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Original Article

The efficacy of posterior scleral contraction in controlling high myopia in young people

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Abstract: Objective: To investigate the clinical effectiveness and safety of posterior scleral contraction (PSC) surgery in controlling high myopia in young people. Methods: Twenty patients with high myopia (30 eyes) were treated with PSC. The average age for the patients was 11.45 ± 5.17 years old (range 3-22). A genipin cross-linked sclera was implanted to the posterior sclera in PSC surgery. Axial length and myopia progression rates were measured at least two years before and after PSC surgery. Results: Prior to surgery, the mean AL progression was 0.73 ± 0.33 mm, compared to -0.08 ± 0.31 mm (P=0.00) post-surgery; the degree of myopia increased was -1.40 ± 0.95 D, compared to 0.18 ± 1.10 D post-surgery (P=0.00). The best corrected visual acuity (BCVA, in LogMAR) improved from 0.21 ± 0.16 preoperatively to 0.13 ± 0.13 two years after PSC (P=0.014). Conclusions: PSC can restrict AL extension and safely control high myopia progression in young people.

Keywords: High myopia, myopia controlling, posterior scleral contraction, young people

Introduction

In recent decades, the prevalence of myopia has increased dramatically. In East and Southeast Asian countries, approximately 80-90% of young people leave high school with myopia [1]. Over the past 60 years, the prevalence of myopia among Chinese young people has increased from 10-20% to 90%. The incidence of myopia (diopter < -0.5 D) is approximately 95% in college students. Among youth with myopia, approximately 19.5% have high myopia (diopter < -6.0 D) [2, 3]. The prevalence of high myopia has also increased significantly [1, 4, 5]. Therefore, the incidence of retinal lesions has also increased [6-8]. After cataracts, high myopia is the second leading cause of visual impairment among adults in China [9, 10].

Non-surgical methods used to treat high myopia progressing are effect including increased outdoor activity, reduced close-up working time, wearing frame, bifocal or multifocal glasses, fitting orthokeratology lenses, and using low concentrations of atropine [11, 12]. However, these methods are generally considered to only have a small effect on low and moderate myopia.

During high myopia processing, posterior scleral expansion and thinning worsen, while the adjacent posterior choroid and retina also expand and thin, leading to the development of fundus lesions [8, 13-15]. In order to control the progression of high myopia, intervening on posterior scleral expansion should be a priority.

In a previous study, we used scleral reinforcement to control the progression of high myopia in children. While the procedure did not contract the sclera or shorten AL, 30 children with progressive high myopia underwent monocular surgery with contralateral eyes used as controls. The sclera materials used in this study were not treated by cross-linking. The results indicate that 2.5 years after the procedure, the AL of non-surgical eyes increased 0.94 ± 0.44 mm compared to 0.75 ± 0.48 mm in surgical eyes. Furthermore, the refractive status of non-surgical eyes increased -1.82 ± 1.11 D compared to -1.12 ± 0.97 D in surgical eyes.

Table 1. The Changes of AL, SE and BCVA before and after the PSC

Items \ Times	2 years before PSC	Prior to PSC	After PSC	6 months after PSC	1 year after PSC	2 years after PSC
AL (mm)	28.54 ± 1.58	29.27 ± 1.45	28.28 ± 1.42	28.88 ± 1.51	29.05 ± 1.48	29.19 ± 1.48
SE (D)	-10.75 ± 3.47	-12.15 ± 3.04	-10.58 ± 3.28	-11.48 ± 2.97	-11.70 ± 3.09	-11.98 ± 3.10
BCVA	0.21 ± 0.16	0.18 ± 0.15	0.17 ± 0.17	0.14 ± 0.13	0.14 ± 0.14	0.13 ± 0.13

AL = axial length; SE = spherical equivalent; BCVA = best corrected visual acuity; PSC = posterior scleral contraction.

Although the AL and diopter increases observed in surgical eyes were less than that of non-surgical eyes (P < 0.05), reductions in AL were limited, and myopia control was not satisfactory [16].

We postulated that the degradable nature of non-crosslinked material limited its efficacy in preventing sclera from expanding into high myopia. Scleral reinforcement is not adequate in controlling the progression of high myopia. Shrinking the posterior sclera and shortening AL is expected to achieve better clinical results [17]. Based on this hypothesis, we improved prior surgical techniques by enhancing AL shortening using sclera treated by genipin (a natural crosslinker) to increase their strength. Recently, we used this improved surgical procedure - termed posterior scleral contraction (PSC) - to treat macular splitting and macular retinal detachment, and the results were satisfactory [18-21]. High myopic young people who had PSC were investigated in this study, and the cases were followed for an extended period before and after surgery to compare the efficiency of PSC.

Material and methods

The following were the inclusion criteria for this study: spherical equivalent (SE) < -6 D, AL > 26 mm, yearly myopia progression greater than 0.5 D, and a follow-up time greater than 24 months preoperatively and postoperatively. Patients with cataracts, glaucoma, retinal detachment, and other eye diseases were excluded from the study. Moreover, the patient must have expressed a strong desire for surgery. This cohort study included 20 young patients (30 eyes) with high myopia (**Table 1**). Among them, there were 15 males (22 eyes) and 5 females (8 eyes) with an average age of 11.45 ± 5.17 years (range 3-22 years). PSC surgery was performed between July 2013 and October 2015. After surgery, patients were followed up as scheduled during the study: 1 day, 1 week, 1 and 6 months, 1 year, 2 years or longer. This clinical study followed the tenets of the Helsinki Declaration and was approved by the Ethics Committee of the Eye Hospital of Wenzhou Medical University. Patients or their guardians provided informed consent prior to surgery.

Examination and equipment

Preoperative and postoperative examinations included evaluation of manifest refraction, evaluation of the best-corrected visual acuity (BCVA) by logMAR, biomicroscopy, determination of intraocular pressure (IOP), and dilated funduscopy. AL was also measured via an optical biometer (IOLMaster, Zeiss, Germany), and OCT (Carl Zeiss Meditec Inc., Dublin, California, USA) was used to obtain high-resolution images of the retina.

Surgical procedures were performed by a single surgeon (A.X.). Surgical materials were allogenic sclera cross-linked by genipin. The strips were sliced into a fusiform, the length was 1.5 times the AL. The width in the middle portion was 0.4 times the AL, while the width at both ends was approximately 2-3 mm.

Procedure

The surgical techniques involved in PSC were published previously [19, 20]. PSC was performed under general anesthesia. A 210° peritomy of the conjunctiva was performed along the inferior temporal axis of the limbus. A radial incision was made at each end of the peritomy to expose the inferior and lateral rectus muscles, and traction sutures were prepared. Pulling the traction sutures to the superior and nasal direction, the inferior oblique muscle was lifted with a muscle hook, and the sclera strip was sequentially passed underneath the inferior oblique, lateral rectus and inferior rectus muscles. During this process, particular attention was paid to protecting the optic nerve and vortex veins from damage. The middle portion

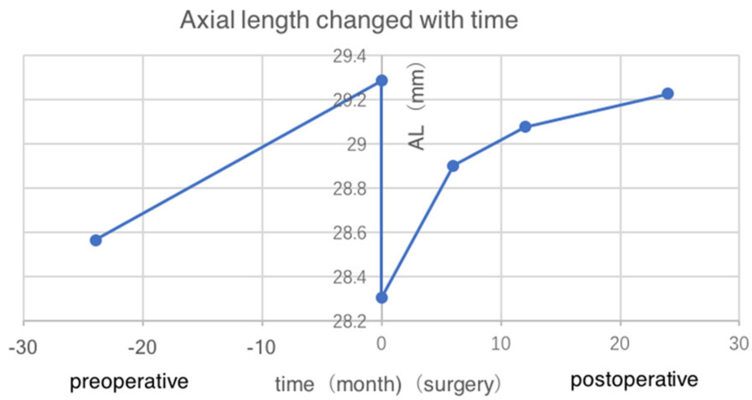

Figure 1. Axial length (AL) changes before and after PSC. Before PSC, the AL elongated 0.37 ± 0.17 mm per year; PSC surgery shortened the AL by 0.99 ± 0.40 mm; After PSC, the AL regressed quickly within 6 months, 1.20 ± 0.57 mm per year; then the AL elongation slowed down, 0.34 ± 0.28 mm per year for 6-12 months postoperatively, and 0.14 ± 0.14 mm per year for 1-2 year postoperatively. The AL elongation slowed down by PSC.

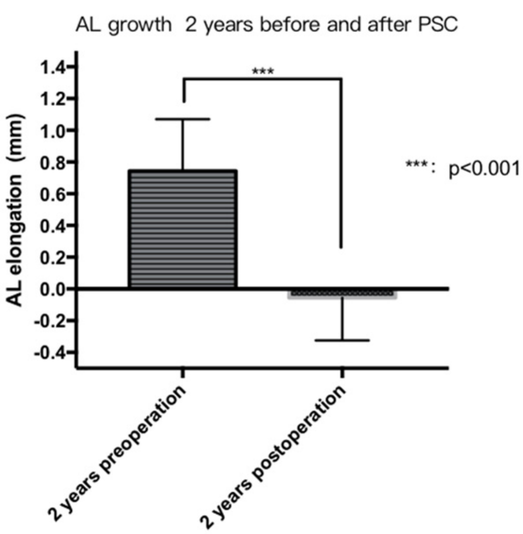

Figure 2. Axial length increased 0.73 ± 0.33 mm within 2 years preoperatively and -0.08 ± 0.31 mm within 2 years postoperatively. AL growth was significantly slower after PSC surgery (paired t-test, P < 0.001).

of the sclera strip was placed at the posterior pole, and the inferior nasal end was sutured to the pre-equatorial sclera 2 mm behind the insertion point of the medial rectus muscle using 5-0 nylon sutures. The other end was stretched around the posterior pole and placed near the pre-equatorial sclera of the superior oblique muscle. Then, approximately 0.05-0.2 mL of aqueous humor was released using a 25-gauge syringe needle (1 mL) inserted into the anterior chamber. The superior temporal end of the strip was tightened and sutured to the pre-equatorial sclera, 2 mm behind and outside the insertion point of the superior rectus muscle, using 5-0 nylon sutures. At the end of the procedure, the scleral strip was checked to assure that it had been correctly positioned and oriented. The posterior pole was inspected with indirect ophthalmoscopy to ensure that the optic nerve head and major blood vessels were normal and that the macular was slightly bulged. Finally, the conjunctival incision was closed using 8-0 absorbable sutures. Postoperatively, antibiotics and non-steroidal anti-inflammatory eye drops were recommended for use four times daily for three weeks.

Reduction of AL and diopter: Due to intraoperative monitoring difficulties, data were obtained within a week after surgery. The AL shortened by 0.99 ± 0.40 mm, while the myopia diopter reduced by 1.58 ± 1.34 D.

Statistical analysis

All statistical analyses were performed using SPSS v.20.0. All continuous variables were described using means and standard deviations. Single-group repeated measures were used to compare the AL, refraction, and BCVA of different periods. Paired t-tests were used to compare whether there was a significant difference in AL and SE progression before and after surgery. Statistically significant differences were defined as $P < 0.05$.

Results

AL changes following PSC

AL was different at different time points (single-group repeated measures, $P < 0.001$) (**Table 1**; **Figure 1**). The AL was shortened 0.99 ± 0.40 mm by PSC surgery. In the two years following time, AL increased 0.73 ± 0.33 mm in 2 years preoperative and -0.08 ± 0.31 mm in 2 years postoperative (paired t-test, $P < 0.001$) (**Figure 2**). AL growth speed was 0.37 ± 0.17 mm per year 2 years preoperative, 1.20 ± 0.57 mm per year 6 months postoperative, 0.34 ± 0.28 mm

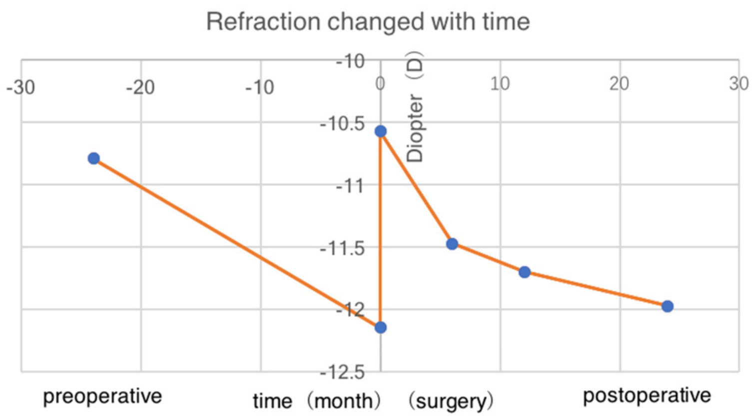

Figure 3. Refraction changes following PSC. Before PSC, the SE increased by -0.70 ± 0.47 D per year; PSC reduced SE by 1.58 ± 1.34 D; After PSC, the SE regressed quickly within 6 months, -1.80 ± 1.83 D per year; then SE increased speed slowed down, -0.45 ± 0.74 D per year for 6-12 months postoperatively and -0.28 ± 0.47 D per year for 1-2 year postoperatively. Myopic growth speed was slowed down by PSC.

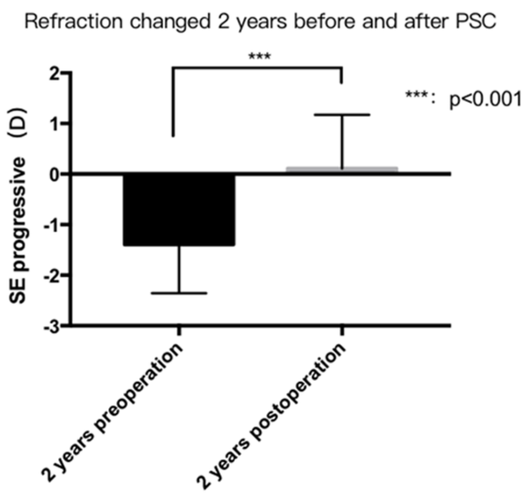

Figure 4. Refraction increased -1.40 ± 0.95 D within 2 years preoperatively and 0.18 ± 1.10 D within 2 years postoperatively. Myopia growth was significantly slower two years after surgery (P < 0.001).

per year 6-12 months postoperative, and 0.14 ± 0.14 mm per year 1-2 year postoperative. There was statistical significance in the AL growth speed (single-group repeated measures, P < 0.001). AL growth speed was slowest after one year postoperative.

Changes in refraction following PSC

SEs (**Table 1**; **Figure 3**) were different at different time points (single-group repeated measures, P < 0.001). Refraction increased -1.40 ± 0.95 D within 2 years preoperative and 0.18 ± 1.10 D within 2 years postoperative. Myopia growth was significantly slower two years after surgery (paired t-test, P < 0.001) (**Figure 4**). The myopic growth speed was -0.70 ± 0.47 D per year in 2 years preoperative, -1.80 ± 1.83 D per year within 6 months postoperative, -0.45 ± 0.74 D per year in 6-12 months postoperative, and -0.28 ± 0.47 D per year in 1-2 year postoperative (single-group repeated measures, P < 0.001). Myopic growth speed was slowest after one year postoperative.

Changes in LogMAR VA following PSC

The LogMAR VA was 0.21 ± 0.16 at 2 years preoperative, 0.18 ± 0.15 immediately after surgery, 0.14 ± 0.13 at 6 months postoperative, 0.14 ± 0.14 at 1 year postoperative, and 0.13 ± 0.13 at 2 years postoperative (**Table 1**; **Figure 5**). The PSC reduced diopter and improved the blood supply of posterior retina, the BCVA increased dramatically after surgery. LogMAR VA was different at different time points (single-group repeated measures, P=0.00). The BCVA improved from 0.21 ± 0.16 preoperatively to 0.13 ± 0.13 2 years after PSC (P=0.014). VA increased postoperatively.

Adverse events

Slight visual distortion occurred in 3 eyes (10.0%) in the early postoperative period. After 3 months, the visual deformation disappeared, and the macular folds returned to normal. No infection, high IOP, retinal detachment, optic nerve damage, and other complications were noted. OCT images in **Figure 6** were from one patient followed over time. **Figure 6A** shows the retina was slightly convex prior to surgery, **Figure 6B** shows the retina was somewhat forward convex with a slight wrinkle after surgery, and **Figure 6C** and **6D** show the retina flattened gradually at 6 and 18 months after surgery.

Discussion

High myopia in children and adolescents tends to progress rapidly and cause early retinal lesions [13]. In this study, we followed young

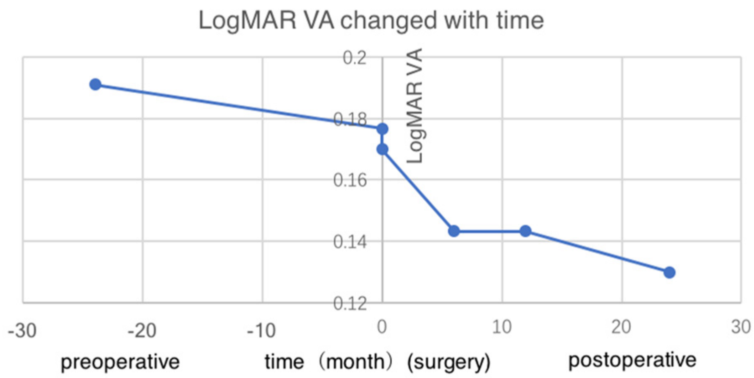

Figure 5. LogMAR VA changes following PSC. The BCVA increased slightly with time preoperatively, the amblyopia improved; 6 months after PSC, the BCVA improved quickly; BCVA keeped steady in 6-12 months; After 1 year, the BCVA increased and amblyopia improved slightly.

people with rapid progression high myopia following PSC surgery with genipin cross-linked sclera. This is the first study to report controlling the progression of high myopia with PSC using a new material.

On average, AL reduced 0.99 ± 0.40 mm, and myopia also decreased 1.58 ± 1.34 D. The strip was designed to be spindle-shaped in order to widely wrap the posterior part of the eye and avoid vortex veins and optic nerve damage that could lead to surgery-related complications [18, 20, 21]. AL shortening was related to the amount of anterior outflowing chamber fluid volume and the degree of tension on the strip. Too much shortening can cause significant macular folds, which can impact the safety of surgery.

The present study found that AL growth was 0.73 ± 0.33 mm at 2 years before surgery and -0.08 ± 0.31 mm at 2 years after surgery ($P < 0.001$). Increases in myopia were -1.40 ± 0.95 D preoperatively and 0.18 ± 1.10 D postoperatively ($P < 0.001$). The treatment effect was significantly better than what we observed in our previous study [16].

AL growth speed and refraction growth speed were slowest one year after surgery. The results showed that PSC is efficient in controlling the progression of myopia. Within 6 months postoperatively, AL growth speed was 1.20 ± 0.57 mm per year, myopia growth speed was -1.80 ± 1.83 D per year, and AL and myopia returned faster (**Figures 1**, **3**). Because of the integration process of the strip and sclera, both gradually fit tightly, and the gap disappeared; furthermore, the strip was stretched [17]. AL and diopter regression rates gradually reduced over time. Rates were relatively stable until one year after surgery (**Figures 1**, **3**).

In this study, high myopia progress was controlled, and the desired results were achieved. We believe that this result was observed because of the use of novel materials: sclera treated by crosslinking. Crosslinked materials are widely used in clinical practice [22, 23], but not commonly used in ophthalmology. The crosslinked material is generated by the reaction between biofilm denatured material and a crosslinking agent, which improves the strength of the material, resistance to degradation, and tissue compatibility [24]. In this study, the cross-linking agent used was genipin, which is the active compound in Fructus Gardeniae extract and a bio-crosslinker with lower toxicity than glutaraldehyde [23, 25].

In this study, patients were children and adolescents with an average age of 11.45 ± 5.17 years, who were in a rapid growth phase. AL growth was not completely prevented postoperatively, as the growth rate was 0.14 ± 0.14 mm per year. Growth was likely related to continued expansion of the equatorial anterior sclera that was not covered by the material. It may also relate to the degree of crosslinking present in the crosslinked membrane. Further study of the procedure and biomaterials are needed in the future.

Early visual distortion is a common postoperative adverse event, and in this study, choroid and retinal shrinkage due to sclera contraction occurred in three cases (10.0%). Mild wrinkles were identified only by OCT (**Figure 6B**). In this group, the fold and visual distortion were both mild. Fortunately, visual distortion disappeared completely after a few weeks (**Figure 6C**, **6D**). This was likely due to the fact that AL shortening was less and young patients typically have good retinal elasticity and recover more easily. Surgery should be performed cautiously in order to avoid optic nerve injury, intraocular

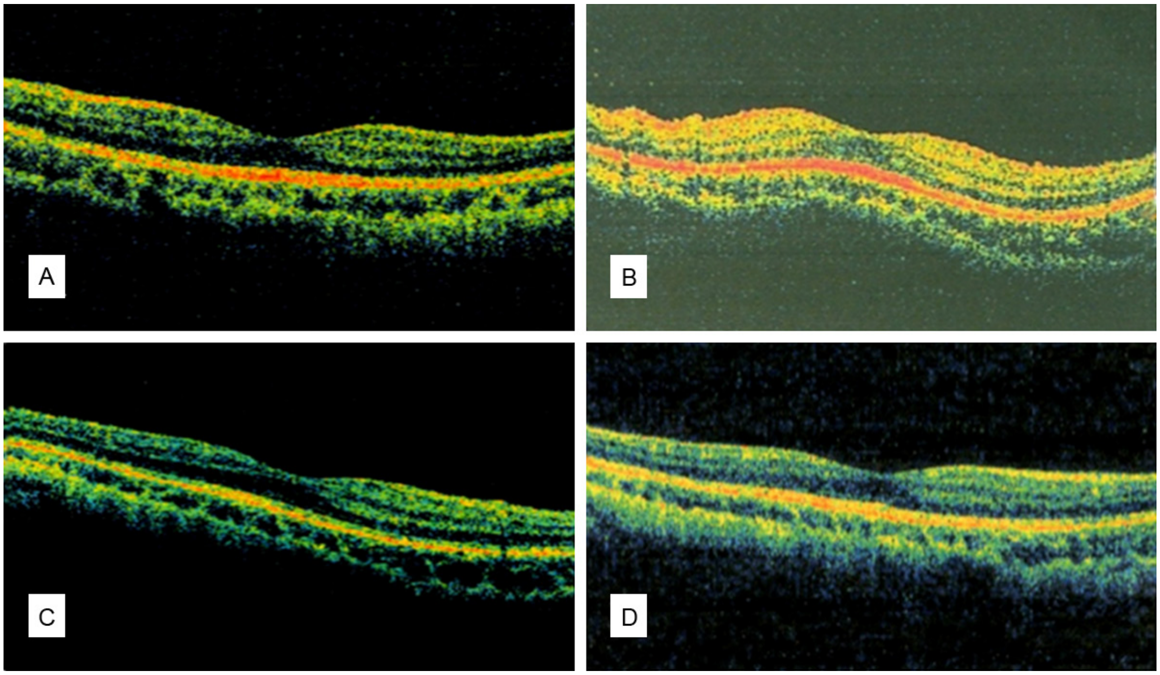

Figure 6. OCT images following PSC. A. Preoperative OCT, retina had backward convex configuration. B. OCT image 1 week postoperatively, the retina had forward convex configuration pressed by the scleral strip, slightly wrinkled. C. OCT image 6 months postoperatively, the retina flattened. D. OCT image 18 months postoperatively, the retina was flat.

hemorrhage, and other serious complications. This study showed that BCVA was 0.21 ± 0.16 at 2 years before surgery and 0.13 ± 0.13 after surgery and significantly increased ($P < 0.01$) (**Figure 5**). Maybe because the PSC reduced diopter and improved the blood supply of posterior retina, so the BCVA increased dramatically. Our study demonstrated that PSC surgery is safe to perform and effective.

PSC surgery can control the progression of high myopia and prevent high myopia sclera expansion. The prevention and treatment of high myopia fundus lesions are of great significance. The effect of posterior scleral contraction in the treatment of high myopia fundus lesions has also been confirmed in our recent study [14, 18, 20, 21].

In conclusion, our study showed that PSC surgery can safely and significantly control high myopia AL elongation and myopia progression among young people and lead to improved corrected visual acuity. However, the quantitative standards of the degree of posterior scleral contraction are still debated. Due to equipment limitations, accurate monitoring of AL cannot be achieved during surgery, therefore AL reduction is prone to bias. The use of the cross-linked allogeneic scleral material is in the early stages of use in operative ophthalmology. Better implantation materials are worth exploring. Since high myopia is a chronic eye disease, large randomized trials are needed to evaluate the long-term effects of PSC.

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Disclosure of conflict of interest

None.

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