

Supplementary Material

Effect of Photobiomodulation-based LED on Myopia Control in Children: An Exploratory Randomized Clinical Trial

Yuye Duan(a,1), Ziyi Qi(b,1), Feiran Yu(c), Kaidi Xiang(d), Haotian Wu(b), Zhenglin Liu(b), Wei Feng(e), Zongyuan Ge(e), Haidong Zou(a), Xun Xu(a), Xiangui He(a)

1 Yuye Duan and Ziyi Qi are joint first authors and contributed equally.

a Shanghai Eye Disease Prevention and Treatment Center / Eye Hospital of Tongji University, National Clinical Research Center for Eye Diseases, Shanghai, China;

b Department of Ophthalmology, Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China;

c School of Public Health, Shanghai University of Traditional Chinese Medicine, Shanghai, China;

d Department of Ophthalmology, The Affiliated People's Hospital of Ningbo University / The Eye Hospital of Wenzhou Medical University (Ningbo Branch), Ningbo, Zhejiang, China;

e Faculty of Information Technology, Monash University, Melbourne, Victoria, Australia.

Corresponding author: Xiangui He; Email: xianhezi@163.com

Supplementary Table S1. Mean Changes in Axial Length and Cycloplegic Spherical Equivalent Refraction

Visit	Intervention	Control	Mean difference (95% CI)*	P values†
Change of AL (mm)				
1 month				
Right eye	-0.018 ± 0.118	0.005 ± 0.061	-0.023 (-0.083, 0.037)	0.443
Left eye	-0.001 ± 0.057	0.021 ± 0.039	-0.023 (-0.054, 0.008)	0.141
3 months				
Right eye	-0.002 ± 0.152	0.060 ± 0.085	-0.062 (-0.140, 0.017)	0.122
Left eye	0.019 ± 0.089	0.075 ± 0.074	-0.056 (-0.109, -0.004)	0.036
Change of SE (D)				
1 month				
Right eye	0.162 ± 0.502	-0.056 ± 0.216	0.219 (-0.029, 0.466)	0.081
Left eye	0.206 ± 0.439	-0.056 ± 0.273	0.262 (0.028, 0.497)	0.029
3 months				
Right eye	0.094 ± 0.603	-0.119 ± 0.318	0.212 (-0.096, 0.521)	0.171
Left eye	0.150 ± 0.544	-0.125 ± 0.339	0.275 (-0.015, 0.565)	0.062

Data are mean +/- SD unless otherwise indicated. Changes were calculated as follow-up values minus baseline values. Mean differences are expressed as the PBM-LED group minus the sham-control group. P values were calculated using independent-samples t tests. AL, axial length; CI, confidence interval; D, diopter; PBM-LED, photobiomodulation-based light-emitting diode; SE, spherical equivalent.

Supplementary Table S2. Mean Changes in Choroidal Thickness in ETDRS Subfields Between Groups After 3 Months

Subfield	Intervention	Control	Mean difference (95% CI)*	P values†	Bonferroni-adjusted P
Right eye					
Central subfield	7.65 ± 11.77	4.19 ± 24.78	3.45 (-8.96, 15.87)	0.577	1.000
Inner temporal	10.37 ± 17.49	7.00 ± 26.29	3.38 (-10.91, 17.67)	0.635	1.000
Inner superior	4.64 ± 18.89	14.83 ± 35.93	-10.19 (-28.57, 8.19)	0.269	1.000
Inner nasal	8.67 ± 14.42	3.95 ± 21.74	4.72 (-7.09, 16.53)	0.423	1.000
Inner inferior	2.74 ± 9.00	5.36 ± 28.78	-2.61 (-16.26, 11.04)	0.701	1.000
Outer temporal	14.51 ± 15.52	10.07 ± 29.46	4.44 (-10.63, 19.51)	0.555	1.000
Outer superior	5.21 ± 15.41	15.24 ± 29.09	-10.04 (-24.94, 4.86)	0.181	1.000
Outer nasal	8.26 ± 12.79	5.26 ± 15.28	3.00 (-6.02, 12.02)	0.505	1.000
Outer inferior	5.04 ± 12.56	10.51 ± 29.35	-5.48 (-19.93, 8.97)	0.448	1.000
Average thickness	7.86 ± 7.94	9.18 ± 24.11	-1.32 (-12.81, 10.17)	0.817	-
Left eye					
Central subfield	7.29 ± 18.03	-4.26 ± 17.13	11.55 (0.29, 22.81)	0.045	0.402
Inner temporal	3.67 ± 18.34	-2.72 ± 19.15	6.40 (-5.61, 18.40)	0.288	1.000
Inner superior	8.55 ± 18.95	6.97 ± 18.77	1.57 (-10.50, 13.65)	0.793	1.000
Inner nasal	8.46 ± 18.80	-2.02 ± 17.90	10.48 (-1.27, 22.23)	0.079	0.710
Inner inferior	6.14 ± 16.86	-2.17 ± 20.66	8.31 (-3.76, 20.38)	0.171	1.000
Outer temporal	8.41 ± 17.58	1.72 ± 20.42	6.69 (-5.51, 18.89)	0.274	1.000

Subfield	Intervention	Control	Mean difference (95% CI)*	P values†	Bonferroni-adjusted P
Outer superior	8.12 ± 17.44	7.38 ± 29.50	0.74 (-14.77, 16.25)	0.924	1.000
Outer nasal	4.47 ± 16.57	0.04 ± 12.47	4.44 (-4.95, 13.83)	0.345	1.000
Outer inferior	9.52 ± 14.41	7.20 ± 26.58	2.31 (-11.37, 16.00)	0.734	1.000
Average thickness	7.42 ± 14.12	3.22 ± 15.24	4.19 (-5.21, 13.60)	0.372	-

Data are mean +/- SD unless otherwise indicated. Changes were calculated as 3-month values minus baseline values. Mean differences are expressed as the PBM-LED group minus the sham-control group. Nominal P values were calculated using independent-samples t tests. Bonferroni-adjusted P values account for the nine ETDRS subfield comparisons within each eye; average-thickness rows were not included in that family of nine comparisons. ChT, choroidal thickness; CI, confidence interval; ETDRS, Early Treatment Diabetic Retinopathy Study; PBM-LED, photobiomodulation-based light-emitting diode.

Supplementary Table S3. Participant-level Sensitivity Analysis Using the Mean of Both Eyes

Outcome / visit	Intervention	Control	Mean difference	95% CI	P value
AL, 1-month	-0.010 ± 0.083 mm	0.013 ± 0.046 mm	-0.023 mm	-0.066 to 0.020	0.283
AL, 3-month	0.009 ± 0.113 mm	0.067 ± 0.077 mm	-0.059 mm	-0.121 to 0.003	0.061
SE, 1-month	0.184 ± 0.428 D	-0.056 ± 0.214 D	0.241 D	0.024 to 0.457	0.030
SE, 3-month	0.122 ± 0.553 D	-0.122 ± 0.302 D	0.244 D	-0.041 to 0.529	0.092

Changes were calculated as follow-up values minus baseline values. The mean difference is the intervention-group mean minus the control-group mean. P values were calculated using independent-samples t tests. AL, axial length; CI, confidence interval; D, diopter; SE, spherical equivalent.

Supplementary Table S4. Adjusted Participant-level Sensitivity Analysis

Outcome / visit	Adjusted difference	95% CI	P value	Model
AL, 1-month	-0.018 mm	-0.065 to 0.029	0.438	Baseline value + age + sex
AL, 3-month	-0.045 mm	-0.111 to 0.021	0.175	Baseline value + age + sex
SE, 1-month	0.177 D	-0.056 to 0.409	0.132	Baseline value + age + sex
SE, 3-month	0.192 D	-0.123 to 0.507	0.225	Baseline value + age + sex

Linear regression models were adjusted for the baseline both-eye mean, age, and sex. The coefficient is the adjusted intervention-minus-control difference. AL, axial length; CI, confidence interval; D, diopter; SE, spherical equivalent.