

## Visual and Surgical Outcomes of Primary Phacotrabeculectomy with Mitomycin C in Patients with Open Angle and Pseudoexfoliative Glaucoma in Sana'a (Yemen)

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### Abstract

**Introduction:** The study aimed to assess the visual and surgical outcomes and the occurrence of intraoperative and postoperative complications after primary phacotrabeculectomy with intraoperative use of Mitomycin C (MMC) in primary open angle (POAG) and pseudoexfoliative glaucoma (PXF) patients.

**Methods:** This cross-sectional hospital-based study included 100 consecutive eyes of 82 patients with POAG (n = 79) and PXF (n = 21), who had planned phacotrabeculectomy with MMC at the Glaucoma Unit in Magrabi Hospital, from January 1 to December 31, 2013. Data were collected using a standardized form that included patient demographic information, ocular characteristics and postoperative complications, including hypotony (defined as intraocular pressure (IOP) < 6 mmHg) and shallow anterior chamber (AC).

**Result:** The mean age  $\pm$  standard deviation (SD) of patients was  $60.5 \pm 13.35$  years with a (range, 17 – 80 years old). Hundred eyes of 82 patients underwent phacoemulsification and trabeculectomy with MMC. A statistically significant improvement was detected in the mean IOP and mean number of glaucoma medication postoperative. The IOP decreased from a preoperative mean of 24.7 to a mean of 15.6 mm Hg ( $p < 0.001$ ;  $z = -8.240$ ) and glaucoma medications decreased from 2.1 to 0.6 ( $p = < 0.001$ ;  $z = -8.688$ ). A statistically significant improvement was detected in postoperative BCVA in which the mean log MAR (Logarithm of the Minimum Angle of Resolution) Best Corrected Visual Acuity (BCVA) improved from preoperative level of 1.0 to 0.5 ( $p < 0.001$ ).

**Conclusion:** The surgical technique used in this study appears to be an effective and safe procedure at restoring good visual acuity, controlling and lowering of intraocular pressure and reducing the postoperative complication rate.

**Keywords:** Cataract, Glaucoma, Intraocular Pressure, Phacotrabeculectomy, Yemen.

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## النتائج البصرية والجراحية لعملية المياه البيضاء والزرقاء المزدوجة مع مادة المايثومييسين سي في مرضى الزرق مفتوح الزاوية ومرضى الزرق بسبب تقشر شبه الكاذب في صنعاء اليمن

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### ملخص الدراسة

**المقدمة:** هدفت الدراسة لتقييم النتائج البصرية والجراحية وحدوث مضاعفات خلال أو بعد عملية المياه البيضاء والزرقاء المزدوجة مع مادة المايثومييسين سي في مرضى الزرق مفتوح الزاوية ومرضى الزرق بسبب تقشر شبه الكاذب في اليمن.

**المنهجية:** هذه دراسة مقطع عرضي تمت في المستشفى وشملت مائة عين متتالية لاثنتين وثمانين مريض مصابين بزرق مفتوح الزاوية (79) وزرق بسبب تقشر شبه الكاذب (21) الذين تم التخطيط لإجراء عملية مزدوجة للمياه البيضاء والزرقاء لهم مع استخدام مادة المايثومييسين سي وحدة المياه الزرقاء في مستشفى المغربي من 1 يناير إلى 31 ديسمبر 2013م. تم جمع البيانات باستخدام استمارة موحدة تضمنت المعلومات الديموغرافية للمريض، خصائص العين، مضاعفات ما بعد العملية الجراحية وتشمل هبوط حاد في ضغط العين (ضغط العين أقل من 6 مم زئبق) والغرفة الامامية الضحلة.

**النتائج:** متوسط العمر  $\pm$  الانحراف المعياري للمرضى كان  $60.5 \pm 13.35$  مع (بمدى 17 إلى 80 عاماً). تم إجراء العملية لـ 100 عين (82 مريض) وهي عملية مزدوجة للمياه البيضاء والزرقاء مع استخدام مادة المايثومييسين سي. تم الكشف عن تحسن ذو دلالة إحصائية في معدل ضغط العين من 24.7 إلى 15.6 مم زئبق ( $p < 0.001$ ،  $z = -8.240$ ) ومتوسط عدد أدوية المياه الزرقاء انخفض من 2.1 إلى 0.6 بعد العملية ( $p < 0.001$ ،  $z = -8.688$ ) تم الكشف عن تحسن ذو دلالة إحصائية في جودة النظر بعد العملية حيث ان معدل log MAR لجودة أفضل نظر تحسن عما كان قبل العملية من 1.0 إلى 0.5 ( $p < 0.001$ ).

**الاستنتاج:** يبدو أن التقنية الجراحية المستخدمة في هذه الدراسة إجراء فعال وآمن في استعادة حدة البصر الجيدة والسيطرة وخفض ضغط العين وتخفيض معدل المضاعفات بعد الجراحة.

**الكلمات المفتاحية:** المياه البيضاء، المياه الزرقاء، ضغط العين، عملية فاكو تراب، اليمن.

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## Introduction

Cataract and glaucoma are the two main causes of blindness in Yemen [1,2] and worldwide [3,4] and they usually co-exist in the same eye in the elderly population. The prevalence of both cataract and glaucoma increases with age. Presence of glaucoma also increases the risk of cataract [5]. Bourne *et al* in their meta-analysis estimated that cataract is responsible for 51% of world blindness representing about 20 million people while another 4.5 million and 3.9 million people are blind due to open-angle and angle-closure glaucoma respectively [6]. In Yemen, in a hospital-based study glaucoma was found to be the second most common cause of blindness and accounted for 10.4% of bilateral blindness and 6.8% of unilateral blindness [2]. Rapid assessment of avoidable blindness (RAAB) in Yemen was done in 2007 and glaucoma was found to be the second most common cause of blindness after cataract and accounted for 6.5% [7].

Glaucoma surgery is indicated in patients who fail to respond to maximally tolerated medical therapy or who continue to have progressive optic nerve damage in spite of medical control. Glaucoma surgery alone can significantly increase the risk of development of cataract [8,9]. Cataract surgery following trabeculectomy can result in bleb failure [9,10]. In Yemen, ophthalmologists usually avoid glaucoma surgery because of lack of experience or to avoid postoperative surgical complications [11]. Glaucoma patients usually don't get better vision after trabeculectomy

surgery and this leaves majority of ophthalmologist to avoid performing surgical intervention for glaucoma patients [11,12].

It is documented that following cataract extraction, intraocular pressure (IOP) is known to lower by 2–4 mm Hg [13]. However, this reduction may not be enough to prevent damage due to glaucoma progression. In these patients, a combined phacotrabeculectomy surgery has advantages such as improved vision and intraocular pressure (IOP) reduction in a single sitting [14,15].

The aim of this study was to document the visual and surgical outcome, the intraoperative and postoperative complications, the effectiveness and safety of combined phacotrabeculectomy with Mitomycin C (MMC) in Yemeni patients with coexisting cataract and primary open angle or pseudoexfoliative glaucoma. The outcome measures included visual recovery, IOP control, reduction in topical anti-glaucoma medications and the safety of the procedure.

## Methods

### Study Site

Medical records of all patients who had a phacotrabeculectomy procedure with intraoperative MMC, (0.2 mg for 2 minutes) at the Glaucoma Unit in Yemen Magrabi Eye Hospital in Sana'a, between 1<sup>st</sup> January 2013 and 31<sup>st</sup> December 2013 were retrospectively reviewed. Data of 100 consecutive procedures performed by the same surgeon were examined.

### **Type of Study**

This cross-sectional hospital-based study included 100 eyes of 82 patients planned for phacotrabeculectomy procedure who had at least 24 months of postoperative follow-up and at regular visits as less than 50 days, six months, one year and two years' interval. Seven eyes were not included in this study because they did not have adequate follow-up. Preoperative baseline information obtained for each patient included age, sex, presence of systemic disease, type of glaucoma, grade of cataract, previous ocular surgery, best spectacle corrected visual acuity (BSCVA), IOP, cup-to-disc (C/D) ratio, number and type of topical medications, exclusion of ocular comorbidities and intraocular lens (IOL) implanted type. IOP was measured with Goldman applanation tonometry.

### **Criteria of Selection**

Phacotrabeculectomy was offered to the patient when there was a visually-significant cataract on slit-lamp examination and open angle glaucoma requiring medications, medically uncontrolled glaucoma, poor patient compliance, advanced glaucomatous optic nerve damage or visual field loss. Patients included in the study did not have any previous surgical or laser operation or history of trauma on the eye. All patients did not have trabeculectomy procedure before. For those who underwent surgery for both eyes, both eyes were included.

### **Surgical Procedure**

The surgical procedure was a two-site incision approach, with fornix-based conjunctival flap trabeculectomy, use of MMC, phacoemulsification was done via the temporal approach and

acrylic IOL implantation. The scleral and conjunctival flaps were sutured and the temporal clear corneal incision was not sutured. Complications were recorded as intraoperative and postoperative.

### **Analysis**

Statistical analysis was performed using SPSS 21.0 (SPSS Inc., Chicago, Illinois). Patient information was anonymized and de-identified prior to analysis. For comparisons between the two groups, the independent samples t-test or the Mann–Whitney–Wilcoxon test for independent samples, the paired samples t test or the Wilcoxon signed-rank test was used for continuous variables, and the  $\chi^2$  test was used for categorical variables, as appropriate. A *p*-value less than 0.05 was considered statistically significant. BCVA was measured in Snellen charts and converted to log MAR scale for statistical purposes. Approval for the study was obtained from the Ethics Committee in Yemen Magrabi Eye Hospital.

## **Results**

A total of 100 eyes of 82 patients were operated between January 2013 and December 2013. Ninety-nine phacotrabeculectomy with posterior chamber IOL and with MMC and one patient had anterior chamber IOL because the crystalline lens was subluxated.

The mean age was  $60.5 \pm 13.35$  years with a range between 17 years and 80 years old. Of the 82 patients included in this study, 62.2% were compared with 37.8% females with insignificant difference between male and female according to mean IOP, mean Log MAR BCVA, glaucoma medications

and cup-disc ratio as preoperative or postoperative during follow up ( $p = 0.417, 0.663, 0.995$  and  $0.506$  preoperative and  $0.992, 0.582, 0.924$  and  $0.215$  postoperative).

Fifty-one patients had the right eye and 49 had the left eye. Sixty-four patients had unilateral treated eye and 18 patients had bilateral treated eyes. Five patients had surgery done to their only single eye where the other eye was blind from glaucoma. Eleven patients had diabetes mellitus, 11 patients had hypertension and one patient had diabetes and hypertension. Pseudoexfoliation (PXS) syndrome was present in 21.0% of eyes as shown in Table 1.

Table 2 shows the follow-up period of 24 months. A statistically significant improvement was detected in the mean IOP and mean number of glaucoma medication postoperative (Table 2 and Figure 1). Regarding the last visit, the IOP decreased from a preoperative mean of 24.7 to 15.6 mm Hg ( $p < 0.001$ ;  $z = -8.240$ ) and glaucoma medications reduced from a mean number of 2.1 to 0.6 at the final follow up ( $p < 0.001$ ;  $z = -8.688$ ).

Preoperatively, 10 eyes were using one glaucoma medication, 66 eyes were using two glaucoma medications and 24 eyes were using three different glaucoma medications. Only one eye used two drugs postoperative (less than 50 days). Six months postoperative, three eyes used single drug and five eyes two drugs.

At one year follow up, seven eyes used single drug and nine used two drugs. At two years follow up, only one eye used three drugs. Majorities were done under local anesthesia (96) and four were done under general anesthesia.

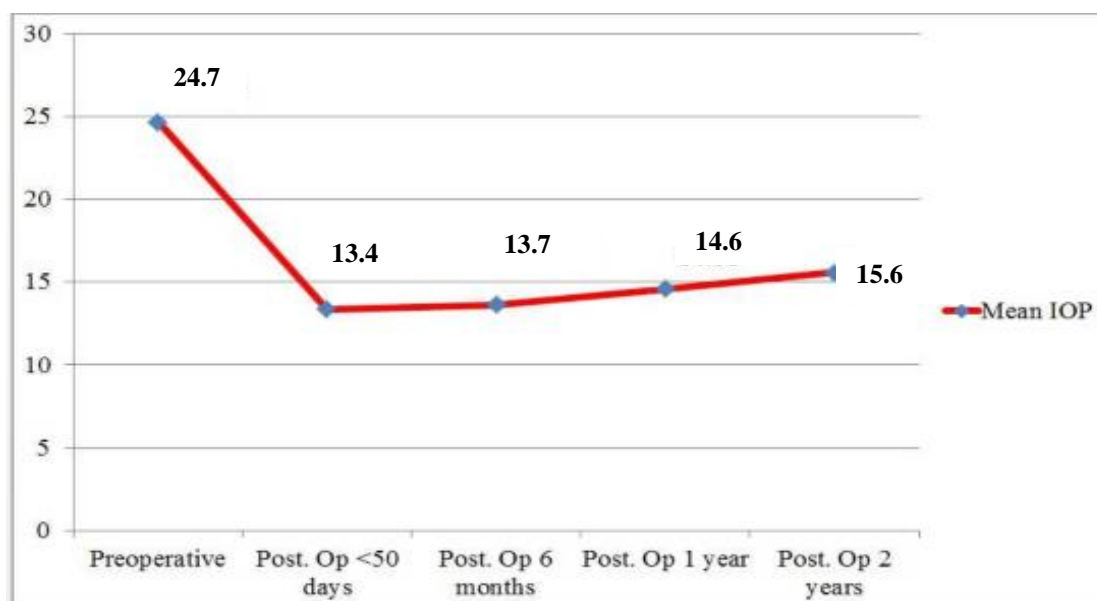
**Table 1:** Demographic Data of 82 Patients (100 eyes)

Characteristics	No.	%
<b>Gender</b>		
Male	51	62.2
Female	31	37.8
<b>Age (Years)</b>		
Less than 40	7	8.5
40 – 65	48	58.5
More than 65	27	33.0
<b>Eye</b>		
Right	51	51.0
Left	49	49.0
<b>Laterality</b>		
Unilateral	64	64.0
Bilateral	18	18.0
<b>Systemic Diseases</b>		
Diabetes Mellitus	11	13.3
Hypertension	11	13.3
Diabetes Mellitus& Hypertension	1	1.2
No Systemic Disease	60	72.2
<b>Glaucoma Type</b>		
Primary Open Angle Glaucoma	79	79.0
Pseudoexfoliative Glaucoma	21	21.0
<b>Type of Anesthesia</b>		
Local Anesthesia	96	96.0
General Anesthesia	4	4.0
<b>Complications</b>		
Suture-Lysis for high IOP	5	5.0
Shallow Anterior Chamber	4	4.0
Corneal Ulcer	2	2.0
Optic Atrophy Secondary to Neovascular Glaucoma	1	1.0
Fibrin Membrane Formation	1	1.0
No complications	87	87.0

**Table 2:** Comparison between Preoperative and Postoperative IOP and Reduction of Glaucoma Medication Number (Mean  $\pm$ SD)

Characteristics		Preoperative	Postoperative			
			< 50 days*	6 months*	one year*	two years*
IOP	Mean $\pm$ SD	24.7 $\pm$ 5.62	13.4 $\pm$ 4.61	13.7 $\pm$ 3.22	14.6 $\pm$ 4.42	15.6 $\pm$ 4.41
	z test		-8.557**	-8.550**	-8.345**	-8.240**
Glaucoma medications	mean $\pm$ SD	2.1 $\pm$ 0.57	0.02 $\pm$ 0.21	0.1 $\pm$ 0.52	0.3 $\pm$ 0.63	0.6 $\pm$ 0.81
	z test		-9.023**	-8.914**	-8.688**	-8.263**

\* Correlation is significant at the 0.0005 level. \*\* Wilcoxon Rank Sum

**Figure 1:** Comparison between Preoperative and Postoperative Mean IOP

A statistically significant improvement was detected in the postoperative BCVA in which, the mean log MAR BCVA improved from preoperative level of 1.0 to 0.5 at the final follow-up visit,  $p < 0.001$  (Wilcoxon test) as shown in Table 3. All eyes had significant improvement in best corrected visual acuity except eight eyes which their vision deteriorated in

the last follow-up. The causes were one eye developed neovascular glaucoma secondary to diabetic retinopathy, five eyes due to increased IOP and lost follow-up and two eyes decrease of their IOP were less than 21 mm Hg preoperatively. Table 4 shows the visual acuity (best-spectacle corrected) improvement during postoperative follow-up period.

**Table 3:** Comparison Between Preoperative and Postoperative BCVA (Mean  $\pm$ SD)

LOGMAR	Preoperative	Postoperative			
		< 50 days*	6 months*	one year*	two years*
BCVA Mean $\pm$ SD	1.0 $\pm$ 0.48	0.5 $\pm$ 0.35	0.4 $\pm$ 0.37	0.4 $\pm$ 0.38	0.5 $\pm$ 0.52
	z test	-6.809**	-7.356**	-7.369**	-6.124**

\*Correlation is significant at the 0.0005 level

\*\*Wilcoxon Rank Sum test

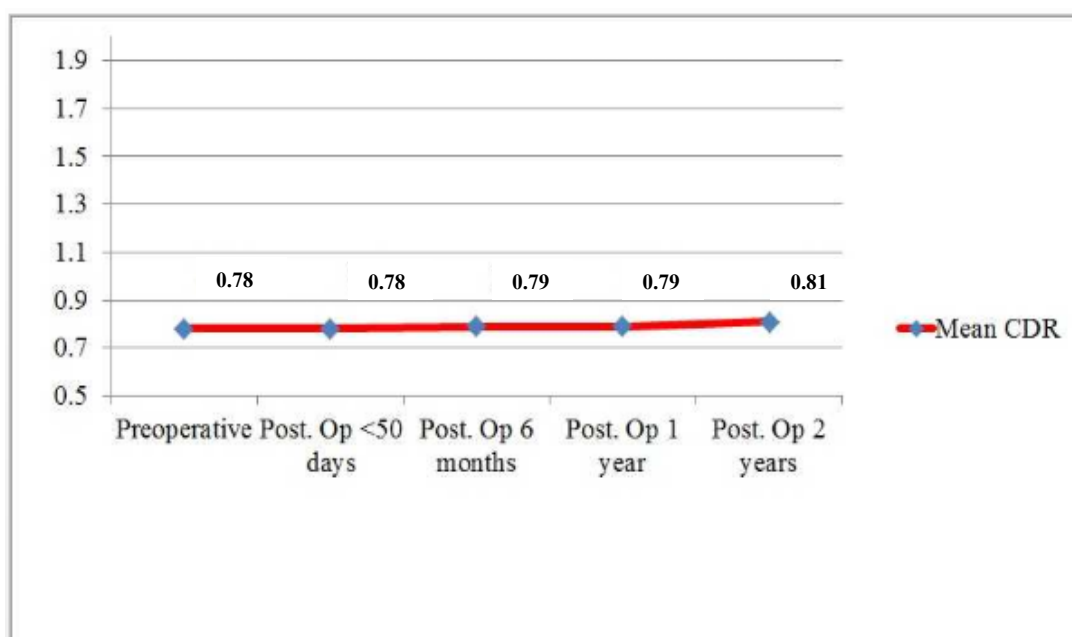


**Table 4:** Improvement of Visual Acuity (Best-Spectacle Corrected) During Postoperative Follow-Up Period.

BCVA Log MAR	Preoperative	Postoperative			
		< 50 days	6 months	one year	two years
Near / Normal Vision (0.0-0.5)	25	69	81	85	76
Low vision (0.6-1.7)	73	31	17	16	21
Near Blindness (1.8-2)	2	0	2	1	3

Most of the eyes Cup/Disc (C/D) ratio remained stationery following surgery, in which, the mean vertical cup-disc ratio preoperative was  $0.8 \pm$

$0.18$  and the mean vertical cup-disc ratio postoperative was  $0.8 \pm 0.18$  that is clinically significant as illustrated in Figure 2.

**Figure 2:** Comparison between Preoperative and Postoperative Mean Cup – Disc

Twenty-one eyes had PXS syndrome whereas 79 eyes had primary open angle glaucoma (POAG). There is a statistically significant difference in favor of the POAG in the reduction number of glaucoma medications used and IOP postoperatively ( $p=0.030$ ,  $0.017$  respectively Mann–Whitney–Wilcoxon test). There was no significant difference between PEX and POAG according to BCVA and cup-disc ratio ( $p = 0.837$  and  $0.332$  respectively, Mann–Whitney–

Wilcoxon test). Five eyes needed suture-lysis post-operatively for high IOP and four eyes had shallow anterior chamber. Two eyes developed corneal ulcer secondary to loos stitches and one eye developed fibrin membrane formation and all cases improved with treatment. One eye developed optic atrophy and became blind secondary to neovascular glaucoma.

## Discussion

Treatment for patients with cataract and glaucoma is either cataract surgery by phacoemulsification or combined surgery by phacotrabeculectomy [16]. There are few published articles regarding combined phacotrabeculectomy with intraoperative MMC [14,15,17,18]. Combined phacotrabeculectomy with MMC is usually performed on patients that have visually disabling cataract and glaucoma [16,17].

It was reported that there is usually progression of cataract after trabeculectomy surgery alone that will need a second procedure to remove the cataract [9,19]. In addition, literature review shows that trabeculectomy failure is higher after sequential cataract surgery compared to combined surgery [10,19]. Combined phacotrabeculectomy has an advantage of reducing the need for a second intra-ocular surgery. As repeatedly reported, with the improvement in phacoemulsification and trabeculectomy, phacotrabeculectomy continues to gain popularity among ophthalmic surgeons [14,15,17,18].

Considering the above facts, in patients with visually significant cataract and glaucoma requiring surgical correction, a combined technique of surgery is considered as a standard surgical method of management. The objective of phacotrabeculectomy is to achieve an adequate long-term control of IOP, obtain an optimal visual rehabilitation, reduce anti-glaucoma medications and improve the quality of life of the patient.

Usually the first postoperative month is the most important period for postoperative monitoring. The Trabeculectomy Outcomes Group Audit Study Group emphasized the importance of intensive proactive postoperative care to reduce rates of surgical complication after trabeculectomy [20]. In their audit of 428 eyes of 395 white patients with open-angle glaucoma, 183 out of 184 (99%) suture manipulations and 21 out of 22 (95%) of re-suturing took place in the first three months, and they proceeded to recommend that close follow-up of patients and proactive intervention are necessary after trabeculectomy, though they did not specify strict duration [20]. In the present study, the commonest postoperative complications were high IOP that needed suture-lysis and shallow anterior chamber respectively. Other authors reported prolonged hypotony, hyphema and bleb leak [16]. In our study hypotony was not seen so often because of the tight sutures used by the surgeon and usually hypotony can be safely managed conservatively if the anterior chamber is not flat and hypotony is not prolonged [21].

Phacoemulsification alone was reported to produce transient decline of IOP in patients with glaucoma [21,22]. Many authors have proposed certain modification in surgical technique which helps in reducing postoperative hypotony [16,23]. Using a more posterior keratome entry in addition to surgeon factor such as tension of sutures, number of sutures and timing of suture-lysis play an important role in determining the early post-operative IOP.



With regards to postoperative IOP (less than 50 days); 94 of the 100 eyes achieved IOP control (less than 21 mm Hg) with or without medications. Seventy-five eyes had an IOP of 15 mm Hg or lower, and 81 had an IOP reduction of at least 30 %. At 6 months, 99 eyes achieved intraocular pressure control (less than 21 mm Hg) with or without medications. Sixty-nine eyes had an IOP OG 15 mm Hg or lower, and 77 had an IOP reduction of at least 30 %. At one-year post-operatively; 95 eyes achieved intraocular pressure control (less than 21 mm Hg) with or without medications. Sixty-one eyes had an IOP of 15 mm Hg or lower, and 71 had an IOP reduction of at least 30%. At two years' follow-up, 88 eyes achieved intraocular pressure control (less than 21 mm Hg) with or without medications. Furthermore, fifty-two eyes had an IOP of 15 mm Hg or lower, and 65 had an IOP reduction of at least 30 %.

Black race is a strong predictor for failure after phacotrabeculectomy and all our patients were Yemeni from Arab origin and were not possible to use it as a predictor [24]. There is no corresponding study which demonstrated any racial or gender predisposition for developing a postoperative complication [25]. It could be helpful to emphasize the importance of wound care in the postoperative period and remind all patients to avoid applying forceful pressure on the eye.

Being a retrospective study, it was impossible to standardize documentation and the complication rates may have been under-reported. Endothelial cell count is usually reduced after phacotrabeculectomy [26] but it was not possible to measure

in our group of patients because there is no specular microscope in Yemen. The low presence of certain complications could have introduced greater statistical uncertainty due to random error, or resulted in a lack of statistical power to detect if less frequent complications (e.g. persistent inflammation) were risk factors for failure. One case had inflammatory reaction and no blebitis was seen but short period of follow-up (two years) can be the reason behind that. Longer follow-up is needed to address the above limitations and also to clearly find the advantage of combined phacotrabeculectomy over trabeculectomy alone for this group of patients.

The limitation of our study is that it included a heterogeneous group of patients with various etiologies of glaucoma. However, in our study, although there was more open angle glaucoma, it was unrelated to the surgical results. Furthermore, the follow up period is relatively acceptable but to determine the long term successful rate of the glaucoma filtration surgery a longer follow up is needed.

## Conclusion

The surgical technique used in this study appears to be effective and safe procedure at restoring good visual acuity, controlling and lowering of IOP and reducing the postoperative complication rate. Transient high intraocular pressure and shallow anterior chamber were the commonest postoperative complications after phacotrabeculectomy with MMC.

This study showed that majority of complications were transient and self-limiting. Patients need reassurance that the procedure is safe but close follow-up is crucial especially in the early post-operative period to prevent complications that might result in surgical failure.

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