

Combination microinvasive glaucoma surgery: 23-gauge cystotome goniotomy and intra-scleral ciliary sulcus suprachoroidal microtube surgery in refractory and severe glaucoma: A case series

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The purpose of this study is to present the efficacy of combined goniotomy and intra-scleral ciliary sulcus suprachoroidal microtube insertion surgery in five patients with refractory and severe glaucoma. This Single-center, case series of five (5)

Black and Afro-Latino patients with refractory and severe glaucoma who underwent combination microinvasive glaucoma surgery; 23-gauge goniotomy and intra-scleral ciliary sulcus suprachoroidal microtube insertion. Patients who underwent the above procedure with 6 months follow-up were included. Investigated parameters were intraocular pressure (IOP), number of medications, visual field findings, and visual acuity. Five patients with moderate to severe refractory glaucoma who had undergone 23-gauge cystotome goniotomy and ciliary sulcus suprachoroidal microtube had a reduction of IOP by 32% (mean pre-op and post-op 16.6 mmHg and 11 mmHg, respectively) and a reduction of ocular medications by 61.5% (mean pre-op and post-op of 5.2 and 2.4, respectively). All patients had either stabilization or improvement of their visual fields. Four of the five patients also showed an improvement in visual acuity. This novel approach of combined 23-gauge goniotomy and intra-scleral ciliary sulcus suprachoroidal microtube insertion surgery is safe and is an affordably effective means of managing patients with moderate to advanced refractory glaucoma, leading to a reduction in IOP and the number of medications with no serious adverse effects.

Key words: 23-gauge cystotome goniotomy, combined microinvasive glaucoma surgery, glaucoma, intra-scleral ciliary sulcus suprachoroidal microtube, microinvasive glaucoma surgery, refractory open angle glaucoma

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Glaucoma, a progressive optic neuropathy, is the second most prevalent eye condition worldwide. According to Tham *et al.*, it is projected that about 111.8 million people aged 40-80 years will be affected by glaucoma by 2040.^[1] Current treatment includes the use of ocular hypotensive medications, laser, and incisional surgery. The effects of selective laser treatment, although initially successful will often need additional medical therapy.^[2] Trabeculectomy has been the gold standard for refractory glaucoma.^[3] However, this has several side effects and potential complications.^[4] Increasingly, microinvasive glaucoma surgery (MIGS) has gained more popularity.

The IOP lowering among MIGS procedures is often limited to expensive devices that target three anatomical areas: Schlemm's canal, the suprachoroidal space, and the subconjunctival space. MIGS devices that target the Schlemm's canal outflow pathway include the Hydrus microstent (Ivantis), iStent inject (Glaukos), Kahook Dual Blade (KDB) (New World Medical), and Omni (Sight Sciences). They all attempt to improve outflow by bypassing the resistance at the trabecular meshwork.^[5] Goniotomy has also been utilized similarly to achieve the same result. Devices improving outflow via the suprachoroidal space include the Cypass (Alcon), iStent Supra (Glaukos), and MinInject (iSTAR) are not currently available on the market in the United States. Recently, combination MIGS has been performed to try to achieve lower intraocular pressures (IOPs), similar to those achieved with trabeculectomy, but with improved safety. Pantaloni *et al.* compared combined phacoemulsification, insertion of two iStents, and endocyclophotocoagulation (ECP) versus phacoemulsification-iStents alone to lower IOP. In this study, 109 eyes with ocular hypertension or early to moderate open angle glaucoma were randomized to two groups. The first group, called the ICE2 group, consisted of patients who underwent two iStents, cataract extraction, and ECP (63 eyes). The second group consists of patients who underwent Phaco-iStent (46 eyes). At 12 months follow-up, the ICE2 group achieved a greater IOP reduction of 6.92 mmHg (35% from baseline) in comparison to 3.54 mmHg (21% from baseline) in the Phaco-iStent group.^[6]

Myers *et al.* demonstrated the efficacy of combination MIGS in 80 patients with failed trabeculectomy who underwent two iStents and one suprachoroidal suprastent in combination with a prostaglandin postoperatively. The study group had a reduction of IOP from 22 ± 0.31 mmHg (post wash out mean of 26 ± 2.4 mmHg) on 1.2 medication to ≤ 13.7 mmHg within a 48 month period (37% reduction in IOP).^[7]

Although very successful, combination MIGS with these devices can be quite costly. These procedures may not be accessible to resource poor areas. The iStent inject can cost over \$1000 US, and other devices over several hundreds of dollars. We previously reported using a straight 25 mm 23 gauge cystotome (\$4US) to lower IOP^[8] and also reported the efficacy of intrascleral ciliary sulcus-suprachoroidal microtube technique^[9] (Tube extender, New World Medical) in four patients with mild, moderate, and severe glaucoma. Both are lower cost options to provide MIGS.

We report five patients who underwent combined procedures to obtain lower IOPs on fewer medications. The combination of goniotomy using 23-gauge cystotome and intrascleral ciliary sulcus-suprachoroidal microtube has not been reported in the literature.

Surgical devices

A 25 mm straight 23-gauge cystotome (Eagle labs) was used to perform goniotomy [Fig. 1]. This technique has been described elsewhere.^[8] The sterile medical grade silicone tube (Tube extender, New World Medical) was used to perform the suprachoroidal microtube technique [Fig. 2]. The surgical technique of placing the tube into the ciliary sulcus and suprachoroidal space has been previously described.^[9]

Combination microinvasive glaucoma surgical technique

The different options of glaucoma surgery procedures were discussed with the patients. The benefits and risks were discussed in detail, including the risk of complete sight loss. The patients agreed to the risks and benefits. Informed consent was obtained from all of the patients. Goniotomy with a 23 gauge cystotome^[8] was performed, followed by intrascleral ciliary sulcus suprachoroidal microtube surgery.^[9]

Case Reports

Case 1

An 87-year-old female nonsmoker with a history of primary open angle glaucoma, hypertensive retinopathy, and pseudophakia both eyes status post cataract extraction and intraocular lens (IOL) implant presented with "cloudy vision" and elevated IOP. She had a history of trabeculectomy in both eyes. Her best corrected visual acuity (BCVA) was 20/50 in the right eye and no light perception (NLP) in the left eye. IOP was 14 mmHg on bimatoprost 0.01% right eye one drop daily, dorzolamide/timolol 22.3-6.8 mg/ml right eye twice a day, brimonidine right eye three times a day, pilocarpine 2% right eye three times a day, and methazolamide 25 mg oral tablets twice a day. Anterior segment exam revealed a flat conjunctival bleb right eye and bleb left eye. Posterior chamber IOLs were in place bilaterally. Cup to disc ratio was 0.9 with advanced cupping and diffuse loss of nerve fiber layer both eyes. Humphrey visual field at the time also revealed a central island of vision in the right eye with a mean deviation (MD) of -30.

The patient agreed to undergo goniotomy with suprachoroidal microtube insertion in the right eye to decrease IOP and reduce dependence on medications. Her IOP on postoperative day 3 was 8 mmHg on no medications. Her IOP remained stable at 7 mmHg on no medications at 1 month and 3 months. At the 6 month visit, IOP remained at 7 mmHg on no medications. Her visual field at the 6 month follow-up improved to a visual field index (VFI) of 13% and MD of -28.20. Her BCVA at her 14 month follow-up was 20/70 in the right eye and NLP in the left eye.

Case 2

A 61-year-old female monocular patient with history of primary open angle glaucoma, dry eye syndrome, and macular drusen left eye, had presented to the office with blurry vision and elevated IOP. The patient had previous enucleation of the right eye. She had undergone multiple surgeries in the left eye including selective laser trabeculoplasty, trabeculectomy, and cataract extraction with iStent. Her vision was 20/20 in the left eye. Left eye IOP was 25 mmHg on dorzolamide/timolol 22.3-6.8 mg/ml left eye three times a day, brimonidine left eye three times a day, latanoprost 0.005% left eye once at night, and acetazolamide 500 mg tablets twice a day. Central corneal thickness was 532 μ m in the left eye. Anterior segment revealed

a failed conjunctival bleb left eye. Posterior chamber IOL was in place in the left eye. The cup to disc ratio was 0.95 with diffuse loss of nerve fiber layer, soft drusen, and arterial attenuation left eye. Optical coherence tomography (OCT) showed nerve fiber layer thickness of 64 μ m left eye. Humphrey visual field at the time also revealed MD of -20.17 and VFI 40%.

The patient agreed to undergo goniotomy with suprachoroidal microtube insertion in the left eye to lower the IOP on less medication. Her IOP on postoperative day 3 was 8 mmHg on no medications. At the one month follow up, IOP was 20 mmHg in the left eye; therefore, two medications (Dorzolamide/Timolol) were restarted. Netarsudil and latanoprost ophthalmic solution (Rocklatan®) was added at the 3 month follow-up because the IOP was 15 mmHg (above target of 8-12). IOP remained stable at 15 mmHg 1 month after this visit but went up to 17 mmHg on three medications at the 6 month follow-up visit. Brimonidine was then added, which reduced the IOP to 13 mmHg. Her visual field at that visit revealed improvement in VFI to 48% and MD to -19.36. Her central vision remained stable at 20/20 in the left eye.

Case 3

An 86-year-old male with a history of primary open angle glaucoma, diabetes mellitus, hypertension, thyroiditis, and pseudophakia both eyes status post cataract extraction with IOL implant presented for follow-up evaluation. Patient had a past surgical history for pars plana vitrectomy and internal limiting membrane peeling (PPV/MP[Pars plana vitrectomy / Membrane Peeling procedure]) in the left eye for an epiretinal membrane. His BCVA was 20/50 in the right eye and counting fingers at 9 feet in the left eye. The IOP was 15 mmHg in both eyes on dorzolamide/timolol 22.3-6.8 mg/ml both eyes twice a day, brimonidine 0.15% both eyes twice a day, latanoprost 0.005% left eye once at night, and rhopressa 0.02% left eye one drop daily. Gonioscopy revealed Schaffer grade III, grade 3 inferior pigmentation, and flat iris bilaterally. The cup to disc ratio was 0.5 in the right eye and 0.75 in the left eye with diffuse loss of nerve fiber layer and arterial attenuation. There is superior thinning of the optic disc in the left eye. OCT showed nerve fiber layer thickness of 86 μ m in the right eye and 75 μ m in the left eye. Humphrey visual field at the time also revealed full field in the right eye and mild depression of the visual field MD of -3.11 and VFI 88% of the left eye. However, the visual field of the left eye was unreliable due to several false positives and did not correspond to the advanced cupping of the optic nerve.

The patient agreed to undergo goniotomy with suprachoroidal microtube insertion in the left eye to lower the IOP on fewer medications. The goal was to improve compliance and reach a lower target. His IOP on postoperative day one (1) in the left eye was 12 mmHg on no medications, and 12 mmHg on no medications after 1 month. At his 4 month follow-up, IOP remained stable at 9 mmHg. IOP at the 6 month visit was 10 mmHg. His visual field at the 6 month follow-up revealed central defects in the left eye with VFI of 83% and MD of -5.35. Due to potential progression of his visual field, two medications, dorzolamide/timolol, were added to lower potential diurnal IOP fluctuation. His BCVA is 20/40 in the right eye and remained at the baseline of counting fingers at 9 feet in the left eye [Table 1].

Case 4

A 63-year-old male with a history of primary open angle glaucoma and pseudophakia both eyes status post cataract extraction with IOL presented to the office for follow-up glaucoma care. His surgical history was trabeculectomy in the right eye. The patient's current topical regimen included bimatoprost 0.01% both eyes one drop daily, dorzolamide/timolol 22.3-6.8 mg/ml both eyes three times a day, and brimonidine 0.15% both eyes twice a day. The IOP was 15 mmHg in the right eye and 13 mmHg in the left eye. The visual acuity was 20/40 in the right eye and 20/20 in the left eye. Gonioscopy showed Schaffer grade III, Grade I pigmentation with flat iris bilaterally. Slit lamp biomicroscopy exam showed superonasal bleb in the right conjunctiva, clear corneas bilaterally, and anterior chambers were deep and quiet. There were posterior chamber IOLs in good position: the cup to disc ratio was 0.8 in the right eye and 0.5 in the left. There was significant loss of nerve fiber layer in the right eye with optic disc pallor. No retinal hemorrhages or edema were observed. OCT showed nerve fiber layer thickness of 40 μ m in the right eye and 77 μ m in the left eye. Humphrey visual field at the time revealed VFI 61%, MD of -17 in the right eye and VFI 98%, MD -2.54 in the left eye.

The patient agreed to undergo goniotomy with suprachoroidal microtube insertion in the right eye to lower the IOP and to take fewer medications. His IOP in the right eye on postoperative day 1 was 12 mmHg on no medications, 11 mmHg on no medications at 1 month, 13 mmHg on no medications at 3 months, and 15 mmHg on one drop of daily bimatoprost at 6 months. His visual field at the 6 months follow-up remained stable at VFI of 56% and MD of -17. The best corrected vision was 20/25 in the right eye and 20/20 in the left eye [Table 1].

Case 5

An 81-year-old female with a history of angle-closure glaucoma, hypertensive retinopathy, cataract right eye, monocular exotropia right eye, and chronic obstructive pulmonary disease presented with worsening vision in the left eye. She has a family history of glaucoma. The surgical history included iridotomy right eye, cataract extraction with IOL, trabeculectomy, and YAG capsulotomy left eye. Her IOP was 19 mmHg right eye and 14 mmHg left eye on rhopressa 0.02% both eyes one drop daily, brinzolamide/brimonidine 1%/0.2% left eye three times a day, latanoprost 0.005% left eye once at night, pilocarpine 1% left eye three times a day, and acetazolamide 500 mg oral tablets twice a day. Her BCVA was NLP right eye and counting fingers at 6 feet in the left eye. Gonioscopy of the left eye revealed Schaffer grade III, grade 1 pigment, and flat iris. Humphrey visual field revealed infranasal central island of vision with MD of -28.77. Posterior segment exam was significant for 3+ nuclear cataract right eye and posterior chamber intraocular lens in the left eye: cup to disc ratio 0.9 in the left eye with diffuse loss of nerve fiber layer and pallor.

The patient agreed to undergo goniotomy with suprachoroidal microtube insertion in the left eye to lower the IOP on fewer medications. Her IOP in the left eye on postoperative day 1 was 2 mmHg on no medications, and IOP of 13 mmHg on no medications at one month. The IOP increased to 20 mmHg at the 4 month follow-up, resulting in the addition of three medications (dorzolamide/timolol and

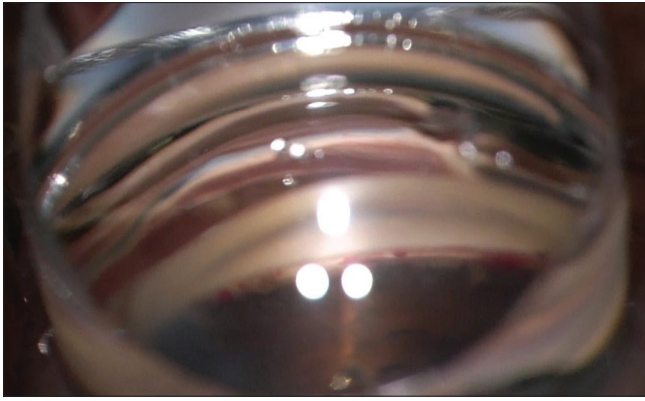


Figure 1: Goniotomy with 23-gauge cystotome: Heme reflux seen in collector channels

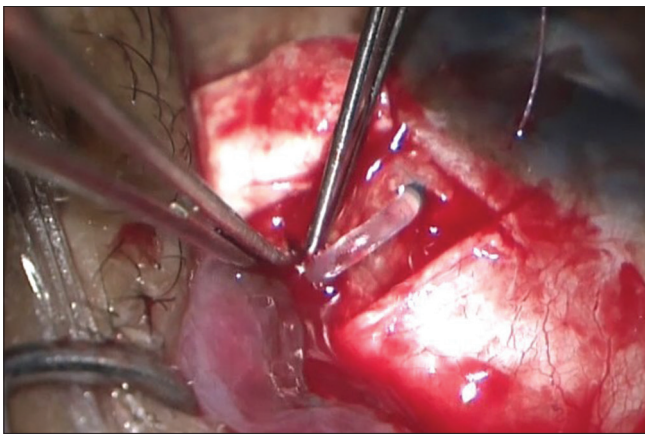


Figure 2: Intrascleral ciliary sulcus microtube being inserted into suprachoroidal space



Figure 3: UBM of microtube and aqueous in suprachoroidal space and away from cornea

latanoprost). IOP remained stable at 10 on three medications at 6 months. Her visual field at the 6 month follow-up revealed stabilized central island of vision. Her BCVA is stable at counting fingers at 6 feet in the left eye [Table 1].

Discussion

MIGS has been shown to be efficacious to lower IOP. In the cases we described herein, we have demonstrated excellent efficacy of combination MIGS using 23-gauge cystotome goniotomy and intra-scleral ciliary sulcus suprachoroidal microtube

surgery. In these five patients the combination MIGS surgery decreased IOP by 32% and number of medications by 61.5% at 6 months [Table 1]. The patients tolerated the procedures well. All patients had mild hyphema, which is common with goniotomy, and it resolved in all cases. Most patients experienced stabilization and/or improvement of visual acuity and visual field (four out of five) within 6 months [Table 1]. The procedure is "bleb-less", reducing the longer term risk of bleb-related endophthalmitis. The microtube made of silicone is biocompatible and well tolerated in the ciliary sulcus, sclera, and the suprachoroidal space.

The suprachoroidal space has no IOP floor and utilizes its own negative gradient to drain aqueous via the uveoscleral pathway leading to a drastic decrease in IOP. The Cypass (Alcon) was removed from the market due to safety concerns of corneal endothelial cell loss attributed to the position of the tube near the cornea.^[10] With our technique the microtube is positioned behind the iris away from the cornea, minimizing the risk of corneal edema or corneal decompensation [Fig. 3]. The patients had no adverse effects from potential complications, such as iritis, corneal edema, loss of visual acuity, cystoid macular edema, choroidal effusion, persistent hypotony, tube obstruction, retinal detachment, ciliary body detachment, ocular hypertensive crisis from sudden suprachoroidal closure, or persistent IOP elevations. All patients in this case series had preserved retinal integrity 6 months after surgery. No complications of tube shunt arose, and shunt placement into the vitreous cavity did not occur. We do not recommend this combined MIGS in patients with uveitis or neovascular glaucoma. We do not recommend placement into the anterior chamber due to the increased risk of corneal edema. The microtube has an internal diameter of 300 μ m and is affordable (\$125 from New World Medical). The sterile silicone tubing from the Aurolab glaucoma tube can be used outside of the US for about \$50 US.

Salinas *et al.* demonstrated the efficacy of goniotomy using Kahook dual blade in patients with refractory and severe glaucoma. Patients were able to achieve 23.9% reduction in IOP and 36.6% reduction in the number of medications ($P < 0.001$).^[11] In this case series, with the combined MIGS we were able to achieve a 32% mean reduction in IOP (range 29%-50%) in 80% of the patients. All patients in this series experienced 20% to 75% decrease in the number of medications (mean decrease 61.5%) [Table 1]. The 23-gauge cystotome is readily accessible to resource poor areas and is less expensive than the KDB (New World Medical), istent (Glaukos), and istent inject (Glaukos). We also believe that performing goniotomy at the time of suprachoroidal surgery helps reduce the ocular hypertensive phase that can occur when the suprachoroidal space closes or scars down. We have experienced this hypertensive crisis in a handful of intrascleral ciliary sulcus suprachoroidal surgery cases alone with 1 year follow-up in our personal experience. This has also been reported by McCartney *et al.* in a patient who had bilateral bypass surgery. Two months after surgery, the patient had a hypertensive crisis with IOPs of 83 mmHg in the right eye and 53 mmHg in the left eye.^[12] They hypothesized that the IOP elevation occurred due to a sudden closure of the suprachoroidal space combined with a possible underlying longer-term increase in trabecular meshwork resistance. They treated the patient with additional medical therapy to successfully lower the pressure. We believe that performing

Table 1: Intraocular pressure, number of medications, visual acuity, and visual field test in patients who underwent combination microinvasive glaucoma surgery; 23-gauge cystotome goniotomy and intra-scleral ciliary sulcus suprachoroidal microtube surgery

Cases	IOP			Medications			VA (Logmar)		VFT	
	Pre-op	6 mo	% change	Pre-Op	6 mo	% change	Pre-Op	6 mo	Pre-Op	6 Mo
1	14	7	50.0%	6	0	100%	20/50 (0.40)	20/70 (0.54)	-30	-28.20
2	25	13	48.0%	5	4	20%	20/20 (0)	20/20 (0)	-20.17	-19.36
3	15	10	33.3%	5	2	60%	CF@ 9' (1.7)	CF@ 9' (1.7)	-3.11	-5.35
4	15	15	0%	4	1	75%	20/40 (0.3)	20/25 (0.10)	-17	-17
5	14	10	28.5%	6	3	50%	CF @ 6' (1.9)	CF @6' (1.9)	-30	-28.89
Mean	16.6	11	32%	5.2	2.0	61.5%	N/A		N/A	

goniotomy at the time of suprachoroidal surgery helps to eliminate the trabecular meshwork resistance reducing the risk of an ocular hypertensive crisis and enhancing the success rate in our case series.

We also noticed no worsening of vision and stabilization to improvement of visual acuity and MD on visual field test in four of the five patients [Table 1]. Although admittedly short term, these results are reassuring and can be attributed to sustained reduction in IOP in these patients. No serious complications were noted.

Conclusion

We have demonstrated that combined 23-gauge cystotome goniotomy and intrascleral ciliary sulcus suprachoroidal microtube surgery technique can safely and significantly reduce IOP and decrease the number of ocular hypotensive medications. The above technique prevents microtube corneal contact by placing the microtube in the ciliary sulcus (posterior chamber) behind the iris inferotemporally [Fig. 3]. This combination MIGS procedure can be employed in patients with pseudophakia and glaucoma, pseudophakic angle closure patients, or glaucoma patients with other failed glaucoma surgeries. We have also used this technique at the time of phacoemulsification and manual small incision cataract surgery. We have also used this technique in resource poor areas to provide more effective and safer glaucoma surgery. This combination MIGS technique may potentially reduce the need for trabeculectomy and glaucoma tube shunts along with their associated complications. This study is limited by the short-term follow-up period. There are also no other suprachoroidal devices or techniques on the market for comparison. Further studies are recommended in different populations and with a larger sample size.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the forms, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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