

THESIS RESULTS

**OUTCOMES OF TRABECULECTOMY AT KENYATTA NATIONAL
HOSPITAL AND UNIVERSITY OF NAIROBI: A RETROSPECTIVE
CASE SERIES**

**DEPARTMENT OF OPHTHALMOLOGY
UNIVERSITY OF NAIROBI**

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**THESIS RESULTS SUBMITTED IN PARTIAL FULFILMENT FOR
THE AWARD OF DEGREE OF MASTER OF MEDICINE IN
OPHTHALMOLOGY**

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DECLARATION

I declare that this thesis is my original work and has not been presented for the award of a degree in any other university.

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DEDICATION

This work is dedicated to my family for their overwhelming sacrifice, support and encouragement throughout the years as I studied for this ophthalmology degree.

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TABLE OF CONTENTS

Contents

DECLARATION	ii
SUPERVISOR'S APPROVAL.....	iii
DEDICATION	iv
ACKNOWLEDGEMENTS.....	v
TABLE OF CONTENTS.....	vi
LIST OF ACRONYMS AND ABBREVIATIONS	ix
DEFINITION OF KEY WORDS.....	xi
ABSTRACT.....	xii
CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW	1
1.1 Introduction	1
1.1.1 Glaucoma and its impact	1
1.1.2 Epidemiology of glaucoma.....	1
1.2 LITERATURE REVIEW	2
1.2.1 Clinical presentation	2
1.2.2 Management of glaucoma	2
1.2.2.1 Medical management of glaucoma	2
1.2.2.2 Surgical management of glaucoma.....	3
1.2.3 Trabeculectomy.....	4
1.2.3.1 History of trabeculectomy	4
1.2.3.2 Indications of trabeculectomy	4
1.2.3.3 Factors Affecting Outcomes of Trabeculectomy	4
1.2.3.4 Outcome measures of trabeculectomy surgery	6
CHAPTER TWO: STUDY JUSTIFICATION.....	8
2.1 Study Rationale	8
CHAPTER THREE: OBJECTIVES	9
3.1 Main Objective	9
3.2 Secondary Objectives included	9
3.3 MATERIALS AND METHODS	9
3.3.1: Study Design	9
3.3.2 Study Location.....	9
3.3.3: Study Population.....	9

3.3.4 Inclusion criteria.....	9
3.3.5 Exclusion Criteria.....	9
3.3.6 Outcome Measures.....	10
3.3.6.1 Primary outcome measure:	10
3.3.3.6.2 Secondary outcome measures:.....	10
3.7 Study Materials	11
3.8 Personnel	11
3.9 Sample size calculation	11
3.10 Data Collection and Analysis.....	12
3.11 Ethical Consideration	12
3.11.1 Ethical Approval and Permission	12
3.11.2 Confidentiality.....	12
3.12 Dissemination Plan.....	13
4. RESULTS.....	14
5. DISCUSSION.....	33
6. STUDY LIMITATIONS.....	40
7. CONCLUSIONS.....	41
8. RECOMMENDATIONS.....	42
REFERENCES.....	43
APPENDICES	48
Appendix 1: Approval letter from Ethics and Research committee	48
Appendix 2: Questionnaire	50
Appendix 3: Budget.....	54

Figure 1: Flow chart of patients included in the study	14
Figure 2: Annual distribution of Surgeries done (n=149)	15
Figure 3: Compliance to follow-up appointments (n=149)	16
Figure 4:Pre-operative IOP (n=149)	18
Figure 5: Indications for surgery (n=149)	20
Figure 6: Trend in mean IOP post-operatively	21
Figure 7: Percentage reduction of IOP from baseline	22
Figure 8 Kaplan-Meier survival analysis for complete success	25
Figure 9: Kaplan-Meier survival analysis for qualified success	27
Figure 10: Trend in CDR and Vision in Logmar	29
Figure 11: Change in the use of anti-glaucoma drugs from pre-operative to post-operative period	30

Table 1: Ideal, Preferred and Acceptable Time Period of Follow-up after Surgery. ³³	11
Table 2: Demographic characteristics (n=138) and Pre-operative Examination Characteristics 17	
Table 3:Pre-operative use of Anti-glaucoma Medication	19
Table 4: Type of TET done in Eyes (n=149)	20
Table 5: Comparison of mean pre-operative and post-operative IOP for different follow-up visits	23
Table 6: Complete success trend (> 5mmHg and < 18mmHg, with 20% reduction from baseline without glaucoma medications)	24
Table 7: Qualified success trend (IOP > 5mmHg and < 18mmHg with or without glaucoma medications, with 20% reduction from baseline)	26
Table 8: Failure at Final Follow-up Visit	28
Table 9: Complications by post-operative period	31
Table 10: Surgical interventions for complications	32
Table 11: Factors that contributed to IOP failure at final follow up visits	32

LIST OF ACRONYMS AND ABBREVIATIONS

AAO	American Academy of Ophthalmology
AC	Anterior chamber
AGIS	Advanced glaucoma intervention study
ALPI	Argon Laser Peripheraliridoplasty
ALT	Argon laser trabeculoplasty
BCVA	Best Corrected Visual Acuity
CDR	Cup disc ratio
HM	Hand Movement
HRT	Heiderberg retina tomography
IOP	Intraocular pressure
KNH	Kenyatta National Hospital
Logmar	logarithm of the minimal angle of resolution
LPI	laser peripheral iridoplasty
NFL	Nerve fibre layer
NPL	Not Perceiving Light
OCT	Optical coherence tomography
OSU)	Ophthalmic Services Units
PACG	Primary angle closure glaucoma
PC	Posterior chamber
POAG	Primary open angle Glaucoma
Post-op	Post operation

Pre-op	Pre operation
SLT	Selective laser trabeculoplasty
SPSS	Statistical package for social sciences
SPSS	Statistical Package for Social Scientist
Trab	Trabeculectomy
UON	University of Nairobi
VA	Visual Acuity
VCDR	Vertical cup disc ratio
WHO	World Health Organisation

DEFINITION OF KEY WORDS

Trabeculectomy- is a surgical procedure used in the treatment of glaucoma to relieve intraocular pressure by removing part of the eye's trabecular meshwork and adjacent structures.

Cornea - Transparent film that covers the iris and pupil. It's a complex structure which, as well as having a protective role, is responsible for about three-quarters of the optical power of the eye. The normal cornea is free of blood vessels.

Iris- The iris is the most anterior extension of the uveal tract. It is made of blood vessels and connective tissue, in addition to the melanocytes and pigment cells responsible for its distinctive color. The mobility of the iris allows the pupil to change size.

Sclera- White, outer coating of the eyeball.

Trabeculoplasty- Laser surgery that creates perforations in the trabeculum, to drain built up aqueous humour and relieve pressure.

Trabeculum - Tissue that is a drainage point for aqueous humour in the eye.

Filtering bleb- A blister of conjunctiva resulting from glaucoma surgery by which a flap of sclera is created in the eye wall, allowing aqueous humour to percolate out of the eye and underneath the conjunctiva, thus lowering intraocular pressure.

Iridectomy- is a procedure in eye surgery in which the surgeon removes a small, full-thickness piece of the iris

Iridoplasty- A technique used to help pull the peripheral iris away from the trabecular meshwork in the angle of the eye

Sclerectomy- Excision of a portion of the sclera

ABSTRACT

Trabeculectomy is the commonest glaucoma surgery done at Kenyatta National Hospital (KNH) and University of Nairobi (UON) School of dental sciences. Few studies have been done in Kenya to assess the outcomes of trabeculectomy. So this study aimed to assess the outcomes in order to provide useful information that will further be used for providing recommendation pertaining management of patients undergoing trabeculectomy.

Study Objective

To assess the outcome of trabeculectomy surgeries done at KNH and University of Nairobi, its complications and need for additional anti-glaucoma medication or glaucoma surgery.

Study Design

Retrospective case series

Materials and Methods

This was retrospective hospital-based case series that aimed to assess the outcomes of trabeculectomy surgeries done at KNH main theatre, UON School of dental sciences theatre and the patients' were followed up at eye clinic at KNH over the study period. The main outcome measures were IOP, CDR and vision. Records of patients done trabeculectomy from 1st January 2006 to 30th December 2015 were retrieved from the hospital records. The files were consecutively selected and reviewed. The relevant information was entered in a pre-designed questionnaire.

Data Management

Data was entered in a coded questionnaire and then entered in MS Excel spread sheet, which was then be cleaned and verified to ensure consistency. Data analysis was done using SPSS computer software.

Results:

A total of 149 records were reviewed. The male to female ratio was 2:1. Most patients (84.1%) were ≥ 50 years of age. Mean age was 60.8 years with a range of 18-81 years. Most (94.7%) of patients had TET in one eye that met the inclusion criteria .The mean pre-operation IOP was 25.4 ± 6.17 mmHg with a range of 14-63mmHg. All eyes were on anti-glaucoma medications before surgery, with the majority being on 2 or more drugs in the pre-

operative period (85.5%) with a mean of 2.2 ± 0.69 . 96% of eyes being on a beta Beta-blockers. Failed medical treatment was the most common indication of trabeculectomy at 58.4%. Majority of TET were done with anti-fibrotic agents (90.6%), of which the most commonly used was MMC (80.5%). There was a statistically significant reduction in the mean IOP after surgery throughout the follow-up period. On the first day after surgery the mean intraocular pressure reduced to 11mmHg increasing to a mean of 16mmHg at year 2 from a mean IOP of 24mmHg before surgery. 76% and 52% achieved qualified and complete success respectively at year 2. At final follow-up visit 17% had failed TET. Mean CDR was 0.9 and Vision was 0.32 logmar equivalent and both were maintained during the follow-up period. Mean number of anti-glaucoma drugs decreased from 2.2 ± 0.69 in pre-operative period to 0.54 ± 0.88 at 2years follow-up visit. Hypotony was the most common early complication seen in 24 eyes (16.1%). The most common late complications was bleb fibrosis, seen in 31 eyes (20.8%). The most serious complications were suprachoroidal haemorrhage (1 eye) and blebitis (1 eye). Needling was the most intervention done for the complications. Most of TET that failed had bleb fibrosis.

Conclusion:

Trabeculectomy is adequate in controlling IOP up to a period of 2years after surgery however there is no effect on change of CDR after surgery and has limited effect in vision change. Use of anti-glaucoma medications is significantly reduced after TET. Bleb fibrosis and encapsulation forms the greatest risk factor for surgical failure in the long term. Patient follow-up drop-out possess a challenge in management post TET.

Recommendation:

Trabeculectomy is a safe and effective procedure in controlling IOP. Patients should be educated to ensure good compliance to medications and to follow-up appointments. Conduct a prospective study with a longer follow-up period to assess the long-term success rates of trabeculectomy.

CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

1.1.1 Glaucoma and its impact

The term glaucoma refers to a group of diseases that have in common a characteristic Optic neuropathy with associated visual function loss. Elevated intraocular pressure (IOP) is one of the primary risk factors for development of glaucoma. Its presence or absence does not have a role in the definition of the disease.

Glaucoma can be classified in primary or secondary. The primary glaucomas are not associated with known ocular or systemic disorders that cause increased resistance to aqueous outflow or angle closure. The primary glaucomas commonly affect both eyes. Secondary glaucomas are associated with ocular or systemic disorders responsible for decreased aqueous outflow.

Glaucoma has been classified as open angle or closed angle. This classification has a therapeutic implication. Open-angle glaucoma is classified as primary when no anatomically identifiable underlying cause of the events that led to outflow obstruction and IOP elevation can be found.

Glaucoma is the second most common cause of vision loss worldwide behind cataracts, but, unlike cataracts, the vision loss associated with glaucoma is largely irreversible.¹ People with glaucoma in developing countries are more at risk of progressing to blindness.^{2,3} Ignorance about glaucoma in developing countries poses a major challenge in the sense that a good number of patients receiving glaucoma treatment expect cure and visual improvement.^{4,5} Medical treatment and follow up also possess a big challenge in developing countries prompting early surgery instead of surgery generally being reserved for failed medical treatment.^{6,7}

1.1.2 Epidemiology of glaucoma

The number of people with glaucoma globally is expected to rise from 64 million to 76 million in 2020 and 111 million in 2040, with Africa and Asia being affected more heavily than the rest of the world.^{8,9} Primary open angle glaucoma (POAG) is the commonest type

and the highest prevalence is in African countries.⁸ People of African descent have been thought to be at risk.^{10, 11} Review of worldwide primary open angle glaucoma(POAG) prevalence among people aged 40-80 years in 2014 showed estimates of 2.31% in Asia, 3.65% in Latin America and the Caribbean, and 4.20% in Africa.⁸ A study, based in West Africa showed primary open angle glaucoma (POAG) prevalence of nearly 15% in individuals over the age of 80.¹² Primary angle closure glaucoma (PACG) has the highest prevalence in Asia.¹³ In a Nigerian eye clinic, new glaucoma patients were evaluated, and 9.2% were found to have angle closure or angle closure glaucoma.¹⁴

1.2 LITERATURE REVIEW

1.2.1 Clinical presentation

Open-angle glaucoma is painless and does not have acute attacks, hence lack of clear symptoms make screening and regular eye check-up very important. The common signs are gradually progressive visual field loss, and optic nerve damage hence an increased cup-to-disc ratio (CDR) on funduscopy examination.

A proportion of people with closed-angles present with acute angle closure. Symptoms mainly are sudden ocular pain, seeing halos around lights, red eye, very high intraocular pressure (IOP), nausea and vomiting, suddenly decreased vision with a fixed or mid-dilated pupil. Acute angle closure is an emergency.

1.2.2 Management of glaucoma

Glaucoma treatment is aimed at preserving visual function by lowering the IOP below a level that is likely to produce further damage to the optic nerve, and preserve visual field and total quality of life for patients, with minimal side effects.^{15, 16} The cost of the treatment of choice should be taken into account. Every patient should have a target intraocular pressure (IOP) which should be set based on the intraocular pressure (IOP) at which damage is thought to have occurred, the severity of the damage, the life expectancy and other associated factors. Individuals should be assessed more often for IOP fluctuations, optic nerve changes and visual field progression. Glaucoma can be managed medically, surgically or both.

1.2.2.1 Medical management of glaucoma

Several classes of medications are used to treat glaucoma, with several medications in each class; mostly eye drops. Poor compliance with medications and follow-up visits is a major reason for vision loss in glaucoma patients.¹⁷ Some classes of medications include. Prostaglandin analogs, such as latanoprost and Bimatoprost, work by increasing uveoscleral

outflow of aqueous humor. Topical beta-adrenergic receptor antagonists, such as timolol, decrease aqueous humor production.

Alpha2-adrenergic agonists, such as brimonidine, work by a dual mechanism, decreasing aqueous humor production and increasing uveoscleral outflow. Less-selective alpha agonists, such as epinephrine, decrease aqueous humor production through vasoconstriction of ciliary body blood vessels. Because it causes midriasis, it's not suitable for angle closure glaucoma.

Miotic agents (parasympathomimetics), such as pilocarpine, work by contraction of the ciliary muscle hence opening trabecular meshwork and allowing increased outflow of the aqueous humour Carbonic anhydrase inhibitors, e.g. dorzolamide and acetazolamide, lower secretion of aqueous humour by inhibiting carbonic anhydrase in the ciliary body

1.2.2.2 Surgical management of glaucoma

Surgery is indicated when glaucomatous optic neuropathy worsens (or is expected to worsen) at any given level of intraocular pressure and the patient is on maximum tolerated medical therapy, poor compliance to medication or if medication is not well tolerated. Surgery is usually the primary approach for patients with pupillary block. From the Collaborative Initial Glaucoma Treatment Study (CIGTS) it was found that initial surgical therapy achieved better IOP control than the previous medical therapy.¹⁸The type of surgical procedure depends on whether the patient has open angle or angle closure glaucoma. Surgery options for angle closure include; laser peripheral iridectomy (LPI) or argon laser peripheral iridoplasty (ALPI)

Surgical options that may be used for primary open-angle glaucoma may include procedures such as argon laser trabeculoplasty (ALT) and a newer procedure, selective laser trabeculoplasty (SLT). Another procedure is trabeculectomy which is the most common conventional surgery performed for glaucoma with the use of antifibrotic agents such as Mitomycin C or 5 – Fluorouracil. Glaucoma drainage implants such as Ahmed glaucoma valve implant or the ExPress Mini Shunt and the later generation pressure ridge Molteno implants can be used. These are indicated for glaucoma patients who may not respond well to maximal medical therapy or with previous failed filtering surgery (trabeculectomy).

Other procedures that lower intraocular pressure (IOP) include Ciliary body ablation which lowers IOP by reducing aqueous secretion by destroying secretory ciliary epithelium. Others may include Deep sclerectomy/viscocanalostomy/with or without collagen implant and lastly 360-degree suture canaloplasty

1.2.3 Trabeculectomy

1.2.3.1 History of trabeculectomy

Trabeculectomy has been the operation of choice since the late 1960s for improving aqueous outflow in glaucomatous eyes and is still regarded as the gold standard to which the newer operations are compared. Its popularity increased over time despite the emergence of non-penetrating glaucoma surgeries. Trabeculectomy is still the most common performed glaucoma surgery in most of the developing world despite newer surgical procedures.¹⁹ In one Nigerian study, trabeculectomy was the most common glaucoma surgery, comprising 81% of all glaucoma procedures.²⁰

1.2.3.2 Indications of trabeculectomy

Trabeculectomy can be considered when surgical risks are outweighed by the potential benefits. Patients are candidates for trabeculectomy if their intraocular pressures (IOP) put them at significant risk for progressive glaucoma damage resulting in visual disability. Other indications are if the intraocular pressure is not adequately controlled on medications, if there are significant barriers to using medications regularly such as cost, compliance, ocular or systemic side effects, inconvenience, physical impairment, or other psychosocial issues. Surgical intervention can also be considered if glaucoma damage is moderate to advanced, if the rate of progression has been rapid, if prior laser has been unsuccessful and if there is significant risk of future progression that will result in a symptomatic disability.^{21,22}

1.2.3.3 Factors Affecting Outcomes of Trabeculectomy

There are several factors that affect the outcome of trabeculectomy surgeries.

Surgical expertise

This is an important factor that determines outcome of the surgery. The more experienced the surgeon the better the outcome. Anand et al in a study in Nigeria demonstrated the importance of surgical expertise in outcome of glaucoma surgery.²³ In that study visiting consultants and registrars from the UK performed the surgery and descriptive statistics and life-table analysis were applied to the data. The study demonstrated better outcomes from the experienced surgeons.²³ Broadway DC Et al also found out that trabeculectomies performed by trainee surgeons tended to be less effective, with more complications, compared with those performed by senior surgeons.³⁰

Race.

Different races have different healing and fibroblasts activity that leads to bleb failure. R Husain et al in a review of trabeculectomy in East Asian people demonstrated that the main cause for failure of trabeculectomy remains excessive fibrosis at the conjunctival–scleral interface. This may lead to healing with scar tissue formation and bleb failure.²⁴ It has been noted that there is an increased risk of trabeculectomy failure in African eyes compared to Caucasian eyes.^{25, 26} The differences in conjunctival cell profile between blacks and whites have already been investigated. It was shown that blacks have a greater amount of fibroblasts and macrophages in their conjunctiva compared to whites, and that this may be why trabeculectomy fails more in blacks than whites.^{25, 26} Skuta GL et al also demonstrated that race is a factor in wound healing and hence could affect surgical outcome.²⁷

Anti-metabolite use.

Antimetabolites are usually used during trabeculectomy surgery to prevent bleb failure due to scarring by the wound healing process. Commonly used antimetabolites are 5-fluorouracil (5-FU) or mitomycin C (MMC). A number of studies have shown that anti-metabolites affect outcome and its use during trabeculectomy surgery has shown to improve outcome. Yorson et al in a study in Kikuyu Eye unit showed better outcomes with use of 5-FU in trabeculectomy.²⁸ Anand et al reported better IOP control with antimetabolite use in a study in Nigeria.²³ Alwitry A et al in a study in Eye, Ear, Nose and Throat Centre, Queens Medical Centre, Nottingham, UK found the use of Mitomycin C (MMC) in trabeculectomy had better outcome in intraocular pressure (IOP) control especially in early post-operative period.

29

The type of glaucoma

Trabeculectomy, still considered the gold standard in glaucoma surgery (commonly performed today with an antimetabolites such as mitomycin-C), remains the most commonly performed glaucoma surgery, with a high success rate in most groups and glaucoma diagnoses. Nderi et al in a study of glaucoma surgery outcomes at Mombasa light House for Christ Eye Centre showed that 96% of glaucoma procedures done were trabeculectomy.¹⁹ However, its popularity has been steadily declining as newer options have appeared. Trabeculectomy is preferred for primary open angle glaucoma (POAG). Trabeculectomy also gives room for other options of surgery unlike implants. Primary open angle glaucoma

(POAG) has been shown have good outcomes with trabeculectomy as shown in a review of the outcome of trabeculectomy in open-angle glaucoma by Vesti E et al.³⁰

Poor outcomes of trabeculectomy include previous intraocular surgery, neovascular or uveitic glaucoma.³¹ Tube shunt—most often an Ahmed or Baerveldt device are alternatives that can be particularly helpful when dealing with categories such as neovascular glaucoma, uveitic glaucoma, iridocorneal endothelial syndrome, fibrous ingrowths, epithelial down growth or patients who have had previous vitreoretinal surgery or penetrating keratoplasty, where the success rate for trabeculectomy are low.

Age

Despite the introduction of potent inhibitors of fibroblastic proliferation nearly two decades ago, the single most common cause of the filtering bleb's failure in trabeculectomy remains fibroplasia, the proliferation of fibroblasts in the tenon's capsule resulting in scarring and shrinkage of the filtering bleb. Young people have high fibroblasts activities compared to older people. However, this may not influence much bleb failure as Duman Et al concluded that outcomes of trabeculectomy in patients older than 80 years were found to be similar to those of younger controls.³²

1.2.3.4 Outcome measures of trabeculectomy surgery

Different studies use different parameters to measure the outcomes and these include intraocular pressure (IOP), progression of the cup disc ratio (CDR), visual fields (VF), optical coherence Tomography (OCT), nerve fibre layer (NFL) and vision.

Intraocular Pressure

IOP has been used in different studies as a measure of trabeculectomy outcome. High intraocular pressure (IOP) being the highest risk factor for development and progression of glaucoma makes it an important factor as an outcome of trabeculectomy. The IOP should be measured by Goldmann. It's important to have a baseline IOP which is the treated IOP just before surgery. This considered the best level of IOP medical treatment has achieved.³³ Most authors consider success rates in trabeculectomy as post-operative IOP control of ≤ 21 mmHg without medication. Manners T et al in a study of Trabeculectomy with mitomycin C in the treatment of post-traumatic angle recession glaucoma in South Africa considered success as IOP control of ≤ 21 mmHg^{34, 35} Other Authors have used a percentage decrease in intraocular

pressure. Anand et al on trabeculectomy outcomes in advanced glaucoma in Nigeria, regarded success as IOP ≤ 21 or 30% reduction from pre-operative levels.²³

Cup disc ratio (CDR)

Vertical cup disc ratio (CDR) is commonly assessed with slit lamp, however it may be sometimes subjective. Other methods of assessment such as OCT and Heidelberg retina tomography (HRT) are available and more objective. Martinez-De-La-Casa JM et al in a study of 47 eyes on agreement between slit lamp examination and optical coherence tomography (OCT) in estimating cup-disc ratios found a difference between OCT findings and the subjective evaluations performed by experienced ophthalmologists.³⁶

Arnalich-Montiel F et al in a study to compare Cup-to-disc ratio found that there is very good agreement among the specialists when estimating CDRs by stereoscopic slit-lamp biomicroscopy however optical coherence tomography (OCT) shows higher values than the specialists; the greatest differences occurred when assessing small CDRs and the differences diminished as the cupping increased.³⁷

Visual fields

Visual fields loss has been used as a parameter for measuring outcomes of glaucoma surgery especially where there is mild loss of in nerve fibre. This may be important in normotensive (NTG) glaucoma. Shigeeda T et al in a 6 year retrospective study used visual fields to monitor progress of glaucoma post trabeculectomy.³⁸ However, the use of visual fields may have confounders such as cataracts and it may be of limited use in short duration studies.

Visual acuity

Best corrected visual acuity (BCVA) is an important however it has several confounders such as corneal pathology, retinal diseases pathologic intracranial diseases and limitations with individual patient reliability. Vision should not be used as an integral part of the definition of failure unless in cases of no light perception (NPL) attributed to glaucomatous damage or surgical complication.

CHAPTER TWO: STUDY JUSTIFICATION

2.1 Study Rationale

Glaucoma is a leading cause of blindness irreversible worldwide. Its management still possess a big challenge in the developing world. Trabeculectomy is still the commonest glaucoma surgery done to control the disease in most of the developing word. Good outcome of the surgeries are of importance hence evaluation of the outcomes is needed. Few studies have been done in Kenya to assess the general outcome of trabeculectomy.^{19,28}

No study had been done at Kenyatta National Hospital hence this study may provide important information regarding the outcomes of trabeculectomy and also factors associated with poor outcomes. Information from this study may act as an audit to affirm, guide or change current clinical practice with regard to trabeculectomy in our setting. This may also contribute to the setting of protocols for patients undergoing trabeculectomy.

CHAPTER THREE: OBJECTIVES

3.1 Main Objective

The main objective of this study was to review outcome of trabeculectomy surgeries done in Kenyatta National Hospital (KNH) and University of Nairobi from 1st January 2006 to 31st December 2015.

3.2 Secondary Objectives included

1. To determine the indications trabeculectomy
2. To determine the change in the use of anti-glaucoma drugs from pre-operative to post-operative period.
3. To describe the trend of intraocular (IOP), cup disc ratio (CDR) and vision changes after trabeculectomy.
4. To describe the complications associated with trabeculectomy and establish the need for further intervention.
5. To determine factors affecting outcome of trabeculectomy.

3.3 MATERIALS AND METHODS

3.3.1: Study Design

This was a retrospective case series.

3.3.2 Study Location

Kenyatta National Hospital (KNH) and University of Nairobi. Located in the Kenya capital city Nairobi, Upper Hill Area. And its 2km west of the Central Business District.

3.3.3: Study Population

Glaucoma patients who were done trabeculectomy surgeries within the study period

3.3.4 Inclusion criteria

All patients aged 16 years and above who had undergone trabeculectomy surgery within the study period.

3.3.5 Exclusion Criteria

The following were excluded from the study:

1. Combined procedures such as: combined cataract and trabeculectomy.
2. Trabeculectomy with Expresss-Mini Shunt

3.3.6 Outcome Measures

3.3.6.1 Primary outcome measure:

The level of Intraocular pressure (IOP) on the first post-operative day, first week, first month, third month, sixth month, first year, eighteen months and second year after the surgery.

3.3.6.2 Secondary outcome measures:

These included;

1. Number of those achieving complete success, qualified success or failure, defined as
 - Complete Success:** IOP > 5mmHg and < 18mmHg, with 20% reduction from baseline without glaucoma medications
 - Qualified Success:** IOP > 5mmHg and < 18mmHg with or without glaucoma medications, with 20% reduction from baseline.
 - Failure:** will include any of the following criteria:
 - ✓ IOP \leq 5 mmHg or
 - ✓ IOP \geq 18 mmHg
 - ✓ Need for additional glaucoma surgeries
 - ✓ The development of NLP vision
2. Number of glaucoma medication needed post trabeculectomy.
3. The change in visual acuity over time.
4. Vertical cup disc ratio (VCDR) ratio change over time
5. Complications during the early (<30 days) and late (>30 days) post-operative period.
6. Number of additional surgical procedures required post trabeculectomy.

Table 1: Ideal, Preferred and Acceptable Time Period of Follow-up after Surgery. ³³

Follow-up Visit	Ideal Time (Days)	Preferred Time (Days)	Acceptable Time (Days)
Day 1	1	1-2	1-3
Week 1	7	4-11	4-14
Month 1	28-31	21-342	15-60
Month 3	90-92	77-106	61-122
Month 6	181-183	161-204	123-272
Year 1	365-366	334-387	273-456
18 Months	547-548	486-609	457-639
Year 2	730-732	669-822	640-913

3.7 Study Materials

- Pre-designed questionnaire (appendix 2) was used
- Patients records at Kenyatta National Hospital and University of Nairobi.

3.8 Personnel

- Principal investigator
- Records officers at KNH and University of Nairobi
- Statistician

3.9 Sample size calculation

The following sample size determination formula for finite population correction (Wanga & Lemeshow,1991) was used to estimate the proportion of population study size. ³⁹

$$n^1 = \frac{NZ^2P(1 - P)}{d^2(N - 1) + Z^2P(1 - P)}$$

Where

n' = sample size with finite population correction,

N = size of the target population = 110 (estimated number of patients who have had trabeculectomy surgery at Kenyatta National Hospital (KNH) between the years 2005 to 2014 according to the registry book)

Z = statistic for 95% level of confidence

P = estimated proportion of patients with glaucoma – 7.3% (Ashaye *et al.*, 2013)⁴⁰

d = margin of error = 2.1%

$$n^1 = \frac{110 \times 1.96^2 \times 0.073 \times 0.927}{(0.021^2 \times 109) + (1.96^2 \times 0.073 \times 0.927)}$$

$n^1 = 92.83$

93 Eyes

3.10 Data Collection and Analysis

Records of all glaucoma patients were retrieved and a list of patients who underwent trabeculectomy in KNH and University of Nairobi between the years 1st January 2006 to 31st December 2015 made. This list showed the name, age, date when trabeculectomy was done, and outpatient (OP) or in patient (IP) number. Those that fulfilled the inclusion criteria were included in the study. The corresponding patients' hospital files were retrieved from the records department with the help of the hospital's records clerk. All information relevant to the study was collected and entered into the pre-designed questionnaire.

Statistical analysis was done using SPSS computer software. The study results describes by summarizes the demographic and clinical characteristics. The was analysed using appropriate statistical tests with the help of a statistician and results presented in terms of tables, graphs, pie charts etc.

3.11 Ethical Consideration

3.11.1 Ethical Approval and Permission

Approval and permission to conduct the study was obtained from the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (KNH/UON-ERC).

3.11.2 Confidentiality

Patients' confidentiality was strictly observed by coding patients' names and these codes subsequently be used for reference, analysis and presentation of the findings of this study. The data and information was only available to the investigators and the statisticians. All raw data, both hard and soft copies were destroyed after results presentation.

3.12 Dissemination Plan

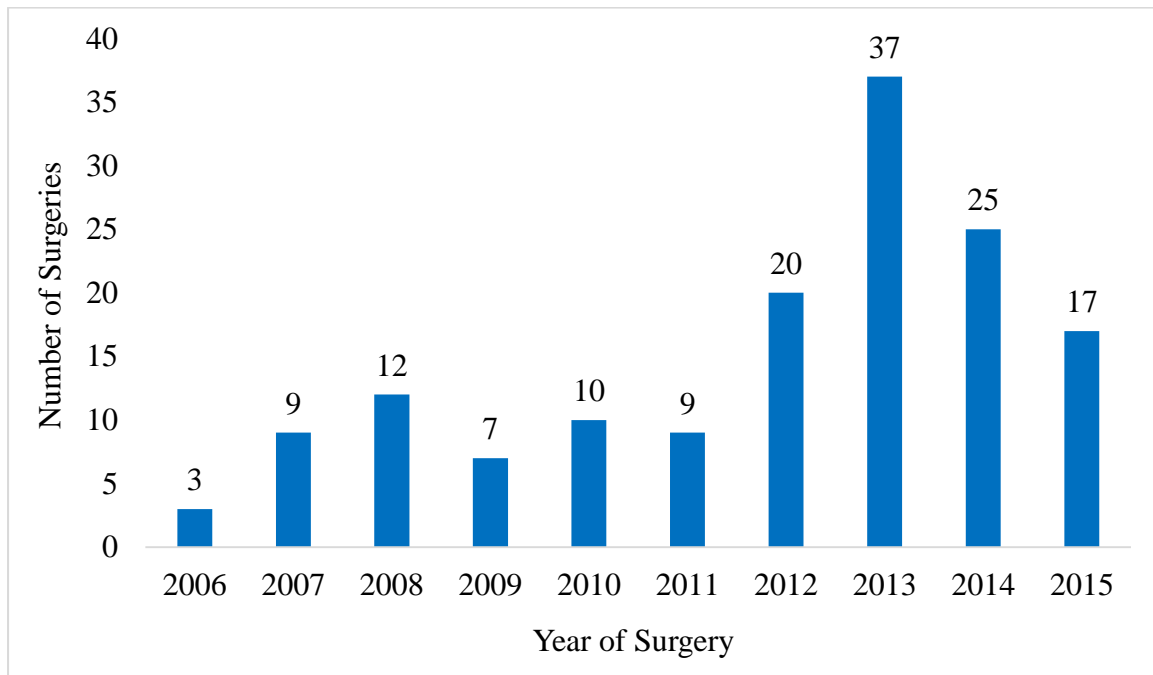
Upon completion of the study, the research findings was presented to the Department of Ophthalmology, University of Nairobi. A summary of the research findings was presented to the Kenyatta National Hospital (KNH)/ University of Nairobi (UON) Ethics and Research Committee (KNH-UON ERC). This study aimed to produce results which would contribute towards evidence-based practice in the management of trabeculectomy and hence results were also shared with the Ophthalmic Services Units (OSU) in the Ministry of Health to help guiding national policy. The findings may also be published in a journal or be presented in a conference.

4. RESULTS

Figure 1: Flow chart of patients included in the study

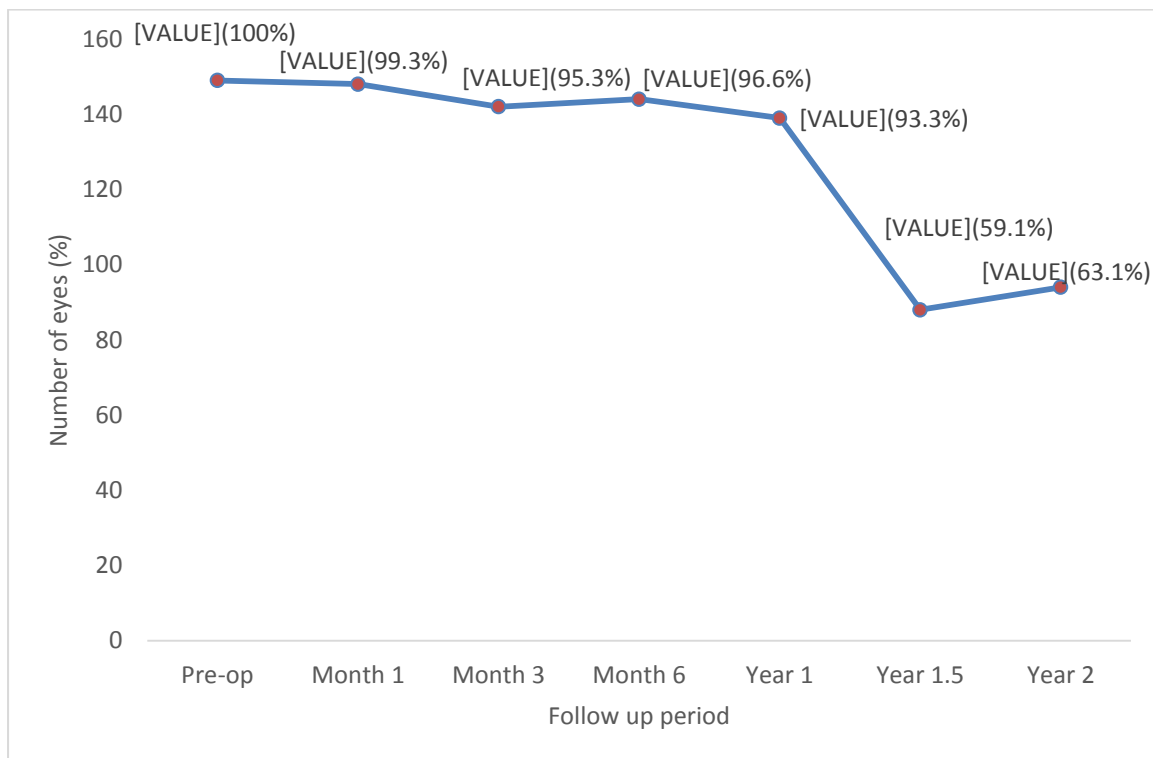


Figure 2: Annual distribution of Surgeries done (n=149)



66.4% of the surgeries were done between 2012 -2015

Figure 3: Compliance to follow-up appointments (n=149)



All eyes were reviewed on the first post-operative day. However, the percentage gradually declined in subsequent follow-up visits, with only 63.1% of eyes being examined during the 2-year follow-up visit.

Table 2: Demographic characteristics (n=138) and Pre-operative Examination Characteristics

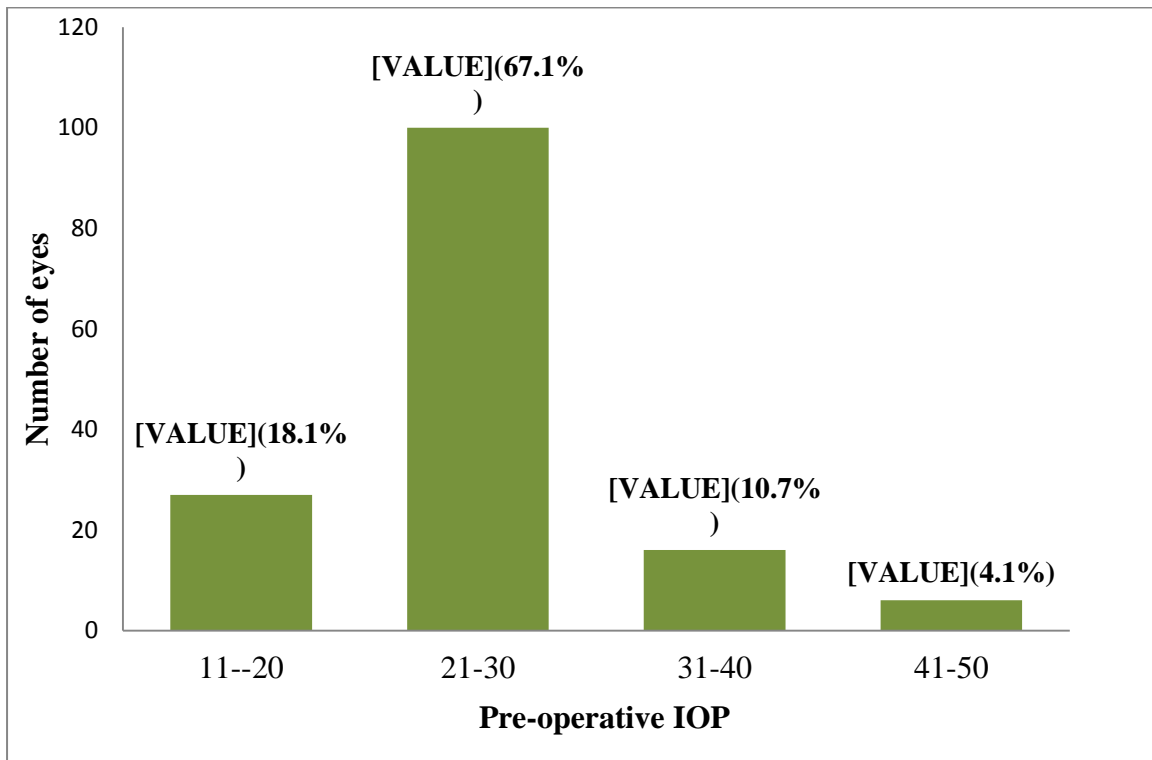
Characteristics (n= 138)		
Sex		
Male	89	(64.5%)
Female	49	(35.5%)
Age		
<35 year	3	(2.2%)
35-49 years	19	(13.8%)
50-69 years	82	(59.4%)
≥70 years	34	(24.6%)
Laterality		
Unilateral	127	(92.0%)
Bilateral	11	(8.0%)
Pre-operative Parameter (n=149)		
Logmar VA	0.32 ± 0.27	Range (0.02-1)
CDR	0.87 ± 0.12	Range (0.4-1)
IOP	25.4 ± 6.17	Range (14-48)

Most patients (84.1%) were ≥50 years of age. Mean age was 60.8 years ± 12. The patients' ages ranged from 18-81 years.

Most (94.7%) of patients had TET in one eye that met the inclusion criteria. All patients were Black Africans.

The distribution of pre-operative IOP of study eyes is given in figure 4 below.

Figure 4:Pre-operative IOP (n=149)



Majority of eyes had pre-operative IOP in the range of 21-30mmHg (67.1%).

94.6% of the eyes had IOP of 18mmHg and above.

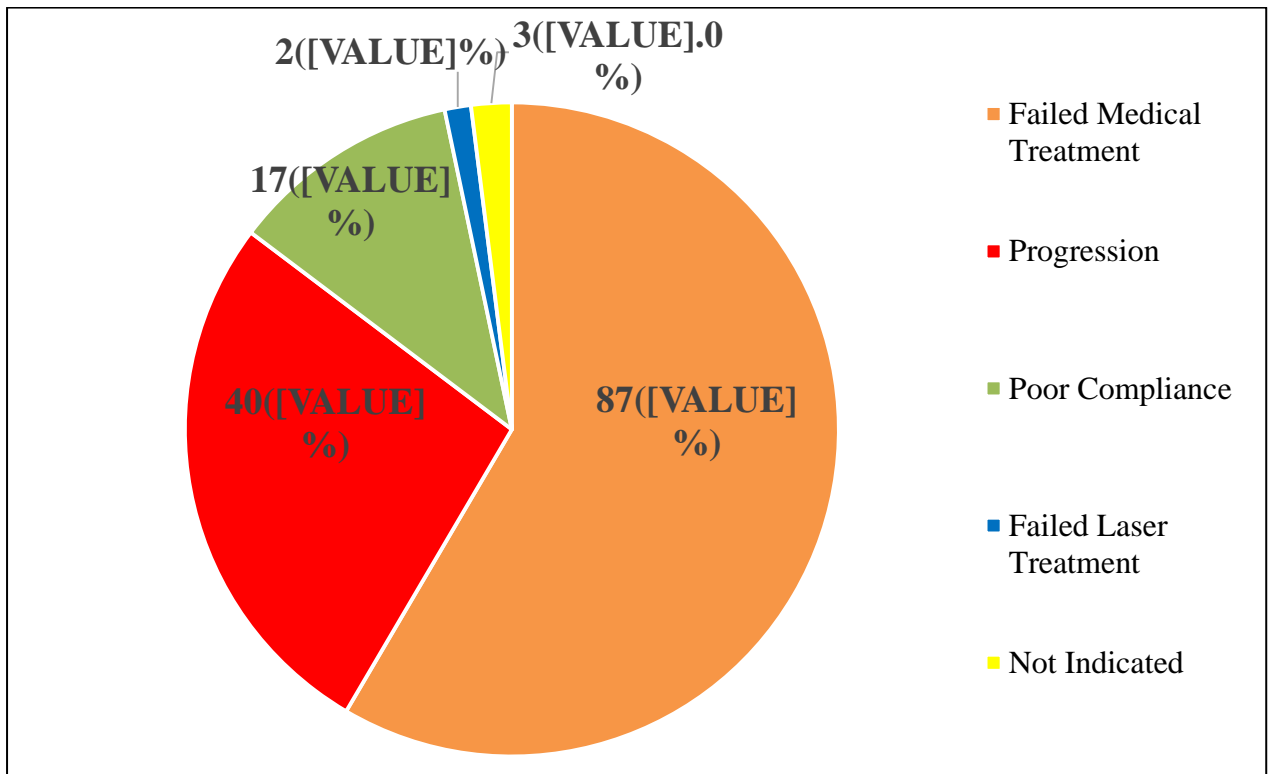
Table 3:Pre-operative use of Anti-glaucoma Medication

Pre-operative glaucoma drugs	Distribution by eyes (n=149)	
Number of drugs	Number of eyes	Percentage (%)
1	37	14.5%
2	76	57.3%
3	33	25.6%
4	3	2.6%
Type of drug	Number of eyes	Percentage
Beta-Blocker	143	95.9%
Alpha-2 Agonist	61	40.9%
Prostaglandin Analogue	54	36.2%
Oral Carbonic Anhydrase Inhibitor (Diamox)	27	18.1%
Topical Carbonic Anhydrase Inhibitor	19	12.8%

All eyes were on anti-glaucoma medications, with the majority being on 2 or more drugs in the pre-operative period (85.5%). The median number of drugs used pre-operatively was 2 (IQR 2-3) and mean was 2.2 ± 0.69 .

Beta-blockers were the most commonly used for IOP control, with 96% of eyes being on a beta-blocker.

Figure 5: Indications for surgery (n=149)



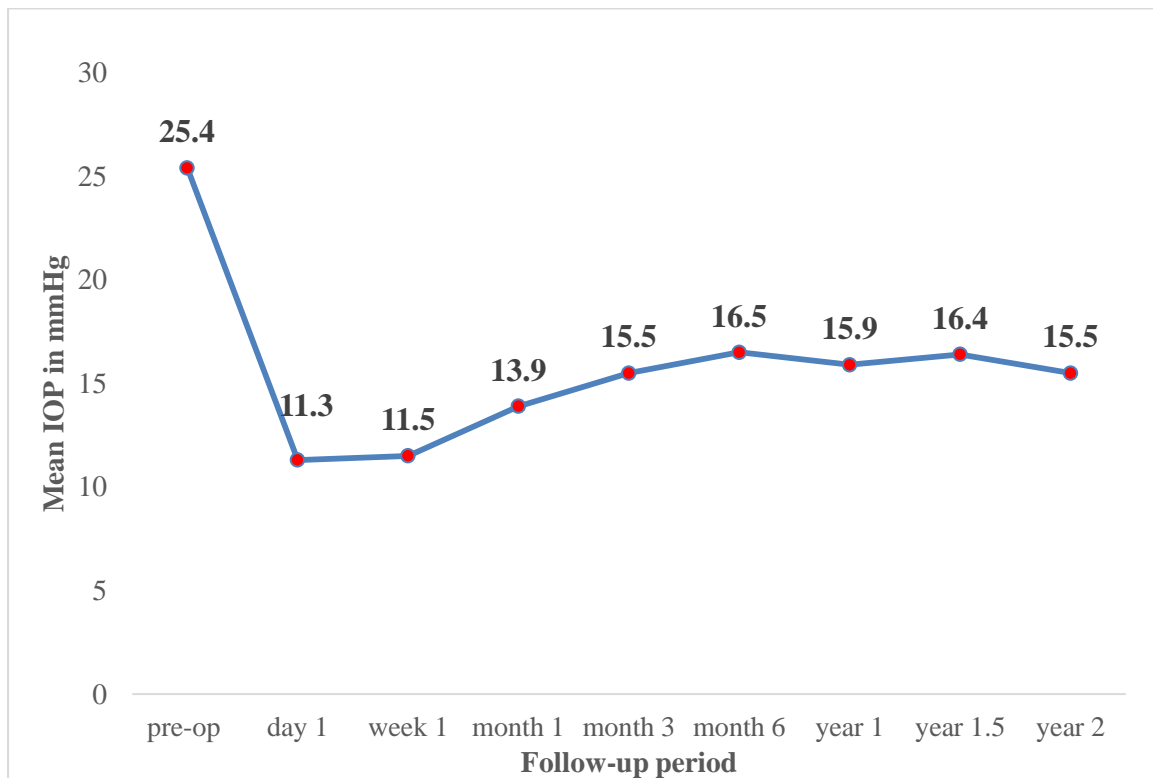
The most common indication for surgery was failed medical treatment (58.4%). There was no indication given for 3 eyes.

Table 4: Type of TET done in Eyes (n=149)

Surgery	Number of eyes	Percentage (%)
TET + MMC	120	80.5%
TET + 5FU	15	10.1%
TET	14	9.4%

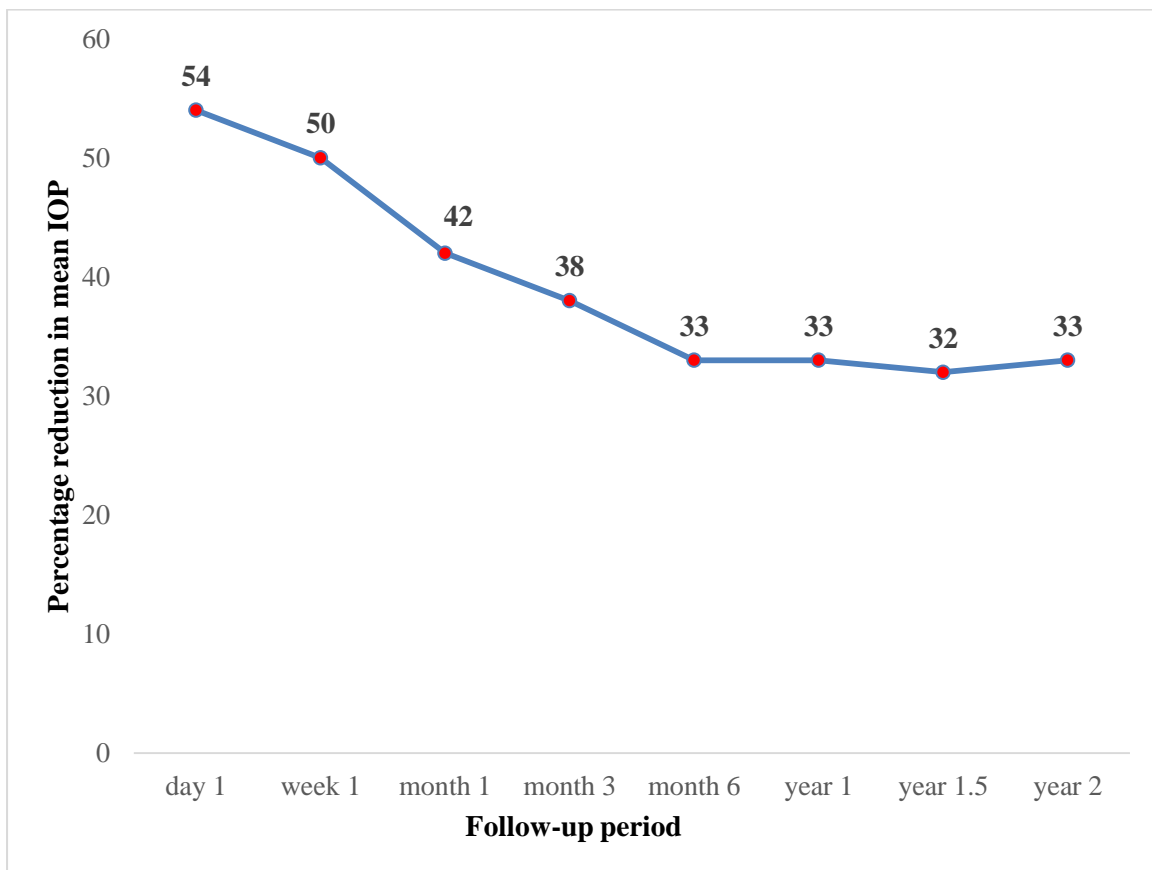
Majority of TET were done with anti-fibrotic agents (90.6%), of which the most commonly used was MMC (80.5%).

Figure 6: Trend in mean IOP post-operatively



Mean IOP was maintained below 18mmHg up to 2 years post-operatively. This was calculated including eyes present at each follow-up visit.

Figure 7: Percentage reduction of IOP from baseline



The peak reduction in mean IOP from baseline was seen in the first post-operative day.

The percentage reduction in mean IOP from baseline was >20% for all follow-up visits.

This was calculated including eyes present at each follow-up visit.

Table 5: Comparison of mean pre-operative and post-operative IOP for different follow-up visits

Follow-up period	Pre-operative mean IOP (SD)	Post-operative mean IOP (SD)	p-value
Day 1 (n=149)	24 (6.02)	11(4.78)	0.00
Week 1 (n=147)	24(6.02)	12(4.37)	0.00
Month 1 (n=148)	24 (6.01)	14(4.24)	0.00
Month 3 (n=142)	24 (6.02)	15 (5.25)	0.00
Month 6 (n=144)	24 (6.03)	16(5.75)	0.00
Year 1 (n=139)	24 (6.02)	16(5.04)	0.00
Year 1.5 (n=88)	23 (6.00)	16(3.83)	0.00
Year 2 (n=94)	24 (5.09)	16(3.41)	0.00

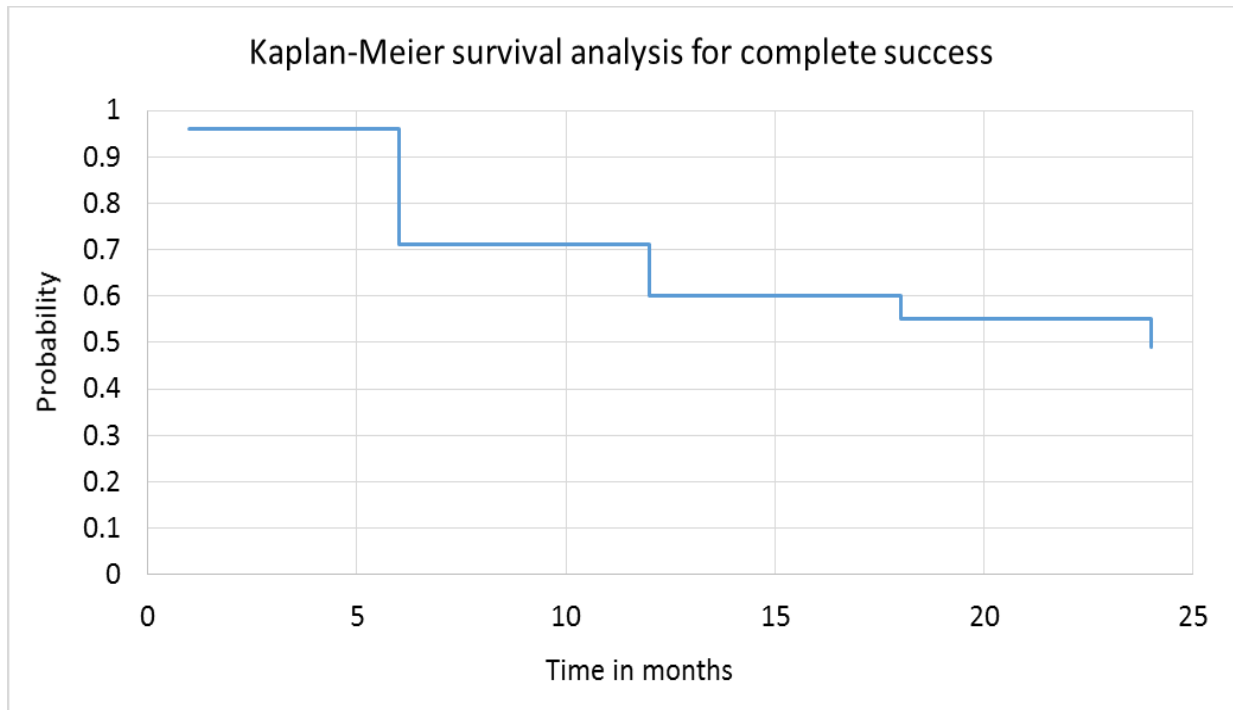
There was a statistically significant reduction in the mean IOP for all follow-up periods.

Table 6: Complete success trend (> 5mmHg and < 18mmHg, with 20% reduction from baseline without glaucoma medications)

Follow-up period	Number achieved complete success	Percentage achieved complete success
Day 1 (n=149)	142	95%
Week 1 (n=147)	132	90%
Month 1 (n=148)	123	83%
Month 3 (n=142)	89	63%
Month 6 (n=144)	86	60%
Year 1 (n=139)	79	57%
Year 1.5 (n=88)	48	55%
Year 2 (n=94)	49	52%

There is a downward trend in the patients who achieved complete success to 57% at year 1 dropping further to 52% at year 2.

Figure 8 Kaplan-Meier survival analysis for complete success



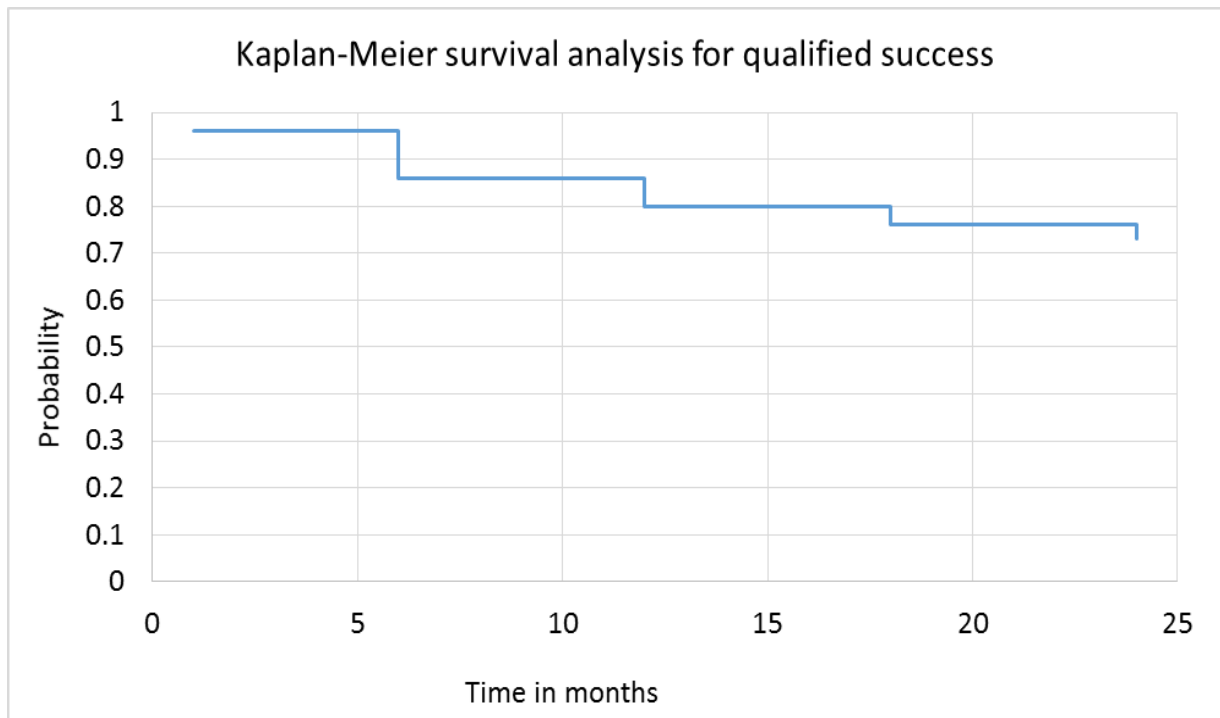
The probability of patients achieving complete success decreases to about 60% at one year and 49 % at 2 years.

Table 7: Qualified success trend (IOP > 5mmHg and < 18mmHg with or without glaucoma medications, with 20% reduction from baseline)

Follow-up period	Number achieved Qualified success	Percentage achieved Qualified success
Day 1 (n=149)	142	95%
Week 1 (n=147)	139	94%
Month 1 (n=148)	129	87%
Month 3 (n=142)	110	77%
Month 6 (n=144)	111	77%
Year 1 (n=139)	111	79%
Year 1.5 (n=88)	68	77%
Year 2 (n=94)	71	76%

The number of patients with qualified success decreases to 79% at year 1 decreasing further to 76% by year 2.

Figure 9: Kaplan-Meier survival analysis for qualified success



The probability of patients achieving complete success decreases to about 80% at one year and 73 % at 2 years.

Table 8: Failure at Final Follow-up Visit

Failure	Number of eyes	Percentage
<input type="checkbox"/> IOP \leq 5 mmHg or	26	17.4%
<input type="checkbox"/> IOP \geq 18 mmHg		
<input type="checkbox"/> Need for additional glaucoma surgeries		
<input type="checkbox"/> The development of NLP vision		

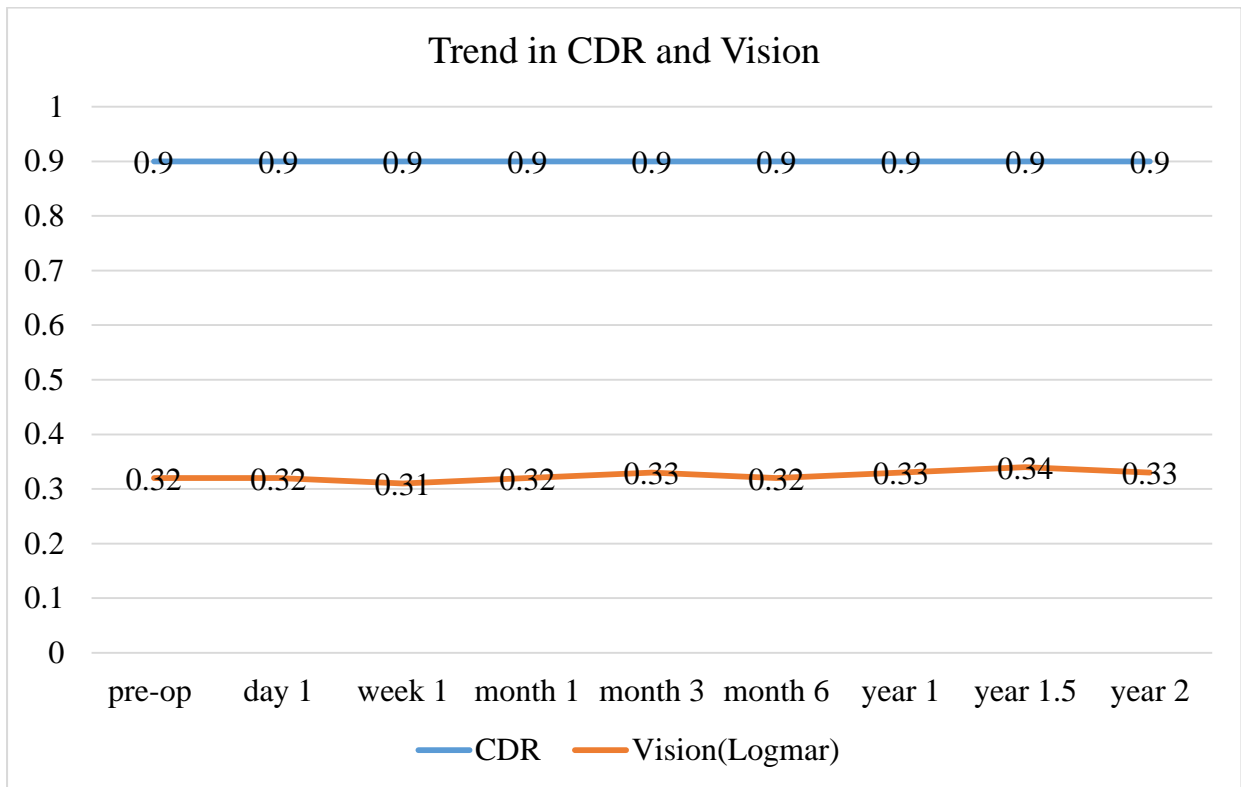
26 patients (17.4%) had failed trabeculectomy and this included;

23 patients had IOP \geq 18 mmHg and 2 patients had IOP \leq 5.

1 patient developed NLP vision as a result of glaucoma

Noted that some patients were lost to follow up as early as month one. Also some patients had failure before year 2.

Figure 10: Trend in CDR and Vision in Logmar

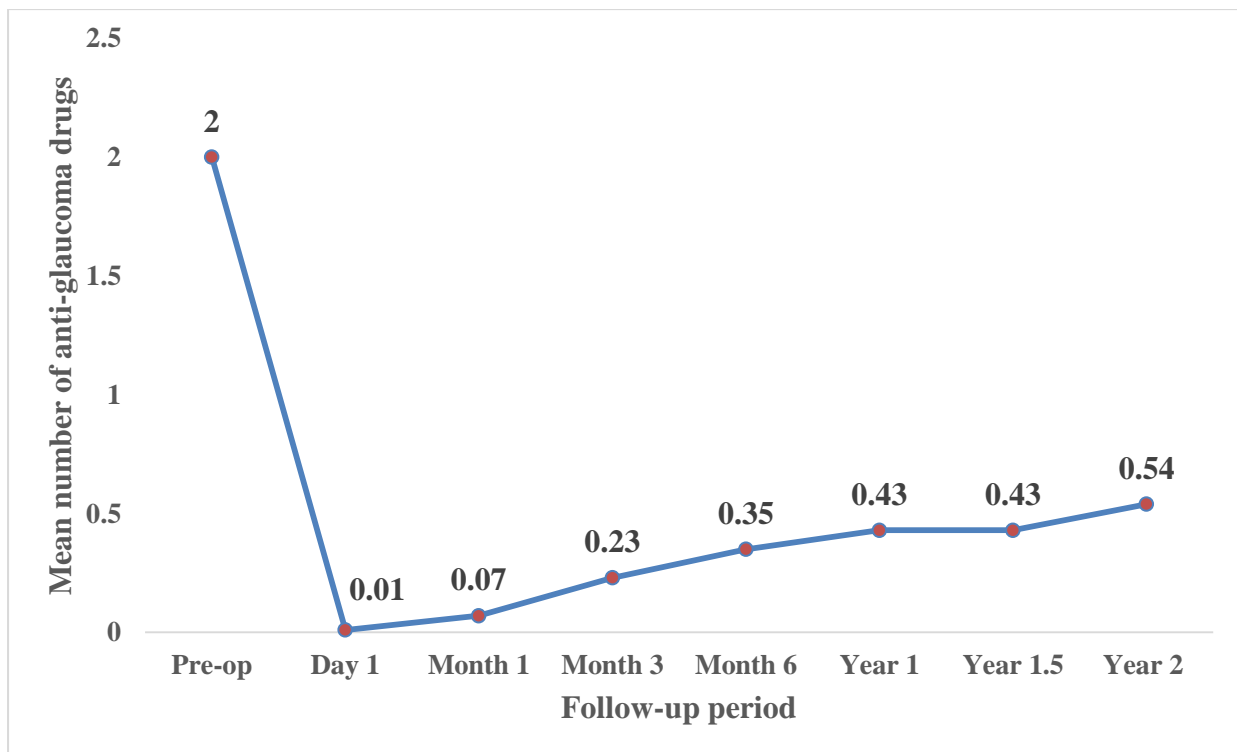


The mean CDR was maintained through the follow up period at about 0.9

Vision was also maintained from pre-operatively to post-operatively.

Note that 4 eyes had no Logmar equivalent VA post-operatively. Of these, 1 had NPL vision, 1 PL and 2 HM.

Figure 11: Change in the use of anti-glaucoma drugs from pre-operative to post-operative period



There was a decrease in the mean number of anti-glaucoma drugs used from 2.0 ± 0.74 in pre-operative period to 0.54 ± 0.88 at 2years follow-up visit.

Table 9: Complications by post-operative period

Complications	Distribution by eyes (n=149)			
	<30 days	>30days	Total	Percentage
None	112	110	-	-
Hypotony	22	2	24	16.1%
Bleb leak	4	-	4	2.7%
Flat/shallow AC	3	0	3	2.0%
Hyphaema	3	0	3	2.0%
Bleb fibrosis	1	31	31	20.8%
Suprachoroidal haemorrhage	1	0	1	0.7%
Blebitis	1	0	1	0.7%
Choroidal effusion	1	0	1	0.7%
Cataract	0	2	2	1.3%
Cystic bleb	0	2	2	1.3%
Encapsulated bleb	0	4	4	2.7%

37 eyes (25%) and 39 eyes (26%) had complications in the early and late post-operative period respectively. Some eyes had more than one complication. 1 eye had a bleb fibrosis in both early and late post-operative periods.

The most common complications was bleb fibrosis, seen in 31 eyes (20.8%) and hypotony, seen in 24 eyes (16.1%) The most serious complications were suprachoroidal haemorrhage (1 eye) and blebitis (1 eye).

Table 10: Surgical interventions for complications

Intervention	<30 Days	>30 Days	Total	Percentage
Needling	2	18	20	77%
Ahmed valve insertion	0	4	4	15%
Repeat TET	0	1	1	4%
AC washout/reformation	1	0	1	4%

Table 11: Factors that contributed to IOP failure at final follow up visits

Variable (n=26)	Number	Percentage (%)
Bleb fibrosis	20	76.9%
Encapsulated bleb	4	15.4%
Hypotony	2	7.7%

5. DISCUSSION

The most common glaucoma surgery was trabeculectomy done at two centres, that's at Kenyatta National Hospital (KNH) and University of Nairobi (UON) from the year 2006 to 2015. In the earlier years few surgeries were done but the number kept on increasing over time. And the bulk of the surgeries amounting to 66.4% were done between 2012 and 2015. This is attributed to the training of a glaucoma surgeon who paid a keen interest of glaucoma patients. It was then that a regular glaucoma clinic was started and the dedication to glaucoma patients explains the increase in number from the year 2012.

Unlike in the earlier years where the surgeries were done by different surgeons most of whom were either general ophthalmologists or ophthalmologists in a different subspecialty. Majority of the surgeries after 2010 were done by the glaucoma specialist and some were done ophthalmology residents under the supervision of the consultant glaucoma specialist. The follow-up of the patients were done at KNH eye clinic and some were followed up at University of Nairobi department ophthalmology. The follow-up period of the study was two years.

All eyes were reviewed on the first post-operative day. However, the percentage gradually declined in subsequent follow-up visits, with only 63.1% of eyes being examined during the 2-year follow-up visit. This trend has been reported also by Ngan Et al⁴¹. Ngan and colleagues' study examining noncompliance risk factors in normal-tension glaucoma cases, 46% of patients were noncompliant with follow-up visits. Also Ke Yang Et al reported poor follow in rural china where⁴². However, he also found out lowering the cost of post-operative follow-up such as free medication improved compliance. He also concluded that low-cost interventions significantly improved postoperative follow-up after glaucoma surgery. In my study majority of the patients did not receive free intervention and neither did they get free follow-up services. This could have contributed to the poor compliance during the follow up period. Also not all patients came from around Nairobi, other were coming from distant areas this could have had an impact in the follow up visits.

This study included 138 patients. The male to female ratio was 1.8:1(64.5 percent were male). This trend is similar to other studies. In Tanzania Bowman RJC Et al in a retrospective study of trabeculectomy combined with cataract surgery with application of antimetabolite showed that 69% were males⁴³. J Kabiru Et al In Kikuyu Eye Unit in a retrospective review of the files of all patients who underwent trabeculectomy surgery at the facility found out that

80% were males⁴⁴. The trend seems to be more men than women because in Africa generally men are economically higher than women and are mostly the bread winners of the family, so they are likely to seek medical care more than women.

Most patients (84.1%) were ≥ 50 years of age. Median age was 62.5 years (IQR 55-69), whilst mean age was 60.8 years \pm 12. The patients' ages ranged from 18-81 years. This is because most patients had POAG which is the commonest glaucoma after the age of 40 years. Similar results were also shown by Bowman Et al in Tanzania where he found a mean age was 67 years \pm 11, range 21–86 years). Most of the patients (94.7%) had trabeculectomy in one eye that met the inclusion criteria despite 91% of the patients' having glaucoma in both eyes. This was because the other eyes were either on medical therapy or a different glaucoma filtering procedure was done. Other eyes had either been done TET at a different centre or the surgery had not been done within the study period.

The pre-operative characteristics in this study included the IOP in millimetres of mercury, the vision in logmar and cup disc ratio.

Mean IOP was 25.4mmHg \pm 6.17. These values are comparable to those described by other studies in the Africa. Adegbehingbe B.O Et al found a pre-operative mean IOP of 32.5.⁴⁵ 94.6% of eyes presented with an IOP of 18mmHg or more. Similar studies in Asia found comparable results such as Liu et al in China.⁴⁶ Results are also comparable to a study by Elad Moisseiev et al in Tel Aviv Medical Centre in Israel where preoperative IOP was 24.5 \pm 9.2 mm Hg.⁴⁷ Of note is that pre-operative central corneal thickness (CCT) was not done for most of the patients. The pre-operative CDR mean was 0.87 \pm 0.12, and the range was 0.4-1.0. Majority of the patients had advanced glaucoma based on the CDR. In the year 2013 Olawoye OO Et al in Nigeria found majority of the patients had severe glaucomatous optic neuropathy of cup to disc ratio of 0.9-1.0.⁴⁸ Comparable pre-operative CDR have also been reported in India by Dacosta S et al.⁴⁹ This is also the trend in many other studies across developing nations. Generally people in developing countries tend to present late and that's why most patients in this study presented with advanced disc cupping. The pre-operative vision was in logmar equivalent and the majority had moderate visual impairment. The mean was 0.32 \pm 0.27 and the range was 0.02-1.0. This is still comparable to findings in other studies in the developing world. Visual acuity is not severely impaired because glaucomatous optic neuropathy affects visual field more than visual acuity. Patients in this study did not have visual field analysis.

All eyes were on anti-glaucoma medications, with the majority being on 2 or more drugs in the pre-operative period (85.5%). The median number of drugs used pre-operatively was 2 (IQR 2-3) and mean was 2.2 ± 0.69 . This lower than what we see in the developed world including some Asian countries where their mean number of pre-operative drugs range between 3 and 4. Liu J et al in Long-Term Outcomes of Primary Trabeculectomy found a mean number of anti-glaucoma medications was 3.4 ± 1.3 .⁴⁶ Beta-blockers were the most commonly used for IOP control, with 96% of eyes being on a beta-blocker. Beta-blockers seems to have been preferred due to their IOP lowering levels, cost and the fact that they are readily available in Kenya especially timolol. Acetazolamide was given to those patients who had poorly controlled IOP despite the use of other anti-glaucoma drugs. Acetazolamide was mainly given orally a few days prior to surgery in order to lower IOP drastically.

There were several indications for surgery however the most common indication for surgery was failed medical treatment (58.4%). This is because long-term use of anti-glaucoma medication leads to tachyphylaxis, beta blockers (the commonest group used in this study) being one of the group's affected. A total of 149 eyes were done tabeculectomy within the study period. Majority of trabeculectomy were done with anti-fibrotic agents (90.6%), of which the most commonly used was MMC (80.5%). The surgeries that were done without anti-fibrotic agent were in the earlier years when the use of these agents were not popular with trabeculectomy. Later some surgeons started using 5-FU before the introduction of MMC. MMC has been advocated for by the glaucoma specialist as the anti-metabolite of choice in TET. This is because it has proven to be more effective than 5-FU in TET. Kim HY et al in a study of long-term comparison of primary trabeculectomy with 5-fluorouracil versus mitomycin C in showed that MMC was superior to 5-FU.⁵⁰ In Tanzania Bowman et al found Mitomycin C (MMC) superior in lowering pressures than 5 fluorouracil (5FU)⁴³ Egbert PR et al has also demonstrated the importance of antimetabolite use in a prospective trial of intraoperative fluorouracil during trabeculectomy in a black population.⁵¹

In this study there was a statistically significant reduction in the mean IOP for all follow-up periods. The mean IOP was maintained below 18mmHg up to 2 years post-operatively. This was calculated including eyes present at each follow-up visit and the highest mean being 16.5mmHg. This is great reduction from baseline IOP of 25.4mmhg. The peak reduction in mean IOP from baseline was seen in the first post-operative week. The percentage reduction in mean IOP from baseline was greater than 20% for all follow-up visits. This was calculated including eyes present at each follow-up visit.

Several studies have reported an improved success rate in IOP control after trabeculectomy across the continent such as the study done by Harry A Quigle Et al in Tanzania. This was trabeculectomy study with application of antimetabolite.⁵² The IOP average declined from 29.9mmhg pre-operatively to 14.7mmgh post-operatively. Other authors have reported a better control than those achieved by medical therapy. Burr J et al in the year 2012 did a clinical trial in 17 centres and concluded that surgery lowers IOP more than primary medication.⁵³ The surgeries in this study have also achieved a great percentage reduction in mean IOP from baseline.

Complete success showed a declining trend to 57% at year one dropping to 52% at year 2. The Kaplan-Meier survival analysis showed probability of patients achieving complete success decreases to about 60% at year 1 and 49 % at year 2. There was also a declining trend in the patients who achieved qualified success to 79% of eyes at year 1 declining further to 76% at year 2. The Kaplan-Meier survival analysis showed probability of patients achieving complete success decreases to about 80% at one year and 73 % at 2 years. At final follow up visit 26 patients (17.4%) had failed trabeculectomy at final follow up visit of which some failed before 2 years.

Generally trabeculectomy has been shown to improve IOP control, however its efficacy has been shown to decrease with time. Several authors have shown this trend in their studies regardless of the race.⁴⁴ Most fail due to bleb fibrosis irrespective of the race, however bleb fibrosis has been found to be the major cause of trabeculectomy failure in African eyes than other races. Differences in conjunctival cell profile between blacks and whites has shown that blacks have a greater amount of fibroblasts in their conjunctiva compared to whites, and that this may be why trabeculectomy fails more in blacks than whites^{25, 26} That's why antimetabolites are usually used during trabeculectomy surgery to prevent bleb failure due to scarring by the wound healing process. Their use is also a factor that affected outcome in this study since most patients had trabeculectomy with antimetabolite. Antimetabolite use has been shown to improve outcomes of trabeculectomy surgery. Yorson D et al has demonstrated this in Kikuyu Eye Unit²⁸. Also Alwitry A et al in Chandka Medical College & Hospital Larkana in a study of primary low-risk trabeculectomy augmented with low-dose mitomycin-C reported the same.²⁹ Antimetabolites are also associated with complications that could lead to surgical failure due to hypotony such as cystic blebs associated with over filtration. In this study there were only 2 patients that had hypotony in the late post-operative period. Another factor that could have affected the outcomes was the declining, irregular and

failure of follow-up of some patients. This could have affected earlier intervention of complications.

IOP cut off could also contribute success and failure rates. The success rates in this study were a bit lower compared to some other studies. Manners Et al in South Africa in a 3 year retrospective analysis of 43 consecutive trabeculectomy procedures in 41 patients. He found that intraocular pressure was successfully controlled at last follow up without topical treatment in 77% of the patients. The difference could be due that fact that the cut off IOP for success was 21mmhg and yet in this study a cut off is 18mmgh was used. The Kaplan Meier survival estimates shows probability is comparable to what T Manners Et al found.⁵⁴ He found out that the cumulative probability of success was 85% at 1 year follow up, 81% at 2 years, and 66% at 3 years and thereafter. Ehrnrooth P Et al in a study of Long-term outcome of trabeculectomy in terms of intraocular pressure showed Kaplan-Meier survival success rates were 82% at 1 year, 70% at 2 years.⁵⁵ They concluded that the IOP-reducing effect of trabeculectomy decreases gradually which is similar to this study found.

The post-operative mean logmar equivalent for vision was a mean of 0.33 ± 0.28 . This shows no improvement from the pre-operative visual acuity of 0.32. Cataract formation post TET has been reported by certain authors to be a major factor influencing deterioration of vision post-surgery. Its effect was demonstrated by Kim J et al in the Advanced Glaucoma Intervention Study: (8. Risk of cataract formation after trabeculectomy).⁵⁶ They concluded that a first trabeculectomy, whether as the first or second AGIS intervention, increased the overall risk of cataract by 78%. On the contrary, some studies have reported improvement of visual acuity after trabeculectomy. Lawan A Et al in a study to review the pattern of presentation and outcome of surgical management of primary open angle glaucoma in Kano, Northern Nigeria reported an slight increase of vision by 10 percent.⁵⁷ They did not report many incidences of cataract formation. Some other authors within the same region have reported a decline in vision. Nitin Anand Et al in the year 2012 reported that 40 eyes (30.3%) had lost more than 2 lines of Snellen visual acuity.⁵⁸ Most of the drop in vision was attributed to the development of cataract. In this study, only 2 patients developed cataract after surgery hence vision was not much affected. The challenge with reporting on cataract and vision assessment in this study was that there was no objective way of reporting cataract by different surgeons hence difficulty in reporting on its effect.

The mean CDR post-operatively was 0.9 ± 0.15 . Compared to the pre-operative mean CDR, there was no change. Of note is that most of the patients in this study had advanced disc cupping at the time of surgery. Glaucomatous optic neuropathy is not reversible and hence the aim of surgery is to slow progression. In this study we see that TET was able to slow progression since CDR was maintained at 0.9 from pre-operative to post-operative year 2. Nderi Et al in Kenya in the year 2009 in a study of outcomes of glaucoma surgery in light House hospital Mombasa also found that there was no change in CDR at the end of the study.¹⁹ This is the trend has also been reported by Hooi et al in a study of trabeculectomy outcomes in a Malaysian general hospital reported no significant change in CDR.⁵⁹

There was a decrease in the mean number of anti-glaucoma drugs used from 2.0 ± 0.74 in pre-operative period to 0 on post-operative day one. Generally, glaucoma medications are not used on day 1 post-operative. The mean number of medications steadily increases over the follow up period to a mean of 0.54 ± 0.88 at 2years follow-up visit. This is a significant decrease in the use of anti-glaucoma pre-operatively. Other authors have also reported a decrease in use of anti-glaucoma medications after surgery. Cankaya AB Et al in Korea reported a reduction in the average number of anti-glaucoma medications from pre-operative value of 2.9 ± 0.7 (range, 2 to 4) to a value of 0.9 ± 1.2 (range, 0 to 4) at final visit and was found to be a significant mean reduction.⁶⁰ This study also shows that trabeculectomy is significant in reducing the number of medications required by glaucoma patients to adequately control IOP.

Complications were seen in 37 eyes (25%) and 39 eyes (26%) in the early and late post-operative period respectively. Some eyes had more than one complication. 1 eye had a bleb fibrosis in both early and late post-operative periods. The most common complications were bleb fibrosis, seen in 31 eyes (20.8%) and hypotony, seen in 24 eyes (16.1%). Bleb fibrosis was seen more in late post-operative period since some fibroblast activity may be present leading to scarring of the conjunctiva in the long run especially in African eyes. Hypotony was the commonest seen in early post-operative period, however 2 eyes still had hypotony in the late post-operative period. The 2 eyes were associated with large cystic over-filtering blebs which is an expected complication of TET with use of anti-metabolites. Other authors have reported persistent hypotony after TET however the causes were different from what we found in this study. Higashide T et al in Japan the year 2016 did a study on Persistent hypotony after trabeculectomy: incidence and associated factors in the Collaborative Bleb-Related Infection Incidence and Treatment Study. They found choroidal detachment that

occurred within 6 months of the surgery was a significant risk factor for persistent hypotony by the end of the study.⁶¹

This complications are also comparable to what Olawoye OO Et al found in outcomes of trabeculectomy with adjunctive 5-Fluorouracil (5- FU) in the year 2013.⁶² He found early postoperative complications included shallow anterior chamber in 6 (12.8%) of which some eyes were associated with hypotony, however most had small bleb leaks. He also reported cataract as the most common late complication which is contrary to this study where bleb fibrosis was the most common long term complication. The most serious complications were suprachoroidal haemorrhage (1 eye) and blebitis (1 eye).

The most common surgical intervention for the complications was needling (20 eyes). Most of the needling (18 eyes) were done after one month post-operatively. In most of these eyes needling was successful, however in 4 eyes needling plus additional medical therapy failed. Ahmed valve insertion was done on the 4 eyes since at the study centre this procedure has been reserved mainly for failed TET. There were 3 eyes that had hyphaema, however only one eye had AC washout since it was not resolving.

Majority of the patients (76.9%) with IOP failure at final follow up visits in this study were found to have bleb fibrosis in the late post-operative period. Bleb fibrosis are associated with failure of drainage of aqueous humour and hence these patients ended up with IOP of ≥ 18 mmHg. Others (15.4%) had encapsulated blebs (Tenon's capsule cyst). Bleb encapsulation also leads to poor aqueous drainage with elevated IOP and hence failure of TET. Hypotony of ≤ 5 mmgh at last follow up visit was seen in 7.7% of the patients with failed TET. This patients had over-filtering blebs that led to persistently low IOP.

6. STUDY LIMITATIONS

Due to the design of this study, the following limitations were encountered in this study:

1. This being retrospective case series, some data for some patients was unavailable or incomplete
2. The surgeries were done by different and surgeons and the variations in their techniques and experiences may also have affected the outcomes
3. The number of patients presenting for subsequent follow-up visits was varied and declined with time, and this may have adversely affected the results
4. Different methods of examinations e.g. IOP readings using different types of instruments may have influenced outcome measures
5. Different examiners with no standardization in VA measurements and estimation of CDR by slit lamp may have influenced the results too.

7. CONCLUSIONS

1. Trabeculectomy is adequate in controlling IOP up to a period of 2 years after surgery.
2. There is no effect on change of CDR after surgery
3. Trabeculectomy has limited effect in vision change
4. Use of anti-glaucoma medications is significantly reduced by trabeculectomy up to a period of 2 years after surgery.
5. Bleb fibrosis and encapsulation is a risk factor for surgical failure in the long term
6. Patient follow-up drop-out possess a challenge in management

8. RECOMMENDATIONS

1. Conduct a prospective study with a longer follow-up period to assess the long-term success rates of trabeculectomy.
2. Trabeculectomy is a safe and effective procedure in controlling IOP and should be done when indicated.
3. Patients should be educated to ensure good compliance to medications and to follow-up appointments.

REFERENCES

1. Vijaya, L., et al., Prevalence and causes of low vision and blindness in an urban population: The Chennai Glaucoma Study. *Indian J Ophthalmol*, 2014. 62(4): p. 477-81.
2. Omoti, A.E., A.I. Osahon, and M.J. Waziri-Erameh, Pattern of presentation of primary open-angle glaucoma in Benin City, Nigeria. *Trop Doct*, 2006. 36(2): p. 97-100.
3. Chen, P.P., Risk and risk factors for blindness from glaucoma. *Curr Opin Ophthalmol*, 2004. 15(2): p. 107-11.
4. Shrestha, M.K., et al., Health literacy of common ocular diseases in Nepal. *BMC Ophthalmol*, 2014. 14: p. 2.
5. Isawumi, M.A., et al., Awareness of and Attitude towards glaucoma among an adult rural population of Osun State, Southwest Nigeria. *Middle East Afr J Ophthalmol*, 2014. 21(2): p. 165-9.
6. Liang, Y.B., et al., Initial Treatment for Primary Angle-Closure Glaucoma in China. *J Glaucoma*, 2015 Aug; 24(6):469-73.
7. Adio, A.O. and A.A. Onua, Economic burden of glaucoma in Rivers State, Nigeria. *Clin Ophthalmol*, 2012. 6: p. 2023-31.
8. Tham, Y.C., et al., Global prevalence of glaucoma and projections of glaucoma burden through 2040: a systematic review and meta-analysis. *Ophthalmology*, 2014. 121(11): p. 2081-90.
9. Quigley, H.A. and A.T. Broman, The number of people with glaucoma worldwide in 2010 and 2020. *Br J Ophthalmol*, 2006. 90(3): p. 262-7.
10. Kosoko-Lasaki, O., et al., Race, ethnicity and prevalence of primary open-angle glaucoma. *J Natl Med Assoc*, 2006. 98(10): p. 1626-9.
11. Tielsch, J.M., et al., Racial variations in the prevalence of primary open-angle glaucoma. The Baltimore Eye Survey. *JAMA*, 1991. 266(3): p. 369-74.
12. Budenz, D.L., et al., Prevalence of glaucoma in an urban West African population: the Tema Eye Survey. *JAMA Ophthalmol*, 2013. 131(5): p. 651-8.
13. Cho, H.K. and C. Kee, Population-based glaucoma prevalence studies in Asians. *Surv Ophthalmol*, 2014. 59(4): p. 434-47.
14. Olawoye, O.O. and T.S. Sarimiye, Is angle closure glaucoma a problem in Nigeria? *Niger J Clin Pract*, 2014. 17(2): p. 159-62.

15. Noecker RJ (June 2006). "The management of glaucoma and intraocular hypertension: current approaches and recent advances". *TherClin Risk Manag* 2 (2): 193–206. doi:10.2147/tcrm.2006.2.2.193. PMC 1661659. PMID 18360593.
16. Parikh RS, Parikh SR, Navin S, Arun E, Thomas R (1 May 2008). "Practical approach to medical management of glaucoma". *Indian J Ophthalmol* 56 (3): 223–30. doi:10.4103/0301-4738.40362. PMC 2636120. PMID 18417824.
17. Jaret, Peter. "A New Understanding of Glaucoma". *NYTimes.com*. *BMC Ophthalmol* 7: 17. Doi:10.1186/1471-2415-7-17. PMC 2093925. PMID 17916260 Retrieved 2014-02-20.
18. Paul R. Lichter, David C. Musch .The Collaborative Initial Glaucoma Treatment Study *Arch Ophthalmol*. 2008; 126(1):122-124. doi:10.1001/archophthalmol.2007.25.
19. Nderi GJ, Gichuhi S, Kollman M, Matende I. Outcome of glaucoma surgery at Mombasa Lighthouse for Christ Eye Center – intraocular pressure control. *East Afr. j. ophthalmol*. 2009; 15(2): 53-60.
20. Adekoya, B.J., et al., Surgical output and clinic burden of glaucoma in lagos, Nigeria. *J Glaucoma*, 2014. 23(1): p. 41-5.
21. American academy of ophthalmology. Section 10 .Glaucoma 2011-2012 edition
22. Jody Piltz-Seymour, M.D. is listed as an author of Epithelial Downgrowth and Glaucoma, IOP and Tonometry, Trabeculectomy. Eye wiki.
23. AnandN,Milke C Dawda VK .Trabeculectomy in advanced glaucoma In Nigeria.*Eye* 2001 June (3)274-8.
24. R Husain et al. A review of trabeculectomy in East Asian people—the influence of race. *Eye* (2005) 19, 243–252. doi:10.1038/sj.eye.6701477 Published online 23 July 2004
25. Broadway, D., I. Grierson, and R. Hitchings, Racial differences in the results of glaucoma filtration surgery: are racial differences in the conjunctival cell profile important? *Br J Ophthalmol*, 1994. 78(6): p. 466-75.
26. Ederer, F., et al., The Advanced Glaucoma Intervention Study (AGIS): 13. Comparison of treatment outcomes within race: 10-year results. *Ophthalmology*, 2004. 111(4): p. 651
27. Skuta GL & Parrish RK. Wound healing in glaucoma filtering surgery (review) (197 refs). *SurvOphthalmol* 1987; 32: 149–170.

28. Yorson D, Khaw PT: A randomised trial of the effect of Intra-op 5-FU on the outcome of TET in East Africa. *Br J Ophthalmol* 2001 Sep 85(9) 1028-30
29. Alwitry A, Abedin A, Patel V, Moodie J, Rotchford A, King AJ. *Eur J Ophthalmol*. 2009 Nov-Dec;19(6):971-6. PMID: 19882580
30. Vesti E. Filtering blebs: follow up of trabeculectomy. *Ophthalmic Surg* 1993. Apr;24(4):249-255 [PubMed]
31. Broadway DC and Chang L. Trabeculectomy, risk factors for failure and the preoperative state of the conjunctiva. *J Glaucoma*, 2001; 10(3): 237-49.)
32. Duman F, Waisbourd M, Faria B, Addis V, Hsieh M, Ekici F, Hark LA, Spaeth GL. *J Glaucoma*. 2015 Feb 23. [Epub ahead of print] PMID: 25715005
33. T. Shaarawy et al. World glaucoma association (WGA) guidelines on design and reporting of glaucoma surgical trials. 2009
34. Manners T, Salmon JF, Barron A, Willies C, Murray AD. *Br J Ophthalmol*. 2001 Feb; 85(2):159-63
35. Jagdish Bhatia *Oman Med J*. 2008 April; 23(2): 86–89. PMID: PMC3282429
36. Martinez-De-La-Casa JM, Saenz-Frances F, Fernandez-Vidal AM, Mendez-Hernandez CD, Pablo-Julvez L, Garcia-Sanchez J, Garcia-Feijoo J. *Eur J Ophthalmol*. 2008 May-Jun; 18(3):423-8.
37. Arnalich-Montiel F, Muñoz-Negrete FJ, Rebolleda G, Sales-Sanz M, Cabarga C. *Eye (Lond)*. 2007 Aug; 21(8):1041-9. Epub 2006 May 5.
38. Shigeeda T, Tomidokoro A, Araie M, Koseki N, Yamamoto S. *Ophthalmology*. 2002 Apr; 109(4):766-70.
39. Lwanga, S. S. Lemeshow. *Sample size determination in health studies a practical manual*. World Health Organization, S. Title. ISBN 92 4 154405 8 1991.
40. A. Ashaye, O. Ashaolu, O. Komolafe, B. G. K. Ajayi, O. Olawoye, B. Olusanya and C. Adeoti, "Prevalence and Types of Glaucoma Among an Indigenous African Population in Southwestern Nigeria," *IOVS*, vol. 54, no. 12, pp. 7410-7416, 2013.
41. Ngan R, Lam DL, Mudumbai RC, Chen PP. Risk factors for noncompliance with follow-up among normal-tension glaucoma suspects. *Am J Ophthalmol*. 2007; 144(2):310-311.
42. Ke Yang Et al, Interventions to Promote Follow-up after Trabeculectomy Surgery in Rural Southern China, *JAMA Ophthalmol*. 2016; 134(10):1135-1141. doi:10.1001/jamaophthalmol.2016.2819

43. R. J. C. Bowman, A. Hay, M. L. Wood, et al., "Combined Cataract and Trabeculectomy Surgery for Advanced Glaucoma in East Africa: Visual and Intra-Ocular Pressure Outcomes," *Eye*, Vol. 24, 2010, pp. 573-577. doi:10.1038/eye.2009.132
44. J. Kabiru, R. Bowman, M. Wood, et al., "Audit of Trabeculectomy at a Tertiary Referral Hospital in East Africa," *Journal of Glaucoma*, Vol. 14, No. 6, 2005, pp. 432-434. doi:10.1097/01.ijg.0000185617.98915.36
45. B. O. Adegbehingbe and T. Majemgbasan, "A Review of Trabeculectomies at a Nigerian Teaching Hospital," *Ghana Medical Journal*, Vol. 41, No. 4, 2007, pp. 176-180.
46. Liu J, Zhang M, Li B, Wang J.J *Ophthalmol.* 2017; 2017:7947854. doi: 10.1155/2017/7947854. Epub 2017 Feb 26.PMID: 28337343
47. Moisseiev E, Zunz E, Tzur R, Kurtz S, Shemesh G.J *Glaucoma.* 2015 Aug; 24(6):410-6. doi: 10.1097/IJG.0000000000000047. Review.PMID: 24633088
48. Olawoye OO, Ashaye AO, Baiyeraju AM, Teng CC, Liebmann JM, Ritch R.J *Ophthalmic Vis Res.* 2013 Apr; 8(2):126-33.
49. Shaun Dacosta, Sheena Bilal, Babu Rajendran, P Janakiraman *Indian J Ophthalmol.* 2008 Mar-Apr; 56(2): 99–102.
50. Kim HY, Egbert PR, Singh K.J *Glaucoma.* 2008 Oct-Nov; 17(7):578-83. doi: 10.1097/IJG.0b013e31816b304a.PMID: 18854737
51. Egbert PR, Williams AS, Singh K, Dadzie P & Egbert TB. A prospective trial of intraoperative fluorouracil during trabeculectomy in a black population. *Am J Ophthalmol* 1993; 116: 612–616. | PubMed
52. H. A. Quigley, R. R. Buhrmann, S. K. West, et al., "Long Term Results of Glaucoma Surgery among Participants in an East African Population Survey," *British Journal of Ophthalmology*, Vol. 84, No. 8, 2000, pp. 860-864. doi:10.1136/bjo.84.8.860
53. Burr J, Azuara-Blanco A, Avenell A, Tuulonen A. *Cochrane Database Syst Rev.* 2012 Sep 12;(9):CD004399. doi: 10.1002/14651858.CD004399.pub3. Review.PMID: 22972069

54. T. Manners, J. F. Salmon and A. Barron, "Trabeculectomy with Mitomycin C in the Treatment of Post-Traumatic Angle Recession Glaucoma," *British Journal of Ophthalmology*, Vol. 85, No. 2, 2001, pp. 159-163. doi:10.1136/bjo.85.2.159
55. Ehrnrooth P, Lehto I, Puska P, Laatikainen L. *Acta Ophthalmol Scand*. 2002 Jun;80(3):267-71. PMID:12059864
56. Kim J, Dally LG, Ederer F, Gaasterland DE, VanVeldhuisen PC, Blackwell B, Sullivan EK, Prum B, Shafranov G, Beck A, Spaeth GL; AGIS Investigators. *Ophthalmology*. 2004 Nov;111(11):2109-16. PMID: 15522379
57. Lawan A. Pattern of presentation and outcome of surgical management of primary open angle glaucoma in Kano, Northern Nigeria. *Ann Afr Med* 2007;6:180-5
58. N. Anand and V. K. Dawda, "A Comparative Study of Mitomycin C and 5-Fluorouracil Trabeculectomy in West Africa," *Middle East African Journal of Ophthalmology*, Vol. 19, No. 1, 2012, pp. 147-152. doi:10.4103/0974-9233.92132
59. Hooi, S. T., and S. H. Hooi. "Trabeculectomy outcomes in a Malaysian general hospital." *MEDICAL JOURNAL OF MALAYSIA* 58.4 (2003): 565-578.
60. Cankaya AB, Elgin U. *Korean J Ophthalmol*. 2011 Dec;25(6):401-8. doi: 10.3341/kjo.2011.25.6.401. Epub 2011 Nov 22. PMID:22131777
61. Higashide T, Ohkubo S, Sugimoto Y, Kiuchi Y, Sugiyama K. Persistent hypotony after trabeculectomy: incidence and associated factors in the Collaborative Bleb-Related Infection Incidence and Treatment Study. *Japanese journal of ophthalmology*. 2016 Jul 1;60(4):309-18
62. Olawoye OO, Ashaye AO, Baiyeroju AM, Teng CC, Liebmann JM, Ritch R.J *Ophthalmic Vis Res*. 2013 Apr;8(2):126-33. PMID: 23943687

APPENDICES

Appendix 1: Approval letter from Ethics and Research committee



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel: (254-020) 2726300 Ext 44355

Ref: KNH-ERC/A/279

Dr. Rotich Manasseh Kipsang
Reg. No. H58/75875/2014
Dept. of Ophthalmology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Rotich,

REVISED RESEARCH PROPOSAL: OUTCOMES OF TRABECULECTOMY AT KENYATTA NATIONAL HOSPITAL AND UNIVERSITY OF NAIROBI: A RETROSPECTIVE CASE SERIES (P441/06/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above proposal. The approval period is from 27th July 2016 – 26th July 2017.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

"Protect to discover"

060 8713



KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: <http://www.erc.uonbi.ac.ke>
Facebook: <https://www.facebook.com/uonknh.erc>
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

To Pay 15007
for Access to Patients
Records Note 4020



KENYATTA NATIONAL HOSPITAL
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27th July 2016

Bill No 9240005

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

Yours sincerely,



PROF. M.L. CHINDIA
SECRETARY, KNH-UoN ERC

- c.c. The Principal, College of Health Sciences, UoN
 The Deputy Director, CS, KNH
 The Assistant Director, Health Information, KNH
 The Chair, KNH- UoN ERC
 The Dean, School of Medicine, UoN
 The Chair, Dept. of Ophthalmology, UoN
 Supervisors: Dr. Marco Sheila, Dr. Kahaki Kimani

“Protect to discover”

Appendix 2: Questionnaire

Demographics

Hospital ID/File number..... Code..... Age.....

Sex.....

African (Black) [] Asian [] Caucasian []

Clinical Presentation:

Eye: Right [] Left []

Pre-operative data

Presenting visual acuity:.....

IOP before Surgery.....

Examination findings

Vertical CDR Gonioscopy Findings.....

Antiglaucoma medications before surgery:

Beta-Blocker

PGA

Alpha-2 Agonist

Pilocarpine

Carbonic anhydrase inhibitor (CAI); oral

Carbonic anhydrase inhibitor (CAI); topical

Other (specify)

Total number of medications

Previous surgical therapy for Glaucoma:

ALT []

SLT []

Other (specify)

Indication for trabeculectomy.....

.....

.....

Post-Operative Data

Date of Surgery/...../.....

Follow-up Period	IOP	VCDR	Visual acuity	Complication	Intervention
Day 1					
Week 1					
Month 1					
Month 3					
Month 6					
Year 1					
Month 18					
Year 2					

Early Complications:

Hypotony [] Flat AC [] SuprachoroidalHaemorrhage []

Hyphaema [] Corneal Decompensation [] Flat bleb []

Endophthalmitis []

Other (specify).....

Intervention

Medical.....

.....

Surgical.....

.....

Late complications

Cataract [] Retinal Detachment [] Phthisis []

Phthisis [] Flat bleb [] Encapsulated Bleb []

Other.....

.....

Intervention

Medical.....

.....

Surgical

Other (specify)

Appendix 3: Budget

Item	Quantity	Unit cost) (Kshs)	Total kshs
Proposal			
Printing and Packing	32 pages	10	320
Photocopy of Proposal	70 pages	3	210
Binding Proposal	3 copies	120	360
Proposal Printing 2 nd draft	30 pages	10	300
Photocopy of proposal 2 nd draft	90 pages	3	270
Binding of proposal 2 nd draft	4 copies	120	480
Ethics			2,000
Sub-total			3,940
Contracted services			
Statistician	1	50,000	50,000
Research assistants	1	15,000	15,000
Sub-totals			75,000
Data Retrieval			
KNH	All Files	2,500	2,500
Sub-total			2,500
Data Collection			
Printing of questionnaire	4pages	10	40
Photocopy of questionnaire	4 * 150	3	1,800
Subtotal			1,840
Communication & Accommodation			
Telephone and Internet			5,000
Transport + Lunch			20,000
Accommodation			25,000
Subtotal			50,000
Results			
Printing of results (black & white)	3*70 pages	10	2,100
Printing of results (color)	3*20 pages	20	1,200
Copy of final book			
Black and white	70*8 copies	3	1,680
Color copies	20*8 copies	20	3,200
Binding of final paper	8 copies	200	1,600
Subtotal			12,220
Grand total			145500