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Research Article

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Efficacy of Posterior Scleral Reinforcement in Children with High Myopia: A Systematic Review and Meta-Analysis

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Abstract

Purpose: *The purpose of this meta-analysis is to evaluate the effect of posterior scleral reinforcement (PSR) on axial length (AL), spherical equivalents (SE) and best corrected visual acuity (BCVA) in children with high myopia.*

Methods: *The databases PubMed, EMBASE, Wanfang Database, CNKI, CSTJ and Cochrane Library from inception to March 2021 were searched to identify the relevant studies which evaluated the efficacy of PSR for patients under 18 years old with high myopia. The main parameters include AL, SE and BCVA. Revman software version 5.3 was used to perform the statistical analyses. Results in proportion with 95% confidence interval were calculated using dersimonian-laird model.*

Results: *8 studies including 383 PSR treated and 281 control eyes were finally included. Our analysis indicated that PSR could slow down the increase of AL and the loss of vision loss (P<.01). However, in the subgroup with a follow-up period shorter than three years, there was no statistical difference in BCVA changes between the PSR and control groups (WMD=-0.02, 95%CI -0.07 to 0.04, P=.58, I2=0%). The BCVA changes is significant after 3 years follow up (WMD=-0.13, 95%CI -0.21 to -0.05, P=0.007).*

Conclusion: *PSR can benefit children in controlling the growth of AL, SE and decrease of visual acuity. 3 years after PSR may be a critical time point. Given the limitations in our study, more research with larger sample sizes and more accurate data are required to reach a firmer conclusion.*

Keywords: High myopia, Meta-analysis, Posterior scleral reinforcement

Introduction

There is an epidemic of myopia in the world now days, with the prevalence of myopia in young adults around 80-90% in East and Southeast Asia and around half in the United States and Europe [1]. More than half of children finishing high school in urbanized East Asia and North America are myopic, and the prevalence of high myopia in children of school-leaving age is up to 10-20% [2]. Holden and colleagues estimated that by 2050, 5 billion people will be affected by myopia and 1 billion people will have high myopia who might loss their visions due to myopic-related ocular complications [3]. Myopic retinopathy has become the first reason causing irreversible blindness in the world.

High myopia is usually defined as the presence of a highly negative refractive error (< -6 to -8 diopters (D)) in the context of eye elongation (26-26.5 mm). Excessive axial elongation of the eye in high myopia can cause mechanical stretching of the outer coats of the eye ball resulting in various pathologic changes such as staphyloma, diffuse chorio-retinal atrophy, patchy chorio-retinal atrophy, macular atrophy, lacquer cracks, myopic choroidal neovascularization (mCNV) and Fuchs' spot, etc. In such situation, usually called pathological myopia, the visual acuity could be impaired obviously and cannot be corrected by the spectacles. Studies have shown that the risk of pathologic myopia is determined by the severity of myopia and axial length [4-7]. The prevalence of myopic retinopathy from 1%-19% in moderate myopia (3D) increased to

50%-70% in high myopia (<9D) populations. Each 1 mm increase in axial length increased the risk of developing pathologic myopia by 1.52 times (p = 0.02). Therefore, preventing the progression of myopia may help reduce the blindness rate of these patients.

To date, several approaches have been used to limit the progression of myopia in children, such as atropine, pirenzepine, orthokeratology, peripheral defocus modifying contact lenses, rigid gas-permeable contact lenses, soft contact lenses, and under-corrected single-vision lenses. A network meta-analysis show that atropine, orthokeratology, peripheral defocus modifying contact lenses, pirenzepine, and progressive addition spectacle lenses were effective in limiting the increase of axial length, among which, the most effective interventions were pharmacologic, that is, muscarinic antagonists such as atropine and pirenzepine [8]. However, the mean refractive error of the participants in these clinical trials is between -2.0D and -4.5D, mostly not the scope of high myopia [9]. So, it is still a big challenge and non-negligible problem for controlling the progression of high myopia in children.

In view of the key role of axial length, especially posterior staphyloma, in the pathogensis of myopic retinopathy, Shevelev first proposed a technique, posterior scleral reinforcement (PSR), in an attempt to control or correct the pathological status of the posterior sclera in 1930 [10]. Snyder and Thompson modified the procedure and reported the result in 1972 and 1978, respectively [11,12]. The PSR was performed using a graft to reinforce the weak sclera at the posterior pole of the eye, thus preventing the progression of posterior scleral staphyloma and the increase of the axial length of the eye so as to halt the progression of high myopia. PSR has been used worldwide since the 1980s and was regarded as an effective approach in the treatment of myopia to date [13,14]. Rozsival, et al. revealed 3 years after correction only changed by 0.27 D on average, as indication for operation was progression of myopia by at least 1 D per year before operation [15]. This is consistent with the results found by Xu, et al., that the increment of refractive diopter was <0.50 D/year [16]. In terms of axial length, the mean elongation was significantly less in the surgery eye group than that in the contralateral eye group [17-19]. Peng and colleagues reported that PSR can effectively stop the progression of pathological myopia. No significant changes were found in axial length (AL), spherical equivalent (SE), best corrected visual acuity (BCVA), choroidal thickness (CT), retinal thickness (RT) during a 3-year follow-up [20]. In a retrospective study, Dong reported that modified PSR can effectively limit the progression of axial elongation in children with high myopia. The operation is safe, causes little damage, and can be customized [21]. However, most of the studies was single center and the samples was limited, therefore, a meta-analysis could be helpful to the clinicians to get a more comprehensive knowledge about the effectiveness of PSR in controlling high myopia in children and thus could help them when making a decision of PSR, which is critical given the progressive nature of the disease. Additionally, by comparing the extent of studies' differences, the factors affecting the outcome of PSR can be elucidated and provide directions for future studies.

Herein, this study systematically synthesized the related published articles and assessed the effectiveness of PSR in controlling high myopia in children, representing with the important parameters of high myopia, namely axial growth, refractive progression, and visual acuity loss by using meta-analysis.

Material and Methods

This study is fully compliant with the "Preferred Reporting Items for Systematic Reviews and Meta-analyses (the 'PRISMA'statement)" [22].

Search Strategy

A systematic search of publications in the electronic databases PubMed, EMBASE, Wanfang Database, CNKI, CSTJ and Cochrane Library from inception to March 2021, was conducted using the following terms and their combination: ((myopia[MeSH]) AND (scleral buckle) OR (posterior sclera reinforce) OR (scleroplasty) OR (Snyder Thompson) OR (buckle reinforce) OR (PSR). Only human studies published in English and Chinese were considered.

Inclusion Criteria and Exclusion Criteria

Inclusion criteria were (1) Participants: Human under 18 years old with myopic negative refractive errors < -5.0 D and axial length (AL)≥24 mm, or with myopic refractive errors < -6.0D. (2) Intervention: PSR. (3) Comparison: untreated eyes in children of similar age and refractive status or the patient's untreated contralateral eye. (4) Outcomes: at least one of the followings:①AL. ②Best corrected visual acuity (BCVA). ③Spherical equivalent (SE). (5) Study design: non-randomized Controlled Trial (non-RCT), randomized Controlled Trial (RCT) and cohort. (6) Full-text is available. (7) Blank control group exists.

Exclusion criteria were (1) Adult patients. (2) Patients who had undergone other treatments for high myopia or have other ocular disorders. (3) Only one article from the same clinical trial was included in the study that was most closely related to this study. (4) The published language of the paper is not Chinese or English (Including Russian and German). (5) Review, letters, or comments.

Data Extraction and Assessment of Methodological Quality

After removing the duplicates by End Note software, the title and abstracts were examined to establish relevance by two investigators (X.-y.Z. and Z.-y.C.) independently. If relevant, the full articles were reviewed for more detailed information. The following data were extracted: the first author, year of publication, study design, group size, patient age, gender ratio, material, operation method, follow-up period, AL, SE and BCVA. The corresponding authors were contacted when requisite data were unavailable in relevant articles. Any disagreements on eligibility and data collection during the reviewing were resolved by a third investigator (J.-y.Y.). As for methodological quality, the Newcastle Ottawa Scale (NOS) was used to test cohort studies and non-RCT. Disagreements over quality assessment were resolved by discussion, or adjudicated by a third investigator.

Statistical Methods

Statistical analyses for the meta-analyses were performed using Review Manager version 5.3 (Cochrane Collaboration) and StataSE V16.0 software respectively. For outcomes in all included studies, the changes of SE, AL and BCVA are defined as the difference between that at the endpoint of follow-up and at the baseline. Through the calculation, mean, the weighted mean difference (WMD) between cases and controls, corresponding 95% CIs and standard errors were presented in forest plots. The heterogeneity across studies was assessed by the chi-square test and I2. A random-effects model would be used if the heterogeneity was large ($P < 0.1$, $I2 > 50\%$) and sensitivity analysis and subgroup analyses would be carried out to identify the origin of the heterogeneity. Begg's funnel plot and Egger's linear regression test was used to evaluating the publication bias [23]. $P<0.05$ was considered to indicate statistical significance.

Results

Study Characteristics

The search yielded 837 potentially relevant articles for the meta-analysis. Among them, 403 duplicates were removed by Endnote software. On review of titles and abstracts of the 434 remaining articles, the full text of 114 articles was retrieved. Then 106 articles were removed because of various reasons (Figure 1). Finally, 8 studies were selected for this meta-analysis [13,14,18,19,21,24-26]. Among these studies, 2 studies were self-control studies using the fellow eye as controls, and 6 studies compared PSR versus a group without PSR treatment. The cumulative sample size of 664 high myopia eyes comprised 383 with PSR and 281 untreated eyes. The demographic characteristics of the two groups were similar in each study. The included studies' main characteristics are presented in table 1, and the literature-exclusion procedures are shown in Figure 1. The average score for the methodological quality of included studies was 7.13 which tested by NOS. Inter-rater agreement was achieved between the investigators regarding eligibility.

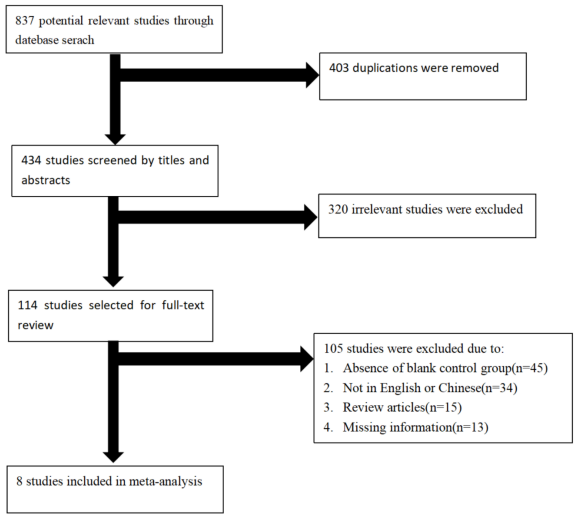

Figure 1: Flowing chart summarizing the selection process

Table 1: Main characteristics of the included studies

source	Material	Operation Method	Control Method	Follow-up, y	Sample size/eyes		Gender ratio (Male/ female)		Average age,y		Change amount of axial length,mm		change amount of Refraction,D		Change amount of BCVA,LogMAR		NOS score
					A	B	A	B	A	B	A	B	A	B	A	B	
Dong, 2020	human sclera	round	non-RCT	3	46/72	43/67	29/17	24/19	7.28±3.69	9.02±3.54	0.29± 0.33	0.82± 0.33	-0.31± 0.81	-2.25± 1.02	− 0.22± 0.38	-0.02± 0.11	9
Xue, 2018	Special sclera	single wide strip	Self-control	1	40/40	40/40	29/11	29/11	10	10	0.02±0.67	0.43±0.67	0.27±1.59	-0.75±1.4	-0.03±0.24	-0.02±0.24	7
Hu, 2018	Bovine pericardium	single wide strip	non-RCT	1	26/32	23/35	13/13	12/11	8.21±3.86	7.28±1.65	0.13 ± 0.17	0.71 ± 1.08	-0.11±1.2	-0.24±1.33	0.16±0.24	0.19±0.2	8
Yi, 2016	Bovine pericardium	single wide strip	non-RCT	3	21/40	13/26	8/13	5/8	10.10±4	9.69±2.81	0.71±0.34	1.18±0.40	-1.13±0.45	-1.93±0.44	-0.25±0.11	-0.16±0.07	6
Xue, 2014	human sclera	single wide strip	Self-control	2.5	30/30	30/30	21/9	21/9	7.5	7.5	0.75±0.48	0.94±0.44	-1.12±0.97	-1.82±1.11	-0.09±0.15	-0.08±0.15	7
Chen, 2013	human sclera	single wide strip	non-RCT	5	41/64	11/17	25/16	6/5	6.5±3.23	7.65±3.61	1.27±0.54	2.05±0.91	-1.5±1.44	-3.02±1.57	-0.32±0.24	-0.16±0.31	7
Guan, 2009	human sclera	round	non-RCT	3.5	31/55	28/50	17/14	15/13	7.9	Similar	0.21±0.04	0.68±0.1	-0.29±0.12	-1.61±0.67	-0.05±0.05	-0.01±0.03	6
Hu, 1998	human sclera	round	non-RCT	1	25/50	8/16	15/10	4/4	9.23	9	-0.15±0.86	0.6±0.89	N/A	N/A	N/A	N/A	7

Notes: BCVA, best-corrected visual acuity; LogMAR, logarithm of the minimum angle of resolution; D, diopter;N/A, indicated data not available; NOS, Newcastle–Ottawa Scale; non-RCT, non-Randomized Controlled Trial; A=surgery group, B=control group; similar=The researchers claimed that the mean age of the control group was the same as the surgical group but did not give specific data; Change amount, the difference between the study's follow-up endpoint data and the Initial data.

Axial Length

Eight studies including 383 eyes in PSR treated group and 281 eyes in the control group were evaluated; random-effect model was used to show a statistical difference of AL increase between the two groups. According to sensitivity analysis, except 4 studies in which the follow-up periods were shorter than 3 years, heterogeneity level of the left 4 studies can be reduced to an ideal level (I^2=0). The elongation of AL in the surgical group was significantly less than that in the control group, both in the two subgroups and in overall (P<.001, shown in Figure 2).

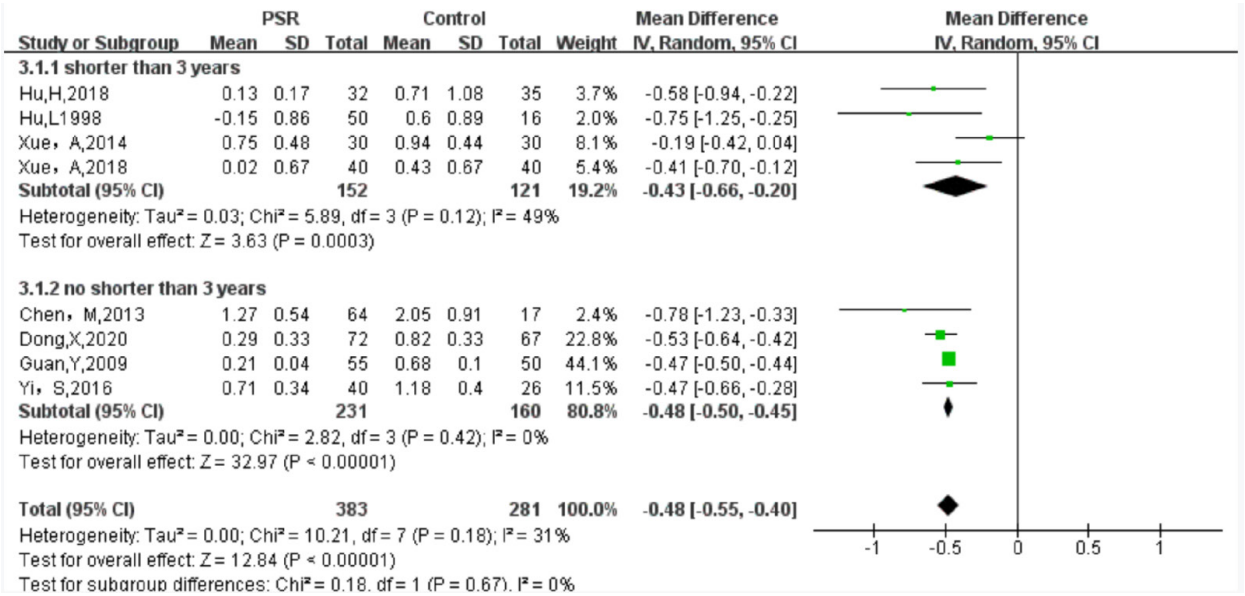

Figure 2: Comparison of axial length change amount between the posterior scleral reinforcement group and control group

Spherical Equivalent

In studies containing a total of 333 treated eyes and 265 control eyes, the increase of SE was significantly lower in the PSR treated group than that in the control group (95% CI -0.14 to -0.03, P < .001), other detailed data were shown in Figure 3. The heterogeneity can be reduced by performing subgroup analysis with a three-year follow-up time cut-off (I^2=50%). Compared with in the subgroup of less than three years following-up (WMD=0.61, 95%CI 0.12 to 1.10, P<.001), the efficacy on slowing down the increase of SE was more pronounced in the long-term subgroup (WMD=1.37, 95%CI 0.87 to 1.88, P<.001).

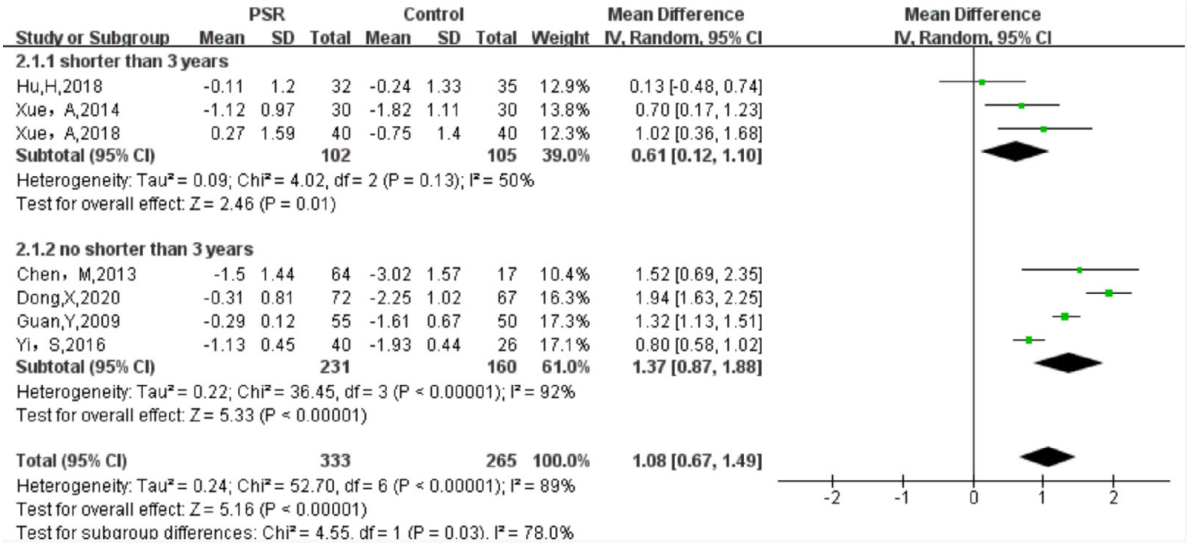

Figure 3: Comparison of Spherical equivalent change amount between the posterior scleral reinforcement group and control group

Best-Corrected Visual Acuity

Seven studies included 333 eyes in the surgery group and 265 eyes in the control group described preoperative and postoperative BCVA in the final follow-up. The pooling results by the random-effect model (P<0.1, I^2>50%) showed a statistical difference of BCVA changes (WMD=−0.09, 95%CI −0.14 to −0.03, P<.001, shown in Figure 4), that is, the PSR group could achieve significantly better BCVA than those in the control group. But the results of these analyses appeared heterogeneous (*P* < .01, I^2>50%), sensitivity analysis detected that the difference of follow-up period was the source of heterogeneity. Therefore, we made subgroup analyses accordingly and found that the heterogeneity could be significantly eliminated (P>.01, I^2=0). The pooling results manifested no significant difference in the changes of BCVA between the surgery and control groups in subgroups with a follow-up time shorter than 3 years (WMD=-0.02, 95%CI -0.07 to 0.04, P=.58, I^2=0%). But in subgroups with a follow-up time longer than 3 years, the improvement of BCVA was significantly higher in the surgical group than in the control group (WMD=-0.13, 95%Cl -0.21 to -0.05, *P* < .01).

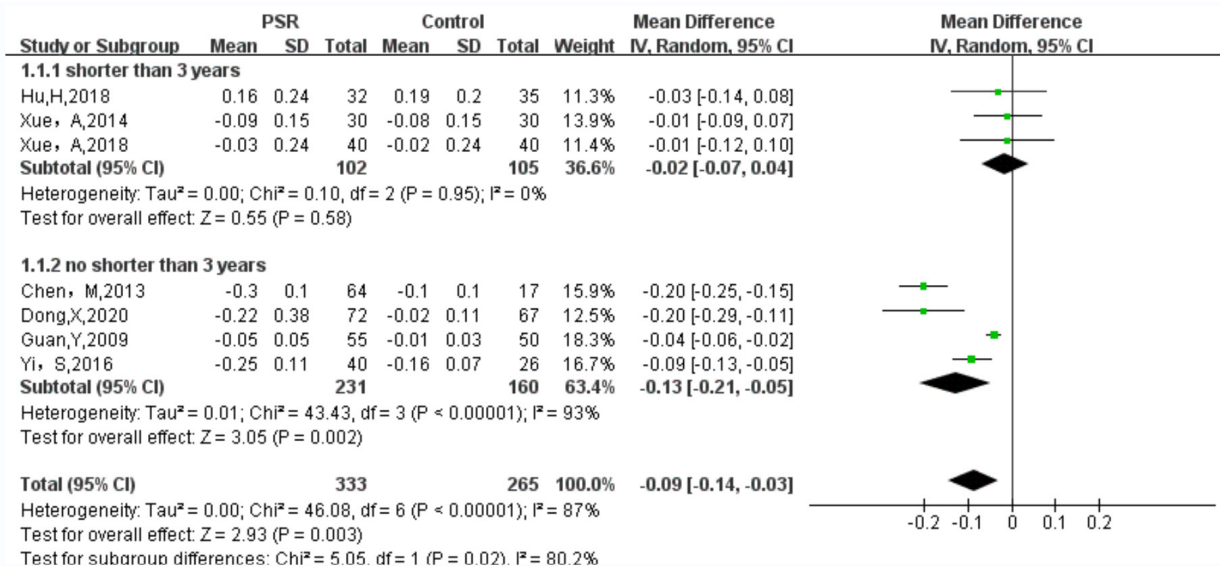

Figure 4: Comparison of BCVA change between the PSR group and control group

Postoperative Complications

Within 1 month after surgery, several complications have occurred in the operated eye, including subconjunctival hemorrhage, mild visual distortion, and conjunctival congestion and edema□but without any complications lasting more than three months.

Publication Bias

There was no significant publication bias present in Egger's linear regression test for refraction progression, axial elongation and change of BCVA.

Discussion

Based on systematically analysis of the results of published articles, we found that PSR can limit the deterioration of myopia by affecting changes of AL, SE and BCVA in children with high myopia. There was large heterogeneity in the study results, but the heterogeneity could be significantly reduced by dividing the subgroups by the time point of follow-up period. The materials used and the way the procedure was performed had no significant effect on the final result.

The most apparent characteristic of high myopia is a gradual growth in AL and subsequent thinning of the posterior sclera, which can change rapidly in childhood [27]. Evidences show that pathological changes in the sclera caused by the elongation of AL contribute largely to the multiple complications in high myopia [28]. So, limiting the growth of AL is the key point in myopia prevention. Therefore, the changes of AL had been considered as the most crucial criterion for evaluating effectiveness of PSR. Currently, clinical follow up reveal that PSR can slow down the AL growth by (1) directly strengthen the mechanical force of the posterior sclera by the reinforcement band surrounding the posterior pole and (2) facilitating the posterior sclera remodeling due to the inflammatory response between the posterior sclera and the reinforcement band [29]. Considering that the effect of PSR surgery in limiting the lengthening of the AL is obviously related to the postoperative time, and its effect is bound to decrease after a sufficient period of time after surgery, the change in the AL is obviously not a linear change, so this analysis compares the overall change in AL rather than the annual average change in AL. Of the eight studies included in this meta-analysis, there was a statistical difference in the progress of AL between the treated and control group, the increase of AL in the surgical group was significantly less than that in the control group. This is consistent with the findings of previous studies [18,19,24].

Changes in SE are closely related to the changes in AL. Previous studies demonstrated that the occurrence rate of myopia re-

lated complications is highly positive to the increase of SE [7]. In this meta-analysis, the heterogeneity in SE changes varied widely across the included studies. Some of the heterogeneity could be reduced by subgroup analysis, but the heterogeneity was still relatively high compared to the other two parameters. This may be because the measurement of SE in children is strongly influenced by the child's cognitive ability and the way the data collected. However, similar to the results in AL, the increase of SE was less in the surgery group than in the control group.

Clinically, the goal of PSR is to control the progression of high myopia, and ultimately maintain or even improve BCVA. In two other meta on the effect of PSR in controlling high myopia, results showed that the change in BCVA was not statistically significant between PSR group and control group [30,31]. In our meta-analysis, different from previous studies, we set subgroups by the duration of follow-up period to eliminate heterogeneity. We found that there was no statistical difference of BCVA change in the subgroup with less than 3 years of follow-up, but in studies that the follow-up period exceeds 3 years, BCVA improvement was more pronounced in the surgical group. This means that in the early postoperative period after PSR the change in BCVA is indeed insignificant, but with the postoperative time increasing, PSR is also helpful in improving BCVA. Taken together, we can conclude that PSR can indeed control the progression of high myopia in AL, SE and BCVA.

In addition, PSR showed a consistently significant beneficial effect on halting the progression of high myopia in children both with classical and modified surgical procedures, that is, PSR can be carried out using different shape of the reinforcement band (round or single wide strip), and multiple kinds of materials (human sclera, Genipin-crosslinked donor sclera bovine pericardium) during the surgical procedure. The reason may be that, regardless of the material used and surgical approach, PSR can works through the significant reinforcement in the posterior sclera as clinical and experimental research showed [18,19,32].

The heterogeneity of the studies was closely related to the duration of follow-up. Heterogeneity can be significantly reduced by subgroup analysis; In the current study, 3 years of follow-up period was chosen as the time point for sub grouping. In terms of AL, the heterogeneity was obvious within 3 years post PSR and become significantly decreased 3 years after. This might be explained as following: PSR surgery directly alters the AL of patients, the extent of AL changes in the early postoperative period might be influenced by the surgical approach carried out by different surgeon in different studies. However, with time going, the difference aroused by surgical technique diminished gradually and the efficacy of PSR stabilized. As for SE and BCVA, contrary to AL, there was less heterogeneity within 3 years follow up and the heterogeneity increased 3 years post PSR. This might because that the BCVA and SE are indirectly affected by surgery, so there is little difference in heterogeneity across studies in the early postoperative period. However, because we included children who were still growing up, individuals might acquire different status after a period longer than three years, a higher heterogeneity then emerged.

In the current meta-analysis, all selected studies are published in Chinese core journals or available in the Science Citation Index database. In previous studies, high myopia was sometimes defined as negative refractive error <-5D rather than <-6D. Considering that PSR is a surgical modality to control axial myopia, we added the requirement of AL >24 mm (i.e., the upper limit of standard eye axis length) for patients with refractive error <-5D to the inclusion criteria to avoid the effect of pure refractive myopia and to ensure the credibility of the study results. We used a random-effects model because of the high overall heterogeneity, and the heterogeneity was eliminated to an acceptable level by subgroup analysis. This implies that the results are relatively reliable.

There are some limitations in the study. Firstly, these studies span a wide range of time from 1998 to 2020. Although the authors state that the procedures are essentially similar, differences in data measurement instruments and surgical experience skills may still confound the results. Secondly, some studies' SD data were not precise enough, so we estimated the covariance (Cov) and correlation coefficient (r) reported by other studies in this meta-analysis to imputed the missing data. Third, although heterogeneity is reduced by subgroup analysis, there is always half of the data with high heterogeneity, which may be somewhat different from the real world in the overall data. Fourth, only Chinese and English studies was included in this study; a large amount of Russian literature (n=29) was not included in the study and thus may have been biased by the study population. However, the Russian and German literature was mainly generated during the Soviet period, and considering the technical differences due to the era, this part of the literature not included may not be very informative for modern treatment. Finally, although all the available data had been pooled together most reliably, our meta-analysis's final sample size was still relatively small, and more high-quality researches were needed to reach a more solid conclusion.

In summary, based on the available evidence, posterior scleral reinforcement can play a positive role in controlling the growth of AL, SE and decline in BCVA in children. The reasons for the emergence of the three-year postoperative time point deserve in-depth study and may change our understanding of postoperative treatment strategies for PSR. Given the limitations in our study, more researches with larger sample sizes and more accurate data are required to reach a firmer conclusion.

Ethics Approval and Consent to Participate

Not applicable.

Conflict of Interest Statement

None

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Author's Contribution

All authors have made substantive intellectual contributions to this study. All authors (ZC, XZ, ZY, YC and QL) contributed to the conceptualisation of the manuscript, overview of literature and interpretation of data. ZC, XZ, QL contributed to the design of this work. ZC prepared the draft manuscript of this overview. ZC and XZ contributed to data acquisition and extraction. XZ and ZC performed the statistical analysis. All authors reviewed and approved the final version of the manuscript.

Data Statement

All data generated or analysed during this study are included in this published article [and its supplementary information files].

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