Comparison of Surgically Induced Astigmatism after Trabeculectomy and Ex-Press Glaucoma Implant

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ABSTRACT

Purpose: To compare surgical and refractive outcomes in patients undergoing trabeculectomy and Ex-Press implantation surgery.

Materials and Methods: The study included 40 eyes underwent trabeculectomy (n=20) and Ex-Press implant (n=20) due to uncontrolled glaucoma. Best corrected visual acuity (BCVA), intraocular pressure (IOP), and keratometry measurements were evaluated preoperatively and on postoperative months 1, 3 and 6 months. During the follow-up, keratometric astigmatism values and surgery-induced astigmatism (SIA) values calculated with Eğrilmez's vector analysis program were analyzed using statistical comparisons.

Results: There were no significant differences in mean age, gender, laterality and glaucoma type (p>0.05) between study groups. Again, no significant differences were found in mean baseline BCVA (0,35±0,36, 0,46±0,33 logMAR), IOP (32,10±7,8, 37,10±8,3 mmHg), keratometry (43, 93±1,16, 43,71±0,61 D), and corneal astigmatism (1,10±0,61, 0,83±0,40 D) (p>0.05) values between trabeculectomy and Ex-Press implant groups. In the Ex-Press group, postoperative IOP reduction was significantly greater on month 1(14,10±4,2, 10,95±2,2 mmHg, p=0.013), but no significant difference was found between the two groups at remaining time points (p>0.05). Corneal astigmatism increased in both groups in the first month, but this increase was not statistically significant (p>0.05). There was no significant difference SIA vector size during the 6-months follow-up between groups (p>0.05). While oblique astigmatism was present in the trabeculectomy group at baseline, rule-compliant astigmatism was observed on postoperative month 6. In the Ex-Press group, the rule-compliant component persisted throughout follow-up period.

Conclusions: No significant difference occurred in IOP, visual outcomes, and astigmatism change after trabeculectomy and Express implantation.

Keywords: Induced astigmatism, Trabeculectomy, Ex-Press, Vectorial analysis.

INTRODUCTION

Glaucoma is one of the leading causes of blindness in developed countries.[1] Glaucoma surgery is indicated in cases where disease progression cannot be controlled despite maximum medical treatment.[2] Trabeculectomy and Ex-Press glaucoma implant (Alcon Laboratories, Fort Worth, TX, USA) are surgical procedures that enhance humor aqeuous drainage to subconjunctival region.[3] When compared to trabeculectomy, considered as gold standard for glaucoma surgery, Ex-Press glaucoma implant is a less invasive alternative treatment option.[4] Both procedures ensure effective intraocular pressure (IOP) reduction by creating a permanent drainage canal for humor aqueous.

Following filtering surgery, alterations in corneal curvature that influence on visual acuity may be problematic for patients. There may be decreased visual acuity through several mechanisms in patients underwent glaucoma surgery. Surgical techniques lead changes in diameter of corneal curvature, corneal astigmatism and corneal axis as they involve limbus and anterior sclera and the visual acuity may be decreased due to induced astigmatism.[5-7] It is well-known that sutures used for conjunctival closure, surgical technique (scleral flap size), suture tightness, cautery use, cauterization technique (wet or dry), surgical time, trabeculectomy device used (blade or stapler) and anti-metabolite use (dose and duration) can lead postoperative astigmatism .[5,7]

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The glaucoma surgery not only aims to decrease IOP but also to ensure visual rehabilitation. Surgery-induced astigmatism (SIA) appears as a problem, particularly in younger patients with well central vision. In our study, it was aimed to assess changes in corneal refractivity over time which occurs after trabeculectomy and Ex-Press implantation.

MATERIALS AND METHODS

We retrospectively reviewed patients underwent trabeculectomy and Ex-Press implantation due to persistent IOP elevation due to maximum medical treatment in our clinic between March, 2017 and October, 2019. All surgical procedures were performed by same surgeon (FÖ). Patients developed intraoperative or postoperative complication, those with history of trauma or ocular surgery within prior 6 months, those without available measurements, those with spherical refractive error >6 diopter (D) and those with diagnosis of neovascular glaucoma were excluded. Study was approved by Institutional Ethics Committee (2022/06-08). The study was conducted in accordance to tenets of Helsinki Declaration.

The study included patients underwent best-corrected visual acuity (BCVA) assessment, refractive and keratometry measurements (auto-refractometry, NIDEK), IOP measurement by Goldmann applanation tonometry, anterior and posterior segment examination by slit lamp, and had follow-up data on months 1, 3 and 6. In all patients, keratometry measurements by auto-refractometry at baseline and on postoperative months 1, 3 and 6 were assessed. Keratometric astigmatism value (as diopter) was determined as difference between horizontal and vertical keratometric values. Before analyses, all keratometric astigmatism values were transposed to a single format, namely hypermetropic astigmatism in order to exclude errors in estimation of mean values. Surgery-induced astigmatism is defined as subtractions of baseline astigmatism from postoperative astigmatism. Astigmatic refractive error is a vector with an axis and magnitude. Thus, induced astigmatism change was calculated by "Vectorial Analysis Software for Analysis of Astigmatism" (Eğrilmez et al.) using keratometric measurements obtained at preoperative period and postoperative months 1, 3 and 6.[8] To calculate IA, the software offers two different options using either refractive or keratometric values. The software has areas to input vertex distance when using surgical quadrant and refractive data.

Surgical Technique

All surgeries were performed via fornix-based conjunctival incision through upper-nasal quadrant. A semi-thickness scleral flap (4x4 mm in size) was harvested in trabeculectomy. Sponge-applied mitomycin-C (MMC) at the dose of 0.2 mg/mL was applied to surgical area over 3 minutes; then, the surgical area was irrigated using balanced saline solution. Paracentesis was performed in anterior chamber to control IOP. Trabeculum tissue (1x2 mm in size) was excised from the area corresponding to gray line; followed by peripheral iridectomy. Scleral flap was closed using four 10/0 nylon sutures (2 sutures at corner and 2 sutures at side of flap). Conjunctiva was closed using 8/0 Vicryl sutures.

For Ex-Press implantation, first steps of trabeculectomy surgery were performed in the same fashion. At gray line, a sulcus parallel to iris was created using 26 Gauge needle in order to advance implant into anterior chamber. The Ex-Press implant was advanced into anterior chamber through the sulcus and positioned as one tip being in anterior chamber and other tip being beneath scleral flap. Scleral flap and conjunctiva were closed in the same fashion as trabeculectomy.

Topical moxifloxacin (over 2 weeks) and topical dexamethasone (over 4 weeks) were given at postoperative period. Topical dexamethasone was tapered over 2-3 months. .

Statistical analysis

Statistical analysis was performed using IBM SPSS version 22.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics are presented as mean±standard deviation for continuous variables and count (percent) for categorical variables. The normality for numerical variables were assessed using Shapiro-Wilk test. Between groups, variables with normal distribution were compared using Independent t test while variables with skewed distribution were compared using Mann Whitney U test. Differences in repeated measures were analyzed using ANOVA test for variables with normal distribution while using Friedman variance analysis for variables with skewed distribution. Categorical variables were compared using Chi-square test. A p value<0.05 was considered as statistically significant.

RESULTS

Overall, 49 patients were assessed for inclusion. Of 49 patients, 40 patients (20 patients who underwent trabeculectomy and 20 patients who underwent Ex-Press implantation) fulfilled inclusion criteria were included in the study. Mean age was 66.42±9.79 years. Of the patients included, there was pseudoexfoliation glaucoma in 23 (57.5%) and primary open-angle glaucoma in 17 patients (42.5%) (Table 1). There were no significant differences in mean age, gender, laterality and glaucoma type between trabeculectomy an Ex-Press implant groups (p=0.184, p=0.525, p=0.744, p=0749, respectively; Table 1).

Table 2 presents pre- and postoperative BCVA, IOP,

Table 1: *Demographic and ocular characteristics of the cases*

	Trabeculectomy (n=20)	Ex-Press (n=20)	P
Age (mean±SD)	68.5±11.22	64.35±7.85	0.184*
Gender (female/male)	12/8	10/10	0.525**
Eye (right/left)	7/13	8/12	0.744**
Glaucoma type			
POAG	8(%40)	9(%45)	0.749**
PEG	12(%60)	11 (%55)	

POAG: Primary open-angle glaucoma. PEG: Primary exfoliative glaucoma. SD:Standard deviation
* Independent samples t test. ** Chi-square tes

Table 2: *Mean BCVA, IOP, keratometry and corneal astigmatism (keratometric) values*

	Time	Trabeculectomy (mean±SD)	Ex-Press (mean±Sd)	P
BCVA (logMAR)	Preoperative	0.35±0.36	0.46±0.33	0.326 ***
	Postoperative month 1	0.39±0.33	0.49±0.33	0.352***
	Postoperative month 3	0.34±0.29	0.47±0.34	0.224***
	Postoperative month 6	0.33±0.29	0.44±0.33	0.276***
	p	0.278*	0.771*	
IOP (mmHg)	Preoperative	32.10±7.8	37.10±8.3	0.058#
	Postoperative month 1	14.10±4.2	10.95±2.2	0.013#
	Postoperative month 3	14.00±4.6	13.10±3.6	0.430#
	Postoperative month 6	13.40±4.0	13.15±2.1	0.810#
	p	<0.001**	<0.001*	
Mean keratometry (D)	Preoperative	43.93±1.16	43.71±0.61	0.221#
	Postoperative month 1	44.00±1.14	43.84±0.75	0.835#
	Postoperative month 3	44.07±1.12	43.76±0.53	0.708#
	Postoperative month 6	44.02±1.22	43.75±0.54	0.429#
	p	0.411*	0.757*	
Corneal astigmatism	Preoperative	1.10±0.61	0.83±0.40	0.758#
	Postoperative month 1	1.13±0.69	0.96±0.38	0.813#
	Postoperative month 3	1.08±0.82	0.90±0.38	0.531#
	Postoperative month 6	1.07±0.62	0.81±0.42	0.718#
	p	0.546**	0.448*	

BCVA: best-corrected visual acuity; IOP: intraocular pressure.
D:Diopter. SD: Standard deviation
* ANOVA for repeated measurements. ** Fridman test. ***Independent samples t test. # Mann Whitney U test

keratometry and astigmatism (keratometric) values. No significant difference was in BCVA obtained at baseline and postoperative control visits between trabeculectomy and Ex-Press implant groups (p>0.05). In both groups, IOP was significantly lower at all time points after surgery when compared to baseline (p<0.001). IOP reduction was significantly greater on postoperative month 1 in Ex-Press group (p=0.013); however, no significant difference was detected at remaining time points between groups (p>0.05).

No significant difference was detected in mean keratometry and corneal astigmatism values within group and between groups at baseline and during postoperative follow-up (p>0.05). Although corneal astigmatism was increased on postoperative month 1 in both groups, the increase did not reach statistical significance.

Table 3 presents SIA vector magnitude and axis. No significant difference was detected in SIA vector magnitude within group and between groups during 6-months follow-up (p>0.05). In trabeculectomy group, there was oblique astigmatism at baseline while rule-compliant astigmatism was observed on postoperative month 6. In Ex-Press implant group, rule-compliant component was maintained throughout study period.

Suturolysis was performed in 9 patients (22.5%) after surgery. No significant difference was detected in SIA changes between patients with or without suturolysis (p=0.306 on month 1, p=0.435 on month 3 and p=0.301 on month 6). Bleb needling was performed in 7 patients (17.5%) after surgery. No significant difference was detected in SIA changes between patients with or without suturolysis (p=0.770 on month 1, p=0.528 on month 3 and p=0.448 on month 6).

DISCUSSION

SIA is a factor which may lead changes in visual acuity following glaucoma surgery.[11] Previous studies have shown that glaucoma surgery can cause decrease in visual acuity by leading alterations in keratometry and corneal topography.[5,9-13] The short-term decrease in visual acuity is a frequent finding at early postoperative period in patients undergoing glaucoma surgery; however, it may be persist at long-term in some patients.

There are many studies reporting discrete outcomes and establishing different mechanisms by investigating effects of glaucoma surgery on astigmatism with changes in keratometry and topography. Watson was the first author reporting changes in vision following glaucoma filtering surgery.[10] Hugkulstone was the first author who investigated SIA using keratometry data as a cause of decreased visual acuity after trabeculectomy.[7] Author found a reduction in vertical diameter together with an increase in horizontal diameter (rule-compliant astigmatism. Again), Hugkulstone proposed that astigmatism results from posterior positioning of scleral flap and flap incisions rather than number of flap sutures since there was no significant difference in scleral flaps closed by 2 or 5 sutures. Hugkulstone found no significant correlation between keratometric measurements and IOP; in addition, author observed that there was no significant correlation between changes in corneal diameter and final visual acuity, suggesting that induced astigmatism is visually irrelevant.[7] Claridge et al., using corneal topography, found superior steeping in corneal curvature following trabeculectomy.[11] Authors attributed this finding to retraction in tissues surrounding trabeculectomy secondary

Table 3: *Vector magnitude and axis value of surgery-induced astigmatism*

Surgery-induced astigmatism	Time	Trabeculectomy (mean±SD)	Ex-Press (mean±Sd)	P
Vector magnitude	Postoperative month 1	0.41±0.28	0.36±.33	0.309***
	Postoperative month 3	0.44±0.34	0.35±0.22	0.416***
	Postoperative month 6	0.38± 0.24	0.34±0.26	0.392***
	P	0.895*	0.161*	
Vector axis	Postoperative month 1	120.5±54.92	92.9±60.00	0.138#
	Postoperative month 3	95.3±61.84	92.8±48.80	0.888#
	Postoperative month 6	101.5±56.30	94.57±56.1	0.701#
	p	0.047**	0.912**	

SS: Standard deviation
*Friedman test. ** ANOVA for repeated measurements. *** Mann Whitney U test.# Independent samples t test

to large scleral cauterization. They suggested that a large bleb or postoperative ptosis might lead corneal steeping; in addition, they defined regional changes in corneal curvature using corneal topography, which cannot be detected by refractive or keratometric changes in corneal curvature. In 6 of 8 eyes developed rule-compliant astigmatism following trabeculectomy, Rosen et al. showed that keratometry was less sensitive than topographic analysis in detecting changes.[14] In a study on changes in corneal refractivity following trabeculectomy, Mayali et al. found that SIA magnitude measured topographically was greater than the change detected by keratometry at all time points.[15] When differences in SIA (as detected by keratometry and topographic analysis) across postoperative time points, it was found that topographic analysis detected more astigmatism although the difference did not reach statistical significance. Kayıkçıoğlu et al. assessed SIA change following trabeculectomy and trabeculectomy plus deep sclerotomy using keratometry and corneal topography and found that induced astigmatism was decreased with both examination methods in both groups and that there was no significant difference in any control visit.[16] In our study using keratometry data, no significant change was detected in SIA within group and between groups throughout follow-up period.

Cunliffe et al. reported that the changes in corneal curvature resulted from flattened at peripheral cornea and decreased vertical diameter caused by sclerostomy performed in trabeculectomy.[12] Authors suggested that vertical corneal diameter returned to preoperative levels 2 months after surgery presumably due to loosening scleral flap sutures allowing corneal margin of sclerostomy into preoperative position.

In our study, all trabeculectomy and Ex-Press implant surgeries were performed through superior nasal quadrant using fornix-based conjunctival opening. Based on vectorial analysis, rule-compliant astigmatism was found in both surgeries. In a large cohort, Ando et al. reported that there was shift in axis of astigmatism towards scleral flap.[17] Authors demonstrated that SIA vector tended to steep towards superior nasal position when scleral flap was performed at superior nasal quadrant while it tended to steep towards superior temporal position when scleral flap was performed at superior temporal quadrant. These findings demonstrated that SIA displaced towards scleral flap and that the site of scleral flap was a factor for axis of astigmatism. Rule-compliant, rule-incompliant and oblique astigmatism might be developed due to different localizations of scleral flap.

The quadrant where glaucoma filtering surgery was performed can affect SIA. Kim et al. reported that trabeculectomy through superior nasal quadrant more commonly caused SIA when compared to trabeculectomy from superior temporal quadrant.[18] Authors explained this finding by more nasal and inferior displacement of optical center of cornea compared to geometrical center. In our study, all surgical interventions were performed through superior nasal quadrant; thus, there was no difference regarding site of surgery between groups.

Shiratori et al. found no significant difference regarding SIA development between fornix-based (n=38) and limbus-based trabeculectomy (n=28).[19] It was predicted that more SIA would develop in fornix-based trabeculectomy when compared to limbus-based trabeculectomy since conjunctival sutures are closer to cornea in fornix-based trabeculectomy; however, no significant difference was detected in the study. It was observed that effects of conjunctival sutures were limited on SIA after removal of sutures. In our study, both procedures were performed in fornix-based fashion.

Hammel et al. periodically monitored 19 eyes underwent Ex-Press implantation for 3 months and reported that astigmatism was increased on postoperative day one in both anterior and posterior cornea; however, the effect disappeared after 3 months.[13]

In a study including Phaco-trabeculectomy and Phaco-Ex-Press groups, Konopińska et al. reported that there was no significant difference in SIA magnitude between groups throughout follow-up period.[20] As similar to Hugkulstone, authors attributed SIA to a surgical gap around flap resulting from posterior positioning of scleral flap and flap incisions; in addition, they also suggested that SIA was not associated to sclerostomy as suggested by Cunliffe et al.[12] The fact that both procedures are identical other sclerostomy and peripheral iridectomy favors this finding.

In a study comparing SIA induced by four different techniques including trabeculectomy and Ex-Press implant, Tanito et al. found that mean SIA was greater in trabeculectomy group than remaining groups.[21] Authors attributed the mechanism to scleral tissue removal as demonstrated by Cunliffe et al.[12] They proposed that lack of tissue removal in Ex-Press implantation may explain lower SIA in the Ex-Press procedure.

Inconsistent results are seen when the literature astigmatism induced by glaucoma surgery. Thus, it remains unclear whether Ex-Press surgery leads less astigmatism than trabeculectomy. There may need for further studies in this field.

Rosen et al. showed that suturolysis of flap sutures had no effect on changes in corneal curvature.[14] This is in agreement with out finding that there was no significant difference regarding astigmatism between groups with or without suturolysis.

In our study, it was found that both surgical procedure were effective in controlling IOP, without significant difference between groups on month 6. It was found that the Ex-Press implant was more effective in IOP reduction on postoperative month 1; however, the difference disappeared on postoperative months 3 and 6. This finding in our study is in agreement with studies reporting no significant difference in IOP between trabeculectomy and Ex-Press implant at final control visit.[22-28]

Our study has some limitations including retrospective design, relatively small sample size and use of auto-keratometry, rather than corneal topography, for assessment of astigmatism. Thus, posterior corneal astigmatism was not evaluated in our study..

In our study, no significant differences were found mean keratometric astigmatism value between groups at baseline and throughout follow-up period. Surgery-induced vectorial astigmatism showed no difference between groups. These results eliminated need for eye glasses at postoperative period.

In conclusion, our study showed that trabeculectomy and Ex-Press implantation are generally neutral procedures regarding astigmatism. This may be important to prevent inappropriate intraocular lens selection when calculating intraocular lens power, particularly in patients underwent glaucoma and cataract surgery at same session. There remains discrepancies in results and pathogenetic assumptions regarding induced astigmatism after glaucoma surgery. We believe that more definitive results can be obtained by prospective, randomized, clinical trials comparing these techniques.

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