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RESEARCH

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Exploration of correlated factors of axial length changes after repeated low-level red-light irradiation in the real world

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Abstract

Background To investigate the factors related to the change in axial length after repeated low-level red-light(RLRL) therapy.

Methods A retrospective case study. A total of 323 children and adolescents who underwent RLRL therapy concurrently with their eye examinations at Wuhan Children's Hospital from 2022 to 2023 were included. The biological eye parameters, including the axial length (AL), spherical equivalent refractive (SER), the subfoveal choroidal thickness (SFCT), intraocular pressure (IOP), corneal curvature and corneal thickness, were recorded at baseline, 3-month, 6-month, 12-month, 12-month, 18-month and 24-month. The factors related to the degree of change in axial length were analyzed.

Results There was a statistical difference in the amount of AL changes during the follow-up ($F = 16.12$, $P < 0.001$), and the amount of AL changes was significant at the 6-month follow-up ($\triangle AL = -0.16 \pm 0.18$), and then gradually decreased with the extension of follow-up time. There was a statistically positive correlation between baseline AL and baseline SER and changes in AL ($P < 0.05$). The axial regression in high myopia group was significantly greater than that in mild and moderate myopia group ($P < 0.05$). There was also a statistically positive correlation between age and changes in AL ($P < 0.05$). At the follow-up of 6 months, 12 months, 18 months, combined with other myopia prevention and control was correlated with the change of AL ($P < 0.05$). Baseline corneal thickness, baseline corneal curvature and baseline IOP were not correlated with changes in AL (all $P > 0.05$).

Conclusion The longer the baseline AL, the higher SER, the thinner SFCT, the older the age and the combination of other myopia prevention and control measures, the more obvious the change of AL. However, the changes of AL were not affected by IOP, corneal curvature and corneal thickness.

Keywords Myopia control, Repeated low-level red light therapy, Axial length

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Background

Myopia is a global public Health problem, affecting nearly 30% of the world's population and predicted to rise to 50% of the population by 2050, 10% of whom are highly myopic [1]. The latest release from the National Health and Wellness Commission (NHWC) shows that the overall myopia rate among children and adolescents in China is already as high as 52.7%, making the prevention and control of myopia a strategic issue for China's development. In recent years, RLRL therapy has received widespread attention in slowing down the progression of myopia, and most studies have found that 650 nm low-level red-light can control the development of myopia in children and adolescents [2–4]. The mechanism of myopia prevention and control may be a response to an improvement in scleral blood perfusion through the choroid and reduced scleral hypoxia [5].

There are many means to prevent and control myopia, with varying degrees of effectiveness in slowing myopia progression. The results of RLRL therapy have mostly focused on its effectiveness in controlling myopia, but the factors affecting the effectiveness of RLRL therapy are not clear. This study is a real-world study to explore the factors associated with changes of AL after RLRL therapy, to clarify the population with a high response to RLRL therapy, to provide more basis for the use of RLRL therapy in the clinic practice, and to explore more appropriate myopia prevention and control tools for different populations.

Objects and methods

Objects

Retrospective case study. A total of 323 children and adolescents diagnosed with myopia or ocular axial lengthening and treated with RLRL in the Department of Ophthalmology of Wuhan Children's Hospital in the years 2022–2023 were selected, of which 58 were treated with combined defocus design spectacle lenses and 4 were treated with combined 0.01% atropine eye drops.

The sample size estimation was conducted based on the assumption of an a level of 0.05, 80% power, a 50% treatment effect (reducing axial elongation by 0.15 mm). Under this conditions, the minimum number of subjects required 224 participants. Adjusting for 15% loss to follow-up yielded a total sample size of 264 participants.

The study was approved by the Ethics Committee of Wuhan Children's Hospital (20211126-E04, 20211126-E05), and the study process followed the principles of the Declaration of Helsinki. The treatment protocols were approved by their parents who signed an informed consent form.

Inclusion criteria: (1) children and adolescents aged 3–18 years; (2) equivalent spherical lens ≤ −0.75D after full cycloplegia; (3) ocular axis length greater than the average ocular axis length for the age; (4) refractive interstitial transparency, and no other ocular diseases except myopia; (5) agreement and signing of the informed consent form; (6) good compliance, and can be followed up on time for examination.

Exclusion Criteria: (1) Those with photosensitivity and other major systemic diseases; (2) Those with refractive media clouding (e.g., keratoconus, crystalline clouding, etc.); (3) Those with retinal, optic nerve, macular degeneration, or other congenital or hereditary diseases of the inner eye; (4) Those who are unable to cooperate with the treatment and follow-up, such as mental retardation or hyperactivity; (5) Other reasons the investigator considers inappropriate for the inclusion of the program.

Methods

All subjects underwent uncorrected and corrected visual acuity, intraocular pressure (IOP), slit -lamp examination n (slit-lamp, Haag-streit, Köniz, Switzerland), cycloplegic refraction testing (1% cyclopentolate hydrochloride), AL measurements, fundus photography, and optical coherence tomography(OCT) at baseline, 1-month, 3-month, 6-month, 12-month,18-month and 24 month follow-ups. The SER was calculated as the average of the spherical power and half the magnitude of the cylinder power. Corneal curvature and AL were measured using a non-contact biometer (IOL Master; Carl Zeiss Meditec AG, Jena, Germany). SFCT was visualized by spectral-domain optical coherence tomography (SPECTRALIS-OCT, Heidel-berg, Germany) with an enhanced depth imaging (EDI-OCT) system and scanned using a 6 mm line scan and eye-tracking systems. SFCT was defined as the distance from the inner scleral border to the outer border of the retinal pigment epithelium under the foveal macula, which was measured on a manually marked image.

All the children wore spectacles and underwent repeated 650 nm, low-intensity, single-wavelength red light treatment twice a day for three minutes each time, with a minimum interval of 4 h between sessions and 5 days per week. The RLRL therapy was conducted at home under the supervision of parents/guardians. The device was connected to the internet with an automated diary function to record treatment sessions and to monitor patient compliance.

Statistical methods

SPSS20.0 software was used for statistical analysis, and the data from the right eyes of all enrolled children were analyzed. All the data were first analyzed by normal test and ANOVA, and the measurements that met the normal

Table 1 Baseline information

Basic information	
Age (years)	8.94 ± 2.22
Sex (male/female)	195/128
SER (D)	−2.93 ± 2.25
AL (mm)	24.79 ± 1.08
SFCT (μm)	251.00 ± 60.82
CCT (mm)	524.71 ± 31.44
LR (mm)	7.80 ± 0.26
IOP (mmHg)	14.40 ± 2.85
Combined with other control measures	261/62

SER spherical equivalent refractive, *AL* axial length, *SFCT* subfoveal choroidal thickness, *CCT* corneal thickness, *LR* corneal radius of curvature, *IOP* Intraocular pressure

Combined with other control measures, there were 58 people wearing defocus design spectacle lenses and 4 people using 0.01% atropine eye drops

distribution, the mean ± SD was recorded, and independent samples t-test and Pearson's correlation analysis were used, and the measurements that did not meet the normal distribution were expressed median (interquartile range), and rank sum test and Spearman's anecdotal correlation were used. One-way repeated-measures ANOVA was used after meeting the chi-square and satisfying the test of sphericity, and the degrees of freedom of the associated mean squares were corrected with the correction coefficients, Epslion, when the test of sphericity was not satisfied. Differences were considered statistically significant at $P < 0.05$.

Results

General information

A total of 323 children and adolescents with a mean age of 8.94 ± 2.22 years, 195 males and 128 females were included in this study. Baseline information is shown in Table 1.

Primary outcome

The AL regressed significantly and became shorter after RLRL treatment. As shown in Table 2, the reduction from baseline 24.79 ± 1.08 mm to 24.66 ± 1.06 mm, 24.63 ± 1.08 mm, 24.64 ± 1.03 mm, 24.69 ± 0.99 mm, and 24.65 ± 1.06 mm at 3-, 6-, 12-, 18-, and 24-month follow-up, respectively, with a statistically significant difference ($F = 16.122$, $P < 0.001$). The amount of change in the AL continued to regress from − 0.14 ± 0.14 mm at 3-month follow-up to −0.16 ± 0.18 mm at 6-month follow-up, with the maximum value of change appearing and then trending gently upward.

Table 3 Correlation between the change in AL at different follow-up time and baseline AL

AL change value	*r*	*P*
△AL(3 months - baseline)	−0.165	0.004
△AL(6 months - baseline)	−0.251	0.000
△AL(12 months - baseline)	−0.298	0.000
△AL(18 months -baseline)	−0.221	0.007
△AL(24 months - baseline)	−0.236	0.016

As shown in Table 3, the changes in the AL at different time points were negatively correlated with the baseline AL, the longer the ocular axis, the greater the change in its ocular axis, and the more pronounced the amount of ocular regression (all $P < 0.05$). The AL was divided by 26 mm, ≥ 26 mm for the high myopia group totaling 40 people, and < 26 mm for mild to moderate myopia totaling 283 people. As shown in Fig. 1, the degree of change of their eye axes was greater in the high myopia group than in the mild-moderate myopia group, and all of them were statistically different in the first 18 months of follow-up (all $P < 0.05$).

As shown in Table 4, the AL after RLRL treatment were positively correlated with SER, the higher the degree of myopia, the thinner SFCT was, and the more significant was the amount of regression of their AL (all $P < 0.05$). Similarly, except for the 24-month follow-up, the thinner the SFCT, the greater the amount of AL regression (all $P < 0.05$), and AL change was positively correlated with SFCT. Age was negatively correlated with AL changes, the older the age, the greater the amount of their AL regression, and the more significant the effect was after RLRL treatment (all $P < 0.05$). There was no statistical correlation between gender and AL change in the first 18 months of follow-up, but the amount of ocular axis regression was more pronounced and statistically correlated in females in the 24-month follow-up ($P = 0.008$). At the 6-, 12- and 18-month follow-ups showed that RLRL treatment combined with other preventive and control measures had greater amount of AL regression in children, which was statistically correlated ($P < 0.05$ for all), whereas there was not correlated with the AL change at the 3- and 12-month follow-ups ($P = 0.703$, $P = 0.426$).

Table 2 Changes in the AL at different follow-up time

Follow-up	Baseline(*n* = 323)	3-month(*n* = 299)	6-month(*n* = 279)	12-month(*n* = 303)	18-month(*n* = 150)	24-month(*n* = 104)	F, *P*
AL	24.79 ± 1.08	24.66 ± 1.06	24.63 ± 1.08	24.64 ± 1.03	24.69 ± 0.99	24.65 ± 1.06	16.122,
△AL		−0.14 ± 0.14	−0.16 ± 0.18	−0.15 ± 0.23	−0.11 ± 0.27	−0.05 ± 0.30	<0.001

△ Al is the follow-up month AL minus the baseline AL

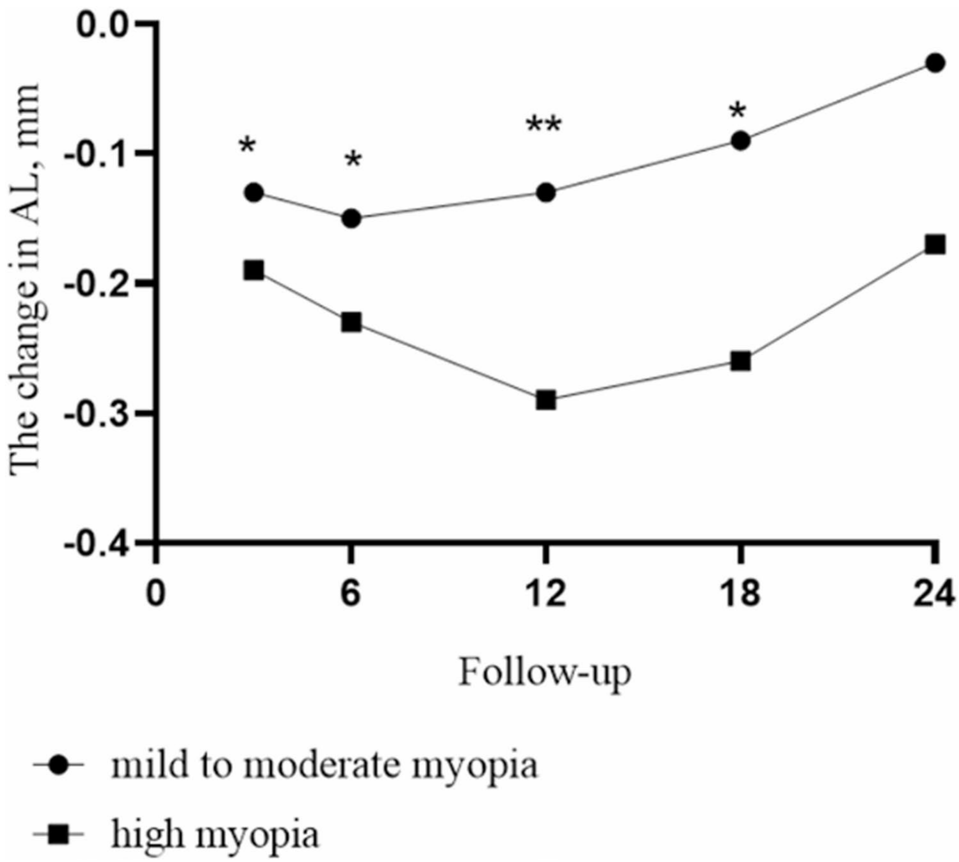

Fig. 1 The changes of AL in two groups at different follow-up. ** and * represent "$p < 0.001$" and "$p < 0.05$" comparing the data of ΔAL between the two groups

Table 4 The correlation factor of AL change at different time points

	SER		SFCT		Age		Sex		combined other measures	
	r	*p*	*r*	*p*	*r*	*p*	*r*	*p*	*r*	*p*
△AL(3 months - baseline)	0.154	0.008	0.136	0.032	−0.169	0.003	−0.015	0.791	−0.022	0.703
△AL(6 months - baseline)	0.197	0.001	0.243	0.000	−0.27	0.000	−0.056	0.355	−0.144	0.016
△AL(12 months - baseline)	0.283	0.000	0.23	0.000	−0.282	0.000	−0.031	0.585	−0.126	0.028
△AL(18 months -baseline)	0.232	0.004	0.185	0.047	−0.305	0.000	−0.095	0.249	−0.191	0.019
△AL(24 months - baseline)	0.329	0.001	0.192	0.118	−0.263	0.007	−0.26	0.008	−0.079	0.426

SER spherical equivalent refractive, *SFCT* subfoveal choroidal thickness

Secondary outcomes

As shown in Table 5, there was no statistical correlation between corneal thickness, corneal curvature, and IOP and the change in the ocular axis at different follow-up time points (all $P > 0.05$), the change in the ocular axis was not affected by corneal thickness, corneal curvature, and IOP in RLRL treatment.

Discussion

How to successfully intervene in the refractive state and slow the progression of myopia is of major therapeutic value, as myopia in children and adolescents in China now exhibits a pattern of low and high myopia. The use of RLRL to slow the evolution of myopia has drawn a lot of interest since it is based on the idea that outdoor activities should be light-based in order to prevent and control myopia [6]. This study, which was observed over a 2-year period in the real world, discovered that RLRL therapy was successful in slowing the advancement of myopia. Strong correlations were found between the efficacy of RLRL treatment and baseline AL, baseline SER, baseline SFCT, baseline age, and whether or not it was combined with other preventative controls.

The refractive status of the eye is mainly composed of the eye axis, corneal curvature and lens curvature, and the AL is the primary factor determining the refractive

Table 5 Factors that are not correlated with the changes in AL at different time points

	CCT		CC		IOP	
	r	*p*	*r*	*p*	*r*	*p*
△AL(3 months - baseline)	0.001	0.984	−0.017	0.77	−0.003	0.958
△AL(6 months - baseline)	0.031	0.875	−0.045	0.454	0.005	0.937
△AL(12 months - baseline)	−0.008	0.902	−0.023	0.69	0.005	0.932
△AL(18 months -baseline)	−0.034	0.736	0.032	0.700	0.022	0.793
△AL(24 months - baseline)	−0.045	0.705	0.019	0.851	0.045	0.651

CCT central corneal thickness, *CC* corneal curvature, *IOP* intraocular pressure

status [7]. It is the primary determinant of refractive status and the main reference for assessing the progression of myopia and judging the effectiveness of myopia prevention and control. It has been shown that AL and SER share common genes in etiology, and AL lengthening is considered an endophenotype of myopia [8, 9]. This study found that the longer the basal AL and the higher the basal SER, the greater the value of AL regression after RLRL treatment (all $p < 0.05$, Tables 3 and 4), and the more effective the myopia prevention and control was. However, Zhao et al. found that the control effect of low-concentration atropine eye drops on the progression of high myopia may be weaker than that of mild-to-moderate myopia [10].Similarly, in treatment with keratoplasty lenses, the growth of the AL in children with low-to-moderate myopia was significantly suppressed within 2 years [11]. Zhu et al. concluded that the control effect was related to baseline SER and was weaker for high myopia than for mild to moderate myopia. In this study, the baseline AL is correlated with the effectiveness of RLRL treatment. Higher baseline AL was associated with slower axial elongation after RLRL treatment. This may be due to the high levels of certain cytokines (IL-1, IL-6) in highly myopic eyes [12, 13], which absorb more energy and thus increase the effects of RLRL. This can provide a new treatment option for children with high myopia.

Most studies have shown that [2, 4, 14, 15] RLRL can effectively slow down or even reverse myopia progression, and is superior to keratoplasty lenses [3] and low concentration of atropine [16]. The increase in blood flow and thickness of the choroid under the macular plexus has been shown to be effective and safe. Consistent with the results of previous studies, it was discovered that following RLRL treatment, there was a statistically significant difference in AL ($F = 16.122$, $P < 0.05$); additionally, the effect of combining with other preventive and control strategies was more positive ($P < 0.05$, Table 4).Liu et al. also found [17] the combination of RLRL and keratoplasty lenses were more effective than keratoplasty lenses alone in improving uncorrected visual acuity, slowing down the axial growth of the eye, increasing SFCT, and controlling progressive myopia in adolescents. Combining with other preventive and control means is positively correlated with the effect of RLRL therapy, and would be a new tool for those with rapid myopia progression.

The choroid, a highly vascularized layer, plays a crucial role in relaying signals derived from the retina to the sclera, producing mediators that regulate scleral metabolism during ocular development, further affecting extracellular matrix (ECM) remodelling in the sclera, and playing an active role in emmetropization or in thepathogenesis of myopia [5, 18]. During normal childhood growth and development, the choroid will gradually thicken, however, when the rate of choroidal thickening is slower than the rate of choroidal thinning due to the growth of myopia, the choroid tends to thin, which in turn suggests the progression of myopia [19] .650 nm red light not only promotes the release of dopamine, but also increases NO release [20], and thus increase choroidal thickness. The increase in choroid thickness can move the retina towards the focal plane of the eye (choroidal accommodation), change the AL. Interestingly, in this study, a negative correlation was found between baseline SFCT and RLRL treatment, the thinner the SFCT, the more pronounced the value of change in AL after RLRL therapy ($P < 0.05$, Table 4). The choroid plays an important role in regulating ocular growth and SER mechanisms. By increasing choroidal blood flow and reducing oxidative stress and inflammation [21, 22], thus ameliorating scleral hypoxia to control myopia progression. The author believes that 650 nm red light irradiation enhances the scleral hypoxic environment. The AL alterations are evident when the SFCT is thinner since there is more space for improvement.

In this study, the amount of AL regression was shown to be larger in older children, and age was found to connect with the amount of AL change in Table 4, in consistent with studies by Zhou [14] and Xiong [3] et al. It is considered to be related to the fact that in the children included in this study, the older the child, the longer the AL, the thinner SFCT, and thus the more significant effect of RLRL on the amount of AL regression.

Whether gender differences affect eye growth is controversial, with one study finding that boys' eye growth is a bit faster than girls' [23–25]. However, there are also studies showing that girls' AL progress faster [26] or that there is no gender difference [27]. In this study, in the first 18 months of follow-up, girls' eye axis change values were greater than boys', but there was no statistical difference until the 24-month follow-up when there was a statistical difference ($P=0.008$). Considering the difference in the age of pubertal development between girls and boys, whether there is a correlation between gender and the amount of AL growth deserves further exploration.

In this study, corneal curvature and corneal thickness were found to have no correlation with the amount of AL change (all $p>0.05$, Table 5), suggesting that RLRL is not affected by corneal curvature and thickness. Although it has been shown that high IOP in developing children may promote myopic progression and ocular axis growth [28]. In this study, there was no correlation between baseline IOP values and the amount of AL changes in table ($p>0.05$).

This study had some limitations. Changes in AL also become smaller over time, meaning that long-term efficacy is unknown, which is a major limitation of myopia control studies. Although a 2-year real world study, the number of people lost to follow after 1 year was high and future studies need a larger sample size. It's real-world data, but that also means it's retrospective and non-randomized, and therefore prone to bias. This study did not have a blank control group for comparison.

In conclusion, it was observed over a 2-year follow-up period in a real-world study that baseline AL, baseline SER, baseline SFCT, baseline age, and whether or not it was combined with other means of prevention and control affected the effectiveness of RLRL therapy. The longer the baseline AL, the higher SER, the thinner SFCT, the older age, and the more significant the amount of change in AL regression. However, the change in AL was not affected by IOP, corneal curvature and corneal thickness. Therefore, the prognosis of myopia progression control by RLRL therapy was predicted by evaluating basic characteristics such as AL, SER, SFCT, age, whether or not it was combined with other means of prevention and control to select the most benefit myopia control methods for children.

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Authors' contributions
Yiyi Peng: Data organization, data analysis, and paper writing; Dan Wang and Nan Ma: Project design, data collection, data analysis and interpretation; Hong Jie: Provide research guidance, revise papers, and participate in the editorial department's revision suggestions.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This research was approved by the Ethics Committee of Wuhan Children's Hospital (20211126-E04, 20211126-E05) and all relevant principles of the Declaration of Helsinki were followed. All eligible patients who were willing to participate signed informed consent from approved by an institutional review board.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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