



Results of Minimally Invasive Device TrabEx+ in Patients with Primary Open Angled Glaucoma

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Abstract

Purpose: The aim of our prospective study is to present the results of trabecular meshwork excision with the minimally invasive device TrabEx+ in patients with Primary Open-Angle Glaucoma (POAG).

Methods: Patients diagnosed with POAG resistant to pharmacological treatment were included. All patients underwent as first non-medical treatment a trabecular meshwork excision with the use of TrabEx+.

Results: 50 eyes of 50 patients with POAG (75.38±8.45 years, 21 males) were evaluated. The use of TrabEx+ resulted in a decrease of IOP the first postoperative day (by 11.2 mmHg) and remained decreased after one month (by 7.3 mmHg), three months (by 7.3 mmHg), six months (by 7.7 mmHg), one year (by 7.3 mmHg) and two years (by 6.7mmHg).

Conclusion: The use of TrabEx+ is associated with a significant reduction in IOP pressure and medication and provides immediate and long-term effective results. TrabEx+ minimally invasive surgery is a safe and reliable alternative that could be added in the armamentarium of glaucoma management.

Keywords

Glaucoma; Type 2 Diabetes Mellitus; Minimally Invasive Glaucoma Surgery; Open-Angle Glaucoma

Introduction

Glaucoma is a leading cause of irreversible blindness worldwide affecting more than 70 million people while almost $\frac{3}{4}$ of these people are affected by Open-Angle Glaucoma (OAG) [1]. A number of risk factors have been reported including but not limited to positive family history (first degree relatives), advanced age, race (African-Americans have greater risk of developing glaucoma), myopia, increased cup-to-disc ration, type 2 diabetes mellitus, hypertension and smoking [2]. It has an insidious onset as it is commonly asymptomatic at early stages. Thus, early detection and timely management are key for improving prognosis [3,4].

Regarding its management, there are currently five major classes of drugs that are used and these are: a) beta-adrenergic antagonists, b) alpha2-adrenergic agonists, c) carbonic anhydrase inhibitors, d) cholinergic agonists and e) hypotensive lipids. Nevertheless, as in the case of most medications, these are also not side effect-free. In addition, surgical approaches such as argon trabeculoplasty and Nd:YAG laser treatment have been added as adjuncts to medical management or even as a primary treatment option. In the last two decades many Minimally Invasive Glaucoma Surgery (MIGS) options have been used to lower and control the Intraocular Pressure (IOP) [5,6].

TrabEx+ (MicroSurgical Technology, Redmond, WA) is a new ab interno trabeculectomy method, a minimally invasive device which is designed for Trabecular Meshwork (TM) excision in patients with glaucoma. This new tool allows precise cut and TM removal as well better visibility throughout surgery. It has a trapezoidal bladehead composed by two serrated blades, able to perform irrigating goniotomy. The design of the device with the incorporation of the Irrigation/Aspiration system (I/A) helps to stabilize and keep clear the Anterior Chamber (AC) as well as to provide the best possible visibility of the angle during the surgery. TrabEx+ can be installed to the standard phacoemulsification devices and can be used for both adult and pediatric patients [7,8].

This study was performed in an effort to highlight the safety and efficacy of this new device in patients with chronic Primary Open-Angle Glaucoma (POAG).

Materials and Methods

Study Design

This is a prospective randomized study conducted at the Departments of Ophthalmology of the General Hospital G. Gennimatas (First Department of Ophthalmology, Medical School, National and Kapodistrian University of Athens, Greece), and of the Sismanogleio General Hospital (Athens, Greece).

Fifty adult patients (50 eyes) with a diagnosis of POAG resistant to pharmacological treatment were included in the study. Exclusion criteria were co-existence of other ocular diseases or ocular intervention such as laser trabeculoplasty, capsule rupture, diabetic retinopathy, intraocular surgery (with exception of phacoemulsification) as well as other types of glaucoma.

Clinical examination included slit-lamp biomicroscopy, fundoscopy, Snellen Best Corrected Visual Acuity (BCVA) and Goldmann applanation tonometry for IOP measurement were performed pre-operatively, at 1st day, 1st week and at month 3, 6, 12, 18 and 24 post-operatively. The patients treated by two experienced surgeons (MMM, SS) between March 9, 2018 and April 30, 2020.

Surgical Method

We performed as first non-medical treatment a trabecular meshwork excision with the use of TrabEx+. For this operation we need to have the TrabEx+ device connected to a phacoemulsification device and a gonioscopy lens. This can be performed in combination with cataract surgery or separately.

The surgical steps of TrabEx+ goniotomy we performed are as follows: Before we start the procedure, the microscope should be tilted 40° towards the surgeon, the surgeon should sit temporally and the head of the patient must be turned 30° away from the main position to provide the best possible view of the Trabecular Meshwork (TM). At the beginning we create a 1.8 mm clear corneal incision temporally with a slit knife and then we tap the corneal incision to drain the aqueous humor and lower the IOP to visualize Schlemm's Canal (SC). Insertion of the tip of TrabEx+ with irrigation on to provide the best possible view of the angle. Orient the dual blade tip parallel to TM and advance it clockwise within the SC to remove the Trabecular Meshwork. When finished with one direction we rotate the tip 180° to remove the TM in the opposite direction. Irrigation, aspiration and incision suture to ensure a leak-tight closure.

In addition, patients continued receiving the preoperative anti-glaucoma medications as prescribed by their doctor with the exception of oral acetazolamide treatment which was not administered postoperatively.

Statistical Analysis

Descriptive statistics were used for presenting the demographic characteristics of the cohort. Analysis of Variance (ANOVA) was used for evaluating the differences within and between groups. IBM SPSS Statistics for Windows (Version 27.0. Armonk, NY: IBM Corp) was used for the statistical analysis. Normality of distribution was tested before applying the statistical tests.

Results

In this study participated 50 patients (42% men) with mean age of 75.38 years old. 31 cases (62%) had positive family history of glaucoma and 27 (54%) had the left eye affected. The mean intraocular pressure at the time of presentation was 21.62 with 26 patients (52%) without any other ocular disease diagnosis (Table 1).

All cases at the beginning were under anti-glaucoma treatment. 11 patients (22%) were using systemic medications (acetazolamide) while 14 (28%) were using 3 topical medications and 25 (50%) 4 topical anti-glaucoma medications. We then re-evaluated their pharmacological treatment at 6 months, 12 months and 24 months after the TrabEx+ trabeculectomy. The result was that 4 patients (8%) who were taking 3 topical medications pre-TrabEx+ needed to continue using the same number of medications 6 months after trabeculectomy while 3 (6%) needed at 12 months and 5 (10%) after 24 months. As for the cases who were using 4 topical anti-glaucoma medications, no one (0%) used 6 months after trabeculectomy but 1 (2%) and 2 (4%) after 12 months and 24 months respectively (Table 2).

An analysis of IOP changes was performed and the results are presented in Table 3. Significant differences over time were noted among groups especially up to month 1 after procedure with mean IOP preoperatively being 21.62 ± 3.62 mmHg, at day 1 being 10.38 ± 2.45 mmHg, at week 1 13.38 ± 2.56 mmHg and at month 1 14.26 ± 2.41 (<0.001). Tukey's analysis revealed that preoperative IOP and IOP at week 1 had overall the most significant differences (Table 3).

In addition, in only 13 out of 50 cases (26%) mild hemorrhage was noted as intraoperative complication while post-operatively mild flare was noted in 3 (6%) patients and vitreous hemorrhage and hyphema was seen in 7 (14%) patients (Fig. 1,2).

Age, yrs mean±SD	75.38±8.45
Male Gender, n (%)	21 (42%)
Family History of glaucoma, n (%)	
Positive	31 (62%)
Negative	19 (38%)
Laterality, n (%)	
Right	23 (46%)
Left	27 (54%)
Best corrected visual acuity at presentation mean±SD	0.61±0.2
Intraocular pressure at presentation mean±SD	21.62±3.62
Diabetes mellitus, n (%)	
Yes	11 (22%)
No	39 (78%)
Alcohol consumption, n (%)	
Yes	5 (10%)
No	45 (90%)
Smoking, n (%)	
Yes	11 (22%)
No	39 (78%)
Presence of other ocular diseases	
No	26 (52%)
Yes	24 (48%)

Table 1: Clinical demographics of the cohort (n=50).

Number of medications	Pre-Goniotome	Post-Goniotome	Post-Goniotome	Post-Goniotome	P-value
		6 months	12 months	24 months	
Topical					< .00001
0	0 (0%)	26 (52%)	21 (42%)	21 (42%)	
1	0 (0%)	13 (26%)	15 (30%)	14 (28%)	
2	11 (22%)	7 (14%)	10 (20%)	8 (16%)	
3	14 (28%)	4 (8%)	3 (6%)	5 (10%)	
4	25 (50%)	0 (0%)	1 (2%)	2 (4%)	
Systemic	11 (22%)	0 (0%)	0 (0%)	0 (0%)	< .00001

Table 2: Pre and post Goniotome medications.

Time	Preoperative	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24	P-value
IOP mean±SD	21.62±3.62	10.38±2.45	13.38±2.56	14.26±2.41	14.28±2.05	14.12±1.74	14.28±1.71	14.84±2.18	14.92±2.53	<0.001

Table 3: Intraocular pressure measurements preoperatively and at follow-ups.

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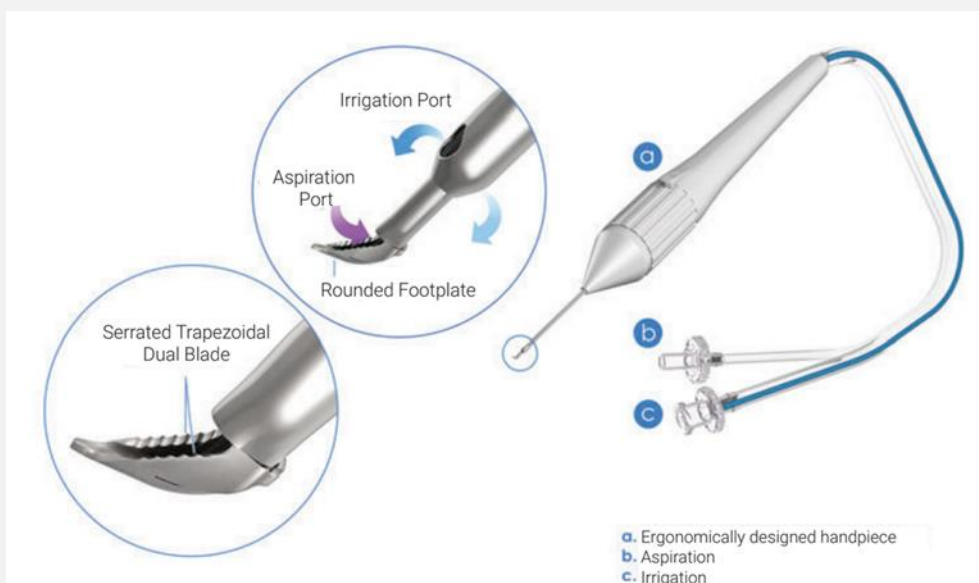


Figure 1: TrabEx+ Goniotomy Device (Source: <https://microsurgical.com>).

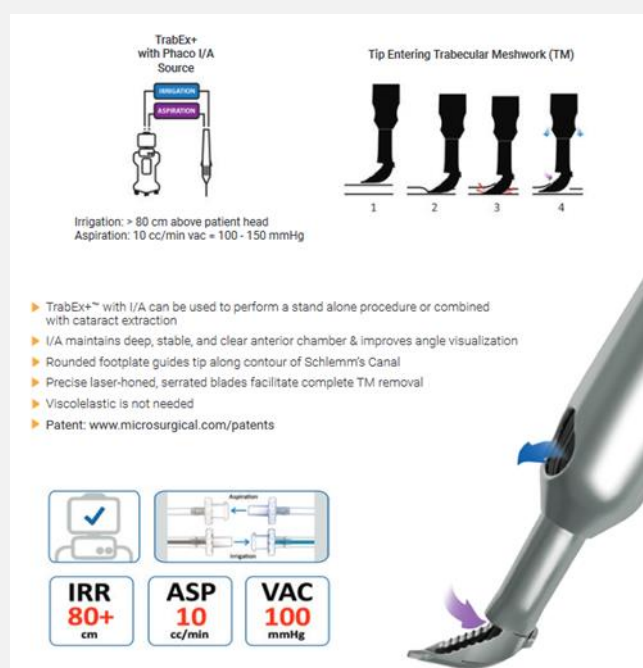


Figure 2: TrabEx+ Instructions how to use (Source: <https://microsurgical.com>).

Discussion

Minimally invasive glaucoma surgery or microinvasive glaucoma surgery techniques, well known as “MIGS”, have been widely used the last 20 years for the management of the

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intraocular pressure in patients diagnosed with glaucoma. These techniques can be classified based on the anatomical action and their physiological mechanisms and also share some important features such as a high safety profile, ab interno microincision, high efficacy, minimal trauma and rapid recovery [9,10]. Patients with mild to moderate glaucoma disease with IOP not well controlled with eye drops or laser techniques or are noncompliant with eye drops are considered candidates for MIGS.

In this study TrabEx+ goniotome was applied to 50 patients with chronic primary open-angle glaucoma for managing their intraocular pressures and these patients were received close short- and long-term follow in order to better investigate the efficacy of this new technique in IOP management. We demonstrate that while patients' mean pressure was at upper limit preoperatively, at day 1 it significantly dropped and was relatively stabilized at about month 1 and until our last follow-up which was at 2 years after procedure.

Furthermore, another interesting finding is that at 24 months, 70% of the patients in our cohort ended up taking none or only 1 medication (topical treatment) and none of them was on systemic therapy for IOP control. Taking into consideration the fact that good control of IOP was achieved without or with only one medication in most of the patients, TrabEx+ goniotome was overall considered a successful approach.

TrabEx+ goniotome similarly to the other ab interno MIGS techniques spares conjunctiva and as a result gives the opportunity for possible future trabeculectomies and/or valve implantation. In addition, it has a fast-learning curve, it doesn't use high thermal energy during the procedure and doesn't implant any device in the eye. The part of the TM removed by this technique can be used if needed for research purposes and analysis as it is taken with a minimally traumatic procedure, in a nondestructive manner [11].

Conclusion

In conclusion, this study supports that TrabEx+ is a safe and effective approach that could be added in the armamentarium of glaucoma management.

Financial Disclosures

The authors have no relevant financial disclosures. The expenses of the procedures were entirely covered by the Social Insurance Institute.

Conflict of Interest

The authors declare that there is no conflict of interest.

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