ORIGINAL RESEARCH

A Modified Knotless Transscleral Intraocular Lens Fixation Technology for Congenital Ectopia Lentis

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ABSTRACT

Introduction: This study aimed to compare modified knotless transscleral suture fixation of intraocular lens (IOL) with traditional transscleral suture fixation for adolescents and young patients with congenital ectopia lentis (CEL).

Methods: This retrospective cohort study included 49 patients with CEL (60 eyes) who underwent surgery at the Zhongshan Ophthalmic Center. Improvements based on knotless Z-suture fixation technique were made to form a modified knotless method, in which thicker 8–0 polypropylene sutures were used,

and double parallel scleral grooves were constructed behind the limbus instead of triangular lamellar scleral flaps to cover suture stitches. Modified knotless transscleral fixation of IOL was conducted on 30 eyes, and the other 30 eyes underwent traditional transscleral fixation surgery. Pre- and postoperative best-corrected visual acuity (BCVA), refractive error, astigmatism, other ocular parameters, and complications were statistically analyzed.

Results: For patients in the modified knotless group, the mean cylindrical refractive error and astigmatism at 1 month and 3 months postoperative were lower (all $P < 0.05$), and the mean IOL tilt degree was smaller at 3 months postoperative ($3.21° \pm 2.13°$ vs. $5.65° \pm 3.66°$, $P = 0.032$). The incidence of suture exposure in the modified knotless group was also lower than in the controls (0 vs. 16.7%, $P = 0.026$). No group differences were observed in mean BCVA, spherical equivalent, or other ocular biometric parameters between groups.

Conclusion: Modified knotless technique was a valid method to achieve optimal IOL position and reduce postoperative astigmatism for adolescents and young patients with CEL. It effectively reduced the incidence of knot-related complications, greatly improved the postoperative comfort, and achieved aesthetic benefits.

Keywords: Congenital ectopia lentis; Knotless; Transscleral suture fixation; IOL

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Key Summary Points

Why carry out this study?

Knot/suture-related complications and intraocular lens (IOL) decentration are common complications in traditional transscleral suture fixation of the posterior chamber intraocular lens surgery. Although sutureless scleral fixation of intraocular lenses has been introduced to avoid suture-related complications, it is not suitable for pediatric patients with congenital ectopia lentis (CEL) whose sclera is too soft, and the eyeball is still growing.

Improvements based on knotless Z-suture fixation technique may achieve better postoperative IOL position and reduce the incidence of knot/suture-related complications for young patients with CEL.

What was learned from the study?

The modified knotless transscleral intraocular lens fixation technology could not only reduce the incidence of knot-related complications but also achieve less postoperative astigmatism and smaller IOL tilt degree.

The modified knotless method is a promising IOL fixation technique for young patients with severe insufficient capsular support such as CEL.

INTRODUCTION

Traditional transscleral suture fixation of the posterior chamber intraocular lens (PCIOL) surgery, which ties knots at suture ends to fixate intraocular lens (IOL) and constructs two sides of scleral flaps to cover the suture knots, is currently one of the most commonly used surgical methods to fixate the IOL in patients without adequate capsular support, such as congenital ectopia lentis (CEL) [1, 2]. However, knot-related complications such as knot exposure, knot erosion, and suture erosion usually occur after this type of surgery. According to previous reports, the incidences of 1-year postoperative knot exposure and suture erosion were as high as 14.7% and 17.9%, respectively [3, 4]. In addition, Solomon et al. reported an incidence of 73% suture knot erosion occurring 2 years after surgery [5]. To reduce knot-related complications, Szurman et al. were the first to describe a knotless transscleral suture fixation of the PCIOL surgery using 10–0 polypropylene sutures and a zigzag-shaped intrascleral suture (Z-suture) to fixate the PCIOL without tying any knots [6]. However, it was reported that there was a 40% probability of long-term suture breakage using the Z-suture technique with 10–0 polypropylene sutures without enough durability [7]. Furthermore, to prevent suture-related complications, Yamane introduced a sutureless fixation method, the flanged intrascleral IOL fixation [8], in which the IOL haptics are inserted into the scleral tunnel to fix the IOL. However, CEL is an early-onset hereditary disease and usually develops in very young age [9, 10]. The sclera of a patient with CEL is softer compared with that of an adult, which means that it is more difficult to conduct the Yamane technique. Besides, a large series reported haptic tip extrusion in intrascleral haptic fixation surgery [11], and for adolescent and young patients, the incidence could be higher. Considering age-related globe enlargement, continual eye rubbing, and the high probability of eye trauma due to the active lifestyles of children and adolescents, sutureless intrascleral IOL fixation has been less often used in children than adults [12, 13]. Moreover, the safety and stability of sutures are particularly important as the majority of patients with CEL are children and adolescents. To safely reduce the risk of suture breakage, the use of thicker sutures for IOL fixation, which can resist the traction from the implanted IOL, has gradually become a new trend [14, 15], and the 8–0 suture is most often used [16–18].

Considering the development characteristics and surgical needs of children and adolescent

patients, we made two improvements based on knotless Z-suture fixation technique to form a modified knotless transscleral suture fixation method, in which 8–0 polypropylene sutures were used and double parallel scleral grooves were constructed behind the limbus, thereby enhancing the durability of suture fixation, and reducing the knot/suture-related complications. In this study, we compared this modified knotless method with most often used traditional transscleral suture fixation surgery and evaluated the efficacy of the modified knotless method.

METHODS

Ethics

This study was approved by the Medical Ethics Committee of Zhongshan Ophthalmic Center (ID 2019KYPJ184) and it adhered to the principles of the Declaration of Helsinki. All patients were aware of the collection of their data for this study and signed a consent form.

Patient Selection

According to previous reports, the incidence of knot exposure after traditional scleral fixation of IOL is about 24% while it is zero in the knotless IOL fixation technique [12]. According to PASS software (PASS 11, NCSS, Kaysville, UT), assuming 80% power and a 5% significance level, a sample size of 27 in each group was calculated according to the Fisher exact test. Considering a lost to follow-up rate of 10%, we estimated the minimum sample size each group to be 30. Sixty eyes received IOL fixation surgeries from October 2019 to November 2021 were included in this study. All patients had a follow-up at least 3 months after the surgery. The inclusion criteria were patients diagnosed with CEL. Exclusion criteria consisted of preoperative inflammatory manifestations, such as conjunctivitis, keratitis, anterior uveitis, and endophthalmitis, as well as other serious ocular diseases, such as glaucoma, retinal detachment, iris defect, and corneal disease.

Data Collection

The following information was collected for each patient: age, gender, pre- and postoperative best-corrected visual acuity (BCVA), intraocular pressure (IOP), refractive error (recorded in diopter, D), ocular parameters such as axial length (AL), flat keratometry (Kf), steep keratometry (Ks), mean keratometry (Km), anterior chamber distance (ACD), astigmatism (D), IOL tilt and decentration, and other complications. IOL tilt and decentration were measured by Pentacam and Scheimpflug images and evaluated with the Image-Pro Plus software (Media Cybernetics Inc., Rockville, MD, USA) as previously described [19].

Surgical Technique

All surgeries were performed by the same surgeon (Dr. Zheng). Patients aged 18 years or younger were given general anesthesia, and those aged older than 18 years were given retrobulbar anesthesia of 2–5 ml 0.75% ropivacaine (AstraZeneca AB, Sweden) combined with 2% lidocaine (Shanghai Zhaohui Pharmaceutical Co., Ltd.). After anesthesia the conjunctival sacs of all patients were routinely flushed before operation, and 5% iodophor solution was used to disinfect the eyelid and skin around the eye. The modified knotless transscleral suture fixation procedure was performed as follows. Two conjunctival peritomies were made at 4 and 10 o'clock, 2 mm from the limbus, to expose the sclera. Two parallel scleral grooves were constructed perpendicular to the limbus, 2 mm posterior to it, with a length of 3 mm and depth of 0.3 mm to 0.4 mm. The parallel grooves were wedge-shaped, the width between the grooves was 3 mm on the surface, and the width at their base was 2.5 mm (Fig. 1a). Next, a 3-mm main corneal incision was made at 12 o'clock, two paracenteses were made at 4 and 10 o'clock as surgery proceeded. After continuous curvilinear capsulorhexis, 2–4 iris retractors (Synergetics, Inc., US) were implanted to symmetrically hook the edge of the lens capsule as a barrier to avoid vitreous prolapse. After the lens cortex was gently extracted, an ophthalmic viscosurgical

device (OVD) was then injected between the capsule and anterior hyaloid membrane to separate them. Under the protection of OVD, residual zonular fibers were resected, and the capsular bag was taken out. Then we refilled with OVD to stabilize the vitreous, and subsequent suturing and implantation were finished in OVD. Thorough removal of the vitreous strands in the anterior chamber was necessary when vitreous prolapsed. A double-armed 8–0 polypropylene suture (Ethicon; Johnson & Johnson, New Brunswick, NJ) was bisected. Then the 8–0 polypropylene suture with curved needle was introduced into the anterior chamber. It was then retrieved using a hollow-bore needle inserted through the opposite scleral groove's innermost point, and the free end of the suture was then pulled externally out from the main corneal incision. The same steps were completed on the other side. The free ends of the sutures were tied to the haptics of the Rayner 970C/920H one-piece IOL (Rayner Company, UK), which was then dialed into the ciliary sulcus. Next, the suture was tightened by equal force with both hands and adjusted to center the IOL optic (Fig. 1b). The suture with curved needle was then used to perform the Z-shaped suturing along the scleral grooves on both sides, moving back and forth five times. The suture was ultimately cut, without leaving any knots, and subtly buried in the wedge-shaped scleral grooves (Fig. 1c). Some critical surgical steps are shown in Supplementary Fig. 1.

In the control group, the traditional transscleral suture fixation of the PCIOL was performed as previously described [20]. In brief, two triangular lamellar scleral flaps were constructed 2 mm posterior to the limbus. After removal of the lens, the 8–0 polypropylene suture with curved needle entered the side corneal incision and passed out from the other side of the scleral flap. The suture tails were drawn out from the main corneal incision and tied to the IOL haptics, after which the sutures under the scleral flap were tightened and tied knots by turns, leaving the knots buried under the sclera flaps, which then were closed with a 10–0 nylon suture.
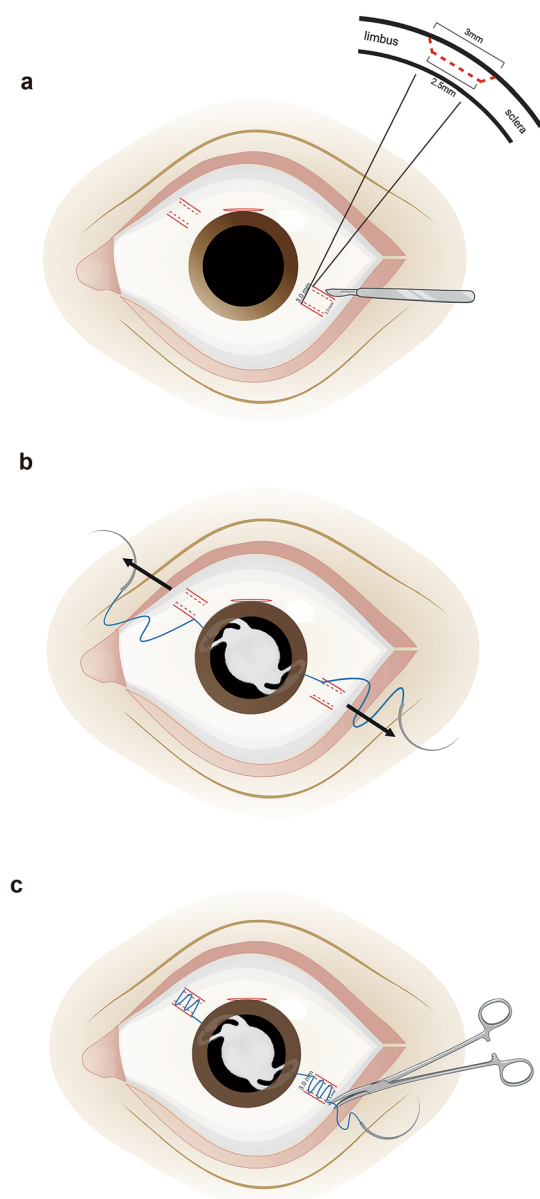

Fig. 1 Schematics of modified knotless transscleral fixation of the PCIOL. **a** Two parallel scleral grooves are constructed perpendicular to the limbus at 4 and 10 o'clock, with a length of 3 mm, a width of 3 mm, and a depth of one-half (around 0.3–0.4 mm) the thickness of the sclera. Beneath the scleral surface, the width at their base was 2.5 mm, forming a wedge-shaped section. A corneal incision is made at 12 o'clock. **b** 8–0 polypropylene sutures are tied to the haptics of the IOL, and the suture is tightened by equal force with both hands and adjusted to center the IOL optic. **c** Z-shaped suturing is performed along the scleral grooves on both sides, moving back and forth five times. The thread is ultimately cut, without leaving knots, and buried in the scleral grooves

Statistical Analysis

Snellen BCVAs were converted to logarithm of the minimum angle of resolution units (logMAR) for statistical analysis. Student's t test was used for the comparison between the groups when normal distribution of data was identified, and the chi-square test was performed between non-normal distribution data. To compare the results before and after surgery within a single group, the paired t test or the Wilcoxon signed-rank test was used. The overall significance level was set to a P value of 0.05. All statistical analyses were performed using SPSS software (version 22.0, SPSS, Inc., Chicago, IL).

RESULTS

There were no significant differences in terms of age, gender, or degree of lens dislocation between the two groups (all $P > 0.05$). The demographics of the study population are summarized in Table 1. During the operations, three cases in the modified knotless group and two cases in the traditional group had vitrectomy. No other intraoperative complication was noted.

As shown in Table 2, no significant differences were detected in terms of the preoperative, 1 month, and 3 months postoperative spherical equivalent (SE) between the two groups. However, the average cylindrical refractive errors in the modified knotless group at 1 month postoperative (-0.58 ± 3.20 D vs. -2.20 ± 1.32 D, $P = 0.027$) and 3 months postoperative (-1.13 ± 1.09 D vs. -2.20 ± 1.07 D, $P = 0.001$) were lower than in the control group. The postoperative BCVA values of both groups were significantly improved compared to the preoperative measurements, but there was no significant statistical difference in postoperative BCVA between the two groups (Supplementary Fig. 2). Likewise, there were no significant differences in IOP, AL, Kf, Ks, ACD, or corneal endothelial cell density between the two groups either pre- or postoperative (all $P > 0.05$). However, the corneal astigmatism in the modified knotless group was significantly lower than in the control group after surgery (-1.39 ± 1.05 D vs. -2.42 ± 0.98 D, $P = 0.003$ at 1 month postoperative; -1.38 ± 0.83 D vs. -2.14 ± 0.88 D, $P = 0.018$ at 3 months postoperative; Table 2).

As shown in Fig. 2, suture knots produced by traditional transscleral method were prone to

Table 1 Demographic characteristics of the study population

	Traditional/control	Modified knotless	*P* value
Patients (no.)	30	30	
Age (years)	17.30 ± 9.71	22.47 ± 10.63	0.110
Gender (male/female)	14:16	13:17	0.795
Eye (right/left)	14:16	18:12	0.438
BCVA (logMAR)	0.47 ± 0.52	0.60 ± 0.62	0.414
Axial length (mm)	26.08 ± 2.61	27.43 ± 3.07	0.073
Intraocular pressure (mmHg)	13.37 ± 2.72	12.08 ± 4.21	0.167
Degree of lens dislocation			0.413
Mild, 0–25%	0	0	
Moderate, 25–25%	16	13	
Severe, > 50%	14	17	

BCVA best-corrected visual acuity

Table 2 Comparisons of manifest refraction outcomes and ocular parameters in the traditional/control and modified knotless groups

	Traditional/control (mean ± SD)	Modified knotless (mean ± SD)	*P* value
Spherical equivalent			
Preoperative	− 3.21 ± 11.74	− 4.03 ± 12.28	0.847
1 month postoperative	− 1.51 ± 1.55	− 1.71 ± 2.14	0.701
3 months postoperative	− 1.71 ± 1.33	− 2.01 ± 1.17	0.398
Cylindrical			
Preoperative	− 3.26 ± 2.83	− 1.83 ± 1.98	0.113
1 month postoperative	− 2.20 ± 1.32	− 0.58 ± 3.20	0.027*
3 months postoperative	− 2.20 ± 1.07	− 1.13 ± 1.09	0.001*
IOP			
Preoperative	13.37 ± 2.72	12.08 ± 4.21	0.167
1 month postoperative	13.83 ± 7.49	12.88 ± 5.07	0.639
3 months postoperative	12.07 ± 3.31	11.69 ± 4.61	0.789
AL			
Preoperative	26.08 ± 2.61	27.43 ± 3.07	0.073
1 month postoperative	26.22 ± 2.71	27.73 ± 2.90	0.107
3 months postoperative	26.64 ± 3.04	28.07 ± 3.68	0.164
Kf			
Preoperative	40.54 ± 1.71	41.10 ± 1.47	0.173
1 month postoperative	40.34 ± 1.51	41.31 ± 1.50	0.065
3 months postoperative	41.24 ± 1.92	41.04 ± 1.47	0.197
Ks			
Preoperative	42.42 ± 1.82	42.46 ± 2.86	0.950
1 month postoperative	42.76 ± 1.54	42.76 ± 1.69	0.985
3 months postoperative	42.39 ± 1.80	42.62 ± 1.62	0.703
Corneal astigmatism			
Preoperative	− 1.89 ± 0.94	− 1.70 ± 0.96	0.445
1 month postoperative	− 2.42 ± 0.98	− 1.39 ± 1.05	0.003*
3 months postoperative	− 2.14 ± 0.88	− 1.38 ± 0.83	0.018*
ACD			
Preoperative	3.50 ± 0.43	3.41 ± 0.54	0.511
1 month postoperative	3.96 ± 0.47	4.04 ± 0.33	0.550
3 months postoperative	3.90 ± 0.48	4.02 ± 0.28	0.385

Table 2 continued

	Traditional/control (mean ± SD)	Modified knotless (mean ± SD)	*P* value
ECD			
Preoperative	3204 ± 265	3108 ± 509	0.364
1 month postoperative	3061 ± 604	2606 ± 733	0.072
3 months postoperative	2729 ± 804	2621 ± 501	0.713

IOP intraocular pressure, *AL* axial length, *Kf* flat keratometry, *Ks* steep keratometry, *ACD* anterior chamber distance, *ECD* corneal endothelial cell density

*Statistically significant

inflammation, and congestion of the knots was heavier than with the embedding suture of the modified knotless group.

In terms of postoperative complications, the average tilt of the IOL in the modified knotless group was significantly smaller than in the control group, with a significant reduction of vertical IOL tilt. Besides, vertical decentration of IOL was smaller. The IOL position of patients in the modified group was more centered and less inclined compared with the traditional group (Fig. 3). In addition, in the modified knotless group, no patients had knot exposure, while five patients (16.7%) in the control group had knot exposure. A statistically significant difference was found in the incidence of suture knot exposure between the two groups ($P < 0.05$). The complications of the two groups of patients are shown in Table 3.

DISCUSSION

Our results suggested that patients could obtain good visual outcomes through the modified knotless method. No significant statistical differences were found when comparing the preoperative and postoperative BCVA values between the two groups of patients, indicating that the visual outcomes of the two groups were equal after surgery. In our study, all of the treated eyes (30/30) either maintained or improved their BCVAs, which is similar to Szurman's original knotless suture fixation of the PCIOL method (21/22) [21], suggesting that

the modified knotless method could be a potentially promising surgery technique for patients with CEL.

The possible reasons for smaller cylindrical refractive error and corneal astigmatism of the modified knotless technique in our study are as follows. First, the modified knotless technique has caused less impact on corneal and scleral morphology. Previous studies have shown that the scleral flap of the traditional method may increase the corneal astigmatism after transscleral suture fixation surgery [22, 23], in contrast to our modified knotless technique, wherein the scleral grooves barely influenced the sclera or corneal morphology. Second, the position of the IOL was less inclined. It was more convenient to adjust the suture tightness by Z-suture, and surgeons could tighten the sutures which tied on the haptics on both sides simultaneously, which was conducive to the centering correction of the IOL position. In contrast, the traditional method requires two sides of the suture to be fixed and knotted in turn, which is not conducive to allowing correction of the IOL position and the probability of IOL tilt was greater. Previous study confirmed that IOL tilt can cause postoperative intraocular astigmatism and influence the refractive error [24], the smaller astigmatism with the modified knotless method may be explained by smaller IOL tilt [25], whereas the smaller IOL tilt was associated with the operation procedures and technique, especially the knotless Z-suture.

In this study, the most common complication of the two groups of patients was
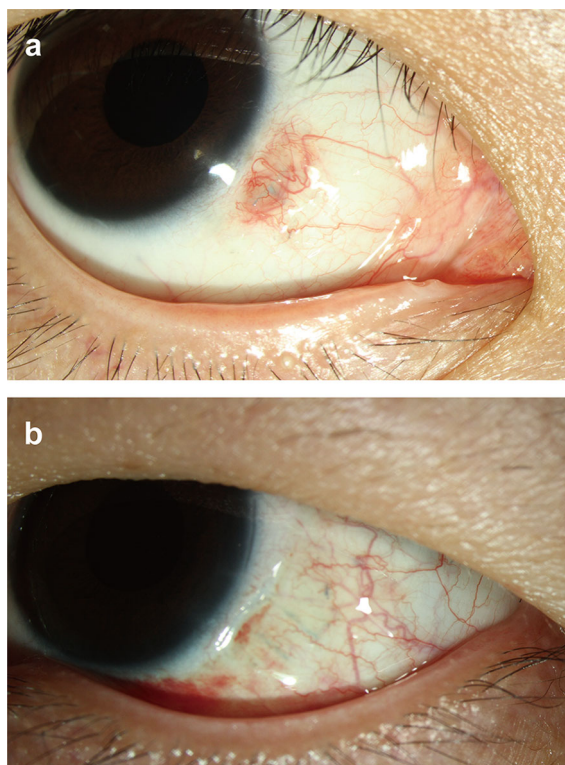
Fig. 2 Inflammatory congestion on knots or embedding suture of two patients from different groups 1 week after surgery. **a** From traditional group, **b** from modified knotless group; the inflammatory congestion on the knot was heavier than that on the embedding suture

postoperative high IOP, which was similar to previous reports [26, 27], but the modified technique did not increase the risk of postoperative high IOP. Furthermore, the damage to the corneal limbus and surrounding trabecular meshwork was reduced owing to no construction of scleral flaps. However, one patient in the modified knotless group developed postoperative macular edema. Szurman et al. reported that none of the 45 patients who underwent knotless scleral suture fixation of the PCIOL developed macular edema within 6–38 months after surgery [6]. Dimopoulos reported that 6 out of 62 patients developed postoperative macular edema during the 36–138 months of follow-up [7]. These data indicate that the knotless method has little effect on the fundus, and individual differences might have been involved in the occurrence of macular edema in this study. In addition, the incidence of

knot/suture exposure in the control group was similar to previous studies [3, 4], while modified knotless technique can effectively prevent knot-related complications.

This study suggests that the modified knotless method could provide better prognosis for children and adolescents patients with CEL than the traditional method, especially in terms of reducing knot/suture-related complications, which were prevented by the modified procedures used in the operations. First, we referred to the Z-suture knotless technique introduced by Szurman et al. [6], which can reliably prevent knot-related complications and help to reduce the postoperative astigmatism. Second, the 10–0 polypropylene suture used in their original technique is too thin for the growing eyeballs of children, as this natural growth increases the risk of 10–0 polypropylene suture breakage over time [7]. Therefore, 8–0 polypropylene suture was used, which may increase the resistance in the sclera to provide longer durability and reduce the possibility of suture slippage and the risk of postoperative suture breakage. Third, considering the habits of young patients with CEL, sutures left on the scleral surface are easily rubbed open or exposed when conjunctiva recedes, which greatly increases the loosening of sutures and even the possibility of intraocular infection. Therefore, scleral grooves are constructed to bury the sutures, which takes less surgical time than constructing scleral flaps and simplifies the procedures. In particular, these scleral grooves are wedge-shaped so that the stitches passing through the sclera can be totally hidden in the groove. This prevents the blue suture from being seen on the scleral surface, thus achieving aesthetic benefits that prevent young patients from developing feelings of self-consciousness and inferiority. As no scleral flaps are constructed, the operation is simplified, and the impact on scleral and corneal morphology is reduced. At the same time, bleeding is also reduced, along with surgical injury and pain [28]. Moreover, owing to the absence of surgical knots and scleral flaps, the local scleral and conjunctival inflammatory response is lighter, the wound heals faster, and patient discomfort is less and subsides earlier. Finally, since knot-tying can result in potential
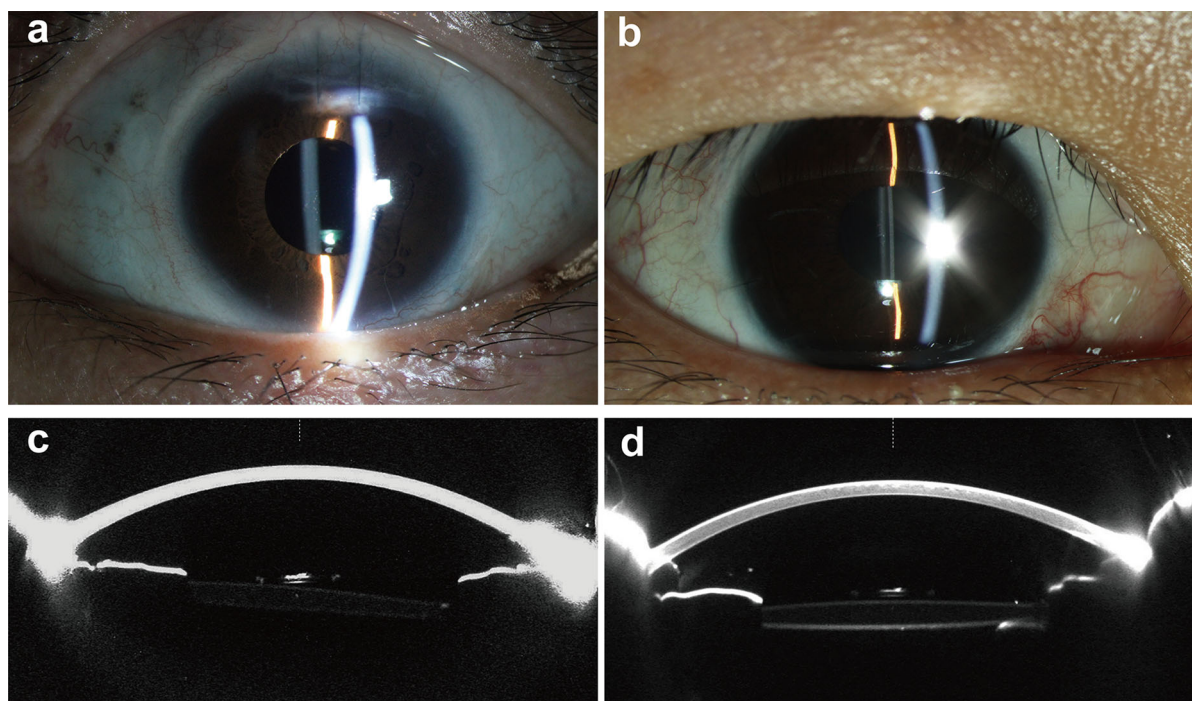
Fig. 3 IOL positions of two patients from different groups: **a**, **c** from traditional group; **b**, **d** from modified knotless group; **a**, **b** captured under the slip-lamp microscope; **c**, **d** obtained from the Pentacam. IOL position of patients from the modified knotless group was less inclined

Table 3 Postoperative complications in the traditional/control group and modified knotless group

	Traditional/control	Modified knotless	*P* value
Average IOL tilt (°, mean ± SD)	5.65 ± 3.66	3.21 ± 2.13	0.032*
Horizontal	2.21 ± 1.79	1.98 ± 1.16	0.697
Vertical	3.44 ± 2.32	1.78 ± 1.17	0.024*
IOL decentration (mm)			
Horizontal	0.38 ± 0.27	0.29 ± 0.14	0.665
Vertical	0.38 ± 0.24	0.23 ± 0.07	0.011*
High intraocular pressure	5 (16.6%)	2 (6.7%)	0.100
Macular edema	0 (0%)	1 (3.3%)	0.500
Vitreous hematocele	1 (3.3%)	1 (3.3%)	1.000
Residue of anterior chamber cortex	1 (3.3%)	0 (0%)	0.500
Knot exposure	5 (16.7%)	0 (0%)	0.026*

IOL intraocular lens
*Statistically significant

asymmetrical knots and unstable IOL position, the IOL position is less inclined when the suture ends are pulled tight by symmetrical force during Z-suturing, which also contributes to reduced astigmatism for better visual quality.

As CEL is a particularly rare disease, the sample size was relatively limited, and the follow-up time was short. A future study with a larger sample size and extended follow-up time is needed to further clarify the long-term safety and clinical efficacy of the modified knotless technique. But the advantages of this study are that all included patients had thorough ophthalmic examinations before surgery and finished at least three follow-up visits. As such, we collected complete and systematic medical records. Second, all surgeries were performed by an experienced surgeon to reduce operator error.

CONCLUSIONS

This modified knotless transscleral fixation of the PCIOL is an alternative, simplified, and knotless method for patients with CEL and others with insufficient capsular support. It not only helps adolescents patients achieve better prognosis but also reduces the incidence of knot/suture-related complications.

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