

# Repeated Low-Level Red Light Therapy for Myopia Control in High Myopia Children and Adolescents: A Randomized Clinical Trial

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- PMID: 38849054
- DOI: [10.1016/j.opthta.2024.05.023](https://doi.org/10.1016/j.opthta.2024.05.023)

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### Abstract

**Purpose:** To assess the effectiveness and safety of repeated low-level red light (RLRL), which is a newly available treatment for myopia control in children and adolescents with high myopia.

**Design:** Multicenter, randomized, parallel-group, single-blind clinical trial (randomized controlled trial; [NCT05184621](https://clinicaltrials.gov/ct2/show/study/NCT05184621)).

**Participants:** Between February 2021 and April 2022, 192 children aged 6 to 16 years were enrolled. Each child had at least 1 eye with myopia of cycloplegic spherical equivalent refraction (SER) at least -4.0 diopters (D), astigmatism of  $\leq 2.0$  D, anisometropia of  $\leq 3.0$  D, and best-corrected visual acuity (BCVA) of 0.2 logarithm of the minimum angle of resolution or better. Follow-up was completed by April 2023.

**Methods:** Participants were randomly assigned at a 1:1 ratio to intervention (RLRL treatment plus single-vision spectacles) or control (single-vision spectacles) groups. The RLRL treatment was administered for 3 minutes per session, twice daily with a minimum interval of 4 hours, 7 days per week.

**Mean outcome measures:** The primary outcome and key secondary outcome were changes in axial length (AL) and cycloplegic SER measured at baseline and the 12-month follow-up visit. Participants who had at least 1 postrandomization follow-up visit were analyzed for treatment efficacy.

**Results:** Among 192 randomized participants, 188 (97.91%) were included in the analyses (96 in the RLRL group and 92 in the control group). After 12 months, the adjusted mean change in AL was -0.06 mm (95% confidence interval [CI], -0.10 to -0.02 mm) and 0.34 mm (95% CI, 0.30 to 0.39 mm) in the intervention and control groups, respectively. A total of 48 participants (53.3%) in the intervention group were still experiencing axial shortening  $>0.05$  mm at the 12-month follow-up. The mean SER change after 12 months was 0.11 D (95% CI, 0.02 to 0.19 D) and -0.75 D (95% CI, -0.88 to -0.62 D) in the intervention and control groups, respectively.

**Conclusions:** Repeated low-level red light demonstrates stronger treatment efficacy among those with high myopia, with 53.3% experiencing substantial axial shortening. Repeated low-level red light provides an excellent solution for the management of high myopia progression, a significant challenge in ophthalmology practice.

**Financial disclosure(s):** The author(s) have no proprietary or commercial interest in any materials discussed in this article.

**Keywords:** Axial shortening; Children and adolescents; High myopia; Repeated low-level red light.

Xu Y, Cui L, Kong M, Li Q, Feng X, Feng K, Zhu H, Cui H, Shi C, Zhang J, Zou H. Repeated Low-Level Red Light Therapy for Myopia Control in High Myopia Children and Adolescents: A Randomized Clinical Trial. *Ophthalmology*. 2024 Nov;131(11):1314-1323. doi: 10.1016/j.opthta.2024.05.023. Epub 2024 Jun 6. PMID: 38849054.