Effect of Repeated Low-Level Red-Light Therapy for Myopia Control in Children: A Multicenter Randomized Controlled Trial

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Abstract

Purpose: To assess the efficacy and safety of repeated low-level red-light (RLRL) therapy in myopia control in children.

Design: Multicenter, randomized, parallel-group, single-blind clinical trial.

Participants: Two hundred sixty-four eligible children 8 to 13 years of age with myopia of cycloplegic spherical equivalent refraction (SER) of -1.00 to -5.00 diopters (D), astigmatism of 2.50 D or less, anisometropia of 1.50 D or less, and best-corrected visual acuity (BCVA) of 0.0 logarithm of the minimum angle of resolution or more were enrolled in July and August 2019. Follow-up was completed in September 2020.

Methods: Children were assigned randomly to the intervention group (RLRL treatment plus single-vision spectacle [SVS]) and the control group (SVS). The RLRL treatment was provided by a desktop light therapy device that emits red light of 650-nm wavelength at an illuminance level of approximately 1600 lux and a power of 0.29 mW for a 4-mm pupil (class I classification) and was administered at home under supervision of parents for 3 minutes per session, twice daily with a minimum interval of 4 hours, 5 days per week.

Main outcome measures: The primary outcome and a key secondary outcome were changes in axial length and SER measured at baseline and the 1-, 3-, 6-, and 12-month follow-up visits. Participants who had at least 1 postrandomization follow-up visit were analyzed for treatment efficacy based on a longitudinal mixed model.

Results: Among 264 randomized participants, 246 children (93.2%) were included in the analysis (117 in the RLRL group and 129 in the SVS group). Adjusted 12-month axial elongation and SER progression were 0.13 mm (95% confidence interval [CI], 0.09-0.17mm) and -0.20 D (95% CI, -0.29 to -0.11D) for RLRL treatment and 0.38 mm (95% CI, 0.34-0.42 mm) and -0.79 D (95% CI, -0.88 to -0.69 D) for SVS treatment. The

differences in axial elongation and SER progression were 0.26 mm (95% CI, 0.20-0.31 mm) and -0.59D (95% CI, -0.72 to -0.46 D) between the RLRL and SVS groups. No severe adverse events (sudden vision loss ≥2 lines or scotoma), functional visual loss indicated by BCVA, or structural damage seen on OCT scans were observed.

Conclusions: Repeated low-level red-light therapy is a promising alternative treatment for myopia control in children with good user acceptability and no documented functional or structural damage.

Keywords: Axial length; Myopia control; Randomized clinical trial; Repeated low-level red-light therapy; Spherical equivalent refraction.

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