

Clinical Outcomes During 0.01% Low-Dose Atropine Therapy in Indian Children with Myopia: A Prospective Cohort Study

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Abstract

Background:

Low-dose atropine is increasingly used for childhood myopia control, but Indian data integrating refractive, biometric, adherence, and safety outcomes remain limited.

Objective:

To evaluate refractive and biometric outcomes, treatment adherence, and safety in Indian children with myopia treated with 0.01% atropine over a 12-month follow-up period.

Methods:

Of 112 children aged 6–16 years enrolled in this prospective single-centre cohort, 100 completed 12 months of follow-up. Preservative-free 0.01% atropine was used in the night in both eyes. Cycloplegic spherical equivalent (SE), axial length, treatment adherence, environmental exposures, and ocular adverse effects were assessed. Twelve-month SE progression and axial elongation were analysed separately for right and left eyes, and their eye-specific associations were evaluated using Pearson correlation. Multivariable predictors of both outcomes were assessed using generalized estimating equations (GEE), with both eyes retained as separate observations while accounting for within-participant inter-eye correlation.

Results:

Mean age was 10.61 ± 2.85 years. At 12 months, mean spherical equivalent progression was 0.560 ± 0.537 D in the right eye and 0.501 ± 0.520 D in the left eye, while mean axial elongation was 0.178 ± 0.225 mm and 0.164 ± 0.247 mm, respectively. Both refractive progression and axial elongation demonstrated statistically significant changes over the 12-month follow-up ($p < 0.001$). SE progression correlated strongly with axial elongation in both right ($r = 0.907$, $p < 0.001$) and left eyes ($r = 0.822$, $p < 0.001$). GEE analysis confirmed a significant association between SE progression and axial elongation ($B = 0.172$ mm/D; 95% CI, 0.129–0.214; $p < 0.001$). Good treatment adherence was observed in 73% of participants. None of the evaluated variables demonstrated a statistically significant independent association with refractive progression or axial elongation. Ocular adverse effects were reported in 26% of children, most commonly itching (15%) and redness (14%).

Conclusion:

Children receiving 0.01% atropine showed modest refractive progression and axial elongation over 12 months. Refractive and biometric changes were strongly correlated, and treatment was generally well tolerated. Because the study lacked a concurrent untreated control group, the findings should be interpreted as clinical outcomes during therapy rather than as evidence of treatment efficacy.

Keywords: low-dose atropine; spherical equivalent; axial length; myopia progression

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INTRODUCTION

Childhood myopia is an increasing public-health concern because of its rising prevalence and the

lifelong risk of vision-threatening complications. Nearly 40% of children and adolescents worldwide are projected to be myopic by 2050.[1] In India, refractive errors affect approximately 11% of school children, with myopia being the most common subtype.[2]

Progressive myopia is characterised by excessive axial elongation, increasing the risk of retinal detachment, myopic maculopathy, glaucoma, choroidal neovascularisation, and irreversible visual impairment.[3,4] Axial-length assessment together with cycloplegic spherical equivalent (SE) refraction therefore provides complementary structural and refractive measures of progression.

Myopia results from interactions between genetic and environmental influences.[5] . A family history of myopia, prolonged near work, digital-device use, intensive educational demands, and reduced outdoor activity have all been implicated.[6,7] As conventional spectacles correct refractive error without modifying axial elongation, contemporary myopia control incorporates optical strategies such as orthokeratology and multifocal contact lenses,[8,9] and pharmacological treatment with topical atropine.

Atropine demonstrates a concentration-dependent treatment response. Higher concentrations provide greater control of refractive progression and axial elongation but are associated with increased photophobia, reduced accommodation, near-vision difficulty, and rebound after discontinuation.[10] ATOM2 and LAMP established the clinical utility of low-dose atropine, although 0.01% atropine has a more modest effect on axial elongation than higher concentrations.[11,12] Recent placebo-controlled evidence suggests that 0.01% atropine provides modest benefit, although treatment effects vary across populations[13].

Prospective real-world Indian data simultaneously evaluating refractive and biometric outcomes, environmental exposures, adherence, and safety remain limited. This study therefore evaluated 12-month refractive, biometric, adherence, and safety outcomes of 0.01% atropine in Indian children with myopia and explored factors associated with refractive progression and axial elongation.

MATERIALS AND METHODS

Study Design

This prospective, single-centre observational cohort study was conducted in the Department of Ophthalmology, NRI Institute of Medical Sciences, Visakhapatnam. Children aged 6–16 years with

myopia were recruited between October 2023 and January 2024 and prospectively followed for 12 months, with final follow-up completed in January 2025. All participants received preservative-free 0.01% atropine according to the departmental clinical management protocol. Refractive progression, axial elongation, treatment adherence, environmental exposures, and safety were evaluated during the follow-up period.

The study was approved by the Institutional Ethics Committee (IEC/NRI/51/2023). Written informed consent was obtained from parents or guardians, and age-appropriate assent was obtained from participating children. The study adhered to the principles of the Declaration of Helsinki.

Children with pathological or secondary myopia, previous ocular surgery, ocular disorders affecting visual acuity or axial length, atropine hypersensitivity, or previous pharmacological or optical myopia-control treatment were excluded. Myopia was categorized as mild (-0.50 D to >-3.00 D), moderate (-3.00 D to >-6.00 D), or high (≤ -6.00 D).

During the four-month recruitment period, 112 children were enrolled. Twelve children did not return for subsequent follow-up and were considered lost to follow-up. The remaining 100 children completed the 12-month follow-up and constituted the final analytic cohort. As this was a time-bound observational cohort, no formal a priori sample-size calculation was performed.

Clinical Assessment

Baseline variables included age, sex, spectacle use, and first-degree family history of myopia. A structured questionnaire recorded daily near-work duration, screen exposure, and outdoor activity. Near work and screen exposure were analysed as continuous variables, while reduced outdoor activity was entered as a binary variable. For descriptive purposes, near work >3 hours/day, screen exposure >2 hours/day, and outdoor activity <2 hours/day were considered increased near work, increased screen exposure, and reduced outdoor activity, respectively.

Ophthalmic Assessment

Comprehensive ophthalmic examinations were performed at baseline and 3, 6, and 12 months. Visual acuity, cycloplegic refraction, slit-lamp examination, tonometry, keratometry, and dilated fundus examination were performed using standardized protocols. Cycloplegic refraction was performed approximately 30 minutes after two

instillations of 1% cyclopentolate administered 5 minutes apart and was verified by subjective refraction when feasible. SE was calculated as spherical power plus half the cylindrical power. Axial length was measured using the Zeiss IOLMaster 500 at baseline and follow-up.

Treatment, Adherence, and Safety

All participants received one drop of preservative-free 0.01% atropine in each eye in the night for 12 months, together with appropriate spectacle correction.

Treatment adherence was assessed at each follow-up visit by interview with the parent/guardian and child, based on reported atropine doses administered and missed since the preceding visit. Interval adherence was expressed as the proportion of prescribed doses reportedly administered. Overall 12-month adherence was calculated from the cumulative reported doses administered relative to the total prescribed doses and classified as good ($\geq 80\%$), moderate (50–79%), or poor ($< 50\%$).

Ocular adverse effects, including photophobia, redness, itching, irritation, blurred near vision, difficulty with near work, and allergic conjunctivitis, were recorded at each visit, along with any treatment interruption or discontinuation. Safety outcomes were assessed among the 100 children who completed the 12-month follow-up.

Outcome Measures and Statistical Analysis

The primary outcomes were 12-month SE progression (baseline SE minus 12-month SE) and axial elongation (12-month axial length minus baseline axial length), calculated separately for each eye. Secondary outcomes included adherence, environmental exposures, adverse effects, the relationship between SE progression and axial elongation, and exploratory predictors of both outcomes. Descriptive thresholds were SE progression ≤ 0.25 and ≤ 0.50 D/year and axial elongation ≤ 0.10 and ≤ 0.20 mm/year; these were not treated as validated response cut-offs.

Analyses were performed using IBM SPSS Statistics version 26.0. Continuous variables are reported as mean $\pm$ SD or median (IQR) as appropriate; categorical variables are expressed as frequencies and percentages. Normality was assessed with Shapiro–Wilk testing, and one-sample Wilcoxon signed-rank tests evaluated whether 12-month progression differed from zero. Pearson correlations were calculated separately for right and left eyes. Analyses including both eyes used GEE models with participant-level clustering, an exchangeable correlation structure and robust standard errors. An interaction between SE progression and eye

laterality was tested to determine whether this association differed between right and left eyes. Multivariable GEE models included age, sex, eye-specific baseline SE, family history, near-work duration, reduced outdoor activity, screen time, adherence, and eye laterality. Adherence was modelled in three categories with poor adherence as the reference. Results are presented as unstandardized B coefficients, 95% CI, and corresponding p-values with statistical significance defined as $p < 0.05$.

RESULTS

Baseline Characteristics

Variable	Overall / Right eye	Left eye
Children analysed, n	100	—
Age (years)	10.61 $\pm$ 2.85	—
Male sex, n (%)	48 (48.0%)	—
Female sex, n (%)	52 (52.0%)	—
Baseline spherical equivalent (D)	-2.90 $\pm$ 1.50	-2.68 $\pm$ 1.55
Baseline axial length (mm)	24.08 $\pm$ 0.58	24.01 $\pm$ 0.62
Mild myopia, n (%)	53 (53.0%)	—
Moderate myopia, n (%)	40 (40.0%)	—
High myopia, n (%)	7 (7.0%)	—

The final analysis included 100 children with a mean age of 10.61 $\pm$ 2.85 years; 48% were boys. Mean baseline SE was -2.90 $\pm$ 1.50 D in right eyes and -2.68 $\pm$ 1.55 D in left eyes, while corresponding axial lengths were 24.08 $\pm$ 0.58 mm and 24.01 $\pm$ 0.62 mm. Mild, moderate, and high myopia occurred in 53%, 40%, and 7%, respectively (Table 1).

Environmental Characteristics and Adherence (Table 2)

Variable	Value
Positive family history of myopia	26 (26.0%)
Reduced outdoor activity	65 (65.0%)
Near work (hours/day)	3.60 $\pm$ 1.00
Near work > 3 hours/day	67 (67.0%)
Screen time (hours/day)	2.63 $\pm$ 0.84
Screen time > 2 hours/day	74 (74.0%)
Good adherence	73 (73.0%)
Moderate adherence	17 (17.0%)

Poor adherence	10 (10.0%)
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Family history of myopia was present in 26%, reduced outdoor activity in 65%, near work >3 hours/day in 67%, and screen exposure >2 hours/day in 74%. Adherence was good in 73%, moderate in 17%, and poor in 10% (Table 2).

Twelve-Month Refractive and Axial-Length Outcomes (Table 3)

Table 3. Twelve-Month Refractive and Axial-Length Progression					
Outcome	Eye	Mean $\pm$ SD	95% CI	Median (IQR)	p-value
Spherical equivalent progression (D)	Right eye	0.56 $\pm$ 0.537	0.453 to 0.667	0.500 (0.250 – 0.750)	<0.001
Spherical equivalent progression (D)	Left eye	0.501 $\pm$ 0.520	0.398 to 0.605	0.250 (0.250 – 0.750)	<0.001
Axial elongation (mm)	Right eye	0.178 $\pm$ 0.225	0.134 to 0.223	0.110 (0.040 – 0.208)	<0.001
Axial elongation (mm)	Left eye	0.164 $\pm$ 0.247	0.115 to 0.213	0.080 (0.030 – 0.178)	<0.001

At 12 months, mean SE progression was 0.560 ± 0.537 D in right eyes and 0.501 ± 0.520 D in left eyes; corresponding axial elongation was 0.178 ± 0.225 mm and 0.164 ± 0.247 mm. All changes differed significantly from zero ($p < 0.001$; Table 3).

Table 4. Exploratory Descriptive Thresholds for 12-Month Refractive Progression and Axial Elongation

Operational definition	Right eye, n (%)	Left eye, n (%)
SE progression ≤ 0.25 D/year	39 (39.0%)	51 (51.0%)
SE progression ≤ 0.50 D/year	69 (69.0%)	74 (74.0%)
Axial elongation ≤ 0.10 mm/year	46 (46.0%)	58 (58.0%)
Axial elongation ≤ 0.20 mm/year	75 (75.0%)	79 (79.0%)

Using study-defined descriptive thresholds, SE progression ≤ 0.50 D/year occurred in 69% of right and 74% of left eyes, while axial elongation ≤ 0.20

mm/year occurred in 75% and 79%, respectively (Table 4).

Correlation and Regression Analyses

Table 5A. Association between Spherical-Equivalent Progression and Axial Elongation			
Analysis	Estimate	95% CI	p-value
Pearson correlation - Right eyes (n=100)	$r = 0.907$	—	<0.001
Pearson correlation - Left eyes (n=100)	$r = 0.822$	—	<0.001
GEE association: SE progression with axial elongation	$B = 0.172$ mm/D	0.129 to 0.214	<0.001
Eye laterality interaction (left vs right)	—	—	0.553

SE progression showed a strong positive correlation with axial elongation in both right ($r=0.907$, $p<0.001$) and left eyes ($r=0.822$, $p<0.001$). GEE analysis confirmed a significant association between SE progression and axial elongation ($B=0.172$ mm/D; 95% CI, 0.129–0.214; $p<0.001$). The relationship did not differ significantly between right and left eyes (laterality interaction $p=0.553$) (Figure 1).

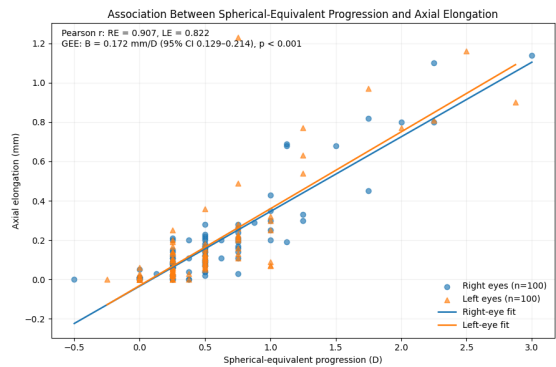


Figure 1. Association between spherical-equivalent progression and axial elongation over 12 months. Separate regression lines are shown for right and left eyes.

Table 5B. GEE Multivariable Analysis of Predictors of 12-Month Progression				
Predictor	SE progression B (95% CI)	p	Axial elongation B (95% CI)	p
Age, years	0.004 (–0.038 to 0.047)	0.846	0.004 (–0.014 to 0.022)	0.641

Female sex	0.097 (−0.067 to 0.262)	0.24 7	0.045 (−0.030 to 0.120)	0.23 5
Baseline eye-specific SE, D	−0.018 (−0.068 to 0.032)	0.48 3	−0.015 (−0.045 to 0.015)	0.31 4
Positive family history	−0.194 (−0.423 to 0.035)	0.09 7	−0.094 (−0.193 to 0.005)	0.06 2
Near work, hours/day	−0.045 (−0.133 to 0.043)	0.31 3	−0.018 (−0.053 to 0.018)	0.33 4
Reduced outdoor activity	−0.069 (−0.222 to 0.084)	0.37 7	−0.031 (−0.093 to 0.032)	0.33 9
Screen time, hours/day	0.016 (−0.082 to 0.113)	0.75 2	0.004 (−0.037 to 0.045)	0.84 4
Good adherence vs poor	−0.183 (−0.584 to 0.219)	0.37 3	−0.108 (−0.320 to 0.104)	0.31 6
Moderate adherence vs poor	−0.074 (−0.549 to 0.400)	0.75 9	−0.067 (−0.304 to 0.170)	0.58 0
Overall adherence effect	—	0.53 7	—	0.49 5
Right eye vs left eye	0.057 (−0.020 to 0.134)	0.14 7	0.011 (−0.027 to 0.050)	0.56 0

GEE: generalized estimating equations. Models used a Gaussian distribution with identity link, participant as the clustering variable, an exchangeable working correlation structure, and robust standard errors. Both eyes were retained as separate observations.

Multivariable GEE analysis identified no statistically significant independent associations with either 12-month SE progression or axial elongation. Positive family history showed the strongest nonsignificant association, particularly with lower axial elongation (B=−0.094 mm; 95% CI, −0.193 to 0.005; p=0.062). Treatment adherence was not significantly associated with either outcome (overall adherence effect: SE progression p=0.537; axial elongation p=0.495) (Figure 2).

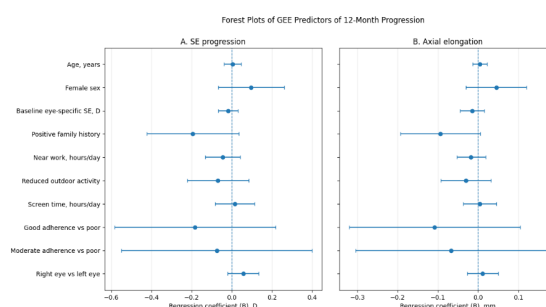


Figure 2. Forest plots of adjusted GEE regression coefficients (B) with 95% confidence intervals for 12-month spherical-equivalent progression (A) and axial elongation (B).

Ocular Adverse Effects

At least one ocular adverse effect occurred in 26% of children. Itching (15%) and redness (14%) were most frequent, followed by photophobia (7%) and blurred vision or difficulty with near work (6%). Allergic conjunctivitis occurred in four children, including three severe cases; two affected children used atropine irregularly and were classified as poorly adherent.

DISCUSSION

This prospective study provides real-world data on refractive, biometric, adherence, and safety outcomes of 0.01% atropine in Indian children with myopia. During 12 months of therapy, children demonstrated continued but modest refractive progression and axial elongation. Refractive progression correlated strongly with axial elongation, while no statistically significant independent associations were detected between the evaluated demographic, clinical, environmental, or adherence-related factors and either outcome. Treatment adherence was generally good and adverse effects were predominantly mild ocular symptoms, although three children developed severe allergic conjunctivitis. Because the study lacked an untreated control group, these observations should be interpreted as outcomes during therapy rather than estimates of atropine efficacy.

Our refractive progression was broadly comparable with that observed during the first year of LAMP, although axial elongation was lower.[12] Differences in age, ethnicity, baseline refraction, previous progression, and measurement protocols limit direct comparison; the older age of our cohort may partly account for the lower axial growth. LAMP demonstrated concentration-dependent efficacy, with 0.05% atropine providing greater refractive and axial control than lower concentrations.[12,14] ATOM2 established favourable long-term tolerability of 0.01%

atropine,[11] while recent meta-analysis indicates modest benefit compared with placebo, with heterogeneity among populations.[13] Continued ocular growth during treatment should therefore not necessarily be regarded as treatment failure.

Our findings are also broadly consistent with Indian evidence. Saxena et al. reported lower refractive progression in a multicentre cohort treated with 0.01% atropine,[15] while Indian randomized trials reported approximately 0.31–0.32 D refractive progression and 0.11–0.24 mm axial elongation.[16,17] Wei et al. similarly demonstrated reduced refractive progression and axial elongation with 0.01% atropine compared with placebo in Chinese children.[18] Differences across studies likely reflect variation in participant characteristics, study design, treatment supervision, and environmental exposures.

An important finding was the strong relationship between refractive and axial progression. SE progression correlated strongly with axial elongation in both right eyes ($r=0.907$, $p<0.001$) and left eyes ($r=0.822$, $p<0.001$). In the GEE analysis incorporating both eyes, greater SE progression was significantly associated with greater axial elongation ($B=0.172$ mm/D; 95% CI, 0.129–0.214; $p<0.001$). This relationship supports axial-length measurement alongside cycloplegic refraction in clinical monitoring. The two measures are nevertheless not interchangeable because developmental changes in crystalline lens power and other optical components may partly offset the refractive consequences of axial growth.[5,19]

Environmental risk exposures were common, but near work, screen exposure, reduced outdoor activity, and family history did not independently predict treatment-period progression. These findings do not contradict their established roles in myopia development. Outdoor exposure has a well-established protective effect against myopia onset, while relationships between progression and near work or digital exposure may also depend on working distance, uninterrupted viewing, illumination, and other behavioural characteristics not captured by exposure duration alone.[6,7]

Multivariable GEE analysis did not identify any statistically significant independent predictor of either refractive progression or axial elongation. Positive family history showed a non-significant tendency toward lower axial elongation ($B=-0.094$ mm; $p=0.062$), but the confidence interval included the null. Good adherence also showed directionally lower SE progression and axial elongation, although neither association was statistically significant. These findings suggest that treatment-period

progression in this cohort was not adequately explained by the measured demographic, environmental, baseline refractive, or adherence-related factors. Larger studies may be required to identify clinically meaningful predictors of response.

Good adherence was observed in 73% of participants. Dalal and Jethani reported approximately 30% irregular or non-compliant atropine use among Indian children,[20] broadly comparable with the 27% showing moderate or poor adherence in our cohort. Although better adherence would be expected to favour treatment response, its independent association with progression was not statistically demonstrable, possibly because relatively few participants had poor adherence. Furthermore, interview-based adherence assessment is susceptible to recall and reporting bias, as emphasised in recent reviews.[21]

Low-dose atropine was generally well tolerated. Ocular adverse effects were reported in 26%, predominantly itching and redness, while photophobia and near-vision symptoms were less common. Allergic conjunctivitis occurred in 4%, including three severe cases, and affected adherence in some participants. These findings are consistent with the known concentration-dependent adverse-effect profile of atropine, with lower concentrations generally offering better tolerability but less control of axial elongation than higher concentrations.[10,22]

The strengths of this study include its prospective design, consecutive recruitment, standardized follow-up, objective assessment of cycloplegic refraction and axial length, and simultaneous evaluation of environmental exposures, adherence, and adverse effects. These features provide clinically relevant real-world data regarding 0.01% atropine use in Indian children. **Korenfeld et al. (2026) conducted the *STudy of Atropine to Reduce (STAR) Myopia Progression in Children*, a multicentre, randomized, double-masked, vehicle-controlled phase 3 trial involving 847 children aged 3–14 years. Children received atropine sulfate 0.01%, atropine sulfate 0.03%, or vehicle. At 24 months, mean annual myopia progression was **−0.31 D/year with 0.01% atropine compared with −0.44 D/year with vehicle**, giving a treatment difference of **0.13 D (95% CI 0.06–0.20; $p=0.0003$)**. Axial length increased by 0.35 mm with 0.01% atropine versus 0.40 mm with vehicle, although this difference was not statistically significant. Photophobia was the most commonly reported ocular adverse effect.[23]**

Important limitations include the absence of a placebo or untreated comparator, the single-centre design, modest sample size, and reliance on self-reported environmental and adherence measures. Working distance, illumination, sleep, and objective digital-device exposure were not assessed. The 12-month follow-up also precluded evaluation of longer-term treatment response, rebound following withdrawal, and the need for dose escalation[11]. Twelve of 112 enrolled children were lost to follow-up; therefore, attrition bias cannot be excluded, and adherence or adverse events among those lost to follow-up are unknown.

CONCLUSION

In this prospective cohort of Indian children with myopia, treatment with 0.01% atropine was associated with continued but modest refractive progression and axial elongation over 12 months. Refractive progression correlated strongly with axial elongation, supporting complementary assessment of both parameters during clinical follow-up. No statistically significant independent associations were detected between the evaluated demographic, environmental, baseline refractive, or adherence-related factors and treatment-period progression. Treatment was generally well tolerated, although ocular adverse effects influenced adherence in a small proportion of participants. Because the study lacked an untreated comparator, these findings describe real-world clinical outcomes during therapy rather than treatment efficacy. Larger controlled studies with longer follow-up are required to define long-term outcomes and predictors of treatment response.

DECLARATIONS

Conflicts of interest: There is no any conflict of interest associated with this study

Consent to participate: There is consent to participate.

Consent for publication: There is consent for the publication of this paper.

Authors' contributions: Author equally contributed the work.

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