• Clinical Research •

Comparison of posterior scleral reinforcement surgery and repeated low-level red-light therapy in controlling high and super high myopia in Chinese children

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Abstract

● **AIM:** To compare the efficacy of posterior scleral reinforcement (PSR) surgery versus repeated low-level red light therapy (RLRL) treatment in controlling high and super high myopia (HM and SHM) of Chinese children.

● **METHODS:** This retrospective case analysis enrolled Chinese children with HM (-6.00 to -10.00 D; 76 children, 120 eyes) or SHM (<-10.00 D; 82 children, 114 eyes) according to spherical equivalent (SE). Each group was further subdivided into PSR subgroup [single-vision spectacle lenses (SVS) combined with PSR surgery], RLRL subgroup (SVS combined with RLRL therapy), and control subgroup (SVS alone). All participants were followed up at baseline, 3mo, 1, and 2y after treatment. The best corrected visual acuity (BCVA), axial length (AL), SE, and adverse reactions were evaluated.

● **RESULTS:** A total of 158 children (234 eyes) aged 6-16y were enrolled consecutively. Baseline BCVA, AL and SE were comparable among subgroups in both HM and SHM groups (all $P>0.05$). In the PSR group, BCVA improved significantly at 1 and 2y in both myopia groups (all $P<0.05$); AL and SE were markedly lower than those in the control group (all $P<0.05$), with no differences of BCVA, AL and SE improvements in HM and SHM groups (all $P>0.05$). In the RLRL group, BCVA was significantly improved at 1 and 2y, while AL shortened and SE decreased obviously from 3mo to 2y after treatment (all $P<0.05$); The SHM group showed greater BCVA improvement and AL reduction than the HM group at 1 and 2y, whereas SE improvement was similar between the two groups. In the control group, BCVA declined significantly, accompanied by continuous increases in AL and SE at the 2-year follow-up (all $P<0.05$).

● **CONCLUSION:** PSR and RLRL effectively improve BCVA in children with HM and SHM. PSR slows AL and SE progression, whereas RLRL reduces AL and SE, with better BCVA and AL outcomes in SHM at 1 and 2y. Both interventions are safe without severe adverse events within 2y. As a non-surgical approach, RLRL has promising clinical value.

● **KEYWORDS:** posterior scleral reinforcement surgery; repeated low-level red-light therapy; high myopia; super high myopia; axial length; spherical equivalent

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INTRODUCTION

Childhood myopia is currently a widespread global public health issue and one of the most significant diseases threatening the visual health of children and adolescents. It is predicted that by 2050, the number of people with myopia worldwide will reach 4.758 billion, among whom the number of those with high (HM) or super high myopia (SHM) will increase to 938 million[1]. We usually define children's eyes with a spherical equivalent (SE) ranging from -6.00 to -10.00 diopters (D) as having HM, and those with an SE of -10.00 D or worse as having SHM[2-3]. Therefore, this study divided the participants into the HM group (SE: -6.00 to -10.00 D) and the SHM group (SE<10.00 D) based on the baseline SE degree.

HM is the most frequent cause of visual impairment among children and teenagers in Asian countries[4]. The characteristic of HM is the continuous elongation of the axial length (AL) and gradual decrease in the thickness of the posterior pole of the sclera[5]. As the severity of myopia increases, excessive

axial elongation of the globe exerts biomechanical stretching on the posterior pole, subsequently leading to a series of ocular complications in the posterior segment, such as thinning of the retina and choroid, myopic macular degeneration, macular splitting, macular hole, posterior staphyloma, rhegmatogenous retinal detachment and choroidal neovascularization. These complications can cause visual impairment, reduced vision, and even blindness[6]. Children are in a critical period of growth and development, during which their AL continues to increase. If they develop into HM or SHM at this stage, it will seriously affect their lives and studies. As myopia progresses, a series of HM-related complications occurs. Therefore, it is extremely important to find an effective method to control the progression of HM in children. The most commonly used intervention is to correct myopia using glasses or contact lenses; however, these treatments do not slow down axial elongation or the progression of myopia. Currently, optical treatments (such as orthokeratology and rigid gas-permeable contact lenses) and pharmaceutical interventions can slow down the progression of myopia, but their effects on children with HM are not yet clear, and their long-term and rebound effects require further research[7].

Posterior scleral reinforcement (PSR) surgery for the treatment of HM was first proposed by Shevelev. Subsequently, through continuous improvements and optimizations, its effectiveness and safety in clinical applications have achieved satisfactory results[8]. PSR applies mechanical force directly to the weak part of the eyeball's posterior pole sclera (especially that in the macular area) using allogeneic biomaterials or artificially synthesized materials. A non-specific inflammatory reaction can occur between the posterior sclera and the reinforcement band, leading to scleral remodeling, which delays the increase in AL and SE[9]. In addition, repeated low-level red-light (RLRL) therapy has been applied in recent years to treat HM and SHM in children. RLRL utilizes the photochemical conversion potential of low-intensity light to induce photochemical reactions in eye tissues. Through a series of special mechanisms, it increases choroidal blood flow and reduces oxidative stress and inflammation, thereby ameliorating scleral hypoxia and preventing or slowing the progression of myopia[10]. The present retrospective study aimed to compare the efficacy of PSR surgery and RLRL therapy in improving best-corrected visual acuity (BCVA), AL elongation, and SE progression in Chinese children with HM or SHM, and to explore whether the efficacy of RLRL therapy and PSR surgery differs between children with HM and SHM.

PARTICIPANTS AND METHODS

Ethical Approval This study was approved by the Ethics Committee of the First Affiliated Hospital of Zhengzhou University (Approval Number: 2024-KY-0131-001). This study complied with the Declaration of Helsinki, and informed consent was obtained from the patients or guardians for the use of all data.

Study Design and Participants This retrospective case analysis study included children with HM and SHM who visited the First Affiliated Hospital of Zhengzhou University between January 2019 and September 2023. All children underwent optometry, measurement of intraocular pressure, AL, SE, and optical coherence tomography (OCT) examination, and they were diagnosed as having HM or SHM by the same professional ophthalmologist. Children were assigned to PSR surgery or RLRL therapy based on parental preference, while those whose parents declined both interventions were included in the control group. A total of 158 children (involving 234 eyes) who met the study inclusion criteria were consecutively enrolled. All participants were divided into HM and SHM groups based on myopia severity, and each group was further subdivided into three subgroups according to the intervention strategy. HM group (SE: -6.00 to -10.00 D) comprised 76 children (120 eyes) and was allocated into three subgroups as follows: 1) PSR group: 24 children (38 eyes) received combined treatment of single-vision spectacle lenses (SVS) and PSR surgery; 2) RLRL group: 29 children (45 eyes) were treated with SVS in combination with RLRL treatment; 3) Control group: 23 children (37 eyes) were managed with SVS alone without additional intervention. SHM group (SE<-10 D) included 82 children (114 eyes) and was divided into three subgroups with the same intervention protocols as the HM group: 1) PSR group: 35 children (46 eyes) underwent combined therapy of SVS and PSR surgery; 2) RLRL group: 25 children (37 eyes) received SVS and RLRL treatment; 3) Control group: 22 children (31 eyes) were only provided with SVS for vision correction. This study observed the BCVA, AL, SE, and adverse reactions of children in each group at baseline, 3mo, 1, and 2y after treatment.

Inclusion and Exclusion Criteria The inclusion criteria for this study were: 1) aged between 6 and 16y (the typical age range for pediatric myopia progression assessment), with no history of systemic diseases (such as diabetes or autoimmune disorders) that could affect ocular development; 2) confirmed diagnosis of HM (SE: -6.00 to -10.00 D) or SHM (SE<-10.00 D) *via* cycloplegic retinoscopy, with an annual increase equal to or greater than 1.00 D; 3) AL above 26 mm, with an annual increase greater than 0.5 mm, and this condition has lasted for 2y or longer; 4) both the children and their guardians voluntarily undergo PSR or RLRL after diagnosis and provide written informed consent. The exclusion criteria included: 1) corneal or crystalline non-axial myopia with visual impairment (such as nystagmus, glaucoma, cataracts, retinal detachment, macular or peripheral retinopathy); 2) systemic diseases that

affect eye health, a history of eye trauma or surgery (such as refractive surgery, scleral buckling surgery, vitrectomy); 3) previous use of other methods to control myopia progression, such as medication or wearing orthokeratology lens and rigid gas permeable contact lens, *etc.*; 4) children with low examination compliance.

Data Collection All selected children underwent examinations before treatment, 3mo, 1 and 2y after treatment, including BCVA, SE, AL, intraocular pressure measurement, dilated pupil fundus examination, OCT, and follow-up as needed. BCVA was examined using an international standard visual acuity chart and converted to the logarithm of the minimum resolution angle (logMAR) scale for analysis when all eyes were in a relaxed state of adjustment. AL was measured using an IOL Master (Carl Zeiss, Germany) prior to ciliary muscle paralysis, which is a device used to determine the distance from the corneal apex to the retinal pigment epithelium, and the average value was calculated after the measurement was performed five times. The eyes were measured three times in a relaxed state using a computerized refractometer (RM8000A, Topcon, Japan), with the error of spherical and cylindrical lenses less than 0.25 D between any two measurements. The same optometrist then conducted an objective examination of the images and obtained the results based on the principle of the lowest myopia degree and BCVA. The degree of myopia was expressed as SE, which is equal to the sum of the spherical diopter and a half of astigmatism. Any adverse reactions that occurred during follow-up were regularly evaluated and recorded.

Treatments All children in the PSR group underwent surgery under general anesthesia, and the surgery was performed by the same ophthalmologist. After routine disinfection preparation, the conjunctiva was incised circularly along the corneal edge, and radial incisions were made on the conjunctiva above the temporal side and below the nasal side to fully expose the sclera and four rectus muscles of the eye. The allogeneic scleral band was trimmed to a width of 4–5 mm at both ends, and the width gradually increased toward the center to approximately 13–14 mm. The allogeneic scleral strip was passed through the inferior oblique muscle, with its upper end passing through the superior rectus muscle; then, its upper end was fixed to the nasal side sclera at the attachment point of the superior rectus muscle with sutures. The lower end of the strip was passed through the inferior rectus muscle and then fixed to the nasal side of the sclera at the attachment point of the inferior rectus muscle with sutures. The allogeneic sclera strip was wrapped around the posterior pole and corresponding sclera in the macular area, ensuring that the strip was flat and did not compress the optic nerve. The conjunctiva was reset and approximately 0.05 mL of aqueous humor was extracted by puncture to prevent postoperative high intraocular pressure. After surgery, 1% atropine eye ointment and tobramycin-dexamethasone eye ointment were applied to the eyes.

The RLRL equipment [Leshi Yangguang (Xiang Medical Device Registration Approval 20212162271); Chenzhou Eye Care Health Technology Co., Ltd., Hunan Province, China] emits diffuse reflection red light at a wavelength of 650±10 nm. At the exit hole, the diameter of the light spot is 10±2 mm, and the energy of the light source is about 0.85 mW. Children in the RLRL group received RLRL treatment twice a day at home, with each treatment lasting three minutes and a minimum interval of four hours between each treatment. The built-in automatic diary function in the RLRL instrument was used to record treatment compliance. Children and their parents logged in to the RLRL devices using designated accounts to initiate and complete the treatment process. The diary function refers to the ability of RLRL devices to automatically record treatment dates and times, and upload them to an online management platform. On this management platform, experimenters could view the children's name, ID, refraction, AL, fundus images, and regularly check the instrument's usage time. If a child completed fewer than two treatment sessions per day, the management platform would send brief mobile reminder messages to parents to promote treatment compliance. A RLRL compliance rate below 90% indicated poor treatment compliance. Children with an RLRL compliance rate of less than 90% were not included in this study.

Statistical Analysis Statistical analysis was performed using SPSS 27.0. All quantitative data were tested for normality using the Shapiro-Wilk test. Variables that did not meet normal distribution were expressed as median [interquartile range (IQR)]. Count data were analyzed using the Chi-square test and expressed as percentages (%). Continuous variables with non-normal distribution were compared between groups using the Kruskal-Wallis H test or the Mann-Whitney U test. For repeated measurement data, generalized estimating equations (GEE) were employed to account for the clustering effect of bilateral eyes from the same child and the correlation among repeated measurements over time. Post-hoc pairwise comparisons were performed with Bonferroni correction to control for type I errors arising from multiple comparisons. P values less than 0.05 were considered statistically significant.

RESULTS

Patient Demographics and Baseline Characteristics This study included 158 Chinese children (234 eyes), including 76 children (120 eyes) in the HM group and 82 children (114 eyes) in the SHM group, respectively. The HM and SHM groups were further divided into the PSR, RLRL, and control subgroups. There were no statistically significant differences in the baseline characteristics of age, sex, and eye laterality

Table 1 Demography characteristics

Items	High myopia group (*n*=120)			Super high myopia group (*n*=114)			Statistics	*P*
	PSR group	RLRL group	Control group	PSR group	RLRL group	Control group		
Numbers	38	45	37	46	37	31		-
Male, *n* (%)	20 (52.6)	24 (53.3)	21 (56.8)	21 (45.7)	19 (51.4)	17 (54.8)	χ^2=1.221	0.943
Age, y, median (IQR)	9 (7, 12)	10 (8, 13)	11 (9, 12)	9.5 (7, 12)	10 (7, 13)	9 (7, 13)	*H*=3.149	0.677
Right eye, *n* (%)	18 (47.4)	25 (55.6)	17 (45.9)	27 (58.7)	18 (48.6)	16 (51.6)	χ^2=7.580	0.670

IQR: Interquartile range; PSR: Posterior scleral reinforcement; RLRL: Repeated low-level red-light.

Table 2 Comparison of baseline characteristics of BCVA, AL, and SE median (IQR)

Items	PSR group	RLRL group	Control group	*H*	*P*
High myopia groups (*n*=120)					
Numbers	38	45	37		-
BCVA (logMAR)	0.00 (0.00, 0.10)	0.05 (0.00, 0.05)	0.00 (0.00, 0.05)	0.244	0.885
AL (mm)	27.02 (26.49, 27.41)	26.66 (26.33, 26.85)	26.89 (26.44, 27.40)	5.039	0.080
SE (D)	-7.75 (-8.50, -7.19)	-7.50 (-8.50, -7.00)	-7.50 (-8.13, -7.00)	0.899	0.638
Super high myopia groups (*n*=114)					
Numbers	46	37	31		-
BCVA (logMAR)	0.10 (0.00, 0.16)	0.16 (0.05, 0.26)	0.10 (0.00, 0.30)	1.658	0.436
AL (mm)	28.06 (27.62, 28.52)	27.60 (27.06, 28.44)	28.14 (27.25, 28.73)	3.112	0.211
SE (D)	-13.00 (-15.25, -11.25)	-12.00 (-14.63, -10.50)	-13.00 (-16.00, -11.75)	4.070	0.131

BCVA: Best corrected visual acuity; AL: Axial length; SE: Spherical equivalent; IQR: Interquartile range; PSR: Posterior scleral reinforcement; RLRL: Repeated low-level red-light; logMAR: Logarithm of the minimum resolution angle.

among the six groups of patients (*P*>0.05; Table 1). There were no statistically significant differences in the baseline characteristics of BCVA, AL, and SE between the three subgroups of patients with HM and the three subgroups of patients with SHM (*P*>0.05; Table 2). The baseline ocular functional and structural indicators of each intervention subgroup in the same myopia severity group were consistent, which ensured the comparability of the therapeutic effect analysis among subgroups.

Changes in BCVA, AL, and SE Before and After Treatment in Children with High Myopia

Changes in BCVA GEE analysis showed significant main effects of group (Wald χ^2=12.342, *P*=0.002), time (Wald χ^2=37.238, *P*<0.001), and group×time interaction (Wald χ^2=54.759, *P*<0.001) on BCVA. Post-hoc pairwise comparisons with Bonferroni correction revealed that the BCVA of children in the PSR subgroup was significantly improved at 1 and 2y after surgery compared with the preoperative level and 3mo after surgery (all *P*<0.05), while no significant improvement was observed at 3mo postoperatively (*P*>0.05). For the RLRL subgroup, BCVA was already significantly improved at 3mo after treatment compared with baseline (*P*<0.05), and was further improved at 1 and 2y post-treatment compared with the preoperative level and 3mo post-treatment (all *P*<0.05). In contrast, the control subgroup showed no significant change in BCVA at 3mo and 1y after enrollment (all *P*>0.05), but a significant decrease at 2y follow-up compared with the baseline, 3mo, and 1y after enrollment (all *P*<0.05; Table 3).

Changes in AL GEE analysis indicated significant main effects of group (Wald χ^2=36.533, *P*<0.001), time (Wald χ^2=1306.676, *P*=0.000), and group×time interaction (Wald χ^2=1100.960, *P*=0.000) on AL. Post-hoc analysis showed that the AL of the RLRL subgroup was significantly shorter at 3mo, 1, and 2y after treatment compared with before treatment (all *P*<0.05) . The AL of the PSR subgroup was significantly shorter than that of the control group at 1 and 2y after treatment (all *P*<0.05; Table 3, Figure 1).

Changes in SE GEE analysis demonstrated significant main effects of group (Wald χ^2=12.601, *P*=0.002), time (Wald χ^2=272.758, *P*=0.000), and group×time interaction (Wald χ^2=356.749, *P*=0.000) on SE. Post-hoc comparisons showed that the SE of the RLRL subgroup at 3mo after treatment was lower than before treatment, and further lower than 1 and 2y after treatment (all *P*<0.05). The SE of the PSR subgroup was significantly lower than that of the control group at 1 and 2y after treatment (all *P*<0.05; Table 3).

Changes in BCVA, AL, and SE Before and After Treatment in Children with Super High Myopia

Changes in BCVA GEE analysis revealed significant main effects of group (Wald χ^2=7.819, *P*=0.020), time (Wald χ^2=27.811, *P*<0.001), and group×time interaction (Wald χ^2=60.628, *P*<0.001) on BCVA (Table 4).

Changes in AL GEE analysis indicated significant main

Table 3 Changes in BCVA, AL, and SE before and after treatment in children with high myopia median (IQR)

Items	Before treatment	3mo after treatment	1y after treatment	2y after treatment
BCVA (logMAR)				
PSR group	0.00 (0.00, 0.10)	0.00 (0.00, 0.05)	0.00 (0.00, 0.05)[a,b]	0.00 (0.00, 0.05)[a,b,d]
RLRL group	0.05 (0.00, 0.05)	0.00 (0.00, 0.05)[a]	0.00 (0.00, 0.00)[a,b,d]	0.00 (0.00, 0.00)[a,b,d]
Control group	0.00 (0.00, 0.05)	0.00 (0.00, 0.05)	0.00 (0.00, 0.07)	0.05 (0.05, 0.10)[a,b,c]
AL (mm)				
PSR group	27.02 (26.49, 27.41)	27.02 (26.42, 27.47)	27.20 (26.59, 27.71)[a,b,d]	27.45 (26.80, 27.99)[a,b,c,d]
RLRL group	26.66 (26.33, 26.85)	26.43 (26.14, 26.81)[a,d]	26.45 (26.10, 26.87)[a,d]	26.45 (26.09, 27.01)[a,d]
Control group	26.89 (26.44, 27.40)	27.10 (26.65, 27.53)[a]	27.67 (27.27, 27.94)[a,b]	28.32 (28.05, 28.70)[a,b,c]
SE (D)				
PSR group	-7.75 (-8.50, -7.19)	-7.75 (-8.31, -7.19)	-8.00 (-8.56, -7.44)[a,b,d]	-8.13 (-9.00, -7.50)[a,b,c,d]
RLRL group	-7.50 (-8.5, -7.0)	-7.00 (-8.25, -6.75)[a,d]	-7.00 (-8.0, -6.50)[a,b,d]	-7.00 (-8.13, -6.50)[a,b,d]
Control group	-7.50 (-8.13, -7.00)	-7.75 (-8.63, -7.25)[a]	-8.50 (-9.50, -8.00)[a,b]	-9.5 (-10.25, -9.0)[a,b,c]

[a]*P*<0.05 *vs* before treatment, [b]*P*<0.05 *vs* 3mo after treatment, [c]*P*<0.05 *vs* 1y after treatment, [d]*P*<0.05 *vs* control group. BCVA: Best corrected visual acuity; logMAR: Logarithm of the minimum resolution angle; AL: Axial length; SE: Spherical equivalent; IQR: Interquartile range; PSR: Posterior scleral reinforcement; RLRL: Repeated low-level red-light.

Table 4 Comparison of children with super high myopia before and after treatment median (IQR)

Items	Before treatment	3mo after treatment	1y after treatment	2y after treatment
BCVA (logMAR)				
PSR group	0.10 (0.00, 0.16)	0.10 (0.00, 0.16)	0.05 (0.00, 0.10)[a,b,d]	0.05 (0.00, 0.10)[a,b,d]
RLRL group	0.16 (0.05, 0.26)	0.16 (0.02, 0.22)	0.05 (0.00, 0.19)[a,b]	0.05 (0.00, 0.16)[a,b,d]
Control group	0.10 (0.00, 0.30)	0.10 (0.00, 0.3)	0.10 (0.05, 0.3)	0.16 (0.10, 0.30)[a,b]
AL (mm)				
PSR group	28.06 (27.62, 28.52)	28.05 (27.51, 28.44)	28.29 (27.75, 28.70)[a,b,d]	28.53 (27.92, 28.98)[a,b,c,d]
RLRL group	27.60 (27.06, 28.44)	27.31 (26.91, 28.31)[a,d]	27.33 (26.74, 28.29)[a,b,d]	27.24 (26.71, 28.32)[a,b,c,d]
Control group	28.14 (27.25, 28.73)	28.42 (27.56, 28.89)[a]	28.87 (28.04, 29.54)[a,b]	29.69 (28.87, 30.21)[a,b,c]
SE (D)				
PSR group	-13.00 (-15.25, -11.25)	-13.00 (-15.00, -11.25)	-13.00 (-15.25, -11.50)[a,b,d]	-13.38 (-15.56, -11.69)[a,b,c,d]
RLRL group	-12.00 (-14.63, -10.50)	-11.25 (-14.50, -10.13)[a,d]	-10.50 (-14.38, -10.00)[a,b,d]	-10.50 (-14.25, -10.00)[a,b,c,d]
Control group	-13.00 (-16.00, -11.75)	-13.50 (-16.75, -12.25)[a]	-14.00 (-17.50, -13.00)[a,b]	-15.25 (-18.00, -13.75)[a,b,c]

[a]*P*<0.05 *vs* before treatment, [b]*P*<0.05 *vs* 3mo after treatment, [c]*P*<0.05 *vs* 1y after treatment, [d]*P*<0.05 *vs* control group. BCVA: Best corrected visual acuity; logMAR: Logarithm of the minimum resolution angle; AL: Axial length; SE: Spherical equivalent; IQR: Interquartile range; PSR: Posterior scleral reinforcement; RLRL: Repeated low-level red-light.

effects of group (Wald χ^2=15.695, *P*<0.001), time (Wald χ^2=623.074, *P*=0.000), and group×time interaction (Wald χ^2=760.457, *P*=0.000) on AL (Table 4, Figure 2).

Changes in SE GEE analysis demonstrated significant main effects of group (Wald χ^2=12.897, *P*=0.002), time (Wald χ^2=249.711, *P*=0.000), and group×time interaction (Wald χ^2=562.488, *P*=0.000) on SE (Table 4).

Comparison of BCVA, AL, and SE between HM and SHM subgroups in PSR and RLRL groups There were no statistically significant differences in the changes of BCVA, AL, and SE (post-treatment minus pre-treatment values) between the HM and SHM subgroups at 3mo, 1, and 2y after surgery (all *P*>0.05; Table 5).

At 3mo after treatment, there were no significant differences in the changes of BCVA, AL, and SE between the HM and SHM subgroups (all *P*>0.05). However, at 1 and 2y post-treatment, the SHM subgroup had more significant improvement in BCVA (1y: *Z*=-2.375, *P*=0.018; 2y: *Z*=-3.112, *P*=0.002) and greater shortening of AL (1y: *Z*=-2.195, *P*=0.028; 2y: *Z*=-2.568, *P*=0.010) than the HM subgroup. There was no statistically significant difference in the improvement of SE between the two subgroups at all follow-up time points (all *P*>0.05; Table 6). The therapeutic effect of RLRL therapy on BCVA improvement and AL shortening was more pronounced in children with SHM, showing a myopia severity-dependent characteristic.

Adverse Events All children in the PSR group experienced conjunctival congestion and edema after surgery, which improved after 2–3wk. Transient intraocular pressure elevation occurred in 28 eyes (11.97%) after PSR surgery, which

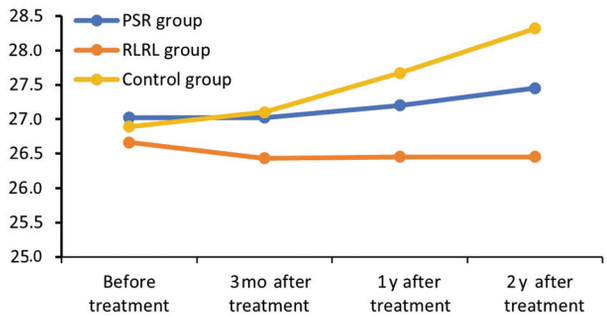

Figure 1 Axial length change trends in three subgroups of children with high myopia PSR: Posterior scleral reinforcement; RLRL: Repeated low-level red-light.

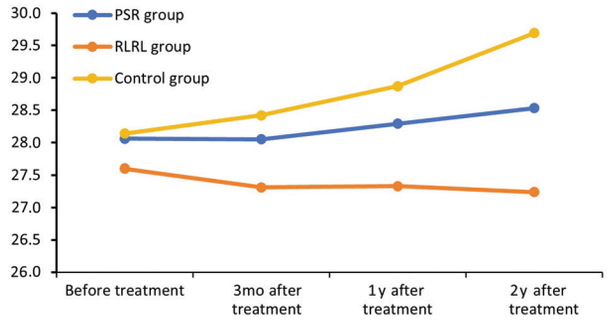

Figure 2 Axial length change trends in three subgroups of children with super high myopia PSR: Posterior scleral reinforcement; RLRL: Repeated low-level red-light.

Table 5 Comparison of the difference between high myopia and the super high myopia group in PSR group median (IQR)

Items	High myopia group	Super high myopia group	*Z*	*P*
3mo after surgery				
BCVA (logMAR)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	-1.200	0.230
AL (mm)	0.03 (-0.08, 0.07)	-0.02 (-0.13, 0.06)	-0.954	0.340
SE (D)	0.00 (0.00, 0.06)	0.00 (0.00, 0.00)	-1.531	0.126
1y after surgery				
BCVA (logMAR)	0.00 (-0.05, 0.00)	-0.05 (-0.05, 0.00)	-1.690	0.091
AL (mm)	0.18 (0.14, 0.29)	0.21 (0.11, 0.30)	-0.315	0.753
SE (D)	-0.25 (-0.25, 0.00)	-0.25 (-0.31, 0.00)	-0.327	0.743
2y after surgery				
BCVA (logMAR)	0.00 (-0.05, 0.00)	-0.05 (-0.05, 0.00)	-1.685	0.092
AL (mm)	0.39 (0.34, 0.48)	0.46 (0.34, 0.62)	-1.632	0.103
SE (D)	-0.50 (-0.56, -0.25)	-0.50 (-0.56, -0.25)	-0.129	0.897

BCVA: Best corrected visual acuity; logMAR: Logarithm of the minimum resolution angle; AL: Axial length; SE: Spherical equivalent; IQR: Interquartile range; PSR: Posterior scleral reinforcement.

Table 6 Comparison of the difference between high myopia and super high myopia group in RLRL group median (IQR)

Items	High myopia group	Super high myopia group	*Z*	*P*
3mo after treatment				
BCVA (logMAR)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	-1.388	0.165
AL (mm)	-0.15 (-0.24, -0.06)	-0.19 (-0.30, -0.08)	-0.970	0.332
SE (D)	0.00 (0.00, 0.25)	0.25 (0.00, 0.63)	-1.432	0.152
1y after treatment				
BCVA (logMAR)	0.00 (-0.05, 0.00)	-0.05 (-0.08, 0.00)	-2.375	0.018
AL (mm)	-0.19 (-0.36, -0.03)	-0.33 (-0.51, -0.15)	-2.195	0.028
SE (D)	0.50 (0.00, 0.75)	0.50 (0.00, 1.00)	-1.670	0.095
2y after treatment				
BCVA (logMAR)	0.00 (-0.05, 0.00)	-0.06 (-0.11, 0.00)	-3.112	0.002
AL (mm)	-0.17 (-0.45, 0.03)	-0.42 (-0.59, -0.14)	-2.568	0.010
SE (D)	0.5 (0.13, 0.75)	0.75 (0.13, 1.38)	-1.921	0.055

BCVA: Best corrected visual acuity; logMAR: Logarithm of the minimum resolution angle; AL: Axial length; SE: Spherical equivalent; IQR: Interquartile range; RLRL: Repeated low-level red-light.

returned to normal after treatment with intraocular pressure-lowering medications. During the 2-year follow-up period, no child experienced visual loss or serious complications such as retinal detachment, optic nerve injury, macular hole, retinal hemorrhage or ischemia, ciliary retinal artery occlusion, or vortex vein injury. During the 2-year follow-up of children receiving RLRL treatment, no serious adverse events occurred, including sudden loss of 2-line vision or dark spots within seconds, minutes, or days. No child reported glare, flash blindness, or residual images lasting more than

6min after treatment[11]. No significant structural abnormalities were observed in the ocular surface or fundus during slit-lamp examination, OCT, or optical coherence tomography angiography (OCTA) examinations.

DISCUSSION

HM is widely recognized as a cause of severe visual impairment and a major cause of visual impairment in children. Therefore, this study aimed to observe the efficacy and safety of different methods for controlling HM in children. This study had a follow-up period of up to 2y, focusing on observing the effect of myopia progression control in children with HM after receiving PSR surgery or RLRL treatment.

The ultimate goal of treating HM is to stop or slow down the elongation of the AL and the progression of SE degree, as well as reduce the occurrence of HM-related complications[12]. Therefore, this study mainly observed BCVA and the two parameters (AL and SE) that best reflect the progression of myopia. Myopia is a complex disease with multiple contributing factors, and multiple myopia-related signaling pathways are interrelated, jointly participating in the occurrence and development of myopia. Multiple studies have shown that the essence of myopia is hypoxia and insufficient blood perfusion. Myopia-related visual signals can lead to a decrease in the patency of choroidal capillaries, a reduction in choroidal blood flow, as well as thinning of the choroid, resulting in hypoxia of the adjacent avascular sclera. Scleral hypoxia is the initiating factor leading to scleral remodeling. During scleral remodeling, collagen synthesis decreases and degradation increases, resulting in reduced scleral strength and thickness and excessive elongation of the eyeball axis. Therefore, improving scleral hypoxia can control the progression of myopia[13-16]. Zhou *et al*[17] reported that increasing choroidal blood flow can alleviate scleral hypoxia, thereby inhibiting myopia development.

PSR is an external eye surgery that can alter scleral remodeling and directly reinforce the eyeball wall mechanically. It does not damage the internal tissue structure of the eyeball, has good safety, and is suitable for controlling the progressive elongation of the eyeball axis in HM. PSR can prevent further development of myopia and delay chorioretinal degeneration to a certain extent[18]. In this study, PSR achieved good results in the treatment of HM in children. Before treatment, there were no statistically significant differences in BCVA, AL, or SE between the PSR and control groups. However, at 1 and 2y after surgery, the AL and SE in the HM and SHM groups were significantly lower than those in the control group, indicating that PSR can slow down the changes in AL and SE, effectively controlling the progression of myopia. Chen *et al*[19] found that using a single wide allogeneic scleral band was more effective by studying different surgical methods and PSR materials; compared with eyes that did not undergo PSR surgery, the PSR group had slower postoperative SE and AL growth. Similar results were obtained in our study using a single scleral band with a width of approximately 13–14 mm. Moreover, both the HM and SHM groups showed improvement in BCVA at 1 and 2y after PSR surgery compared with the preoperative levels, while the control group showed a decrease in BCVA in the second year of follow-up compared with baseline, indicating that BCVA can be improved after PSR surgery. Miao *et al*[20] also reported a significant improvement in BCVA after PSR surgery compared to the preoperative level. They also pointed out that the improvement in BCVA may be due to the slowing down of axial elongation and myopia progression after PSR surgery (which prevents visual deterioration), and may also be related to the natural development of children's vision. Based on an animal experiment[21] and Peng *et al*'s[22] research, it was concluded that secondary non-specific inflammatory reactions occur after PSR surgery, and neovascularization begins to form at the junction of the donor and host sclera, gradually extending into the deeper sclera. After long-term repair and reconstruction, the implanted scleral graft finally fused with the recipient sclera, significantly increasing the thickness and hardness of the sclera, achieving the purpose of mechanical reinforcement of the sclera and limiting axial elongation. In addition, the implanted allogeneic sclera can improve the local retinal and choroidal circulation through inflammatory proliferation and neovascularization, increase the blood supply to the retina and choroid, improve the hypoxic state of the sclera to regulate scleral remodeling and inhibit the progression of myopia, and improve the nutritional status of the posterior pole in patients with HM, thereby enhancing postoperative visual functions such as vision and contrast sensitivity. Zhang *et al*[23] also reported using OCTA to detect the choroidal and retinal microvascular systems and found that patients with HM had significantly increased choroidal thickness and choroidal blood flow after undergoing PSR surgery.

HM has traditionally been considered progressive and irreversible; however, in this study, children who received RLRL treatment showed improvement in BCVA at 1 and 2y after treatment compared with before treatment in both the HM and SHM groups. AL was significantly shorter at 3mo, 1 and 2y after treatment than before treatment, and SE was significantly lower at 3mo, 1 and 2y after treatment than before treatment. Wang *et al*[24] reported that RLRL treatment can shorten the AL of myopic children and showed significant thickening of the choroid after RLRL treatment. Since the AL is measured by the IOL Master instrument from the cornea to the retinal pigment epithelium (RPE), the thickened choroid may shorten the AL by pushing the retina forward. However, the increase in choroid thickness cannot fully explain the

observed AL shortening; the main reason for AL shortening is suggested to be related to scleral remodeling. Some studies have reported that increased choroidal thickness and choroidal blood flow can alleviate scleral hypoxia and remodeling, thereby slowing down or even reversing the progression of AL and SE, while improving the nutritional status of the posterior pole, thereby enhancing visual function[25-26]. During the follow-up process of this study, when using OCTA to scan the fundus of children in the RLRL group, an increase in choroidal thickness was observed during RLRL treatment. However, our study did not further statistically analyze this result. Therefore, the underlying mechanism responsible for AL shortening remains to be fully elucidated. This study also found that the SE of children with SHM in the RLRL group showed a progressive decrease during follow-up, and the AL of children with SHM in the RLRL group was shorter at 2y after treatment than 1y after treatment. However, there was no statistically significant difference in SE between the 1 and 2y after treatment in the HM group, and there were no statistically significant differences in AL at 3mo, 1 and 2y after treatment in the HM group. This may mean that children with SHM can achieve further improvement treatment effectiveness over time after receiving RLRL treatment, although this requires further long-term follow-up to confirm. Moreover, by comparing the differences in BCVA, AL, and SE (post-treatment minus pre-treatment) between the HM and SHM subgroups in the RLRL group at each follow-up time point, we found that the SHM subgroup had more significant improvements in BCVA and greater shortening of AL than the HM subgroup at 1 and 2y after treatment. Xu *et al*[27] found that children with HM showed improved vision, shortened AL, and reduced SE after receiving RLRL treatment, and the treatment effect of RLRL might be more significant for children with more severe myopia. Liu *et al*[28] investigated the axial shortening effects of RLRL therapy in children with HM in their study. They found that after 1y, the mean AL in the RLRL group was shortened by 0.11±0.25 mm, while the AL in the control group was elongated by 0.32±0.09 mm. This indicates that RLRL therapy can effectively shorten the AL of children. They also concluded that after receiving RLRL therapy, children with mild to moderate myopia achieved better control over AL and SE compared to premyopic children. Therefore, we may infer that the higher the degree of myopia, the more significant the effect of RLRL therapy. However, this association should be interpreted with caution due to the retrospective design of the present study. The exact mechanism by which RLRL controls the progression of myopia is not yet fully understood, and further research is needed to uncover these potential processes.

This study had several limitations. First, this study is a retrospective study, and its results may be affected by confounding factors. Without further research on changes in retinal thickness, choroidal thickness, and choroidal blood flow, it is impossible to directly observe the impact of changes in retinal blood flow on the progression of myopia. In addition, it is necessary to further expand the sample size, extend the follow-up time, and observe the long-term efficacy of PSR and RLRL treatment. Xiong *et al*[29] found a slight rebound effect when stopping RLRL treatment, but this study cannot describe the rebound effect or continued effect after stopping RLRL treatment. Therefore, although RLRL treatment has shown significant advantages in controlling myopia, its therapeutic effect and duration still need further research and validation. A recent study reported a case of retinal injury after RLRL treatment[30]. Although the energy and frequency of RLRL used in this study did not cause retinal damage during follow-up, the safety of long-term or higher-energy use requires further observation.

In conclusion, for the treatment of HM and SHM in children, PSR can delay the progression of myopia, while RLRL can induce myopia regression, and the higher the degree of myopia, the better the effect of RLRL treatment.

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