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Evaluation of Ex-Press Glaucoma Filtration Device in Primary Open Angle Glaucoma

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Abstract

Purpose: *The aim of this study was to compare the outcomeof Ex_PRESS mini shunt versus standard trabeculectomy in cases of primary open angle glaucoma.*

Setting: *Mansoura Ophthalmic Center, Mansoura University, Mansoura, Egypt.*

Design: *comparative prospective non randomaized study.*

Methods: *study included 36 eyes of 25 patients with uncontrolled primary open angle glaucoma. 17 eyes had trabeculectomy and 19 eyes had Ex-PRESS glaucoma mini shunt. Demographic data, preoperative complete ophthalmic examination, surgical procedure used are all recorded. Postoperative examination included intraocular pressure (IOP), visual acuity and number of glaucoma medications. Surgical success and complications were recorded.*

Results: *We reported no significant difference between Ex-PRESS and trabeculectomy groups regarding IOP reduction, success rates and use of postoperative glaucoma medication except that IOP in the early post-operative period was lower in the trabeculectomy group. At 12 months IOP Complete success was achieved in 76.5% and 84.2% in trabeculectomy and Ex_PRESS groups respectively. Early hypotony was slightly higher in trabeculectomy group (29.4%) than in Ex_PRESS group (10.5 %) but not statistically significant. Faster recovery of vision was achieved following Ex_PRES Simplantation as vision near baseline levels was achieved from 1 week to 1 month post-operatively.*

Conclusion: *Ex-PRESS mini shunt is a safe and effective device for treating cases of primary open-angleglaucoma. It is comparable to trabeculectomy as regard IOP, number of anti glaucoma medications and success rate with slightly lower early postoperativecomplications and faster recovery of visual acuity*

Keywords: *glaucoma, trabeculectomy, Ex-PRESS, intraocular pressure*

Introduction

Glaucoma is considered the most common cause of irreversible blindness in the world, 64.3 million patients worldwide are affected with glaucoma in 2013. Glaucoma patients are supposed to reach 76 million worldwide in 2020, and this number may increase more to 111.8 million in 2040.[1]

For over 40 years, the main procedure to control high intraocular pressure (IOP) in patients with glaucoma is trabeculectomy. It has well stablished success and complication rates. [2]

Trabeculectomy has been modified to lower the mean postoperative intraocular pressure and to improve its efficacy as using adjunctive anti-fibrotic drugs. [3] However, postoperative complications have a significant rate,as early hypotony, hypotonic maculopathy, choroidal detachment, endophthalmitis and other complications, so there was a need for safer alternatives. [4]

The EX-PRESS glaucoma filtration device (Alcon Laboratories. Fort Worth, TX, USA) was created aiming to be alternative to trabeculectomy to increase its safety with similar IOP reduction. Ex_PRESS is a mini shunt which is non-valved. It is made of medical-grade stainless steel. It got the U.S. Food and Drug Administration (FDA) approval in 2002. Using this mini shunttheaqueous humor is diverted from the anterior chamber to a created intrascleral space. [5]

This 2.64 mm device is available in two different internal lumen size,either a 50 or 200 um. In the original procedure the Ex_PRESS was implanted directly under the conjunctiva. This old procedure had many complications as extrusion, hypotony, conjunctival erosion, and others. [6] Dahan and Carmichael started to implant if under a scleral flap in 2005. [7] This technique had the advantages of successful reduction of IOP with decreasing the rates of postoperative complication as conjunctival erosions which significantly reduced.[8]

The EX-PRESS device is used to decrease the intraocular pressure in cases of uncontrolled glaucoma. The indications include patients with failed medical treatment or recurrent glaucoma after previous conventional surgery.[9]

In this study was aimed to evaluate the safety and efficacy of the Ex-PRESS mini glaucoma shunt in Egyptian patients with primary open angle glaucoma in comparison with the conventional subscleral trabeculectomy.

Methods

This was a comparative, prospective, non-randomized study. It was performed in Mansoura Ophthalmic Center, Faculty of Medicine, Mansoura University, Egypt. 36 eyes of 25 patients were included in the study. 17 eyes underwent subscleral trabeculectomy (group 1) and 19 eyes underwent EX-Press P 50 mini shunt implantation (group 2). The study was carried out through 24 months in the period from November2015 to November 2017.

Inclusion Criteria

The study included patients above age of 18 diagnosed as primary open angle glaucoma (by IOP measurement, gonioscopy, optic nerve evaluation and visual field assessment) with one of the following indications of surgery:

1. Failure to control IOP inspite of maximum medical or laser therapy.
2. Noncompliance with medications due to financial or physical restrictions.
3. Need to achieve lower target IOP in the presence of progressive optic nerve and visual field loss.
4. Intolerance to medical therapy secondary to allergies.
5. Advanced glaucomatous optic neuropathy

In this study we excluded patients with other types of glaucoma as uveitic, pseudoexfoliation, pigmentary and pseudophakic glaucoma. Also patients with previous ocular surgery or trauma and patients with ocular diseases were excluded.

Pre-Operative Evaluation

Complete ophthalmic evaluation was done to all patients including: best corrected visual acuity (BCVA), slit lamp biomicroscopy, gonioscopy, Goldmann applanation tonometry and dilated fundus examination

Surgical Technique

In trabeculectomy cases, we started with opening a fornix based peritomy. Scleral flap was then fashioned measuring 3X4 mm then dissected up to clear cornea. Opening of sclerotomy and entering the anterior chamber was done using superblade, followed by peripheral iridectomy. Suturing of scleral flap by 2 10-0 nylon sutures was done at angles of the flap. Finally, suturing the conjunctiva to the limbus using 2 10-0 nylonsutures and formation of a bleb.

For Ex_PRESS shunt the surgical technique included a fornix-based conjunctival periotomyfollowed by a larger 5X 5 mm scleral flap which depth was about 50% then dissection to up clear cornea. For entering the anterior chamber, a 25 G needle supplied by the manufacturer was used. The site of entry was in the center of the blue-gray transition zone just anterior to scleral spur .Holding the needle during entry had to be parallel to the iris plane towards the center of the pupil for proper positioning of the device. Before entering with the needle release of traction helps to allow the eye to return to primary position and holding the scleral flap in a manner that allows visualization of the needle as it fully enters the anterior chamber.

Viscoelasticmaterial was used to partially fill the anterior chamber. The implant was then inserted through the perforation site using its special injector, first the posterior slit opening of the device parallel to the limbus then dialing it 90 degree to its final position perpendicular to the limbus. The scleral flap was then sutured securely using 5 10/0 nylon sutures to properly cover the flange of the implant. Finally the conjunctiva was sutured with 2 10-0 nylonsutures.

Postoperatively, all eyes received the same medications Topicalsteroid / antibiotic combination (dexamethazone/to bramycin) eye drops and ointment were used. Dose of drops was 4 times daily in the first week with gradual tapering along the following 4 to 6 weeks.

Follow-Up

Postoperatively, the patients were examined at 1, 7, 14 days, 1, 3, 6, 9 and 12 months. Examination included BCVA, slit lamp biomicroscopy of the anterior segment, gonioscopy, Goldmann applanation tonometry, fundus examination and photoslit. VF and OCT were repeated at 6, 12 month.

Postoperative IOP more than 5 and less than18 mm Hg was considered as successful surgery. This success was complete when reached without using antiglaucoma medications postoperatively. Success was qualified in cases which needed additional treatment. Failure was considered if there was a recurrence of high levels of IOP postoperatively over 18 mm Hg inspite of medical therapy with the need of another glaucoma surgery. Also persistent hypotony (IOP< 5 mm Hg) was considered as failure.

Our study protocol has been approved from medical research ethics committee, faculty of medicine, Mansoura University. Informed written consent was obtained from all patients after informing them with the advantages, disadvantages and alternatives of this surgery.

Statistical Analysis

IBM's SPSS statistics (Statistical Package for the Social Sciences) for windows (version 24) was used for statistical analysis of the collected data. Shapiro-Wilk test was used to check the normality of the data distribution. Normally distributed continuous variables were expressed as mean ± SD while categorical variables and the abnormally distributed continuous ones were expressed as number and percentage or median and inter-quartile range respectively. Inter-group comparisons were conducted using Student t test and Mann-Whitney for normally and abnormally distributed continuous data respectively while intra-group comparisons were conducted using related samples Wilcoxon signed rank test (for non-parametric data) or paired student t test (for parametric data). Cramer's V Chi square test was used for comparing nominal data using the crosstabs function. All tests were conducted with 95% confidence interval. Follow-up of the success rates was done using the survival function (Kaplan-Meier curve) and its p value was generated using the Log rank (Mantel-Cox) test. Line charts were generated using SPSS' chart builder. Microsoft word for windows (2016) was used for generating the complications' bar chart. P (probability) value < 0.05 was considered statistically significant.

Results

Comparison between both groups revealed statistically insignificant difference as regard demographic and cilinical data. Age range was51.12 ± 13.38 years in group 1 and 51.32 ± 12.28 years in group 2(P=0.963). Group 1 included 13 males (76.5%) and 4 females (23.5%) and group 2 included 16 male (84.2%) and 3 female (15.8%).Follow up period was 15 months in group 1 and 13 months in group 2(P=0.34). Both groups had similar glaucoma severity before operation in terms of mean cup-discratio and visual field mean deviation. (table 1)

Table 1. *Demographic data and medical history of the studied groups*

		Trabeculectomy group (n= 17)	Express group (n= 19)	Test value	P value
Age (year)		51.12 ± 13.4	51.32 ± 12.3	t= 0.05	0.96
Sex	**Male**	13 (76.5 %)	16 (84.2%)	χ^2 = 0.1	0.56
	Female	4 (23.5%)	3 (15.8%)		
Follow up period (months)		15 (12, 20)	13 (12, 19)	Z= 0.96	0.34
Central corneal thickness (nm)		517.24 ± 32	529.58 ± 27.6	t= 1.2	0.22
Optic disc cup		0.79 ± 0.10	0.82 ± 0.09	0.887	0.381
Pre-operative Visual field mean deviation		-16.1 ± 8.5	-13.5 ± 7.4	t = 0.98	0.34

Preoperative IOP was slightly higher in trabeculectomy group (27.1 mm Hg) vs. (23.1 mm Hg) the Ex_PRESS group, but this difference had no statistical significance (P=0.55). During the follow up period IOP showed no statistically significant difference between the two groups except at the early postoperative period 1st day and 1st week where the mean IOP in the trabeculectomy group was statistically significantly lower than Ex_PRESS group (P<0.001)(Table 2) (Figure 1). This early difference may be related to tight closure of scleral flap in the Ex_PRESS group and use of viscoelastic material. At 12 months postoperatively degree of IOP reduction was similar between two groups 39% in group 1 and 38.3% in group 2 which showed no statistical difference between them P=0.9

Table 2. *pre- and post-operative intra-ocular pressure (IOP)*

	Trabeculectomy group (n= 17)	Express group (n= 19)	Test value	P value
Pre-operative IOP	27.1 (21.4, 29.1)	23.1 (23.1, 27.1)	Z = 0.6	0.55
Post-operative IOP at 1st day	7 (6, 8)#	10 (8, 13.8)#	Z =4	<0.001
Post-operative IOP at 1st week	8 (7.1, 8.5)#	12 (10, 14)#	Z = 3.76	<0.001
Post-operative IOP at 1st month	10.2 (9, 13) #	14 (12, 16.5) #	Z = 2.88	0.004
Post-operative IOP at 3rd month	16 (12, 16.8) #	14 (12, 16.5) #	Z = 0.55	0.58
Post-operative IOP at 6th month	16 (14, 18.1) #	16 (12, 16.5) #	Z = 0.84	0.4
Post-operative IOP at 1st year	14 (14, 16.5) #	14.6 (12, 16) #	Z = 0.63	0.53
Reduction of IOP at one year	39%	38.3%	t= 0.13	0.9

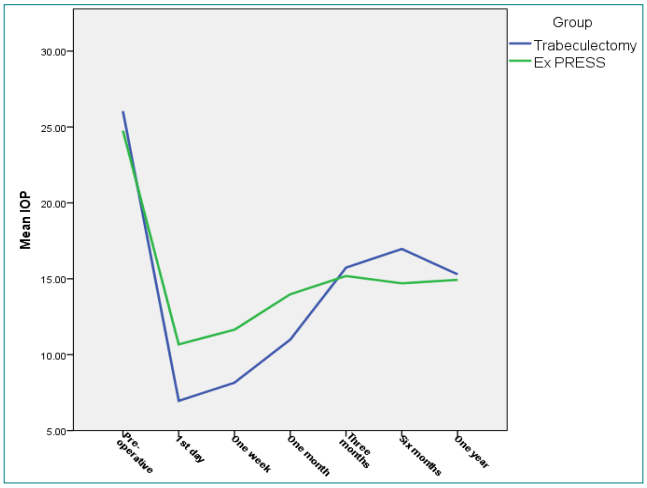

Figure 1. *shows difference between IOP in both groups along the follow up period*

The preoperative number of antiglaucoma medications was 3 in group 1 and 3 in group 2 with no statistical difference (P=0.68) between the two groups. The degree of reduction in number of antiglaucoma medications was 82% in group 1 and 89% in group 2 (P=0.55) (table3)

Table 3. *pre- and post-operative antiglaucoma medications*

	Trabeculectomy group (n= 17)	Express group (n= 19)	Test value	P value
Pre-operative number of medications (number)	3 (2, 3)	3 (2, 3)	Z = 0.41	0.68
Number of treated patients postoperatively	4 (23.5%)	3 (15.8%)	χ^2 = 0.34	0.56
Post-operative medications among treated patients (number)	2 (1.25, 2.75)	2 (1, -)	Z = 0	1

Post-operative medications among all patients (number)	0 (0, 0.5)	0 (0, 0)	Z = 0.57	0.57
Percentage of medications reduction	82%	89%	Z = 0.6	0.55

Table 4 shows success rates at 12 month postoperative. There was no statistically significant difference between the two groups in the success or failure rates. The total success rate (the sum of complete and qualified success) (IOP below 18 mm Hg either with or without medications) was 94.1% in group I and 94.7 % in group II. Complete success was achieved in 13 out of 17 eyes (76.5 %) in group I and in 16 out of 19 eyes (84.2%) in group II. Qualified or partial success was in four eyes (17.6%) in group I and 3 eyes (10.5%) in group II where IOP was controlled with adjunctive topical medications below 18 mmHg.

Table *4. Success rate after one year*

	Trabeculectomy group (n= 17)	Express group (n= 19)	Test value	P value
Total	16 (94.1%)	18 (94.7%)	χ^2 =0.01	0.94
Complete	13 (76.5%)	16 (84.2%)	χ^2 = 0.34	0.56
Qualified	3 (17.6%)	2 (10.5%)	χ^2 = 0.1	0.54
Failure	1 (5.9%)	1 (5.3%)	χ^2 =0.01	0.94

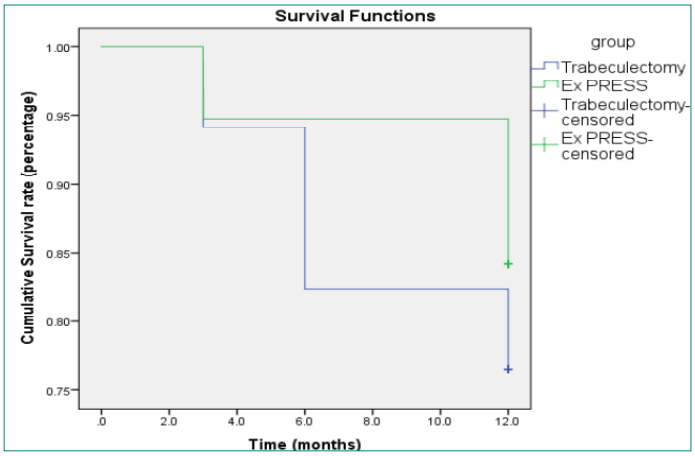

Figure 2. *Kaplan-Meier life table curve for intraocularpressure (IOP) ≤18 mmHg without medications (complete success) showing no significant difference between the two groups (p=0.53)*

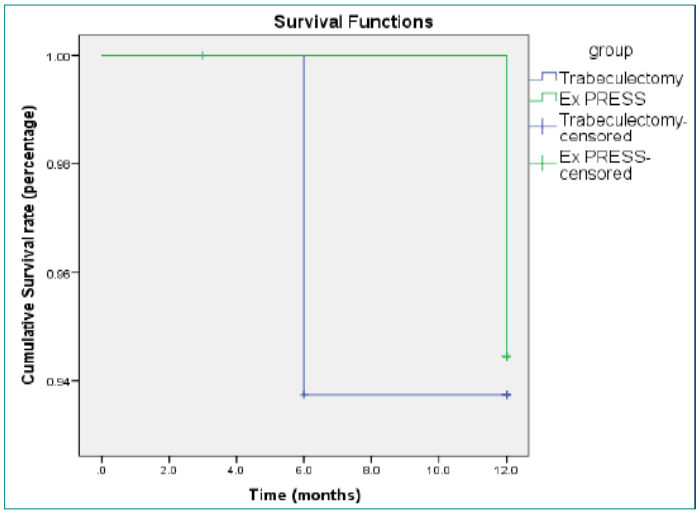

Figure 3. *Kaplan-Meier life table curve for intraocularpressure (IOP) ≤18 mmHg with or without medicationsshowing no significant difference between the two groups(p=0.9)*

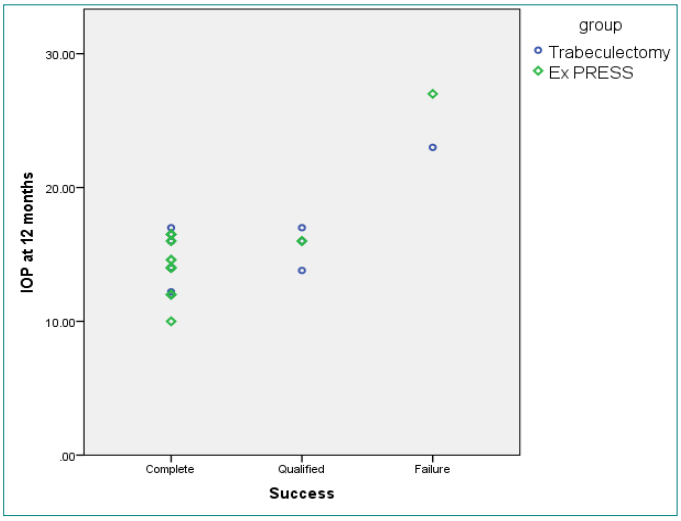

Figure 4. *Scatter dot plot showing the relation between the case success and the IOP at 12 months*

There was no statistical difference between the 2 groups as regard preoperative visual acuity. In both the groups, VA was significantly reduced following surgery. In the Ex-PRESS group, VA was significantly decreased compared with baseline at day 1 and weeks 1 and however, by month 1, VA in the Ex-PRESS group was no longer significantly different from baseline and remained nonsignificant at subsequent visits. In the trabeculectomy group, VA remained significantly lower than baseline at each study visit from day to 3 months .So VA recovery was faster in the Ex_PRESS group,also in the early postoperative period there was more loss of visual acuity in trabeculectomy group than express group...(Figure 5)

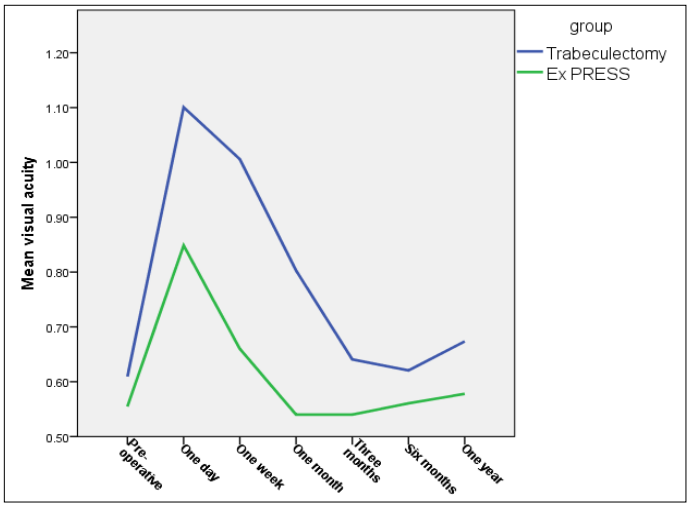

Figure 5. *Visual acuity changes along the follow up period between two groups*

Table 5 shows changes of visual acuity at 1 year in from the baseline value.10 cases in trabeculectomy group (59%) and 7 cases in the Ex_PRESS group (36.8%) showed decrease of visual acuity in last follow up . Most of these cases (52 %& in group 1 and 26 % in group 2) were mild reduction of VA (loss of less than 2 snellen lines) and the rest showed moderate reduction of VA (loss of 4-5 snellen lines).

Table 5. *Numbers of patients with visual acuity changes at one year postoperatively in both groups*

	Trabeculectomy group (n= 17)	Express group (n= 19)	Test value	P value
Worsened	10 (59%)	7 (36.8%)	$\chi^2 = 1.7$	0.19
improved	3 (18%)	3 (16%)	$\chi^2 = 0.02$	0.88
Unchanged	4 (23%)	9 (47%)	$\chi^2 = 2.2$	0.14

Complications encountered in this study are shown in table 6. Early hypotony was slightly higher in group 1 (29.4%) than group 2 (10.5 %) but not statistically significant. All of these complications were transient and improved with conservative treatment except one case in trabeculectomy group which needed conjunctival suturing for bleb leak and another case in Express group which had overfiltration that needed resuturing of scleral tunnel.

Among cases of Ex_PRESS group 4 cases had a small patch of iris atrophy at the site of the device internal opening with patent opening and no device iris touch. One case had device iris touch but with patent opening. One case of device malposition in which the internal opening was implanted in the cornea and occluded this case had successful repositioning of the device. no cases of displaced od exposed device were detected in the study. (Figure 6)

Table 6. *postoperative complications in both groups*

Complications	Group 1		Group 2		$\chi 2$	P
	No	%	No	%		
Shallow AC	4	23.5%	2	10.5%	1.092	0.296
Early hypotony	5	29.4%	2	10.5%	2.043	0.153
Bleb leak (conjunctival)	1	5.9%	0	0%	1.150	0.284
Choroidal detachment	1	5.9%	0	0%	1.150	0.284
Early hyphaema	1	5.9%	0	0%	1.150	0.284
Iridodyalisis	0	0%	1	5.3%	0.920	0.337

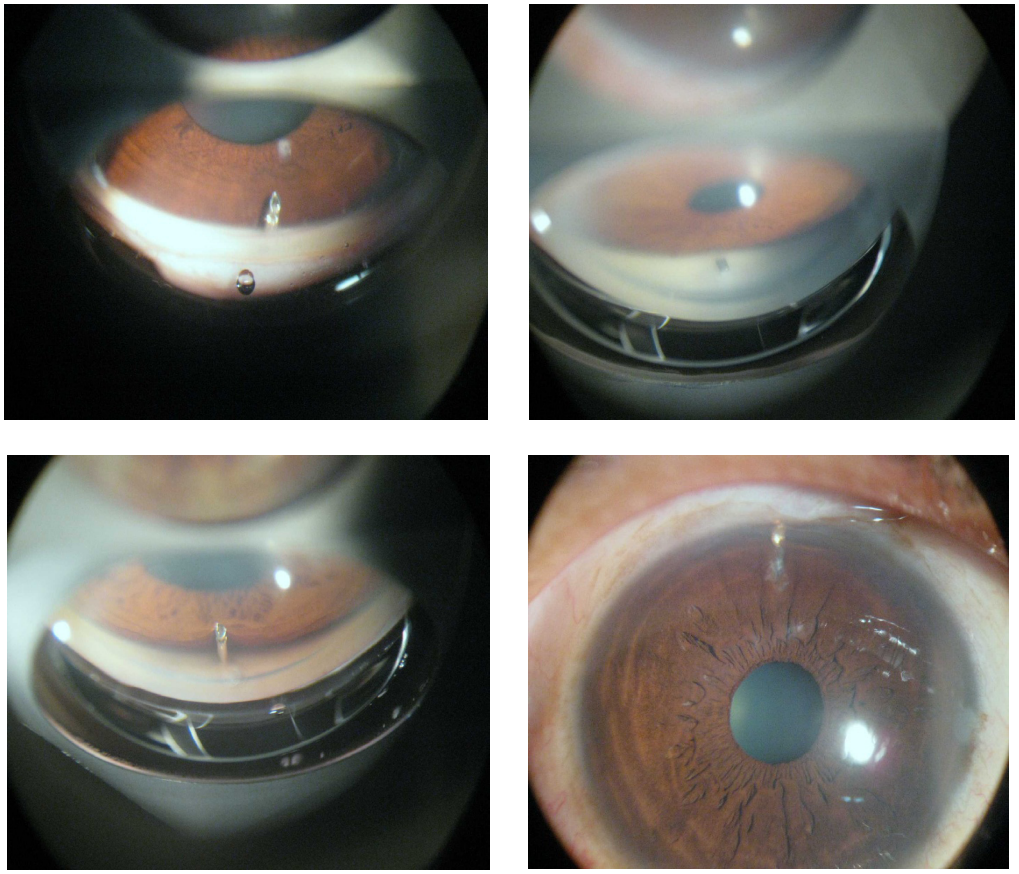

Figure 6. *photoslit images showing position of the Ex_PRESS device in relation to iris and cornea: (a) proper position of the implant without iris or corneal touch using gonioscopy. (b) malpositioned implant with the internal opening implanted in the cornea. (c) device iris touch with patent internal opening of the device. (d) small patch of iris atrophy without device iris* touch

Discussion

Recently, as alternatives to standard trabeculectomy many new IOP-lowering procedures havebeen developed. One of them is the Ex_Press mini shunt implantation, which is a new procedure for standardizing trabeculectomy. Ithas results quitsimilar to those of trabeculectomy.[10]Although similar to trabeculectomy in many ways, using Ex-PRESS eliminates the needfor iridectomy and sclerectomy. [11] Ex_PRESS has the advantage of draining aqueous humour through a tube of consistent size. Instead of a fstula of variable size, so, the outflow in Ex-PRESS may be more predictable and controlled and in comparison with that in traditional trabeculectomy [12]

In this study we reported no significant difference between Ex-PRESS and trabeculectomy groups regarding IOP reduction, success rates and use of postoperative glaucoma medication except that IOP in the early post-operative period was significantly lower in the trabeculectomy group. Dahan and colleagues[13]demonstrated similar results to ours with IOP reductionat last follow-up 48% for the trabeculectomy group and 44% for the device group(from baseline level). Also similar to the present study, IOP lowering effect, success rate and antiglaucoma medications changes in Lee GY et, al study were not statistically different between the two groups however, the rate of IOP fluctuation was statistically significant lower in the EX_PRESS group from1st week to 3rd month. Their possible explanation for this finding is that the Ex_PRESS provides greater resistance to aquos outflow in the early postoperative period due to its narrow lumen that maintains constant flow than the wide sclerectomy of trabeculectomy, [14]

In De Jong study there was no significant difference between the two groups in the number of post-operative IOP-lowering medications although the number of patients using IOP-lowering medications ateach time point was lower in the device group. [15]

As regard visual acuity we reported rapid recovery following Ex_PRESS as compared to trabeculectomy with more loss of VA in trabeculectomy group in early postoperative period. Good and Kahook[16] also reported faster recovery of vision following Ex_ PRES Simplantation asvision near baseline levels was achieved 1 week post-operatively. Mendoza ME et al. [17] reported more delayed recovery of vision in the Ex-PRESS group where vision near baseline levels of log MAR was achieved 1 month post-operatively.

Recovery of visual acuity (VA) was also assessedat 6 month by BeltranAgullo et al [18] and at 1 year by Wagschal et al [10]. They reprted that VA in the Ex_ PRESS group returned to baseline within1 month post-operative and was stable along the one yearduration of the study. In contrast, in the trabeculectomygroup VA throughout the study was significantly lower than baseline.

Rates of hypotony, bleb leak,shallow AC, and additional procedures in this study were slightly higher in trabeculectomy group than express group but not statistically different. Maris et al. [19]compared standard trabeculectomy to Ex-PRESS implantation and found similar IOP reduction but a lower rate of early hypotony in the EX-PRESS group (4% vs 32%). Marzette L et al., [20]reported early hypotony in 4% of their cases of Ex_press implant. Netland et al[21] reported that in the EX_press group there was lower rates of complications than with trabeculectomy (P ¼ 0.013) , in their study visual acuity recovery tobaseline occurred more rapidly (within 1 month) in the EX-PRESS group (0.3 vs 0.28 logMAR) as compared to 3 months in the trabeculectomy group (0.25 vs 0.37 logMAR).

The limitations of this study may include the relatively small samplesize, short-term follow-up, despite these limitations, this is of the first studies to evaluate the Ex-PRESS device in our country .We plan for further long term results and evaluation of the device in cases with other types of glaucoma.

Conclusion

Ex-PRESS mini shunt is a safe and effective device for treating cases of primary open-angle glaucoma with IOP control similar to trabeculectomy and slightly lower early postoperative complications and better stability of visual acuity.

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