A MULTICENTER STUDY OF THE OUTCOMES OF COMBINED CATARACT AND TRABECULECTOMY SURGERY IN KENYA

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A DISSERTATION PRESENTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR DEGREE OF MASTER OF MEDICINE (OPHTHALMOLOGY) AT THE UNIVERSITY OF NAIROBI.

DECLARATION

I declare that this dissertation is my original work and has never been published or presented for a degree in any other University.

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DEDICATION

This work is dedicated to my beloved wife for her love, prayers and support. Our son (Papa) for the joy he brings. My late father for the foundation he set. My mother: for her encouragement. The entire extended family and friends: for their motivation and prayers.

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LIST OF ABBREVIATIONS AND ACRONYMS

AL	–	Axial Length
ECCE	–	Extra-Capsular Cataract Extraction
IOP	–	Intraocular Pressure
KNH	–	Kenyatta National Hospital
KEC	–	Kisii Eye Center
MMC	–	Mitomycin C
OCO	–	Ophthalmic Clinical Officer
PCIOL	–	Posterior Chamber Intraocular Lens
Phaco	–	Phacoemulsification
POAG	–	Primary Open-Angle Glaucoma
PXF	–	Pseudoexfoliation
SICS	–	Small Incision Cataract Surgery
TMH	–	Tenwek Mission Hospital
UCVA	–	Uncorrected Visual Acuity
VA	–	Visual Acuity
WHO	–	World Health Organization

ABSTRACT

Background: More than90% of the world's visually impaired people live in developing countries. Globally, cataract and glaucoma are the leading causes of blindness accounting for 43% and 12% of the total cases respectively.

Objective: To evaluate the outcome of combined trabeculectomy and cataract surgery in terms of intraocular pressure, visual acuity, associated complications, and clinically relevant factors associated with poor outcome.

Study Design: Hospital-based retrospective case series.

Study Population: Patients who underwent combined cataract and glaucoma surgery at Kisii Eye Hospital, Tenwek Mission Hospital and the Kenyatta National Hospital from January 2012 to December 2016.

Data Management and Analysis: Data was collected using questionnaire, analysed using SPSS version 23. Descriptive analysis was done to determine means, frequencies and proportions of the various variables. Where appropriate, Chi-square was used to test association. The confidence level was taken as 95% ($p < 0.05$) where applicable.

Results: Study found no statistically significant differences in baseline characteristics and mean IOP between phaco-trab and SICST surgery groups except for LogMAR visual acuity ($p = 0.015$).Majority of the patients had sustained pressure control especially for the subgroups of patients with longer follow-up. Over 62% of those who returned for 4 – 8 weeks follow-up

achieved an improvement in visual acuity and nearly 21% achieving 6/18 or better. Acute post-operative complications included corneal edema, Flat Bleb, Encapsulated Bleb among others. Different age groupings were found to be a significant risk factor for poor visual outcome in patients who underwent combined surgery.

Conclusion: Study found different age groupings to be a significant risk factor for poor visual outcome in patients who underwent combined surgery.The poor follow-up limits the precision of the findings but also means that a 'one stop' operation for glaucoma and cataract may be a viable and practical approach to management in this setting.

1.0 INTRODUCTION

About 90% of the world's visually impaired people live in developing countries. Globally, cataract is the leading cause of blindness accounting for 43% of the total cases. [1] [2] Cataract and glaucoma are the most common causes of visual impairment worldwide. [3]Both cataracts and glaucoma are likely to express themselves more during later stages of life. Many people over 60 years old may have both [3][4].

According to WHO (2016) in spite of the progress made in surgical techniques in many countries during the last ten years, cataract (47.9%) remains the leading cause of visual impairment in all areas of the world, except for developed countries [1]. In the least-developed countries, and in particular Sub-Saharan Africa, the causes of avoidable blindness are primarily cataract (50%), glaucoma (15%), corneal opacities (10%), trachoma (6.8%), childhood blindness (5.3%) and onchocerciasis (4%) [1].

The management of glaucoma is based on the severity and loss of visual acuity and not just the visual field defect[5]. Decision can be based on nerve damage, Visual Field (VF), Optical Coherence Tomography (OCT) findings, Intraocular Pressure (IOP) control, compliance to medication, etc.Researchers and experts stipulate that when the decision has been made to perform cataract surgery in a glaucoma patient, the options of cataract surgery alone or combined with glaucoma surgery are available to the surgeon [6]. Thus, the presence of a cataract may drive the decision for combined surgery. For instance, if the surgeon deems it

likely that the patient will need to return to the operating room for a cataract surgery, following the trabeculectomy, it may be best to perform both surgeries at the same operative session [7].

It is evident from literature that the status of the glaucoma and the target intraocular pressure are key factors to consider in deciding to pursue a combined cataract extraction and glaucoma procedure versus a cataract procedure alone [8]. The patient is likely to have more IOP lowering with a combined procedure versus cataract extraction alone [9]. This has been shown since the initiation of the combined procedure.

POAG is typically a chronic slowly progressive optic neuropathy with characteristic patterns of optic nerve damage and visual field loss[10]. In PACG elevated IOP results from narrowing or closure of the anterior chamber angle; relative pupillary block and plateau iris are the main angle-closure mechanisms[11]. Thus, this study is designed to evaluate the outcome of combined procedure with SICS or phacoemulsification in glaucoma coexistent with cataract. Of those with glaucoma, study will target both Primary Open-Angle Glaucoma (POAG) and Primary Angle-Closure Glaucoma (PACG) patients.

2.0 LITERATURE REVIEW

2.1 Surgical Options

The surgical options currently available when cataract and glaucoma coexist are: (1) cataract extraction alone; (2) cataract extraction followed by glaucoma surgery; (3) glaucoma surgery and afterwards, if necessary, cataract extraction; (4) combined cataract and glaucoma surgery by one site or by two separate sites. Cataract alone is suggested when glaucoma can be sufficiently controlled by medication and visual field defect is moderate and not progressive [5] [12]. When glaucoma needs three or more types of medication to reduce IOP or when the offset is unpredictable, phacoemulsification associated with glaucoma surgery performed at two different times allows a higher IOP reduction than that with a cataract extraction alone [13]. Finally, when glaucoma is prevailing and the surgeon fears that an IOP spike after phacoemulsification may cause significant damage to the optic nerve, combined surgery allows to achieve a greater IOP decrease and a more predictable low-IOP range in the immediate postoperative period than phacoemulsification alone [5] [14].

2.2 Trabeculectomy

Trabeculectomy is the glaucoma procedure that has been most frequently and for the longest time combined with cataract surgery, to assist in the control of intraocular pressure (IOP) [6]. Progression of cataract is a known complication of trabeculectomy [7] [15].

Trabeculectomy was originally combined with extra-capsularcataract extraction (ECCE) with an 11-mm wound, as studied by Bobrow in 1999. He was able to follow 35 patients for at least 80 months. He found the eyes which underwent the combined procedure had an IOP reduction of 8.2± 4.6 mmHg versus 4.4 ± 3.3 mmHg in those that underwent cataract surgery alone. Medications were reduced by 1.76 ± 0.82 versus 1.28 ± 0.86, respectively [16] [17].

Experts posit that as cataract incisions have gotten smaller, the results of combined surgery have improved. For incisions of 6 mm and under, the effect of the incision length on IOP outcomes does not appear to be as significant, although the globe remains better formed in surgery with a smaller incision [6]. Mitomycin C (MMC) has assisted in the success of the procedure, even including surgery with larger incisions for ECCE. A capsulorhexis smaller than the size of the IOL optic, helps to prevent IOL capture should the anterior chamber shallow in the postoperative period. The impact on refractive error has also lessened with the adoption of smaller incision cataract procedures combined with glaucoma surgery [18] [19].

2.3 General Principles for Combined Cataract and Trabeculectomy Surgery

Johnson (2009) explained that surgeons should carefully review the visual field status, level of IOP control, maximal therapy for glaucoma, and the status of the optic disc and/or retinal nerve fiber layer [6]. General principles to consider are as follows:

First, a patient with advanced visual field loss and disc damage who is not likely to withstand any elevated postoperative IOP, due to the risk of further damage, is less likely to have elevated IOP following a combined procedure [20].

Second, a patient who cannot tolerate medical therapy due to drop allergies, cost, or compliance issues such as dementia or tremor will likely lessen the burden of medical therapy more so with a combined procedure, although compliance with drops is essential during the postoperative period.

Third, a patient who is on maximal medical therapy and has no further options for escalation of therapy in case of loss of IOP control post cataract surgery may be better served with a combined procedure.

Fourth, a narrow angle patient with poor IOP control and permanent synechial angle closure will be easier to manage postoperatively if the chamber is deepened with concurrent cataract surgery at the time of filtration surgery. There will be the added option of YAG laser capsulotomy and laser to the anterior hyaloid face, should aqueous misdirection present.

Finally, as noted previously, if a patient is undergoing a trabeculectomy for loss of IOP control and there is a significant or near significant cataract present, then a combined procedure should be considered, as cataracts often progress following trabeculectomy [21]. There may be some added lowering of IOP by removing a cataract with pseudoexfoliation (PXF) present or for an angle-closure glaucoma patient [22].

A two-staged procedure, with cataract extraction later, may be pursued if the IOP is very elevated and the risk of suprachoroidal hemorrhage is high, as it may be more likely to occur intra-operatively with combined surgery which is a more prolonged surgery [23]. In these

instances, it is best to gain control of the IOP initially and then pursue visual rehabilitation with cataract surgery later.

2.4 Past Studies on Combined Cataract Surgery and Trabeculectomy

2.4.1 Global

Several studies have been carried out to look at combined cataract and trabeculectomy surgery across the globe. Law *et al.* (2005) [19] aimed to characterize changes in ocular dimensions after combined cataract operation and trabeculectomy with Mitomycin C using separate incisions (combined operation). Khurana *et al.* (2011) [24] compared the results and complications of combined manual small-incision cataract surgery (SICS) and posterior chamber intraocular lens (PCIOL) implantation with trabeculectomy by sutureless versus W-shaped incision technique. Khandelwal *et al*. (2015) [25] conducted a study to determine the efficacy of safe surgery system trabeculectomy combined with manual small incision cataract surgery/phacoemulsification in primary glaucoma coexistent with cataract.

The sample size has been found to be a major issue when it comes to studies on combined cataract and trabeculectomy surgery. For instance, Law *et al.* (2005) [19] enrolled 24 consecutive eyes that had combined operation and 16 eyes that had cataract operation alone. Khurana *et al.* (2011) [24] study included 30 eyes of 28 patients with senile cataract and primary open-angle glaucoma (POAG) who were randomly divided into two groups. The patients in Group A underwent SICS with sutureless trabeculectomy and thosein Group B underwent SICS with trabeculectomy using W-shaped incision with onesuture.Khandelwal *et al*.

(2015) [25] conducted a retrospective analysis of 105 cases who underwent single-site combined surgery between January 2008 and December 2009.

Studies that were undertaken applied several interventions. Law *et al.* (2005) [19] determined the axial lengths before and after surgery with non-contact optical coherence biometry. The intraocular pressures (IOP), axial lengths, corneal curvatures, and the expected and observed refractive errors before and after operations were compared. Khurana *et al.* (2011) [24] intervention involved 15 patients undergoing SICS with sutureless trabeculectomy and the other 15 patients undergoing SICS with trabeculectomy using W-shaped incision with one suture. Post-operative evaluation was done at the first post-operative day and thereafter on follow-ups at 1 week, 2 weeks, 4 weeks and 8 weeks. Khandelwal *et al*. (2015) [25] intervened by performing safe surgery system trabeculectomy with diffuse and posterior application of Mitomycin C in all cases. Main outcome measures were success rate of trabeculectomy, as determined by four different IOP goals and incidence of postoperative complications.

Results were varied on the outcome of combined cataract and trabeculectomy surgery. For example, Law *et al*[19]found that the mean axial length reduction after combined surgery was significantly larger than the reduction after cataract operation alone, and correlated significantly with the postoperative IOP (p, 0.002). However, there was no significant difference between the expected and observed refractive errors. Khurana *et al.*[24]established that the mean reduction in IOP after 8 weeks of follow-up in single surgery was 12.52 ± 3.59 mmHg and that in combined surgery was 16.47 ± 3.79 mmHg (p less than 0.001). The uncorrected visual acuity (UCVA) was better in combined surgery postoperatively with less surgically-induced

against-the-rule (ATR) astigmatism. Khandelwal, *et al*. [25] found that mean IOP reduction was 43.8% with MSICS and 42.08% with phacoemulsification. The surgical outcome was not significantly different for both techniques. Postoperative complications were infrequent and comparable.

Interesting conclusions were established by various studies reviewed. Law *et al.*[19]concluded that despite an alteration of the axial length and corneal curvature, the refractive outcome after a combined operation did not differ significantly from the predicted refraction. Khurana *et al.*[24] determined that combined SICS with trabeculectomy using W-shaped incision offers better prospects in terms of glaucoma control and visual performance than sutureless combined surgery. The study by Khandelwal *et al*. [25]concluded that the Safe Surgery System Trabeculectomy combined with cataract surgery offers excellent IOP control with minimal postoperative complications. It offers an effective and improved solution for primary glaucoma coexistent with cataract found in developing countries.

2.4.2 Africa and Regional

To determine the outcome of combined cataract and trabeculectomy surgery in African countries, Soatiana *et al.* (2013) [26]reviewed literature for trabeculectomy conducted in Africa from January 2000 to December 2012. They conducted an electronic search from the following databases: PubMed, Science Direct, Google, and Google scholar websites for articles of original studies on trabeculectomy conducted in Africa. A study by Bowman *et al.* (2010) investigated

visual and intra-ocular pressure (IOP) outcomes of combined cataract and glaucoma surgery at a high-volume centre in East Africa carried out over a 1-year period (2006) [27].

Study by Bowman *et al.* (2010) was a retrospective analysis of patient records. A total of 163 patients were identified [27]. Soatiana *et al.* (2013) [26] on the other hand, reviewed a total of 109 articles, published from January 2000 to December 2012 that were retrieved with only 12 articles meeting their inclusion criteria. The follow-up duration ranged from 6 months to 60 months.

Results by Soatiana *et al.* (2013) [26] established that the post-trabeculectomy IOP range was 10 mmHg to22 mmHg with rates varying from 61.8% to 90%. The visual acuity was unchanged among 19% to 30% of the participants in the last follow-up, and the improvement rate was 36% to 81.5% while those whose condition worsened ranged from 8.9% to 30.8%. The cup-disc ratio was ≤0.5 in 13% and ≥0.8 in 83% of the participants. According to Bowman *et al.* established presenting visual acuity in the operated eye was 6/60 or worse in 135/163 (93%) and was <3/60 in 76 of 163 (47%) patients. Pre-operative cup disc ratio of 0.9 or greater, predicted failure to improve VA at follow-up (OR 4.0 95% confidence interval (CI) 1.30-12.1). 59 (62% (95%CI 52-71%)) patients had follow-up IOPs of 6-15 mm Hg and 82 (85% (95% CI 78-92%)) had follow-up IOPs of 6-20 mm Hg [27].

Soatiana *et al.* (2013) concluded that trabeculectomy with or without application of antimetabolite appears to be a good way to lowering the IOP in Africa. In addition, the combined effect of trabeculectomy and cataract surgery produces visual benefits for the

patients [26]. Bowman *et al.* concluded that combined surgery produces visual benefit for most patients with similar pressure control to pure trabeculectomy and is therefore a useful option in practices where follow-up may be doubtful [23].

3.0 JUSTIFICATION

In developing countries, glaucoma is generally diagnosed at an advanced stage, only when the patient seeks advice for cataract surgery. Trabeculectomy is thus performed as a primary procedure with cataract extraction and implantation of an intraocular lens (IOL) [28] [27]. Combined surgery has an advantage of controlling IOP without requiring the use of lifelong anti-glaucoma medication or reduces the number of medication used. It also improves vision and does require additional cataract surgery later on as trabeculectomy is associated with progression of cataracts.

Kenya being a developing nation, the most economically feasible surgery for cataract here is small incision cataract surgery, looking at the high prevalence of glaucoma (15% of blindness) [3]in the elderly and the economic burden of medical management in our underprivileged population, quite a large number of patients could potentially benefit from trabeculectomy combined with cataract surgery. This study will be done in order to evaluate the results of small incision cataract surgery and/or phacoemulsification combined with trabeculectomy in terms of intraocular pressure control, visual acuity and surgical complications.

4.0 OBJECTIVES

4.1 Broad Objective

The broad objective of this study is to evaluate the outcome of combined cataract and trabeculectomy surgery in Kisii Eye Hospital, Tenwek Mission Hospital and Kenyatta National Hospital.

4.2 Specific Objectives

1. To assess the visual outcome after combined small incision cataract surgery/ trabeculectomy and phacoemulsification/ trabeculectomy.
2. To assess the change in IOP after combined SICS + trabeculectomy and phacoemulsification + trabeculectomy.
3. To determine the complications associated with combined SICS + trabeculectomy and phacoemulsification+trabeculectomy.
4. To compare the outcome of combined cataract and trabeculectomy surgery in terms of intraocular pressure control, change in visual acuity and surgical complications.
5. To list clinically relevant factors that are associated with a poor outcome.

5.0 MATERIAL AND METHODS

5.1 Study Design

This study was a hospital based, retrospective case series comprising of a 5-year analysis of patients undergoing combined surgery for cataract and glaucoma between January 2012 and December 2016.

5.2 Study Setting

The study was conducted at the eye departments of three tertiary eye hospitals in Kenya, where most combined surgeries are done. These were:

Kisii Eye Centre (KEC) – It's an initiative that is using a social entrepreneurial business model approach to address the challenging problem of blindness and visual impairment in Kenya. The Centre provides high-quality comprehensive eye care services and is equipped with the latest state-of-the-art equipment for the diagnosis and treatment of eye diseases.

Tenwek Mission Hospital (TMH) – The Eye Unit is one of the busiest departments at Tenwek Hospital, providing primary outpatient eye care services to over 300 patients every week, both at Tenwek Hospital as well as a Mobile Clinic, which provides services within a 3 hour radius. Tenwek Eye Unit is the primary referral center for Southwest region of Kenya.The 20 bed eye ward at Tenwek serves over 40 surgical patients a week. On average the institution performs 1,600+ cataract surgeries and 150+ retina surgeries/year and 700+ other eye surgeries/year including glaucoma, strabismus, cornea transplants and more.

Kenyatta National Hospital (KNH) – The Department of ophthalmology staff and students review patients at the eye clinic of Kenyatta National Hospital. Being the National teaching and referral hospital and the largest referral hospital in the region, the eye clinic is a valuable facility available for hands on training for post-graduate ophthalmology students.The department uses the facilities at Kenyatta National hospital for ophthalmology consultations and surgeries. The following are the services offered at the department offices teaching and research, laser photocoagulatin, fluorescein angiography, ocular ultrasound, and fundus photography.

5.3 Study Population

Study population included all patients who underwent combined surgery (Small incision cataract surgery /Phaco + Trabeculectomy) in the past 5 years (i.e. January, 2012 to December 2016) at the three institutions mentioned above.

5.4 Inclusion Criteria

The inclusion criterion of the study was all patients with primary open or closed angle glaucoma who underwent combined cataract and glaucoma surgery (SICS /Phaco + Trabeculectomy) within the study period.

5.5 Exclusion Criteria

The following were excluded from the study:

I. Patient with incomplete or lost records.

II. Those with secondary glaucoma or glaucoma associated with other ocular or systemic anomalies.

III. Patients with traumatic cataracts

IV. Previous glaucoma surgery

V. Surgical techniques other than phaco and SICS

VI. Patients with other techniques of glaucoma surgery other than Trabeculectomy

5.6 Outcome Measures

The primary outcome IOP was at 24 weeks

These included:

1. Proportion of patient achieving complete success, qualified success or failure, defined as:
    - Complete Success: IOP> 5mmHG and < 18mmHG without glaucoma medications or further glaucoma surgery.
    - Qualified Success: IOP > 5mmHG and < 18mmHG with glaucoma medications, without further glaucoma surgery.
    - Failure: will include any of the following criteria:
        - IOP < 5mmHG or > 18mmHG at the last visit
        - Need for additional glaucoma surgeries
        - The development of non-light perception (NLP) vision

2. The proportion of surgical complications during the early (<30 days) and late (≥30 days) post-operative period in each treatment group.
3. Number of additional laser or surgical procedures and medication required.

5.7 Sample Size

The following formula was used to calculate the required sample size for the study:

$$N = \frac{Z\alpha/2^2\{P(1-P)\}}{d^2}$$

$$= \frac{1.96^2 (0.3x\ 0.7)}{0.1^2}$$

$$= 80.1$$

Where:

- Zα/2is critical value for 95% confidence interval, that is 1.96
- P is estimated proportion of population value, in this case estimated failure rate = 30%
- d is margin of error = 10%

After correcting for finite population, N = 78.9

This was done using the following formula = $\frac{N\ x\ X}{X + N - 1}$

Where:

- N is population size (assumed to be 100,000 if you don't know the actual value)
- X is previous sample size calculated

The minimum sample size required for this study to have adequate power of 80% was 40 eyes.

This was calculated using the formula:

$$n' = \frac{n}{1 + \frac{n}{N}}$$

Where:

- n is sample size after population correction
- N is previous sample size calculated

5.8 Data Collection Procedure

Approval was sought from the administration at the Kisii Eye Centre, Tenwek Mission Hospital, and KNH. All the targeted institutions approved to participate in the study.

A list of cases for the study was generated by entering the ICD-10 code into the computer at the hospital registry. The patients' files were then retrieved by the principal investigator with the aid of the Disease Index Code. The details of the records that meet the inclusion criteria were entered into a questionnaire by the principal investigator. The study population included all patients who underwent combined surgery (SICS /Phaco + Trabeculectomy) in the past 5 years (i.e. January 2012 to December 2016) at the three institutions mentioned above.

The patient's name, age, date of attendance/hospitalization and hospital number was obtained from the clinic, ward and theatre records.

All information relevant to the study was collected and entered into the pre-designed questionnaire. Data included:

1. Demographic details: such as age, sex, race and residence
2. Examination findings: presenting vision, IOP
3. Examination findings: Vertical CDR, gonioscopy findings, type of cataract
4. Type of surgery done, complications and post-operative examination

5.9 Materials

A pre-designed questionnaire was used to collect the data. (See Appendix 1)

This study was a 5 year retrospective analysis of patients who underwent combined cataract and glaucoma surgery between January 2012 and December2016 at the 3 centers mentioned above. Computerized and paper surgical databases, was used to identify the patients. Both eyes of patients who underwent combined surgery in both eyes during this period were included in the study.

5.10 Data Management and Analysis

The data was entered into Microsoft Excel 2010 and a copy of the entry was made, for backup purpose.

SPSS version 23 was used for data analysis.

Descriptive analysis was done to determine the frequencies and proportions of the variables and presented in tables and graphs where appropriate. The normality of the data was assessed using histograms. If not normally distributed, transformation of the data was attempted, when

appropriate, to find the best possible normal fit. The mean with standard deviations was reported when the data is normally distributed and medians when it is not.

Pearson coefficient was used to determine correlations between outcome measures and demographic characteristics and presenting features of the patients. The strength of these correlations was further tested using univariable regression analysis. For each outcome variable, based on the univariate analysis, any associations with a p-value of <0.05 was included in a multivariable analysis according to strength of association.

Simple bivariate analysis (x^2 and odds ratios with 95% confidence intervals) was used to identify risk factors for successful or poor outcomes.

5.11 Ethical Considerations

Ethical approval was sought from KNH/ UON Ethics and Research Committee. Permission to conduct the study was also sought from the administrative heads/ ethics committees of the other hospitals.

Patient details and identity were kept anonymous at all times through the use of coded questionnaires with matching codes on the patient's file. Information on the questionnaire was only accessible to the primary investigator and research assistants who upheld confidentiality and adhere to data protection standards.

Data was stored only in a computer with a password to facilitate confidentiality. The coded questionnaire was destroyed after data was analyzed.

This study aimed to produce results which will contribute towards evidence-based practice in the management of patients with combined cataract and glaucoma. As such, hopefully the results can be published and will serve as a basis for future studies in this area. After publication, the digital records of the data will be deleted to ensure confidentiality is maintained.

The primary investigator had no conflict of interest.

5.12 Study Limitations

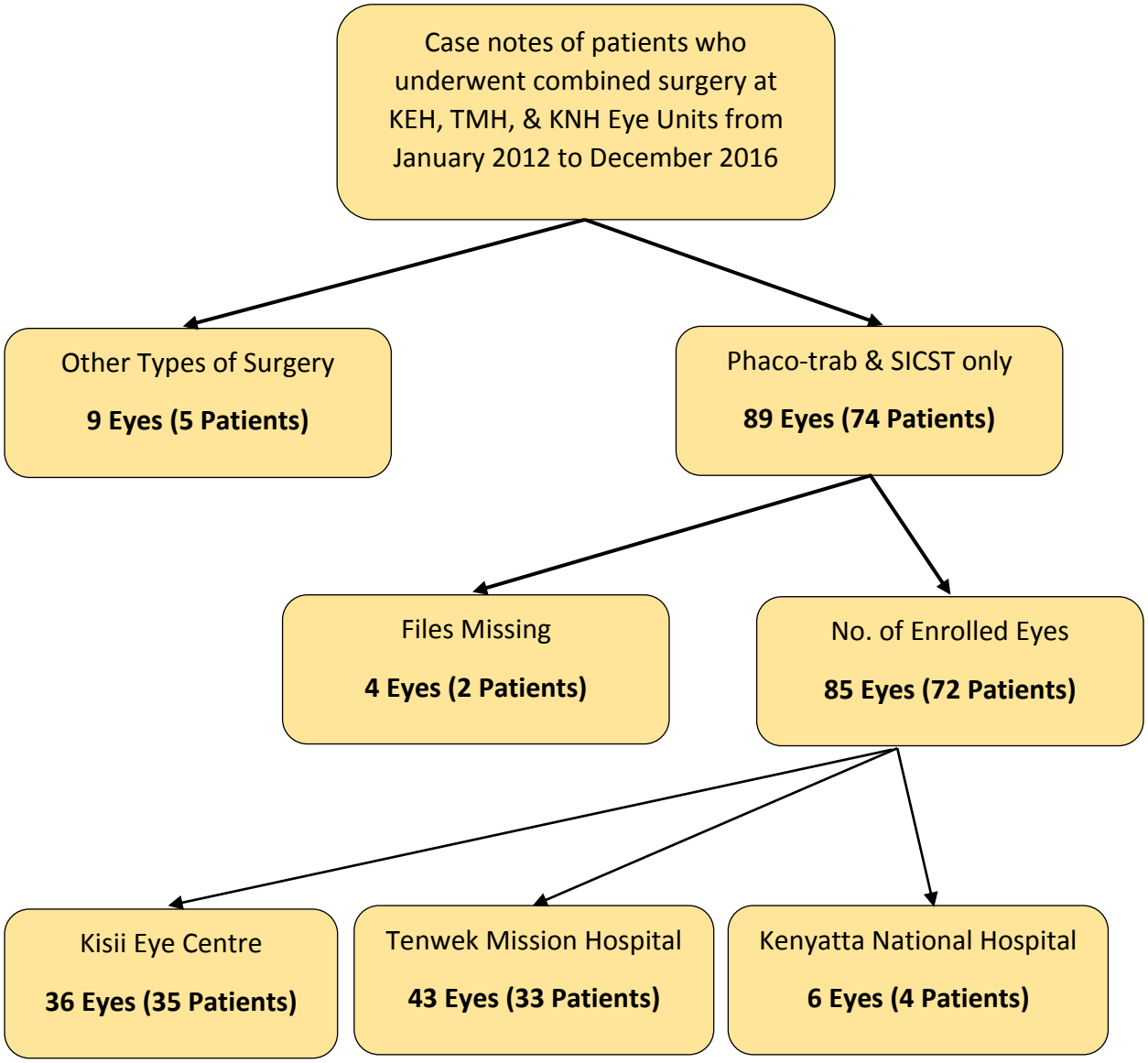
Due to the nature of the study, some of the following limitations were encountered. First, this was a retrospective case series. As such data was unavailable or incomplete for some patients. However, data was still be collected and analyzed for those patients with complete data. Second, different surgeons and the variations in their techniques and experiences might also have affected the outcomes. Nevertheless, this study was not aimed at comparison among the surgeons' outcomes. Third, the number of patients presenting for subsequent follow up might also have declined with time, and this may adversely affect the results. Whilst this was taken into account, the analysis was still performed for those patients who had data for the different follow up periods. Finally, due to the retrospective nature of the study, different methods of IOP measurement (applanation tonometry, rebound tonometry) under different conditions might have influenced outcome measures.

5.13 Work Plan

This study period was from April 2017 to March 2018 (see appendix 2).

6.0 RESULTS

Figure 6.1: *Flow Chart showing data collection of patient's records reviewed at selected health facilities from January 2012 to December 2016*



A total of 27 eyes (20 patients) that underwent Phaco-trab surgery and 58 eyes (52 patients) that underwent SICST surgery were enrolled in the study. The minimum sample size required for this study to have adequate power of 80% was 40 eyes.

Table 6.1: *Pre-operative demographic characteristics (n=72 patients)*

Demographics	*Number of patients (%)*
Health Facility	
Kisii Eye Centre	35 (48.6)
Tenwek Mission Hospital	33 (45.8)
Kenyatta National Hospital	4 (5.8)
Age (Years)	
Mean (± Standard Deviation)	71.7 (±12.50)
Range	26 – 102
Sex	
Male	43 (59.7)
Female	29 (40.3)
Laterality	
Unilateral	59 (81.9)
Bilateral	13 (18.1)

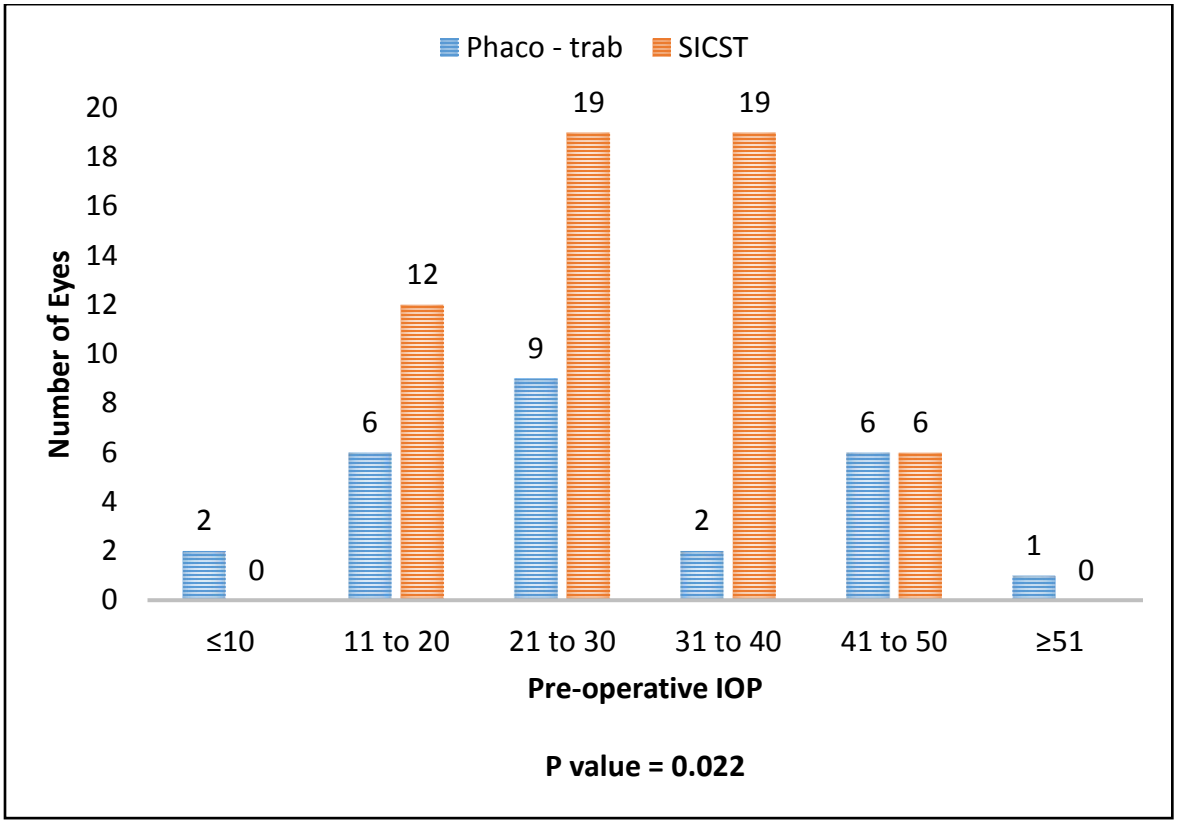
85% eyes of 72 patients were identified. The mean age was 72 years (SD 12.5, range 26–102 years) and 43 (59.7%) were men. KNH had the least number of patients that had surgery during the study period.

Table 6.2: *Baseline and ocular characteristics of patients undergoing phaco-trab and SICST surgery (n=85 eyes)*

Characteristics	*Surgery type*		*P Value*
	Phaco-trab (n = 27 eyes)	*SICST (n = 58 eyes)*	
Sex			
Female	17 (63.0)	33 (56.9)	0.597
Male	10 (37.0)	25 (43.1)	
Age (years)			
Mean age in years (SD)	72.8 ±10.77	72.0 ±12.53	0.777
Range	57 (45 – 102)	69 (26 – 95)	
LogMAR visual acuity	1.4 ± 0.64	1.7 ± 0.62	0.015
IOP (mmHg)	28.9 ± 13.22	28.6 ± 9.96	0.910
Pathologies affecting outcome			
With pathologies	10 (37.0)	35 (60.3)	0.045
Without pathologies	17 (63.00	23 (39.7)	
Type of cataract			
Nuclear Sclerosis	11 (40.7)	27 (46.6)	0.841
Cortical	13 (48.1)	24 (41.4)	
Posterior Subcapsular	3 (11.1)	7 (12.1)	

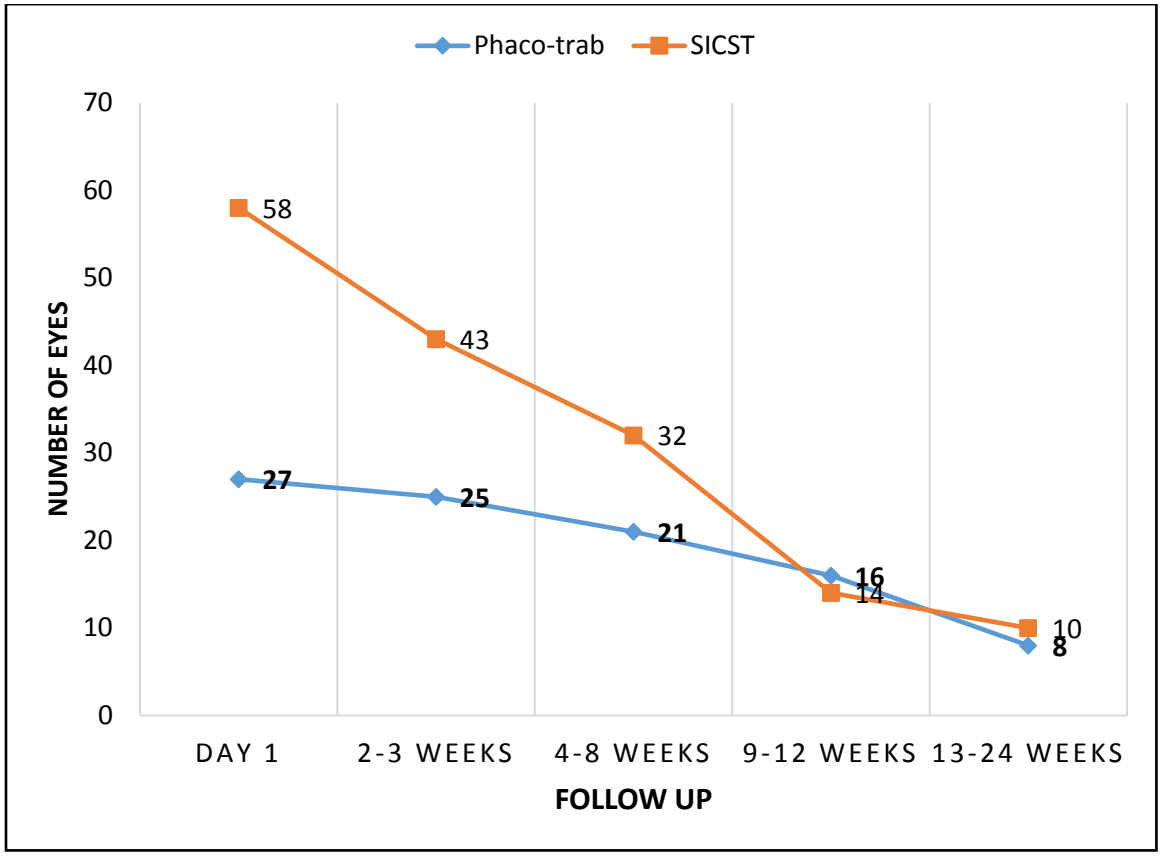
Files were documented based on the more prominent cataract type.

Figure 6.2: *Preoperative intraocular pressure of the study population (n=85 eyes)*



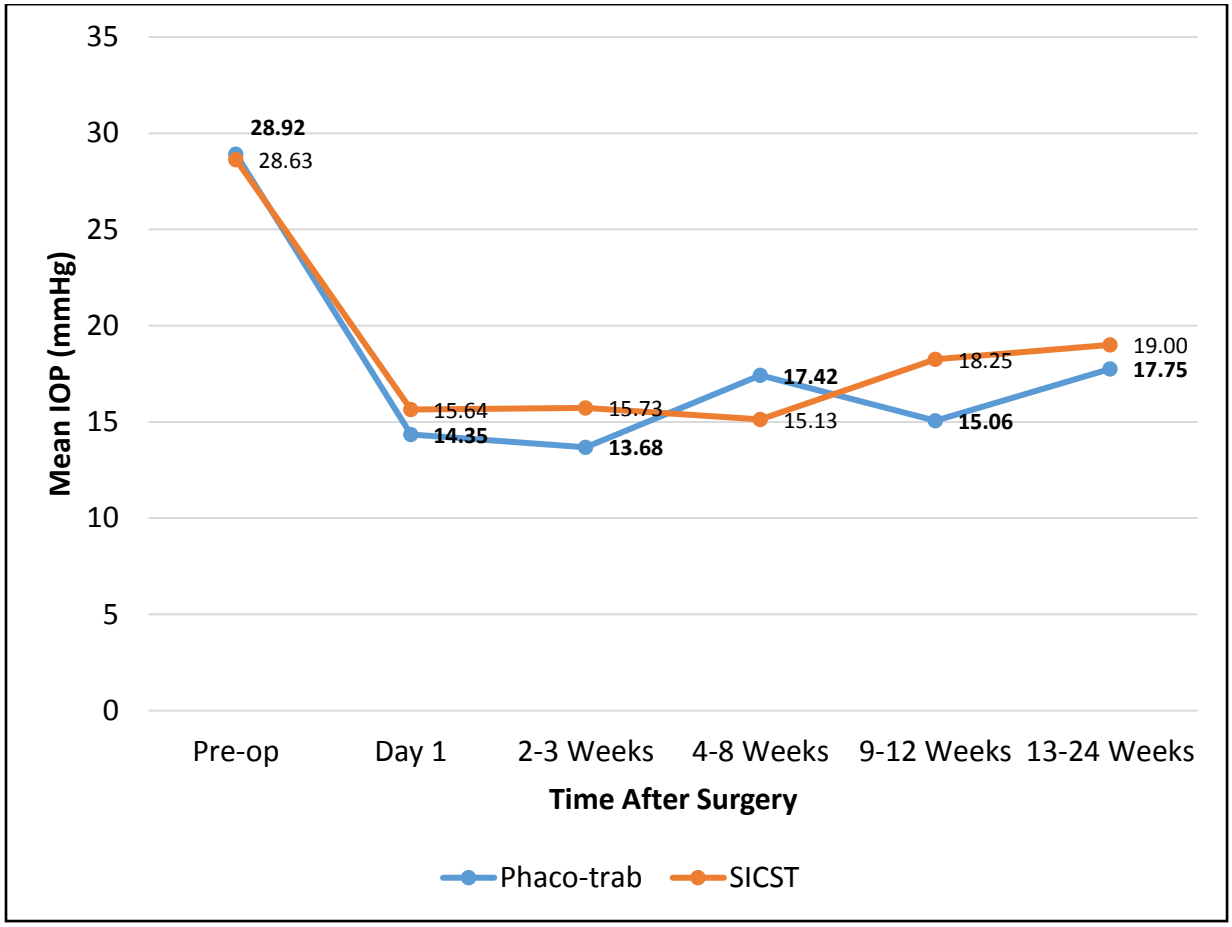
Most of the eyes (34.6%) that underwent phaco-trab had preoperative IOP in the range of 21-30 mmHg. Majority of the eyes (67.8%) that underwent SICST had preoperative IOP in the range of 21-40 mmHg. Overall, majority of the eyes (82.9%) had IOP of 18 mmHg and above.

Figure 6.3: *Loss to follow up after surgery in the study population (n=85 eyes)*



The maximum follow-up period was at 6 months and the percentage drop at 6 months was 21.2%.

Figure 6.4: *Mean intraocular pressure trend from baseline to 24 weeks*



Mean IOP for eyes that underwent phaco-trab was maintained below 18 mmHg up to 24 weeks post-operatively, with eyes that underwent SICST showing increased mean above 18 mmHg from 9 weeks to 24 weeks. This was calculated including eyes present at each follow-up visit. There was no significance difference in the IOPs at each time point.

Table 6.3: *Success trendof Phaco-trab & SICST surgeries according to different IOP criteria at > 3 months*

IOP Success Rate	*Surgery type*		*Overall Outcome*	*P Value*
	Phaco-trab (n = 8 eyes)	*SICST (n = 9 eyes)*		
Complete success	2 (25.0)	1 (11.1)	3 (17.6%)	0.765
Qualified success	3 (37.5)	4 (44.4)	7 (41.2%)	0.497
Failure	3 (37.5)	4 (44.4)	7 (41.2%	0.497

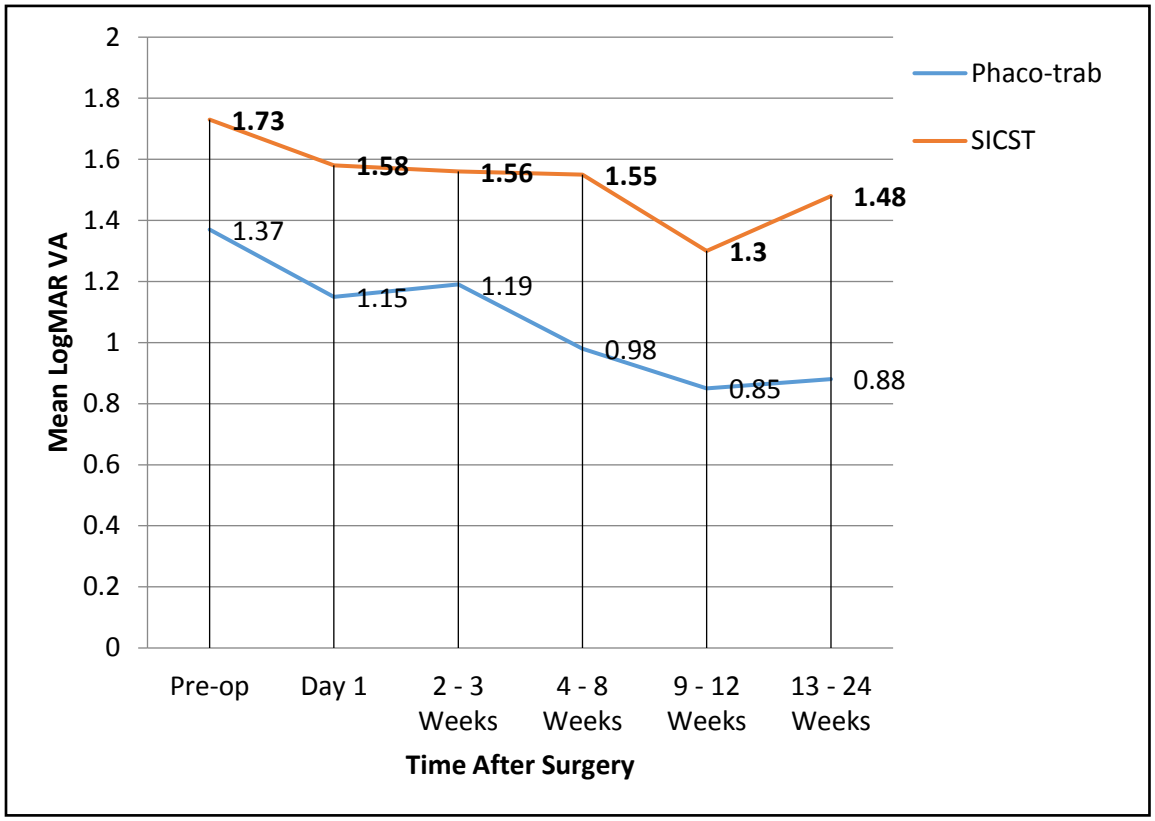
Complete Success = IOP <18 mmHg at the end of follow up

Qualified Success = IOP <18 mmHg with medication at the end of follow up

Failure = IOP >18 mmHg at the end of follow up

The complete success rate (IOP < 18 mmHg without medication at the end of follow-up >3 months) was seen in 3/17 (17.6%) eyes and failure (IOP >18 mmHg at the end of follow up >3 months) of the procedure performed was observed in 7/17 (41.2%) eyes.

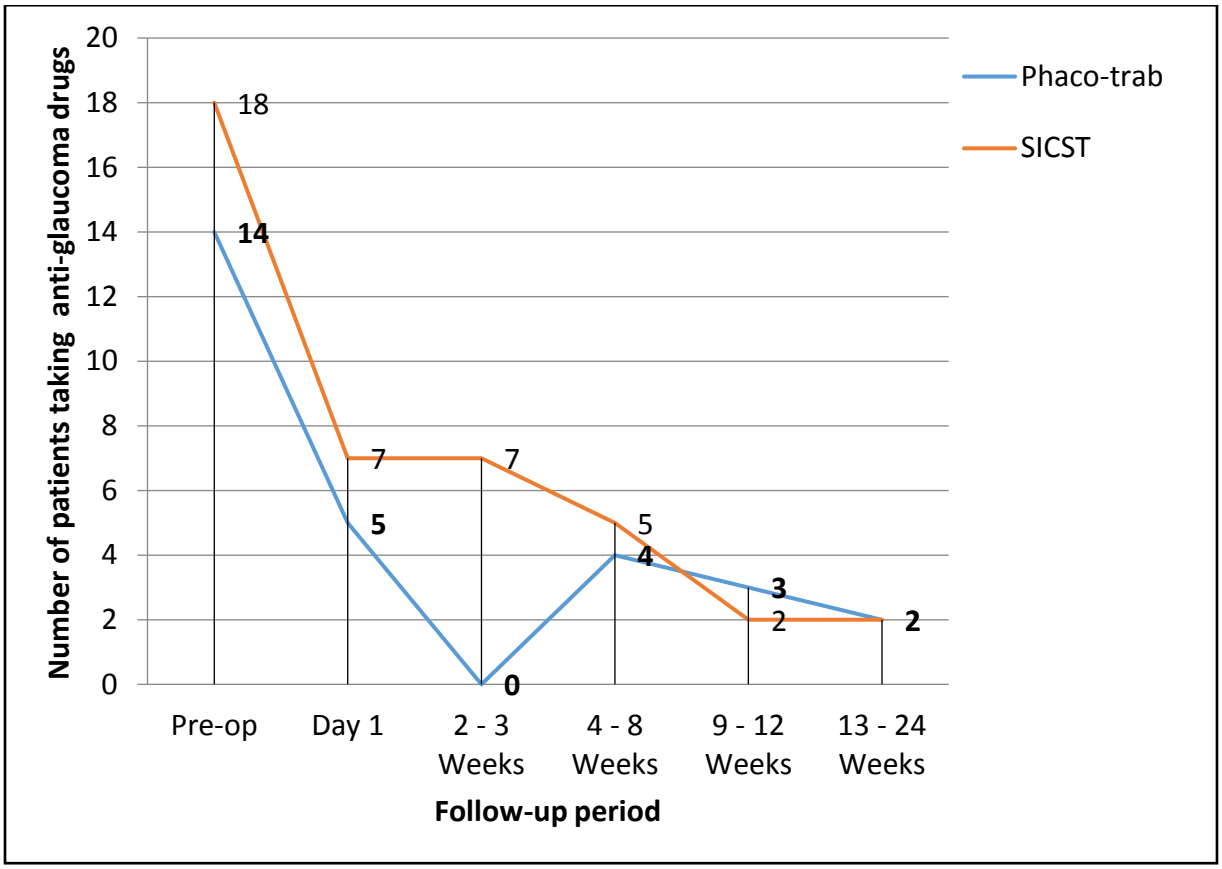
Figure 6.5: *Mean LogMAR visual acuity trend from baseline to 24 weeks*



There was a significant difference in VA from Pre-op to 4 – 8 weeks (Pre-op = 0.015, Day 1 = 0.023, 2 – 3 weeks = 0.050, 4 – 8 weeks = 0.011) in the 2 groups with SICS having worse vision all through the follow-up.

Visual acuity after surgery was recorded at 4-8 weeks postoperatively. Using the best acuity recorded in the files at follow-up, 11 (20.8%) achieved 0.50 LogMAR (6/18 or better), and 13 (24.5%) achieved 1.00 LogMAR (6/60 or better).

Figure 6.6: *Change in the use of anti-glaucoma drugs from pre-operative to post-operative period*



There was a decrease in the number of patients taking anti-glaucoma drugs in the different types (14 phaco-trab and 18 SICST) in preoperative period to 2 in each different typesat 24 weeks follow-up visits. There was no significant difference between the two groups.

Table 6.4:*Intraoperative complications*

Complications	*Surgery type*		*Overall outcome*
	Phaco-trab	*SICST*	
Posterior Chamber (PC) Tear	0	5	5
Vitreous Loss	0	5	5
Flat Anterior Chamber	0	3	3
Zonular Dialysis	0	2	2

All of the Intraoperative complications present were identified from the SICST surgery.

Table 6.5: *Complications based on follow up after surgery*

Complications	*Phaco-trab*		*SICST*		*Overall outcome*	
	<30 Days	*≥30 Days*	*<30 Days*	*≥30 Days*	*<30 Days*	*≥30 Days*
Uveitis	1	0	2	4	3	4
Flat Bleb	2	0	5	1	7	1
Vitreous Hemorrhage (VH)	0	0	1	0	1	0
Hyphema	0	0	2	0	2	0
Edema	0	0	3	0	3	0
Corneal Ulcer	1	0	1	0	2	0
Cystic Bleb	0	0	2	0	2	0
Dislocated Intraocular Lens	0	0	2	0	2	0
Overdrainage	0	0	2	0	2	0
Posterior Capsular Opacification (PCO)	0	1	1	6	1	7
Endophthalmitis	0	0	1	0	1	0
Hypotony	0	0	1	0	1	0
Flat Anterior Chamber (AC)	0	0	2	0	2	0
Corneal Scar	0	1	0	1	0	2
Total	**4**	**2**	**25**	**12**	**29**	**14**

Most complications occurred in SICS especially within the first 30 days

Table 6.6: *Causes of poor vision outcome after surgery*

Complications	*Surgery type*		*Overall outcome*
	Phaco-trab (n=27)	*SICST (n=58)*	
None	21 (77.8%)	33 (56.9%)	54 (63.5%)
Corneal Edema	3 (11.1%)	10 (17.2%)	13 (15.3%)
Corneal Decompensation	0 (0.0%)	1 (1.7%)	1 (1.2%)
Hyphaema	0 (0.0%)	4 (6.9%)	4 (4.7%)
Uveitis	1 (3.7%)	5 (8.6%)	6 (7.1%)
PCO	1 (3.7%)	4 (6.9%)	5 (5.9%)
Endophthalmitis	1 (3.7%)	1 (1.7%)	2 (2.4%)

There was a relatively high rate of corneal edema defects that occurred after eight (8) weeks of surgery.

Table 6.7: *Association between poor visual outcome and various patient-related factors and procedure-related factors*

			Poor visual outcome		
Visual outcome	*Total*	*%*	*OR*	*95%CI*	*P*
Age grouping					
≤60	12	14.1	REF		
61-70	21	24.7	0.629	(0.16-2.47)	0.506
71-80	33	38.8	0.560	(0.19-1.69)	0.302
≥81	19	22.4	0.231	(0.05-0.99)	0.050
Sex					
Male	50	58.8	REF		
Female	35	41.2	0.560	(0.19-1.69)	0.302
Type of cataract					
Nuclear Sclerotic	38	44.7	REF		
Cortical	37	43.5	1.199	(0.40-3.75)	0.745
Posterior Subcapsular	10	11.8	1.120	(0.23-5.58)	0.890
Type of surgery					
Phaco-trab	27	31.8	REF		
SICST	58	68.2	0.227	(0.07-0.74)	0.014

There was no difference in poor visual outcomes between the different age groupings, but for patients who were 81+ years. This age group showed a significant difference in poor visual outcomes with the younger patients (≤ 60 years), p = 0.050 OR 0.23195% CI 0.05-0.99. Type of surgery also showed a significant difference in poor visual outcomes between Phaco-trab and SICST, p value = 0.014 (95% CI 0.07-0.74). Other parameters that were tested were found not to be predictors of poor visual outcomes.

7.0 DISCUSSION, CONCLUSION AND RECOMMENDATIONS

7.1 Discussion

The coexistence of cataract and glaucoma and their management represents a challenging and unsolved problem. Our study evaluated the outcome of combined cataract and trabeculectomy surgery in Kisii Eye Hospital, Tenwek Mission Hospital and Kenyatta National Hospital.

As per the selection criteria of our study, 27 eyes Phaco-trab and 58 eyes SICST were included in the analysis. Study by Bowman *et al.*[27]confirms that phacoemulsification remains uncommon in the Africa settings. However, manual small incision cataract surgery is gradually overtaking traditional ECCE even among non-physician cataract surgeons. There were no statistically significant differences inbaseline characteristics between phaco-trab and SICST surgery groups except for LogMAR visual acuity ($p = 0.015$).

In our study, there was no significant difference in mean IOP betweeneyes treated with phaco-trab and SICST. Both procedures demonstrated a significant difference in the mean reduction of IOP from baseline to 24 weeks. The outcome of Phaco-trab and SICST surgery in terms of IOP control showed that majority of the patients had no sustained pressure control especially for the subgroups of patients with longer follow-up. For instance, in our study majority of the eyes (82.9%) had IOP of 18 mmHg and above.

Our results in terms of IOP control are similar to past studies, for example Kabiru *et al.* (2005) achieved 73% post-operative IOPs of 15 mm Hg or less and 90% 21 mm Hg or less for 8 months

follow-up. However, there were no significant baseline differences between these subgroups and those with a shorter follow-up (p = 0.645). Previous studies (Soatiana *et al.* and Bowman *et al.*) [26] [27]found similar results where there is no significant difference between subgroups with a longer and a shorter follow-up.

Our study aimed for an IOP of 18 mmHg or less because of the advanced disease and this was achieved this in 82.9% of the eyes. This is a similar proportion to a series of reports (Bowman *et al.*, and Chang et al.) [27] [29], 66% and 62% respectively. The secondary target of 20 mmHg was achieved in 80.2%, ECCE was less likely to achieve this target pressure than Phaco-trab or SICST, probably because of greater conjunctival dissection and more post-operative inflammation.

Visual outcomes were encouraging, with 62.4% of those who returned for 4 – 8 weeks follow-up achieving an improvement in visual acuity and nearly 21% achieving 6/18 or better. Study by Bowman *et al.* [27]report an improvement in visual acuity by 40% for 6/18 or better. Yet another study by Gous and Roux [30] for Phacotrabeculectomy in patients with relatively advanced glaucoma from South Africa showed that 6 of 8 patients improved their acuity. In both groups, visual acuity improved at 24 weeks frombaseline.The vision was worse in the phaco-trab group as compared to baseline for the first 6 months post-op.pre-op (p=0.015), day 1 (p=0.023), 2 – 3 weeks (p=0.050), and 4 – 8 weeks (p=0.011); however there was no significant difference between the two groups at 9 – 12 weeks (p=0.066) and 13 – 14 weeks (p=0.113). Lima [31] [32] also found a significantimprovement in the logMAR visual acuity (*P* =

0.01) inpatients treated with phaco alone. Thus, bothprocedures appear to be similar in terms of visual acuity

Other reports from centres in developed countries with less advanced disease have reported higher proportions of patients improving their acuities, 96% in USA and 80% in Finland (Stark *et al.*, and Pera¨salo, respectively). [33] [34] Therefore, measuring visual acuity outcomes alone may underestimate the visual benefit to the patient from this procedure. Even in the absence of improvement in visual acuity, the operation may protect patients against future loss of acuity from glaucoma.

Our study found out that most of the patients who underwent SICST surgery had surgical complications (corneal oedema), particularly on the intra-operative complications, intraoperative complications during the Phaco-trab surgery were not observed for any patient. The high rate of corneal oedema could however be related to the learning curve of different surgeons in SICS. Previous studies (Khandelwal *et al.*) [25]have shown that postoperative complications are uncommon. However, because of the large difference between Phaco-trab and SICST in terms of number of eyes that underwent surgery, we cannot distinguish the effect of surgical complications vs. operation type in this study. More information is required about the outcomes of this operation, especially as phacoemulsification is available in relatively few centres.

On outcome of Phaco-trab and SICST surgery in terms of surgical complications corneal edema and flat blebs were the most common acute post-op complications (table 6.6). There was a high

rate of corneal edema and flat bleb defects that occurred after surgery. Bowman *et al.* [27]also found that there was high rate of corneal epithelial defects that occurred during a 2–3-month period.

In our study, there were cases of uveitis, flat bleb, hyphema, edema among other post-operative complications; earlier studies have also reported these complications in Phaco-trab and SICST surgery (Mittal *et al.*, and Jampel *et al.*). [28] [12] However, it is important to note that most of these complications were reported on cases of SICST surgery. There were a few cases of post-operative complications among patients who underwent Phaco-trab surgery possibly due to small sample size and shorter follow-up period.

We found different age groupings to be a significant risk factor for poor visual outcome in patients who underwent combined surgery. This implies that there's effect of advanced disease with age. Specifically, there was a significant difference in poor visual outcomes between the age groupings for patients who are ≤ 60 years and ≥ 81 years (p = 0.050, OR 0.231, 95% CI 0.05-0.99). Other significant risk factors in this group included the type of surgery that showed a significant difference in poor visual outcomes between Phaco-trab and SICST, p value = 0.014 (95% CI 0.07-0.74). An earlier literature review (Jampel *et al*.) [12] [35]suggested that there is an insufficient evidence to conclude whether different types of surgery give better outcome in glaucoma or cataract.

Sex, pathologies affecting outcome, type of cataract, pre-operative IOP (mmHg), and IOP success rate had no significant effect on visual outcome at discharge or follow-up.

Moreprevious studies; (Bowman *et al.*) [27]also found that type of operation, surgeon, and presence of intra-operative or post-operative complications had no significant effect on visual outcome.

Our study is a retrospective study with losses to follow-up typical of our setting which limits the precision of our findings. It is this poor follow-up that presents a potential benefit from combined cataract and glaucoma surgery at one sitting over a staged procedure (either cataract or trabeculectomy first) in which the patient may default from the second stage and hence lose vision.

7.2 Conclusion

1. There were no statistically significant differences inbaseline characteristics between phaco-trab and SICST surgery groups except for LogMAR visual acuity ($p = 0.015$).
2. Visual outcomes were encouraging, with 62.4% of those who returned for 4 – 8 weeks follow-up achieving an improvement in visual acuity and nearly 21% achieving 6/18 or better.
3. In terms of surgical complications corneal edema and flat blebs were the most common acute post-op complications.
4. Different age groupings and type of surgery were significant risk factors for poor visual outcome.

7.3 Recommendations

1. The poor follow-up limits the precision of the findings but also means that a 'one stop' operation for glaucoma and cataract may be a viable and practical approach to management in this setting.
2. The shortcomings of this study include its retrospective design and unequal sample size due to preference for SCIST surgery over Phaco-trab, more information is required about the outcomes of this type of surgery.

7.4 Limitations

1. Our study is a retrospective study with losses to follow-up typical of the study, which limits the precision of our findings.
2. Certain variables could not be interpreted as the data were unrecorded or missing.

8.0 References

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9.0 Appendices

9.1 Questionnaire

1. DEMOGRAPHICS:

Hospital ID/File Number: _____ **Code:** _____ **Hospital:** _____

Age: _____

Sex: _____

Race: African [ ] Asian [ ] Caucasian [ ]

2. PREOPERATIVE EXAMINATION:

Eye Operated: Right [ ] Left [ ]

Presenting Visual Acuity: Right [ ] _____Left [ ] _____

Pinhole/BCVA: Right [ ] Left [ ]

IOP: Right [ ] Left [ ]

Biometry: Yes [ ] No [ ]

PATHOLOGIES POSSIBLY AFFECTING THE OUTCOME:

Corneal Scar ☐ Pseudoexfoliation ☐ Subluxated Lens ☐ Optic atrophy ☐

AMD ☐ Glaucoma ☐ Retinal Diseases ☐ Diabetes ☐ Others_____

3. EXAMINATION FINDINGS:

Type of cataract: _____ Right [ ] Left [ ]

VCDR: _____

CCT: _____

Gonioscopy Findings: Open [ ] Closed [ ] None [ ]

4. ANTIGLAUCOMA MEDICATION BEFORE SURGERY:

Beta-Blocker [ ]

PGA [ ]

Alpha-2 Agonist [ ]

Pilocarpine [ ]

CAI (Oral) [ ]

CAI (Topical) [ ]

None [ ]

Other (specify) _____

Total Number of Medications: _____

6. POST-OPERATIVE DATA

Date of Surgery: _____/_____/____

Surgery Type:

Phacoemulsification/Trab [ ]

SICST [ ]

IOL Power Inserted: _____

IOL Type: _____ **MMC** Y / N **5-FU** Y/N

7. INTRAOPERATIVE COMPLICATIONS:

☐None

☐Hyphema

☐PC tear

☐Vitreous loss

☐Zonular Dialysis

☐Others_____

8. POSTOPERATIVE EXAMINATION:

	DATE	UNCORRECTED VA	BCVA/PIN HOLE	IOP	COMPLICATIONS	INTERVENTIONS
Day 1						
2-3 weeks						
4 -8 weeks						
9-12 weeks						
13–24 weeks						

9. CAUSES OF POOR OUTCOME:

Surgical Complications:

Hypotony [ ]

Encapsulated Bleb [ ]

Flat bleb [ ]

Corneal edema [ ]

Corneal Decompensation [ ]

Flat AC [ ]

Hyphaema [ ]

Uveitis [ ]

Vitreous loss [ ]

PCO [ ]

Endophthalmitis [ ]

Retinal Detachment [ ]

Suprachoroidal Haemorrhage [ ]

Phthisis [ ]

None [ ]

Others (specify) _____

10. ANTIGLAUCOMA MEDICATION AFTER SURGERY:

Beta-Blocker [ ]

PGA [ ]

Alpha-2 Agonist [ ]

Pilocarpine [ ]

CAI (Oral) [ ]

CAI (Topical) [ ]

None [ ]

Other (specify) _____

Total Number of Medications: _____

9.2 Study Time Frame

Activities	APR 2017	MAY 2017	JUN 2017	JUL 2017	AUG 2017	SEP 2017	OCT 2017	NOV 2017	DEC 2017	JAN 2018	FEB 2018	MAR 2018
Proposal Development												
ERC Approval												
Data Collection												
Data Analysis												
Report Writing												
Dissemination of Findings												

9.3 Budget

Item	Quantity	Unit cost) (Kshs)	Total kshs
Proposal			
Printing and Packing	35 pages	10	350
Photocopy of Proposal	70 pages	3	210
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			3,000
Sub-total			**4,970**
Contracted services			
Statistician	1	20,000	20,000
Sub-totals			**20,000**
Communication & Accommodation			
Telephone			5,000
Transport			10,000
Accommodation			20,000
Subtotal			**35,000**
Results			
Printing of questionnaire	4pages	10	40
Photocopy of questionnaire	4 * 200	3	2,400
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			**72,190**

9.4 KNH-UON ERC Approval Letter

9.5 Permission Letter from Kisii Eye Centre

9.6 Permission Letter from Tenwek Mission Hospital

9.7 Permission Letter from Kenyatta National Hospital