Evaluation of the early results of ab interno trabeculectomy surgery applied with trabectome device

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Abstract
The aim of the current study was to assess efficacy and safety of ab interno trabeculectomy surgery applied with trabectome device in early period. The study was designed among the 30 eyes of 26 patients who had undergone trabectome surgery with the diagnosis of open-angle glaucoma. Patients were evaluated as retrospectively in terms of preoperative and postoperative intraocular pressure (IOP), number of drugs used and complications. While the preoperative mean IOP was 28.78±5.57 mmHg (n:30) with the mean number of medications 3.40±1.04, the mean IOP was 18.24±5.54 mmHg (n:30) with the mean number of medications 0.90±1.27 at 1st month. At 3rd month the mean IOP was 16.37±3.36 mmHg (n:28) with the mean number of medications 0.70±1.10 and at 6th month the mean IOP was 16.51±3.80 mmHg (n:28) with the mean number of medications 1.13±0.96. When postoperative measurements compared with preoperative values, detected reductions in IOP and number of medications were statistically significant (p<0.01). Postoperatively decrease in IOP was 40% at 1st month, 38.1% at 3rd month and 33.4% at 6th month while the reduction in the number of medications was 73.5% at 1st month, 79.8% at 3rd month and 65.8% at 6th month. Trabectome surgery is an effective and safe option for open-angle glaucoma. This procedure is an appropriate surgical alternative for patients that targeted to have IOP at moderate levels without need for any topical medication or with less topical medication.

Keywords: Trabectome surgery, open angle glaucoma, minimally invasive glaucoma surgery

Introduction
Glaucoma is a progressive optic neuropathy for which the early diagnostic and treatment methods have been intensively investigated because of its insidious course and severe threat to vision if not treated. Trabeculectomy and glaucoma drainage devices have become the standard treatment method for patients with open angle glaucoma (OAG) that cannot be controlled with medical treatments [1,2]. New procedures called micro-invasive or minimally invasive glaucoma surgery (MIGS) are performed to avoid the possible complications of these surgeries. The features of an ideal micro-invasive procedure could be summarized as: operation with microincision that preserves the conjunctiva, minimal trauma to the target tissue, minimal negative effect on the quality of life, fast healing process, with effective and high safety profile [3].

The trabectome microelectrocautery device (Trabectome, Neomedix, Inc., Tustin, CA, USA), one of the MIGS techniques, was approved in 2004 by FDA and began to be used worldwide. The trabectome surgery has an increasing popularity due to the new perspective it has brought to angle surgery. The purpose of this study was to investigate the efficacy and safety of ab interno trabeculectomy operation with trabectome device in the early period.

Material and Methods
Patients that had undergone ab interno trabeculectomy with the trabectome device between November 2013-April 2014 while they were being followed-up at the GATA Haydarpasa Training Hospital (GATA HTH), Department of Ophthalmology, Glaucoma Clinic with the diagnosis of OAG were included in the study. The study was approved by the GATA HTH Ethical Committee. The patient records from the archives were inspected retrospectively and age, gender, history, ocular and systemic diseases, intraocular pressure (IOP) measurements with Goldmann applanation tonometry before the operation, anterior segment and angle examinations, fundus findings, visual acuity, optic nerve head depression rates, and medication information of the patients were investigated. Postoperative follow-up was performed regularly and IOP values and medication on day 1, week 1, month 1, month 3 and month 6 were inspected. Intraoperative and postoperative early period complications were evaluated from in-patient charts. 30 eyes of 26 patients were evaluated. All of the cases had undergone the operation by the same surgeon. Patients
with previous glaucoma surgery or any other ocular surgery were also included in the study. Each eye of the patients, who had undergone surgery for both eyes, was evaluated separately. Patients with missing data in the follow-up records or who were not under follow-up, or those who had been followed-up for less than 6 months were not included in the study.

The number of medications was counted according to the medication names and each anti-glaucoma medication was recorded as one agent. Oral acetazolamide was also recorded as an agent. Pilocarpine eye drops administered for 1 month to prevent postoperative peripheral adhesions was not included among the anti-glaucoma agents.

The postoperative IOP and medication data were evaluated separately for 2 different success criteria. Criteria A was accepted as an IOP of ≤21 mmHg or an IOP decrease of ≥30%. Criteria B was an IOP of ≤21 mmHg and a decreased number of medications postoperatively. Any second surgical intervention was accepted as failure for both criteria.

**Surgical Technique**

Miosis was obtained by administration of 2% pilocarpine drops 1 hour before the operation, while the routine operation preparations were being performed. The patient’s head was rotated 25-30 degrees towards the opposite direction of the operated eye for a better gonioscopic image while the microscope was tilted 30-45 degrees towards the surgeon. Intra-chamber 1% preservative free lidocaine anesthesia was performed following a 1.7 mm clear corneal incision from the temporal. Viscoelastic was injected into the anterior chamber. The power unit of the trabectome device was set to 0.8 Watt (W). A modified Swan-Jacops surgical gonioscopy lens (Ocular Instruments, Bellevue, WA) on the left hand was placed on the cornea showing the targeted trabecular meshwork on the nasal side following administration of 1% sodium hyaluronate onto the cornea. The needle part on the tip of the device was introduced into the Schlemm’s canal by insertion through the trabecular meshwork after localization of the band of trabecular meshwork. The tip of the device was rotated counter-clockwise with the support of corneal entry point first, while the aspiration and cautery were activated with the foot control pedal. The tip was able to proceed through the Schlemm’s canal easily and it was visualized that the band formed by the trabecular meshwork and the inner wall of the Schlemm’s canal were crushed and open with the electrocautery part. At the same time, bubbles, which are the sign of correct ablation, were observed. The tip was rotated 180 degrees and the tip was rotated clockwise after the entry from the same point that the device had first been inserted into the trabecular meshwork. An area of around 60-90 degrees was removed with ablation through a corneal incision. Viscoelastic and hemorrhage in the anterior chamber were removed. The trabectome surgery was first performed in cases with combined operation. The pre-prepared 1mg/0.1cc cefuroxime axetil was injected into the anterior chamber at the end of the procedure.

The patient was positioned as lying on the side of the operated eye after surgery. Prednisolone acetate 1% eye drops q6h, pilocarpine 2% eye drops q8h for 1 month and ofloxacin 0.3% eye drops q4h for 7 days were prescribed. The IOP was measured postoperatively and every visit and medications were regulated.

**Statistical Investigation**

The NCSS (Number Cruncher Statistical System) 2007&PASS (Power Analysis and Sample Size) 2008 Statistical Software (NCSS LLC, Kaysville, Utah, USA) program was used for the statistical analysis. Definitive statistical methods (Average, standard deviation, median, frequency and ratio) and the Paired Samples test for the in-the-group comparison of quantitative variables with normal distribution were used for evaluation of the data. The Mann Whitney U test was used for the inter-group comparison of the variables without normal distribution and the Wilcoxon test was used for the in group comparison.

**Results**

The study was conducted with 30 eyes of 26 cases that had undergone trabectome surgery. Age interval of the cases is between 42 and 85 and the mean age is 68.6±11.4 (Table I). Ten (38.5%) of the cases were female, 16 (61.5%) were male. Three eyes (10%) underwent trabectome surgery combined with phacoemulsification, and 27 (90%) eyes underwent trabectome surgery only. Eighteen (60.1%) eyes were diagnosed as POAG; 10 (33.3%) were diagnosed as pseudoexfoliation (Pex) glaucoma, 2 (6.6%) was diagnosed as pigment dispersion glaucoma. Twenty four eyes of 23 patients had uncontrolled glaucoma besides previous glaucoma surgery and maximal tolerable medication. Three cases, who were under control with medication, but were unable to take medicines due to the allergic reaction and ocular surface problems. Preoperative IOP ranges between 14 and 36mmHg and the mean is 28.78±5.57mmHg. The preoperative anti-glaucoma medication number was 3.40±1.04. The other definitive data have been presented in Table I.

The mean preoperative IOP of 30 eyes was 28.78±5.57mmHg and it was determined as 18.24±5.54 mmHg with a 33% decrease in the first month. 13 (43%) eyes were administered medication and the number of medications decreased from 3.40±1.04 to 0.90±1.27 with a 73.5% fall (Table II).

The mean preoperative IOP of 28 eyes, which was 28.48±6.19 mmHg, was determined as 16.37±3.66mmHg with a 38.1% decrease in the third month. 8 (35%) eyes were administered anti-glaucoma medication and the number of medications dropped to 0.70±1.10 from 3.48±0.9 with a 79.8% decrease.
Table 1. Baseline demographics of patients

<table>
<thead>
<tr>
<th>Age (year)</th>
<th>Min-Max</th>
<th>Mean±SD</th>
<th>Sex</th>
<th>n</th>
<th>Female</th>
<th>10</th>
<th>38.5%</th>
<th>Male</th>
<th>16</th>
<th>61.55</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>Right</td>
<td>13</td>
<td>43.3%</td>
<td>Left</td>
<td>17</td>
<td>56.7%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis of glaucoma; n</td>
<td>Primary open angle glaucoma</td>
<td>18</td>
<td>60.1%</td>
<td>Pseudoexfoliation glaucoma</td>
<td>10</td>
<td>33.3%</td>
<td>Pigment dispersion glaucoma</td>
<td>2</td>
<td>6.6%</td>
<td></td>
</tr>
<tr>
<td>Lens status; n</td>
<td>Phakic</td>
<td>18</td>
<td>60.0%</td>
<td>Pseudophakic</td>
<td>12</td>
<td>40.0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery; n</td>
<td>Phacotrabectome</td>
<td>3</td>
<td>10.0%</td>
<td>Trabectome</td>
<td>27</td>
<td>90.0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative visual acuity; (LogMAR)</td>
<td>Min-Max</td>
<td>0-1.30</td>
<td>Mean±SD</td>
<td>0.30±0.45</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central corneal thickness; (µm)</td>
<td>Min-Max</td>
<td>440-600</td>
<td>Mean±SD</td>
<td>534±41.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative IOP; (mmHg)</td>
<td>Min-Max</td>
<td>14-36</td>
<td>Mean±SD</td>
<td>28.8±5.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cup-to-disc ratio; Mean± SD</td>
<td>&lt;0.4</td>
<td>12</td>
<td>42.9%</td>
<td>0.4-0.8</td>
<td>12</td>
<td>42.9%</td>
<td>&gt;0.8</td>
<td>4</td>
<td>14.3%</td>
<td></td>
</tr>
<tr>
<td>Schaffer grade; n</td>
<td>I</td>
<td>0</td>
<td></td>
<td>II</td>
<td>4</td>
<td>13.3%</td>
<td>III</td>
<td>9</td>
<td>30.0%</td>
<td>IV</td>
</tr>
<tr>
<td>Prior glaucoma surgery; n</td>
<td>Selective laser trabeculoplasty</td>
<td>6</td>
<td>20%</td>
<td>Trabeculectomy</td>
<td>4</td>
<td>13.3%</td>
<td>Laser iridotomy</td>
<td>1</td>
<td>3.3%</td>
<td>Tube shunt surgery</td>
</tr>
</tbody>
</table>

In the 6th month, the mean postoperative IOP was determined as 16.51±3.80 mm Hg with a 33.4% decrease. 75% of the eyes were administered medication and the number of medications decreased to 1.13±0.96 from 3.31±1.14 with a 65.8% decrease (Table II). The success rate according to criteria A was 83.3% in the first month, 80% in the 3rd and 6th month. The success rate according to the criteria B was 76% in 1st and the 3rd month, and 70% in the 6th month.

When the changes in IOP during the study compared to the preoperative levels, there were statistically significant decrease (p<0.01) (Table II). The decrease in the number of medications at all times compared to the preoperative data was also found to be statistically significant (p<0.01).

Table 2. Changes in IOP and number of anti-glaucoma medications

<table>
<thead>
<tr>
<th>Time</th>
<th>Eyes (n)</th>
<th>IOP (mmHg)</th>
<th>p</th>
<th>Medications</th>
<th>Percentage of medication use</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>30</td>
<td>28.78±5.57</td>
<td></td>
<td>3.40±1.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 day</td>
<td>30</td>
<td>15.67±6.99</td>
<td>42.9</td>
<td>0.67±1.29</td>
<td>%80.3</td>
<td>%23</td>
</tr>
<tr>
<td>1 week</td>
<td>30</td>
<td>16.47±6.10</td>
<td>40.4</td>
<td>0.57±1.04</td>
<td>%83.3</td>
<td>%26</td>
</tr>
<tr>
<td>1 month</td>
<td>30</td>
<td>18.24±5.54</td>
<td>33.0</td>
<td>0.90±1.27</td>
<td>%73.5</td>
<td>%43</td>
</tr>
<tr>
<td>3 months</td>
<td>28</td>
<td>16.37±3.36</td>
<td>38.1</td>
<td>0.70±1.10</td>
<td>%79.8</td>
<td>%35</td>
</tr>
<tr>
<td>6 months</td>
<td>28</td>
<td>16.51±3.80</td>
<td>33.4</td>
<td>1.13±0.96</td>
<td>%65.8</td>
<td>%75</td>
</tr>
</tbody>
</table>

IOP: intraocular pressure, *Paired Samples test, bWilcoxon Signed Rank test, *p<0.01(calculated according to the preoperative values of each group)

IOP measurements of the phakic and pseudophakic eyes at all periods did not demonstrate a statistically significant difference (p>0.05). The difference between the preoperative and postoperative visual acuity measurements of phakic and pseudophakic groups was not found to be statistically significant (p>0.05).

The differences among the IOP measurements on day 1,
and it targets to decrease the IOP by increasing the physiological outflow with selective removal of inner wall of trabecular meshwork and Schlemm’s canal with ablation [4-6]. This technique is similar to goniotomy or ab interno trabeculotomy procedures and the micro-electrocautery is the definitive feature of this surgery. Thicker trabecular meshwork and less elastic fibers in adults have been shown to cause scar tissue after goniotomy as the wound edges return to the original position [7,8]. Thus, complete removal of the trabecular meshwork to prevent the wound edges from reuniting has led to the development of the trabectome device. It was seen that the trabecular meshwork separates as a whole layer leaving an open cleavage and no thermal damage to surrounding tissues was observed during the histological examination of donor cornea-scleral samples after trabectome in in vitro studies [5].

Candidates for trabectome surgery should have; mild-moderate OAG patients with open angle, normal episcleral venous pressure (EVP), distinguishable angle anatomy, and translucent cornea. Trabectome surgery can be performed in pigmentary, pseudoexfoliation, steroid-related, congenital and juvenile glaucoma cases and OAG cases with history of failed glaucoma surgery. Patients with neovascularization in the angle, close angle glaucoma, cornea edema or scarring, and non-visualized angle with gonioscopy are not candidates for this operation [9].

The first pilot study about trabectome was conducted by Minckler at the Codet Eye Institute, Mexico at 2003 and 2004 [10]. Trabectome surgery was performed on 37 adult patients with uncontrolled glaucoma. At the end of 12 months (n:15), the decrease of IOP compared to the beginning was 31% and the decrease in the number of medications was determined as 90% [10]. The Trabectome device was in clinical use in the USA in 2006 after approval of the US Food and Drug Administration in April 2004. Minckler et al. widened the first original case studies and published it in 2006 with up-to-date results as a multi-centered prospective study including 101 patients [4]. The success rate was determined as 84% if the IOP of ≤21 were accepted as a success criteria with or without treatment as a result of a thirty-month follow-up. When 30% or higher decrease of IOP was also included in the success criteria, the success rate was 79.24% in the 12th month and 71% in the 24th month. The number of surgeries performed by Trabectome Study Group had reached 1127 and the results of the 60-month follow-up was published [11]. The mean preoperative IOP values of all patients had reached from 23.8±7.7 mmHg to a mean IOP value of 16.5±4.0 mmHg with a decrease of 39% at the end of 24 months (n:50). The number of medications had decreased to 1.2 from 2.8. As a result, Trabectome was reported as a minimally invasive method to control IOP in OAG patients [11].

The decrease of IOP and the number of medications was higher among exfoliation glaucoma patients compared to POAG patients [12,13]. The IOP values of the Pex

Discussion

Trabectome is a new technique that functions simultaneously with high frequency micro-electrocautery, and it targets to decrease the IOP by increasing the
glaucoma group was recorded to be lower than the POAG group at all follow-up times in our study also, but only the difference of IOP values at the 1st month was found to be statistically significant. Similarly, the mean number of medications in the Pex glaucoma group was lower during the follow-up, but no statistical significance was found. A higher decrease of IOP in exfoliation glaucoma shows that the obstruction level is primarily in the trabecular meshwork. It is accepted that the clearance of pseudoexfoliation material also has a contribution besides the widening of the anterior chamber, especially when combined with cataract surgery in Pex glaucoma cases [14]. No significant difference was determined between phakic and pseudophakic patients, similar to other studies comparing the results of trabectome surgery results [13].

The success rates was determined as 83.3% in the first month, 80% in the 3rd and 6th month, compared to other studies conducted with same success criteria (criteria A); while Ahuja et al. reported first year success rate as 64%, Minckler et al. [11] reported the success rate as 75% in the series study with 1127 cases. Minckler et al. [11] reported the 24-month success as 65% and Ahuja et al. [13] reported the rate as 36.2%, especially in cases of trabectome surgery only. The difference between the results may be caused by the differences in patient selection and surgical process. The success rate is around 60-70% if the success criteria is accepted as an IOP below 21mmHg, while it drops as low as 20% if the success criteria is accepted as below 18mmHg, which is a stricter value [13]. The differences among the patient groups included in studies, inclusion of combined surgeries in the study, differences among the surgical techniques and heterogeneity of success criteria are obstacles for comparison of the clinical results and the success rates of current publications about the efficacy and safety of trabectome surgery. Thus, it is obvious that evaluation of the decrease in IOP and the number of anti-glaucoma medication as success criteria is more significant. The IOP decrease observed at the 1st month in our cases was around 33% to 38.1% while the decrease in the number of medications was 65-79.8%. These successful results at the early period raise the question whether or not these results will show differences in the long-term follow-up. The study by Mosaed et al. is the first and the widest study about the long term results of trabectome surgery also including the 90 month follow-up results of some of 4659 cases. [15] It was reported in this study that the IOP decrease was around 30% and the rate of medication decrease was 60%, similar to previous studies and also to our study in which we presented the early period results.

Phacoemulsification combined with trabectome surgery had resulted in a more significant decrease in both IOP and the number of anti-glaucoma medications compared to cataract surgery only in the presence of accompanying cataract in glaucoma patients [16-18]. It could be recommended for patients who will undergo cataract surgery as it is performed through the same incision for better control of glaucoma or to decrease the number of medications [19].

The rates of second trabectome surgery intervention demonstrate big differences (2.9-43.5%) among studies. These differences are caused by probable differences among patient selection and preoperative IOP levels. A second glaucoma surgery was performed at the 1st month on 2 (6.6%) cases, one trabeculectomy and one trabectome surgery. Minckler et al. reported the number of trabectomectomy rates acquired because of failed trabectome surgery as 5.9% (n:67) and rates of shunt operation as 1.6% (n:18) [11]. Trabectome surgery does not affect the conjunctiva; therefore, a failed trabectome did not affect the success rate of a subsequent trabeculectomy. Thus, the trabectome procedure could be applied as an initial incisional procedure to treat medically refractory glaucoma before considering trabeculectomy [20].

The most common complication is intraoperative or postoperative development of temporary hyphema due to blood reflux from the Schlemm’s canal and it is reported to range from 73% to 100% in other studies [21]. Hemorrhage usually disappears in 1 week [5,10]. The most common complication seen in our cases similar to other studies was intraoperative reflux bleeding that was present in 28 (93.3%) cases. The intraoperative reflux of blood from opened trabecular cleavage to the anterior chamber is a sign of appropriate opening of the Schlemm’s canal roof [22,23]. Hemorrhage was observed puddled at the angle and on iris crypts on the postoperative 1st day and usually disappeared in one week. Patients may benefit from lying on the side of the operated eye at the early postoperative period or sitting with the head at 45 degrees.

Minimally blood reflux from the angle was observed during indentation gonioscopy in the postoperative first month in 21 cases in our study. This finding, which has not been reported in any previous publication, is a sign confirming the adequate removal of Schlemm’s canal roof and also a sign of preservation of this opening during the early postoperative period. We think that this hemorrhage is caused by an increase in EVP at the area of indentation. In addition, in one case that had been follow-up without medication after the procedure, trabecular cleavage was seen to be open, and no hemorrhage was seen in the angle, but reflux hemorrhage from the angle was observed after the goniolens removed from the eye in the late postoperative period. We think that this hemorrhage is caused by the reflux bleeding due to the decrease in IOP to 7mmHg from 14mmHg after indentation, which is below EVP levels.

Epithelial erosion, which was mostly seen in the temporal quadrant in 40% of our cases, is observed to have been caused by the friction of the slightly sharp edge of the goniolens. Mosaed et al. [19] reported 5% of temporary
epithelial defect, and Minckler et al. [10] reported this as 8% in their pilot study. This complication was healed without sequelae. Early hypotonia was reported at very low rates in other studies (<5mmHg, 0.6–1.5%), while no postoperative hypotonia was seen in our cases. The other complications reported in the studies were irides and capsule injuries caused by tip-end and they were observed in less than 2% [19].

The ab interno trabeculectomy performed with the trabecome device is stated as a promising, efficient and safe surgical approach in OAG types, to stop or slow glaucomatous optic neuropathy development as the result of all studies. Utilization of trabecome in OAG types is supported by researchers despite some research results showing that trabecome surgery is less effective for the decrease in IOP and the number of medications in comparison to trabeculectomy and tube shunt surgery [20].

**Conclusion**

Trabecome surgery is a minimally invasive glaucoma surgery method that is safe and effective for the different types of open-angle glaucoma that is uncontrolled despite maximal therapy and/or associated with ocular surface problems caused by topical medication. This procedure is an appropriate surgical alternative for patients that targeted to have IOP at moderate levels without need for any topical medication or with less topical medication.

**References**