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Effect of repeated Low-Level red light therapy on axial length in myopic individuals: predictors for a good response

Daohuan Kang[1], Lu Yuan[1], Jia Feng[1], Rui Yu[1], Andrzej Grzybowski[2], Kai Jin[3*] and Wen Sun[1*]

Abstract

Purpose This study aimed to investigate the effects of Repeated Low-Level Red Light (RLRL) therapy on axial length (AL) in myopic individuals and to identify key predictors for a good response to the treatment, with a focus on baseline ocular characteristics and treatment compliance.

Methods A total of 91 participants were enrolled, with 50 classified in the poor responders' group and 41 in the good responders' group. Baseline characteristics, including age, gender, pupil constriction diameter (PCD), intraocular pressure (IOP), spherical equivalent refraction (SER), AL, corneal curvature (ACC), and choroidal thickness (CT) were recorded. Compliance and AL changes were tracked over one year. Univariable and multivariable analyses identified factors associated with AL changes.

Results Good responders' group showed a significant AL reduction (-0.29 ± 0.16 mm, $p < 0.001$), while poor responders' group had an increase (+ 0.23 ± 0.12 mm, $p < 0.001$). Good responders' group had lower initial SER (-4.15 ± 2.87 D vs. -2.62 ± 1.80 D, $p = 0.004$) and longer AL (24.76 ± 1.21 mm vs. 24.15 ± 0.99 mm, $p = 0.010$). Both groups showed CT changes ($p < 0.001$), with greater increases in good responders. Univariable analysis identified initial AL and SER as predictors of a good response (both $p < 0.001$). Compliance showed a trend toward significance in multivariable analysis (β = -0.196, $p = 0.052$).

Conclusion Longer baseline AL and lower SER are key predictors of a good response to RLRL therapy. Moreover, treatment compliance showed a trend toward significance, emphasizing its crucial role in achieving optimal outcomes.

Keywords Myopia, Axial length, Red light therapy, Treatment compliance, Predictors

*Correspondence:
Kai Jin
jinkai@zju.edu.cn
Wen Sun
drsunwen@zju.edu.cn
[1]Department of Ophthalmology, Children's Hospital, Zhejiang University School of Medicine, National Clinical Research Center for Child Health, Hangzhou, China
[2]Institute for Research in Ophthalmology, Foundation for Ophthalmology Development, Poznan, Poland
[3]Eye Center, The Second Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou, Zhejiang, China

Background

Myopia is an increasingly prevalent global public health issue, particularly among children and adolescents. The rising rates of myopia are of concern, as high myopia can lead to sight-threatening complications such as retinal detachment, myopic maculopathy, and glaucoma [1, 2]. Various interventions, including pharmacological approaches like low-dose atropine [3], optical devices such as orthokeratology [4, 5], peripheral defocus lenses [6], and lifestyle modifications like increased outdoor time [7], have been explored to slow the progression of myopia. Recently, RLRL therapy has emerged as a novel non-invasive approach to myopia control, gaining attention for its potential to slow axial elongation [8–12].

RLRL therapy involves the application of red light, typically at a wavelength of 650 nm, to stimulate photoreceptors in the eye, which may help slow the growth of AL– a key factor in myopia progression. Clinical studies have shown that RLRL therapy can significantly slow myopia progression in children by reducing the rate of AL elongation [13–15]. For instance, one meta-analysis found that children treated with RLRL experienced a 0.22 mm/year reduction in axial elongation compared to controls [16]. Moreover, combining RLRL with orthokeratology shows a positive trend, enhancing its efficacy [17]. The precise mechanisms through which RLRL controls myopia progression remain unclear. However, studies suggest that RLRL intervention increases blood flow and reduces oxidative stress and inflammation, which helps alleviate scleral hypoxia and prevents the development of myopia [18, 19]. Additionally, the study hypothesizes that red light therapy may promote scleral remodeling or shortening, potentially reducing AL and controlling myopia progression [20].

Myopia control methods may have some side effects, such as photophobia and allergic conjunctivitis associated with low-concentration atropine [21]. Although most clinical studies show that RLRL therapy is well tolerated with only minor adverse reactions, such as temporary discomfort from bright light exposure [16], emerging studies highlight potential side effects and safety concerns. A two-year randomized controlled trial identified a rebound phenomenon in therapeutic outcomes upon discontinuation of sustained RLRL application [22]. Notably, clinical case reports have documented retinal injury in a pediatric patient (12-year-old female) manifesting retinal abnormalities following multiple low-intensity RLRL sessions [23]. Concurrently, safety assessments have raised concerns that some RLRL devices may exceed the established thermal and photochemical maximum permissible exposure limits, increasing the risk of retinal damage [24]. These findings are consistent with recent insights from Schaeffel and Wildsoet, who stress the need for thorough investigation into these risks, especially in terms of long-term ocular safety [25].

This study aims to investigate the clinical characteristics and treatment outcomes of myopic individuals undergoing RLRL therapy, with a focus on changes in AL and identifying key predictors of a good response. By analyzing these predictors, this research seeks to contribute to the development of more personalized and effective strategies for managing myopia progression.

Methods

Study population

The study, approved by the hospital's ethics committee in accordance with the Declaration of Helsinki, obtained written parental consent. This retrospective study analyzed device readouts and medical records of children who underwent RLRL therapy for myopia control at the Children's Hospital, Zhejiang University School of Medicine, from October 2022 to October 2023. To ensure confidentiality, each child was assigned a unique ID, and only right-eye data were collected to avoid redundancy. Of the 157 screened subjects, those with myopia who wore only regular glasses and used RLRL, 44 were excluded for inconsistent RLRL use, low compliance (< 60%), prolonged afterimage (> 6 min), or discomfort, and 22 for insufficient AL change (< 0.1 mm/year) (Fig. 1). A total of 91 children were included. Data collection was carefully conducted using device readouts and medical records. Participants were classified as good responders (AL decrease > 0.1 mm) or poor responders (AL increase > 0.1 mm), facilitating a clear comparison of AL change. This threshold was established based on AL measurement accuracy and clinically significant progression criteria adapted from published research [26].

Intervention

Participants used a red light device from Suzhou Xuanjia Optoelectronics Technology, This device emits red light at a wavelength of 650 ± 10 nm, with an illumination intensity around 1600 lx and an optical power of 0.29 mW through a 4 mm pupil. It meets IEC 60825-1:2014 safety standards and is certified as a class IIa medical device by the China National Medical Products Administration. However, starting from July 2024, red light therapy devices will be classified as Class III medical devices, according to the notice issued by the National Medical Products Administration (NMPA) on July 11, 2023.

The treatment plan involved administering RLRL therapy twice daily, five days a week, with a minimum interval of four hours between sessions, and each session lasting three minutes. Participants were given detailed instructions on the correct use of the device and were required to maintain usage logs. Compliance with the treatment protocol was monitored by reviewing these

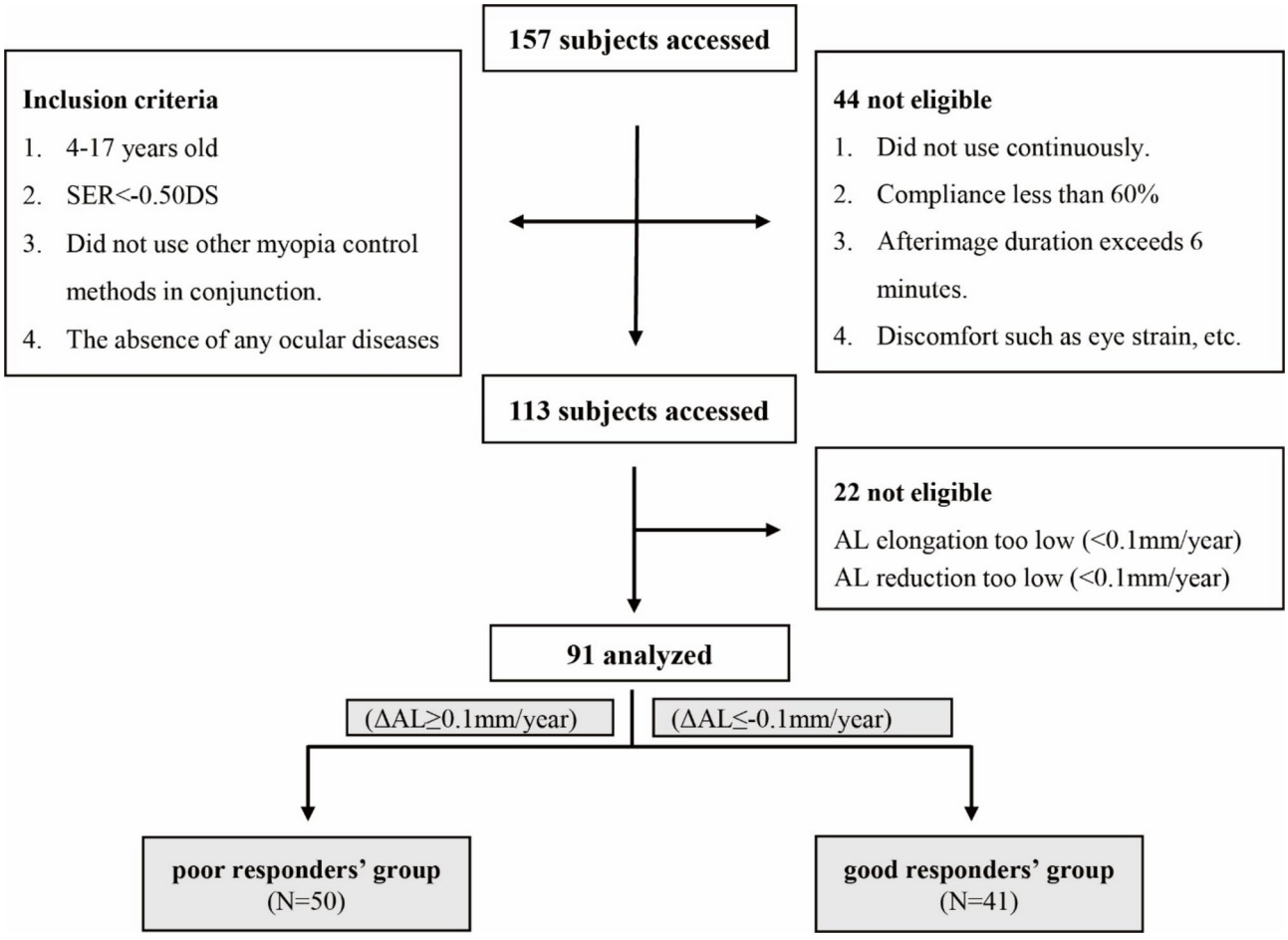

Fig. 1 Flowchart of participant recruitment and grouping.
AL: axial length, ΔAL: Change in AL (AL at the one-year visit – AL at baseline)

logs in conjunction with the device's built-in usage tracking system. It indicates the ratio of actual time to the prescribed time.

Measurements

All measurements were conducted by trained ophthalmic technicians using standardized procedures to ensure consistency. AL was measured with the LS900 optical biometer (HAAG-STREIT), with three measurements per eye, achieving an accuracy of ≤ 0.05 mm. SER and ACC were obtained via cycloplegic refraction using the KR-8800 automatic refractometer (Topcon), with SER calculated as spherical power + (cylinder power)/2, and ACC as (Flat K + Steep K)/2. Measurements were repeated three times per eye, with spherical and cylindrical accuracy ≤ 0.25 D and axial accuracy ≤ 5°. Complete ciliary muscle paralysis was confirmed with compound tropicamide drops. IOP was assessed using the CT-800 non-contact tonometer (Topcon), and PCD was measured by an infrared pupillometer (Eyerising) after red light stimulus. OCT imaging was conducted using the RS-3000 Advance OCT (NIDEK) with a 9 mm radial scan centered on the macula in a dark room to reduce ambient light, allowing automated calculation of CT from the outer choroid to Bruch's membrane.

Statistical analysis

The statistical analysis was conducted using SPSS Version 26 (IBM). Continuous variables were presented as mean ± standard deviation (SD). Differences in the male/female (M/F) ratio between groups were assessed using the Chi-squared (χ^2) test. Unpaired t-tests were used to compare changes in age, compliance, PCD, SER, IOP, AL, ACC, and CT between groups. Paired t-tests were employed to compare SER, AL, ACC, and CT between baseline and one year after RLRL therapy. Pearson correlation coefficients were calculated to assess the relationships between age and changes in AL. Univariable and multivariable regression analyses were performed to identify significant predictors of a good response. The regression coefficients are presented with their corresponding 95% confidence intervals (CIs). A p-value

Table 1 Demographics and ocular biometrics of the right eyes in two groups

Variables	poor responders' group (Mean ± SD) *N* = 50	good responders' group (Mean ± SD) *N* = 41	t	*P*
Age (years)	9.18 ± 2.32	10.00 ± 2.85	-1.515	0.133
Gender (M/F)	28/22	16/25	-	0.107
Compliance (%)	83.00 ± 11.06	85.67 ± 8.51	-1.265	0.209
PCD (mm)	2.89 ± 0.39	2.85 ± 0.36	0.406	0.686
SER (D)	-2.62 ± 1.80	-4.15 ± 2.87	2.969	**0.004**
IOP (mmHg)	16.62 ± 2.76	16.76 ± 2.89	-0.229	0.819
AL (mm)	24.15 ± 0.99	24.76 ± 1.21	-2.642	**0.010**
ACC (D)	43.79 ± 1.49	43.85 ± 1.29	-0.210	0.834
CT (μm)	247.02 ± 28.06	242.02 ± 28.13	0.844	0.401

M: male, F: female, PCD: Pupil Constriction Diameter, SER: Spherical Equivalent Refraction, IOP: Intraocular Pressure, AL: Axial Length, ACC: Average corneal curvature, CT: Choroidal Thickness, D = diopters

SD: standard deviation

Chi-square analysis was used for gender comparisons, while independent sample t-tests were applied to all other variables. Statistical significance was defined as a P-value < 0.05, with significant differences highlighted in bold

Table 2 Summary of results at one-year follow-up

Variables	poor responders' group				good responders' group				*P*
	baseline	1 year	*p*	1-year changes	baseline	1 year	*p*	1-year changes	
SER (D)	-2.62 ± 1.80	-3.12 ± 1.80	**< 0.001**	-0.50 ± 0.28	-4.15 ± 2.87	-3.61 ± 2.70	**< 0.001**	0.54 ± 0.36	**< 0.001**
AL (mm)	24.15 ± 0.99	24.38 ± 0.99	**< 0.001**	0.23 ± 0.12	24.76 ± 1.21	24.47 ± 1.15	**< 0.001**	-0.29 ± 0.16	**< 0.001**
ACC (D)	43.79 ± 1.49	43.61 ± 1.49	**< 0.001**	-0.17 ± 0.20	43.85 ± 1.29	43.65 ± 1.33	**< 0.001**	-0.19 ± 0.22	0.909
CT (μm)	247.02 ± 28.06	261.54 ± 28.40	**< 0.001**	14.20 ± 2.94	242.02 ± 28.13	263.93 ± 28.02	**< 0.001**	21.90 ± 4.50	**< 0.001**

SER: Spherical Equivalent Refraction, AL: Axial Length, ACC: Average corneal curvature, CT: Choroidal Thickness

P-values were calculated using Student's t-test for paired samples and unpaired samples, respectively. Statistical significance was defined at the 0.05 level, with significant differences indicated in bold (P-value < 0.05)

of < 0.05 was considered statistically significant for all analyses.

Results

Participant characteristics

We collected 157 cases of myopia control using red light therapy. Among these, 50 cases exhibited an axial growth of more than 0.1 mm and were classified as poor responders. In contrast, approximately 40% (63/157) of subjects showed effectiveness, with axial growth of less than 0.1 mm over one year. Within this group, 41 cases demonstrated an axial shortening of more than 0.1 mm, classifying them as good responders, while 22 cases showed mild to moderate responses. The mean age of participants was slightly lower in the good responders' group (10.00 ± 2.85 years) compared to the poor responders' group (9.18 ± 2.32 years), though the difference was not statistically significant ($p = 0.133$). Gender distribution was also similar, with 28 males and 22 females in the poor responders' group, and 16 males and 25 females in the good responders' group ($p = 0.107$). Compliance with RLRL therapy was comparable between the two groups, with 83.00 ± 11.06% in the poor responders' group and 85.67 ± 8.51% in the good responders' group, showing no significant difference ($p = 0.209$). Other baseline ocular factors, including PCD and IOP, also showed no significant differences between the groups ($p > 0.05$). These baseline characteristics are summarized in Table 1.

AL changes over time

Over the one-year follow-up period, significant changes in AL were observed between the two groups. The poor responders' group showed a mean increase in AL of 0.23 ± 0.12 mm ($p < 0.001$), indicating progression of myopia, while the good responders' group experienced a significant mean reduction in AL of -0.29 ± 0.16 mm ($p < 0.001$). This demonstrates that RLRL therapy can result in good treatment responder in certain individuals, as seen in the one-year AL changes in Table 2. Additionally, the Fig. 2 scatter plot illustrates the differences in AL changes between the groups, highlighting the relationship between AL changes and participants' age. Pearson correlation analysis between age and AL change showed a weak negative correlation (r = -0.127) with a non-significant p-value of 0.232, indicating no strong association between these two factors.

Differences in ocular parameter characteristics between the two groups

Significant differences in ocular parameters were observed between the two groups. The good responders' group had a significantly lower initial SER compared to the poor responders' group (-4.15 ± 2.87 D vs. -2.62 ± 1.80

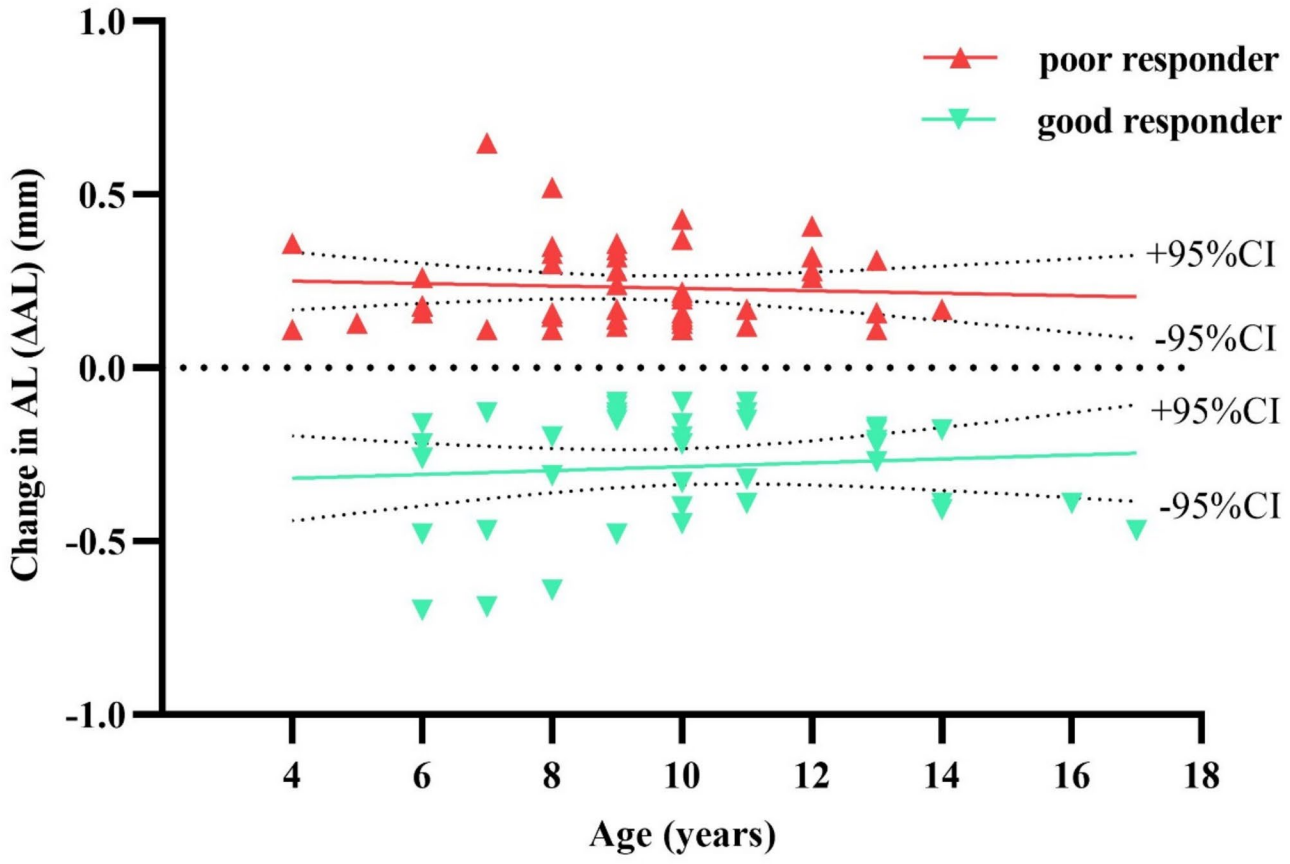

Fig. 2 Scatter plots showing differences in the ΔAL and age between the two groups
AL: axial length, ΔAL: Change in AL, 95% CI: 95% confidence interval

D, $p = 0.004$), indicating that individuals with more severe initial myopia were more likely to have a better response to the treatment. Additionally, the good responders' group had a longer initial AL (24.76 ± 1.21 mm) compared to the poor responders' group (24.15 ± 0.99 mm, $p = 0.010$). However, parameters such as ACC, CT and IOP showed no statistically significant differences between the groups at baseline ($p > 0.05$), as shown in Table 1.

At the one-year follow-up, both groups demonstrated changes in ACC and CT. In the good responders' group, CT increased significantly from 242.02 ± 28.13 μm to 263.93 ± 28.02 μm ($p < 0.001$), while the poor responders' group showed a smaller, yet still significant, increase from 247.02 ± 28.06 μm to 261.54 ± 28.40 μm ($p < 0.001$). The increase in CT over one year was significantly greater in the good responders' group compared to the poor responders' group ($p < 0.001$). The changes in CT over time for both groups are presented in detail in Table 2.

Factors associated with reduction in AL after one year of treatment

Univariable analysis identified initial AL and SER as significant predictors of AL reduction (both $p < 0.001$). Specifically, participants with longer initial AL and lower SER were more likely to experience a reduction in AL after one year of RLRL therapy. Other factors, including age, gender, treatment compliance, CT, PCD, and IOP, did not show significant associations with AL reduction in the univariable analysis ($p > 0.05$).

In the multivariable analysis, although none of the factors reached statistical significance at the $p < 0.05$ level, treatment compliance demonstrated a trend towards significance (β = -0.196, $p = 0.052$), suggesting that higher compliance may contribute to greater reductions in AL. These findings are summarized in Table 3.

Discussion

This study aimed to explore the clinical characteristics and treatment outcomes of myopic individuals undergoing RLRL therapy, with a focus on AL changes and identifying predictors of a good response. The findings offer valuable insights into the efficacy of RLRL therapy in managing myopia and highlight several factors that may influence treatment success.

Table 3 Univariable and multivariable analyses of the associations between all potential factors and changes in AL

Variables	Univariable analysis		Multivariable analysis*	
	β (95% CI)	*p*	β (95% CI)	*p*
Age (years)	-0.127(-0.336 ~ 0.082)	0.232	-0.021(-0.034 ~ 0.029)	0.881
Gender (M/F)	0.103 (-0.060 ~ 0.181)	0.330	0.162(-0.026 ~ 0.215)	0.127
Compliance (%)	-0.16 (-0.011 ~ 0.001)	0.129	-0.196(-0.011 ~ -0.000)	0.052
PCD (mm)	0.090 (-0.087 ~ 0.234)	0.370	0.094(-0.079 ~ 0.224)	0.348
SER (D)	0.443(0.031 ~ 0.075)	**< 0.001**	0.362(-0.009 ~ 0.095)	0.106
IOP (mmHg)	-0.023 (-0.024 ~ 0.019)	0.827	-0.023(-0.023 ~ 0.018)	0.82
AL (mm)	-0.360 (-0.144 ~ -0.043)	**< 0.001**	-0.159(-0.175 ~ 0.092)	0.547
ACC (D)	-0.043(-0.053 ~ 0.035)	0.685	0.09(-0.051 ~ 0.090)	0.598
CT (μm)	-0.030(-0.002 ~ 0.002)	0.777	-0.046(-0.003 ~ 0.002)	0.652

M: male, F: female, PCD: Pupil Constriction Diameter, SER: Spherical Equivalent Refraction, IOP: Intraocular Pressure, AL: Axial Length, ACC: Average corneal curvature, CT: Choroidal Thickness, D = diopters

Regression coefficients (β) and their 95% confidence intervals are presented; *Multivariable analysis results are adjusted for age and sex. P-value < 0.05, with significant differences highlighted in bold

Participant characteristics and treatment compliance

The baseline characteristics, including age, gender, compliance, PCD, CT, and IOP, showed no significant differences between the two groups, suggesting that these factors did not influence RLRL therapy outcomes. Both groups demonstrated high treatment compliance, with the good responders having a compliance rate of 85.67 ± 8.51, slightly higher than the 83.00 ± 11.06 observed in the poor responders. However, this difference was not statistically significant ($p = 0.209$).

Efficacy of RLRL therapy in poor or good responders' group

A major finding of the study was the significant difference in AL changes between the two groups. The poor responders experienced a mean AL increase of 0.23 mm over one year, indicating continued myopia progression. In contrast, the good responders showed a mean AL decrease of 0.29 mm, suggesting that RLRL therapy effectively stabilized or reduced myopia progression in this group. These results emphasize that RLRL therapy elicits varying responses depending on individual characteristics. While some individuals benefit greatly, others show minimal improvement, underscoring the need for identifying predictors of treatment success.

Scleral hypoxia has been proven to be a promoter of myopia progression [27]. The effects of RLRL therapy may stem from enhanced retinal blood flow and metabolism, along with reduced scleral hypoxia, which helps control myopia progression. However, the exact mechanisms remain unclear. Determining predictors of a good response, such as baseline ocular characteristics and treatment compliance, is vital for optimizing RLRL therapy and customizing it for those most likely to achieve positive outcomes.

Differences in ocular characteristics between the two groups

The initial SER and AL were significantly different between the two groups. Good responders had more severe initial myopia (lower SER) and longer AL compared to poor responders, suggesting that individuals with more advanced myopia may respond better to RLRL therapy. Other ocular parameters, including CT, IOP, PCD, and ACC, did not show significant differences between the groups. While CT [28] and IOP [29] are important in myopia control, their direct influence on RLRL therapy outcomes was not evident in this study.

The increase in CT over the year was significant in both groups, with good responders showing a significantly greater increase ($p < 0.001$). However, in the good responders' group, the CT increase (21.9 μm) was much smaller than the AL shortening (0.29 mm). This suggests that the AL shortening might be due to possible scleral remodeling or contraction. The study does not clarify why the group of good responders performed better than the other group, despite the observed results. While one potential explanation could involve the more prolate retinal shape and misalignment of photoreceptors in longer eyes, this remains a hypothesis. Consequently, the discussion around this matter remains speculative and warrants further investigation.

PCD, which reflects pupil constriction in response to light, may influence the amount of red light entering the eye during therapy. While no significant differences in PCD were found between the groups, despite studies indicating a correlation between pupil diameter and myopia progression [30, 31], its role in myopia progression and treatment outcomes warrants further research. Similarly, although previous research has indicated that corneal curvature can influence myopia progression [32, 33], ACC did not show significant differences between the groups, suggesting that it may not be a critical factor in determining the outcomes of RLRL therapy.

Predictors of AL reduction after one year

Univariable analysis identified initial AL and SER as significant predictors of a good response, with individuals having longer AL and lower SER showing greater reductions in AL after one year ($p < 0.001$). This finding aligns with previous studies, which have demonstrated that red light therapy plays a key role in treating severe myopia [34].

While no factors were statistically significant in the multivariable analysis ($p > 0.05$), treatment compliance showed a near-significant trend ($\beta = -0.196$, $p = 0.052$), reinforcing its importance in treatment success. Age and gender were not significantly associated with AL changes, which is consistent with previous studies suggesting that there were no significant differences in the efficacy of myopia prevention among different age groups of children [26].

Clinical implications and future research

The findings of this study suggest that RLRL therapy is effective in controlling myopia progression, especially in individuals with more severe initial myopia and longer AL. These factors are key predictors of a positive response. The results could aid clinical decision-making by identifying patients who are more likely to benefit from RLRL therapy based on their baseline ocular characteristics. Future research is needed to assess the long-term effects of RLRL therapy on AL and myopia progression and to better understand its biological mechanisms. Combining RLRL therapy with other myopia control methods, such as orthokeratology or anti-myopia glasses, may lead to improved outcomes.

Limitation

This study has several limitations. First, the retrospective design, small sample size (91 participants), and 42% exclusion rate limit the generalizability of the findings and may introduce selection bias. Second, the one-year follow-up period may be too short to fully assess the long-term effects of RLRL therapy on a good response. Third, important environmental factors, such as outdoor time and near-work activities, which may influence myopia progression [35], were not considered. Fourth, relying on the device's built-in and usage logs may not fully capture true compliance. Lastly, the biological mechanisms by which RLRL therapy reduces AL remain unclear.

Conclusion

This study highlights the potential of RLRL therapy in distinguishing between good and poor responders among myopic patients, with the treatment proving effective for approximately 40% of those treated. Key factors for better patient selection include longer AL and greater myopia. Future research should explore why patients with these characteristics tend to respond better to red light therapy than others, and consider recruiting a control group for comparison to further validate the findings.

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Author contributions

Study design: Daohuan Kang, Lu Yuan, Wen Sun, Andrzej Grzybowski, and Kai Jin.Data collection: Daohuan Kang, Rui Yu, and Jia Feng.Statistical analysis: Lu Yuan and Rui Yu.Writing and figure preparation: Daohuan Kang.Manuscript revision: Wen Sun, Kai Jin, and Andrzej Grzybowski.Final approval of the submitted manuscript: all authors.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study was approved by the institutional research ethics committee of Children's Hospital, Zhejiang university School of Medicine (2021-IRB-107). All examinations and procedures were conducted in accordance with the Declaration of Helsinki, and written informed consent was obtained from the participants' parents.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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