

Comparison Efficiency of Combined Trabeculectomy with MMC and Gonioscopy-Assisted Transluminal Trabeculotomy

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Abstract

Purpose: To compare the efficacy of gonioscopy-assisted transluminal trabeculotomy combined with cataract surgery (PGATT) and trabeculectomy combined with cataract surgery (PTRAB) in open-angle glaucoma patients.

Methods: A multicentered, retrospective, non-randomized study included 67 PGATT patients and 70 PTRAB patients. We compared preoperative intraocular pressure (IOP), best-corrected visual acuity (BCVA) compared with early and final IOP, medication numbers, and BCVA levels. Success was determined as IOP reduction >20% from baseline, IOP between 5-21 mmHg, preoperative IOP of higher than 21 mmHg with medication and postoperative IOP of less than 21 mmHg without medication for surgeries performed for intolerance to medication, postoperative IOP <21 mmHg as well as <18 mmHg separately without medications, and no need for further glaucoma surgery.

Results: Preoperative IOP values were 28.61 ± 6.02 mmHg in PTRAB group and 23.99 ± 8.00 mmHg in PGATT group ($P < 0.0001$). Early postoperative IOP values were found lower in PTRAB group as 12.19 ± 3.41 mmHg and as 15.69 ± 4.67 mmHg in PGATT group ($P < 0.0001$). Last follow-up IOP reading were lower in PGATT group ($P = 0.009$). IOP difference values were found higher both in early and last postoperative periods in PTRAB group (respectively, $P < 0.0001$, $P = 0.018$). Success rates were found higher in both at lower than 21 and 18 mmHg levels in PGATT group (respectively, $P = 0.014$, $P = 0.010$).

Conclusion: We found the PGATT combined procedure to be a well-tolerated, effective procedure that can lower IOP both early and late in the postoperative period with different rates of IOP success compared with the combined PTRAB procedure.

Introduction

Glaucoma is one of the world's leading causes of irreversible blindness and is expected to affect 76 million people worldwide.[1] Whereas trabeculectomy remains the most commonly performed glaucoma surgery worldwide, minimally invasive glaucoma surgery (MIGS) is rapidly gaining ground, chiefly due to its safer surgical profile. Even though very low target intraocular pressure (IOP) may be necessary for advanced glaucoma and achievable with trabeculectomy, a considerable number of sight-threatening complications may occur, including hypotonia, retinal detachment, and endophthalmitis. By contrast, MIGS is easily combined with surgery for cataract[2], which among older adults is frequently associated with glaucoma requiring surgical intervention.[3] Even so, Schlemm's canal surgeries offer a less invasive approach and an improved outflow pathway by either bypassing or removing diseased trabecular meshwork.[4]

As a novel clear corneal approached gonioscopy-assisted transluminal trabeculotomy (GATT) technique provides alternative bleb-less glaucoma treatment option for anterior segment surgeons.[5] Since its first introduction this new modality reported successful outcomes on numerous open angle glaucoma types. However, there are still lacks of studies comparing and searching the surgical outcomes to long-standing

known techniques such as trabeculectomy. In our study, we aimed to compare the efficiency of trabeculectomy combined with phacoemulsification (PTRAB) and gonioscopy-assisted transluminal trabeculotomy combined with phacoemulsification (PGATT).

Material And Methods

In a multicentered, non-randomized, comparative, observational retrospective study, we collected, analyzed, and followed up on data of eyes undergoing PTRAB and PGATT surgery. All patients who were diagnosed as having open-angle glaucoma, had an IOP exceeding 21 mmHg, and thus underwent phacoemulsification surgery from 2014 to 2019 were enrolled in the sample. The same ophthalmologist (A.O.) performed all PTRAB surgeries, while the same ophthalmologist (E.B.) performed all PGATT surgeries. The study was conducted in accordance with the Declaration of Helsinki, and the local ethics committee approved the study protocol. The written consent to participate was obtained from each patient before the operation.

Patients aged 18 years and older with the diagnosis of primary open-angle glaucoma (POAG), pseudoexfoliative glaucoma (PXF), or uveitic glaucoma (UG), with inadequately controlled IOP, despite maximum tolerated medical therapy, or intolerant to glaucoma medications, therefore requiring surgical intervention. The participants underwent ophthalmological examinations, including visual acuity and refraction, slit-lamp biomicroscopy, gonioscopy, Goldman applanation tonometer (Haag - Streit, Koeniz, Switzerland), visual field (VF) examination with the Humphrey Visual Field 30 – 2 (HFA II 750, Carl Zeiss Meditech Inc., Dublin, CA) and dilated fundoscopy. Visual acuities were converted from Snellen to approximate logMAR ($-1 \times \log[\text{Snellen fraction}]$) for analysis. A diagnosis of open-angle glaucoma (OAG) was made if all of the following criteria were satisfied: the presence of glaucomatous optic disk neuropathy (a cup/disk ratio of 0.8 or the presence of notching) accompanied by corresponding visual field defects (a threshold examination of SITA 30–2 showing a glaucoma hemifield test “outside normal limits,” and a cluster of three contiguous points on the pattern deviation plot depressed at a P-value of 5% (occurring in age-matched healthy subjects) not crossing the horizontal meridian, which were compatible with glaucoma; and assessed as an open angle on gonioscopy. Other types of glaucoma, except open-angle glaucoma, were excluded. Additionally, if the patients had grade 2–3 nuclear cataracts based on the classification of the Lens Opacity Classification System III¹⁶ (LOCS III) combined with phacoemulsification and intraocular lens implantation.

Patients with normal-tension glaucoma, neovascular glaucoma, pigmentary glaucoma, steroid-induced glaucoma, glaucoma associated with ocular dysgenesis, congenital glaucoma, history of ocular trauma, or previous glaucoma surgery, including laser trabeculoplasty, in the study eye, were excluded from this study. The patients with a history of previous ocular surgery, eye trauma, uveitis, or any systemic disease such as diabetes mellitus, thus carrying an increased risk of postoperative inflammation following surgery, were excluded from the study.

Surgical Procedure

PGATT Operations

In all PGATT operations, the same surgeon (E.B.) began with cataract extraction. A combination of phenylephrine 2.5% and tropicamide 1% was given for mydriasis before surgery. After a standard sterile preparation, the surgical eye was draped, and an open wire nasal lid speculum was inserted to hold the eyelids open. Under sub-Tenon's anaesthesia, phacoemulsification was performed. A 2.4-mm temporal clear corneal incision was created, and sodium hyaluronate–chondroitin sulphate (Viscoat, Alcon Inc., Fort Worth, TX, USA) was injected into the anterior chamber. A 5.0–5.5-mm anterior curvilinear capsulorhexis and coaxial phacoemulsification with irrigation–aspiration (Centurion Vision System, Alcon Inc., Fort Worth, TX, USA) were performed. After the capsular bag was filled with sodium hyaluronate 1% (Healon AMO Inc., Abbott Park, IL, USA), a one-piece hydrophobic acrylic intraocular lens (IOL) was implanted in the bag. The intraocular viscoelastic was completely cleaned to ease its removal, after which the miotic agent Miochol-E (i.e. acetylcholine chloride intraocular solution) and 1.4% sodium hyaluronate (Healon GV; AMO Inc., Abbott Park, IL, USA) were administered in the anterior chamber. Once the nasal angle was displayed with a Swan Jacob gonioscope, using the same clear corneal main incision a 1- to 2-mm goniotomy was created in the nasal angle with a microvitrectomy (MVR) microsurgical blade through the temporal site (Fig. 1). A 6/0 Prolene suture was rounded by hand cautery (Fig. 2), after which a blunted suture was introduced through the paracentesis and retrieved intracamerally. The microsurgical forceps were used to guide the tip of the 6/0 Prolene suture through the goniotomy cleft into Schlemm's canal and to advance the tip approximately 360° (Fig. 3). After the suture was coursed through the entire canal, the tip appeared on the opposite side of the goniotomy cleft, and the leading tip was grasped with the forceps and pulled to the center of the anterior chamber (Figs. 4). The suture was externalized from the temporal corneal incision, thereby creating the 360° ab interno trabeculotomy. Last, the anterior chamber was washed with a 2-handed irrigation aspiration system to remove viscoelastic material and blood, and the wounds were checked to ensure watertight closure.

PTRAB Operations

In all PTRAB operations, performed by the same surgeon (A.O.) under general anaesthesia, a limbus-based conjunctival-Tenon flap and a scleral flap 4 × 4 mm were opened for all patients who received trabeculectomy. Next, sponges impregnated with 0.02 mg/ml mitomycin-C were kept under the conjunctival and scleral flaps for 2 min, after which a second transparent corneal incision at the supero-temporal area 2.75 mm wide was made on patients who received phacotrabeculectomy. Sodium hyaluronate–chondroitin sulphate (Viscoat, Alcon Inc., Fort Worth, TX, USA) was injected into the anterior chamber, followed by the installation of a dispersive ocular viscosurgical device (OVD) to protect the corneal endothelium during surgery. After capsulorhexis, hydro-dissection, and hydro-delineation, phacoemulsification was performed (Infinity Vision System with Ozil IP, Alcon Inc., Fort Worth, TX, USA). Once the capsular bag was filled with OVD, a one-piece hydrophobic acrylic IOL was implanted in the bag. An excision 3 × 1 mm was made in the trabecular tissue, after which peripheral iridectomy was performed. Last, the OVD was removed from the anterior chamber by bimanual irrigation and aspiration,

and the scleral flap was sutured with 3 separate 10/0 nylon. A balanced salt solution was used for anterior chamber reformation in all surgeries.

Postoperative Assessment and Success Criteria

We followed up on patients postoperatively on the first day and during the first week, as well as in the first, 3rd, 6th, and 12th months. We analyzed as early postoperative IOP on the first week and as late postoperative IOP on last recorded visit. We compared preoperative IOP values with final IOP values, the latter defined as the value of at least 12 months postoperative. Patients' BCVA, IOP values, and anterior and posterior segment findings were recorded. Anti-glaucoma medications were also administered as needed based on a target IOP of less than 21 mmHg at 2 weeks after surgery.

The primary outcome measures were success rate, IOP, and the number of glaucoma medications. Success was defined according to four criteria: 1) IOP reduction of greater than 20% from baseline, 2) postoperative IOP 5–21 mmHg as well as 5–18 mmHg separately, 3) preoperative IOP of higher than 21 mmHg with medication and postoperative IOP of less than 21 mmHg without medication for surgeries performed for intolerance to medication, and 4) lack of need for further glaucoma surgery.

Failure, by contrast, was defined in light of necessary reoperation to control IOP, a postoperative IOP not at least 20% lower than preoperative levels at last follow-up, or an IOP exceeding 21 mmHg at last follow-up.

Statistical Analyses

Statistical analyses were performed using SPSS (version 20.0, Chicago, IL, USA). The variables were investigated using visual histograms, probability plots, and the Shapiro–Wilk test to determine whether they were normally distributed. A statistical power analysis was also performed. Descriptive analyses were recorded using means and standard deviations because the variables were normally distributed. The mean between-group differences in baseline demographic and clinical characteristics were compared with the independent samples *t* test or chi-square test as applicable. All *p* values less than 0.05 were evaluated as indicating statistical significance.

Results

Measurements obtained from all cases included in the sample were analyzed. Among the demographic data (i.e. age, gender, glaucoma type, follow-up time, preoperative IOP, pachymetry, BCVA, and number of medications), mean age, gender distribution, and preoperative IOP values differed significantly between the groups. In particular, the PGATT group had a statistically higher mean age than the PTRAB group ($P = 0.005$) and more males, whereas the PTRAB group included more females ($P = 0.013$). No significant between-group differences arose in mean preoperative IOP, pachymetry reading, and preoperative use of medication, surgical side, or type of glaucoma. Similar mean LogMAR BCVA values were observed in both groups, although mean follow-up time was significantly longer in the PTRAB group. Table 1 shows the demographic characteristics of the groups.

Table 1
Demographics of the study groups

| Demographics and Exam findings | PGATTP(n = 67) | PTRAB (n = 70) | P Value |
|--|----------------|----------------|-----------|
| Age, mean ± SD | 69.22 ± 11.68 | 64.26 ± 8.27 | *0.005 |
| Gender n, Male/Female | 41/26 | 28/42 | **0.013 |
| Side, n, R/L | 37/30 | 34/36 | **0.492 |
| Pachymetry, micron ±SD | 562.48 ±28.24 | 556.18 ±30.34 | *0.161 |
| Glaucoma Type n, PEX/POAG | 44/23 | 46/24 | **0.996 |
| Preop-BCVA, mean LogMAR ± SD | 0.62 ±0.44 | 0.71 ±0.30 | *0.183 |
| Preop-IOP, mean mmHg ± SD | 23.99 ±8.00 | 28.61 ±6.02 | *< 0.0001 |
| Preop-Medication, n, ±SD | 2.59 ±1.24 | 3.00 ±1.21 | *0.051 |
| Mean Follow-Up Time, n, ±SD | 18.13 ±6.08 | 56.13 ±10.23 | *< 0.0001 |
| <p><i>PGATT:Phacoemulsification combined with Gonioscopy-Assisted Transluminal Trabeculotomy PTRAB:Phacoemulsification combined with Trabeculectomy. SD; Standard Deviation, n;participant number. PEX:Pseudoexfoliation glaucoma, POAG: Primary open angle glaucoma. Preop-BCVA: Preoperative Best Corrected Visual Acuity, Preop-IOP:Preoperative Intraocular Pressure. *Independent Sample T test to compare the means of two independent groups ** Pearson's chi-square test to compare the frequencies of two independent groups in one or more categories. P < 0.05 are noted as significant.</i></p> | | | |

Early postoperative IOP readings in the PGATT, and PTRAB group were 15.69 ± 4.67 , 12.19 ± 3.41 mmHg respectively ($P < 0.0001$), whereas the last readings were 15.04 ± 4.26 , 16.96 ± 4.11 mmHg respectively ($P = 0.009$). Early and final postoperative IOP differences compared to preoperative levels were statistically higher in the PTRAB group. When the last postoperative target IOP level was lower than 18 mmHg, complete success rates were 57/10 in the PGATT group and 47/23 in the PTRAB group ($P = 0.014$). However, when the last postoperative target IOP level was lower than 21 mmHg, success rates increased 64/3 in the PGATT group and 57/13 in the PTRAB group ($P = 0.01$). Table 2 shows the results of IOP analyses and comparisons. Apart from the surgical outcome differences, there was no early and late postoperative complication was noted on our study.

Table 2
IOP changes between groups and follow up

| IOP findings | PGATTP(n = 67) | PTRAB (n = 70) | P Value |
|---|----------------|----------------|-----------|
| Preop-IOP, mean mmHg ± SD | 23.99 ±8.00 | 28.61 ±6.02 | *< 0.0001 |
| Early Postop-IOP, mean mmHg ± SD | 15.69 ±4.67 | 12.19 ±3.41 | *< 0.0001 |
| Last Postop-IOP, mean mmHg ± SD | 15.04 ±4.26 | 16.96 ±4.11 | 0.009 |
| P Value | ***< 0.0001 | ***< 0.0001 | |
| IOP Differences | | | |
| Preop vs Early Postop IOP, mean mmHg ± SD | 8.29 ±9.48 | 16.42 5.40 | *< 0.0001 |
| Preop vs Late Postop IOP, mean mmHg ± SD | 8.94 ±8.15 | 11.65 ±4.74 | *0.018 |
| IOP Success | | | |
| 18 mmhg- Success/Failed | 57/10 | 47/23 | **0.014 |
| 21 mmhg-Success/Failed | 64/3 | 57/13 | **0.010 |
| <i>PGATT:Phacoemulsification combined with Gonioscopy-Assisted Transluminal Trabeculotomy PTRAB:Phacoemulsification combined with Trabeculectomy. SD; Standard Deviation, n;participant number. PEX:Pseudoexfoliation glaucoma, POAG: Primary open angle glaucoma. Preop-BCVA: Preoperative Best Corrected Visual Acuity, Preop-IOP:Preoperative Intraocular Pressure. *Independent Sample T test to compare the means of two independent groups ** Pearson's chi-square test to compare the frequencies of two independent groups in one or more categories. P < 0.05 are noted as significant.</i> | | | |

Discussion

The incidence of glaucoma and cataract increases during the natural ageing process of the human eye. The need for surgery depends upon the dominance of visual deterioration and the extent to which glaucoma has progressed. If both conditions apply, then surgeries can be combined. Combining cataract and glaucoma surgeries affords several benefits over separate operations, including reduced morbidity, lower costs, and faster recovery. Performing combined procedures also reduces the risk of postoperative IOP spikes and the need for ocular hypotensive. Cataract surgery in an eye with a filter in place poses a risk of a filtering flap; however, performing both operations at the same time can result in significant inflammation. Filtering procedures alone are prone to complications such as inflammation, hypotony, and hyphaemia. Beyond that, a filtering bleb can fail at any time in the postoperative period, from minutes to decades after surgery.[6]

The demographic characteristics of groups in our study were statistically similar. The effects of age on wound healing are evident in filtering surgeries. Because wound healing decreases with aging, advanced age can be regarded as a positive factor in trabeculectomy surgery.[7] GATT surgery is conjunctiva-sparing surgery; it is not affected by wound healing or ocular surface disorder due to topical drugs.

However, the success of GATT surgery decreases in patients with advanced glaucoma due to reasons such as possible collector duct atrophy.[8] Therefore, the age and gender distributions of the groups needed to be matched in our study to ensure their comparability.

In our study, preoperative IOP was significantly higher in the PTRAB group, largely because trabeculectomy surgery, a conventional filtering surgery, is a more effective method of lowering target IOP. Likewise, preoperative IOP values were lower in the other group because GATT is preferred in patients with lower IOP, for it causes less vision-threatening complications in early- and middle-stage glaucoma. GATT also seems to be more successful when the target pressure is in the mid-teens, because GATT provides an IOP directly proportional to the episcleral venous pressure. Early IOP was significantly lower in the trabeculectomy group, although its long-term success decreased due to wound healing, as commonly seen in filtering surgeries over time. That situation increases considerably due to intense inflammatory mediator release, especially during combined phacoemulsification surgery. We also compared combined trabeculectomy with combined GATT and noticed that the long-term effect was more pronounced in the trabeculectomy group, most likely due to the increased inflammatory mediator release after peripheral iridectomy in trabeculectomy surgery and the fact that wound healing in the conjunctiva and scleral flap is more affected by inflammation. However, Siriwardena et al. found that anterior chamber inflammation and the breakdown of the blood–aqueous barrier are far more prolonged after uncomplicated small-incision cataract surgery than after glaucoma filtration surgery with peripheral iridectomy.[9] We thought that, inflammation might be a obstructing factor that affect surgical outcomes, especially after traditional filtration surgeries.

At present, glaucoma surgery comes in different types for different indications. The top reason for the surgery is to reduce complication rates, specifically bleb-related complications. In particular, Schlemm's canal surgeries have the advantage of using the natural outflow route.[10] Although glaucoma surgery's effectiveness notoriously decreases in combination with cataract surgery, combined surgery sometimes needs to be performed due to the difficulty of following up with the patient and the intensity of the cataract. The factors that cause PTRAB to be less successful than trabeculectomy include the disruption of the blood–aqueous barrier, the release of inflammatory mediators, the acceleration of wound healing, and secondary bleb failure.[11] In that light, minimally invasive surgery confers the benefits of less inflammatory reaction. Even so, combined surgery should generally be avoided in interventions for glaucoma.

Epithelial cells of the human lens are released after uneventful cataract surgery, which is the principal reason for long-term inflammation and the source of inflammatory mediators. Because postoperative inflammation involves fibrogenesis, all filtration procedures are affected by the wound-healing effect. Despite the lack of proof that natural IOP-reducing procedures such as GATT are affected by postoperative inflammation, we recently found that combined surgery causes shorter-term success. Our findings herein are additional proof that the higher the inflammation following combined trabeculectomy operations other than GATT, the less the long-term complete success. However, additional preclinical studies are needed to clarify the effect of type of glaucoma surgery and inflammation on long-term IOP-

reducing potency.[12] One of the best explanations for the inflammatory effect on glaucoma surgery surveillance is uveitic glaucoma surgery. Ample literature on that topic commonly acknowledges that inflammation causes the failure of interventions for glaucoma, especially if they are combined.[13] When we applied glaucoma surgery only in the case of uveitic glaucoma, as a type of surgery that is gaining ground, the effect on the failure could be better understood.[14] Bettis et al[14] found that implanting an Ahmed glaucoma valve (AGV) outperformed the trabeculectomy procedure for uveitic glaucoma, particularly in the first year, possibly because peripheral iridectomy was applied only in the classical trabeculectomy operation. Implanting an AGV can be applied without iridectomy, and the bleb will be more posterior than the trabeculectomy, such that the inflammatory effect is less than the effect of trabeculectomy. Our study shows that amid inflammatory conditions that may affect surgery, type of surgery becomes important for long-term success.

Among our study's limitations, the long-term results of both groups were not analysed. Because trabeculectomy surgery is an older method, postoperative follow-up times were longer, and we observed that its success decreased over time. Another limitation was that the early and end-stage IOP values were approximate in the PGATT group based on their average scores at 18-month follow-up. That situation decreased efficiency, because combined surgery was significantly less successful in the PGATT group than in the PTRAB group.

In conclusion, we found the PGATT combined procedure to be a well-tolerated, effective procedure that can lower IOP both early and late in the postoperative period with different rates of IOP success compared with the combined PTRAB procedure.

Declarations

Compliance with Ethical Standards

Funding:

This study has not any financial support.

Conflict Of Interest:

Author Ali Olgun declares that he has no conflict of interest.

Author Fatih Yenihayat declares that he has no conflict of interest.

Author Hacı Uğur Çelik declares that he has no conflict of interest.

Author Ercüment Bozkurt declares that he has no conflict of interest.

Author İbrahim Şahbaz declares that she has no conflict of interest.

Ethical approval:

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional ethical committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent:

Informed consent was obtained from all individual participants included in the study.

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Figures

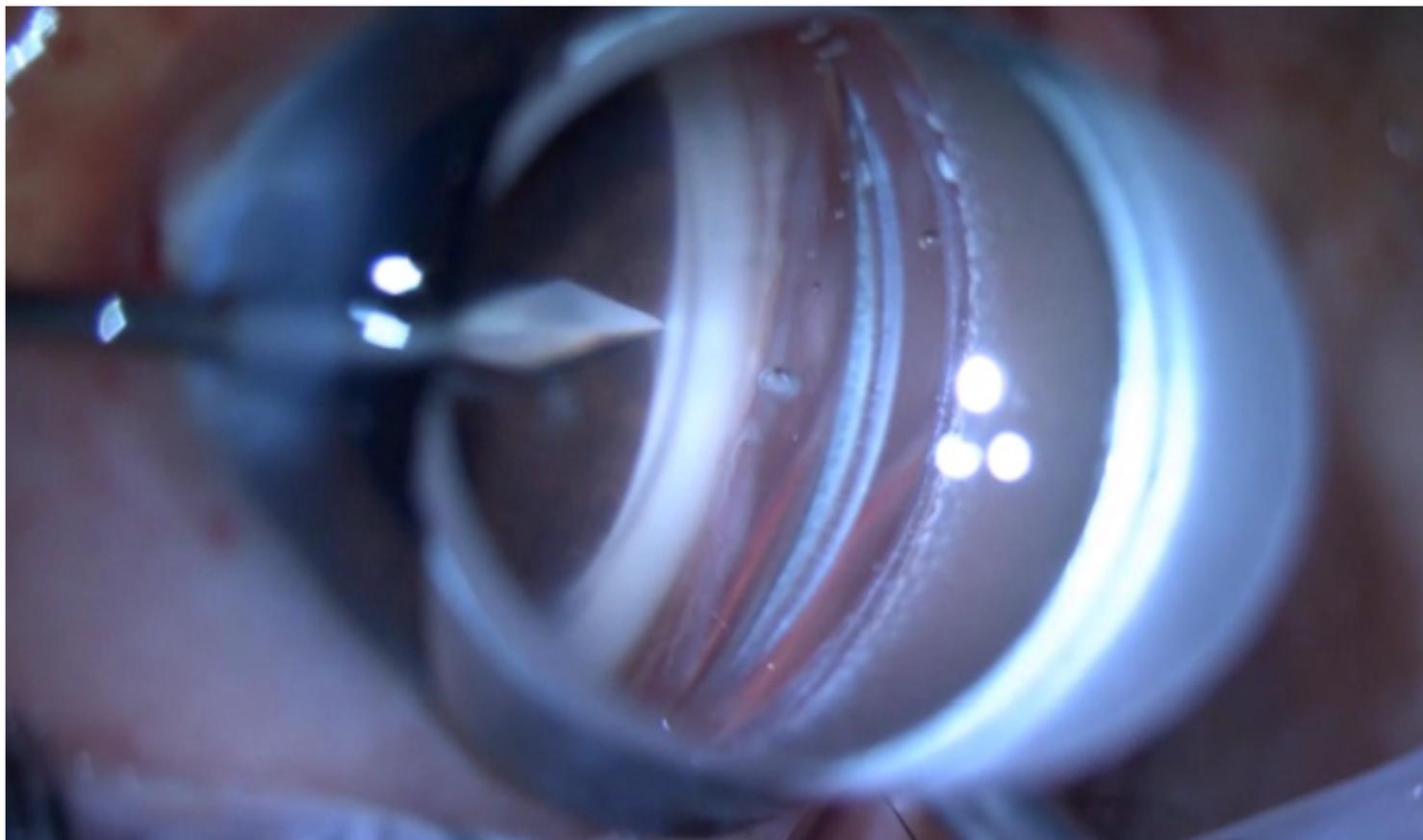


Figure 1

1- to 2-mm goniotomy was created in the nasal angle with an MVR microsurgical blade through the temporal corneal incision.

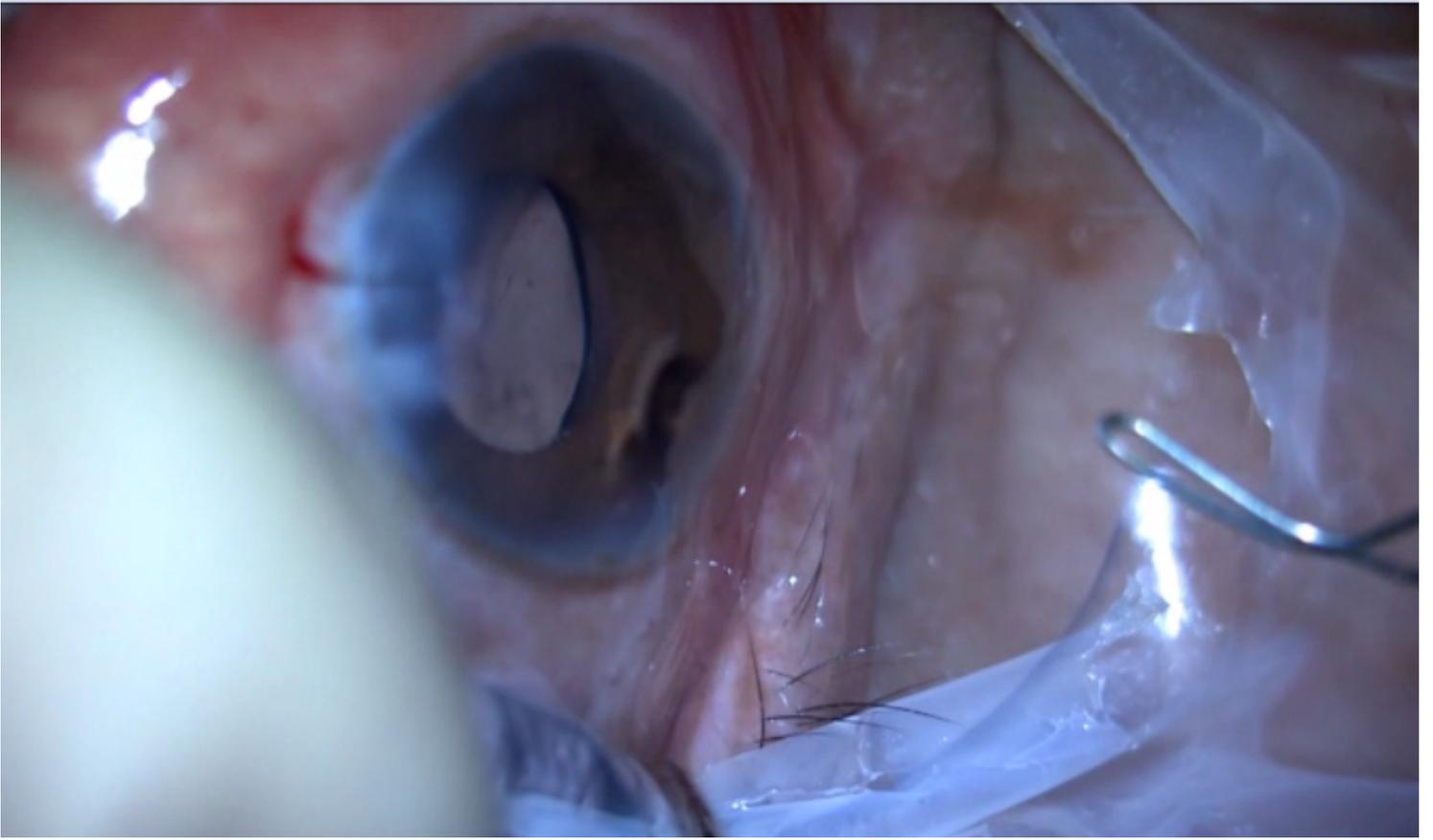


Figure 2

6.0 prolene suture tip was rounded by hand cautery



Figure 3

The microsurgical forceps was used to guide the tip of 6/0 prolene suture through the goniotomy cleft into the Schlemm canal and to advance the tip around 360°

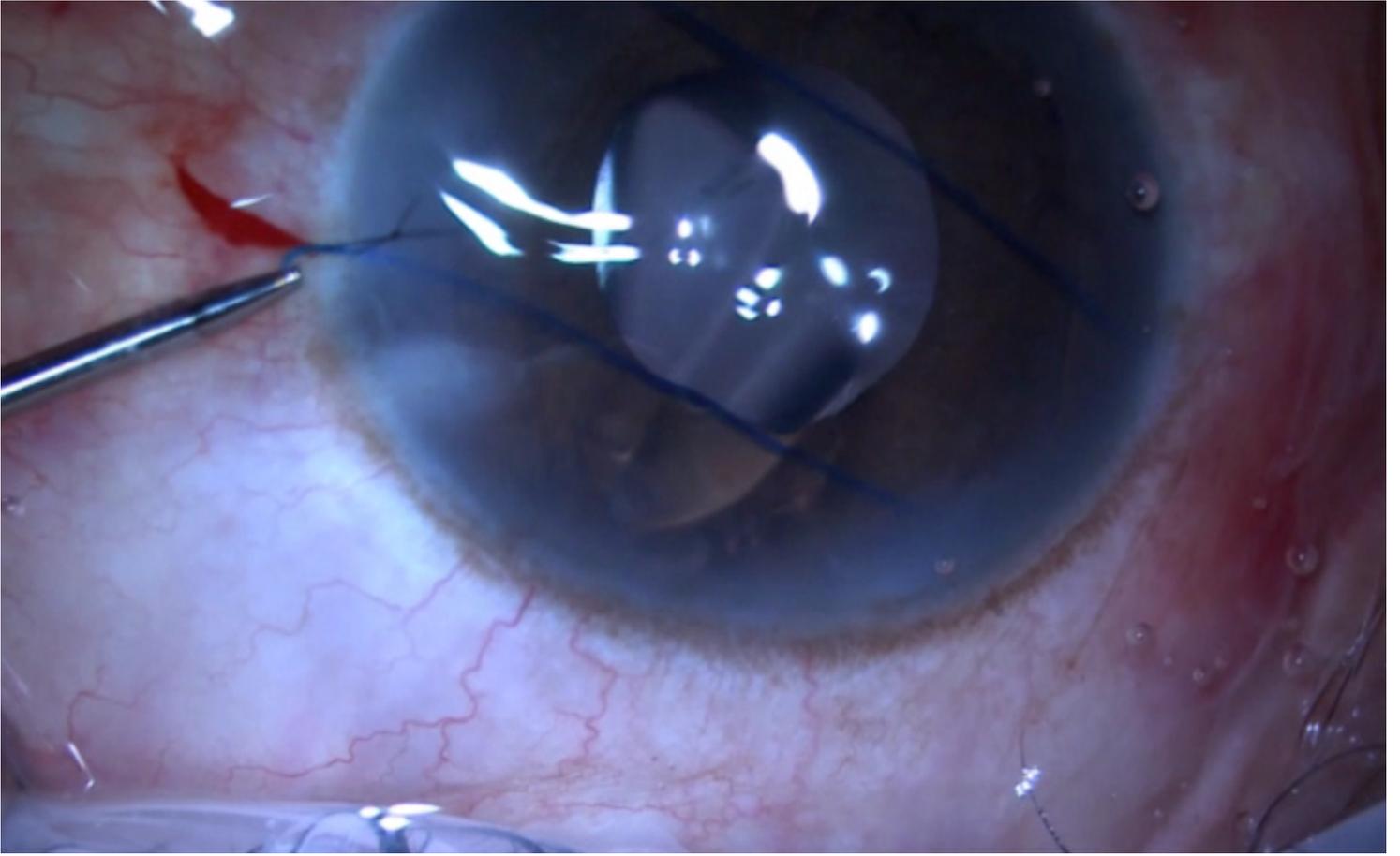


Figure 4

The leading tip is grasped with the microforceps and pulled to the center of the anterior chamber