OUTCOME OF CHILDHOOD CATARACT SURGERY AT SABATIA EYE HOSPITAL

A dissertation submitted in part fulfilment for degree of Master of Medicine (Ophthalmology), Faculty of Medicine, Department of Ophthalmology, University of Nairobi.

By:-

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H58/69897/2011

2014

DECLARATION

This dissertation is my original work and has not been presented for a degree in any other University.

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APPROVAL BY SUPERVISORS

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DEDICATION

To all the Children visually impaired by cataracts.

ACKNOWLEDGEMENTS

I would like to thank the following for their invaluable contribution to the completion of this study;

My supervisors, Dr. Kariuki, M. M, Dr. Nyenze E. M and Dr. Ollando A. E, who had to read through many drafts of my proposal and dissertation, their input is highly appreciated.

Sabatia Eye Hospital, for allowing me to conduct this study.

My sponsors, Light for the World, they provided the funds.

Special thanks to my wife Lilian Jematia and my son Baraka for their patience and support.

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ABSTRACT

Background: - Cataract is the most common cause of blindness in children in the developing countries. It is largely reversible and is one of the main targets for treatment in the WHO elimination of preventable blinding diseases. Cataract surgery outcome in children is poorer than adults in Africa. Few studies have been done to determine outcomes in Kenya and none had been done at Sabatia Eye Hospital, an eye hospital located in Western Kenya.

Objectives: - The aim of this study was to determine the outcome of cataract surgery both in the intraoperative and postoperative period.

Methodology: -

Study Design: This was a retrospective case series study done at Sabatia Eye Hospital reviewing all records of children aged less than 15years who underwent cataract surgery in 2012.

Study duration:-January2013 to February 2014.

Study Variables: -Intra-operative and postoperative complications, visual acuity and refractive status outcome of cataract surgery and associated factors up to 6 months after the surgery.

Data Management: -Descriptive analysis was undertaken to determine outcomes. Proportionate test was used to compare proportions. Chi-square was used to test factors associated with poor outcome.

Results:-

A total of 90 patients (123 eyes) were included in the study, 62.2% of them being male and female at 37.8 %, this was a statistically significant sex difference (**p-value<0.001**). Pre-operatively, 61eyes (49.59%) were blind (WHO Visual Acuity <3/60). There was a

long delay between onset and presentation with a mean duration of 40.23months (1-168mnths) for congenital and 29.37months (2-168mnths) for developmental cataract. A majority of the cases – 92eyes underwent Lens Washout with Primary Posterior Capsulotomy, Anterior Vitrectomy and Intraocular Lens Placement. Of note, 91.06% had Primary IOL placement. Intraoperative complications were seen in 12 (9.76%) eyes. Late refraction findings showed a mean absolute spherical refractive error of 3.51D (mean of 2.61D in those who had biometry) and cylindrical error mean of 1.80D. Poor visual outcome at 12+weeks was 32.26% with Ambylopia being commonest cause of poor vision. Commonest early complication was corneal haze in 25 eyes (20.33%) and late (12+weeks) was PCO noted in 26.67%, Pupillary abnormality (37.78%) and Ambylopia (24.44%). Congenital cataracts was associated with a worse outcome than developmental cataract, OR 0.19(0.03-1.17),(*p-value=0.0444*).

Conclusion:-

Majority of the children had good or borderline visual acuity outcome, with poor outcome also noted in some due to various factors.

The rate of complications was similar to other studies. Corneal haze was the commonest early complication while pupillary abnormality, Ambylopia and PCO were the most common later complications. Refractive outcome was better and less variable in patients who had biometry before surgery. Congenital cataract had poorer outcome. Ambylopia was the commonest cause of poor vision.

LIST OF ABBREVIATIONS

AC	-	Anterior Chamber
AV	-	Anterior Vitrectomy
DALY	-	Disability Adjusted Life Years
ECCE	-	Extra-Capsular Cataract Extraction
GA	-	General Anaesthesia
IATS	-	Infant Aphakia Treatment Study
IOL	-	Intra-ocular Lens
KEU	-	Kikuyu Eye Unit
KNH	-	Kenyatta National Hospital
LAV	-	Lensectomy with Anterior vitrectomy
LogMAR	-	Logarithm of Minimum Angle of Resolution
LWO	-	Lens Wash Out
Nd:YAG	-	Neodymium: Yttrium laser
PCO	-	Posterior Capsule Opacity
PMMA	-	Polymethylmethacrylate
PPC	-	Primary Posterior Capsulotomy
SD	-	Standard Deviation
WHO	-	World Health Organisation

1. INTRODUCTION/BACKGROUND

Cataract refers to opacification of the crystalline lens [1]. It is a largely preventable cause of blindness since it is possible to remove the opacified lens and replace it with a clear optical device such as an intraocular lens(IOL) or contact lenses [2]. An estimated 190,000 children are blind from cataract worldwide with a higher prevalence in developing countries at 1-4/10,000 as compared to 0.1-0.4/10,000 in the industrialized world. The lower prevalence in the developed countries has been attributed to better Cataract services in industrialized countries as well as more causative factors of cataract in the poorer countries [1,3]

An East Africa study done by Waddell showed Cataract to be the leading cause of blindness at 30.7%. [4.]

A study involving schools in Kenya, Uganda and Malawi reported that of the severe visually impaired children, 13.5% was due to cataract, second only to corneal pathology.[5]

There is a narrow window of opportunity in treating a visually impaired infant. Binocular single vision develops by 6 months of life and a visual deficit, if not detected and treated in time, may leave the child bereft of stereopsis. The amblyopia that develops from visual deprivation of early onset, irrespective of the cause, can be dense and difficult to treat[6].

Cataract surgery remains largely unavailable to many patients due to factors such as cost, lack of trained staff and delayed presentation [7,8]. In addition, in children cataract

surgery has to be done under general anaesthesia as compared to adults in whom local anaesthesia is adequate. This limits cataract surgery for children to the few main hospitals.

Following improvements in research and manufacture methods, cheaper intraocular lenses are now available and can be used in most surgeries for older children in developing countries. Meanwhile improvements and standardisation of cataract surgery for children has resulted in better outcome following cataract surgery [9].

In Kenya, Childhood cataract surgery is routinely performed in only 5 centres which do not adequately cover the population in need.

Three studies have previously been done looking at the outcome of cataract surgery in Children in Kenya, one at Kenyatta National Hospital and two at Kikuyu Eye unit, the main referral centres in Kenya. The studies had reported many complications from childhood cataract surgery. In the study done in Kenyatta National Hospital, Saiba et al had reported poor outcomes attributable to late presentation, poor aphakic correction, development of PCO and loss to follow up [10]. The previous studies have studied cataract surgery in children aged 15years and less and for comparability reasons, this study will also study those aged 15years and less.

In His study, Saiba et al established that most patients presented late, many waited for long before the actual surgery and many more were lost to follow-up. The study also recommended follow-up studies on the outcome of cataract surgeries. The situation is the same in the other centres that offer childhood cataract surgeries with lack of

adequately trained personnel, delayed presentation, delayed referral and long waiting time for surgeries.

Sabatia Eye Hospital is one of the main eye hospitals in Kenya and is located in Western Kenya serving a large population. Childhood cataract surgery is increasingly being performed in the hospital with use of foldable IOLs. A total of 450 children underwent surgery in 2012 for eye problems of which a large percentage were due to cataract.

This study will review the outcome of cataract surgery in children aged less than 15 years at Sabatia Eye Hospital in the year 2012. It will be the first such study in the hospital and will provide a baseline for future comparisons, provide appropriate recommendations and guide future training of Ophthalmologists in Childhood cataract surgery.

2. LITERATURE REVIEW

2.1. Epidemiology

The prevalence of blindness among children varies from 0.2/1,000 children to over 1.5/1,000 children with a global figure estimated at 0.7/1,000 and 1-4/1,000 in developing countries. This means that there are an estimated 1.4 million blind children worldwide. The proportion of blindness in children due to cataract varies considerably between regions from 10%-30% with a global average estimated at 14%, giving 190,000 children blind from cataract[3,1].

In Malawi, Chirambo et al showed a prevalence of 6.25% among blind children [11].

An East Africa study done by Waddell showed Cataract to be the leading cause of blindness at 30.7% [4].

A study involving schools in Kenya, Uganda and Malawi reported that of the severe visually impaired children, 13.5% was due to cataract second only to corneal pathology[5].

A study by Njuguna et al in Kenya, Malawi, Tanzania and Uganda in schools for the blind, found lens related disorders at 13.1% to be the third commonest cause of visual impairment and blindness.[12]

2.2. Management of childhood cataract

2.2.1. Introduction

Children who are blind have to overcome a lifetime of emotional, social and economic difficulties which affect the child, the family and society. Loss of vision in children influences their education, employment and social life[3] .

Timely recognition and intervention can eliminate many blind-years due to childhood cataract, as the condition is treatable thus reducing the Disability Adjusted Life Years (DALY) [3,1,13]

Although adult cataract surgery can be taken to the people, paediatric cataract surgery is better performed in regional centres where general anaesthesia is practiced and the surgeons perform childhood surgery often[13]

Management of congenital and childhood cataracts remains a challenge. Increased intraoperative difficulties, propensity for increased postoperative inflammation, changing refractive state of the eye, more common postoperative complications and a tendency to develop amblyopia, all add to the difficulty in achieving a good visual outcome in the paediatric patient. Adaptation of techniques for cataract surgery specific to children is necessary owing to low scleral rigidity, increased elasticity of the anterior capsule, and high vitreous pressure. Also, microphthalmia and pupillary miosis often add to the surgical complexity. Finally, surgical timing and adequate visual rehabilitation are paramount, to avoid irreversible visual damage secondary to amblyopia [9,1,14,15]

Optimum time for surgery depends on several factors including if it is a congenital or developmental cataract and whether it is unilateral or bilateral. In unilateral congenital cataract some authorities advocate waiting upto 8 weeks of age, waiting upto this age minimises complications while waiting beyond this time affects visual outcome[16]. In cases of dense bilateral cataract timing for the first eye surgery is as unilateral cataract with the second eye one to two weeks later to avoid amblyopia [1,15,14]. For older children who had developed normal binocular vision, surgical timing depends on the degree of visual defect from the cataract [1]

2.2.2. The Surgery and techniques

Cataract surgery for children in developing countries is beset with many challenges top of which is lack of resources, delay in presentation and inadequate skills all contributing to poor outcome [8,10].

A reputation for good results from the surgery is essential. Thus, especially in the initial phase, patient selection is very important. Children with good visual potential (bilateral dense cataracts without nystagmus or microphthalmia) should be treated first to ensure that parents and community leaders will trust in and advocate the surgery being offered to the blind children[13]

Paediatric cataract surgery is done under general anaesthesia. Preoperative evaluation is important to rule out other associated ocular anomalies and causes of cataract prior to subjecting the child to anaesthesia [9,17,18].

Many procedures have been described for paediatric cataract surgery and most are more relevant in the developed countries[9]. Extracapsular cataract extraction (ECCE) techniques described in the literature for the paediatric cataract management include automated lensectomy with anterior vitrectomy(LAV); extracapsular cataract extraction with intraocular lens implantation ((ECCE + IOL) manual or automated with an intact posterior capsule), and ECCE, primary posterior capsulotomy, anterior vitrectomy with intraocular lens implantation ((ECCE + PPC + AV + IOL), manual or automated posterior capsulectomy with automated vitrectomy). Variations on the latter technique have been proposed in the hope of eliminating the vitrectomy, while still performing the posterior capsulotomy at the time of surgery. However there are no

clear-cut guidelines about when to use these various techniques. This is especially important in developing countries [9].

The results of using the various surgical techniques mentioned above have been reported in some of the studies concerning paediatric cataract management. Yorston et al in a study in East Africa studied 118 eyes in 71 children who had cataract surgery and IOL implantation of which fifty seven eyes (48.3%) had an anterior vitrectomy, followed by lens aspiration, with preservation of the posterior capsule and attempted lens placement in the capsular bag. The majority of these (86.0%) were carried out in children over the age of 3 years. In 61 eyes (51.7%), following anterior capsulotomy, the lens matter was removed by an automated vitrectomy instrument, followed by primary posterior capsulectomy and anterior vitrectomy. In most of these patients the lens implant was placed in the sulcus. Most of these operations (91.8%) were carried out in children under 4 years old [19].

In a study done by Namani at Kikuyu Eye Unit on 1,514 eyes in children under 15 years, 61.2% (927 eyes) had Lensectomy + Anterior Vitrectomy, 21.5%(326 eyes) had ECCE + IOL and 7.2%(110 eyes) had ECCE + PPC + IOL [20]. A similar study by Saiba et al at Kenyatta National Hospital showed that 36.4% (44 eyes) had LWO, 34.7% (42 eyes) had LWO + PPC + AV, 21.5% (26 eyes) had LWO + PPC + AV + IOL[10].

Most authors agree that extracapsular cataract surgery, primary posterior capsulectomy and anterior vitrectomy (ECCE, PPC, and AV) provide the best chance of a long term clear visual axis. When long term follow up is not likely and Nd:YAG laser treatment is not available, ECCE, PPC, and AV with IOL implantation for all children 8

years of age and younger is recommended. From age 8 until the end of growth, PPC is still recommended, although the AV is optional [9,18].

When it comes to choosing the correct optical device, the age and laterality of the cataract is taken into consideration. For Children aged 1-2 years and older, IOL implantation is widespread and many studies have shown its efficacy. In infants due to complications and rapid shift of refractive state, IOL use is controversial. A clinical trial, the Infant Aphakia Treatment Study(IATS) is currently underway to assess IOL implantation in infants[15,18,22,].

Because the child's eye continues to elongate throughout the first decade of life and beyond, the selection of an appropriate IOL power is complicated. Power calculations in infants and young children may be unpredictable due to several factors, including widely variable growth of the eye, difficulty obtaining accurate keratometry and axial eye length measurements, and the use of power formulas that were developed for adults rather than children. Studies have shown that the refractive error of aphakic children undergoes a variable myopic shift of approximately 7-8 D from age 1 to age 10, with a wide standard deviation (SD). This would suggest that if a child is made emmetropic at age 1 with an IOL, refraction at age 10 would be expected to be up to -8 D or greater (refractive change below age 1 year is even more unpredictable). This approach assumes that presence of an IOL does not alter this normal aphakic growth curve, an assumption that may not be valid based on both animal and early human studies. Lens implantation in children requires a compromise that accounts for the age

of the child and the target refraction at the time of surgery. There are 2 approaches to this situation. Some surgeons implant IOLs with powers that are expected to be required in adulthood, allowing the child to grow into the power selection of the lens. Thus, the child is undercorrected and requires hyperopic spectacles of decreasing powers until the teenaged years. Other surgeons aim for emmetropia at the time of lens implantation especially in unilateral cases, believing that this approach may decrease the risk of amblyopia and facilitate development of binocular function by decreasing anisometropia. These children can be expected to become progressively more myopic with time and eventually may require a secondary procedure in order to eliminate the increasing anisometropia, [18,22,23,24,25].

Both single-piece polymethylmethacrylate (PMMA) and foldable acrylic lenses have been widely used in paediatric cataract surgery in recent years. Many studies have shown them to be well tolerated. Silicone lenses have not been well studied in children[18] . In developing countries the PMMA IOL is the most affordable type used[26].

Intraocular lens optic capture, while helpful in implant centration (especially, when the IOL haptics are in the ciliary sulcus), does not assure a permanent clear visual axis in children less than 6–8 years of age. An anterior vitrectomy is recommended whether posterior IOL optic capture is utilised, or not. While foldable IOLs can be inserted through either a corneal or a scleral tunnel, the (PMMA) IOLs manufactured in the developing world should be inserted through a scleral tunnel which is securely sutured. A superior approach is favoured since the wound is protected beneath the brow[26].

2.2.3. Post Operative Complications and Outcomes

Children require more careful follow-up after cataract surgery. It is a long term follow-up and involves both proper refractive correction and management of surgical complications. Post-operative topical antibiotics, steroids and cyloplegics are used for a few weeks after the surgery. In patients with an IOL, more aggressive steroid treatment is used. Ambylopia treatment is also begun soon after the surgery; this includes correction of any remaining refractive error[18].

Careful follow-up of post-operative children however still remains a challenge in our setting and further results in poor outcome due to loss to follow-up, missed appointments, unavailable or unaffordable drugs and glasses[10,20]. Research in Tanzania focusing on follow up (even when transport costs were provided) indicated a number of factors associated with poor follow-up such as: parental lack of awareness of its importance, long distances, female gender of patient and poor pre-operative vision[27]. The availability of donated or low cost and attractive frames for children has increased the number of children being fitted with and using spectacles[28]. In addition, units like Sabatia Eye Hospital have established Low Vision Units that have dedicated staff who deal with low vision in children.

Children have more complications as compared to adults; if a posterior capsulotomy is not done, the child will invariably develop a posterior opacity (PCO). This is usually treated by use of laser (Nd: YAG) or use of a needle. An alternative anterior vitrectomy can be done, together with removal of the anterior vitreous. If anterior vitrectomy is not done, the opacification may recur on the anterior hyaloid face [3,9].

A fibrinous reaction at 30% and PCO at 37.5% were the most common early and late complications as seen by Yorston et al[19], Saiba et al[10] showed a prevalence of 28.1%

and 11.6% at 2 months and 6 months respectively while Namani[20] had Fibrinoid reaction at 59.2% and PCO at 15.4% on follow up. The studies were carried out in KNH and Kikuyu Eye Unit respectively. Other complications seen with decreasing frequency were updrawn pupil, corneal decompensation, glaucoma, IOL decentration, Occlusion pupillae, hyphema, hypopyon, endophthalmitis, Phthisis bulbi and shallow AC.

On refraction, in the study done by Yorston et al, difficulties in obtaining correct frames for children and reluctance of parents to pay for astigmatic and bifocal lenses was encountered. Studies in other African countries had similar problems[19,28].

In a study done in Tanzania, 51% of the refracted children had a post operative error of 2 diopters equivalent, 47% had 3 diopters of astigmatism (18% on follow-up). A pre-operative biometry reading was not associated with smaller refractive errors post-operatively. In this study, Acrysof (acryric) lenses were inserted in 149 eyes out of the 232 while 83 eyes had the PMMA lens, on analysis; smaller astigmatism refractive errors were found in eyes with the Acrysof lens. The complications noted in this study were similar to other studies with fibrinous uveitis occurring in 30 cases (12%), and transient corneal haze occurred in 20 cases (8%). Poor post-operative outcome was predicted by pre-operative blindness[29].

3. STUDY JUSTIFICATION

Paediatric cataract remains a major cause of morbidity beset with problems of delay in presentation[8], lack of access to health facilities and limited skilled personnel to manage the largely preventable cause of blindness. This study builds onto the body of knowledge and guides interventions.

Childhood blindness from cataract results in a greater magnitude of Disability Adjusted Life Years (DALY) as compared to age related cataracts and therefore important to inform decision making on the management.

So far studies done in Kenya have reported poor outcome of Childhood cataract surgery in the referral centres due to various factors. This study investigates outcomes in a community based eye unit.

4. OBJECTIVES

4.1. Main Objective

To determine the outcome of cataract surgery in children aged 15 years and less, performed in the year 2012 at Sabatia Eye Hospital.

4.2. Specific Objectives

- To determine the post operative visual outcomes of cataract surgery in children at Sabatia Eye Hospital.
- To establish the common intra-operative and post-operative complications of cataract surgery in children at Sabatia Eye Hospital.

- To establish the refractive correction needed after childhood cataract surgery at Sabatia Eye Hospital.
- To identify any factors that may contribute to poor outcome in patients with such outcome following cataract surgery.

5. METHODOLOGY

5.1. Study site

This study was done at Sabatia Eye Hospital, an eye hospital located in Western Kenya and serving as an eye referral hospital.

5.2. Study Design

The study was a retrospective case series study.

5.3. Study Population

All children aged 15 years and below who had cataract surgery at Sabatia Eye Hospital.

5.4. Sample Size

All children meeting the inclusion criteria and who underwent cataract surgery between 1st January 2012 and 31st December 2012 were included in the study.

5.5. Study Period

The study period was a one year period from 1st January 2012 to 31st December 2012, while follow-up data was collected for up to 6month follow-up.

5.6. Data Management

The patient's records to be included in the study were identified using the theatre and clinic record books with the assistance of the records staff. The details of those records that met the inclusion criteria were entered into a questionnaire and verified by the principal investigator. Relevant data included demographic data (age and sex), the date of surgery, baseline/preoperative assessment, visual acuity, refractive status, biometry and ocular co morbidities. Classification of type of cataract, whether congenital or developmental was as per the record in the file as made by the clinicians, congenital cataracts were those which had onset at 1year or less of age while developmental cataracts had onset of the problem after one year of age. Intra-operative information extracted was the type of surgery, lens used and complications. Post operative data collected was the visual acuity, refraction and complications at the first post operative day, at 1-3weeks, at 4-11weeks and at 12+ weeks and/or 6months. Data was then keyed into Microsoft (MS) Excel 2007, cleaned and validated before analysis on STATA version 11.

Descriptive analysis was undertaken for the patients to determine the outcomes, duration and demographics. Proportion test was used to compare different proportions. Chi-square test was used to determine the factors associated with poor outcomes. An alpha value of 0.05 was taken for the significance test

Data was analysed in conjunction with a Biostatistician.

The findings were presented in form of tables and charts.

The raw data was retained in confidentiality until the thesis was accepted and marked for any verification. It was then destroyed.

5.7. Data Analysis

The collected data was keyed into Microsoft Excel 2007 database, cleaned and validated. Analysis was done on STATA version 11.

5.8. Inclusion Criteria

All records of children aged 15 years or less, who underwent cataract surgery at Sabatia Eye Hospital between 1st January 2012 and 31st December 2012 were included in the study.

5.9. Exclusion Criteria

Records of children who underwent traumatic cataract surgery during the study period were excluded.

5.10. Study materials

A preset questionnaire was used to capture data. An assistant was trained to assist in the research; a records officer (Qualification - Certificate in Health Records) to assist in the retrieval and records management. All filled questionnaires were checked by the principal investigator for completeness.

5.11. Ethical Considerations

The identity of the patients was kept anonymous during data collection. No record of the identity of the patient or file number was made. No photocopies of medical records were made. The questionnaires were only available to the investigator and Biostatistician for analysis only.

Written ethical approval was sought from the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (**Appendix 11.5**). Approval was also sought from Sabatia Eye Hospital (**Appendix 11.6**).

The raw data will be retained for a maximum of 1 year after. The questionnaires and other materials will then be destroyed.

5.12. Study Variables

There are different visual acuity measurements for different children depending on the age of the child and his/her cooperation. For preverbal children, the preferential looking test is normally used, results that were obtained pre and post-operatively were recorded in the questionnaire from the patient's file, for those who were uncooperative, the best estimate of vision was normally recorded in the files, that is ability to follow light or objects. For school going children, the Snellen and LogMar equivalent vision had been used to take vision and findings that were documented in the file were recorded in the questionnaire. The WHO system of classifying visual acuity (VA) was used to make conversions between the various systems. This is as shown below:-

V A METHOD	**Snellen Chart**	**Decimal**	**LogMar**	**WHO CLASSIFICATION OF VISION**
1.	**6/6**	**1**	**0**	**NORMAL**
2.	**6/9**	**0.63**	**0.2**	**(6/18 or Better)**
3.	**6/12**	**0.50**	**0.3**	
4.	**6/18**	**0.33**	**0.5**	
5.	**6/24**	**0.25**	**0.6**	**IMPAIRED**

6.	**6/36**	**0.17**	**0.8**	**(<6/18 to 6/60)**
7.	**6/60**	**0.10**	**1.0**	
8.	**3/60**	**0.05**	**1.3**	**SEVERELY IMPAIRED (<6/60 to 3/60)**
9.	**1/60**	**0.02**	**1.8**	**BLIND (<3/60)**
10.	**PL+**	**PL+**	**3**	
11.	**NPL**	**NPL**	**4**	
12.	**Can pick 1mm object at 33cm**			**Better than 6/60**
13.	**Cant pick 1mm object at 33cm**			**<6/60**
14.	**Follows Light**			

Good outcome was defined as visual acuity (VA) better than 6/18 (WHO Normal VA), borderline as 6/18 to 6/60 (WHO Impaired VA) and Poor Outcome as less than 6/60(WHO severely Impaired and Blind VA)[30]. Kilimanjaro Centre for Community Ophthalmology (KCCO) guidelines for Childhood Cataract surgery in Africa are also shown below[31]:-

Visual Outcome		**Post –Operative Visual Acuity with available correction**			**Study Definitions for analysis of causes of poor outcome**
		WHO Guidelines %	**KCCO %**		
			Less than 2yrs old	**Older than 2yrs old**	
Good	6/18 and better	>80% (>90% with BCVA*****)	>50%	>70%	"***Good Outcome***"
Borderline	<6/18 to 6/60	<15% (<5% with BCVA)			

Poor	<6/60	<5% (<5% with BCVA)	<10%	<5%	***"Poor outcome"***

***** Best Corrected Visual Acuity

For purposes of analysis of causes of poor visual outcome, the classification of Severe Impairment and Blindness was taken as "poor visual outcome" for this study while ''Good outcome' included those who had both WHO good outcome (better than 6/18 VA) and WHO borderline VA outcome (6/18-6/60). This was for comparability with other studies.

The investigator had no control on patient selection for surgery which was at the discretion of the surgeons at Sabatia Eye Hospital.

Incomplete records formed a limitation in the study. Data from all records that met the inclusion criteria was collected. Flowchart and analysis has been done to show reasons for such incompleteness (e.g. Loss to follow-up & misplaced records).

5.13. Timeframe

The study concept and preparation of the proposal under supervision was done from January to March 2013 (**see Gantt chart in Appendix 11.2**). It was subsequently presented to faculty, Department of Ophthalmology and approved in April 2013

Ethical approval was sought from May to December 2013 from the ERC, KNH/UON.

Budget approval, preparation of materials and training of research assistants was done in December 2013 and January 2014.

Data collection was done in January 2014, analysis in January-February 2014 and results presented end of February 2014. The final thesis was then prepared and handed in May 2014.

6. RESULTS

6.1. Pre-operative Characteristics

Figure I: Flowchart showing subjects included in the study.

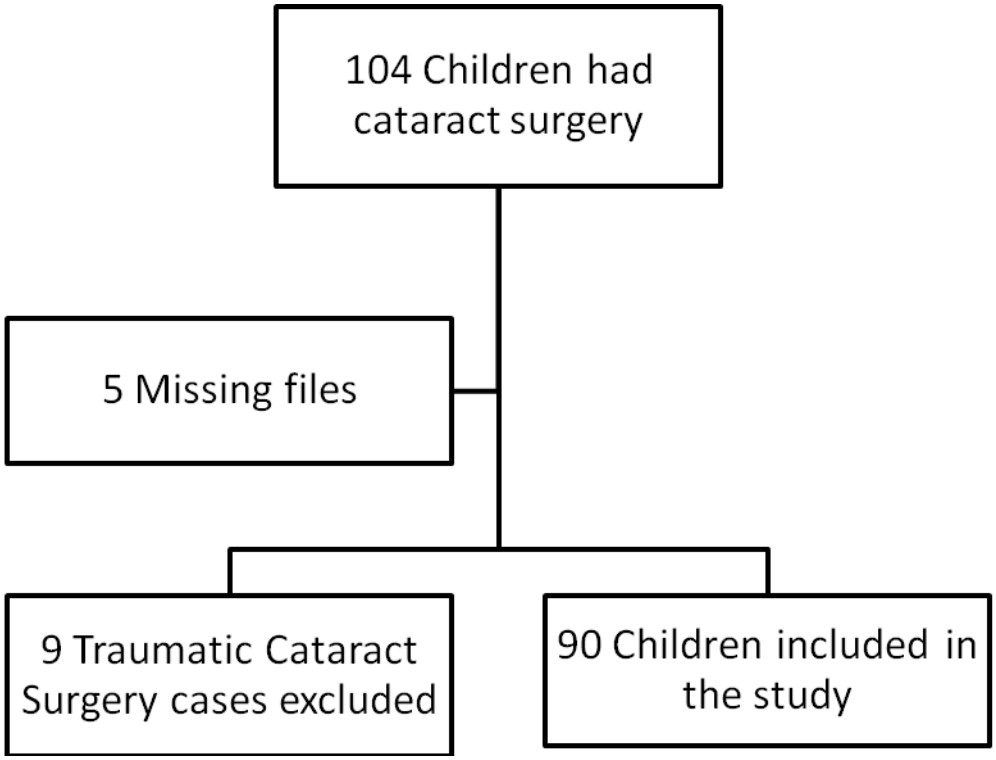


Table 1.Demographic Characteristics

Characteristics, N=90	**n (%)**
Sex	
Male	56 (62.22%)
Female	34 (37.78%)
Age	
<1 year	13 (14.44%)
1 – 5 years	22 (24.44%)
6 - 10 years	30 (33.33%)
More than 10 years	25 (27.78%)
Laterality of Eyes	
Unilateral	57 (63.33%)
BE	33 (36.67%)

There was a significant difference in sex, male: female ratio, 1.6:1 (p-value=0.001)

The mean age was 80.7 months (SD: 54.25), median age was 72 months, range (2 – 180 months)

The total number of eyes operated was 123

Table 2: Age distribution as per sex. (n=90)

Age distribution	**Male, N=56 n(%)**	**Female, N=34 n (%)**	**Total, N=90**
<1 year	5 (8.93%)	8 (23.53%)	13 (14.44%)
1 – 5 years	14 (25.00%)	8 (23.53%)	22 (24.44%)
6 - 10 years	16 (28.57%)	14 (41.18%)	30 (33.33%)
More than 10 years	21 (37.50%)	4 (11.76%)	25 (27.78%)

Table 3: Pre-operative Visual Acuity

Pre-operative visual acuity, N=123	**n (%)**
6/18 or better	4 (3.25%)
<6/18-6/60	11 (8.94%)
<6/60-3/60	6 (4.88%)
Less than 3/60	61(49.59%)
Can pick 1mm object at 33 cm	0
Can't pick 1 mm object at 33 cm	13 (10.57%)
Following Light	24(19.51%)
Not recorded*	4 (3.25%)

*Not recorded; - included VA that was not available or could not be tested.

Many (49.59%) of the patients were classified as blind pre-operatively.

Table 4: Duration of problem before presentation

Duration , N=85*	**Type of cataract**			**Total N=85**
	Congenital N=37	**Developmental N=38**	**Unknown N=10**	
≤6 months	11 (29.73%)	11 (28.95%)	5 (50.00%)	27 (31.46%)
7 - 12 months	6 (16.22%)	8 (21.05%)	2 (20.00%)	16 (18.82%)
13 - 24 months	3 (8.11%)	6 (15.79%)	2 (20.00%)	11 (12.94%)
25 - 36 months	4 (10.81%)	5 (13.16%)	1 (10.00%)	10 (11.76%)
37 - 48 months	2 (5.41%)	2 (5.26%)	0	4 (4.71%)
49 - 60 months	3 (8.11%)	2 (5.26%)	0	5 (5.88%)
≥ 61 months	8 (21.62%)	4 (10.53%)	0	12 (14.12%)

*5 patients did not have duration recorded.

The mean duration for all the patients was 32.13months (SD 40.11), median=12 months (range from 1 – 180 months).

Mean duration of congenital cataract was 40.23 (SD 46.98) months, median=24 months, range (1-168 months)

Mean duration of developmental cataract 29.37(SD 36.00) months, median =14.5months, range (2 -168 months)

Table 5: Ocular co morbidities

Problems, N=123	**n (%)***
Nystagmus	35 (28.46%)
Strabismus	33 (26.83%)
Microphthalmos	8 (6.50%)
Uveitis|Synechiae	8 (6.50%)
Photophobia	6 (4.88%)
Allergic Conjuctivitis	6 (4.88%)
Corneal opacity	5 (4.07%)
Glaucoma	1 (0.81%)
Pannus	1 (0.81%)
Others	2 (1.63%)
None	47 (38.21%)

*Some had multiple responses

The commonest ocular co morbidity was nystagmus in 35 eyes (28.46%).

Table 6: Preoperative Posterior Segment Examination

Posterior segment , N=123	**n (%)**
Accessible	8 (6.50%)
Not accessible/available	115 (93.50%)
If accessible, N=8	
Normal	8 (100%)
Abnormal	0

Posterior segment pre-operative examination was done in 8 eyes which were all normal.

Table 7: Types of cataract, N=123

Type, N=123	**Laterality**		**Total Patients, N=90**	**Total Eyes, N=123**
	Unilateral, N=57	**Bilateral, N=33**		
	n(%)	**n(%)**	**n(%)**	**n(%)**
Congenital Developmental Unknown/ other	22 (38.60%) 23 (40.35%) 12 (21.05%)	15 (45.45%) 18 (54.55%) 0	37 (41.11%) 41 (45.56%) 12 (13.33%)	52 (42.28%) 59 (47.97%) 12 (9.76%)

Table 8: Corneal diameter

Corneal diameter measurement (N=123) :-

Done 12

Not done 111

Corneal diameter done– horizontal N=12	**n (%)**
Less than 9 9 More than 9	1 (8.33%) 2 (16.67%) 9 (75.00%)

The corneal diameter range was 8-13mm.

Table 9: Axial Length

Axial length measurement (N=123) :-

Done 54

Not done 69

Axial length(AXL), N=54	**n(%)**
Axial length	
<20	12 (22.22%)
20 – 24.5	35 (64.81%)
≥24.5	7 (12.96%)

The mean AXL was 21.56 (SD 2.31), median 21.525, range 15.54 – 25.41

Table 10: Keratometry values

Keratometry measurement (N=123) :-

Done 59

Not done 64

Keratometry (Dioptres), N=59	**n(%)**
<40	1(1.69%)
40 - 43	4 (6.78%)
43 – 44	1 (1.69%)
44 – 47	52 (88.14%)
≥47	1 (1.69%)

The keratometry mean was 43.90D, (SD 1.07), median 44, range 39.44 – 48.24.

The youngest patient who had keratometry readings was 7 months old, mean age for patients with keratometry readings was 91.29months, median 84months, (SD 49.17) range (7 – 180months)

6.2 Type of Surgery done

Table 11: Surgical Procedure done

Surgical procedure, N=123	**n(%)**
LWO+PPC+AV+IOL	92(74.80%)
LWO+IOL	20 (16.26%)
LWO	8 (6.50%)
LWO+PPC+AV	2 (1.63%)
ICCE	1 (0.81%)

Majority of the eyes -92 (74.80%) had LWO+PPC+AV+IOL, a majority of eyes-112(91.06%) had IOL inserted while the rest were planned for secondary IOL placement.

Table 12: Age and Surgical Procedure done

Surgical Procedure, N=123	**<1 year, N(20)**	**1 – 5 years, N(30)**	**6 - 10 years, N(42)**	**More than 10 years, N(31)**	**Total**
	n(%)	**n(%)**	**n(%)**	**n(%)**	
LWO+PPC+AV+IOL	12 (60.00%)	27 (90.00%)	35 (83.33%)	12 (38.71%)	86 (69.92%)
LWO+IOL	1 (5.00%)	2 (6.67%)	4 (9.52%)	13 (41.94%)	20 (16.26%)
LWO	6 (30.00%)	0	0	2 (6.45%)	8 (6.50%)
LWO+PPC+IOL	0	0	3 (7.14%)	3 (9.68%)	6 (4.88%)
LWO+PPC+AV	1 (5.00%)	1 (3.33%)	0	0	2 (1.63%)
ICCE	0	0	0	1 (3.23%)	1 (0.81%)

Majority of the younger patients (60% of those <1year and 90% of those 1-5years) underwent LWO+PPC+AV+IOL.

6.3 Post-operative Visual Acuity Outcome

Table 13**: Post-operative Visual Acuity**

Post-operative visual acuity, N=123	**Pre-op VA n (%)**	**Post operative VA**				
		1st POD N=123	**1-3 wks N=106**	**4-11 wks N=69**	**12+ weeks N=48**	**6 months N=33**
6/18 or better	4 (3.25%)	9 (7.32%)	17(16.04%)	9 (13.04%)	9 (18.75%)	7 (21.21%)
<6/18-6/60	11 (8.94%)	26(21.14%)	25 (23.58%)	23 (33.33%)	12 (25.00%)	6 (18.18%)
<6/60-3/60	6 (4.88%)	8 (6.50%)	4 (3.77%)	2 (2.90%)	1 (2.08%)	0
<3/60	61(49.59%)	30 (24.39%)	25(23.58%)	16 (23.19%)	9 (18.75%)	7 (21.21%)
Can pick 1mm object at 33 cm	0	4 (3.25%)	10 (9.43%)	9 (13.04%)	2(4.17%)	5 (15.15%)
Cant pick 1 mm object at33cm	13 (10.57%)	5 (4.07%)	4 (3.77%)	2 (2.90%)	3 (6.25%)	5 (15.15%)
Following Light	24(19.51%)	24(19.51%)	15(14.15%)	6(8.70%)	12(25.00%)	3(9.09%)
Not recorded*	4 (3.25%)	17 (13.82%)	6 (5.66%)	2 (2.90%)	0	0

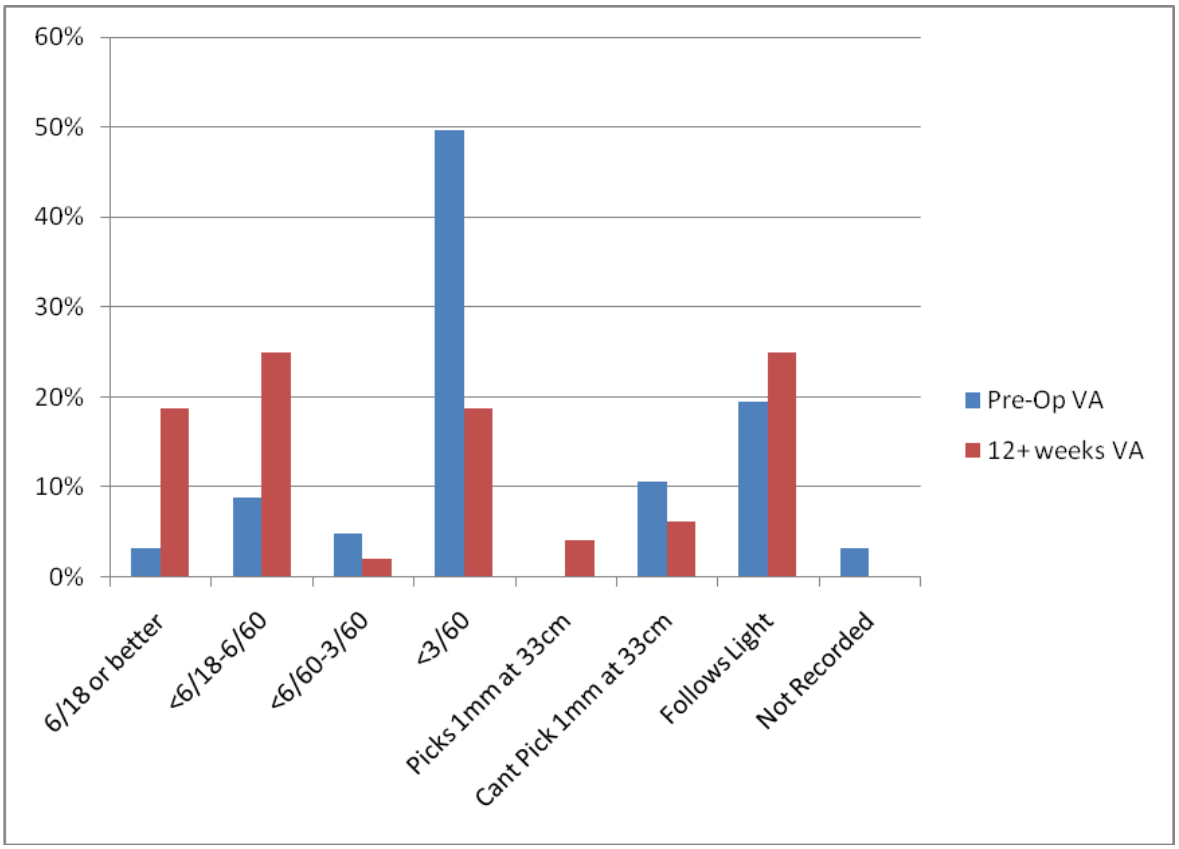
There was a statistically significant improvement in visual acuity (VA) on subsequent follow-up from the Pre –operative to 1st POD (***p-value<0.001***), also between the 1st POD and 1-3weeks (***p-value<0.012***), There was no subsequent further improvement of VA at 4-11 weeks onwards (*p-value=0.333*)**.**

Table 14: Visual acuity outcome classification as per WHO expected outcome at 4-11weeks and 12+ weeks*****.

Visual Acuity Outcome		**Post –Operative Visual Acuity with available correction**			
		Guidelines		**4-11 weeks**	**12+ weeks**
		WHO	**KCCO**	**N=50**	**N=31**
Good	6/18 or better	**>80%**	**>70%**	9(18.00%)	9(29.03%)
Borderline	<6/18-6/60	**<15%**		23(46.00%)	12(38.71%)
Poor	<6/60	**<5%**	**<5%**	18(36.00%)	10(32.26%)

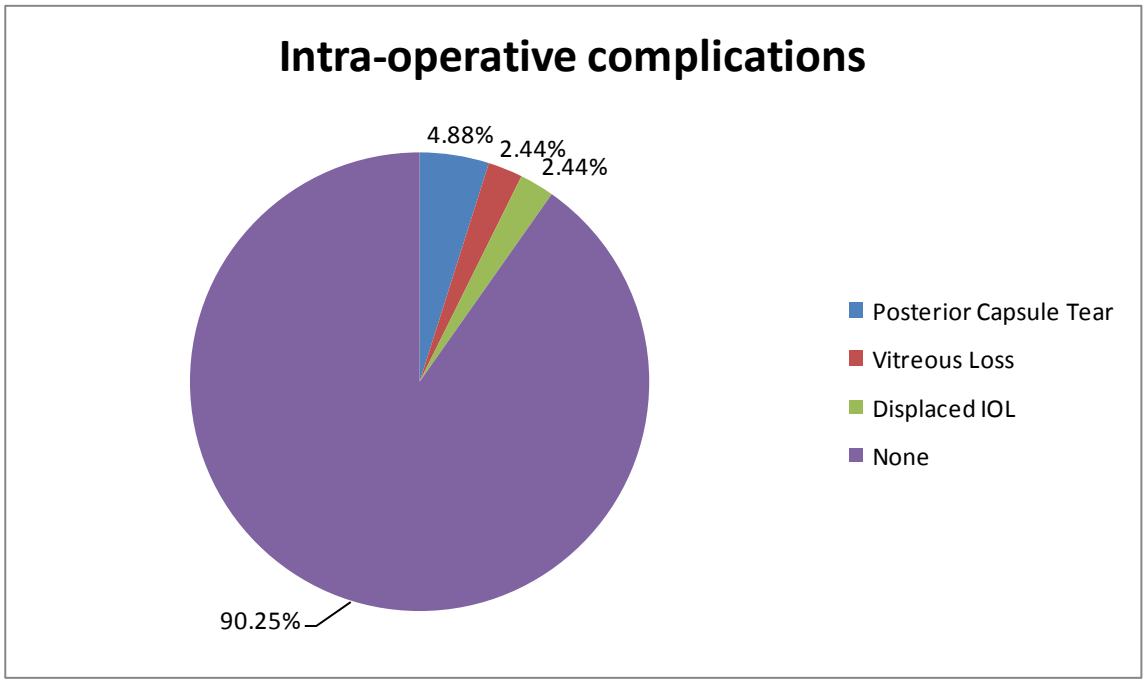
***** Only includes patients who had quantitative VA assessment.

Figure II: Graph depicting Visual acuity outcome at 12+weeks



6.4 Intra-operative/Post-operative complications

Figure III: Intra-operative complications, N=123



Intraoperative complications were noted in 12eyes (9.76%), with the most common being posterior capsule tear in 6 eyes (tear of posterior capsule before intended primary posterior capsulotomy).

Table 15: Post-Operative Complications

Post-operative complications, N=123	**Post –Operative period**				
	1st POD N=123	**1-3 wks N=101**	**4-11 wks N=63**	**12+ weeks N=45**	**6 months N=33**
Corneal haze	25 (20.33%)	11 (10.89%)	5 (7.94%)	3 (6.67%)	2 (6.06%)
Shallow ac	1 (0.81%)	1 (0.99%)	1 (1.59%)	0	0
Fibrin/ uveitis	9 (7.31%)	13 (12.87%)	9 (14.29%)	2 (4.44%)	2 (6.06%)
Hyphema	2 (1.63%)	0	0	0	0
Glaucoma	0	1 (0.99%)	2 (3.17%)	2 (4.44%)	0
Pupil abnormality	11 (8.94%)	16 (15.84%)	19 (30.16%)	17 (37.78%)	10 (30.30%)
Decentred IOL	0	6 (5.94%)	5 (7.94%)	5 (11.11%)	2 (6.06%)
PCO	3 (2.44%)*	11 (10.89%)	9 (14.29%)	12 (26.67%)	8 (17.78%)
Ambylopia	2 (1.63%)	9 (8.91%)	10 (15.87%)	11 (24.44%)	11 (33.33%)
Discharge	1 (0.81%)	0	3 (4.76%)	0	0
Synechiae	0	5 (4.95%)	3 (4.76%)	2 (4.44%)	4 (12.12%)
None	79 (64.23%)	56 (55.45%)	25 (39.68%)	16 (35.56%)	11 (33.33%)

* fibrous posterior capsule / plaque

No cases of Endophthalmitis/hypopyon were reported.

6.5 Refractive Outcomes

Table 16: Biometry results

Biometry (N=123):-

Done 58

Not done 65

IOL Power(Dioptres), N=58	**IOL Calculated, N= 58**
	n(%)
<15	1 (1.72%)
15-19.99	13(22.41%)
20-24.99	12(20.69%)
25-29.99	16(27.59%)
>30	16 (27.59%)

The IOL power calculated on biometry; - Mean was 25.76D (SD=6.97), median=26D, range (14-42.5D)

IOL power inserted; - Mean was 23.36D (SD=4.17), median = 23.5D, range (15-30D)

Table 17: Type of post operative correction

Type of post operative correction, N=123	**<1 year, N=20**	**1 – 5 years, N=30**	**6 - 10 years, N=42**	**More than 10 years, N=31**	**Total, N=123**
	n(%)	**n(%)**	**n(%)**	**n(%)**	
IOL	8 (40.00%)	18 (60.00%)	21 (50.00%)	13 (41.94%)	60 (48.78%)
IOL + Spectacles	4 (20.00%)	9 (30.00%)	21 (50.00%)	12 (38.71%)	46 (37.40%)
Spectacles	0	0	0	1 (3.23%)	1 (0.81%)
Spectacles + telescope	0	0	0	1 (3.23%)	1 (0.81%)
IOL +spectacles+IOL exchange	0	2 (6.67%)	0	0	2 (1.63%)
IOL exchange/ secondary	5 (15.00%)	0	0	2 (6.45%)	7 (5.69%)
None	3 (15.00%)	1 (3.33%)	0	2 (6.45%)	6 (4.88%)

57 patients (46.34%) had further post-operative refractive correction after the primary surgery procedure.

Table 18: Post –op spherical refractive error

Refraction (N=123)

Done 72

Not done 51

Post-op error, N=72	**Biometry done, N=46**	**Biometry not done, N=26**	**Total, N=72**
	n(%)	**n(%)**	**n(%)**
Absolute Spherical error N=72			
0 -0.99	10 (21.74)	2 (7.69%)	12 (16.67%)
1-1.99	12 (26.09%)	5 (19.23%)	17 (23.61%)
2-2.99	9 (19.57%)	3 (11.54%)	12 (16.67%)
3-3.99	4 (8.70%)	5 (19.23%)	9 (12.50%)
>4	11 (23.91%)	11 (42.31%)	22 (30.56%)

The mean absolute spherical error in eyes who had pre-operative biometry was 2.61D (SD=2.20), median=2, range (0.125 – 9D)

The mean absolute spherical error in eyes who did not have pre-operative was5.11D (SD=4.48), median=3.375, range (0.125 – 17D)

The mean absolute spherical error for all the eyes was 3.51D (SD=3.40), median=2.375, range= 0.125 – 17

Table 19: Post-operative cylindrical refractive error

Post-op error, N=72	**n(%)**
Cylindrical error N=72	
0 -0.99	16 (22.22%)
1-1.99	30 (41.67%)
2-2.99	13 (18.06%)
3-3.99	7 (9.72%)
>4	6 (8.33%)

The Mean cylindrical error was 1.80D (SD1.4), median=1.5D, range (0 – 6D)

6.6: Causes of Poor Visual Outcome

Table 20: Causes of poor Vision Outcome at 12+ weeks.

Attributable cause of poor vision	**No. Of Eyes with poor Visual Outcome (VA<6/60)**
	12weeks, N= 13
	n(%)
Patient Selection	9(69.23%)*
Ambylopia	6(46.15%)
Intra-op Complications	1(7.69%)
Keratopathy	2(15.38%)
PCO	3(23.08%)
Glaucoma	2(15.38%)
Unknown	3(23.08%)

*Nystagmus (5), Squint (1), Microphthalmos (2), Uveitis (1)

Multiple responses

Of the 2 eyes seen at 12+ weeks with glaucoma, both had poor visual outcome.

Table 21: Correlation between various variables` and visual outcome at 12+ weeks of follow-up, N=36.

Variable N= 36 eyes	**Good outcome N=23**	**Bad outcome N=13**	**OR (95% CI)**	**p-value**
Gender				
Male (23)	14	9	0.69 (0.16 –	0.6208
Female (13)	9	4	3.01)	
Nystagmus				
Present (10)	5	5	0.44 (0.10 –	0.2887
Absent (26)	18	8	2.07)	
Type of cataracts*				
Congenital (12)	6	6	0.19 (0.03 –	***0.0444***
Developmental (19)	16	3	1.17)	

*Does not include 5 observations for unknown type of cataract.

Good outcome at 12 week was in 25 eyes (52.08%) while bad outcome was 23 eyes (47.92%)

7. DISCUSSION

7.1. Pre-operative Characteristics

The records of 104 children who had cataract surgery were identified, 5 files were missing and 9 cases of traumatic cataract were excluded from the study (Figure I).

A total of 90 patients were included in the study, with 62.2% of them being male and female at 37.8 %(Table 1), this was a statistically significant sex difference (**p-value<0.001**). Such a statistically significant difference was also noted in a Kenyan study done by Saiba et al at Kenyatta National Hospital (KNH) who had a male: female ratio of 3:2[10]. Mwende et al in a study done in Tanzania had a 55% to 45% male: female ratio while in another previous Kenyan study done at Kikuyu Eye unit by Yorston et al, two thirds of the patients were male[8,19]. The reasons for the male preponderance is not known although it is postulated that it was due to greater value accorded to male children in traditional societies and girls eye conditions are not prioritised[19,8]. A study done in Denmark, a developed nation, showed a higher male number with childhood cataract as compared to female children, however the difference was not significant[32].

In the age distribution (Table 1), only 14.44% of the patients were less than 1year, with the youngest child being 2months old while the oldest was 15years old, mean age was 80.7 months, (SD: 54.25), median 72 months. A larger proportion of female patients (23.53%) presented at an age less than one year compared to male patients (8.93%) (Table 2).

A total of 123 eyes of the 90 patients underwent surgery with 57 unilateral cases and 33 bilateral cases (Table 1).

In the pre-operative visual acuity (Table 3), a large proportion of the eyes,61 (49.59%) were classified as blind (WHO Visual Acuity <3/60), while a further 13(10.57%) eyes of children assessed using 100/1,000 could not pick a 1mm object at 33cm. Only in a minority 4 eyes the visual acuity could not be assessed or was not documented. Visual acuity testing involved use of different tests. In the Kikuyu Eye Unit study, 75% of the eyes had a visual acuity less than 3/60[19]. Accurate VA evaluation in this diverse group of patients being difficult especially in the non-verbal children because of age, cultural or linguistical challenges[33], this was reflected in the number of children who had visual acuity taken using the non quantitative method of ability to follow light, 24(19.51%).

The study showed a long delay between onset and presentation with 68.54% later than 6 months after the onset.(Table 4). In this study, there was a longer delay in presentation among patients with congenital cataract (mean duration of 40.23months (1-168mnths), median 24months) than those with developmental cataract (mean 29.37(2-168mnths), median 14.5months). This is in comparison to the study at KNH which had a mean of 6.4months for congenital and 35.7months in developmental cataract[10], and 25.3 and 40.8months respectively in a Tanzanian study[8]. The longer mean delay in presentation among patients with congenital cataract was probably related to the accessibility to healthcare, with Mwende et al in their study in Tanzania on delay in presentation finding that in congenital cataract there was a wide variance in presentation delay with proximity to the hospital being the most important contributing

factor. Sabatia hospital receives patients with congenital cataract from remote districts/outreach programs resulting in larger numbers of older children with congenital cataracts. Other factors relating to presentation delay in other studies were awareness of the problem (and surgical interventions) and acceptance of surgical services[8]. For childhood cataract, the need for early surgery is influenced by occurrence of ambylopia and severe visual impairment[18,33].

Preoperative examination revealed the most common associated problems were nystagmus and strabismus in 35 and 33 eyes respectively (Table 5). This is probably due to the delay in presentation. These two problems have been shown to be a poor prognostic factor in childhood cataract surgery outcome. Other associated problems were microphthalmos and synechiae that have been described to contribute to difficulty in surgery.

Posterior segment examination was only possible in a small minority of the eyes preoperatively (8 eyes or 6.50%), all of which had a normal posterior segment (Table 6). A similar distribution of bilateral and unilateral cataracts was noted for both congenital (16 and 21 patients) and developmental cataracts (18 and 23 patients) respectively (Table 7).

The corneal diameter was done in 12 patients with a range of 8-13mm, the smallest measured corneal diameter was 8mm and the longest was 13mm. Patients with corneal diameters less than 9mm were regarded as having microphthalmos/nanopthalmos. Axial length and keratometry values were available for 54 and 59 patients, with the youngest patient being 7months old, range of 7-180 months, mean of 91.29months

(Table 9 & Table 10). The mean axial length was 21.56mm (SD 2.31), while the mean keratometry finding was 43.90D. Biometry requires the cooperation of the child, and few young children less than 3years had biometry done, as described also in the study done at Kikuyu[19].

7.2. The Surgery

A majority of the cases – 92eyes (74.80%) of the patients underwent Lens Washout with primary posterior capsulotomy, anterior vitrectomy and intraocular Iens placement (Table 11). Of note, 91.06% of the eyes had intraocular lens placement (Table 12), with a higher proportion of those above 1 year having the lens placement. 11 patients did not have IOL placement due to factors that included small eye, lack of capsular support or very young age. Fewer patients aged more than 10years old (38.71%of the eyes) had an anterior vitrectomy and primary posterior capsulotomy as compared to younger patients. A study done in Ethiopia showed a lower number having intraocular lens placement in 65% of the eyes and vitrectomy was performed in only 44 of the 91 eyes[33]. The KNH study had a low rate of primary IOL placement at 23.1%[10].

7.3. Post operative visual acuity outcome

On post-operative follow-up, there was general reduction in the number of eyes reviewed in subsequent visits with 69 eyes seen at the 4-11 weeks follow-up, at 6+months follow-up only data found was for 33 eyes (Table 13). There was an improvement of visual acuity in subsequent visits from the first post-operative day with

47.92% of the eyes having vision better than 6/60 and/or picking 1mm objects at 33cm at 12+weeks. A significant proportion of eyes still had poor vision at the 12+ weeks of follow-up period, with 27.08% or 10eyes of those seen having vision less than 6/60, the major reason for the poor vision being ambylopia and posterior capsular opacity with 11 (33.33%) eyes and 8 (17.78%) eyes respectively. In this study, there was statistically significant improvement of vision in the follow-up periods from pre-operative to 1-3weeks of follow-up (***p=<0.001*** at 1st POD and ***p=0.012*** at 1-3weeks). This is similar to the study at KNH that showed statistically significant improvement at 2months and no further improvement subsequently[10]. This shows the importance of good follow-up for these children with other treatment such as ambylotherapy and refractive correction as they still have ability to gain useful vision[8]. Visual outcome was poor using the WHO visual outcome guidelines(Table 14) at 4-11 weeks and 12+weeks with 32.26% of those who had the quantitative visual acuity record having 'poor' outcome at 12+weeks (versus guideline of <5%) and 29.03% having 'good' outcome[31,30]. In the Ethiopian study, the target post-operative visual acuity was defined as "ambulatory'' vision which is vision better than hand movement, which was achieved in 82% of the eyes. VA improvement has been shown to result in a decrease of the socioeconomic burden of the treated children[33]. Yorston et al had 37.3% of eyes on follow-up upto 24 months having "good" visual outcome(vision 6/18 or better)[19], while the study at KNH had 33.3% of the eyes at 6months having vision less than 6/60[10].

7.4. Intra-operative/post operative VA

Intraoperative complications noted were (Figure III) in 12 eyes(9.76%), the reported complications were as follows: posterior capsular tear in 6 eyes (4.88%) which was a capsular tear that occurred prior to the planned posterior capsulotomy, vitreous loss and displaced IOL were the other complications noted. This was similar to the Indian study that had posterior capsule tear at 7.6% and total complications at 8.9%[15]. The study done in Ethiopia had 9.9% having complications [33].

In the early post- operative period, on the first post-operative day, the commonest eye examination finding was corneal haze in 25 eyes (20.33%) which decreased in the subsequent visits (Table 15). There was little fibrinous uveitis (highest at 4-11weeks of follow-up with 9 eyes (14.29%)) as compared to 59.2% noted in a study by Namani at 1-2weeks of follow-up[20], in this study, it was found in 13eyes(12.87% at 1-3weeks of follow-up. Saiba et al however had 4.1% at 2months follow-up with no report at an earlier follow-up period[10]. In a study done in India by Khanna et al, fibrin reaction was the most common early (occurring within 3 months) post-operative complication at 13.3%[15], while the most common late(occurring after 3months) post-operative complication in the same study was PCO at 27.4%. In this study, PCO was noted in 26.67% of eyes at a similar follow-up period of 12weeks. Pupillary abnormality (37.78% at 12weeks and 30.30% at 6months) and Ambylopia (24.44% at 12weeks and 33.33% at 6months) were the most common complications noted on longer follow-up. There were no cases of endophthalmitis, other studies in similar centres did not report

such cases[10,33]. However in an Indian study with larger number of eyes, 2 cases of endophthalmitis were noted[15].

7.5. Refractive Outcomes

A comparison between the IOL power calculated on biometry and the IOL actually inserted in 58 eyes which had both values are analysed in (Table 16), the mean IOL inserted was 23.36D (median=23.5D) as compared to a mean calculated of 25.76D (median=26D) showing a tendency to under correct the operated eyes which had biometry by a mean value of 2.4D, although this was also influenced by the availability of IOL powers ranging from 15 to 30D as opposed to biometry results giving a range of 14 to 42.5D, however a majority of patients had under correction by 0.50 to 1D.

Type of post-operative correction used was also investigated (Table 17), 46 cases had spectacle correction given in addition to the IOL. Most patients got lost to follow-up before refraction would be done and correction dispensed, with refraction results only available for 72eyes. A total of 9(7.32%) eyes underwent IOL exchange or secondary IOL placement, 6 patients who did not have a primary IOL placement were lost to follow-up and therefore had no refractive correction.

A total of 72 eyes had refraction done during the 6 month follow-up period. The late refraction findings showed a mean absolute spherical refractive error of 3.51D (SD=3.40), range (0-125-17D), median 2.375D, Cylindrical error mean 1.80D (SD=1.4), range (0-6) and median of 1.5D (Table 18 and Table 19).A Tanzanian study had early post-operative spherical error of more than 2D in 51% of the eyes and a cylinder of more than 3D in 47% of the eyes[29]. Of note, as shown in the table, patients who had

biometry done had a smaller refractive error (mean=2.61D) than those who did not have any biometry done (mean=5.11D). A similar study had shown higher post-operative refractive errors in eyes that did not have biometry but also questioned the role of biometry in children who undergo a large refractive change as they grow[19], while in the Tanzanian study biometric data was not associated with a smaller post-operative error[29].

7.6. Causes of Poor VA outcome

Both of the eyes with glaucoma seen at 12+weeks had poor visual acuity outcome (Table 20). Significant complications in eyes with poor visual acuity were pupillary abnormalities and Ambylopia at 12 weeks.

Correlation between factors of interest, i.e. gender, type of cataract, pre-operative presence of nystagmus and the outcome of cataract surgery at 12 weeks of follow-up was analysed by chi-square (Table 21), and showed male children were less likely to have better outcome, OR 0.69 (0.16-3.01) but was not statistically significant (*p =0.6208*), congenital cataracts was associated with a worse outcome, OR 0.19(0.03-1.17) and was statistically significant (***p=0.0444***), presence of nystagmus was less likely to have a good outcome, OR 0.44 (0.10-2.07) but was not statistically significant (*p=0.2887*). This was similar in to the other African study in Ethiopia which showed a poorer visual outcome (p<0.001) in patients who had pre-operative nystagmus[33] . However with only 36 eyes (29.27%) of the initial 123 operated eyes, the number used for correlation analysis was small and limited interpretation of the results. In the Indian study, on multivariate analysis only congenital cataract and total cataract were noted to be a significant risk factor for poor outcome. Congenital cataract surgery visual outcome

was 20 times likely to be poor as compared to developmental cataract in that study[15].
In our study, ambylopia was the significant cause of poor vision at 12+ weeks and also at 6 months of follow-up, Saiba et al also concluded that ambylopia was the most common cause of poor vision in his study[10].

8. CONCLUSION

In conclusion, Visual acuity improved in the subsequent follow-up periods, however there was a higher proportion of children who had poor visual acuity outcome as compared to WHO and KCCO guidelines.
Commonest intra-operative complication seen was posterior capsular tear. The rate of complications was similar to other studies.
Corneal haze was the commonest complication early in the post-operative period while Pupillary abnormality, Ambylopia and PCO were the most common later complications.
Many patients had IOL of lesser power than calculated inserted.
Refractive outcome was better and less variable in patients who had biometry before surgery.
There was a high loss to follow-up with resultant lack of refraction/spectacle correction.
Congenital cataract was significantly associated with a poorer outcome in this study.
Development of Ambylopia was the commonest cause of poor vision.

9. RECOMMENDATIONS

There is need to develop and strengthen follow-up programs for the children undergoing cataract surgery to avoid high drop-out from follow-up.

There is need to have biometry readings done for all patients undergoing cataract surgery.

The hospital to ensure that all patients undergoing cataract surgery have spectacle correction postoperatively.

Enhancement of ambylopia treatment for patients on follow-up.

To consider pre-operative use of B-scan ultrasound in those patients whose posterior segment cannot be accessed to rule out posterior abnormalities that could have contributed to poor outcome.

There is need for long-term prospective study of children undergoing cataract surgery to document long-term outcome.

10. STUDY LIMITATIONS

This was a retrospective study and data available for extraction was only that which the different attending clinicians had recorded.

The cataract surgeries were performed by different surgeons.

There was a high loss of follow-up with only 39% of eyes seen at 12+ weeks and this may have affected outcome results interpretation as it is not known whether a disproportionate number of children with either poor or good outcome got lost to follow-up.

11. REFERENCES

1. Wilson E, Triveldi R. Cataract in Children. The Epidemiology of Eye Disease. 3rd Ed. London: Imperial College Press; 2012. p. 331–40.

2. WHO. VISION 2020 Global Inititiative for the elimination of avoidable blindness - Action Plan 2006-2011 [Internet]. WHO; 2007. Available from: www.who.int

3. Shammana B, Muralikkrish R. Childhood Cataract:Magnitude, Management, Economics and Impact. CEH. 2004;17(50):17–8.

4. Waddell KM. Childhood blindness and low vision in Uganda. Eye (Lond). 1998;12 (Pt 2):184–92.

5. Gilbert CE, Wood M, Waddel K (et al). Causes of childhood blindness in east Africa: results in 491 pupils attending 17 schools for the blind in Malawi, Kenya and Uganda. Ophthalmic Epidemiol. 1995 Jun;2(2):77–84.

6. Gogate P, Gilbert C, Zin A. Severe visual Impairment and blindness in infants: Causes and opportunities for control. Middle East African Journal of Ophthalmology. 2011;18(2):109.

7. Brian G, Taylor H. Cataract blindness-challenges for the 21st century. Bulletin of the World Health Organisation. 2001;79(2):249–56.

8. Mwende J, Bronsard A, Mosha M (et al). Delay in presentation to hospital for surgery for congenital and developmental cataract in Tanzania. British Journal of Ophthalmology. 2005 Nov 1;89(11):1478–82.

9. Wilson ME, Pandey SK, Thakur J. Paediatric cataract blindness in the developing world: surgical techniques and intraocular lenses in the new millennium. Br J Ophthalmol. 2003 Jan;87(1):14–9.

10. Saiba S, Kimani K, Ilako D. Outcome of childhood cataract surgery. East African Journal of Ophthalmology. 2008 Nov;13–8.

11. Chirambo MC, Tielsch, West KP (et al). Blindness and Visual Impairment in Southern Malawi. Bulletin of the World Health Organisation. 1986;64(4):567–562.

12. Njuguna M, Msukwa G, Shilio B (et al). Causes of Severe Visual Impairment and Blindness in Children in Schools for the Blind in Eastern Africa: Changes in the Last 14 Years. Ophthalmic Epidemiol. 2009 Jan 1;16(3):151–5.

13. Wilson E, Triveldi R. Childhood Blindness and Pediatric Cataract. Cataract&Refractive Surgery Today. 2005 Oct;52–4.

14. Kugelberg U. Visual acuity following treatment of bilateral congenital cataracts. Doc Ophthalmol. 1992 Sep 1;82(3):211–5.

15. Khanna R, Foster A, Krishnaiah S (et al). Visual outcomes of bilateral congenital and developmental cataracts in young children in south India and causes of poor outcome. Indian Journal of Ophthalmology. 2013;61(2):65.

16. Laurence C, Jean LA, Eric CC (et al). Visual outcome after paediatric cataract surgery: is age a major factor? Br J Ophthalmology. 1998;82(9):1022–5.

17. Sandford-Smith J. Eye diseases in Hot Climates. Fourth Edition. India: Elsevier; 2003. 434 p.

18. AAO. Paediatric Ophthalmology and Strabismus. BASIC CLINICAL SCIENCE COURSE. 2012/13 ed. San Francisco: American Academy of Ophthalmology; 2012. p. 245–66.

19. Yoston D, Wood M, Foster A. Childhood Blindness and Pediatric Cataract. Br J Ophthalmology. 2001;85:267–71.

20. Namani M. Review of Childhood Cataract Surgery at Kikuyu Eye Unit. [Department of Ophthalmology]: University of Nairobi; 2007.

21. Gradin D, Mundia D. Simultaneous Bilateral Cataract Surgery With IOL Implantation in Children in Kenya. J Pediatr Ophthalmol Strabismus. 2012 Jun;49(3):139–44.

22. Infant Aphakia Treatment Study (IATS) [Internet]. ClinicalTrials.gov; 2013. Available from: Lambert Scott R

23. Lambert SR, Lynn MJ, DuBois LG (et al). Axial Elongation following Cataract Surgery during the First Year of Life in the Infant Aphakia Treatment Study. Investigative Ophthalmology & Visual Science. 2012 Oct 16;53(12):7539–45.

24. Eibschitz-Tsimhoni M, Archer SM, Del Monte MA. Intraocular lens power calculation in children. Surv Ophthalmol. 2007 Oct;52(5):474–82.

25. Neely DE, Plager DA, Borger S (et al). Accuracy of intraocular lens calculations in infants and children undergoing cataract surgery. J AAPOS. 2005 Apr;9(2):160–5.

26. Wilson ME, Pandey SK, Thakur J. Paediatric cataract blindness in the developing world: surgical techniques and intraocular lenses in the new millennium. British Journal of Ophthalmology. 2003 Jan 1;87(1):14–9.

27. Eriksen JR, Bronsard A, Mosha M,(et al). Predictors of poor follow-up in children that had cataract surgery. Ophthalmic Epidemiol. 2006 Aug;13(4):237–43.

28. Courtright P. Childhood cataract in sub-Saharan Africa. Saudi Journal of Ophthalmology. 2012 Jan;26(1):3–6.

29. Bowman RJC, Kabiru J, Negretti G (et al). Outcomes of bilateral cataract surgery in Tanzanian children. Ophthalmology. 2007 Dec;114(12):2287–92.

30. WHO Programme for the Prevention of Blindness and Deafness. Informal Consultation on Analysis of Blindness Prevention Outcomes (1998: Geneva, Switzerland). WHO/PBL/9868. 1998;1–23.

31. Courtright P, Bowman R, Gilbert C (et al). Childhood Cataract in Africa. Kilimanjaro Centre for Community Ophthalmology (KCCO); 2008.

32. Haargaard B, Wohlfahrt J, Fledelius HC (et al). Incidence and Cumulative Risk of Childhood Cataract in a Cohort of 2.6 Million Danish Children. Investigative Ophthalmology & Visual Science. 2004 May 1;45(5):1316–20.

33. Tomkins O, Ben-Zion I, Moore DB (et al). OUtcomes of pediatric cataract surgery at a tertiary care center in rural southern Ethiopia. Arch Ophthalmol. 2011 Oct 1;129(10):1293–7.

12. APPENDIX

12.1. Questionnaire

OUTCOME OF CHILDHOOD CATARACT SURGERY AT SABATIA EYE HOSPITAL

A. SOCIO – DEMOGRAPHIC DATA

No.....

Sex :- 1. ☐ Male 2. ☐ Female

Age:- Years:-..... Months:-.....

B. PRE-OPERATIVE EXAMINATION

Eye RE ☐ LE ☐

VISION :- (*tick)

				RE V/A		LE V/A	
	Snellen	**Decimal**	**Logmar**	**Presenting**	**Best/PH**	**Presenting**	**Best/PH**
1.	**6/6**	**1**	**0**				
2.	**6/9**	**0.63**	**0.2**				
3.	**6/12**	**0.50**	**0.3**				
4.	**6/18**	**0.33**	**0.5**				
5.	**6/24**	**0.25**	**0.6**				
6.	**6/36**	**0.17**	**0.8**				

7.	**6/60**	**0.10**	**1.0**				
8.	**3/60**	**0.05**	**1.3**				
9.	**1/60**	**0.02**	**1.8**				
10.	**PL+**	**PL+**	**3**				
11.	**Can pick 1mm object at 33cm**						
12.	**Cant pick 1mm object**						
13.	**Cannot be tested**						

Duration..... ....

Other Problems: 1. Strabismus ☐ ☐

2. Nystagmus ☐ ☐

3. Photophobia ☐ ☐

4. Glaucoma ☐ ☐

5.Corneal opacity ☐ ☐

5. Other(specify:- ☐ ☐

....

RE **LE**

Posterior Segment accessible:- 1. Yes ☐ ☐

2. No ☐ ☐

If yes: Findings:-1. Normal ☐ ☐

2. Abnormal (specify)..... .....

 ☐ ☐

Type of Cataract: 1. Congenital

2. Developmental ☐ ☐

3. Other (specify) ....

Corneal diameter: 1. Horizontal .....mm .....mm

2. Vertical .....mm .....mm

Biometry :- 1. Axial length ....

2. Keratometry ....

3. IOL Power ....

Target Post-Op spherical equivalent ....

Pre-op Cycloplegic Refraction:- ....

C. SURGICAL PROCEDURE

1. LWO ☐ ☐
2. PPC ☐ ☐
3. AV done ☐ ☐

	RE	LE
4. IOL inserted	☐	☐
5. Other (specify)	.....	.....

Post-Operative Correction (tick all that apply)

1. IOL ☐ ☐
2. Contact Lenses ☐ ☐
3. Spectacles ☐ ☐
4. Other (specify) ....

Refraction:-

1. Post-Op Refraction ....
2. Time of refraction post-op(weeks)..... .....

D. INTRAOPERATIVE COMPLICATIONS

1. Hyphema ☐ ☐
2. Iris tear/trauma ☐ ☐
3. PC tear ☐ ☐
4. Vitreous loss ☐ ☐
5. Displaced IOL ☐ ☐
6. Other (list) ....

E.POST-OPERATIVE FOLLOW - UP

Visual Acuity:

	Week of presentation	Presenting VA		Best Corrected VA		
		RE	LE	RE	LE	
1st PostOp day						
1-3 weeks post-op						
4-11 weeks post op						
12+ weeks follow-up						
6 months						

POST-OPERATIVE COMPLICATIONS

1. Iris prolapsed
2. Corneal haze
3. Shallow AC
4. Fibrin
5. Hyphema
6. Endophthalmitis/Hypopyon
7. Glaucoma
8. Pupil abnormality
9. Seclusio/Occlusio
10. Decentered IOL
11. PCO
12. Amblyopia
13. Other (specify:-)

***List all (code above) that apply**

	RE	**LE**
1st Post- Operative day		
1-3weeks Post op		
4-11 weeks post op		
12+ weeks		
6 months		

12.2. Timeframe

TIME(YEAR &MONTH) / ACTIVITY	2013												2014				
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M
Concept and Preparation of Proposal	■	■	■														
Presentation to Departmental Faculty				■													
Ethical Approval					■	■	■	■	■	■	■						
Budget Approval											■	■					
Preparation of Study materials/Training of Assistants												■	■				
Data collection													■				
Data Analysis and Results presentation													■	■			
Preparation and Submission of Thesis															■	■	■

12.3. Budget

ITEM	QUANTITY	UNIT COST (Ksh)	TOTAL (Ksh)
PRINTING			
Pilot questionnaires	6 pages	10	60
Photocopy pilot questionnaires	6*5	3	30
Proposal draft printing	33 pages	10	330
Final proposal printing	33 pages	10	330
Photocopy draft + final proposal	165	3	495
Proposal Binding	6	100	600
Printing of Questionnaire	6 pages	10	60
Photocopy of questionnaire	6*150	3	2,700
Printing results B/W	3*55	10	1,650
Photocopy B/W	55*8	3	1,320
Printing results color	3*15	20	900
Photocopy color	15*8	15	1,800
Binding final thesis	8	200	1,600
Subtotal			**11,875**
Ethics Committee fee			**2,000**
Travel, meals and Accomodation			
Pilot study bus fare	2 - Return	1,400	2,800
Meals			500
Main study bus fare	2 - Return	1,400	2,800
Accomodation	12days	2,000	24,000
Meals	12days	500	6,000
Subtotal			**36,100**
Contracted labor			
Biostatistician	1		35,000
Training of assistants	1*2days	2,000	4,000
Research assistant	1 *10 days	2,000	20,000
Subtotal			**83,000**
Communication			
Telephone, data and courier			**9,000**
GRANDTOTAL			**117,975**

12.4 Map

Location of Sabatia Eye Hospital:-

12.5 ETHICAL APPROVAL

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

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

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

Ref: KNH-ERC/A/397 Link:www.uonbi.ac.ke/activities/KNHUoN 9th December 2013

Dr. Samuel R.Ngandu
Dept.of Ophthalmology
School of Medicine
University of Nairobi

Dear Dr. Ngandu

RESEARCH PROPOSAL: OUTCOME OF CHILDHOOD CATARACT SURGERY AT SABATIA EYE HOSPITAL (P268/05/2013)

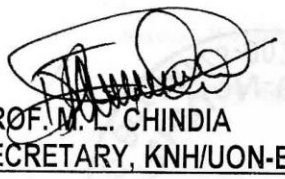
This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 9th December 2013 to 8th December 2014.

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 severe 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) 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*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
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 **www.uonbi.ac.ke/activities/KNHUoN.**

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. Prof. A.N.Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
The Dean, School of Medicine, UoN
The Chairman, Dept. of Ophthalmology, UoN
AD/Health Information, KNH
Supervisors: Dr. Kariuki M.M. Wanyoike, Dr. Nyenze E. Muindi, Dr. Ollando A.Ernest

12.6 APPROVAL FROM SABATIA EYE HOSPITAL

Friends Church - Sabatia Eye Hospital

P.O.Box 214
Wodanga 50311
Vihiga District, Kenya
Chavakali-Kapsabet-Eldoret Rd.
www.sabatiaeyehospital.org

Fax: 020 2393883
Zain: 0733 731013
Safaricom: 0723 721316
Landline: 020 2393883
email: sabeyehosp@gmail.com

28th January 2014

Dr. Samuel R. Ngandu,
Department of Ophthalmology,
University of Nairobi,
P.O. Box 30197 -00202
KNH- NAIROBI.

Dear Dr. Ngandu,

RE: OUTCOME OF CHILDHOOD CATARACT SURGERY AT SABATIA EYE HOSPITAL STUDY

Approval to carry out the above study is granted subject to ethical considerations as approved by the Ethics and Research Committee of KNH/UON.
Results and Recommendations from the study to be communicated to the hospital on conclusion of the study.
Kindly provide a bound copy of the study including results and recommendation to help improve services at the hospital.

Thank you,

Yours faithfully,

FRIENDS CHURCH
P. O. BOX 214,
WODANGA.
SABATIA EYE HOSPITAL

Dr. Ernest Ollando,
Medical Director /Consultant Ophthalmologist.

OUR MOTTO: "WE TREAT, HE HEALS"