

# Myopi-X lenses vs. low-dose atropine in myopia control: a Turkish retrospective study

Study design: retrospective observational study

Nilay Akagun<sup>1\*</sup> and Ugur Emrah Altiparmak<sup>1</sup>

## Abstract

**Background** The global prevalence of myopia is rising rapidly, with projections indicating that by 2050, half of the world's population will be affected. High myopia is associated with an increased risk of sight-threatening complications, contributing to a substantial public health burden. Atropine 0.01% has been widely used for myopia control in non-Asian populations, supported by evidence demonstrating its efficacy. Myopi-X<sup>®</sup> lenses, designed to induce myopic defocus, represent an optical alternative to pharmacological intervention. Given that atropine requires monthly preparation, long-term adherence, and may cause mild side effects, (Myopi-X<sup>®</sup> Novax<sup>®</sup>) lenses offer a non-pharmacological option that may be preferable for some patients. This study compares the effectiveness of these two treatment strategies in comparison with single vision lenses to provide further insights into their role in myopia management.

**Methods** This retrospective observational study was conducted at Acıbadem Hospital, Ankara, between September 2022 and September 2023. A total of 128 patients aged 5 to 16 years with myopia were included and divided into three groups: peripheral progressive addition lenses (Myopi-X<sup>®</sup> Novax<sup>®</sup>), atropine 0.01%, and single vision lenses. Baseline characteristics, including age, gender, and axial length, were recorded. Cycloplegic autorefraction and axial length measurements were performed, and statistical analyses were conducted to assess changes in spherical equivalent refraction and axial length over 12 months. Additionally, the potential effects of baseline axial length, gender, and age group on spherical equivalent progression and axial length elongation were evaluated.

**Results** Significant differences were observed among the treatment groups in changes in spherical equivalent refraction and axial length (p < 0.001). Both the Myopi-X<sup>®</sup> lenses and atropine 0.01% groups exhibited significantly less myopia progression compared to the single vision lenses group (p < 0.001 for both). However, no significant difference was observed between the Myopi-X<sup>®</sup> lenses and atropine 0.01% groups at 12 months (p = 0.79), and axial length changes remained comparable between these two groups (p = 0.76). Regarding potential confounding factors, age had a significant effect on spherical equivalent refraction progression, with older children experiencing less myopic progression (p = 0.02), whereas no significant effect was observed on axial length change (p = 0.11). Gender was not

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significantly associated with changes in spherical equivalent (p = 0.21) or axial length (p = 0.32). Similarly, baseline axial length showed no significant association with changes in spherical equivalent (p = 0.17) or axial length (p = 0.36).

**Conclusion** Both Myopi-X<sup>®</sup> lenses and atropine 0.01% effectively slowed myopia progression over 12 months compared to single vision lenses. Spherical equivalent progression and axial length elongation were comparable between these two treatment groups. Gender and baseline axial length did not significantly affect the outcomes, whereas older children exhibited less myopic progression in terms of spherical equivalent change. This study aimed to compare the clinical effectiveness of these two treatment strategies. Further studies with longer follow-up periods are required to evaluate the long-term sustainability of these effects.

Keywords Myopia management, Myopia, Myopia control, Myopi-X lenses, Low dose atropine

## Introduction

The prevalence of myopia is increasing worldwide, and it is estimated that by 2050, half of the world's population will be myopic [1]. Myopia, particularly high myopia, is associated with sight-threatening complications such as early cataract, glaucoma, retinal detachment, and subretinal neovascularization [2]. Therefore, it creates a longterm burden on public health and economies [3].

Current main approaches for myopia control include atropine eye drops of varying concentrations, orthokeratology, dual-focus contact lenses, multifocal contact lenses, and myopia control spectacle lenses [4]. Atropine eye drops have been widely used to reduce the progression of myopia. The anti-myopic effect of atropine is thought to involve a non-accommodative mechanism, bypassing the lens and ciliary body to act on receptors in the sclera, thereby inhibiting cell proliferation in human scleral fibroblasts [5, 6].

Early myopia control spectacle lenses included executive bifocal spectacle lenses and progressive addition spectacle lenses (PALs) [7, 8]. These first-generation lenses, with continuous power profiles, found limited success but spurred significant research in this area. New spectacle lens designs for myopia control now incorporate lenslet, segment, or diffusion technology [9–11].

It is well-known that optical interventions designed to correct myopia should consider the focal state of both the central and peripheral retina. In this regard, it has been suggested that it may be possible to slow the progression of myopia by altering the curvature of the image shell while simultaneously correcting the central refractive error, thereby either partly or fully correcting any hyperopic defocus at the periphery or even inducing peripheral myopic defocus [12, 13].

The Miyopi-X<sup>°</sup> spectacle lenses represent an innovative peripheral defocus progressive addition design aimed at slowing myopia progression. Unlike traditional progressive addition lenses, the Myopi-X lenses feature a unique design with a central 12 mm optical zone for distance correction, surrounded by a 24 mm transitional zone that includes an additional 2 or 3 diopters of power as illustrated in Fig. 1. Technologies like Defocus Incorporated Multiple Segments (Defocus Incorporated Multiple Segments) and Highly Aspherical Lenslets (Highly Aspherical Lenslets Technology) create myopic defocus by allowing clear central retinal imaging while inducing peripheral myopic defocus. In Defocus Incorporated Multiple Segments lenses, small myopic segments are strategically positioned across the lens surface, allowing clear central vision while inducing peripheral myopic defocus. This peripheral defocus is believed to slow axial length elongation, a key factor in myopia progression. Similarly, Highly Aspherical Lenslets Technology utilizes aspherical lenslets to generate peripheral defocus, aiming to reduce myopia progression through a comparable mechanism. This study aims to evaluate the effectiveness of Miyopi-X<sup>®</sup> lenses in comparison to atropine 0.01% eye drops and single vision lenses (SVLs).

## Subjects and methods

This is a retrospective observational study. The study was approved by the Acıbadem Healthcare Institutions Medical Research Ethics Committee (Ethics Approval No: 2023-21/733). Informed consent forms were obtained from the parents/guardians of all patients included in the study.

Clinical records of patients using Myopi-X<sup>®</sup> lenses, single vision lenses, and those receiving atropine 0.01% eye drops from September 1, 2022, to September 30, 2023, were reviewed. Inclusion criteria included ages 5-16 at the start of therapy, initial spherical equivalent refraction between -0.50 and -6.25 diopters (D), astigmatism under 2.0 diopters, anisometropia under 1.5 diopters, and a minimum follow-up of 12 months. Patients with conditions affecting refractive stability, including unstable diabetes, the use of certain medications; ocular diseases such as glaucoma, cataracts, keratoconus, or strabismus, and genetic syndromes were excluded. Additionally, patients with a history of or currently undergoing any form of myopia control treatment were not included in the study. While corneal topography was not routinely performed, it was conducted in patients with suspected keratoconus based on slit-lamp findings, and those with abnormal results were excluded.



Fig. 1 Design Features of Myopi-X<sup>®</sup> Lens. Note: This figure illustrates the three zones of the Myopi-X<sup>®</sup> lens: a single vision zone, a transition zone with additional power, and a constant myopic value zone to manage myopia progression

A total of 128 patients who met our study criteria were included, with 45 in the Myopi-X<sup>®</sup> lenses group, 41 in the single vision lens group, and 42 in the atropine 0.01% group. Patients in the Myopi-X<sup>®</sup> group were prescribed Myopi-X° progressive addition lenses for myopia control and were advised to wear them throughout the day, except during sleep and bathing. Those in the atropine 0.01% group received a compounded 0.01% atropine solution, as atropine eye drops are not commercially available in Turkey. The solution was prepared by pharmacies using atropine sulfate 1 mg/1 mL ampoules (Atropin°, Türk Tıpsan, Ankara, Turkey), which were diluted with sodium hyaluronate 1.5 mg/1 mL (Eyestil<sup>®</sup>, SIFI Pharmaceuticals, Catania, Italy) to achieve a 0.01% atropine concentration. The prepared solution was stored under appropriate conditions and renewed every 30 days to maintain stability and sterility. The single vision lens group served as the control, receiving standard single vision spectacle lenses without any additional optical or pharmacological intervention.

The records of the patients included age, gender, date of visit, prescription, cycloplegic autorefraction for spherical-equivalent refraction, and axial length measurements. Both eyes of each patient were included in the analysis. To assess the potential influence of gender, age, and baseline axial length on treatment outcomes, patients were categorized into subgroups based on these factors. Gender was included as an independent variable to evaluate its effect on the 12-month change in spherical equivalent refraction and axial length. Patients were also divided into two age groups (5–10 years and 11–16 years) to assess the impact of age on treatment response. Given that myopia progression is more rapid in younger children, a cutoff age of 10 years was used, classifying patients into younger (<10 years) and older ( $\geq$ 10 years) groups [14]. Additionally, the potential effect of baseline axial length on treatment efficacy was examined using age-specific axial length growth charts to categorize patients into moderate and high baseline axial length groups based on percentile distributions [15].

The standard process to determine cycloplegic autorefraction was carried out after the instillation of tropicamide 1% (Bilim Ilac Tropamid<sup>®</sup> %1 forte 10 mg/ml), with two drops in each eye administered five minutes apart, and refraction measured (Topcon CKR®-8900 autorefractometer) 30 min later (set to 0.25D median mean of 5 readings of each measurement). As tropicamide is an effective and safe alternative to cyclopentolate for cycloplegia in non-strabismic children aged 3–16 years, we used tropicamide in this study [16]. Axial length was measured in each eye with a Zeiss® IOL Master 700 instrument. For each patient, a minimum of five axial length measurements were obtained. If the standard deviation (SD) did not fall below 0.05 mm after five measurements, additional measurements were performed until this criterion was met.

The primary outcome variables were changes in spherical-equivalent refraction (SER) and axial length (AL) over 12 months.

## **Power analysis**

An a priori power analysis was conducted using GPower software (Version 3.1.9.7, Heinrich-Heine-University, Düsseldorf, Germany), with an alpha level of 0.05 (two-tailed) and a desired power of 80% [17].

Since previous studies did not explicitly report effect sizes, Cohen's d values were computed based on their published mean changes and standard deviations. For spherical equivalent progression over 12 months, Cohen's d values were 1.42 for atropine vs. control, 1.48 for Defocus Incorporated Multiple Segments vs. control, based on Nucci et al. [18]. Additionally, based on the Low-concentration Atropine for Myopia Progression 2 study (LAMP 2) Cohen's d for atropine vs. control was 1.09, indicating a large effect [19]. For axial elongation, Cohen's d values were 2.17 for atropine vs. control, 2.06 for DIMS vs. control, based on Nucci et al. (2023). From the Low-concentration Atropine for Myopia Progression 2 study, Cohen's d for atropine vs. control was 1.72, suggesting a very large effect.

According to Cohen's classification, effect sizes of 0.2 are considered small, 0.5 moderate, and 0.8 or higher represent a large effect [20]. The observed values confirm the strong impact of both optical and pharmacological interventions on myopia control.

Based on these effect sizes, power analysis indicated that the minimum required sample size for detecting significant differences in spherical-equivalent refraction progression was 14 patients per group (total 28 patients), and for axial elongation, it was 6 patients per group (total 13 patients). Given that our study included 128 patients (256 eyes), the sample size exceeds the required minimum for both primary outcomes, ensuring the robustness of our findings.

## Statistical analysis

Continuous variables were presented as mean±standard deviation, while categorical data were expressed as frequencies and percentages. Baseline characteristics among treatment groups were compared using the Kruskal-Wallis test for continuous variables and the chi-square test for categorical variables. The 12-month changes in spherical equivalent refraction and axial length were analyzed using a Generalized Linear Mixed Model (GLMM) to account for the inclusion of both eyes from each patient and the correlated nature of repeated measurements. The fixed factors included treatment group, gender, age group, and baseline axial length category, while the patient ID was included as a random effect to control for intra-subject correlation. Post-hoc pairwise comparisons between treatment groups were performed using Bonferroni-adjusted tests to correct for multiple comparisons. Two-sided p-values < 0.05 were considered statistically significant. All statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 29.0.1.0 (IBM Corp., Released 2023, Armonk, New York, USA).

## Results

A total of 128 patients were included in the study, with 45 in the Myopi-X lenses group, 41 in the single vision lenses group, and 42 in the atropine 0.01% group. Among the participants, 57 (44.5%) were female, and 71 (55.5%) were male. The mean baseline age was  $10.01 \pm 2.60$  years (range: 5–16 years). The mean baseline spherical equivalent refraction was  $-2.63 \pm 1.3$  diopters (D) (range: -0.50 to -6.25 D) and the mean axial length was  $24.32 \pm 0.93$  millimeters (mm) (range: 22.32-27.46 mm).

Baseline characteristics, including SER and AL, were similar between the three treatment groups (p = 0.71 and p = 0.58, respectively). A borderline significant difference in age was observed among the groups (p = 0.05), with post-hoc analysis revealing that patients in the Myopi-X lenses group were significantly younger than those in the single vision lenses group (p = 0.01) and the atropine 0.01% group (p = 0.004). No significant difference in age was found between the single vision lenses and atropine 0.01% groups (p = 0.82, Bonferroni-adjusted Mann-Whitney U test). Gender distribution did not significantly differ among the groups (p = 0.72).

The detailed baseline characteristics of the study groups are presented in Table 1.

At 12 months, a significant difference was observed in spherical equivalent refraction change among the three treatment groups (p < 0.001, Generalized Linear Mixed Model [GLMM]). Post hoc pairwise comparisons indicated that both the atropine 0.01% and Myopi-X lenses groups exhibited significantly less myopic progression compared to the single vision lenses group (p < 0.001 for both, Bonferroni-adjusted pairwise comparisons). However, no significant difference in SER change was

 Table 1
 Baseline characteristics of participants by treatment group

	Myopi-X <sup>®</sup> Group	SVL Group ( $N = 41$ )	Atropine 0.01% Group (N=42)	P value	
	(N=45)				
Age (years)	9.29 (±0.26)	10.51(±0.39)	10.67 (±0.39)	0.05*	
SER (D)	-2.63(±0.16)	-2.51(±0.22)	-2.42 (±0.20)	0.71*	
AL (mm)	24.39 (±0.1)	24.11(±0.22)	24.34(±0.16)	0.58*	
Gender				0.73**	
-Male, n (%)	25 (55.6%)	24 (58.5%)	22 (52.4%)		
-Female, n (%)	20 (44.4%)	17 (41.5)	20 (47.6%)		

Note: Data are presented as mean ± standard deviation for spherical equivalent refraction and axial length. SER = Spherical Equivalent Refraction; AL = Axial Length. (\* = Kruskal-Wallis test; \*\* = Chi-square test; D = Diopters; mm = Millimeters)

observed between the atropine 0.01% and Myopi-X lenses groups (p = 0.79) (Table 2; Fig. 2).

Similarly, axial length change significantly differed among the treatment groups p < 0.001, Generalized Linear Mixed Model [GLMM]). Post hoc analyses confirmed that both the atropine 0.01% and Myopi-X lenses groups experienced significantly less axial elongation compared to the SVLs group (p < 0.001 for both, Bonferroni-adjusted pairwise comparisons). However, there was no significant difference in axial elongation between the atropine 0.01% and Myopi-X lenses groups (p = 0.76) (Table 2; Fig. 2).

Regarding potential confounding factors, gender (p=0.21 for SER, p=0.32 for AL) and baseline axial length (p=0.17 for SER, p=0.36 for AL) were not significantly associated with the twelve-month changes in SER or AL (GLMM). However, age group had a significant effect on SER (p=0.02), while its effect on AL was not statistically significant (p=0.11) (Table 3).

A comparison of spherical equivalent and axial length changes between younger and older children is presented in Table 4, demonstrating the effect of age on myopia progression.

## Discussion

Our results indicate that both Myopi-X lenses and atropine 0.01% are individually effective in controlling the progression of spherical equivalent and axial elongation. Over a 12-month period, both treatments showed similar efficacy in managing in spherical equivalent and axial length changes.

After 12 months, a significant reduction in myopia progression was observed in the Myopi-X lenses and atropine 0.01% groups compared to the single vision lenses group. Myopi-X lenses achieved a 63.52% reduction in spherical equivalent progression and a 67.90% reduction in axial length elongation, while atropine 0.01% resulted in a 70.44% reduction in spherical equivalent progression and a 74.07% reduction in axial length elongation. However, expressing myopia control treatment effects as percentage reductions can be misleading, as this approach often overlooks long-term variability and diminishing effects over time. While initial effects may appear significant, the long-term efficacy often proves to be smaller. Therefore, it is recommended to use absolute treatment effects, such as changes in axial length, for a clearer and more accurate understanding of myopia control efficacy [21]. Nonetheless, to allow for comparison with previous studies, we also included percentage reduction metrics in our analysis.

Progressive addition lenses slow myopia progression by creating peripheral myopic defocus, which inhibits axial elongation [22]. The Correction of Myopia Evaluation Trial study demonstrated that progressive addition lenses slow reduced spherical equivalent refraction progression and axial elongation by a small, but statistically significant, amount (approximately 10-15%) over three years, with the greatest effect occurring during the first year of treatment. While this effect is too small to warrant a change in clinical practice, it does support the role of myopic defocus in managing myopia [23]. The design of Myopi-X lenses differs from traditional pogressive addition lenses, featuring a central 12 mm optical zone for distance correction and a 24 mm transitional zone with an additional 2 or 3 diopters. Given the presumed stronger effect of myopic defocus, we hypothesized that Myopi-X lenses would be more effective than traditional progressive addition lenses in controlling spherical equivalent refraction and axial length. As anticipated, Myopi-X lenses provided higher efficacy in both spherical equivalent refraction and axial length control compared to traditional progressive addition lenses.

Age is one of the most critical factors influencing myopia progression, as younger children typically exhibit faster axial elongation and greater refractive changes. Weise et al. reported that younger children and those with higher baseline myopia exhibit faster progression and greater axial elongation [24]. Similarly, studies identify age and baseline myopia severity as key risk factors, while gender appears to have no significant effect [25, 26]. Refractive error results from an imbalance among the cornea, crystalline lens, and axial length (AL). During

Table 2	Spherical ec	quivalent and axi	al length pro	paression in trea	atment groups af	t 12 months
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	Myopi-X Group	Atropine 0.01% Group	SVL Group	<i>P</i> value
SER change in 12 months	-0.58±0.34	-0.47±0.52	$-1.59 \pm 1.62$	Overall: <i>p</i> < 0.001*
(D)				SVL vs. Myopi-X: <i>p</i> < 0.001*
				SVL vs. Atropine: $p < 0.001^*$
				Myopi-X vs. Atropine: <i>p</i> < 0.79*
AL change in 12 months	$0.26 \pm 0.13$	0.21±0.27	$0.81 \pm 0.88$	Overall: <i>p</i> < 0.001*
(mm)				SVL vs. Myopi-X: <i>p</i> < 0.001*
				SVL vs. Atropine: <i>p</i> < 0.001*
				Myopi-X vs. Atropine: <i>p</i> =0.76 *

Note: Data are presented as mean ± standard deviation for spherical equivalent refraction (SER) in diopters (D) and axial length (AL) in millimeters (mm). (= Generalized Linear Mixed Model; D = Diopters; mm = Millimeters)



Fig. 2 Spherical equivalent and axial length changes in 12 months across treatment groups. Note: Bars represent the mean changes in spherical equivalent refraction (SER) and axial length (AL) over 12 months for the Myopi-X, Atropine 0.01%, and Single Vision Lenses (SVL) groups. Error bars indicate standard deviations. Both Myopi-X and Atropine 0.01% groups demonstrated less myopic progression and axial elongation compared to the SVL group

**Table 3** Analysis of potential confounding factors affecting spherical equivalent and axial length changes at 12 months

	0	0
Variable	SER Change (p-value)	AL Change (p-value)
Gender	0.21*	0.32*
Age Group	0.02*	0.11*
Baseline AL	0.17*	0.36*

Note: The results present the p-values for the effects of gender, age group, and baseline axial length on spherical equivalent refraction and axial length changes over 12 months. (\* = Generalized Linear Mixed Model; SER=Spherical Equivalent Refraction; AL=Axial Length)

 Table 4
 Effect of age on spherical equivalent and axial length changes

Age Group	Younger Children	Older Children	P value
SER Change (D)	-1.07±1.26	$-0.65 \pm 0.85$	0.01*
AL Change (mm)	$0.50 \pm 0.64$	$0.33 \pm 0.52$	0.09*
	0.00 - 0.01	0.00 = 0.02	0.09

Note: Data are presented as mean  $\pm$  standard deviation for spherical equivalent refraction (SER) and axial length (AL). (\* = Mann-Whitney U test). (D=Diopters; mm=Millimeters)

early childhood, corneal and lens power decrease [27, 28], while AL elongates, leading to myopia when excessive [29]. Given AL's role, rapid myopia progression in young children (5–10 years) is expected. However, in our study, age, gender, and baseline AL did not significantly influence AL elongation. Small annual AL changes may not reach statistical significance within 12 months, while SER progression, influenced by additional optical factors, showed clearer age-related differences. Longer follow-up is needed to clarify these effects.

Defocus Incorporated Multiple Segments (DIMS) and Highly Aspherical Lenslets (H.A.L.T.) are new-generation myopia control spectacle lenses. Studies have shown that DIMS reduces spherical equivalent progression and axial elongation by 57% (-0.36 D; 0.13 mm) over one year, while H.A.L.T. achieves a 63% and 61% reduction (-0.27 D; 0.13 mm), respectively [30, 31]. In comparison, In the present study, Myopi-X lenses reduced spherical equivalent progression by 63.52% and axial length elongation by 67.90%, with absolute changes of -0.58 D and 0.26 mm, respectively. In our previous study, we reported a spherical equivalent progression of -0.44 D and axial elongation of 0.23 mm over one year with Myopi-X lenses [32]. However, as previously mentioned, percentage-based reductions can be misleading, as they do not fully account for long-term variability. When assessed based on absolute changes, DIMS and H.A.L.T. exhibited greater control over both spherical equivalent progression and axial length elongation compared to Myopi-X lenses.

Since our study is a retrospective analysis covering the period from September 1, 2022, to September 30, 2023, a direct comparison with DIMS and H.A.L.T. lenses was not feasible, as these lenses only became commercially available in Turkey in June and September 2023, respectively. Therefore, while our study focused on Myopi-X lenses, we have included a comparison with previously published data on DIMS and H.A.L.T. lenses to provide context on their reported efficacy.

Different studies have reported varying results regarding the efficacy of 0.01% atropine in slowing myopia progression. The Low-concentration Atropine for Myopia Progression 2 study reported no significant difference between the efficacy of atropine 0.01% and placebo [19]. Since most studies have been conducted on Asian populations, data on the effectiveness of atropine in European populations remain limited. Given the behavioral, environmental, epidemiological, and genetic differences between children in Asian and non-Asian countries, more data are needed on the safety and efficacy of lowconcentration atropine in non-Asian populations.

The Childhood Atropine for Myopia Progression study, an international, multi-center, placebo-controlled trial conducted across 27 clinical sites in North America and 5 European countries, showed that 0.01% atropine was associated with a significantly lower proportion of responders and slower progression of spherical equivalent refraction and axial length [33]. The Myopia Outcome Study of Atropine in Children trial supports these findings, indicating that atropine 0.01% slows myopia progression and axial elongation in children. Notably, The Myopia Outcome Study of Atropine in Children study is the first placebo-controlled randomized clinical trial to investigate the safety, tolerability, and efficacy of 0.01% atropine treatment for myopia management in a predominantly White, European population [34].

Myles et al. studied the effects of 0.01% and 0.005% atropine eye drops on myopia progression in 13 Australian children, observing them for two years without treatment and for an average of 2.8 years with treatment. They reported a 75% reduction in spherical equivalent refraction progression, though this large reduction may be exaggerated due to the small sample size and the relatively long observation period [35].

Clark et al. retrospectively analyzed the efficacy of atropine 0.01% eye drops, reporting a 75% reduction in spherical equivalent refraction progression among 'higher myopes' (those with myopia greater than -2.00 D) in California [36]. Sacchi and colleagues reported a 55% reduction in spherical equivalent refraction progression compared to the control group after one year of atropine 0.01% treatment in an Italian pediatric population [37]. Joachimsen et al. found a 62% reduction in myopic progression among German schoolchildren [38]. Diaz-Llopis and Pinazo-Durán reported a 77% reduction in spherical equivalent refraction progression after one year of atropine 0.01% treatment in Spanish schoolchildren [39]. Moriche-Carretero et al. also suggested that atropine 0.01% is effective in slowing myopia progression in European populations [40]. Considering studies conducted in non-Asian countries, we assessed both SER and

AL changes, noting that some previous studies lacked axial length measurements. Our findings are largely consistent with the existing literature, though some slight variations were observed. These differences may stem from variations in study design, patient adherence, baseline refractive error, and follow-up duration. Moreover, inconsistencies in reporting treatment efficacy, such as whether it is expressed as absolute changes in spherical equivalent and axial length or as percentage reductions, complicate direct comparisons between studies. Standardizing outcome measures in future research will be essential for improving the comparability of findings.

## **Strengths and limitations**

This study has several strengths. The clinic conducting this study had a strong reputation for myopia control, which contributed to high levels of patient participation and compliance. This ensured that the study had sufficient power to effectively assess the efficacy of different treatment groups under real-world clinical conditions. Additionally, this is the first study to evaluate the efficacy of Myopi-X lenses and low-dose atropine 0.01% in a Turkish child and adolescent population, providing valuable insights into the literature on myopia management in diverse populations.

However, this study has several limitations. The relatively small sample size and the 12-month follow-up period restrict the generalizability of our findings. Larger-scale studies with extended follow-up durations are necessary to validate these results and assess the longterm efficacy of Myopi-X lenses and atropine in myopia control. Additionally, while a significant difference in spherical equivalent change was observed between the Myopi-X and Atropine 0.01% groups, no significant difference was detected in axial length elongation. This discrepancy may stem from the differential mechanisms of action of these interventions on refractive and structural ocular changes, warranting further investigation.

Furthermore, a borderline significant difference in age was observed among the treatment groups. Post-hoc analysis indicated that patients in the Myopi-X lenses group were significantly younger than those in the single vision lenses and atropine 0.01% groups, while no significant age difference was found between the latter two groups. The potential impact of age differences on treatment outcomes should be considered when interpreting the findings. Future research with age-matched comparisons and longer follow-up periods is needed to clarify the role of age in treatment efficacy and myopia progression.

In conclusion, both Myopi-X lenses and atropine 0.01% were effective in controlling myopia progression in children over a 12-month period, significantly reducing both spherical equivalent progression and axial elongation. This suggests that Myopi-X lenses remain a viable

non-pharmacological alternative, particularly for patients or parents hesitant to use atropine. Additionally, age and baseline myopia severity have been identified as key factors influencing myopia progression, with younger children and those with higher baseline myopia typically exhibiting faster progression. While our study did not find a significant impact of age or baseline axial length on treatment efficacy within 12 months, longer follow-up periods and randomized controlled trials are necessary to fully assess their role in long-term myopia control and optimize treatment strategies.

#### Abbreviations

## AL Axial Length

D Diopters

- D.I.M.S Defocus Incorporated Multiple Segments
- PAL Progressive Addition Spectacle Lenses
- RCT Randomized Clinical Trial
- SER Spherical Equivalent Refraction
- SVL Single Vision Lenses

#### Acknowledgements

We would like to express our sincere gratitude to the patients who generously provided consent for the use of their data in this study. Their cooperation and willingness to contribute to scientific research have been invaluable.

#### Author contributions

N.A. collected and analyzed the data, wrote the manuscript, prepared the Table 1, and 2, and contributed to the statistical analysis and discussion of the results. U.E.A. contributed to the discussion of the results, reviewed the manuscript, and approved the final version. Both authors read and approved the final manuscript.

#### Funding

The authors declare that there was no financial support or sponsorship for this study.

#### Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

## Declarations

#### Ethics approval and consent to participate

This is a retrospective observational study. The study was approved by the Acıbadem Healthcare Institutions Medical Research Ethics Committee (Ethics Approval No: 2023-21/733). Informed consent forms were obtained from the parents/guardians of all patients included in the study.

#### **Competing interests**

The authors declare no competing interests.

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## Received: 12 December 2024 / Accepted: 24 March 2025 Published online: 17 April 2025

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