DISSERTATION

PATTERN AND OUTCOME OF PEDIATRIC CATARACT SURGERY AT KWALE EYE CENTRE

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DECLARATION

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

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LIST OF ABBREVIATIONS AND ACRONYMS

AAO	–	American Academy of Ophthalmology
AV	–	Anterior Vitrectomy
BSV	–	Binocular Single Vision
TORCHES	-	Toxoplasmosis Rubella Cytomegalovirus Herpes Simplex
SICS	-	Small Incision Cataract Surgery
WTR	-	With the Rule
Nd: YAG	-	Neodymium -doped yttrium aluminum garnet
PPC	-	Primary Posterior Capsulotomy
KCCO	-	Kilimanjaro Centre for Community Ophthalmology
BRJO	–	British Journal of Ophthalmologists
DALY	–	Disability Adjusted Life Years
ECCE	–	Extra Capsular Cataract Extraction
HM	–	Hand Movement
VA	-	Visual Acuity
IOP	-	Intra ocular pressure
IOL	–	Intra-Ocular Lenses
KEU	–	Kikuyu Eye Unit
KNH	–	Kenyatta National Hospital
LAV	–	Lensectomy Anterior Vitrectomy
PCO	–	Posterior Capsular Opacity
PL	–	Perception of Light
WHO	–	World Health Organization

IMPORTANT DEFINITIONS

Child –A person aged below 15 years as defined by WHO

Outcome –Will be defined as visual acuity and complications post operation. Other measures of outcome will be intra-operative and postoperative complications.

Ambulatory vision –Visual acuity better than hand movement at last follow-up.

Congenital cataract - Cataract that occurred before 1 year of age.

Developmental cataract - Cataract that occurred after one year of age.

ABSTRACT

Objective

To assess the outcome of childhood cataract surgery in Kwale Eye Centre of surgeries performed between 1st January 2013 and 30th June 2016; to assess various factors such as pre-and post-operative visual acuity, complications that occurred intra and post-operatively and their pattern.

Methods

The study was a retrospective case series conducted at Kwale Eye Centre which is a hospital found in Kwale County of Kenya. Records of all children less than 15 years old who had surgery for congenital or developmental cataracts during the study period were assessed. Data was entered into a pre-formed questionnaire and analyzed. 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

Seventy-four patients (128 eyes) were included in this study the M: F ratio was 2:1. Most eyes were blind pre-operatively (42.2%). With available correction 47.0% of eyes had good and borderline visual acuity at the week twelve follow up visit. Most eyes were lost to follow-up by week 12 (61.7%).

The commonest early and late post- operative complications were corneal haze (11.72%) and posterior capsular opacity (21.05%) respectively. Post-operative complications (fibrinous uveitis), uncorrected refractive errors and pre-operative ocular comorbidities contributed to poor outcomes.

Refraction was done in most patients (92.9% of eyes) but spectacles were given only to 30% of children.

Conclusion

The percentage of eyes with good visual outcome was below WHO recommended standards 46.4 versus the recommended 80%. The intraoperative complication rate was low (10.1%) the commonest was hyphema which occurred in 2 eyes which thereafter resolved. The commonest early postoperative complication was corneal haze which was encountered on day 1 while the commonest late complication was posterior capsular opacity. Pre-operative ocular comorbidities (disc & chorodial coloboma, maculopathy, retinitis pigmentosa), post-operative fibrinous uveitis and uncorrected refractive errors contributed to poor visual acuity.

Recommendations

A standardized tool for capturing pre-operative, intra-operative and post-operative notes should be designed and used to avoid erroneous or missing data.

A vitrector should be functional at all times when doing cataract surgery in children so as to prevent PCO formation. Biometry should be done for all patients pre-operatively. Spectacles should be issued to all patients with post-operative refractive error.

1.0 INTRODUCTION

Cataract remains one of the most important avoidable causes of blindness in children. It has been estimated that there are 200,000 children blind from cataract worldwide, and that 20,000 - 40,000 children are born with cataract every year [1]. In developing countries, the prevalence of blindness from cataract is thought to be about 1–4/10,000 children. This is about 10 times higher than the figure for industrialized countries [1]. Waddell in Uganda (1998) showed Cataract to be the leading cause of blindness (30.7%) in East Africa [2].

Cataract accounts for 10% of all preventable visual loss in children globally [3]. Visual loss is mainly due to stimulus deprivation amblyopia, strabismus and nystagmus which are proportionately related to the size, location and density of the opacity, especially if bilateral[4].Severaldifferent classification systems exist including morphology, etiology, presence of specific metabolic disorders, associated ocular anomalies or systemic findings [3].

Cataracts in children present financial challenges to caregivers including lost earnings of visually impaired children's caregivers cost of visual aids, home modifications, and rehabilitation among others. It is also expensive to educate and care for a child with a cataract. Such a child has more (DALY) disability adjusted life years than an adult. Restoring the sight of one blind child may be equivalent to restoring the sight of 10 adults i.e. operating one cataract in a child is equivalent to operating ten cataracts in adults[5].

1.1 Definition of Cataracts

A cataract is defined as an opacification of the lens. In a child, they can be isolated or be part of a systemic condition and they can be unilateral or bilateral. When bilateral they are associated with

other systemic conditions. There's a short period before which intervention can be effective in preventing amblyopia [6].

The fixation reflex develops between 2-3 months of age and those that occur before this age have more impact on the child's visual development. Binocular single vision develops by 6 months of life and if intervention is not undertaken before this time the child may be left without stereopsis. The child may develop amblyopia which is difficult to treat [7]. Cataracts are common in older adults because the lens gets cloudy with age. However, a cataract can be present at birth or develop in childhood. If left untreated, a cataract in childhood can have lasting effects [8].

1.2 Childhood Blindness

1.2.1 Vision 2020

There are approximately 1.5 million blind children in the world; 90% of them live in developing countries [1]. The control of blindness in children is considered a high priority within the World Health Organization's (WHO's) VISION 2020 - The Right to Sight [9, 10]. There are several reasons for this: the great emotional, social, and economic costs to the child, the family, and society; in addition, many of the causes of blindness in children are either preventable or treatable. Although the total number of blind children is lower than of adults, the number of "blind years" due to childhood blindness is estimated to be like the number of cataract blind years" in adults [11].

1.2.2 Congenital Cataract

Congenital cataract is the leading cause of reversible blindness in childhood. Its occurrence, depending on the regional socioeconomic development, is 1- 6 cases per 10,000 live births in industrialized countries, and of 5 -15 per 10,000 in the poorest areas of the world [12]. They occur due to different causes, including metabolic disorders (galactosemia), infections during embryogenesis, gene defects and chromosomal abnormalities. Cataract may be an isolated anomaly, seen in association with another ocular developmental abnormality, or part of a multisystem syndrome, such as Down's syndrome, Wilson's disease, and myotonic dystrophy [13].

Inherited cataracts correspond to 8 to 25% of congenital cataracts, particularly for bilateral cataract, Rahi and Dezateux found that 27% of children with bilateral isolated congenital cataract had a genetic basis compared with 2% of unilateral cases [14]. Although X-linked and autosomal recessive transmission has been observed, the most frequent mode of inheritance is autosomal dominant with a high degree of penetrance. Inherited cataracts are clinically highly heterogeneous and show considerable inter and interfamilial variability.

1.3 Risk Factors, Prevention and Treatment

Pediatric cataracts may be congenital (hereditary/genetic; metabolic e.g. galactosaemia; and in-utero infection related, (toxoplasmosis, rubella, cytomegalovirus herpes simplex) TORCHES, developmental (genetic; and metabolic e.g. galactokinase deficiency); or acquired (metabolic e.g. diabetes mellitus; traumatic; and post radiotherapy).

There are at present no medical treatments available for congenital or developmental cataracts. However, in cases of galactosaemia early diagnosis and management of diet and enzyme

replacement therapy may allow mild cataracts to stop progressing and even regress [15]. Conservative management of partial cataracts may be considered using dilating drops to increase light entering the eye. While visual acuity is the main assessment of visual function, other testing methods (glare testing and contrast sensitivity) should also be used.

1.4 Childhood Cataract Surgery in Kenya

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

Several studies have previously been done looking at the outcome of cataract surgery in children in Kenya. These studies have reported many complications from childhood cataract surgery. For instance, in Kenyatta National Hospital, Saiba *et al* reported poor outcomes attributable to late presentation, poor aphakic correction, development of PCO and loss to follow up [16].

2.0 LITERATURE REVIEW

Literature reveals that Prevalence of childhood blindness varies from 0.2/1,000 children to over 1.5/1000 children worldwide. In East Africa prevalence of blindness from cataract is thought to be 1-4/10000 children; 10 times higher than the figure in developed countries [17].

2.1 Cataract surgery

Cataract is defined by WHO as clouding of the crystalline lens of the eye which prevents clear vision.

Various surgical techniques are currently used i.e.; Manual Small Incision Cataract Surgery (SICS) and Phacoemulsification (Phaco).

Gogate (2001) promulgates that all techniques of cataract extraction are being modified to achieve best uncorrected visual acuity and early rehabilitation. Therefore, conventional extra capsular cataract extraction was improved to manual small incision cataract surgery (SICS) and Phacoemulsification. Phacoemulsification is expensive due to high cost of foldable intraocular lenses IOLs and high cost of machine [18]. For developing countries like Kenya, Manual SICS is affordable and has given encouraging results [19].

Small incision cataract surgery is a technique whose aim is to extract the lens through a scleral tunnel and replace it with an artificial lens. In phacoemulsification, the aim is similar although it varies in terms of nucleus extraction, corneal incision and machinery used. The clear corneal incision used offers an advantage over SICS in that there is less post-operative astigmatism. Some surgeons use the clear corneal incision in SICS for the same reasons as above stated as well as the fact that pre-existing astigmatism can be corrected by the incision. The clear corneal

incision however has some disadvantages including wound leak, irregular astigmatism among others [8,21,22,23,24.]

The most common technique used in the developing countries is small incision cataract surgery due to lack of availability of phacoemulsification machinery and lack of familiarity with the technique among the surgeons in these countries [19]. A superior or temporal approach of forming the tunnel can be used although the former is commonly favored. Junejo *et al* (2009) review of visual outcomes and surgically induced astigmatism using manual extra capsular cataract extraction (ECCE) through a temporal approach followed by posterior chamber rigid intraocular lens (IOL) implantation found no increase in against the rule astigmatism, as the corneal incision was given through temporal approach [25].

2.2 Management of Pediatric Cataracts

The management of pediatric cataracts is mainly surgical. Various surgical techniques have been described in children. The procedure of cataract surgery is similar to small incision cataract surgery with some variations in the technique used.

The type of capsulotomy done; most surgeons use the envelope technique also known as push pull technique as opposed to can-opener or continuous curvilinear capsulorrhexis used in adults.

After nucleus delivery depending on the age of the child posterior capsulotomy and anterior vitrectomy is done (those younger than six years of age) while in older children the posterior capsule is left intact. The posterior capsulotomy and anterior vitrectomy are done to prevent formation of a posterior capsular opacification which is a common complication in cataract surgery in children. Another difference is the method of nucleus delivery whereby the lens is either aspirated out or Lensectomy done.

The rest of the surgery is similar to the adult surgery though the scleral tunnel is smaller 3mm as opposed to 6-8 mm in adults [8].

Various surgeons vary these techniques and studies have been done to assess the effectiveness of various combinations of the above techniques.

S. Fenton *et al* in a children's hospital in Dublin (1999) to assess the effectiveness of primary posterior capsulorrhexis without anterior vitrectomy in preventing posterior capsular opacification and showed that this technique was safe and that 84.4% had a clear visual axis at last follow up and 15.6% required Nd; YAG capsulotomy post op [20]. Khana's study in South India (2013) assessing visual outcomes in pediatric cataract surgery showed that the commonest technique they used was ECCE, PPC and AV and the eyes that didn't undergo PPC developed PCO and those that underwent it did not developed it [21].

Yorston *et al* in East Africa (2001) compared anterior vitrectomy, followed by lens aspiration, with preservation of the posterior capsule to posterior capsulorrhexis and attempted lens placement in the capsular bag and found that 44% of the eyes had good visual acuity and 91.2% had borderline and most of the eyes that did not have posterior capsulotomy at surgery required it post operatively [22.]

Namani in Kikuyu eye unit (2007) found that most of the patients had surgery via Lensectomy, Anterior Vitrectomy (LAV) & IOL insertion with preservation of the posterior capsule (61.2%), another group (21.5%) had extra-capsular cataract extraction(ECCE) plus IOL and 7.2% had ECCE, PPC and IOL and 15.4% of the patients developed PCO post-operatively [23].

Ngandu at Sabatia Eye Hospital (2012) found that many of the cases underwent Lens Washout with Primary Posterior Capsulotomy, Anterior Vitrectomy and Intraocular Lens Placement in the

bag and visual outcomes at 12 weeks' post–op was as follows 18.75 % of patients had good visual acuity, 25% had borderline visual acuity and 26.67% of patients developed posterior capsular opacification [24].

As part of cataract surgery in children it may be necessary to put in an optic device. When it comes to choosing the correct optic device for a child their age and laterality of the cataract are considered. For children aged 1-2 years and older IOL use is advocated. In infants, due to complications and rapid shift of refractive state, IOL use is controversial. Scott Lambert et al Infant Aphakia Treatment study (2014) New York is underway to asses IOL implantation in infant [25].It has so far shown that there was no difference in visual acuity when comparing IOL to aphakia with contact lens visual acuity at 1 and 4½ years .It has recommended that for children with unilateral cataracts under 7 months of age the eye be left aphakic and corrected with contact lenses because of more intra and perioperative complications in this age group IOL use is not indicated and for those [25].

Jaspreet *et al* in India (2014) assessed the outcome of IOL use in children under 2 years found that 92% of patients achieved good visual acuity at last follow up and 73% had visual acuity of 6/12 or better. Average age at surgery was 14.15 months the range was between 3 and 23 months and only 2 children were less than 6 months at the time of surgery. This study showed that use of IOL is safe in children under 23 months [26].

Gouws *et al* (2006) in Bristol Eye Hospital on long term results of primary posterior chamber intraocular lens implantation for congenital cataract in the 1st year of life on patients with bilateral and unilateral cataracts found that that those in the bilateral group achieved better outcome than the unilateral group and the mean refractive shift between first refraction after

surgery and refraction at *36* months after surgery was more in the unilateral than the bilateral group [27].

Selection of appropriate IOL power in a child is complicated because the child's eye continues to elongate throughout the first decade of life [8]. In addition, challenges are also encountered when calculating IOL power because of difficulty in obtaining accurate keratometry, and axial length measurements and use of power formulas that were developed for adults. Studies have also shown that the refractive error of an aphakic child undergoes a variable myopic shift of about 7-8 diopters from age 1-10 years if the presence of an IOL doesn't alter this [8].

Scott Lambert et al Infant Aphakia Treatment Study (2012) on axial elongation following cataract surgery during the first year of life showed that children with cataracts in whom an IOL was put had a more significant change in axial length than those for whom contact lenses were used [25].

Some surgeons under-correct the child and they use decreasingly hyperopic spectacles and attain emmetropia during teenage while others aim for emmetropia to prevent anisometropic amblyopia and encourage binocular function [8, 25].

Most authors agree that extra capsular cataract surgery, primary posterior capsulorrhexis and anterior vitrectomy provide the best chance of a clear visual axis in the long term.

2.3 Visual Outcomes

For pediatric cataract surgery, the outcome measures include not only visual acuity but assessment of complications due to surgery. For infants, visual behavior including fixation and ocular stability (i.e. lack of nystagmus) is an important outcome assessment also [28]. Variations in visual outcomes are still seen despite significant improvement in treatment over the past 30 years.

Patients with monocular cataracts have two predisposing factors for the development of amblyopia: binocular rivalry and visual deprivation [29]. With the advancement of modern adult small incision cataract surgery, surgical techniques for pediatric cataract have also evolved significantly over the past 30 years [30]. However, children's eyes are not miniature adult eyes, and multiple challenges distinguish pediatric cataract surgery from that performed on their adult counterparts.

Ondráâek & Lokaj evaluated the results of congenital cataract extraction in patients who underwent cataract surgery in terms of postoperative visual acuity and binocular vision [31]

Fifty-one percent of the patients with bilateral aphakia and 47% with bilateral intraocular lens (IOL) implantation had Log Mar visual acuity of 0.5 or higher on the last visit. Similar values were achieved in 36% and 61% of the patients with unilateral aphakia and IOL implantation, respectively. In terms of achieving stereopsis 29% of patients with bilateral aphakia and 18% of those with unilateral attained stereopsis and most of the patients who had IOL implantation before 6 months of age achieved stereopsis. They concluded that surgery and optical correction should be performed at a very early age.

In Murtala *et al* study done in Nigeria (2015) majority of the children had borderline visual acuity at four weeks and 12 weeks postoperatively [32].

Ngandu's study in Sabatia found that majority of the children had good or borderline visual acuity outcome, with poor outcome also noted in some [24].

In summary, there has been limited research on outcome of cataract surgery in children.

2.4 Predictors of Poor Outcome

In children, the younger the child the greater the urgency in removing the cataract for purposes of preventing amblyopia. For optimal results, unilateral cataracts should be removed before the age of 6 week and bilateral should be removed before 10 weeks of age [8, 33].

Yoston in an article on surgery for congenital cataract with reference to an earlier study stated that in infants if the cataract is not removed during the first year of life, the vision will never be fully regained after surgery [22, 34]. Murtala et al study in Nigeria (2015) showed that the average age at presentation of their patients with congenital cataracts was 7 years by which time amblyopia would have set in already this was one of the contributing factors towards the borderline post-operative visual acuity of their patients [32].

Melanie Chak *et al* The British Congenital Cataract Study on long term visual acuity predictor after surgery for congenital cataracts (2006) found that poor compliance with occlusion was the factor most strongly associated with poorer acuity, unilateral cataract was associated with poorer visual acuity than bilateral and for bilateral cataracts younger age was associated with better vision [28.]Abdelmoaty et al study in Kuwait (2011) concluded that bilateral cataracts had better visual outcome [35].

Post-operative follow-up of children has also been identified as a challenge and results in poor outcomes due to loss to follow-up, missed appointments, unavailable or unaffordable drugs and glasses. A study by Saiba at KNH showed that amblyopia was the leading cause of poor outcome in cataract surgery followed by delay in presentation and loss to follow-up [16]. Namani at Kikuyu Eye Unit Kenya showed amblyopia and loss to follow-up as the commonest cause of poor outcome [23] and Ngandu showed that amblyopia was the commonest complication and there was a delay between onset and presentation which contributed to poor outcome [24] all had similar findings.

Similarly, a study done in Tanzania at Kilimanjaro Christian Medical Centre on follow-up indicated that parental lack of awareness of its importance, long distances, female gender of patient and poor postoperative vision were some of the factors contributing to poor outcomes [36].

2.5 Complications of cataract surgery in children

Children require more careful post-operative follow-up than adults. This is because they have more propensities for inflammation than adults and are more likely to get posterior capsular opacities and their complications may lead to amblyopia. Post-operative steroids, cycloplegics and antibiotics are used for a few weeks after the surgery. Their long-term follow-up involves both proper refractive correction and management of surgical complications [8]

Increased intraoperative difficulties such as low scleral rigidity, increased elasticity of the anterior capsule, high vitreous pressure, microphthalmia and pupillary miosis contribute to poor outcomes. Otherwise complications are similar to those in adults. In Murtala's study in Nigeria (2015) intraoperative complications included miosis, posterior capsule rupture with vitreous loss

and hyphema [32]. In Ngandu's study the most common intraoperative complications noted was posterior capsule tear followed by vitreous loss and displaced IOL [24].

Posterior capsular opacification commonly occurs in children under 6 years of age and its incidence is reduced by posterior capsulotomy and anterior vitrectomy [37, 38]

A fibrinous reaction with formation of secondary membranes commonly occurs usually in association with chronic uveitis and commoner in microphthalmic eyes. In Yorston's study in East Africa (2001) fibrinous reaction at 30% and PCO 37.5% were the commonest early and late complications [22]. Saiba *et al* showed a prevalence of 28.1% and 11.6% at 2 months and 6 months respectively while Namani had fibrinoid reaction at 59.2% and PCO at 15.4% [16,23].

Closed angle Glaucoma also occurs in the immediate post-operative period in microphthalmic eyes and secondary open angle years after the initial surgery [39]. Some studies have shown that it occurs more in eyes that have had lensectomy in the 1st week of life and less glaucoma occurred in lens aspiration with primary posterior capsulotomy and more when it was done alone [39, 40]. Matafatsi *et al* found that the glaucoma risk after infantile cataract surgery is associated with surgery within the first month of life [41]. Retinal detachment is uncommon and is usually a late complication. It occurs 35 years or more after the operation [35.]

Amblyopia is a common complication of cataract surgery and occurs as a late complication. In patients with an IOL amblyopia treatment is started soon after surgery and more aggressive steroid treatment is used [8]. Kenyan studies by Saiba, Yoston and Ngandu's found amblyopia to be a common late complication causing poor vision post-operatively which was attributed to late presentation of children with cataract to hospitals [16,22,24].

Ng'andu in Sabatia Eye hospital (2012) found corneal haze as the commonest early complication while pupillary abnormality, amblyopia and PCO were the most common later complications. [24]

3.0 JUSTIFICATION

Compared to adults, decision for surgery is more difficult as subjective visual assessment in children cannot be obtained, and surgeons rely largely on the morphology and location of the cataract and behavior of the child. Surgery needs to be undertaken within the first three months of life as indicated by experimental and clinical research, as early detection and management is directly related to the visual outcome[14, 28]

In East Africa, cataract is a major cause of childhood blindness and causes significant morbidity due to delayed presentation, lack of access to health facilities and limited skilled personnel. This study will build on the body of knowledge in this field and guide interventions. Studies that have been done so far in East Africa, including Kenya, have reported poor outcomes of childhood cataract surgery in the referral centers due to various factors. Few studies have been done to determine outcomes of cataract surgery in Kenya and the East African region.

In fact, no study has been done in Kwale Eye Center to determine outcomes of pediatric cataract surgery. This is 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.

4.0OBJECTIVES

4.1Main Objective

To determine the outcome of cataract surgery in children aged 15 years or less performed in Kwale Eye Center from 1st January 2013 to 30th June 2016.

4.2Specific Objectives

1. To determine the post-operative visual acuity of cataract surgery in children at Kwale eye hospital.
2. To establish the common intra-operative and post-operative complications of cataract surgery in children at Kwale Eye Unit.
3. To identify any factors that may have contributed to poor outcome in patients with such outcome following cataract surgery.

5.0 STUDY MATERIAL AND METHODS

5.1 Study Design

The study was a retrospective case series and was designed to look at cataract surgeries performed at Kwale Eye Centre on children below the age of 15 for a three-year period between 1st January 2013 and 30th June 2016.

5.2 Study Area

The study was carried out at Kwale Eye Centre, a hospital located in Kwale County. The health facility is one of the main eye hospitals in Kenya and it serves a large population of 649,931 that accounts for 1.7 % of the total Kenyan population

Kwale Eye Hospital has a well-established low vision department where measurement of visual acuity is done using tens and thousands pictorial charts and Sheridan Gardner's Test. A wide range of tools are used by well-trained low vision workers.

The surgeries are done by a surgeon trained in pediatric cataract surgery; a temporal approach is used. In this center axial length and keratometry was done using an auto-refractor for children who could stand in front of it but for those who were too young the axial length was calculated in theatre using an A scan ultrasound machine and keratometry average of 43.5 was used for children 1-3 years old while for those above 3 an average of 44 was used. The type of surgery done is manual small incision cataract surgery, lens aspiration primary posterior capsulotomy and anterior vitrectomy and primary IOL implantation. Follow- up of the children (post-operative) is done by well-trained community-based workers. Follow up include spectacle use and amblyopia therapy.

Figure 1: Map of Kenya

Figure 2: Map showing Coastal Region

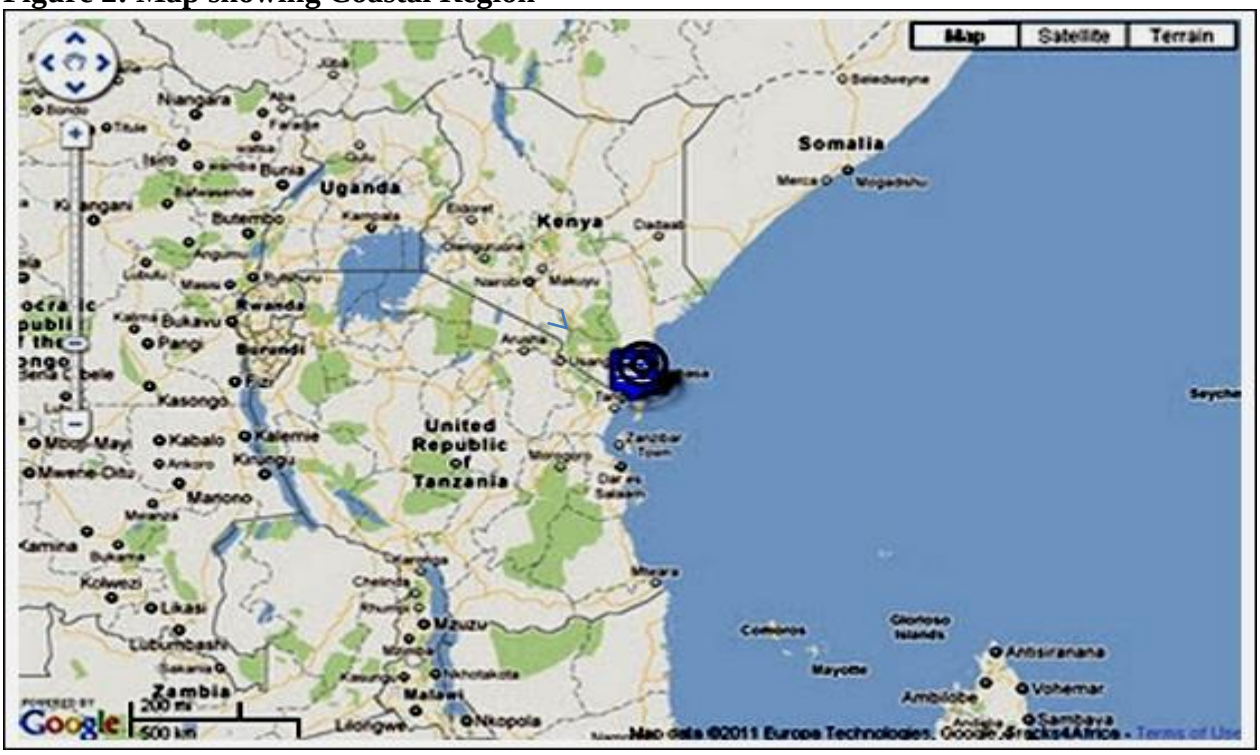


Figure 3: Kwale Eye Centre

5.3 Inclusion Criteria

All records of children aged 15 years or less, who underwent cataract surgery at Kwale eye unit between 1st January 2013 and 31st December 2015.

5.4 Exclusion Criteria

Records of children who underwent traumatic cataract surgery during the study period were excluded. Children aged 15 years or less with incomplete or missing records were also excluded.

5.5 Study Period

The study period was from 1st December 2015 to 31st October 2017. Data collection was in December 2016. Records from 1st January 2013 to 30th June were reviewed. It took a period of four weeks.

5.6 Study Population

All children aged 15 years and below who underwent cataract surgery between 1st January 2013 and 30th June 2016 were included.

5.7 Sample Size

The sample size was 72 as calculated below for children meeting the inclusion criteria and who underwent surgery between 1st January 2013 and 30th June 2016.

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

Where Z α/2 is the critical value for 95% confidence interval which is 1.96

P is the estimated proportion of population of patients with poor outcome =22%

D is the margin of error at 10%

$$N = \frac{1.96^2 x 0.22 x 0.78}{0.1^2} = 65.9$$

Correction for finite population

P=size of population with congenital cataract since this is unknown it is estimated to be 100,000

$$\frac{65.9 \times 100,000}{100,000+65.9-1} = 65.8$$

Add 10% for margin of error which comes to 6.58

Sample size=72

The least sample size was 72

5.8 Study Materials

A questionnaire was used to capture data (see appendix 2). The outcome of cataract surgery was defined according to the Kilimanjaro Centre for Community Ophthalmology Guidelines for Childhood Cataract Surgery in Africa (KCCO) and WHO guidelines [10](see appendix 3).

5.9 Data Collection Procedure /Study Procedures

The principal investigator obtained authorization letter from the hospital management to carry out the study. The authorization letter was used to access Kwale eye Centre registry and work with assigned records clerks to extract files matching study criteria. The data used was from personal medical records of children operated for cataracts.

For the school going children the, Snellen and Log Mar equivalent vision recorded in the file was recorded in the questionnaire.

Acceptable files were used to fill in questionnaires (with the help of a research assistant) and create data tables from filled questionnaires. One questionnaire was filled per eye. In terms of visual acuity for preverbal children, the preferential looking test is normally used and recorded. Results that were obtained pre-and post-operatively were recorded in the questionnaire from the patient's files i.e. ability to follow objects or light. Others were recorded as Central Steady Maintained or Not Central Steady and Maintained. Intra-operative information extracted was the type of surgery, lens used and complications. Post-operative data collected was visual acuity, refraction and complications at the first post-operative day, at 1-3 weeks, at 4-11 months at 12 weeks and or at 6 months.

Files with missing information that was relevant to the study were not excluded altogether. Files with incomplete information were assessed on a case by case basis.

5.10 Data Management and Analysis

All filled questionnaires were checked by the principal investigator for completeness with one questionnaire being filled per eye. The raw data was kept in confidentiality until the thesis was accepted and marked for any verification and then destroyed on completion of the study. The records were accessible to the principal investigator and the statistician.

The collected data was keyed into Microsoft Excel 2007 database, cleaned and confirmed. The data was summarized in Microsoft spreadsheets and analyzed using SPSS version 20.0 and represented using various tools. Descriptive analysis was undertaken for the patients to determine the outcomes, duration and demographics. Chi square test was used to determine the factors associated with poor outcomes. Data was analyzed with the help of a statistician. The findings were presented in the form of tables and charts.

5.11 Ethical Consideration

The identity of the patients was kept anonymous during data collection. No record of the identity of the patient was made. No photocopies of medical records were made. The questionnaires were only being available to the principal investigator and statistician for analysis. Written ethical approval was sought and granted from the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee and from Kwale Eye Centre.

5.12 Study Variables

Relevant data was collected including demographic data, (age and sex), date of surgery, baseline/preoperative assessment, visual acuity, refractive status, biometry and ocular comorbidities. Visual acuity for pre-verbal children was recorded using qualitative and preferential looking tests and recorded as such while for school-going children quantitative tests were used.

Classification of type of cataract whether congenital or developmental was as per the records or deduced if not recorded.

5.13Study Limitations

Study limitations were missing records, incomplete records and loss to follow-up.

5.14 Dissemination Plan

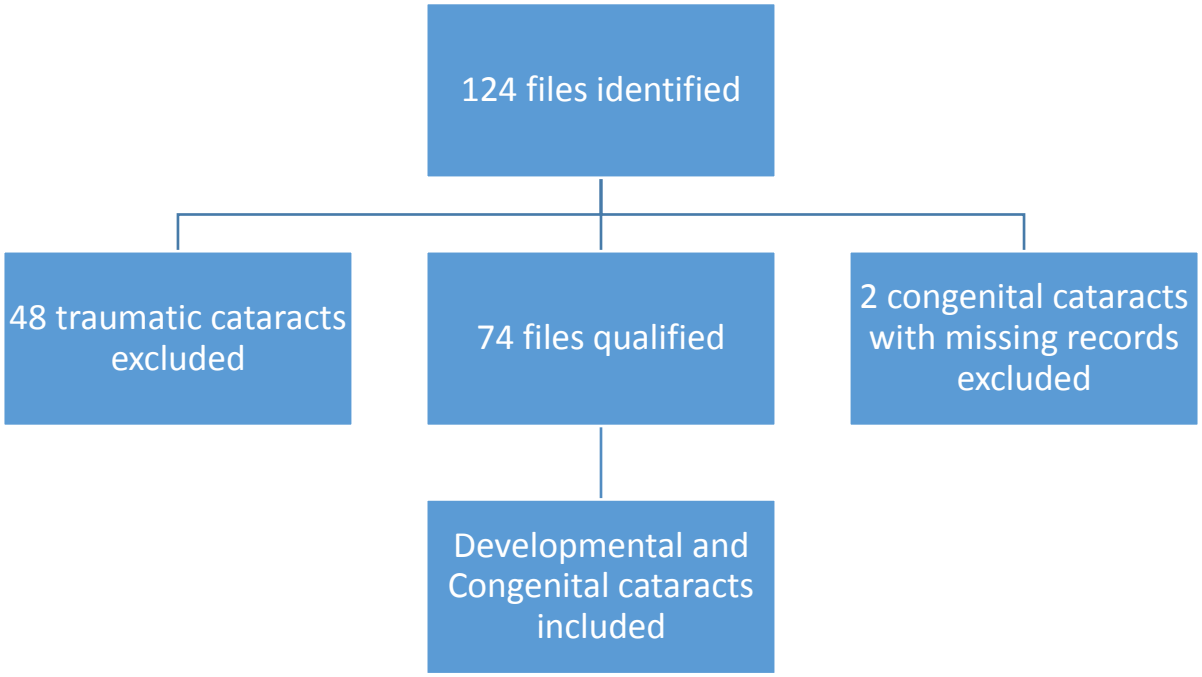
After analysis, findings were presented to the University of Nairobi department of Ophthalmology and a bound copy of the study and results was sent to Kwale Eye Centre. One copy of the study was kept.

The study will be self-archived within the library system of the University of Nairobi. It will be published in a peer reviewed journal as well as presented in a medical conference if possible.

6.0 RESULTS

6.1 Pre-operative characteristics

Figure 4: Flow chart showing all children operated for cataracts in the study period



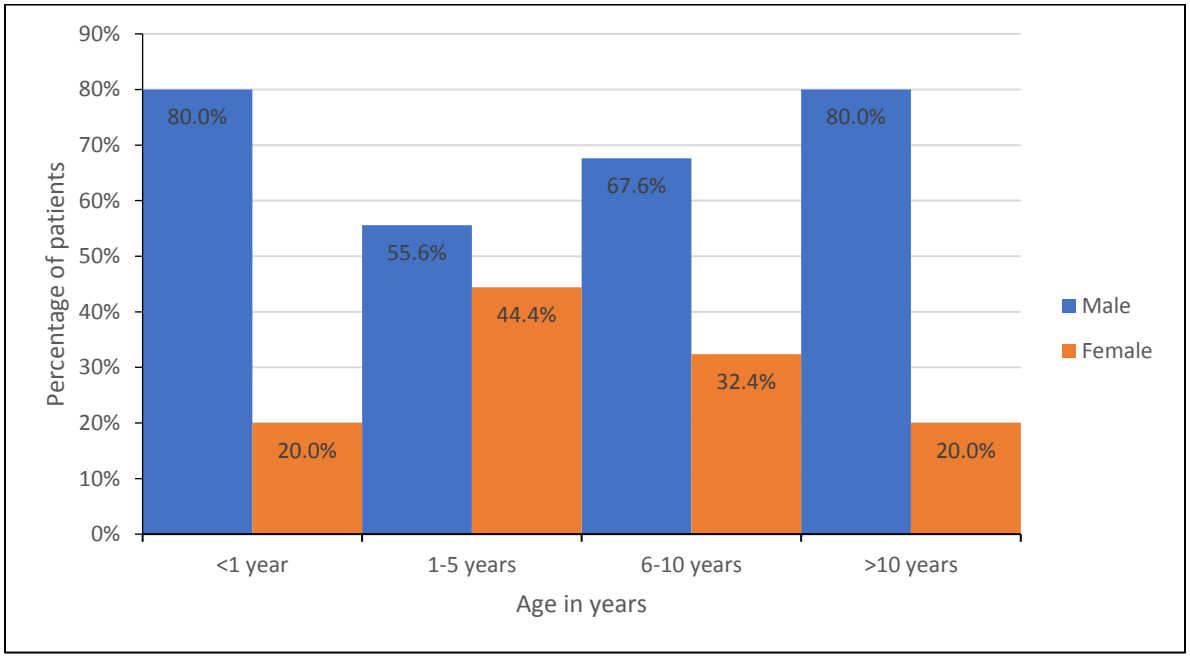
The records of 124 files of children operated for cataracts were found 48 children with traumatic cataract were excluded from the study and 2 of the remaining 76 had missing records and were excluded. Seventy-four files were assessed.

Table 1: Demographic characteristics of the patients

Variable	Frequency (%)
Sex	
Male	49 (66.2)
Female	25 (33.8)
M: F ratio	2:1 p-value=0.001
Age in years	
Mean (SD)	5.7 (3.6)
Min-Max	0.42-13
Category	
<1	5 (6.8)
1-5	25 (33.8)
6-10	34 (45.9)
>10	10 (13.5)

Majority of the operated children were males (M: F ratio of 2:1) and more than 5 years old.

Figure 5: Distribution by Age according to Gender



Males were the majority in all age groups.

Table 2: Distribution by types of cataracts and laterality

	Laterality		Total patients (N=74) (%)	Total eyes (n=128) (%)
	Unilateral (n=20) (27 %)	**Bilateral (n=54) (73%)**		
Type of cataract				
Congenital	1 (4.0)	24 (96.0)	25 (33.8)	49 (38.3)
Developmental	15 (34.9)	28 (65.1)	43 (58.1)	71 (55.5)
Not indicated	4 (66.7)	2 (33.3)	6 (8.1)	8 (6.3)
	Laterality Unilateral (n=20) (27 %)	**Bilateral (n=54) (73%)**	**Total patients (N=74) (%)**	**Total eyes (n=128) (%)**

Most cataracts were bilateral (73%) and developmental (58.1%)

Table 3: Pre-existing systemic conditions

Variable	Frequency (%)
Documented associated systemic conditions(patients) n=74	
Yes	13 (17.6)
No	37 (50.0)
Not indicated	24 (32.4)
Distribution of systemic conditions n=13	
Epileptic	2 (15.4)
Known asthmatic	1 (7.7)
Mentally challenged	4 (30.8)
Malnutrition	1 (7.7)
Delayed milestones	3 (23.1)
Sero-reactive on HAART	1 (7.7)
Speech and hearing problem	1 (7.7)

There were a small number of documented associated systemic conditions (17.6%) of which a majority were mentally challenged (30.8) and delayed milestones (23.1).

Table 4: Pre-existing Ocular comorbidities

Variable	Frequency (%) n=128
Ocular comorbidities	
Micropthalmos	4 (3.1)
Peters anomaly	5 (3.9)
Others	7 (5.5)
Corneal opacity	9 (7.0)
Nyastagmus	10 (7.8)
Nyastagmus & Strabismus*	11 (8.6)
Strabismus	31 (24.2)
None	63(49.2)
Accessibility of Posterior segment	**n=128**
Yes	9 (7.0)
No	119 (93.0)
Posterior segment findings	
Normal	6 (4.7)
Abnormal	3 (2.3)
Maculopathy retinitis pigmentosa	2 (66.7)
Disc & choroidal colobomas	1 (33.3)

*multiple responses

Others included glaucoma (1), disc and choroidal coloboma (1), retinitis pigmentosa (2), maculopathy (1), dislocated lens (2)

Table 5: Biometry and cornea diameter measurement findings, n = 128

Variable	Frequency (%)
Axial length (in millimeters)	
Done	60 (46.9)
Not done	68 (53.1)
Category, n =60 (%)	
<20	1 (1.6)
20-24.5	53 (86.9)
>24.5	7 (11.5)
Mean (SD)	23.3 (4.6)
Median	22.6 (21.6-23.7)
Min-Max	12.2-45.1
Keratometry (Dioptres)	
Done	48 (37.5)
Not done	80 (62.5)
Categories n=48(%)	
<40	3 (6.3)
40-43	12 (47.9)
43-44	2 (4.2)
44-47	17 (35.4)
>47	3 (6.3)
Categories n=48(%)	
Mean (SD)	43.4 (2.1)
Median (IQR)	43.2 (242.2-44.7)
Min-Max	39.7-48.6
Corneal diameters (in millimetres) (n=8)	
< 9	2 (25)
9	1 (12.5)
> 9	5 (62.5)
Mean (SD)	10.0(1.2)
Median (IQR)	10.5(8.6-11.3)
Minimum-Maximum	8.5-11.3

Only a few patients had their biometry or cornea diameter measurements done (axial length 46.9 %, keratometry 37.5 %, and corneal diameter 9 eyes)

6.2 Type of surgery done

Majority of the patients underwent Lens Washout, Primary Posterior Capsulotomy, Anterior Vitrectomy and Intra-ocular lens insertion (69.5%) as shown in Figure 6.

Figure 6: Cataract surgical procedures performed, n=128

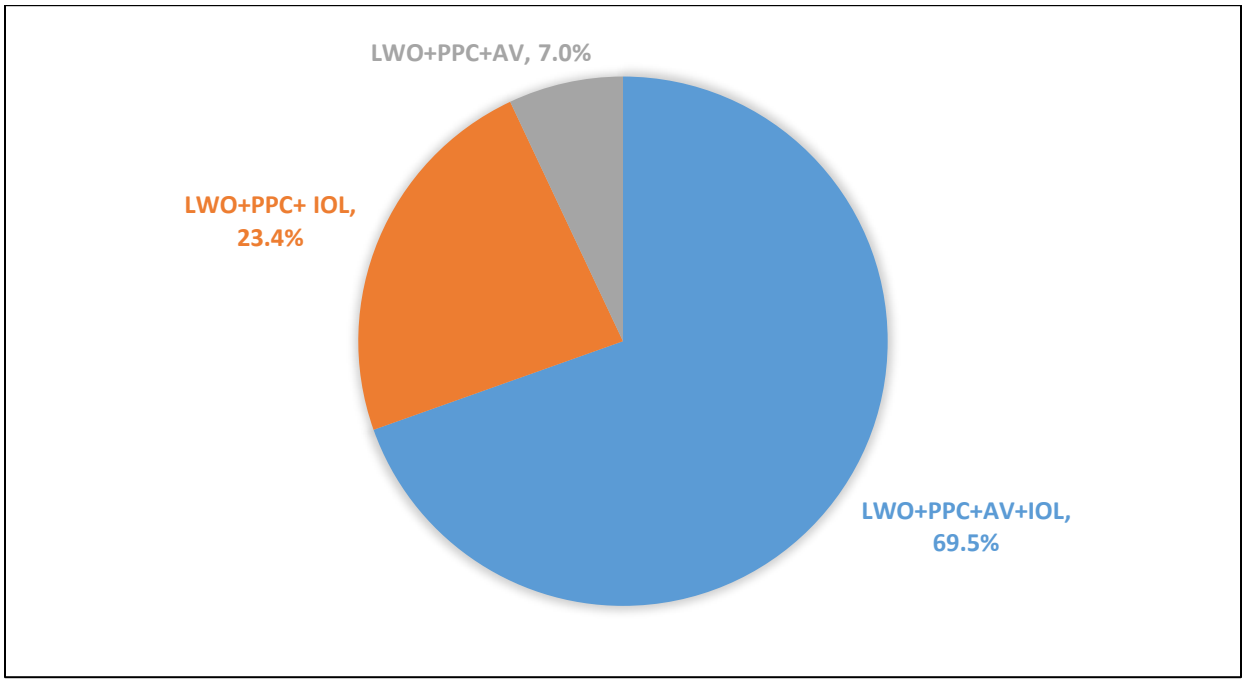


Table 6: Distribution of cataract surgical procedures performed by age

LWO+PPC+AV+IOL LWO+PPC+AV LWO+PPC+IOL	89 9 30	4 (4.5) 2 (22.2) 4(13.3)	36 (40.4) 0 11(36.7)	37 (41.6) 7 (77.8) 12(40.0)	12 (13.5) 0 3(10.0)	0.054
	Total N=128	**<1 year n=10**	**1-5 years n=47**	**6-10 years n= 56**	**>10years n=15**	**P-value**

There was no association between the surgical procedure and age.

6.3 Intra-operative and Post-operative complications

Out of the 128 eyes only three got intraoperative complications (two had hyphema and one IOL dropped into the vitreous)

Table 7: Post-op complications recorded during follow-up period

Post-operative complications N=128	**Day 1, n=128**	**1-3 weeks, n=115**	**4-11 weeks, n=71**	**12+ weeks, n=49**	**6 months, n=38**
Iris prolapsed	1(0.78)	3 (2.60)	0	0	0
Corneal haze	15 (11.72)	3 (2.60)	1 (1.41)	0	0
Shallow AC	2 (1.56)	2 (1.74)	0	0	0
Fibrin / membranes	6 (4.69)	8 (6.96)	3 (4.22)	2(4.08)	4 (10.53)
High IOP	9 (7.08)	4 (3.48)	1 (1.41)	0	0
Decentered IOL	1 (0.78)	1 (0.87)	1 (1.41)	1 (2.04)	0
PCO	0	0	7 (9.86)	5 (10.20)	8 (21.05)
Others	4(3.12)	2(1.74)	1 (1.41)	1(2.04)	2 (5.26)
None	90(70.31)	92(80.00)	57(80.28)	40(81.63)	27(71.05)

The most common early and late complications seen were Cornea haze and PCO respectively

6.4 Visual Outcomes

Table 8: Refractive Status of the Eye

Spherical Equivalent n=119/128 (92.9%)	Intra-op n=4	Day 1 post-op n=13	Week 1-3 post -op n=33	Week 4-11 post-op n=31	Week 12 post-op n=14	6 months post-op n=24
-6.0 to -4.1	0	4	0	1	0	11
-4.0 to -2.1	1	2	0	0	7	3
-2.0 to -0.1	0	3	9	10	7	4
0.0 to +2.1	2	1	13	12	0	6
+2.2 to +4.1	1	1	3	6	0	0
+4.2 to +6.1	0	0	2	1	0	0
+6.2 (+12 to +18)	0	2	6	0	0	0

Refraction was done for the majority (92.6%) of the eyes at different hospital follow-up visit.

Table 9: Best corrected visual acuity

	Day 1 (%)	1-3 weeks (%)	4-11 weeks (%)	12+ weeks (%)	6 months (%)
N	17	23	22	9	10
Normal	14 (82.3)	11 (47.8)	15 (68.2)	5 (55.5)	7(70)
Impaired	3 (17.6)	9 (39.1)	5 (22.7)	1 (22.2)	3 (10)
Blind	0	0	0	0	0
No fixating/following object	0	0	1 (4.5)	0	0
Fixating/following object	0	3 (13.0)	1 (4.5)	0	0
Can pick 1mm object at 33 cm	0	0	0	1(22.2)	0
Can't pick 1mm object at 33 cm	0	0	0	0	0

Only 57 out of 128 eyes (44.5%) had Best Corrected visual acuity recorded

Table 10: Pre-operative and Post-operative quantitative and qualitative visual acuity

	Pre-op VA	Post-operative VA				
		1st POD	1-3 weeks	4-11 weeks	12+ weeks	6 months
	(n=128)	(n=128)	(n=115)	(n=71)	(n=49)	(n=38)
Normal	3 (2.3)	31(24.2)	24(20.9)	20(28.2)	15(29.4)	12(31.6)
Impaired	36(28.1)	39(30.5)	36(31.3)	2 (32.4)	9(17.6)	11(28.9)
Severely impaired	11 (8.6)	2 (1.6)	4 (3.5)	1 (1.4)	2(3.9)	1 (2.6)
Blind	54(42.2)	16(12.5)	3 (2.6)	0	4 (7.8)	3 (7.9)
Fixating/following object	0	12 (9.4)	15(13.0)	14(19.7)	9 (17.6)	0
Not Fixating/following object	21(16.4)	9 (7.0)	5 (4.3)	5 (7.0)	4(7.8)	0
Can pick 1mm object at 33 cm	0	9 (7.0)	15(13.0)	4 (5.6)	4 (7.8)	11(28.9)
Can't pick 1 mm object at 33cm	1(0.8)	5 (3.9)	6 (5.2)	1 (1.4)	2 (3.9)	0
Central stable maintained	2(1.6)	4 (3.1)	4 (3.5)	1 (1.4)	2 (3.9)	0
Not central stable maintained	0	1 (0.8)	3 (2.6)	2 (2.8)	0	0

Table 11: Pre and Postoperative Quantitative Visual Acuity

	Pre-op VA (n=104)	Post-operative VA									
		1st POD (n=89)	P value	1-3 weeks (n=68)	P value	4-11 weeks (n=47)	P value	12+ weeks (n=28)	P value	6 months (n=27)	P value
Normal	3 (2.9)	31 (34.8)	<0.001	24 (35.3)	<0.001	20 (45.5)	<0.001	13 (44.8)	0.001	12 (44.4)	0.001
Impaired	36 (34.6)	40 (44.9)		37 (54.4)		23 (52.3)		12 (44.8)		11 (40.7)	
Severely impaired	12 (11.5)	2 (2.2)		4 (5.9)		1 (2.3)		0		1 (3.7)	
Blind	53 (51.0)	16 (18.0)		3 (4.4)		0		3 (10.3)		3 (11.1)	

There was a statistically significant improvement in visual acuity on subsequent follow-up visits from pre-operative to 1st post-operative day (p-value < 0.01) a similar statistically significant difference was seen between pre-op and weeks 1-3 and week 4- 11 visits. Similarly, in the week 12 plus visit and the 6 months visit the difference between pre-op visual acuity and that at those visits was statistically significant p-value 0.01

Figure 7: Visual Acuity as at Pre-Op and 12+weeks post-Op

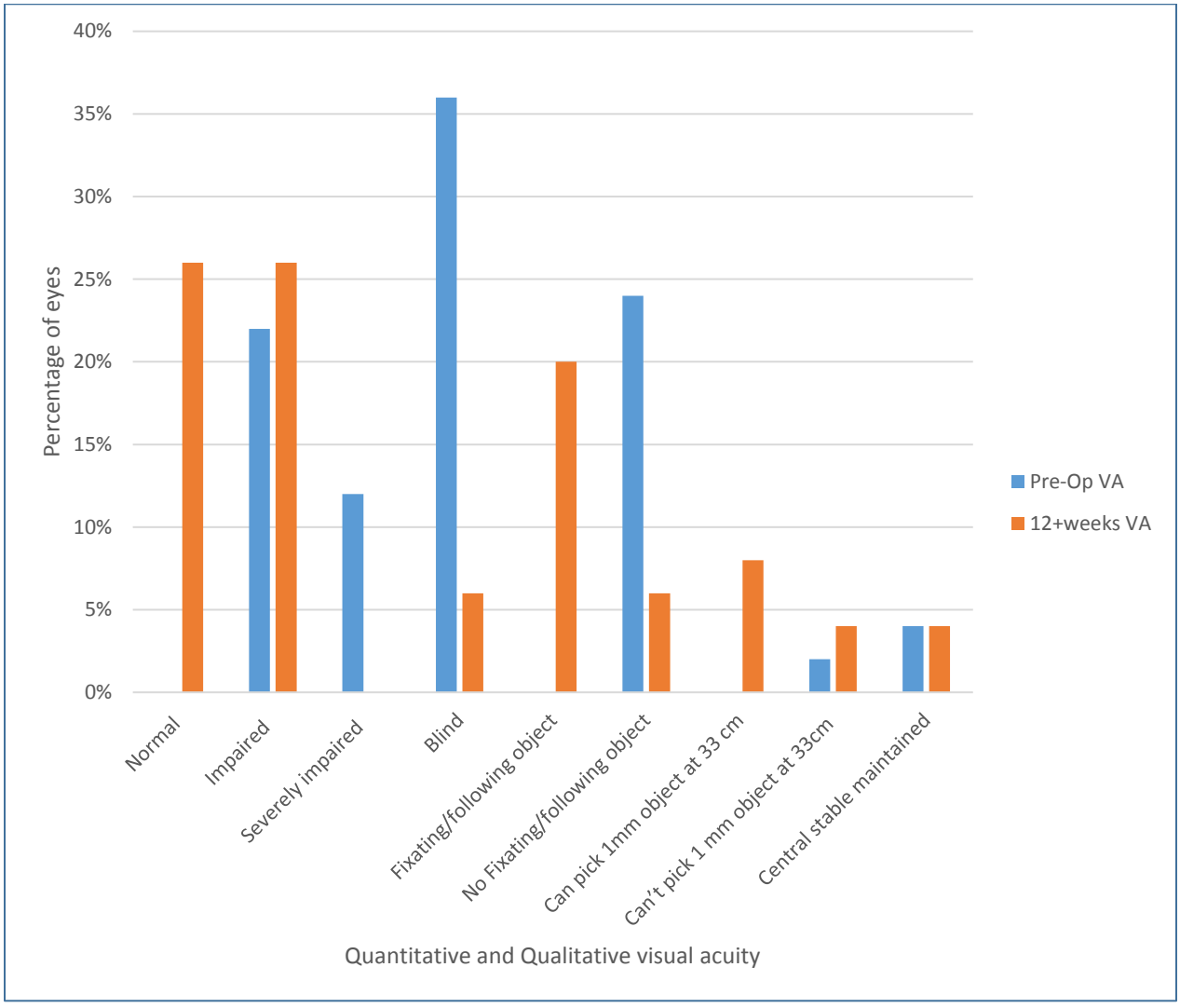


Figure 8: Visual Acuity as at Pre-op and at last follow up

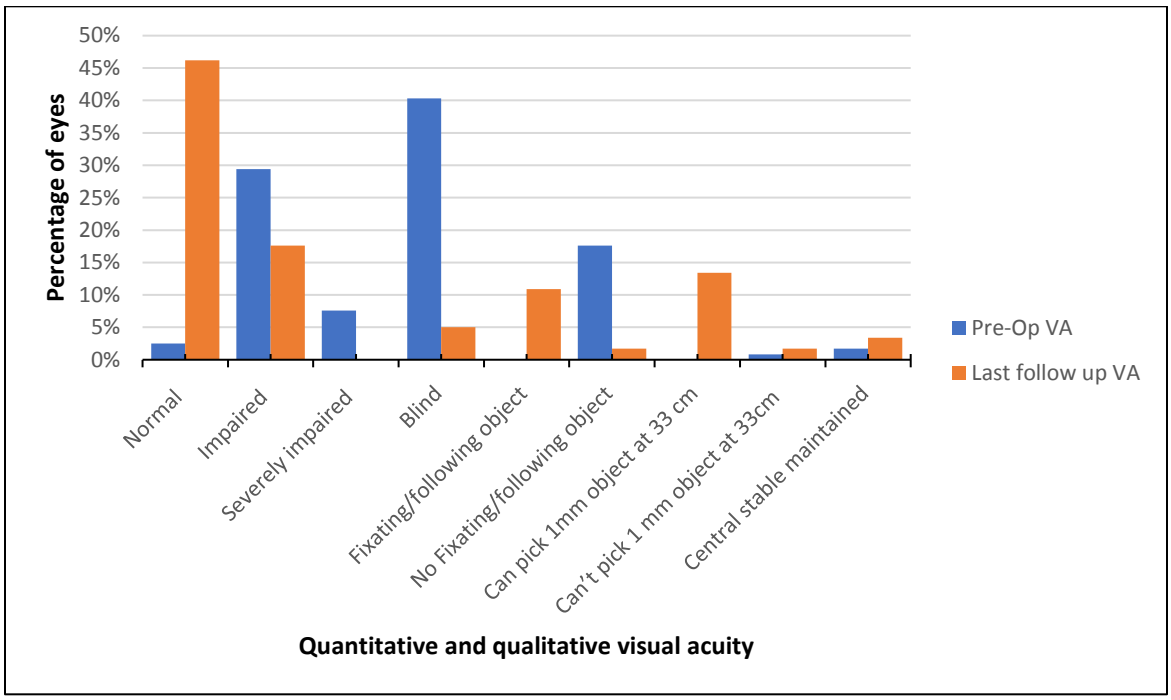


Table 12: Post-operative Visual acuity classification as per WHO expected outcome

Visual Acuity Outcome		Post-Operative Visual Acuity with available correction			
		Guidelines		4-11 weeks N=44	12+ weeks N=28
		WHO	KCCO		
Good	6/18 or better	>80%	>70%	20(45.5)	13(46.4)
Borderline	<6/18-6/60	<15%		24(54.5)	9(32.1)
Poor	<6/60	<5%	<5%	0(0)	6(21.5)

*Done for eyes that were quantitatively assessed

*Visual outcomes were below WHO expected outcomes in all categories

Table 13: Post-operative visual acuity in eyes with biometry versus those without

Visual Acuity	Biometry Done 59(46%)	Biometry not done 69 (54%)	P value
Good (6/6-6/18)	33(55.95)	28(40.58)	0.006
Borderline (6/18 – 6/60)	8(13.57)	13(18.84)	
Poor (>6/60)	1(1.7)	6(8.7)	
NFFO	1(1.7)	0	
FFO	13(22)	2(2.9)	
Can pick 1mm object at 33cms	3(5.08)	10(14.48)	
Can't pick 1mm object at 33cms	0	3(4.35)	
Not central stable maintained	0	4(5.8)	
Central Stable Maintained	0	3(4.35)	

There was a statistically significant difference in visual acuity between those who had biometry and those who did not (p=0.006).

6.5Causes of poor visual outcome

Table 14: Causes of poor visual acuity at week 12

Attributable Cause of Poor Visual Acuity n=6	Eyes %
Post-op uveitis	2(33)
Pre-operative posterior segment pathologies	2*(33)
Post-operative complications	1(17)
Patient selection	2*(33)
Unknown	2(33)
Uncorrected refractive error	1(17)

* 2 eyes had posterior segment pathologies disc and choroidal coloboma and maculopathy with strabismus **(**poor visual acuity was taken as not fixating and Following Objects, Not Central Steady Maintained, Can't Pick 1mm object at 33 centimeters and < 6/60)

Association of outcomes at 12+ weeks

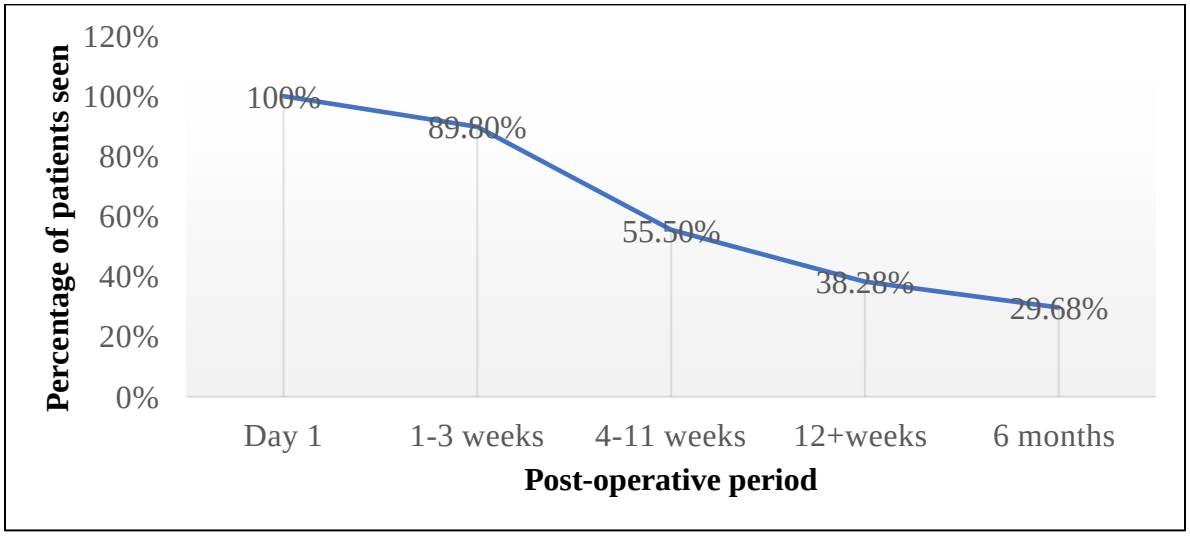
Table 15 shows association of outcome at 12+ weeks and gender, ocular comorbidities and type of cataract for patients operated on during the period under study at KDEC.

Table 15: Association of outcomes at 12+ weeks of follow up, n=50

	Outcome			P value
	Good (%)	Poor (%)		
Sex				
Male	18 (62.1)	11 (37.9)	2.7 (0.8-8.5)	0.094
Female	8 (38.1)	13 (61.9)	1.0	
Nystagmus				
Yes	0	5 (100.0)	-	0.020
No	26 (57.8)	19 (42.2)		
Strabismus				
Yes	6 (30.0)	14 (70.0)	0.2 (0.1-0.7)	0.011
No	20 (66.7)	10 (33.3)	1.0	
Cataract				
Congenital	5 (21.7)	18 (78.3)	0.1 (0-0.3)	<0.001
Developmental	19 (79.2)	5 (20.8)	1.0	

Among the selected variables, only Gender did not have any association with the visual outcome.

Figure 9: Loss to follow up



There was generally a high rate of loss to follow-up over time as depicted in Figure 9.

7.0 DISCUSSION

Records of 74 children were included in the study. Most were males 66.7% (2:1) this was similar to Mwende's (2005), Saiba *et al* (2008) and Ngandu's (2013) studies done in Tanzania, Kenyatta and Sabatia where male predominance was seen [5,16,24]. The sex difference was statistically significant (p-value 0.0001) similar to the studies above. Melanie's British congenital cataract study (2006) showed slight male preponderance (52%) while Abdelmoaty *et al* Kuwait study showed slight female preponderance (58%) [28, 35]. The reason for this is unclear though African tradition presumably accords more importance to the male than female child [5, 22]. In terms of age distribution (Table 1) 6.6% were aged less than 1 year while in Ngandu's Sabatia study done in Western Kenya (2013) where 14.4% were aged less than 1 year [24].This is because in our setting patients with cataracts present late and those of this age group are referred to other hospitals. In Abdemoaty et al's study (2011) in Kuwait which is in a different setting, most patients presented at less than 1 year 42% [35]. The mean age was 5.7 years which was similar to Ngandu's findings in Sabatia (6.7) and Murtala et al in Nigeria (6.8) [24, 32].

More children had bilateral cataracts 65.4% (53) than unilateral 34.6% (23) the ratio being 2:1 (Table 5). This is because the hospital prefers bilateral cases because of their better outcomes as shown in British congenital Cataract study where the odds of poor vision in unilateral cataract is 7.92 more [28]. Saiba (KNH), Namani (Kikuyu) and Ngandu (Sabatia) also found bilateral cases were more than unilateral [24, 16, and 23]. This is also similar to findings in Kuwait [35]. The unilateral cataracts were still operated on so as to give the child a chance of good vision regardless. More patients had developmental 46(58.9%) than congenital cataracts 26(33. 3%) similar to Mwende's study in Tanzania (105 vs. 75) [5].

One hundred and twenty eight eyes were identified. Most were blind pre-operatively (WHO VA < 3/60) 42.2% (Tables 10 and 11) which was similar to other Kenyan studies by Saiba et al Namani and Ngandu's where majority of patients were blind pre-op by WHO classification [16,23,24]. Those assessed using qualitative methods were18.8%, (not fixating and following objects 16.4%, 100s and 1000s 0.8 % and central stable maintained 2%). The large percentage of children assessed using qualitative methods is attributable to difficulty in visual acuity testing in this age group. This is comparable to Yorston's study in Kikuyu Eye Unit where 19.51% of children had visual acuity tested using fixation behavior [22]. Majority of our patients had visual acuity testing done using quantitative methods since, for children older than a year K pictures and Cardiff charts were used and these parameters were convertible to Log Mar which was convertible to Snellen's. There was a 7-year-old child whose visual acuity was assessed using qualitative methods due to mental retardation. Some patients with good visual acuity pre-operatively were operated in cases where there was no central red reflex or the central opacity measured 3mm or more [3].

The duration of time with the cataract was not clearly captured in our study as it was not documented in the patients records but could be extrapolated based on the number of eyes that had nystagmus10(15.4%) and or strabismus 31(47.7%) and some with both 11(16.9%)13 (Table 4). Also, the average age of patients was 5.7 years even though many cataracts were congenital 37.2%. Delay between onset and presentation has been implicated as a factor contributing towards poor outcome [5]. Literature shows that a patient with nystagmus due to cataract has had it for at least two months and nystagmus and strabismus can occur together especially in patients with infantile esotropia and dissociated vertical deviation [3,38].

Most patients had no associated systemic conditions (82.4 %) recorded and of those that had them the majority were mentally challenged (30%) or had delayed milestones (23.1%) (Table 3) which may have had a negative impact on post-operative visual outcome. Likewise, in a Nigerian study 93.1% didn't have ocular comorbidities of those who had 5 (71.4%) had delayed developmental milestones while 1 child (14.2%) had mental retardation [32]. Pre- operative ocular comorbidities {Table 4}were found in 50.8% of eyes the commonest being strabismus 31 eyes (41.7%) followed by nystagmus 10(14.4%) and both 11(16.9%) this was similar to findings by Ngandu (2014)and Saiba et al (2008) studies where the commonest comorbidities were strabismus and nystagmus, [24,16].Microphthalmos was seen in 4 eyes in the present study, in Khana's South Indian study(2013) it was seen in 18 eyes while in Ngandu et al study it was seen in 8 eyes [21,24].In the present study and Ngandu et al study glaucoma was seen in 1 eye while in Murtala *et al* Nigerian study(2015)it was seen in 2 eyes [24,32] .

Biometry was performed in 59(46%) of eyes while it was not recorded in 69(54%) which is comparable to Ngandu's study where it was done in 60(47%) of eyes [24.] The biometry was based on axial length and keratometry in this centre. Axial length was done in 61 eyes and the mean was 23.3mm. Keratometry was done in 49 eyes and the mean was 43.4D. In many cases patients were under-corrected. However, in another group of eyes the surgeons aimed for emmetropia. The age of the child did not influence the decision to put an IOL as those under a year old had IOLs inserted. Those with microphthalmos, Peter's anomaly and subluxated lenses were left Aphakic. Corneal diameter was measured in 8 eyes one had 9 and 2 had less than 9(8.5 and 8.5) the other 5 had more than 9 see table. The range was 8.5 to 11.5 mm. Those whose corneal diameters were below 9 mm were deemed to have microcornea and were left aphakic. In Ngandu's study it was measured in 12 eyes one of whom it measured less than 9 [24].Most eyes

were either left emmetropic or hypermetropic (Table 8) meaning that if we assume pre-op hypermetropia most eyes were either under corrected or left emmetropic which is in keeping with pre-operative guidelines and studies [8, 25]. Refraction was done in many eyes (89.8%) of the eyes however best corrected visual acuity was recorded in few files only in 37 patients (48.6%) and only 23 patients got spectacles. This could have been due to the high rate of loss to follow up. Another challenge may have been lack of proper record keeping with some patients getting spectacles and not being recorded as having received.

Most eyes (69.5%) had LWO+PPC+AV+IOL. (Figure 6) This was similarly the commonest procedure done in other studies; one in South India by Khana *et al* (2013) and another in Sabatia [21,24] . Across the board most eyes had anterior vitrectomy and primary posterior capsulotomy done 76.6%. However, in the present study there was a period during which the vitrector was not functioning which could explain why some patients aged less than one and others aged 1-5 didn't have anterior vitrectomy done (40% and 29.7%). Many patients older than 6 years had primary posterior capsulotomy and anterior vitrectomy done because at the time of the study YAG laser was not available at the hospital. Age was not used as a determinant of whether to put an IOL. Five patients were left Aphakic; 1 had bilateral microphthalmos and was less than a year old, another had bilateral ectopic lenses, 3 had Peters Anomaly one unilateral and two bilateral. Many patients 60% of those under one year had IOLs put as was the case in a study by Jaspreet et al (India 2014) that showed the safety of use of IOLs in that age group [26]. Many patients older than 6 years had primary posterior capsulotomy and anterior vitrectomy done because at the time of the study YAG laser was not available at the hospital.

The intraoperative complication rate was low (2.3%); likewise, in Nigeria (2015) it was 4.4%; the commonest one being hyphema in 2 eyes. Similarly, Jaspreet et al in India (2014) and Murtala *et al* in Nigeria (2015) each had one case of hyphema [26, 32.] They both resolved post-operatively and had no implication on visual acuity. On the first postoperative day, the commonest complication was corneal haze in 15 eyes (11.72%) which reduced during subsequent visits. This is similar to Ngandu's study where it was found in 25 eyes (20.33%) [24]. High IOP was found in 9 eyes (7.08%) and was associated with corneal haze both of which reduced during subsequent visits in most eyes. Fibrinous membranes occurred in 8 eyes (6.96%) at week 1-3 these also reduced over later visits. This was different from Namani's and Khana's studies where the commonest post-operative complication was fibrinous membranes at 1-3 weeks occurring in 59.2 % of eyes and 13.3% of eyes respectively [23, 21]. Yorston found the commonest early complication to be fibrinous reaction at (30%) and the commonest late complications to be PCO at 37.5% [22]. Posterior Capsular Opacity peaked at 6 months (8 eyes; 21.05%). It was the commonest late complication in our study which is similar to studies by Khana in South India and KEU [21, 22]. This may have been due to the vitrector malfunction that was reported during the study period (in 2014).

There was improvement in visual acuity with subsequent visits with the number of eyes with normal visual acuity increasing.(Table 10).This difference between pre-op and week 12 VA was statistically significant p-value 0.001(Table 11).This is similar to studies at KNH and Sabatia where there was a statistically significant difference in visual acuity at the week 8 (p-value < 0.001) and week 1-3 (p-value 0.012)visits respectively[16,24].This shows the importance of good follow-up for these children with other treatment modalities as they still have the ability to improve their vision. At the week 12+ visit, 46.4 % of eyes had good vision (Table 12). These

visual outcomes were below WHO standard recommended outcomes 46.4 % compared to >80% and is similar to findings in KNH and Sabatia [16, 24]. This could be due to many patients having been assessed using qualitative methods. The poor outcome can also be explained by the number of patients who had ocular comorbidities. Tomkins et al in Ethiopia (2011) used ambulatory vision at last follow-up as the outcome measure where 82% of eyes achieved it. In the present study 96% of eyes had ambulatory vision [42]. There were several patients who got lost to follow up as evidenced by the reducing number of eyes seen post-operatively (Figure 9) Similar findings of loss to follow-up were seen in other Kenyan studies and in some of them it was implicated as a cause of poor outcome [16,21,24,32.]

Only 6 eyes (%) out of those who came for follow-up, had poor visual outcome at the week 12 plus visit where poor outcomes were taken as visual acuity less than 6/60, not fixating and following objects, can't pick 1 mm object at 33 centimeters and not central steady and maintained. Nystagmus has been found to be an indicator of poor vision [8.] Most of the eyes (5/6) with poor outcome had strabismus and /or, nystagmus or both. In our study there was a statistically significant correlation between presence of nystagmus and poor visual outcome p-value of 0.020(Table 15) which was similar to South Indian (2013) and Ethiopian (2011) studies [21, 42]. A similar inference was made regarding presence of strabismus and poor visual outcome where p-value was 0.011[8].Two of the eyes with poor outcome had pre-operative posterior segment pathologies which additionally contributed to poor outcome; one had a disc and choroidal coloboma and the other had retinitis pigmentosa and a maculopathy. Although disc and choroidal coloboma has a bigger influence on visual field than visual acuity it causes moderate to severe visual acuity and the said patient used a low vision device prior to the surgery. .The postoperative complication implicated as a cause of poor visual outcome was post-operative

chronic fibrinous uveitis which occurred in four eyes. Fibrinous uveitis was similarly implicated as a cause of poor visual outcome in Kenyan studies by Yorston et al (2001) where 30% of eyes developed it, Saiba et al in KNH (2008) where the prevalence was at 28.1% and 11.6% at 2 and 6 months respectively and Namani (2007) where 59.2% of eyes had a fibrinoid reaction. [16, 22, 23].

Correlation between factors of interest such as sex, type of cataract and performance of biometry and the outcome of surgery at the week 12 visit was made. It was found that sex was not statistically significantly associated with outcome-value (p-value 0.094) which was similar to Ngandu's study (2014) where the p=0.620.Congenital cataracts were more likely to have worse outcomes than developmental cataract the difference being statistically significant (p-value of <0.001) which was similar to Khana's *et al* (2013) study (p <0.001) [21].There was a statistically significant difference in visual acuity between those who had biometry and those who didn't; p value (0.006) studies by Yorston et al in KEU and Ngandu's in Sabatia showed that the absolute spherical error was higher in eyes that didn't have biometry than in those that did which may have contributed to reduced vision if uncorrected [22,24].

7.8 CONCLUSION

The percentage of patients with good visual acuity at the week 12 visit was below WHO recommended standards although visual acuity improved during subsequent visits.

The intraoperative complication rate was low (10.1%) and they did not contribute to poor outcome. The commonest early and late postoperative complications were corneal haze in 11.6% of eyes and posterior capsular opacity in 21% of eyes at 6 months.

Pre-operative ocular comorbidities (disc and choroidal coloboma and maculopathy and retinitis pigmentosa), post-operative fibrinous uveitis, uncorrected refractive errors contributed to poor visual acuity

7.9 RECOMMENDATIONS

Vitrector should be functional at all times when doing cataract surgery in children so as to prevent PCO formation. Biometry should be done for all patients pre-operatively. Spectacles should be administered to all patients post-operatively and documentation of the same done.

Better patient selection should be done i.e. those with pre-operative posterior segment pathologies should not be operated.

Formation of a standardized tool for capturing pre-op, intra-op and post-op notes should be done to avoid erroneous or missing data.

7.10 STUDY LIMITATIONS

Poor record keeping.

Lack of information on duration between onset of presentation and presentation to the hospital.

Lack of follow-up records.

Lack of follow-up at week 12+ some patients come at week 1, week 1-3 then 6 months therefore their week 12 findings weren't available.

High rate of loss to follow-up only saw 39% of eyes which may mask the true findings possibly more or less good outcomes.

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APPENDIX 1: LETTER OF AUTHORIZATION

Dr. Vivian Ongore

18th October 2016

Dear Vivian,

Re: Research on Outcome of pediatric Cataract surgery at Kwale Eye Centre

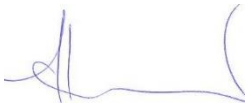
We thank you for you your interest to have research on the above-mentioned subject done at Kwale Eye Centre

Kwale Eye Centre support staff development and we look forward to you accomplishing your studies with the highest grades and being able to offer your services to the community.

We hereby approve the research to continue. Kindly share the report with Kwale Eye Centre so that we could also have the opportunity of understanding our work from a different perspective

All the best

Yours Sincerely,

For 

Dr. H. E. Roberts MBE MBChB FRCO Ophth FCOECSA

Medical Director

APPENDIX 2: Questionnaire
OUTCOME OF CHILDHOOD CATARACT SURGERY AT KWALE EYE CENTRE

A. SOCIO-DEMOGRAPHIC DATA

1) Serial No.: _____

2) Date: _____

3) Sex: - a) Male ☐ b) Female ☐

4) Date of Birth: _____

B. PRE-OPERATIVE EXAMINATION

1) Associated Systemic Condition/Syndrome

a). Yes ☐ b). No ☐ c) Not Indicated ☐

If Yes List _____

2) Eye: - a) RE ☐ 2. b) LE ☐

3) Vision: - (tick)

				RE V/A		LE V/A	
	Snellen	Decimal	Log mar	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.	Fixating and following objects						
12.	Not fixating and following objects						
13.	Picks up 1mm object at 33cm						
14.	Cannot pick up 1mm object at 33cm						
15.	Central Stable maintained						
16.	Not Central Stable Maintained						

RE **LE**

4) Other Problems: a) Strabismus ☐ ☐

b) Nystagmus ☐ ☐

c) Glaucoma ☐ ☐

d) Corneal Opacity ☐ ☐

e) Micropthalmos ☐ ☐

f). None ☐ ☐

g) Others _____ _____

5) Posterior Segment Accessible: - a). Yes ☐ ☐

b) No ☐ ☐

c) If yes: Findings: - i) Normal ☐ ☐

ii) Abnormal (specify) _____ _____

6) Type of Cataract: - a). Congenital ☐ ☐

b) Developmental ☐ ☐

c). Not indicated _____ _____

7) Corneal Diameter: - a). Horizontal _____mm _____mm

b). Vertical _____mm _____mm

8) Biometry: - a). Axial Length _____ _____

b) Keratometry

i) K1 _____ _____

ii) K2 _____ _____

iii) K average_____ _____

9) IOL Power _____ _____

10) Target Post-Op spherical equivalent: - _____ _____

C. SURGICAL PROCEDURE

	RE	LE
1. LWO	☐	☐
2. PPC	☐	☐
3. AV Done	☐	☐
4. IOL Inserted	☐	☐
5. No IOL Inserted	_____	_____

6). Post-Operative Correction (tick all that apply)

	RE	LE a).
Contact Lenses	☐	☐
b) Spectacles	☐	☐

7. Refraction: -

a) Post-Op Refraction	(Indicate actual refraction)	_____	_____
b) Post-Op Spherical equivalent		_____	_____
c) Time of refraction post-op (weeks)		_____	_____

D. INTRAOPERATIVE COMPLICATIONS

	RE	LE
1. Hyphema	☐	☐
2. Iris tear/trauma	☐	☐
3. PC Tear	☐	☐
4. Vitreous loss	☐	☐
5. Displaced IOL	☐	☐
6. Other (specify)	_____	_____

E. POST-OPERATIVE COMPLICATIONS

1. Iris prolapsed
2. Corneal haze
3. Shallow AC
4. Fibrin / membranes
5. Hyphema
6. Endophthalmitis/Hypopyon
7. Glaucoma / high IOP
8. Decentered IOL
9. PCO
10. Amblyopia
11. Other (specify :-)

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

	RE	LE

1st Post-op day		
1-3 weeks post-op		
4-11 weeks post-op		
12+ weeks follow-up		
6 months		

E. POST-OPERATIVE FOLLOW-UP

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

APPENDIX 3: WHO and KCCO post-operative visual outcome guidelines

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

APPENDIX 4: BUDGET

ITEM	QUANTITY	UNIT COST (Ksh)	TOTAL (Ksh)
PRINTING			
Proposal draft printing	54 pages	10	540
Photocopy of Proposal 2 copies	108 pages	3	324
Proposal Binding	3 copies	120	360
Printing of Questionnaire	4*1 page	10	40
Photocopy of questionnaire	4*99	3	1,188
Printing results B/W	3*70	10	2,100
Photocopy B/W	70*8	3	1680
Printing results colour	3*30	20	1800
Photocopy colour	30*8	20	4800
Binding final thesis	8	200	1,600
Subtotal			14,432
Ethics Committee Fee			2000
Travel, meals and accommodation			
Main study bus fare	1-return	1500	3,000
Accommodation	20 days	2,000	40,000
Meals	20 days	500	10,000
Subtotal			55,000
Contracted labour			
Biostatician	1		50,000
Training of assistants	1 or 2 days	2,000	4,000
Research assistant	2	7500	15,000
Subtotal			69,000
Communication			
Telephone, data and courier			9,000
GRAND TOTAL			**147,432**

Approved by_____

Signed: _____

Date_____

APPENDIX 5: TIMEFRAME

Data collection was in December 2016.

	December 2015-April 2016	May 2016	July – October 2016	December 2016	December-July 2017	October 2017
Proposal development						
Proposal presentation						
Submission to ethical review committee						
Data collection						
Data Analysis						
Dissertation writing						
Dissertation Presentation						

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Ref: KNH-ERC/A/444

9th November 2016

Dr. Vivian Ongore
Reg. No.H58/69388/2013
Dept.of Ophthalmology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Ongore

REVISED RESEARCH PROPOSAL- OUTCOME OF PEDIATRIC CATARACT SURGERY AT KWALE EYE CENTRE (P575/08/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 9th November 2016- 8th November 2017.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) 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 ERC 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 **http://www.erc.uonbi.ac.ke**

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chairperson, Dept.of Ophthalomology,UoN
Supervisors: Dr. Margaret W. Njuguna, Dr.Kahaki Kimani