

# Long-term results of combined viscotrabeculotomy–trabeculectomy in refractory developmental glaucoma

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CLINICAL STUDY

## Abstract

**Background** To evaluate the outcomes of combined viscotrabeculotomy–trabeculectomy in patients with refractory developmental glaucoma and to compare the success and complication rates with classical trabeculotomy–trabeculectomy procedure.

**Patients and Methods** Patients who were selected for this study had cloudy corneas with a diameter of 13 mm or greater and with an initial intraocular pressure (IOP) of 27 mmHg or more, and they were divided into two groups. Group 1 consisted of 40 eyes of 24 patients who had undergone combined viscotrabeculotomy–trabeculectomy with a mean follow-up time of  $55.6 \pm 18.4$  months, and group 2 consisted of 35 eyes of 20 patients who had undergone classical trabeculotomy–trabeculectomy with a mean follow-up time of  $57.2 \pm 19.0$  months. Pre- and postoperative IOPs, mean antiglaucoma medication, mean corneal diameter, success rates, intra- and postoperative complications were compared between two groups.

**Results** Mean IOP reduced from a preoperative level of  $33.2 \pm 5.3$  and  $32.8$  mmHg to  $14.2 \pm 3.1$  and  $15.3 \pm 3.3$  in group 1 and group 2, respectively ( $P < 0.001$ ). The mean number of antiglaucoma medications used after surgery was significantly lower in group 1 ( $P < 0.05$ ). Kaplan–Meier survival analysis showed that the success probability at the last visits was 90 and 71.4% in group 1 and group 2, respectively, and the difference was statistically significant ( $P = 0.01$ ). The most common early postoperative complication was transient IOP elevation in group 1 and hyphema in group 2 (for each,  $P < 0.001$ ).

**Conclusion** Use of viscoelastic materials during trabeculotomy–trabeculectomy may increase the success rate of the procedure by prevention of postoperative hemorrhage, anterior chamber shallowing, adhesion of the incision lips or fibroblastic proliferation. *Eye* (2010) 24, 613–618; doi:10.1038/eye.2009.185; published online 4 September 2009

**Keywords:** congenital glaucoma; trabeculotomy; trabeculotomy–trabeculectomy; viscotrabeculotomy–trabeculectomy

## Introduction

Congenital glaucoma is an uncommon, inherited abnormality of the trabecular meshwork that manifests itself during the first years of life with intraocular pressure (IOP) elevation, edema and enlargement of the cornea, and optic nerve damage. Management of the disease is surgical, and goniotomy or trabeculotomy ab externo are the classic procedures. Both surgical techniques are approximately equally effective with more than a 77% success rate.<sup>1–5</sup> Goniotomy requires a transparent cornea for angle visibility and considerable surgical experience.<sup>5,6</sup> In contrast, trabeculectomy has also been shown to achieve adequate control of IOP in congenital glaucoma and several published reports have documented successful results following primary trabeculectomy for congenital glaucoma that are comparable to or are higher than the most reported series on goniotomy or trabeculotomy. The problems of goniotomy in children with hazy corneas, the advantages of trabeculotomy over goniotomy and

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encouraging reports of primary trabeculectomy in congenital glaucoma<sup>7–12</sup> prompted us to combine trabeculotomy ab externo with trabeculectomy during the initial surgery. In recent years, viscoelastic materials are used as multipurpose in ocular surgery. As viscoelastic materials separate or stabilize tissues, stop bleeding and protect the tissues against undesired damage, we considered that use of viscoelastics during combined trabeculotomy–trabeculectomy might increase the success rate by prevention of postoperative hemorrhage and fibroblastic proliferation, and adhesion of the incision lips, and we named this modified technique as combined viscotrabeculotomy–trabeculectomy.

This study evaluated the long-term results of combined viscotrabeculotomy–trabeculectomy and classical trabeculotomy–trabeculectomy, and compared the outcomes of these two techniques.

## Patients and methods

### Patient selection

The charts of 44 patients with refractory developmental glaucoma who underwent either combined viscotrabeculotomy–trabeculectomy (group 1) or classical combined trabeculotomy–trabeculectomy (group 2) between March 1993 and July 2005 were retrospectively reviewed. All patients were of Caucasian origin and had at least 3 years of follow-up. All procedures were performed at Istanbul University Cerrahpasa Medical Faculty, Department of Ophthalmology, and the local Ethics Committee of Cerrahpasa Medical Faculty approved the study. Informed written consent was obtained for all patients before operation. All parents were fully informed of the relative advantages and disadvantages of these two techniques, and selection of technique to be used in this series was determined by the preference of the patient's parents.

Group 1 consisted of 40 eyes of 24 patients who had undergone combined viscotrabeculotomy–trabeculectomy, and group 2 consisted of 35 eyes of 20 patients who had undergone classical trabeculotomy–trabeculectomy. Patients with a history of previous surgery or with secondary glaucoma were excluded from the study.

Diagnosis of congenital glaucoma was established by an examination under inhalation anesthesia using 1% halothane. Age, sex, family history, main presenting features, antiglaucoma medications, time of surgery, follow-up time, intra- and postoperative complications and success rates were all recorded. Pre- and postoperative examinations included measurement of

IOP, biomicroscopy, determination of horizontal corneal diameters and funduscopy. IOP measurements were assessed with Perkins hand-held applanation tonometer in the early phase of inhalation anesthesia using 1% halothane.

### Surgical technique

All surgeries were performed by the same surgeon (NT). Classical trabeculotomy–trabeculectomy was performed using a standardized technique similar to that described before.<sup>12</sup> In viscotrabeculotomy–trabeculectomy, Schlemm's canal was cannulated with Grieshaber viscocanalostomy cannula on either side after performing radial incision and high viscosity sodium hyaluronate (Healon GV, Pfizer, NY, USA) was injected into the Schlemm's canal. An angled Harms trabeculotome was passed into the canal; the tip of the probe was gently rotated into the anterior chamber, and pulled back toward the incision. The probe was removed and the procedure was repeated in the opposite direction with the paired trabeculotome. Then, a little amount of high viscosity sodium hyaluronate was injected to prevent adhesion of incision lips and shallowing of anterior chamber. After the viscotrabeculotomy was completed, trabeculectomy was completed by removing the deeper block marked previously. A peripheral iridectomy was performed, and a little amount of sodium hyaluronate was injected into the anterior chamber. The triangular scleral flap was sutured with one 10/0 nylon suture; the conjunctiva was closed with absorbable suture. At the end of the procedure, one drop of antibiotic-corticosteroid preparation was instilled into the lower conjunctival sac, and a patch was applied on the eye.

Postoperatively, topical corticosteroids and cycloplegics were administered until there was a complete resolution of postoperative inflammation. Topical antibiotics were administered five times a day, tapered gradually over a 4-week period. In group 1,  $\beta$ -blockers were used two times for 4 days to control transient IOP elevation. The patients were examined two times during the first week, weekly during the first month, monthly during the first year, and then every 3 months.

Complete surgical success was determined by an IOP <18 mmHg under general anesthesia without medication or resurgery, with no progression of disc cupping or corneal diameter, and no devastating visual complications. Qualified success was defined as an IOP <18 mmHg with antiglaucomatous medication or transient ocular hypotony without visual loss. Failure was defined as IOP  $\geq$ 18 mmHg in patients with medication, resurgery, or sight-threatening complications. Transient hypotony was not considered a failure, but hypotony-related maculopathy was defined as a failure.

**Statistical analysis**

Results were presented as means ± SD and were analyzed statistically by using the Student *t*-test, two-way ANOVA, Kaplan–Meier survival plots and  $\chi^2$  test as indicated. A *P* value <0.05 was considered statistically significant. Statistical analysis was performed with Statistical Package for the Social Sciences for Windows (SPSS/PC + Inc., Release 10.0, Chicago, IL, USA).

**Results**

The characteristics of the patients are given in Table 1. All the patients were of Caucasian origin and had cloudy corneas with a diameter of 13 mm or greater and with an initial IOP of 27 mmHg or more. Axenfeld–Rieger syndrome was present in 9/40 eyes (22.5%) in group 1 and 7/35 eyes (20%) in group 2. The percentage of aniridia in group 1 was 12.5% (5 eyes) and 17.1% (6 eyes) in group 2. Seventeen patients (70.8%) in group 1 and 13 patients (65%) in group 2 underwent bilateral glaucoma surgery but in separate operative sessions.

The mean pre- and postoperative IOPs at 3, 12, 24, 36 months, and at the last visit with antiglaucoma medications, mean follow-up time, the success rates and the percentage of IOP reduction are shown in Table 2. There was no significant difference between two groups when preoperative mean IOPs, antiglaucoma medications and corneal diameters were compared (for each, *P* > 0.05). Postoperatively, mean IOPs and antiglaucoma medications were significantly lower in group 1 (for each, *P* < 0.05). Mean postoperative corneal diameter was significantly lower in both groups (for each, *P* < 0.001), but there was no statistically significant difference between two groups (*P* > 0.05). The percentage of mean reduction in IOP pressure from baseline to the

**Table 1** The characteristics of the patients

	Group 1 (n = 40 eyes)	Group 2 (n = 35 eyes)
Mean age (months)	5.9 ± 3.1	5.7 ± 3.6
Sex		
Female	10	11
Male	14	9
Diagnosis		
Congenital glaucoma	26	22
Aniridia	5	6
Axenfeld–Rieger syndrome	9	7
Positive family history	6/24 (25.0 %)	4/20 (20.0%)
Bilateral glaucoma	17/24 (70.8%)	13/20 (65.0%)
Race	Caucasian	Caucasian
Lens status	Phakic (all)	Phakic (all)
Follow-up time (months)	55.6 ± 18.4	57.2 ± 19.0

**Table 2** Mean IOPs, antiglaucoma medications and success rates before and after glaucoma surgery

	Group 1 (n = 40)										Group 2 (n = 35)										
	Preop.					Postoperative					Preop.					Postoperative					
	3 months	12 months	24 months	36 months	LV	3 months	12 months	24 months	36 months	LV	3 months	12 months	24 months	36 months	LV	3 months	12 months	24 months	36 months	LV	
Mean IOP (mmHg)	33.2 ± 5.3	14.1 ± 3.3	14.3 ± 3.2	14.3 ± 3.1	14.2 ± 3.1	32.8 ± 5.2	15.0 ± 3.7	15.3 ± 3.4	15.4 ± 3.5	15.3 ± 3.4	15.0 ± 3.7	15.3 ± 3.4	15.4 ± 3.5	15.2 ± 3.4	15.3 ± 3.3	32.8 ± 5.2	15.0 ± 3.7	15.3 ± 3.4	15.4 ± 3.5	15.2 ± 3.4	15.3 ± 3.3
Mean AM	2.4 ± 0.7	0.3 ± 0.5	0.3 ± 0.4	0.3 ± 0.5	0.3 ± 0.5	2.3 ± 0.6	0.4 ± 0.5	0.4 ± 0.5	0.5 ± 0.5	0.3 ± 0.5	2.3 ± 0.6	0.4 ± 0.5	0.4 ± 0.5	0.5 ± 0.5	0.5 ± 0.6	2.3 ± 0.6	0.4 ± 0.5	0.4 ± 0.5	0.5 ± 0.5	0.5 ± 0.5	0.5 ± 0.6
Mean HCD (mm)	14.5 ± 0.6	13.9 ± 0.9	13.9 ± 0.8	13.9 ± 0.9	13.9 ± 0.8	14.4 ± 0.6	13.8 ± 0.9	13.9 ± 0.8	13.9 ± 0.8	13.9 ± 0.8	14.4 ± 0.6	13.8 ± 0.9	13.8 ± 0.9	13.9 ± 0.9	13.9 ± 0.8	14.4 ± 0.6	13.8 ± 0.9	13.8 ± 0.9	13.8 ± 0.9	13.9 ± 0.9	13.9 ± 0.8
IOP reduction (%)	—	92.5%	90%	90%	90%	—	57.2%	92.5%	90%	90%	—	53.3%	74.2%	71.4%	71.4%	—	77.1%	74.2%	71.4%	71.4%	71.4%
Success rate	—	92.5%	90%	90%	90%	—	57.2%	92.5%	90%	90%	—	53.3%	74.2%	71.4%	71.4%	—	77.1%	74.2%	71.4%	71.4%	71.4%

Abbreviations: Preop, preoperative; AM, antiglaucomatous medication; HCD, horizontal corneal diameter.

**Table 3** Complications encountered during and after surgery

	Group 1 (n = 40)	Group 2 (n = 35)
Hyphema*	2/40 (5%)	11/35 (31.4%)
Iridodialysis	0/40	2/35 (5.7%)
Iris injury	0/40	3/35 (8.5%)
Iris prolapsus	1/40 (2.5%)	6/35 (17.1%)
Descemet's membrane detachment	1/40 (2.5%)	1/35 (2.8%)
Lens injury	0/40	1/35 (2.8%)
Schlemm's canal not visualized	4/40 (10%)	3/35 (8.5%)
Transient IOP elevation**	13/40 (32.5)	2/35 (5.7%)1/35 (2.8%)
Vitreous prolapse	0/40	

\**P* < 0.001.

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**Table 4** Postoperative complications

	Group 1 (n = 40 eyes)	Group 2 (n = 35 eyes)
Shallow anterior chamber	1/40 (2.5%)	4/35 (11.4%)
Persistent hypotony	—	—
Cystic bleb	5/40 (12.5%)	4/35 (11.4%)
Blebitis	1/40 (4%)	1/35 (2.8%)
Bleb leak	1/40 (4%)	1/35 (2.8%)
Retinal detachment	—	—
Cataract	1/40 (2.5%)	3/35 (8.5%)
Endophthalmitis	—	1/35 (2.8%)

last follow-up was 57.2% in group 1 and 53.3% in group 2. The success rates assessed by Kaplan–Meier survival analysis in group 1 at 3, 12, 24, 36 months and at the last visit were 92.5, 92.5, 90, 90 and 90%, respectively. In group 2, they were 77.1, 74.2, 71.4, 71.4 and 71.4%, respectively. At the last visits, the success rate of group 1 was statistically higher when compared with group 2 (*P* = 0.01), and 9 eyes in group 1 and 12 eyes in group 2 required antiglaucoma medications to control IOP. As antiglaucoma medications,  $\beta$ -blockers, topical carbonic anhydrase inhibitors and prostaglandin analogs were used to control IOP. Additional surgery was performed in 4 eyes in group 1 and 10 eyes in group 2.

Complications encountered during surgery and in the postoperative period are listed in Table 3. The most common complication in the early postoperative period was hyphema in group 2 and transient IOP elevation in group 1, which was treated with antiglaucoma medications a few days (Table 4).

## Discussion

IOP in congenital glaucoma is raised by developmental anomalies in the trabecular meshwork. The management

is surgical and the outflow is enhanced by incising or cleaving the abnormal trabecular meshwork. The primary surgical procedures in congenital glaucoma are goniotomy or trabeculectomy. Goniotomy and trabeculectomy are approximately equally effective at controlling IOP.<sup>1–6</sup> The success rate of goniotomy and trabeculectomy is related with the age of the patient at the onset of glaucoma and types of abnormalities.<sup>13</sup> When the signs and symptoms of glaucoma were present at birth or over 24 months, the success rate was close to 30%.<sup>6</sup> It has been reported that the surgical results are more favorable if the operation is performed within the first 2 to 12 months of life.<sup>14–16</sup> However, up to 50% of the population are reported to have varying degrees of corneal edema, rendering goniotomy technically impossible.<sup>17</sup> Trabeculectomy ab externo is an alternative surgical technique that is possible even in the presence of severe corneal edema. The only disadvantage of trabeculectomy is that Schlemm's canal may not be found in 11–15% of procedures. This may be caused by surgical inexperience, abnormal anatomy, or hypoplasia of the canal.<sup>18–20</sup> However, if the IOP is already elevated at birth or soon after, irreparable damage may have been done to the developing trabecular meshwork and Schlemm's canal, which cannot be reversed by trabeculectomy alone. Trabeculectomy then provides an additional pathway for outflow. A combined procedure of trabeculectomy–trabeculectomy might then be indicated for difficult cases. Compared with the European population, a large number of children in our country present with a severe cloudy cornea at birth. Poor socioeconomic status can lead these patients to present late and an advanced stage of the disease.

In this study, combined trabeculectomy–trabeculectomy was undertaken as the surgical procedure of primary choice because all of the patients are unsuitable for goniotomy. The technique of combined trabeculectomy–trabeculectomy offers many theoretical and practical advantages. It is less dependent on corneal clarity than goniotomy, provides an additional pathway for the outflow of aqueous through the trabeculectomy bleb site and trabeculectomy creates a direct continuity between the anterior chamber, Schlemm's canal and episcleral veins. Therefore, the combined procedure is superior to trabeculectomy alone in controlling the IOP even if one or the other pathway has failed to function. Technically, this procedure requires minimal extra surgical time over just trabeculectomy or just trabeculectomy and the complication rates are no different from either procedure on its own.<sup>10,21</sup>

In recent years, viscoelastic materials have become a predominant element in the performance of ocular surgery. Viscoelastic materials are indispensable in the prevention of damage to ocular tissue and are also used

as multipurpose tools in all surgical phases.<sup>22,23</sup> The term of viscosurgery was first introduced by Balazs and Denlinger,<sup>24</sup> and one of the aims of this procedure is to accomplish the procedures and maneuvers during the surgery. In addition, viscoelastics separate or stabilize tissues, stop bleeding and protect the tissues against undesired damage.<sup>25,26</sup> The disadvantage of viscoelastic materials is that they not metabolized in the eye and will leave the anterior chamber through the trabeculum. Clearance of viscoelastic materials depends on the volume injected, the concentration and viscosity of the material and the amount left in the anterior chamber. When left in the anterior chamber or partly removed at the end of surgery, they can cause a temporary IOP elevation.<sup>27</sup> In our study, a little amount of high viscosity sodium hyaluronate was injected into the Schlemm's canal on either side to prevent late bleeding and adhesion of the incision lips. Viscoelastic materials remain in the canal for 4 to 6 days, prevent collapse of the Schlemm's canal, and create a barrier to the migration of fibrinogen released by the ciliary body during surgery.<sup>28</sup> As a result, polymerization of the fibrin to fibrinogen in the lake and Schlemm's canal was almost eliminated and remove the stimulus for fibroblastic proliferation. Moreover, prevention of adhesion of the incision lips or anterior chamber shallowing with sodium hyaluronate may decrease postoperative inflammation, limit the wound healing process and cicatrization. Otherwise, the meshwork tissues may gradually overgrow the trabeculotomy site and this may explain some of the declining success with time. The only disadvantage of using viscoelastics may be transient IOP elevation that can be controlled with antiglaucoma medications in a few days.

The results of combined trabeculotomy–trabeculectomy procedures have been reported by several authors. Turut *et al*<sup>29</sup> have used this procedure for infantile glaucoma with a similar success rate of 70%. Elder *et al*<sup>11</sup> reported the success rate of combined trabeculotomy–trabeculectomy 93.5% after 24 months of follow-up. In another study by Mullaney *et al*,<sup>10</sup> the success rate of combined trabeculotomy and trabeculectomy as an initial procedure in uncomplicated congenital glaucoma was found to be 78% after a mean follow-up period of 304 days. The success rates of this procedure reported by Mandal *et al*<sup>21</sup> were 94.4, 90.9 and 81% in congenital, infantile and juvenile glaucoma, respectively. Campos-Mollo *et al*<sup>30</sup> reported that cumulative probabilities of success, after performing combined trabeculotomy–trabeculectomy as the initial operative procedure, were 95.5% after 12 months and 78.2% after 24 months. To the best of our knowledge, this study is the first evaluating the long-term results of combined viscotrabeculotomy–trabeculectomy and classical trabeculotomy–trabeculectomy, and comparing the outcomes of these two techniques. In this study, the

success rate of classical trabeculotomy–trabeculectomy at the last visits was 71.4 and 90% of viscotrabeculotomy–trabeculectomy, and the difference between the two groups was statistically significant. This may be explained by prevention of postoperative hemorrhage or fibroblastic proliferation, nontraumatic cannulation of Schlemm's canal after dilation with viscoelastic material, keeping away the lips of trabeculotomy incision, and prevention of anterior chamber shallowing, which has important functions in decreasing anterior chamber inflammation and retarding wound healing process.

The most common early postoperative complication was transient IOP elevation in group 1 (32.5%). The incidence of hyphema in group 1 was only 5% in the early postoperative period. These low rates of hyphema may only be explained by using viscoelastic materials in group 1. Viscoelastic materials may prevent bleeding because they form a physical barrier and concentrate coagulation factors at the site of bleeding to achieve hemostasis. Prevention of bleeding from incision lips may, therefore, decrease the inflammation and risk of adhesion of incision lips, and also may increase the success rate. In addition, viscomaterials may facilitate cannulation of Schlemm's canal by maintaining a stable and larger canal, provide a safe and convenient tissue incision and stable anterior chamber.

This study has several limitations. First, it is a non-randomized retrospective study with a rather limited number of patients. Second, a non-masked examiner performed clinical examinations. Therefore, this study may serve as a pilot study reporting the clinical outcome of the patients undergoing combined viscotrabeculotomy–trabeculectomy surgery. However, the follow-up time was relatively long that allowing conclusions on the final outcome of both procedures, and anatomical and functional results were apparent during the follow-up time.

In conclusion, we think that viscotrabeculotomy–trabeculectomy is safer and more effective than classical trabeculotomy–trabeculectomy. Dilation of the possibly narrow Schlemm's canal, keeping away the lips of trabeculotomy incision, possibly prevention of the postoperative hemorrhage, fibroblastic proliferation prevention and anterior chamber shallowing by means of high viscosity sodium hyaluronate are the possible factors that have important functions in overall success of this procedure. However, studies with larger numbers and longer follow-up are required to determine the role of this procedure in congenital glaucoma.

#### Conflict of interest

The authors declare no conflict of interest.

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