The effectiveness and safety of modified posterior scleral reinforcement in Chinese children with high myopia

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Abstract

Background To evaluate the effectiveness and safety of modified posterior scleral reinforcement in controlling the progression of myopia in patients with high myopia and provide reference information on surgical treatment for these patients.

Methods The study included 32 patients (55 eyes) with high myopia who were treated with modified posterior scleral reinforcement and were followed up at 3 months, 6 months, 1 year and 2 years after the operation.

The axial length, refractive error, best corrected visual acuity (BCVA) and fundus colour photographs after the operation were compared with those before the operation, and whether there were any complications was recorded.

Results The axial length of the eye increased by 0.07 mm, 0.12 mm, 0.31 mm and 0.19 mm at 3 months, 6 months, 1 year and 2 years after the operation, respectively. The refractive error increased by 0.05 D, 0.28 D, 0.53 D and 0.50 D at 3 months, 6 months, 1 year and 2 years after the operation, respectively, and the differences were not significant ($P > 0.05$). There were no statistically significant changes in BCVA, but there was an upward trend. No severe complications occurred.

Conclusion Modified posterior scleral reinforcement can effectively delay the worsening of the ocular axis and refractive error, without severe complications in the short term.

Introduction

Myopia affects 20–40% of adults[1]. In the past 50–60 years, the prevalence of myopia in urban areas of developed countries in East and Southeast Asia has increased rapidly, with 80–90% of children who have completed high school suffering from myopia and 10–20% exhibiting high myopia (myopic refractive error ≥ 6 dioptres (D))[2]. Worldwide, the number of people with high myopia is approximately 163 million, or 2.7% of the population. By 2050, the number of people with high myopia is expected to rise to 938 million, or 9.8% of the total population[3]. Asian populations are known to have a higher prevalence of myopia than are white populations[4]. High myopia is characterized by a prolonged axial length of the eyeball and can lead to conditions such as retinal detachment, macular holes with or without retinal detachment, distortion around the optic papilla, dome-shaped maculae, thinning of the choroid, myopic choroidal neovascularization and glaucoma[5]. Even in adults, the axial length of the eye continues to increase at a significantly higher rate in high myopia patients than in non-high myopia patients[6]. Night-wearing keratoplasty lenses can effectively delay the worsening of the eye axis and refractive error, but they are mostly suitable for patients with low and moderate myopia[7]. Posterior scleral cross-linking surgery can also enhance scleral strength, but this surgery is still being tested in vitro and animal experiments[8, 9]. Posterior scleral reinforcement provides mechanical reinforcement of the equatorial region and around the sclera using biological or abiotic materials. It was first proposed by Shevelev[10] and then modified and simplified by Snyder and Thompson[11]. In recent years, there have been other
modified posterior scleral reinforcement operations that can delay the axial growth and progression of high myopia[12–14]. In this study, we hope to find an improved posterior scleral reinforcement procedure that is simpler for operators and more effective for patients.

**Subjects And Methods**

**Subjects**

This study involved 32 patients (55 eyes) with high myopia.

The study was approved by the Medical Ethics Committee of Peking University People's Hospital and conducted in accordance with the Declaration of Helsinki for research involving human subjects. We conducted a retrospective analysis of high myopia patients who underwent posterior scleral reinforcement surgery from August 2018 to August 2020 in Peking University People's Hospital. The parents or guardians of the patients provided informed consent before the children underwent surgery.

Individuals with myopic refractive errors \( \geq 6.0 \) dioptres and aged between 3 and 18 years were included in this study. The following patients were not included in this study: (1) patients who had previously received myopia treatment other than wearing glasses; (2) patients who had other eye diseases that affect visual function, such as cataracts, glaucoma, nystagmus, ocular trauma, and retinal detachment; (3) patients with non-axial myopia; (4) patients who had undergone vitrectomy, scleral buckling and other surgical treatments; and (5) patients with systemic diseases that may affect the results. We followed up these patients for up to 2 years.

**Surgical procedure**

Human sclerae were obtained from a local eye bank. All the donors of the sclerae had negative serology test results for HIV and hepatitis B. Before use, the sclerae were soaked in 0.9% saline for 10 minutes to reactivate them.

All operations were performed under general anaesthesia. An allogeneic sclera patch with a diameter of approximately 12 mm was implanted. At approximately 8 mm from the temporal inferior limbus, a 2-mm conjunctival incision was made. Then, 8 – 0 sutures were inserted 2 mm from the edge of sclera patch, hooking the external rectus muscle; the sclera patch was sutured to the anterior corner of the inferior oblique muscle, and the upper part and the lower part of the grafts were pressed onto the sclera surface of the posterior pole through the inferior and inferior oblique muscles, respectively. The sclera was straightened, and its position was checked to ensure that it did not compress the optic nerve. The scleral patch was fixed on the sclera of the anterior border of the inferior oblique muscle with 8 – 0 sutures. The size of the scleral patch and the schematic diagram of the operation are shown in Fig. 1 and Fig. 2, respectively. All operations were performed by Dr. Wang (Peking University People's Hospital). After surgery, 0.5% levofloxacin and 0.1% fluorometholone eye drops were administered four times a day for two weeks.

**Outcome measures**
Axial length (AL) was measured using IOL Master (Zeiss 500; Carl Zeiss Meditec, Inc., Dublin, CA). Refractive error was determined using an automatic refractometer (Auto Refractometer RM-8900, Topcon, Inc., Tokyo, Japan) under ciliary muscle anaesthesia (1% tropicamide drops six times with an interval of 5 minutes). Refractive error is presented as the mean spherical equivalent (SE). At each visit, the patients underwent a logMAR best-corrected visual acuity examination. All patients underwent widefield fundus photography examinations with wide-field photography (Optos 200Tx, Optos, Dunfermline, Scotland; Spectralis).

**Statistical analysis**
The AL, refractive error, and BCVA recorded pre- and postoperatively were compared. A paired t test was used to compare the pre- and postoperative data. All analyses were performed using SPSS statistics 27.0 (SPSS Inc., Chicago, Illinois, USA).

**Results**

**The demographic and clinical characteristics**
The current analysis included 32 patients, 22 males and 10 females. The average age of the patients was 6.38 ± 3.35 years and ranged from 3 to 16 years. The patients were followed up 3 months, 6 months, 1 year and 2 years postoperatively. Due to the influence of the COVID-19 pandemic, the patients were unable to attend follow-ups from January 2020 to July 2020, and the loss to follow-up rate was high.

**Clinical data**
The patients were divided into four groups according to the duration of the follow-up period, and the changes in refractive error from before the operation to the different follow-up times were compared. The results showed that there were no significant changes in the equivalent sphere from preoperatively to postoperatively in all patients ($P < 0.05$). The changes in AL were different in almost all patients ($P > 0.05$). There were no statistically significant differences between the two-year follow-up and the last follow-up ($P = 0.063$), which was considered an unrepresentative error due to the small sample size (6 cases). There were no significant differences in BCVA between the baseline and follow-up time points (all $P < 0.05$), but there was a slight decrease in BCVA. The results for each time point and baseline information are summarized in Tables 1–4.

| Table 1 | Comparisons of refractive error, axial length, and BCVA in baseline and 3 months of follow-up |
|---------|----------------------------------------------------------------------------------|
| number of eyes | baseline | 3 months | $t$ | $P$ |
| Refractive error,D | 25 | -9.61 ± 2.28 | -9.66 ± 2.35 | 0.938 | 0.358 |
| Axial length, mm | 24 | 25.93 ± 1.18 | 26.00 ± 1.18 | -2.649 | 0.014 |
| BCVA,logMAR | 23 | 0.43 ± 0.46 | 0.37 ± 0.32 | 0.926 | 0.365 |
Table 2
Comparisons of refractive error, axial length, and BCVA in baseline and 6 months of follow-up

| number of eyes | baseline | 6 months | t       | P       |
|----------------|----------|----------|---------|---------|
| Refractive error,D | 22       | -10.04 ± 2.95 | -9.76 ± 3.00 | -1.33   | 0.198   |
| Axial length, mm  | 16       | 26.44 ± 1.68 | 26.56 ± 1.61 | -3.255  | 0.005   |
| BCVA,logMAR      | 14       | 0.33 ± 0.49  | 0.26 ± 0.31  | 1.085   | 0.298   |

Table 3
Comparisons of refractive error, axial length, and BCVA in baseline and 1 year of follow-up

| number of eyes | baseline | 1 year | t       | P       |
|----------------|----------|--------|---------|---------|
| Refractive error,D | 26       | -9.75 ± 4.46 | -10.28 ± 2.76 | 0.72    | 0.478   |
| Axial length, mm  | 15       | 25.73 ± 0.86 | 26.04 ± 0.87 | -9.61   | 0       |
| BCVA,logMAR      | 27       | 0.33 ± 0.49  | 0.26 ± 0.31  | 0.588   | 0.561   |

Table 4
Comparisons of refractive error, axial length, and BCVA in baseline and 2 years of follow-up

| number of eyes | baseline | 2 year | t       | P       |
|----------------|----------|--------|---------|---------|
| Refractive error,D | 9        | -10.15 ± 3.06 | -10.65 ± 3.09 | 1.079   | 0.312   |
| Axial length, mm  | 6        | 26.83 ± 1.79 | 27.02 ± 1.80 | -2.382  | 0.063   |
| BCVA,logMAR      | 7        | 0.13 ± 0.11  | 0.11 ± 0.15  | 0.548   | 0.604   |

Safety and complications

No severe complications were found in this study, and patients’ vision improved slightly from baseline to the follow-up. Slit-lamp microscopy revealed slight oedema and inflammation of the conjunctiva at 1 week postoperatively. The oedema and inflammation disappeared completely at 1 month postoperatively. There were no new pathological changes or abnormalities in the fundus findings from preoperatively to postoperatively. Figure 3 shows the fundus images and OCT of one patient taken before and 2 years after surgery.

Discussion
As the myopic refractive error increases, excessive axial elongation of the eyeball occurs, applying biomechanical tension to the posterior pole of the eyeball, and the sclera becomes thinner, leading to a series of complications[15]. As the degree of myopia increases, the prevalence of pathological myopia also increases[16]. Pathological myopia can lead to an irreversible decline in BCVA, which is one of the important causes of blindness[17]. After a long period of repair and reconstruction, the implanted sclera eventually fuses with the recipient's sclera. Scleral thickness increases significantly, and scleral hardness increases significantly, yielding mechanical reinforcement of the sclera. Neovascularization improves visual function in patients with high myopia by improving the nutritional status of the posterior pole of the eye. Yan[18] implanted allogeneic sclera into the posterior part of rabbit eyes and assessed biomechanical factors. It was found that allogeneic sclera is a good biomechanical material. All these results indicate that posterior scleral reinforcement is a good method to strengthen the sclera and delay the progression of myopia.

Snyder-Thompson percutaneous stereotaxic rhizotomy (PSR) surgery[11] is characterized by severe injury, marked scar formation after myotomy, and high operational requirements. Our posterior sclera reinforcement operation is easy for operators to learn. The macular area and the optic nerve are not touched, and the degree of disturbance to the extraocular muscles is small, which means that the operation is very safe.

In our study, the AL increased by 0.07 mm, and the myopic refractive error increased by 0.05 D at 3 months after surgery. At 6 months postoperatively, the AL increased by 0.12 mm, and the myopic refractive error decreased by 0.28 D. At 1 year postoperatively, the AL and myopic refractive error increased by 0.31 mm and 0.53 D. The AL increased by 0.19 mm, and the myopic refractive error increased 0.50 D at 2 years after the operation. In a follow-up study on the changes in AL and myopic refractive error of school-age children (6–8 years old) in Shanghai, China[19], the baseline myopic refractive error was ± 0.04 ± 0.80 D, and the baseline AL was 22.75 mm ± 0.72 mm. The AL of the eye increased by 0.27 mm at 1 year and 0.52 mm at 2 years. In our study, 1 year after PSR, the AL of the eyes increased to nearly the AL of children with emmetropia of the same age, and the AL of the eyes at two years after operation was much shorter than that in the children with emmetropia. Perhaps because the sample size of the 2-year group was too small, the changes were not statistically significant. However, a significant reduction in the rate of axial growth was beneficial for this group.

In a follow-up study by Hu[20] on the effects of posterior scleral reinforcement surgery, the AL of the control group increased by 0.75 mm within one year. Compared with this method, our modified posterior scleral reinforcement method was effective in controlling AL. In addition, a follow-up study of Chen's[12] modified Snyder-Thompson posterior scleral reinforcement surgery showed a 0.41 mm increase in the number of myopia cases in the control group within a year. In Shen's[21] study, the control group wore rigid gas permeable (RGP) lenses to correct high myopia and exhibited an average annual increase of 0.44 mm in AL.
Statistical analysis of myopic refractive error in the four groups yielded $P > 0.05$, which indicated that there were no significant differences between the postoperative and preoperative myopic refractive errors; that is, the increase in myopic refractive error was not obvious. At six months after the operation, the myopic refractive error decreased. At 1 year, the error increased by 0.53 D. In the study by Shen[21] et al., the myopic refractive error of the control group increased by 1.00 D and that of the PSR group increased by 0.44. Similarly, the control group had an annual increase of 0.75 D, and the PSR group had an annual increase of 0.45 D in Xue[13] et al.'s study. In our study, at 1 year, the increase in myopic refractive error was also largely consistent with the findings of these two previous studies. In Chen's[12] study, the operator made a conjunctival incision from the temporal side, extending to the nasal side to the superior rectus muscle and then to the inferior rectus muscle. Shen[21] underwent a 210-degree periconjunctival incision along the inferior temporal margin, followed by a radial incision at both ends. Both surgical procedures are difficult for beginners to learn and traumatic for patients. In contrast, our surgical method is minimally invasive and easy to perform.

It is worth considering that there was a relatively large increase in AL and refractive error in this study one year after the operation, and we found that almost all of these patients underwent surgery after July 2019. Due to the impact of the COVID-19 pandemic, this group of patients were quarantined at home for at least six months, and some patients even needed to attend online courses. During the pandemic, there were fewer outdoor activities, more near activities and a lack of physical exercise. According to the research of Tideman JWL[22] et al., reading time, not participating in sports activities and less time for outdoor activities are all independent factors leading to the acceleration of eye axis growth in school-age children. Therefore, we speculate that the AL and refractive error of this group may have been affected by the pandemic.

Although the changes in logMAR visual acuity in the four groups were not statistically significant, they all showed a downward trend (BCVA increased). BCVA did not decrease significantly in any of the patients, which indicated that the operation does not cause damage to patients' vision within a short period of time, but follow-ups should be performed.

There are some limitations of our study: (1) because of the lack of a control group, we can compare the follow-up results with those of only previous studies of the same type; (2) the long-term effect of the surgery was not assessed due to the short follow-up period; and (3) due to the influence of the COVID-19 pandemic, the loss to follow-up rate of the patients in this study was high, and almost no patients returned for all the follow-ups.

**Conclusions**

In summary, our results show that this modified PSR has the potential to delay the axial prolongation of high myopia. This is a relatively simple, safe and minimally invasive operation, but studies with longer follow-up periods are needed to evaluate the long-term safety and effectiveness of the operation.
Declarations

*Ethics approval and consent to participate*

The study was approved by the Medical Ethics Committee of Peking University People’s Hospital and conducted in accordance with the Declaration of Helsinki for research involving human subjects. The parents or guardians of the patients provided informed consent before the children underwent surgery.

*Consent for publication*

Not applicable

*Availability of data and materials*

The data analysed during the current study are not publicly available due to limitations of ethical approval involving the patient data and anonymity but are available from the corresponding author on reasonable request.

*Competing interests*

The authors declare that they have no conflict of interest.

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*Authors’ contributions*

Lejin Wang and Lvzhen Huang designed the study. Lejin Wang did all the surgeries. Qianru Ouyang, Zequn Miao, Xin Xu, Lili Guo, Qingyu Meng, Shuting Liang, Jingyi Zhang and Haoli Fu recruited the participants. Qingyu Meng, Shuting Liang and Jingyi Zhang collected the subjects’ research files. Qianru Ouyang, Zequn Miao and Yu Cao performed the data organization and analysis. Lejin Wang, Lvzhen Huang, Qianru Ouyang and Zequn Miao wrote the manuscript. All authors critically revised and gave final approval to this manuscript.

Qianru Ouyang and Zequn Miao contributed equally.

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