PATTERN OF CORNEAL CURVATURE, AXIAL LENGTH AND IOL POWERVALUES IN CHILDREN UNDER FIVE YEARS WITHCATARACTS AT KIKUYU EYE UNIT.

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DECLARATION

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

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APPROVAL

THIS DISSERTATION HAS BEEN SUBMITTED IN PART FULFILLMENT OF THE DEGREE OF MASTER OF MEDICINE (OPHTHALMOLOGY) WITH APPROVAL OF THE SUPERVISORS

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DEDICATION

This dissertation is dedicated to my family for their endless love, patience and support through this journey of making this a reality.

ACKNOWLEDGEMENTS

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LIST OF ABBREVIATIONS

AL   Axial length

CL   Contact Lens

D   Dioptres

IOL   Intraocular lens

IOP   Intraocular pressure

K   Keratometry

KEU   Kikuyu Eye Unit

KNH   Kenyatta National Hospital

UON   University of Nairobi

WHO   World Health Organisation

ABSTRACT

Objectives: - The aim of the study was to determine the pattern of corneal curvature, axial length and IOL power in children under five years with congenital or developmental cataracts.

Design: - Retrospective case series.

Setting: - The study was carried out in Kikuyu Eye Unit.

Study population: - Children under five years with either unilateral or bilateral cataracts with records of axial length, keratometry and IOL power were included in the study. Children with complicated/ traumatic cataracts, microphthalmos, microcornea and megalocornea were excluded.

Study period: - January 2008 - December 2012.

Materials and methods: - Data was collected using a structured questionnaire. Meansof the different measures were compared with a student t-test for a difference after adjusting for clustering within individuals for patients with bilateral cataracts. Scatterplots were then generated with an overlaid fitted linear regression line and accompanying 95% confidence interval.

Results: - A total of 295 patients met the inclusion criteria, out of these 218 had bilateral cataracts while 77 had unilateral cataracts. The median age (inter-quartile range) at surgery was 18 months, with a range of 2-60months. Males were the majority at 59% while females constituted 41%. The males were found to have a longer axial length compared to the females (21.44mm versus 20.56mm; $p<0.001$). There was a rapid increase in AL in the first 2 years of 3.6mm. The females were however found to have steeper corneas than males (44.18D versus 43.38D; $p<0.001$). IOL power needed for emmetropia in 0-6 months and 47-60 months age groups were34.00D and 24.00D respectively.

Conclusion: - The greatest increase in AL is within the first two years of life. Corneal curvature probably stabilises at 6 months of age. IOL power needed for emmetropia decreases as the child grows older.

1.0 INTRODUCTION

1.1 BACKGROUND INFORMATION

Cataract remains one of the most 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. In developing countries the prevalence of blindness from cataract is thought to be 1-4/10,000 children. This is about 10 times higher than the figure for industrialised countries. The lower prevalence of blindness in developed countries is as a result of better management of cataracts.[1]

In a total of 1.5 million blind children in the world, 1.3 million live in Asia and Africa, and 75% of all cases are preventable or curable.[2,3,4] In East Africa, cataract is now the leading cause of blindness in children. A published study from Uganda estimated that cataract was responsible for over 30% of all cases of blindness and visual impairment in children. Furthermore, the outcome of surgery for cataract in Uganda was poor. Of those children for whom follow-up data were available, 56% had a corrected vision of 6/60 and the main reason for this was thought to have been the failure to wear aphakic correction.[5] A study done in East Africa in schools for the blind found that lens related disorders were found to contribute to 13.1% of severe visual impairment or blindness.[6] A study done by Yorston et al. (2001) found that three quarters of eyes had a pre-operative visual acuity of less than 3/60, post-operatively the eyes with a minimum follow-up of 3 months, 91.2% had a latest corrected vision of 6/60 or better. A corrected vision of 6/18 or better was more likely in children with zonular cataracts and in children operated on after the age of 2 years. The worse results in younger children were most likely to have been due to the greater frequency of mature cataracts leading to more severe visual deprivation during the critical period of visual development.[7]

A study done in East Africa in schools for the blind found that 18% of children examined had undergone cataract surgery or had cataract as the major cause of visual impairment; 83% of the children had either bilateral (71%) or unilateral (12%) cataract surgery, the remaining 17% had not had surgery: Of the eyes that were operated on 41% had a visual acuity of ≥20/200, 65% of the eyes had intraocular lenses and were found to have had better vision

than those without. Amblyopia was found to have been the commonest cause of poor vision in those who had undergone cataract surgery.[8]Chirambo et al.(1996) found 27% of children in Malawi to have been blind due to cataracts.[9] In Jamaica, 39% of the blind children were due to cataract. Of more concern, was the observation that the visual outcome was poor even after cataract surgery in about 14% due to deprivation amblyopia and posterior capsule opacification.[10]

Paediatric cataract blindness presents an enormous problem to the developing world in terms of human morbidity. Restoring the sight of one child blind from cataract maybe equivalent to restoring the sight of 10 elderly adults.[2] Due to the effect of childhood blindness not only on the child, but also on the whole family, the control of childhood cataract has been identified as a priority of the World Health Organization's (WHO) global initiative for the elimination of avoidable blindness by the year 2020.[3,4]

2.0 LITERATURE REVIEW

2.1 MANAGEMENT OF CONGENITAL OR DEVELOPMENTAL CATARACTS

The aim of paediatric cataract surgery is to provide and maintain a clear visual axis and a focused retinal image. This is accomplished by timely removal of the opacified crystalline lens and optical rehabilitation. Management of childhood aphakia post-cataract extraction can be through use of aphakic glasses, contact lenses (CL) and use of intraocular lens (IOL). Aphakic spectacles are a safe, reliable and easily adjustable method of optical correction, but are of little use in the unilaterally aphakic child. They are also heavy, ill-fitting, and uncomfortable and have a magnification factor of 20-30%. Lenses scratch easy and frames easily break. It is difficult to replace spectacles once broken or damaged, owing to the expense and unavailability of the small sized frames.[11, 12]

The success of a child's visual correction using CL often depends on the training and understanding of the parents or caregivers who will be responsible for the child's eyes and lens. CL correction has the major advantage of allowing easy adjustment of dioptric power to compensate for axial elongation and corneal flattening of the rapidly growing infant globe. However, non-compliance is a significant problem, [12, 13] and lenses are frequently lost and infectious keratitis, hypoxic corneal ulceration and corneal vascularisation can occur. In our

setting CL are impractical because majority of the people live in rural areas where suboptimal living standards and scarcity of clean water makes personal and ocular hygiene difficult. Regular follow-up visits to eye care clinics are problematic owing to cost and distance of travel.

Progress in paediatric cataract surgery over the past 20 years now allows cataract removal and primary IOL implantation very early in life, even before one year of age.[14, 15] Early cataract removal and replacement with an IOL represents the most appropriate treatment to avoid irreversible amblyopia[16, 17] because it offers a permanent optical correction that ensures compliance, provides a precise retinal image, and induces minimal aniseikonia. A study done by Yorston et al. (2001) in East Africa advocated implantation of an IOL as the treatment of choice for most children with cataracts in Africa.[7]

Achievement of desired refractive outcome after primary IOL implantation is, therefore, as crucial as surgery itself to minimize anisometropia and ensure acceptable refraction for the long-term. In ideal conditions, the IOL power for infants or non-cooperative children is selected according to individual keratometry and biometry measurements performed under general anaesthesia. Autokeratometers and especially the handheld type, however, are still not available in most medical centres, especially in non-paediatric ophthalmology units.

2.2IOL POWER CALCULATION

Although surgical techniques have improved over the past several years, IOL power calculation issues have not necessarily kept up.Calculating and selecting an "optimum" IOL power for the small eye of a growing child presents unique challenges. The need to implant a fixed power lens into an eye that is still growing makes it difficult to choose an "optimum" IOL power that best benefits the child's eye. The younger the child at the time of surgery, the more difficult is the problem.

Both the biometry and the age of the child determine the choice of IOL dioptric power. Two main age groups exist in paediatric cataract surgery: patients younger than 2 years and patients between 2 and 8 years. In the first group the axial length (AL) and keratometry readings change rapidly, whereas in the second group the changes are slower and more

moderate.[18, 19, 20] In order to minimize the need to exchange IOLs later in life, when a large myopic shift occurs, it is advisable to under-correct children with IOLs so that they can grow into emmetropia or mild myopia in adult life.[19] In children less than 1 year, the K readings are not crucial for calculating IOL power because these readings rapidly change from 52.00+/-4.00D to 42.00+/-4.00D in the first 6 months of life.[21] Therefore, the K readings in infants can be ignored and replaced by the average adult K-reading of 44.00D.[19] Those that are under 2 years of age should receive 80% of the power needed for emmetropia at the time of surgery. Since the keratometry readings also change rapidly during the first 18 months of life, it is practical to rely on the AL only when the IOL dioptric power is chosen for infants. For the age range 2 to 8 years, the IOL dioptric power should be 90% of that needed for emmetropia at the time of surgery.[19]

2.2.1 AXIAL LENGTH MEASUREMENT

Axial length is a measurement from the anterior surface of the cornea to the posterior pole of the eye, its value is essential in the calculation of the power of the IOL to be used. Various publications in the literature have reported that growth of the eye is influenced by the visual experience.[22, 23, 24] Visual deprivation leads to excessive eye elongation.[22, 23, 25-27] Growth of cataractous eyes may be influenced by two mechanisms: Amblyopia may lead to a longer axial length, and associated ocular anomalies may be associated with a shorter AL. The human eye undergoes extensive growth in the postnatal period[21, 28.]Theincrease of approximately 7mm in the AL from birth to adulthood requires a reduction of approximately 30 dioptres of total refractive power to maintain an emmetropic state.

Larsen(1971) reported a "rapid, postnatal phase" with an increase in AL of 3.7-3.8mm in the first year and a half of life: followed by a "slower, infantile phase" from 2-5 years, with an increase in AL of 1.1-1.2mm: and finally a "slow juvenile phase" lasting until the age of 13 years, with an increase of 1.3 to 1.4mm.[28] Subsequently Gordon and Donzis(1985) noted that the mean axial length of a full term new-born child is 16.8mm and the greatestincrease in AL occurred in the youngest age groups. By the age of 2-3 years the rate of growth slowed to approximately 0.4mm per year over the next 3-4 years. After 5 or 6 years the AL increased

by approximately 1mm for the next 5 years. No significant increase in AL was reported after 10 or 15 years of age.[21]

In younger children with cataracts, the eye with a cataract has a shorter AL compared with their normal fellow eye or data of paediatric population without cataract.[20,21,29] With advancing age, eyes with cataract have a longer AL than their normal fellow eyes.[30] In cataractous eyes, girls have shorter AL than boys.[30]The difference in AL in different ethnic groups has been controversial, Trivedi et al.(2007) found significantly longer eyes in African-Americans than in Caucasian patients with cataracts.[30] However,Gwiazda et al.(2002)did not find a difference in AL in different ethnic groups.[31]

An error in AL measurement is the most significant error in IOL power calculation and equates to almost 2.5 dioptres (D)/mm. However, this error jumps to 3.75D/mm in very short eyes (20mm). Thus, every possible step should be taken to minimize errors in AL measurement. Methods for AL measurement include the contact and immersion techniques. In the contact technique the probe touches the cornea and may result in corneal compression giving a shorter AL.[32] AL measurement by the contact technique is shorter on average by 0.24 to 0.32mm as compared to the immersion technique:[33, 34] This is mainly due to a shallow anterior chamber depth measurement, this results in the use of on average 1D stronger IOL power than is actually required. This can lead to induced myopia in the post-operative refraction.

2.2.2 KERATOMETRY

This is the objective measurement of the curvature of the anterior surface of the cornea. It uses the reflective properties of the cornea in order to measure its radius of curvature. Central corneal power values can be obtained by manual keratometry, autokeratometry or simulated keratometry. In the paediatricage group, hand held keratometry offers the convenience of obtaining keratometry measurements (K reading) under anaesthesia. Noonan et al.[35] found that theNidek automated keratometer was accurate, reliable and easy to use and its results compared favourably with those of the manual Zeiss keratometer when

measuringthe corneal curvature. Inaccuracies in keratometry have a 1:1 correlation with the post-operative refraction at the spectacle plane.

K readings of younger children have been found to be steeper than older children. Ehlers and colleagues[36] obtained 47.50D as the mean K-value for mature infants and 43.69D for children aged 2 to 4 years. They concluded that corneal curvature reaches the adult range at about 3 years of age. Gordon and Donzis[21] noted their average K-value of full-term infants as 45.20D and suggested that K-values stabilized at 6 months of age. With increasing age, mean decrease in K-values might reflect the compensatory changes in AL to keep the refractive power of the eye at a constant state.

Several publications have noted girls having steeper corneas than boys.[31, 37]Gwiazda and colleagues (2002) noted girls have significantly steeper corneas in both meridians (horizontal meridian, 44.00D versus 43.50D; vertical meridian, 44.80D versus 44.20D girl to boy).[31]Zadnik et al. reported that girls had steeper corneas than boys (0.74D steeper in the vertical meridian and 0.63D steeper in the horizontal meridian, $p < 0.001$).[37] African Americans have been found to have flatter corneas than whites; however the compensatory flatter cornea values are expected because they have significantly longer ALs.[38]K-values in eyes with unilateral cataracts have been found to be steeper than the non cataractous eyes.[37]

3.0 JUSTIFICATION

Paediatric cataract blindness presents an enormous problem in terms of morbidity, economic loss and social burden. A blind child has many blind person years ahead and, therefore, the number of disability adjusted years is more than in adults.In infants following cataract surgery spectacle fitting can be used, although their faces are poorly suited to supporting the weight of high power required (frequently in excess of +20.00D). The high power spectacles of a high refractive index are also expensive and hard to obtain. The preferred method for correcting aphakia is IOL implantation and in special cases aphakic CL.

Currently only Kikuyu Eye Unit and Lighthouse for Christ Eye Centre Mombasa perform high volume paediatric cataract surgery and obtain keratometry readings using a hand held keratometer in young children prior to surgery to determine the power of IOL to be used. The keratometry values obtained from this study will be used as a reference point in contact lens fitting in children who are left aphakic for correction of their aphakiaif the parents are able to afford.

Data from the range of IOL power inserted during surgery will be a useful guide in the choice of IOLs to be procured at the high volume centres for paediatric cataract surgery in the country. Data also from the range of AL readings and IOL power will also be useful as reference values in cases where the biometry equipment is out of order or is not available.

4.0 OBJECTIVES

4.1 BROAD OBJECTIVE

1. To determine the pattern of axial length, keratometry readings and IOL power in children with congenital and developmentalcataracts in KEU.

4.2 SPECIFIC OBJECTIVES

1. To determine the pattern of AL measurements in children with cataracts.
2. To determine the patternof keratometryreadings in children with cataracts.
3. To determine the IOL power in different age groups for emmetropia.

5.0 RESEARCH METHODOLOGY

5.1 STUDY SETTING

The study was carried out in KEU, which is located about 17 miles from Nairobi City. The eye unit was established in 1975 as part of a collaborative effort between P.C.E.A Kikuyu hospital and ChristoffelBlinden Mission (CBM). It serves patients mainly from Nairobi and other parts of the country. It is also serves as a referral centre for the East African region. It handles between 70-80,000 patients per year and performs about 6,000 operations per year.

There are currently two ophthalmologists in the facility who operate on children with cataracts, one being the resident paediatric ophthalmologist the other, a general ophthalmologist. They operate on about 300 children per year and these include self-referrals or those sponsored by various organisations mainly the "Standard Chartered Bank SEEING-IS-BELIEVING"initiative a beneficiary of the annual Nairobi marathon. The sponsored patients make up two thirds of the patients operated on annually.

At KEU all children under the age of 5 years who undergo paediatric cataract surgery have the following ocular investigations done routinely before surgery. Ocular measurements of AL and keratometry are taken with the children under general anaesthesia just before the surgery under pharmacologic mydriasis with tropicamide. The lids are kept open with a wire speculum, with the cornea being frequently lubricated with normal saline. Keratometry readings are obtained using a handheldNidek auto keratometer model KM 500 while the axial length is determined using the Alcon Ocuscan using the contact method, aiming for a standard deviation of 0.05. The keratometry values are then fed into the biometry machine (Alcon Ocuscan) and the IOL power thereafter automatically calculated using the SRK II formula.Primary IOL implantation is donein all children who undergo cataract surgery except in those who have corneal diameters of 9.00mm or less or any other contraindications. Primary posterior capsulotomy and anterior vitrectomy is performed in all the operated eyes irrespective of whether an IOL is implanted or not.

5.2 STUDY DESIGN
It was a retrospective case series.

5.3 STUDY POPULATION

Children under five years with either,unilateral or bilateral congenital or developmental cataracts who had undergone cataract surgery in the aforementioned hospital. Children above 5 years can use adult sized IOLs hence were not included in the study population.

5.4 STUDY PERIOD

January 2008-December 2012.

5.5 INCLUSION CRITERIA

All available and complete ophthalmic records of children under five years with either unilateral or bilateral cataracts and had axial length readings, keratometry readings and IOL calculation done prior to surgery.

5.6 EXCLUSION CRITERIA

Eyes with the following findings were excluded from the study:-

- Microphthalmia
- Microcornea or megalocornea
- Glaucoma
- Traumatic or complicated cataract
- Corneal opacities

5.7 SAMPLE SIZE DETERMINATION

The sample size calculation for this study aimed at determining the minimum number of case reviews required to report the AL and IOL within a certain precision.

Adopted from Lemeshow and Lwanga WHO 1991 method;

$$n = \frac{z^2 \; x \; s^2}{d^2}$$

n = required sample size

z= confidence level at 95% (standard value of 1.96)

s =Estimated standard deviation in a similar setting.

d = margin of error 0.2

Based on published and grey literature we computed using the above sample size formula several estimates for the required sample size for the various standard deviations identified and a margin of error of 0.2 to 0.5 mm/dioptres

No data from African studies was available to allow a sample size calculation, however data from other settings reported that informed this sample size calculation were: mean globe axial length of 20.52mm (±2.87) for children aged 0 to 10 years with the standard deviation for those aged less than 5 years ranging 1.34 to 1.92. A study undertaken in Italy for children aged less than 42 months reported and axial length (SD) of 20.03mm (±2.25).

We, therefore, computed a sample size based on these three conservative standard deviations assuming a precision of ±2 and ±3 mm and results are shown in the table below.

Similarly no African studies were available reporting on IOL estimations and hence a study from South Carolina informed the sample size calculation for case reviews required to estimate the IOL within ±2 or ±3 dioptres. This study reported a mean (SD) 23.95 (±0.87) for children aged 3 weeks to 24 months and the estimated sample size is presented in the table below

Table 1:- Estimated sample size calculation.

	Precision (d)	Standard deviation (s)	Sample size (n)
Axial length			
0-10 years	0.2	2.9	807
	0.3	2.9	359
Under 5 years	0.2	1.9	347
	0.3	1.9	154
0-42 weeks	0.2	2.25	486
	0.3	2.25	216
IOL			
1-24months	0.1	0.87	291
	0.2	0.87	73
	0.3	0.87	32

Based on the above estimates the largest most conservative sample size of 347 was identified that would allow the estimation of the axial length with a precision of ±2 and IOL with a precision of ±1 or more.

Further the sample was adjusted for possible clustering within individuals for patients with bilateral cataracts using a design effect of 1.4.

$n = 347 \times 1.4 = 486$

Further the sample size was increased by 5% to cater for data collected with key fields missing e.g. age.

$n = 486 \times 1.05 = 510$

Sample size required is 510.

300 paediatric cataracts surgeries are done per year, assuming a record retrieval of 60-70%, a study period of 3 years is required to meet the required sample size.

5.8 MATERIALS
Patient records

Structured questionnaire

5.9 DATA COLLECTION AND ANALYSIS
Children under five years who had cataract surgery with primary IOL implantation were identified from the theatre records after which the records clerk assisted in retrieval of the records from the records office. A structured questionnaire was used to collect data. Each patient record had a serial number which had a matching number on the questionnaire. Both eyes of children with bilateral cataracts were included.

Data was collected, cleaned and appropriately labelled with records with key data missing like age being dropped from the analysis. Descriptive statistics for the demographic factors of age and gender are presented as proportions for categorical data, mean (SD) for continuous normally distributed data and median (IQR) for skewed data.

Age was then categorised into different age groups in which data on AL, IOL and keratometry are presented. For each of the measurements the mean and the median were calculated for each eye affected and the means compared using a student t-test for a difference after adjusting for clustering within individuals for patients with bilateral cataracts.

The mean and median of the different measurements by eye affected was found not to be different between the right and left eyes. A student t-test further showed that there was no significant difference in the measurements as well; therefore, subsequent tables and scatter plots will include both right and left eyes.

Scatter plots were then generated with an overlaid fitted linear regression line and accompanying 95% confidence interval plotted by age group and overall. Correlation coefficients were then computed for the overall model. To further explain the results a regression model for each of the measurements was run with either AL, keratometry or IOL as the independent variable to obtain predicted values for each age group, significance for linearity and the R-squared which shows how much data explains the variation observed in the model.

5.10 ETHICAL APPROVAL

Ethical approval was sought from the KEU and KNH/UON ethics committees prior to commencing the study.

All information obtained from patients' records was treated with utmost confidentiality.

Information filled in the questionnaires was only accessible to the principal investigator and statistician.

6. RESULTS

A total of 527 children below five years underwent cataract surgery at KEU between January 2008 and December 2012 according to the theatre records. However, 79 files were found to be missing therefore only a total of 448 files were retrieved for analysis. The patient selection strategy is shown in Figure 1.

Out of the 448 files, 36 files were found to have no relevant documentation/ information in that 25 files had missing printouts of the keratometry, axial length and IOL power readings while 11 files had the wrong age indicated in the theatre records but in the file they were found to be older than 5 years. Another 60 children were excluded on the basis of the diagnosis out of these, 29 had lens washout for traumatic cataracts, 14 had secondary PCIOLs implanted and 17 children had plain lensectomies done. 57 children were excluded from the study because of pre-set K- readings of 44.00D; this value was used when the hand held keratometer was out of order.

Figure 1:- Patient selection strategy

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                    │    527 Children     │
                    │  underwent surgery  │
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                               │                │  79 files missing │
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                    ┌─────────────────────┐
                    │     448 files       │
                    │     retrieved       │
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│ 36 files with no relevant │◄─│
│ documentation/information │  │
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│  57 files with preset K-  │◄─│
│        readings           │  │
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                    │ 295 children included in │
                    │        the study         │
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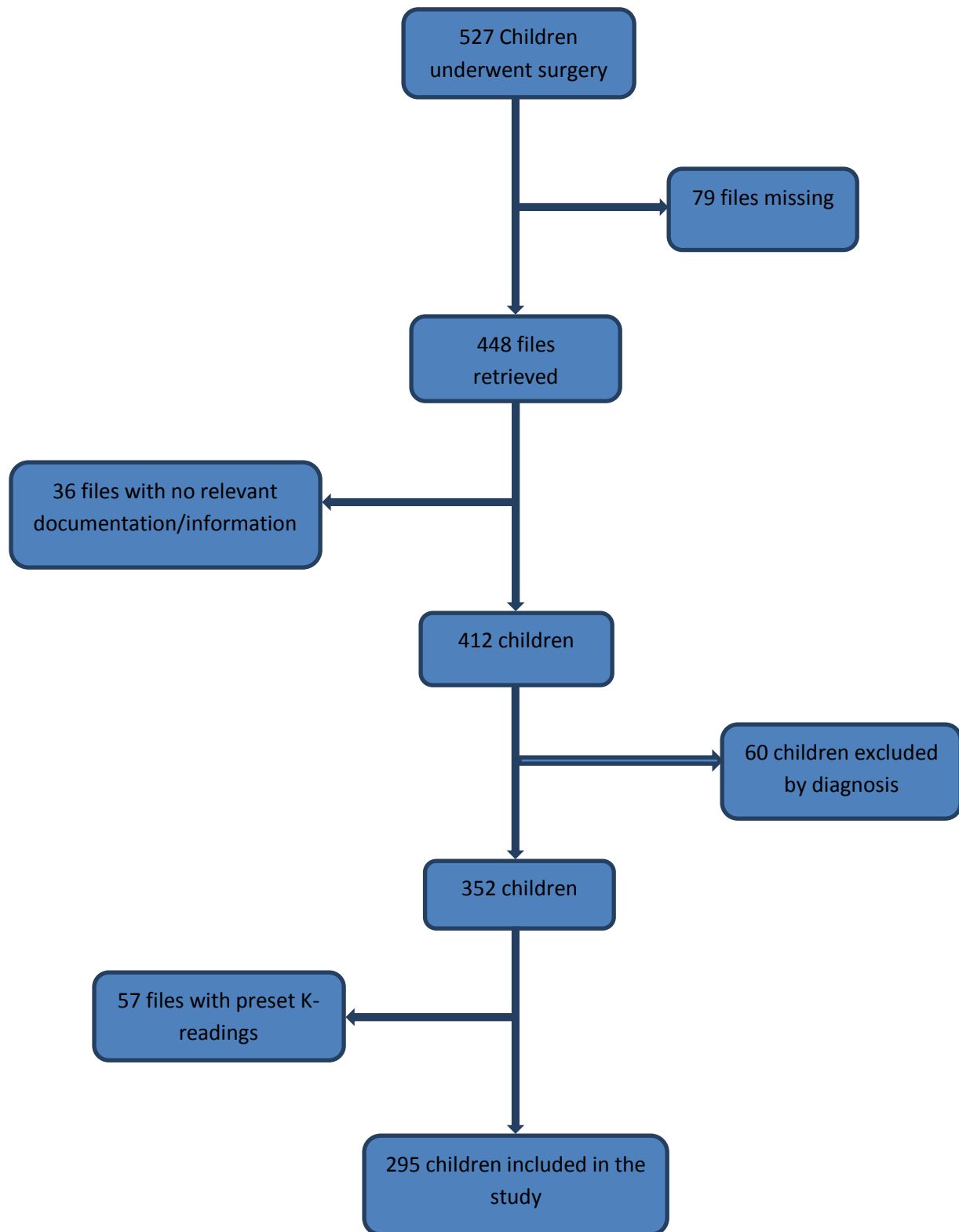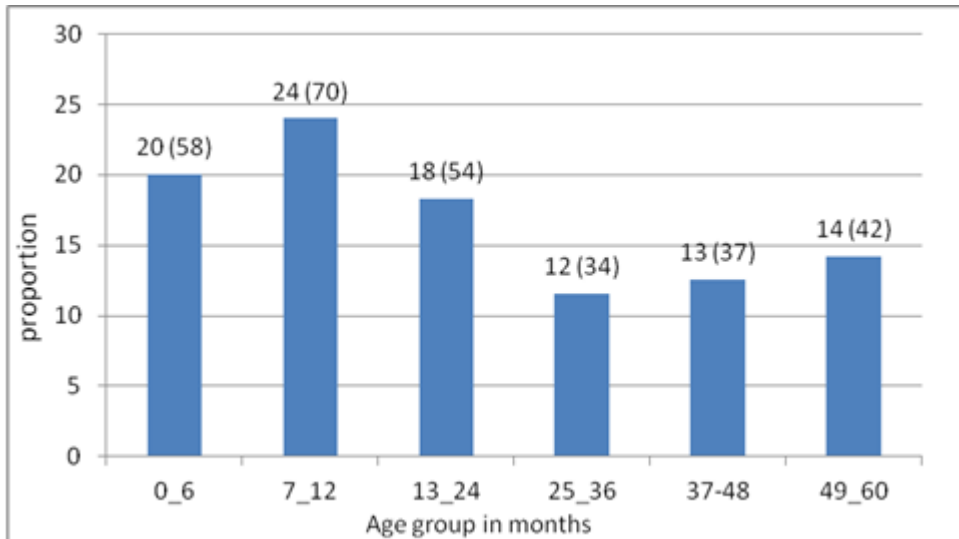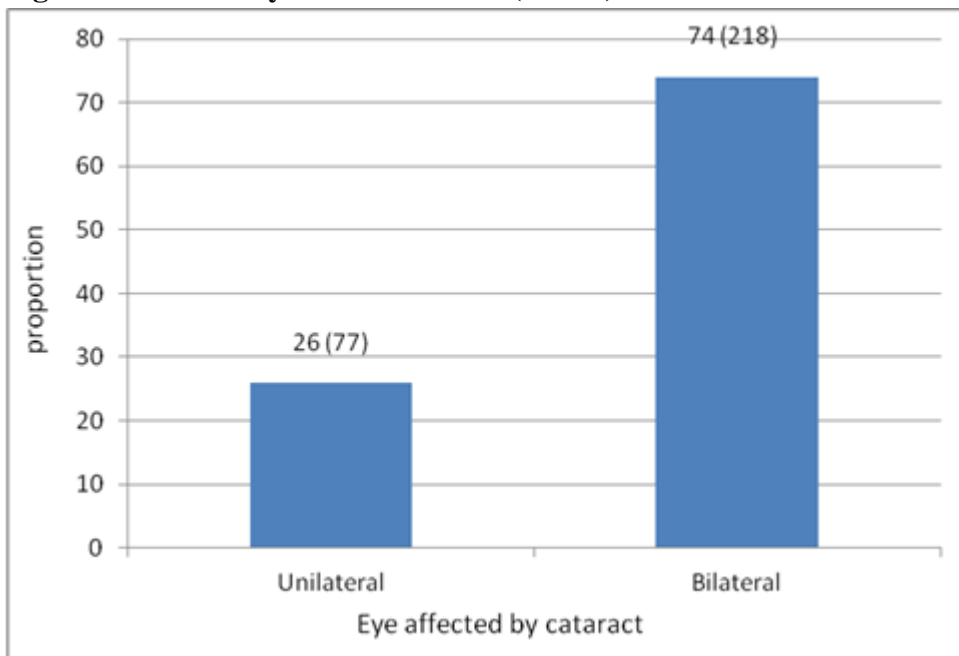**Figure 2:- Distribution of children by age (n=295)**

The median age (Inter–quartile range) at surgery was 18 (8 -42) monthswith a range of 2-60 months, with most children being 12 months and below (44%). The age group with the least number of children was 25 to 36 months with 12% (34).

Figure 3:- Laterality of the cataracts (n=295)

Majority of the children had bilateral cataracts (74%)

Figure 4:- Distribution by sex (n=295)
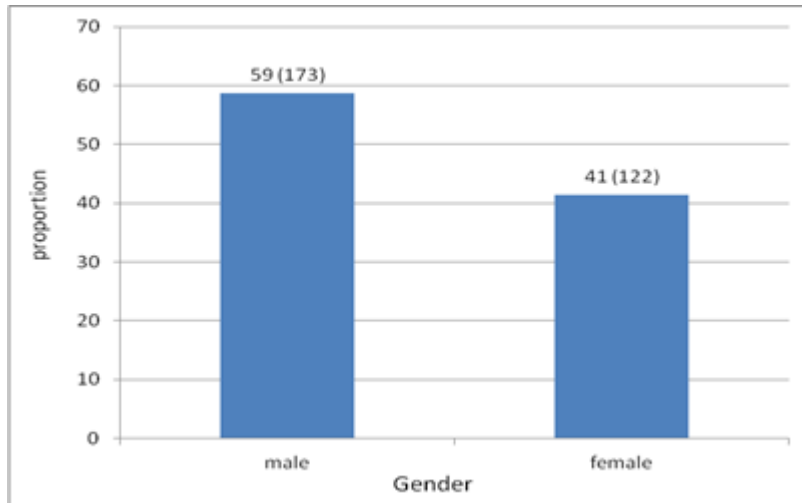
Majority of the children were male.

Table 2:- Summary of measurements by sex

	Male (n=173)		Female(n=122)			
	Median (IQR)	**Mean (SD)**	**Median (IQR)**	**Mean (SD)**	**T statistic**	**P value**
AL	21.64[19.90-22.73]	21.44 (2.25)	20.59[19.15-22.12]	20.56 (1.91)	4.435	<0.001
Keratometry	43.25[41.75-44.88]	43.38 (2.51)	44.00[42.63-45.75]	44.18 (2.40)	-3.611	<0.001
IOL	26.00[23.00-32.00]	27.20 (6.45)	29.00[23.50-34.00]	28.89 (5.99)	-3.014	0.003

For measures of AL, keratometry and IOL a significant difference existed between males and females (p value <0.01)

6.1 AXIAL LENGTH

Figure 5:- Scatter plots of axial length with a linear regression line of age and axial length (as the independent) and its accompanying 95% CI by age group

Figure 6:-Scatter plot of axial length with a linear regression line of age and axial length (as the independent) and its accompanying 95% CI pooled for all ages
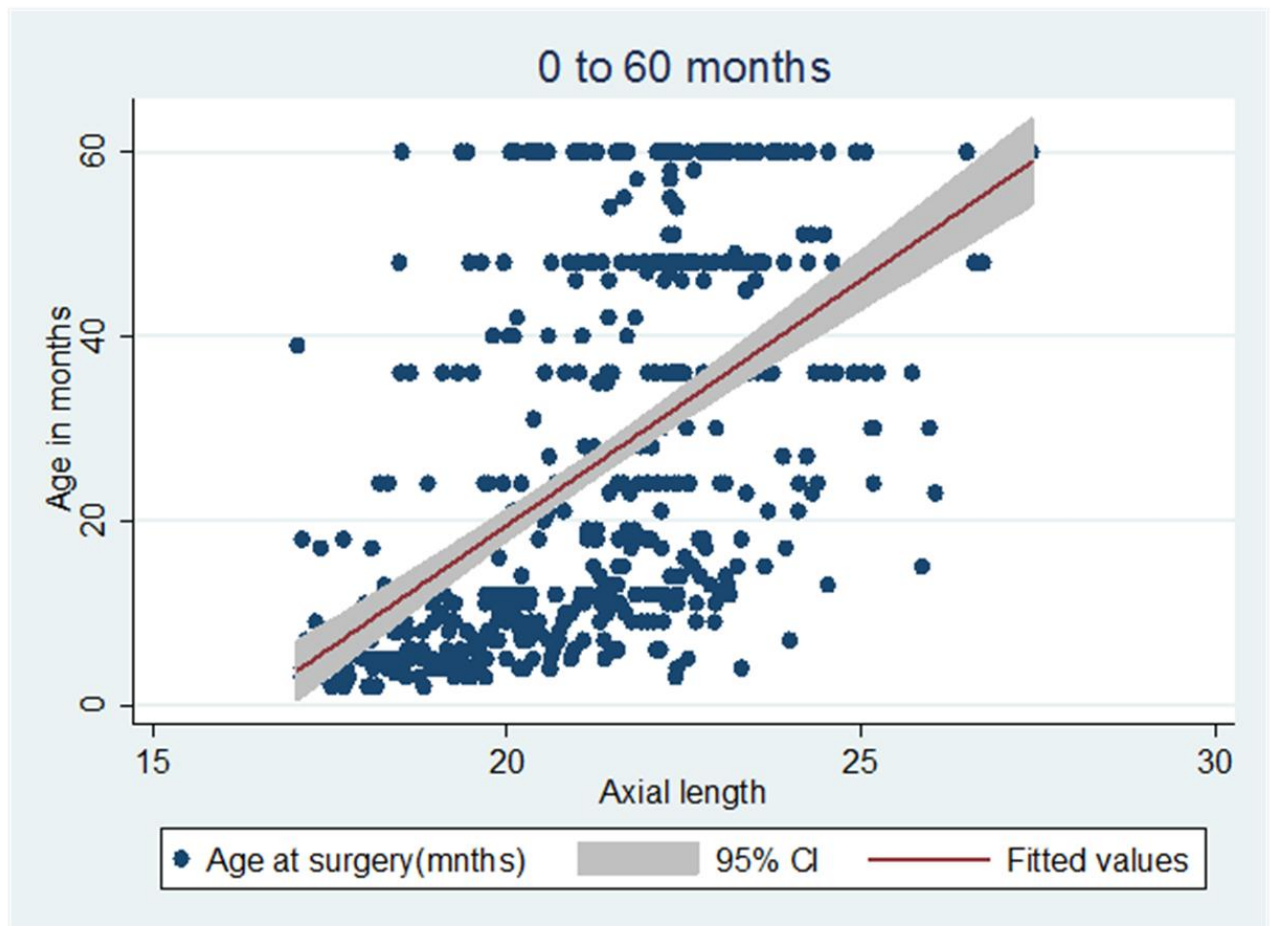
While the pooled data shows a significant positive correlation (correlation 0.55; p value<0.001) indicating an increase in AL with an increase in age, scatter plots of 6 to12 month age group show different direction and degree of correlation. However a linear regression exists in all the age groups except age group 37 to 48 months as shown by the significant p values in Table 3.

Table 3:- Linear regression model values for the various age groups with AL as the independent variable

Age (months)	constant	Standard error	p value	coefficient	R^2	n
0_6	17.83	0.54	<0.001	0.26	0.047	102
7_12	16.87	0.95	<0.001	0.34	0.0123	120
13_24	21.82	0.96	<0.001	0.00	0.000	88
25_36	23.01	2.40	<0.001	-0.02	0.001	58
37-48	7.87	4.72	0.1	0.31	0.127	67
49_60	27.46	3.82	<0.001	-0.09	0.023	76
All pooled	19.6	0.13	<0.001	0.06	0.295	511

Although a linear regression exists for almost all the age groups the regression model and line fit are only best described by the data in the age group 0 to 12 months and overall model as illustrated by R-squared values of greater than 0.2 as shown in Table 3.

Table 4:- Measurements of AL as categorised by age

Age (months)	eyes (n)	Mean (SD)	95% CI	median	range
0_6	102	18.99[1.39]	18.71-19.25	18.72	17.11–23.32
7_12	120	20.22[1.45]	19.96-20.49	20.22	17.31–24.00
13_24	88	21.73[1.77]	21.36-22.11	21.75	17.11-**26.06**
25_36	58	22.49[1.75]	22.03-22.95	22.38	18.50-25.97
37_48	67	22.18[1.72]	21.75-22.61	22.30	17.05-**26.73**
49_60	76	22.39[1.56]	22.03-22.75	22.34	18.52-**27.42**
Total	511	21.06[2.06]	20.88-21.24	21.24	17.05 – 27.42

Test for trend Z value 13.39; p value <0.001

Similar to the above results of a linear relationship between age and AL a test for trend in the means by age group was significant (p value <0.001), however the overlapping confidence intervals from 13-60 months suggest wide standard errors.

6.2 KERATOMETRY

Figure 7:- Scatter plots of keratometry with a linear regression line of age and keratometry (as the independent) and its accompanying 95% CI by age group
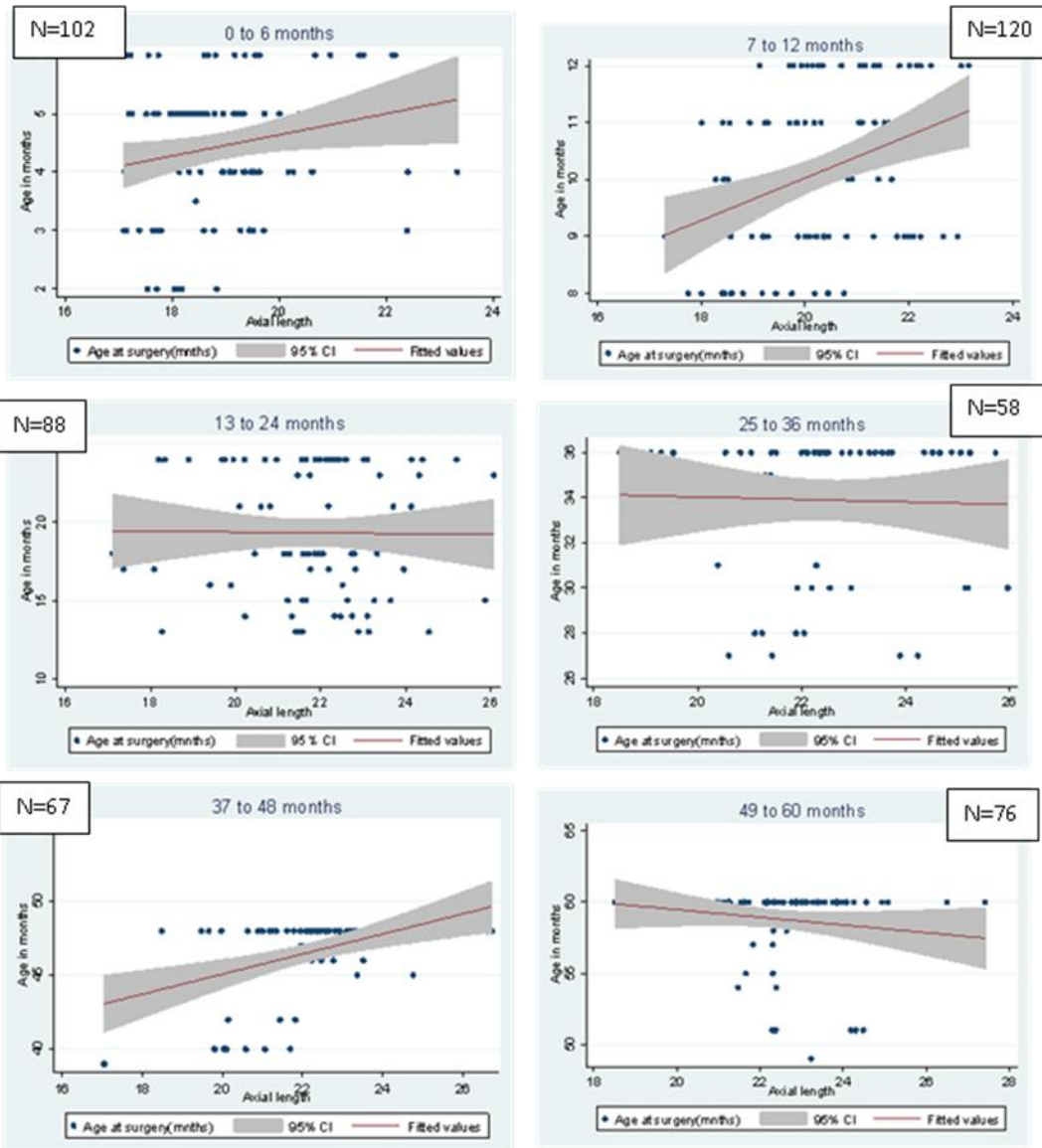
Figure 8:- Scatter plot of keratometry with a linear regression line of age and keratometry (as the independent) and its accompanying 95% CI pooled for all ages
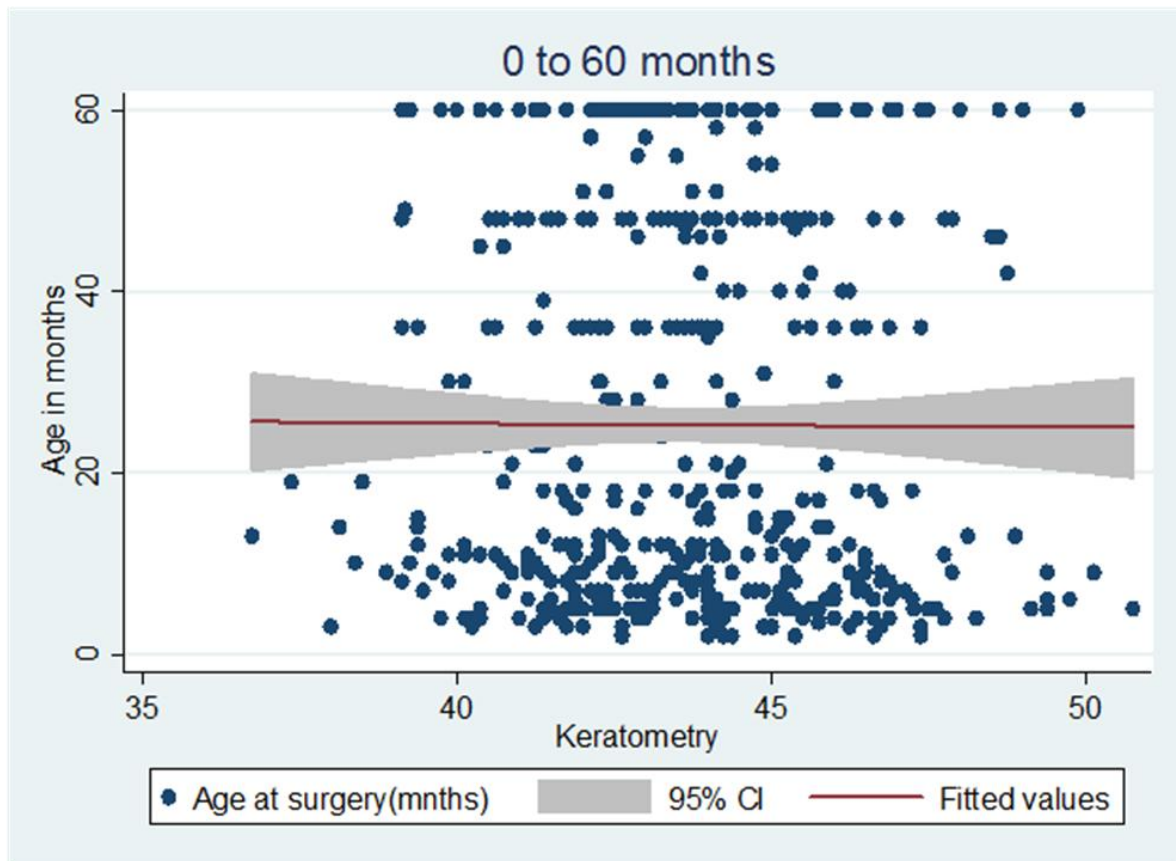
Overall there was no correlation between age and keratometry (correlation -0.02; p value =0.653) indicating no change in keratometry with age despite strong evidence (p value <0.001) for linear relationship. The lack of no correlation is further augmented by a very low R-square (0.001) suggesting that very little data explains the linear model.

Similar to the overall model there is a linear relationship between age and keratometry. The scatter plots of age by keratometry plotted by age group show a linear relationship however, the low R-square values ($R^2 < 0.12$) suggest that very little data explains the linear models as described in detail in Table 5.

Table 5:- Linear regression model values for the various age groups on keratometry as the independent variable

Age in months	constant	Standard error	p value	coefficient	R^2	n
0_6	43.07	1.00	<0.001	0.24	0.012	102
7_12	46.46	2.10	<0.001	-0.30	0.022	120
13_24	43.39	1.42	<0.001	0.00	0.000	88
25_36	42.69	2.89	<0.001	0.02	0.001	58
37-48	51.37	4.52	<0.001	-0.16	0.040	67
49_60	37.50	5.80	<0.001	0.10	0.015	76
All pooled	43.76	0.18	<0.001	-0.00	0.001	511

Table 6:- Measurements of keratometry as categorised by age

Age	Eyes (n)	Mean (SD)	95% CI	Median	Range
0_6	102	44.15[2.54]	43.65-44.66	44.13	39.75-50.75
7_12	120	43.54[2.75]	43.04-44.04	43.38	38.88-55.75
13_24	88	43.46[2.61]	42.91-44.02	43.88	36.75-50.38
25_36	58	43.37[2.11]	42.82-43.93	43.44	39.13-48.25
37_48	67	43.95[2.15]	43.42-44.47	43.88	39.13-48.75
49_60	76	43.66[2.36]	43.12-44.20	43.31	39.13-49.88
Total	511	43.71[2.49]	43.50-43.95	43.63	36.75 – 55.75

Test for trend Z value -0.47; p value =0.638

A test for trend to determine if keratormetry changes with a change in age group highlights a no trend (p value =0.638) a finding consistent with overlapping confidence intervals.

6.3 IOL POWER

Figure 9:- Scatter plots of IOL with a linear regression line of age and IOL power (as the independent) and its accompanying 95% CI by age group
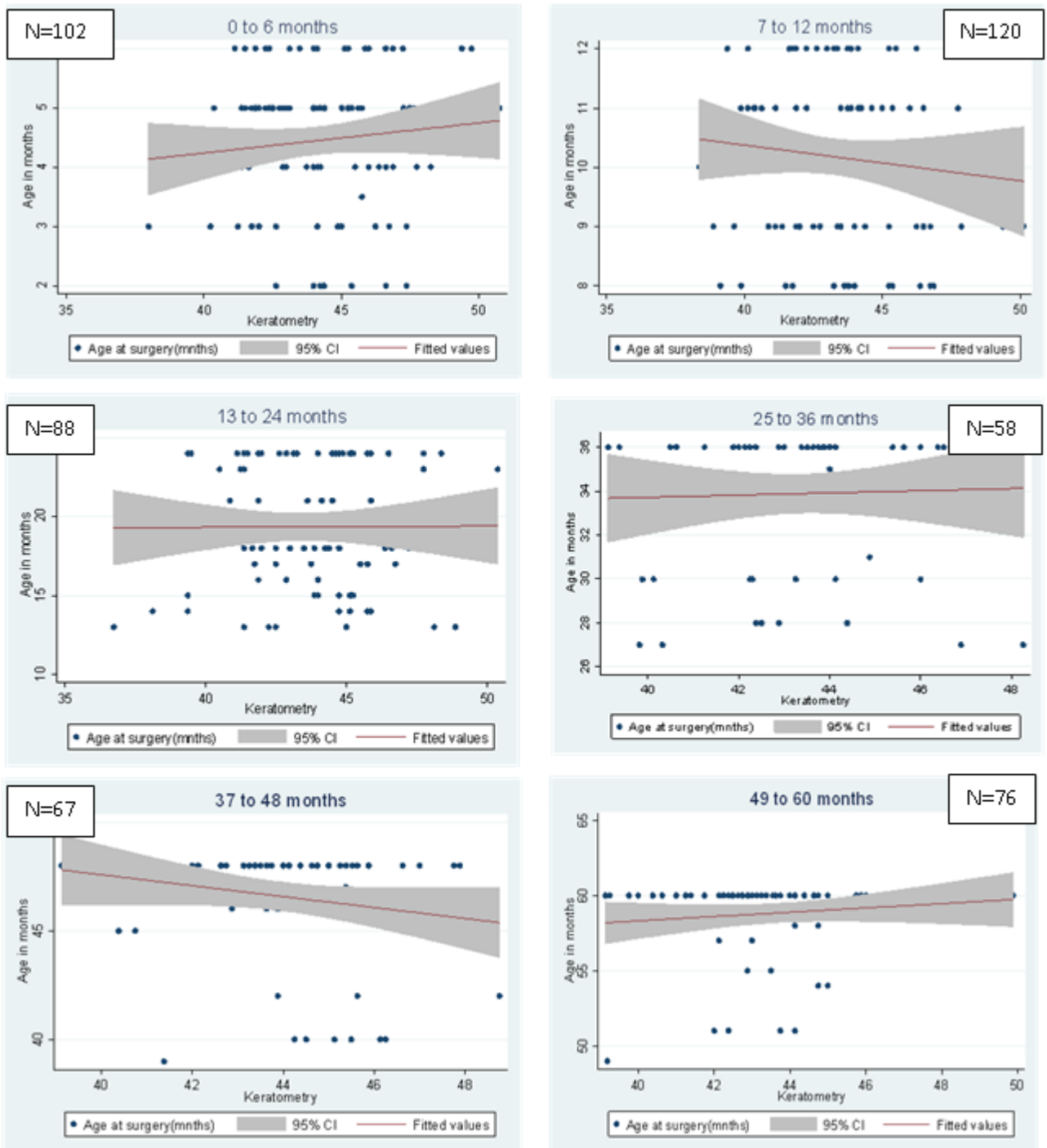
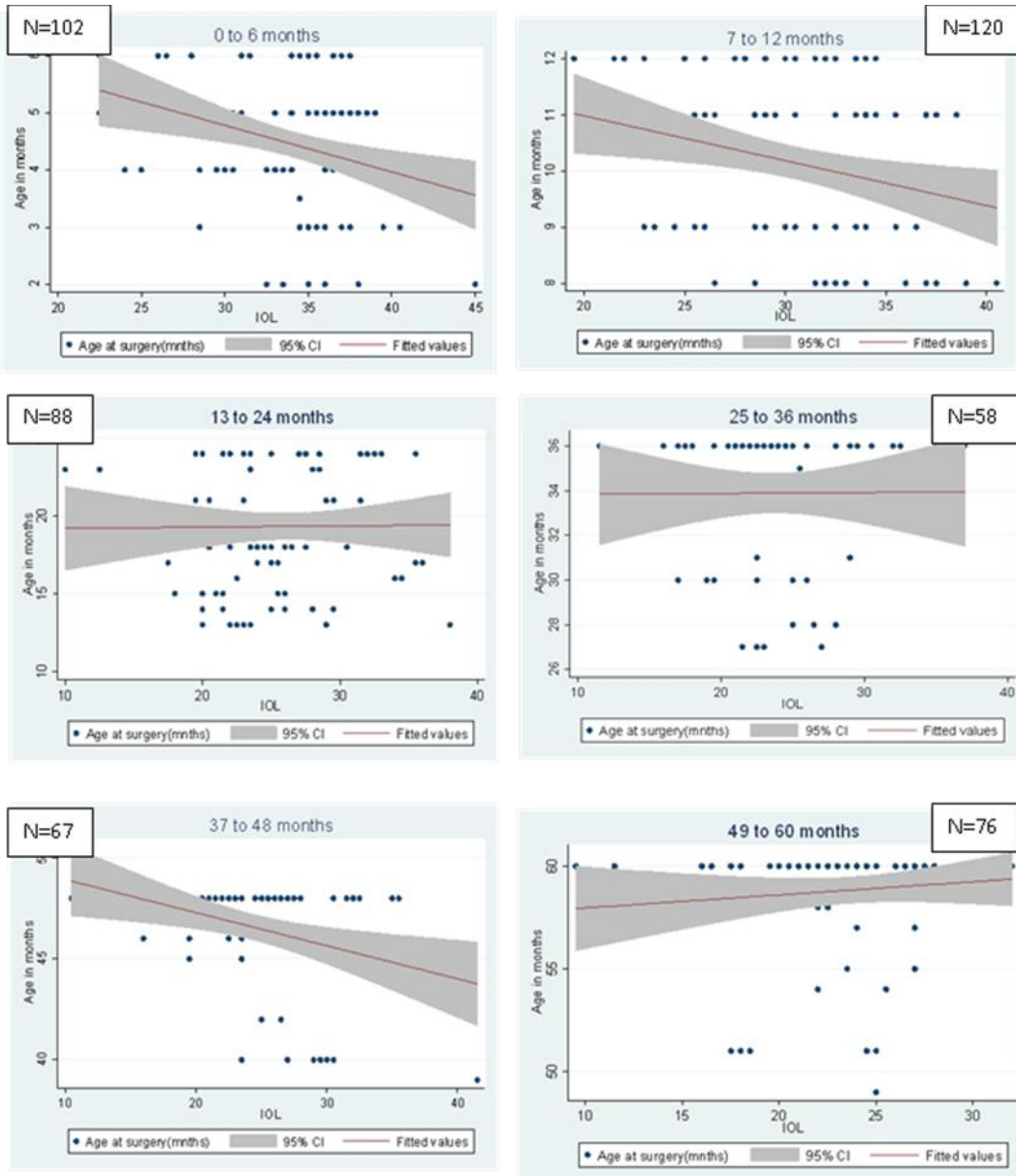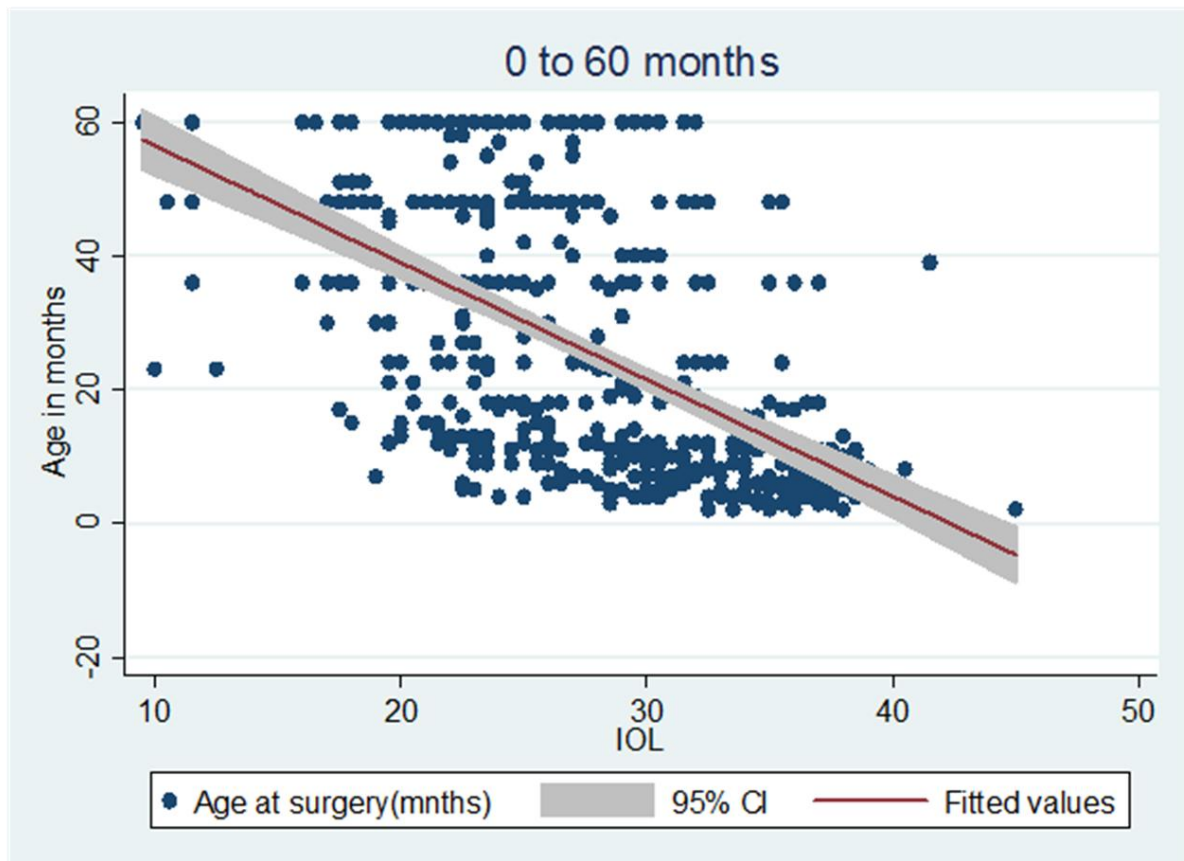**Figure 10:- Scatter plot of IOL with a linear regression line of age and IOL power (as the independent) and its accompanying 95% CI pooled for all ages**

There was a significant (p value<0.001) negative correlation (-0.57) between age and IOL for the pooled age data indicating an decrease in IOL power with an increase in age, further, there was strong evidence for a linear relationship between age and IOL (Figure 9).

Table 7:- Linear regression model values for the various age groups on IOL as the independent variable

Age in months	constant	Standard error	p value	coefficient	R^2	n
0_6	39.08	1.64	<0.001	-1.14	0.093	102
7_12	39.26	3.38	<0.001	-0.88	0.07	120
13_24	25.82	2.89	<0.001	0.02	0.000	88
25_36	23.32	7.16	0.002	0.01	0.000	58
37-48	55.82	11.07	<0.001	-0.68	0.111	67
49_60	13.11	11.48	0.257	0.18	0.012	76
All pooled	32.36	0.38	<0.001	-0.18	0.310	511

Although there was strong evidence for a linear relationship between age and IOL for the different age groups except the age group 49 to 60 months, the linear regression model estimates were explained by less than 12% (R^2 0.121) of the data (Table 7).

Table 8:- Measurements of IOL power needed for emmetropia as categorised by age

Age (months)	n	Mean (SD)	95% CI	Median	Range
0_6	102	34.00[4.34]	33.15-34.85	35.00	22.50-45.00
7_12	120	30.66[4.75]	29.80-31.52	31.00	19.50-40.50
13_24	88	26.11[5.34]	24.98-27.24	25.75	10.00-38.00
25_36	58	23.67[5.22]	22.30-25.05	23.00	11.50-37.00
37_48	67	24.34[5.48]	23.01-25.68	23.50	10.50-41.50
49_60	76	23.74[4.66]	22.68-24.81	24.00	9.50-32.00
total	511	27.89[6.32]	27.35 – 28.44	27.00	9.50 – 45.00

Test for trend Z value -13.23; p value =<0.001

Although there is no linear trend for the means a test for trend demonstrates strong evidence (p value <0.001) for a trend from age group to another a finding supported by non-overlapping confidence intervals for the first three age categories.

Table 9:- Measurements of IOL power inserted at time of surgery as categorised by age

Age (months)	n	Mean (SD)	Median	Range	95% CI
0_6	102	26.56[3.15]	27	18.00-32.00	25.93-27.18
7_12	120	24.35[3.41]	25	16.00-31.00	23.73-24.97
13_24	88	21.68[4.14]	22	8.00-29.50	20.80-22.55
25_36	58	20.28[4.79]	20	7.00-33.00	19.02-21.54
37-48	67	21.58[4.23]	21	11.00-30.00	20.55-22.61
49_60	76	21.69[4.26]	22	6.50-30.00	20.71-22.67

The table above shows that there is a decrease in the power of IOL with an increase in age.

7. DISCUSSION

A total of 295 files of children with either congenital or developmental cataracts were reviewed. Almost all the children were African (99.7%), aged 0-60 months. The mean age (IQR) at surgery was 18 months with most children (24%) being in the 7-12 months age group (Figure 2). This was different from a study done by Yorston (1993)[7] who found that the average age of patients at their first operation was 3.5 years though he included children under 11 years of age, however, those aged 5 years and below were 67.6%. A total of 21 children underwent surgery before 3 months of age, unlikethe findings by Yorston et al. where no child was operated on before 3 months of age. This contrast could be attributed to increased awareness leading to early diagnosis and the fact that there is an improvement in paediatric anaesthesia and surgical techniques over the years.

We noted a male preponderance of 59% as opposed to 41% of females; findings similar to the study done by Yorstonet al.[7] who found males to be the majority at 69%. The girl child has been empowered in the last decade and therefore we attribute the male preponderance to the higher incidence of cataracts in males rather than the greater value accorded to the boy child in society as Yorston et al did in their study.

7.1AXIAL LENGTH

Growth ofcataractous eyes may be influenced by two mechanisms: Amblyopia may lead to a longer AL, and associated ocular anomalies may be associated with a shorter AL. Visual deprivation has been shown to lead to excessive eye elongation[22, 23]. Our study had three children who had AL of greater than 26mm (Table 4); two of them had bilateral cataracts while one had a unilateral cataract. Of the two children with bilateral cataracts, one was 60months of age and had an AL of 27.42mm and 26.5mm, right and left eye respectively: The second one was 48months of age with an AL of 26.73mm and 26.61mm, right and left eye respectively: The child with the unilateral cataract was 23months of age and had an AL of 26.06mm. We can attribute the high AL readings to visual deprivation though from our study it is difficult to establish for how long the children had the cataracts before surgery was

done. Only one child was found to have an AL reading of 26.26mm in the 3-4 years age group in a study done by Trivedi et al.

It has been documented in literature that the human eye undergoes extensive growth in the postnatal period.[21, 28]The increase of approximately 7.0mm in AL from birth to adulthood requires a reduction of approximately 30D of total refractive power to maintain an emmetropic state.

In children aged less than 6 months we found a mean AL of 18.99mm ± 1.39mm (Table 4); whereas Fan et al.[39]and Trivedi et al.[30] found it to be 18.92mm ± 1.32mm and17.07mm respectively. Our study was similar to that of Fan et al.[39]in thatonly eyes that had IOL implantation were analysed, this was different from the study by Trivedi et al. where all consecutive eyes with cataracts were analysed and thus could have introduced selection bias (inclusion of eyes with microphthalmos) and this may explain the discrepancy in AL. Children aged 7-12 months had a mean AL of 20.22mm ± 1.45mm while Fan et al. found it to be 20.29mm ± 1.00mm.

We found there was a rapid increase in AL in the first 2 years of 3.6mm (Table3) suggestive of a rapid post-natal phase. This is similar to what Larsen[28] reported as the 'rapid post-natal phase' with an increase in AL of 3.7-3.8mm in the first one and a half years of age. Our study showed a slower infantile phase from 2-5 years of age (increase of 2.74mm), which was different from what Larsen[28] found (an increase of 1.1-1.2mm), this discrepancy may be explained by the high standard errors in the age groups between 25-60 months (Table 3) and this is due to the clustering of the data around the extreme of ages in different age groups hence reducing the variability of the data. Gordon and Donzis[21] also noted that the greatest increase in AL occurred in the youngest age group that is below 2 years and by the age of 2-3 years the rate of growth slowed to approximately 0.4mm per year over the next 3-4 years.

Sex differences have been reported in various studies, males were found to have longer AL compared to females in our study (21.44mm versus 20.56mm: p<0.001). Trivedi et al.[30] found females had shorter AL than males (20.23mm versus 20.78mm: p=0.09). Larsen[28] reported shorter mean AL in non cataractous eyes of females than the mean AL in non cataractous eyes of males (23.92mm versus 24.36mm: p<0.001).

Differences inAL among various races have been reported. Trivedi et al.[30] found longer eyes in African American patients than in Caucasians; in those aged 60 months and belowthe mean AL was 20.33mm and 19.69mm respectively, however this difference became more visible as age advanced (21.66mm versus 20.14mm, p<0.001). The mean AL in our study was found to be 21.10mm and the greater majority of patients were Africans (99.7%). Gwiazdaet al.[31] did not find a difference in axial dimensions in different ethnic groups.

7.2 KERATOMETRY

A homogenous population was studied as a result of exclusion of cases ofmicrocornea, megalocornea, glaucoma and corneal opacities. In our study the range of keratometry readings was 36.75-55.75D, this is different from a study done by Trivedi et al. who found a range of 39.25-63.50D, the high reading of 63.50D was in a patient with persistent foetal vasculature. They however failed to find such steep corneal curvature from any of the published literature. It has been previously reported that K-readings of younger children have been found to be steeper than those of older children. The findings from our study suggest that children aged 0-6 months have significantly steeper corneas than children aged above 6 months. Children aged 0-6 months had a mean K-reading of 44.15D (SD 2.54) while children in the other age groups had overlapping K-readings of 43.37-43.95D (Table 6). Gordon and Donzis[21] suggested that corneal curvature (K-readings) stabilised at 6 months of age, but our study could not provide a definitive conclusion regarding when K-readings stabilise because it was not a longitudinal study, but the overlapping K-readings in the age groups of 7 months and above suggest that K-readings probably stabilise at 6 months of age. With increasing age, the mean decrease in K-readings may reflect the compensatory changes in AL to keep the refractive power of the eye at a constant state. Because the mean decrease in corneal curvature cannot match the mean increase of AL in later years of life, changes in the lens may compensate in later years if a constant ocular refraction is to be maintained.

It has been reported in various studies that females have steeper corneas than males.[31, 36, 38]This is similar to what we found in ourstudy 44.18D versus 43.38D; p value < 0.001.

Trivedi et al.[38] reported that African Americans have flatter corneas than that of white subjects (45.14D vs. 45.47D) though the difference was not statistically significant (p=0.42) and the sample size of African Americans was also small(African Americans n=19 while that

of the white subjects n=75). Comparing the two studies, the mean K-readings of white subjects in the Trivedi et al.[38] study was 45.47D while in our study the average K-reading was found to be at 43.71D. There is an expected compensatory flatter keratometry readings for African Americans due to the significantly longer AL.

7.3 IOL POWER

Calculation and selection of an 'optimum' IOL power in children presents unique challenges. Eyes of normal children grow from an average of 16.8mm at birth to 23.6mm in adult life. In children less than 1 year, IOL power can be determined using AL measurements only because the K readings rapidly change from 52.00+/-4.00D to 42.00+/-4.00D[21], we found a mean AL of 18.99mm [1.39] and 20.22mm [1.45] in the 0-6months and 7-12 months age groups respectively (Table 4). Using the above values, the power of IOL can be determined.[19]From our study, children aged 24 months and below had an average under-correction of 19% while those 25 months and above had an average under-correction of 11.2% , this is similar to what was recommended by Dahan et al[19] at 20% and 10% respectively. The under-correction is advocated for so that the children with IOLs can grow into emmetropia or mild myopia in adult life. This minimizes the need for exchange IOL later in life when a large myopic shift occurs. The initial hypermetropia is effectively treated with corrective spectacles.

From our study we found that the power of the IOL needed for emmetropia in the 0-6months age group was 34.00D while that of children aged 49-60months was found to be 24.00D (Table 9), this shows a decrease in the optical component of the eye as it increases in size. The natural lens power has also been shown to decrease from 34.4D to 18.8D by 7 years of age; this indicates a proportional decrease in the optical component of the eye as it increases in size.

8. LIMITATIONS

While it is possible to predict values of the various measurements for certain ages when using the regression models, little data (less than 30%) for all the measurements has been used to make predictions and hence the potential of imprecise predictions.

Further, most of the data is clustered around whole numbers for age in months especially in the age groups from 25-60 months, hence reducing the variability in the data.

AL and keratometry readings were not taken by one person, they were taken by different people and this could have introduced inter user errors.

9. CONCLUSIONS

From this study a number of conclusions can be drawn:-

1. The greatest increase in AL is within the first 2 years of life, with an increase of 3.6mm; thereafter the increase in the AL slows.

2. Males were found to have longer AL compared to females (mean of 21.44mm vs 20.56mm: p value < 0.001)

3. Children aged 0-6 months have significantly steeper corneas than children over 6 months. This is an indicator that corneal curvature probably stabilises by 6 months.

4. Females have steeper corneas compared to males (mean 44.18D vs 43.38D: p value <0.001)

5. IOL power needed for emmetropia decreases as the child grows. Mean IOL needed for children aged 0-6 months is 34.00D, while that of children aged 49-60 months is 24D.

10. RECOMMENDATIONS

To make useful extrapolations of data there is need to improve on the approach for routine data collection; Instead of using age of the child, it would be more useful to use the date of birth from which the age of the child can be deduced.

A prospective study should be undertaken to determine the long term refractive change in paediatric pseudophakia, to establish whether as the children grow they achieve emmetropinisation with the under-corrected IOL power inserted at the time of surgery in our setting.

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12. APPENDICES

APPENDIX 1: ETHICAL APPROVAL

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14ᵗʰ May 2013

Dr. Kareko Catherine Wamuyu
Dept. of Ophthalmology
School of Medicine
University of Nairobi

Dear Dr. Kareko

RESEARCH PROPOSAL: PATTERN OF CORNEAL CURVATURE, AXIAL LENGTH AND IOL POWER VALUES IN CHILDREN UNDER FIVE YEARS WITH CONGENITAL OR DEVELOPMENTAL CATARACTS IN KIKUYU EYE UNIT (P34/02/2013)

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 periods are 14ᵗʰ May 2013 to 13ᵗʰ May 2014.
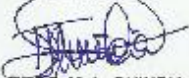
This approval is subject to compliance with the following requirements:

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.

Protect to Discover

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
        Dean, School of Medicine
        Chairman, Dept of Opthalmology, UoN
        The HOD, Records, KNH
        Supervisor: Dr. Njuguna W. Margaret, Dr. Sheila Marco, Dr. Daniel G. Mundia

APPENDIX 2: QUESTIONNAIRE

BIODATA

Patient's Name:-

Patient's Number:-

Race:-

Sex   Male   ☐   Female   ☐

Ageat surgery   Months   ☐

PRE-OPERATIVE EVALUATION

Operated Eye   RE ☐ E   ☐

INVESTIGATIONS

RE   LE

Axial length   ----------------------   -------------------------

Keratometry   ----------------------   -------------------------

IOL power (emmetropia)   ----------------------   -------------------------

IOL power inserted at surgery   ----------------------   --------------------------

APPENDIX 3: DISSERTATION BUDGET

ITEM	QUANTITY	UNIT COST (KSH)	TOTAL (KSH)
Proposal printing	26 pages	10	260
Photocopy of proposal	26 pages	3 copies @ 3	234
Binding proposal	3 copies	150	450
Proposal printing 2nd draft	26 pages	10	260
Photocopy of proposal 2nd draft	26 pages	3 copies@ 3	234
Binding of proposal 2nd draft	3 copies	150	450
Ethics committee fee			2000
Printing of questionnaire	1 page	10	10
Photocopy of questionnaire	350pts*1 questionnaire	3	1050
Preliminary results	40 pages	10	400
2 copies to supervisors	80 pages	3	240
Revision of results	80 pages	3	240
Printing of Results (Black & White)	3 * 70	10	2100
Printing of results (colour)	3* 70	20	4200
Copy final book (black & white)	8* 70	3	1680
Copy final book (colour)	8* 20	20	3200
Binding final paper	8 copies	200	1600
CONTRACTED SERVICES			
Quantitative researcher	1		35,000
Internet services			3000
TRANSPORTATION			
Nairobi – kikuyu eye unit	3 weeks(private car)	2500	7500
FOOD			
lunches	15 days	500	7500
GRAND TOTAL			**71608**