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This is to certify that the dissertation entitled "**SQUARE EDGE INTRAOCULAR LENS VERSUS CONVENTIONAL ROUND EDGE INTRAOCULAR LENS IN PREVENTION OF POSTERIOR CAPSULE OPACIFICATION—A RANDOMIZED CONTROLLED TRIAL AT KLE'S DR. PRABHAKAR KORE HOSPITAL**" is a bonafide research work done by **REGISTRATION NO: BK0108001**.

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ACO	Anterior Capsule Opacification
CCC	Continuous Curvilinear Capsulorrhesis
ECCE	Extracapsular cataract extraction
IOL	Intraocular lens
LECs	Lens Epithelial Cells
MSICS	Manual Small Incision Cataract Surgery
Nd:YAG	Neodymium – doped Yttrium Aluminium Garnet
PCIOL	Posterior chamber intraocular lens
PCO	Posterior capsule opacification
PMMA	Poly Methly Methacrylate
RNA	Ribonucleic Acid
SICS	Small Incision Cataract Surgery

**LIST OF
ABBREVIATIO
NS USED**

ABSTRACT

BACKGROUND AND OBJECTIVES:

Posterior capsule opacification is the most common complication after cataract surgery occurring in up to 50% of patients and is associated with decreased vision. It can be treated by Nd:YAG (neodymium-doped yttrium aluminium garnet) laser capsulotomy, which, however, can cause complications such as retinal detachment, endophthalmitis and raised intraocular pressure. In developing countries like India Nd:YAG laser capsulotomy puts additional economical burden on patients.

Recent trials have showed that in the context of phacoemulsification, intraocular lens design has a significant influence on posterior capsule opacification rates, with square edge profile lens having lower rates of posterior capsule opacification (10% at the end of one year) than conventional round edge lens.

This study is undertaken to determine whether square edge polymethylmethacrylate (PMMA) intraocular lens is superior in preventing clinically significant posterior capsule opacification and better visual outcome when compared with conventional round edge PMMA intraocular lens in context of manual small incision cataract surgery in a developing country.

METHODOLOGY:

The present randomized clinical trial was conducted at KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum, over a period of one year, from 1st January 2009 to 31st December 2009. In the study, 128 patients were included, who met the inclusion criteria. After detailed evaluation, informed consent was taken and they were randomized into two groups to receive either round edge

intraocular lens (Group A) or square edge intraocular lens (Group B) after manual small incision cataract surgery. All patients completed the study with a minimum follow up of 10 months. A detailed documentation of best corrected visual acuity, grades and type of posterior capsule opacification was done during follow up.

OBSERVATION AND RESULTS:

The majority of patients in our study were in the age group of 60-69 years (39.8%). Mean age in Group A was 62.7 years and in Group B was 62.8 years. Male to female ratio was 1:1.06. Out of 128 patients overall incidence of posterior capsule opacification was 83.6%, in which 85.9% were in Group A and 81.2% were in group B.

The Grade 3(Posterior capsule opacification well inside intraocular lens edge but clear visual axis) and Grade 4(Posterior capsule opacification across visual axis) posterior capsule opacification which we considered as clinically significant was seen in 37.5% patients in Group A and 17.2% patients in Group B. The difference between the two groups was statistically not significant ($\chi^2 = 6.900$, DF = 3, p=0.075), but clinically significant.

Visual outcome was better in Group B which was statistically significant (0.003). Fibrous type of posterior capsule opacification was the commonest type seen in our study irrespective of the groups. There was less incidence of posterior capsule opacification in capsulorrhexis (with relieving incisions) and complete cortical clean up cases. The difference in Nd:YAG laser capsulotomy rates were not statistically significant between the two groups (χ^2 with Yates' correction = 0.075, DF = 1, p=0.784)

CONCLUSION:

From our study we conclude that square edge PMMA intraocular lens gave less clinically significant posterior capsule opacification rates and better visual outcome when compared to round edge PMMA intraocular lens.

Key words: Posterior capsule opacification; Square edge lens; Round edge lens; Small incision cataract surgery; Randomized

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INTRODUCTION

Cataract is the leading cause of blindness worldwide including India. In addition to the backlog, an additional 3.8 million become blind each year because of cataract.¹

Cataract surgery has evolved from couching in ancient times to modern day phacoemulsification and Manual Small Incision Cataract Surgery (MSICS).²

The modern cataract surgery has given good visual results, but this could deteriorate over time because of posterior capsule opacification (PCO) which is the most frequent complication after cataract extraction which can occur in up to 50 % of cases.³

PCO can be treated by Nd:YAG (neodymium-doped yttrium aluminium garnet) laser capsulotomy, which, however, can cause adverse complications such as retinal detachment, endophthalmitis, intraocular pressure rise, cystoid macular edema, and damage to intraocular lens (IOL). In developing countries, laser treatment is often not available. Posterior capsule opacification often disturbs fundus examination and optimal treatment by photocoagulation or vitrectomy in eyes with vitreo-retinal disorders. Socio-economic consequences are also enormous. Thus resolution of posterior capsule opacification is an urgent task in cataract surgery.⁴

Lens epithelial cells (LECs) left behind in the capsular bag after cataract extraction is mainly responsible for the development of posterior capsule opacification.⁵

Recent work worldwide attempting to eliminate PCO development are focusing on several strategies, including improving surgical techniques, IOL materials, IOL designs, use of therapeutic agents, and combination therapy.⁶

The modern cataract surgery with continuous curvilinear capsulorrhexis (CCC) and in-the-bag fixation of intraocular lens has resulted in decline of PCO rates.⁷

Evidence strongly suggests that lens implant design rather than lens material may be the more important factor in the prevention of PCO. A square-edged optic rim appears to cause blockade of LECs at the optic edge, preventing epithelial in-growth over the posterior capsule and subsequent development of posterior capsule opacification.⁸

In developing countries Manual Small Incision Cataract Surgery is the most favoured procedure as it is economical and offers faster visual recovery and better uncorrected visual acuity than conventional extracapsular cataract extraction (ECCE).⁹

Thus this study is being done to evaluate posterior capsule opacification after implantation of conventional round edged IOL (Single piece polymethylmethacrylate) versus square edged IOL (Single piece polymethylmethacrylate) in manual small incision cataract surgery.

AIMS AND OBJECTIVES

1. The purpose of this study is to compare the rate of posterior capsule opacification after implantation of square edge intraocular lens versus round edge intraocular lens in patients undergoing manual small incision cataract surgery.
2. To compare the visual outcome between square edge and round edge intraocular lenses.

REVIEW OF LITERATURE

Historical aspect

Posterior capsule opacification (PCO) was first described clinically by Detmar Wilhem Soemmerring (1828) and shortly thereafter by Werneck (1833) and Textor (1842).¹⁰

Posterior capsule opacification is not a new complication. In a 1901 textbook, Schmidt-Rimpler said, “Even after successful and uneventful cataract extraction, a secondary cataract often develops.”¹¹

Schlote et al summarized the status of cataract surgery at the end of the 19th century as follows: “We reviewed records from the year 1895. With use of Graefe’s technique of cataract extraction, the early postoperative visual acuity was 20/200 or better in 63% and 20/40 or better in 5%. A secondary cataract developed in about 30% of eyes”.¹¹

It was particularly common and severe in the early days of intraocular lens (IOL) surgery when the importance of cortical cleanup was less appreciated. Through the 1980s & early 1990s, the incidence of PCO ranged between 25-50%.¹²

Incidence

In 1998, Schaumberg and coauthors published a meta-analysis of the published literature on PCO and found the postoperative incidence to be 11.8% at one year, 20.7 % at three years, and 28.5 % at five years.¹³

A study conducted in India (Madurai) showed incidence of PCO after 4 years to be 13.1%.¹⁴

Investigators from Nepal reported a 21% incidence of PCO in a 2 year study after extracapsular cataract extraction with posterior chamber intraocular lens (PCIOL).¹⁵

But reported rates of PCO vary widely and are based on various definitions of PCO, varying interval of follow-up, use of different lens material, design and methods of lens implantation.

Anatomy of Lens

The lens is a transparent, biconvex, elliptical, semisolid, avascular body of crystalline appearance located between the iris and the vitreous. It is unique among organs in that it contains cells solely of a single type, in various stages of cytodifferentiation. Lens has two surfaces, anterior and posterior, and a border where these surfaces meet, known as the equator.

The lens consists of capsule, epithelium and fibers.

- 1) Lens capsule – It is the basement membrane of the lens epithelium and is thickest basement membrane in the body. It is much thicker in front than behind and the anterior and posterior portions are thicker towards the periphery.

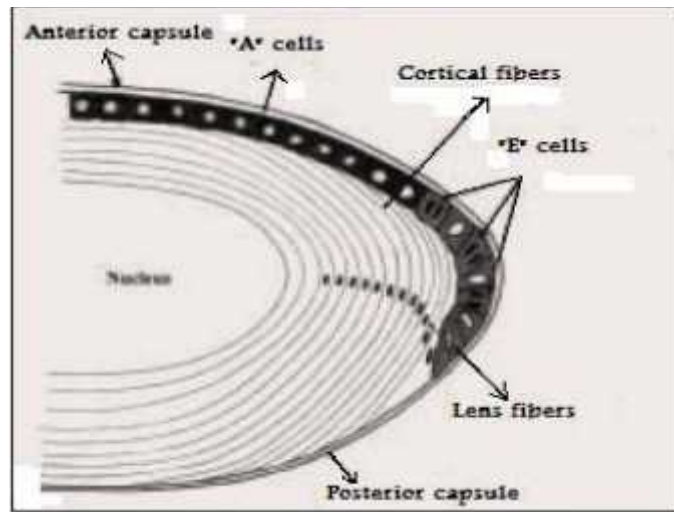
Under light microscope capsule appears transparent, homogenous, and under polarized light, birefringent with an indication of a lamellar structure with fibres arranged parallel to its surface.

The lens capsule is rich in type IV collagen. It also contains types I & III collagens, in addition to a number of extracellular matrix components, which include laminin, fibronectin, heparin sulphate and entactin. The capsule

is freely permeable to water, ions and other small molecules, and offers barrier to protein molecules.¹⁶

- 2) The lens epithelium – It consists of a single sheet of cuboidal cells spread over the front of the lens, deep to the capsule and extending outwards to the equator. There is no corresponding posterior layer.

Central zone – It consists of cuboidal cells (A cells) which are polygonal in flat section. These cells are stable in number, slowly reduces with age. Under normal circumstances, these cells do not mitose, but can do so in response to a wide variety of injurious insults. These cells have a propensity toward fibrous metaplasia, which causes wrinkling and thickening of posterior capsule after cataract extraction. It is possible that these cells play a dominant role in the development of fibrosis-type of PCO.



Intermediate zone – It consists of comparatively smaller and more cylindrical cells located peripheral to central zone. These cells mitose occasionally.

Germinative zone – It consists of columnar cells (E cells) which are most peripheral and located just pre-equatorial. These are actively dividing to form new cells which migrate posteriorly to become lens fibres. These actively

mitotic cells are the origin for bladder cells that tend to migrate along posterior capsule to form posterior sub-capsular cataracts. The swollen cells seen in pearl-type PCO are histologically and morphologically identical to bladder cells, thus the pathogenesis of pearl-type PCO could be primarily associated with the equatorial epithelium.¹⁷

- 3) The lens fibres – Lens fibres are strap-like or spindle shaped cells which arch over the lens in concentric layers from front to back.

Physiology and biochemistry

Human lens grows throughout life. Metabolism is chiefly anaerobic through the glycolytic pathway. Only 3% of the glucose utilization is aerobic, via Krebs cycle. Pentose shunt pathway is involved in RNA synthesis.

The lens capsule is normally under tension, so when cut or ruptured its edges roll out and then curl up. This property of elastic recoil is used during extra capsular cataract extraction (ECCE), or in the Nd:YAG-capsulotomy.

Water constitutes 65% of the lens wet weight. Proteins constitute 34% of the total weight of an adult lens which include, insoluble albuminoids (12.5%), alpha-crystallins (31.7%), beta-crystallins (53.4%), gamma-crystallins (1.5%), mucoproteins and nucleoproteins.¹⁶

Mechanism of PCO development

Lens epithelial cells (LECs) left behind in the capsular bag after any type of extracapsular cataract surgery is mainly responsible for PCO development. Proliferation, migration, epithelial-to-mesenchymal transition, collagen deposition, and lens fiber regeneration of LECs are the main causes of opacification.

Cataract surgery induces a wound-healing response & left over LECs proliferate & migrate across the posterior capsule. The molecular mechanisms influencing leftover LEC behavior after cataract surgery are not completely clear. In vitro studies & animal models of PCO suggest that several cytokines & growth factors play a major role in the pathogenesis of PCO. Studies show that transforming growth factor beta, fibroblast growth factor -2, hepatocyte growth factor, interleukins 1 & 6, matrix metalloproteinase play important role in development of PCO.⁶

Classification of Posterior Capsule Opacification

The two morphologically distinct types of PCO are fibrosis & Elschnig's pearls, which occur independently or in combination. In addition, ECCE procedures may result in the formation of a Soemmering's ring.

- a) Fibrosis type – These tends to appear within 2-6 months after ECCE, many are clinically insignificant. Remnant LECs left on anterior capsule differentiate into spindle-shaped, fibroblast-like cells (myofibroblasts), which express alpha-smooth muscle actin & become highly contractile. This forms a cellular layer which secretes extracellular matrix components, which is composed of types I and III fibrillar collagen with proteoglycans. Cellular contraction results in formation of folds and wrinkles in the posterior capsule.
- b) Elschnig's pearls – These arise from bladder cells of germinative zone (Equatorial lens epithelial cells). Clinically pearl formation occur somewhat later than those of fibrosis. Visual acuity is affected only if the pearl protrude into visual axis.

- c) Soemmerring's ring – After extracapsular cataract extraction, cut edge of remaining anterior capsular flap may attach itself to the posterior capsule within 4 weeks postoperatively. Any residual cortical fibres & epithelial cells are trapped within this sealed area. LECs proliferate & differentiate into lens fibres filling the space between anterior & posterior capsule, which results in the formation of ring like structure. Vision is usually not affected.¹⁸

Pathogenesis of Posterior Capsule Opacification

Cell culture is the simplest method to study lens epithelial cells. It can identify which factors can stimulate or inhibit proliferation, migration, differentiation, transdifferentiation of LECs to myofibroblast or matrix contraction.

In order to establish a system that replicates the *in vivo* situation as closely as possible, capsular bag models have also been developed to aid understanding of PCO. These involve performing a sham cataract operation & were first developed using human donor eyes (Nagamoto and Bissen-Miyajima, 1994), but have since applied to bovine, dog, and more recently to rabbit and chick lenses. This model best replicates the *in vivo* situation & is the premier *in vivo* model to study PCO.¹⁹

Study of capsular bag preparations after sham cataract surgery on human donor eyes showed cell growth in equatorial region during first 1 or 2 days. After 2 to 3 days cells progressed beyond the capsulorrhexis & were growing toward the center. Vimentin staining clearly showed these cells growing toward the center of the capsule, cells also grew upward from the capsulorrhexis & back across the exterior surface of capsule. Within 6 to 10 days the cells became confluent on posterior capsule. Wrinkles began to appear by this stage & these were areas of light scatter.

Cells closed packed within the wrinkle and appeared to have major actin filaments running parallel along the length with clear area along each side of the wrinkle where actin filaments aligned at right angles.²⁰

When a PMMA IOL is implanted, growth could also be seen on its anterior optical surface. Growth was preceded by formation of an adherence zone between the capsulorrhexis edge & the IOL.

In the presence of serum there was rapid & complete coverage, which lagged only a day or so behind the coverage of the posterior capsule. In the absence of serum, complete cell coverage of IOL was never achieved, but growth still occurred on the posterior capsule. Given the appropriate combination of stability, density, and space, human LECs can readily proliferate & migrate in a protein free medium & that it is cells in the normally active equatorial region that first divide, rather than those in the “wounded” capsulorrhexis region. Lens cells can produce a range of growth factors which may act as stimulation.²¹

A study showed the up-regulation of lumican in LECs in association with epithelial-mesenchymal transition in wild-type mouse lenses in organ culture, which may play role in pathogenesis of PCO.²²

Cellular events on the anterior surface of IOL has been studied in vivo by specular microscopy. A study showed proliferation of LECs on IOL occurs irrespective of the surgical technique, which is seen as early as one week and by three months cells disappear. Findings suggest that on contact with the implant surface LECs from anterior capsular margin start proliferating & migrating forming continuous sheet which later breaks up. The onset of anterior capsular opacification

seems to coincide with a decrease in LEC migration which might be due to adhesion of capsule to implant.²³

Effect of PCO on vision

Patients with PCO have been shown to have worse visual acuity and diminished contrast sensitivity, but most studies do not clearly describe the types of PCO under study or they concentrate mainly on Elschnig's pearls.

A study by Cheng et al demonstrated that patients with pearl type PCO had worse visual acuity and contrast sensitivity than those with fibrosis type PCO. Fibrosis type PCO, which resembles ground glass, serves mainly to attenuate the light, whereas pearl-type PCO, primarily causes light scattering and superimposes a forward veiling light on the retina, reducing the contrast of the retinal images.¹⁷

Short and long term changes in PCO

Development of PCO is a very dynamic process is a very dynamic process that includes not only growth of preexisting structures and occurrence of new Elschnig's pearls, but also reorganization and even disappearance of pearls within a short period of time. Quite a few studies have shown alterations in pearl size, fusion of pearls and even complete disappearance of pearls. These changes were also observed after Nd:YAG capsulotomy, outside the capsulotomy opening.²⁴

A study on long term changes in PCO showed that the morphology of PCO is multifaceted. Apart from the Elschnig's pearls, other categories such as cheese holes, plates, islands, and traces of PCO were distinguished. Over the years, the formation of pearls becomes more common. Pearls increase in size and number. Layers increase in thickness and mostly expand. This indicates that there may be a type of PCO that covers parts of posterior capsule within the first few weeks after surgery. This early

type shows little change over time and even shows regression over the years. The late type of PCO is usually a sign of barrier loss of the optic edge and shows progression from years 1 to 3 after surgery and typically does not fuse with the early type. Further investigations were necessary to assess factors such as IOL material and design and surgical technique that may influence morphology of PCO and its change over time.²⁵

Prevention of PCO

PCO is of main concern to ophthalmologists worldwide for its medical, social, and economic implications. Many preventive factors and surgical techniques decreasing PCO development exist, but there is still no procedure for its complete eradication.

Surgical factors in prevention of PCO

- 1) **Hydrodissection-Enhanced cortical clean-up** – A very important and underrated surgical step is hydrodissection. Dr. Howard Fine perfected & popularized this technique & coined the term cortical cleaving hydrodissection. In this technique edge, the anterior capsule is slightly tented up by the tip of the cannula, while injecting the fluid, the cannula is bent at the tip allowing a flow of fluid toward the capsule to efficiently separate capsule from cortex.¹²
- 2) **In the bag IOL fixation** – The hallmark of modern cataract surgery is the achievement of consistent and secure in-the-bag IOL fixation. This functions primarily to enhance the IOL-optic barrier effect.¹⁸

A study showed PCO incidence of 42.45% in the ECCE group, 19.18% in the phacoemulsification group after 15 months follow-up. Most of the IOLs in ECCE group (60.79%) had one or both haptics out of the bag, probably

because can opener capsulotomy technique was required for nuclear removal. In contrast in phacoemulsification group, in which a CCC was used in all cases, 79.25% of IOLs had in-the bag haptic fixation.²⁶

- 3) **Capsulorrhexis size** – There is evidence that PCO is reduced if the capsulorrhexis diameter is slightly smaller than that of the lens optic, so that the anterior edge rests on the optic. A study demonstrated that PCO was less when the anterior capsule was in contact with the lens optic for 360 degrees, by one year the average percentage of PCO for patients with large capsulorrhexis was 66.2% compared with 32.7% for the patients with in the small capsulorrhexis group.

Small CCC provide a tight fit of the capsule around the optic analogous to “shrink-wrap”, which has beneficial effects in maximizing the contact between the optic & posterior capsule. Another advantage may be due to sequestration of the interior compartment of the capsule containing the IOL from surrounding aqueous humor & any potentially deleterious factors within it, such as inflammatory mediators.²⁷

- 4) **Biocompatible IOL** – With regards to PCO, materials with the ability to inhibit stimulation of cell proliferation are more “biocompatible”. A randomized controlled trial showed significantly more PCO with hydrogel lenses. In that study, the mean percentage area of PCO was 63% for hydrogel lenses, 46% for PMMA lenses, and 17% for silicone lenses at two years follow up. Laser capsulotomies were required in 28% of patients with hydrogel lenses & 14% with PMMA lenses, whereas none with silicone lenses needed capsulotomy.²⁸

A quantitative study clarified that the degree of PCO in the eyes with the PMMA lenses was considerably more extensive than that with either the silicone or soft acrylic IOL.²⁹

Oner et al, found PCO rate of 8.7% in foldable acrylic group and 24.7% in the PMMA group with mean follow up period of 17.3 months, the difference was statistically significant. But the study concluded that the rectangular optic edge was more important than the material itself in less occurrence of PCO.³⁰

A study by Kugelberg et al indicated that the surface of the IOL exerted greater influence on PCO than the material itself. Hydrophobic acrylic resulted in significantly less percentage area and severe PCO at one year than the hydrophilic acrylic IOL.³¹

However a study on rabbit model did not show any statistically significant difference in PCO between hydrophilic and hydrophobic acrylic material.³²

Schauersberger et al found that IOL material was important determinant in PCO rather than the edge design. No significant differences between the sharp-edged and the round-edged acrylic IOL was found concluding that LECs that proliferate onto the anterior IOL surface primarily originate from that anterior capsule close to the capsulorrhexis.³³

IOLs made of polyacrylic have a tacky surface. Anterior capsule was much more stable on the anterior surface of a polyacrylic lens than PMMA or silicone IOL. This postulated bioadhesion between the capsule and the IOL would mean that there is no space for the LECs to migrate between IOL and

posterior capsule. This might explain differences of PCO rates observed between different biomaterials.³⁴

A comparative study by Nishi et al concluded that capsular bend formation by sharp optic edge is the key to understanding how IOLs prevent PCO. Optimizing the edge design and material of an IOL to bend the capsule, combined with techniques to enable capsulorrhexis with full confidence may reduce PCO to a clinically negligible level.³⁵

- 5) **Contact between the IOL optic and the posterior capsule** – Optic/haptic angulation displacing the optic posteriorly and stickiness of the IOL optic material are the most important features to obtain a tight fit between lens and capsule, contributing to the so-called “No space, no cells” concept. In general three piece lenses have a posterior optic/haptic angulation ranging from 5⁰ to 10⁰.¹⁸
- 6) **IOL optic geometry** - The concept of the barrier effect of an IOL (No space-no cells) is an established one, dating back to Sir.Harold Ridley. The IOL barrier effect has been an under-recognized but major factor that has played a significant role in preventing PCO after ECCE, especially in the early days of IOL implantation.

For the first few decades of PCIOL implantation, most IOL optics were plano posterior-anterior convex, which could only adequately create a barrier effect if both haptics were securely fixed in the capsular bag.

An early attempt to enhance the IOL barrier effect was Hoffer’s design of a 360 degree ridge, which created the equivalent of a square optic edge and would function as an effective barrier to cell in-growth only if both haptics

securely fixated in the capsular bag. Unfortunately in-the-bag fixation occurring in only about 30% of cases, the ridge model was therefore not consistently effective.

The next stage of IOL optic evolution was the use of biconvex designs. The posterior convex surface was better suited to provide close contact between an in-the-bag IOL optic and the posterior capsule and thus would enhance the effectiveness of barrier effect. Several early IOL designs were characterized by an optic design with square, often sharp edges, caused largely as a result of insufficient or poor polishing and were not manufactured with the purpose of influencing PCO.³⁶

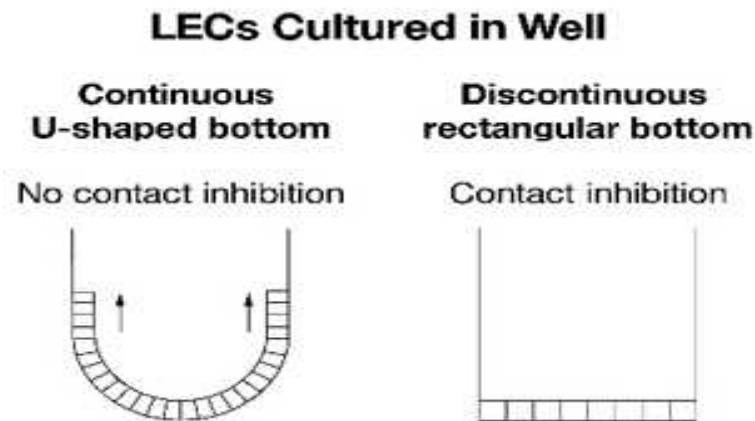
Initial studies by Nishi et al on rabbits showed effectiveness of sharp rectangular edges in preventing epithelial cell migration. Their study with different biomaterials in rabbit eyes concluded that both silicone and acrylic IOLs with sharp edges had significant inhibitory effect on migration of LECs regardless of biomaterial of IOL.³⁷

These findings were confirmed by Kruger et al with three piece silicone IOL with sharp optic edge at the end of two years after surgery. Nd:YAG laser capsulotomy had to be performed in 6.9% of eyes with round edged group.³⁸

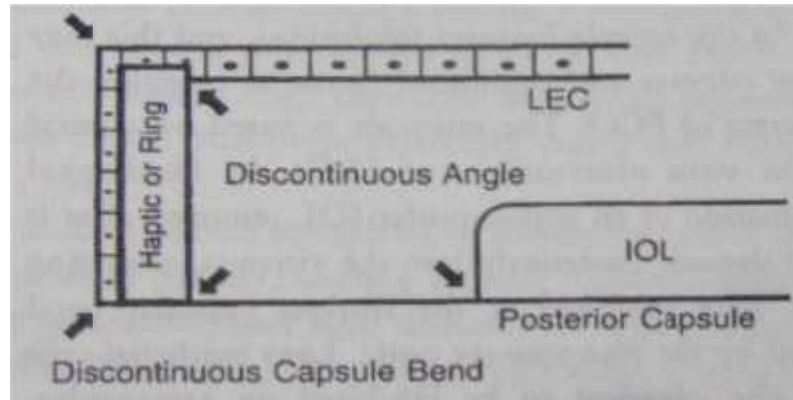
Nishi et al investigated the expression of the unique protein Ki-67 in the nuclei of LECs at the capsular bend in the eyes with a sharp-optic-edge IOL design. In these eyes, all LECs that accumulated in multiple layers along the side edges of the IOLs before the capsular bend were Ki-67 negative in their nuclei, with the exception of a few cells in some eyes, indicating that

most LECs were in G₀ phase of cell cycle, which is the state of cell rest. These findings stand in stark contrast to the Ki-67 positive LECs abundantly observed beyond the capsular bend toward the posterior capsule.³⁹

Mechanism of sharp optic edge in prevention of PCO



Studies by Nishi et al shows that the sharp bend and complex folds in the posterior capsule created by the sharp edges of the IOL induced contact inhibition of migrating LECs. The rationale is based on clinical and in vitro observations of LECs. During culture LECs ceased to proliferate when they reached the rectangular well wall as seen in above diagram, which is known as “confluent culture”. However, along the wall of U-shaped wells, LECs grew and ascended along the walls. All these findings suggest that a sharp bend in the capsule can induce contact inhibition of LECs migrating on capsule as seen in diagram below, where discontinuous capsular bend and angle created by sharp optic edges of an IOL is seen, LEC (lens epithelial cells) underneath the anterior capsule can be seen in the diagram.⁴⁰



Creation of this sharp bend in the capsule depends not only on optic design but also on IOL material (adhesiveness), surgical technique (well centered CCC).⁴¹

Vyas A et al found as many as 63% of the eyes had complete barrier function at both the optic edge and optic-haptic junction over the first two years of follow-up. A further 13 % had a partial barrier effect around the 360 degrees of the optic. Here hydrophilic acrylic IOL was used.⁴²

As stated earlier capsular bend formation is crucial in preventing PCO. However, such a bend is not created immediately after surgery, and abundant LECs may migrate onto the posterior capsule before the bend is complete. The arising issue is how and how fast the capsular bend is created postoperatively.

Nishi et al evaluated speed of capsular bend formation with acrylic, silicone and PMMA lenses, and found that bend formation was significantly delayed with PMMA IOL, which had round edge. Early and fast formation of capsular bend by silicone IOL was noted but it was slightly inferior to that of acrylic IOL, perhaps because the bend created by silicone IOL was not as sharp as created by acrylic, which has sharp edges.⁴³

Another study developed a classification scheme for the capsular bend configuration which was highly variable. Four capsular bend types were seen –

Parallel, Y shaped, Right-angle, and wrapping. The right angle type was most common configuration. Eyes with parallel configuration showed less capsulorrhexis contraction and less ACO. Eyes with wrapping configuration showed more capsulorrhexis contraction and more ACO. The wrapping type was observed more often with silicone IOLs.⁴⁴

These findings were confirmed in one more study by the same authors, which showed acrylic and silicone IOLs with sharp edge leading to significantly less fibrotic PCO but more ACO than round-edged acrylic and silicone IOLs.⁴⁵

Nagamoto et al stressed that contact pressure between posterior capsule and optic as determinant factor in prevention rather than capsular bend formation. According to their contact pressure theory, during early period after cataract surgery, the anterior and posterior capsules adhere, which induces movement of the posterior capsule toward the anterior capsule, increasing the contact pressure between the optic edge and posterior capsule.⁴⁶

When a CCC is smaller than an optic and the anterior capsule covers the entire optic edge, this movement is enhanced and the contact pressure stronger. Capsular contraction after surgery might also result in increased contact pressure. Capsule adhesion and contraction in vivo might be major factors in the inhibition of PCO by a sharp optic edge.

Regarding the issue of three piece IOL in relation to PCO, a study found no significant difference in PCO at two years between three piece acrylic hydrophobic sharp edge IOL and single piece acrylic hydrophobic sharp edge IOL.⁴⁷

A meta-analysis by Cheng et al, examined 23 clinical trials and focused on direct comparisons of different IOL biomaterials and optic edge designs. It was found

that acrylic IOLs and silicone IOLs were more effective than PMMA IOLs and that hydrogel IOLs were as effective as PMMA IOLs in lowering the rates of Nd:YAG laser capsulotomy. Sharp optic edge IOLs made with PMMA or silicone were more effective in reducing the use of Nd:YAG laser capsulotomy than the rounded optic edge IOLs, and no significant difference was found between the two edge designs of acrylic IOLs. Sharp-edged acrylic and silicone IOLs were significantly more effective than the rounded ones for preventing PCO.⁴⁸

A systematic review summarizing the effects of IOL geometry and haptics on PCO was done by Buehl et al. In that review one study compared sharp and round optic edges in PMMA IOLs and found no significant difference in best corrected distant visual acuity between the two groups.

The same study found significantly higher PCO score in the round-edged group and a significantly higher Nd:YAG capsulotomy rate in the round-edge group. Two studies reported visual acuity to be significantly better in the sharp-edged acrylic IOL group, but result was inconclusive due to statistical heterogeneity. Without considering the lens material seven studies reported better visual acuity with sharp-edge group and two studies quoting no significant difference.

Fifteen studies in the review reported PCO scores; all but one favored the sharp-edge group, one favored the round-edge group. Eleven studies reported Nd:YAG laser capsulotomy rates; 10 favored the sharp-edge group and one, the round-edge group.⁴⁹

Effect of square edge IOL on vision

Experimental studies demonstrate that glare symptoms in pseudophakic patients are associated with three risk factors related to the IOL and reflection: Square edge, flat anterior surface, and high refractive index material.

A study concluded that mesopic contrast sensitivity was significantly impaired as a result of glare, even in eyes with a modified-edge acrylic IOL. On the other hand, loss of contrast sensitivity from glare was approximately the same between the IOL with a textured edge and the IOL with a round anterior, slope-sided edge.⁵⁰

Square edge IOL and Manual SICS

In industrialized countries, the transition to phacoemulsification has been completed. However, this technique is not appropriate in many developing countries because of the high capital cost of equipment, maintenance, and consumables and the need to retrain the surgeons. Extracapsular cataract extraction has the advantages of increased surgical safety, less technical complexity, and reduced infrastructure requirements and capital outlay. Refractive correction with PMMA IOL is easily performed and these lenses are produced by non-profit organizations.

However PCO can lead to visual loss after an initially successful operation, which poses challenge as Nd:YAG laser capsulotomy is not easily available.

A complete capsulorrhexis is difficult to achieve with Manual SICS as the diameter has to be large enough for nucleus expression. Also cortical clean-up might not be as complete as it is in phacoemulsification. Nevertheless a study has shown reduced PCO area with square edge PMMA IOL with ECCE, but no significant difference in visual acuity at the end of two year follow up.⁵¹

Treatment of PCO

Involves the creation of an opening in the posterior capsule, with Nd:YAG laser. Indications include diminished visual acuity, diplopia, glare, inadequate fundus view impairing diagnosis, monitoring or treatment of retinal disease.

Laser power of 1 mJ/pulse is used. An opening of 3mm is usually adequate. Complications of laser include damage to IOL, cystoid macular edema, rhegmatogenous retinal detachment, elevation of IOP, posterior IOL subluxation, chronic endophthalmitis.⁵²

Recent advances

- 1) Dr. Anthony Maloof has developed a new concept in irrigation of the human lens capsule following lens surgery called sealed capsule irrigation device, which allow the isolated safe delivery of irrigating solutions containing pharmacological or non pharmacological agents into capsular bag.¹⁸

Duncan et al tested various agents, applied for a 2 minute period, in human capsular bag. In this in vitro study greatest effect was seen with agent called thapsigargin.¹⁹

- 2) Capsular adhesion prevention ring was found to inhibit PCO formation in rabbits, may be useful in humans.⁵³

METHODOLOGY

The present study was conducted in the Department of Ophthalmology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum on patients undergoing MSICS during the period of January 2009 to December 2009.

Study design

One year randomized clinical trial.

Study period

The present study was conducted during January 2009 to December 2009.

Method of collection of data

Source of Data

Patients undergoing MSICS at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Sample size

A sample size of 128 cases (64 in each group).

Sampling procedure

A sample size of 128 cases was calculated considering Using the formula;

$$n = \frac{2 \times (Z_{\alpha} + Z_{\beta})^2 \times (S_1^2 + S_2^2)}{(p_1 - p_2)^2}$$

Selection criteria

Inclusion Criteria

- Patients undergoing MSICS with posterior chamber IOL, at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
- Age group between 40 to 80 years.
- Patients willing to give informed consent.

Exclusion Criteria

- Age below 40 yrs or above 80 yrs.
- Congenital & developmental cataract.
- Traumatic cataract.
- Intra-operative complications.
- Diabetic patient.
- Pre-senile cataract.
- Associated glaucoma or complicated cataract.

Procedure

The study is conducted in Department of Ophthalmology at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during one year duration. The study was approved by the Ethical and Research Committee of Jawaharlal Nehru Medical College, Belgaum.

The patients were assigned randomly into two groups according to the type of intraocular lens used, by computer generated table of two. Patients were briefed about the nature of the study, the interventions used and written informed consent was

obtained (Annexure–II). Further, descriptive data of the participants like name, age, sex, detailed history, were obtained by interviewing the participants and clinical examination and necessary investigations were recorded on predesigned and pretested proforma (Annexure-I).

- Group A - Patients undergoing MSICS using conventional round edge IOL.
- Group B - Patients undergoing MSICS using Square edge IOL.

Preoperative evaluation

All patients were admitted one day prior to the surgery.

- Visual acuity, both unaided as well as aided using spectacle or pin hole was checked with snellen’s visual acuity chart.
- The anterior segment evaluation was done using the slit lamp. Particular attention was paid for the presence of signs of inflammation like keratic precipitates, posterior synechiae.
- After pupillary dilatation, the cataract was assessed and graded. Presence of pseudoexfoliation noted. A thorough posterior segment evaluation was done. Presence of diabetic retinopathy, macular lesions led to the exclusion of the patients.
- Keratometry was done using manual Bausch and Lomb keratometer. Axial length was measured with a ‘A’ scan unit and the IOL power was calculated using SRK (Sanders-Retzlaff-Kraff) II formula.
- IOP was measured using a schiötz indentation tonometer. Patency of lacrimal passages was checked using lacrimal sac syringing.

All patients received one hourly topical antibiotic (ciprofloxacin) eye drop one day prior to surgery. Systemic oral antibiotics (Tab.Ciprofloxacin 500 mg) were given on night before surgery and on the day of surgery in morning. Tropicamide 0.8% and phenylephrine 5% eye drops were instilled for mydriasis, every 15 minutes, starting two hours prior to surgery

Surgical technique

All cases were done under local peribulbar anesthesia. Under all aseptic precautions the eye to be operated was painted with povidone iodine and spirit and was draped. A wire speculum was placed and a superior rectus bridle suture was placed and secured. A fornix based conjunctival flap was made superiorly with corneoscleral scissors and hemostasis was achieved by cautery of bleeding vessels.

The extent of incision was marked on the sclera with calipers and a 6.5 mm straight incision was made 1.5 mm posterior to the surgical limbus with 11 number surgical blade. Scleral tunnel was constructed using a crescent knife and dissection continued 1 mm into clear cornea. Anterior chamber was entered from the anterior limit of sclero corneal tunnel using a 3.2 mm entry keratome without loosing the anterior chamber. Viscoelastic was injected into the anterior chamber. A continuous curvilinear capsulorrhexis with relieving incisions or can opener capsulotomy was done using bent 26 gauge needle according to the grade of the cataract. Hydrodissection was done. The tunnel was extended with keratome. Nucleus was prolapsed into anterior chamber and delivered out using sandwich technique by vectis & dialer. Cortical matter was aspirated using a classical simcoe cannula. In group A patients Polymethyl Methacrylate (PMMA), modified C loop PCIOL(6mm optic) with round edge of appropriate power was implanted. In group B patients Polymethyl Methacrylate (PMMA), modified C loop IOL(6mm optic) with 360 degree square

edge of appropriate power was implanted. Viscoelastic was aspirated with simcoe cannula. Anterior chamber formed with ringer lactate and side port opening sealed by stromal hydration.

Conjunctiva and Tenon's capsule were repositioned back over the wound. Antibiotic steroid eye drops were administered six times per day and gradually tapered over six weeks.

Postoperative evaluation

A detailed postoperative examination of the patients was done on 1st day, first month, six months and 12 months with regard to the following points.

- At each visit patient was asked about subjective complaints such as diplopia, glare, halos etc
- Visual acuity recorded on Snellen's chart and pin hole improvement noted.
- Anterior segment evaluation on slit lamp was done. Presence of cells and flare, iris abrasion, left out cortical matter noted.
- Pupils were dilated and examined on slit-lamp using retro illumination to assess posterior capsule opacification.

Posterior capsule opacification was graded as

- Grade-0 Nil.
 - Grade-1 Not reaching IOL edge.
 - Grade-2 Just within the IOL edge.
 - Grade-3 Well Inside IOL edge but visual axis clear.
 - Grade-4 Across visual axis.
- Subjective refractive correction was given at six weeks

STATISTICAL ANALYSIS

Statistical analysis

Data analysis was done using chi square test.

RESULTS

The present study was conducted on 128 patients who underwent MSICS at Department of Ophthalmology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during study period. The patients were divided into two groups that is Group A (Patients who underwent MSICS with round edge lens implantation) and Group B (Patients who underwent MSICS with square edge lens implantation). The data obtained was tabulated as below

Table No 1: Age distribution

AGE (YRS)	GROUP A	GROUP B	TOTAL	% ge
50-59	17	22	39	30.5
60-69	28	23	51	39.8
70-79	19	19	38	29.7
Total	64	64	128	100

In the present study 39.8% of the patients belonged to age group of 60-69 years of age, 30.5% belonged to 50-59 years of age and 29.7% belonged to the age group of 70-79 years.

Mean age in Group A was 62.7 ± 7 years (mean \pm SD), range 50-79 years.

Mean age in Group B was 62.8 ± 8.7 years (mean \pm SD), range 50-79 years.

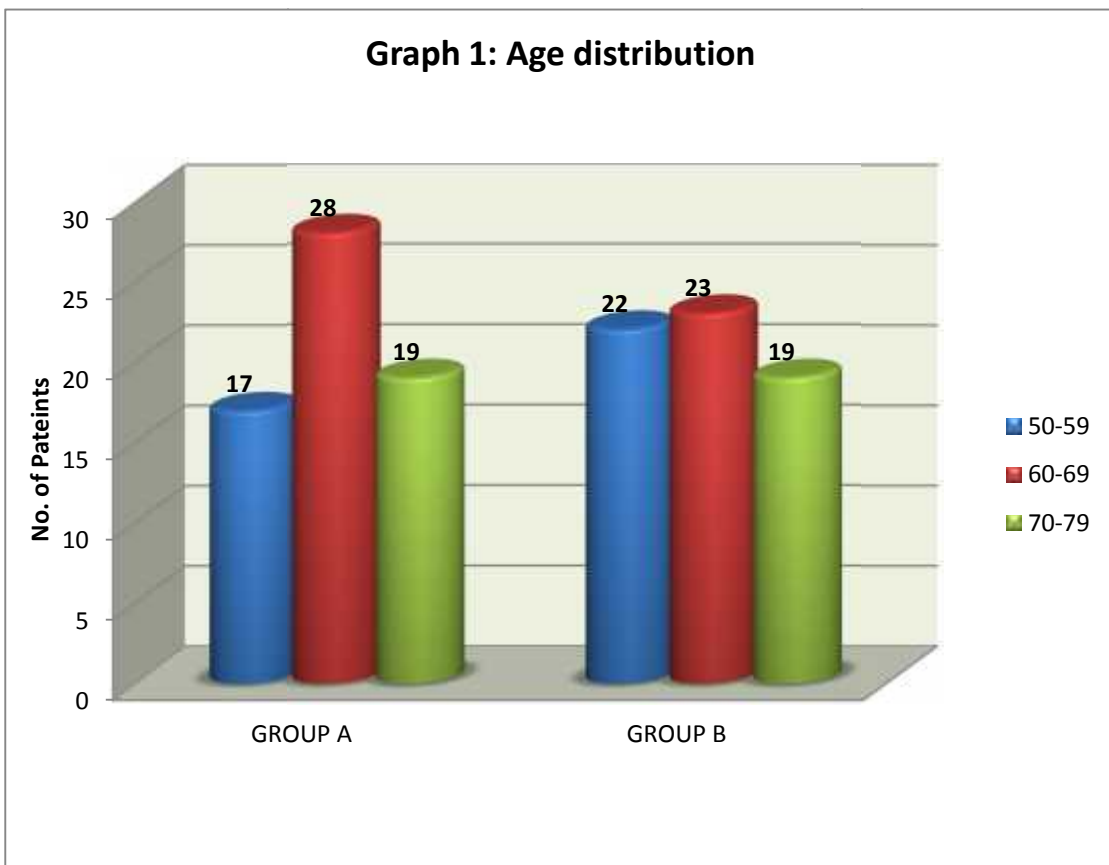


Table No 2: Gender distribution

GENDER	GROUP A	GROUP B	TOTAL	% ge
Male	33	33	66	51.6
Female	31	31	62	48.4
Total	64	64	128	100

Out of 128 patients, 66 (51.6%) were men and 62 (48.4%) were women. In both Group A and Group B, 33 were men and 31 were women. Male to female ratio was 1:1.06

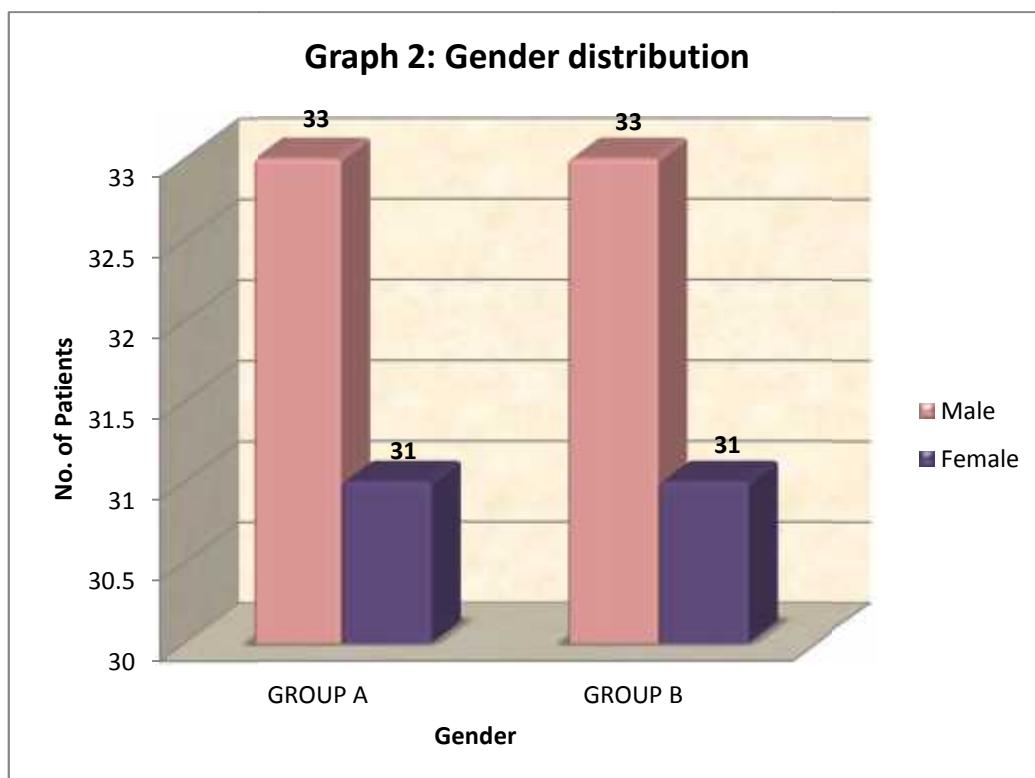


Table No 3: Posterior Capsule Opacification (PCO)

PCO	GROUP A	%	GROUP B	%	TOTAL	% ge
Absent	9	14.1	12	18.8	21	16.4
Present	55	85.9	52	81.2	107	83.6

In our study out of 128, 107(83.6%) patients had presence of posterior capsule opacification, with 55 (85.9%) patients in Group A and 52 (81.2%) patients in Group B. Posterior capsule opacification was absent in 9 (14.1%) patients in Group A and 12 (18.8) patients in Group B.

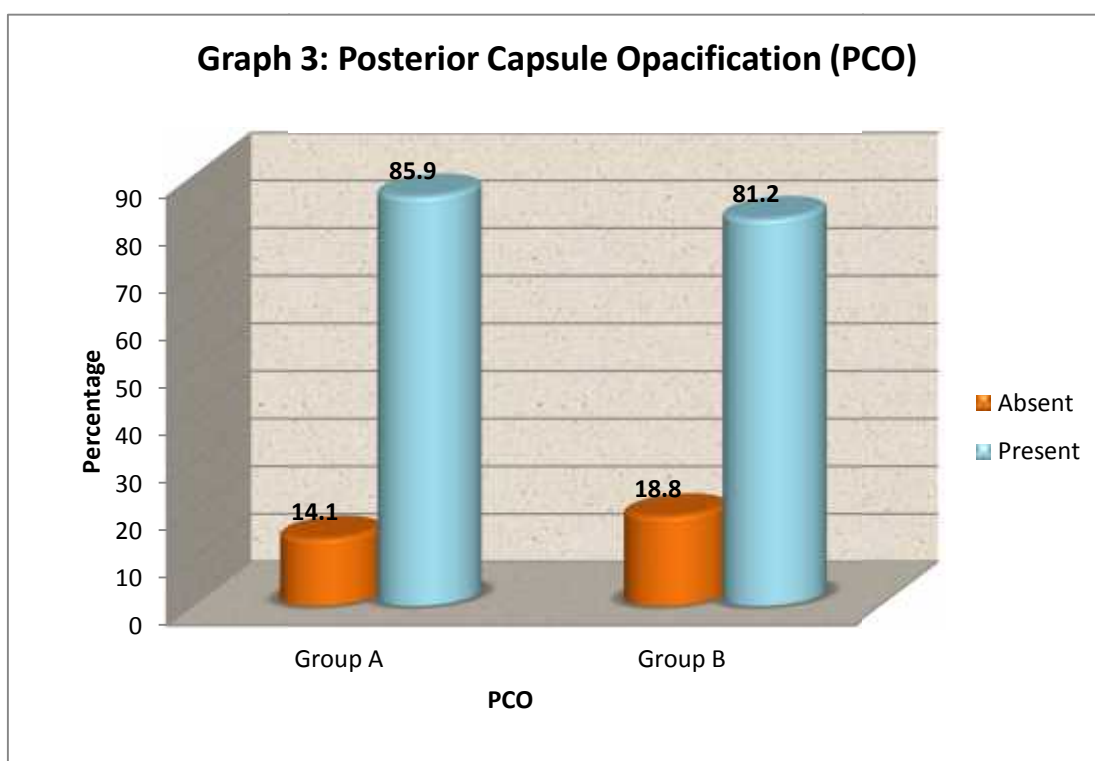


Table No 4: Grades of Posterior Capsule Opacification

GRADES	GROUP A	%	GROUP B	%	TOTAL	%
Grade 0	9	14.1	12	18.8	21	16.4
Grade 1	6	9.3	10	15.6	16	12.5
Grade 2	25	39.1	31	48.4	56	43.8
Grade 3-4	24	37.5	11	17.2	35	27.3

Out of 128 patients, in Group A, 24 (37.5%) patients had Grade 3-4 PCO and in Group B 11 (17.2%) patients had Grade 3-4 PCO.

25 (39.1%) patients in Group A and 31 (48.4%) patients in Group B had Grade 2 PCO.

6 (9.3%) patients in Group A and 10 (15.6%) patients in Group B had Grade 1 PCO.

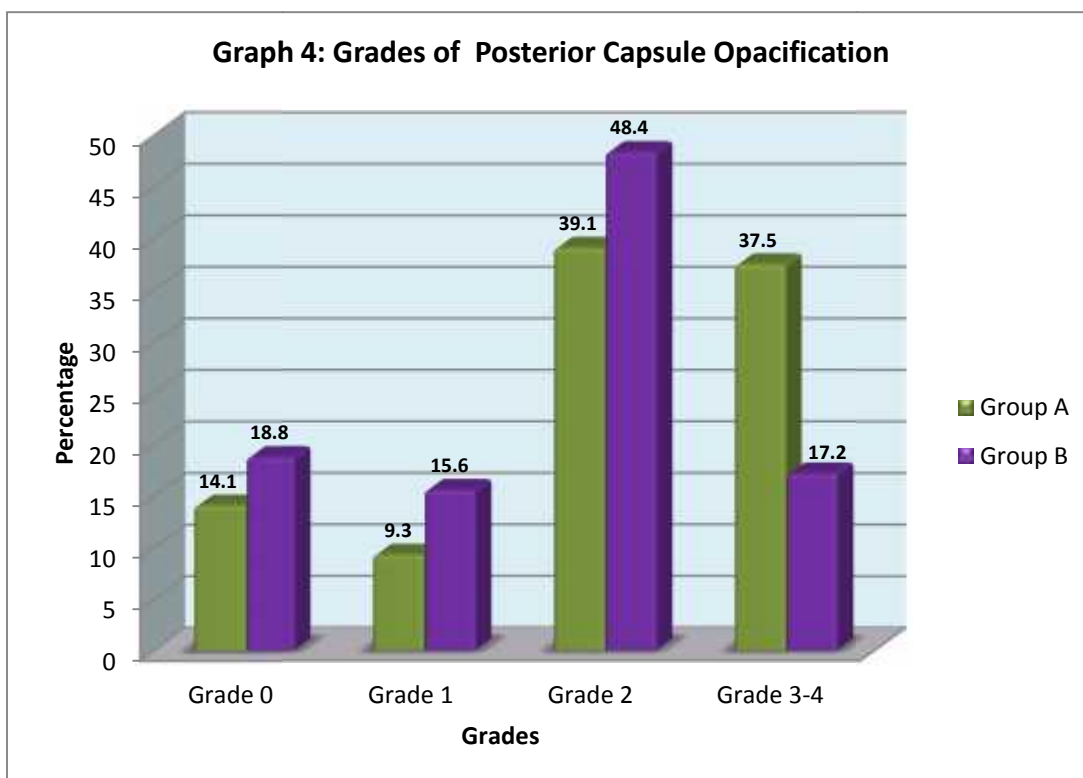


Table No 5a: Incidence of PCO in relation to type of cataract in Group A

CATARACT	GRADE 1-2 PCO	%	GRADE 3-4 PCO	%	TOTAL	%
Immature	26	83.9	19	79.2	45	81.8
Mature	5	16.1	5	20.8	10	18.2

In Group A out of 55 patients who developed PCO, 45 (81.8%) patients had immature cataract and 10 (18.2%) patients had mature cataract.

Out of 55 patients, Grade 3-4 PCO was seen in 19 (79.2%) patients when cataract was immature and 5 (20.8%) patients when cataract was mature. Grade 1-2 PCO was seen in 26 (83.9%) patients when cataract was immature and 5 (16.1%) patients when cataract was mature.

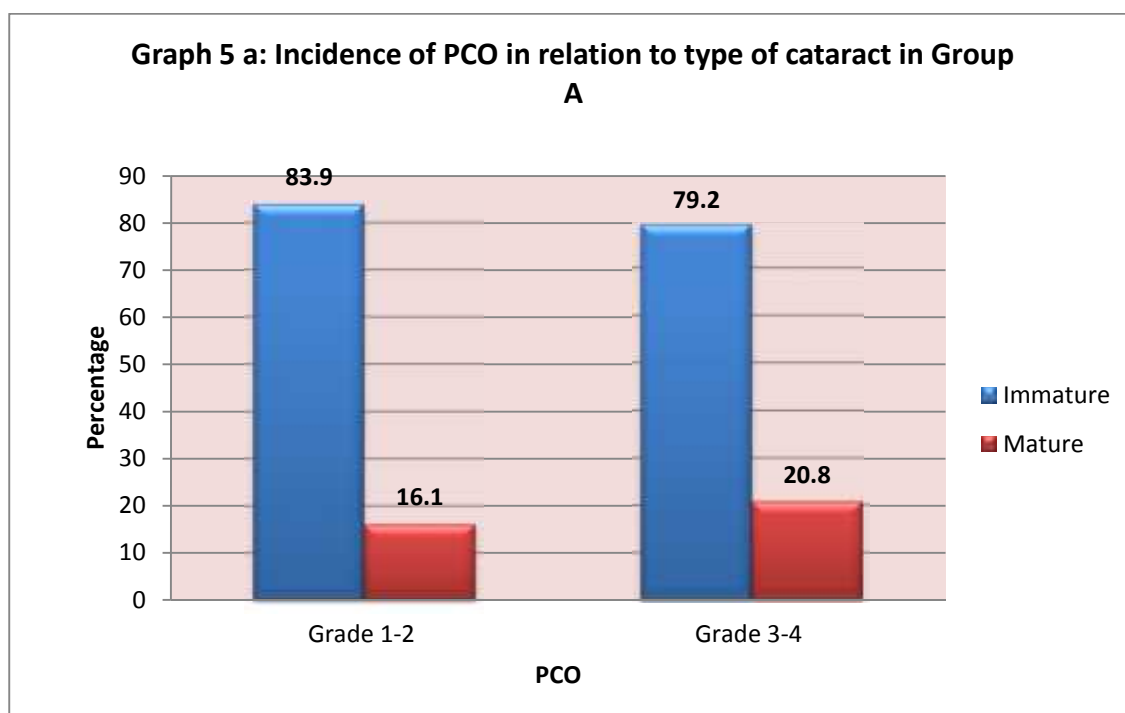


Table No 5b: Incidence of PCO in relation to type of cataract in Group B

CATARACT	GRADE 1-2 PCO	%	GRADE 3-4 PCO	%	TOTAL	%
Immature	32	78	8	72.7	40	76.9
Mature	9	22	3	27.3	12	23.1

In Group B out of 52 patients who developed PCO, 40 (76.9%) patients had immature cataract and 12 (23.1%) patients had mature cataract.

Out of 52 patients, Grade 3-4 PCO was seen in 8 (72.7%) patients when cataract was immature and 3 (27.3%) patients when cataract was mature. Grade 1-2 PCO was seen in 32 (78%) patients when cataract was immature and 9 (22%) patients when cataract was mature.

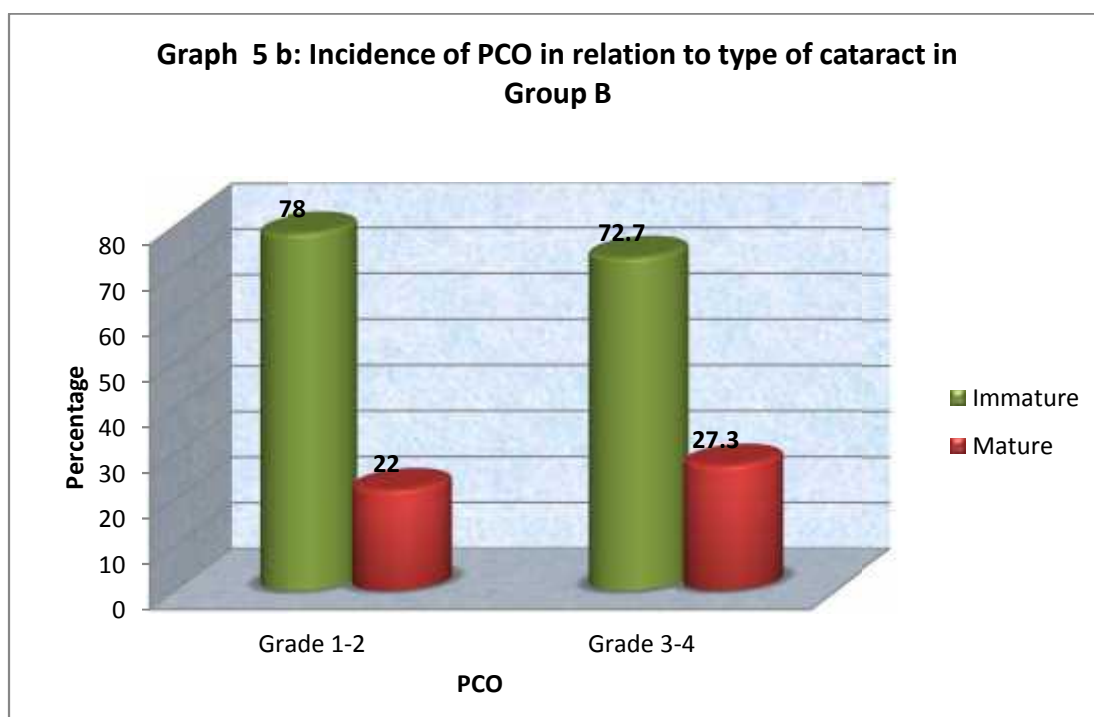


Table No 6a: Incidence of PCO in relation to type of anterior capsulotomy in**Group A**

Capsulotomy	Grade 1 to 2 PCO	%	Grade 3 to 4 PCO	%	Total	%ge
CCC with relieving incision (RI)	16	51.6	0	0	16	29.1
Can opener	15	48.4	24	100	39	70.9

In Group A out of 55 patients who developed PCO, Grade 3-4 PCO was seen in 24 (100%) patients when can opener capsulotomy technique was used, whereas no patient had Grade 3-4 PCO when CCC with relieving incision was done. Grade 1-2 PCO was seen in 16 (51.6%) patients when CCC with relieving incision was done and 15 (48.4%) patients when can opener technique was used.

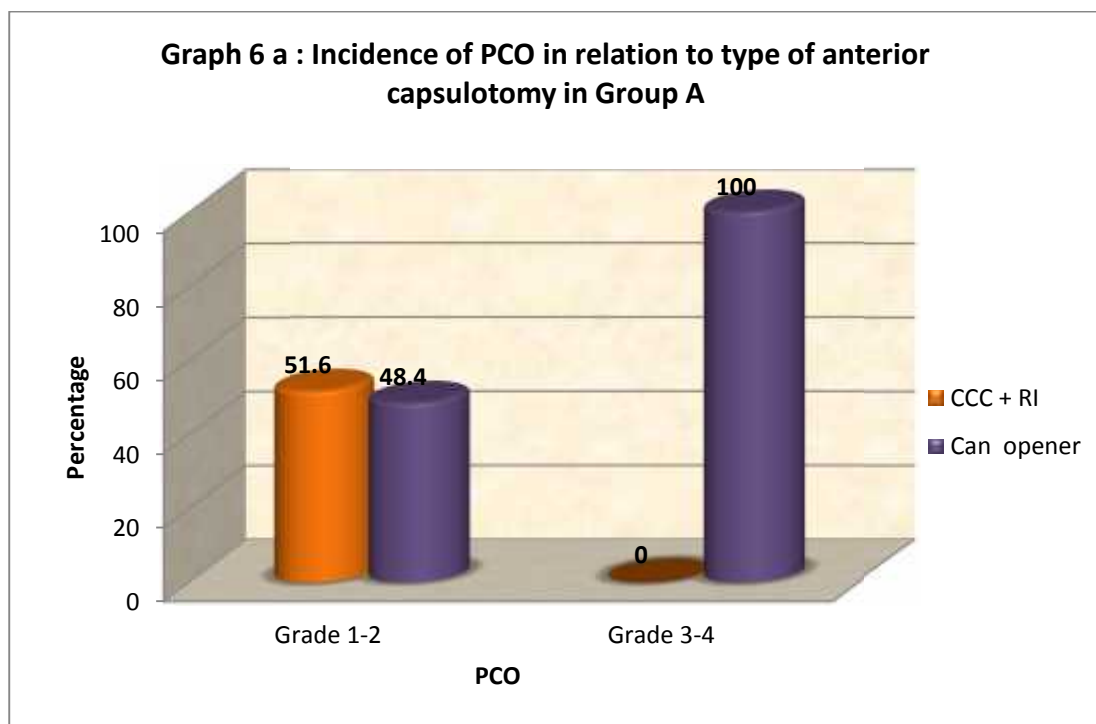


Table No 6b: Incidence of PCO in relation to type of anterior capsulotomy in

Group B

Capsulotomy	Grade 1 to 2	%	Grade 3 to 4 PCO	%	Total	%ge
CCC with relieving incision (RI)	16	39	0	0	16	30.8
Can opener	25	61	11	100	36	69.2

In Group B out of 52 patients who developed PCO, Grade 3-4 PCO was seen in 11 (100%) patients when can opener capsulotomy technique was used, whereas no patient had Grade 3-4 PCO when CCC with relieving incision was done. Grade 1-2 PCO was seen in 16 (39%) patients when CCC with relieving incision was done and 25 (61%) patients when can opener technique was used.

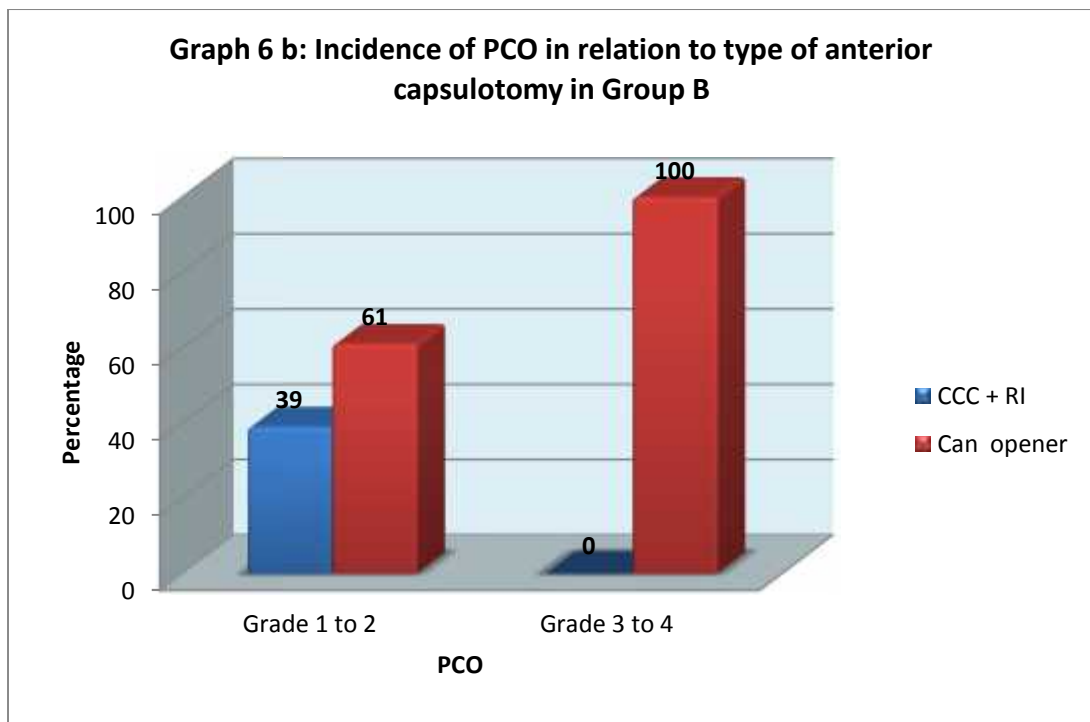


Table No 7a: Incidence of PCO in relation to cortical clean up in Group A

Cortical cleanup	Grade 1 to 2	%	Grade 3 to 4	%	Total	%
Complete	24	77.4	10	41.7	34	61.8
Incomplete	7	22.6	14	58.3	21	38.2

In our study, out of 55 patients in Group A who had PCO, 14 (58.3%) patients developed grade 3-4 PCO when cortical clean up was incomplete compared to 10 (41.7%) patients when it was complete.

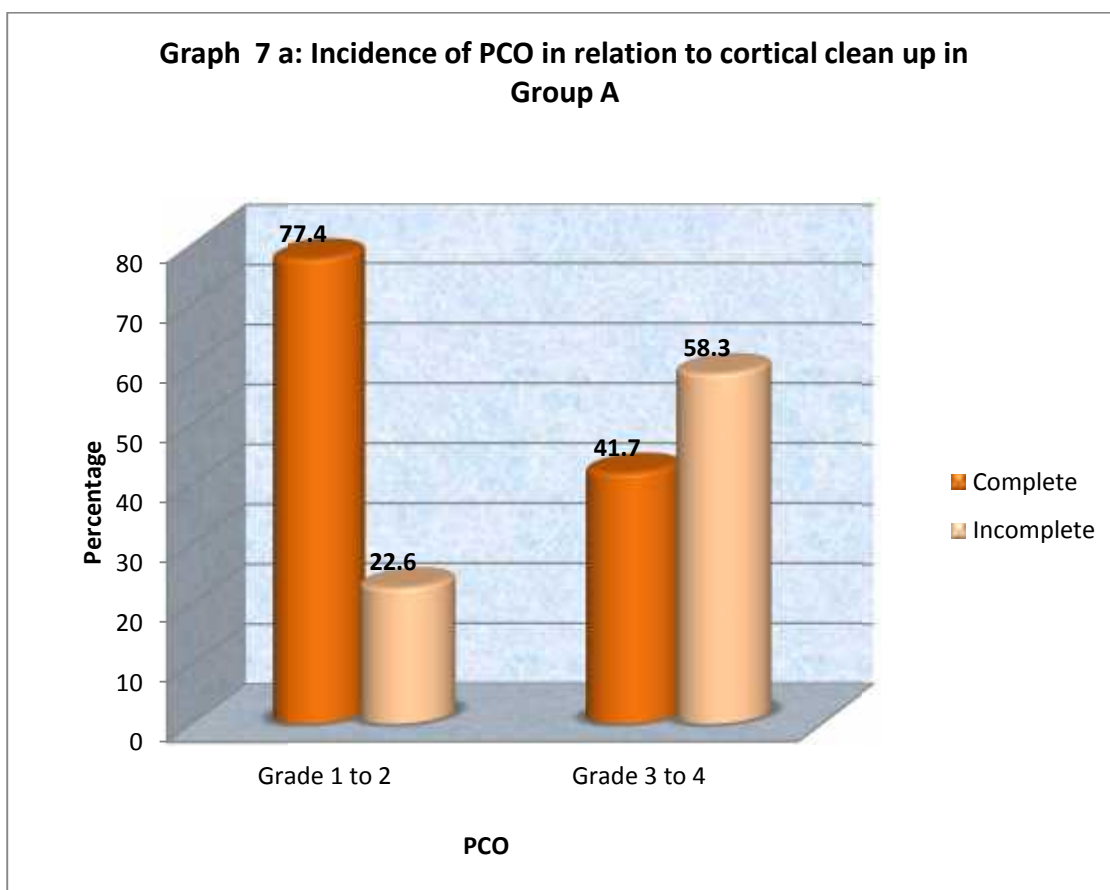


Table No 7b: Incidence of PCO in relation to cortical clean up in Group B

Cortical cleanup	Grade 1 to 2	%	Grade 3 to 4	%	Total	%
Complete	30	73.2	2	18.2	32	61.5
Incomplete	11	26.8	9	81.8	20	38.5

Out of 52 patients in group B who had PCO, 9 (81.8%) patients developed grade 3-4 PCO when cortical clean up was incomplete compared to 2 (18.2%) patients when it was complete.

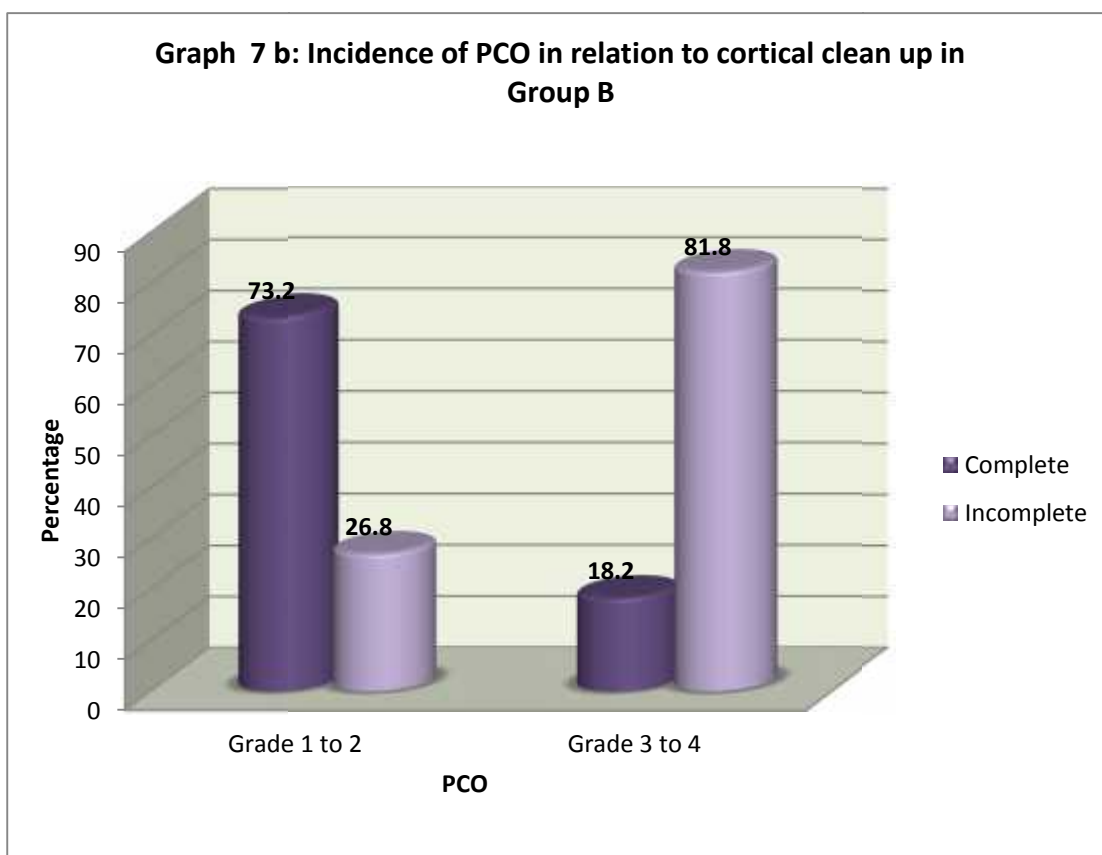


Table No 8: Post-operative visual acuity

Visual acuity	Group A	%	Group B	%	Total	%
6/18 – 6/12	18	28.1	5	7.8	23	18
6/9 – 6/6	46	71.9	59	92.2	105	82

In our study 71.9 % patients in Group A and 92.2% patients in Group B achieved 6/9 to 6/6 best corrected visual acuity. 28.1 % patients in Group A and 7.8% patients in Group B had visual acuity in the range of 6/18-6/12

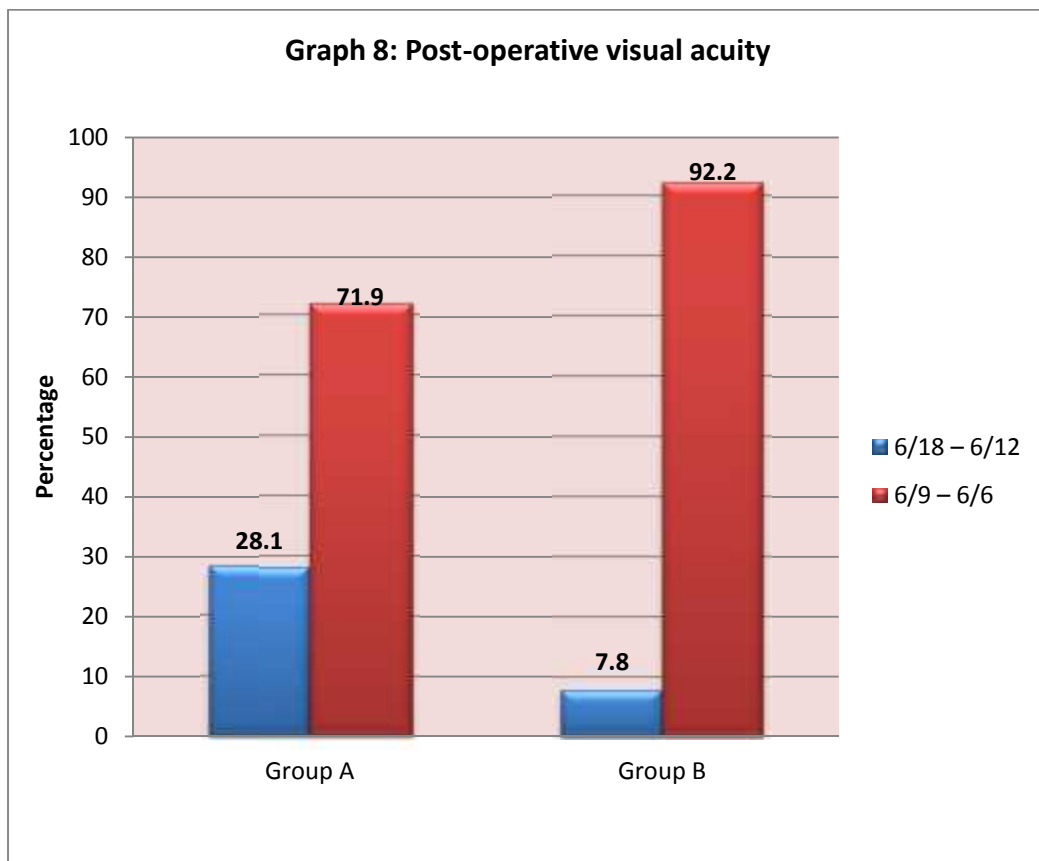


Table No 9: Types of PCO

PCO	Group A	%	Group B	%	Total	%
Fibrous	43	78.2	44	84.6	87	81.3
Elschnig's pearls	4	7.3	4	7.7	8	7.5
Fibrous + Elschnig's pearls	8	14.5	4	7.7	12	11.2

Fibrous PCO was the commonest type found in our study (81.3%). Mixed type (Fibrous with Elschnig's pearls) was seen in 11.2 % patients. 7.5 % patients had Elschnig's pearls type PCO.

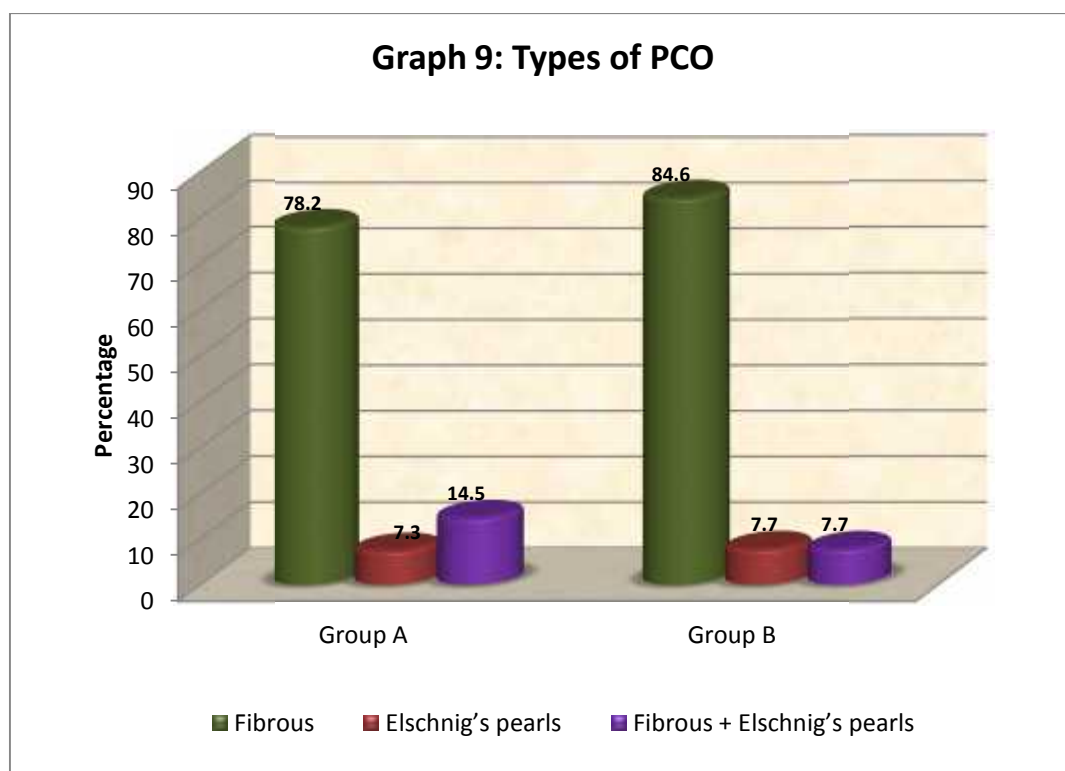
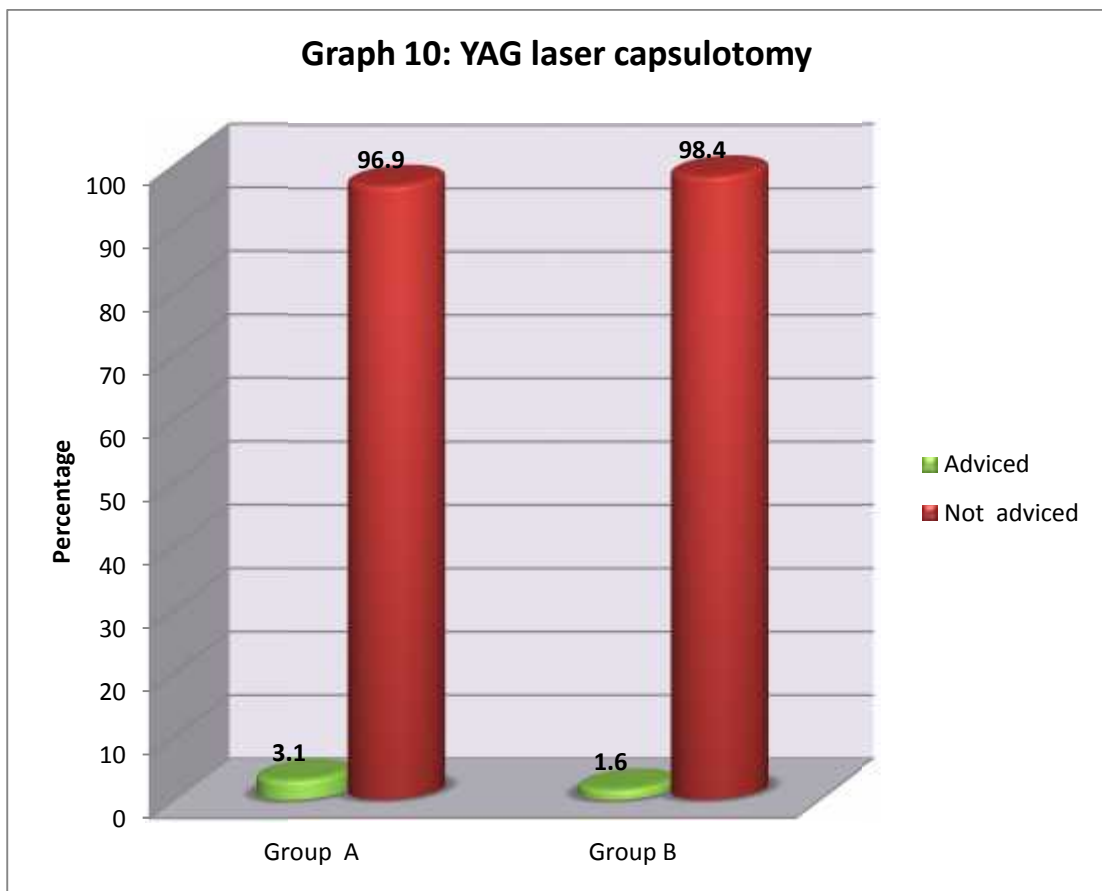


Table 10: YAG laser capsulotomy

YAG laser capsulotomy	Group A	%	Group B	%	Total	%
Advised	2	3.1	1	1.6	3	2.3
Not advised	62	96.9	63	98.4	125	97.7

In our study 3 (2.3%) patients required Nd:YAG laser capsulotomy, two (3.1%) in Group A and one (1.6%) patient in group B.



DISCUSSION

128 patients were included in our study. They were randomly assigned to either Group A or Group B. Those in Group A underwent Manual SICS with implantation of conventional round edge PCIOL and those in Group B were implanted with square edge PCIOL. Both groups had 64 patients each.

1. AGE:

In our study mean age of patients in Group A was 62.7 ± 7.02 years (mean \pm SD). In Group B it was 62.8 ± 8.7 years (mean \pm SD). More patients belonged to age group of 60 to 69 years (39.8%). In a study by Prajna et al the median age of patients was 60 years.¹⁴

2. SEX

Out of 128 patients 66 (51.6%) were males and 62 (48.4%) were females. Male to female ratio was 1:1.06. As senile cataract doesn't exhibit sexual predilection, there was no significant difference between number of male and female patients in this study.

3. Posterior Capsule Opacification

In our study the overall incidence of PCO was 83.6%. The incidence was 85.9% in Group A and 81.2% in the Group B. Oner et al reported 24.7% PCO rates with PMMA intraocular lens.³⁰ The higher rates of PCO noted in our study might be related to can opener capsulotomy technique and incomplete cortical clean up in several cases. These rates were in accordance with results of Madurai intraocular lens study where 91% patients showed PCO at the end of one year.¹⁴

In our study the difference in PCO incidence was not statistically significant (Chi Square = 0.513 DF=1 p=0.474)

4. Grades of PCO

In our study Grade 3 (PCO well inside IOL edge not involving visual axis) and Grade 4 (covering the visual axis) PCO, which we considered as clinically significant was seen in 37.5% of patients in Group A. Ram J et al in their study with conventional ECCE and PMMA IOL found PCO rates of 42.45 % after a mean follow up of 2.4 years.²⁶ The slightly lower incidence of PCO in our study might be due to shorter follow up period.

In Group B 17.2% patients had Grade 3 and Grade 4 PCO. Nagata et al in their study found Grade 3 (moderate) and Grade 4 (severe) PCO in 4 % of patients with sharp edge PMMA intraocular lens implantation with CCC.⁵⁴ The higher incidence in our study was related to can opener anterior capsulotomy technique, which might allow one or both haptics to come out of the bag, loosing the barrier effect of sharp optic edge. This same fact is elucidated by Ram J et al ²⁶ in their study with higher PCO rates in eyes having ECCE when the IOL was fixated out of the capsular bag. This shows the importance of in-the-bag fixation of IOL with capsulorrhexis to achieve low PCO rates.

In our study the difference between Group A and Group B in occurrence of Grade 3 & Grade 4 PCO was not statistically significant (Chi Square =6.900, DF=3, p=0.075) but clinically significant.

5. Incidence of PCO in relation to type of cataract

In Group A out of 55 patients, Grade 3-4 PCO was seen in 19 (79.2%) patients when cataract was immature and 5 (20.8%) patients when cataract was mature. Grade 1-2 PCO was seen in 26 (83.9%) patients when cataract was immature and 5 (16.1%) patients when cataract was mature.

In Group B out of 52 patients, Grade 3-4 PCO was seen in 8 (72.7%) patients when cataract was immature and 3 (27.3%) patients when cataract was mature. Grade 1-2 PCO was seen in 32 (78%) patients when cataract was immature and 9 (22%) patients when cataract was mature.

In our study there was no significant difference between PCO rates in mature and immature cataract patients. Search of literature has not yielded conclusive answer to this issue of whether PCO occurrence is dependent on maturity of cataract, but in a study by Mootha et al mature cataracts appeared to predispose to residual capsule opacity after cataract surgery. Only 11% of these residual posterior capsule opacities were visually significant at the 6-week postoperative period. But whether these residual capsule opacities contribute to the formation of visually significant PCO over time is not known.⁵⁵ Such residual capsule opacity was not seen in our study.

Prajna et al states that complete removal of cortex, leaving minimal scaffolding for epithelial cells, is easier with mature cataracts.¹⁴ But impact of this on PCO rates is not known.

6. Incidence of PCO in relation to type of anterior capsulotomy

In our study, in majority of the patients anterior capsulotomy was done by can opener technique. Since present study was done in cases of Manual SICS a intact capsulorrhexis was not possible, so relieving incisions were done whenever capsulorrhexis was performed.

In our study out of 55 patients in group A who had PCO, Grade 3-4 PCO was seen in 24 (100%) patients when can opener capsulotomy technique was used, whereas no patient had Grade 3-4 PCO when CCC with RI was done. Ram J et al in their study found 42.45% PCO with envelope capsulotomy technique, which is similar to can opener technique in terms of in-the-bag fixation of IOL.²⁶ The incidence was higher in our study, which might be due to incomplete cortical clean-up in several cases.

In our study out of 52 patients in Group B who had PCO, Grade 3-4 PCO was not seen in any patients (0%) when CCC with RI was done, whereas 11 patients had Grade 3-4 PCO when can opener technique was used. Nagata et al found 4 % grade 3-4 PCO after two year interval in cases of square edge PMMA IOL with CCC.⁵⁴ The incidence was slightly lower in our study which might be due to less follow up period.

The PCO rates were high when can opener capsulotomy was done irrespective of IOL design.

7. Incidence of PCO in relation to Cortical clean-up

In our study out of 55 patients in group A who had PCO, 14 (58.3%) patients developed grade 3-4 PCO when cortical clean up was incomplete compared to 10 (41.7%) patients when it was complete.

In our study out of 52 patients in group B who had PCO, 9 (81.8%) patients developed grade 3-4 PCO when cortical clean up was incomplete compared to 2 (18.2%) patients when it was complete.

Grade 3-4 PCO was more when cortical clean up was incomplete irrespective of type of IOL used

Retained cortical matter is important because of its potential to provide cells which result in PCO. A previous study clearly demonstrates that although improvements have been made, on average, we have not reached a threshold at which sufficient cell removal has occurred to minimize or prevent formation of a nidus of cells that can lead to cell proliferation/regeneration.⁵⁶ If excessive masses of retained cortex remain after surgery, no matter what the geometry of the optical component is, it cannot always block massive levels of cells. In such cases, the optic cannot resist an overwhelming cell ingrowth of cells past the IOL optic.³⁶

Our results indicate attention to cortical clean up is warranted for significant reduction in incidence of PCO.

8. Postoperative vision

In our study 71.9 % patients in Group A and 92.2% patients in Group B achieved 6/9 to 6/6 best corrected visual acuity. A study in India found 58.9% had good visual acuity (6/12 or better, corrected) in both

eyes, one eye had round edge IOL and other eye had square edge IOL, there was no significant difference between visual outcome.⁵¹

28.1 % patients in Group A had vision in the range of 6/18 to 6/12. In another study from India 4 years after ECCE, the incidence of PCO affecting vision was 13.5% (vision < 6/12)¹⁴

The visual outcome was better in group B in our study which was statistically significant (Chi Square =8.957,DF=1,p=0.003)

9. Type of PCO

Fibrous PCO was the commonest type found in our study (81.3%). Mixed type (Fibrous with Elschnig's pearls) was seen in 11.2 % patients. 7.5 % patients had Elschnig's pearls type PCO.

Fibrous PCO can appear 2 months to 6 months after surgery with Elschnig's pearls somewhat later. Higher fibrous PCO in our study might be because of less study duration. In a study by Cheng et al¹⁷ showed that fibrous PCO developed earlier after surgery than pearl type which supports our finding.

10. YAG laser capsulotomy

In our study 3 (2.3%) patients required Nd:YAG laser capsulotomy, two (3.1%) in Group A and one (1.6%) patient in group B

Hollick et al reported 14 % Nd:YAG laser capsulotomy rate with PMMA IOL after two year of follow up.²⁸

Oner et al reported 26.3 % Nd:YAG laser capsulotomy rate with PMMA IOL after mean follow up of 17.8 months.³⁰

The lower Nd:YAG laser capsulotomy rates in our study might be due to less study duration

There was no significant difference in YAG laser capsulotomy rates between both groups. (Chi Square with Yate's correction = 0.075, DF = 1, p=0.784)

CONCLUSION

The modern cataract-intraocular lens surgery has given good visual results, but this effect could be short term with the development of posterior capsule opacification which is the most frequent complication after extracapsular cataract extraction (upto 50%)

In our study the rate of moderate to severe grades of PCO was less with square edge IOL when compared to round edge IOL, the difference was statistically not significant but clinically significant. Visual outcome was better with square edge PMMA IOL when compared to round edge PMMA IOL which was statistically significant.

The can opener capsulotomy technique was associated with incomplete cortical cleanup in several cases and lead to overall higher incidence of PCO in our study

Thus we conclude that introduction of square edge IOL is an important step in preventing posterior capsule opacification with subsequent visual deterioration and the benefits would be still higher with capsulorrhexis and complete cortical clean up.

SUMMARY

A one year randomized clinical trial was done to compare the posterior capsule opacification rates by square edge intraocular lens implantation versus round edge intraocular lens implantation in patients undergoing manual small incision cataract surgery in KLES Dr.Prabhakar Kore Hospital and Medical Research Center, Belgaum.

A total of 128 study subjects fulfilling the inclusion criteria were randomized into two groups by computer generated blocks of two. In Group A, 64 cases underwent MSICS with round edge PMMA lens implantation. In Group B, 64 cases underwent MSICS with square edge PMMA lens implantation.

- Mean age of patients in Group A was 62.7 ± 7.02 (mean \pm SD) years and 62.8 ± 8.7 years in Group B. More patients (39.8%) belonged to age group of 60-69 years.
- Male to female ratio was 1:1.06
- Overall incidence of posterior capsule opacification was 83.6%, with 85.9% Group A and 81.2% Group B.
- Clinically significant posterior capsule opacification (Grade 3-4) was seen in 37.5% patients in Group A and 17.2% patients in Group B. The difference between the two groups was statistically not significant but clinically significant.
- There was no significant difference in posterior capsule opacification rates between immature and mature cataracts.
- There was less incidence of posterior capsule opacification when CCC with relieving incision capsulotomy technique was used, irrespective of the Groups.

- Cases with complete cortical clean-up showed less posterior capsule opacification irrespective of the groups.
- Visual outcome was better in Group B when compared to group A which was statistically significant.
- Fibrous posterior capsule opacification was the commonest type seen in both the groups.
- Nd:YAG laser capsulotomy rates between the two groups were statistically not significant.

Thus our study showed less clinically significant posterior capsule opacification rate and better visual outcome with square edge intraocular lens.

Limitations in our study include can opener capsulotomy technique and incomplete cortical clean-up in several cases.

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ANNEXURE – I

PROFORMA

DATA COLLECTION INSTRUMENT

IP No :

Name :
(First Name) (Middle Name) (Surname)

Age : Years

Sex : 1 – Male ; 2 – Female

Address : _____

Occupation :

Religion : 1- Hindu 2 – Muslim 3 – Christian 4 – Sikh 5 Others(Specify)

Date of Admission:

Date of Discharge :

Provisional Diagnosis : _____

Proposed Surgery : _____

Is the patient eligible for Study ? 1 – Yes 2 – No

Has informed consent been taken ? 1 – Yes 2 – No

Final Result Information :

1. Ineligible

2. Eligible, Refusal

3. Eligible, Participating

I.D. No :

Doctor's Name : _____

Doctor's Signature : _____

Date :

I.D. No :-

Chief complaints :

Diminution of vision

Duration _____ months / years

RE

LE

History of present illness :

-
-
1. Diminution of vision Gradual Sudden
 Progressive Static
 Painless Painful

(1-Distance; 2 Near; 3 Both)

2. History of Diplopia / polypia 1 - Yes 2 - No
3. History of Coloured halos 1 - Yes 2 - No
4. History of Black spots in front of the eyes 1 - Yes 2 - No
5. History of watering / Discharge 1 - Yes 2 - No
6. History of Redness 1 - Yes 2 - No

7. H/o wearing spectacles : (1- Distance ; 2 Near ; 3 Both)

Duration _____ months / years

8. Any other complaints (if present, specify):

Past history

Diabetes : Duration : _____ months / years

Hypertension : Duration : _____ months / Years

Asthma: Duration : _____ months / Years

Any other medical disorders : _____

General physical examination

Pallor: Vital signs :

Oedema : Pulse rate (Per minute):

Blood Pressure : /
(mm of Hg)

Lymphadenopathy : Temperature : °C

Cardiovascular system : 1-Normal ; 2-Abnormal; If abnormal specify : _____

Respiratory system : 1-Normal ; 2-Abnormal; If abnormal specify : _____

Nervous System : 1-Normal ; 2-Abnormal; If abnormal specify : _____

Per abdomen : 1-Normal ; 2-Abnormal; If abnormal specify : _____

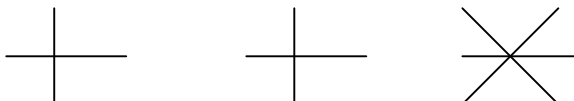
Ocular Examination :

Head Posture : (1- Errect ; 2 Tilted)

Facial Symmetry: (1-Symmetrical ; 2-Asymmetrical)

Visual Axes: (1-Parallel ; 2-Deviated)

Extra Ocular Movements: Right Eye Left Eye Binocular



Investigation :

1. Random Blood Sugar _____ mg%

2. Urine - Albumin (1-Present ; 2-Absent)

- Sugar (1-Present ; 2-Absent)

- Microscopy (1-Pus cells ; 2-No pus cells)

3. Lacrimal Sac patency : (1 – Patent ; 2 – Blocked)

Right Eye Left Eye

4. Intra ocular Pressure : Right Eye . Left Eye

(mm of Hg)

5. Any other:

Diagnosis: _____

Treatment Group:

1- Group A (Round edge lens)

2- Group B (Square edge lens)

DATE OF SURGERY (dd/mm/yy)

Intraoperative Complications:

1-YES 2-NO

If YES: _____

Post-operative follow up:

_Subjective complaints:

Post Operative Best Corrected Visual Acuity (BCVA)

OD				OS			
VA	SPH	CYL	AXIS	VA	SPH	CYL	AXIS

Anterior segment

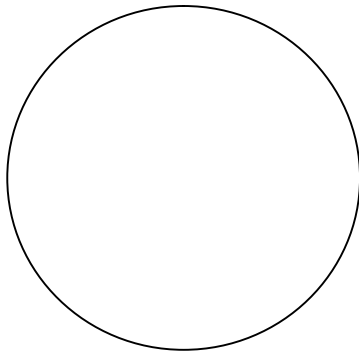
	(RIGHT EYE)	(LEFT EYE)
Adnexa		
Conjunctiva		
Cornea		
Sclera		
Anterior chamber		
Iris		
Pupil		
Lens		

Grading of posterior capsule opacification

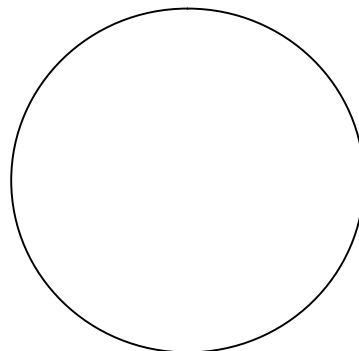
<input type="checkbox"/>	Grade 0 – None visible at all
<input type="checkbox"/>	Grade 1 – Visible But None Reaching IOL Edge
<input type="checkbox"/>	Grade 2 – Just within the IOL edge
<input type="checkbox"/>	Grade 3 – Well Inside IOL Edge But Visual Axis Clear
<input type="checkbox"/>	Grade 4 – Across Visual Axis

Retroillumination view

OD



OS



ANNEXURE II - INFORMED CONSENT DOCUMENT

I.D. No

Mr.

/Mrs./Ms _____

you are invited to participate in our research study titled

“SQUARE EDGE INTRAOCULAR LENS VERSUS CONVENTIONAL ROUND EDGE INTRAOCULAR LENS IN PREVENTION OF POSTERIOR CAPSULE OPACIFICATION—A RANDOMIZED CONTROLLED TRIAL AT KLE’S DR. PRABHAKAR KORE HOSPITAL”

conducted by Dr. _____ Post-Graduate student in M.S. Ophthalmology under the guidance of Dr. _____ M.S, D.O.M.S Professor, Department of Ophthalmology, J N Medical College, Belgaum.

Respected sir/ madam, we request you to enroll yourself to participate in our study as, you are eligible for participating in this study. During the study you will be asked some questions in detail regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary, your decision whether or not to participate in the study will not affect your relationship with J N Medical college. If you decide to participate you are free to withdraw at any time.

Purpose of the Study :

The purpose of research is to compare the effectiveness of square edge intraocular lens in prevention of posterior capsule opacification with that of conventional round edge intraocular lens.

Procedure Involved:

If you agree to participate in this study, you will be asked to give detailed history of the disease you have and you will have to undergo necessary investigations that may be required. You will then be allotted to one of the two groups by randomization and then implanted with respective intraocular lens depending on the group. Whichever group is allotted to you, You will have to agree upon it. You would be asked to follow up on specified dates when your progress would be monitored, documented and if necessary photographed.

Risks and Benefits :

As such there are no major risks involved, however some discomfort may occur during the process of investigations and the risks involved with the anaesthetic procedure and with cataract surgical procedure for which all precautions will be taken. As such minimal risk is involved in the operative procedure mentioned above. If you agree to enroll in the study you will be helpful in choosing better intraocular lens in terms of prevention of posterior capsule opacification . Your participation may benefit you and others with cataract in future, by helping us to learn more about the posterior capsule opacification and it's prevention. No financial incentives are promised to you for being a part of study.

Alternatives:

Your decision whether or not to participate in this study will not affect the quality of treatment you receive and if you are not willing to participate, Further you may withdraw from the study at any time.

Costs for participating in this research :

There will not be any extra cost incurred by you. The participant will have to pay for the investigations which are the part of the existing management protocol for this ailment. There is not commitment for any reimbursement or any other compensation for the participant.

Privacy and Confidentiality :

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to others without your written permission, except :

1. In emergency to protect your rights and welfare.
2. If required by law

Authorization to Publish Results :

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential .

Compensation :

In the event of injury related to the study, treatment will be made available through KLE Prabhakar Kore Hospital and M R C, Belgaum. There is no compensation or payment for such medical treatment by law. The doctors and the staff will provide facilities and medical attention to you.

Questions:

If you have any questions about the research you may please contact:

- 1) Chief investigator, Dr. _____ P.G. Department of Ophthalmology,
J N Medical College, Belgaum . Contact No: _____.
- 2) Guide, Dr. _____, Professor, Department of Ophthalmology, J N
Medical College, Belgaum . Ph: _____.
- 3) Dr. _____, Principal, J N Medical College Belgaum and
Chairman of Institutional Ethics Committee. Ph: _____.

Consent Statement

I.D. No :

I Mr./Ms./Mrs. _____ Voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print of Subject: _____

Witness Name: _____

Signature of Witness : _____

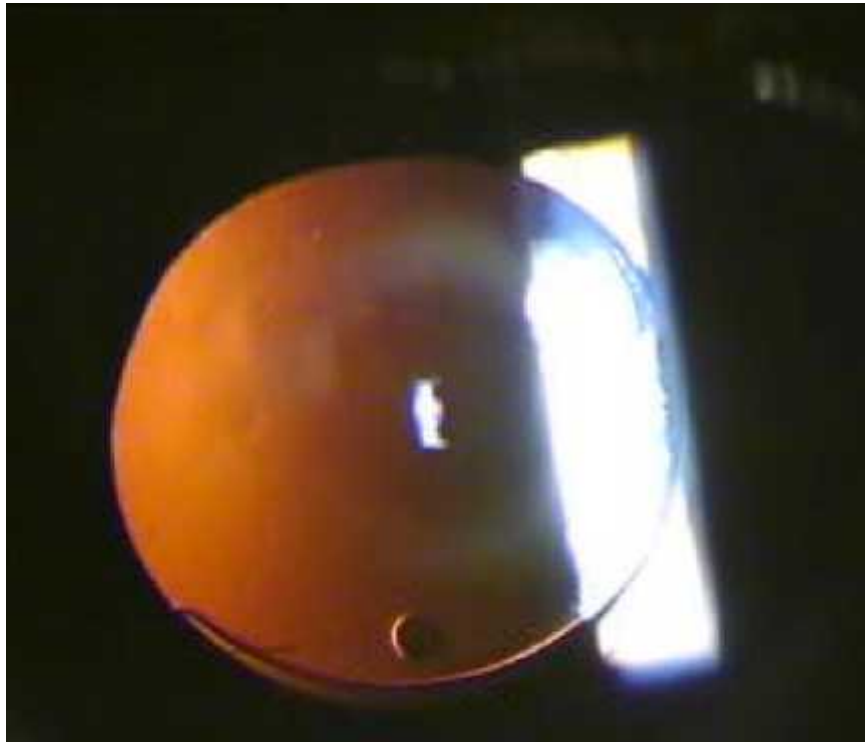
Investigators Name : _____

Signature of Investigator : _____

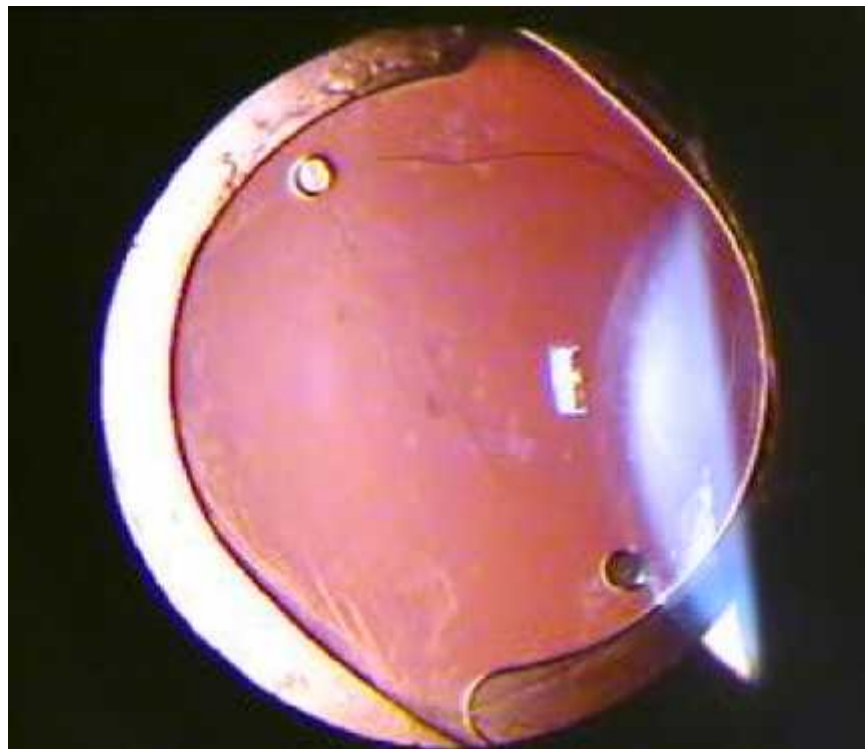
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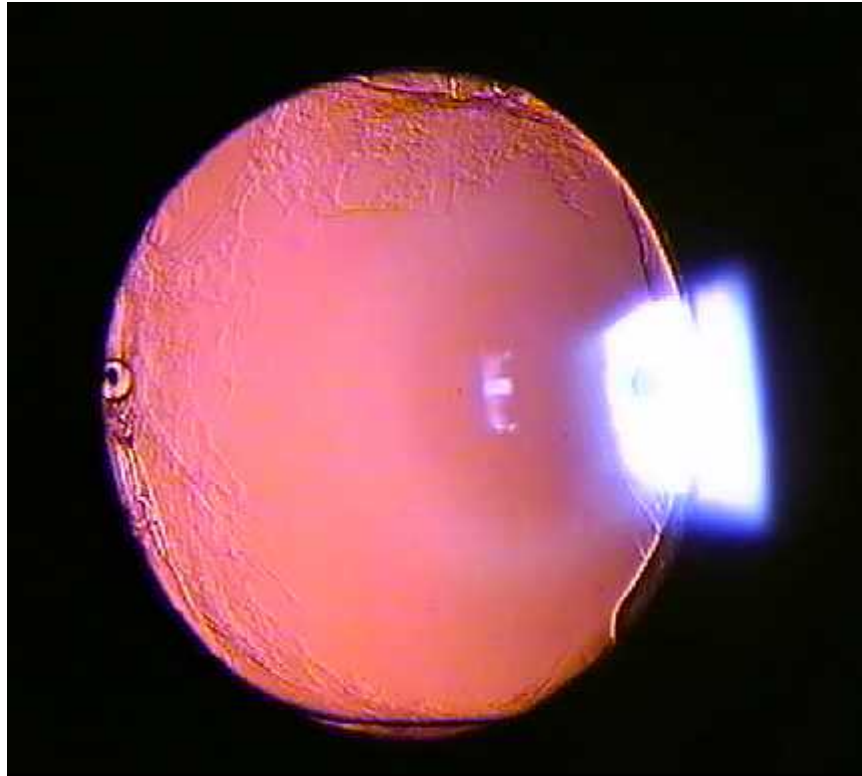
ANNEXURE – III: PHOTOGRAPHS



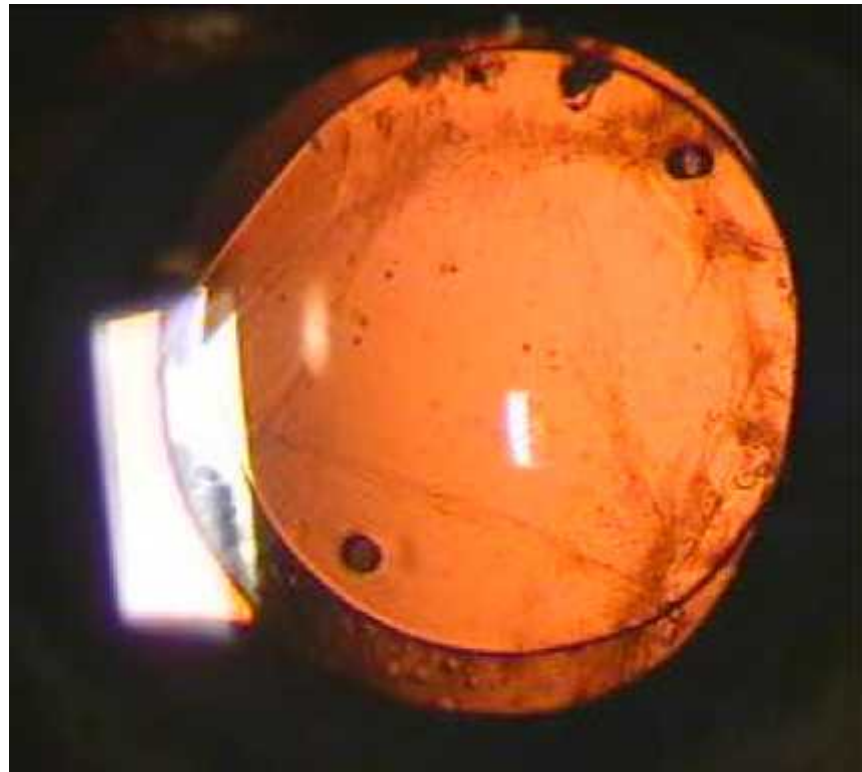
Photograph 1: Group A- Grade 0 PCO



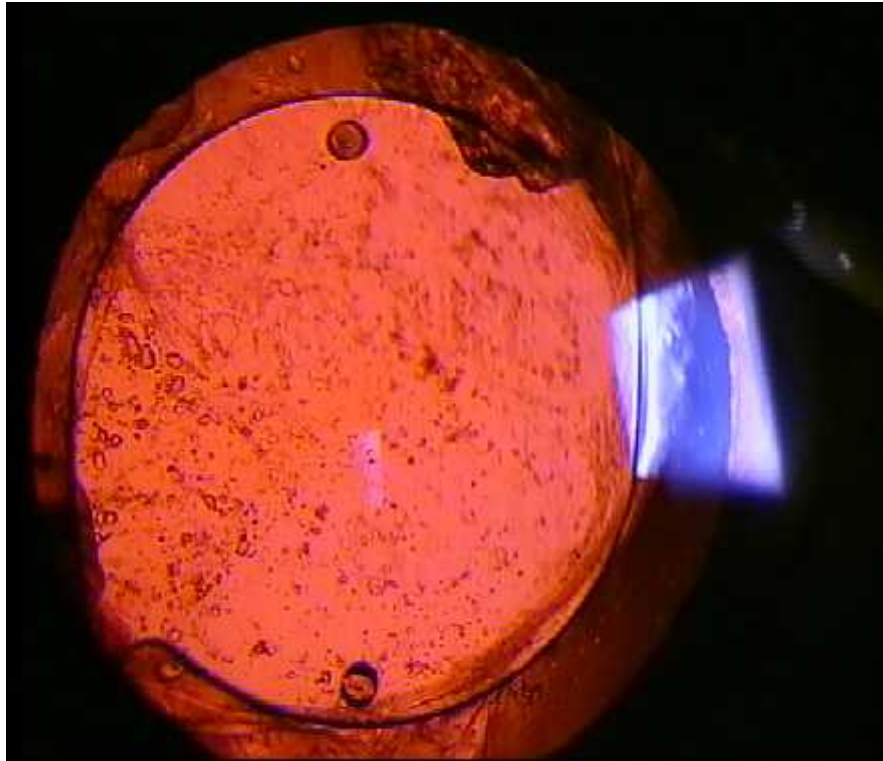
Photograph 2: Group A- Grade 1 PCO



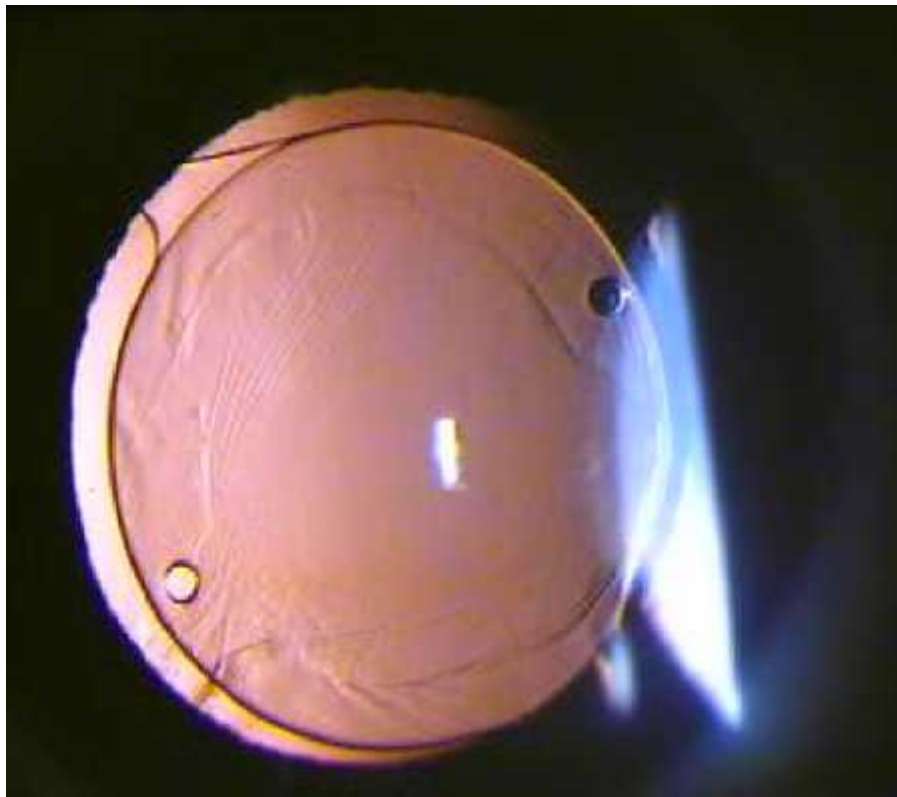
Photograph 3: Group A- Grade 2 PCO



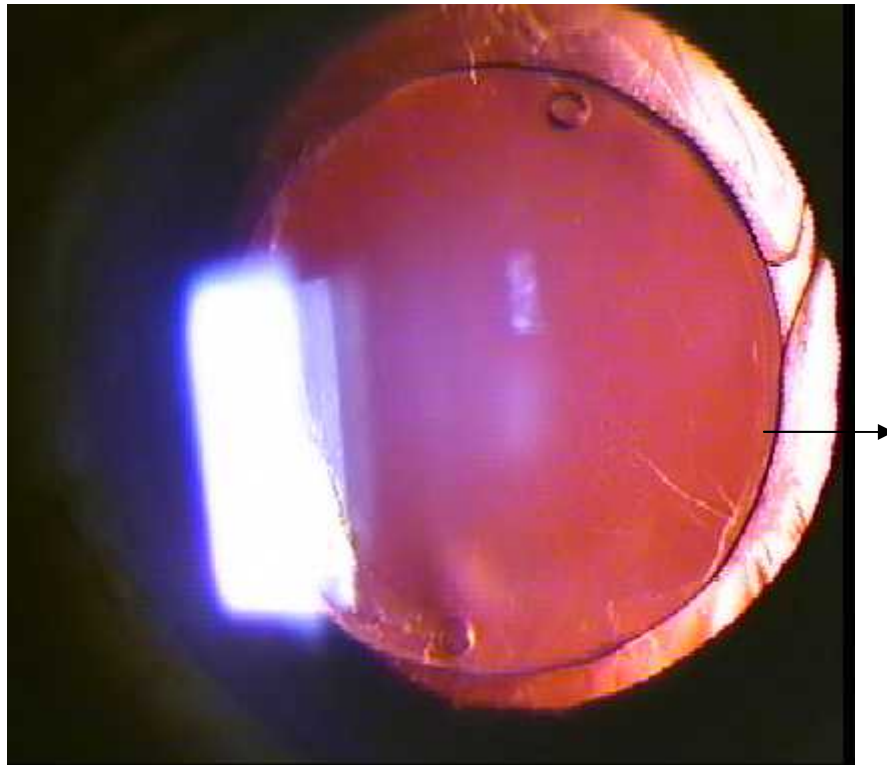
Photograph 4: Group A- Grade 3 PCO



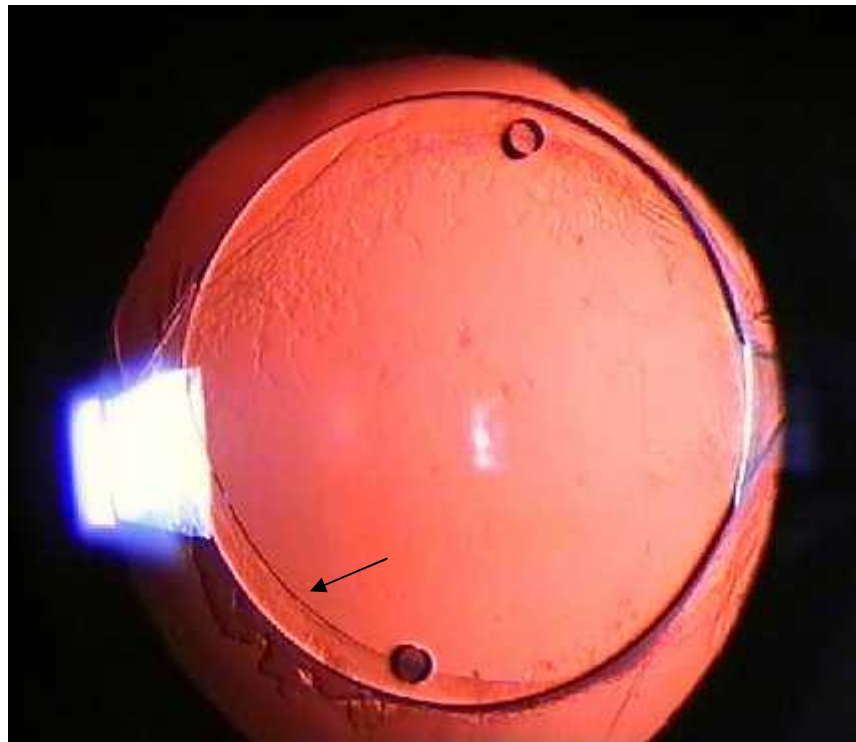
Photograph 5: Group A- Grade 4 PCO (Elschnig's pearls)



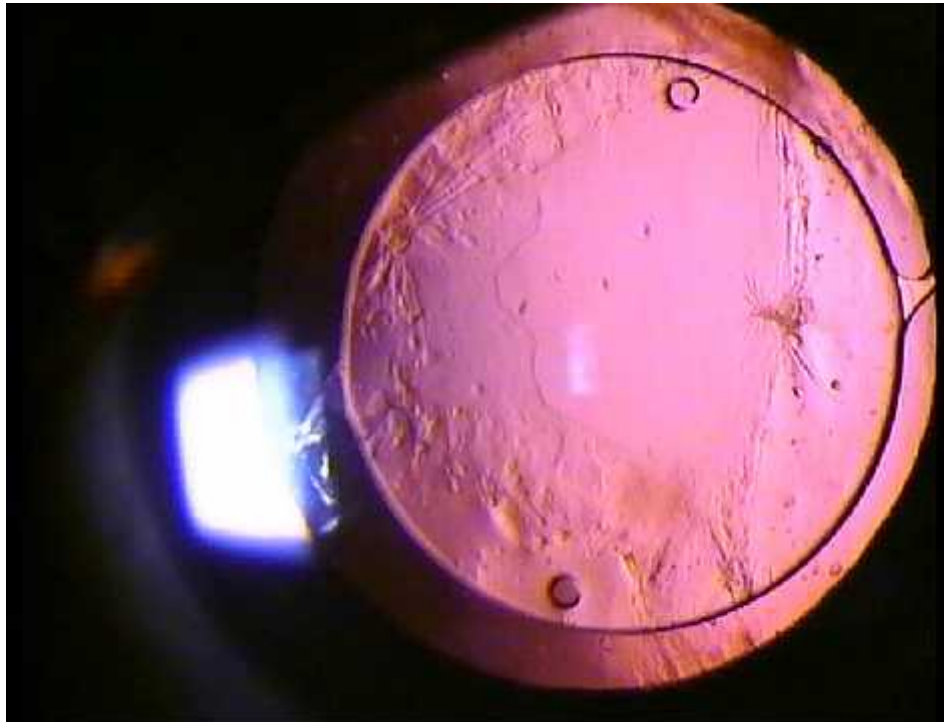
Photograph 6: Group B- Grade 0 PCO



Photograph 7: Group B- Grade 1 PCO
(arrow shows inhibition of PCO at the edge)



Photograph 8: Group B- Grade 2 PCO
(arrow shows CCC margin and inhibition of PCO at the edge)



Photograph 9: Group B- Grade 3 PCO

ANNEXURE – IV: MASTER CHART

KEY TO MASTER CHART

IP No. – In Patient No.

M – Male

F – Female

LE – Left eye

RE – Right eye

SIMC – Senile immature cataract

SMC - Senile mature cataract

HMSC – Hyper mature senile cataract

CF – Counting finger

PL - Perception of light

HMCF – Hand movements close to face

CCC+RI – Continuous curvilinear capsulorrhexis + Relieving incision

PCO – Posterior capsule opacification

mt – Meters

Adv – Advised

N.Adv- Not advised

MASTER CHART – GROUP A

SL No	Name	IP No	Age/Sex	Diagnosis	Pre-operative vision	Capsulotomy	Cortical cleanup	Post - Operative vision	PCO grade	YAG laser	Remarks
1	GCK	292403	70/M	LE SIMC	6/18	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO
2	MYK	294642	54/M	LE SIMC	CF1mt	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous+Elschnig's pearls
3	RSB	982279	65/F	RE SIMC	6/18	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
4	SDJ	296341	55/M	RE SIMC	6/24	Can opener	Incomplete	6/6	Grade 3	N. Adv	Fibrous PCO
5	INB	296194	60/F	RE SIMC	CF-3mt	Can opener	Incomplete	6/12	Grade 4	N. Adv	Elschnig's pearls
6	KSM	296528	70/M	RE SIMC	6/18	Can opener	Complete	6/12	Grade 2	N. Adv	Fibrous PCO
7	BAA	296214	50/F	LE SMC	PL+ve	Can opener	Complete	6/9	Grade 3	N. Adv	Fibrous PCO
8	SSV	297016	62/F	LE SIMC	CF-1mt	Can opener	Complete	6/12	Grade 2	N. Adv	Fibrous PCO
9	BBP	297638	65/F	RE SIMC	CF-3mt	Can opener	Complete	6/18	Grade 4	Adv	Fibrous PCO
10	SBP	297640	67/F	RE SMC	HMCF	Can opener	Complete	6/9	Grade 3	N. Adv	Fibrous PCO
11	SHP	297665	70/F	LE SIMC	CF1mt	Can opener	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO
12	MYK	298382	66/M	LE SIMC	CF-3mt	Can opener	Incomplete	6/12	Grade 3	N. Adv	Fibrous PCO
13	MDK	298578	56/M	RE SIMC	6/36	Can opener	Complete	6/18	Grade 3	N. Adv	Fibrous+Elschnig's pearls
14	MRS	299311	59/M	LE SIMC	CF-1mt	CCC+RI	Complete	6/9	Grade 0	N. Adv	Nil
15	LKB	301009	54/F	LE SIMC	6/36	CCC+RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
16	IBP	300968	70/F	LE SIMC	CF-4mt	CCC+RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO

Annexure IV: Master Chart

SL No	Name	IP No	Age/Sex	Diagnosis	Pre-operative vision	Capsulotomy	Cortical cleanup	Post - Operative vision	PCO grade	YAG laser	Remarks
17	BNB	302473	64/M	RE SIMC	6/18	Can opener	Complete	6/12	Grade 4	N. Adv	Elschnig's pearls
18	MKG	302470	72/M	LE SIMC	6/24	CCC+RI	Complete	6/12	Grade 2	N. Adv	Fibrous PCO
19	RAK	304779	60/M	LE SIMC	CF-1mt	CCC+RI	Complete	6/9	Grade 0	N. Adv	Nil
20	GKT	304787	70/M	LE SIMC	6/18	CCC+RI	Complete	6/9	Grade 1	N. Adv	Fibrous PCO
21	SVP	305922	54/M	LE SIMC	6/18	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO
22	BMD	305938	59/M	RE SIMC	6/36	CCC+RI	Complete	6/6	Grade 0	N. Adv	Nil
23	PAH	308482	62/F	RE SIMC	CF-3mt	Can opener	Incomplete	6/6	Grade 2	N. Adv	Fibrous PCO
24	IPT	309069	62/F	LE SMC	PL+ve	CCC+RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
25	LBK	309090	60/M	RE SIMC	6/24	CCC+RI	Complete	6/12	Grade 1	N. Adv	Fibrous PCO
26	SMP	310511	64/M	RE SIMC	6/60	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO
27	PVT	311120	52/M	RE SMC	HMCF	Can opener	Complete	6/9	Grade 3	N. Adv	Fibrous PCO
28	KRB	311366	60/F	LE SIMC	6/18	CCC+RI	Complete	6/6	Grade 1	N. Adv	Fibrous PCO
29	RHK	312992	70/M	LE SMC	HMCF	Can opener	Complete	6/12	Grade 2	N. Adv	Fibrous PCO
30	SMP	313151	70/M	LE HMSC	HMCF	Can opener	Complete	6/12	Grade 0	N. Adv	Nil
31	JMP	312998	70/F	LE SIMC	6/36	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
32	MRP	312961	50/F	LE SMC	HMCF	Can opener	Incomplete	6/12	Grade 3	N. Adv	Fibrous+Elschnig's pearls
33	MMK	314000	60/F	RE SIMC	6/18	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO

Annexure IV: Master Chart

SL No	Name	IP No	Age/Sex	Diagnosis	Pre-operative vision	Capsulotomy	Cortical cleanup	Post - Operative vision	PCO grade	YAG laser	Remarks
34	PVK	316561	70/F	RE SIMC	6/36	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO
35	SCK	1096691	60/F	LE SIMC	6/18	CCC+RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
36	GCP	320188	63/M	RE SMC	HMCF	Can opener	Complete	6/12	Grade 2	N. Adv	Fibrous PCO
37	BDP	321015	70/M	LE SIMC	PL+ve	Can opener	Complete	6/12	Grade 2	N. Adv	Fibrous PCO
38	HYM	321952	60/F	LE SMC	PL +ve	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
39	STB	322561	79/M	RE SIMC	CF-1mt	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
40	MMT	322958	52/F	RE SIMC	6/18	CCC+RI	Complete	6/9	Grade 0	N. Adv	Nil
41	HDJ	323529	70/F	RE SIMC	CF-1mt	CCC+RI	Complete	6/9	Grade 1	N. Adv	Fibrous PCO
42	CRM	323944	65/F	RE SMC	HMCF	Can opener	Complete	6/9	Grade 0	N. Adv	Nil
43	GRT	324282	60/F	RE SMC	PL +ve	Can opener	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO
44	GNP	324786	70/F	RE SIMC	6/60	Can opener	Complete	6/12	Grade 0	N. Adv	Nil
45	SBS	324936	50/M	LE SIMC	CF-2mt	Can opener	Complete	6/12	Grade 3	N. Adv	Fibrous PCO
46	DGP	327752	70/F	LE SIMC	CF-3mt	Can opener	Incomplete	6/12	Grade 3	N. Adv	Fibrous+Elschnig's pearls
47	RBP	328688	60/F	RE SIMC	CF-3mt	Can opener	Incomplete	6/9	Grade 4	N. Adv	Fibrous PCO
48	YNP	328685	65/F	LE SMC	PL +ve	Can opener	Complete	6/9	Grade 0	N. Adv	Nil
49	GAB	329674	50/M	RE SIMC	6/24	CCC+RI	Complete	6/9	Grade 2	N. Adv	Fibrous+Elschnig's pearls
50	SCK	331607	60/M	RE SIMC	CF-1mt	Can opener	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO

Annexure IV: Master Chart

SL No	Name	IP No	Age/Sex	Diagnosis	Pre-operative vision	Capsulotomy	Cortical cleanup	Post - Operative vision	PCO grade	YAG laser	Remarks
51	DSH	331609	58/M	RE SIMC	CF-2mt	CCC+RI	Complete	6/9	Grade 1	N. Adv	Fibrous PCO
52	PSP	332486	60/F	RE SMC	HMCF	Can opener	Incomplete	6/12	Grade 3	N. Adv	Fibrous+Elschnig's pearls
53	BRP	332495	61/M	RE SIMC	CF-3mt	Can opener	Incomplete	6/12	Grade 2	N. Adv	Fibrous PCO
54	BBP	333322	65/F	LE SIMC	CF-3mt	CCC+RI	Incomplete	6/9	Grade 1	N. Adv	Fibrous PCO
55	SSS	333467	57/F	RE SIMC	6/24.	CCC+RI	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO
56	LBP	333511	71/M	RE SIMC	6/18	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous+Elschnig's pearls
57	MLP	333509	75/F	RE SIMC	6/18	CCC+RI	Complete	6/18	Grade 2	N. Adv	Fibrous PCO
58	MMW	337109	60/M	RE SIMC	6/24	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
59	KSS	346274	55/M	RE SIMC	CF-1mt	Can opener	Complete	6/12	Grade 3	N. Adv	Fibrous+Elschnig's pearls
60	SRP	347295	52/M	RE SIMC	6/60	CCC+RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
61	GRK	347944	67/M	LE SIMC	HMCF	Can opener	Complete	6/9	Grade 3	N. Adv	Elschnig's pearls
62	NSH	347911	75/F	RE SIMC	CF-5mt	CCC+RI	Complete	6/6	Grade 0	N. Adv	Nil
63	LKS	339047	60/F	LE SIMC	CF-3mt	Can opener	Complete	6/18	Grade 4	Adv	Elschnig's pearls
64	MKJ	348016	73/M	RE SIMC	6/24	CCC+RI	Complete	6/12	Grade 2	N. Adv	Fibrous PCO

MASTER CHART – GROUP B

SL No	Name	IP No	Age/Sex	Diagnosis	Pre-operative vision	Capsulotomy	Cortical cleanup	Post-operative vision	PCO grade	YAG laser	Type of PCO
1	GSB	948464	50/M	LE SIMC	6/24	CCC + RI	Complete	6/6	Grade 2	N. Adv	Fibrous PCO
2	LDC	295546	68/M	LE SIMC	6/18	CCC + RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
3	NBK	295570	55/F	RE SIMC	6/18	Can opener	Incomplete	6/6	Grade 2	N. Adv	Fibrous PCO
4	NSM	296348	65/F	LE SIMC	6/24	CCC + RI	Complete	6/9	Grade 0	N. Adv	Nil
5	CVH	304758	70/M	LE SIMC	CF-6mt	Can opener	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO
6	SGK	305041	60/M	LE SIMC	6/24	CCC + RI	Complete	6/9	Grade 1	N. Adv	Fibrous PCO
7	MCB	305516	50/M	LE SMC	PL +ve	Can opener	Complete	6/6	Grade 2	N. Adv	Fibrous+Elschnig pearls
8	SBD	1032939	60/M	LE SIMC	6/24	CCC + RI	Complete	6/6	Grade 0	N. Adv	Nil
9	SRK	305791	70/F	RE SIMC	CF-1mt	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO
10	ASK	306089	75/F	LE SIMC	CF-3mt	Can opener	Complete	6/9	Grade 0	N. Adv	Nil
11	KPD	306220	78/M	RE SIMC	6/24	CCC + RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
12	HBK	308150	58/M	RE SIMC	6/60	Can opener	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO
13	SCK	308558	67/F	RE SIMC	6/36	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
14	AVK	308903	78/F	LE SIMC	CF-2mt	Can opener	Incomplete	6/18	Grade 3	Adv	Fibrous PCO
15	KSH	309045	65/M	RE SMC	PL +ve	Can opener	Complete	6/6	Grade 3	N. Adv	Fibrous+Elschnig pearls
16	PFT	309496	50/M	RE SMC	HMCF	Can opener	Complete	6/6	Grade 1	N. Adv	Fibrous PCO
17	HMM	310679	77/M	LE SIMC	6/24	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO

Annexure IV: Master Chart

SL No	Name	IP No	Age/Sex	Diagnosis	Pre-operative vision	Capsulotomy	Cortical cleanup	Post-operative vision	PCO grade	YAG laser	Type of PCO
18	BSK	311557	65/M	RE SIMC	6/60	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO
19	MIK	313150	60/F	LE SIMC	CF-2mt	CCC + RI	Complete	6/9	Grade 1	N. Adv	Elschnig's pearl
20	LNA	313289	60/F	LE SMC	HMCF	Can opener	Incomplete	6/6	Grade 3	N. Adv	Fibrous PCO
21	SMC	314015	50/M	RE SIMC	6/60	CCC + RI	Complete	6/6	Grade 2	N. Adv	Fibrous PCO
22	SMK	314580	75/F	RE SMC	PL +ve	Can opener	Complete	6/9	Grade 0	N. Adv	Nil
23	VIA	315651	61/M	LE SIMC	CF-1mt	CCC + RI	Complete	6/6	Grade 2	N. Adv	Fibrous PCO
24	PMT	316544	50/F	RE SMC	HMCF	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous+Elschnig pearls
25	BAP	317449	59/F	RE SIMC	6/18	CCC + RI	Complete	6/6	Grade 0	N. Adv	Nil
26	DBS	319234	59/M	LE SMC	PL +ve	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
27	FKD	320175	65/F	RE SIMC	CF-3mt	CCC + RI	Complete	6/9	Grade 0	N. Adv	Nil
28	KFP	321147	65/F	LE SIMC	6/24	Can opener	Incomplete	6/18	Grade 3	N. Adv	Fibrous PCO
29	RBV	321930	65/F	LE SIMC	CF-1mt	Can opener	Complete	6/12	Grade 3	N. Adv	Fibrous+Elschnig pearls
30	PVK	321948	70/F	LE SIMC	6/18	Can opener	Incomplete	6/9	Grade 2	N. Adv	Elschnig's pearl
31	SBK	322074	53/M	RE SIMC	CF-1mt	CCC + RI	Complete	6/6	Grade 0	N. Adv	Nil
32	MNH	324941	50/F	RE SMC	PL +ve	Can opener	Complete	6/6	Grade 2	N. Adv	Fibrous PCO
33	SSH	325036	60/F	RE SIMC	6/24	CCC + RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
34	BLK	325900	79/M	LE SIMC	6/24	CCC + RI	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO
35	ISK	325901	73/M	LE SIMC	6/60	CCC + RI	Complete	6/9	Grade 1	N. Adv	Fibrous PCO

Annexure IV: Master Chart

SL No	Name	IP No	Age/Sex	Diagnosis	Pre-operative vision	Capsulotomy	Cortical cleanup	Post-operative vision	PCO grade	YAG laser	Type of PCO
36	BKT	326859	50/M	RE SIMC	6/24	CCC + RI	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO
37	SCB	326843	70/F	RE SIMC	CF-1mt	Can opener	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO
38	DBG	328684	65/F	RE SIMC	6/60	CCC + RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
39	SHL	329662	65/F	RE SMC	PL +ve	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
40	JKK	330654	65/F	RE SIMC	CF-1mt	Can opener	Complete	6/9	Grade 1	N. Adv	Fibrous PCO
41	SMM	331567	62/M	RE SMC	PL +ve	Can opener	Complete	6/9	Grade 0	N. Adv	Nil
42	VRS	331554	64/M	LE SMC	PL +ve	Can opener	Incomplete	6/6	Grade 2	N. Adv	Fibrous PCO
43	BNT	333478	73/F	RE SMC	PL +ve	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
44	MAK	333561	56/M	LE SMC	HMCF	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO
45	SBS	335479	75/M	LE SIMC	HMCF	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO
46	LBG	337104	51/M	LE SMC	HMCF	Can opener	Incomplete	6/9	Grade 2	N. Adv	Fibrous PCO
47	KVM	337125	51/F	RE SIMC	6/18	CCC + RI	Complete	6/9	Grade 1	N. Adv	Elschnig's pearl
48	MKJ	337254	73/M	RE SIMC	6/24	CCC + RI	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
49	PLB	337587	50/F	RE SIMC	6/24	CCC + RI	Incomplete	6/9	Grade 1	N. Adv	Fibrous PCO
50	NBB	337930	75/F	RE SIMC	HMCF	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
51	RAM	337922	50/M	RE SIMC	6/18	Can opener	Complete	6/9	Grade 1	N. Adv	Fibrous PCO
52	KHT	338143	58/M	LE SIMC	HMCF	CCC + RI	Complete	6/9	Grade 0	N. Adv	Nil
53	SSR	339732	62/M	RE SIMC	CF-5mt	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO
54	VNP	339735	73/M	RE SIMC	6/18	Can opener	Incomplete	6/9	Grade 3	N. Adv	Fibrous PCO

Annexure IV: Master Chart

SL No	Name	IP No	Age/Sex	Diagnosis	Pre-operative vision	Capsulotomy	Cortical cleanup	Post-operative vision	PCO grade	YAG laser	Type of PCO
55	KMM	344940	54/F	LE SIMC	6/60	Can opener	Incomplete	6/12	Grade 2	N. Adv	Fibrous PCO
56	VYP	344930	60/M	RE SIMC	CF-4mt	Can opener	Complete	6/12	Grade 2	N. Adv	Fibrous PCO
57	MRJ	345046	70/M	LE SIMC	6/24	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO
58	AMN	347299	65/F	LE SMC	PL +ve	Can opener	Complete	6/12	Grade 0	N. Adv	Nil
59	KFH	347807	59/F	LE SIMC	6/60	CCC + RI	Complete	6/6	Grade 1	N. Adv	Fibrous PCO
60	SPA	347937	52/F	LE SIMC	CF-3mt	Can opener	Complete	6/9	Grade 1	N. Adv	Elschnig's pearl
61	SBS	347943	51/F	RE SIMC	CF-1mt	CCC + RI	Complete	6/9	Grade 0	N. Adv	Nil
62	BNI	347908	65/F	LE SIMC	CF-1mt	CCC + RI	Complete	6/6	Grade 0	N. Adv	Nil
63	KFS	348419	72/M	RE SIMC	6/24	Can opener	Complete	6/12	Grade 2	N. Adv	Fibrous PCO
64	RBK	348657	74/M	RE SIMC	6/60	Can opener	Complete	6/9	Grade 2	N. Adv	Fibrous PCO