INDICATIONS AND OUTCOMES OF TRABECULECTOMY AT PCEA KIKUYU HOSPITAL- EYE UNIT; A RETROSPECTIVE STUDY

DEPARTMENT OF OPHTHALMOLOGY
UNIVERSITY OF NAIROBI

DR. HELLEN NYAMBURA KIRUBI
H58/87112/2016

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

DECLARATION

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

PRINCIPAL INVESTIGATOR:

Dr. Kirubi Hellen Nyambura

MBChB (University of Nairobi)

Resident, Department of Ophthalmology.

Signed:..... Date:.....

SUPERVISORS:

Dr. Marco Sheila

MBChB, M.MED (Ophthalmology), FEACO, Glaucoma Specialist

Senior lecturer, Department of Ophthalmology, University of Nairobi

Signed:..... Date:.....

Dr. Margaret W. Njuguna

MBChB, M.MED (Ophthalmology), FEACO, Paediatric Ophthalmologist

Senior lecturer, Department of Ophthalmology, University of Nairobi

Signed:..... Date:.....

Dr. Faith Masila

MBChB, M.MED (Ophthalmology), FCOECSA

Consultant Ophthalmologist, PCEA Kikuyu Hospital

Signed:..... Date:.....

ACKNOWLEDGEMENT

First and foremost I want to give thanks to the Almighty for His grace throughout my residency and in carrying out my thesis. I also wish to acknowledge the following people for their contribution towards this study.

Dr Sheila Marco, Dr Margaret Njuguna and Dr Faith Masila for their guidance, advice and encouragement, without which this dissertation would not have been possible. I would also want to thank the members of faculty, Department of Ophthalmology in the University of Nairobi, my fellow students ,the Presbyterian Church of East Africa Kikuyu Hospital Eye-Unit staff and my family for the encouragement and support

Table of Contents

List of Tables

List of Figures

LIST OF ACRONYMS AND ABBREVIATIONS

5FU	5 FlouroUracil
CDR	Cup-Disc-Ratio
HRT	Heidelberg Retina Topography
IOP	Intraocular pressure
PCEA-KEU	The Presbyterian Church of East Africa- Kikuyu Hospital Eye Unit
MD	Mean Deviation
MLHFC	Mombasa Lighthouse For Christ
MMC	Mitomycin C
OCT	Optical Coherence Tomography
UON	University Of Nairobi
VF	Visual Fields

ABSTRACT

Introduction and background: Trabeculectomy is the most common glaucoma surgery done at PCEA Kikuyu Hospital-Eye Unit (KEU), in Kenya and in the world. Few studies have been done looking at the indications and outcomes of the surgery in Kenya yet glaucoma remains the leading cause of irreversible blindness.

Objectives: To determine the indications, outcomes, complications and factors affecting outcomes of trabeculectomy at PCEA Kikuyu Hospital-Eye Unit (KEU).

Study design: Retrospective case series

Study population: All patients who had trabeculectomy done in PCEA Kikuyu Hospital- Eye Unit from 1st January 2012 to 31st December 2016.

Results: There were 318 eyes of 265 patients who were recruited into the study. The mean age of the participants was 56.5 years (SD ± 15.8). There were 164 (61.9%) males and 101 females (38.1%). Failed medical therapy was the most common indication in 165 eyes (60.1%) followed by advanced glaucoma in 60 eyes (22.1%). The mean pre-operative IOP (27.8mmHg) showed a remarkable drop compared to Day 1 mean post-operative IOP (7.6mmHg). The difference between the mean IOP pre-operative and post-operative was statistically significant (<0.05) at all follow up periods. There were 67.4% and 74.2% patients who achieved complete and qualified success at 1 year respectively while 56.1% and 66.3% achieved complete and qualified success respectively at 2 years post-operative. At final follow up, 31 eyes (9.7%) had failure. The most frequent early complication was shallow AC in 35 eyes (48.6%) and bleb leak in 22 eyes (30.6%) while cataract was the most frequent late complication in 41 eyes (87.2%). Age of patient, use of antimetabolite and type of glaucoma were not found to affect IOP outcomes of trabeculectomy in this study due to the low numbers in some of the groups.

Conclusions: Failed medical therapy was the most common indication of trabeculectomy. Trabeculectomy is effective in reducing uncontrolled IOP up to 2 years post-operative. Shallow AC and hypotony were the most common early complications of trabeculectomy while bleb fibrosis and cataract were the most frequent late complications.

1. INTRODUCTION

1.1.Definition

Glaucoma: Refers to a group of diseases characterised by optic neuropathy and loss of neural tissue associated with the eventual development of distinctive patterns of visual field loss. Although the intraocular pressure (IOP) level is one of the primary risk factors for development of glaucoma, it does not have a role in the definition of the disease [1].

Trabeculectomy is a type of surgery performed in the treatment of glaucoma to relieve and reduce intraocular pressure by removing a section of the trabecular meshwork of the eye and the abutting structures thereby allowing flow of aqueous from the anterior chamber to the sub-tenon and subconjuctival space [2].

1.2.Magnitude of glaucoma blindness

Glaucoma is the leading cause of irreversible blindness. There are 4.5 million people estimated to be blind from primary glaucoma worldwide. This accounts for 12% of all global blindness[3]. In Africa, blindness from glaucoma is estimated at 15% second to cataract[4]. In Kenya, Glaucoma was found to be the third leading cause of blindness in the Ocular Status Survey results from the Kenya Rural Blindness Prevention Project at a frequency of 0.6/1000[5].

1.3.Classification

Glaucoma is broadly classified into primary and secondary. Primary glaucoma occurs where there is no identifiable secondary cause, resulting in increased resistance to aqueous outflow or angle closure. Secondary glaucoma occurs in the presence of a second ocular pathological process. These processes may include: neovascularisation, uveitis, trauma or lens related. Glaucoma can further be classified as open or closed angle which is determined by evidence of gonioscopic findings[6].

1.4.Epidemiology of Glaucoma

The global prevalence of glaucoma for population is 3.54% (ages 40-80 years). In 2013, the number of people with glaucoma worldwide was estimated to be 64.3 million between the ages 40-80years, projected to increase to 76.0 million (2020) and further to 111.8 million (2040).Africa has the highest prevalence of primary open angle glaucoma (POAG)at 4.20% while Asia has the highest prevalence of primary angle closure glaucoma (PACG) at 1.09%[7].

A study in West Africa, showed the prevalence of POAG as 3.7% among individuals between age 40 to 49 years and 14.6% among patients who were 80 years and older[8].

In East Africa, the prevalence of all types of glaucoma in the adult population was found to be 4.16% and POAG was found to be 3.1%[9].

2. LITERATURE REVIEW

2.1.Management of Glaucoma

Glaucoma management is aimed at reducing IOP, which is currently the only known modifiable risk factor, with the ultimate goal being to slow or stop structural and functional progression. Lowering the pre-treatment IOP by ≥25% slows down progression of glaucoma in most patients[10].The treatment of glaucoma is individualised, with each patient having a target IOP above which progression occurs and below which progression is halted with the most benefit versus risk/side effects[11].

Glaucoma can either be managed medically or surgically.

In the Collaborative Initial Glaucoma Treatment Study (CIGTS), it was found that there was no difference in visual preservation between initial medical therapy as compared to initial surgical therapy. However, patients preferred medical therapy mainly because the side effects that were associated with initial surgical therapy were more distressing as compared to those found with medical therapy[12].

2.2.Medical management

Medical therapy is the most common initial method of lowering IOP and usually involves topical agents delivered as eye drops as well as oral medication. Medical therapy is indicated in open angle glaucoma and initial treatment of angle closure before definitive treatment of surgery[11]. There are several effective classes of topical therapies for glaucoma, including prostaglandin analogues (PGAs), β-blockers, α-adrenergic agonists and carbonic anhydrase inhibitors (CAIs).

Prostaglandin analogues include travoprost, latanoprost and bimatoprost. They act by increasing uveoscleral and trabecular meshwork outflow[13]. Topical adrenergic Alpha2-

adrenergic agonists, such as brimonidine, act on the ciliary body epithelium thereby decreasing aqueous humor production and have also been found to increase uveoscleral outflow of aqueous. Non-selective alpha agonists, such as epinephrine, cause vasoconstriction of the ciliary body blood vessels therefore decreasing aqueous humor production. It also causes mydriasis and is therefore unsuitable for angle closure glaucoma. Beta adrenergic receptor antagonists, such as timolol, act by decreasing aqueous humor production[14].

Carbonic anhydrase inhibitors e.g. dorzolamide and acetazolamide, act by reducing secretion of aqueous humour by inhibiting carbonic anhydrase enzyme found in the ciliary body epithelium while miotic agents (parasympathomimetics), such as pilocarpine, work by opening the trabecular meshwork through ciliary muscle contraction and as a result allowing increased outflow of the aqueous humour.

Medical treatment is said to fail once there is disease progression despite the patient being on maximal medical therapy. Maximal medical therapy refers to use of every available glaucoma medication. This has since evolved into optimum medical therapy which refers to the use of 2 or 3 different types of glaucoma drugs as it has been found that there are diminishing returns with each additional medication [13].

2.3.Surgical management

Glaucoma surgery has the benefit of a more optimal lowering of IOP and a better diurnal control compared to medical treatment[15].

Glaucoma surgery is indicated in cases of progressive optic neuropathy despite maximal medical management and also in patients with angle closure glaucoma[16].It is also indicated in cases of low socioeconomic status and poor adherence to medical management.

In the paediatric age group, surgery is the definitive treatment of congenital glaucoma[17]. Different types of glaucoma surgery are indicated for different patients and surgical management is largely tailored to suit individual requirements.

Trabeculectomy with mitomycin C is the surgery of choice for medically uncontrolled glaucoma. The goal of treatment is to establish a permanent outflow of aqueous humor into the subconjunctival space through the sclera thereby reducing the intraocular pressure (IOP). Trabeculotomy alone, trabeculotomy and trabeculectomy and goniotomy are the surgical

treatments of choice for congenital glaucoma. In goniotomy, the trabecular meshwork is surgically opened from within, while in trabeculotomy the trabecular meshwork is opened from without, to create a direct communication between the anterior chamber and Schlemm's canal.

Laser techniques used in glaucoma include: laser trabeculoplasty (selective laser trabeculoplasty and argon laser trabeculoplasty), which is typically indicated in patients with early glaucoma disease. Laser iridectomy or peripheral iridoplasty are options for angle closure glaucoma, while laser cyclophotocoagulation is used to decrease production of aqueous by impairing the non-pigmented epithelial cells of the ciliary body that produce it[18].

Glaucoma drainage devices are designed in such a way whereby, a tube is placed in the anterior chamber allowing aqueous to flow out of the anterior chamber through the device to an external reservoir on the sclera: they include ahmed valve, express minishunt and Baerveldt shunt[19].

Other surgical options include: ciliary body ablation, cyclodialysis and viscocanalostomy.

2.4.Trabeculectomy

2.4.1. History of trabeculectomy.

Trabeculectomy was first suggested by Sugar in 1961 and later popularised by Cairns in 1968[20]. It has since been the surgical operation of choice for improving aqueous outflow in glaucoma patients. Since then, the operation has undergone modifications but persists to the present day.

The main challenge of trabeculectomy is excessive scarring with resultant reduction of aqueous flow from the eye into the subconjunctival space leading to the introduction of concurrent use of antimetabolites like 5-Flourouracil in the mid-80s[21]. Newer modifications include use of releasable sutures.

A study done in Kenya at the Mombasa Lighthouse for Christ Eye Centre showed that trabeculectomy was the most common glaucoma surgery of choice at 96%[22].

2.4.2. Indications of trabeculectomy

The most common indications for trabeculectomy are uncontrolled IOP despite maximum tolerated medication and disease progression[23].

Other indications include high cost of medications, non-compliance, physical impairment or disability, significant or debilitating ocular or systemic side effects, or other psychosocial issues in a patient whose optic nerve function is failing[13].

In certain cases, trabeculectomy has been indicated for advanced glaucoma largely due to unavailability of topical therapy as well as high cost of topical medications, as was reported by Anand et al in a study done in Nigeria[24].

2.4.3. Outcome measures of trabeculectomy

There are several parameters which have been used to measure the outcomes of trabeculectomy surgeries. These parameters include intraocular pressure (IOP), progression of the cup disc ratio (CDR), visual fields (VF), optical coherence tomography (OCT) and visual acuity.

2.4.3.1. Intraocular pressure

IOP being the only modifiable risk factor for glaucoma progression is an important measure of outcome of trabeculectomy. As such, a target IOP is required which is the upper limit of a stable range of measured IOP's above which the disease progresses and below which progression halts[13].

Older studies consider success as IOP<21mmHg without medication [23] whereas newer studies have defined success as an IOP cut off of <18mmHg or 30% of the initial IOP. In one recent German study by Joannah Poslednik et al, complete success (target IOP without glaucoma medication) and qualified success (target IOP with glaucoma medication) after trabeculectomy with mitomycin C, was defined by multiple success criteria:

a) IOP ≤ 15 mmHg
b) IOP ≤ 18 mmHg or
c) A mean IOP reduction > 30%, referring to the highest IOP value measured under treatment assessed preoperatively[25].

In a more recent study by Romero et al, the success rate post trabeculectomy was also defined by multiple criteria:

(a) Intraocular pressure (IOP) ≤18 mm Hg with IOP reduction of 20%

(b) IOP≤15 mm Hg with IOP reduction of 25% and

(c) IOP≤12 mm Hg with IOP reduction of 30%[26].

Early trabeculectomy, has been shown to significantly reduce IOP and consequently reduce the optic disc cup size and the likelihood of loss of vision[27].

In this study, success will be reported as in the World Glaucoma Association guidelines that define success as:

(a) Complete success: IOP <18mmHg and >5mmHg with a 20% reduction from baseline without any glaucoma medication.

(b) Qualified success: IOP<18mmHg and >5mmHg with a 20% reduction from baseline with or without hypotensive medications therefore including those with complete success.

Failure will be defined as IOP ≥18mmHg or below the lower limit ≤5mmHg on two consecutive study visits, or need for additional glaucoma surgery or loss of light perception vision and complete failure defined as loss of light perception attributable to glaucoma[28].

2.4.3.2. Cup disk ratio

Vertical CDR is another outcome measure although subjective is useful in our setting due to the unavailability of Heidelberg retina tomography (HRT) and OCT. Arnalich-Montiel et al demonstrated acceptable accuracy between OCT and slit lamp assessment of CDR especially for large cups[29]. In a Kenyan study at Kenyatta National Hospital by Kipsang et al, the mean vertical CDR was found to be maintained post trabeculectomy[30].

2.4.3.3. RNFL and OCT changes

These are considered more objective measures of outcomes compared to slit lamp examination and CDR. In one study, patients with early glaucoma were reported to have shown significant optic disc parameter changes on the HRT 4.5 months after trabeculectomy surgery[31], whereas in another study, patients with advanced glaucoma were found to have an initial increase in RNFL thickness which reverted back to baseline values 3 months after trabeculectomy[32]. In the same study on advanced glaucoma patients, OCT parameters (decreased cup area), also showed reversal of all evident improvements 3 months post trabeculectomy. Due to these findings, there appears no need of redefining baseline values and preoperatively established values can be used for follow-up after 3 months of surgery.

2.4.3.4. Visual fields

Post trabeculectomy, visual fields are used to monitor long term progression of glaucoma and are performed every 4 months. In one study by Kotecha et al, it was shown that visual field changes are determined by the IOP control and as such IOP values post operatively will determine the degree of visual field changes detected. In the study, approximately one-third of eyes continued to show progression of visual field changes, 5 years post trabeculectomy[33]. In another study which evaluated the rates of mean deviation (MD) loss, before and after trabeculectomy they found a considerable reduction in the rate of MD loss after surgery [34].

Of note is the limitation of confounders like cataracts and refractive errors which may give erroneous results.

2.4.3.5. Visual acuity

Various studies have shown unfavourable changes in best corrected visual acuity (BCVA) post trabeculectomy. A study by Costa et al showed that 8% of patients experienced visual loss 3 months post trabeculectomy and this was attributed to various factors including lens opacification, hypotony maculopathy and severe unexplained visual loss (wipe out)[35]. In another study by Franci et al, 56% of patients experienced transient visual loss upto 2 years post trabeculectomy, while 2% had severe unexplained visual loss (wipe out). These visual loss findings were found to be associated with risk factors that included; preoperative split fixation on visual fields, number of quadrants with split fixation preoperative, and postoperative choroidal effusions with eventual resolution[36].

Kashiwagi K et al showed significant visual acuity deterioration 5 years post trabeculectomy with 12.2%, 12.1% and 28.3% of the patients experiencing blindness, low vision and visual acuity loss respectively. The risk factors associated with visual impairment included poor preoperative visual function, glaucoma subtypes, and postoperative complications[37].

As such, visual acuity should not be used as an outcome measure of failure in isolation unless in cases of no light perception due to trabeculectomy complications.

2.4.4. Factors affecting outcomes of trabeculectomy

There are a number of factors that have been found to affect the outcomes of trabeculectomy surgery. These factors include, race, age, antimetabolite use, surgical experience, duration of topical medication use and the type of glaucoma.

2.4.4.1. Race

Traditionally, patients of African origin, both in Africa and the rest of the world, have worse outcomes after trabeculectomy compared to Caucasians because they have more fibroblasts and macrophages compared to Caucasians[38]. Broadway et al also found that conjunctiva obtained from the patients with failed trabeculectomies contained more macrophages, fibroblasts and basal epithelial pale cells explaining the likelihood of lower success rate of trabeculectomy in black populations[39].

2.4.4.2. Antimetabolite use

The natural healing process of the sclera results in fibrosis formation and in the setting of trabeculectomy surgery, this healing process may impair the success of the surgery. The use of antimetabolites has thus been incorporated in trabeculetomies in order to counter the natural healing response which would otherwise lead to bleb failure. Antimetabolites commonly used are mitomycin C (MMC) or 5-fluorouracil (5-FU).

A study done by Beatty et al in the United Kingdom, found the use of mitomycin C (MMC) in trabeculectomy had better outcome in IOP control especially in early post-operative period[40]. In a Nigerian study, intraoperative MMC use was found to be more effective than 5-FU in lowering IOP after initial trabeculectomy, however, MMC use was associated with delayed ocular hypotony[41].

Locally, a study at PCEA Kikuyu Hospital- Eye Unit by Yorston et al, reported better IOP long term control with the use of 5-FU in trabeculectomy[42]. Antimetabolite use has therefore been shown to afford better outcomes of trabeculectomy surgeries in relation to IOP lowering effects.

2.4.4.3. Surgical experience

Studies have shown that experienced surgeons have better outcomes than trainee surgeons. In one study done in Norwich, trainee surgeons had a higher likelihood of developing early post-operative hypotony (low IOP, shallow anterior chamber, choroidal effusion and maculopathy) compared to experienced surgeons[43].

2.4.4.4. Age

Young people have high fibroblasts activities compared to older people[44]. A study by Gressel et al on trabeculectomy in young patients <50 years, showed, that of trabeculectomies performed on patients aged 10 to 29 years, 38% were successful compared to 65% success in patients aged 30 to 49 years[45].

In another study by MC Briggs et al in patients aged 46-85 years, results suggested no verifiable effect of age on the outcome of trabeculectomy in the age group 46-85 years[46].

2.4.4.5. Duration of topical medications prior to trabeculectomy

Studies indicate that long-term medical therapy administered before trabeculectomy, increases the number of tissue inflammatory cells thus increasing the risk of external bleb scarring and failure of the trabeculectomy [23]. In one study by Abraham et al, use of miotics prior to trabeculectomy was found to increase the likelihood of failure[47].Another study by Broadway et al, found that those patients who used beta blockers prior to trabeculectomy had better success rates (93%) compared to those who used beta blockers plus miotics (72%) and even poorer success rates (45%) in those who used beta blockers plus miotics plus sympathomimetics[48].

2.4.4.6. Type of glaucoma

The type of glaucoma has been found as a risk factor for trabeculectomy failure in some studies. The types of glaucoma related to a higher risk of trabeculectomy failure included posttraumatic glaucoma, uveitic glaucoma and neovascular glaucoma[49]. Primary open angle glaucoma has been associated with better outcomes of trabeculectomy.

2.4.5. Complications of trabeculectomy

Complications of trabeculectomy surgery have been categorized as early onset and late onset whereby the former is within <30days post-surgery and the latter is >30days post-surgery. Early onset complications include hypotony, hyphaema and microhyphaema, bleb leak, choroidal effusion and the late onset complications include bleb leak, hypotony, choroidal effusion, visual loss and cataract.

In a national survey of trabeculectomy in the United Kingdom on complications of trabeculectomy: hyphaema, shallow anterior chamber, hypotony, wound leak and choroidal

detachment, were found to be the most common early complications whereas cataract, loss of vision and encapsulated bleb were identified as the commonest late complications[50].

In another study by Olayanju J et al, majority of the early onset complications were noted to be self-limiting, while surgical intervention was required for the late onset complications. Of the complications, the main indications for bleb revisions were hypotony and bleb leaks. The most frequent surgical interventions identified included bleb revision, drainage of choroidal effusion or hemorrhage, and intraocular injections[51].

3. JUSTIFICATION

Glaucoma is the number one cause of irreversible blindness in Kenya and in the world. The disease is challenging to manage in our setting because of the high cost of medication that is lifelong as well as the disease burden that converts the once independent person into a dependent one. As such, surgical management suffices as a primary or adjunct treatment that delays onset of irreversible blindness while alleviating the total dependence and expense on drugs. This study looks at the common indications and outcomes of trabeculectomy which is the commonest glaucoma surgery performed both regionally and in the world.

Very few local studies have been done to assess the outcomes of trabeculectomy. No such study has been done at PCEA Kikuyu Hospital-Eye Unit which is both a local and regional referral centre. At least 90 glaucoma surgeries are performed at the centre every year. A study of the outcomes will enable an objective assessment of the success of the surgery .This may enable an informed evidence based approach as regards choice of patients and practise of the procedure. This may also enable the ophthalmologists tailor specific characteristics of the procedure for particular patients so as to ensure the best possible outcomes.

4. OBJECTIVES

4.1.Main Objective

1. To determine the indications and outcomes of Trabeculectomy surgeries done in PCEA Kikuyu Hospital- Eye Unit (KEU) between 1st January 2012 to 31st December 2016.

4.2.Secondary Objectives

1. To determine the indications of trabeculectomy surgery at PCEA Kikuyu Hospital-Eye Unit (KEU).
2. To determine the outcomes of trabeculectomy surgery at PCEA Kikuyu Hospital-Eye Unit (KEU).
3. To determine the complications of trabeculectomy at PCEA Kikuyu Hospital-Eye Unit (KEU).
4. To determine the factors affecting outcomes of trabeculectomy at PCEA Kikuyu Hospital-Eye Unit (KEU).

5. MATERIALS AND METHODS

5.1.Study Design

A retrospective case series.

5.2.Study Location

PCEA Kikuyu Hospital-Eye Unit is located 20km northwest of Nairobi in Kikuyu town, Kiambu County. The county is estimated to have a population of about 1.623 million (2009 Kenya census). PCEA Kikuyu Hospital Eye Unit is a Christian based eye centre serving mainly Nairobi and Kiambu counties. It is also a referral centre for the East African region. As such, it offers a wide geographical catchment area for the study. In addition, the eye unit serves an average of 3500 glaucoma patients per year and an average of 90 glaucoma surgeries are done per year. During the study period, the unit had 11 ophthalmologists who performed the surgeries. The study will therefore be of significant impact to the eye unit's vast number of glaucoma clients.

Map showing the location of PCEA Kikuyu Hospital- Eye Unit.

5.3.Study Population

Case notes of glaucoma patients (all clinical types) who presented to PCEA Kikuyu Hospital-Eye Unit (KEU) and had trabeculectomy surgeries performed at the hospital within the study period, January 2012- December 2016.

5.4.Inclusion Criteria

Case notes of all glaucoma patients aged 16 years and above who underwent trabeculectomy surgery at PCEA Kikuyu Hospital- Eye Unit (KEU) within the study period.

5.5.Exclusion Criteria

The following were excluded from the study:

1. Case notes of patients who had combined surgeries.
2. Case notes of patients who had undergone repeat trabeculectomy surgery, glaucoma drainage devices or CPC in the same eye.
3. Files with missing critical data or incomplete information.

5.6.Sample size calculation

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

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

Where

n' = sample size with finite population correction,

N = size of the target population = 350 (estimated number of patients who have had trabeculectomy surgery at PCEA Kikuyu Hospital- Eye Unit between the years 2012 to 2016 according to the registry)

Z = statistic for 95% level of confidence

P = estimated proportion of patients with glaucoma – 7.3%[52]

d = margin of error = 2.1%

$$n^1 = \frac{350x1.96^2x0.073x0.927}{(0.021^2x349)+(1.96^2x0.073x0.927)}$$

n^1 = 219.8440

Sample Size = 220 Eyes

5.7.Outcome Measures

5.7.1. 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.

Recommended Ideal, Preferred and Acceptable follow up time[28].

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	21-42	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

5.7.2. Secondary outcome measures:

1. Number of patients achieving complete success, qualified success or failure, defined as;
    - **Complete Success**: IOP < 18mmHG and >5 mmHg with a 20% reduction from baseline IOP without any glaucoma medications or further glaucoma surgery.
    - **Qualified Success**: IOP <18mmHG and >5mmHg with a 20% reduction from baseline IOP including that with or without any glaucoma medication, without further glaucoma surgery.
    - **Failure:** will include any of the following criteria:
        - ✓ IOP ≥ 18mmHG and ≤5mmHG in the last visit
        - ✓ Worsening of vision to non-light perception (NLP) vision
        - ✓ Need for additional glaucoma surgery
2. Number of glaucoma medication needed post trabeculectomy.

3. Vertical cup disc ratio (VCDR) change during the follow up period.
4. Number of surgeries post trabeculectomy.
5. Visual Acuity.

5.8.Study Materials

- Data collection tool in form of a questionnaire with details of the biodata, investigations, the surgical procedure together with the pre-operative and post-operative information from the case files that met the inclusion criteria
- Patients record files at PCEA Kikuyu Hospital- Eye Unit.

5.9.Data Collection

Records of patients, who underwent trabeculectomy in PCEA Kikuyu Hospital-Eye Unit (KEU) between 1st January 2012 to 31st December 2016, were retrieved from theatre registry and were crosschecked with records department. Those that fulfilled the inclusion criteria were included in the study. The corresponding patients' hospital files were retrieved from the records department. All information relevant to the study was collected and entered into the pre-designed data collection tool.

5.10. Data Management

During the study, the coded data collection forms were stored in a cabinet under lock and key and the electronic data stored in a password protected computer to ensure confidentiality. The data was validated to check for data entry errors. Data was accessible through use of unique IDs allocated to each data collection tool. A backup copy of the data was made to ease reliability in case of laptop loss or system crash. The coded data collection forms and all digital records of the data will be destroyed after publication to ensure confidentiality is maintained.

5.11. Data Analysis

Descriptive analysis was used to determine frequencies of variables and presented in graphs and tables as appropriate. The first objective on indications of trabeculectomy was analysed using descriptive analysis. The second objective on outcomes of trabeculectomy was analysed using both descriptive analysis and student's t-test while the complications of trabeculectomy were analysed using descriptive analysis. The factors affecting outcomes of trabeculectomy were analysed using descriptive analysis, student's t-test and univariate

regression analysis. Statistical analysis using SPSS software was done with the help of a statistician.

5.12. Ethical Consideration

So as to adhere to ethical codes, authority and permission to conduct the study was sought from the Ethics and Research Committee of University of Nairobi/Kenyatta National Hospital. Permission was also sought from the administration of PCEA Kikuyu Hospital –Eye Unit (KEU).

5.13. Confidentiality

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

6. RESULTS

A total of 297 patients underwent trabeculectomy surgeries at PCEA Kikuyu Hospital-Eye Unit (KEU) between 1st January 2012 and 31st December 2016. Of these, 265 patients (318 eyes) were recruited in the study.

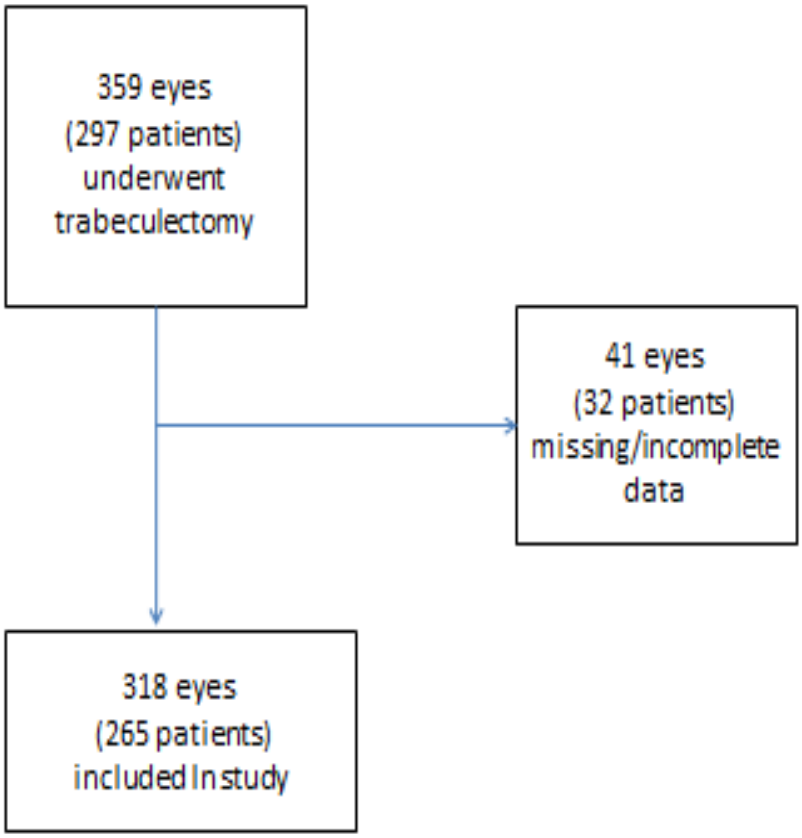


Figure 1: Study flow chart

Most surgeries were performed in 2013 over the 5-year period (Jan 2012- Dec 2016).

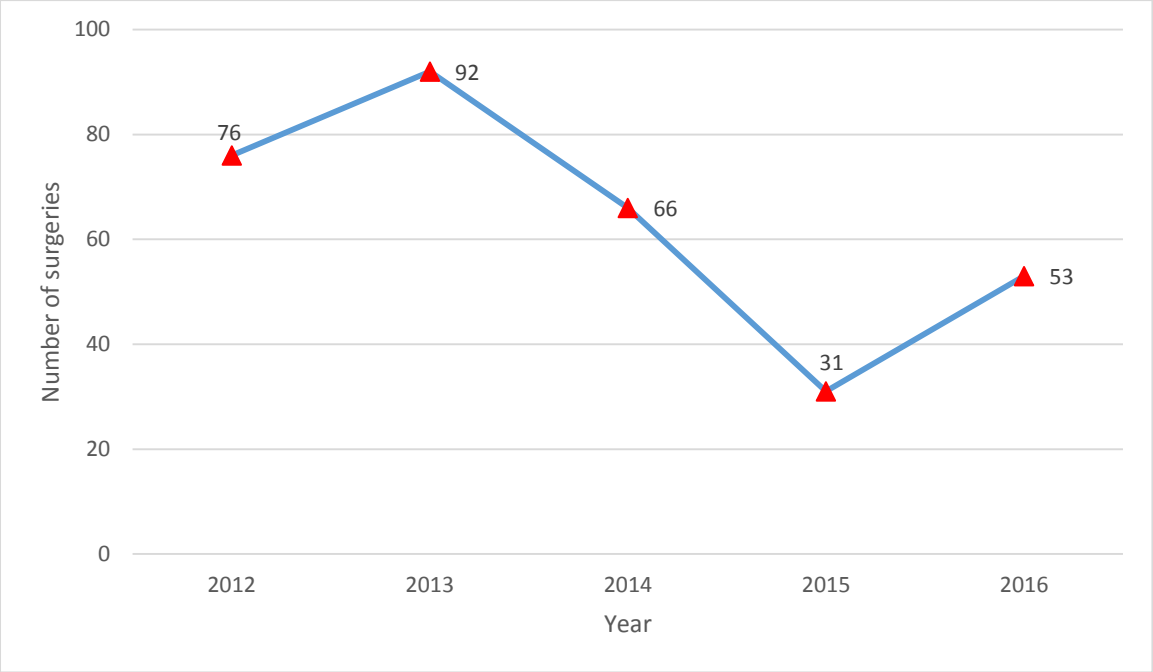


Figure 2: Annual distribution of trabeculectomy surgery at KEU(n=318)

Out of the 265 recruited patients 212(80%) had unilateral trabeculectomy and 53(20%) bilateral trabeculectomy. The pre-operative mean CDR for the 318 eyes was 0.82 ± 0.17 (range 0.2 - 1).

The mean age of the participants was 56.5 years (SD ± 15.8), range 17 to 92 years. There were 164 (61.9%) males and 101 females (38.1%).

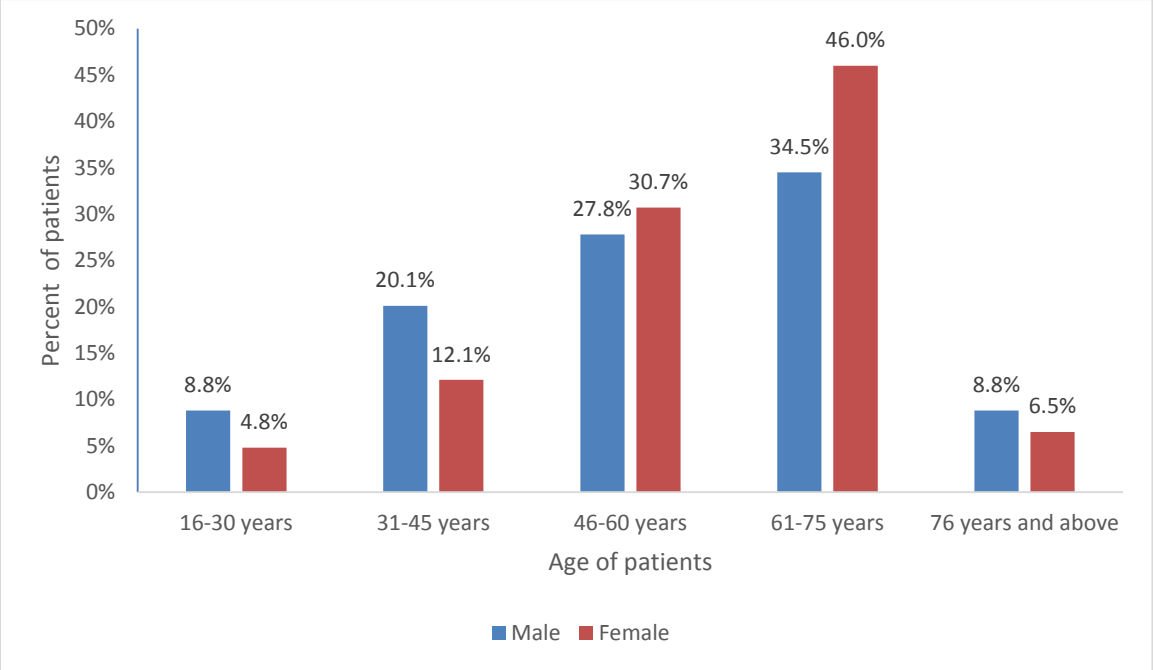


Figure 3:Distribution by age and sex of the study population (n=265).

The mean IOP was 27.8 (SD ± 11.7) in the preoperative period. Figure 3 shows IOP distribution with majority of the patients (65.7%) having IOP's ranging from 11-30mmHg. The IOP range was 7-70 mmHg.

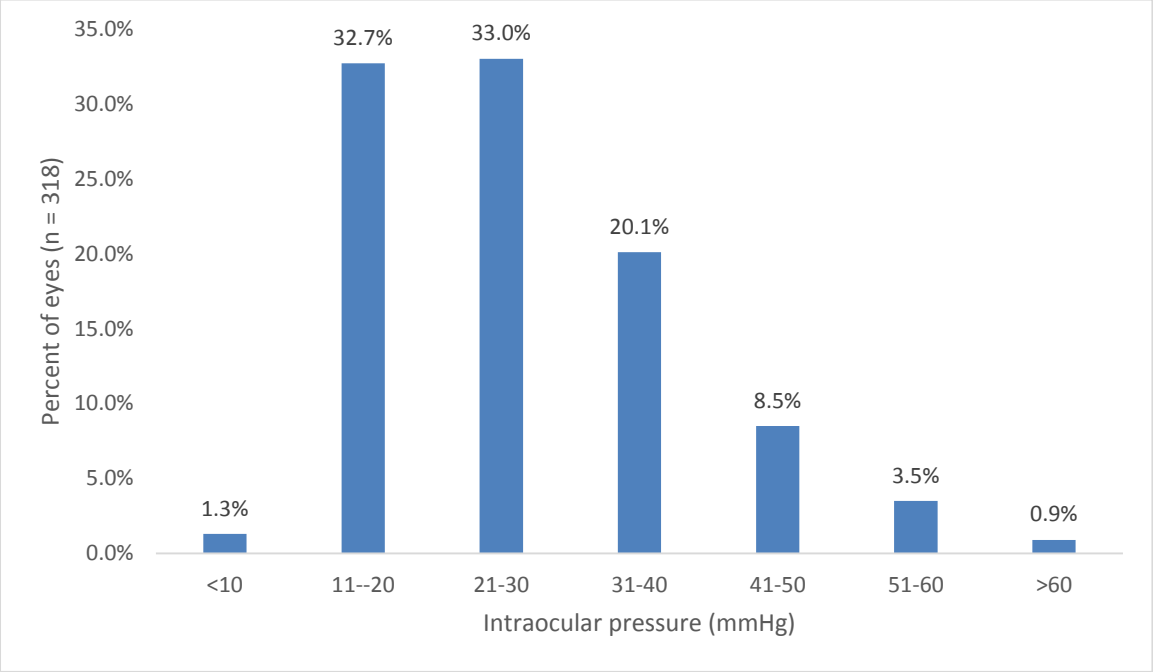


Figure 4: Distribution of pre-treatment IOP in eyes of patients who underwent trabeculectomy at KEU (n=318).

The preoperative visual acuity of eyes of patients who underwent trabeculectomy at KEU is shown in Table 2. The range of visual acuity was 6/4 to Perception of light with the most common visual acuity being 6/36 (15.1%). 58 eyes (18.2%) had vision <3/60.

Table 1: Pre-operative visual acuity(n=318)

	Number of eyes**(n)**	Percentage**%**
No visual impairment(6/18 or better)	132	41.5
Visual impairment(<6/18-6/60)	110	34.6
Severe visual impairment(<6/60-3/60)	18	5.7
Blind(< 3/60-NPL)	58	18.2
Total	**318**	**100**

The most common type of glaucoma among the eyes of patients who underwent trabeculectomy was Primary Open Angle Glaucoma in 265 eyes (83.3%) while Secondary Glaucoma was in 23 eyes (7.2%)

Table 2: Summary of types of glaucoma

Type of glaucoma	**Number of eyes(n)**	**Percentage (%)**
POAG	265	83.3
Secondary	23	7.2
Not indicated	16	5.0
Ocular hypertension	6	1.9
PACG	5	1.6
Normotensive glaucoma	3	0.9
Total	**318**	**100**

The mean number of anti-glaucoma drugs used in the eyes of patients preoperatively was 2.3 (SD± 0.75). Most patients were on two (39.6%) or three (38.7%) drugs (Table 5). The most common used topical anti-glaucoma drugs used prior to trabeculectomy were beta-blockers (89.9%) and prostaglandin analogues (61.3%). Alpha 2 agonists were used in 55.4% of eyes.

Table 3: Number of glaucoma drugs used pre-operative and at 2 years post-operative

	Preoperative		**2 years postoperative**	
	Number of eyes(n)	Percentage (%)	Number of eyes(n)	Percentage (%)
Total number of drugs				
0	8	2.5	77	77.4
1	39	12.3	18	19.4
2	126	39.6	3	3.2
3	123	38.7	-	-
4	22	6.9	-	-
Total	**318**	**100**	**98**	**100**

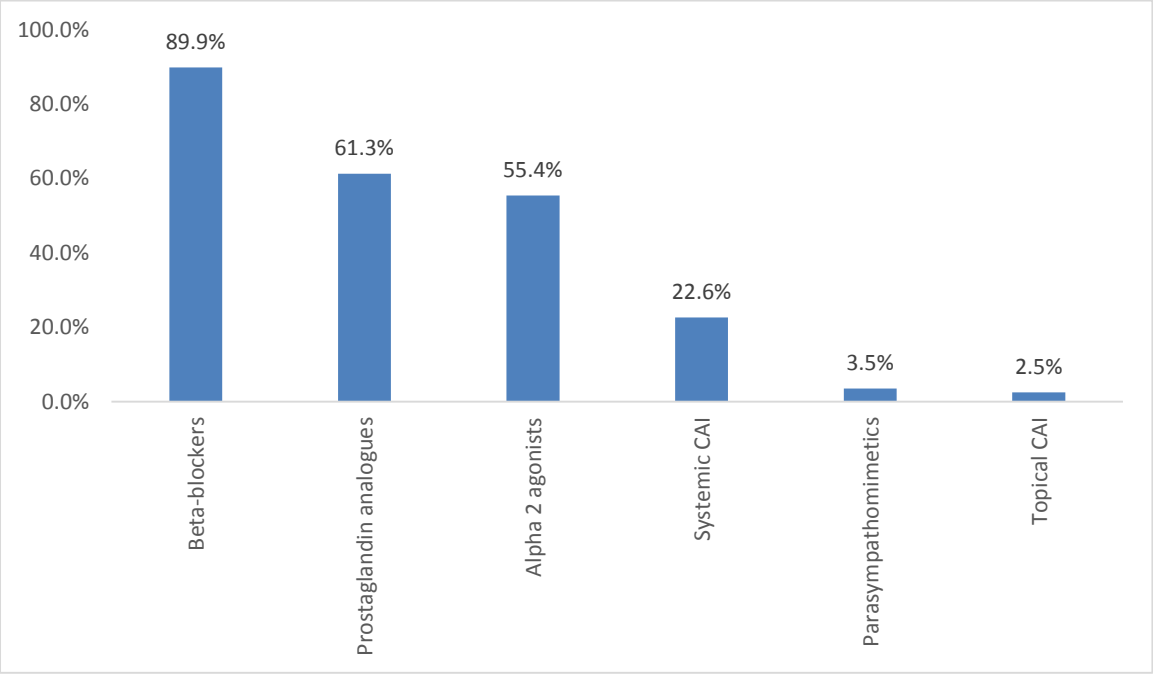


Figure 5: Type of drugs used pre-operatively

Most eyes that underwent trabeculectomy did not have a pre-existing ocular condition (87.1%). There were 41eyes (12.9%) that had pre-existing ocular conditions (Table 6). The leading pre-existing ocular condition was cataract in 10 eyes (3.1%) and refractive errors in 9 eyes (2.8%).

Table 4: Pre-existing ocular conditions in patients who underwent trabeculectomy at KEU

	Number of eyes(n)	**Percentage (%)**
None	277	87.1
Cataract	10	3.1
Refractive errors	10	3.1
Diabetic Retinopathy	5	1.8
Diabetic Macula Edema	4	1.3
Uveitis	2	0.6
Age Related Macula Degeneration	2	0.6
Branch Retinal Vein Occlusion	2	0.6
Commotio retina	1	0.3
Cornea scar	1	0.3
Central Serous Retinopathy	1	0.3
Hypertensive retinopathy	1	0.3
Macula hole	1	0.3
Optic disc coloboma	1	0.3
Total	**318**	**100**

Preoperatively 7 eyes (2.2%) had Glaucoma laser surgery. Gonioscopy was done in 21 eyes (6.6%) while Humphrey's visual field test was done in 71 eyes (22. 3%).Central corneal thickness was done in 8 eyes (2.5%).

Table 5: Previous laser and preoperative investigations performed

	Number of eyes(n=318)	**Percentage (%)**
Glaucoma laser surgery		
Laser PI	7	2.2
None	311	97.8
Gonioscopy		
No	297	93.4
Yes	21	6.6
Gonioscopy finding (n = 21)		
Closed angle	6	28.6
Open angle	15	71.4
HVF		
No	247	77.7
Yes	71	22.3
HVF mean deviation	- 19.98 ± 9.6	Range(-33.5 to -3)
CCT		
No	310	97.5
Yes	8	2.5
CCT findings	539.9 ± 32.95	Range(515- 600)

The indication for trabeculectomy was specified in 271 eyes (85.2%). Of these, failed medical therapy was the most common indication in (60.1%) followed by advanced glaucoma (22.1%).

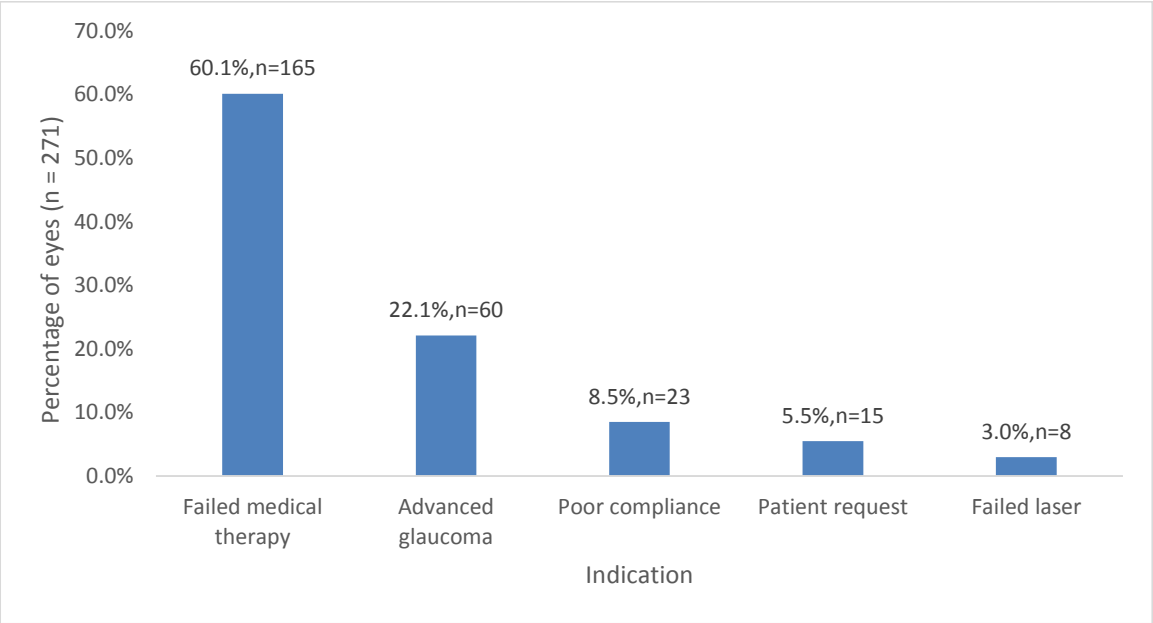


Figure 6: Indications for trabeculectomy (n=271).

All eyes were examined on the 1st day post op with a subsequent reduction of the number who came for follow up at week one followed by an increase in month one and a gradual reduction in follow up afterwards with the 2 year follow up being slightly below half at 45%.

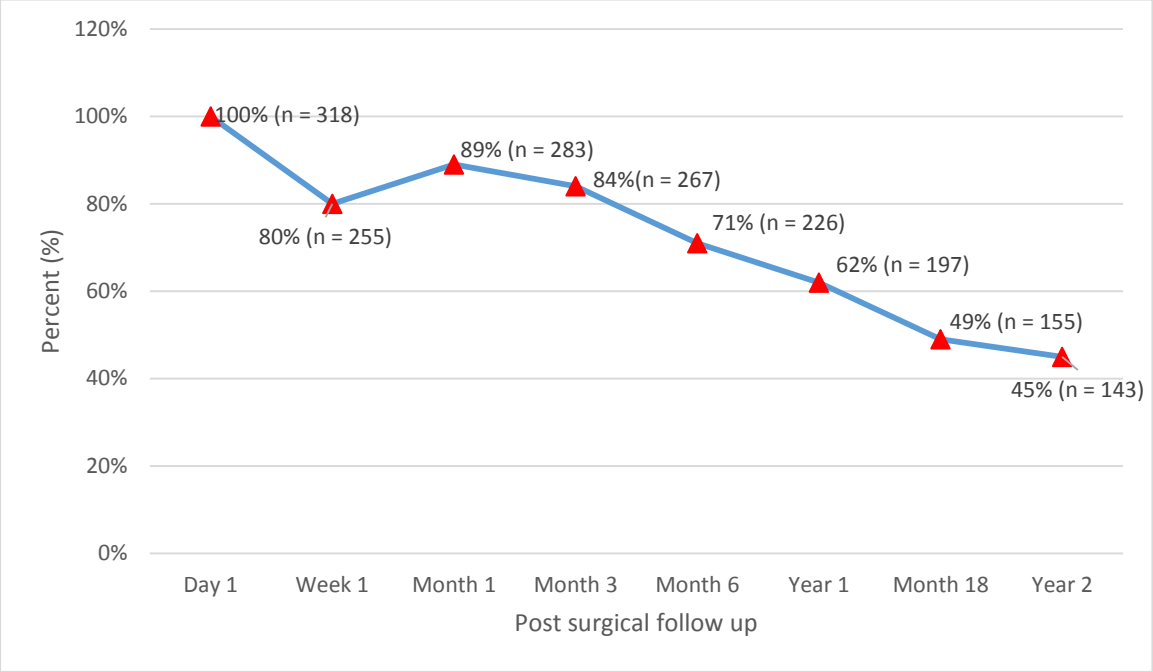


Figure 7: Compliance to follow-up visits

Mean IOP preoperative (27.8) had a remarkable drop compared to Day 1 post op IOP (mean 7.6). Of note is that day 1 IOP readings are not routinely taken (n=81) at the centre. The IOP trend after day 1 showed a gradual increase to a mean of 13.8 (n=98) at 2 years post-operative.

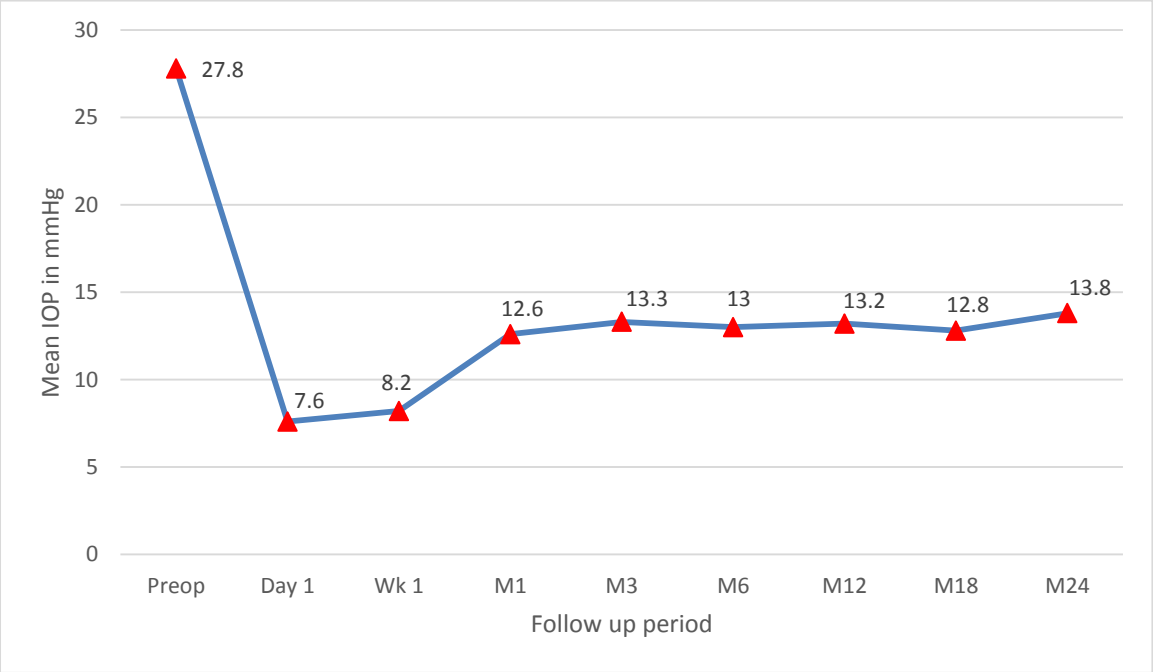


Figure 8: IOP trend pre-operative and post-operative

The difference between the preoperative mean IOP and postoperative IOP was statistically significant (<0.05) at all follow up periods.

Table 6: Pre-operative and post-operative mean IOP

Follow up period	**Preoperative mean IOP (SD)**	**Post-operative mean IOP (SD)**	**P value**
Day 1 (n = 83)	28.1 (SD±10.3)	7.6(SD±6.6)	0.00
Week 1 (n = 167)	28.5 (SD±11.6)	8.2 (SD±5.3)	0.00
Month 1 (n = 257)	27.3 (SD±11)	12.6 (SD±6.5)	0.00
Month 3 (n = 205)	27.1 (SD±10.8)	13.3 (SD±6.4)	0.00
Month 6 (n = 184)	25.2 (SD±10.3)	13.0 (SD±8.9)	0.00
Month 12 (n = 147)	25.8 (SD±10.5)	13.2 (SD±7.2)	0.00
Month 18 (n = 114)	24.6 (SD±9.5)	12.8 (SD±4.7)	0.00
Month 24 (n = 98)	25.9 (SD±10.6)	13.8 (SD±5.5)	0.00

The peak percentage reduction of IOP was at Day 1 post op at 73% with a subsequent decline to 50% at 2 years

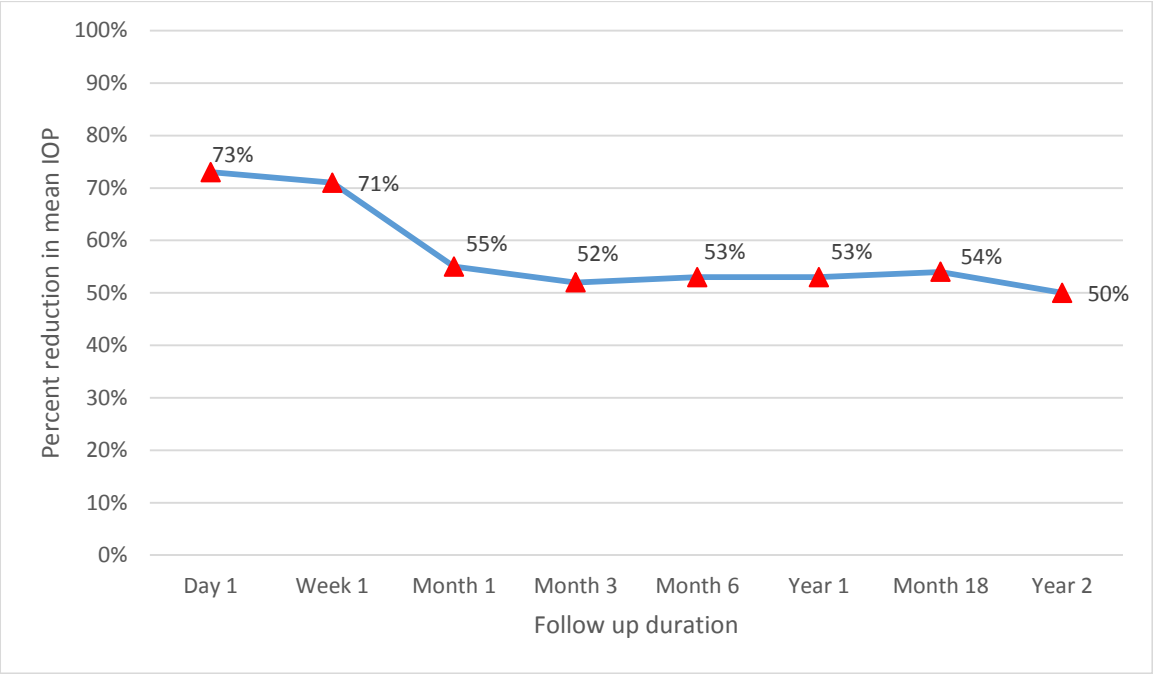


Figure 9: Percentage reduction of IOP from baseline

A comparison between the mean CDR preoperative and postoperative shows a slight change with minimal rise as there are reductions, with the 2 year CDR being similar to the preoperative CDR of 0.82.

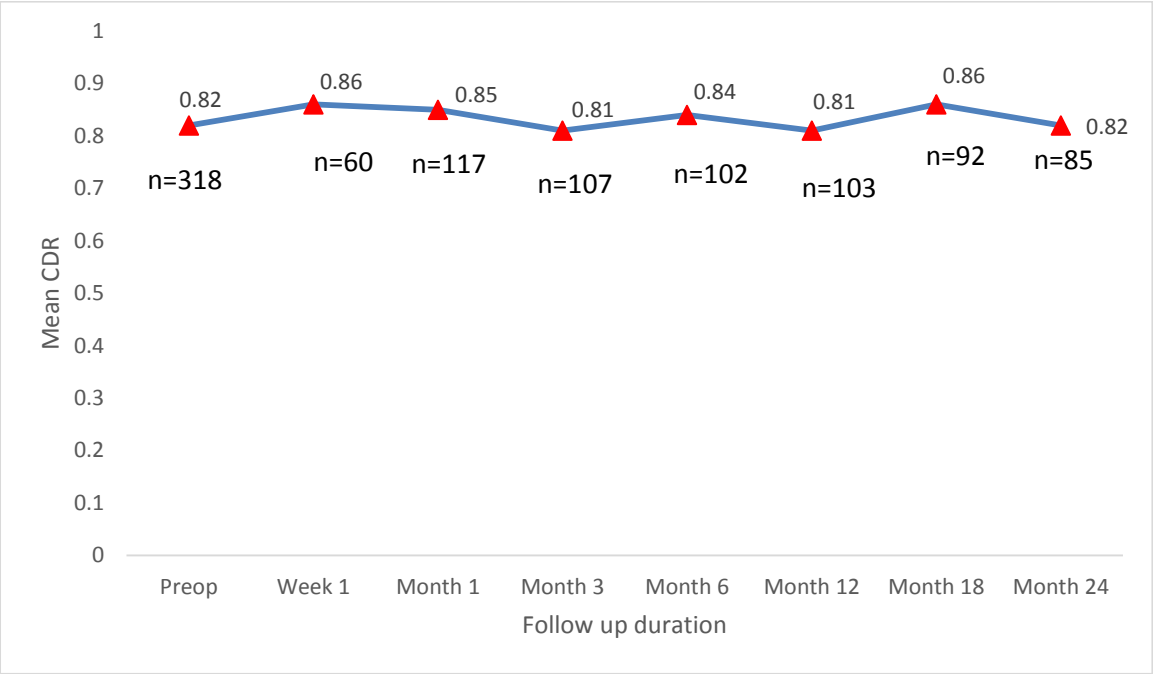


Figure 10: Trend of pre-operative and post-operative CDR

The visual acuity chart shows an initial decline at week 1 post-operative followed by a gradual improvement to the Logmar equivalent visual acuity preoperative.

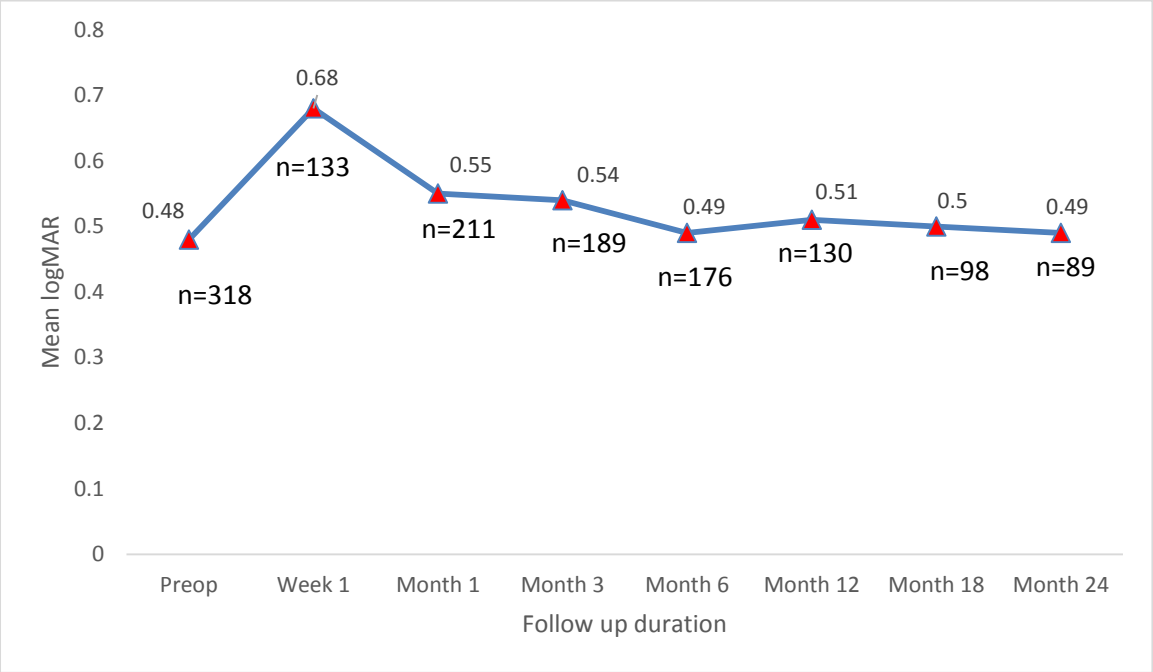


Figure 11: Trend of pre-operative and post-operative visual acuity

There was a striking decline in the mean number of glaucoma drugs both at day 1 post-operative and at 2 years post-operative 0.26 (SD 0.51) compared to the preoperative 2.3 (SD 0.75)

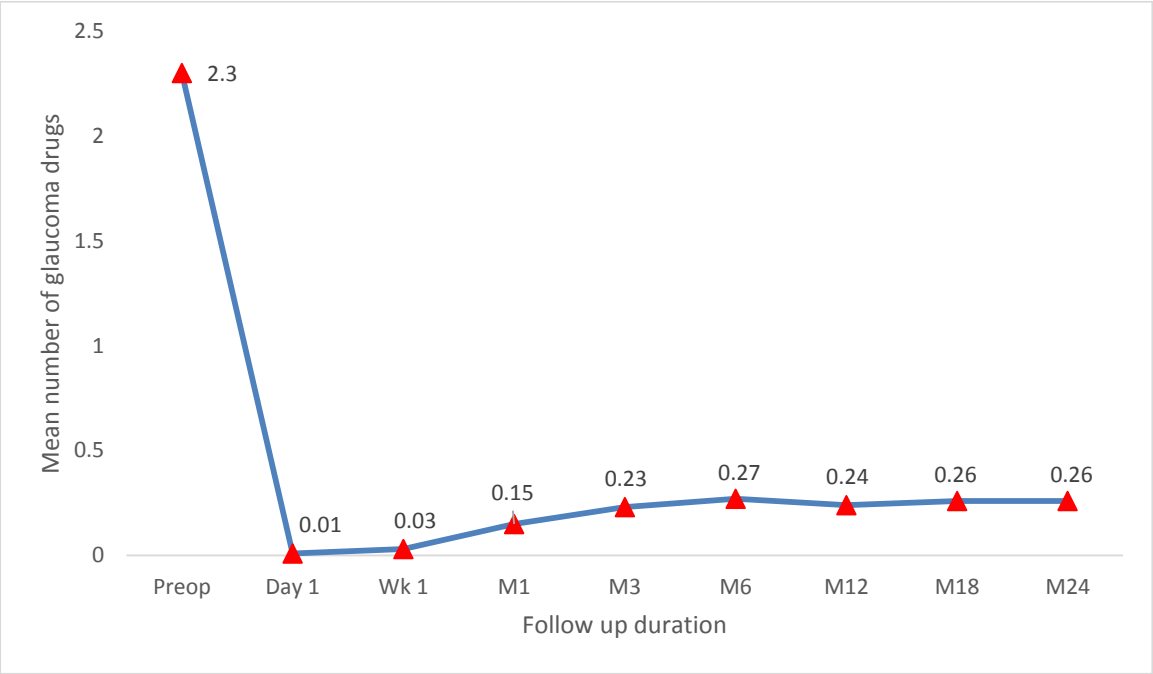
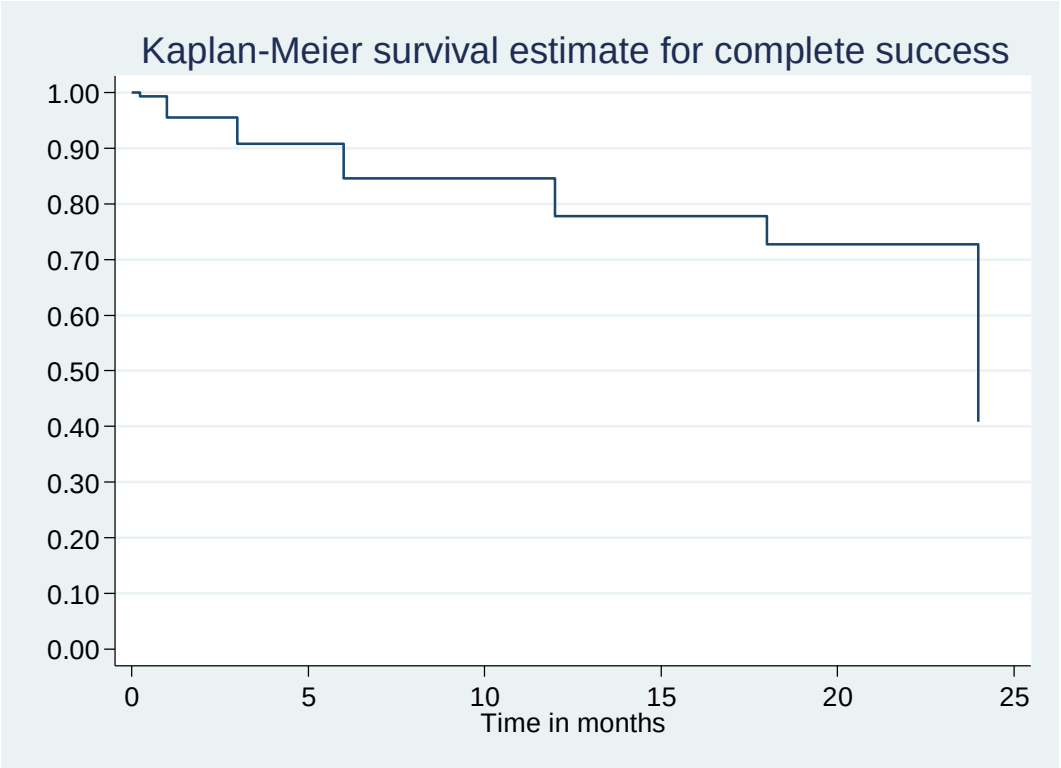


Figure 12: Mean number of glaucoma drugs used pre-operative and post-operative at different follow-up visits

The proportion of patients achieving complete success was 67.4% at 1 year and 56.1 at 2 years post-operative.

Table 7:Percentage achieving complete success (IOP >5mmHg and <18mmHg, with 20% reduction from baseline without glaucoma medication)

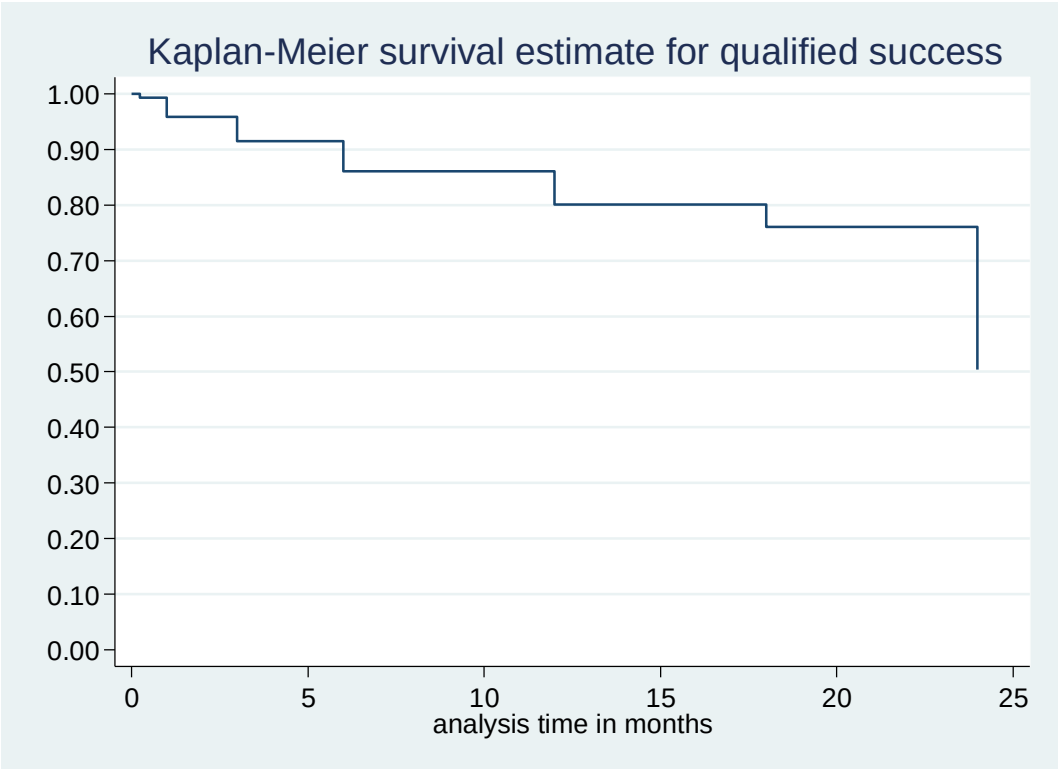
	Complete success	
Follow up period	N	Percentage (%)
Day 1 (n = 83)	46	55.4
Week 1 (n = 167)	108	64.7
Month 1 (n = 257)	168	65.4
Month 3 (n = 205)	134	65.4
Month 6 (n = 184)	119	64.7
Month 12 (n = 147)	99	67.4
Month 18 (n = 114)	78	60.4
Month 24 (n = 98)	55	56.1



The probability of qualified success at 1 year is 74.2% and 66.3% at 2 years

Table 8: Percentage of patients achieving qualified success (IOP > 5mmHg and < 18 mmHg, with 20% reduction from baseline with or without glaucoma medications)

	Qualified success	
Follow up period	N	Percentage (%)
Day 1 (n = 83)	46	55.4
Week 1 (n = 167)	108	64.7
Month 1 (n = 257)	171	66.5
Month 3 (n = 205)	139	67.8
Month 6 (n = 184)	130	70.7
Month 12 (n = 147)	109	74.2
Month 18 (n = 114)	91	79.8
Month 24 (n = 98)	65	66.3



At final follow up 31 eyes (9.7%) had failure with 22 eyes having IOP≥18 and 2 eyes with IOP ≤5. 2 eyes needed additional glaucoma surgery (repeat trabeculectomy and a shunt) while 5 eyes developed no light perception.

Table 9: Final failure

Follow up period	**Number of eyes**	**Percentage (%)**
Total final failures	31	9.7
IOP ≤ 5 mmHg	2	0.6
IOP ≥ 18 mmHg	22	6.9
Needed additional glaucoma surgeries	2	0.6
Developed NLP vision	5	1.6

Intraoperative, 249 eyes (78.3%) had an antimetabolite used. 8 eyes were noted to have intraoperative complications. The most common was conjunctival buttonhole (3eyes) and hypotony (3eyes)

Table 10: Intraoperative findings

	Number (n)	**Percentage(%)**
Antimetabolite use		
No	69	21.7
Yes	249	78.3
Name of antimetabolite		
5FU	236	94.8
MMC	13	5.2
Intraop complication		
None	310	97.5
Yes	8	2.5
Specified intraop complication		
Conjunctival buttonhole	3	
Descemet tears	1	
Hypotony	3	
Shallow AC	1	

Postoperatively, 73 eyes had early post-operative complications while 51 had late complications. The most frequent early complication was shallow AC in 35 eyes (48.6%) followed by bleb leak in 22 eyes (30.6%) and hypotony in 13 eyes (18.1%). Of the late complications, cataract was the most frequent in 41 eyes (87.2%) while shallow AC was found in 3 eyes (6.4%). Of note is that 10 eyes had recorded cataract preoperative no grading was done and therefore difficult to quantify progression of the same post-operative.

Table 11: Post-operative complications

Complication	**< 30 days n=318**	**> 30 days n=318**	**Total**	**Percent**
None	246	271	-	-
1 complication	52	46	-	-
2 complications	20	5	-	-
Cataract	10*	41	51	16%
Flat/ shallow AC	35	3	38	11.9%
Bleb leak	22	1	23	7.2%
Hypotony	13	0	13	4.1%
Hyphaema	8	0	8	2.5%
Bleb fibrosis	1	4	5	1.5%
Choroidal effusion/detachment	4	0	4	1.2%
Bleb encapsulation	0	1	1	0.3%
Pthysical eye	0	1	1	0.3%
Blebitis	0	1	1	0.3%

*There were 10 pre-existing cataracts.

The most frequent additional postoperative surgical intervention was cataract surgeries in 32 eyes (58.2%).19 (34.5%) surgical interventions were done in the early post-operative period.

Table 12: Additional post-operative surgical interventions

	<30 days	>30 days	**Total**
AC reformation	5		5
Bleb revision	1		1
Conjuctival resuturing	3		3
Iris reposition	1		1
Needling	2	7	9
Cataract surgery	3	29	32
Suture release	4		4
Repeat trabeculectomy		1	1
AGV implantation		1	1
Total	**19**	**38**	**57**

Eyes of patients <35 years of age showed a higher IOP level post-operative with a peak at 6 months post op and a slightly higher IOP as at last follow up at 2 years compared to older patients. The numbers were as shown in the table below. The 35-60 group and 60+ group have comparable numbers but the <35 group had much fewer numbers.

Table 13: Age of patients at different follow up periods

	< 35 yrs	35-60 yrs	60+ yrs
Preop	37	132	149
Week 1	16	80	71
Month 1	34	106	117
Month 3	22	89	94
Month 6	21	74	89
Year 1	13	59	75
Month 18	8	43	63
Year 2	9	35	54

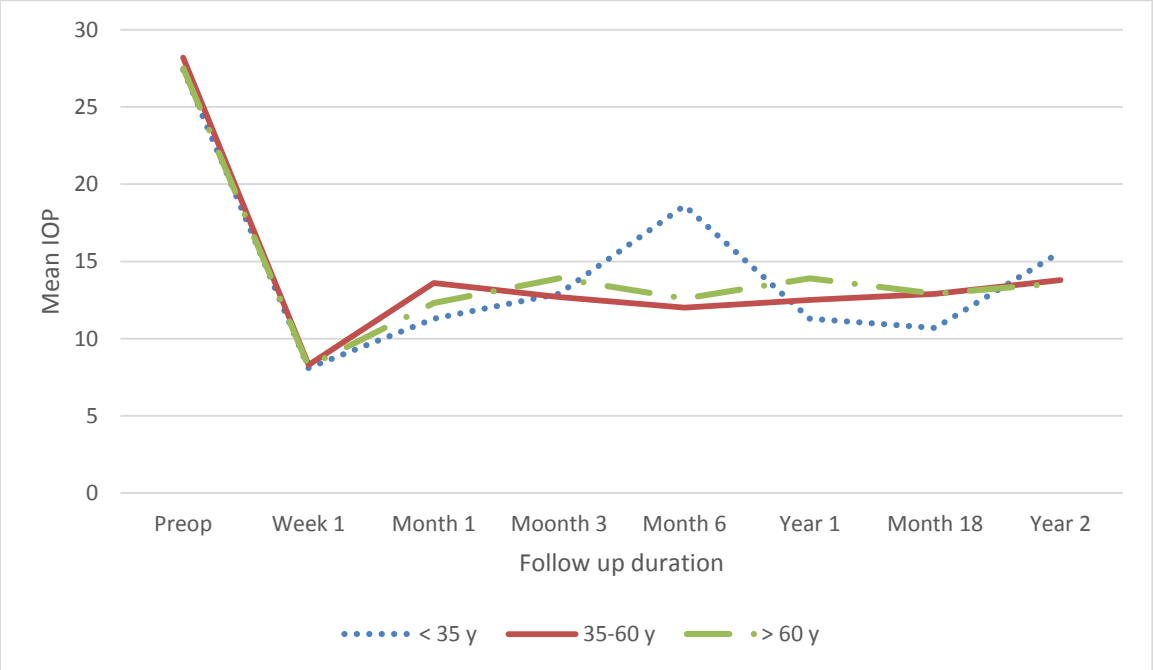


Figure 13: The effect of age on the IOP outcomes

On comparing IOP values in eyes that had antimetabolite vs those without antimetabolites. There was a minimal difference with those eyes having had no antimetabolite use having a slightly elevated IOP. At 2 years post op there was no difference between the two groups. It is important to note that only 69 eyes (21.7%) did not have antimetabolite use compared to 249 eyes (78.3%)

Table 14: Number of eyes with antimetabolites at different follow up

	No antimetabolite	Antimetabolite
Preop	69	249
Week 1	36	131
Month 1	59	198
Month 3	43	162
Month 6	37	147
Year 1	28	119
Month 18	22	92
Year 2	21	77

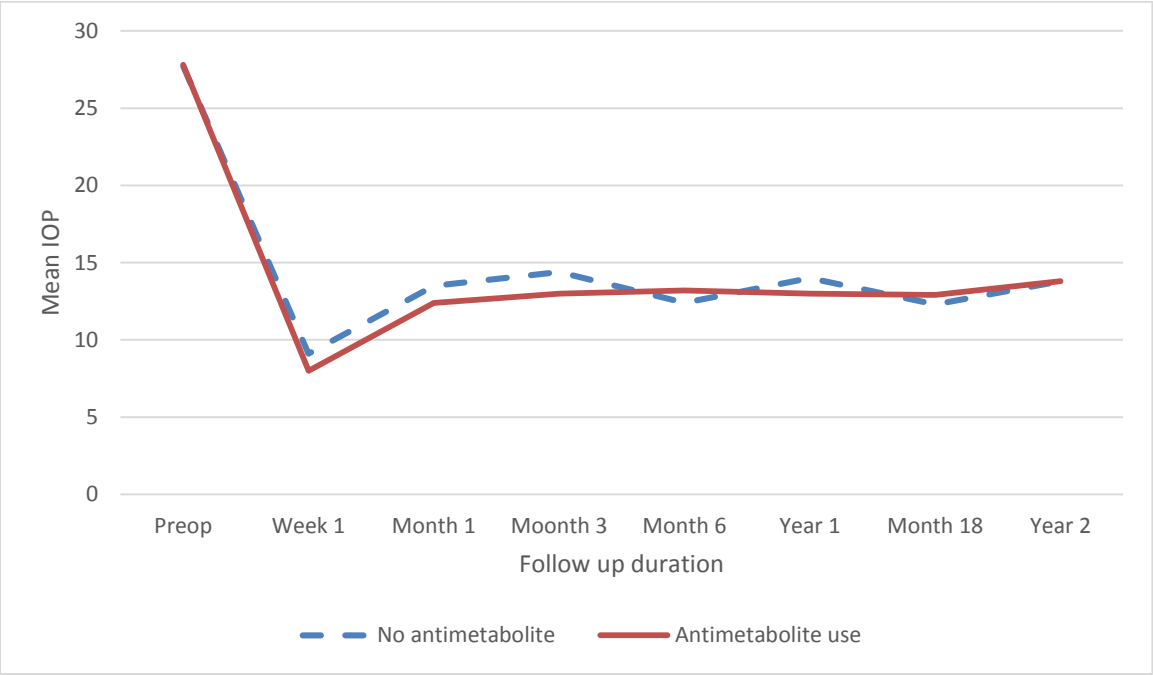


Figure 14: Mean IOP in eyes with and without antimetabolite

The proportion of eyes that failed treatment at month 24 according to type of glaucoma was 9.1% for POAG, 5.1% for Secondary glaucoma and 20% for PACG. There were no failures in ocular hypertension and normotensive glaucoma. There was no significant association between type of glaucoma and outcome of trabeculectomy (p value=0.651)

Table 15: Univariate regression showing type of glaucoma as a predictor of IOP outcome

	Final outcome			
	Failure (n=27)	**Success (n=291)**	**OR (95% CI)**	**P value**
Type of glaucoma				
POAG	24(9.1)	241(90.9)	1.00	0.651
Secondary	2(5.1)	37(94.9)	0.42(0.06-3.16)	
Ocular hypertension	0(0.0)	6(100.0)	-	
PACG	1(20.0)	4(80.0)	3.12(0.1-109.8)	
Normotensive	0(0.0)	3(100.0)	1.00(1.00-1.00)	

Of the factors assessed, there was no significant factor that affected outcome in the eyes that had failure at 2 year follow up.

Table 16: Univariate regression analysis showing factors affecting trabeculectomy outcomes

	Final treatment outcome		**OR**	
	Failure	**Success**	**(95% CI)**	**P value**
Age	**N=22**	**N=243**		
16-30 years	0(0.0)	20(100.0)	-	
31-45 years	2(4.4)	43(95.6)	1.00	
46-60 years	7(8.8)	73(91.3)	2.17(0.26-21.8)	0.548
61-75 years	10(10.2)	88(89.8)	3.34(0.39-35.5)	
76 years +	3(13.6)	19(86.4)	4.36(0.27-83.4)	
Type of glaucoma	**N=27**	**N=291**		
POAG	24(9.1)	241(90.9)	1.00	0.651
Secondary	2(5.1)	37(94.9)	0.42(0.12-2.39)	
Ocular hypertension	0(0.0)	6(100.0)	-	
PACG	1(20.0)	4(80.0)	3.12(0.27-23.37)	
Normotensive	0(0.0)	3(100.0)	-	
Antimetabolite use	**N=27**	**N=291**		
Yes	21(8.4)	228(91.6)	1.00	
No	6(8.7)	63(91.3)	0.84(0.20-3.69)	0.830

7. DISCUSSION

Trabeculectomy is the commonest glaucoma surgery performed at PCEA Kikuyu Hospital-Eye Unit-KEU. A total of 318 eyes that had trabeculectomy done at the hospital between 1st January 2012 and 31st December 2016 were included in the study. 2013 had the highest number of surgeries while 2015 had the least. This is because some surgeons left the institution in that year. The numbers gradually increased in 2016 due to rehiring of new ophthalmologists.

7.1.Demographics

Out of the 265 recruited patients, 164 (61.9%) were males and 101 were females (38.1%). The mean age of the participants was 56.5 years (SD ± 15.8). This is comparable with a study done by Kabiru et al in a tertiary facility in East Africa that found majority of the patients who had trabeculectomy were males at 80% and the mean age was 61(SD±12)[53].In India, Rayees et al studied merits of trabeculectomy in advanced glaucoma and found the ratio of men to women in their study to be 4:1 and the age range 55–83 years with the mean of 66.13 years[51].Although many studies show POAG is more common in males there is no consistent association between sex and trabeculectomy. In our setting males are more economically empowered and therefore have a better health seeking behaviour compared to females.

7.2.Follow up

All eyes were examined on the 1st day post op with a subsequent reduction of the number who came for follow up at week one (80%) ,89% in month one ,71% at month 6,62% at year 1 and 45% at 2 years(Figure 8). In rural southern China, Yang K et al[54]reported lower rates at 60.8%, 75.9% and 26.9% at 1 week, 2 weeks and 1 month, respectively. However in Nigeria, a study by Anand et al found the follow up rate was 83% for less than 6 months[21] which was better than in our study. Ín our study some of our patients were referrals from distant towns while others were referrals who went back to continue follow up at their primary doctors' clinic. Follow up post trabeculectomy is crucial as early interventions (massage, needling, suture manipulation) contribute to success of the surgery.

7.3.Indication of trabeculectomy

Failed medical therapy was the most common indication in 165 eyes (60.1%). Advanced glaucoma was an indication in 60 eyes (22.1%) while poor compliance, patient request and

failed laser were in 23(8.5%), 15(5.5% and 8(3.0%) eyes respectively. This may be due to the fact the most commonly used drug, timolol, is known to develop tachyphylaxis thereby reducing its effectiveness long term. The current approach to a glaucoma patient in the West as demonstrated in a study by Hitchings et al in the UK is to initiate treatment with topical antiglaucoma drugs, resorting to laser or fistulising surgery only if the 'target pressure' is not reached[55].In Nigeria, Anand et al also found that trabeculectomy is indicated in advanced glaucoma cases due to unavailability or high cost of topical medication in addition to failed medical therapy[21].

7.4.Outcomes of trabeculectomy

The mean pre op IOP was 27.8mmHg (SD ± 11.7), comparable to a study by Kabiru et al where they found mean preoperative IOP to be 25 mm Hg (6-70, SD = 10). However, in an American study on trabeculectomy with MMC by Hector Fontana et al the mean pre-operative IOP was 18.8mmHg (±6.1 mmHg) much lower than in our setting. The mean post op IOP at 1 and 2 years was 13.2 and 13.3 mmHg respectively in our study (Figure 9). The post op reduction of IOP was statistically significant at all follow up time periods. The mean post-operative IOP in the American study by Hector et al was 11.3 mmHg (±4.5 mmHg) at 1 year and 11.1 mmHg (±4.2 mmHg) at 3 years (P<0.001 for both),a bit lower than our setting. The post-operative IOP was however comparable to that in the study by Kabiru et al at 11 mm Hg (0-32, SD = 5) at 2 weeks postoperatively, and 13 mm Hg (0-42, SD = 6) at latest follow-up (1 year). The mean number of medications in the study by Hector et al decreased from 2.8 (±1.0) to 0.4 (±0.7) at 1 year and 0.7 (±1.0) at 3 years (P<0.001 for both[56]. The mean number of drugs both at 1 year post-operative and at 2 years post-operative in our study was comparable to the American study at 0.24 and 0.26 (SD 0.51) compared to the preoperative 2.3 (SD 0.75).

7.4.1. Complete and qualified success

The probability of success (IOP<18mmHg and >5mmHg with 20% reduction without antiglaucoma therapy being complete and with or without antiglaucoma therapy being qualified) at day one was 55.4% (Table 9,10) .Of note is that most surgeons do not routinely take IOP's on day one. Only 83 eyes (26%) had their IOP taken on the day. The complete success at 1 year was 67% and 56% at 2 years, while the qualified success was 74% and 66%

at 1 and 2 years respectively. There were 31 eyes (9.7%) which had failure at final follow up visit. There was a gradual drop at final follow up which is expected as trabeculectomies lose their effectiveness overtime due to bleb fibrosis. In Germany, Joannah et al looked at IOP fluctuations post trabeculectomy with MMC and found 77.2% of eyes showed an IOP ≤18mmHg at 6 months post trabeculectomy while 69.6% patients achieved IOP ≤18 mmHg with topical antiglaucoma therapy[23]. In a Nigerian study, cumulative success rates by the criterion (lOP less than 22 mmHg and visual acuity loss of 2 lines or less) were 85% at the end of 1 year, falling to 71% in 5 years. By a second criterion, (lOP less than 16 mmHg and visual acuity loss of 2 lines or less) success rates were much lower, being 65% at 1 year and 46% at 5 years[21].

The results seem comparable even though the rates are dependent on the criteria for success that the investigators choose to use. A challenge however, is with the loss to follow up as one is unable to comment whether those who were lost to follow up were in the success group or not.

7.4.2. Vertical Cup Disk Ratio

The VCDR preoperative and post trabeculectomy had minimal fluctuations with the preop mean being 0.82 and that at 2 year follow up being similar at 0.82 indicating that perhaps the trabeculectomy halted progression (Figure 11). VCDR is however not an objective way of assessing progression due to variabilities as eyes are examined by different surgeons at different follow up visits. ONH imaging with retinal tomograph would be ideal but is unavailable in our setting. OCT was not available at the time of the study at the facility. Previous studies in Kenya by Nderi et al and Kipsang et al have shown no significant changes in the preoperative and post-operative VCDR[19, 28].In the UK Kotecha et al in 2009, found 28% progression post trabeculectomy using ONH imaging and VF progression over a 5 year period.

7.4.3. Visual Acuity

The visual acuity showed a remarkable decline (0.2 logmar units) in the 1st week post op followed by a gradual improvement to near preoperative VA at 2 year follow up (Figure 12). The causes of decline VA included hypotony, bleb leak, shallow /flat AC and hyphaema which were the most common early post-operative complications. Costa et al found that 8 % of patients experienced vision loss at 3 months post-operative which was attributed to lens

opacification, hypotony maculopathy and severe unexplained vision loss(wipe out)[34]. A study by Kipsang et al at Kenyatta National Hospital found visual acuity to be maintained post trabeculectomy[28]. In our study, cataract was the most common complication and also cataract surgery was the most common surgical intervention post trabeculectomy and could explain the return of visual acuity to preoperative value. Postoperatively, 5 patients developed no perception of light, of which 4 had HM vision, while 1 had PL pre trabeculectomy. Visual acuity is however not a measure of success of trabeculectomy except in cases where NPL develops whereby it becomes a measure of failure.

7.5.Complications of trabeculectomy

In our study we found the most common early complications to be shallow AC, bleb leaks, hypotony, hyphaema and choroidal detachment. The late complications were cataracts, bleb fibrosis and shallow AC (Table 13). Of the most serious complications, 1 patient had blebitis together with a bacterial conjunctivitis 1 year post op while 1 developed a pthysical eye 3 months post op after having persistent hypotony that did not improve post AC reformation. In the national survey (UK) on trabeculectomy complications by Edmumd et al, the commonest complications were hyphaema, bleb leak, shallow AC, choroidal effusion and hypotony maculopathy [50]which is comparable to our study. In a Nigeria Anand et al found the common complications to be shallow AC, hyphaema, choroidal detachment, wound leaks and cataract progression was 29% over the 5 year period[21]. In our study, cataract was the most common complication at 16% which is lower compared to AGIS study (approximately 50%). In Nigeria, Olawoye et al reported 30.8% cataracts at 1 year post trabeculectomy. It is important to note that with the retrospective nature of our study, there was no standardised way of reporting cataract progression and so the subjective nature of reporting may result in underreporting of cases. Bleb fibrosis was much lower in our study than reported in a similar study in Kenya by Kipsang et al despite more use of MMC in the latter.

In our study, surgical interventions done for the complications included additional glaucoma surgeries, cataract surgery, needling, AC reformation, suture release, conjunctival resuturing, bleb revision and iris repositioning. Cataract surgery was the most common intervention done in 58% of all interventions. Needling was done in 9 eyes, 7 of whom achieved success with glaucoma medications while 2 failed and had the additional glaucoma surgery. One got an AGV while the other was scheduled for a repeat trabeculectomy. AC reformation was done in 5 patients all in the early post op period.

7.6. Factors affecting outcomes of trabeculectomy

In this study, factors assessed were age, use of antimetabolites, and type of glaucoma. Patients younger than 35 years had higher IOPs at 6 months post op and at final follow up at 2 years although this was not statistically significant (Figure 14, Table 18). Young age has been shown to a risk factor for failure of trabeculectomy due to the high number of fibroblasts in younger patients leading to fibrosis and failure. In a study by Gressel et al, patients aged 10 to 29 years had 38% success compared to 65% success in patients aged 30 to 49 years[44]. In our study, there were fewer numbers in the younger age group compared to the older patients and this number may not be enough to demonstrate this effect.

There was no difference in the IOP values for those who had antimetabolite use vs those who did not (Figure 15, Table 17) contrary to a study by Yorston et al in the same facility which found that eyes with 5FU use had better IOP control long term compared to those without antimetabolite[41]. In our study, this difference is likely due to the significantly lower numbers in the group without antimetabolite use (21%) and the number may have been too small to demonstrate an effect.

The type of Glaucoma did not also affect the IOP values post-operative. We compared POAG vs secondary glaucoma vs Normotensive vs ocular hypertension vs PACG. The differences in success and failure among the different types were not statistically significant (Table 17, 18). Previous studies have identified the type of glaucoma as a risk factor for trabeculectomy failure. Secondary glaucoma types are associated with higher risk of trabeculectomy failure including posttraumatic, uveitic, neovascular and PACG with uncontrolled IOPs[49]. From our study, we had 6 patients with Pseudo-exfoliative glaucoma, 6 with uveitic glaucoma, 8 post-traumatic glaucoma, 2 neovascular glaucoma and 1with Posner Schlossman Syndrome. Due to the few numbers in each type of secondary glaucoma we grouped them together during the analysis. The numbers however, were still few compared to POAG (265 eyes) for us to make a conclusion that secondary glaucoma did not truly affect the success of trabeculectomy.

8. LIMITATIONS

1. Decline and variations in number of patients at subsequent follow up visits affecting outcomes.

9. CONCLUSIONS

1. Failed medical therapy was the most common indication of trabeculectomy

2. Trabeculectomy is effective in reducing uncontrolled IOP up to 2 years post-operative, with few failures noted and a marked reduction of number of drugs postoperative.

3. Shallow AC and hypotony were the most common early complications of trabeculectomy while bleb fibrosis and cataract were the most frequent late complications.

4. Age, use of antimetabolite and type of glaucoma were not found to affect postoperative IOP.

10. RECOMMENDATIONS

1. Offer trabeculectomy as an option for patients with failed medical therapy.

2. Emphasize on follow up preoperatively as interventions done post-operative increase success of the surgery.

3. A study should be carried out to assess long term success rates.

4. Minimise subjective variability describing VCDR, grading of cataracts, bleb characteristics by having the primary surgeon review the patients postoperative.

11. REFERENCES

[1] American Academy of Ophthalmology, "Basic and Clinical Science Course," 2016, 192.

[2] To Jack Kanski, *Clinical Ophthalmology, A Systemic Approach 7th Edition*, 2012.

[3] "WHO | Priority Eye Diseases," *WHO*, 2018,https://www.who.int/blindness/causes/priority.

[4] Scott D. Lawrence and Donald L. Budenz, "Meeting the Challenge of Glaucoma in Africa," *Glaucoma Today*, 2013, http://glaucomatoday.com/pdfs/gt0713_international;.pdf.

[5] R Whitfield, Schwab L, Ross-Degnan D et al., "Blindness and Eye Disease in Kenya: Ocular Status Survey Results from the Kenya Rural Blindness Prevention Project.," *British Journal of Ophthalmology* 74, no. 6 (June 1, 1990): 333–40, https://doi.org/10.1136/bjo.74.6.333.

[6] Paul J Foster, Buhrmann Ralf, Quigley Harry A et al., "The Definition and Classification of Glaucoma in Prevalence Surveys.," The British Journal of Ophthalmology 86, no. 2 (February 2002): 238–42, http://www.ncbi.nlm.nih.gov/pubmed/11815354.

[7] Yih-Chung Tham, Li Xiang,Wong Tien Y et al., "Global Prevalence of Glaucoma and Projections of Glaucoma Burden through 2040: A Systematic Review and Meta-Analysis.," Ophthalmology 121, no. 11 (November 1, 2014): 2081–90, https://doi.org/10.1016/j.ophtha.2014.05.013.

[8] Donald L. Budenz, Barton Keith,Whiteside-de Vos Julia et al., "Prevalence of Glaucoma in an Urban West African Population," JAMA Ophthalmology 131, no. 5 (May 2013): 651, https://doi.org/10.1001/jamaophthalmol.2013.1686.

[9] R R Buhrmann, Quigley H A, Barron Y et al., "Prevalence of Glaucoma in a Rural East African Population.," Investigative Ophthalmology & Visual Science 41, no. 1 (January 2000): 40–48, http://www.ncbi.nlm.nih.gov/pubmed/10634599.

[10] Anders Heijl, Leske M Cristina, Bengtsson Bo et al., "Reduction of Intraocular Pressure and Glaucoma Progression: Results from the Early Manifest Glaucoma Trial.," *Archives of*

Ophthalmology (Chicago, Ill. : 1960) 120, no. 10 (October 2002): 1268–79, http://www.ncbi.nlm.nih.gov/pubmed/12365904.

[11] Kuldev Singh and Anurag Shrivastava, "Medical Management of Glaucoma: Principles and Practice.," *Indian Journal of Ophthalmology* 59 Suppl, no. Suppl1 (January 2011): S88-92, https://doi.org/10.4103/0301-4738.73691.

[12] Brenda W. Gillespie, Musch David C, Guire Kenneth E et al., "The Collaborative Initial Glaucoma Treatment Study: Baseline Visual Field and Test–Retest Variability," *Investigative Opthalmology & Visual Science* 44, no. 6 (June 1, 2003): 2613, https://doi.org/10.1167/iovs.02-0543.

[13] Paul Harasymowycz, Birt Catherine, Gooi Patrick et al., "Medical Management of Glaucoma in the 21st Century from a Canadian Perspective," *Journal of Ophthalmology* 2016 (November 8, 2016): 1–22, https://doi.org/10.1155/2016/6509809.

[14] ArvindKumar Yadav and Varsha Patel, "Drug Use in Primary Open Angle Glaucoma: A Prospective Study at a Tertiary Care Teaching Hospital," *Indian Journal of Pharmacology* 45, no. 2 (2013): 117, https://doi.org/10.4103/0253-7613.108279.

[15] R Ramakrishnan and Mona Khurana, "Surgical Management of Glaucoma: An Indian Perspective.," *Indian Journal of Ophthalmology* 59 Suppl, no. Suppl1 (January 2011): S118-22, https://doi.org/10.4103/0301-4738.73697.

[16] Tarek Sharaawy and Shibal Bhartiya, "Surgical Management of Glaucoma: Evolving Paradigms.," *Indian Journal of Ophthalmology* 59 Suppl, no. Suppl1 (January 2011): S123-30, https://doi.org/10.4103/0301-4738.73692.

[17] T S Dietlein, P C Jacobi, and G K Krieglstein, "Prognosis of Primary Ab Externo Surgery for Primary Congenital Glaucoma.," *The British Journal of Ophthalmology* 83, no. 3 (March 1999): 317–22, http://www.ncbi.nlm.nih.gov/pubmed/10365040.

[18] Thomas S Dietlein, Manuel M Hermann, and Jens F Jordan, "The Medical and Surgical Treatment of Glaucoma.," *Deutsches Arzteblatt International* 106, no. 37 (September 2009): 597–605; quiz 606, https://doi.org/10.3238/arztebl.2009.0597.

[19] K Loise, "INDICATIONS AND OUTCOMES OF AHMED GLAUCOMA VALVE IMPLANTS IN KENYA PRINCIPAL AUTHOR :," n.d.

[20] J E Cairns, "Trabeculectomy. Preliminary Report of a New Method.," *American Journal of Ophthalmology* 66, no. 4 (October 1968): 673–79, http://www.ncbi.nlm.nih.gov/pubmed/4891876.

[21] D K Heuer, Parrish R K, Gressel M G et al., "5-Fluorouracil and Glaucoma Filtering Surgery. III. Intermediate Follow-up of a Pilot Study.," *Ophthalmology* 93, no. 12 (December 1986): 1537–46, http://www.ncbi.nlm.nih.gov/pubmed/2433656.

[22] Dr Gideon Jacob Nderi, "OUTCOME OF GLAUCOMA SURGERY AT MOMBASA LIGHT HOUSE FOR CHRIST EYE CENTRE UNIVERSITY OF NAIROBI MEDICAL Library," n.d.

[23] Jagdish Bhatia, "Outcome of Trabeculectomy Surgery in Primary Open Angle Glaucoma.," *Oman Medical Journal* 23, no. 2 (April 2008): 86–89, http://www.ncbi.nlm.nih.gov/pubmed/22379543.

[24] N Anand, C Mielke, and V K Dawda, "Trabeculectomy Outcomes in Advanced Glaucoma in Nigeria," *Eye* 15, no. 3 (May 1, 2001): 274–78, https://doi.org/10.1038/eye.2001.93.

[25] Joanna Wasielica-Poslednik, Schmeisser Julian, Hoffmann Esther M et al., "Fluctuation of Intraocular Pressure in Glaucoma Patients before and after Trabeculectomy with Mitomycin C," ed. Sanjoy Bhattacharya, *PLOS ONE* 12, no. 10 (October 4, 2017): e0185246, https://doi.org/10.1371/journal.pone.0185246.

[26] Pablo Romero, Hirunpatravong Pradtana, Alizadeh Reza et al., "Trabeculectomy with Mitomycin-C," *Journal of Glaucoma* 27, no. 2 (December 2017): 1, https://doi.org/10.1097/IJG.0000000000000842.

[27] Y K Dastur, "The Role of Early Trabeculectomy in the Control of Chronic Simple Glaucoma.," *Journal of Postgraduate Medicine* 40, no. 2: 74–77, accessed February 7, 2018, http://www.ncbi.nlm.nih.gov/pubmed/8737557.

[28] Tarek M Shaarawy, Mark B Sherwood, and Franz Grehn, *Guidelines on Design and Reporting of*, n.d.

[29] F Arnalich-Montiel, Muñoz-Negrete F J, Rebolleda G et al., "Cup-to-Disc Ratio: Agreement between Slit-Lamp Indirect Ophthalmoscopic Estimation and Stratus Optical Coherence Tomography Measurement," *Eye* 21, no. 8 (August 5, 2007): 1041–49, https://doi.org/10.1038/sj.eye.6702391.

[30] Kipsang Rotich, "Outcomes of Trabeculectomy at Kenyatta National Hospital and University of Nairobi: A Retrospective Case Series," 2017.

[31] I Irak, Zangwill L, Garden V et al., "Change in Optic Disk Topography after Trabeculectomy.," *American Journal of Ophthalmology* 122, no. 5 (November 1996): 690–95, http://www.ncbi.nlm.nih.gov/pubmed/8909209.

[32] N Raghu, Pandav S S, Kaushik S et al., "Effect of Trabeculectomy on RNFL Thickness and Optic Disc Parameters Using Optical Coherence Tomography.," *Eye (London, England)* 26, no. 8 (August 2012): 1131–37, https://doi.org/10.1038/eye.2012.115.

[33] Aachal Kotecha, Spratt Alexander, Bunce Catey et al., "Optic Disc and Visual Field Changes after Trabeculectomy," *Investigative Opthalmology & Visual Science* 50, no. 10 (October 1, 2009): 4693, https://doi.org/10.1167/iovs.08-3115.

[34] Valérie Bertrand, Fieuws Steffen, Stalmans Ingeborg et al., "Rates of Visual Field Loss before and after Trabeculectomy," *Acta Ophthalmologica* 92, no. 2 (March 1, 2014): 116–20, https://doi.org/10.1111/aos.12073.

[35] V P Costa, Smith M, Spaeth G L et al., "Loss of Visual Acuity after Trabeculectomy.," *Ophthalmology* 100, no. 5 (May 1993): 599–612, http://www.ncbi.nlm.nih.gov/pubmed/8493002.

[36] Brian A. Francis, Hong Bryan,Winarko Jonathan et al., "Vision Loss and Recovery After Trabeculectomy," *Archives of Ophthalmology* 129, no. 8 (August 1, 2011): 1011, https://doi.org/10.1001/archophthalmol.2011.182.

[37] Kenji Kashiwagi, Kogure Satoshi, Mabuchi Fumihiko et al., "Change in Visual Acuity and Associated Risk Factors after Trabeculectomy with Adjunctive Mitomycin C," *Acta Ophthalmologica* 94, no. 7 (November 2016): e561–70, https://doi.org/10.1111/aos.13058.

[38] Olusola Olawoye, Tarela Sarimiye, and Adeyinka Ashaye, "Surgical Outcomes of Membrane-Tube-Type Glaucoma Shunt Device in Indigenous West Africans," 2018, 279–86, https://doi.org/10.2147/OPTH.S148325.

[39] D Broadway, I Grierson, and R Hitchings, "Racial Differences in the Results of Glaucoma Filtration Surgery: Are Racial Differences in the Conjunctival Cell Profile Important?," *The British Journal of Ophthalmology* 78, no. 6 (June 1994): 466–75, http://www.ncbi.nlm.nih.gov/pubmed/8060931.

[40] S Beatty, Potamitis T, Kheterpal S et al., "Trabeculectomy Augmented with Mitomycin C Application under the Scleral Flap.," *The British Journal of Ophthalmology* 82, no. 4 (April 1998): 397–403, http://www.ncbi.nlm.nih.gov/pubmed/9640188.

[41] Nitin Anand and Vinod K Dawda, "A Comparative Study of Mitomycin C and 5-Fluorouracil Trabeculectomy in West Africa.," *Middle East African Journal of Ophthalmology* 19, no. 1 (January 2012): 147–52, https://doi.org/10.4103/0974-9233.92132.

[42] D Yorston and P T Khaw, "A Randomised Trial of the Effect of Intraoperative 5-FU on the Outcome of Trabeculectomy in East Africa.," *The British Journal of Ophthalmology* 85, no. 9 (September 1, 2001): 1028–30, https://doi.org/10.1136/BJO.85.9.1028.

[43] David C Broadway and Allan Clark, "The Norwich Trabeculectomy Study: Long-Term Outcomes of Modern Trabeculectomy with Respect to Risk Factors for Filtration Failure," *Journal of Clinical & Experimental Ophthalmology* 5, no. 6 (November 15, 2014), https://doi.org/10.4172/2155-9570.1000371.

[44] Fulya Association for Research in Vision and Ophthalmology. et al., *Investigative Ophthalmology & Visual Science.*, *Investigative Ophthalmology & Visual Science*, vol. 55 (C.V. Mosby Co, 1977), http://iovs.arvojournals.org/article.aspx?articleid=2269772.

[45] Gressel MG, "Trabeculectomy in Young Patients. - PubMed - NCBI," https://www.ncbi.nlm.nih.gov/m/pubmed/6083518/.

[46] M C Briggs and J L Jay, "Age over 46 Years Does Not Affect the Pressure Lowering Effect of Trabeculectomy in Primary Open Angle Glaucoma.," *The British Journal of Ophthalmology* 83, no. 3 (March 1, 1999): 280–84, https://doi.org/10.1136/BJO.83.3.280.

[47] Abraham S V, "Miotic Iridocyclitis: Its Role in the Surgical Treatment of Glucoma. - PubMed - NCBI," https://www.ncbi.nlm.nih.gov/m/pubmed/13791534.

[48] D C Broadway, Grierson I, O'Brien C et al., "Adverse Effects of Topical Antiglaucoma Medication. II. The Outcome of Filtration Surgery.," *Archives of Ophthalmology (Chicago, Ill. : 1960)* 112, no. 11 (November 1994): 1446–54, http://www.ncbi.nlm.nih.gov/pubmed/7980134.

[49] Marie Cruz, Franz O Khu, Patricia M et al, "Predictors for Failure of Primary Trabeculectomy," *PHILIPPINE JOURNAL OF Ophthalmology JANUARY – JUNE* 34, no. 1 (2009), https://apamedcentral.org/Synapse/Data/PDFData/0014PJO/pjo-34-8.pdf.

[50] B Edmunds, Thompson J R, Salmon J F et al., "The National Survey of Trabeculectomy. III. Early and Late Complications," *Eye* 16, no. 3 (May 28, 2002): 297–303, https://doi.org/10.1038/sj.eye.6700148.

[51] Rayees Ahmad Sofi, Shafi Shahnawaz, Qureshi Waseem et al., "Merits of Trabeculectomy in Advanced and End-Stage Glaucoma.," *International Journal of Health Sciences* 12, no. 2 (2018): 57–60, http://www.ncbi.nlm.nih.gov/pubmed/29599696.

[52] Adeyinka Ashaye, Ashaolu Olumide, Komolafe Opeyemi et al., "Prevalence and Types of Glaucoma Among an Indigenous African Population in Southwestern Nigeria," 2018, https://doi.org/10.1167/iovs.13-12698.

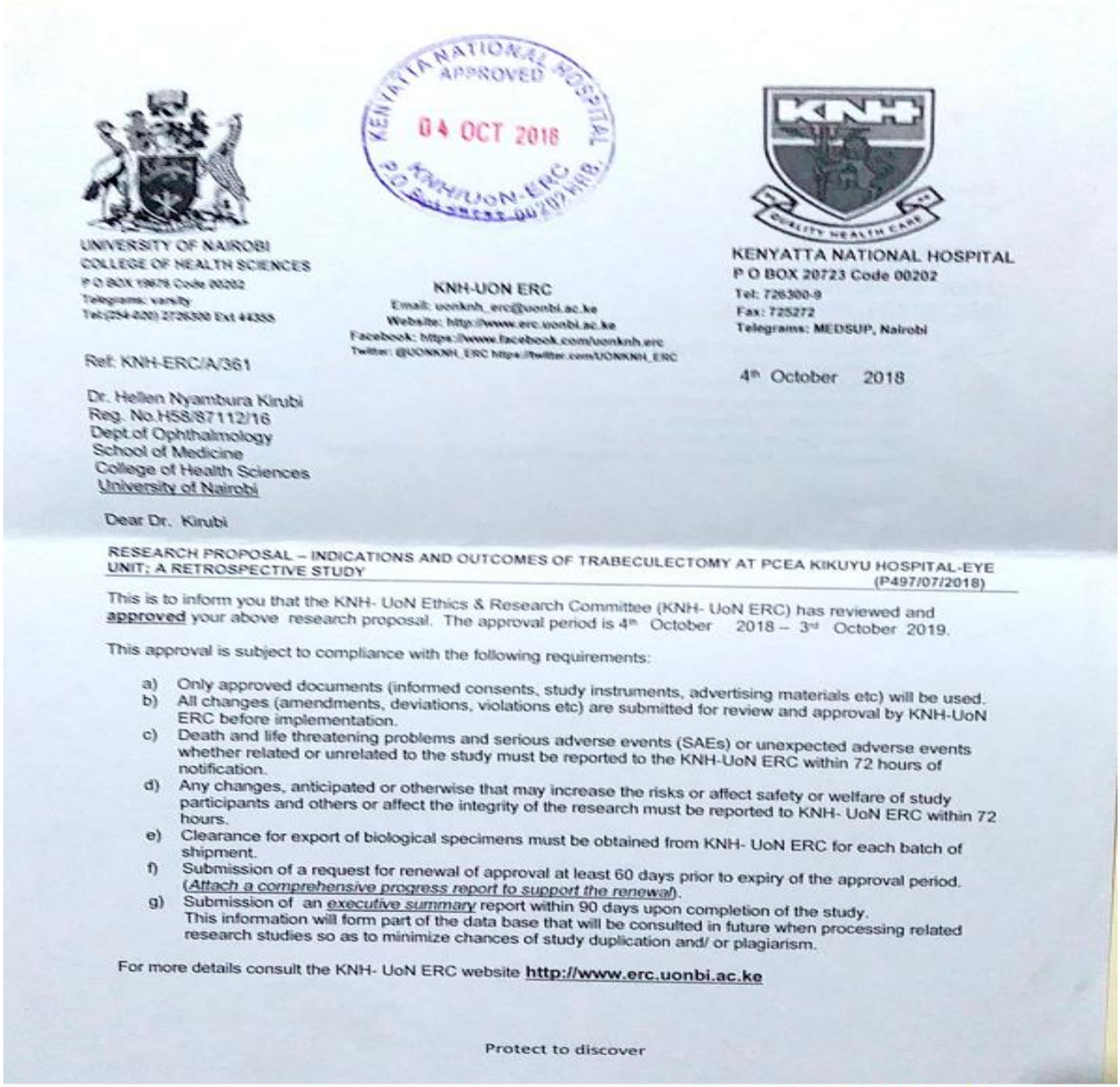
[53]Joy Kabiru, Bowman Richard, Wood Mark et al., "Audit of Trabeculectomy at a Tertiary Referral Hospital in East Africa.," *Journal of Glaucoma* 14, no. 6 (December 2005): 432–34, http://www.ncbi.nlm.nih.gov/pubmed/16276273.

[54] Ke Yang, Jin Ling, Li Li et al., "Preoperative Characteristics and Compliance with Follow-up after Trabeculectomy Surgery in Rural Southern China," *British Journal of Ophthalmology* 101, no. 2 (February 2017): 131–37, https://doi.org/10.1136/bjophthalmol-2015-308331.

[55]R A Hitchings, "Primary Surgery for Primary Open Angle Glaucoma-Justified or Not?," *BritishJournal ofOphthalmology* 77 (1993): 445–48, https://doi.org/10.1136/bjo.77.7.445.

[56] Hector Fontana, Nouri-Mahdavi Kouros, Lumba Joanna et al., "Trabeculectomy with Mitomycin C," *Ophthalmology* 113, no. 6 (June 2006): 930–36, https://doi.org/10.1016/j.ophtha.2006.01.062.

Appendix 1:Ethics Approval



KENYATTA NATIONAL HOSPITAL APPROVED 04 OCT 2018 P.O. Box 20723-00202 KNH/UON-ERC

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

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

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/361

4th October 2018

Dr. Hellen Nyambura Kirubi
Reg. No.H58/87112/16
Dept.of Ophthalmology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Kirubi

RESEARCH PROPOSAL – INDICATIONS AND OUTCOMES OF TRABECULECTOMY AT PCEA KIKUYU HOSPITAL-EYE UNIT; A RETROSPECTIVE STUDY (P497/07/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 4th October 2018 – 3rd October 2019.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) 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.
d) 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.
e) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f) 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*).
g) 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.

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

Protect to discover

Scanned by CamScanner

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH-UON ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine,UoN
The Chair, Dept.of Ophthalmology, UoN
Supervisors: Dr. Marco Sheila, Dr. Margaret W. Njuguna, Dr. Faith Masila

Appendix 2: Study Tool

Form Number……

File No _____ Date of data collection _____

Demographics

1. Date of Birth _____
2. Age in years: _____(At first presentation)
3. Race: African(0) □ Caucasian (1) □ Asian(2) □
4. Sex: Male(0) □ Female (1) □
5. Eye: Right(0) □ Left (1) □

PARTICULAR		**RESPONSE**	
PRE-OPERATIVE (LAST VISIT)			
1.	Visual Acuity	SNELLEN	LOGMAR
2.	IOP(Goldmann applanation tonometry)		
3.	CDR (Slit lamp)		
4.	Type of Glaucoma	POAG (0) PACG (1) Ocular Hypertension(2) Normotensive Glaucoma (3) Secondary (4) Specify type…….. .. Not indicated (5)	
5.	Date of initiation of medical treatment		
6.	Duration of topical medication use(weeks)		

7.	Type of drugs Write name of drug…….	Prostaglandin analogues (0) □ Beta Blockers (1) □ Parasympathomimetics (2) □ Alpha agonist (3) □ Topical Carbonic anhydrase inhibitor (4) □ Systemic Carbonic anhydrase inhibitor (5) □ None (6) □ **If Other,(Non Glaucoma) please specify* ……..
8.	Total number of drugs	
9.	Any pre-existing ocular conditions	Yes (0) □ None (1) □ Not documented (2) □ ** If yes ,* Corneal Scar (0) □ Cataract (1) □ DME (2) □ AMD (3) □ **If Other, please specify……*
10.	Any pre-existing systemic conditions	Yes (0) □ None (1) □ Not documented (2) □ **If yes,* Diabetes Mellitus (0) □ Hypertension (1) □ **If Other, please specify……*
11.	History of Glaucoma Laser surgery	Yes (0) □ None (1) □ Not documented (2)□ **If yes,* SLT (0) □ ALT (1) □ Laser PI (2) □ **If other, please specify……..*
	INVESTIGATIONS	

12.	Was Gonioscopy done during the pre-operative visits?	Yes (0) □ No (1) □ Not documented (2) □ **If yes,* Open Angle (0) □ Closed Angle (1) □
13.	Was HVF done during the pre-operative visits?	Yes (0) □ No (1) □ Not documented (2) □ **If yes,* Date HVF was performed…….. Mean Deviation……..
14.	Was CCT done during the pre-operative visits?	Yes (0) □ No (1) □ Not documented (2) □ **If yes,* CCT findings……..
15.	Was the indication for trabeculectomy specified preoperatively?	Yes (0) □ No (1) □ ** If yes,* Failed medical therapy (0) □ Progression (1) □ Poor compliance (2) □ Failed Laser (3) □ **If Other, please specify……..*
	INTRAOPERATIVE	
16.	Date of surgery	
17.	Was an Antimetabolite used intraoperatively?	Yes (0) □ No (1) □ **If yes,* 5FU (0) □ MMC (1) □
18.	Were there any intraop complications?	Yes (0) □ None (1) □ **If yes,* Conjunctival buttonhole (0) □ Hyphaema (1) □ Hypotony (2) □ Scleral flap complications (3) □ Choroidal detachment (4) □ *If Other, please specify……..*

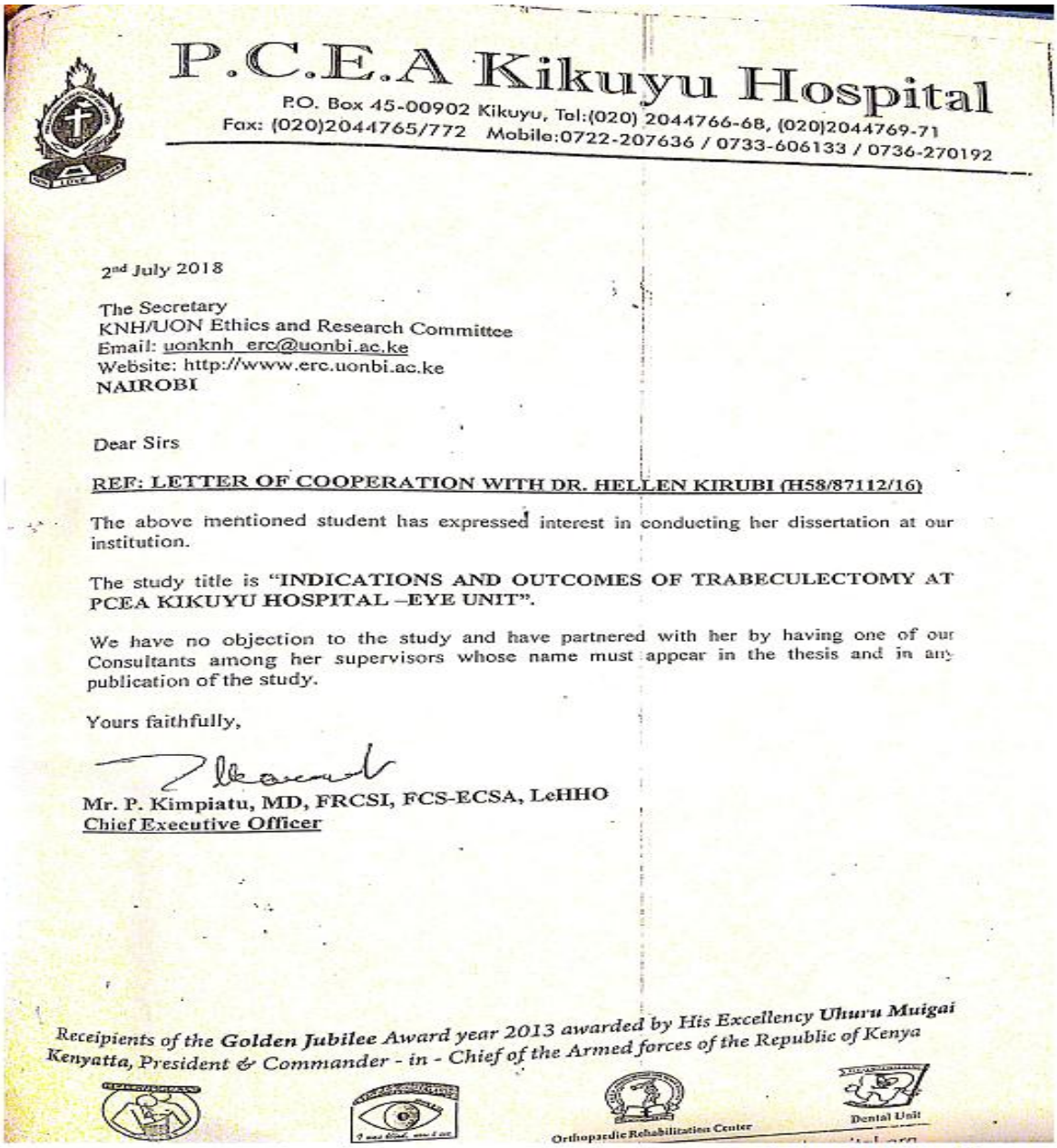
POSTOPERATIVE

Follow-up Period	IOP (mmHg)	VCDR	Visual acuity	No. of glaucoma drug(s)	Complication(s)	Intervention(s):		
						Conservative	Medical: type(s)	Surgical
Day 1								
Week 1								
Month 1								
Month 3								
Month 6								
Year 1								
Month 18								
Year 2								

Appendix 3: Budget

Item	Quantity	Unit cost(Kshs)	Total kshs
Proposal			
Printing and photocopy of Proposal	60 pages	3	480
Binding Proposal	3 copies	120	360
Proposal Printing 2nd draft	30 pages	10	300
Photocopy of proposal 2nd draft	90 pages	3	270
Binding of proposal 2nd draft	4 copies	120	480
Ethics			2,000
Contracted services			
Statistician	1	30,000	30,000
Data Collection			
Printing and photocopy of questionnaire	4pages	10	3040
Communication & Accommodation			
Telephone and Internet			5,000
Transport + Lunch			20,000
Results(estimate)			20,000
Miscellaneous			**5,000**
Grand total			**86,930**

Appendix 4 : Letter of co-operation



P.C.E.A Kikuyu Hospital

P.O. Box 45-00902 Kikuyu, Tel:(020) 2044766-68, (020)2044769-71
Fax: (020)2044765/772 Mobile:0722-207636 / 0733-606133 / 0736-270192

2nd July 2018

The Secretary
KNH/UON Ethics and Research Committee
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
NAIROBI

Dear Sirs

REF: LETTER OF COOPERATION WITH DR. HELLEN KIRUBI (H58/87112/16)

The above mentioned student has expressed interest in conducting her dissertation at our institution.

The study title is "INDICATIONS AND OUTCOMES OF TRABECULECTOMY AT PCEA KIKUYU HOSPITAL –EYE UNIT".

We have no objection to the study and have partnered with her by having one of our Consultants among her supervisors whose name must appear in the thesis and in any publication of the study.

Yours faithfully,

Mr. P. Kimpiatu, MD, FRCSI, FCS-ECSA, LeHHO
Chief Executive Officer

*Receipients of the **Golden Jubilee** Award year 2013 awarded by His Excellency **Uhuru Muigai** Kenyatta, President & Commander - in - Chief of the Armed forces of the Republic of Kenya*

Orthopaedic Rehabilitation Center

Dental Unit