both parents were verbally informed about the study objectives, and written informed consent was obtained from both parents and children. Participant anonymity was strictly preserved, with all identifying information removed from the dataset prior to statistical analysis.

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REFERENCES

1. Rudnicka AR, Kapetanakis VV, Wathern AK, Logan NS, Gilmartin B, Whincup PH, et al. Global variations and time trends in the prevalence of childhood myopia, a systematic review and quantitative meta-analysis: implications for aetiology and early prevention. *Br J Ophthalmol*. 2016;100:882–90.
2. Morgan I, Rose K. How genetic is school myopia? *Prog Retin Eye Res*. 2005;24:1–38.
3. Morgan IG, Rose KA. Myopia and international educational performance. *Ophthalmic Physiol Opt*. 2013;33:329–38.
4. Saw SM, Wu HM, Seet B, Wong TY, Yap E, Chia KS, et al. Academic achievement, close up work parameters, and myopia in Singapore military conscripts. *Br J Ophthalmol*. 2001;85:855–60.
5. Holden BA, Fricke TR, Wilson DA, Jong M, Naidoo KS, Sankaridurg P, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. *Ophthalmology*. 2016;123:1036–42.
6. Sankaridurg P, Tahhan N, Kandel H, Naduvilath T, Zou H, Frick KD, et al. IMI impact of myopia. *Invest Ophthalmol Vis Sci*. 2021;62:2.
7. Pan W, Saw SM, Wong TY, Morgan I, Yang Z, Lan W. Prevalence and temporal trends in myopia and high myopia children in China: a systematic review and meta-analysis with projections from 2020 to 2050. *Lancet Reg Health West Pac*. 2025;55:101484.
8. Sanchez VIR, Latino SG, Torres VE, Gramajo AL, Artal ME, Yadarola MB, et al. Prevalence of refractive errors in Villa Maria, Córdoba, Argentina. *Eye Sci*. 2016;31:68–77.
9. Schellini SA, Durkin SR, Hoyama E, Hirai F, Cordoero R, Casson RJ, et al. Prevalence of refractive errors in a Brazilian population: the Botucatu eye study. *Ophthalmic Epidemiol*. 2009;16:90–7.
10. Franco PJ, Suwezda A, Schlottmann P, Destefanis MP, Rosenstein RE, Iribarren R, et al. Analysis of

- visual disability in Buenos Aires, Argentina. Pathologic myopia is the leading cause in working age. *Medicina (Kaunas)*. 2021;81:735–41.
11. Ohno-Matsui K, Wu PC, Yamashiro K, Vutipongsatorn K, Fang Y, Cheung CMG, et al. IMI pathologic myopia. *Invest Ophthalmol Vis Sci*. 2021;62:5.
 12. Jones D, Luensmann D. The prevalence and impact of high myopia. *Eye Contact Lens*. 2012;38:188–96.
 13. Cortinez MF, Chiappe JP, Iribarren R. Prevalence of refractive errors in a population of office-workers in Buenos Aires, Argentina. *Ophthalmic Epidemiol*. 2008;15:10–6.
 14. Wildsoet CF, Chia A, Cho P, Guggenheim JA, Polling JR, Read S, et al. IMI - Interventions Myopia Institute: interventions for controlling myopia onset and progression report. *Invest Ophthalmol Vis Sci*. 2019;60:M106–31.
 15. Galan MM SA, Fernandez Irigaray L, Rodriguez G, Aguirre R, Kotlik C, Iribarren R. Myopia Consensus. *Oftalmologia Clinica y Experimental* 2022; 15. <https://revistaoce.com/index.php/revista/article/view/160/247>.
 16. Kesarwani SS. Consensus statement and guidelines for use of dilute atropine sulphate in myopia control. *Indian J Ophthalmol*. 2019;67:461–3.
 17. WSPOS. Myopia Consensus Statement 2023. 2023.
 18. Lanca C, Pan CW, Grzybowski A. Anti-myopia Spectacles: The Standard of Care in the Future? *Ame J Ophthalmol*. 2024;263:xi–xiii.
 19. Wolffsohn JS, Flitcroft DI, Gifford KL, Jong M, Jones L, Klaver CCW, et al. IMI - myopia control reports overview and introduction. *Invest Ophthalmol Vis Sci*. 2019;60:M1–19.
 20. Charman WN, Radhakrishnan H. Peripheral refraction and the development of refractive error: a review. *Ophthalmic Physiol Opt*. 2010;30:321–38.
 21. Szeps AKC, Fernández Irigaray L, Saracco G, De Tomas M, Martin G, Iribarren R. Baseline data in the study on the tolerance and efficacy of peripheral defocus spectacles for the control of myopia progression in Argentina (Myofix Defocus Study). *Oftalmol Clin Exp*. 2024;17:352–8.
 22. Picotti CSV, Fernandez Irigaray L, Morgan IG, Iribarren R. Myopia Progression in Children during COVID-19 Home Confinement in Argentina. *Oftalmologia Clinica y Experimental* 2021; 14: 156–61. <https://revistaoce.com/index.php/revista/article/view/73/07>.
 23. Repka MX, Weise KK, Chandler DL, Wu R, Melia BM, Manny RE, et al. Low-dose 0.01% atropine eye drops vs placebo for myopia control: a randomized clinical trial. *JAMA Ophthalmol*. 2023;141:756–65.
 24. Naduvilath T, He X, Saunders K, Demir P, Leighton R, McCullough S, et al. Age, gender and regional/ethnic variations in emmetropic axial growth rate. *Ophthalmic Physiol Opt*. 2025. <https://doi.org/10.1111/opo.13545>.
 25. Yam JC, Jiang Y, Tang SM, Law AKP, Chan JJ, Wong E, 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.
 26. Bullimore MA, Brennan NA. Myopia: an ounce of prevention is worth a pound of cure. *Ophthalmic Physiol Opt*. 2023;43:116–21.
 27. Chamberlain P, Lazon de la Jara P, Arumugam B, Bullimore MA. Axial length targets for myopia control. *Ophthalmic Physiol Opt*. 2021;41:523–31.
 28. Bullimore MA, Brennan NA, Flitcroft DI. The future of clinical trials of myopia control. *Ophthalmic Physiol Opt*. 2023;43:525–33.
 29. Rappon J, Chung C, Young G, Hunt C, Neitz J, Neitz M, et al. Control of myopia using diffusion optics spectacle lenses: 12-month results of a randomised controlled, efficacy and safety study (CYPRESS). *Br J Ophthalmol*. 2022. <https://doi.org/10.1136/bjo-2021-321005>.
 30. Saxena R, Dhiman R, Gupta V, Kumar P, Matalia J, Roy L, et al. Atropine for the treatment of childhood myopia in India: multicentric randomized trial. *Ophthalmology*. 2021;128:1367–9.
 31. Lam CSY, Tang WC, Tse DY, Lee RPK, Chun RKM, Hasegawa K, 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.
 32. Alvarez-Peregrina C, Sanchez-Tena MA, Martinez-Perez C, Villa-Collar C, Ohlendorf A. Clinical evaluation of MyoCare in Europe (CEME): study protocol for a prospective, multicenter, randomized, double-blinded, and controlled clinical trial. *Trials*. 2023;24:674.
 33. Bao J, Yang A, Huang Y, Li X, Pan Y, Ding C, Lim EW, Zheng J, Spiegel DP, Drobe B, Lu F, Chen H. One-year myopia control efficacy of spectacle lenses with aspherical lenslets. *Br J Ophthalmol*. 2021;106(8):1171–6. <https://doi.org/10.1136/bjophthalmol-2020-318367>

34. Tarutta EP, Proskurina OV, Tarasova NA, Milash SV, Markosyan GA [Long-term results of peripheral defocus spectacle lens correction in children with progressive myopia]. *Vestn Oftalmol.* 2019;135:46–53.
35. Yuval C, Oztzem C, Laura BS, Shirel R, Dana GN, Atalia W, et al. Evaluating the effect of a myopia control spectacle lens among children in Israel: 12-month results. *Am J Ophthalmol.* 2024;257:103–12.
36. Liu X, Wang P, Xie Z, Sun M, Chen M, Wang J, et al. One-year myopia control efficacy of cylindrical annular refractive element spectacle lenses. *Acta Ophthalmol.* 2023;101:651–7.
37. Kanda H, Oshika T, Hiraoka T, Hasebe S, Ohno-Matsui K, Ishiko S, et al. Effect of spectacle lenses designed to reduce relative peripheral hyperopia on myopia progression in Japanese children: a 2-year multicenter randomized controlled trial. *Jpn J Ophthalmol.* 2018;62:537–43.
38. Wolffsohn JS, Kollbaum PS, Berntsen DA, Atchison DA, Benavente A, Bradley A, et al. IMI - Clinical myopia control trials and instrumentation report. *Invest Ophthalmol Vis Sci.* 2019;60:M132–60.
39. Fernandez Irigaray LBJ, Szeps A, Albertazzi R, Cortinez F, Lanca C, Iribarren R. Children's bedroom illumination while reading at night. *Oftalmol Clin Exp.* 2024;17:e516–22.
40. Szeps A, Dankert S, Saracco G, Iribarren R. A pilot study of axial length changes associated with myopia control spectacles in subjects reading under mesopic conditions. *J AAPOS.* 2024. <https://doi.org/10.1016/j.jaapos.2024.103857>.
41. Swiatczak B, Schaeffel F. Transient eye shortening during reading text with inverted contrast: effects of refractive error and letter size. *Transl Vis Sci Technol.* 2022;11:17.
42. Swiatczak B, Schaeffel F. Myopia: why the retina stops inhibiting eye growth. *Sci Rep.* 2022;12:21704.
43. Swiatczak B. Chromatic light therapy for inhibiting myopia progression: human studies. *Klin Monatsbl Augenheilkd.* 2024;241:1126–8.
44. Schaeffel F, Swiatczak B. Mechanisms of emmetropization and what might go wrong in myopia. *Vis Res.* 2024;220:108402.
45. Ingrassia L, Swiatczak B, Schaeffel F. Two different visual stimuli that cause axial eye shortening have no additive effect. *Vis Res.* 2024;224:108485.
46. Saxena R, Gupta V, Dhiman R, Phuljhele S, Kumar P, Sharma N, et al. Effect of low-dose atropine (0.01%) on crystalline lens power among school-aged children with progressive myopia. *Ophthalmic Physiol Opt.* 2023. <https://doi.org/10.1111/opo.13192>.
47. Rozema J, Dankert S, Iribarren R. Emmetropization and nonmyopic eye growth. *Surv Ophthalmol.* 2023;68:759–83.
48. Xiong S, He X, Sankaridurg P, Zhu J, Wang J, Zhang B, et al. Accelerated loss of crystalline lens power initiating from emmetropia among young school children: a 2-year longitudinal study. *Acta Ophthalmol.* 2022;100:e968–76.
49. Ma Y, Cao J, Yu Y, Fukuyama T, Bao Y, Ding X, et al. A Brillouin microscopy analysis of the crystalline lenses of Chinese adults with myopia. *Graefes Arch Clin Exp Ophthalmol.* 2024;262:3243–52.
50. Gawne TJ, Khanal S, Norton TT. An alternative mechanism for the anti-myopia effectiveness of diffusion optics technology (DOT) lenses. *Transl Vis Sci Technol.* 2025;14:15.
51. Swiatczak B, Scholl HPN, Schaeffel F. Retinal, “sweet spot” for myopia treatment. *Sci Rep.* 2024;14:26773.
52. Guggenheim JA, Terry L. Mechanism of optical treatments for myopia: are lenslets joining the DOTs? *Ophthalmic Physiol Opt.* 2025;45:337–9.
53. Su B, Cho P, Vincent SJ, Zheng J, Chen J, Ye C, et al. Novel lenslet-ARray-integrated spectacle lenses for myopia control: a 1-year randomized, double-masked, controlled trial. *Ophthalmology.* 2024;131:1389–97.
54. Neitz J, Neitz M. The predictive and explanatory power of the contrast theory of myopia. *Transl Vis Sci Technol.* 2025;14:11.
55. Chu CH, Deng L, Kee CS. Effects of hemiretinal form deprivation on central refractive development and posterior eye shape in chicks. *Vis Res.* 2012;55:24–31.
56. Smith EL 3rd, Hung LF, Huang J. Relative peripheral hyperopic defocus alters central refractive development in infant monkeys. *Vis Res.* 2009;49:2386–92.
57. Schippert R, Schaeffel F. Peripheral defocus does not necessarily affect central refractive development. *Vis Res.* 2006;46:3935–40.