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This is to certify that the dissertation entitled "**A CROSS SECTIONAL STUDY OF THE OUTCOME OF SMALL INCISION CATARACT SURGERY IN PSEUDOEXFOLIATION SYNDROME CASES DONE AT KLE'S DR. PRABHAKAR KORE HOSPITAL AND MRC, BELGAUM.**" is a bonafide research work done by **Registration No. BK0108002.**

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LIST OF ABBREVIATIONS

CTR	»	Capsular Tension Ring
CTS	»	Capsular Tension Segment
IOP	»	Intraocular Pressure
MSICS	»	Manual Small Incision Cataract surgery
PCR	»	Posterior capsular rent
PEX	»	Pseudoexfoliation
POAG	»	Primary Open Angle Glaucoma
PxS	»	Pseudoexfoliation syndrome
SHMC	»	Senile Hyper-mature Cataract
SIMC	»	Senile Immature Cataract
SMC	»	Senile Mature Cataract
VL	»	Vitreous loss
ZD	»	Zonular dehiscence

ABSTRACT

BACKGROUND

Pseudoexfoliation syndrome is a common clinically important systemic condition characterized by the pathological production and accumulation of an abnormal fibrillar extracellular material in many intraocular and extra-ocular tissues. Many studies have shown that Pseudoexfoliation syndrome patients have higher rates of intraoperative complications during cataract surgery compared to the patients without the condition.

OBJECTIVES

- 1) To study the clinical features of pseudoexfoliation syndrome.
- 2) To study the intraoperative complications of manual small incision cataract surgery in eyes with pseudoexfoliation syndrome.

METHODS

It is a hospital based cross-sectional study of 45 eyes of 45 patients with cataract and Pseudoexfoliation syndrome attending Ophthalmology OPD at KLE Dr. Prabhakar Kore Hospital and MRC, Belgaum. The average age of patients in the study was 65.83 years with a male predominance with higher incidence of unilateral than bilateral involvement. In the study, 24 (53.4 %) of the patients had intraoperative complication while 21 (46.6%) did not. 12 (26.7 %) of the patients had Zonular dehiscence, 8 (17.8 %) of the patients had Posterior Capsular Rent and 8 (17.8 %) of the patients had Vitreous loss. 44 (97.8 %) of the patients were implanted with intraocular lens after employment of various surgical modifications. 1 (2.2 %) of the patients were left aphakic due to the above mentioned complications.

INTERPRETATION & CONCLUSION

Inadequate mydriasis is one of the major preoperative complications in eyes with Pseudoexfoliation syndrome which has a bearing on the intraoperative complications. Pupil enlargement procedures are advocated during cataract surgery. Corneal endothelial touch was noted as one of the major complications due to excessive handling of the large and hard nucleus.

Though Small incision cataract surgery in eyes with Pseudoexfoliation syndrome is associated with intraoperative complications, they can be managed well and good outcome can be expected.

KEYWORDS

Pseudoexfoliation syndrome; Manual Small Incision Cataract Surgery; Intraoperative Complications; Inadequate mydriasis; Intraocular Pressure; Glaucoma; Zonular dialysis; Posterior capsular rent; Vitreous Loss.

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INTRODUCTION

Pseudoexfoliation Syndrome is an age related generalized disorder involving abnormal production or turnover of extra-cellular matrix in ocular tissues, orbital tissues, skin and visceral organs.

The exact aetio-pathogenesis of this condition and chemical composition of the material still remains unknown.

Renewed interest in this long known entity results from better awareness of the spectrum of intra-ocular risks not only for open angle glaucoma but also in conjunction with/or intra-ocular surgery, especially cataract extraction.

In the eye, Pseudoexfoliation syndrome is characterized clinically by small white deposits of material in the anterior segment, most commonly in the pupillary border and the anterior Lens capsule. The most consistent diagnostic feature is three distinct zones of pseudoexfoliation material seen on the lens capsule after full dilatation.

1. A translucent, central disc with occasional curled edges.
2. Middle clear zone corresponding to probable contact with the moving iris.
3. Peripheral granular zone, which may have radial striations.

(Central zone is absent in 20% or more cases, but peripheral defect is a consistent finding in all cases. Therefore, pupillary dilatation is a must before lens changes can be seen.)

Additional subtle clinical signs that help in early diagnosis are loss of pigment from peri-pupillary area producing transillumination defects, insufficient mydriasis, and pigment dispersion into anterior chamber after mydriasis, deposition of melanin

over trabecular meshwork and Schwalbe's line. The existence of posterior synechiae without any other cause and hemorrhage in the iris stroma after mydriasis are also suggestive of pseudoexfoliation syndrome. Deposition of material on the zonular fibres weakens it leading to phacodonesis, subluxation and dislocation of lens. The presence of secondary open angle glaucoma is known as glaucoma capsulare. The glaucoma has more serious clinical course and worse prognosis than primary open angle glaucoma, often not responding to medical therapy and requiring early surgical intervention. Angle closure glaucoma may also be seen due to pupillary block by forward displaced lens. The corneal epithelium shows decreased cell count and pleomorphism leading to early corneal decompensation at moderate rises in intraocular pressure and after cataract surgery. An increased incidence of nuclear cataract is seen.

Making the diagnosis often requires a careful slit-lamp examination after pupillary dilatation and pseudoexfoliation syndrome frequently goes undiagnosed leading to unexpected problems in management and during surgery.

Due to involvement of virtually all structures by pseudoexfoliation material, patients have a significantly greater risk for a variety of complications during cataract surgery. Poor mydriasis, pigment dispersion, combined with phacodonesis and zonular dialysis predisposes to capsular rupture and vitreous loss. Breakdown of blood-aqueous barrier leads to transient elevations of intraocular pressure and fibrinoid uveitis after surgery. Late complications include posterior capsular opacification, secondary cataract, and decentration of intra-ocular lens and decompensation of corneal endothelium.

Possible pre-operative and intra-operative measures to avoid or minimize these complications include an increased awareness of pseudoexfoliation syndrome, a careful slit lamp examination after full pupillary dilatation, adequate control of intra-ocular

pressure pre-operatively, avoidance of iris manipulation, adequate pupillary dilatation, use of heparin coated intra-ocular lenses and judicious use of steroids post-operatively.

Much remains to be learnt about the pseudoexfoliation material not only at the basic levels of production and by the chemical nature but also with regard to its genetics, epidemiology and treatment. There is an increasing prevalence of pseudoexfoliation syndrome as the mean age of general population increases. Yet the clinical implications of the systemic manifestations of this disorder remain unclear.

In view of the multitude of clinical complications, we need to be aware of the risks and specially look for clinical signs of this entity. Pseudoexfoliation syndrome should not be considered as harmless anomaly of the anterior segment but as a potentially catastrophic disease.

MANIFESTATIONS OF PSEUDOEXFOLIATION SYNDROME

TISSUE INVOLVED		CLINICAL SIGNS
Ocular	Lens	Zonular instability Phacodonesis Subluxation Nuclear cataract
	zonules	Zonular instability
	Iris	Vacuopathy: blood aqueous barrier defect, pseudo-uveitis, anterior chamber hypoxia, capillary hemorrhage, iris rigidity, posterior synechiae, poor mydriasis, asymmetric pupillary reaction, stromal/pigment epithelial atrophy, melanin release
	Trabecular meshwork	Increased resistance to aqueous outflow, elevated intraocular pressure
	cornea	Reduced endothelial cell count Corneal decompensation Corneal endothelial proliferation
Extraocular	Skin, extraocular muscles, heart, liver, kidney, meninges	As yet unknown

**OCCURRENCE OF COMPLICATIONS OF
PSEUDOEXFOLIATION SYNDROME**

Spontaneous		Ocular hypertension/glaucoma Lens Subluxation, Nuclear cataract, Pseudo-uveitis, Corneal endothelial decompensation
Pre-operative (by medication)	Mydriatics	Poor dilatation, Melanin dispersion, iris hemorrhage.
	Miotics	Posterior synechiae, Pupillary block, Ciliary block.
Intra-operative	SICS	Poor mydriasis, Zonular dehiscence, PC Rent, Vitreous loss.

AIMS AND OBJECTIVES

- 1) To study the clinical features of pseudoexfoliation syndrome.
- 2) To study the intraoperative complications of manual small incision cataract surgery in eyes with pseudoexfoliation syndrome.

REVIEW OF LITERATURE

HISTORY AND NOMENCLATURE

In 1917, **Lindberg**¹ described grayish or bluish flakes of material on the pupillary border in some patients with glaucoma. **Vogt**² later hypothesized that this material represented degenerative changes of the lens capsule followed by secondary desquamation and proposed the term senile exfoliation of the lens capsule. **Busacca**³ argued that the exfoliative material represented deposition of material formed elsewhere in the eye rather than degenerative changes of the lens capsule.

Dvorak-Theobald⁴ subsequently showed that exfoliative material differed histochemically from lens capsule and, to differentiate this condition from true exfoliation of the lens capsule secondary to infrared exposure, suggested the term pseudoexfoliation of the lens capsule. Subsequent electron microscopic studies by **Ashton**⁵ and associates and **Bertelsen**⁶ and coworkers indicate that the anterior lens capsule was directly affected in this disorder. Bertelsen and associates suggest that pre-equatorial lens epithelial cells produced the abnormal fibrillar substance and recommend the term fibrillopathia epitheliocapsularis. **Eagle and colleagues**⁷, who believe that the material represented abnormal basement membrane secretions, have called this condition basement membrane exfoliation syndrome.

The terms exfoliation syndrome and pseudoexfoliation syndrome are now most commonly used to designate this disorder and are used interchangeably in current literature. However, since recent ultrastructural studies indicate that the material on the lens capsule is derived, at least in part, from the lens, it is proposed that the disorder be called exfoliation syndrome (XFS).⁸⁻¹⁰

EPIDEMIOLOGY

Pseudoexfoliation Syndrome is of global distribution. The reported prevalence of Pseudoexfoliation Syndrome both with and without glaucoma has varied widely. This reflects a combination of true difference due to racial, ethnic or as yet unknown factors; the clinical criteria used to detect early stages and/or more subtle changes, the method and thoroughness of examination and awareness of the examiner. In US population, the **Framingham Eye Study**¹¹ revealed the overall prevalence of Pseudoexfoliation syndrome to be 0.6% in 52 - 64 years old, rising to 5% in 75 - 85 years old. In India, the prevalence rates reported were 1.88% **Sood N.N.**¹² (1965), 7.4% **Lamba and Giridhar**¹³ (1984). The prevalence rate in south India is 3.8% **Aravind H et al**¹⁴ (2003). In a given population, the actual prevalence of Pseudoexfoliation Syndrome is probably twice that which is visible on clinical examination. Many cases go undetected because of failure to dilate the pupil or to examine the lens with the slit lamp after dilatation of the pupil.

The prevalence increases with age, the disease most commonly manifesting between 60- 70 years. But Pseudoexfoliation Syndrome might well be a condition that starts in mid-adulthood but becomes frankly manifest only in later years. Sex ratio reports are conflicting.

A hereditary transmission of Pseudoexfoliation Syndrome is not yet clarified. **Tarkkanen**¹⁵ (1962) suggested the presence of a gene bearing 3 characteristics, an abnormality of the drainage channels of the aqueous, Pseudoexfoliation and degeneration of the pigment epithelium of the iris. Variations in the expressivity of this gene would explain why the 3 events are sometimes found together and why sometimes only 1 or 2 is present.

Kelvin Y.C. Lee et al¹⁶ studied about XFS/XFG associations with polymorphisms with R141L, G153D and intronic located in the 1st exon of the lysyl oxidase like 1 gene (LOXL1) on Chromosome 15q 21 (1). Asian populations including Indians reported associations with LOXL1 and XFS.

R.R. Allingham et al¹⁷ (2001) investigated 6 islandic families each of which had at least 1 member affected by Pseudoexfoliation Syndrome they concluded that Ps Pseudoexfoliation Syndrome is an inherited condition with transmission to the 2nd generation through an affected mother.

There are no unequivocal findings regarding the role of environmental factors in the development of Pseudoexfoliation Syndrome.

It is now know that Pseudoexfoliation Syndrome is essentially a bilateral condition and unilateral cases only represent an earlier period in the natural history of the condition. When only 1 eye is involved clinically, the other eye often has abnormal aqueous humour dynamics or glaucomatous damage.

CL I N I C A L F E A T U R E S

1. OCULAR MANIFESTATIONS^{18,19, 20, 21, 22, 23, 24}

a) LENS AND ZONULES

Deposits of white flaky material on the anterior lens surface are the most consistent and important diagnostic of Pseudoexfoliation Syndrome. The classic pattern consists of 3 distinct zones that become visible when the pupil is fully dilated - a relatively homogeneous central disk corresponding roughly to the diameter of the pupil, a granular often layered peripheral zone and a clear area separating the two. The central zone is homogeneous white sheet lying on the anterior pole of the lens capsule. Its diameter varies between 1.5 - 3 mm and it is usually slightly smaller than the

physiological pupil. The edges of the disk are often rolled equatorially. The central disk is absent in 20 - 60% of cases. It is often initially overlooked but with careful examination after dilatation, a subtle area of Pseudoexfoliation material may be noted especially when compared to the adjacent intermediate clear zone. It may be granular in the periphery and frosty white centrally and radial striations are often seen. It may be layered. Axially it is bounded partly by curled edges and partly by tongue shaped projections. Equatorially it extends as granular tongue shaped projections which merge into the normal capsule before reaching the anterior zone of insertion of the zonular fibres. The peripheral band may be situated close to the equator in some eyes and more axially in others. The granularity of the peripheral layers is consistent with undisturbed accumulation of Pseudoexfoliation material.

Whereas the classical picture of Pseudoexfoliation Syndrome has often been described, the early stages have not been well defined. A precursor of Pseudoexfoliation material is thought to be initially deposited diffusely on the lens surface. A homogeneous "ground glass" or "matte" appearance of the lens surface in one eye compared to the other may represent a very early (pre-capsular) stage. In a perhaps slightly later (pre-granular) stage, there may be very faint radiant non-granular striae on middle third of the anterior capsule behind the iris. Ultra structurally, the pre-capsular layer at this stage consists of micro-fibrils, but not mature exfoliation fibrils.

To visualize the earlier stages at the slit lamp, placing the slit beam at 45° to the axis of observation reducing the light source and focusing temporarily 2 - 3 mm from the centre of the lens may help to highlight the subtle deposits on the lens surface. The intermediate clear zone is created by rubbing of the iris over the surface of the lens during pupillary movement. As the pre-capsular layer becomes thicker the iris sphincter begins to rub against it during normal pupillary movement. Faint clefts begin

to form where Pseudoexfoliation material is rubbed away in what will eventually become the clear zone. With time, these clefts increase in size and begin to become confluent. Eventually only small bridges may remain as an indication of the previous layer of Pseudoexfoliation material in the intermediate zone. In some patients the central disk may become thick enough to peel away in sheets from the lens, as may the peripheral zone, giving rise to appearance of True Exfoliation Syndrome. Chronic pupillary dilatation also permits undisturbed accumulation of Pseudoexfoliation material.

Clinical classification of various stages is based mainly but not only on the findings of the anterior lens capsule.¹⁸

SUSPECT PSEUDOEXFOLIATION SYNDROME:

- Early Pseudoexfoliation Syndrome (Electron Microscopy): Pre-capsular layer.
- Masked/Suspected Pseudoexfoliation Syndrome: Posterior synechiae without any obvious cause.

DEFINITE PSEUDOEXFOLIATION SYNDROME:

- Mini-Pseudoexfoliation Syndrome: Focal defects in pre-capsular layer especially supero-nasally.
- Classic Pseudoexfoliation Syndrome: Late stage.

Phacodonesis is common but not always associated with iridodonesis, perhaps attributable to increased iris rigidity.

Spontaneous subluxation and dislocation of lens can occur; the denser the Pseudoexfoliation material, the more likely there is to be phacodonesis. Lens dislocation is more common inferiorly.

The Zonular fibrils coated with varying amounts of Pseudoexfoliation material become stretched and eventually break. Break is not seen to occur from the attachment to the zonular lamellae but at their ciliary attachments. The broken fibers may be seen waving gently in the aqueous. Subsequently the fibers become shorter and thicker and finally appearing as irregular clumps on the lens surface. The fibers that break 1st are those behind the equator and those just anterior to the equator remain intact the longest.

b) IRIS AND PUPIL

Next to lens, Pseudoexfoliation material is most prominent at the pupillary border. It may be extensive or minimal. The iris is more rigid because of the material. Pigment loss from the iris sphincter region and its deposition on the anterior chamber structures is the hallmark of Pseudoexfoliation Syndrome. The material on the lens causes rupture of iris pigment epithelial cells at the ruff and sphincter region with concomitant dispersion of pigment into anterior chamber. Loss of iris pigment and its deposition throughout the anterior segment are reflected in iris sphincter region transillumination, loss of pupillary ruff, increased trabecular pigmentation and pigment deposition on the iris surface.

Extensive depigmentation may be noted over the entire sphincter region, which appears as a diffuse starry sky pattern on transillumination or moth eaten appearance.

Pseudoexfoliation Syndrome predisposes to formation of synechiae between iris pigment epithelium and the anterior lens capsule. Posterior synechiae are more prone to form between the iris and intra-ocular lens post operatively. Iris blood vessel

abnormalities include narrow or obliterate lumen, with marked alteration of iris vasculature, vessel dropout with collateral formation and iris hypo perfusion leading to patchy iris neo-vascularization.¹⁹

Inflammation after cataract extraction is more common and a transient fibrinoid reaction attributed to breakdown of Blood-aqueous barrier may occur.²⁰

Intra-stromal hemorrhage after mydriasis is indicative of vascular damage. Atrophic changes of sphincter and dilator muscle tissues, possibly because of hypoxia, and apparent impairment of muscle cells by Pseudoexfoliation material may contribute to poor pupillary dilatation.

Reduction of stromal elasticity by accumulating Pseudoexfoliation material may also play a role in poor mydriasis. Dispersion of melanin granules after diagnostic mydriasis or surgery can be so pronounced that heterochromia iridium may be produced. The mechanism of melanin liberation is related to degenerative changes and cell membrane ruptures of the posterior pigmented epithelial cells due to extra-cellular Pseudoexfoliation material. Marked intra-ocular pressure rise after mydriasis correlates with the amount of the pigment liberated.

c) CILLIARY BODY

The ciliary processes were examined clinically by **Mizuno and Muroi**²¹ with special type of Gonioscopy lens, almost all eyes with exfoliation showed accumulation of material on the zonules and ciliary body.

d) GLAUCOMA AND PSEUDOEXFOLIATION SYNDROME^{22,23:}

While the existence of association between Pseudoexfoliation Syndrome and Open Angle Glaucoma has been well known, the mechanisms are still not clarified. There is an increase in the aqueous outflow resistance probably due to trabecular cell dysfunction, blockage of meshwork by Pseudoexfoliation Syndrome liberated pigment and concomitant primary open angle glaucoma.

In patients with pseudoexfoliation syndrome, 20% have glaucoma and increased IOP at the time of diagnosis. Patients who have pseudoexfoliation syndrome but not glaucoma should be considered vulnerable to glaucoma, because 15% of such patients develop increased IOP within 10 years. This underscores the need for careful follow-up in patients who have pseudoexfoliation syndrome. Pseudoexfoliation syndrome accounts for 15-20% of cases of open angle glaucoma.

Glaucoma in Pseudoexfoliation Syndrome has a more serious clinical course and worse prognosis than Primary Open Angle Glaucoma. There is a significantly higher frequency and severity of optic nerve damage at the time of diagnosis, worse visual field damage, and poorer response to medications, more severe clinical course and more frequent necessity of surgical interventions. In normotensive eyes, with Pseudoexfoliation Syndrome the mean Intra-ocular pressure is higher than in eyes without Pseudoexfoliation Syndrome. In patients with elevated Intra-ocular pressure, mean intra-ocular pressure is higher at the time of diagnosis in patients with Pseudoexfoliation Syndrome, than in those with primary open angle glaucoma. Glaucomatous damage at the time of diagnosis is more severe and progression is also more rapid in eyes with Pseudoexfoliative glaucoma.

A number of characteristics predispose to development of angle closure glaucoma in eyes with Pseudoexfoliation Syndrome. Pupillary block may be caused by combination of posterior synechiae, increased iris thickness or rigidity or anterior lens movement secondary to zonular weakness or dialysis.

e) ANGLE CHARACTERISTICS²²:

As the iris is more rigid than normal, aqueous presence in the posterior chamber causes it to bulge at the weakest point which is the iris root. Thereby, the localized iris bombe near the iris root narrows the angle, giving a pseudo-plateau iris configuration on gonioscopy and leads to chronic angle closure glaucoma.

Increased trabecular pigmentation is a prominent sign and is apparent in virtually all patients with clinically evident disease. The pigment is splotchy and less well defined. It is an early diagnostic finding preceding appearance of Pseudoexfoliation material on the pupillary margin and the anterior lens capsule. It is almost always dense in the involved eye and increases in eyes with Pseudoexfoliative glaucoma.

The degree of pigmentation correlates with elevated intra-ocular pressure. Pigment on Schwalbe's line is seen as a wavy line known as Sampolesi's Line which is also an early sign of Pseudoexfoliation Syndrome.

f) VITREOUS

Vitreous changes commonly accompany Pseudoexfoliation Syndrome since hyaluronic acid and Pseudoexfoliation material are both acid mucopolysaccharides. A change in composition of aqueous in Pseudoexfoliation Syndrome could derange metabolism of hyalocytes leading to impaired production of hyaluronic acid and liquefaction.

g) CONJUNCTIVA AND CORNEA:

Clinically the conjunctiva is normal. However, fluorescein angiography reveals loss of regular limbal vascular pattern and areas of neovascularisation and congestion of anterior ciliary vessels. Scattered flakes of Pseudoexfoliation material may be observed on the endothelial surface of the cornea. Specular microscopy demonstrates a significantly reduced endothelial cell density even with normal intra-ocular pressure, together with morphological changes in size and shape of the endothelial cells in both affected eyes and un-involved fellow eyes. Decreased endothelial cell density does not necessarily correlate with the severity of glaucoma but it has been correlated with the extent of pigment dispersion. Central corneal thickness is increased reflecting early corneal dysfunction. These changes may help in early diagnosis and in pre-operative assessment prior to cataract extraction. These eyes can develop early corneal endothelial decompensation at only moderate rises of intra-ocular pressure or after cataract surgery.

2. SYSTEMIC MANIFESTATIONS ^{23, 25, 26}

Ultrastructural studies performed on eyes during autopsy suggest that Pseudoexfoliation syndrome is a multisystem disorder, Pseudoexfoliation material has been found in a number of organs, which include skin, lungs, gallbladder, liver, myocardium, kidney, bladder and Meninges. Associations of aneurysms of abdominal aorta and Pseudoexfoliation syndrome have been extensively studied. The staining of the material in these organs is positive for elastin and human amyloid P protein, which is similar to the staining pattern characteristic of the material found in the eye. These findings provide evidence for the systemic nature of Pseudoexfoliation syndrome, which involves an aberrant connective tissue metabolism throughout the body. Patients with pseudoexfoliation syndrome are found to have sensory neural-deafness.

THEORIES ON ORIGIN OF PSEUDOEXFOLIATION MATERIAL

1. BASEMENT MEMBRANE THEORY:

There is extensive support for the hypothesis that pseudoexfoliation syndrome represents a disorder of extra-cellular matrix characterized by overproduction or abnormal breakdown of cell surface associated material, the biochemical nature of which remains unclear. With the advent of the electron microscope, extensive studies on the pseudoexfoliation material were done and its origin was ascribed to be basement membrane of the lens capsule, iris, ciliary body and conjunctiva. **Schlotzer-Schrehardt et al**²⁵ in 1992 confirmed systemic involvement of the viscera by pseudoexfoliation material using a transmission electron microscopy. Typical pseudoexfoliation fibers were identified in autopsy tissue specimens of skin, heart, lungs, liver, kidney and cerebral meninges in addition to the classic intraocular locations leading to the term pseudoexfoliation syndrome.

The production of the exfoliation material may be related to disordered basement membrane metabolism and **Harnisch et al**²⁷ in 1981 using the indirect immunoperoxidase method, found that the fibrils contained a basement membrane proteoglycan. Anti-basement membrane proteoglycan antibodies to lens material reacted strongly with exfoliation material, implicating lens epithelium and its production.

2. ELASTIC MICRO-FIBRAL THEORY

Since exfoliation material is immunologically related to elastic tissue, **Li et al** in 1989 proposed that exfoliation fibers have peripheral binding sites for Amyloid P protein similar to those present on normal elastic fibers. There are histochemical and antigenic similarities between zonular elastic micro- fibrils and exfoliation material.

Garner and Alexander²⁸ in 1984 suggested that Oxytalan, a micro-fibrillar component of elastic tissue present in the body in areas of mechanical stress is a constituent of the exfoliation fibrils. **Roh et al** in 1987 found mature and intermediate micro-fibrils adjacent to fibroblasts in close proximity to elastic tissue in the conjunctiva. **Streeten et al**²⁹ in 1987 found histochemical similarities between zonular elastic micro-fibrils and pseudoexfoliation material and a resemblance of the larger micro-fibrils of a ground substance to zonular and other oxytalan micro-fibrils. The strong anatomic association between pseudoexfoliation fibers with elastosis in conjunctival specimens led the authors to suggest that pseudoexfoliation fibers themselves might be a form of elastosis, possibly resulting from abnormal aggregation of components related to elastic micro-fibrils. Elastin and elastic micro-fibril protein were demonstrated in pseudoexfoliation material - their production might reflect an abnormal stimulus or defective regulation of matrix synthesis.

Schlotzer - Schrehardt et al³⁰ in 1998 analyzed by electron microscopy the matrix of the pseudoexfoliation material and demonstrated it to be fibrillin positive fibers, supporting the elastic micro fibril theory of its production.

3. AMYLOID THEORY

Repo L.P. Naucharinen et al³¹ in 1996 examined by light and electron microscopy 13 biopsy specimens of iris tissue from patients with pseudoexfoliation syndrome undergoing cataract surgery. They showed that pseudoexfoliation material is associated with amyloid and in some eyes; miosis is associated with degenerative changes, both in stromal tissue and in muscular layers of the iris.

Tsukahara and Matsuo³² described patients with both primary familial amyloidosis and exfoliation.

4. LYSOZOMAL THEORY

Mizuno et al³³ in 1980 found histochemical evidence of high acid phosphatase activity, suggesting that lysozymes were involved in the production of exfoliation material. Possible rupture of pigment epithelial cells may account for lysosomal involvement. Proteolytic enzymes present in lysosomes may facilitate granular disintegration.

Baba³⁴ in 1982 demonstrated a lipoprotein in exfoliation material and felt that this might be the result of the high permeability of vessels in the anterior segment.

He also found that material was a sulphated lycosaminoglycan and suggested that abnormal glycosaminoglycan metabolism precedes the formation of the material. Immunochemical studies have revealed heparin sulphate, chondroitin sulphate proteoglycans, laminin, entactin/nidogen, fibronectin and amyloid P protein to be integral constituents of exfoliation material. Type IV collagen is restricted to a microfibrillar layer interposed between the capsular surface and typical exfoliation material. Type IV collagen mediates cell attachment and might be instrumental in adherence of exfoliation material to the anterior central capsule. The additional presence of elastin epitopes indicate that exfoliation material is a multi-component expression of a disordered extra-cellular matrix synthesis, including the incorporation of the principle non-collagenous basement membrane components. Extensive labelling of exfoliation material for chondroitin sulphate suggests an over-production and abnormal production of glycosaminoglycans to be one of the key changes in this disorder. Exfoliation material contains but does not represent true basement membrane material because of absence of Type IV collagen and the additional presence of elastin epitopes.

Transmission electron microscopy and high resolution scanning electron microscopy and demonstrated pseudoexfoliation material to contain keratan and dermatan sulphate. They postulated that pseudoexfoliative material was produced due to abnormality in proteoglycans. None of the histochemical or enzymatic studies have succeeded in elucidating the exact source of pseudoexfoliation material. This along with the increased chances of surgical complications continues to arouse great interest in pseudoexfoliation syndrome.

STRUCTURE OF PSEUDOEXFOLIATION MATERIAL

The Pseudoexfoliation Material consists of an irregular meshwork of randomly oriented cross-banded fibrils measuring about 30 nm in diameter within a loose fibro-granular matrix containing 6 - 10 nm micro fibrils.

Davanger^{35,36} (1978) described the fibrils as consisting of a protein core surrounded by polysaccharide side chains. The fibrils are formed from lateral aggregations of filaments.

The abnormally produced Pseudoexfoliation Material on light microscopy is a PAS positive, eosinophilic brush like nodular or feathery aggregate. On scanning electron microscopy these aggregates are composed of an irregular tangle of fibrils.

The fibrils are intermingled with normal micro-fibrils and are embedded in an amorphous inter-fibrillar ground substance, most probably glycosoaminoglycans. The extra-ocular Pseudoexfoliation Material is similar except that there is more matrix and less distinct banding pattern.

Indirect histochemical and immune histochemical evidence suggests a complex glycoprotein/proteoglycan like structure composed of a protein core surrounded by glycol-conjugates probably glycosoaminoglycans forming the amorphous substance.

CATARACT SURGERY IN PSEUDOEXFOLIATION SYNDROME

Patients with Pseudoexfoliation Syndrome are much more prone to have complications at the time of cataract extraction. Eyes with Pseudoexfoliation Syndrome dilate less well and have greater incidence of capsular rupture, zonular dehiscence and vitreous loss. Pupillary diameter and zonular fragility have been suggested as the most important risk factors for capsular rupture and vitreous loss.

The presence of phacodonesis has been related to poor mydriasis, cataract, and presence of glaucoma and trabecular pigmentation, all a reflection of the severity of involvement and should serve a warning sign. A shallow anterior chamber may indicate zonular instability. Post-operatively, transient intra-ocular pressure elevations are common. Posterior capsular opacification is more common. Late post-operative decentration of intra-ocular lens and capsular bag are common, and is related to zonular weakness. Capsular contraction syndrome if exaggerated, can lead to intra-ocular lens dislocation. Secondary cataract is more common because of aggravated blood-aqueous barrier breakdown.

Skuta G. L., Parrish R. K. et al³⁷ (1987) showed an increased incidence of zonular dialysis in patients with Pseudoexfoliation Syndrome during cataract surgery. They stated that pre-operative phacodonesis, anterior chamber depth asymmetry and excessive lens movement during anterior capsulotomy should alert to the presence of zonular dialysis.

Naumann G. O., Kuchle M. Schonherr U³⁸ (1989) noted a seven fold increase in vitreous loss in 72 patients with Pseudoexfoliation Syndrome undergoing cataract surgery.

Wang L., Yamasita R. et al³⁹ (1999) studied 26 eyes with Pseudoexfoliation Syndrome with specular microscopy and quantified the aqueous flare with laser flare cell meter. They showed that the corneal endothelial cell density was significantly decreased in eyes with Pseudoexfoliation Syndrome and an inverse correlation was shown with the flare. The authors concluded that a decrease in the endothelial cells may correlate with a disruption of blood-aqueous barrier.

Kuchle M, Naumann.H et al⁴⁰ (1997) emphasized the fact that pseudoexfoliation syndrome is frequently associated with impairment of blood-aqueous barrier and thereby have higher frequency of secondary cataract post cataract surgery.

Lumme P. Lattikainen L⁴¹ (1993) performed a prospective study of 351 patients undergoing cataract surgery. In their study the prevalence of Pseudoexfoliation Syndrome was more in patients greater than 70 years. Pseudoexfoliation Syndrome increased the risk on intra-operative complications either directly (rupture of zonules) or through poor dilation of pupil (rupture of posterior lens capsule). The occurrence of vitreous loss was four fold and the need to use anterior chamber intra-ocular lens was tenfold in these patients.

Moreno et al⁴² (2000) suggested irido-phacodonesis, poor dilatation and presence of glaucoma as the clinical factors related to capsular rupture during cataract surgery.

Freyler H. Radax U⁴³ (1994) compared Extra-capsular cataract surgery with phacoemulsification in 311 and 68 patients respectively. Miosis and phacodonesis were reported as the primary risk factors for cataract surgery associated with Pseudoexfoliation Syndrome. Compared with extra-capsular cataract surgery, phacoemulsification had significantly fewer complications with regard to miosis but not phacodonesis. They advised applying a small iris retractor, hooks to stem the complications arising from miosis.

Stanila A⁴⁴ (1996) noted that out of 868 patients undergoing cataract surgery, 10% had Pseudoexfoliation Syndrome and these patients had an increased incidence of insufficient dilatation of pupil, posterior capsular tears, Vitreous loss, increase in post-operative intra-ocular pressure and more frequent opacification of posterior capsule.

Kuchle et al⁴⁵ (2000) suggested that a shallow anterior chamber depth of less than 2.5 mm pre-operatively was indicative of zonular instability and should alert the surgeon of intra-operative complications.

Bayramlar et al⁴⁶ (2007), conducted a retrospective study in 225 eyes of 187 patients, of which 99 eyes had pseudoexfoliation syndrome. Preoperative data collected were cataract maturity level, best corrected visual acuity and intraoperative posterior capsule complications. In this study, he interpreted that in manual small incision cataract surgery, pseudoexfoliation syndrome has an increased intraoperative posterior capsule complication rate that increases at the level of cataract maturity increases and the preoperative visual acuity decreases.

Albert Galand MD, Michael Kuchle MD, Etienne Thchet MD⁴⁷ (2004) at a symposium held during the 21st congress of the ESCRS reviewed the pathophysiological alterations associated with pseudoexfoliation, the consequences of cataract surgery, and the considerations for surgical modifications and intraocular lens

selection. They stressed on poor mydriasis, a prominent feature of pseudoexfoliative eyes and its management by injection of high viscosity viscoelastic agent, also advocated use of iris hooks, either plastic or metallic as necessary. Dr. Hachet cautioned against performing sphincterotomy, which resulted in persistent dilatation and poor postoperative cosmesis, he recommended against use of circular plastic dilator to push the pupil rim aside, also advocated on use of capsular tension rings. Foldable intraocular lens is desirable to minimize the induction of blood-aqueous barrier breakdown and the accompanying increased risks for postoperative complications. Also hydrophobic acrylic and silicone are associated with a low rate of posterior capsular opacification, but hydrophobic acrylic has an additional advantage as it causes the least amount of capsular contraction. For haptics, overall, open loop haptics are probably preferred, and PMMA may be better than prolene. Dr Kuchle also discouraged the use of plate haptic design or accommodative intraocular lens in patients with pseudoexfoliation.

Vickie Lee and Anthony Maloof⁴⁸ (2002) stated that a CTR allows for the expansion and stabilization of the capsular bag by redistributing forces with the resulting tautness of bag providing counter-traction to facilitate cataract surgery and cortical aspiration. This is extremely useful for moderate degrees (i.e. up to 5 hours) of zonular dialysis. The CTR can be inserted after the completion of capsulorrhexis but before hydrodissection.

Howard Fine⁴⁹ (2008) CTR will convert a high risk case into a routine case when there is compromised zonular integrity. CTR work because the ring diameter is larger than the capsule diameter so that there is centrifugal force on the capsular fornix and this distributes focal forces. Any focal force on the capsule cannot be transmitted only to the adjacent zonules with an unzipping of the zonular apparatus - the ring

makes that focal force distributed circumferentially to the entire zonular apparatus. In cases of advanced zonulopathy with overt subluxation of the capsular bag, the capsular tension segments (CTS) can be used instead of CTR. The CTS is a 120° partial CTR that features an islet positioned within the capsulorrhexis that can receive an iris hook for support. Two CTS can be used to support a very loose bag. The CTS can also be used in eyes with anterior or posterior capsular tears. The CTS are also designed for suture sclera fixation, for long term capsular bag centration.

MANAGEMENT OF CATARACT SURGERY IN PSEUDOEXFOLIATION

SYNDROME ^{50,51,52,53,54}

These are several important points to remember for cataract surgery in eyes with Pseudoexfoliation syndrome.

1. MAKING THE DIAGNOSIS

Limited pharmacological mydriasis can adversely affect the ability to make the diagnosis. Flaky deposits on the corneal endothelium is one, due in assessing the condition. This material can be differentiated from true keratic precipitate by their bright white color and fluffy appearance. When differentiation is difficult, a one to two week course of topical steroids can aid in diagnosis, as keratic precipitates change in appearance or location or disappear with topical steroid use but have no effect on Pseudoexfoliation material.

An unusually shallow anterior chamber depth from zonular instability can indicate Pseudoexfoliation especially if it is asymmetrical. Even though a patient's cataract and symptomatic complaints are monocular, the contra-lateral eye may have subtle findings of Pseudoexfoliation which may not be seen in the planned surgical eye.

Even if Pseudoexfoliation material is not clinically visible on the corneal endothelium, the cell count may be significantly reduced and the cells that remain may not function well, hence additional endothelial protection including a "pseudoplastic" viscoelastic such as healon is advised.

2. MAXIMAL DILATATION OF PUPIL DURING SURGERY.

Poor mydriasis, a well known feature of Pseudoexfoliation syndrome can seriously hamper the surgeon's view, additional pupillary dilatation may also be necessary. Several mechanical means can temporarily dilate the pupil during surgery. These include flexible iris retractors, titanium iris retractors, flexible pupil dilating rings and rigid dilating rings. Pupil stretching maneuvers like sphincterotomies are an inexpensive and easier alternative. While these are effective, excessive inflammatory responses due to the compromised blood-aqueous barrier in these eyes are well documented. Further, the iris is more flaccid in Pseudoexfoliation syndrome and more likely to be inadvertently aspirated; mechanical means to augment mydriasis is to also keep the floppy iris margin away from the aspiration port or cannula. Care should be taken to avoid excessive iris trauma and over-inflation of the anterior chamber with viscoelastic, which can cause posterior pressure on the lens and can further damage the weakened zonules

3. ENSURING ADEQUATE CAPSULORRHEXIS/CAPSULOTOMY.

Capsulorrhexis/capsulotomy creation is more difficult in these cases, as there is no counter-traction during tearing of the anterior lens capsule. This can present as a star pattern of capsular folds radiating from your instrument when piercing the anterior lens capsule and as wrinkling and looseness of the capsule³¹.

The solution, as described by Thomas Neuhann, MD, of Germany, is to provide counter-traction via the non-dominant hand using a chopper or other second instrument via the paracentesis, while using the dominant hand to perform the capsulorrhexis via the main incision. Because of the tendency for anterior capsular phimosis and further zonular stress, a large capsulorrhexis should be performed, at least 5.5 mm in diameter. Staining the capsule with indocyanine green or trypan blue is useful. The Pseudoexfoliation material has higher affinity for indocyanine green stain than unaffected capsule.

4. ATTENTION TO PHACODONESIS WHILE PERFORMING CAPSULORRHEXIS/CAPSULOTOMY.

Weak zonules is one of the most notorious, common and significant problem faced by cataract surgeon in Pseudoexfoliation syndrome. The degree of weakening though highly variable appears to increase with apparently increasing amount of deposits. Dislocation of the nucleus into the vitreous cavity may occur even during routine hydrodissection. During capsulorrhexis or capsulotomy creation, diffuse zonular weakness or laxity may be sensed. Once this weakness is apparent, the risk of creating zonular dialysis looms large. In such cases, flexible "iris" retractors can engage the capsulorrhexis margin and stabilize the loosened capsular bag³².

5. MANAGEMENT OF ZONULAR DIALYSIS.

If a small or moderate zonular dehiscence occurs, a standard capsular tension ring can re-expand the capsular bag and redistribute the mechanical stresses evenly across the remaining zonules. The capsular tension ring (CTR) can be manually implanted into the fornix of the capsular bag or injected with the inserter device. For a large zonular dehiscence, a suture-fixated, modified Cionni ring with one or two

fixation eyelets will re-expand the capsular bag and secure the capsular bag or intraocular lens complex to the sclera wall.

6. CHOICE OF INTRAOCULAR LENS.

Capsular contraction is more likely since there is reduced zonular counter-traction against the centripetal forces of the remaining lens epithelial cells. Capsulorrhexis of 5mm or greater, and use of a capsular tension ring to reduce the risk of this complication is advisable. As capsular contraction is more common with silicone intraocular lens, another material is preferred. An intraocular lens with a sharp posterior edge to reduce lens epithelial cell migration and subsequent posterior capsular opacification is recommended.

Pseudoexfoliation syndrome adds to the challenges of cataract surgery. Some of these challenges are significant. With the use of dyes, capsule retractors and implant rings and meticulous attention to surgical technique, cataract surgery in Pseudoexfoliation syndrome may be safely performed.

METHODOLOGY

TITLE OF THE STUDY:

"A cross sectional study of the outcome of small incision cataract surgery in pseudoexfoliation syndrome cases done at KLE'S Dr Prabhakar Kore Hospital and MRC,Belgaum"

SOURCE OF DATA:

Patients attending Ophthalmology OPD at KLE Dr Prabhakar Kore Hospital and MRC,Belgaum from January to December 2009.

SAMPLE SIZE:

A total number of 45 eyes with 45 patients were selected for the study that had cataract in patients with pseudoexfoliation syndrome.

Inclusion Criteria

- I. Cataractous changes including cortical, nuclear, sub capsular, capsular.
- II. All patients diagnosed with Pseudoexfoliation syndrome.
- III. Normal posterior segment findings.
- IV. Patients willing to give consent.

Exclusion Criteria

- I. Previous ocular trauma, manifest luxation or extensive sub-luxation of the lens.
- II. Previous intra-ocular surgery & laser treatment
- III. Patients with Diabetes Mellitus, secondary cataract & anterior uveitis

IV. Glaucoma cases

V. Patient not willing to give consent.

PREOPERATIVE EVALUATION.

1. Visual acuity testing for distance and near using Snellen's distant chart and near vision chart respectively.
2. Refraction and correction where required.
3. External ocular examination.
4. Slit lamp biomicroscopic examination for evidence of the following findings.
 - Pseudoexfoliation material in the pupillary margins.
 - Morphological alterations of the cornea
 - Anterior chamber depth and pigment dispersion in the anterior chamber
 - Iridodonesis.
 - Presence of posterior synechiae.
 - Zones of Pseudoexfoliation on the anterior surface of the lens capsule.
 - Phacodonesis or frank subluxation/dislocation of lens.
 - Measurement of pupil size before and after dilatation of pupil.
 - Pupillary reactions.
5. Tonometry using Schiottz tonometer.
6. Gonioscopy with Goldmann three mirror lens in all patients with pseudoexfoliation syndrome. The following points were specifically evaluated.

- The extent of trabecular pigmentation which was graded as:

Grade 0	Nil
Grade 1	Faint Pigmentation
Grade 2	Average Pigmentation
Grade 3	Moderate Pigmentation
Grade 4	Heavy Pigmentation

- The presence of pseudoexfoliation material in the angle.
- The presence of Sampolesi's line.
- The grading of angle width according to Shaffer's grading.

Grade	Angle width (degree)	Configuration	Chance of closure	Structure visible on gonioscopy.
4	35-45	Wide open	Nil	From Schwalbe's line to cilliary
3	20-35	open	Nil	From Schwalbe's line to sclera spur
2	30	Moderately narrow	Possible	From Schwalbe's line to trabecular meshwork
1	10	Very narrow	High	Schwalbe's line only
0	0	Closed	Closed	None of the structures visible.

7. The pupils were then dilated with a combination of 5% phenylephrine and tropicamide 0.8mg 1 drop was instilled every 5 minutes over a 15 minute interval.
8. This was followed by slit lamp examination for
 - Measuring pupil dilatation.
 - Examination of lens capsule for central and peripheral zones of pseudoexfoliation material deposition.
 - Evaluation of lens for the type of cataract.
9. Fundoscopy
10. Lacrimal patency test
11. Keratometry
12. A-scan and Intraocular lens power calculation by SRK-2 formula.

Other investigations included

- Urine examination for detection of sugar and albumin.
 - Random blood sugar

SURGICAL TECHNIQUE

All patients were given systemic antibiotics (tablet ciprofloxacin 500mg b.d.) on the preoperative day. On the day of surgery pupils were dilated adequately using instillation of 0.8mg tropicamide and 5% phenylephrine eye drops every 10 minutes, one hour before surgery. To sustain the pupil dilatation the anti- prostaglandin eye drops such as flurbiprofen should be instilled three times one day before surgery and half hourly for two hours immediately before surgery.

SURGICAL STEPS OF MANUAL SMALL INCISION CATARACT SURGERY

1. The eye to be operated is painted, draped and prepared for surgery under aseptic precautions.
2. Local anesthesia is given using 2% xylocaine mixed with 1500 units of hyaluronidase.
3. Universal wire speculum applied.
4. Superior rectus (bridle) suture is passed to fix the eye in downward gaze.
5. A small fornix based conjunctival flap is made, and sclera is exposed.
6. Haemostasis is achieved by applying gentle and just adequate electrocautery.
7. A self sealing sclera-corneal tunnel incision is made.
8. Anterior capsulotomy by continuous curvilinear capsulorrhexis or can-opener's technique was left to surgeon's choice.
9. Hydrodissection is done to separate cortico-nuclear mass from the posterior capsule.
10. Depending on the degree of mydriasis the pupil was stretched mechanically or sphincterotomies were done, depending on the operating surgeon's discretion.
11. Synechiolysis was done if required
12. Nucleus was delivered.
13. Cortical matter was removed by irrigation and aspiration.

14. In case of a posterior capsule tear, the integrity of the capsular bag was assessed to place the intraocular lens.

15. In case of vitreous loss, manual anterior vitrectomy was done.

16. If there were no complications, posterior chamber intraocular lens was placed in the capsular bag.

17. The viscoelastic was cleared from the anterior chamber.

18. Subconjunctival gentamycin and dexamethasone 0.5cc was given at the end of the procedure.

19. Pad and bandage applied.

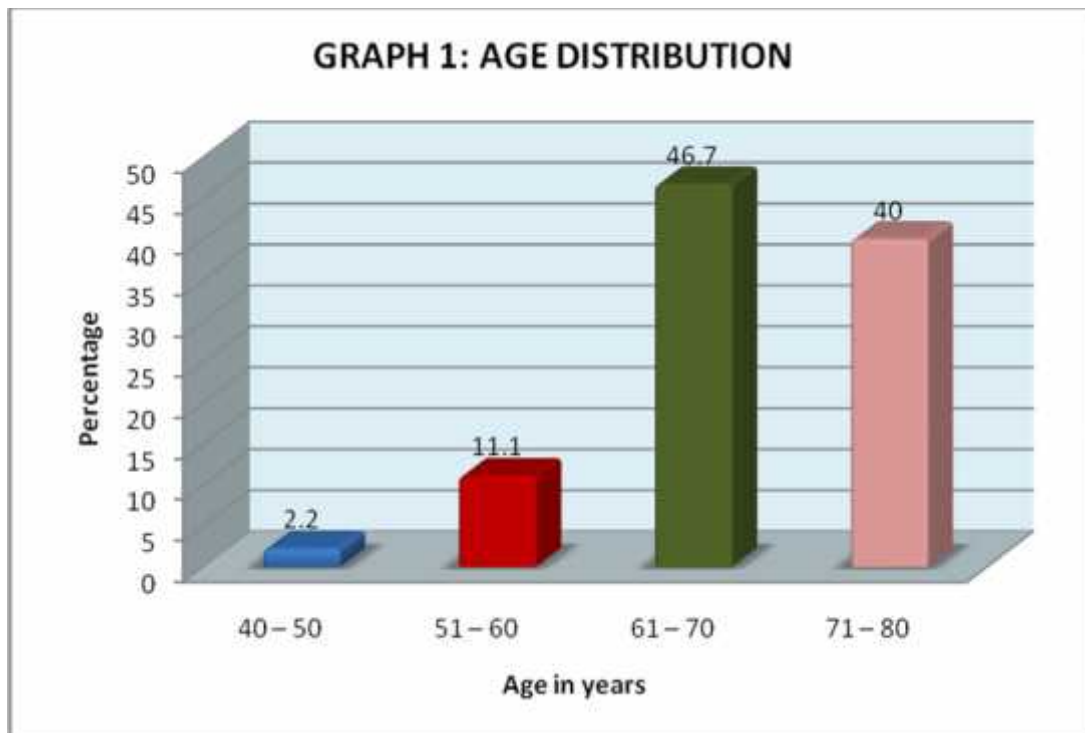
Postoperatively all the patients received a course of topical antibiotic and steroid eye drops one hourly. Systemic antibiotic was given for 5 days postoperatively.

RESULTS

ANALYSIS PLAN

TABLE 1 AGE DISTRIBUTION :

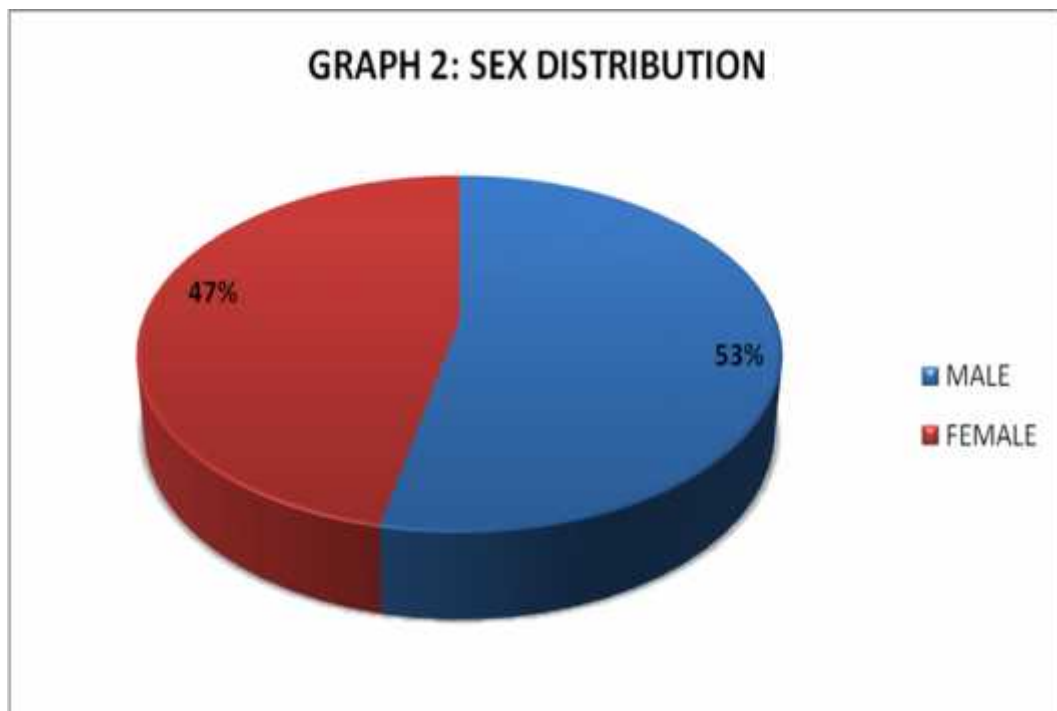
AGE (YEARS)	No of cases	%
40 – 50	1	2.2
51 – 60	5	11.1
61 – 70	21	46.7
71 – 80	18	40



As shown in table 1, in our study there were 1 (2.2 %) patients of age group 40-50 years, 5 (11.1%) patients of age group 51-60 years, 21 (46.7 %) of age group 61- 70 and 18(40%) of age group 71-80. The average age of patients was 65.83 years and about 39 (86.4 %) of patients were above 60 yrs of age.

TABLE 2 SEX DISTRIBUTION :

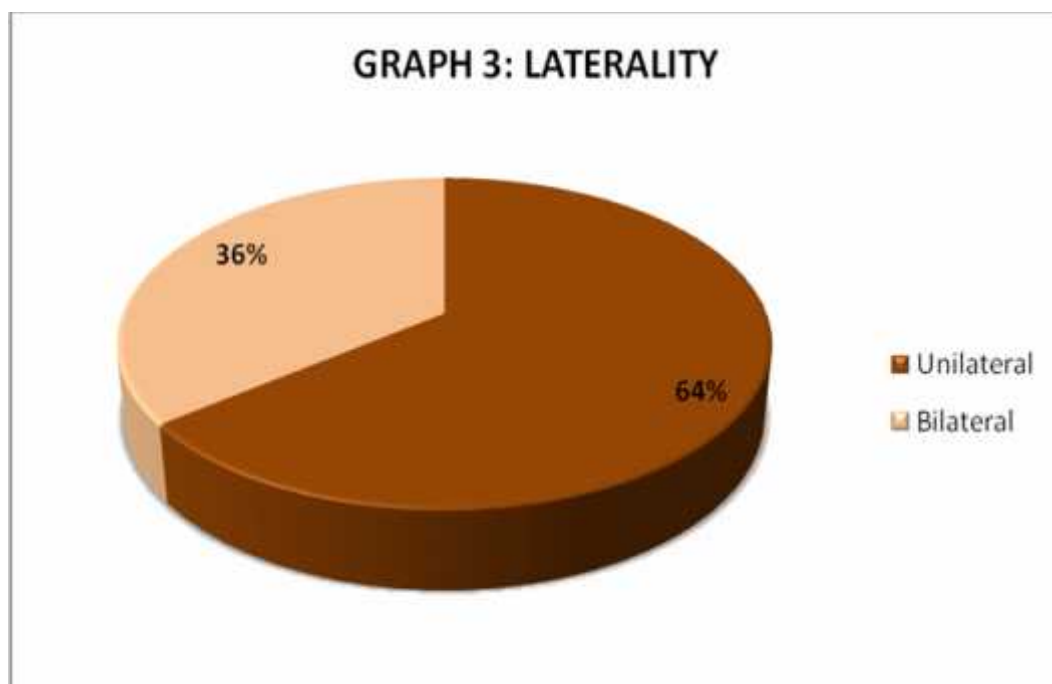
SEX	No of cases	%
MALE	24	53.3
FEMALE	21	46.7



As shown in table 2, in our study 24 (53.3%) were males and 21 (46.7%) were females.

TABLE 3 LATERALITY

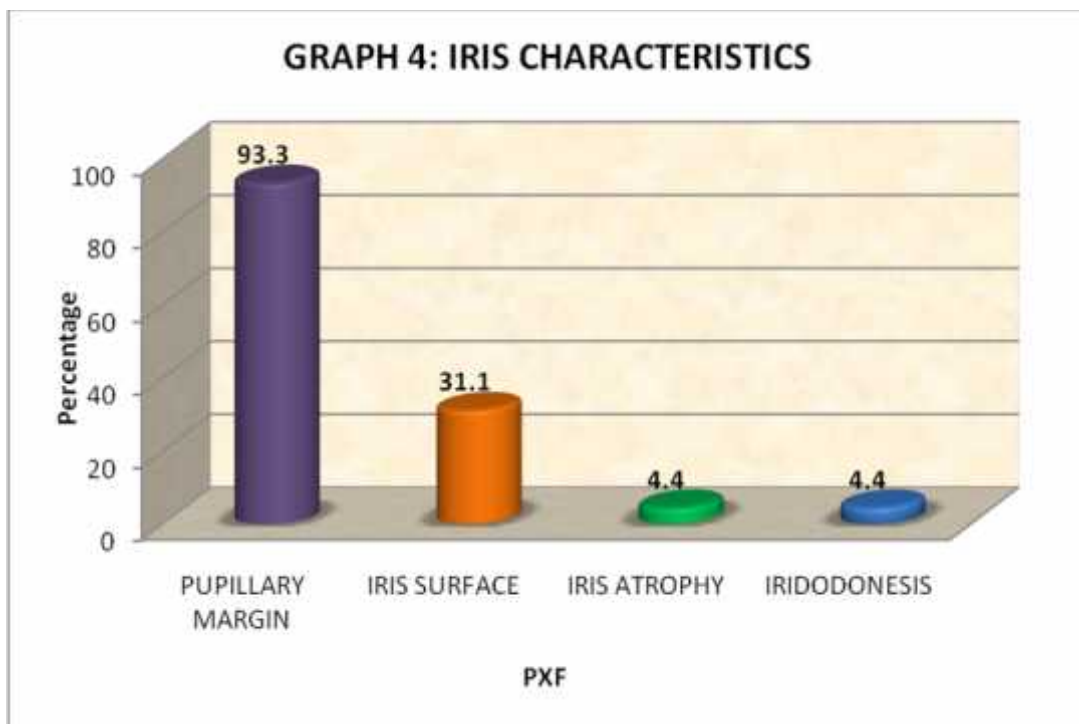
LATERALITY	No of cases	%
Unilateral	29	64.4
Bilateral	16	35.6



As shown in table 3, in our study 16 (35.6%) of patients had clinical bilateral involvement of Pseudoexfoliation syndrome and 29 (64.4%) had unilateral involvement.

TABLE 4 IRIS CHARACTERISTICS

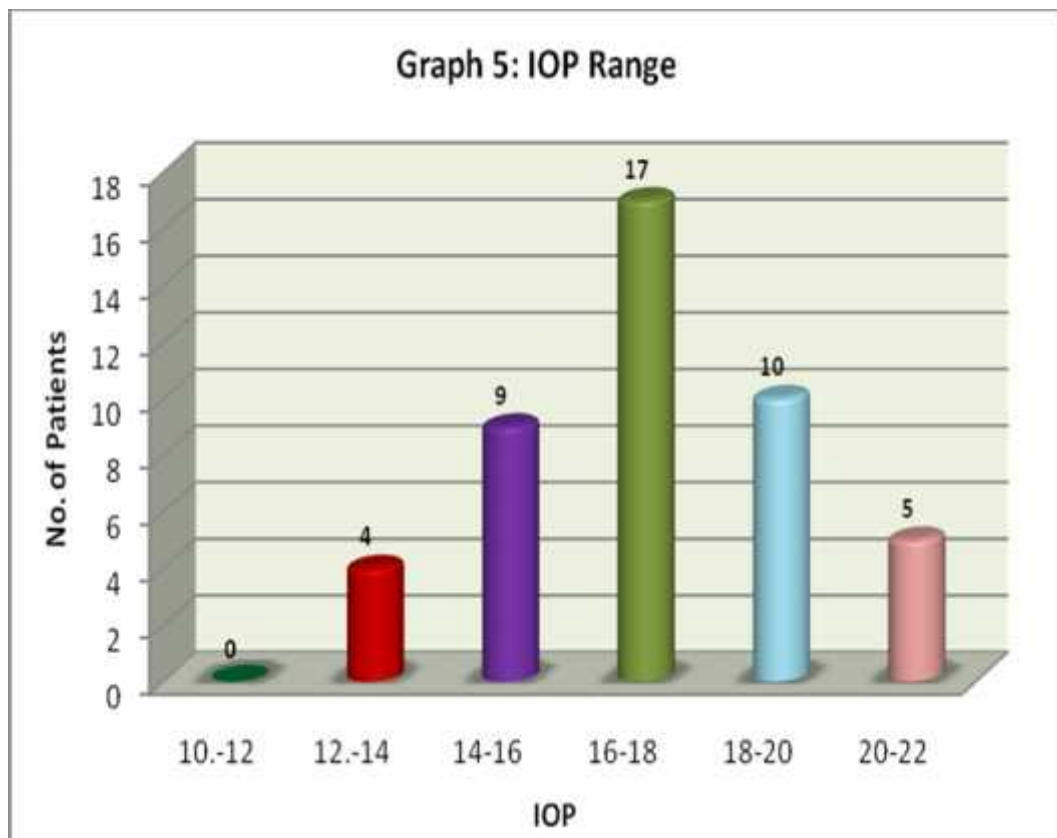
PXF	NO OF CASES	%
PUPILLARY MARGIN	42	93.3
IRIS SURFACE	14	31.1
IRIS ATROPHY	2	4.4
IRIDODONESIS	2	4.4



As shown in table 4, in our study 93.3% of patients had Pseudoexfoliation material on the pupillary margin, 14 (31.1%) on the iris surface, 2 (4.4 %) have Iris Atrophy, 2 (4.43) have Iridodonesis and none had posterior synechiae.

TABLE 5: IOP RANGE

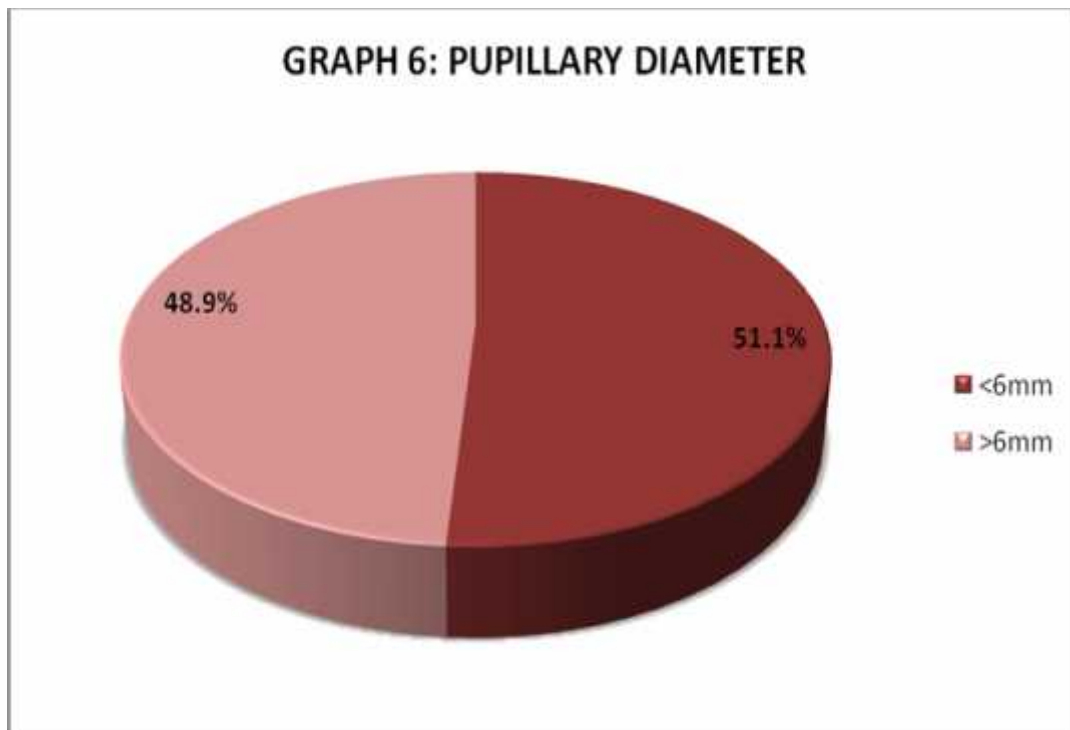
IOP	No.of Patients
10.-12	0
12.-14	4
14-16	9
16-18	17
18-20	10
20-22	5



As shown in Table 5, out of 45 patients in the present study group, the range of IOP was from 7.8 mm Hg to 20.6 mm Hg with an average IOP reading of 17 mm Hg.

TABLE 6 PUPILLARY DIAMETER:

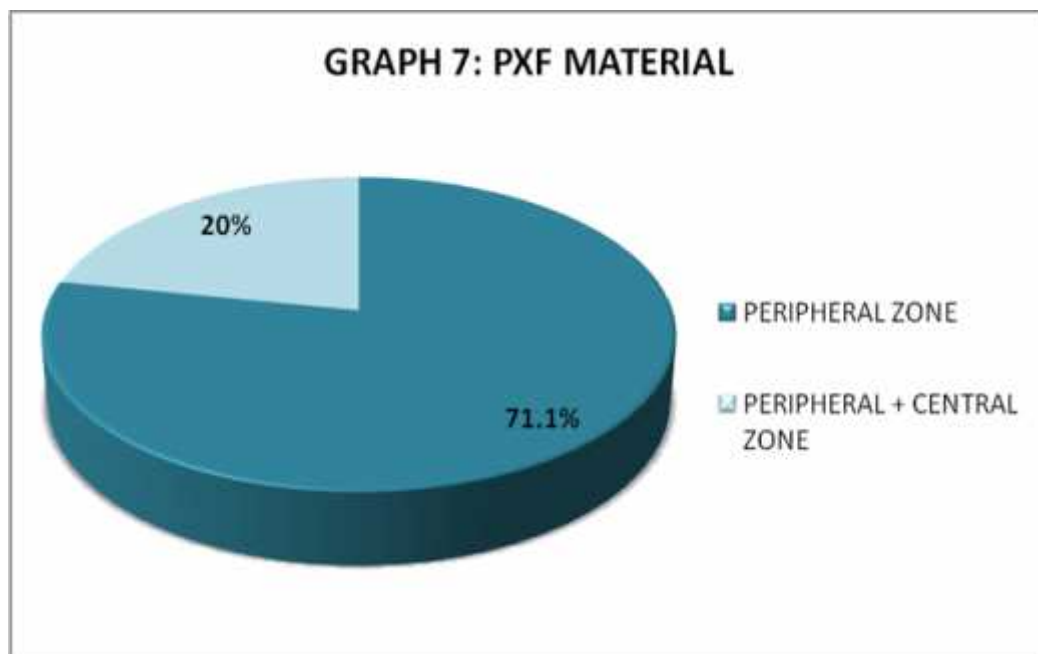
	NO OF CASES	PERCENTAGE
<6mm	23	51.1
>6mm	22	48.9



As shown in Table 6, 23 (51.1 %) of patients had insufficient mydriasis, and 22 (48.9 %) of the patients had sufficient mydriasis.

TABLE 7 PXF MATERIAL

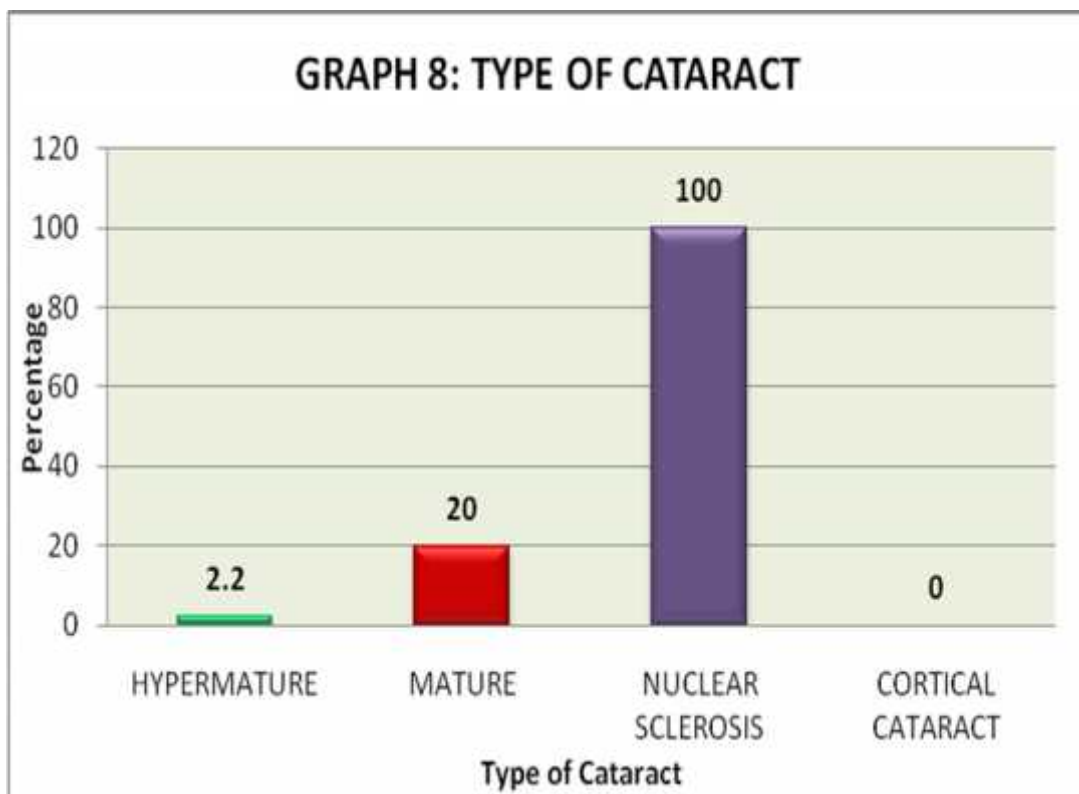
PXF	NO OF CASES	%
PERIPHERAL ZONE	32	71.1
PERIPHERAL + CENTRAL ZONE	9	20



As shown in Table 7, in our study 32 (71.1 %) of the patients had PXF material deposited on the peripheral zone, 9 (20 %) had PXF deposition on both peripheral zone and central zone and none of them had only central zone.

TABLE 8 TYPE OF CATARACT

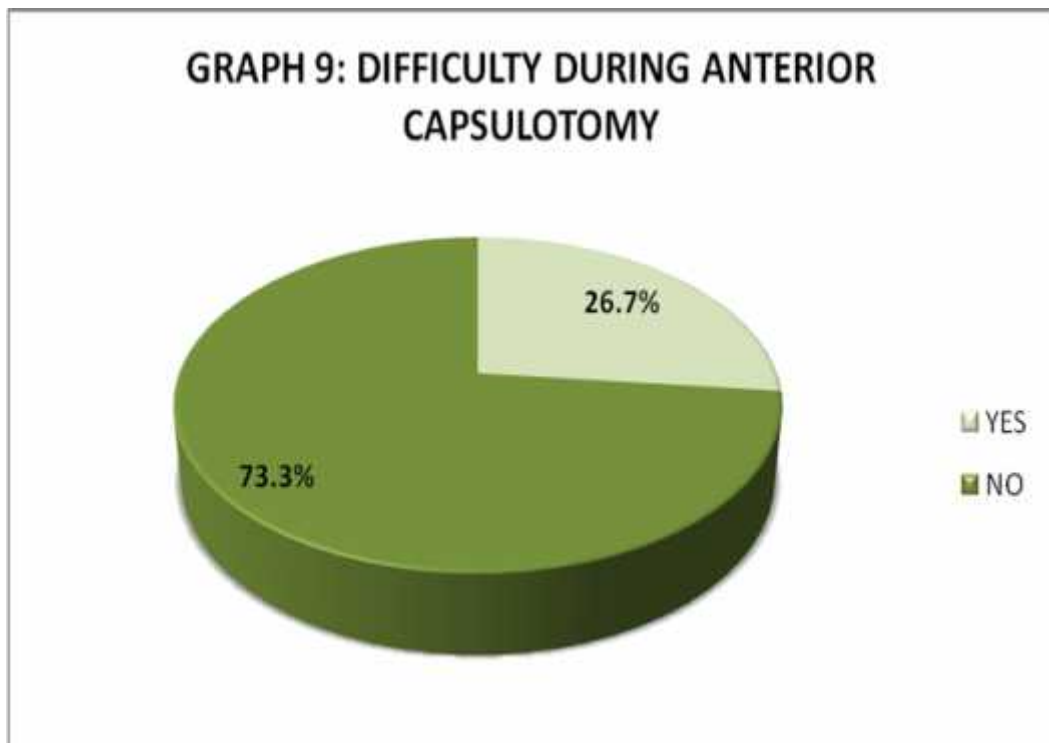
TYPE OF CATARACT	NO OF CASES	%
HYPERMATURE	1	2.2
MATURE	9	20
NUCLEAR SCLEROSIS	45	100
CORTICAL CATARACT	0	0



As shown in Table 8, in our study 9 (20%) of the patients had Mature Cataract, 1 (2.2%) had hypermature cataract. All of them, i.e. 100%, had Nuclear Cataracts. None had isolated cortical cataract.

TABLE 9 DIFFICULTY DURING ANTERIOR CAPSULOTOMY:

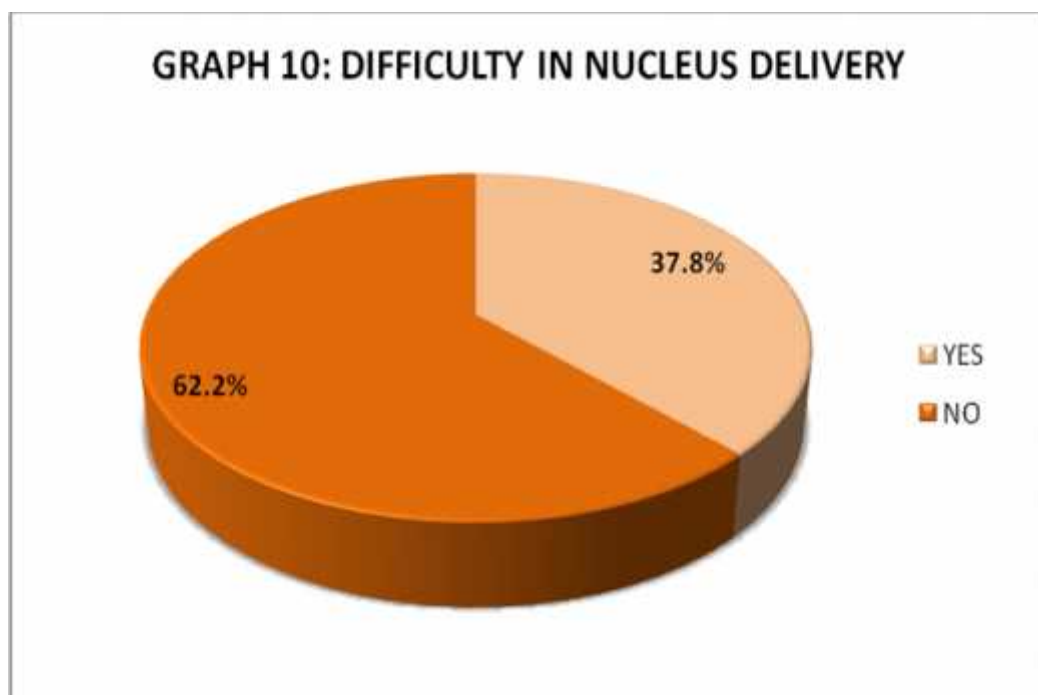
	NO OF CASES	PERCENTAGE
YES	12	26.7
NO	33	73.3



As shown in table 9,difficulty during anterior capsulotomy was noted in 12(26.7%) cases.

TABLE 10 DIFFICULTY IN NUCLEUS DELIVERY:

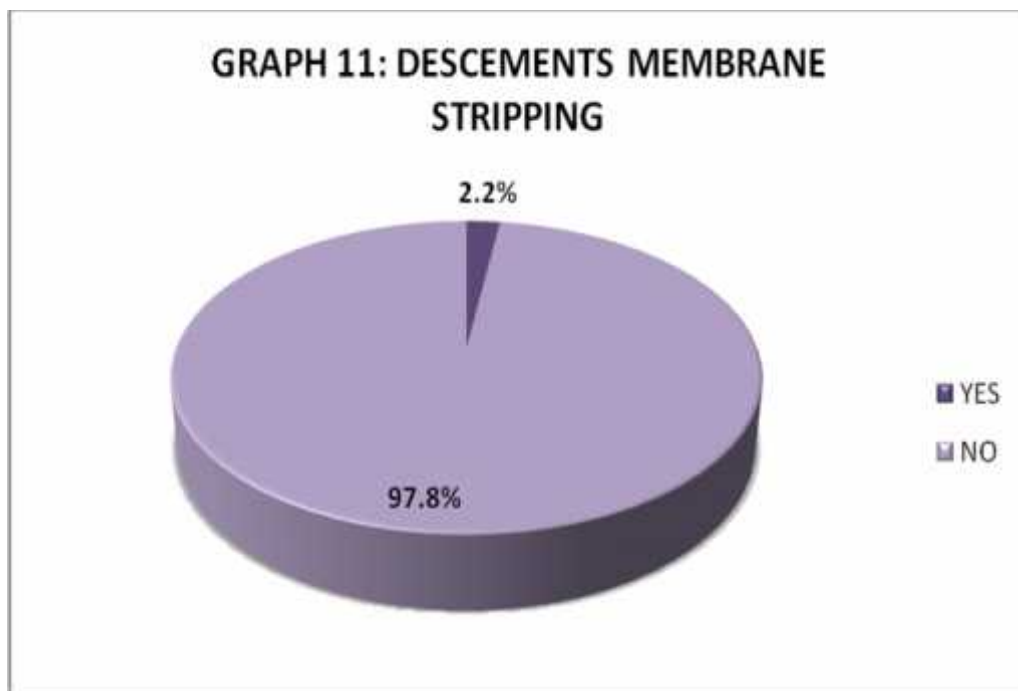
	NO OF CASES	PERCENTAGE
YES	17	37.8
NO	28	62.2



As shown in table 10, difficulty in nucleus delivery was noted in 17(37.8%) cases.

TABLE 11 DESCEMENTS MEMBRANE STRIPPING:

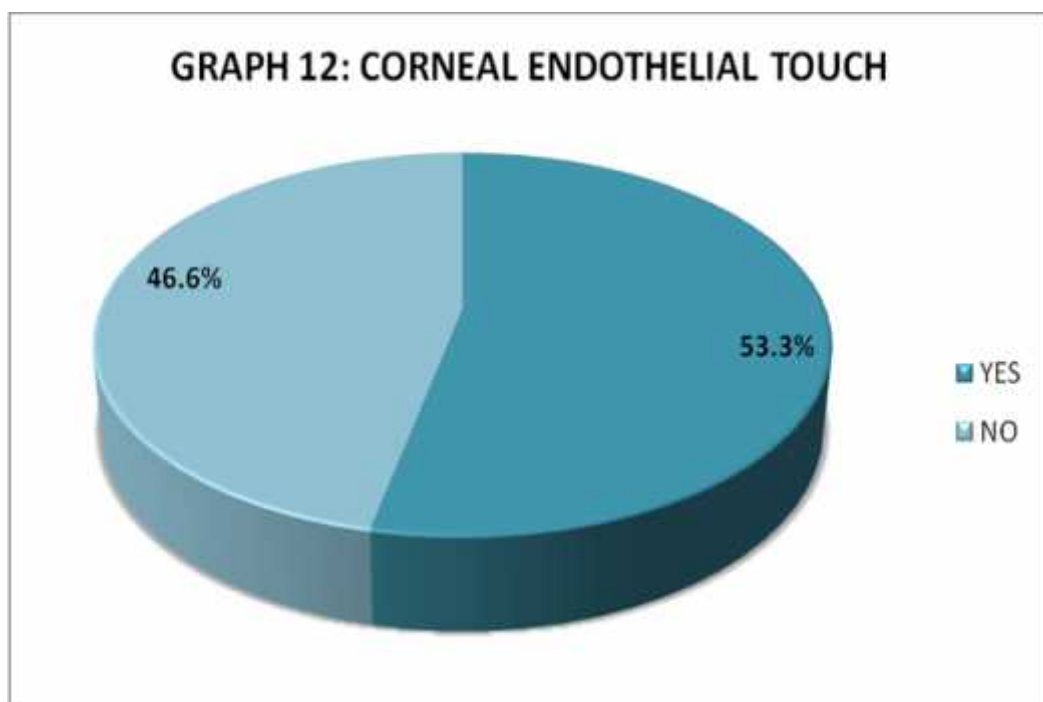
	NO OF CASES	PERCENTAGE
YES	1	2.2
NO	44	97.8



As shown in table 11, descements membrane stripping was seen in only 1(2.2%) cases.

TABLE 12 CORNEAL ENDOTHELIAL TOUCH:

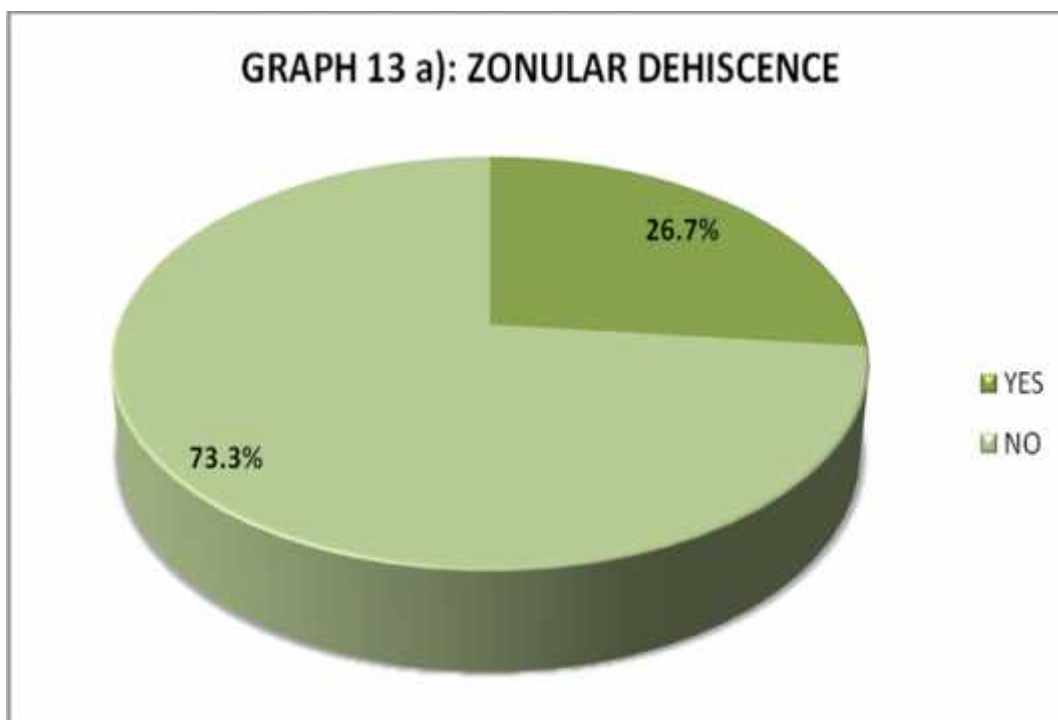
	NO OF CASES	PERCENTAGE
YES	24	53.3
NO	21	46.6



As shown in table 12, in our study corneal endothelial touch was noted in 24(53.4%) cases. It was documented when the operating surgeon told about it, and also the subsequent post-operative corneal edema.

TABLE 13 ZONULAR DEHISCENCE:

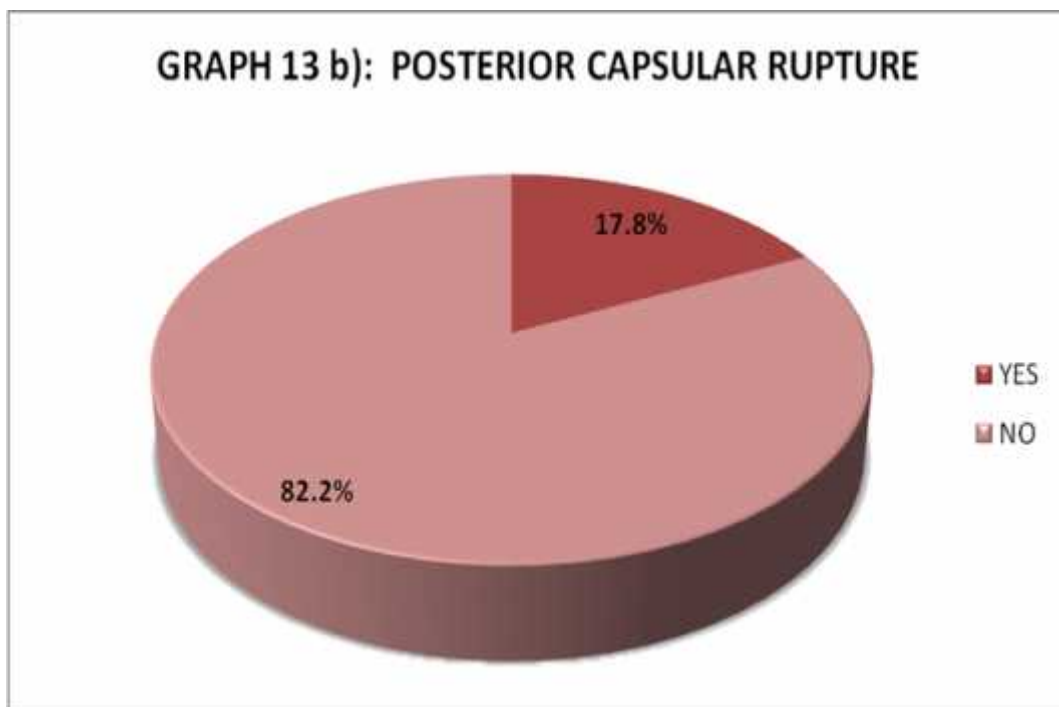
	NO OF CASES	PERCENTAGE
YES	12	26.7
NO	33	73.3



As shown in Table 13, 12 (26.7 %) of patients had Zonular dehiscence.

POSTERIOR CAPSULAR RUPTURE:

	NO OF CASES	PERCENTAGE
YES	8	17.8
NO	37	82.2



In our study 8 (17.8 %) of the patients had Posterior Capsular Rent.

VITREOUS LOSS:

	NO OF CASES	PERCENTAGE
YES	8	17.8
NO	37	82.2

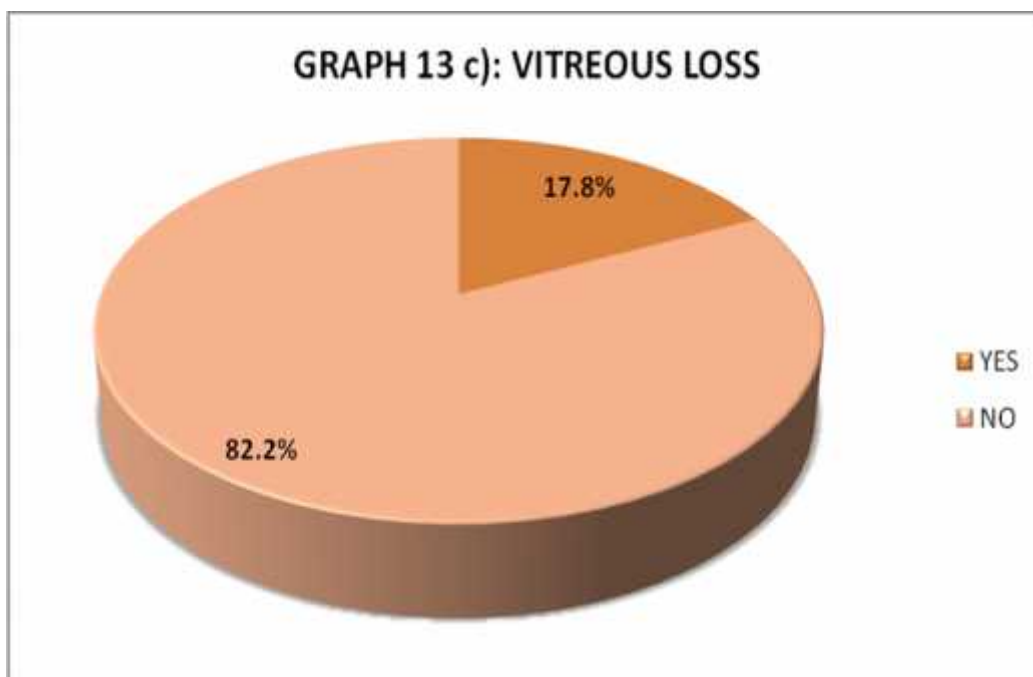
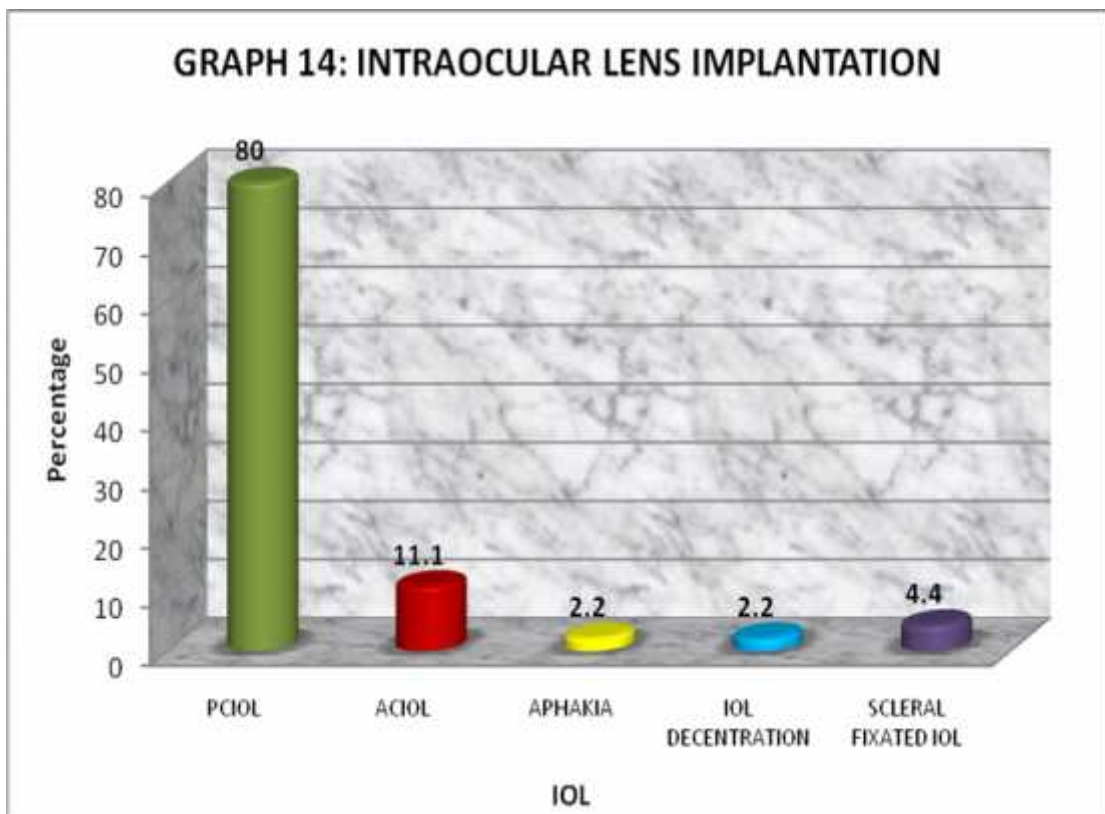


TABLE 14 INTRAOCULAR LENS IMPLANTATION

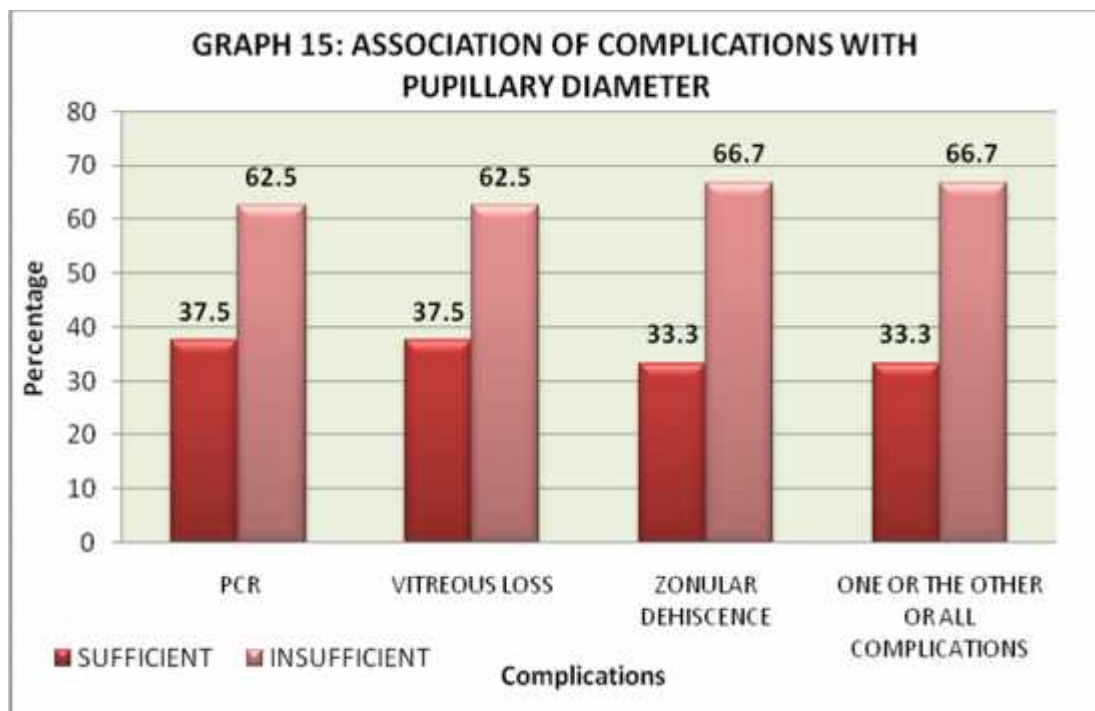
IOL	NO OF CASES	PERCENTAGE
PCIOL	36	80
ACIOL	5	11.1
APHAKIA	1	2.2
IOL DECENTRATION	1	2.2
SCLERAL FIXATED IOL	2	4.4



As shown in Table 14, 44 (97.8 %) of the patients were implanted with intraocular lens after employment of various surgical modifications like Sphincterotomy, Synecholysis, manual Anterior Vitrectomy. 1 (2.2 %) of the patients were left aphakic due to the above mentioned complications.

TABLE 15 ASSOCIATION OF COMPLICATIONS WITH PUPILLARY DIAMETER

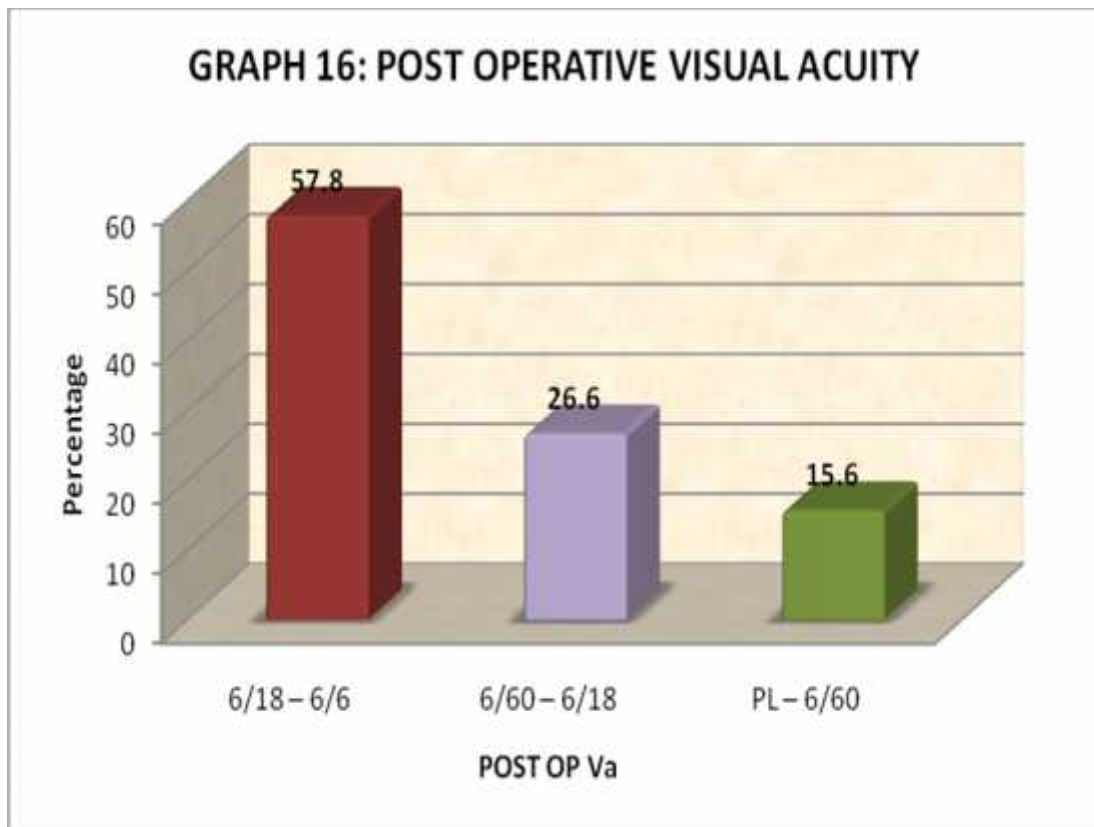
COMPLICATION	NO OF CASES	%	MYDRIASIS			
			SUFFICIENT		INSUFFICIENT	
			NO OF CASES	%	NO OF CASES	%
PCR	8	17.8	3	37.5	5	62.5
VITREOUS LOSS	8	17.8	3	37.5	5	62.5
ZONULAR DEHISCENCE	12	26.7	4	33.3	8	66.7
ONE OR THE OTHER OR ALL COMPLICATIONS	24	53.4	8	33.3	16	66.7



As shown in Table 15, out of 8 (17.8 %) of the patients with posterior capsular rent, 5 (62.5%) of them had insufficient mydriasis while 3 (37.5 %) of them had adequate mydriasis. Out of 8 (17.8 %) of the patients who had Vitreous loss, 5 (62.5 %) of them had insufficient mydriasis while 3 (37.5 %) of them had adequate mydriasis. Of the 12 (26.7 %) of the patients with Zonular dehiscence, 8 (66.7 %) of them had insufficient mydriasis while 4 (33.3 %) of them had adequate mydriasis. Out of the total 45 patients, 24 (53.4 %) patients who had one or the other or all of the above complications, 16 (66.7 %) of them had insufficient mydriasis and 8 (33.3 %) of the patients had adequate mydriasis.

TABLE 16 POST OPERATIVE VISUAL ACUITY

POST OP Va	NO OF CASES	%
6/18 – 6/6	26	57.8
6/60 – 6/18	12	26.6
PL – 6/60	7	15.6



As shown in table 16, post operative vision of 6/18-6/6 was noted in 23(51.1%) cases, visual acuity of 6/60 – 6/18 was noted in 15(33.3%) cases and visual acuity of perception of light to 6/60 was noted in 7(15.6%) cases.

DISCUSSION

This study consisted of 45 eyes of 45 patients with Pseudoexfoliation syndrome who underwent manual small incision cataract surgery in KLE Dr Prabhakar Kore Hospital and MRC, Belgaum.

As shown in table 1, there were 1 (2.2 %) patients of age group 40-50 years, 5 (11.1%) patients of age group 51-60 years, 21 (46.4 %) of age group 61- 70 and 18(40%) of age group 71-80. The average age of patients was 65.83 years and about 39 (86.4 %) of patients were above 60 yrs of age. The prevalence of Pseudoexfoliation syndrome increases with age. Pseudoexfoliation syndrome usually occurs between 60 to 80 yrs, the average age being 70 yrs. In this study, 86.4 % of the patients are in the age group of 60 - 80 years which is in concurrence with the mentioned studies.

As shown in table 2, 24 (53.3%) were males and 21 (46.7%) were females. Studies regarding the sex distribution of Pseudoexfoliation syndrome are conflicting. Women have predominated in some series while other studies have found equal or greater prevalence in men.

As shown in table 3, 16 (35.6%) of patients had clinical bilateral involvement of Pseudoexfoliation syndrome and 29 (64.4%) had unilateral involvement. A review of literature comparing the frequency of monocular versus binocular involvement in various series is not conclusive. Many series have reported bilateral involvement to be more common with ratios as high as 3:1 while other studies have reported unilateral involvement to predominate again with ratios as high as 3:1.

Hammer, Schlotzer- Schrehardt, Naumann⁵⁵ in 2001 carried out an ultrastructural study of the contralateral eye in 5 pairs of donor eyes with unilateral Pseudoexfoliation syndrome. They showed "ultrastructural" alterations in anterior

segment tissues of all the eyes. They concluded that basically Pseudoexfoliation syndrome is a bilateral disease with clinically marked asymmetric manifestations. The reasons for this marked asymmetry remain unknown. Clinically unilateral involvement is often a precursor to bilateral involvement within 5- 10 yrs after diagnosis.

As shown in table 4, 93.3% of patients had Pseudoexfoliation material on the pupillary margin, 14 (31.1%) on the iris surface, 2 (4.4 %) have Iris Atrophy, 2 (4.43) have Iridodonesis and none had posterior synechiae in this study group. This is in concurrence with the study by **Ritch Schlotzer. Scherhardt**⁵⁶ (2001) stated that deposits of Pseudoexfoliation material on the iris sphincter and pupillary margin are seen in 84% patients. Thus next to the lens Pseudoexfoliation material, the most prominent and consistent clinical finding is the Pseudoexfoliation material at the pupillary border.

In the present study, 13 (43.33 %) of patients had average trabecular pigmentation, and 10 (33.33 %) of patients had 'moderate trabecular pigmentation' and 7 (23.33 %) of patients had 'heavy pigmentation'. None of the patients had 'Absent Or Faint Pigmentation'.

The extent of trabecular pigmentation has been correlated to the degree of increased intraocular pressure.

In this present study, 24 (53.3 %) of the patients had Pseudoexfoliation material in the angle and the same was absent in 21 (46.7 %) of the patients. In the present study is very close by to the study conducted by **Sunde** (1956).

Sunde (1956) found flakes of Pseudoexfoliation material in the angle in 18.75% of the patients with pseudoexfoliative glaucoma. But **Tarkkanen** (1962) found Pseudoexfoliation material in the angle on gonioscopic examination in 46% of

glaucomatous eyes and 50% of non glaucomatous eyes. Thus the two conditions can occur simultaneously or separately and the relation between them is not clear.

Schlotzer-Scherhardt et al (1992) found a significant correlation between the extent of Pseudoexfoliation material in the angle and Pseudoexfoliation syndrome. Of the 45 patients, all had open angles. In studies of patients with Pseudoexfoliation syndrome, occludable angles were noted in 9-18% of patients (**Bruce shields** 1999, fourth edition).

Ritch, Schlotzer - Scherhardt (2001) noted 23% of patients with pseudoexfoliation syndrome and glaucoma to have grade 2 or narrow angles.

Wishart et al⁵⁷ (1985) noted 32% of patients in their study to have narrow angles.

As shown in Table 5, out of 45 patients in the present study group, the range of IOP was from 7.8 mm Hg to 20.6 mm Hg with an average IOP reading of 17 mm Hg.

In patients with pseudoexfoliation syndrome, 20% have glaucoma and increased IOP at the time of diagnosis. Patients who have pseudoexfoliation syndrome but not glaucoma should be considered vulnerable to glaucoma, because 15% of such patients develop increased IOP within 10 years. This underscores the need for careful follow-up in patients who have pseudoexfoliation syndrome. Pseudoexfoliation syndrome accounts for 15-20% of cases of open angle glaucoma. In the present study only the patients having normal IOP were enrolled and cases with glaucoma were excluded as this would hinder on the visual outcome.

As shown in Table 6, 23 (51.1 %) of patients had sufficient mydriasis, and 22 (48.9 %) of the patients had insufficient mydriasis. This is in concurrence with the following studies.

Freyler H, Radax U (1990) noted pupillary dilatation less than 4 mm in 19 of 32 patients with pseudoexfoliation syndrome who underwent cataract surgery.

Asano N, Schlotze - Scherhardt, Naumann (1996) attributed poor mydriasis in Pseudoexfoliation syndrome to degenerative changes of sphincter and dilator muscle tissues and apparent involvement of the muscle cells in Pseudoexfoliation material fiber formation.

Repo L.P. et al (1996) found degenerative changes in both the stromal tissue and in the muscular layer of iris and regarded this as one of the causes for miosis.

Alfaite et al (1996) noticed significant insufficient mydriasis (p value < 0.001) in their study of 31 patients with Pseudoexfoliation syndrome. Reduction of stromal elasticity by accumulation of pseudoexfoliation material may also play a role in poor mydriasis.

Stanila A (1996) also noted an increased incidence of insufficient pupil dilatation in the 10 patients with Pseudoexfoliation syndrome undergoing cataract surgery in their study.

Avramides S, Trainanidis P, Sakkias G (1997) in their study of 84 patients with Pseudoexfoliation syndrome who underwent ECCE, noted that 61.90% of them had pupillary dilatation less than 5 mm.

In the present study, NONE had pigment dispersion after mydriasis. **Prince, A.M., Ritch R**⁵⁹ (1986) reported that anterior chamber melanin dispersion after mydriasis may be seen as a whorl like pattern of pigment particles on iris sphincter and peripheral iris.

Ritch R, Schlotze - Scherhardt (2000) reported pigment dispersion in the anterior chamber after mydriasis to be common and profuse in Pseudoexfoliation

syndrome. Pigment dispersion after mydriasis is one of the suspicious sign to meticulously look out for Pseudoexfoliation syndrome in preclinical stages.

As shown in Table 7, 32 (71.1 %) had peripheral zone, 9 (20 %) had both peripheral zone and central zone and none of them had only central zone. The peripheral zone of pseudoexfoliation material is a consistent finding and the central zone is not always apparent (**M. Bruce Shields**). **Tarkkanen** (1962) found the central zone absent in 18% of cases in his study while **Rtich, Schlotzer - Scherhardt** (2001) found it absent in 20 - 60% of their cases.

As shown in Table 8, 9 (20%) of the patients had Mature Cataract, 1 (2.2%) had hypermature cataract . All of them, i.e. 100 %, had Nuclear Cataracts.

Cortical Cataract was present along with advanced nuclear cataract and none of the patients had isolated cortical cataract.

Seland et al⁶⁰ (1982) have reported a higher incidence of nuclear cataract in eyes with pseudoexfoliation syndrome with fewer cortical cataracts. **Hietanen J.** et al have also reported nuclear cataract to be the predominant type of cataract in Pseudoexfoliation syndrome.

Ritch R, Schlotze - Scherhardt (2001) have also reported an increased incidence of nuclear cataract in Pseudoexfoliation syndrome. In the present study, 3 (6.7%) of patients had phacodonesis. **Futa R. Furnyoshi**⁶¹ (1989) reported an 8.4% incidence, while **Moreno J., Duch S., Harara J** (1993) reported a 10.6% incidence of phacodonesis. 1 (3.33 %) of the patients had iridodonesis. This is because the iris in Pseudoexfoliation syndrome is more rigid due to vascular compromise and various other changes like deposition of Pseudoexfoliation material, Atrophy, Loss of iris stroma - Moth Eaten Appearance.

As shown in table 9, difficulty during anterior capsulotomy was noted in 12(26.7%) cases.

6 (13.33 %) patients underwent sphincterotomy.

As shown in table 10, difficulty in nucleus delivery was seen in 17(37.8%) cases. The main reason behind this complication was of the presence of large and hard nucleus.

As shown in table 11, descemments membrane stripping was seen in only 1(2.2%) cases. Due to more handling of the nucleus and more manipulation it occurred and a air bubble was put after attaching it.

As shown in table 12, corneal endothelial touch was seen in 24(53.4%) cases. It was documented when the operating surgeon told about it. Correspondingly corneal edema was noted on the first post op day. The main step where it invariably occurred was during nucleus delivery.

As shown in Table 13, 12 (26.7 %) of patients had Zonular dehiscence, 8 (17.8 %) of the patients had Posterior Capsular Rent and 8 (17.8 %) of the patients had Vitreous loss. As shown in Table 9, 24 (53.3 %) of the patients had intraoperative complication while 21 (46.7 %) did not.

As shown in Table 14, 44 (97.8 %) of the patients were implanted with intraocular lens after employment of various surgical modifications like Sphincterotomy, Synecholysis, manual Anterior Vitrectomy. 1 (2.2 %) of the patients were left aphakic due to the above mentioned complications.

Scrolloli et al⁶² (1998) have found that PEX patients were five times more likely to develop intraoperative complications during cataract surgery compared to patients without the condition.

Schonherr U et al (1989) found a statistically significant increase in intraoperative and postoperative complication in eyes with Pseudoexfoliation syndrome in their study of 436 patients.

Freyler H, Radax U (1990) found 26 of their 36 patients with Pseudoexfoliation syndrome undergoing ECCE to have intraoperative complication - Zonular dehiscence, Posterior capsular rent and Vitreous loss.

Various studies in eyes with Pseudoexfoliation syndrome have quoted the incidence of Zonular dehiscence to be 17.90%. **Hovding G** (1998), 13.1% by **Avramides S** (1997) and 14.8% by **Lumme P, Laatikanan** (1993).

Alfaite et al (1996) in their study of 31 patients found zonular dehiscence to be more common in eyes with Pseudoexfoliation syndrome but this was not statistically significant when compared to eyes without Pseudoexfoliation syndrome.

Stanila (1996) also reported an increased incidence of Posterior capsular rent and Vitreous loss in their study of 10 eyes with Pseudoexfoliation syndrome undergoing ECCE.

Kuchle et al (2000) found 6.9% of their 11 patients to have intraoperative complication namely - zonular dehiscence and vitreous loss. Zonular fragility in Pseudoexfoliation syndrome increases the risk of lens dislocation, zonular dehiscence and vitreous loss up to 10 times (Ritch R, 2001).

Lumme P, Laatikanan L (1993) found the incidence of vitreous loss to be fourfold more in eyes with Pseudoexfoliation syndrome and Posterior capsular rent to be 10 fold higher in eyes with Pseudoexfoliation syndrome.

Avramides S., Travamidies P, Sakkias G (1997) found the incidence of Posterior capsular rent and vitreous loss to be 10.4% and 7.14% respectively in this

study of 84 patients with Pseudoexfoliation syndrome undergoing cataract surgery.

The incidence of vitreous loss in eyes with Pseudoexfoliation syndrome undergoing cataract surgery has been reported by various authors as 11.9% by **Kuchle** (1989) and 6.7% by **Junemann A, Martus P, et al** (1997).

Naumann G.O., Kucle M. Schonher U (1978) in their study of 72 eyes with Pseudoexfoliation syndrome found a seven fold increase for vitreous loss in eyes with Pseudoexfoliation syndrome as compared to those without Pseudoexfoliation syndrome. They also noted the incidence of posterior capsular rent to be 4.2% in eyes with Pseudoexfoliation syndrome and 2.8% without Pseudoexfoliation syndrome.

As shown in Table 15, out of 8 (17.8 %) of the patients with posterior capsular rent, 5 (62.5%) of them had insufficient mydriasis while 3 (37.5 %) of them had adequate mydriasis. Out of 8 (17.8 %) of the patients who had Vitreous loss, 5 (62.5 %) of them had insufficient mydriasis while 3 (37.5 %) of them had adequate mydriasis. Of the 12 (26.7 %) of the patients with Zonular dehiscence, 8 (66.7 %) of them had insufficient mydriasis while 4 (33.3 %) of them had adequate mydriasis. Out of the total 45 patients, 24 (53.4 %) patients who had one or the other or all of the above complications, 16 (66.7 %) of them had insufficient mydriasis and 8 (33.3 %) of the patients had adequate mydriasis.

This correlates with the other studies conducted by **Freyler H., Radax U** (1990), **Asano N. et al** (1996), **Repo L.P. et al** (1996), **Stanilla A.** (1996) and **Avramides S et al** (1997).

Alfaite et al (1996) in their study of 31 eyes of Pseudoexfoliation syndrome undergoing ECCE noted a statistically significant increase (p value < 0.01) in the need to perform sphincterotomies.

Kuchle et al (2000) noted 3.4% of their 76 patients to require surgical Synechiolysis and/or mechanical dilatation of pupil intraoperatively.

Vickie Lee and Anthony Maloof (2002) studied extensively on small pupils and their management during cataract surgery. They advocated that small pupils could be enlarged by prosthetic and non - prosthetic methods. Non - prosthetic techniques include visco-mydriasis, manual iris stretching and iris micro- sphincterotomies. Prosthetic techniques include iris hooks and use of pupil expansion devices.

In the present study, 9 of them had Senile Mature Cataract, 1 of them had Senile Hypermature Cataract while the remainder 35 had Senile Immature Cataract. The patient with hypermature cataract had Zonular dehiscence, Posterior capsular rent, Vitreous loss, Corneal edema by the end of the surgery and excessive lens mobility while performing capsulotomy. This is in concurrence with the study mentioned below.

As shown in table 16, post operative vision of 6/18-6/6 was seen in 23(51.1%) cases, visual acuity of 6/60 – 6/18 was seen in 15(33.3%) cases and visual acuity of perception of light to 6/60 was seen in 7(15.6%) cases.

Bayramlar et al (2007) conducted a retrospective study in 225 eyes of 187 patients of which 99 eyes had Pseudoexfoliation syndrome. Pre-operative data collected were - Cataract maturity level, Best corrected Visual acuity and Intraoperative posterior capsule complications. In this study, he interpreted that in MSICS, Pseudoexfoliation syndrome has an increased intraoperative posterior capsule complication rate that increases as the level of cataract maturity increases. Thereby, it is advisable to operate early on cataracts in patients with Pseudoexfoliation syndrome to have better results and prevent the compromised Zonular and posterior capsule changes.

CONCLUSION

The following conclusions were drawn from the study.

Patients with pseudoexfoliation syndrome and cataract posted for manual small incision cataract surgery, have to be carefully looked for zonular weakness, insufficient mydriasis, IOP , subluxation or dislocation of cataractous lens because these preoperative factors have bearing on the intraoperative complications.

Inadequate mydriasis one of the major pre operative complications in eyes With Pseudoexfoliation syndrome which has a bearing on the intraoperative complications like posterior capsular rent and vitreous loss. Intraoperatively corneal endothelial touch and subsequent corneal edema was seen in majority of patients in this study. Adequate surgical modifications such as Sphincterotomy and/or synechiolysis, pupil stretching in these eyes with inadequate mydriasis reduce the intra operative complications. These pupil enlargement procedures are advocated during cataract surgery.

All though cataract surgery in Pseudoexfoliation syndrome is challenging, if the surgeon is aware of the condition pre operatively and pays meticulous attention to the surgical technique during manual small incision cataract surgery, the intraoperative complications can be managed and a good outcome can be expected.

Manual small incision cataract surgery is safe in eyes with pseudoexfoliation syndrome.

SUMMARY

In the present study titled "A cross sectional study of the outcome of small incision cataract surgery in pseudoexfoliation syndrome cases done at KLE'S Dr Prabhakar Kore Hospital and MRC,Belgaum" 45 eyes of 45 patients with both Cataract and Pseudoexfoliation syndrome, attending KLE Dr. Prabhakar Kore Hospital and MRC,Belgaum were included. The study included patients of average age group of these patients was 65.83 years with preponderance of males with increased incidence of unilateral involvement.

In the present study, majority of the patients had Pseudoexfoliation material on the pupillary margin with 100% patients having different grades of trabecular pigmentation with all of the patients having open angles and IOP within normal range.

51.1 % of the patients had insufficient mydriasis. 100 % of the patients had either peripheral zone or central zone or both of the pseudoexfoliation material on the anterior surface of the lens suggesting Pseudoexfoliation syndrome. 20 % of patients had cataract maturity level more than nuclear sclerosis grade 4.

In the present study, 53.3% of the patients had either Zonular dehiscence, Posterior capsular rent, Vitreous loss, Corneal edema, Excessive lens mobility during capsulotomy and combination of the above. Majority of these patients with intraoperative complications had insufficient mydriasis and higher cataract maturity level. The surgical modifications like Sphincterotomy, Synechiolysis, Manual anterior vitrectomy, use of CTR can improve the outcome of the surgery and give better visual quality to the patients with Pseudoexfoliation syndrome.

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**ANNEXURE : I
: PROFORMA :**

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:

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

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

Past history

Diabetes : 1-Y,2-N Duration : _____ months / years
 Hypertension : 1-Y,2-N Duration : _____ months / Years
 Asthma: 1-Y,2-N Duration : _____ months / Years

Any other medical disorders : _____

General physical examination

Pallor: 1-Y,2-N Vital signs :
 Pulse rate (Per minute):
 Oedema : 1-Y,2-N Blood Pressure : /
 (mm of Hg)
 Lymphadenopathy : 1-Y,2-N
 Temperature :⁰ 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

Visual Acuity : Right Eye Left Eye

Distant :

Pinhole :

Near :

	(RIGHT EYE)	(LEFT EYE)
Adnexa		
Conjunctiva		
Cornea		
Sclera		
Anterior chamber		
Iris <ul style="list-style-type: none"> - Pattern - PXF on pupillary margin - PXF on surface - Atrophy - Iridodonesis 		
Pupil <ul style="list-style-type: none"> - Size(predilatation) - Size(postdilatation) - Pigment dispersion 		
Lens <ul style="list-style-type: none"> - Type - PXF on peripheral zone - Peri+central zone - Phacodonesis - Subluxation/dislocation - Zonular dialysis 		

GONIOSCOPY: OPEN NARROW CLOSED

Deposition of pseudoexfoliative material in schwalbe's line/TM

1-Y,2-N

FUNDUS :

Right Eye

Left Eye

1. WNL
2. No glow due to cataractous lens
3. Findings (Specify)

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:

TYPE OF SURGICAL PROCEDURE :

MANUAL SMALL INCISION CATARACT SURGERY

COMPLICATIONS OBSERVED:

1) Non dilating pupil 1-YES 2-NO

- stretching of pupil 1-YES 2-NO

- Sphinterotomy	<input type="checkbox"/>	1-YES 2-NO
- other means	<input type="checkbox"/>	1-YES 2-NO
2)Difficulty during anterior capsulotomy	<input type="checkbox"/>	1-YES 2-NO
3)Difficulty in nucleus delivery	<input type="checkbox"/>	1-YES 2-NO
4)Corneal endothelial touch	<input type="checkbox"/>	1-YES 2-NO
5)Decements membrane stripping	<input type="checkbox"/>	1-YES 2-NO
6)Zonular dialysis	<input type="checkbox"/>	1-YES 2-NO
7)Posterior capsular rupture	<input type="checkbox"/>	1-YES 2-NO
8)Vitreous loss	<input type="checkbox"/>	1-YES 2-NO
9)Any other complications-		

1ST POST OP DAY VISION -

DISCUSSION:

ANNEXURE –II

INFORMED CONSENT DOCUMENT

I.D. No

Mr/Mrs/Ms _____

You are invited to participate in our research study titled

“A cross sectional study of the outcome of small incision cataract surgery in pseudoexfoliation syndrome cases done at KLE’S Dr Prabhakar Kore Hospital and MRC,Belgaum” conducted by Dr. _____ Post-Graduate in M.S. Ophthalmology under the guidance of Dr. _____ Department of Ophthalmology, J N Medical College, Belgaum.

Respected sir/ madam, we request you 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 with draw at any time.

Purpose of the Study :

The purpose of research is to study the outcome of small incision cataract surgery in pseudoexfoliation syndrome cases.

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 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 small incision cataract surgical procedure for which all precautions will be taken. As such the cataract surgery will be performed by an experienced surgeon. Your participation may benefit you and others suffering from same ailment in future, by helping us learn more about the disease. No financial incentives are promised to you for being a part of study.

Costs for participating in this research :

There will not be any extra cost paid by you. The participant will have to pay for the investigations which are the part of the routine for this ailment.

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 PrabhakarKore 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. _____, Associate 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 Subect: _____

Witness Name : _____

Signature of Witness : _____

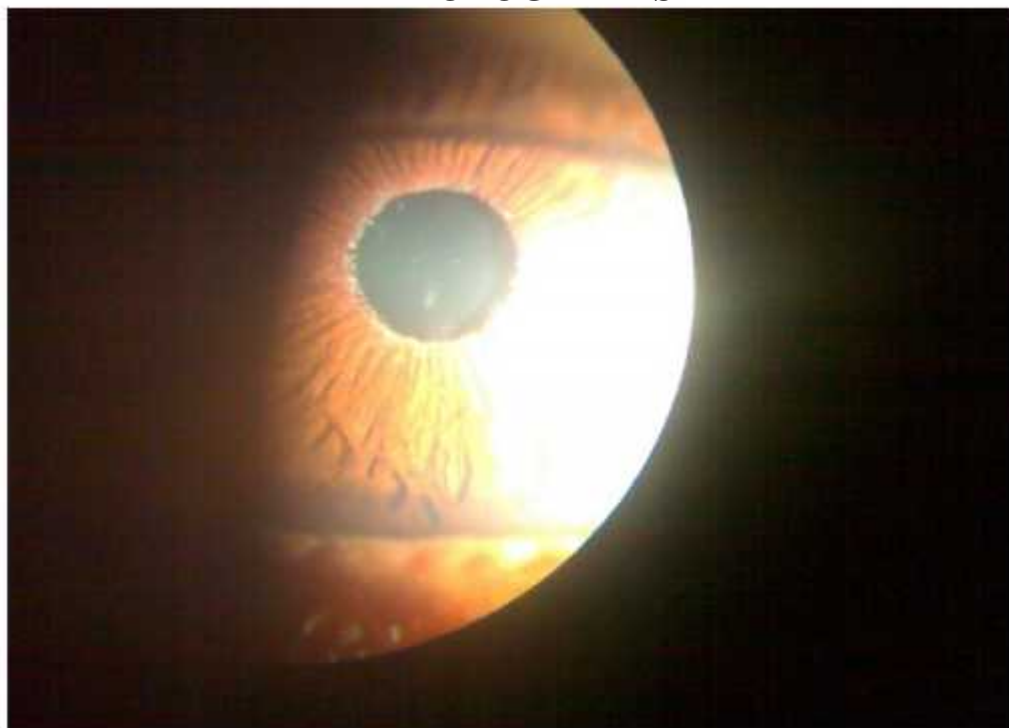
Investigators Name : _____

Signature of Investigator : _____

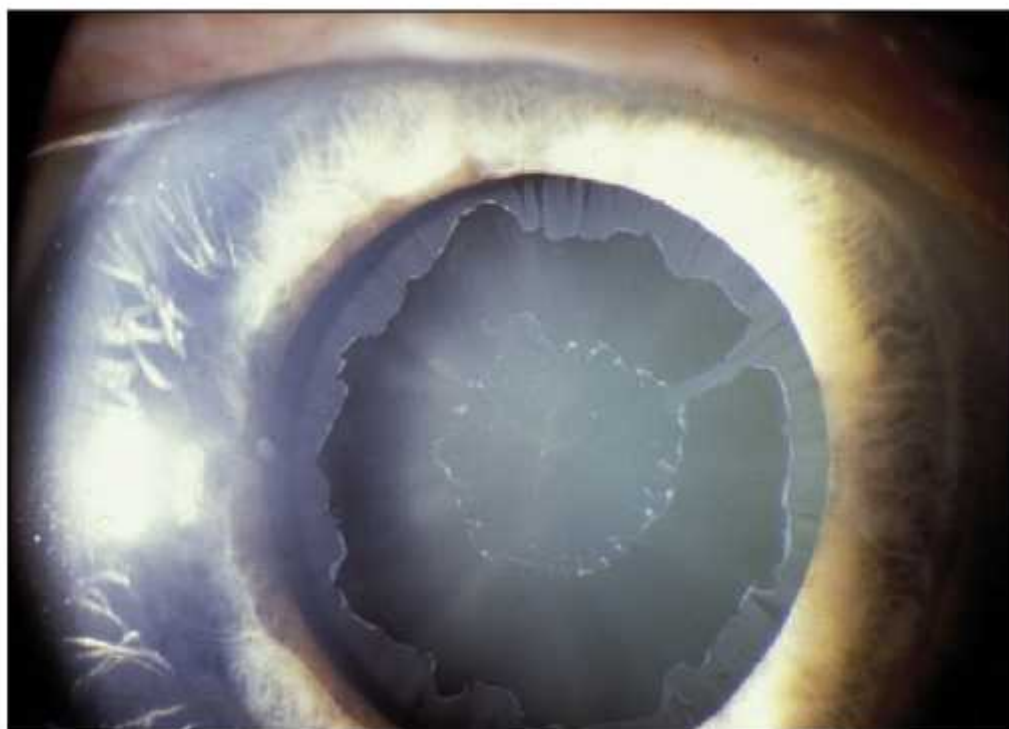
Date : _____

Place : _____

ANNEXURE- III
PHOTOGRAPHS



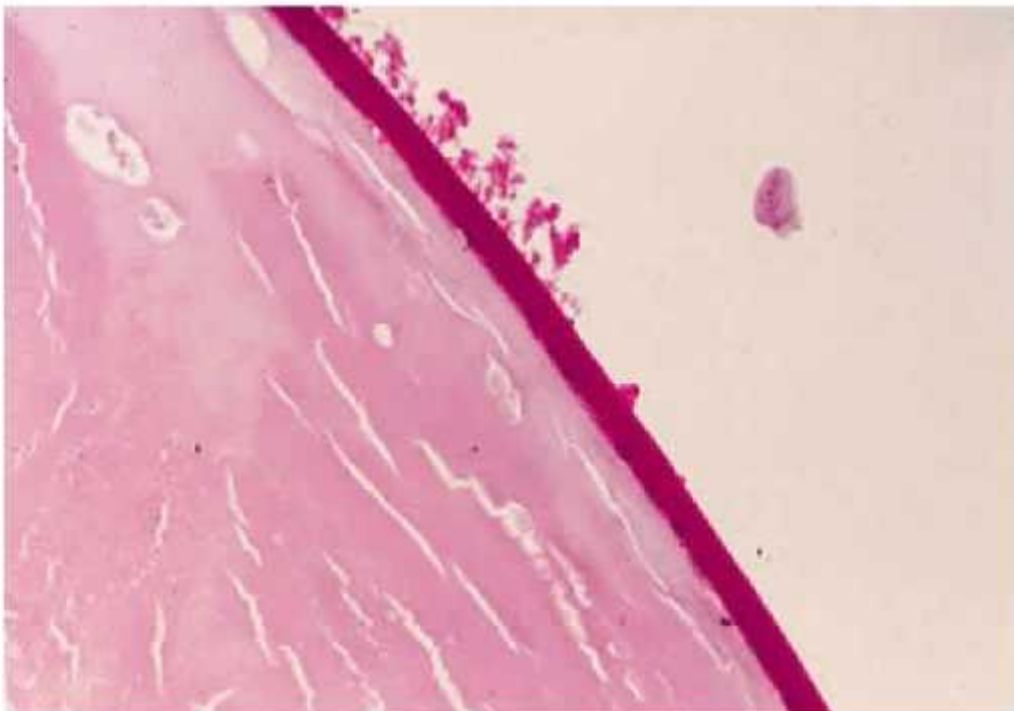
Photograph 1: Pseudoexfoliation material at the papillary margin and anterior surface of lens capsule with undilated pupil



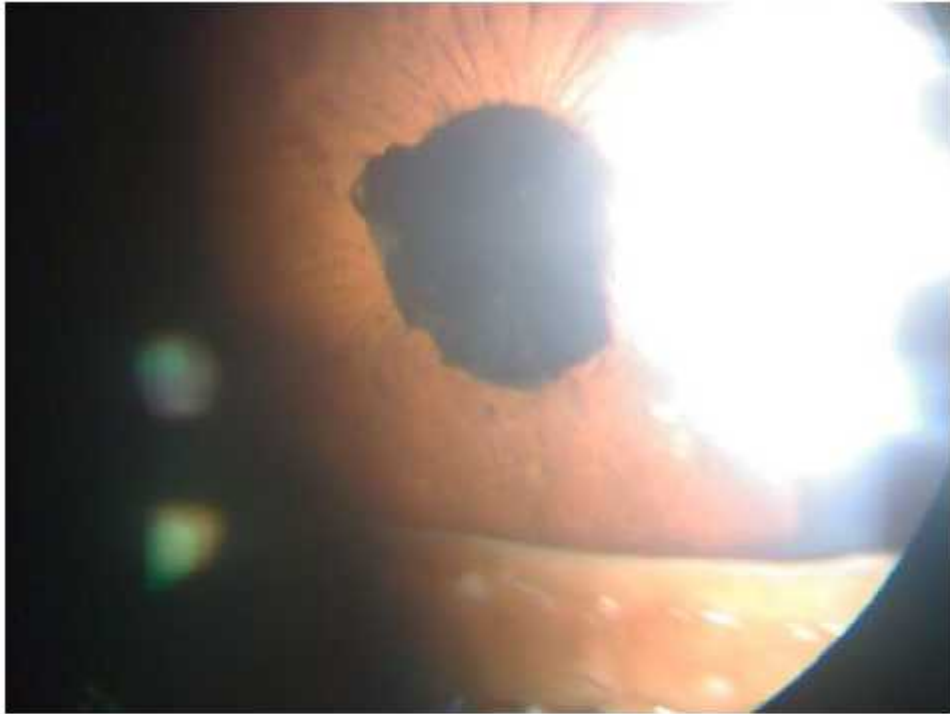
Photograph 2: Zone of Pseudoexfoliation material on the anterior capsule of lens after papillary dilatation



Photograph 3: Moth Eaten Appearance in Pseudoexfoliation syndrome



Photograph 4: Histopathology of Pseudoexfoliation material on the anterior lens capsule.



Photograph 5: Sphincterotomy cut at 10 O clock position. Seen postoperatively

KEY TO MASTER CHART

IP No – Inpatient number

UL/BL – Unilateral/Bilateral

N – Normal

N + -- Normal surface with presence of PXF material on surface

PM – PXF on pupillary margin

PS – Posterior synechiae

RRR – Round regular reactive

RRS –Round regular sluggishly reactive

PID – Pigment dispersion

NS – Nuclear sclerosis

PSC – Posterior subcapsular cataract

Pz – PXF material on peripheral zone of anterior capsule

Pz+Cz – Peripheral zone + central zone

PD – Phacodonesis

SL/DL – Subluxation/Dislocation

ZD – Zonular dialysis

IOP – Intraocular pressure

PxM – PXF material present in trabecular meshwork

PxS – PXF material present on schwalbes line

MSICS – Manual small incision cataract surgery

PCIOL – Posterior chamber intraocular lens

ACIOL - Anterior chamber intraocular lens

SFIOL – Scleral fixated intraocular lens

Sph – Sphinterotomy

DC – Difficulty during anterior capsulotomy

DN – Difficulty during nucleus delivery

CET – Corneal endothelial touch

PCR – Posterior capsular rent

VL – Vitreous loss

UCVA – Uncorrected visual acuity

**ANNEXURE - IV
MASTER CHART**

Sl.No	IP No.	Age	Sex	UL/ BL	Iris					Pupil				Lens					
					Pattern	PM	PS	Atrophy	I/D	Pre-Dilatation		Post-Dilatation		Type of Cataract	Zones				
										Size	Reaction	Size	PID		Pz	Pz+Cz	PD	SL/D L	ZD
1	294712	75	M	UL	N	+	-	-	-	3	RRR	5	-	IIINS	-	+	+	-	+
2	298354	65	F	UL	N	+	-	-	-	3	RRS	5	-	IIINS+PSC	+	-	-	-	-
3	300571	72	F	BL	N +	-	-	-	-	4	RRR	8	-	IINS+PSC	+	+	-	-	-
4	300845	65	F	BL	N	+	-	-	-	4	RRR	5	-	IIINS+PSC	+	-	-	-	-
5	300849	65	F	UL	N	-	-	-	-	3	RRR	7	-	IIINS+PSC	+	+	-	-	-
6	300843	60	F	UL	N	+	-	-	-	4	RRS	6	-	IIINS	+	-	-	-	-
7	301344	72	M	UL	N +	-	-	+	-	3	RRS	8	-	IINS+PSC	+	-	-	+	-
8	308613	65	M	UL	N	+	-	-	-	4	RRR	5	-	IIINS+PSC	-	+	+	-	-
9	310695	70	F	BL	N	+	-	+	+	3	RRS	5	-	IIINS	+	+	+	-	+
10	309474	67	M	UL	N	+	-	-	-	4	RRS	5	-	IINS	-	+	+	-	-
11	308398	76	F	BL	N +	+	-	-	-	3	RRR	6	-	IIINS	+	+	+	-	-
12	310859	70	M	BL	N +	+	-	-	+	3	RRS	4	-	IIINS+PSC	+	-	-	-	-
13	312576	60	M	UL	N	+	-	-	-	3	RRR	8	-	IIINS+PSC	-	+	+	-	-
14	311557	65	M	BL	N	+	-	-	-	3	RRR	5	-	IINS+PSC	-	+	+	-	-
15	310327	65	F	UL	N	+	-	-	-	3	RRR	5	-	IIINS+PSC	+	-	-	-	-

MASTER CHART

Sl.No	IP No.	Age	Sex	UL/ BL	Iris8					Pupil				Lens					
					Surface	PM	PS	Atrophy	I/D	Pre-Dilatation		Post-Dilatation		Type of Cataract	Zones				
										Size	Reaction	Size	PID		Pz	Pz+Cz	PD	SL/D L	ZD
16	316143	85	M	UL	N +	+	-	-	-	3	RRS	5	-	IIINS	+	-	-	-	-
17	318784	72	M	UL	N +	+	-	-	-	4	RRR	5	-	IIINS+PSC	+	-	-	-	-
18	319699	60	F	UL	N	+	-	-	-	3	RRR	8	-	MATURE	-	+	-	-	-
19	323124	70	F	UL	N +	+	-	-	-	3	RRR	4	-	MATURE	+	-	-	-	-
20	320554	80	M	UL	N +	+	-	-	-	3	RRS	8	-	IIINS	+	-	-	-	-
21	321675	72	M	UL	N +	+	-	-	-	3	RRR	5	-	MATURE	+	+	-	-	-
22	327867	65	F	UL	N	+	-	-	-	3	RRR	7	-	IIINS	+	+	-	-	-
23	329470	65	M	UL	N	+	-	-	-	4	RRR	8	-	IINS	+	+	-	-	-
24	328548	75	F	UL	N +	+	-	-	-	4	RRR	5	-	MATURE	+	-	-	-	-
25	334053	78	M	UL	N +	+	-	-	-	3	RRR	8	-	IIINS+PSC	+	+	-	-	-
26	340816	65	F	UL	N	+	-	-	-	3	RRR	8	-	IIINS	+	-	-	-	-
27	341236	71	M	BL	N	+	-	-	-	3	RRS	6	-	MATURE	+	-	-	-	-
28	341880	60	M	BL	N	+	-	-	-	3	RRR	6	-	IIINS	-	+	-	-	-
29	342222	65	F	BL	N	+	-	-	-	4	RRR	5	-	MATURE	-	+	-	-	-
30	342439	85	M	UL	N	+	-	-	-	4	RRR	6	-	IIINS	-	+	-	-	-

MASTER CHART

Sl.No	IP No.	Age	Sex	UL/ BL	Iris					Pupil				Lens					
					Surface	PM	PS	Atrophy	I/D	Pre-Dilatation		Post-Dilatation		Type of Cataract	Zones		PD	SL/D L	ZD
										Size	Reaction	Size	PID		Pz	Pz+Cz			
31	343364	65	F	BL	N	+	-	-	-	4	RRS	6	-	IINS+PSC	-	+	-	-	-
32	345285	80	F	UL	N +	+	-	-	-	3	RRS	8	-	HMATURE	+	+	+	-	-
33	340167	76	M	BL	N	+	-	-	-	4	RRS	5	-	MATURE	+	-	-	-	-
34	337922	50	M	UL	N	+	-	-	-	4	RRR	8	-	INS+PSC	-	+	-	-	-
35	345567	70	F	UL	N	+	-	-	-	3	RRS	7	-	IIINS+PSC	+	+	-	-	-
36	354995	76	M	BL	N +	+	-	-	-	4	RRS	8	-	IIINS	+	-	-	-	-
37	353816	70	F	UL	N	+	-	-	-	4	RRS	5	-	MATURE	+	-	-	-	-
38	349425	65	F	UL	N	+	-	-	-	4	RRS	9	-	IIINS	+	-	-	-	-
39	344778	73	F	UL	N	+	-	-	-	3	RRR	5	-	IINS+PSC	+	-	-	-	-
40	345388	70	M	UL	N	+	-	-	-	3	RRR	5	-	IIINS	+	-	-	-	-
41	354048	70	F	BL	N	+	-	-	-	4	RRS	5	-	MATURE	-	+	-	-	-
42	356272	60	F	BL	N	+	-	-	-	4	RRR	8	-	IINS+PSC	+	-	-	-	-
43	388878	84	M	BL	N +	+	-	-	-	3	RRR	5	-	IINS+PSC	-	-	-	-	-
44	337930	75	F	UL	N	+	-	-	-	4	RRR	8	-	IIINS+PSC	+	-	-	-	-
45	398208	65	M	UL	N	+	-	-	-	3	RRS	7	-	IIINS	+	+	-	-	-

MASTER CHART

Sl. No	IP No.	IOP (mm Hg)	Gonioscopy			Surgery											
			Angle	PxM	PxS	Technique	Outcome	Sph	Complications								
									DC	PD	ZD	DN	CET	PCR	VL	UCVA	
1	294712	14.6	OPEN	+	-	MSICS	ACIOL	-	-	+	+	-	+	+	+	2mts	
2	298354	17.3	OPEN	+	-	MSICS	PCIOL	-	-	-	-	-	-	-	-	6/9	
3	300571	17.3	OPEN	+	+	MSICS	PCIOL	-	+	-	-	-	-	-	-	6/18	
4	300845	17.3	OPEN	+	-	MSICS	PCIOL	-	+	-	-	+	+	-	-	6/12	
5	300849	18.9	OPEN	-	-	MSICS	PCIOL	-	-	-	-	+	-	-	-	6/12	
6	300843	17.3	OPEN	-	-	MSICS	PCIOL	-	+	-	-	+	+	-	-	6/24	
7	301344	17.3	OPEN	-	-	MSICS	PCIOL	-	-	-	-	-	-	-	-	6/9	
8	308613	18.9	OPEN	+	-	MSICS	PCIOL	-	-	-	-	-	+	-	-	6/18	
9	310695	17.3	OPEN	+	+	MSICS	SFPCIOL	-	-	+	+	+	+	+	+	6/36	
10	309474	18.9	OPEN	-	-	MSICS	PCIOL	-	+	-	-	-	-	-	-	6/9	
11	308398	18.9	OPEN	-	-	MSICS	PCIOL	-	+	-	-	-	-	-	-	6/12	
12	310859	12.2	OPEN	+	+	MSICS	PCIOL	-	+	+	+	+	+	-	-	6/24	
13	312576	17.3	OPEN	-	-	MSICS	PCIOL	-	-	-	-	-	+	-	-	6/12	
14	311557	14.6	OPEN	+	-	MSICS	PCIOL	-	-	-	+	-	+	-	-	6/24	
15	310327	17.3	OPEN	+	+	MSICS	PCIOL	-	+	-	-	+	+	-	-	6/24	

MASTER CHART

Sl. No	IP No.	IOP (mm Hg)	Gonioscopy			Surgery											
			Angle	PxM	PxS	Technique	Outcome	Sph	Complications								
									DC	PD	ZD	DN	CET	PCR	VL	Va	
16	316143	18.9	OPEN	+	+	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/9
17	318784	17.3	OPEN	+	-	MSICS	PCIOL	-	+	-	-	-	-	-	-	-	6/24
18	319699	15.9	OPEN	+	+	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/12
19	323124	14.6	OPEN	+	-	MSICS	PCIOL	-	-	-	-	-	+	-	-	-	6/12
20	320554	18.9	OPEN	-	-	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/12
21	321675	18.9	OPEN	+	-	MSICS	PCIOL	-	+	-	-	+	-	-	-	-	6/24
22	327867	17.3	OPEN	-	-	MSICS	ACIOL	-	+	-	+	+	+	+	+	+	6/18
23	329470	17.3	OPEN	-	-	MSICS	PCIOL	-	-	-	-	+	+	+	+	+	2mts
24	328548	18.9	OPEN	+	+	MSICS	APHAKIA	-	+	-	-	-	+	-	-	-	6/12
25	334053	17.3	OPEN	+	-	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/12
26	340816	14.6	OPEN	-	-	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/12
27	341236	14.6	OPEN	+	+	MSICS	ACIOL	-	-	-	-	-	-	+	+	+	6/12
28	341880	12.2	OPEN	-	-	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/12
29	342222	17.3	OPEN	-	-	MSICS	PCIOL	+	-	-	-	+	+	-	-	-	1mt
30	342439	17.3	OPEN	+	+	MSICS	PCIOL	-	-	-	-	-	-	+	-	-	1mt

MASTER CHART

Sl. No	IP No.	IOP (mm Hg)	Gonioscopy			Surgery											
			Angle	PxM	PxS	Technique	Outcome	Sph	Complications								
									DC	PD	ZD	DN	CET	PCR	VL	Others	
31	343364	14.6	OPEN	+	+	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/12
32	345285	13.3	OPEN	+	+	MSICS	PCIOL	-	-	+	+	-	+	-	-	-	1mt
33	340167	17.3	OPEN	+	-	MSICS	PCIOL	+	-	-	+	-	+	-	-	-	6/18
34	337922	14.6	OPEN	-	-	MSICS	ACIOL	-	-	-	-	+	+	+	+	+	6/36
35	345567	15.9	OPEN	-	-	MSICS	PCIOL	-	-	-	-	+	-	-	-	-	6/12
36	354995	18.9	OPEN	-	-	MSICS	PCIOL	-	-	-	-	+	-	-	-	-	6/24
37	353816	19.3	OPEN	+	+	MSICS	PCIOL	+	-	-	+	-	+	-	-	-	6/36
38	349425	12.2	OPEN	-	-	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/9
39	344778	18.9	OPEN	-	-	MSICS	PCIOL	-	-	-	-	+	+	-	-	-	6/18
40	345388	17.3	OPEN	-	-	MSICS	PCIOL	-	-	-	-	+	+	-	-	-	6/24
41	354048	17.3	OPEN	+	-	MSICS	ACIOL	+	+	+	+	+	+	+	+	+	2mts
42	356272	14.6	OPEN	-	-	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/12
43	388878	20.6	OPEN	+	-	MSICS	SFPCIOL	-	+	+	+	+	+	+	+	+	3mts
44	337930	20.6	OPEN	-	-	MSICS	PCIOL	-	-	-	-	-	-	-	-	-	6/12
45	398208	20.6	OPEN	-	-	MSICS	PCIOL	-	-	-	+	-	+	-	-	-	6/60