

# Therapeutic effect analysis on the treatment of congenital glaucoma through modified combined trabeculotomy-trabeculectomy

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Received: 2015-06-01 Accepted: 2015-07-27

DOI:10.18240/ijo.2016.02.11

Wu ZK, Wu J, Tan Q, Jiang J, Song WT, Xia XB. Therapeutic effect analysis on the treatment of congenital glaucoma through modified combined trabeculotomy-trabeculectomy. *Int J Ophthalmol* 2016;9(2):243-248

## INTRODUCTION

Congenital glaucoma is a kind of blinding eye disease that severely affects the development of visual acuity among children, infants and teenagers. It is caused by the obstruction of the aqueous outflow by the maldevelopment of the anterior chamber angle and the trabecular meshwork of the eye during the embryonic development phase<sup>[1]</sup>. The surgical management of congenital glaucoma is still a clinical challenge, largely because of its greater potential for failure and complications as compared with surgery in adults<sup>[2]</sup>. The operations that are currently used for the treatment of glaucoma are mainly goniotomy<sup>[3-4]</sup>, trabeculotomy<sup>[5]</sup>, trabeculectomy<sup>[6]</sup> and glaucoma valve implantation<sup>[7-8]</sup>. The successful rate of the goniotomy designed by Barkan<sup>[9]</sup> is 80% -90%. However, its clinical application is limited because of the high requirements on the operation equipment and the technologies and the requirement that the cornea of the patient must be transparent. According to the report by Gressel *et al*<sup>[10]</sup>, the successful rate of trabeculectomy alone is only 44% in glaucoma patients. And the operation successful rate of external trabeculotomy alone is also not satisfactory, between 35% -93%<sup>[11]</sup>. The combined trabeculotomy-trabeculectomy can effectively reduce the intraocular pressure (IOP) through the construction of an internal channel and an external channel to lead the aqueous outflow<sup>[12]</sup>. According to the report by Mandal *et al*<sup>[13-14]</sup>, primary combined trabeculotomy-trabeculectomy is safe, effective, and sufficiently predictable to be considered the first choice of surgical treatment in primary congenital glaucoma with corneal edema and in early-onset glaucoma associated with Sturge-Weber syndrome.

However, this operation is very difficult and there are many complications. According to the report by Essuman *et al*<sup>[15]</sup>, the overall success for combined trabeculotomy-trabeculectomy was 79%, and the probability of success reduced from more than 66% in the first 9mo post

## Abstract

• **AIM:** To evaluate the therapeutic effect and the safety of the treatment of congenital glaucoma through modified combined trabeculotomy-trabeculectomy.

• **METHODS:** The clinical data of 27 cases (altogether 42 eyes), which included 7 cases of infants (10 eyes) and 20 cases of teenagers (32 eyes), of congenital glaucoma undertook modified combined trabeculotomy - trabeculectomy were analyzed retrospectively. The parameters evaluated included the post operation visual acuity, the anterior chamber, the filtering bleb, the intraocular pressure, the C/D ratio, visual field, the retinal nerve fiber layer changes and the complications.

• **RESULTS:** The follow-up period was 1 to 29mo, averaging 13.3 ±7.7mo. Upon the last visit after the operation, functional filtering blebs developed in all the involved eyes. The intraocular pressure was controlled under 21 mm Hg, which was decreased by 60% when compared with that before the operation, without using any medication. There were no significant changes in the post operation visual acuity and the retinal nerve fiber layer thickness before and after the operation in teenager group ( $P>0.05$ ), and both the post operation C/D ratio and the visual field mean defect (MD) were reduced compared with those before the operation ( $P<0.05$ ). There were no severe complications in any of the patients.

• **CONCLUSION:** The modified combined trabeculotomy-trabeculectomy can effectively reduce the intraocular pressure and control the development of glaucoma in cases of congenital glaucoma. It is a safe and effective operative method for the treatment of congenital glaucoma.

• **KEYWORDS:** congenital glaucoma; trabeculotomy; trabeculectomy

operatively to below 45% after that. Because the cut end of the Schlemm canal is not sufficiently exposed, so sometimes the Schlemm canal cannot be found. It is likely to create a false channel when cutting with a trabeculotome. This can not only cause such complications as anterior chamber bleeding during and after the operation, but also cause unsatisfactory control of the intraocular pressure in a long term after the operation because the trabecula is not really cut. In recent years, our group made some modifications based on the traditional combined trabeculotomy-trabeculectomy to solve these problems. The retrospective results of the data on 40 eyes in 27 cases are reported below.

### SUBJECTS AND METHODS

**Subjects** The study adhered to the tenets of the Declaration of Helsinki and the protocol was approved by the the ethics committee of Xiangya Hospital of Central South University, and all participants or their statutory guardians gave informed consent. The subjects are patients suffering from congenital glaucoma admitted to Xiangya Hospital of Central South University from the January 2010 to the February 2013, altogether 27 cases (42 eyes), including 21 males (31 eyes) and 6 females (11 eyes), with an age of 0.3-30y (average  $16.7 \pm 11.1$ y). Inclusion criteria: 1) patients clinically diagnosed as suffering from congenital glaucoma; 2) the operation performed with modified combined trabeculotomy-trabeculectomy. Exclusion criteria: 1) glaucoma with combination of other congenital abnormalities; 2) a history of other eye diseases; 3) systemic diseases that can affect the prognosis of the operation such as hypertension or diabetes. The patients were divided into two groups, infant group (0-3y), 7 cases (10 eyes) with an age of 0.3-3 (average  $1.2 \pm 1.0$ y), and teenager group (3-30y), 20 cases (32 eyes) with an age of 10-30 (average  $22.2 \pm 6.9$ y).

Before surgery, all patients underwent detailed ocular examination that included slit-lamp examination, gonioscopy, and ocular fundus examination. Visual acuity test, visual field test and optic nerve fiber layer test were also performed in teenager group. Visual field was checked with the Humphrey 750 Visual Field Analyzer (Carl Zeiss Meditec, Inc. Dublin, CA, USA), optic nerve fiber layer was checked with a GDxVCC instrument (Carl Zeiss Meditec, Inc. Dublin, CA, USA). Because of the limited cognitive ability, visual acuity test, visual field and optic nerve fiber layer were not tested in the infant glaucoma patients. IOP was measured by Goldmann appalnation tonometer (Haag-Streit, Koeniz, Switzerland) if the patient was cooperative and Perkins hand-held appalnation tonometer (Haag-Streit, Koeniz, Switzerland) was used if the patient was not cooperative. The follow up tests include the visual acuity test, slit-lamp examination, gonioscopy, and ocular fundus examination. Surgical success at the last follow-up was defined as IOP  $\leq 21$  mm Hg with allowance for antiglaucoma medications therapy and without serious complications such as retinal

detachment, suprachoroidal hemorrhage, or endophthalmitis.

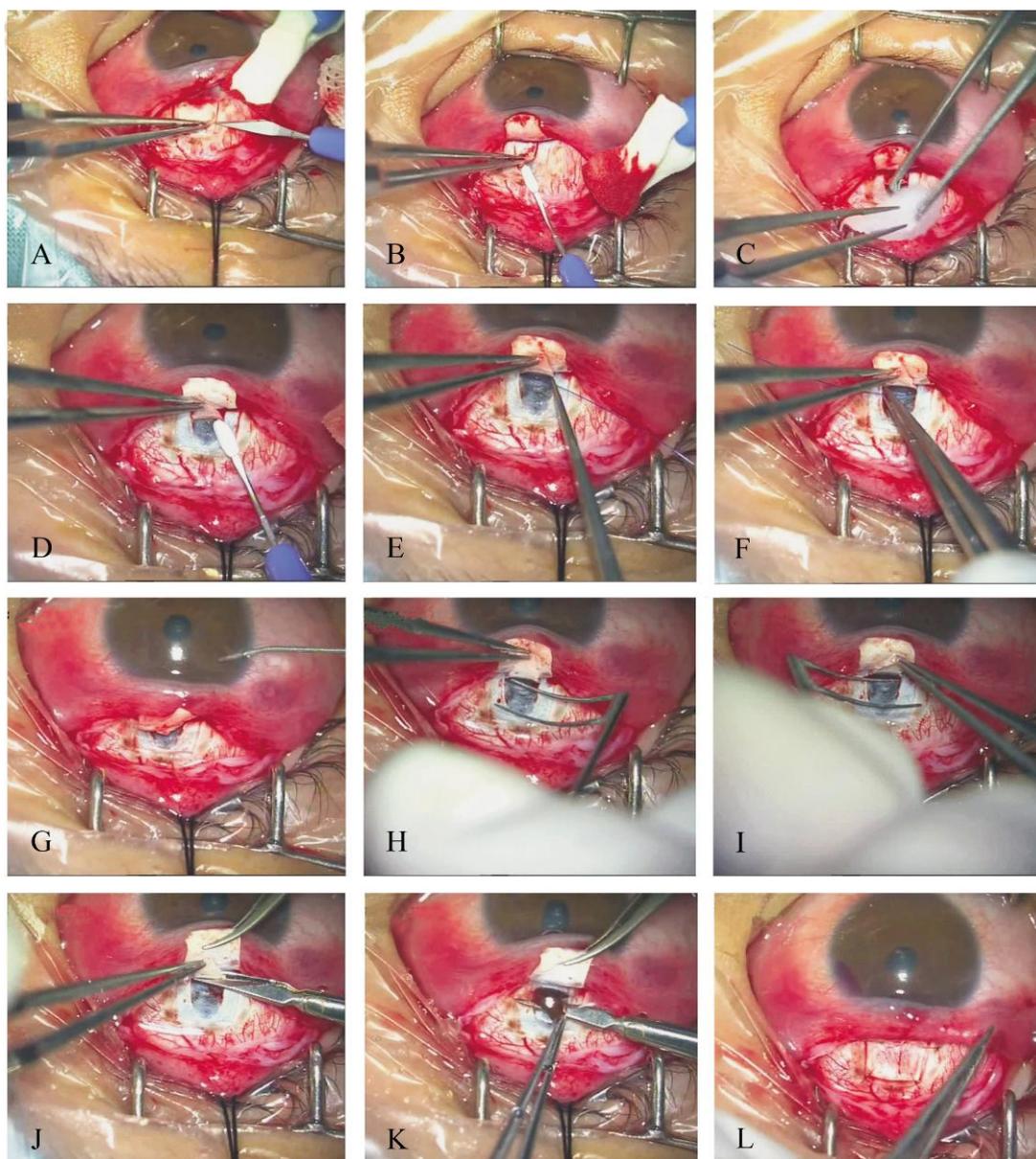
**Surgical Procedures** Lidocaine (2%) and bupivacaine (0.75%) were used in combination for periocular anesthesia and oxybuprocaine (0.4%) was used for surface anesthesia in teenager glaucoma patients. Systemic surface anesthesia was used in infant glaucoma patients. After successful anesthesia a conjunctival flap was made at the top with the corneal limbus as the bottom, a  $4 \times 5$  mm<sup>2</sup> rectangular shallow sclera flap with a deepness 1/2 of the sclera was made, a  $3 \times 4$  mm<sup>2</sup> tongue shaped deep sclera flap incision was made, and a scleral tunnel knife was used to cut from the top to the front with a deepness to 2/3 of the sclera, leaving only a thin layer of the sclera on the surface of the uvea. During the operation the dark brown uvea can be faintly seen through the thin layer of sclera. A piece of cotton sheet soaked in mitomycin C (with a concentration of 0.2 to 0.4 mg/mL) under above and under the deep scleral flap and under the conjunctival flap. After 3 to 5min, rinse thoroughly with more than 50 mL of physical saline. Cut the outer wall tissue of the Schlemm canal, use a dental swap to gently push the deep scleral flap into the transparent cornea to a distance of about 1 mm when aqueous out flow is seen, expose the Schlemm canal cavity and the trabecular meshwork, remove the deep sclera-cornea flap tissue to form a sclera concave pool (pressure reduction chamber), and explore the Schlemm canal from the cut section of the Schlemm canal with a piece of nylon monofilament. Inject the viscoelastic substance (sodium hyaluronate) through the incision at the lateral side of the 3 o'clock and 9 o'clock of the cornea to deepen the peripheral anterior chamber, introduce the trabecula knife (Hams Knife) into the Schlemms canals at both sides respectively, and rotate it towards the trabecula so that it can reach the anterior chamber. Cut about 120 degree of the inner wall of the Schlemm canal. Cut the deep scleral flap and the surrounding iris, suture the scleral flap with a piece of 10/0 nylon suture thread, and suture the conjunctival flap with a piece of 8/0 absorbable suture thread. Form the anterior chamber with balanced salt solution, and apply 1% pilocarpine and tobramycin and dexamethasone ophthalmic ointment to the eye (Figure 1).

**Statistical Analysis** All the data collected in this study were analyzed and statistically processed using the SPSS18.0 statistical software package. The statistical method used include the  $t$ -test for quantitative data and the  $\chi^2$  test for the enumeration data and it is considered as statistically significant if  $P < 0.05$ .

### RESULTS

The patients were followed up for 1 to 29mo, averaging  $13.3 \pm 7.7$ mo.

**Forming of Filtering Bleb in Infant Group and Teenager Group** The filtering blebs were divided into 4 types referencing the methods used by Kronfeld<sup>[6]</sup>. The rate of forming functional filtering blebs (include type I filtering



**Figure 1 Surgical technique of modified combined trabeculotomy-trabeculectomy** A: Make shallow sclera flap; B: Make deep sclera flap; C: Dispose the conjunctival and scleral flap with Mitomycin C; D: Expose the Schlemm canal cavity and the trabecular meshwork; E, F: Explore the Schlemm canal with nylon monofilament; G: Deepen the anterior chamber with sodium hyaluronate; H, I: Cut the inner wall of the Schlemm canal; J, K: Cut the deep scleral flap and the surrounding iris; L: Suture the scleral flap.

blebs and type II filter blebs) upon the last follow up visit was 100% in both the teenager group and the infant group (Table 1).

**Comparison of Intraocular Pressure Before and After Operation in Infant Group** The IOP was controlled below 21 mm Hg without using any medication upon the last follow up visit in both the groups of glaucoma patients after the operation (Table 2).

**Comparison of Visual Acuity Before and After Operation in Teenager Group** There was no significant changes in the visual acuity before and after the operation in teenager group ( $P > 0.05$ , Table 3).

**Comparison of C/D Ratio Before and After the Operation in Infant Group** The C/D ratio after the operation was lower compared with that before the operation in teenager group

( $t=3.552$ ,  $P=0.001$ ) and the difference in infant group is not statistically significant ( $t=0.000$ ,  $P=1.0$ ; Table 4).

**Comparison of Retinal Nerve Fiber Layer Before and After the Operation in Teenager Group** The data on the retinal nerve fiber layer before the operation were missing for 8 eyes in teenager group. So the analysis on the retinal nerve fiber layer was performed on the residual 24 eyes only. There are no statistically significant differences in nerve fiber indicator (NFI) superior average, inferior average and inter-eye symmetry ( $P > 0.05$ ; Table 5).

**Comparison of Visual Field Index Before and After the Operation in Teenager Group** The data on visual field index were missing in 6 out of 32 eyes in teenager group and the visual field index analysis was performed on the 26 eyes only. The absolute value of the mean deviation (MD) was

**Table 1 Functional filtering bleb in infant group and teenager group**

Group	No. of eyes	Type I filtering blebs	Type II filtering blebs	Rate of functional filtering blebs
Infant group	10	10	0	100%
Teenager group	32	30	2	100%

**Table 2 IOP before and after operation**

Group	No. of eyes	$\bar{x} \pm s$ , mm Hg			
		Before operation	After operation	<i>t</i>	<i>P</i>
Infant Group	10	38.2±8.8	13.6±3.1	7.743	<0.001
Teenager Group	32	27.9±9.8	10.2±4.0	9.596	<0.001

**Table 3 Visual acuity before and after operation in teenager group**

Visual acuity	Before operation (n)	After operation (n)
<0.1	10	10
0.1-0.5	16	18
0.6-1.0	5	4
>1.0	1	0

**Table 4 C/D ratio before and after operation**

Group	No. of eyes	$\bar{x} \pm s$		
		Before operation	After operation	<i>P</i>
Infant Group	10	0.84±0.97	0.84±0.11	1.000
Teenager Group	32	0.85±0.13	0.79±0.17	0.001

**Table 5 Retinal nerve fiber layer before and after operation in teenager group**

Item	$\bar{x} \pm s$ , n=24			
	Before operation	After operation	<i>t</i>	<i>P</i>
Inter-eye symmetry	0.56±0.33	0.38±0.37	1.724	0.113
NFI	65.71±29.62	65.42±31.75	0.063	0.950
Superior average (μm)	48.46±26.48	46.21±17.59	0.465	0.647
Inferior average (μm)	47.79±21.85	47.38±16.69	0.101	0.921

reduced after the operation ( $t=-2.190$ ,  $P=0.038$ ) and there are no statistically significant differences in the pattern standard deviation (PSD) ( $t=1.443$ ,  $P=0.161$ ) in teenager group (Table 6).

**Complications** After the operation, anterior chamber bleeding was observed in 6 eyes, and hyphema was observed in 37 eyes. Among them the hyphema was less than 1/3 of the anterior chamber capacity in 35 eyes and more than 1/3 and less than 1/2 of the anterior chamber capacity in 2 eyes. The hyphema was completely absorbed in all the patients after 2 to 4d of treatment. Such severe complications as choroidal detachment or cystoid macular edema were not observed in any of the patients.

**Operation Successful Rate** The IOP was controlled under 21 mm Hg upon the last follow up visit in the glaucoma patients of both the groups without using any antiglaucoma medications. The operation successful rate is 100%.

**DISCUSSION**

Our group made some modifications based on the traditional trabeculotomy and trabeculectomy. Firstly, we create a sclera concave pool (Figure 1D) during the operation, which increased the aqueous outflow volume. Secondly, the Schlemm canal is cut when the Schlemm canal is observed directly, so the successful rate can be 100%. So the aqueous outflow can really be through the canal, and the aqueous outflow can also be through the incision on the trabecula,

**Table 6 Visual field index before and after operation in teenager group**

Parameters	$\bar{x} \pm s$ , n=26			
	Before operation (dB)	After operation (dB)	<i>t</i>	<i>P</i>
MD	-14.998±11.685	-13.330±10.973	-2.190	0.038
PSD	7.135±4.318	6.100±4.471	1.443	0.161

which further enhanced the IOP control after the operation. Finally, because of the accurate positioning of the trabecula canal, it is unlikely to create a false channel when cutting with the trabeculotome. And the use of viscoelastic substance (sodium hyaluronate) in the anterior chamber (Figure 1J) can prevent bleeding in a certain extent, thus reducing the incidence of complications.

The key to the success of an operation for glaucoma is whether functional filtering blebs can be formed and whether the IOP can be ideally controlled [17], and controlling IOP had a positive effect on the central corneal thickness, horizontal corneal diameter, and axial length in patients with congenital glaucoma [18]. In this study, the filtering blebs were flat and disperse, which were type II filtering blebs, in 2 cases upon the last follow up visit in teenage group. And the filtering blebs were type I filtering blebs in all the other 30 cases. Functional blebs were formed in all the 32 cases with a formation rate of 100%. Raised filtering blebs, which are type I filtering blebs, were formed in 10 of the patients upon the last follow up visit in infant group. The formation rate of functional filtering blebs is 100%. The IOP was controlled under 21 mm Hg in all the cases without using any IOP reducing medication. And the average IOP was reduced by more than 60% compared with that before operation without any intraocular hypotension. The above results show that the combined modified trabeculotomy-trabeculectomy can effectively cause the formation of functional filtering blebs and control the established target IOP.

The visual acuity was not tested in infant glaucoma patients because of their inability in cooperation. The visual acuity analysis is only performed for the teenager patients. The visual acuity was dropping during the early phase after the operation in most of the teenager glaucoma patients in this study. This is related to the inflammation reactions, the hyphema, and the residual sodium hyaluronate in the anterior chamber and the changes in the refraction after the operation. While upon the last follow up visit, the visual acuity of the exposed eye resumed to the level before the operation in

most of the cases. The visual acuity of the exposed eye dropped to some degree compared with that before the operation in the other cases. However, it can recover to the level before the operation through optometry. So we can say that the dropping of the visual acuity in these patients was related to the changes in the refraction and not directly related to the development of glaucoma. We believe that the modified combined trabeculotomy-trabeculectomy basically does not affect the visual acuity. The possible reasons are: 1) although there is anterior chamber bleeding during and after the operation, the amount of bleeding is relatively small and the accumulated blood in the anterior chamber can be rapidly absorbed within 2 to 4d; 2) the viscoelastic substance (sodium hyaluronate) used during the operation can maintain a satisfactory IOP, which prevents any sudden drop in the IOP. This can significantly prevent the occurrence of lesions caused by retinal ischemia resulted from a sudden drop in the IOP; 3) there are fewer complications and no such factors as choroidal detachment or macular edema that can cause the drop in visual acuity were observed; 4) the long term IOP is reduced significantly after the operation. This reduces the further damages to the visual function caused by high IOP.

Studies have shown that when an operation for the treatment of glaucoma has been performed for an infant patient suffering from congenital glaucoma, if the IOP can return to normal, the C/D ratio may reduced compared with that before the operations<sup>[19]</sup>. Through analysis it is believed that this is probably because infants have stronger recovery capability and the optic nerve fiber can be healed to certain degrees after the stress on the optic nerve is released in time<sup>[20]</sup>. In this study the average C/D ratio after the operation was reduced compared with that before the operation in the teenager patients and there were no significant changes in the average C/D ratio before and after the operation in the infant patients. This is different from the results reported in some other reports. The possible reasons are: 1) the C/D ratio of the optic nerve head can be reversed after being reduced after the IOP is controlled in both infant and teenager glaucoma patients; 2) there are less infant glaucoma cases, which affects the statistic analysis results; 3) the duration of the increased IOP is too long in some infant cases and the extension of the connective tissue because permanent and the neuraxons and the colloid have been lost, so that the injury to the optic nerve has become irreversible. Generally speaking, the C/D ratio did not increase further in any of the 42 eyes of the patients underwent modified combined trabeculotomy-trabeculectomy, and there was even a trend of decreasing in teenager group. This indicates that the optic nerves of the patients had been effectively protected to some extent.

The visual field and the retinal nerve fiber layer thickness are important parameters for the diagnosis, therapeutic effect assessment and post operation follow up for glaucoma<sup>[21-22]</sup>. Because the visual field and the GDxVCC system retinal

nerve fiber layer thickness cannot be checked in infants, so they were evaluated only in the teenager patients in this study. In this study, the data before the operation are missing for 6 eyes in teenager group. The false positive (FP) error score is no more than 15% for the rest of the patients and the post operative checks. So it is considered that the fixation loss (FL) score is no more than 20%, which indicates that the results are reliable. The average visual field defect is the difference in light sensibility between the inspected eye and that of normal persons of the same age. It is a factor that can reflect whether there is a reduction in the light sensibility of the entire retina and the degree of reduction. Through it was found that the average visual field defect was significantly reduced after the operation in teenager group, indicating that the light sensibility of the retina was significantly improved and the visual function was protected to some extent. When performing the GDxVCC systematic inspection, the data before the operation were missing in 8 eyes in teenager group and the analysis was performed on the rest of the 24 eyes. Quigley *et al*<sup>[23]</sup> believe that the optic nerve injuries of glaucoma can likely to occur the earliest above or under the optic disk, because the area above and under the optic disk is rich in larger nerve fibers. After an statistical analysis it was found that there were no significant changes before and after the operation in the retina fiber layer indexes such as the nerve fiber glaucoma identification index (NFI), superior retina nerve fiber layer thickness (superior average), the inferior retina nerve fiber layer thickness (inferior average) and the inter-eye symmetry, indicating that the retina nerve fiber layer thickness did not change and the retina nerve fiber injuries have been effectively controlled.

Hyphema is the most common complication of trabeculotomy<sup>[24]</sup>, which is possibly caused by the drop in the IOP during and after the operation causing the back flow of the blood in the episcleral vein to the anterior chamber through the Schlemm canal. So Mepherston and Mcfarland<sup>[25]</sup> believe that mild bleeding at the anterior chamber is the characteristic of an accurate incision of the Schlemm canal. Mild bleeding at the anterior chamber was observed during and after the operation in both the infant group and the teenager group of this study. And after symptomatic treatment the hyphema was resolved in 2 to 4d after the operation in all the cases. Our experience is that the first is to ensure that the Schlemm canal is accurately cut to prevent an error in invading the superior chamber of the ciliary body. Because the extension of the corneoscleral limbus in infant patients, the position of the Schlemm canal would be shifted to the front or to the back. So the site of incision on the trabecula shall also be adjusted accordingly. A 5-0 nylon thread shall be used for testing before the trabeculotomy (Figure 1H, 1I). Attention shall be paid to keep in parallel to the cornea limbus when cutting into the Schlemm canal with the trabeculotome. When cutting the trabecula it is just like

cutting through a piece of paper. If there is a resistance that means that the trabeculotome might have drifted to the cornea or the sclera, so the orientation shall be adjusted. Secondly, before cutting the internal wall of the Schlemm canal and the trabecular network, the viscoelastic substance (sodium hyaluronate) shall be injected through the incision at the lateral side of the cornea, which can prevent the shallowing and the bleeding in the anterior room on one hand and prevent an error in injuring the root of the iris on the other hand. When suturing the scleral flap, use the scleral flap to completely cover the incision on the Schlemm can prevent over filtration after the operation, which can prevent a shallow anterior chamber or a low intraocular pressure. With the injection of viscoelastic substance into the anterior chamber, any sudden changes in the IOP can be avoided. There were no such severe complications such as cystoids macular edema or choroidal detachment after the operation. The above information shows that the treatment of congenital glaucoma through modified combined trabeculotomy–trabeculectomy is safe.

In summary, the modified combined trabeculotomy–trabeculectomy of our study is simple, with precise positioning, with a high functional filtering bleb forming rate, can effectively control the IOP in a long term, and can protect the visual function to some extent. There were only a few and mild complications during and after the operation. It is effective and safe in the treatment of congenital glaucoma.

**ACKNOWLEDGEMENTS**

**Foundations:** Supported by National Scientific Foundation of China (No.81400400); Natural Science Foundation of Hunan Province, China (No.12JJ3120).

**Conflicts of Interest:** Wu ZK, None; Wu J, None; Tan Q, None; Jiang J, None; Song WT, None; Xia XB, None.

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