

POSTERIOR CAPSULAR OPACIFICATION AT LIONS SIGHT FIRST EYE HOSPITAL

A dissertation in part fulfillment for the degree of Master of Medicine,
Ophthalmology, University of Nairobi.

DR HATIM SHABBIRALI YUSUFALI

2010

University of NAIROBI Library




0407013 2

**UNIVERSITY OF NAIROBI
MEDICAL LIBRARY**

DECLARATION

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

Signed: 

Date: 27-9-2010

Dr. Hatim Shabbirali Yusufali, M. B. Ch. B (UON)

APPROVAL BY SUPERVISORS

This dissertation has been submitted with the approval of my supervisors, namely:

Sign: 

Date: 19/10/2010


Dr Kahaki Kimani

M. B. Ch. B; M. Med Ophthalmology (Nairobi), MSc C.E.H (London), FEACO

Senior Lecturer,

Department of Ophthalmology,

University of Nairobi.

Sign: 

Date: 27th September 2010

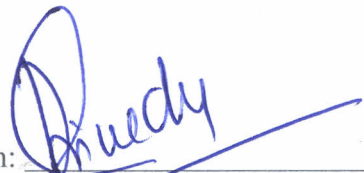
Dr Sheila Marco

M. B. Ch. B; M. Med Ophthalmology (Nairobi), FEACO

Lecturer,

Department of Ophthalmology,

University of Nairobi.

Sign: 

Date: 27/9/10

Dr Jyotee Trivedy

M.B.B.S (Pune), M. Med Ophthalmology (Nairobi), FEACO

Senior Ophthalmologist,

Lions Sight First Eye Hospital,

Nairobi.

DEDICATION

To my loving parents and siblings for their continued support and encouragement

To my dearest friend and soul-mate, Khadija

TABLE OF CONTENTS

TITLE PAGE	i
DECLARATION	ii
APPROVAL BY SUPERVISORS.....	iii
DEDICATION	iv
TABLE OF CONTENTS	v
ABBREVIATIONS.....	vii
LIST OF TABLES AND FIGURES.....	viii
FIGURES.....	viii
TABLES	viii
ACKNOWLEDGEMENTS	ix
ABSTRACT	1
1.0 LITERATURE REVIEW.....	3
1.1 INTRODUCTION	3
1.2 TYPES OF PCO AND ANALYSIS.....	3
1.3 FACTORS THAT AFFECT PCO DEVELOPMENT.	6
1.3.1 IOL RELATED FACTORS.....	6
1.3.2 SURGERY RELATED FACTORS.....	7
1.4 PCO IN DIABETIC PATIENTS.....	9
2.0 STUDY JUSTIFICATION	10
3.0 OBJECTIVES	11
3.1 MAIN OBJECTIVE	11
3.2SPECIFIC OBJECTIVES.....	11
4.0 RESEARCH METHODOLOGY	12
4.1 STUDY SETTING	12

4.2 STUDY DESIGN	12
4.3 STUDY POPULATION.....	12
4.4 CASE DEFINITION	12
4.5 CONTROLS	12
4.6 EXCLUSION CRITERIA	13
4.7 SAMPLE SIZE	13
4.8 ETHICAL CONSIDERATIONS	14
4.9 STUDY MATERIALS	14
5.0 PROCEDURE AND DATA ANALYSIS.....	15
6.0 RESULTS.....	16
7.0 DISCUSSION.....	24
8.0 STUDY LIMITATIONS.....	29
9.0 CONCLUSIONS.....	29
10.0 RECOMMENDATIONS	29
APPENDIX	30
QUESTIONNAIRE	30
REFERENCES.....	31

ABBREVIATIONS

BCVA	Best corrected visual acuity
CCC	Continuous curvilinear capsulorrhexis
ECCE	Extra capsular cataract extraction
HSM PMMA	Heparin surface modified poly methyl methacrylate
ICCE	Intracapsular cataract extraction
IOL	Intra ocular lens
KNH	Kenyatta National Hospital
LEC	Lens epithelial cells
LSFEH	Lions Sight First Eye Hospital
MSICS	Manual small incision cataract surgery
Nd:YAG	Neodymium: yttrium-aluminium-garnet laser
OR	Odds Ratio
PCO	Posterior capsular opacity
Phaco	Phacoemulsification
PMMA	Poly methyl methacrylate
SD	Standard Deviation

LIST OF TABLES AND FIGURES

FIGURES

Figure 1.Flow chart of the cases selected.....	16
Figure 2.Sex distribution	17
Figure 3.Age distribution	18
Figure 4.Age distribution of uveitis patients.....	21
Figure 5.Mean age of Diabetics v/s non diabetics	22

TABLES

Table 1.Type of lens and PCO	18
Table 2.Time between surgery and PCO diagnosis	19
Table 3.Surgeon's PCO rates	19
Table 4.MSICS v/s PHACO with AcrySof [®] lens	20
Table 5.History of Uveitis and PCO formation.....	20
Table 6.Diabetes and PCO	22
Table 7.Univariate analysis.....	23
Table 8.Multivariate analysis	23

ACKNOWLEDGEMENTS

I wish to acknowledge the following persons for their invaluable support towards my dissertation:

My supervisors Dr K. Kimani, Dr S. Marco and Dr J. Trivedy for their unparalleled assistance throughout this study

Dr J. Trivedy for the original idea, liaison and facilitation of data collection in LSFEH

I wish to thank Dr S. Gichuhi for his valuable advice at various stages of this dissertation and

Dr W. Njoya for her assistance in data collection

ABSTRACT

Objective: To determine the factors associated with posterior capsular opacification (PCO) at Lions Sight First Eye Hospital (LSFEH).

Design: Case control study

Setting: Lions Sight First Eye Hospital

Subjects: 130 patients who underwent cataract surgery in LSFEH meeting the inclusion criteria: 65 cases and 65 controls. The cases were the patients who had posterior capsular opacification, diagnosed using a slit lamp, and who required capsulotomy. The controls were patients who did not develop posterior capsular opacification two years post cataract surgery.

Data collection: Data was collected using questionnaires and analysed using SPSS version 11.5.

Results: The ratio of males: female was 1:1.32. The mean age of the cases was 57.4 years as compared to the controls of 64.0 years, which was statistically significant ($p < 0.017$). AcrySof[®] lens had PCO rate of 20(33.3%), which was lower than Poly methyl methacrylate (PMMA) lens of 45(64.3%) ($p < 0.001$). All the 10 patients with prior uveitis developed PCO. Diabetics were noted to have significantly less PCO rates compared to the non-diabetic patients ($p = 0.028$). There was no significant difference between the phaco-emulsification and manual small incision cataract surgery (MSICS) method of surgery. After multivariate analysis PCO was found to be associated with type of IOL [adjusted (adj) OR 0.28, 95% CI 0.13, 0.61] and Diabetes Mellitus (adj OR 0.33, 95% CI 0.13-0.88).

Conclusion: AcrySof[®] lens has lower PCO rates compared to PMMA. The method of surgery (MSICS v/s Phaco-emulsification) had no impact on PCO rates. Diabetic patients had less PCO rates in comparison to the non- diabetics. The factors which may predict risk of PCO are the type of lens and diabetes.

Recommendation: AcrySof[®] lens be the preferred intra-ocular lens (IOL) to reduce posterior capsular opacification rates post cataract surgery when affordable.

1.0 LITERATURE REVIEW

1.1 INTRODUCTION

Cataract is a major cause of global blindness, accounting for nearly half (47.8%) of all cases of blindness.¹ In Kenya the prevalence of blindness is 0.7%, of which 43% is due to cataract.² Currently there is no proven prevention measure for cataract and surgery is the only form of treatment. In Kenya, cataract surgery has evolved from intra-capsular cataract extraction (ICCE) to extra-capsular cataract extraction (ECCE) and currently the preferred practice is Manual small incision cataract surgery (MSICS). However phaco-emulsification is limited to few centers because of cost.

Posterior capsular opacification (PCO) also called secondary cataract or after cataract, is one of the most common early long term complications of cataract surgery with Intra-ocular lens implantation leading to visual impairment.^{3, 4} PCO has been recognized since the origin of extra-capsular cataract surgery and was first noted by Sir Harold Ridley.⁵ PCO is caused by the proliferation of the lens epithelial cells that remain after cataract surgery and is more common in children than in adults.

The incidence of PCO after cataract surgery approaches 50%.⁶ A retrospective study in Kenya by Jafferji S S et al on phaco-emulsification outcomes showed a 1.3% incidence of PCO in a total of 507 eyes studied.⁷

1.2 TYPES OF PCO AND ANALYSIS

Clinically PCO has two components: fibrotic and regenerative. Regenerative component is the commoner type responsible for low visual function after implantation of intraocular lens. There

are three types of PCO: fibrotic, Elschnig pearls and Soemmerring ring. The latter two are regenerative.

Fibrotic PCO occurs as a result of proliferation of lens epithelial cells which are deposited in a multilayer fashion on the posterior capsule and synthesize extracellular matrix. Cellular contraction of the posterior capsule results in its folding and wrinkling. Visual impairment occurs if the visual axis is affected.

Elschnig pearls have similar appearance to Wedl (bladder) cells involved in the formation of posterior subcapsular cataracts. It represents an aberrance of the remaining lens epithelial cells to form fibers. Each pearl represents the attempt of one epithelial cell to differentiate into a new lens fiber.

Soemmerring's ring was first described in 1828 by Soemmerring. It is a ring like opacity that forms as the lens epithelial cells proliferate when the anterior and posterior lens capsule fuse. The lens cells are protected from the aqueous by the fusion. It usually passes undiagnosed unless the pupil is very wide, a congenital or operative coloboma is present, or the Soemmerring ring has become dislocated.⁸

A study by Thomas Neumayer et al distinguished other forms of PCO such as cheese holes, plates, islands and traces of PCO.⁹

There are several systems used to analyze PCO but none of them have been proven to be a gold standard as there is limited knowledge on the effect of PCO on vision. The systems used to evaluate PCO include: visual acuity reduction/ visual psychophysics, Neodymium: yttrium-aluminium-garnet (Nd:YAG) laser capsulotomy rates, slit lamp grading, fundus visibility, Schiempflug system, density map, computerized analysis of density boundaries, texture analysis and colour coded grid.¹⁰ Visual acuity as a sole measure of PCO grading is not suitable as it is

affected by many other factors following cataract surgery with intra-ocular lens implantation.¹¹

Nd:YAG capsulotomy rate is not a very sensitive and specific way of determining rates of PCO as it is influenced by many factors like patients subjective complaints, the surgeons preference and economic considerations.¹²

There are many criteria for grading the PCO using the slit lamp. Kruger et al used a grading of 0-3 for PCO evaluation. The capsule was evaluated within an area of 3mm diameter central area and in the periphery behind the optic. The criteria used were 0=absent, 1=very mild, 2=moderate and 3=dense. Distinction was also made between fibrotic and Elschnig pearls. It was noted that the silicone IOL with the sharp optic edge design was associated with significantly reduced PCO 2 years postoperatively.¹²

In the Madurai intraocular lens study, a grading system was used for PCO assessment which graded PCO as: No posterior capsular opacification, grade 1, grade 2 and grade 3. This classification is based on the visualization of the fundus with the direct ophthalmoscope in the presence of a PCO. This study showed a four year incidence of grade II or III PCO, including eyes already treated with laser capsulotomy, was 13.1% (95% confidence interval, 9.7% to 17.3%). Based on best corrected visual acuity of 20/40 or worse without co-existing pathology, the four year incidence of PCO was 13.5%.¹³

The Schiempflug system is based on the use of the EAS-1000 anterior eye segment analysis system (Nidet, Gamori, Japan) equipped with area densitometry to measure the scattering light intensity. The scattering light intensity is deemed equal to opacification density. The method is easy and can be performed within a few minutes for each eye. Its main draw-back is that it is not easily available in all eye departments and that it cannot be used to differentiate the various types of PCO.

1.3 FACTORS THAT AFFECT PCO DEVELOPMENT.

The factors that reduce the PCO development during cataract surgery with intraocular lens implantation can be divided into: IOL related and surgery related factors.

1.3.1 IOL RELATED FACTORS

1.3.1.1 IOL Material

The IOL material has a profound effect on the proliferation of the remaining epithelial cells in the capsule bag after cataract surgery. David J Apple et al showed that there was a significantly higher rates of Nd:YAG lasers done with the 1 and 3 piece Poly methyl methacrylate (PMMA) optic IOLs of 26.2% and 32.8% respectively. In the same study the rates of Nd:YAG laser was higher in the rigid lenses as compared to the foldable IOLs of 13.5% and 30.2% respectively.¹⁴

Gisela Wejde and colleagues showed that patients with AcrySof[®] IOL developed significantly less PCO than those with silicone or Heparin surface modified poly methyl methacrylate (HSM PMMA) group with a rounded edge design. The Nd:YAG capsulotomy rates was 20% in the HSM PMMA group, 22% in the silicone group, and 8% in the AcrySof[®] group.¹⁵ In Japan, K Hayashi and H Hayashi et al showed that there is a significant increase in the PCO in the hydrophilic hydrogel lens (28%) than hydrophobic acrylic IOL (2%) with a p value <0.0001.¹⁶

In a retrospective study in Sweden comparing the PMMA with AcrySof[®] lens concluded that there was a significant difference between the PCO in the 2 groups. The relative risk was 3.6 times higher in the PMMA group.¹⁷

1.3.1.2 Maximum IOL Optic-posterior capsule contact.

One of the factors in reducing posterior capsule opacification is the posterior angulation of the IOL haptic and the posterior convexity of the optic. This is due to the creation of a 'shrink wrap', a tight fit of the posterior capsule against the back of the IOL optic. The relative stickiness of the

IOL optic biomaterial probably helps to produce an adhesion between the capsule and the IOL optic.¹⁸ The adhesion between the capsule and IOL optic helps prevent migration of the lens epithelial fibres by leaving no space.

1.3.1.3 Barrier effect of the IOL Optic

The optic barrier effect plays an important role in the case where there is retained cortical matter and cells especially in the cases of ECCE. The contact of the IOL optic with the posterior capsule leaves no space for the cells to thrive.¹⁸

However, there are subtle differences in the rates of PCO development in different types of optics used. A truncated, square edged optic rim appears to cause a complete blockade of cells at the optic edge, preventing epithelial in-growth over the posterior capsule. The effect of the sharp edge is obtained regardless the IOL material used.^{19,20,21}

1.3.2 SURGERY RELATED FACTORS

1.3.2.1 Hydro-dissection and cortical clean up.

Hydro-dissection is a very important step which is often under-rated. Removal of all or most of the equatorial cells helps in prevention of PCO. A study by Peng Q et al showed that use of hydro-dissection during cataract surgery allowed more efficient removal of cortex and lens epithelial cells (LECs), which in turn reduces the rates of PCO formation.²²

In a study done by M Quinlan et al found that there was no difference in the cell growths on the posterior capsule when comparing ECCE with the phacoemulsification technique of cataract surgery.²³ However Michael G Davidson et al revealed that phacoemulsification with and without anterior and equatorial capsular vacuuming led to less initial LEC density in the capsular bag than ECCE.²⁴ The lower density of the LEC's in the capsular bag leads to less PCO formation.

1.3.2.2 Capsular fixation

The hallmark of modern cataract surgery is the consistent and secure in-the-bag (capsular) fixation. The most obvious advantage of in-the-bag fixation is the accomplishment of good optic centration and sequestration of the IOL from adjacent uveal tissues. This also reduces the amount of PCO.

IOL fixation in the bag helps in enhancement of the IOL optic barrier effect since there is no space left between the IOL optic and the capsular bag. The in-the-bag fixation of IOLs occurs about 60% of the time in non-phaco ECCE.²⁵ In many cases this is due to combination of rigid design IOLs and can-opener anterior capsulotomies. With the modern foldable lens implantation, in-the-bag fixation has increased to over 90%.²⁵ It is not the foldable IOL, or the small incision that has contributed to this success, rather it is the meticulous surgery including a continuous curvilinear capsulorrhexis (CCC) and secures implantation of both IOL loops in the bag.²⁵

In a joint study in India and USA, Jagat Ram et al documented that visually significant PCO occurred in 42.45% of eyes having ECCE and 19.18% of eyes having phacoemulsification ($p < 0.001$) after a mean follow-up of 2.4 years \pm 0.7 (SD).²⁶ In both groups PCO was significantly less in eyes with IOL fixation in the bag as compared to those with one haptic in the sulcus and one in the bag and those with both haptics in the sulcus.

Precise in the bag fixation of IOL is aided by creating a continuous curvilinear capsulorrhexis diameter slightly smaller than that of the IOL optic. This places the cut anterior capsule edge on the anterior surface of the optic, providing a tight fit (analogous to a "shrink wrap") and helping to sequester the optic in the capsular bag from the surrounding aqueous humor, which contains macromolecules and inflammatory mediators.

Ravalico and associates studied the ideal capsulorhexis size for minimising the incidence of PCO. They concluded that capsulorhexis with a slightly smaller diameter than the IOL optic appears to be better than a large-size capsulorhexis in reducing the incidence of PCO.²⁷

In UK, William Meacock and colleagues showed that a larger IOL optic is associated with lower rates of PCO.²⁸

1.4 PCO IN DIABETIC PATIENTS

Although it has been reported that PCO is more severe in patients with diabetes mellitus than those without by Hayashi K et al²⁹, reports of the clinical association between diabetes and PCO are conflicting. A study by Zaczek A et al reported that PCO is less severe in Diabetes patients than, those without. They found no significant difference between the two groups in the total PCO score one year after phacoemulsification.³⁰

However a more recent study by Yoko Ebihara et al in Japan revealed that diabetic patients had significantly more severe PCO after cataract surgery than non-diabetic patients. This was a prospective study in which showed that at six months, the mean PCO values were 10.85 % ± 10.09% and 3.70 % ± 4.04% and at twelve months the mean PCO values were 10.01% ± 13.66% and 4.14 % ± 3.28% in the diabetic group and the control group respectively.³¹

2.0 STUDY JUSTIFICATION

Posterior capsular opacification is both an early and late complication of cataract surgery with intraocular lens implantation. It is one of the causes of reduced visual acuity post surgery and a reason for debilitation for the patient. It also has an additional cost implication to the patient in terms of its management and potential risks.

No study has been done in Kenya and only few in Africa to look at the factors associated with PCO formation. This study will provide important information regarding PCO rates with existing cataract surgery practices and the association with various factors and also form a data base for comparing with studies done elsewhere. The results will also enable us to modify these factors in order to reduce the incidence of PCO in our set up.

3.0 OBJECTIVES

3.1 MAIN OBJECTIVE

To determine the factors associated with PCO formation post cataract surgery at LSFEH.

3.2 SPECIFIC OBJECTIVES

1. To determine the effect of IOL type implanted on PCO formation.
2. To compare the rates of PCO formation with the surgeons.
3. To determine the effect of pre-existing co-morbidities on posterior capsular opacification.

4.0 RESEARCH METHODOLOGY

4.1 STUDY SETTING

The study was carried out at Lions Sight First Eye Hospital which is situated in Loresho, Nairobi. This hospital is located in the outskirts of Nairobi and caters for patients from within the city and outside through outreach programs. Their outreach programme is very extensive and serves areas in Central Province and Eastern Province of the country. They carry out an average of about 6000 cataract surgeries per year. It is a charitable hospital funded by the Lions International organization.

4.2 STUDY DESIGN

This was a case control study.

4.3 STUDY POPULATION

All the patients who had cataract surgery performed at LSFEH.

4.4 CASE DEFINITION

All patients who had cataract surgery at LSFEH with implantation of posterior chamber intraocular lens and had Nd:YAG capsulotomy.

4.5 CONTROLS

Patients who had cataract surgery at LSFEH with implantation of posterior chamber intraocular lens without significant PCO development (not requiring Nd:YAG capsulotomy) after at least two years of follow up after the cataract surgery.

4.6 EXCLUSION CRITERIA

Patients who had the following intra-operatively:

1. primary posterior capsulotomy
2. posterior capsular tear
3. left aphakic
4. anterior chamber IOL

Those who had a Nd:YAG capsulotomy done in LSFEH but had the cataract surgery done in another institution

4.7 SAMPLE SIZE

$$n = \frac{(P_0Q_0 + P_1Q_1)(Z_{1-\alpha} + Z_{1-\beta})^2}{(P_1 - P_0)^2}$$

Where;

n = Total required sample size for equally matched cases and controls i.e. (cases = controls).

p_1 & p_0 = are probabilities of having 50% in cases and controls respectively. It is an assumption since no study available.

$p_1 - p_0$ = expected differences in the exposure prevalence. Relative Risk of PCO in PMMA versus AcrySof[®] lenses at 3.6 times.¹⁷

$Z_{1-\alpha/2}$ = Probability of detecting a real difference between the two groups in Comparison.

$Z_{1-\beta}$ = Probability of detecting a false difference in the two groups (the power of test set at 80%)

$Z_{1-\alpha/2}$ & $Z_{1-\beta}$ are both cut off points along the x-axis of the standard normal probability distribution that represents probabilities matching the 95% confidence interval (1.96) and the statistical power of 80% (0.842), respectively.

Using the above formula with an assumption of having 50% of patients in the cases and controls the sample size obtained was **30 cases** and **30 controls**.

A total of **65 cases** and **65 controls** were obtained.

4.8 ETHICAL CONSIDERATIONS

All information acquired from the patients' files was kept confidential.

The study proposal was presented to the department of ophthalmology and approved.

Approval was obtained from LSFEH before undertaking the study at their institution.

Ethical approval was obtained from the KNH ethical committee.

4.9 STUDY MATERIALS

Questionnaires and files from the patient registry of those who had cataract surgery at LSFEH.

5.0 PROCEDURE AND DATA ANALYSIS

Files were retrieved using their Nd:YAG capsulotomy laser registry records of January to December, 2008. The files were retrieved from the patient registry for those who had been recorded as having had received Nd:YAG capsulotomy and the data entered. For the controls, files from the theatre records were retrieved from the December 2007 and before. Those patient who had at least two years of follow up and had not required or received Nd:YAG capsulotomy and not meeting the exclusion criteria were selected as controls.

The data from the files was entered into the questionnaire by the investigator and an assistant. Data input was done using Scientific package for Social Scientists (SPSS) Version 11.5 package for Windows. After cross checking for missing entries, the data was analyzed using SPSS and presented in tables and figures. Odds Ratios and their 95% confidence intervals and P values were calculated to ascertain factors associated with PCO formation.

6.0 RESULTS

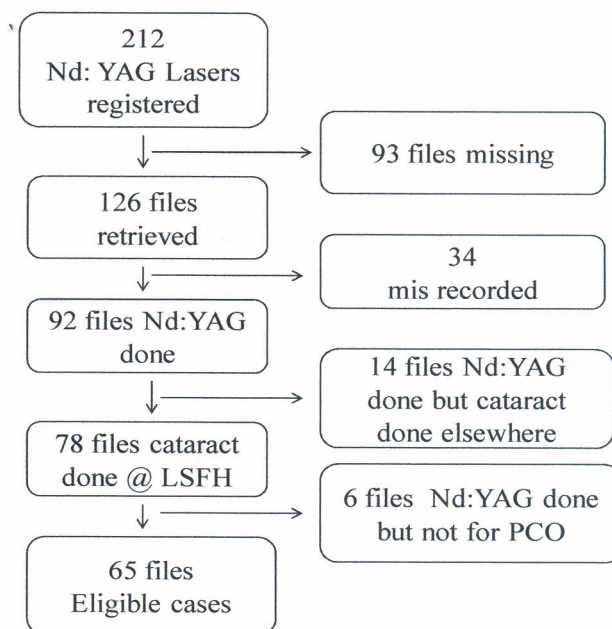
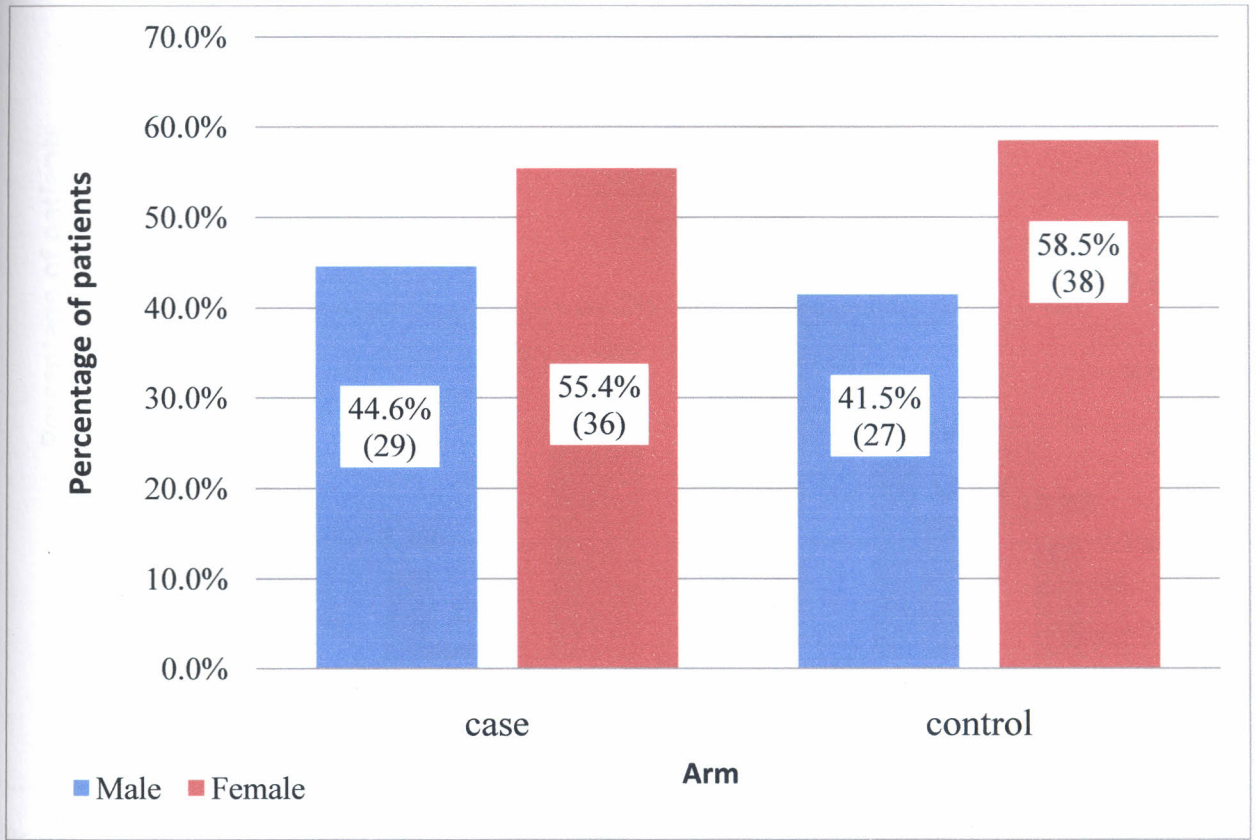


Figure 1. Flow chart of the cases selected

6 patient had Nd:YAG laser for other conditions; anterior capsule tag, vitreous tag, iris pigment on the IOL and exudative membrane.

Figure 2. Sex distribution (n=130)

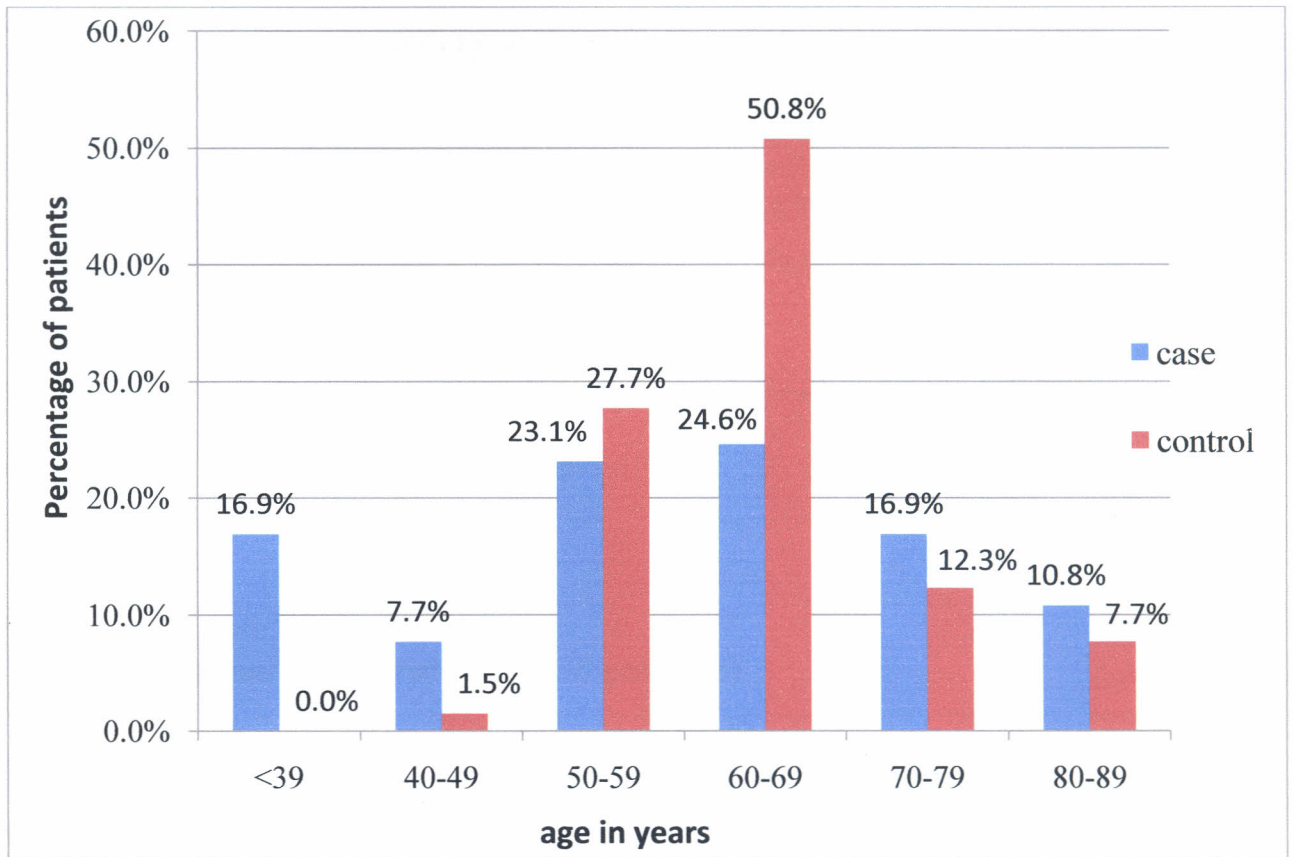


P=0.723

ODDS RATIO (OR) = 0.882, 95% CI 0.44, 1.77

The ratio of males to females was 1:1.32. The difference between the two sexes was not statistically significant (p=0.723)

Figure 3. Age distribution (n=130 patients)



P < 0.017

The mean age of patients in the cases was 57.4 years and of the controls was 64.0 years. This difference was statistically significant (p < 0.017).

Table 1. Type of lens and PCO (n= 130 patients)

TYPE OF LENS	CASES (n=65)	CONTROLS (n=65)	ODDS RATIO 95% CI	P VALUE
AcrySof [®]	20 (33.3%)	40 (66.7%)	3.60 (1.74-7.44)	p < 0.001
PMMA	45 (64.3%)	25 (35.7%)		

Patients with AcrySof[®] lens were less likely to develop PCO.

Table 2. Time between surgery and PCO diagnosis

	AcrySof[®]	PMMA	P VALUE
MEDIAN NUMBER OF DAYS	63.0 (37.5-89.5) days	88.0 (46.0-254.0) days	0.101

PMMA lenses had a longer duration of time for PCO development than AcrySof[®] lenses, but the difference was not statistically significant (p=0.101).

Table 3. Surgeon's PCO rates (n=130 patients)

	CASES(n=65)	CONTROLS(n=65)	P VALUE
SURGEON 1	11(16.9%)	48(73.8%)	<0.001
SURGEON 2	40(61.5%)	15(23.1%)	
SURGEON 3	14(21.5%)	2(3.1%)	

There was a significant difference in PCO development among the 3 surgeon's (p<0.001).

Table 4. MSICS v/s PHACO with AcrySof[®] lens (n=60 patients)

	CASE	CONTROL	ODDS RATIO (95% CI)	P VALUE
PHACO	15(75%)	35(87.5%)	2.33(0.59-9.27)	0.278
MSICS	5(25%)	5(12.5%)		

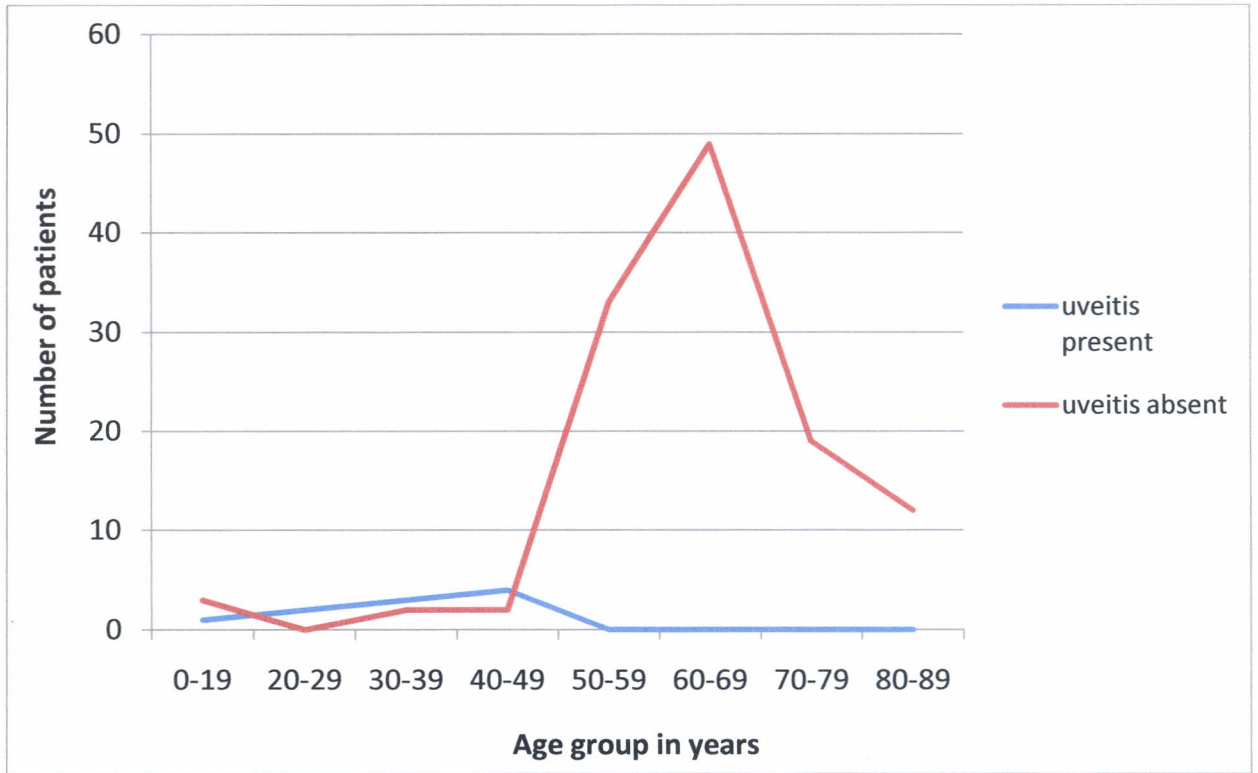
60 patients received an AcrySof[®] lens; phaco was done for 50 patients and the 10 patients had MSICS. There was no statistically significant difference in the rate of PCO among the 2 groups (p=0.278)

Table 5. History of Uveitis and PCO formation (n=10 patients)

VARIABLE	CASE	CONTROL	ODDS RATIO 95% CI	P VALUE
HISTORY OF UVEITIS	10 (15.4%)	0 (0.0%)	2.19 (1.80-2.65)	0.001

All the 10 patients with pre-operative uveitis developed a PCO, with only 1 patient receiving an AcrySof[®] lens and 9 patients with PMMA lens.

Figure 4. Age distribution of uveitis patients (n=130 patients)



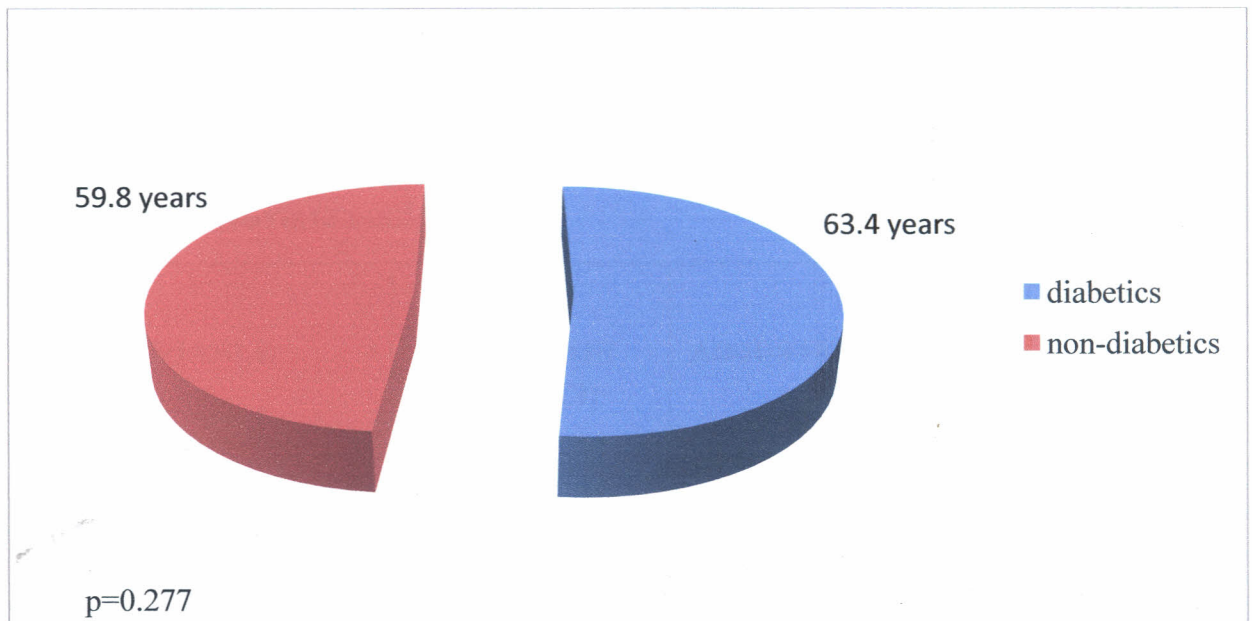
As noted from the figure above the patients with uveitis were much younger than the ones without. The mean age of patients with uveitis was 32.70 years and for the patients without uveitis was 62.79 years, and the difference was significant ($p < 0.001$)

Table 6. Diabetes and PCO (n=130 patients)

	CASE	CONTROL	ODDS RATIO 95% CI	P VALUE
DIABETICS	8 (12.3%)	18 (27.7%)	2.73(1.09-6.83)	0.028
NON-DIABETICS	57 (87.7%)	47 (72.3%)		

The non-diabetics were more likely to develop PCO than the diabetics. There was a statistically significant difference between the diabetic and non-diabetic patients (p=0.028).

Figure 5. Mean age of Diabetics v/s non diabetics



The mean age of non- diabetics, 59.8 years was lower than that of diabetics of 63.4 years, but the difference was not statistically significant (p=0.277).

Table 7. Univariate analysis

RISK FACTOR	CASES	CONTROLS	CRUDE OR (95%CI)	P-VALUE
AGE, MEAN(YEARS)	57.4	63.0	0.97 (0.95-1.00)	0.017
TYPE OF IOL				
- ACRYSOF [®]	20	40	3.60 (1.74-7.44)	<0.001
- PMMA	45	25		
DIABETES MELLITUS	8	18	2.73 (1.09-6.83)	0.028
UVEITIS	10	0	2.18(1.80-2.65)	0.001

The factors that influenced the occurrence of PCO were the age of the patient, type of IOL, diabetes mellitus and uveitis.

Table 8. Multivariate analysis

VARIABLE	CRUDE OR (95% CI)	ADJUSTED OR (95% CI)	P VALUE
AGE	0.97 (0.95-1.00)	0.98 (0.95-1.00)	0.147
DIABETES MELLITUS	2.73 (1.09-6.83)	0.33 (0.13-0.88)	0.027
TYPE OF LENS	3.60 (1.74-7.44)	0.28 (0.13-0.61)	0.001
UVEITIS	2.18(1.80-2.65)	-	0.999

Diabetes mellitus and type of lens were the only independent determinants for PCO development.

7.0 DISCUSSION.

A total of 130 subjects were studied, 56(43%) males, 74(57%) females, with M: F ratio of 1:1.32 (figure 2). There were 29(44.60%) males in the cases and 27(41.50%) in the controls. 36(55.40%) cases and 38(58.50%) of the controls, were females. At LSFEH there are more female patients seen as compared to male patients. This explains the difference noted.

In this study the mean age of cases was 57.4years \pm 18.96 [standard deviation (SD)] and 63.0years (SD=8.62) for controls (figure 3). The cases had a significantly lower mean age than the controls ($p < 0.017$). A study by Britta Lundqvist and Eva Mönestam showed that PCO is age dependent and occurs more frequently in younger patients.³² All the patients in our study who were below the age of 39 years developed PCO. This could be due the complicated nature of the cataracts in this age group and more post operative inflammation.

AcrySof[®] lens had a PCO rate of 20(33.7%) in this study. PMMA lens had a higher PCO rate of 45(64.3%). The difference was statistically significant ($p < 0.017$) as shown in table 1. A retrospective study in Sweden by Karin Sundelin et al showed a 3.6 times relative risk for the PMMA lens developing PCO compared to AcrySof[®].¹⁷ This is similar to what we found in our study. Gisela Wejde et al showed that the patients with AcrySof[®] IOL developed significantly less PCO than those with silicone or HSM PMMA group with a rounded edge design. The Nd:YAG capsulotomy rate was 20% in the HSM PMMA group, 22% in the silicone group, and 8% in the AcrySof[®].¹⁵

Patients with AcrySof[®] lens had a median of 63.0 days [interquartile range (IQR) 37.5-89.5] of clinical PCO diagnosis from the time of surgery. PMMA group had a median of 88.0 days (IQR 46.0-254.0) (table 2). Phaco-emulsification is a modern method of cataract extraction compared

to MSICS. It requires an expensive machine with its accessories. Furthermore, the AcrySof[®] lenses are more expensive than the PMMA lenses. This cost is transferred to the patient thus making phaco-emulsification a much more expensive surgery. Hence the patients who undergo phaco-emulsification pay more for their cataract surgery and are presumed to be of higher socio-economic background. MSICS is the preferred choice when the cataracts are more mature and most patients are implanted with PMMA lenses. However a few of the patients who had mature cataracts and are not suitable for phaco-emulsification, but pay for the AcrySof lens, are implanted with an AcrySof[®] lens during MSICS.

Patients who have undergone phaco-emulsification tend to come earlier in case of any visual complaints like glare while driving and hence they tend to receive Nd:YAG capsulotomy much earlier than the group with PMMA lens, who present much later when the vision has deteriorated significantly. Phaco-emulsification patients are more critical of their visual outcomes post operatively and present even with a slight drop in best corrected visual acuity (BCVA) from their immediate post-operative BCVA. This might be due to their higher educational and socio-economic background. They also tend to receive Nd:YAG capsulotomy much earlier.

Surgeon 1 had 11(16.9%) cases and 48(73.8%) controls. Surgeon 2 on the other hand, had 40(61.5%) cases and 15(23.1%) controls. There were 14(21.5%) cases and 2(3.1%) controls for surgeon 3 as shown in table 3. When we compared the PCO rates among the 3 surgeons, the difference was statistically significant ($p < 0.001$). This difference could be attributed to the type of IOL used by the surgeons and their surgical experience. A study by Peng Q et al showed that use of hydro-dissection during cataract surgery allowed more efficient removal of cortex and lens epithelial cells (LECs), which in turn reduces the rates of PCO formation.²² Removal of all or most of the equatorial cells helps in prevention of PCO.

Amongst the study subjects, 60 patients had an AcrySof[®] lens implanted into the eye. Of these, 50 had phaco-emulsification done and the remaining 10 had MSICS (table 4). There was no statistically significant difference in the PCO rates between the two methods of surgery ($p=0.278$). The findings were similar to a study by M Quinlan and colleagues, who found that there was no difference in the cell growths on the posterior capsule when comparing ECCE with the phaco-emulsification technique of cataract surgery.²³ However Michael G Davidson et al revealed that phaco-emulsification with and without anterior and equatorial capsular vacuuming led to less initial LEC (lens epithelial cells) density in the capsular bag than ECCE.²⁴ The lower density of the LEC in the capsular bag leads to less PCO formation.

All the 10 patients who had prior uveitis developed PCO, 1 patient had an AcrySof lens and rest had a PMMA lens (table 5). This difference was statistically significant ($p=0.001$). The mean age of uveitis patients, 32.70 years \pm 9.84 (SD), was significantly lower compared to those patients without prior uveitis who had a mean age of 62.79 years \pm 12.90 (SD) ($p<0.001$) (figure 4). Patients with prior uveitis usually develop cataracts at a younger age as a complication of the uveitis. Steroids are the mainstay treatment of uveitis, which may lead to early cataract formation. The patients with prior uveitis, who undergo cataract surgery, post-operatively are prone to more inflammatory response which may lead to an occurrence of PCO. A study by Dana MR et al revealed that Crude incidence rates for visually significant PCO were 54% over a mean follow-up of 4.3 years in uveitic cases and 40% over a mean follow-up of 3.9 years among non-uveitic cases ($p= 0.02$). They concluded that the apparent higher rate of PCO in patients with uveitis is primarily due to their younger age at the time of surgery.³³

In our study, diabetics were shown to have lower rates of PCO (table 6). The diabetics had a PCO rate of 8(12.30%) and this was statistically significant ($p=0.028$). AcrySof[®] lens was

implanted in 11 patients of whom 2(10.0%) were cases and 9(22.5%) were controls. Fifteen patients received PMMA lens; 6(13.3%) were cases and 9(36.0%) were controls. The mean age of the diabetic patients was 63.4 years \pm 8.76 (SD) and for the non-diabetics was 59.8 years \pm 16.14 (SD) (figure 5), however the difference between the mean ages of the two groups was not statistically significant ($p=0.277$). Hayashi K et al reported that PCO is more severe in patients with diabetes mellitus than those without.²⁹ In Japan, Yoko Ebihara et al revealed that diabetic patients had significantly more severe PCO after cataract surgery than non-diabetic patients. This was a prospective study in which showed that at six months, the mean PCO values were 10.85 % \pm 10.09% and 3.70 % \pm 4.04% and at twelve months 10.01% \pm 13.66 %and 4.14 % \pm 3.28% in the diabetic group and the control group respectively.³¹ A study by Zaczek A et al reported that PCO is less severe in patients with diabetes than, those without. They found no significant difference between the two groups in the total PCO score after one year of phacoemulsification.³⁰ In our study the limitation was that the diabetic glycaemic control was not available in the form of HbA1c levels (glycated haemoglobin) and the duration of diabetes was not available from the patient records.

In the univariate analysis, the factors that were shown to have an association with PCO were age of patient, type of IOL implanted, diabetes mellitus and prior uveitis (table 7). On multivariate analysis the following factors emerged as significant risk factors; type of IOL [adjusted (adj) OR 0.28, 95% CI 0.13, 0.61] and Diabetes Mellitus (adj OR 0.33, 95% CI 0.13-0.88) (table 8). Patients who had an AcrySof[®] lens had lower PCO rates compared to the PMMA lens. Diabetic patients had less PCO rates than non diabetic patients. However the glycaemic control of the diabetic patient was not taken into account during this study, due to unavailability of this data

from the patient records. Patients with poorly controlled diabetes may have accumulation of sorbitol which may lead to damage of the LEC's, thus reduced LEC proliferation and PCO. Therefore the glycemic control is important to take into account. Uveitis and age (adj OR=0.98, 95%CI 0.95-1.00) did not have a significant statistical difference on multivariate analysis.

8.0 STUDY LIMITATIONS

1. Data was not available from the patient records on their type of diabetes, duration and their control.
2. Many patient files were missing as noted in the flow chart(figure 1)

9.0 CONCLUSIONS

1. AcrySof[®] lens has lower PCO rates than PMMA lens.
2. PCO rates among the surgeons differed.
3. The method of surgery has no impact on PCO formation.
4. Prior history of uveitis increases the risk of PCO after cataract surgery.
5. Diabetic patients have lower PCO rates compared to the non diabetic patients.

10.0 RECOMMENDATIONS

1. Acrysof[®] lens be the lens of choice to reduce the PCO rates after cataract surgery when affordable.
2. More studies need to be done with respect to Diabetes and PCO formation and also uveitis and PCO formation.

APPENDIX

QUESTIONNAIRE

PATIENT BIODATA

1. SUBJECT NO: ----- CASE: ----- CONTROL: -----

2. FILE NO: ----- a) SEX: ----- b) AGE: -----

3. PRE-EXISTING CONDITIONS

a) DIABETES: YES: ----- NO: ----- DURATION: -----

TYPE OF MEDICINE USED: INSULIN: ----- OHA: -----

b) UVEITIS: YES: ----- NO: ----- DURATION: -----

TYPE OF UVEITIS: -----

DRUGS USED: -----

c) GLAUCOMA: YES: ----- NO: ----- DURATION: -----

TYPE OF GLAUCOMA: -----

DRUGS USED: -----

SURGERY DETAILS

4. DATE OF SURGERY: ---/---/----- 5. SURGEON: -----

6. EYE OPERATED: a) RIGHT EYE: ----- b) LEFT EYE: -----

7. TYPE OF SURGERY: a) PHACO; ----- b) MSICS; -----

8. TYPE OF LENS IMPLANT: a) ACRYSOFT; ----- b) PMMA; -----

PCO DIAGNOSIS DATE

10. DATE OF PCO DIAGNOSIS: -----/-----/-----

MODE OF MANAGEMENT

11. DATE OF MANAGEMENT: -----/-----/-----

12. METHOD USED: Nd:YAG CAPSULOTOMY: -----

PARS PLANA CAPSULOTOMY: -----

REFERENCES

- 1 Resnikoff S, Pascolini D, Etya'ale D, et al. Global data on visual impairment in the year 2002. *Bull World Health Organ* 2004; 82:844–851.
- 2 Fred Hollows Foundation. Facts and Figures for Kenya, 2010.
- 3 Spalton D.J. Posterior capsular opacification after cataract surgery. *Eye* 1999; 13:489-492
- 4 Bertelmann E, Kojebinsky C. Posterior capsular opacification and anterior capsule opacification. *Current opinion ophthalmology* 2001; 12:35-40
- 5 Ridley H. The origin and objectives of intraocular lenticular implants. *Trans American Academy Ophthalmology and Otolaryngology* 1976; 81:65-66
- 6 Apple D.J, Solomon K.D, Tetz M.R, et al. Posterior capsule opacification. *Survey of Ophthalmology* 1992; 37:73-116
- 7 Jafferji S, Khan F. Outcome of phacoemulsification in patients with age related cataracts at Lions Sightfirst Eye Hospital Nairobi. *East African Journal of Ophthalmology* 2008; 14:24-30.
- 8 Stokoe N.L. Soemmering ring, a review and three illustrative cases. *British journal of Ophthalmology* 1957; 41,348
- 9 Thomas Neumayer, Oliver Findl, Wolf Buehl, Stefan Sacu, Rupert Menapace, Michael Georgopoulos. Long term changes in the morphology of posterior capsule opacification. *Journal of cataract and refractive surgery* Nov 2005; 31:2120-2129.

-
- 10 Aslam T, Dhillon B, Werghi N, Taguri A, Wadood A. Systems of analysis of posterior capsular opacification. *British Journal Ophthalmology* 2002; 86:1181-1186
- 11 Tetz M, Auffarth G, Sperker M, et al. Photographic image analysis system of posterior capsule opacification. *J Cataract Refract Surgery* 1997; 23:1515-20.
- 12 Kruger A, Schauersberger J, Abela C, et al. two year result: sharp versus rounded optic edges on silicone lenses. *J Cataract Refract Surg* 2000; 26:566-70.
- 13 Venkatesh P, Leon B, Selvaraj S, Manjula K, Kupfer C. The Madurai intraocular lens study IV: Posterior capsule opacification. *American Journal of Ophthalmology* 2000; 13:304-309.
- 14 Apple D.J. Influence of intraocular lens material and design on postoperative intracapsular cellular activity. *Tr Am Ophtha Soc* 2000; 98:257-283.
- 15 Gisela W, Maria K, charlotte Z. Posterior capsule opacification: comparison of 3 intraocular lenses of different materials and design. *Journal of cataract Refractive Surgery* 2003; 29:1556-1559.
- 16 Hayashi K, Hayashi H. Posterior capsule opacification after implantation of a hydrogel intraocular lens. *Br J Ophthal* 2004; 88:182-185.
- 17 Karin S, Ylva F, Anders O, Johan S. Posterior capsular opacification with AcrySof and poly(methylmethacrylate) intraocular lenses. *J Cataract Refract Surg* 2001; 27: 1585- 1590.

-
- 18 Pandey S.K, Apple D.J, Maloof A.J, Milverton E.J. Posterior capsule opacification: A Review of the Aetiopathogenesis, Experimental and Clinical Studies and Factors for Prevention. *Indian Journal Ophthalmology* 2004; 52: 99-112.
- 19 Nishi O, Nishi K, Wickstrom K. Preventing lens epithelial cell migration using intraocular lenses with sharp rectangular edges. *J Cataract Refract Surg* 2000; 26:1543-1549.
- 20 Nishi O, Nishi K, Akura J, Nagata T. Effect of round-edged acrylic intraocular lenses on preventing posterior capsule opacification. *J Cataract Refract Surg* 2001; 27:608-613.
- 21 Nishi O, Nishi K, Yashuhiro O. Effect of intraocular lenses on preventing posterior capsule opacification: Design versus material. *J Cataract Refract Surg* 2004; 30:2170–2176.
- 22 Peng Q, Apple D, Visessook N, Werner L, Pandey S, Escobar-Gomez M, et al. Surgical prevention of posterior capsule opacification. Part II. Enhancement of cortical clean up by focusing on hydrodissection. *J Cataract Refract Surg* 2000; 26:188-97.
- 23 Quinlan M, Wormstone I, Duncan G, Davies P. Phacoemulsification versus extracapsular cataract extraction: a comparative study of cell survival and growth on the human capsular bag in vitro. *British Journal of Ophthalmology* 1997; 81:907–910.
- 24 Michael G, Duncan K, Morgan M, Christine M. Effect of surgical technique on in vitro posterior capsule opacification. *J Cataract Refract Surg* 2000; 26:1550-1554.
- 25 Ram J, Apple D, Peng Q, Visessook N, Auffarth G, Schoderbek R, et al. Update on fixation of rigid and foldable posterior chamber intraocular lenses. Part II. Choosing the correct haptic fixation and intraocular lens design to help eradicate posterior capsule opacification. *Ophthalmology* 1999; 106:891-900.

-
- 26 Ram J, Pandey S, Apple D, Werner L, Brar G, Singh R, Gupta A. Effect of in-the-bag intraocular lens fixation on the prevention of posterior capsule opacification. *J Cataract Refract Surg* 2001; 27:1039-46.
- 27 Ravalico-Ravalico G, Tognetto D, et al. Capsulorhexis size and posterior capsule opacification. *J Cataract Refract Surg* 1996; 22:98-103.
- 28 William M, Spalton D, Boyce J, Jose R. Effect of optic size on posterior capsule opacification: 5.5mm versus 6.0mm AcrySof intraocular lenses. *Journal of cataract Refract Surg* 2007; 8:1194-1198.
- 29 Hayashi K, Hayashi H, Nakao F, Hayashi F. Posterior capsule opacification after cataract surgery in patients with diabetes mellitus. *American Journal Ophthalmology* 2002; 134:10-16.
- 30 Zaczek A, Zetterstrom C. Posterior capsule opacification after phacoemulsification in patients with diabetes mellitus. *J Cataract Refract Surg* 1999; 25:233-237.
- 31 Yoko Ebihara, Satoshi Kato, Tetsuro Oshika, Mayumi Yoshizaki, Gentaro Sugita.
Posterior capsule opacification after cataract surgery in patients with diabetes mellitus.
J Cataract Refract Surg 2006; 32:1184–1187.
- 32 Lundqvist B, Mönestam E. Ten-Year Longitudinal Visual Function and Nd: YAG Laser Capsulotomy Rates in Patients Less Than 65 Years at Cataract Surgery. *American Journal of Ophthalmology* 2009; 149:238-244.e1
- 33 Dana M, Chatzistefanou K, Schaumberg D, Foster C. Posterior capsule opacification after cataract surgery in patients with uveitis. *Ophthalmology* 1997; 104(9):1387-93.