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Coarsened Exact Matching of Excisional to Plasma-Ablative Ab Interno Trabeculectomy

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Abstract

Purpose: To compare ab interno trabeculectomy by trabecular meshwork excision to plasma-mediated ablation in primary open-angle glaucoma.

Methods: Retrospectively collected data of TrabEx+ (n=56) and Trabectome (n=99) were compared by coarsened exact matching to reduce confounding and matched based on baseline intraocular pressure and age. Primary outcomes were intraocular pressure and the number of glaucoma medications. Complications and the need for additional glaucoma surgery were assessed. Patients were followed for up to one year.

Results: 53 TrabEx+ could be matched to Trabectome. Baseline intraocular pressure was 16.5 ± 4.6 mmHg in both; age was 73.7 ± 8.8 years and 71.5 ± 9.9 years in TrabEx+ and Trabectome, respectively. TrabEx+ were taking more medications than Trabectome (p<0.001). Intraocular pressure was reduced to 14.8 ± 4.3 in TrabEx+ and 13.4 ± 3.4 in Trabectome at 6 months, and to 14.9 ± 6.0 (p=0.13) in TrabEx+ and to 14.1 ± 3.8 mmHg (all p<0.05) in Trabectome at 12 months. Medications were reduced at both 6 and 12 months (p< 0.05). No differences were seen between both groups at 6 and 12 months. In TrabEx+, only one serious complication occurred, and two patients required further glaucoma surgery.

Conclusion: Although both groups had a baseline intraocular pressure considered low for ab interno trabeculectomy, intraocular pressure and medications were reduced further at 6 and 12 months. Intraocular pressure reduction did not reach significance in TrabEx+ at 12 months. The inter-group comparison did not reveal any significant differences. Both had a low complication rate.

1. Introduction

1.1 Glaucoma - Definition and Epidemiology

Glaucoma is an ophthalmological disorder characterized by progressive optic neuropathy that leads to increasing visual field defects [1]. It is the most frequent cause of irreversible blindness in the world[1]. Although there are no accurate figures, it is estimated that more than 70 million people are currently living with this condition[2]. In Germany, this condition is said to be responsible for 15% of blindness in the country[3]. Due to the slow, discrete onset of the disease, less than 50% of affected persons in industrialized nations are aware of their condition[4]. The incidence of glaucoma increases with age and the condition has a predisposition for men[1]. Although it affects African Americans more often than Caucasians, the prevalence in Caucasians is increasing more rapidly than that in African Americans [5].

In this disease, the retinal ganglion cells and their axons undergo a slow progressive degeneration [6] which leads to characteristic optic disc changes and visual field defects[7]. It is only second to cataracts as a leading cause of blindness worldwide[8]. Although most of the time, no direct cause is found, it is frequently associated with increased intraocular pressure, the only modifiable factor until this day[6]. If left untreated, the retinal ganglion cells continue to degenerate, leading to larger visual field defects and eventually, visual disability and blindness[4,6].

1.2 Intraocular Pressure and Aqueous Humor Flow

The intraocular pressure of the eye is based on two factors: the rate of aqueous humor production and the outflow rate[9]. The ciliary body epithelium is responsible for the production of aqueous humor and does so at a rate of approximately 2.5 µL/min[9]. The aqueous humor then flows from the ciliary body, around the iris to reach the anterior chamber of the eye. In the anterior chamber, there are two outflow tracts into which the aqueous humor flows: the trabecular meshwork and the uveoscleral tissue[9]. The trabecular meshwork accounts for the majority of the outflow and represents the conventional outflow tract, while the uveoscleral tissue is the unconventional outflow tract[9]. Figure 1 demonstrates both of these outflow patterns. The trabecular meshwork outflow rate is pressure-dependent and increases with increased intraocular pressure. The conventional outflow tract, which contains the trabecular meshwork, consists of a proximal and a distal component. During an

ophthalmological examination, gonioscopy enables the visualization of the angle of the eye and the trabecular meshwork. Figure 2 depicts the structures typically visible. The trabecular meshwork represents the proximal part of the conventional outflow tract. When in equilibrium with a normal outflow tract, the average intraocular pressure of the eye is at 15.5 mmHg, with normal values ranging from 10 to 21 mmHg[10].

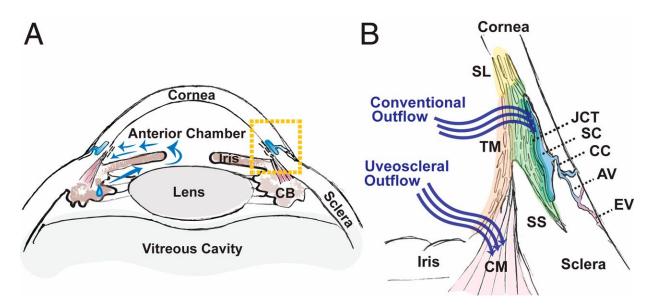


Figure 1: Aqueous humor outflow of the eye. A: Image of the anterior chamber of the eye. B: The aqueous humor outflow consists of two pathways: the conventional outflow and the uveoscleral outflow. [11]

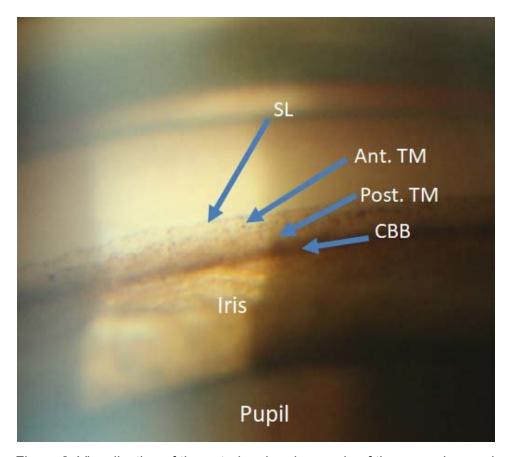


Figure 2: Visualization of the anterior chamber angle of the eye using gonioscopy. SL: Schwalbe's Line. Ant. TM: Anterior Trabecular Meshwork. Post. TM: Posterior Trabecular Meshwork. CBB: Ciliary Body Band. [12]

Out of these two outflow systems, only the conventional outflow system is subject to surgical modification, as the uveoscleral pathway is pressure-independent and absorbs aqueous humor at a constant rate.

Concerning aqueous humor dynamics, the Goldmann equation below describes the outflow in the anterior chamber as the difference between the intraocular pressure and the episcleral vein pressure divided by the flow resistance[13].

Outflow = (Intraocular Pressure - Episcleral Venous Pressure) / Flow Resistance and because the resistance is the inverse of the outflow facility, the following equation can be derived:

 $Outflow = (Intraocular \, Pressure - Episcleral \, Venous \, Pressure) \, x \, Outflow \, Facility$

As primary glaucoma is a disease of the elderly and aqueous humor production decreases with age, one can logically deduce that impedance in the outflow system is the main cause of a pressure build-up in the eye[14,15]. The causes of this are abundant and range from anatomical changes in Schlemm's canal to the obstruction of the trabecular meshwork by debris coming from the iris or other structures in the eye[16].

1.3 Glaucoma Types

Glaucoma is divided into two major categories: primary and secondary[17]. Primary glaucomas are glaucomas that do not arise due to other conditions or syndromes. Primary open-angle glaucoma is the most common type and is characterized by the existence of this neuropathy in the absence of a distinguishable cause[18]. It is usually asymptomatic and discovered accidentally[19]. Primary angle-closure glaucoma, on the other hand, arises from the closure of the angle of the eye due to synechiae or the forward displacement of the peripheral iris[20]. This can be an acute or a chronic process. Acute angle-closure glaucoma is almost always detected as this condition presents with intense symptoms such as vomiting, headache, nausea, and ocular pain[19]. These symptoms are a consequence of a rapid build-up of pressure in the eye. Chronic angle-closure glaucoma on the other hand is a slower process in which the iris gradually grows and covers up the trabecular meshwork by forming synechiae[21].

Secondary glaucomas are glaucomas that arise from a variety of ocular conditions. They include uveitic, pigmentary, steroid-induced, traumatic, neovascular, and pseudoexfoliation glaucoma among others. The treatment of these glaucomas is normally linked to their cause. Pseudoexfoliation glaucoma arises from the deposition of extracellular fibrillar material in the trabecular meshwork[22]. Pigmentary glaucoma occurs due to a similar obstruction, but due to pigment particles emitted from the posterior iris[23].

1.4 Treatment Modalities - Topical Treatment

The sole treatment of glaucoma is the reduction of intraocular pressure. This can be achieved surgically or with the aid of medication[24]. Normally, for the treatment of primary open-angle glaucoma, first-line treatment is selective laser trabeculoplasty or topical medication[25]. Treatments of other kinds of glaucoma depend on the cause. For example, the end treatment of acute angle-closure glaucoma is a peripheral iridotomy, which also prevents future attacks[26].

There are five major classes of topical medication for the treatment of glaucoma: alpha agonists, carbonic anhydrase inhibitors, beta-blockers, prostaglandins, and cholinomimetics[27]. The latter two function by increasing the outflow of aqueous humor, while the first three decrease its production. Side effects include blurry vision, periocular pigmentation, increased eyelash growth, and contact dermatitis[28]. The table below (Table 1) summarizes the most important classes of glaucoma drugs, their mechanism of action, and common side effects [27,29].

Table 1: The most common classes of glaucoma medications.

Drug Class	Mechanism of Action	Common Side Effects
Beta-Blockers	Decreases production of aqueous humor	None to minor
Prostaglandins	Improves outflow of aqueous humor	Increased eyelash growth, iris, and periocular hyperpigmentation
Cholinomimetics	Improves outflow of aqueous humor	Cyclospasm and Miosis
Carbonic Anhydrase Inhibitors	Decreases production of aqueous humor	None to minor
Alpha Agonists	Decreases production of aqueous humor	Conjunctivitis, blurry vision, contact dermatitis

The only available oral medication is Acetazolamide, which is a carbonic anhydrase inhibitor[29].

1.5 Treatment Modalities - Surgical & Laser Treatment

1.5.1 Laser Treatment - Selective Laser Trabeculoplasty

Selective laser trabeculoplasty is one of the first-line treatments (along with topical medication) for the treatment of glaucoma. It aims at increasing the outflow of aqueous humor by inducing cellular modulation in the trabecular meshwork[25]. It deploys an Nd:YAG laser to supply energy at a wavelength of about 530 nm and subsequently, shots of about 1 mJ are delivered throughout the trabecular meshwork (90 – 360 degrees)[30]. As melanin absorbs energy from 400 nm upwards (up to 720 nm), the energy supplied by the laser lies within this range and is absorbed by the pigment[31]. This uptake of thermal energy by melanin is thought to induce a biological reformation in the trabecular meshwork, thus, improving the outflow. Although this often achieves good results, the effects seen are temporary and the procedure often needs to be repeated[25,32,33].

1.5.2 Laser Treatment - Trabeculopuncture

Although this treatment modality is not common practice anymore, it was carried out quite frequently until the introduction of ab-interno trabeculectomy in the early 1990s. The idea behind trabeculopuncture is to use Nd:YAG, argon, or ruby laser to create micropunctures in the trabecular meshwork into Schlemm's canal, thereby creating a direct connection between the anterior chamber and the latter structure[34]. Although one study has shown that a puncture diameter of 100 µm was sufficient for good outflow, no exact size has been agreed upon[35]. It is common for several punctures to be performed simultaneously in order to increase the chances of success.

This procedure has few complications and is relatively easy to perform; however, its effects are temporary [36]. Common complications include intraocular pressure spikes, mild anterior chamber inflammation, and hemorrhage[37,38]. Although not a long-lasting treatment for glaucoma, trabeculopuncture may aid in delaying surgery for up to two years[39]. Studies have also shown that this procedure decreased intraocular pressure in patients with juvenile open-angle glaucoma but failed to do in

those with primary open-angle glaucoma[40]. Nd:YAG lasers are still very commonly used in ophthalmology for post-cataract surgery capsulotomies and iridotomies due to angle-closure glaucoma[41,42].

The failure of trabeculopuncture has been attributed to the inflammatory reaction that it induces in the anterior chamber. This can lead to tissue repair in the form of scarring, which closes the patent puncture. The use of 5-Fluorouracil has been attempted to prevent this from happening; however, to no avail[43]. In summary, although this procedure induces a good intraocular pressure drop of up to 16 mmHg, its effects are too short-lived to be considered clinically useful.

1.5.3 Trabeculectomy

The above medical treatment and selective laser trabeculoplasty may achieve satisfactory intraocular pressure control in about 50% of patients. However, the other half will eventually end up requiring at least one surgical intervention[44]. Trabeculectomy is a well-established surgical procedure that is indicated in patients with an unsatisfactory clinical response despite maximal topical treatment. It involves the creation of a fistula between the anterior chamber of the eye and the subconjunctival space (figure 3). This results in a so-called "bleb" (figure 4) and a scleral flap due to the iatrogenic opening of the sclera [45].

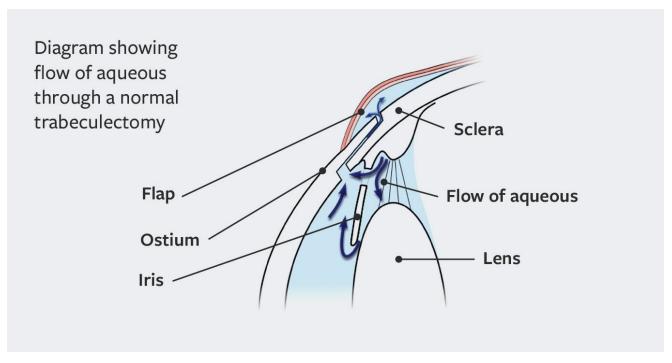


Figure 3: Traditional trabeculectomy. This procedure aims at providing an artificial outflow tract from the anterior chamber through the sclera and into the subconjunctival space. [46]

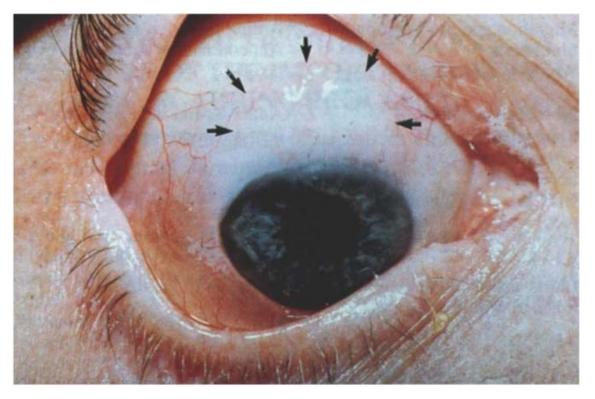


Figure 4: Post-glaucoma surgery bleb. Aqueous humor drains into this space and is then absorbed. The arrows mark the borders of the bleb. [47]

The success of trabeculectomy is dependent on many factors such as postoperative care, and the procedure is often accompanied by a high complication rate[48,49]. Failure has been associated with diabetes, younger age, postoperative complications, and a higher baseline intraocular pressure[50]. With the development of tube implant shunts, the popularity of trabeculectomies has been decreasing[51]. Despite that, some studies have shown that this procedure is superior to tube shunts, especially in patients with normal-tension glaucoma who have a very low target intraocular pressure[52,53].

Possible complications of trabeculectomy include[54,55]:

- increased intraocular pressure
- anterior chamber flattening (due to hypotony)
- choroidal effusion (figure 5)
- cataract formation
- fibrosis
- blebitis
- anterior chamber bleeding

To avoid post-surgical fibrotic reactions, injections of an anti-metabolite such as 5-Fluorouracil are usually deployed[54]. An insufficiently reduced intraocular pressure can be treated using suture lysis. Furthermore, bleb fibrosis can be treated with needling if needed[56].

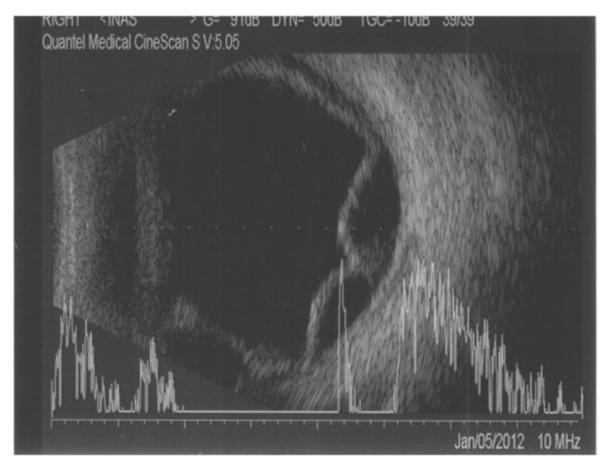


Figure 5: An ultrasound image showing chorioretinal detachment and an impressive choroidal effusion. [57]

1.6 Microinvasive Glaucoma Surgery (MIGS)

MIGS is a relatively recent category of surgeries developed for the treatment of glaucoma. They aim at excising or bypassing the trabecular meshwork and improving the overall outflow facility[58,59].

1.6.1 The iStent

One device that was invented for such a purpose is the trabecular micro-bypass stent, also known as iStent (Glaukos Corporation, San Clemente, California, United States). This device connects the anterior chamber directly to Schlemm's canal, thereby circumventing the trabecular meshwork (figure 5)[60]. The implantation of these stents is usually combined with phacoemulsification and intraocular lens insertion

surgeries[61]. Studies have shown that combining the two results in a satisfactory reduction of the intraocular pressure and reduces the number of drops required for topical therapy[60,62]. Even though these stent implantation surgeries are usually not performed as standalone surgeries, a recent meta-analysis demonstrated the effectiveness of these stents in independently achieving the two goals above and that these benefits were present for at least 42 months postoperatively[63].

Central Outlet 80 µm diameter

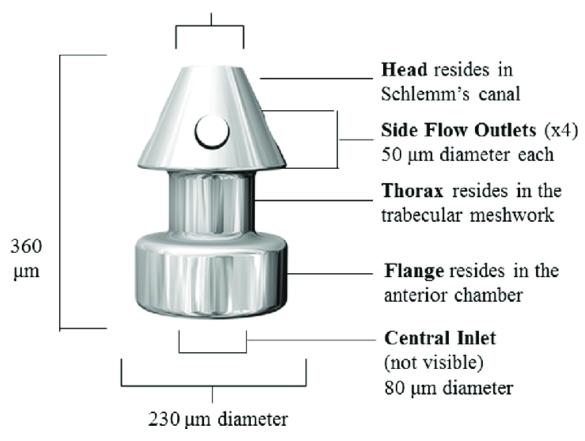


Figure 6: Stent design and dimensions of the iStent inject. The head is inserted directly into Schlemm's canal, while the flange is located in the anterior chamber. This enables a direct connection between the two compartments. [61]

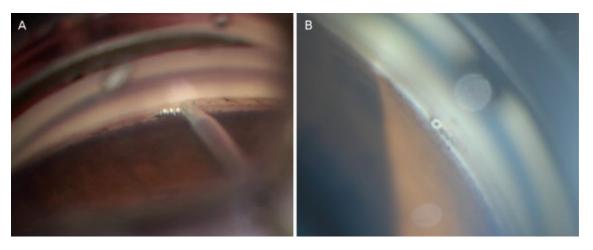
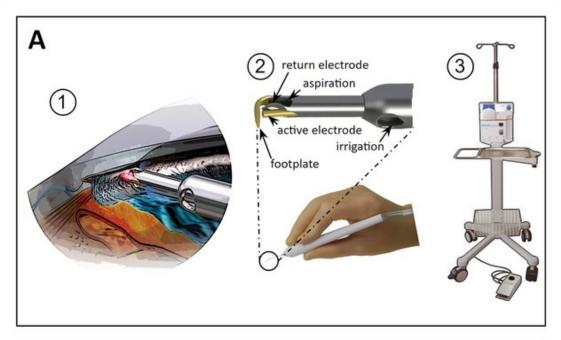


Figure 7: (A) Insertion of the stent. (B) Visualization of the iStent in the trabecular meshwork. [64]

1.6.2 The Trabectome

While some devices simply bypass the trabecular meshwork; others use more destructive methods to get to Schlemm's canal. Ab-interno ablation, excision, and disruption of the trabecular meshwork can also lower intraocular pressure effectively in glaucoma [65]. This is especially true for primary open-angle glaucoma with an outflow resistance at the most proximal part of the conventional outflow tract. Secondary open-angle glaucomas that have pathomechanisms that principally affect the trabecular meshwork such as pigmentary [66,67], pseudoexfoliation [68], steroid- [69], and anti-VEGF (vascular endothelial growth factor)-agent-induced [70] glaucoma benefit from these procedures even more.

One device that functions using plasma-mediated ablation (ionization and disintegration) is the Trabectome (MicroSurgical Technology, Redmond, WA, USA). Plasma-mediated ablation of the trabecular meshwork with this device has been available to surgeons for a longer time [71] than other techniques such as excisional removal [72,73]. During this procedure, the tip of the device is inserted into the anterior chamber of the eye and the trabecular meshwork along the nasal 180-degree circumference is ablated[74]. This effectively eradicates outflow resistance coming from the nasal trabecular meshwork[75]. The Trabectome is also equipped with a footplate at its tip, which prevents the removal of the outer wall of Schlemm's canal[76]. Figure 8 demonstrates how this device functions.



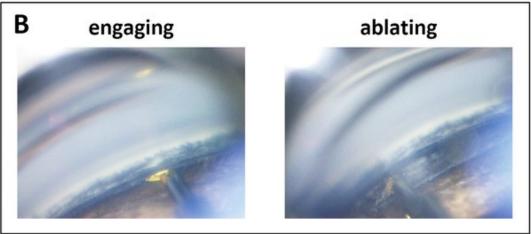


Figure 8: Ab-interno trabeculectomy using the Trabectome. (A) The tip of the device is inserted into the angle of the eye (1), engaging the trabecular meshwork between the bipolar electrodes and the footplate (2). The device operates with the aid of a stand equipped with a footswitch, generator, and a pump (3). (B) Gonioscopic view during the engaging (left) and ablating (right) processes. [77]

The Trabectome is a relatively well-studied device, and there is abundant evidence of its efficacy in reducing intraocular pressure in glaucoma patients[78–82]. It has also been efficacious in controlling pressures in early, mild and moderate glaucoma, although pressure reduction has been reported to be greater in patients with higher pressures[68]. Furthermore, although useful in primary open-angle glaucoma, it

has an even greater success in patients with pseudoexfoliation and steroid-induced glaucoma[68].

1.6.3 The TrabEx+

Another ab-interno trabeculectomy device that involves the manipulation of the anterior chamber and the trabecular meshwork is the TrabEx+ (figure 9) (MicroSurgical Technology, Redmond, WA, United States). Unlike the Trabectome, which ablates the trabecular meshwork, this device excises it. It has a dual-blade function which enables lifting and excising sections of the trabecular meshwork[73]. Furthermore, it includes an active irrigation and aspiration port which maintains depth and visibility in the anterior chamber[76].

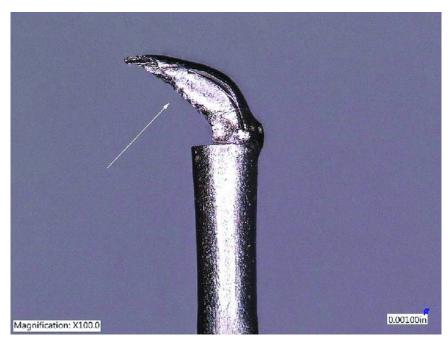


Figure 9: The TrabEx+ with its dual serrated blades. [83]

Dual blade excision was invented earlier than ablation but was only used to obtain biopsies [84]. The current leading modalities of this excisional TM removal are the TrabEx+ and the Kahook Dual Blade (New World Medical, Rancho Cucamonga, CA, USA). The absence of a bleb and the theoretical limit of maximal IOP reduction to the level of episcleral venous pressure constitute important safety features in comparison to traditional trabeculectomy. They avoid hypotony as well as leaks which can occur after filtering surgery and epibulbar glaucoma drainage implants [85].

1.6.4 Ablation versus Excision

There are compelling advantages to both plasma-mediated ablation (Trabectome) and dual blade excision (TrabEx+). Ablation enables the atraumatic molecularization and aspiration of the trabecular meshwork [71]. In contrast, excisional methods can be used to obtain biopsies and excise the trabecular meshwork to a similar extent but without the need to purchase a high-frequency alternating current generator. An advantage of TrabEx+ over the Kahook dual blade is the active irrigation and aspiration [76]. A downside of both excisional techniques is that a dual cut of the trabecular meshwork cannot always be initiated, and such remaining TM lips can reapproximate [86]. The same impediment causes traditional goniotomy to be unreliable in adult primary-open angle glaucoma compared to pediatric glaucomas because the scleral spur is more elastic in children [86]. It visibly retracts the posterior trabecular meshwork lip during incision. Literature regarding TrabEx+ is limited to studies of its efficiency in obtaining TM biopsies in vivo [73] and ex vivo porcine anterior segments [66,76,87].

1.6.5 Treatment Goals

Irrespective of whether the selected treatment is surgical or medical, the goal of therapy is to reduce the intraocular pressure to adequate levels, as this is the only modifiable factor in the disease[29]. The appropriate level is usually defined by the treating physician based on the patient's age, life expectancy, and other ocular and systemic comorbidities. The final goal is to preserve useful vision[29]. A step-up of treatment is usually indicated when intraocular pressure levels are unsatisfactory or the patient develops further scotomas.

1.6.6 Complications of MIGS

MIGS are associated with the following complications[88]:

- Intraocular pressure spikes
- Transient visual deterioration
- Anterior chamber bleeding
- Hypotony

- Infections
- Possible revisions and additional surgeries
- Cystoid macular edema (especially when performed with cataract surgery)
- Toxic anterior segment syndrome

Toxic anterior segment syndrome is a condition defined by corneal edema and a sterile anterior segment inflammation 1-2 days after intraocular surgery[89]. Symptoms include a decrease in vision and hypopyon (collection of pus in the anterior chamber). It is usually treated with steroid drops and responds well to therapy[90].

1.7 Hypothesis

Given the many treatment options and therapy modalities, it is worthwhile to compare different surgical instruments to discern the efficacy differences between them. Most studies carried out on these devices test for their efficacy in reducing intraocular pressure levels and medications; however, there are comparatively fewer studies that compare surgical instruments directly to each other. Given the effectiveness of excisional and ablative ab interno trabeculectomy in clinical studies [72,91,92], we hypothesized that relevant differences between two devices, the Trabecome and TrabEx+ could be discovered by applying a modern statistical method to existing data in the form of coarsened exact matching (CEM). CEM reduces confounding by enabling a highly balanced comparison [93,94]. Using this method, it was previously found in two studies that Trabectome performed significantly better than trabecular bypass implants [37,94,95].

H0: No statistically significant differences exist in the long-term outcomes of TrabEx+ and Trabecome, with regard to intraocular pressure, medication count, and postoperative complications.

H1: Statistically significant differences exist in the long-term outcomes of TrabEx+ and Trabecome, with regard to intraocular pressure, medication count, and postoperative complications.

2. Methods

2.1 Study Design

This study was a retrospective study that was approved by the institutional review board (IRB) of the University of Würzburg. Due to its retrospective nature, informed consent was waived. The study abided by the principles stated in the declaration of Helsinki and its subsequent amendments. We performed a chart review of all patients with open-angle glaucoma who had undergone TrabEx+ surgery from February 2020 to February 2021. The surgical indication for Trabectome and TrabEx+ was an IOP value above target level on maximally tolerated topical treatment, or a desire to reduce the number of glaucoma medications. Those with a follow-up of 6 months or longer were matched to existing Trabectome data [96,97] using *coarsened exact matching (CEM)*.

A total of 155 patients were included in the study: 56 of which underwent TrabEx+ surgery, while the rest (n = 99) underwent Trabectome surgery. The patients were then matched based on their intraocular pressure levels and age. After the matching process, 53 patients in each group were assigned to each other as pairs. The intraocular pressure was exactly matched while age was only coarsely matched.

2.2 Matching

Matching is a statistical method in which the baseline demographics are matched for similarity to decrease confounding variables and enable a more direct comparison of two or more groups[98]. Exact matching ensures the pairing of identical values, while CEM involves grouping the data and matching groups instead of individual values[93].

2.3 Surgical Interventions

Trabectome / TrabEx+ Surgeries

All surgeries were carried out by the same surgeon. The patient's head was tilted 45° away from the surgeon. After a temporal clear corneal incision, light pressure

was applied to the posterior lip of the incision to release a small amount of aqueous humor. The resulting hypotension, caused venous blood to reflux into Schlemm's canal and helped identify the proper location. The tip of the instrument was inserted. The trabecular meshwork was visualized with a goniolens, and then ablated (Trabectome) or excised (TrabEx+) along approximately 120° of the nasal circumference. Subsequent blood reflux indicated a successful removal of the trabecular meshwork and the inner wall of Schlemm's canal. After retraction of the instrument, the anterior chamber was reformed by injecting balanced salt solution (BSS) and the corneal incision was sealed by hydration. The postoperative treatment was similar for both procedures and consisted of dexamethasone eye drops tapered by one drop per week and antibiotic eye drops for one week; glaucoma drops were continued as deemed necessary.

Phacoemulsification - Intraocular Lens Insertion

If the glaucoma procedure was combined with cataract surgery, the latter was usually performed second. The initial incision was then expanded with a keratome in the right position. A capsulorhexis (anterior lens capsule removal) was initiated centrally with Utrata forceps and carried out continuously, linearly, and circularly. After hydrodissection with a cannula, the lens was checked for rotational mobility.

The lens was subsequently approached and split in a direct chop maneuver with the Nagahara device in the left hand. The nucleus and epinucleus were broken into six wedge-like pieces by repeated chopping with vertical and horizontal chops, which were rotated counterclockwise. Thereafter, each piece was aspirated with the phacoemulsification needle and crushed.

The remaining cortex was removed with irrigation and aspiration, and the anterior and posterior capsules were carefully polished. The capsular bag was shaped with viscoelastic, followed by the insertion of an intraocular lens, which was rotated into the appropriate position. The viscoelastic was then aspirated. Finally, the corneal incision was sealed with hydration and checked for integrity.

2.4 Inclusion Criteria

We defined our inclusion criteria as any patient over the age of 18 with primary open-angle glaucoma that underwent either TrabEx+ surgery at our institution (Universitätsklinikum Würzburg) in the period from February 2020 to February 2021. A minimum follow-up duration of 6 months was also required to be included in the study.

2.5 Exclusion Criteria

Our exclusion criteria were:

- Patients below the age of 18 years
- Patients with glaucoma types other than primary open-angle glaucoma
- Patients with a follow-up of less than 6 months
- Patients with a history of ocular surgeries

2.6 Patient Examination

Surgical glaucoma patients were examined once preoperatively and daily postoperatively during their inpatient stay. Thereafter, they presented at certain intervals for check-ups. During every examination, the patients were asked about their symptoms and their general satisfaction with their vision. After that, visual acuities and intraocular pressures were recorded. The anterior and posterior chambers of the eye were examined using various magnifying lenses and a slit lamp. The existence of complications, need for further surgery, and medications were assessed at every visit.

2.7 Demographic Information

Demographic parameters recorded during follow-up examinations included age, gender, glaucoma type, number, and type of glaucoma drops (therapy regimen). Additionally, the date of surgery, along with the type (Trabectome or TrabEx+) and whether complications arose was also noted. Glaucoma surgeries carried out with concomitant cataract surgeries were likewise marked.

2.8 Glaucoma Drop Modification

At every follow-up visit, intraocular pressure was assessed, and glaucoma drops were correspondingly increased or decreased.

2.9 Visual Acuity Determination

Visual acuity was measured using the same protocol for all included subjects. Patients were seated 5 meters away from a standardized Snellen chart (see figure below) and asked to read letters. We tested one eye at a time by trial frame refraction with the other eye covered. Patients read the letters or numbers from left to right and from top to bottom, each descending line corresponding to a sharper visual acuity. We considered the patient to have a visual acuity of the final line that he or she could read 3/5 letters or numbers correctly from.

If the patient could not read anything at all, a similar board was brought closer to the patient (1 m away) and the patient was then asked to read. The failure of this technique was followed by having the patient count fingers, detect hand motion and finally, perceive light.

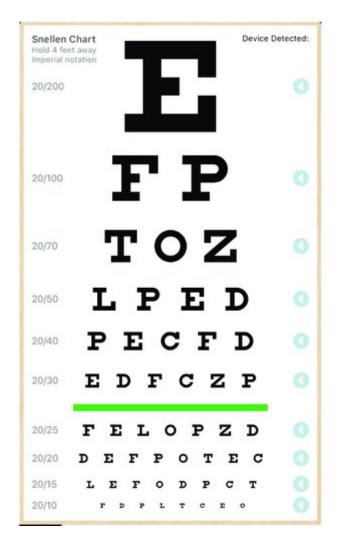


Figure 10: An example of a Snellen chart. The ability to read the lines at the bottom corresponds to a greater visual acuity. [99]

2.10 Measurement of Intraocular Pressure

The intraocular pressure was measured with a Goldmann applanation tonometer (Haag-Streit, Köniz, Switzerland). The value was determined at the slit lamp with the aid of cobalt blue light. Before the start of the measurement, 1-2 drops of Thilorbin® eye drops were instilled into each eye. Thilorbin® is a pharmaceutical product that contains a mixture of Fluorescein (a fluorescent dye) and Oxybuprocain (a local anesthetic). The tonometer head was then mounted on the slit lamp and brought to the center of the patient's cornea.

The application is based on the principles of the Imbert-Fick law. This law states that the force needed to applanate (flatten) a certain area of a sphere is equal to the

pressure inside the sphere multiplied by the respective area[100]. The intraocular pressure is read in millimeters of mercury (mmHg). This value is read 3 times a day at the inpatient unit and once during follow-up visits.



Figure 11: A Goldmann applanation tonometer. [101]

2.11 Surgical Success

Surgical success was defined as a total intraocular pressure decrease \geq 20%, with a final pressure \leq 21 mmHg. In addition, patients who had a medication reduction of one drop or more were also considered to have undergone a successful intervention. Intraocular pressure levels and medications were not only compared between groups, but also within groups to check for significant differences between preoperative and postoperative values. Visual acuity was also compared pre- and postoperatively.

2.12 Statistical Analysis

Our sample size calculation indicated that 48 patients would be needed in the TrabEx+ group to compare them to Trabectome patients and achieve a statistical power of 80%. This calculation was carried out with the aid of G*Power (Version 3.1.9.7., Heinrich Heine University, Düsseldorf, Germany). Data were analyzed using SPSS Statistics (Version 26, IBM, New York, USA). Means and standard deviations were calculated for continuous variables, while frequencies and percentages were used for categorical variables. The Kolmogorov-Smirnov test was run to test for a normal distribution of data. Patients were exactly matched by baseline intraocular pressure and coarsened matched by age. To compare the means of the primary outcome parameters, a t-test or a Mann-Whitney U test was used. A p-value of 0.05 or less was considered statistically significant. The statistical analysis was conducted by Mohamad Dakroub.

3. Results

3.1 Demographics

A total of 106 patients were included in our final analyses, divided into 53 patients in each of the Trabectome and TrabEx+ groups. Table 2 shows the baseline characteristics of the matched groups. There were no differences in age, gender, glaucoma type, baseline intraocular pressure, and visual acuity between both groups (all p-values > 0.05).

3.1.1 Intraocular Pressure

Matched baseline intraocular pressure was the same in both groups with a value of 16.6 ± 4.6 mmHg (p = 0.97), which is quite low for glaucomatous eyes.

3.1.2 Age and Gender

Age was also similar, with values of 73.7 ± 8.8 years in the TrabEx+ group and 71.9 ± 9.9 years in the Trabectome group (p = 0.24). Both groups had more females than males, but the proportions of both were similar between groups (p = 0.7).

3.1.3 Medications

TrabEx+ patients were taking significantly more medications, 2.1 ± 1.4 drops, than their Trabectome patients with 1.4 ± 1.1 drops (p < 0.001).

3.1.4 Visual Acuity

Visual acuity was similar between groups, with the TrabEx+ patients having a non-significantly better vision than their Trabectome counterparts (0.7 versus 0.6 for TrabEx+ and Trabectome patients, respectively, p = 0.07).

3.1.5 Glaucoma Type

Primary open-angle glaucoma patients represented the majority, 73.6%, of patients in both groups; low-tension glaucoma comprised the remaining 26.4%.

3.1.6 Simultaneous Cataract Surgery

Most patients (> 80% in both groups) had a simultaneous phacoemulsification/intraocular lens insertion (Phaco/IOL) with their TrabEx+ or Trabectome procedure.

Table 2 Matched baseline characteristics of TrabEx+ and Trabectome

Variable	TrabEx+ (n = 53)	Trabectome (n = 53)	p-value
Age (years)	73.7 ± 8.8	71.5 ± 9.9	0.24
Female (n, %) Male (n, %)	31 (58.5 %) 22 (41.5 %)	29 (54.7 %) 24 (45.3 %)	0.7
POAG (n, %) LTG (n, %)	39 (73.6 %) 14 (26.4 %)	39 (73.6 %) 14 (26.4 %)	1.0
IOP _{BL} (mmHg)	16.6 ± 4.6	16.6 ± 4.6	0.97
Med _{BL}	2.1 ± 1.4	1.4 ± 1.1	< 0.001*
VA _{BL}	0.7 ± 0.3	0.6 ± 0.3	0.07
With Phaco (n, %)	45 (84.9 %)	44 (83.0%)	0.8

POAG = Primary Open-Angle Glaucoma; LTG = Low-Tension Glaucoma; IOP $_{\rm BL}$ = Intraocular Pressure at Baseline; Med $_{\rm BL}$ = number of medications at baseline; VA $_{\rm BL}$ = visual acuity at baseline; With Phaco = in combination with cataract surgery; * p-value < 0.05

3.2 Comparison to Baseline

3.2.1 6-Month Postoperative Intraocular Pressure

From a baseline intraocular pressure of 16.6 ± 4.6 mmHg in both groups, our 6 months postoperative mean intraocular pressure was reduced to 14.8 ± 4.3 mmHg in the TrabEx+ group and 13.4 ± 3.4 mmHg in the Trabectome group. Both values were significantly lower than baseline (p < 0.01 for both, table 3).

3.2.2 12-Month Postoperative Intraocular Pressure

At 12 months, intraocular pressure levels in TrabEx+ were similar to baseline values (14.9 \pm 6.0 mmHg, p = 0.135). Trabectome values were significantly lower than baseline (14.1 \pm 3.8, p < 0.001).

3.2.3 Medications

Both groups took significantly fewer glaucoma medications at 6 and 12 months compared to baseline values (Table 3, both p < 0.005).

3.2.4 Visual Acuity

In the TrabEx+ group, vision remained stable at 0.7 ± 0.3 6 and 12 months postoperatively (both p-values > 0.05). In the Trabectome group, vision improved non-significantly from 0.6 ± 0.3 to 0.7 ± 0.3 at 6 months (p = 0.13). At 12 months, a further significant improvement was seen (0.8 ± 0.3, p = 0.02).

3.3 Intergroup Comparison

3.3.1 Intraocular Pressure

In the inter-group comparison, intraocular pressure levels at the 6 and 12-month follow-ups were similar (p = 0.12 and p = 0.99, respectively; Table 3). Total pressure reduction at 6 months was 2.0 ± 5.0 mmHg in TrabEx+ and 3.2 ± 4.8 mmHg in

Trabectome. These values at 12 months were 0.6 ± 5.9 mmHg in TrabEx+ and 2.4 ± 4.8 mmHg in Trabectome. There was no significant difference in these values between both groups at 6 or 12 months (p = 0.41 and 0.2, respectively).

3.3.2 Medications

Similar to their baseline medications, TrabEx+ patients still used more glaucoma medications compared to their Trabectome counterparts at both 6 and 12 months (p < 0.001). Medication reduction in TrabEx+ and Trabectome was 0.43 ± 1.3 and 0.88 ± 1.4 drops at 6 months and 0.63 ± 1.29 and 0.75 ± 1.25 drops at 12 months, respectively. These values did not differ significantly between both groups (p >0.05).

Table 3 Follow-up parameters compared between TrabEx+ and Trabectome

Variable/Group	TrabEx+ (n = 53)	Trabectome (n = 53)	p-value TrabEx+ vs Trabectome	p-value baseline vs. follow-up (TrabEx+/Trabecto me)
IOP _{BL} (mmHg)	16.5 ± 4.6 (n = 53)	16.5 ± 4.6 (n = 53)	0.97	
IOP ₆ (mmHg)	14.8 ± 4.3 (n = 46)	13.4 ± 3.4 (n = 52)	0.12	0.002*/<0.001*
IOP ₁₂ (mmHg)	14.9 ± 6.0 (n = 40)	14.1 ± 3.8 (n = 53)	0.99	0.13 / < 0.001*
Med _{BL} (drops)	2.1 ± 1.4 (n = 53)	1.4 ± 1.1 (n = 53)	0.004*	
Med ₆ (drops)	1.7 ± 1.5 (n = 47)	0.5 ± 0.8 (n = 52)	< 0.001*	0.03*/<0.001*
Med ₁₂ (drops)	1.5 ± 1.3 (n = 40)	0.6 ± 1.0 (n = 53)	< 0.001*	0.005*/<0.001*

VA _{BL}	0.7 ± 0.3 (n = 53)	0.6 ± 0.3 (n = 53)	0.07	
VA ₆	0.8 ± 0.3 (n = 47)	0.7 ± 0.3 (n = 52)	0.12	0.39 / 0.14
VA ₁₂	0.7 ± 0.3 (n = 40)	0.8 ± 0.3 (n = 53)	0.76	0.45 / < 0.01*
Complications (n, %)	4 (7.5%)	1 (1.9%)	0.17	

 IOP_{BL} = intraocular pressure at baseline; IOP_6 = intraocular pressure at 6 months; IOP_{12} = intraocular pressure at 12 months; Med = medication; VA = visual acuity; * p-value < 0.05

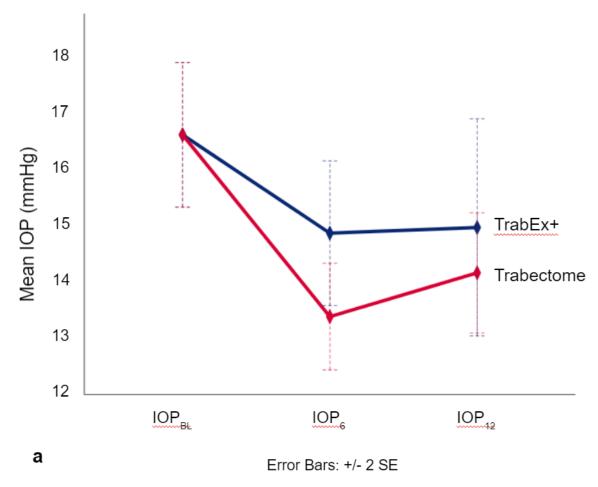


Fig. 12a Mean intraocular pressure (IOP) for TrabEx+ (blue) and Trabectome (red). Trabectome and TrabEx+ had a low baseline intraocular pressure. A pressure reduction occurred in both, but was more pronounced in Trabectome. IOP_{BL} = IOP at baseline; IOP₆ = IOP at 6 months; IOP₁₂ = IOP at 12 months; SE = standard error.

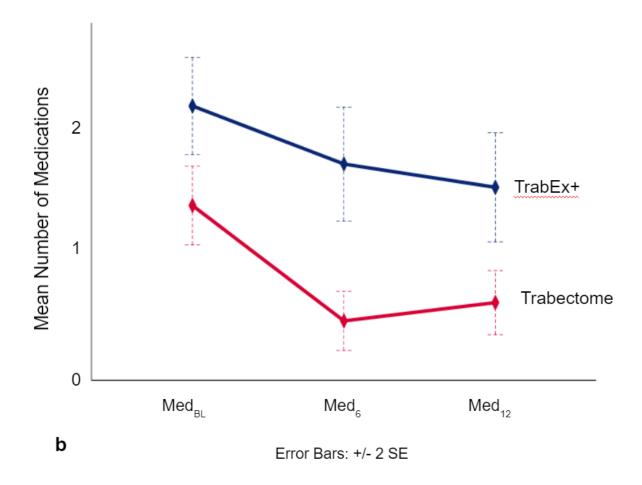


Fig. 12b Mean number of medications for TrabEx+ (blue) and Trabectome (red). TrabEx+ took more medications than Trabectome at baseline. A reduction in medications was achieved in both T and TEx, and to a similar extent. $Med_{BL} = number$ of medications at baseline; $Med_6 = number$ of medications 6 months after surgery; $Med_{12} = number$ of medications 1 year after surgery; SE = standard error.

3.4 Unmatched Data

Table 4 depicts the unmatched data for each group. The following differences were found compared to the matched data:

There was a significant difference in age between both patient groups with
 TrabEx+ patients being significantly older than Trabectome patients (p = 0.002).

- Here, both TrabEx+ and Trabectome showed a significant postoperative IOP decrease at both 6 and 12 months (all p-values < 0.05).
- TrabEx+ patients had a significantly better baseline visual acuity than
 Trabectome patients (p = 0.03).
- Visual acuity was improved in Trabectome patients at both 6 and 12 months postoperatively (p-value < 0.01).

Similarly to our matched data, intraocular pressure levels were similar in both groups at all time points (all p-values > 0.05). Once again, compared to their baselines, TrabEx+ and Trabectome used fewer medications 6 and 12 months postoperatively (all p-values < 0.05) and Trabectome needed fewer medications than TrabEx+ at both follow-ups (both p < 0.001*).

Table 4 Unmatched Comparison of TrabEx+ and Trabectome

Variable/Group	TrabEx+ (n = 56)	Trabectome (n = 99)	p-value TrabEx+ vs. Trabectome	p-value baseline vs. follow-up (TrabEx+/Trabectome)
Age (Years)	74.0±9.1 (n = 56)	68.84±10.4 (n = 99)	0.002*	
Gender Ratio (M:F)	1:1.4	1:1.25	0.68	
Phaco/IOL (n, %)	45 (80.4%)	86 (86.9%)	0.28	
IOP _{BL} (mmHg)	17.5±5.9 (n= 56)	17.1±5.1 (n = 99)	0.92	

IOP ₆ (mmHg)	14.8±4.2 (n = 49)	13.6±3.3 (n = 95)	0.11	0.001*/<0.001*
IOP ₁₂ (mmHg)	15.1±5.9 (n = 44)	14.3±3.9 (n = 99)	0.82	0.037* / < 0.001*
Med _{BL} (Drops)	2.2±1.3 (n = 56)	1.4±1.2 (n = 99)	0.001*	
Med ₆ (Drops)	1.7±1.5 (n = 50)	0.6±0.9 (n = 95)	< 0.001*	0.03*/<0.001*
Med ₁₂ (Drops)	1.6±1.3 (n = 44)	0.7±1.0 (n = 99)	< 0.001*	0.005*/<0.001*
VA _{BL}	0.7 ± 0.3 (n = 56)	0.6 ± 0.3 (n = 99)	0.03*	
VA ₆	0.8 ± 0.3 (n = 50)	0.7 ± 0.3 (n = 95)	0.17	0.26 / < 0.01*
VA ₁₂	0.7 ± 0.3 (n = 44)	0.7 ± 0.3 (n = 99)	0.90	0.52 / < 0.01*

 IOP_{BL} = intraocular pressure at baseline; IOP_6 = intraocular pressure at 6 months; IOP_{12} = intraocular pressure at 12 months; Med = medication; VA = visual acuity; *p-value < 0.05.

3.5 Success Rates

3.5.1 Success Rate: Intraocular Pressure ≤ 21 mmHg OR Reduction ≥ 20%

Applying success criteria common to minimally invasive surgeries, an intraocular pressure decrease of \geq 20% or a final intraocular pressure \leq 21 mmHg, TrabEx+ and Trabectome were at or exceeded 93% at six months and 95% at one year. Success rates were similar between both groups (p-values > 0.05)

3.5.2 Success Rate: Intraocular Pressure ≤ 21 mmHg AND Reduction ≥ 20%

Using the more stringent criteria of intraocular pressure decrease of \geq 20% and final intraocular pressure \leq 21 mmHg, success was achieved in more than 40% at six months and in more than 32% at one year. These values were, expectedly, lower than those of the OR criteria. Both values were similar between groups (p-values \geq 0.05).

3.5.3 Success Rate: Intraocular Pressure Reduction and Medication Reduction

Success in both intraocular pressure reduction and at least one medication reduction was achieved in 15.2% in TrabEx+ and 13.5% in Trabectome at 6 months. These values were 10.0% (TrabEx+) and 7.7% (Trabectome) at one year, respectively.

Table 5 Success rates of TrabEx+ and Trabectome.

Success / Group	TrabEx+	Trabectome	p-value
IOP (OR criterion) 6 months (n, %)	43/46 (93.5%)	50/52 (96.0%)	0.55
IOP (OR criterion) 12 months (n, %)	38/40 (95.0%)	52/53 (98.1%)	0.40
IOP (AND criterion) 6 months (n, %)	21/46 (45.6%)	21/52 (40.4%)	0.60
IOP (AND criterion) 12 months (n, %)	13/40 (32.5%)	17/53 (32.1%)	0.97
IOP (AND criterion) AND medication reduction, 6 months (n, %)	7/46 (15.2%)	7/52 (13.5%)	0.80

IOP (AND criterion) AND Medication Reduction, 12 months (n, %)	4/40 (10.0%)	4/53 (7.7%)	0.68
Medication Reduction, 6 months (n, %)	20/46 (43.4%)	30/52 (57.7%)	0.16
Medication Reduction, 1 year (n, %)	17/40 (42.5%)	28/53 (52.8%)	0.32

OR criterion = IOP decrease of \geq 20% or final IOP \leq 21 mmHg; AND criterion = IOP decrease of \geq 20% and final IOP \leq 21 mmHg; med reduction = at least 1 drop less compared to baseline

3.6 Complications

Four (7.5%) TrabEx+ patients experienced postoperative complications, while in the Trabectome group this value was only 1 (1.9%). Both values are quite low, and no significant differences were seen between groups (p-value = 0.17).

The table below depicts the complications in both groups.

Table 6 Postoperative complications

TrabEx+	Trabectome
- Toxic Anterior Segment Syndrome (n = 1, 1.9%)	- Cystoid macular edema (n = 1, 1.9%)
- Cystoid macular edema (n = 3, 5.6%)	

3.7 Need For Further Surgery

Two TrabEx+ patients (3.8%) required further glaucoma surgeries and received a microshunt (Preserflo, Santen, Osaka, Japan, n = 2). No Trabectome patients underwent further surgeries within the time frame of the study.

4. Discussion

In this study, we applied coarsened exact matching to compare the 1-year outcomes of excisional ab interno trabeculectomy between a newer dual-blade device (TrabEx+) and an established plasma-mediated ablation (Trabectome). The advantage of matching is that small intraocular pressure differences caused, for instance, by wound healing, can be detected. Using matching, it was previously found that an intraocular pressure increase seen in trabecular bypass stents is absent in ab interno trabeculectomy [94,95]. The observed difference in intraocular pressure reduction around the time a foreign body reaction and fibrosis were also observed in other trabecular bypass studies, suggesting this may be the underlying cause [102,103].

For the present study, we had chosen baseline intraocular pressure and age as the matching criteria because they are the two most important determinants of postoperative intraocular pressure. According to a recently published study, the formula with which they can diminish the intraocular pressure is 0.73 mmHg × baseline pressure plus 0.03 mmHg × age [104]. In contrast, the preoperative number of medications affects the postoperative IOP result only in a minor way, by reducing the intraocular pressure by 0.09 mmHg × number of medications [104]. Because the difference in the average medication intake was only 0.7 drops, we would expect the intraocular pressure reduction difference due to medications in this particular case to be negligible (0.063 mmHg). The match caused our patient demographics to have the exact same baseline intraocular pressure as well as adequate similarities in other variables, all of which were found to not be significantly different, except for medication intake. Patients who underwent TrabEx+ were taking more medications than Trabectome. This could imply that the pressure in these patients was more refractory to medical treatment than in Trabectome. It is important to point out that this would not have disadvantaged TrabEx+. On the contrary, it is often eyes with more advanced glaucoma, not milder glaucoma, that have a larger response to ab-interno trabeculectomy, possibly because their trabecular meshwork is more diseased and less permeable [68,105]. When this large resistance is removed, a greater total intraocular pressure decrease can ensue.

Remarkably, both TrabEx+ and Trabectome showed an intraocular pressure reduction despite a relatively low preoperative pressure of 16.6±4.6 mmHg. Such a low preoperative pressure is rather close to some postoperative values achieved in other studies. For instance, in a retrospective Trabectome analysis [106], the mean

postoperative pressure was 16.5 ± 2.8 mmHg; in a propensity score-matched comparison of Trabectome and Baerveldt implants [107], this value was 16.1 ± 4.1 mmHg. Indeed, the preoperative intraocular pressure in our present study is almost equal to the computed, achievable postoperative value for a typical glaucoma patient. Using a hypothetical patient, a 75-year-old pseudophakic patient with primary open-angle glaucoma and a baseline intraocular pressure of 21 mmHg on two medications, a final postoperative value of 16.8 mmHg would be expected [104]. TrabEx+ and Trabectome appear to be most appropriate for patients who already have a low preoperative intraocular pressure if they want to avoid the complications of filtering surgery. It is also appropriate for those, who primarily need cataract surgery but also want to give intraocular pressure and medication reduction a chance at the same time. As the low rate of patients who fulfilled both the intraocular pressure and the medication success criteria (8-15%) highlights, the riskier trabeculectomy may be better able to achieve freedom from drops and reduce the intraocular pressure by a larger amount [108]. The reduced success rate of Trabectome in the setting of a low preoperative IOP has already been established before in other studies [78,109,110].

Despite similar baselines and TrabEx+ patients taking more medications to achieve this intraocular pressure, there was no statistically significant difference between the postoperative intraocular pressure of TrabEx+ and Trabectome when compared directly. The intraocular pressure reduction in TrabEx+ was significant at 12 months in the unmatched data, but the focus of our study was to detect differences in outcomes of two already quite similar surgical modalities. The pressure reduction in TrabEx+ appeared not to be statistically significant at 12 months in the matched comparison because the match eliminated unmatched data, and also because of the low baseline intraocular pressure. A low baseline pressure increases the number of subjects required to detect a before-after difference while maintaining a sufficient statistical testing power. A medication washout is often performed in clinical trials with a prospective design for this reason. Upon first glance, the intraocular pressure reduction seemed larger at 12 months in Trabectome than in TrabEx+, but this has to be interpreted with caution since the comparison of both groups did not show a difference. It is possible that these differences exist but remain undiscoverable with the numbers used here and are therefore not clinically relevant. A truly larger reduction in Trabectome could have pointed towards a less traumatic trabecular meshwork ablation with this technique. Plasma-mediated ablation is drag-free, while dual blade ablation requires that the trabecular meshwork be put under stretch before the cut can be

initiated. It is a common occurrence during surgery with the TrabEx+ and Kahook Dual Blade that drag transmits to the ciliary body band via processes that insert into the trabecular meshwork. Occasionally, this can cause a shallow and inconsequential cyclodialysis to form. It is also not unusual with excisional devices to catch the scleral spur, the outer wall of Schlemm's canal, or the innermost part of the roof of Schlemm's canal, potentially causing trauma. A full trabecular meshwork strip can also not always be excised, which causes the procedure in such patients to be more akin to a traditional goniotomy, including a chance that trabecular meshwork lips might reapproximate as is known to occur in trabeculotomy [86]. These concerns do not exist with Trabectome.

As is common to minimally invasive glaucoma surgeries in general, only a handful of complications occurred, too few for a meaningful statistical comparison. Both TrabEx+ and Trabectome can be considered very safe as only one serious and temporary complication occurred, toxic anterior chamber syndrome, that resolved with medical treatment. In comparison to our complications of 7% in TrabEx+ and 2% in Trabectome, previous Kahook Dual Blade studies reported complication rates ranging from 7% to 14% [92,111,112].

Our study had several limitations. The design was chosen to display intraocular pressure differences between TrabEx+ and Trabectome that cannot be easily detected without matching. We did so because there is already a considerable body of evidence demonstrating the effectiveness of excisional ab interno trabeculectomy, both ex vivo [66,76,87] and in vivo [72,91,92]. Our patients had a relatively low baseline pressure with small intraocular pressure and medication reduction. Patients with a higher baseline would likely have experienced a larger pressure reduction, as seen in prior studies [113,114]. Same-session cataract surgery does not have a clinically significant impact on Trabectome [104,115]. While it is reasonable to assume that the same applies to TrabEx+, this has not been established yet.

5 Conclusion

Although glaucoma is sometimes treated solely with topical medication, it is often the case that patients with the disease eventually undergo surgery. Ab interno ablation, excision, and disruption of the trabecular meshwork effectively lower intraocular pressure in primary open-angle glaucoma when the outflow resistance is at the most proximal part of the conventional outflow tract. Plasma-mediated ablation of the trabecular meshwork with the Trabectome has been available to surgeons since 2004, while excisional removal (Kahook Dual Blade, TrabEx+) was first introduced in 2014. This study aimed at comparing both techniques and applied coarsened exact matching to highlight small, device-specific differences between the Trabectome and TrabEx+. Despite a relatively low baseline intraocular pressure, both devices reduced this parameter significantly at 6 months, but only Trabectome managed to do so at 12 months. Both reduced medication count significantly at both points in time (6 and 12 months). When considering surgical success as a decrease in the intraocular pressure by more than 20%, success rates in both groups were relatively low, probably due to the low baseline intraocular pressure. With regard to intraocular pressure levels, visual acuity, success rates, and complications, there were no major differences between both devices; TrabEx+ were taking more medications than Trabectome patients at all points in time.

6 Conclusion in German

Das Glaukom wird initial häufig mit topischen Medikamenten behandelt. Es ist jedoch oft der Fall, dass Patienten im Verlauf operiert werden. Ablation, Exzision und Disruption des Trabekelmaschenwerks senken bei einem primären Offenwinkelglaukom den Augeninnendruck effektiv, wenn der Ausflusswiderstand im proximalsten Anteil des konventionellen Ausflusstraktes liegt. Die plasma-vermittelte Ablation des Trabekelmaschenwerks mit dem Trabektom steht Chirurgen seit 2004 zur Verfügung, während die Exzision mit dem TrabEx+ 2014 erstmals eingeführt wurde. Diese Studie zielte darauf ab, beide Geräte zu vergleichen und verwendete Coarsened Exact Matching, um kleine, gerätespezifische Unterschiede zwischen Trabektom und TrabEx+ festzustellen. Trotz eines relativ niedrigen Augeninnendrucks reduzierten beide Geräte diesen Parameter nach 6 Monaten signifikant, aber nur das Trabektom schaffte dies nach 12 Monaten. Beide reduzierten die Anzahl der drucksenkenden Medikamente zu beiden Zeitpunkten (6 und 12 Monate) signifikant. Definiert man den chirurgischen Erfolg als Abnahme des Augeninnendrucks um mehr als 20%, so waren die Erfolgsraten in beiden Gruppen relativ niedrig. Erklärbar ist dies am ehesten durch die niedrigen Ausgangswerte des Augeninnendrucks. In Bezug auf Augeninnendruck, Sehschärfe, Erfolgsraten und Komplikationen gab es keine wesentlichen Unterschiede zwischen beiden Geräten. TrabEx+ Patienten applizierten zu allen Zeitpunkten mehr drucksenkende Augentropfen als Trabektom-Patienten.

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8.0 Appendix

I. Abbreviations

Ant. TM Anterior Trabecular Meshwork
 BSS Balanced Saline Solution

CBB Ciliary Body Band

CEM Coarsened Exact Matching

MIGS Microinvasive Glaucoma Surgery

Nd:YAG
 Phaco/IOL
 Neodymium-Doped Yttrium Aluminum Garnet
 Phacoemulsification/ Intraocular lens insertion

Post. TM
 Posterior Trabecular Meshwork

• SL Schwalbe's Line

VEGF Vascular Endothelial Growth Factor

II. Figures

Figure 1: Aqueous humor outflows of the eye.

Figure 2: Visualisation of the angle of the eye using gonioscopy.

Figure 3: Traditional trabeculectomy.

Figure 4: Post-glaucoma surgery bleb.

Figure 5: An ultrasound image showing chorioretinal detachment and an

impressive choroidal effusion.

Figure 6: Stent design and dimensions of the iStent inject.

Figure 7: Insertion and visualization of the iStent in the trabecular meshwork.

Figure 8: Ab-interno trabeculectomy using the Trabecome.

Figure 9: The TrabEx+ with its dual serrated blades.

Figure 10: An example of a Snellen chart.

Figure 11: A Goldmann applanation tonometer.

Figure 12a: Mean intraocular pressure for TrabEx+ and Trabectome.

Figure 12b: Mean number of medications for TrabEx+ and Trabectome.

III. Tables:

Table 1: The Most Common Classes of Glaucoma Medications.

Table 2: Matched Baseline Characteristics of TrabEx+ and Trabectome

Table 3: Follow-up Parameters Compared between TrabEx+ and Trabectome

Table 4: Unmatched Comparison of TrabEx+ and Trabectome

Table 5: Success Rates of TrabEx+ and Trabectome

Table 6: Postoperative complications

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