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# Two Year Outcomes of Mitomycin C Augmented Primary Trabeculectomy Surgery Among Patients with Primary Open Angle Glaucoma: A Retrospective STU

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# Abstract

**Background:** Mitomycin C (MMC) augmented primary trabeculectomy surgery is a very viable option for controlling primary open angle glaucoma (POAG) in a low income country like Nigeria in West Africa. There is limited information about the outcome of trabeculectomy surgery in northwestern Nigeria, West Africa.

Aim: To determine the outcomes of trabeculectomy surgery regarding reduction of post-operative Intra Ocular Pressure (IOP), as well as preserved functional vision among glaucoma patients attending Makkah Specialist Eye Hospital Kano (MSEHK) Nigeria, West Africa.

**Materials and Methods:** A retrospective glaucoma case notes search for data concerning history of MMC augmented trabeculectomy with a minimum of 6 months post-operative follow-up visit between January 2021 and December 2022 was done. The criteria for a good outcome were post-operative IOP of  $\leq$  18 but  $\geq$ 5 mmHg. Consultant ophthalmologists that are contract staff of MSEHK and with expertise in trabeculectomy performed the surgeries.

**Results:** A total of sixty patients aged 43.32 years ( $\pm$  12.83), at presentation had a mean aided Snellen's visual acuity (VA) of 6/10.5 partial; 0.56 ( $\pm$  0.36) but reduced to 6/12 partial; 0.46 ( $\pm$  0.31) post-operatively, p = 0.00, mean cup disc ratio was 0.82 ( $\pm$  0.12) but slightly changed to 0.82 ( $\pm$  0.12) p = 0.16, and mean spherical equivalence was -0.31D ( $\pm$  1.45) but also slightly changed to -0.30D ( $\pm$  1.20) at six months post-surgery. Complete success, qualified success with postoperative use of Misopt and Xolamol were 56 (93.33%), 3 (5.50%), and 1 (1.67%), respectively, no failure observed.

**Conclusion:** MMC augmented primary trabeculectomy surgery was an effective means as to IOP reduction for POAG patients attending MSEHK, Nigeria with significant topnotch success rates, preserve functional vision but loss of one line of Snellen's VA. MMC augmented primary trabeculectomy is a very viable treatment option for POAG especially in the low income countries like Nigeria in West Africa.

**Keywords:** Mitomycin C Augmented Primary Trabeculectomy Surgery; Intra Ocular Pressure; Primary Open Angle Glaucoma; Makkah Specialist Eye Hospital Kano

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### Introduction

Glaucoma is an irreversible blinding group of eye diseases that both the eye doctors and patients with glaucoma or glaucoma suspects, want to explore together because even the eye doctors do not know the main cause of this disorder but they are aware of the genetic, ethnic, and environmental factors that are consistence with it worldwide [1-4]. Primary open angle glaucoma (POAG) is the most common type and its prevalence is highest in sub Saharan African countries [2].

Relative abnormally elevated intraocular pressure (IOP) has been the only treatable sign in the control of glaucoma and that is why a lot of efforts is exerted on the possible ways to achieve a targeted IOP for each patient based on the corneal biomechanical properties such as hysteresis and the type of glaucoma that the patient is diagnosed with [5-12]. Hence, the pharmacological classes of mostly topical drugs called anti-glaucoma drugs such as beta-blocker, carbonic anhydrase inhibitor, as well as prostaglandin analogue etc., and surgical intervention like trabeculectomy and minimal invasive glaucoma surgery (MIGS) were introduced to achieve a targeted IOP to control glaucoma progression in patients that are managed for glaucoma [13-17].

However, the anti-glaucoma drugs are often too expensive to keep up with, since they are to be use for a lifetime and sometime the maximum tolerated medical therapy would fail to achieve the targeted IOP to control the damage that is caused by glaucoma due to poor compliance or drug intolerance [18-21]. A new affordable drug that will guarantee expected outflow of aqueous humor through the trabecular pathway with minimal side effects, to control glaucoma is still a major challenge in the glaucoma pharmaceutical space [11,22-25].

More so, MIGS and trabeculectomy are the primary and viable surgical option to effectively treat or control IOP in patient with glaucoma worldwide but in Nigeria, there limited resources to carryout MIGS [24]. Hence, trabeculectomy remain the gold standard in the effective treatment or control of glaucoma in a low income country like Nigeria in West Africa [25].

Trabeculectomy is a conventional glaucoma control eye surgery done (with the use of antifibrotic agents such as Mitomycin C (MMC) or 5 - Fluorouracil) by creating a viable ostium in trabecular pathway to enhance ease of outflow of aqueous humor into a drainage conjunctival blister under the upper eyelid called bleb [31,32]. Trabeculectomy like every other surgical procedure have its risks and complication like ocular hypotony, choroidal detachment, as well as endophthalmitis, that often give glaucoma patients as wells as eye care practitioners genuine concern regarding the outcomes [26-29]. Although, it is reported in a review that POAG have good outcomes with trabeculectomy in Africa (with a success rate of 61.8% to 90% as to postoperative IOP less than 20mmHg) especially when augmented with an antifibrotic agent like MMC [30,31].

However, there is only a few studies done regarding the outcomes of trabeculectomy surgery in Nigeria especially in northwestern Nigeria. In this retrospective study, an effort was made to assess a two year outcomes of MMC augmented trabeculectomy surgery done on patients with POAG in Makkah Specialist Eye Hospital Kano (MSEHK), Nigeria at six months post-operative followup treatment with emphasis on targeted post-operative IOP as well as preserved functional vision.

#### **Patients and Methods**

This two year retrospective study was approved by the Makkah Specialist Eye Hospital Ethical Committee and Review Board and was conducted in accordance with the declaration of Helsinki.

#### Study design

Patients aged 16 years and above with POAG who undergone trabeculectomy surgery between January, 2021 to December, 2022 as well as completed six month post-operation follow-up at MSE-HK, Nigeria were retrospectively searched and analyzed. Patients' informed consent was skipped. Well-seasoned consultant ophthalmologist with expertise in trabeculectomy, that are staff of MSEHK performed the trabeculectomy surgeries. Visiting doctors/glaucoma specialist in the glaucoma clinic saw the patients on post-operative visits. All trabeculectomy surgeries were augmented with MMC. Patients that are yet to meet up with minimum of 6 months post-operative follow-up visits were excluded. Patients who underwent combined procedures such as cataract and trabeculectomy were also excluded.

## Surgical technique

All procedures were done with initial topical 1% tetracaine drops followed by injection of 2 - 2.5 ml of lidocaine without adren-

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aline that was administered in the sub-tenon space. Corneal traction suture (with a 7-0 Vicryl suture on a semicircular needle) is placed to achieve maximal traction before initiating a posterior dissection for conjunctival flap and Tenon's capsule in the dissected area was mobilized and excised. A 2.5mm by 3mm scleral flap of two-third thickness was constructed with a crescent knife after which a sterile 7 x 7 mm sponge soaked in MMC with concentration of 0.5 mg/ml was placed under the conjunctival flap for 3 minutes (all surgeries were augmented with MMC), the sponge is removed and the area is adequately rinsed with balanced salt solution. A temporal paracentesis that is needed to administer 2% pilocarpine is made, then a 1.5 mm sclerostomy was done using Kelly's punch before a peripheral iridectomy was done with a vannus. Aqueous humour filtration was tested by anterior chamber inflation with balanced salt solution before and after closing the scleral flap with a nylon 10-0 sutures (this preplaced sutures is of suture tension that allows a relatively slow and continuous flow of aqueous humour under the flap). A two sided conjunctival closure was done to close the flap with 8-0 Vicryl suture that formed a bleb when saline was again injected into the anterior chamber through the paracentesis. At the end of each surgery, 1% atropine drops was instilled, 0.2 ml of 0.5% Moxifloxacin (preservative free) was administered intracamerally and sub-conjunctival steroid injection was also given to all patients.

## **Data collection procedures**

Primarily, a hundred and fifty four MMC augmented primary trabeculectomies were done between January, 2021 to December, 2022, and only a total of 60 patients' data were extracted for analysis because other patients did not meet up with at least 6 months post-operative follow-up assessments criteria. The data was collected from patients' files in a session by the optometrists and the data was entered into a standardized Microsoft Excel 2016 spreadsheet. The data collected included: baseline demographic data, preoperative VA, IOP, cup-to-disc ratio (CDR), stages of glaucoma, types of topical and systemic anti-glaucoma medications, and postoperative VA, IOP, CDR as well as the use of anti-glaucomatous medication.

# **Outcome measures**

The level of IOP on the first post-operative day, first week, first month, third month, and six month after the surgery was documented. Complete success refers to IOP > 5 mmHg and < 18mmHg

without glaucoma medications. Qualified success is > 5mmHg and < 18 mmHg with glaucoma medications. Failure refers to IOP  $\leq$  5 mmHg or  $\geq$  18 mmHg even with medications as well as complications during post-operative period, need for additional glaucoma surgeries, and development of no perception of light (NPL).

### Statistical analysis

Demographic and ocular characteristics of these subjects including age, sex, eye, IOP, anti-glaucoma medication, stage of glaucoma, as well as successes and failure were described with frequency and percentage. A line chart was use to show the pattern of mean IOP measured before and after surgery. Paired Samples T-test was used to find the comparison between preoperative and postoperative IOP, VA, and CDR, p-value < 0.05 was statistically significant.

# Results

# Patients' profile

A total of 60 eyes (53.33% were right eye only while 46.67% left eye only) out of 154 (38.96%) that already undergone MMC augmented trabeculectomy surgery between the years 2021 to 2022 with at least 6 months postoperative follow-up visit were analyzed. The patients were aged  $43.32 \pm 12.83$  (Range: 14 - 70) years. Sixty percent of the subjects were male while 40% were female. Majority (56.67%) had the surgery when the glaucoma is in the advanced stage.

Demographics of the subjects (n = 60)	Frequency	Percentage
Age category (43.32 ± 12.83) years		
10 - 30	12	20.00
31 - 50	27	45.00
51-70	21	35.00
Sex		
Male	36	60.00
Female	24	40.00
Eye		
Right	32	53.33
Left	28	46.67
Stages of glaucoma		
Mild	4	6.67
Moderate	22	36.67
Advanced	34	56.67
Types of medication		

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Xolamol + Brimonidine	13	21.67
Micropost + Diamox	1	1.67
Xolamol + Brimonidine + Diamox	2	3.33
Xolamol	25	41.67
Timolol	2	3.33
Xolamol + Diamox + Brimonidine	3	5.00
Xolamol + Diamox	8	13.33
Diamox + Slow K + Xolamol + Latanoprost	2	3.33
Micropost + Latanoprost + Brimonidine + Diamox	1	1.67
Xolamol + Latanoprost	3	5.00

**Table 1:** The demographic and pre-operative examination characteristics of the subjects with POAG that undergone MMC augmented trabeculectomy surgery at MSEHK, Nigeria, 2023. Pre-operative examination findings for patients with POAG (initially placed on pressure reducing medications) just before the surgery are as follows. Snellen's mean aided VA of all eyes was 6/10.5 partial (p); 0.56 ( $\pm$  0.36), mean spherical equivalence of -0.31D ( $\pm$  1.45), mean IOP was 20.88 mmHg ( $\pm$  4.81), mean CDR was 0.82 ( $\pm$  0.15). At six months post-operative follow-up visit, the findings are as follows: mean VA was 6/12p; 0.46 ( $\pm$  0.31), p = 0.00, mean spherical equivalence was -0.30D ( $\pm$  1.20), p = 0.95, mean IOP was 12.45mmHg ( $\pm$  4.68) and mean CDR was 0.82 ( $\pm$  0.15), p = 0.16.

All the MMC augmented primary trabeculectomy surgeries were successful at six months postoperative follow-up, regardless of the age, gender, eye, stage of POAG. Complete success was recored in 93.33% of the cases, qualified success with misopt eyedrop in 5%, as well as with Xolamol eyedrop in 1.67% of the case but there was no failure at 6 months post-operative follow-up visit, details in Table 3.



Figure 1: The trend in mean IOP from first visit to six month post-operative follow-up visit of patients with POAG and undergone MMC augmented primary trabeculectomy surgery in MSEHK, Nigeria.

Parameters	Preoperative	Postoperative	P-value
Aided Visual Acuity	0.56 ± 0.36	$0.46 \pm 0.31$	0.00
Spherical Equivalence	-0.31± 1.45	-0.30 ± 1.20	0.95
IOP	20.88 ± 4.81	12.45 ± 4.68	0.00
CDR	0.82 ± 0.15	0.82 ± 0.15	0.16

**Table 2:** Comparison between pre-operative and post-operative examination of the eyes with POAG that underwent MMC augmentedprimary trabeculectomy surgery at MSEHk, Nigeria, 2023.

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Types of postoperative medication	Frequency	Percentage
Complete success (no medication)	56	93.33%
Qualified success with Misopt Eyedrop	3	5.00%
Qualified success with Xolamol Eyedrop	1	1.67%
Failure	0	0%

 Table 3: The Outcomes of MMC Augmented Primary Trabeculectomy Surgery among Patients with POAG at Makkah Specialist Eye

 Hospital Kano Nigeria, 2023.

#### Discussion

This study provides vital information as to outcomes of primary trabeculectomy augmented with MMC in Nigeria, West Africa. Although, it is a retrospective study and as such, it is subject to established problem of data collection reliability but we tried our best to put together the pre- and post-operative a credible data. MMC augmented primary trabeculectomy surgery has been a routine surgical intervention for POAG at MSEHK Nigeria since the year 2020. In the earlier years few trabeculectomies were done augmented with MMC as an anti-fibrotic agent but afterwards, the number kept on increasing over time. And the bulk of the surgeries were done between 2021 and 2022 due to the Christian Blind Mission (CBM) sponsorship and training of residents who paid a keen interest in trabeculectomy procedure. It was then that a regular glaucoma clinic commenced and the commitment to glaucoma patients explains the increase in patient load of the hospital.

There is unavoidably some heterogeneity in technique, now, unlike in the earlier years where the trabeculectomy surgeries were done by one surgeon. The recruitment of more expatriates ophthalmologist and/or glaucoma specialist with expertise in trabeculectomy surgery, from Sudan and Pakistan enhanced the outcome of primary trabeculectomy surgeries since 2020. The followup visit were attended to by the glaucoma specialists in glaucoma clinic at MSEHK, Nigeria. The follow-up period of the study was 6 months.

More so, the glaucoma surgeons and/or specialist could have done eyeball massage or early post-operative manipulation of the filtering bleb that may had an impact in higher success rates. However, a few serious complication (a case of shallow anterior chamber which was reformed with 2% hydroxypropyl methylcellulose, a case of marked ocular hypotony which was resolved via suture compression, a case of late bleb leak which was repaired by conjunctival autograft and a case of post-operative endophthalmitis which was resolve with intravitreal combination of 2.25 mg/0.1 c cceftazidime + 1 mg/0.1 cc vancomycin) were observed but they were managed properly and may not affect the outcomes, see Figure 1 for the mean IOP trend from baseline to 6 months post-surgery.

All eyes that underwent MMC augmented primary trabeculectomy were reviewed a day after surgery. However, the percentage gradually declined in subsequent follow-up visits, with only 38.96% of the eyes being examined during 6 months post-operative visit, see Table 1. This percentage is lower compared to what was reported by Soatiana., et al. [32] who examined the noncompliance risk factors in normal-tension glaucoma (NTG) cases but find out that 46% of patients were noncompliant with follow-up visits as well as Ke Yang., et al. [33] who mentioned poor follow-up in rural china but suggested that lowering the cost of post-operative follow-up like giving free medication could improve compliance. Kipsang [34] also reported that 63.1% of patients were examined during the second year follow-up visit in his retrospective study. In this study majority of the patients did not benefit from free followup services and this may have contributed to the poor compliance during the follow-up period. Also not all patients came from around Kano city, others were coming from distant areas and that may also prevent them from meeting up with follow-up visits.

This study included 60 patients, male to female ratio was 3:2 (60% were male) just like the other similar retrospective studies done in Africa, reported higher percentage of men undergoing trabeculectomy surgery when compared to the women, see Table 1 [32]. This also emphasized that there are more men than women have undergone trabeculectomy in Africa, perhaps because they are bread winners of the family and they feel threat regarding loss of sight due to glaucoma more than the female counterpart.

Citation: Husam Osman Balla Abdalla., et al. "Two Year Outcomes of Mitomycin C Augmented Primary Trabeculectomy Surgery Among Patients with Primary Open Angle Glaucoma: A Retrospective STU". Acta Scientific Ophthalmology 7.5 (2024): 35-42. In this study, all patients had trabeculectomy done in one only they were aged  $43.32 \pm 12.83$  years; range: 14 - 70 years but 80% are  $\geq 31$  years, see Table 1. This is because most patients had POAG which is the most common glaucoma after the age of 40 years. In same vein, in the retrospective study done by Bowman., *et al.* in Tanzania, the patients were aged 67 ± 11 years; range: 21 - 86 years. Most of the patients (94.7%) had the trabeculectomy in one eye.

In this study, more than half (55%) of the patients are on more than one anti-glaucoma medication (both topical and systemic) before surgery and more than half (56.67%) of the patients had advanced stage glaucoma before surgery, see Table 1. The pre-operative as well as the post-operative examination findings in this study included the best vision in decimal notation/Snellen's ratio, refractive status in diopters, IOP in millimeters of mercury and cup to disc ratio.

At six months follow-up post-surgery the mean aided visual acuity of the subjects significantly reduced from 6/10.5 partial (p);  $0.56 \pm 0.36$  to 6/12p;  $0.46 \pm 0.31$  (loss by one line of Snellen VA) on a Nidek projected Sloan letters chart (p = 0.00), see Table 2. This is in concordance with the studies which reveal that reduction in the visual acuity after long term post-trabeculectomy surgery is a common occurrence [33,34]. It is also emphasized that glaucoma patients would probably experience deterioration of aided VA in long term or in advance stage but on the contrary, some studies reported improved VA after trabeculectomy [35]. The one line of Snellen VA reduction in the patients vision may probably be due to cataracts progression or increasing damage to central visual field because glaucoma cannot be cured but we can only slow down the progression with IOP control [36]. However, the changes observed in the CDR of their eyes at 6 months post-operative follow-up visit was not statistically significant (p = 0.16) when compared to the pre-operative assessments which make us feel that patients' functional vision may still be preserved despite slight reduced VA, see Table 2. More so, the spherical equivalence or refractive status of their eyes at 6 months post-operative follow-up did not significantly changed (p = 0.95) when compared to baseline pre-operatively because the small induced corneal astigmatism from conjunctival closure that often cause with-the-rule astigmatism shift [37].

There is no strict rule regarding success rate criteria for trabeculectomy surgery as surgical intervention for glaucoma control but majority of the studies used 21 mmHg or less as a criterion for success. However, in this study on MMC augment primary trabeculectomy surgery done of patients with POAG, despite using 18 mmHg is set for upper limit and 5 mmHg is the lower limit for success (either complete or qualified), no failure was recorded (93.33% won't use anti-glaucoma medication again) in the surgeries done after assessment at six months post-surgery. The intraoperative use of antimetabolites or anti-fibrotic agents like MMC has been proved to significantly enhance the success rates of primary trabeculectomy in all patients regardless of the perceived risk factors for surgery failure [38]. However, other studies reported higher incidence of post-operative endophthalmitis, and cystic avascular thin walled blebs with intraoperative use of MMC [39,40].

### Conclusion

MMC augmented primary trabeculectomy surgery was an effective means as to IOP reduction for POAG patients attending MSEHK, Nigeria with significant topnotch success rates, preserve functional vision but loss of one line of Snellen's VA. Patients' compliance with scheduled and post-operative follow-up visit may be a predictor for good outcomes of trabeculectomy surgery in an expert driven practice. MMC augmented primary trabeculectomy is a viable treatment option for POAG especially in the low income countries like Nigeria in West Africa. A long term prospective study is needed to provide a more reliable evidence for this claim.

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#### **Conflict of Interest**

No conflict of interest was declared by any of the authors.

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