OUTCOME OF AGE RELATED CATARACT SURGERY AT MBINGO BAPTIST HOSPITAL EYE UNIT, NORTH WEST REGION, CAMEROON

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A THESIS PROPOSAL PRESENTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTERS IN MEDICINE (OPHTHALMOLOGY), FACULTY OF MEDICINE, DEPARTMENT OF OPHTHALMOLGY,UNIVERSITY OF NAIROBI

DECLARATION

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

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LIST OF ACRONYMS AND ABBREVIATIONS

AC IOL	Anterior Chamber Intraocular Lens
AMD	Age related Macula Degeneration
AD	Autosomal Dominant
BCVA	Best Corrected Visual Acuity
CCC	Continuous Curvilinear Capsulorrhexis
DM	Diabetes Mellitus
ECCE	Extra-Capsular Cataract Extraction
ICCE	Intra-Capsular Cataract Extraction
IOL	Intraocular Lens
IOP	Intraocular Pressure
MSICS	Manual Small Incision Cataract Surgery
PC IOL	Posterior Chamber Intraocular Lens
PC tear	Posterior Capsule tear
Phaco	Phacoemulsification
RACSS	Rapid Assessment of Cataract Surgical Services
SPSS	Statistical Package for Social Scientists
VA	Visual Acuity
WHO	World Health Organization

ABSTRACT

Objective: The overall objective was to assess the outcome of age related cataract surgery at Mbingo Baptist Hospital, Eye Unit, North West Region, Cameroon from the 1st January 2014 till 31st of December 2014

Methods: This was a retrospective hospital based case series conducted at Mbingo Baptist Hospital, Eye Unit, North West Region, Cameroon**.** Data was abstracted from files of patients 40 years old and above, who had undergone cataract surgery for age related cataract. The data was captured using a data collection tool and analyzed using STATA Version 20.0. Descriptive and univariate analysis was carried out.

Results: Of the 230 files analyzed 82.2 % of eyes were blind and 3.5 % had severe visual impairment preoperatively. The uncorrected visual acuity was 6/18 or better in 2.3% eyes on day one and improved to 10.2 % eyes at 4-6 weeks. The uncorrected visual acuity was less than 6/60 in 30.3 % of eyes on day one and reduced to 20.4% eyes at 4-6weeks.Only 6% of the eyes had refraction done. All the eyes had biometry done. Intraoperative complication rate was 13% with vitreous loss accounting for 4.3%. At 4-6 weeks post-operatively the major cause of poor outcome was ocular comorbidity and found to be statistically significant (p-value 0.040).

Conclusion: Uncorrected visual acuity at 4-6 weeks was below the WHO bench mark and ocular comorbidity was a major cause of poor outcome.

Recommendations: Provide a wide variety of IOL powers and refraction should be made as a rule for all patients with provision of affordable spectacles for those with refractive errors. Device ways to improve patient follow up.

CHAPTER ONE: INTRODUCTION

Blindness (visual acuity of less than 3/60 in the better eye with available correction) is estimated to affect around 39 million people in the world out of which 19.9 million due to cataract. An additional 246 million have low vision (visual acuity of <6/18to $\geqslant 3/60$ in better eye with available correction) giving a total of 285 million people with visual impairment (visual acuity <6/18 to ⩾6/60 in the better eye with available correction).Ninety percent of worlds visually impaired reside in developing countries with preventable causes accounting for as high as 80% global visual impairment burden[1]. From the 1990 global estimate of visual impairment it was projected that by the year 2020, seventy nine million people will become blind if no intervention is made. The World Health Organization (WHO) came up with a intervention strategy called VISION 2020 "The Right to Sight" .This is a global initiative of the World Health Organization and the International Agency for Prevention of Blindness whose main aim is to eliminate the main causes of avoidable blindness by 2020 [2].

CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology of cataract

Cataract as defined by WHO is clouding of the crystalline lens of the eye which prevent clear vision[3].Cataract is leading cause of blindness and visual impairment.Globally as at 2010 it was estimated that cataract was responsible for 51% of world blindness, representing about 19.9 million people with 65 % of people visually impaired and 82% of all blind being 50 years and older[4].The other leading causes of blindness included glaucoma (8%), Age related Macular Degeneration (5%), childhood blindness and corneal opacities (4%), uncorrected refractive errors and trachoma (3%), and diabetic retinopathy (1%). The undetermined causes where 21%.[4] Cataract was also found to be principal cause if visual impartment (33%) after uncorrected refractive errors(43%).The other causes of visual impairment where glaucoma (2%), age related macular degeneration (AMD), diabetic retinopathy, trachoma and corneal opacities, all about 1% each. A large proportion of causes, 18%, remained undetermined. [4]

In Cameroon a RACSS survey on people age 40 and above in the Limbe urban area and Muyuka rural area by Oye et al showed prevalence of bilateral blindness to be 1.1% and 1.6% respectively with cataract to be the leading cause of blindness 21% and 62.1 respectively.[5,6]

In Nigeria a national survey found cataract to be responsible for 45.3% of severe visual impairment and 43% of blindness [7]. Similar results were also noted in RACSS survey at Embu district Kenya which showed cataract to be the commonest course of blindness (39.7%).[8]

2.2 Classification of Cataract

Cataract can be classified as either congenital (developmental) or acquired. Acquired cataract can be classified as Age-related cataract, Secondary cataract and Cataract associated with systemic diseases. Systemic diseases associated with cataract include Diabetes Mellitus, Myotonic dystrophy, Atopic dermatitis and Neurofibromatosis-2.Secondary (complicated) cataract develops as a result of some other primary ocular disease commonly chronic anterior uveitis, acute congestive angle-closure, high myopia and hereditary fundus dystrophies.

Systemic medication e.g. Steroids, and Ionizing radiation and ultra violet rays are also associated with cataracts. [9]

2.2.1 Age related Cataract

Prevalence of age-related cataract increases with age and prevalence doubles with each decade of age after forty years, so that everyone in their nineties is affected. Age related cataract usually begins after the age of 40years, although in some parts of Asia it is not uncommon for them to begin earlier.[10] As the lens ages, it increases in weight and thickness and decreases in accommodative power. As new layers of cortical fibres are formed concentrically, the lens nucleus undergoes compression and hardening (nuclear sclerosis). Chemical modification of the nuclear proteins also increases pigmentation, such that the lens increasingly takes on a yellow or brownish hue with advancing age.[11]Age-related cataract can be classified into subscapular, nuclear, cortical cataract. Anterior subscapular cataract lies directly under the anterior lens capsule and is associated with fibrous metaplasia of the lens epithelium. Posterior subscapular opacity lies just in front of the posterior capsule. Due to its location at the nodal point of the eye, a posterior subscapular opacity has a more profound effect on vision than a comparable nuclear or cortical cataract. Near vision is frequently impaired more than distance vision. Nuclear cataract is an exaggeration of the normal ageing changes involving the lens nucleus and often associated with myopia due to an increase in the refractive index of the nucleus and with increased spherical aberration. Cortical cataract may involve the anterior, posterior or equatorial cortex. Patients with cortical opacities often complain of glare due to light scattering.[11]

2.3 Risk Factors for Cataract

There are various risk factors for cataract. These include: smoking, diabetes, ultraviolet-B (UV-B) radiation, ionising radiation, medications such as steroids and topical intra-ocular pressure lowering agent and genetics. [12]

2.4 Management of cataract

The mainstay of treatment is surgery and cataract surgery is the removal of the opacified crystalline lens and insertion of a synthetic intraocular (IOL) lens. If an IOL cannot be used,

contact lenses or eyeglasses must be worn to compensate for the lack of a natural lens. Cataract surgery aims to rehabilitate blind or visually impaired persons by restoring their eye sight so that their quality of life and ability to function are returned to normal or as near normal as possible.

Although cataract surgery has been shown to be one of the most cost-effective health interventions, the outcome of cataract surgeries is often not optimal especially in Africa and Asia.[13]

Cataract surgery visual outcome can be used as an indicator to measure performance so as to monitor the quality of cataract services. The outcome can be assessed with full spectacle correction ('best vision') or with available correction ('functioning vision'). Good outcome is defined as 6/6–6/18 (available and best correction grades = >85% and >90% respectively), borderline outcome as <6/18–6/60(available and best correction =<15% and <5% respectively), and poor outcome as <6/60 (available and best correction =<5% for each type). These broad categories can further be subdivided into: 6/6 excellent, 6/9 very good and 6/12 good.[14]

2.4.1 Indications for cataract surgery

Mainly indicated in the restoration of visual function and improving the quality of vision. Also indicated were cataract is a cause of ocular morbidity like in phacomorphic glaucoma or hinders manoeuvres on the retina as in diabetic retinopathy. It can also be cosmetic such as in case of a mature cataract in an otherwise blind eye to restore a black pupil. [9]

2.4.2 Pre-operative evaluation

More often than not patient will present with poor vision on the affected eye. Visual acuity is tested for both far and near. A cover-uncover test may reveal possibility of amblyopia if strabismus is present. Examination of ocular adnexa may reveal abnormalities and infections that may predispose to endophthalmitis and which may require effective preoperative treatment. Anterior segment findings such as corneal scar, shallow anterior chamber and a poorly dilating pupil can render a cataract surgery difficult. A relative afferent pupillary defect may highlight problems with optic nerve. Pseudoexfoliation may result in complications and the surgery should therefore be done cautiously. Fundus pathology such as

age-related macular degeneration may affect the visual outcome.[9] B-scan ultrasonography of the posterior segment of the eye is useful whenever it is impossible to visualize the retina because of a dense cataract. Ultrasonography can elucidate whether a retinal detachment, vitreous opacity, posterior pole tumour, or staphyloma is present.[11] A general medical evaluation aims at identifying comorbidity that may affect surgery. A history of cardiac, pulmonary events especially if recent is important. Adverse drug reactions and use of anticoagulants and prolong oral steroids is also important.

2.4.3 Biometry

Biometry facilitates calculation of the lens power likely to result in the desired postoperative refractive outcome. It involves the measurement of two ocular parameters; Keratometry which measures the curvature of the anterior corneal surface expressed in dioptres or mm of radius of curvature and; axial length which is the anteroposterior dimension of the eye in millimetres[9].This is achieved by use Sanders-Retzlaff-Kraff (SRK II), SRK/T, Holladay 1, Holladay 2 and Hoffer Q formulae and have been demonstrated to have equivalent refractive results.[15]

2.4.4 Types of cataract surgery

Techniques for cataract surgery has changed dramatically over the past decades. However the ancient technique of couching is still practice parts of Sub-Saharan AfricaandAsia.[16, 17, 18, 19.]

Couching involves the use of a sharp or blunt instrument to dislocate the cataract lens and push it back into the posterior chamber of the eye.[21]

Extra capsular cataract extraction (ECCE), manual small incision cataract extraction (MSICS), phacoemulsification (Phaco) are the common type of cataract surgery techniques performed worldwide.[22]

Extra capsular cataract extraction: It involves manual expression of the lens through a large (usually 10–12 mm) incision made in the cornea or sclera. Although it requires a larger incision and the use of stitches, the conventional method may be indicated for patients with very hard cataracts or other situations in which phacoemulsification are problematic.[23]

Manual small incision cataract surgery (MSICS): The lens nucleus is prolapsed through a self-sealing scleral tunnel wound. An appropriately constructed scleral tunnel is watertight and does not require suturing.[24]

Intra-capsular cataract extraction: Involves removing the whole lens still within its intact capsule. This technique is hardly used in the developed world as the visual results are generally poorer and the operative and postoperative complications greater due to the large incision required and pressure placed on the vitreous body.It remains common in the developing world, however, because it requires less costly and sophisticated instruments, there is less dependency on back-up services and a reliable electricity supply, and it can be performed after a minimum of training.[25]

Phacoemulsification: This is the most common technique used in developed countries. Phacoemulsification with foldable IOLs is undoubtedly the gold standard wherever Phaco machines and trained surgeons are available and the service affordable. Unfortunately, the technique depends upon not only just a costly piece of technology, but also on more expensive consumables and trained human resource. [25]

Both Phacoemulsification and MSICS achieved excellent visual outcomes with low complication rates. MSICS is significantly faster, less expensive, and less technology dependent than phacoemulsification. MSICS is a more appropriate surgical procedure for the treatment of advanced cataracts in the developing world .[26, 27].

2.5 Complications of cataract surgery

Complication following cataract surgery represent a significant obstacle to the success of any blindness prevention programme and to the successful implementation of VISION 2020.At a conservative estimate, at least 25% (or 1.5 million) of the six million cataract operations performed annually in developing countries will have poor outcomes. About one quarter of these poor outcomes are due to surgical complications. Over 375,000 people can therefore suffer permanent visual impairment every year as a result of surgical complications [28]. Studies in, Bangladesh, Kenya, Pakistan showed poor outcome due to surgical complications to be 30%, 22%, and 25% respectively. [29, 30, 31] the most important surgical complications that affect the visual outcome are capsular rupture and vitreous loss, which is relatively common and potentially serious post-operative endophthalmitis. These complications may occur in

about 6% of cataract surgeries cases in the developing world compared to about 4% in developed countries.[28] Prophylactic intra-operative intracameral antibiotics has reduced this risk of developing endophthalmitis significantly. [32] In high-income countries, the incidence of capsular rupture and vitreous loss appears to be declining and is now in the region of 1–2%. This improvement may be related to the use of phacoemulsification and to earlier intervention, which means that the great majority of cataracts are now removed before they are mature. In low- and middle-income countries, however, the incidence of capsular rupture and vitreous loss appears to be higher. [32] This is probably due to the greater complexity of many cataract operations in developing countries, rather than to specific deficiencies of training, expertise, or equipment used.

The incidence of endophthalmitis may vary. Studies from Europe give the estimated incidence as 0.14% [33.]at Aravind eye hospital, in India, this incidence is about 0.05%.[34]

The causes of endophthalmitis might vary with geography. In most European studies, *Staphylococcus epidermidis* is the most common infecting microorganism. This bacterium is found in normal eyelid skin and conjunctiva, and it enters the eye during surgery. However, in South India, *Nocardia* species were the commonest cause of infection[34].When endophthalmitis does occur, the prognosis is grim. In the UK, one third of patients who suffered this complication had a final visual acuity (VA) of less than 6/60, and 13% had lost all light perception[33].At Aravind Eye Hospital in India, 65% of eyes had VA <6/60 .[34] However, these figures also show that the prognosis following endophthalmitis is by no means hopeless.

Studies in Ghana showed early surgical complications occurred in 10.1% of eyes with cornea oedema being common followed by hyphema. Other early complication noted were high IOP, iridodialysis, dislocated IOL, striate keratitis, posterior synechiae, posterior capsule tear, iritis, vitreous haemorrhage. Posterior capsule opacification was the most common late surgical complication and occurred in 1.4% of eyes this was followed by vitreous loss which occurred in 0.5% of eyes. Other late complications noted were macularoedema.[35]

In western region of Nigeria studies done also demonstrated posterior capsular rupture with vitreous loss (27.35%) and posterior capsular rupture without vitreous loss (6.28%) as

commonest intraoperative complication while posterior capsular opacity being the most common post-operative complication. Other complication noted were, retained lens material, bullous keratopathy, intra ocular lens dislocation and, endophthalmitis.[36]

In Kenya posterior capsule (PC) tear without vitreous loss and PC tear with vitreous loss was0.8 % and 0.5%respectively.Other post-operative complications were corneal oedema with descemet folds, shallow anterior chamber mild iritis and peaked pupil, PCO, cystoid macular oedema .[37]

CHAPTER THREE: JUSTIFICATION

According to the World Health Organization (WHO), cataract is the leading cause of blindness and visual impairment throughout the world. Despite an increase in the number of people who undergo cataract surgery the visual outcome has remained poor necessitating the need for a continuous audit. Studies done in Limbe and Muyuka, south west region of Cameroon showed 57% and 63.4% of eyes operated had poor visual outcomes (presenting VA <6/60) respectively which falls short of the WHO recommendation that poor (BCVA <6/60) borderline (BCVA <6/18) outcomes after cataract surgery should not be more than 10% to 20% .[5,6]

Cataract audit is an essential tool in monitoring quality of cataract surgical services. This study aims at looking at the outcome of age-related cataract surgery done in this hospital. In addition, no similar study has been done previously in Mbingo Baptist Eye Hospital and the region at large. Information obtained in this study will be used to institute the basis for a prospective monitoring of outcome of cataract surgery in the hospital and the region at large.

CHAPTER FOUR: Objectives

4.1 Broad Objectives

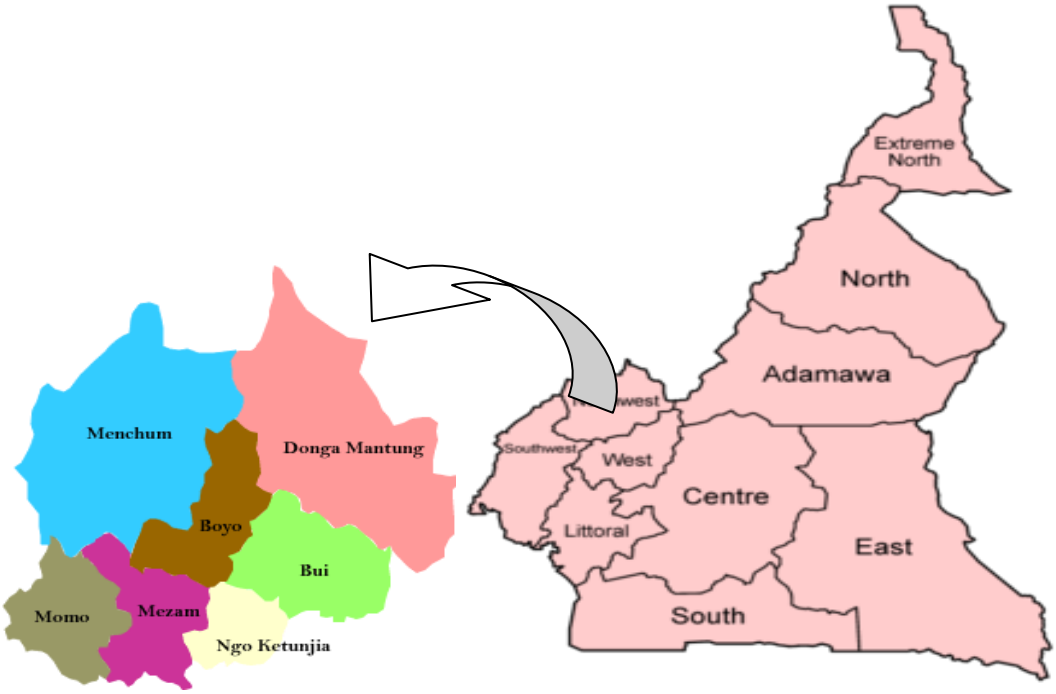
To assess the outcome of age related cataract surgery in Mbingo Baptist hospital Eye Unit, North West Region of Cameroon

4.2 Specific Objectives

1. To determine the visual outcome of age related cataract surgery done at Mbingo Baptist hospital Eye unit.
2. To determine factors influencing outcome of age related cataract surgery done at Mbingo Hospital Eye unit.

CHAPTER FIVE: MATERIALS AND METHODS

5.1 Study Area



The study was conducted in Mbingo Baptist Hospital Eye Unit. The hospital is located in the Boyo Division, North West Region of Cameroon. It is located 37 km north of Bamenda and 366km north of Yaoundé the capital city and somewhat accessible by tarmac and untarmacked roads to all the six divisions that make up the region and remaining nine other regions. The hospital is a regional referral hospital with an eye unit and has two resident ophthalmologist and occasionally visiting ophthalmologist and at times residents on training. About 14440 patients were seen between 1stJanuary 2014 to 31st December 2014 and approximately 360 underwent cataract surgery.

5.2 Study Design and Study Period

The study was a retrospective hospital based case series. The study period was from1st January 2014 to 31st December 2014.

5.3 Study population

All patients over 40 years who underwent cataract surgery at Mbingo Baptist Hospital from1st January 2014 to 31st December 2014.

5.4 Sampling

5.4.1 Sample Population

Patients 40 years of age and above who were seen at Mbingo Baptist Hospital, Eye Unit

5.4.2 Sampling size determination

Sample size calculation was done using the following sample size formula for finite population (Lwanga SK &Lameshow S, 1991). [38]

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

Where

n' = sample size with finite population correction,

N = size of the target population = 360 (estimated number of cataract surgery done in Mbingo Baptist eye hospital in year 2014 from hospital registry)

Z = statistic for 95% level of confidence equal to 1.96

P = estimated outcome of age related cataract-63.4% [6]

d = margin of error = 5%

$$n' = \frac{360 \times 1.96^2 \times 0.634 \times (1-0.634)}{0.05^2 \times (360-1)+1.96^2 \times 0.634(1-0.634)} = 178$$

Therefore, for statistical power purposes, an estimated 178 patients would form the minimum sample size, however, all patients who meet the inclusion criteria will be recruited into study

5.4.3 Sampling procedure

A consecutive sampling method was used to select the patient files. Patient files were allocated serial numbers. The files were selected consecutively beginning with the first file till the total number of files were exhausted. In the course of sampling files that did not meet the inclusions criteria were discarded and next file taken.

5.5 Eligibility Criteria

5.5.1 Inclusion Criteria

Eyes of patients 40 years old and above who had age related cataract surgery at the center.

5.5.2 Exclusion Criteria

Any eye with missing or incomplete records (visual acuity)

Eyes of patients with other causes of cataract.

5.6 Data Collection

Information was extracted from patient files into the questionnaire. Retrieval of files was done by an assistant. Information that was collected will include: Demographics, preoperative examination, intraoperative findings and post-operative examination. Preoperative examination included visual acuity, intra ocular pressure, biometry and ocular comorbidity. Intraoperative information included; date of surgery, surgical techniques, intraocular lens position, method of capsulotomy, use of sutures, intraoperative complications. Post-operative examination included; visual acuity day 1, 2-3 weeks, 4-6weeks, 7 -10 weeks, 11 weeks plus and complications after surgery.

5.7 Data Management and Analysis

The data collected at the end of each day be entered daily and analysis was be done by use of the Statistical Package for Social Sciences (SPSS) version 20 and with daily backups on

external hard disc. Descriptive data was summarized in charts, tables and graphs. Preoperative examination, intraoperative findings and post-operative examination was summarized into proportions, means and medians as relevant. Proportionate test was used to compare the different proportions and it was done at 5% significance level (P value less than 0.05).

5.8 Data Presentation

Data was presented in tables, graphs, charts. Descriptive information showed mean, frequency and proportion of various variables. Tables with univariate analysis that showed the comparison between variables with the specific *p*-value obtained.

5.9 Ethical considerations

5.9.1 Ethical approval

Prior to carrying out this study approval was sought from the Kenyatta National Hospital/University of Nairobi Ethics & Research Committee (KNH/UON-ERC),the management and ethics committee of the Mbingo Baptist Hospital.

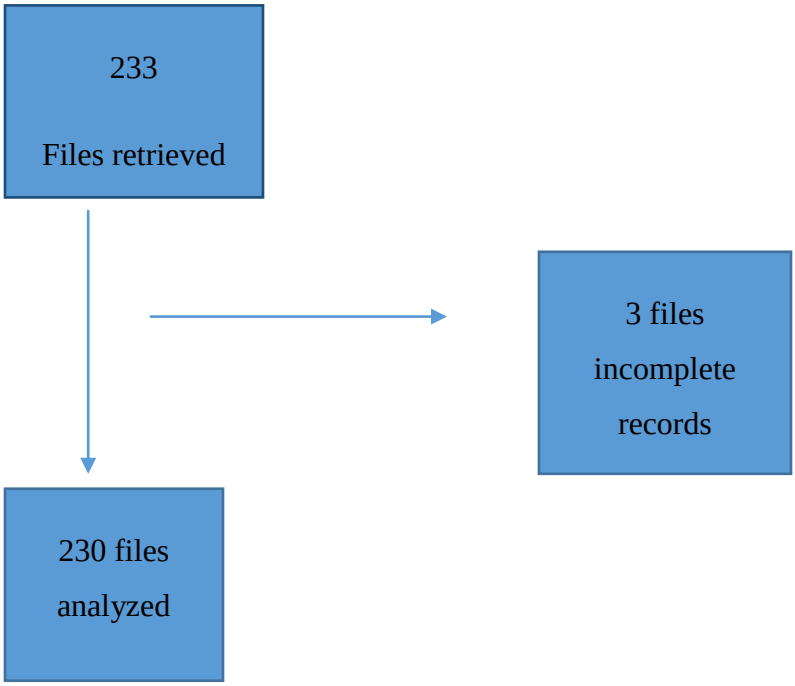
5.9.2 Confidentiality

All data was handled with strict confidentiality in this study and shall remain so until the thesis is accepted. Nothing to identify the patient or clinician was reflected in analysed works of this study.The findings in this study will be disseminated to the faculty in the department of ophthalmology, the Mbingo hospital management board. They may also be disseminated during the August ophthalmology annual conference usually organized by the College of ophthalmology of Eastern, Central and Southern Africa. The study findings shall thereafter be put forth for publication.

CHAPTER SIX: RESULTS

Figure 1: Flow diagram

A total of 233 files were retrieved out of which three had incomplete records. Two hundred and thirty files were analyzed.



6.1 Demographic data

The study targeted all patients 40 years and above who underwent cataract surgery at Mbingo Baptist Hospital from 1st January 2014 to 31st December 2014. A total of 230 eyes of 203 patients underwent surgery during this period. The commonest age group was 70-79 (40.9%), with 81.3% of patients over 60 years. This is shown in figure 2 and table 1 below.

Figure 2: Distribution of study population by age (n= 203)

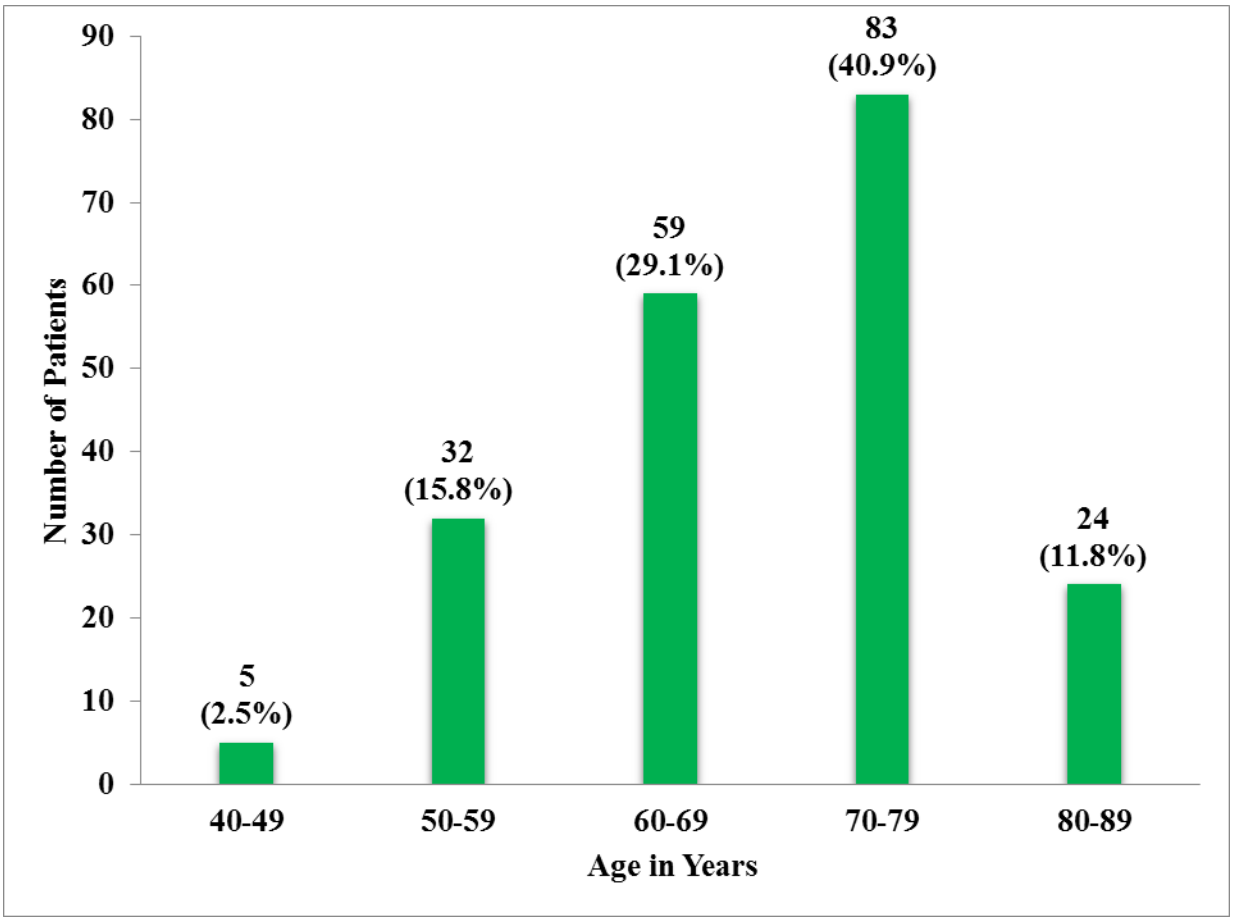


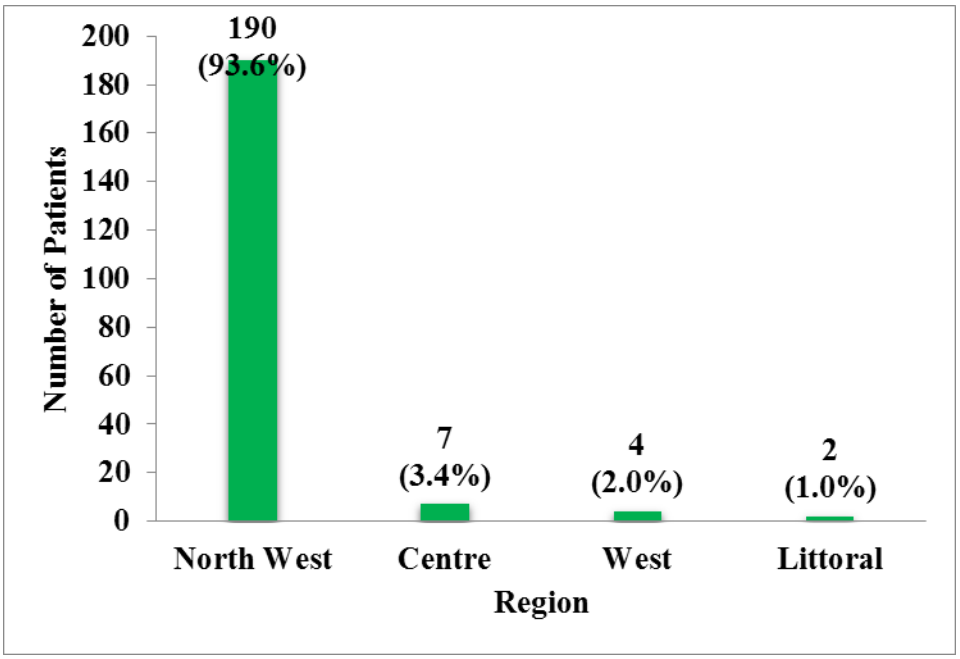
Table 1: Demographic characteristics

Gender	Total	Mean Age (years)	Median Age (years)	Interquartile range	M:F
Male	86(42.4%)	68	70	13	1:1.3
Female	117(57.6%)				

M: F=1:1.3(p=1.26)

Majority of patients (93.6%) seen where from North West as most of patient tend to seek medical attention in their respective district hospitals.

Figure 3: Distribution of patients by Region (n =203)



6.2 Preoperative evaluation

Biometry was done for all patients. Intraocular pressure was measured in 97 eyes of which 35.7% was within normal this is shown in table 2 below

Table 2: Preoperative Evaluation

	n = eyes	
	Frequency	**Percent**
Eyes to be Operated On (n = 230)		
LE	129	56.5
RE	101	43.5
IOP (n=230)		
Low(<5mmHg)	8	3.5
Normal(5-20mmHg)	82	35.7
High (>21mmHg)	7	3.0
Not done	133	57.8
Biometry (n=230)		
Yes	230	100

Presenting visual acuity was less than 3/60 in 82.2% of the eyes as shown in table 3 below

Table 3: Pre-operative Visual Acuity (n=230)

PRE-OP VISUAL ACUITY	n = 230 eyes	
	Frequency	**Percent**
Visual Impairment (< 6/18–6/60)	33	14.3
Severe Visual Impairment (<6/60 -3/60)	8	3.5
Blind (<3/60)	189	82.2
Total	230	100

A total of 23(13.4%) patients were blind bilaterally and 149(86.6%) unilaterally. The M: F=1.3:1. This is shown in table 4 below.

Table 4: Pre-operative Visual Acuity and Laterality in Patients (n=203)

PRE-OP VISUAL ACUITY	**LATERALITY**		
	Total (n)	**Unilateral**	**Bilateral**
Visual Impairment (< 6/18–6/60)	27	23 (85.2)	4 (14.8)
Severe Visual Impairment (< 6/60 -3/60)	4	3 (75.0)	1 (25.0)
Blind (< 3/60)	172	149 (86.6)	23 (13.4)

6.3 Comorbidities

The frequency of ocular comorbidity was 34.9% with glaucoma seen in 40(17.4%) of the eyes. Some ocular comorbidities were diagnosed preoperatively and some post operatively. This is shown in table 5 below. Only significant comorbidity was indicated on the patients file. There was no record of systemic comorbidities

Table 5: Ocular Comorbidities Recorded (n=230 eyes)

Comorbidities	**Number of Eyes**	**Percent**
None	150	65.2
Glaucoma	40	17.4
Retinal Diseases	16	7.0
Non-glaucomatous Optic Atrophy	10	4.3
Corneal Scar	7	3.0
AMD	4	1.7
Subluxated Lens	3	1.3
Total	230	100

6.4 Surgical techniques and intraoperative findings

The commonest surgical technique performed was MSICS (98.3%).ECCE with limbal incision was done for 4(1.7%) of eyes. All the surgeries where done by ophthalmologist .IOL placement was not indicated for 8(3.5%) eyes. The eyes with subluxted lens had ACIOL.This is shown in table 6 below.

Table 6: Surgical Techniques

	n = 230	
	Frequency	Percent
Type of Surgical Technique		
MSICS	226	98.3
ECCE	4	1.7
IOL		
Capsular Bag	214	93.0
Sulcus	4	1.7
AC IOL	4	1.7
Not Indicated	8	3.5
Incision		
Scleral Tunnel	226	98.3
Limbal	4	1.7

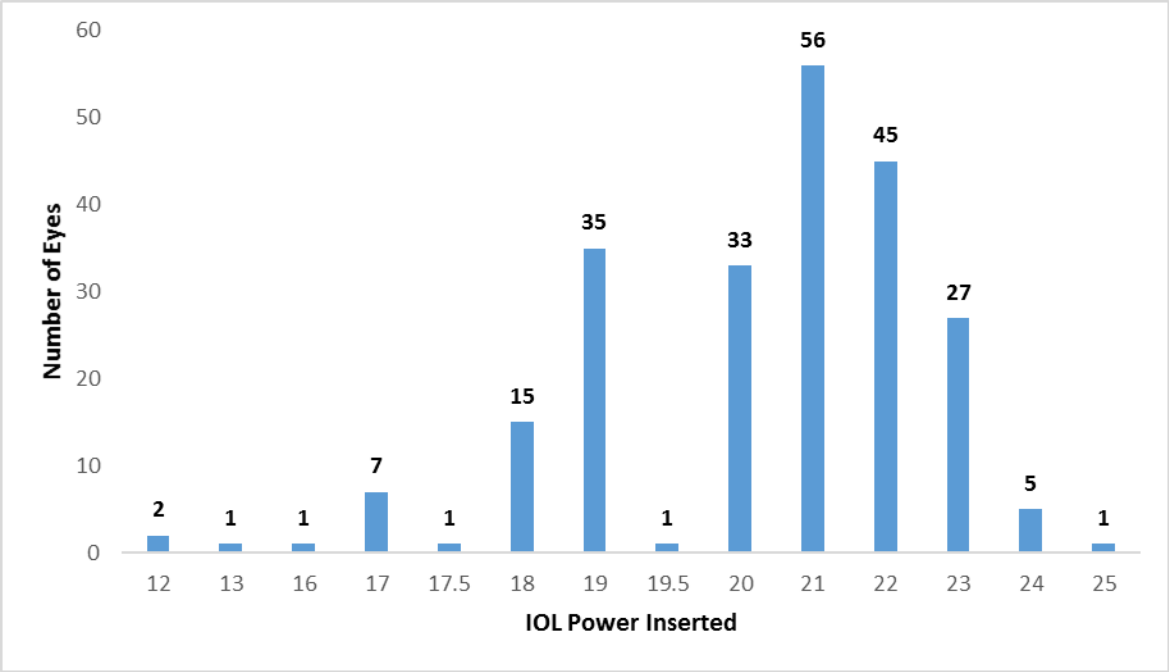
One hundred and eight eyes (47%) had correct IOL as per biometry readings. This is shown in the table 7 below

Table 7: Comparison of Biometry Readings versus the Power IOL Inserted (n=230)

Difference between IOL Power Inserted and Biometry Readings	Number of Eyes	Percent
2.50+	9	3.9
2.00	2	.9
1.50	4	1.7
1.00	8	3.5
0.50	53	23.0
0.00	108	47.0
-0.50	35	15.2
-1.00	5	2.2
-1.50	1	.4
-2.00	2	.9
-2.50	3	1.3

The most commonly inserted IOL power was 21.00 DS (56 eyes, 24.3%).Figure 4 shows the power of the IOLs which were inserted in the files reviewed.

Figure 4: Power of the Implanted IOLs (n = 230)



6.5 Complications

The frequency of intraoperative complication was 30(13.0%) (Table 8) and postoperative complication was 90(39.1%) (Table 9).Only the significant intraoperative complications was indicated in the patients file. The commonest intraoperative complication was PC tear with vitreous loss 10(4.3%)

Table 8: Intra-operative Complications (n = 230)

INTRA-OP COMPLICATION	**n = 230 eyes**	
	Frequency	**Percent**
None	200	87
PC tear with vitreous Loss	10	4.3
PC Tear without vitreous loss	9	3.9
Hyphema	4	1.7
Zonular Dialysis	3	1.3
Iris Prolapsed	2	0.9
Others *	2	0.9
Total	230	100

* Others includes Descemet stripping and Button hole (cornea)

At day one post follow up visit forty eight eyes recorded complications with eight eyes having more than complication. At 2-3 weeks follow up visit twenty one yes had complications with four eyes having more than one complication. Fifteen eyes did not have record of day one post-operative complication. This is shown in table 9 below.

Table 9: Post-operative Complications

POST-OP COMPLICATIONS	**N= complications**									
	1st Post – op Day (N = 223)		**2 - 3 wks. (N= 169)**		**4 - 6 wks. (N= 59)**		**7- 10 wks. (N = 61)**		**11+ wks. (N = 38)**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Corneal complications [1]	50	22.4	11	6.5	0	0.0	1	1.6	0	0.0
Hyphema	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0
Endophthalmitis	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
PCO[2]	0	0.0	0	0.0	1	1.7	2	3.3	4	10.5
Uveitis	0	0.0	10	5.9	3	5.1	2	3.3	2	5.3
Decentered IOL[3]	2	0.9	2	1.2	2	3.4	1	1.6	2	5.3
Cortical Matter[4]	2	0.9	2	1.2	0	0.0	0	0.0	0	0.0
TASS	2	0.9	0	0.0	0	0.0	0	0.0	0	0.0
None	167	74.9	143	84.6	53	89.8	55	90.2	29	76.3
Total	**223**	**100**	**169**	**100**	**59**	**100**	**61**	**100**	**38**	**100**

[1] Corneal complication comprised corneal oedema, striate keratopathy, descemet folds, and bullous keratopathy.

[2] PCO was seen as from sixth week

3 One eye had washout of remnant cortical matter

[4] Redialing was done in one eye with decentered IOL

6.6 Visual outcome

Good outcome was seen in 2.3%(5) eyes at day one ,4.2%(7) eyes at 2-3 weeks ,10.2%(6) eyes at 4-6 weeks,9.8%(6) eyes at 7-10 weeks and 7.9%(3) eyes at 11 +weeks. 15 eyes did not have visual acuity recorded at day one follow up visit. This is shown in table 10 below

Table 10: Presenting visual acuity at follow up

FOLLOW UP	**N (eyes)**	**Good (6/6-6/18) N (%)**	**Borderline (<6/18-6/60) N (%)**	**Poor (<6/60) N (%)**
Day 1	**215**	5 (2.3)	145 (67.4)	65 (30.3)
2-3 Weeks	**165**	7 (4.2)	117 (70.9)	41 (24.9)
4-6 Weeks	**59**	6 (10.2)	41(69.5)	12 (20.4)
7-10 Weeks	**61**	6 (9.8)	46 (75.4)	9 (14.7)
11+ Weeks	**38**	3 (7.9)	27 (71.1)	8 (21.1)

At 4-6 weeks follow up visit of the 21 eyes left emmetropic (similar IOL power to biometry readings), 3(50.0%) had good visual outcome, 17(41.5%) moderate and 1(8.3%) had poor visual outcome. This is shown in table 9 below.

Table 11: Comparison of IOL Power versus biometry to visual outcome at week 4 – 6 weeks follow up visit (n=59)

Visual Outcome	IOL Power Versus Biometry					
	Total (n)	**Over corrected by >+2.5 DS**	**Over corrected by +0.5 to +2D**	**Emmetropic**	**Under corrected by -0.5 to --2DS**	**Under corrected >-2.5 DS**
Good	6	0 (0.0)	1 (16.7)	3 (50.0)	1 (16.7)	1 (16.7)
Moderate	41	1 (2.4)	12 (29.3)	17 (41.5)	10 (24.4)	1 (2.4)
Poor	12	0 (0.0)	9 (75.0)	1 (8.3)	2 (16.7)	0 (0.0)

At 4-6 weeks follow up visit for the patients that came for follow up the cause of poor outcomes is as shown in table 12 below.

Table 12: **Causes of poor outcome (VA<6/60) at 4-6 weeks follow up visit**

Causes of poor surgical outcome VA <6/60	**Number of patients**	**Percentage**
Comorbidity/Patient selection	7	58.3%
Surgical complications	1	8.3%
Refractive error	1	8.3%
Not indicated	3	25.0%
Total	12	100%

Only 14 eyes where refracted.40%(2) had good visual outcome at 4-6 weeks and 83.3%(5) had good visual outcome at 11+ weeks as shown in table 12 below.

Table 13: **Post-op Best Corrected Visual Acuity at Follow Up**

FOLLOW UP	**Refracted eye (N= 14)**	**6/6 - 6/18 N (%)**	**<6/18 -6/60 N (%)**
4-6 Weeks	**5**	2 (40.0)	3 (60.0)
7-10 Weeks	**3**	1 (33.3)	2 (66.7)
11+ Weeks	**6**	5 (83.3)	1 (16.7)

All the patients refracted where found to be myopic and 57.1 %(8) has significant astigmatism this is shown in the table below

Table 14: Spherical equivalence and cylindrical power from refraction

Absolute spherical error	N (Eyes)	**Percentage**
1-1.99	3	21.4
2-2.99	7	50
3-3.99	4	28.6
4+	-	-
Total	**14**	**100**
Cylinder		
0-0.99	3	21.4
1-1.99	8	57.1
2-2.99	1	7.1
3-3.99	1	7.1
4+	1	7.1
Total	**14**	**100**

Table 15: Univariate analysis poor visual outcome at 4-6weeks

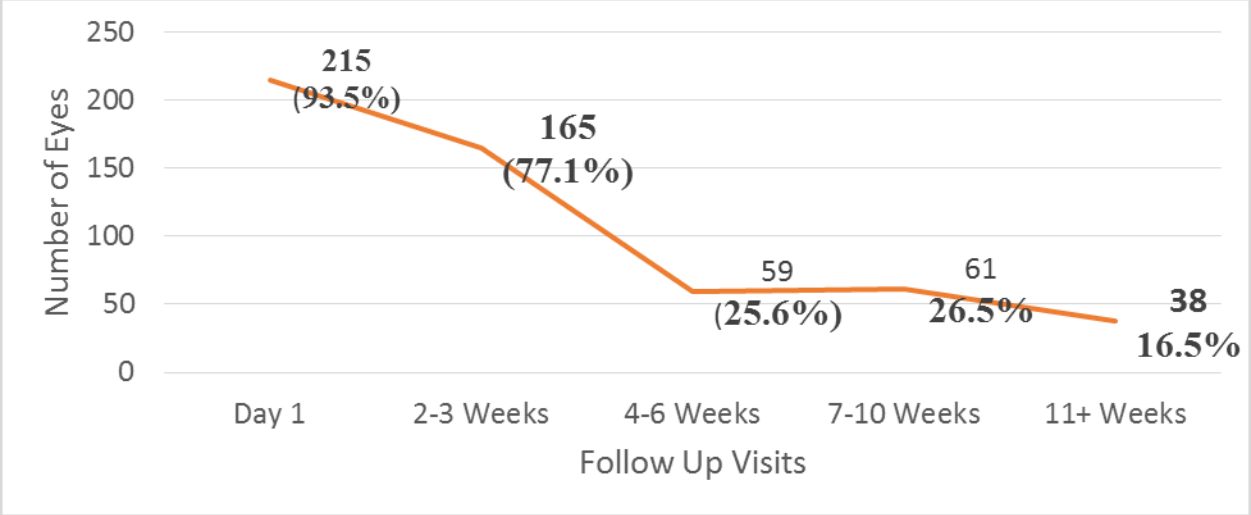
Variables/ Factors	Total (n)	Poor Visual Outcome		OR (95% CI)	P Values
		Yes	No		
Laterality (n=52 patients)					
Unilateral	41	7 (17.1%)	34 (82.9%)	0.360 (0.083-1.572)	0.164
Bilateral	11	4 (36.4%)	7 (63.6%)		
Age (n=59 eyes)					
40-49	2	0 (0.0%)	2 (100.0%)	-	0.795
50-59	8	2 (25.0%)	6 (75.0%)		
60-69	24	4 (16.7%)	20 (83.3%)		
>69	25	6 (24.0%)	19 (76.0%)		
Complications (n=59 eyes)					
Yes	6	2 (33.3%)	4 (66.7%)	2.150 (0.344-13.424)	0.404
No	53	10 (18.9%)	43 (81.1%)		
Ocular comorbidities (n=59 eyes)					
Yes	24	8 (33.3%)	16 (66.7%)	3.875 (1.011-14.848)	0.040
No	35	4 (11.4%)	31 (88.6%)		

Comorbidity was found to significantly affect visual outcome (p=0.04)

6.7 Follow up

There was a decline in follow up of from 215 (93.5%) seen day one follow up visit to 59 (25.7%) at 4-6 weeks follow up visit. This is shown in figure 5 below

Figure 5: Patient Follow Up



CHAPTER SEVEN: DISCUSSION

7.1 Demographic characteristics

From the records reviewed the ages of patients ranged from 40 years to 87 years with 81.8% of patients over 60 years. The average age was 68.6 years with 57.6% of the patients being female. This is comparable to a study done in Kenya by *trivedy et al* at the Lions Sight First Eye Hospital that found an average age of 67 years with 54.5% of patients being females. *Njoya et al* at the Litein Mission Hospital that found an average age of 64 years with 52% of patient being female.[37, 42] Our study found a female predominance as opposed to male predominance (60.1%) observed by *Isawumi et al* in western Nigeria. However it's been found that there's gender inequality in the uptake of cataract services where women are disadvantaged.[43] Furthermore, literature review and meta-analysis of cataract surveys in developing countries found that the cataract surgical coverage rate was 1.2-1.7 times higher for males than for females.[44]The female predominance in our study could be explained by the fact that most women engage in income generating activities and as such financially capable to go to hospital should need arise coupled with incentives from women support groups that exist in the area.

7.2 Preoperative evaluation

A thorough preoperative evaluation is necessary to establish expected surgical problems, expected benefits and comorbid conditions having an influence on cataract surgery. This is advocated in the Royal College of Ophthalmology guidelines on cataract surgery. In our study all the eyes had vision taken at presentation and biometry done. Intraocular pressure measurement was not routinely done and systemic comorbidity were not captured on patient files.

7.3 Presenting Visual acuity

In this study 189(82.2%) of the eyes were blind and 8(3.5%) had severe visual impairment. This is comparable to the findings by *Ilechie et al,* in Ghana that showed 99.7% of the operated eyes were blind and to the study by *Isawumi et al,* in western Nigeria that showed 96.1% of patients had presenting visual acuity of less than 6/60. *Yorston et al, at* the Kikuyu eye unit in Kenya, found 93.8% of the eyes had presenting visual acuity of less 6/60.[39] Looking at the studies done in the developing world which more or less make up the low income countries it appears late presentation is a common feature. This is in contrast to the high income level countries, such as the United Kingdom where no patient presented with a vision poorer than 6/18.[45].Furthermore, a review done in 13 European countries in the European cataract outcome study, showed 31.5% of eyes had presenting visual acuity of less 6/60 which was less than what we found in our study.[51] A possible reason for late presentation in our study could have been due to difficulty in accessing the hospital from the surrounding districts. In addition farming is the major preoccupation in the region which most times does not need pristine vision making them report late.

7.4 Visual Outcome

This study found on the first post-operative day good outcome in 2.3% of eyes and poor outcome in 30.3% of eyes. This fell short of WHO recommended guidelines for outcome of cataract surgery .This could have been due in part to the corneal complications documented on the first operative day at 23.3%. Our study was comparable to that by *Ilechie et al,* that recorded a 29.2% poor outcome within 48 hours though the good outcome at 22% was more than what we found on day one follow up visit.[35] The good outcomes in our study were considerably low compared to observations made by *Obiudu et al,* in South East Nigeria were 29.6% of the eyes had good outcome and 19.5% poor outcome at the time of discharge which was lower than what we found.[40] *Bitok et al,* in Kenya had day one poor outcome of 23.3% which is comparable to what we found in our study and this was attributable to the corneal complications recorded in both studies. In their study however they recorded a day one good outcome of 40.8% as opposed to 2.3% recorded in our study.[45]

At the week 4 – 6 weeks follow up visit, out of the 59 patients who came for review 6(10.2%) had good outcome, 41(69.5 %) borderline and 12 (20.4%) poor outcome. Again, this values fall below WHO benchmark of greater than 85% good outcome, less than 15% borderline, less than 10% poor outcome for uncorrected visual acuity following cataract surgery. The outcomes in our study differ from findings by *Oye et al,*in the south west region of Cameroon were 64.3% of eyes had poor outcome and 25% good outcome, their study was however a community based as opposed to our study which was hospital based.[6] In a study done in Nigeria by *Mpyet et al*, at 6-weeks follow up visit 69.0 % had good outcome and 5.6% poor outcome much better compared to the findings in our study though in their study they excluded all those with preexisting ocular comorbidity which was not the case in our study .[41]Furthermore, *Ilechie et al,* in a study done in Ghana on the evaluation of post-operative visual outcome at 4-6 weeks follow up visit 41.2 % had good outcome and 9.5% had poor outcome which again was better that what we found.[35] A similar study done *Yuan et al* in China showed good outcome in 61.0% of eyes and 12.2% poor outcome which is in contrast to what we found in our study.[52]The good outcomes in the above studies even though better than what we found still fell below the >85% bench mark for uncorrected visual acuity following cataract surgery. In contrast a UK study showed 85% good outcome achieving greater than 6/12 vision.[45] For the eyes that where refracted at 4-6 weeks 2(40.0 %) had good outcome, 3(60.0 %) borderline and none had poor outcome. At 11 weeks plus 5(83.3%) had good outcome, 1(16.7%) had borderline and none had poor outcome. This was almost in keeping with the WHO recommendations, for BCVA of 90% for good outcome, and <5% for poor outcome. Our study could in part be compared to observations by *Yorston et al* at the Kikuyu eye unit, Kenya where 82.9% eyes had good outcome 8 weeks after refraction. In their study as much as 81.6%(330) eyes out of 404 eyes had refraction done as opposed to just 14 eye out of 230 eyes in our study.[39]Similarly *Hennig et al* in Nepal, found good outcome in 96.2% of eyes at 6 weeks and *Yuan et al*, in china had good outcomes of 69.5% eyes at 6-8 weeks following refraction. This shows that postoperative refraction was indeed an important factor in obtaining good visual outcome.

7.5 IOL Power

This study found that all the eyes received intraocular lenses (93.0% PC-IOL and 1.7% % AC-IOL, not indicated in 1.7%). A total of 108(47.0%) of the eyes were left emmetropic as per biometry readings. The other eyes were either under-corrected or over-corrected compared to their biometry readings, due to lack of the exact IOL power as per the biometry, leading to the use of the next available IOL power. This was in part due to non-availability of IOL as most of stock came as donations so they had to use what was available which could have adversely affect visual outcome. For the eyes left emmetropic as per the biometry readings in the 4-6 weeks follow up visit only 50 %(3) had good outcome, 41.5%(17) moderate and 8.3 %(1) poor outcomes. Out of the 12 patients that recorded poor outcome 75 %(9) were over corrected as per biometry and 16.3% (2) where under corrected (table 11).This could have been attributed to the inaccuracies noted during biometry measurement as biometry was done by ophthalmic attendants with in-service Furthermore given that only 14 eyes had refraction done it becomes difficult to significantly correlate the absolute spherical error with findings at biometry.

7.6 Intra-operative Complications

In this study, a total of 30(13.0%) eyes had intra-operative complications. Only the most significant complication was indicated in patient's files. *Bitok et al*, in Kenya had a similar observation. The commonest intraoperative complication was posterior capsule tear with vitreous loss (4.3 %).The intraoperative complication rate was outside the recommended WHO standard by being greater than 10% though the vitreous loss rate was not more than 5% as per WHO standards. Our study recorded less intraoperative complication compared to a study by *Isawumi et al*, in western Nigeria were 27.35% of eyes had vitreous loss and 6.28% posterior capsule tear. A study done in India by *Ajith et al* found intraoperative complications to be 11.5 % with PC tear accounting for 2.5% which was similar to what we found.[47]In the same vain the complications recorded in our study was more than that observed by *trivedy et al* in Kenya, where 1.6% of eyes had intraoperative complication of which 0.5% had PC tear with vitreous loss and 0.3% with PC

tear alone. Lastly, our study recorded a higher intraoperative complication rate compared to the 1-2% normally observed in high income countries. [32, 36]

7.7 Early post-operative complications

At day one post operatively the complication rate was 25%. Corneal complications were the commonest constituting 22.4 %. At the week 2 – 3 follow up visit, the complication rate was 14.2%, the commonest was uveitis (5.9%).This study recorded more complications compared to observations made by *Ilechie et al,* in a study done in Ghana which found early surgical complications in 10.1% of the eyes, with the most common being cornea oedema (3.4%), and hyphema (2.2%), [35]*Trivedy et al,* in a study done in Kenya recorded a day one post-operative complication rate of 12.6 % with most being corneal oedema plus descemet folds (6.6%) and cornea oedema (4.8%).[37]In this study corneal complications were the commonest, this is comparable to that found by *Bitok et al*, in Kenya where corneal complications made up 70.94% on day one follow up visit as opposed to 22.4 % in our study. However, in their study the day one post-operative complication rate was 5% as opposed to 25% found in our study.

7.8 Late post-operative complications

At the 4 – 6 week follow up visit, 6 eyes (10.2%) had complications with uveitis accounting 5.1 %(3). At 7- 10 week follow up visit 6 eyes (9.8%) had complications of which uveitis and PCO accounted for 3.3 % (3) each. At 11 weeks plus 9 eyes (23.9%) had complications with PCO constituting 10.5% (4) followed by uveitis 5.3% (2). Similar observations were made by *Ilechie et al,* in Ghana, where late surgical complications occurred in 2.8% of the eyes; as well as *Obiudu et al,* in Nigeria where late complication occurred in 5% of eyes .[35,40] This study did not show any statistical relationship between late complication and poor outcome at 4-6 weeks post operatively.

7.9 Comorbidity/patient selection

In this study, 34.7% patients had comorbidities, some of which were diagnosed pre-operatively and others post-operatively. Glaucoma was the commonest comorbidity at 17.4%.Comorbidity

has been found to adversely affect visual outcome as seen in the study by *Sonron et al* in Trinidad where 32 % of eyes had ocular comorbidities with the bulk constituted by glaucoma and ARMD. This was comparable to what we found in our study. *Isawumi et al* in Nigeria found a lower frequency of co-morbidity at 17.3% compared to our study with glaucoma accounting for 11.7%.[36]*Nganga et al* in Kenya found 15.3% of the eyes to have ocular comorbidity with glaucoma making up 6.76%. Despite comorbidities being recorded surgery was still carried out with the intent of achieving navigational vision in a previously blind patient. Overall excluding the Comorbidity visual outcome remain poor in 36% of eyes and good outcome in 3% with a majority of eyes (74%) having moderate outcomes. Our study showed a statistical significant relationship between comorbidity and poor visual outcome (p value- 0.040)

7.10 Causes of Poor Outcome

Overall, causes of poor outcome included comorbidity/patient selection in 34.7% of patients, surgical complications in 20.4% of patients, late surgical complications in 13.3% of patients and refractive error in 6.0 % of patients. Comorbidity as a cause of poor outcome was found to be higher in our study as oppose to the finding by *Malik et al* in Pakistan that showed 7 % as cause of poor outcome. In terms of comorbidity our study showed similar findings with that done by *Lindfield et al* in Kenya and Pakistan where comorbidity accounted for 26% and 27% of adverse outcome respectively. However, in their study refractive error accounted for 37% and 49% of adverse outcome respectively. The same cannot be said for our study as only 6 % of patients were refracted. At 4-6 weeks post-operative follow up visit poor outcomes were seen in 12 eyes with comorbidity accounting for 58.3%(7), surgical complication/sequelae 8.3 %(1), refractive error 8.3 %(1), cause was not indicated in 25%(3).

7.11 Follow up

In this study of the 230 eyes operated, 93.5% were seen on day one after which there was a drop to 71.7% at 2 to 3 weeks follow up visit, 25.6 % at 4 – 6 weeks, 26.5 % at 7-10 weeks and only 16.5% at above 11 weeks. A presumed reason could be that the level of post-operative vision was adequate for their main occupation which predominantly is farming. Despite the low cost of

services in the hospital access from the surrounding district is costly and this could in part be responsible for low turn up. Also patients might have been dissatisfied with the outcome and elected to go to another facility as was observed by *Ilechie et al* in Ghana.[35]The high percentage of those lost to follow up at this early postoperative time is not uncommon in the developing countries. Our study had a far lower follow up rate compared to the findings *Yorston et al* that showed 87.6% and 75.1% at 4 weeks and 8 weeks respectively.[39]Howerever, in their study the patients were contacted by writing to them in their last known address which was not the case in our study.

CHAPTER EIGHT: CONCLUSIONS

1. The post-operative BCVA at 4-6 weeks post-operative was found to be below the WHO guidelines
2. Ocular comorbidity was major cause of poor outcome
3. Refraction was scarcely done for patients post operatively
4. Low follow up rate may have adversely affected outcomes.

CHAPTER NINE: RECOMMENDATIONS

1. Device a patient information capture form and institute a cataract audit system via electronic data base. This will improve documentation and keep track of patients for future reference.

2. Device a means of reaching out to the patients to ensure there come for follow up visits either by use of SMS to remind patients when follow update is due or community health workers to reach out to them in case there fail to turn up

3. Provide wide variety of IOL powers and improve biometry and IOL power calculation through capacity building

4. Refraction for all patients should be made as a rule

CHAPTER TEN: STUDY LIMITATIONS

1. Surgical outcomes of the patients who were lost to follow up were not captured.

2. This was a retrospective study and there dependent on availability and accuracy of patient records

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CHAPTER TWELVE: APPENDICES

Appendix I: Questionnaire

1.0 Demographic data

1.1. Date_____

1.2. PIN no. _____1.3. File no._____ 1.4. Age (yrs.) _____

1.5. Sex Male ☐ Female ☐ 1.6. Region _____

2.0. Preoperative examination

2.1. Eye Operated: RE☐ LE ☐

2.2. VA: Presenting _____ 2.3. Biometry: YES ☐

Pinhole/BCVA ____ NO ☐

IOL POWER _____

2.4. IOP_____

2.5. Pathologies possibly affecting the outcome:

☐ Corneal Scar ☐ Pseudoexfoliation ☐ Subluxated Lens ☐ Optic atrophy☐

☐AMD ☐ Glaucoma ☐ Retinal Diseases☐ Diabetes ☐ Others_____

3.0 Surgery

3.1. Date _____

3.2. Surgeon: ☐Ophthalmologist ☐Ophthalmology resident

3.3. IOL-Power inserted _____

3.4. IOL-Type: ☐ AC IOL ☐PC IOL

3.5. Surgical Technique:

3.5.1. Type:☐SICS☐ECCE

3.5.2. Capsulotomy: ☐Can Opener☐CCC☐Linear ☐Other☐Not indicated

3.5.3. IOL:☐ Capsular Bag ☐Sulcus ☐AC IOL☐ No IOL☐Not indicated

3.5.4. Suture :☐ Yes ☐No

3.5.5. Incision:☐ Scleral tunnel ☐ Corneal ☐ Limbal

3.6. Intra-op Complications:

☐None ☐ iris prolapsed ☐ Hyphema ☐ PC tear ☐Vitreous loss

☐ Zonular Dialysis ☐Others_____

4.0 Post-operative examination and complications

	Date	**Presenting VA**	**BCVA/Pin Hole**	**IOP**	**COMPLICATIONS**
Day 1					
2-3 weeks					
4 -6 weeks					
7-10 weeks					
11 + weeks					

4.1. Surgical complications

☐ Corneal edema(1) ☐Hyphema(2) ☐Vitreous loss(3) ☐Endophthalmitis(4 ☐Retinal detachment(5)☐Cystoid macula edema(6) ☐PCO(7) ☐Uveitis(8) ☐Decentered IOL(9)☐Others_____

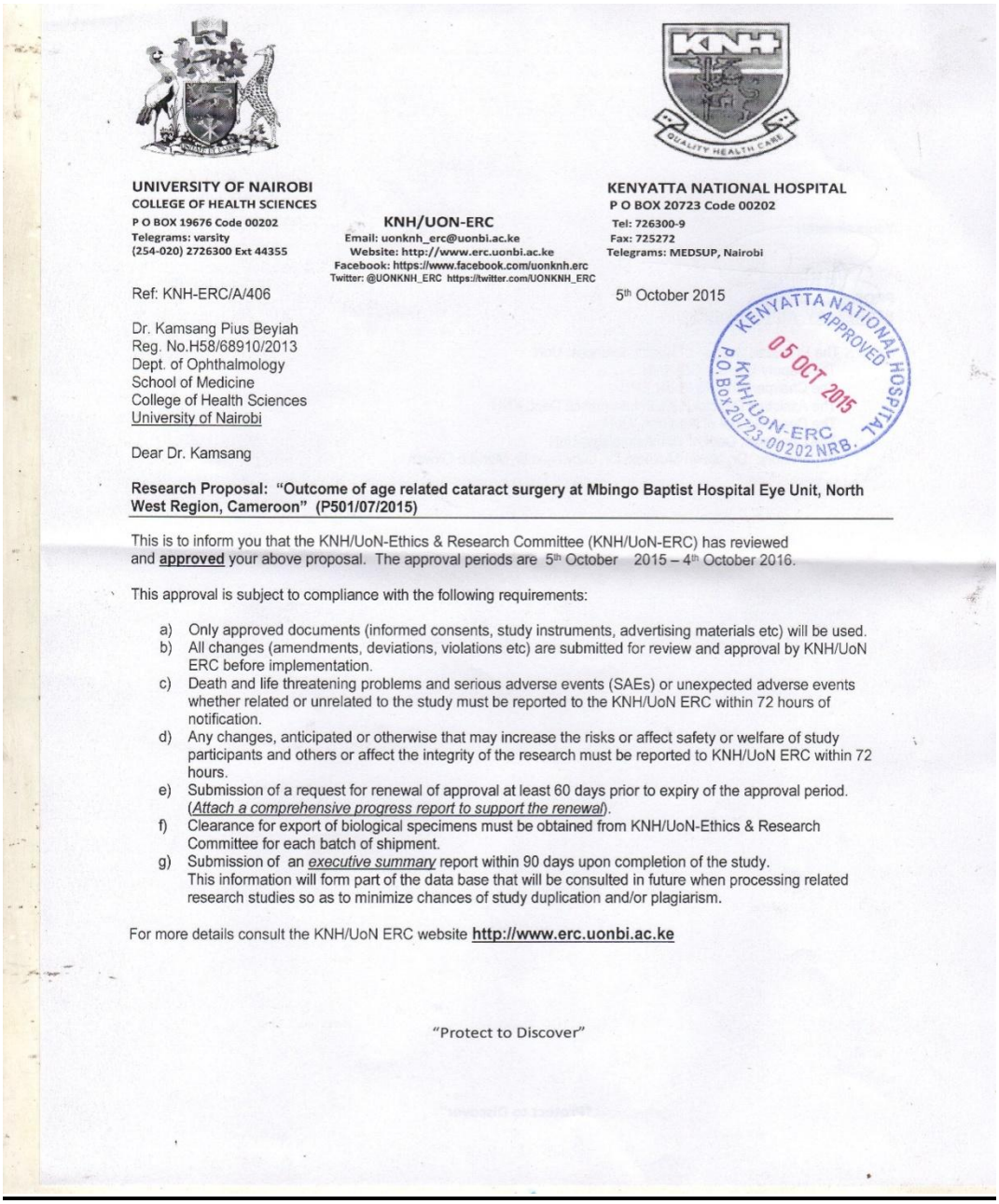
Appendix II: WHO Categories of visual impairment

Category	**Visual Acuity with BCVA in the better eye**	**Degree of Visual Impairment**
0	6/6 – 6/18	Normal Vision
1	<6/18-6/60	Visual Impairment
2	<6/60-3/60	Severe Visual Impairment
3	<3/60-1/60	Blind
4	<1/60 – Light perception	Blind
5	No Light Perception	Blind
6	Undetermined or Unspecified	

Appendix III: WHO guidelines on outcome of cataract surgery

POST-OPERATIVE ACUITY		WITH AVAILABLE CORRECTION	WITH BEST CORRECTION
GOOD	6/6 – 6/18	>80%	> 90%
BORDERLINE	<6/18 – 6/60	<15%	<5%
POOR	<6/60	<5%	<5%

Appendix IV: Letter of Approval from KNH/UoN-Ethics and Research Committee (KNH/UoN-ERC)



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Ref: KNH-ERC/A/406

5th October 2015

KENYATTA NATIONAL HOSPITAL APPROVED 05 OCT 2015 P.O.Box 20723-00202 NRB. KNH/UoN-ERC

Dr. Kamsang Pius Beyiah
Reg. No.H58/68910/2013
Dept. of Ophthalmology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Kamsang

Research Proposal: "Outcome of age related cataract surgery at Mbingo Baptist Hospital Eye Unit, North West Region, Cameroon" (P501/07/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 5th October 2015 – 4th October 2016.

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-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

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

"Protect to Discover"

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 Dept. KNH
The Dean, School of Medicine, UoN
The Chairman, Dept.of Ophthalmology, UoN
Supervisors: Dr. Mukiri Mukuria, Dr. Lucy Njambi, Marvice Okwen

Appendix V: Letter of Approval from Cameroon Baptist Convention Health Board Ethics and Review Board.

CAMEROON BAPTIST CONVENTION HEALTH BOARD
INSTITUTIONAL REVIEW BOARD

Baptist Centre, Nkwen, P.O. Box 1, Bamenda, Northwest Region

13 October 2015

Beyiah Kamsang Pius,
piuskamsang@gmail.com

Re: IRB2015-09, "Outcome of age related cataract surgery at Mbingo Baptist Hospital Eye Unit, North West Region, Cameroon"

Dear Dr. Kamsang,

Your study protocol was reviewed by two members of the CBC Health Board IRB and was granted expedited and exempt approval on the 12 October 2015. It will be presented to the entire Board during our next Board meeting to get the Board to validate the decision of the Chairperson. Thereafter, an email will be sent to you to inform you of the decision. It was granted Exempt approval due to the following reasons:

1. Your protocol does not record any names or other identifying information of participants and therefore no risk involved.
2. Your protocol deals with already existing data with patient-identifying information deleted.

Please understand that this is the ethical and human safety approval for your study. You must present this IRB approval letter and the email stating that the contingencies have been met to the Hospital Administrator and Chief Medical Officer or to the Chief of Center (if at a health Centre) for approval to do the study in that institution(s).

It is expected that the research will begin at the time specified in your protocol. If you need to delay the beginning of the research more than one month, please notify the IRB.

If you make any changes in the research protocol, please immediately send the IRB an amendment specifying the changes proposed.

Your protocol has been assigned the above reference IRB protocol number. All correspondence to us should include 1) the IRB protocol number 2) Name of the principal investigator and 3) full title of the study.

You should understand that, your file will be closed because your protocol is exempt. However, all abstracts, manuscripts, posters and presentations pertaining to the above protocol, must be submitted to the IRB for pre-publication approval.

Please feel free to contact me with any questions and/or concerns regarding the above. Copies of all correspondence regarding this proposal should be sent to me and to Zita Acha secretary, e-mail CBCHBIRB@gmail.com.

Sincerely,

Nancy Palmer Ph.D.

Nancy Palmer, Ph.D.

CAMEROON BAPTIST CONVENTION HEALTH BOARD INSTITUTIONAL REVIEW BOARD

Nancy Palmer, Ph.D., Chairperson, palmernancylea@gmail.com
Mrs. Acha Zita, Secretary, cbchbirb@gmail.com