Dissertation on

A MULTIVARIATE ANALYSIS OF THE FACTORS AFFECTING THE VISUAL OUTCOME AND COMPLICATIONS FOLLOWING SCLERAL FIXATED INTRAOCULAR LENS IMPLANTATION

Submitted in partial fulfillment of requirements of

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MADRAS MEDICAL COLLEGE

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CHENNAI

APRIL 2013

<u>CERTIFICATE</u>

This is to certify that this dissertation titled "A MULTIVARIATE ANALYSIS OF THE FACTORS AFFECTING THE VISUAL OUTCOME AND COMPLICATIONS FOLLOWING SCLERAL FIXATED INTRAOCULAR LENS IMPLANTATION" is a bonafide record of the research work done by DR. ANANDALAKSHMI.R, post graduate in the Regional Institute of Ophthalmology & Government Ophthalmic Hospital, Madras Medical College and Research Institute, Chennai – 03, in partial fulfillment of the regulations laid down by The Tamil Nadu Dr. M.G.R. Medical University for the award of M.S. Ophthalmology Branch III, under my guidance and supervision during the academic years 2010 – 2013.

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Finally, I sincerely thank all the patients for their kind consent and cooperation without which I would not be the person I am.

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"A MULTIVARIATE ANALYSIS OF THE FACTORS AFFECTING THE VISUAL OUTCOME AND COMPLICATIONS FOLLOWING SCLERAL FIXATED INTRAOCULAR LENS IMPLANTATION"** is a bonafide and genuine research work carried out by me under the guidance of Prof. Dr. R. Ravikumar.

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Dear Dr. Anandalakshmi.R

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled "A Multivariate analysis of the factors affecting the visual outcome and complications following scleral fixated intraocular lens implantation "No. 13112011

The following members of Ethics Committee were present in the meeting held on 22.11.2011 conducted at Madras Medical College, Chennai -3.

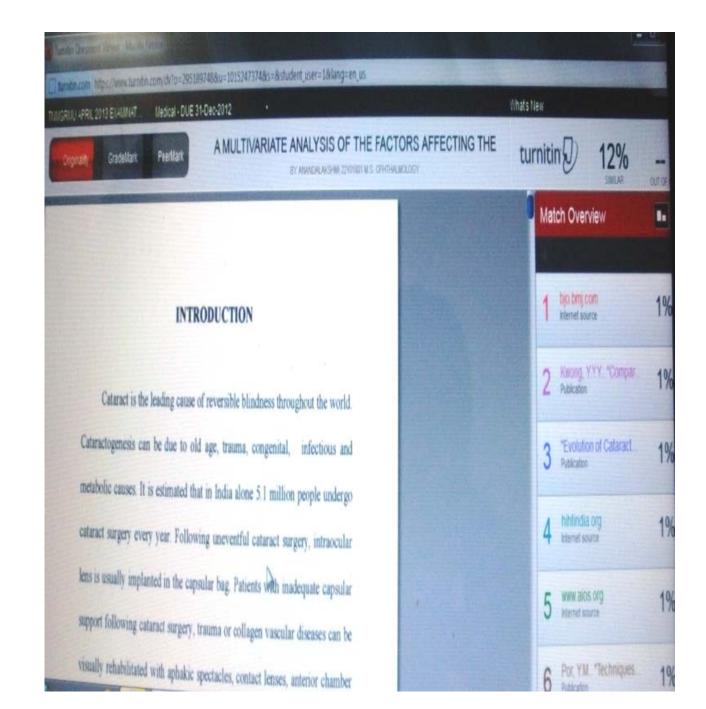
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We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee



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INTRODUCTION Cataract is the leading cause of reversible blindness throughout the world. Cataractogenesis can be due to old age, trauma, congenital, infectious and metabolic causes. It is estimated that in India alone 5.1 million people undergo cataract surgery every year. Following uneventful cataract surgery, intraocular lens is usually implanted in the capsular bag. Patients with inadequate capsular support following cataract surgery, trauma or collagen vascular diseases can be visually rehabilitated with aphakic spectacles, contact lenses, anterior chamber intraocular lenses, iris fixated lenses and scleral fixated intraocular lenses. These intraocular lenses can be implanted as a...

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CONTENTS

S.NO	Title	Page No.
	PART I	
1.	INTRODUCTION	1
2.	REVIEW OF LITERATURE	2
3.	ANATOMY OF THE HUMAN LENS	3
4.	EVOLUTION OF CATARACT SURGERY	10
5.	DEVELOPMENT OF MODERN INTRAOCULAR LENS IMPLANTATION SURGERY	14
6.	OCULAR INJURIES AND TRAUMATIC CATARACT	27
7.	POST SURGICAL APHAKIA	31
8.	OPTICS OF APHAKIA	34
9.	SECONDARY INTRAOCULAR LENS IMPLANTATION	37
10.	SCLERAL FIXATED INTRAOCULAR LENS IMPLANTATION	40
11.	COMPLICATIONS OF SCLERAL FIXATED INTRACOULAR LENS IMPLANTATION	49
	PART II	
12.	OBJECTIVES OF THE STUDY	50
13.	MATERIALS AND METHODS	51
14.	OBSERVATION AND RESULTS	54
15.	DISCUSSION AND ANALYSIS	78
16	LIMITATION OF THE STUDY	83
16.	CONCLUSION	84
17.	FUTURE SCOPE	85
	PART III	
18.	BIBLIOGRAPHY	86
20.	PROFORMA	91
21.	KEY TO MASTER CHART	93
22.	MASTER CHART	96

ABBREVIATIONS

AC	Anterior chamber
ACIOL	Anterior chamber intra ocular lens
CME	Cystoid macular edema
ECCE	Extra capsular cataract extraction
IOL	Intra ocular lens
ICCE	Intra capsular cataract extraction
OCT	Optical coherence tomography
РС	Posterior chamber
PCIOL	Posterior chamber intraocular lens
PCIOL PCR	Posterior chamber intraocular lens Posterior capsular rent
PCR	Posterior capsular rent
PCR PVD	Posterior capsular rent Posterior vitreous detachment
PCR PVD PXF	Posterior capsular rent Posterior vitreous detachment Pseudo exfoliation
PCR PVD PXF RD	Posterior capsular rent Posterior vitreous detachment Pseudo exfoliation Retinal detachment

INTRODUCTION

Cataract is the leading cause of reversible blindness throughout the world. Cataractogenesis can be due to old age, trauma, congenital, infectious and metabolic causes. It is estimated that in India alone 5.1 million people undergo cataract surgery every year. Following uneventful cataract surgery, intraocular lens is usually implanted in the capsular bag. Patients with inadequate capsular support following cataract surgery, trauma or collagen vascular diseases can be visually rehabilitated with aphakic spectacles, contact lenses, anterior chamber intraocular lenses, iris fixated lenses and scleral fixated intraocular lenses. These intraocular lenses can be implanted as a primary or as a secondary procedure.

Since the discovery of the scleral fixated intraocular lenses by Parry¹ in 1950, various changes and various techniques have emerged for its fixation. Placement of the IOL in the posterior chamber, reduces the risk of bullous keratopathy, damage to anterior chamber angle structures, damage to corneal endothelium, pupillary block glaucoma, and pseudophakodonesis .In addition positioning the lens closer to the rotational centre of the eye, may reduce the centrifugal forces on the lens and stabilize the ocular contents, decrease the magnification associated with contact lenses, optical aberrations associated with aphakic spectacles and imparts superior optical properties to the eye.

REVIEW OF LITERATURE

Cataract extraction is the most common intraocular surgery worldwide. In the absence of posterior capsular support, the surgeon is faced with many decisions including when to implant the IOL and which type of IOL to implant. Results of a few studies that had tried to answer the first question indicate that primary ACIOL implantation had better visual outcome compared to secondary ACIOL implantation (Bayramlar.G.et al study)².In Lee et al study, similar visual outcome was obtained with primary and secondary SFIOL implantation.

However results of the studies answering the second question have been conflicting and most studies have so far focussed on the comparison between primary ACIOL and primary SFIOL implantation (Kwong et al)³ and secondary ACIOL and secondary SFIOL implantation (Dadeya et al)⁴. A systematic review of both these issues by the American Academy of Ophthalmology indicates that there is little evidence available regarding the visual outcome and complication profile of the implantation of these IOLs. Some surgeons prefer to implant SFIOL in the absence of posterior capsular support while others prefer ACIOL. No consensus currently exists on the optimal method for IOL implantation without capsular support. In our study, considering the advantages of SFIOL over ACIOL and iris fixated IOLs, we assessed and compared the factors affecting the visual outcome and complications following SFIOL implantation.

ANATOMY OF HUMAN LENS

DEFINITION:

The lens is a highly organized transparent structure that has evolved to alter the refractive index of light entering the eye⁵.

GROSS ANATOMY OF ADULT LENS:

The adult human lens is a transparent biconvex crystalline structure placed between the iris and the vitreous in a saucer shaped depression called patellar fossa. This asymmetrical oblate spheroid does not possess nerves, blood vessels or connective tissue. The biconvex shape results from the anterior surface (average radius of surface 10 mm) being less convex than the posterior surface. The poles represent the centre points of these 2 surfaces. The anteroposterior axis runs from anterior pole to posterior pole (polar axis). The equator represents the lateral region of the lens, where anterior and posterior surfaces meet. The equatorial axis is at right angles to the anteroposterior axis. Weight of the lens varies from 135µg (0-9 years) to 225 µg(40-50 years).

The anterior surface is in contact with the aqueous and the anterior pole of the lens is separated from the cornea by approximately 3.5 mm. The posterior surface of the lens is in intimate contact with the vitreous with ligamentum hyaloidocapsulare (Weigert's ligament)⁶.Between the hyaloid face and the lens capsule is a small potential space called Berger's space.

Lens is held in place by the zonular fibres(suspensory ligament) which runs between the lens and ciliary body⁷.

Refractive index of the lens is 1.39 (nucleus 1.42, cortex 1.38). Refractive power is about 16- 17 diapters. Its accommodative power varies with age being 14-16D at birth, 7-8D at 25 years and 1-2 at 50 years of age.

The transparent lens acquires yellow tinge after 30 years of age and appears amber coloured in old age. Lens comprises of 3 parts:

- 1) Lens capsule
- 2) Lens epithelium
- 3) Lens substance

STRUCTURE OF THE LENS

LENS CAPSULE

Lens is ensheathed by an elastic acellular envelope secreted by the basal cell area of lens epithelium anteriorly and by basal cell area of the elongated fibres posteriorly. The capsule allows the passage of small molecules both into and out of the lens. The thickest region (up to 23μ m) is located close to the equator. On both the anterior and posterior surfaces , the thinnest region is that of the posterior pole (4µm), while the equator (17µm) and the anterior pole (9-14µm) are the intermediate thickness.

The lens capsule is continuously synthesized throughout life and represents the thickest base membrane in the body. It is composed of number of lamellae stacked on top of each other. The structural proteins (type 4 collagen, laminin, heparan sulphate) and a small amount of fibronectin are found within the lamellae of the capsule.

LENS EPITHELIUM

Lens epithelium arises as a single layer of cells beneath the anterior capsule and extends to the equatorial lens bow. These cells have a cuboidal shape being approximately 10 μ m height and 15 μ m wide. Their basal surface adhere to the capsule whereas their anterior surface abuts to the newly formed lens fibres. Post- operative proliferation of these cells may lead to opacification of the posterior lens capsule which in turn contributes to decreased vision⁸.

The anterior lens epithelium can be divided in to 3 zones:

1) Central zone- It consists of relatively quiescent cuboidal epithelial cells with minimal mitotic activity. Metaplasia of these cells to spindle shaped myofibroblast can lead to anterior subcapsular cataract like shield cataract in atopic dermatitis and glaucomaflecken in acute congestive closed angle glaucoma. 2) Intermediate zone- It consists of more cylindrical cells located peripheral to central zone which mitose occasionally.

3) Germination zone- It consists of columnar cells which are most peripheral and located just pre- equatorial. These cells are actively dividing which migrate posteriorly to become lens fibres throughout life. Dysplasia of these cells lead to posterior subcapsular cataract as seen in radiation induced cataract, myotonic dystrophy and neurofibromatosis II.

During lens enlargement the location of older fibres become more central as new fibres are formed at the periphery.

LENS SUBSTANCE

Lens substance is composed of densely packed fibres with very little intracellular space. Lens fibres are arranged in zones that delineate the various periods of development of the lens. This stratification is due to optical differences between the older more sclerotic regions. The lens fibres are arranged compactly as nucleus and cortex.

NUCLEUS

The embryonic nucleus is the innermost part formed at 1-3 months of gestation. The lens fibres are arranged such that they terminate with Y shaped sutures on anterior (upright Y) and the posterior (inverted Y) surface of lens).Outside this is the fetal nucleus corresponding to lens from

3 months of gestation till birth, infantile nucleus(from birth to puberty) and the adult nucleus(corresponding to lens in adult life).

CORTEX

It is the peripheral part of the lens which comprises the youngest lens fibres.

CILIARY ZONULES

The ciliary zonules (zonules of zinn or suspensory ligament of lens) consist essentially of a series of fibres which run from the ciliary body and fuse into the outer layer of lens capsule around the equatorial zone⁹. Thus they hold the lens in position and the ciliary muscle to act on it.

Main fibres are :

- 1) Orbiculoposterior capsular fibres
- 2) Orbiculoanterior capsular fibres
- 3) Cilioposterior capsular fibres
- 4) Cilioequatorial fibres

LENS TRANSPARENCY

Factors that play a major role in the transparency of the lens are:

1) Single layer of epithelial cells which is not thick.

2) Semipermeable character of lens capsule.

3) Spasticity and highly packed nature of lens cells. The lens extracapsular space is less than 5% of its total volume, so the zones of discontinuity are very small compared to wavelength of light.

4) Characteristic arrangement of lens proteins.

5) Pump mechanism of lens fibre that maintains relative dehydration of lens.

6) Avascularity of lens.

7) Auto oxidation : High concentration of reduced glutathione in the lens maintains the lens proteins in a reduced state and ensure the integrity of the cell membrane pump.

METABOLISM OF THE LENS

The metabolism of the lens is directed towards maintenance of transparency. The lens epithelium is the main site of lens metabolism. The lens derives 70% of its energy by anaerobic glycolysis. Besides glycolysis the lens metabolises glucose via Kreb's cycle and hexosemonophosphate pathway. Regulation of the lens electrolyte balance serves to maintain the normal hydration of the lens. The adult lens has 65% water. The Na⁺K⁺ATPase pump is responsible for removing sodium out and potassium to accumulate within the lens¹⁰.

Figure 1 - Cross section of the human crystalline lens showing the relationship of the lens to surrounding ocular structures.

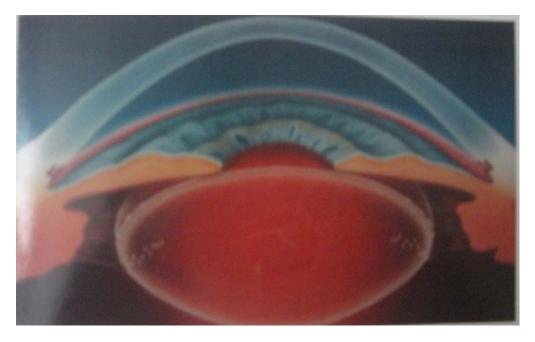
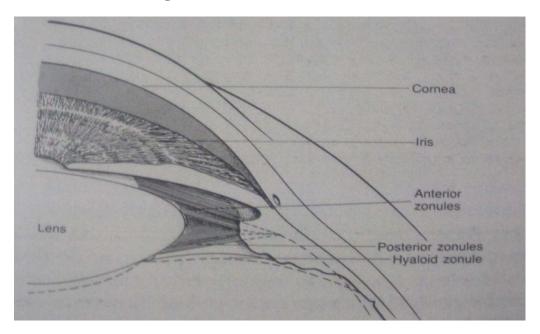


Figure 2 - Schematic view showing the relationship of the lens to the surrounding structures



EVOLUTION OF CATARACT SURGERY

The term cataract was introduced by Constantinus Africanus(ad 1018), a monk and an Arabic oculist. He translated arabic 'suffusion' in to Latin 'Cataract' meaning ' waterfall'. Cataract surgery was in practice from ancient time by the Indians, Egyptians and Greeks in the form of reclination, depression or couching.

For more than 20 centuries, couching was the primary method for dislodging the cataract away from the pupil. The first written description of couching came from Sushruta, an ancient Indian surgeon. Daviel (1696-1762), a French oculist, started a revolution of surgical innovation by describing a new planned method for extraction of the cataract from the eye. Samuel Sharp(1753) described surgery that introduced the subject of taking the entire lens out of the eye with the capsule intact. IOL development from 1940 through 1970 enhanced rehabilitation during this period.

Harold Ridley performed the first lens implantation at St. Thomas hospital in London on Nov 29, 1949¹¹. Between 1965 and 1972, Cornelius Binkhrost of Holland was modifying the IOL concept¹².

Kelman introduced the ultrasonic breakup of the nucleus coupled with the Schei's concept of irrigation and aspiration of the cortex in 1967¹³. In the early 1980s, Gimbel and Neuhann recognized their important contribution towards the continuous curvilinear capsulorrhexis(CCS) for safe in the bag nuclear emulsification. The next enhancement phacoemulsification came through the evolution of ways to achieve nucleus manipulation and disassembly by Faust's hydrodissection in 1984. Gimbel propelled a giant advancement to phacoemulsification by showing that the nucleus could be fractured within the bag by cracking the nucleus by his divide and conquer nucleofractis. Kunihiro Nagahara form Japan stunned the surgical world with his clever phaco chop technique.

The next advance to phacoemulsification was the revolutionary concept of moving the incision to clear cornea. Fine in 1992 described a new concept of a planar temporal clear corneal sutureless incision which was self sealing and astigmatically neutral. Bimanual phacoemulsification through 1 mm incision was first described by shearing in 1985.

In 1998, Amar Agarwal of India fully revived this technique & he named it a 'phakonit' (phaco done with a needle through an incision & with a phaco tip).

Cataract surgery has undergone a major evolution over the past few decades and quest for a safer & more effective operation seems far from over.

MAJOR DEVELOPEMENTS IN CATARACT SURGERY

- 800 BC Couching performed by Indian surgeons.(Sushruta)
- 1750 Daviel carried out the first ECCE
- 1753 Samuel sharp performed the first ICCE
- 1949 Ridley implanted the first IOL
- 1967 Kelman introduced phacoemulsification
- 1980 Miller and Shegman used healon to stabilize AC
- 1993 Nagahara demonstrated the "phaco chop" technique
- 1997 Accommodating IOL by Cunnings
- 1998 Agarwal presents the bimanual microincision and phacoemulsification

Figure 3 - Couching

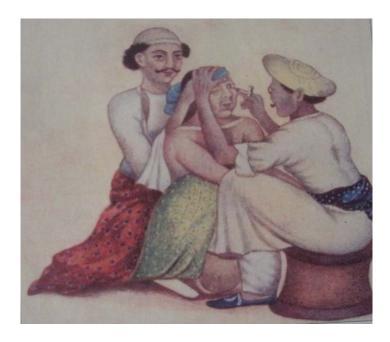
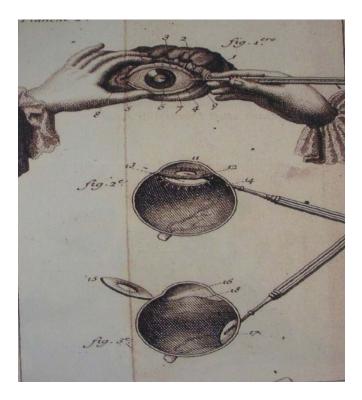


Figure 4 - Illustration of the operation of depression by Brisseau



DEVELOPMENT OF MODERN INTRAOCULAR LENS IMPLANTATION SURGERY

Although cataract surgeries were carried out 2000 years ago, the history of intraocular lens implantation is only 60 yrs old.

IOL GENERATION I (1949-1954) (ORIGINAL RIDLEY POSTERIOR CHAMBER LENS)

The development of modern cataract surgery with IOL implantation began after world war II with the first implantation of IOL by Sir Harold Ridley in the St. Thomas Hospital in London on 29 Nov 1949 on a 45 year old woman. The IOL material used was polymethylmethacrylate (PMMA, Plexiglas) after learning that these splinters remained inert. The most serious complications are lens luxation and inflammatory reactions.

IOL GENERATION II (1952-1962)

As a result of the high incidence of dislocations with the Ridley lens, new implantation site was considered in the anterior chamber angle , ACIOL can be implanted after ECCE or ICCE.ACIOL implantation was considered as quicker and simpler procedure as compared to placement of IOL behind the iris. Baron first performed ACIOL implantation on May 13, 1952. There were two design groups one being the rigid or semi rigid ACIOL fashioned after Baron, Scharf and Strampelli, the other group being flexible or semi flexible ACIOL which further can be classified into lens with open or closed haptic loops. Peter Choyce modified the Strampelli lens. Barraquer modified the Dannheim lens and developed the first open loop ACIOL with J haptic¹⁴. Due to biodegradation of the material , decentration occured over time and the haptics eroded the ciliary body leading to chronic uveitis. The main complications of ACIOL implantation were corneal decompensation and uveitis- glaucoma-hyphaema syndrome due to poorly manufactured AC lens.

IOL GENERATION III (IRIS SUPPORTED LENS)

Iris supported or iris fixated IOL were introduced to overcome the frequent dislocation of Ridley lens and high rate of corneal decompensation associated with AC lenses. In 1957, Binkhorst developed the first iris clip lens. It had 4 haptics, 2 of which were fixated in front of the iris and the other 2 behind. Fyodorov modified this design constructing the Fyodorov I and later Fyodorov II also named Sputnik lens due to it appearance . This lens had 3 haptics in front and 2 behind the iris. Jan Worst conceived a new concept of iris claw lens (lopster claw). Through 2 slits in both haptics, the lens was clamped in to the mid iris periphery tissue. Binkhorst implanted the

4 loop lens in eyes after ECCE, where 2 haptics were fixated in the capsular bag. He recognized that through this manner a significantly more stable fixation could be reached. So he developed a 2 loop iris clip lens for iridocapsular fixation in 1965.The complications of iris fixated IOL were pseudophakic bullous keratopathy, iris pigment epithelial defects or atrophy and pigment dispersion glaucoma. The change to capsular fixation after ECCE was a fore runner of the capsular bag fixation of modern posterior chamber IOL¹⁵.

IOL GENERATION IV (INTERMEDIATE ANTERIOR CHAMBER LENSES)

Several changes in designs of ACIOL were introduced. Lenses with closed haptic loops like Surgidev style 10 Leiske lens, Cilco optiflex ACIOL and Iolab Azar 91Z caused corneal decompensation, uveitic reaction and eroded the chamber angle and ciliary body area(cheese cutter effect). The best ACIOL were the various rigid and flexible open loop, one piece Kelman PMMA lenses. These IOLs were well designed, critically vaulted, properly sized and provided excellent long term results. The elimination of sharp optic edges is critical in the production of ACIOL. This is because the ACIOLs are fixated in a confined space directly adjacent to delicate angle structures. In the past most common causes of ACIOL failure were related to ACIOLs that were incorrectly sized, too steeply vaulted or with inappropriate flexibility. Haptics or foot plates popularized by Peter Choycee are often likened to the flattened portion of spatula¹⁶. Iris or scleral fixated, sutured PCIOLs may be used instead of ACIOL.

IOL GENERATION V (IMPROVED POSTERIOR CHAMBER LENSES)

The return to Harold Ridley's original concept of IOL implantation in the posterior capsule occurred after 1975. John Pearce of England implanted the first uniplanar PC lens after Ridley. It was a rigid tripod design with 2 inferior feet implanted in the capsular bag and the superior foot implanted in the joint of the anterior capsule and sutured to the iris.

Steven Shearing introduced a major lens design breakthrough in early 1977 with his PC lens. William Simcoe introduced his C-looped posterior chamber lens shortly after introduction of Shearing's J-loop design.

Continued improvements of phacoemulsification techniques, the introduction of hydrodissection by Faust and the introduction of the capsulorrhexis technique by Neuhann and Gimbel led to definitive improvements in cataract surgery. ICCE had been almost completely replaced by ECCE. Due to capsulorrhexis, capsular bag had become a safe implantation site. Through the means of surface modification (heparin

coating, polyfluorocarbon, teflon coating) an attempt was made to develop lenses that would cause less post operative inflammatory reactions and less cell adhesion.

In 1976 Epstein implanted the first soft foldable lenses in human eyes. Zhou implanted the first silicone IOLs in human eyes in 1978.Familiar techniques were utilized and implantation into the sulcus took place in an unfolded state. The windshield wiper effect or the propellar effect was observed. The lenses became dislodged moved in a propellar fashion on the posterior iris surface finally erasing the pigment epithelium of the iris. This complication was prevented by capsular bag implantation of IOLs by means of an injector.

Silicone PCIOL had a comparable biocompatibility to PMMA lenses. The first multifocal and bifocal lenses were the so called diffractive or refractive IOLs which simultaneously potrayed distance image and a near image on the fovea.

During the late 1990s, experimental lenses were developed that depending on the lens content, would completely fill the capsular bag thereby restoring the natural form of the lens. Examples include Blumenthal/Apple's expansile lenses, Hettlich's injectable lenses and the silicone balloon lens developed by Nishi et al.

27

IOL GENERATION VI (MODERN CAPSULAR , RIGID PMMA, SOFT FOLDABLE, MODERN ACIOL, SPECIAL LENSES)

Generation VI lenses represent the present generation of implants¹⁷. It is no longer possible to categorize lens types through simple criteria like implantation site, unique design or on an individual person. Selection of IOL options exists depending on a myriad of specific indicators and surgical situations.

Standard age related cataract surgery has evolved into a relative procedure. Standard PMMA lenses, commonly one piece designs with various optic/haptic dimensions and configurations are used for this procedure.

Modern foldable lenses made of silicone and hydrogels while newer lenses made of acrylate/methacrylate polymers are developed. A reduction of the incision size by 3-4 mm induces only a slight operative astigmatism. The development of corneal and corneo-scleral tunnel incisions have allowed a watertight, seamless wound closure.

Special lenses for the purpose of complicated cataract surgeries exist. Lenses specifically fitted for the pediatric age group, lenses used in inflammatory diseases with IOL surface coating, aniridia lenses, equipment such as capsular tension rings and iris retractors were introduced.

A new group of IOLs were implanted in refractive procedures. Theoritically it can be said that a secondary implantation of a lens into an aphakic eye represents a refractive procedure. Binkhorst began by implanting his first iris clip lenses exclusively into aphakic eyes. Over time ACIOL as well as PCIOL (sulcus fixation or transscleral suture fixation) were used as secondary implants.

Toric IOLs were designed to correct pronounced astigmatism. Due to low complication rate of modern cataract surgery, the attempt to correct high myopia through removing a clear lens (clear lens extraction) is now getting a lot of popularity. The phakic IOL group of special lenses, special ACIOL, iris fitted lenses and between posterior iris surface and lens posterior chamber lenses (intra ocular contact lenses) are implanted to correct myopia. The advantage of these lenses in phakic eyes is that the accommodative ability remains intact. Due to young age of these patients, complications such as corneal decompensation, iritic irritation and cataract formation cannot always be prevented.

29

IOLs - GENERATION I

Figure 5- Schematic representation of an implanted Ridley lens

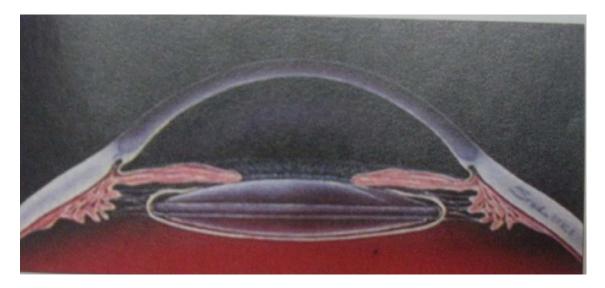
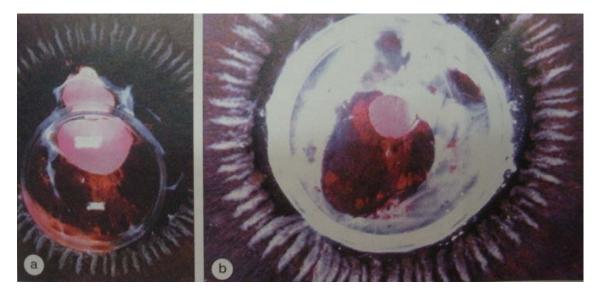


Figure 6- Photographs of two autopsy eyes with Ridley lenses



IOLs - GENERATION II

Figure 7- Schematic representation of an implanted ACIOL

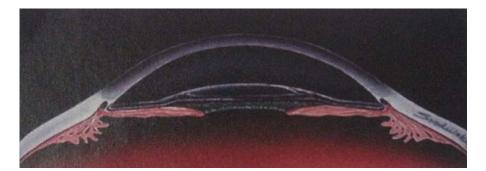


Figure 8- Examples of early ACIOL

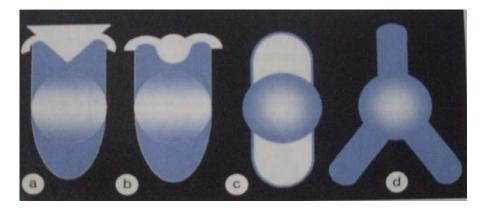


Figure 9- Barraquer ACIOL with open J- haptic loops



IOLs- GENERATION III

Figure 10- Examples of iris fixated IOLs

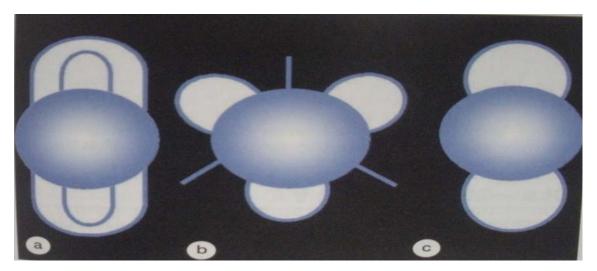


Figure 11- Schematic representation of an iris- fixated IOL



IOLs GENERATION IV

Figure 12- Examples of Generation IV(a) ACIOL with semi flexible ACIOLS closed haptics

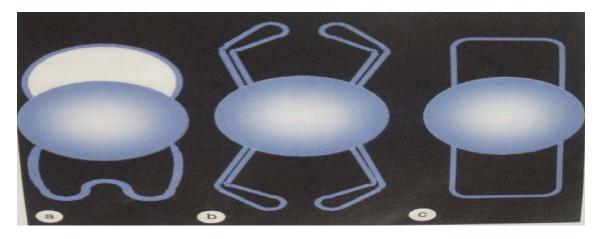


Figure 13- Examples of generation IV (b) ACIOL (flexible ACIOL with open loos

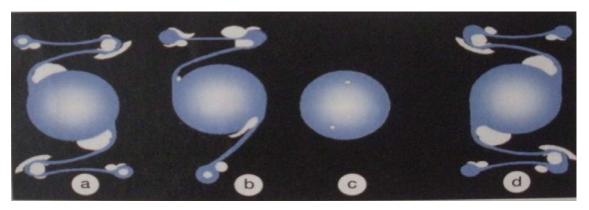


Figure 14- An autopsy eye with a Feaster Universal lens



IOLs GENERATION V

Figure 15- Examples of generation V (a) early PCIOLs

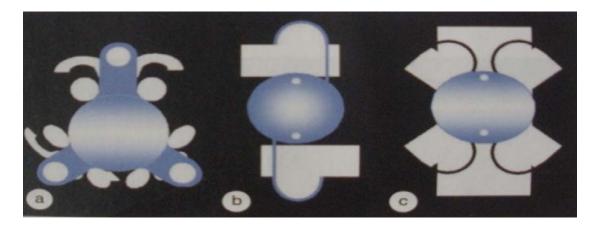


Figure 16- Examples of generation V (b) PCIOLs

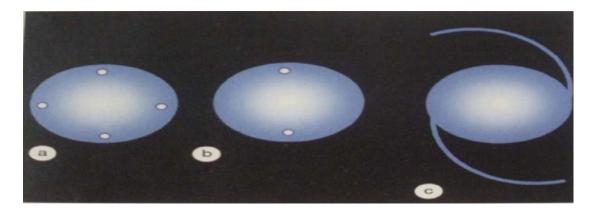


Figure 17- Schematic representation of implanted PC lenses

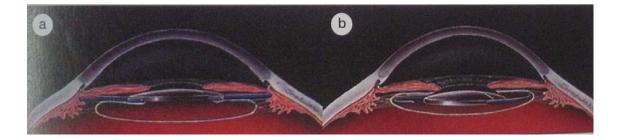
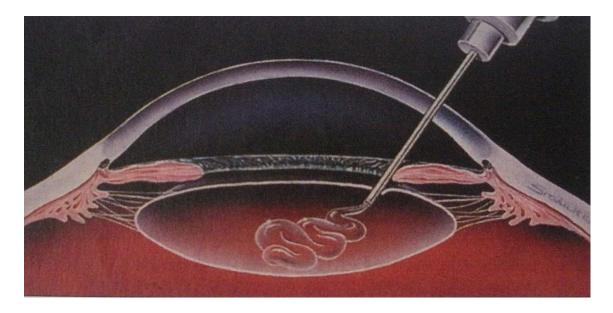


Figure 18- An autopsy eye with capsular fixation of an Alcon acrysof foldable lense



Figure 19- Schematic representation of the concept of injectable lens following endocapsular cataract extraction



OCULAR INJURIES AND TRAUMATIC CATARACT

CLASSIFICATION OF OCULAR INJURIES

Ocular injuries can be anatomically classified as intraocular and extraocular injuries. Extraocular injuries include lid lacerations, orbital fractures, orbital hemorrhage and traumatic optic neuropathy. Ocular Trauma classification group has classified intraocular mechanical injuries into closed globe and open globe injuries¹⁸. The classification is based on the type of injury:

1.CLOSED GLOBE INJURIES - Ocular injury without full thickness defect of the coats. They are contusion or lamellar laceration(partial thickness injury of the coats).

2.OPEN GLOBE INJURIES - Full thickness defects in the corneoscleral coat of the eye. They are full thickness laceration outside to inside break in ocular coats (can be penetrating injury if the object traverses the coats only once or perforating injury if both an entry and exit wounds are present) and rupture globe (full thickness inside to outside break in ocular coats).

Injuries can be:

1.Mechanical injuries : i. Blunt injuries ii. Penetrating injuries2.Non mechanical injuries : i. Electric cataract ii. Thermal cataract

iii. Radiational cataract iv. Chemical injuries induced cataract

BLUNT INJURIES

Blunt trauma of eyeball produces damage by different forces which include:

1) Direct impact on the globe : It produces maximal effect at the point where the blow is received (COUP)

2) Compression wave force : Transmitted force appearing as a wave of pressure when the eye is suddenly compressed, travelling throughout its fluid contents in all directions and the maximum damage may be at a point distant from the actual place of impact (CONTRE COUP).

3) Reflected compression wave force : After striking the outer coats, the compression waves are reflected towards the posterior pole and cause foveal damage.

4) Rebound compression wave force : After striking the posterior wall of the globe, the compression waves round back interiorly. This force damages the retina and the choroid by forward pull and lens iris diaphragm by forward thrust from the back.

5) Indirect force : Globe is suddenly hurled against the elastic contents of the orbit and its resistant walls.

PATHOPHYSIOLOGY

1.When the anterior surface of the eye is struck bluntly, there is a rapid anterior posterior shortening accompanied by equatorial expansion. This equatorial stretching can disrupt the lens capsule, zonules or both. Combination of coup, contrecoup and equatorial expansion is responsible for formation of traumatic cataract following blunt injury.

2. Even when the capsule is not torn, the slightly traumatised lens imbibes twice as much water as controls. This has been attributed to a separation of the normal integrity of lens fibres.

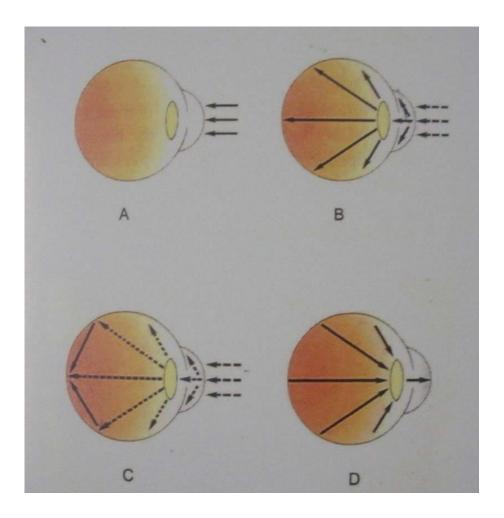
3. Damage to capsule due to concussion may impair its semipermiability, allowing the imbibation of aqueous by the lens substance and distributing the active transport of metabolites.

The various forms of cataract following blunt trauma include:1. Discrete subepithelial opacities 2.Traumatic rosette cataract 3. Traumatic zonular cataract 4.Early maturation of senile cataract 5.Diffuse concussion cataract.

Blunt trauma causes traumatic cataract, anterior subluxation or dislocation and posterior dislocation or subluxation of lens¹⁹.

38

Figure 20- MECHANISMS OF BLUNT TRAUMA TO EYE BALL



- A. Direct impact
- B. Compression wave form
- C. Reflected compression wave form
- D. Rebound compression wave

POST SURGICAL APHAKIA

Cataract surgery is by far the most common intraocular surgery performed world wide. It may not be possible to implant PCIOL in the posterior chamber in all cases due to unforeseen intraoperative complications during surgery. The incidence of posterior rupture is higher in ICCE followed by ECCE,SICS and phacoemulsification.

POSTERIOR CAPSULAR TEAR

Posterior capsule rupture is the most common serious intraoperative complication of cataract surgery. A posterior capsular rent is more likely to occur in eyes with small pupils, hard nucleus, or pseudoexfoliation syndrome. Recent reports suggest that the visual prognosis of patients who have broken posterior capsules is excellent. The key factors are to minimize ocular trauma, meticulously clean prolapsed vitreous from the anterior segment, if present, and ensure secure fixation of the IOL.

BEFORE NUCLEUS REMOVAL.

A capsular break noted before nucleus extraction is a potential disaster. The first objective is to prevent the nucleus from being dislodged into the vitreous cavity by using an OVD injected posterior and anterior to the nucleus to prevent its posterior displacement and to cushion the corneal endothelium. Another alternative is to insert an instrument through a pars plana incision 3 mm posterior to the limbus into the vitreous, which Kelman has described as "posterior assisted levitation". The nucleus is pushed gently anteriorly, so that it can be captured in front of the iris and safely removed from the eye.

In most circumstances, the nucleus should be managed by sufficiently enlarging the wound to facilitate easy extraction of the nucleus on a lens loop. However, in the case of a small break or when only a small amount of nucleus is left, it may be possible to cover the posterior capsular opening with a retentive OVD and complete the phacoemulsification. One can also use a Sheets glide as a "pseudo–posterior capsule" to facilitate completion of phacoemulsification.

Vitreous loss almost always accompanies posterior capsular rupture and vitrectomy should be performed before the nuclear pieces are removed. Clearly, one should not do this if it makes loss of the nucleus into the vitreous more likely.

DURING CORTICAL IRRIGATION-ASPIRATION.

When capsular rupture occurs during aspiration of the cortex (the most common cause), a key factor is the status of the vitreous. If no vitreous is present in the anterior segment, vitreous loss often can be averted. An OVD can be injected through the capsular opening to push the vitreous

posteriorly. Cortical removal can be completed using low-flow irrigation. Options include using a manual system; a dry approach, aspirating with a cannula in the chamber filled with OVD; a bimanual approach through two paracentesis openings; and automated irrigation-aspiration with all settings reduced. Cortex should be stripped first in the region farthest from the rent, and the direction of stripping should be toward the rent. Because it can be hazardous to remove cortex in the region of the rent, the cortex is sometimes better left in the eye, to avoid the possibility of enlarging the rent and precipitating vitreous loss. One option to prevent extension of the rent is to convert the tear into a small posterior capsulorrhexis, which eliminates any radially orientated tears that could extend with further surgical manipulation.

If vitreous is present in the anterior segment, vitrectomy should be performed first, with the necessary caution being taken to prevent extension of the rent. Depending on the type of capsular tear, the vitrectomy is performed through either the limbal incision or the pars plana. In either case, irrigation is provided with an infusion cannula in the paracentesis opening. After a thorough anterior vitrectomy, the remaining cortical material can be removed using one of the techniques described earlier or using the vitrector in the aspiration mode without cutting²⁰.

42

OPTICS OF APHAKIA AND PSEUDOPHAKIA

The normal 72 yrs old man has total dioptric power of 58 D, with nearly 75% of the power from the cornea and 25% of the power from the crystalline lens. Removal of the crystalline lens leaves the eye extremely deficient in dioptric power, which must be replaced to restore vision.

The replacement of the dioptric power can be in the form of spectacles, contact lenses or intraocular lenses. Although each modality can restore the patient's vision the optical consequences are dramatically different.

OPTICS OF APHAKIA:

Replacement of crystalline lens power with spectacle lenses causes the image that is formed on the patients retina to be roughly 25% larger than that of the image formed by the crystalline lens. There is approximately 2% magnification for each dioptre of power in the spectacles. The average aphakic spectacle is therefore 12.5 dioptre²¹.

The magnification from aphakic spectacle causes other optical aberrations such as a ring scotoma. The magnification from other spectacle causes other optical aberrations such as a ring scotoma, jack in the box phenomenon and pin cushion distortion. Magnification of about 25% by aphakic spectacles reduces field of vision by 25%, a loss of vision of peripheral fields or a ring scotoma.

When an object moves from the peripheral field of vision towards the centre of fixation it disappears through the ring scotoma till it appears in the central island of vision.

The jumping in to and out of the patients vision has been referred to as the jack in box phenomenon. Pin cushion effect is the property of all plus lenses and is directly proportional to their power. The square looks like a pin cushion with sides pushed in and the corners have a stretched out appearance. Every object viewed through aphakic spectacles appear this way. This would be a handicap for professional like Draftsman or an architect.

OPTICS OF CORRECTION OF APHAKIC WITH CONTACT LENSES

To correct aphakia at the corneal plane involves the use of contact lenses or surgery that adds refractive power to the cornea.

The power at the corneal plane that is equivalent to 12.5D at a vertex of 12mm is 14.7D; a patient who needs a 12.5D in aphakic spectacles would need 14.7D in a soft or rigid contact lens.

At the corneal plane the magnification is 6-8%. This value is near the limit of aniseikonia, (image size disparity between the eyes), so that unilateral aphakic patients can have binocular vision, with the aphakic eye corrected using a contact lens and the other eye aphakic. Binocular vision is not the possible with one aphakic spectacle and a normal phakic lens.

OPTICS OF PSEUDOPHAKIA

A posterior chamber lens in the bag following cataract extraction just as the average spectacle power for aphakia is 12.5D, the average power for an equiconvex lens is 21.0D.The average magnification of an IOL in this position is 1.5% compared with the original crystalline lens.

For an anterior chamber IOL the average power would be less, approximately 18.0D, and the magnification would be approximately 2.0%.Almost every one can achieve binocular vision with one eye pseudophakia and other eye phakic.

IOLs available are either biconvex, convexoplano or meniscus. As a result of clinical performance and optical analysis the majority of lenses implanted today are biconvex. The quality of the optical designs of an IOL 70% is measured based on its performance with respect to tilting, decentration and spherical aberration. The optimal mechanical and optical functions of an IOL in the human eye is that of biconvex lenses. They reduce effect of tilt, decentration and spherical aberration²².

SECONDARY INRAOCULAR LENS IMPLANTATION

Secondary intraocular lens implantation (IOL) is defined as insertion of lens into an eye which is rendered aphakic by prior cataract extraction by any methods, or by an exchange IOL which is a special case of secondary IOL implantation. In Sanjeev Kumar et al and Lee et al study, it is found that secondary SFIOL implantation has better visual outcome compared to primary SFIOL implantation^{23, 24}.

IOL exchange or explantation is a special case of secondary IOL implantation where the original AC or PC lens may have to be removed due to excessive corneal decompensation, UGH syndrome and CME.

INTRAOCULAR LENS INSERTION.

Careful inspection of the anatomy of the capsule and zonules is required to determine the appropriate site for IOL implantation. There are five choices: capsular bag, ciliary sulcus, sutured posterior chamber, and anterior chamber.

1.CAPSULAR BAG

If the rent is small and relatively central, and if the anterior capsular margins are well defined, the posterior chamber IOL can be implanted into the capsular bag. If possible, conversion of posterior capsule tears to posterior continuous curvilinear capsulorrhexis (CCC) is recommended. This technique is applied to avoid an anticipated extension of the inadvertent linear or triangular tear during manoeuvers such as a required vitrectomy or lens placement. The surgeon should ensure that the haptics are orientated away from the rent (to avoid haptic placement or subsequent migration into the vitreous) and that the lens is inserted gently to avoid enlargement of the rent.

2.CILIARY SULCUS

If the rent exceeds 4–5mm in length or there is extensive zonular loss, the capsular bag probably is not adequate for IOL support. In such cases, the ciliary sulcus is opened with an OVD, and the iris is retracted in all quadrants to assess the status of the peripheral capsule and zonules. The IOL is inserted with its haptics oriented away from the area of the rent and positioned in areas of intact zonules and capsule. Another alternative, if the anterior capsulorrhexis is intact, is sulcus placement of the IOL, with capture of the optic through the capsulorrhexis²⁵.

3.IRIS FIXATION

Some surgeons advocate iris suture fixation of one or both haptics to prevent IOL decentration. After the IOL optic is captured through the pupil, McCannel sutures are used to secure the haptics to the iris, and then the optic is repositioned through the pupil. The complications include iris chafe (motility of iris over the lens), chronic inflammation or intraocular hemorrhage²⁶.

4.SUTURED SCLERAL FIXATED INTRAOCULAR LENS

If loss of more than 4–5 clock hours of capsule or zonules occurs, the ciliary sulcus may be inadequate for lens stability. The lens can be fixated to the sclera using single or dual 10–0 polypropylene sutures. If one region of solid peripheral capsule and zonules exists, one haptic can be inserted into the sulcus in this area, and the opposite haptic can be sutured to the sclera²⁷.

5.ANTERIOR CHAMBER

A Kelman-type multiflex anterior chamber IOL design is a good option for patients who do not have glaucoma, peripheral anterior synechiae, or chronic uveitis²⁸. A peripheral iridectomy should be performed in these patients to prevent pupillary block²⁹.

SCLERAL FIXATED INTRAOCULAR LENSES

The posterior chamber is the normal anatomic position of the human lens. Here the lens reduces the risk of bullous keratopathy, injury to angle structures, pseudophacodonesis and the risk of pupillary block glaucoma as it is closer to the rotational centre of the eye. The centrifugal forces acting on the lens is reduced and ocular contents are stabilised thus reducing the risk of iritis, CME & retinal detachment. It improves the optical properties of the eye. In the eye without an intact posterior capsule, a PCIOL can be inserted only if it is sutured to either the sclera or the iris. Another advantage of positioning the lens closer to the nodal point and centre of rotation of the eye is the superior optical properties acquired by the lens in this position³⁰. The indications for placement of a PCIOL fixated to the sclera include the following:

1) Patients with fibrosed anterior-posterior capsule, with extensive posterior synechiae or zonular or posterior capsular tears.

2) An eye with inadequate capsular support or zonular support(more than three clock hours).

3) An aphakic patient who is contact lens intolerant.

4) An eye that has undergone an ICCE.

5) For secondary IOL used in combination with penetrating keratoplasty.

6) In young patients to avoid the risk of corneal decompensation and other ACIOL complications.

7) In cases of inadequate intact iris diaphragm where iris fixated IOLs cannot be used.

Suture fixated IOLs were first introduced by Parry in the 1950s.PCIOLs designed for suturing to the sclera have eyelets on both haptics as well as a large diameter (6.5-7mm) optic to decrease the risk of decentration. Although suture fixated lenses are technically difficult to insert, they often provide good results when implanted as secondary IOLs. There are many methods for scleral fixation of posterior chamber lenses.

SURGICAL TECHNIQUES

1. CLASSIC AB EXTERNO TECHNIQUE FOR CILIARY SULCUS FIXATION

In 1991,Lewis described a technically facile technique for ab externo sulcus fixation of PCIOL. By definition, the ab externo technique avoids the passage of a needle from the inside of the eye to the outside through the sclera. The surgeon can thus reduce the risk of hemorrhage, retinal detachment and lens malposition by avoiding the potential inaccuracies of suture placement that are inherent to the ab externo technique. One disadvantage of the Lewis method is that the one - point fixation of the suture to the sclera creates a less stable fixation than would a two - point fixation. The basic surgical technique includes:

After creating a conjunctival peritomy from 4 o'clock to 10 0'clock position a partial thickness limbal based triangular scleral flap that is 3mm high and 2mm wide is made. Complete anterior vitrectomy is made through a 7mm corneal scleral wound. A straight needle carrying a 10-0 polypropylene suture is passed through the 10 o'clock scleral bed 1mm posterior to surgical limbus. When the needle tip is visualised through the pupil, insert the straight needle into the barrel of a 28 - gauge needle on a standard insulin syringe at 4 o'clock position and withdraw the syringe from the eye. Deliver a loop of suture through the corneal scleral incision. Cut the loop and tie the free ends to the haptics of the lens. Insert the lens into the ciliary sulcus. Dial the lens while removing slack from the sutures. Use a second 10-0 polypropylene suture on a half- circle needle to take a short bite in the 4 o'clock scleral bed just anterior to the first suture's exist. Suture together the short end of this suture to the IOL fixated suture and consider this as a hybrid suture. Tie the long end of the second suture to the hybrid suture in a square knot with four throws. The same steps are followed in the 10 o'clock position. Close the scleral flaps and reapproximate the conjunctiva.

2. CLASSIC AB INTERNO TECHNIQUE FOR CILIARY SULCUS FIXATION

1n 1990,Smiddy described a straight forward technique that produces good visual results and decreasing the risk of decentration. The main disadvantage of this method is the hemorrhage risk and decreased stability of the one-point fixation. After preparing a shelved limbal incision pass the needle transsclerally 1 mm posterior to the limbus in the 3 o'clock meridian. Apply gentle counter pressure with the forceps externally while passing the suture through the sclera. Pass the second needle in a similar manner at 9 o'clock meridian. A properly positioned scleral fixated lens with the haptics oriented in the 3 and 9 o'clock meridians is obtained after making a mid thickness scleral pass with the needle and tying the suture to itself.

3.SMALL INCISION AB EXTERNO TECHNIQUE FOR CILIARY SULCUS FIXATION

Regillo and Tidwell published a modified version of the Lewis technique. The straight needle end of the 10-0 polypropylene suture is inserted through the scleral bed temporally and retrieved within the barrel of a 28 gauge needle. The single transscleral suture is externalised through the temporal incision and the loop is cut. The two free ends are tied to the haptics of the silicone lens. The folded silicone lens is inserted through the 4mm corneal incision. The lens is secured in the ciliary sulcus with the haptics at 3 and 9 o'clock position.

4.KNOTLESS AB EXTERNO TECHNIQUE FOR CILIARY SULCUS FIXATION

In 1995, Erylidirim introduced the knotless ab externo ciliary sulcus fixation of PCIOL. The disadvantage of this method is that though this

method leaves the surgeon with two lines of suture at each scleral clock hour at the end of the operation, these sutures cannot be used to perform a more stable two- point fixation because the two strands exit through the same port.

After preparing the flaps, a needle is inserted in reverse position. The suture is captured with the lens dialer and pulled through the corneal incision. The procedure is repeated on the other port. The suture is passed through the passing the lens through the loop and is locked in place. The procedure is repeated in the other haptic. The haptic is passed through the loop and the suture is tightened with an equal pulling force on either side. One part of the suture is passed to the other side of the haptic. A 8-0 suture can be used as a guide to 10-0 suture through the eyelet³¹.

5.AB INTERNO TECHNIQUE WITH TWO POINT CILIARY SULCUS FIXATION

This technique is a stable two point fixation because two sutures exit the sclera at two different spots. After dissecting two limbal based, partial thickness scleral flaps 180° apart, a double armed suture is passed through the ciliary sulcus and out through the sclera 1 mm posterior to limbus. The other needle of the double armed suture is passed in a similar manner, exiting 1mm lateral to the first exit site. A girth hitch is used to affix the haptics to the double armed suture. Once the lens is centred in the ciliary sulcus, a 3-1-1 surgeon's knot is used to tie the superior and inferior loops.

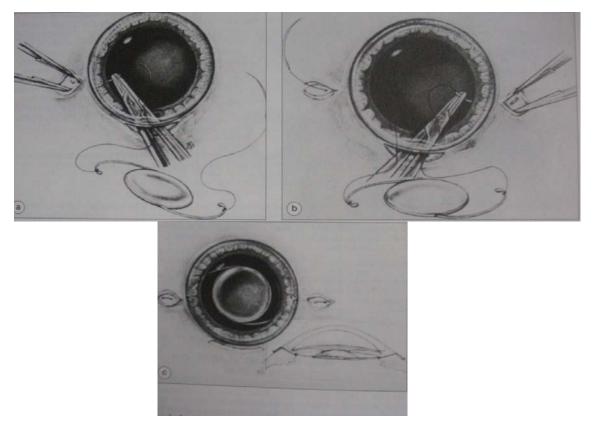
6.AB INTERNO TECHNIQUE WITH PARS PLANA FIXATION

In 1981,Girard introduced the pars plana fixation technique. The advantage of this technique is that hemorrhagic complications, retinal detachments and iris pigment dispersion can be reduced. The diameter of the lens is increased to 17mm, the diameter of the biconvex optic to 7mm and the haptics have to be angled backward at 10° or 20°.Teichman advised that to enter the pars plana safely, the sclera should be entered 3-5 mm behind the limbus.

TECHNIQUES OF SFIOL IMPLANTAION

Figure 21- Classic ab externo technique

FIgure 22- Classic ab interno technique



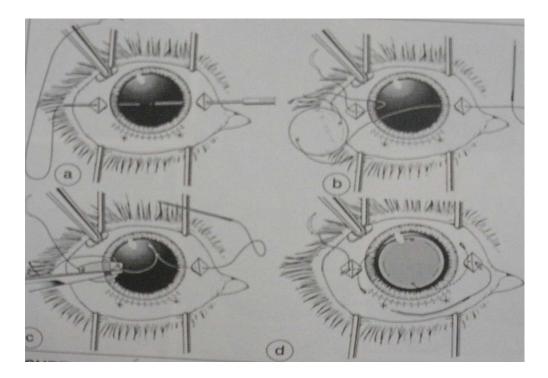
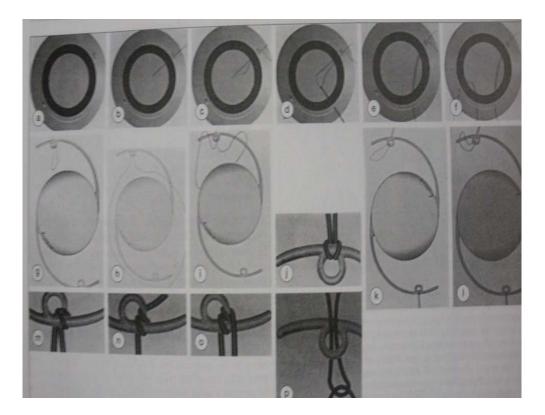


Figure 23- Small incision ab externo technique

Figure 24- 'Knotless' ab externo technique



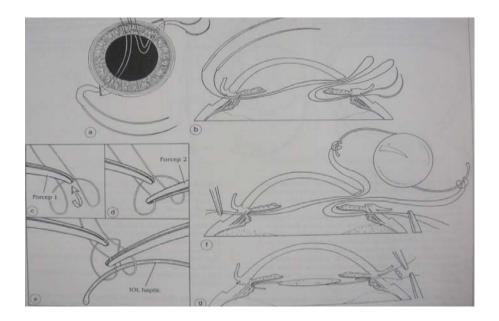
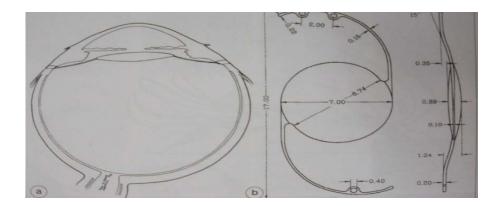


Figure 25- Ab interno two point technique

Figure 26- Ab interno technique with pars plana fixation



COMPLICATIONS OF SFIOL IMPLANTATION

There is a 12% risk of serious complications with SFIOL implantation which include :

1. CYSTOID MACULAR EDEMA - This is one of the most common complications seen in 9% to 36% of the patients after SFIOL implantation.

2.GLAUCOMA - Glaucoma after SFIOL implantation is seen in 30.3% of the patients when the surgery is performed at the same time as penetrating keratoplasty.

3.LENS DECENTRATION - Lens tilt or decentration is found in 5%-10% of patients. Proper polypropylene suture placement and tension are more important in avoiding this complication.

4.RETINAL DETACHMENT - The risk of retinal detachment is 2.3% in patients with SFIOL implantation³³.

5.UVEITIS - There is increased risk of uveitis in diabetic patients and in patients with recurrent anterior uveitis.

6.CHOROIDAL DETACHMENT - The risk of choroidal detachment is3.6% in patients with transscleral sutures.

7. SUTURE RELATED COMPLICATIONS - Suture related complications include suture granuloma, suture irritation or loose sutures³⁴.

AIMS/OBJECTIVES OF THE STUDY

PRIMARY OBJECTIVE

To determine the factors affecting the visual outcome following vitrectomy & scleral fixated intraocular lens implantation in:

1. Post surgical aphakia

2. Post traumatic cataract, subluxation of lens and anterior lens dislocation

3. Spontaneous subluxation or anterior lens dislocation in collagen vascular diseases or pseudoexfoliation.

SECONDARY OBJECTIVE

To study about the various factors during SFIOL implantation like:

1. Preoperative corneal opacity, striate keratopathy, chronic uveitis, cystoid macular edema, type of cataract surgery done, mode of injury, duration between trauma/cataract surgery and SFIOL implantation, associated systemic diseases.

2.Intraoperative factors like duration of surgery, complications during SFIOL implantation.

3.Postoperative complications like striate keratopathy, iritis, corneal decompensation(<500 cells/cu.mm),IOL malposition, cystoid macular edema (OCTthickness>250 μ),retinal detachment, rise of IOP, endophthalmitis, vitritis.

4. Measurement of refraction at the end of 6 weeks.

MATERIALS AND METHODS

This prospective study was conducted in Regional Institute of Ophthalmology and Government Ophthalmic Hospital, Egmore, Chennai from September 2010 to August 2012 for a period of 24 months.

INCLUSION CRITERIA

All patients with postsurgical aphakia, posttraumatic cataract, posttraumatic subluxation/ anterior dislocation, spontaneous subluxated or anteriorly dislocated lenses, patients with endothelial cell count >1200 cells/cu.mm.

EXCLUSION CRITERIA

Patients with endothelial cell count less than 1200 cells/cu.mm ,retinal detachment, vision not improving with aphakic correction, macular disorder, previous intraocular surgery other than cataract surgery and corneal tear suturing.

METHODOLOGY:

In this study totally 50 patients were included based on the inclusion criteria. Pre-operative evaluation in these patients include visual acuity by Snellen's chart, applanation tonometry ,Slit lamp biomicroscopy, B-Scan Ultrasonography, A-Scan Biometry, Keratometry, Indirect ophthalmoscopy, Specular Microscopy, Blood sugar, Optical coherence Tomography. 1. Anterior vitrectomy with ab externo two point scleral fixated intraocular lens implantation is done with Aurolab single piece SFIOL (with overall diameter of 13 mm and optic diameter of 6 mm with single eyelet at each haptic) and 10-0 polypropylene suture.

2. Postoperatively patients are treated with topical eyedrops like 1%prednisolone acetate & 0.5% moxifloxacin 6 times/day tapered over 6 weeks,0.5%ketorolac tromethamine 4 times/day for 1 week and Prednisolone tablets 1mg/kg in cases of vitritis which is tapered later.

3. Postoperative evaluation includes-visual acuity by Snellen's chart, applanation tonometry, Slit lamp biomicroscopy, indirect ophthalmoscopy and specular microscopy, OCT,UBM.

4. During the follow up period of 1,4,6 weeks and late follow up at 12 months complications if any are treated, retinoscopic refraction is done and best glasses are prescribed. Success rate of the surgery was defined as vision $\geq 6/18$.

SCREENING PROCEDURES PROCEDURES

Best corrected Snellen's visual acuity, IOP, B-scan ultrasonography, indirect ophthalmoscopic examination, slit lamp biomicroscopy, A-Scan Biometry, keratometry, specular microscopy, OCT for macular thickness, X-ray orbit (if required), Blood sugar. UBM

61

FOLLOW UP PROCEDURES/VISITS

Best corrected Snellen's visual acuity, IOP, slit lamp biomicroscopy, indirect ophthalmoscopic examination, specular microscopy, OCT, retinoscopic refraction, UBM at 1,2,4, 6 weeks and 12 months.

ASSESSMENT OF PARAMETERS

- a) Age, sex, Visual acuity better in which group.
- b) Pre-operative factors corneal opacity, striate keratopathy, chronic uveitis, cystoid macular edema, type of cataract surgery done, mode of injury, duration between trauma/cataract surgery and SFIOL implantation, associated systemic diseases.
- c) Intraoperative factors like duration of surgery, complications during SFIOL implantation.
- d) Postoperative complications like striate keratopathy, iritis, corneal decompensation(<500 cells),IOL malpositon, cystoid macular edema(OCT thickness>250µ),retinal detachment, rise of IOP, endophthalmitis, vitritis.

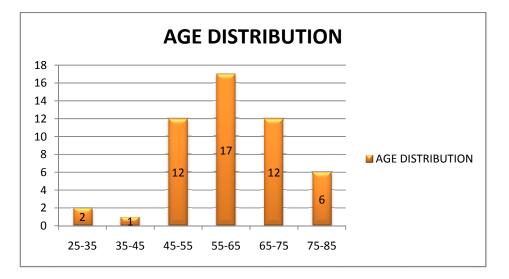
RESULTS

1.AGE AT PRESENTATION

S.NO	AGE OF THE PATIENTS	NO. OF PATIENTS
1	25-35	02
2	35-45	01
3	45-55	12
4	55-65	17
5	65-75	12
6	75-85	06

Table no 1 : Age distribution of patients

Chart no. 1: Age distribution of patients



The mean age of presentation in our study is 61.54(SD-11.49)

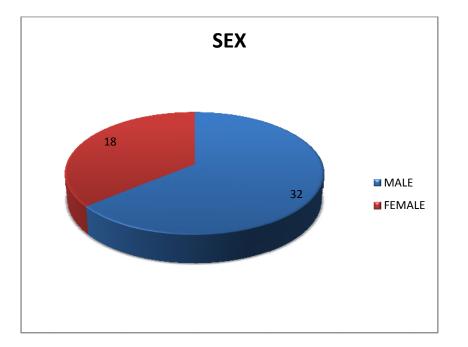
years. 58% of patients were between 45-65 yrs

2. SEX DISTRIBUTION

Table No 2 : Sex distribution

NO. OF PATIENTS
32
18

Chart No 2. : SEX DISTRIBUTION



In this study out of 50 patients 32(64%) were males and

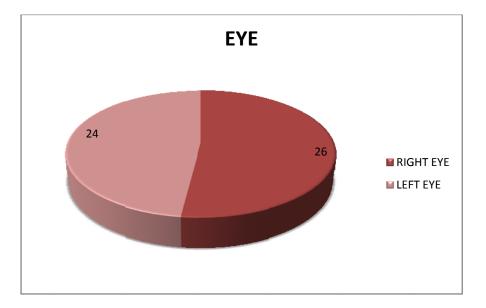
18(36%) were females.

3.LATERALITY

Table No 3 : Laterality

EYE	NO. OF PATIENTS
Right	26
Left	24

Chart No 3 : Laterality



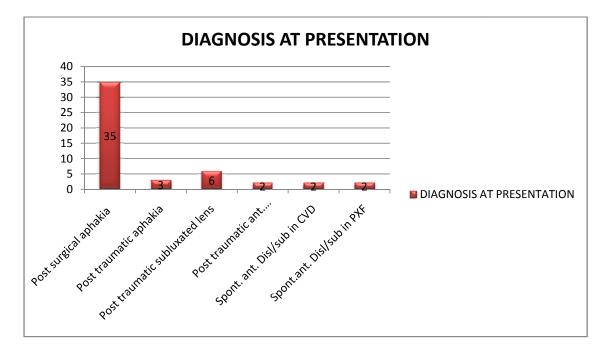
In this study both eyes were equally involved.

4. DIAGNOSIS AT PRESENTATION

S.NO	DIAGNOSIS	NO.OF PATIENTS	PERCENTAGE %
1	Post surgical aphakia	35	70
2	Post traumatic cataract	3	6
3	Post traumatic subluxated lens	6	12
4.	Post traumatic ant. dislocation of lens	2	4
5	Spontaneous anterior dislocation or subluxation in collagen vascular disease	2	4
6	Spontaneous anterior dislocation or subluxation in PXF	2	4

Table.No 4 : Diagnosis at presentation

Chart no 4 : Diagnosis at presentation



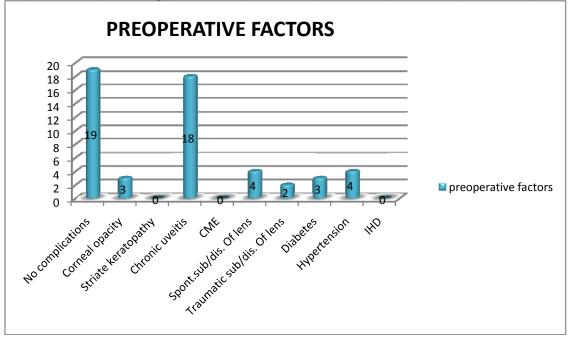
Majority of the patients were in the post surgical aphakia group (70%).

5. PRE - OPERATIVE FACTORS

S.NO	PREOPERATIVE FACTORS	NO. OF PATIENTS	PERCENTAGE
1	No complications	19	38
2	Corneal opacity	3	6
3	striate keratopathy	0	0
4	Chronic uveitis	18	36
5	Cystoid macular oedema	0	0
6	Spontaneous	4	8
	subluxation/dislocation of lens		
7	Traumatic	2	4
	subluxation/dislocation of lens		
8	Diabetes mellitus	3	6
9	Hypertension	4	8
10	Ischaemic heart disease	0	0

Table no 5: Pre-operative factors

Chart No 5: Preoperative factors



The most common factors were chronic uveitis (38%) followed by spontaneous dislocation / subluxation of lens (8%) and hypertension (8%).

6. TYPE OF CATARACT SURGERY

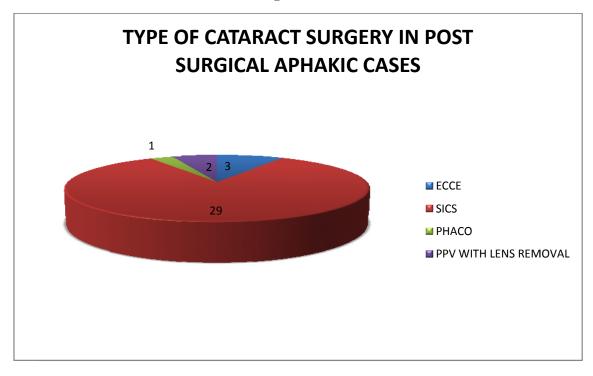
Table No 6 : Type of cataract surgery in post surgical aphakics

S.NO	TYPE OF CATARACT SURGERY	NO OF PATIENTS	PERCENTAGE %
1	ECCE	03	06
2	SICS	29	58
3	РНАСО	01	02
4	PVP WITH LENS REMOVAL	02	04

patients

Chart No.6 : Type of cataract surgery in post surgical aphakics

patients



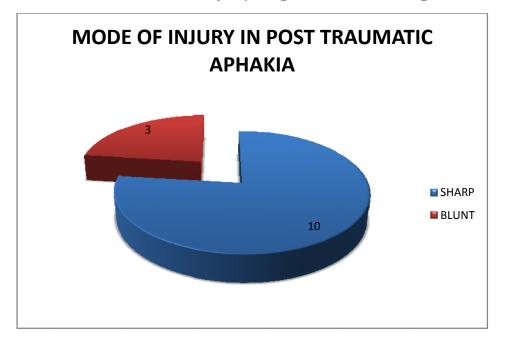
Majority of the post surgical aphakia patients had undergone SICS (58%).

7.MODE OF INJURY IN POST TRAUMATIC APHAKIA

Table No 7: Mo	ode of injury	in post trauma	atic aphakia
	U U		L

MODE OF INJURY	NO.OF PATIENTS
Blunt trauma	10
Sharp injury	03

Chart no 7 : Mode of injury in post traumatic aphakia

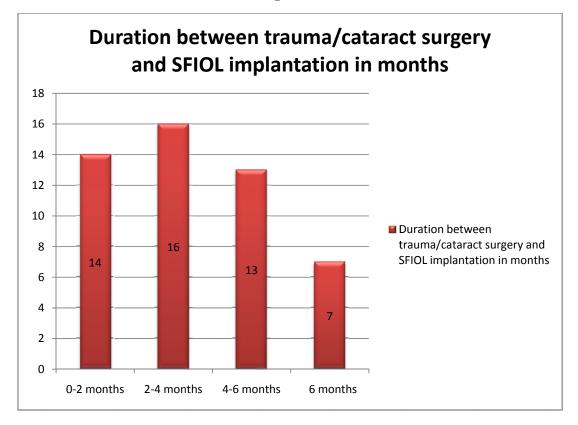


Total number of patients presenting with history of trauma were 13(26%) and among them 10(77%) had blunt trauma to the eye and 3(23%) had sharp injury.

8.DURATION BETWEEN TRAUMA OR CATARACT SURGERY AND SFIOL IMPLANTATION

Chart no 8: Duration of trauma/cataract surgery and SFIOL

implantation



Duration of trauma or cataract surgery and SFIOL implantation varied between minimum of 1 month to maximum of 25 years. But most the patients presented within 2 to 6 months duration.

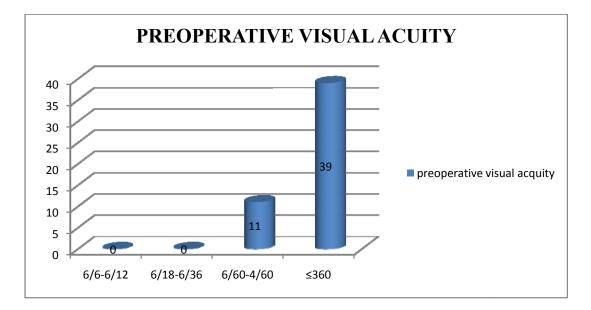
9..PRE OPERATIVE VISUAL ACUITY

Preoperative visual acuity was measured in all patients. Out of these 50 patients 11(22%) patients had visual acuity of 6/60 to 4/60 and 39(78%) patients had visual acuity of $\leq 3/60$.

S.NO	VISUAL ACUITY	NO. OF PATIENTS
1	6/6-6/12	0
2	6/18-6/36	0
3	6/60-4/60	11
4	≤360	39

Table No 8 : Preoperative visual acuity

Chart No. 9: Preoperative visual acuity



10. SLIT LAMP FINDINGS

S.NO	SLIT LAMP FINDING	NO. OF
		PATIENTS
1.	Normal	22
2	Ant. subluxation of cataract/lens	06
3	Ant. dislocation of cataract/lens	02
4	Aphakia	03
5	Iris pigment dispersion	13
6	PXF	04
7	Corneal opacity	03
8	Corneal oedema	01
9	Cortical matter	01
10	Iris atrophic patches	02
11	Uveitis	06

Table N o 9 :Preoperative slit lamp examination

The most common slit lamp examination findings in preoperative evaluation was found to be iris pigment dispersion in 13(26%) patients, followed by uveitis in 6 patients(12%).

11. B SCAN FINDINGS

S.NO	B SCAN FINDING	NO. OF PATIENTS
1	Normal	43
2	PVD	7
3	Retinal detachment	0
4	Vitritis	0

Table No 10: Preoperative B scan findings

Table No 11: Post operative B scan findings

S.NO	B Scan finding	No. of patients
1	Normal	39
2	PVD	7
3	Retinal detachment	0
4	Vitritis	4

Table no 11 shows the postoperative B scan findings and was normal in 39(78%) patients and 7 patients had PVD and 4 patients had vitritis on B scan examination.

Preoperative fundus examination was normal in 47(94%) patients and 2 (4%) patients had hypertensive changes .Fundus could not be visualised in one of the patient due to corneal opacity.

12. ENDOTHELIAL COUNT BY SPECULAR MICROSCOPY

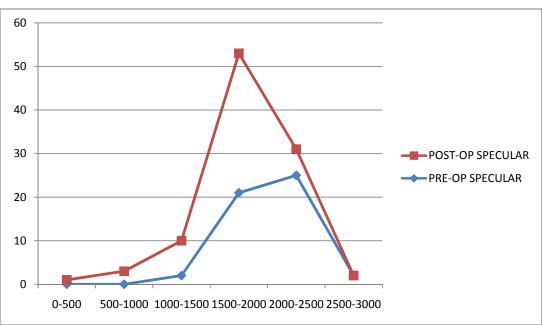


Chart No.10 : Pre-op and post -op endothelial count on

specular microscopic examination

Specular microscopic examination was done for all patients. Mean endothelial count for pre-op and post-op patients was $2021(SD\pm 297)$ and $1647.04(SD\pm 378.01)$ respectively.

13.DURATION OF SURGERY FOR SFIOL IMPLANTATION

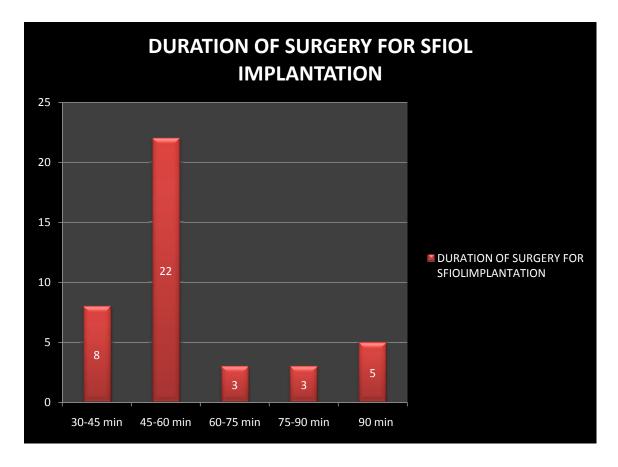


Chart No.11 : Duration of surgery for SFIOL implantation

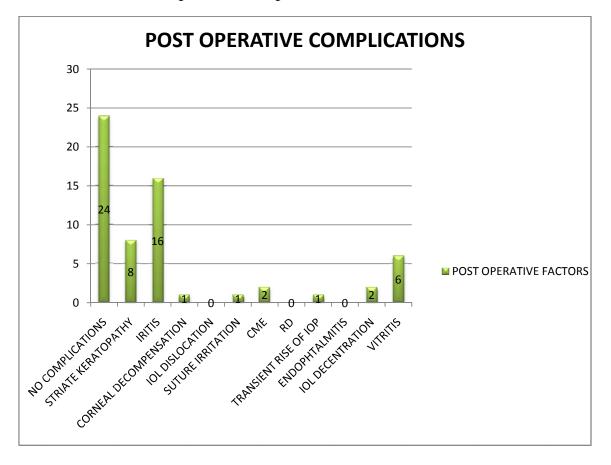
In this study 60% of patients were operated within 60 minutes and 10 were operated for more than 90 minutes.

14.POST OPERATIVE COMPLICATIONS

S.NO	POST- OP COMPLICATIONS	NO. OF PATIENTS	PERCENTAGE
1	No complications	24	48
2	Striate keratopathy	08	16
3	Iritis	16	32
4	Corneal decompensation	01	2
5	Suture irritation	01	2
6	Cystoid macular oedema	02	4
7	Retinal detachment	0	0
8	Transient rise of IOP	1	2
9	Endophthalmitis	0	0
10	Vitritis	06	12
11	Psudophakodonesis/ IOL decentration	02	4
12.	IOL dislocation	0	0

Table No 12: Post operative complications

Chart No. 12 : Post operative complications



During post operative period all patients were monitored for complications. 24(48%) patients did not develop any complications. Post operative iritis in 16(32%) patients, was the most common complication noticed during the post operative period in our study, followed by striate keratopathy and vitritis in 8(16%) and 06(12%) patients respectively. There was no post operative endophthalmitis, retinal detachment, IOL malposition and transient rise of IOP in any of the patients included in our study.

15. COMPARISON OF PREOPERATIVE AND POSTOPERATIVE VISUAL ACUITY

S.NO	VISUAL ACUITY	PRE OP	PO 1 WEEK	PO 4 WEEKS	PO 6 WEEKS
			NO. OF	PATIENTS	
1	6/6-6/12	0	0	15	23
2	6/18-6/36	0	23	19	16
3	6/60-4/60	11	23	15	11
4	≤3/60	39	4	1	0

Table No. 13 : Comparison of visual acuity in pre-op and post-op period

At 6 weeks, the post-op visual acuity improved to 6/6-6/12 in 46% of cases.

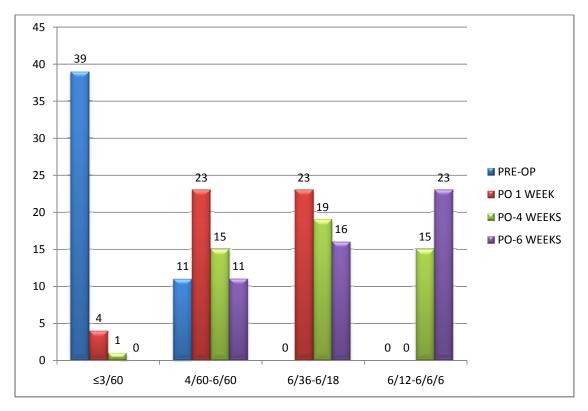


Chart No.13 : Comparison of visual acuity in pre-op and post-op period

16.SUCCESS OF SURGERY

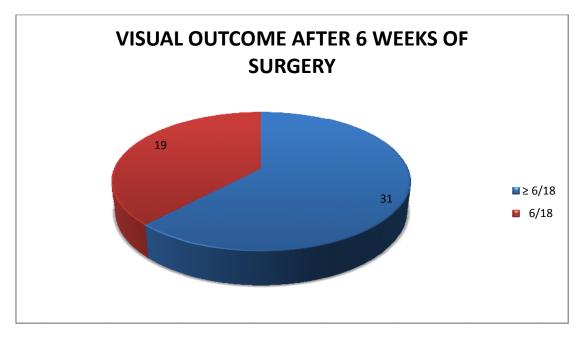


Chart No.14 : Visual outcome after 6 weeks of surgery

In our study, the success rate was 62 %.

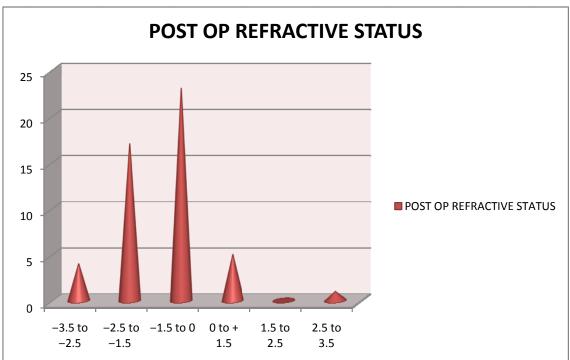


Chart No.15: .Refraction after 6 weeks

The refraction was more towards myopic side in our study.

Chart No.16 : Visual outcome in primary SFIOL and secondary

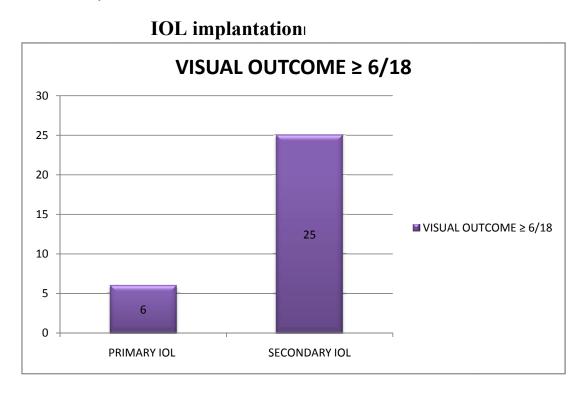


Table No.14 : Comparison of visual outcome in primary and secondarySFIOL implantation

S.NO	SURGERY	NO.OF PATIENTS	NO. OF PATIENTS WITH VISUAL OUTCOME OF ≥6/18	PERCENTAGE (%)	p VALUE (<0.05 SIGNIFICANT)
1	PRIMARY	15	06	40	0.657
2	SECONDARY	35	25	71	0.031

In our study secondary IOL implantation was associated with

significant visual outcome compared to primary SFIOL implantation with

p value (0.031) which is statistically significant.

Table No.15 : MUTIVARIATE ANALYSIS OF PRE-OP FACTORS ANALYSED FOR IMPROVEMENT IN VISUAL OUTCOME (≥6/18)

S.NO	PRE-OP FACTORS	NO. OF PATIENTS	p VALUE	SIGNIFICANCE (<0.05)
1	No pre op factors	19	0.001	Significant
2	Corneal opacity	03	0.117	Not significant
3	Spontaneous dislocation of lens	04	0.275	Not significant
4	Traumatic dislocation of lens	02	0.687	Not significant
5	Diabetes	03	0.393	Not significant
6	Hypertension	04	0.182	Not significant
7	Type of cataract surgery	35	0.073	Not significant
8	history of injury	13	0.057	Not significant
9	Duration of trauma/cataract surgery and SFIOL implantation<4months months	30	0.436	Not significant

Above table shows the mutivariate regression analysis of preoperative factors for significant improvement in vision($\geq 6/18$). Visual outcome was significantly improved $\geq 6/18$ in patients those who did not have any of the pre-op factors(**p value of 0.001**). All other factors were not significantly associated with improved vision in this study.

In this study other pre-operative factors like IHD, striate keratopathy and CME were not present in any of the patients.

Table No. 16: MUTIVARIATE ANALYSIS OF POST-OP FACTORS ANALYSED FOR IMPROVEMENT IN VISUAL OUTCOME (≥6/18)

S.NO	POST-OP	NO OF	P VALUE	SIGNIFICANCE
	FACTORS	PATIENTS		(<0.05)
1	No post -op	24	0.001	SIGNIFICANT
	complications			
2	Striate	08	0.518	Not significant
	keratopathy			
3	Iritis	16	0.187	Not significant
4	Corneal	0	1.000	Not significant
	decompensation			
5	IOL diclocation	0	1.000	Not significant
6	CME	02	0.999	Not significant
7	Suture irritation	01	1.000	Not significant
8	Transient IOP	01	1.000	Not significant
	rise			
9	Vitritis	06	0.300	Not significant
10	Pseudo	02	1.000	Not significant
	phacodonesis			

In patients with no post op complications there was significant visual improvement after 6 weeks of SFIOL implantation. Presence of other postop factors were not significantly associated with improvement in visual outcome in this study. In intra-op factors **prolonged duration of surgery >60 min(p value 0.010)** was associated with poor visual outcome in this study.

Table No. 17: MULTIVARIATE ANALYSIS OF PRE-OP FACTORSANALYSED FOR DECREASE IN VISUAL OUTCOME (<6/18)</td>

S.NO	PRE-OP	NO. OF	P VALUE	SIGNIFICANCE
	FACTORS	PATIENTS		(<0.05)
1	No pre op	19	0.986	Not Significant
	factors			_
23	Chronic uveitis	03	0.001	Significant
3	Spontaneous	04	0.577	Not significant
	dislocation of			-
	lens			
4	Traumatic	02	0.721	Not significant
	dislocation of			
	lens			
5	Diabetes	03	0.864	Not significant
6	Hypertension	04	0.975	Not significant
7	Type of	35	0.330	Not significant
	cataract			
	surgery			
8	history of	13	0.003	Significant
	injury			_
9	Duration of	30	0.187	Not significant
	trauma/cataract			
	surgery and			
	SFIOL			
	implantation<4			
	months			

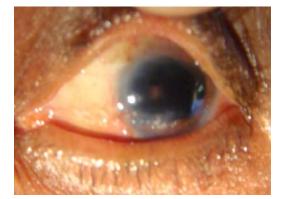
Presence of chronic uveitis and history of injury to the eye were significantly associated with poor visual outcome with **p value of 0.001(<0.05) and 0.003(<0.05)** respectively after 6 weeks of SFIOL implantation. Other factors like DM, hypertension, type of cataract surgery, traumatic or spontaneous dislocation of lens and duration between trauma / cataract surgery and SFIOL implantation were not significantly associated with poor visual outcome.

Table No. 18: MUTIVARIATE ANALYSIS OF POST-OP FACTORSANALYSED FOR DECREASE IN VISUAL OUTCOME (<6/18)</td>

S.NO	POST-OP	NO OF	P VALUE	SIGNIFICANCE
	FACTORS	PATIENTS		(<0.05)
1	No post -op	24	0.120	Not Significant
	complications			
2	Striate	08	0.049	Significant
	keratopathy			
3	Iritis	16	0.001	Significant
4	Corneal	0	0.197	Not significant
	decompensation			
5	IOL dislocation	0	0.429	Not significant
6	CME	02	0.065	Not significant
7	Suture irritation	01	0.429	Not significant
8	Transient IOP	01	0.197	Not significant
	rise			
1	Vitritis	06	0.519	Not significant
11	Pseudo	02	0.258	Not significant
	phacodonesis			

Presence of post complications like striate keratopathy and iritis were significantly associated with poor visual outcome (<6/18) with P value of 0.049(0.05) and 0.001(0.05) respectively. All other factors like corneal decompensation, IOL malposition, suture irritation, transient rise of IOP, vitritis and pseudo phacodonesis were not significantly associated with poor visual outcome in this study.

CLINICAL PHOTOGRAPHS



Pre-operative

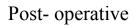
Case 1: Patient with post surgical aphakia

Post-operative



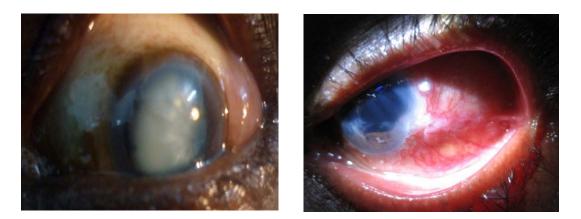
Pre-operative



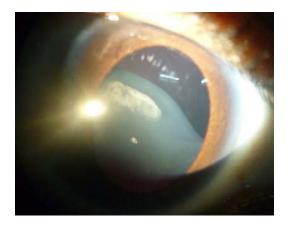


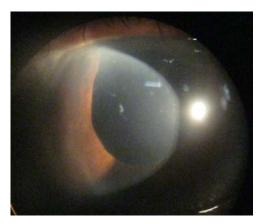
85

Case 3: Patient with anterior dislocation of lens

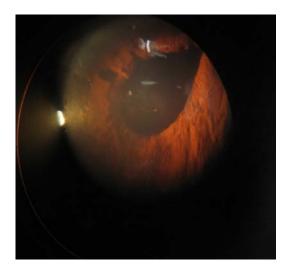


Case 4: patient with anterior subluxation of lens





Case 5: Patient with post-operative iritis



DISCUSSION

SFIOL is a safe and effective option for visual rehabilitation of patients with inadequate capsular support following cataract surgery, subluxation or anterior dislocation of lens following trauma , collagen vascular diseases or pseudoexfoliation.

50 eyes of 50 patients were selected for scleral fixated intraocular lens implantation. The mean age of the patients was 61.54 years(25-80). In kwong et al study the mean age of the patients was 76.7 years(57-98)³. This can be attributed to the fact that in japan there are more number of elderly people compared to India.

In our study there were 32 males and 18 females. This can be possibly explained by the fact that males are at higher risk of occupational injury and being the earning member of the family they report earlier for visual rehabilitation.

Regarding laterality both the eyes were almost equally affected(26right eyes, 24 left eyes). The mean follow-up period in our study was 12 months in Lee et al study the follow-up period was 19.2 months. The most common diagnosis at presentation was post surgical aphakia(70%) followed by post traumatic anterior subluxation of lens(12%). There were no studies which have included all the above inclusion criteria for SFIOL implantation. The preoperative factors which were statistically significant in terms of post operative visual outcome were chronic uveitis (p value-0.001) and history of trauma/injury (p value -0.003). On literature search it is found that there are no articles to support the effect of pre-operative factors on visual outcome.

The mean duration between trauma/cataract surgery and SFIOL implantation was 18.03 months(range 1months to 300 months). Naresh K Yadav et al study the mean interval was 9.6 months. In our study though majority of our patients (60%) presented within 4 months, 3 patients presented years after cataract surgery²⁴.

In post surgical aphakia group the majority of patients(58%) had undergone SICS. In Lee et al study the majority of patients(68%) had undergone ECCE, as the study was done in 1997 when ECCE was more commonly practised. In the trauma group blunt injury was the most common mode of injury in our study.

In our study 15 patients (30%) had undergone primary SFIOL implantation and 35(70%) had undergone secondary SFIOL implantation. All the post surgical aphakia patients had undergone secondary procedure and all the traumatic patients had undergone primary procedure. In Lee et al study there were 30(54.5%) in the primary group and 25(45.5%) in secondary SFIOL group²⁴.

88

In majority of the patients(78%) the pre-operative visual acuity was $\leq 3/60$ and between 4/60 and 6/60 in 22% of cases. The mean duration of SFIOL implantation was 56.80 min(SD±27.23 min) and the increased duration of surgery was statistically significant (0.001) in terms of poor visual outcome after SFIOL implantation in our study. In Kwong et al study the mean duration was 65min (SD±24.12 min).

The post operative period was uneventful in 48% of the patients. The most common post -operative complication were iritis (32%) and followed by striate keratopathy/ corneal edema(16%) and vitritis(12%). Among these iritis(p value 0.001) and striate keratopathy(p value 0.049) were statistically significant in terms of poor visual outcome. The other complications were cystoid macular edema(4%), IOL decentration(4%), corneal decompensation(2%) and suture irritation(2%) in Lee et al study corneal edema was the only statistically significant(p value 0.027) post operative complication affecting the visual outcome. The other complications were increased IOP (36.6%), hyphaema(26.6), vitreous haemorrhage(26.6%), deformation (56.7%), cystoid macular edema (6.7%), IOL pupil decentration (3.3%) and corneal decompensation (3.3%). In Vote et al study there was increased incidence of spontaneous suture breakage.

The mean pre-op endothelial count was $2021(SD\pm297.0)$ and the mean post-operative endothelial count was $1647.04(SD\pm378.01)$. In Dadeya S et al study the mean post-operative endothelial count was 1723 ± 363 .

The post operative visual acuity at 1 week was between 6/18-6/36 in 46% of case,6/60 - 4/60 in 46% of cases $\leq 3/60$ in 8% of cases. At 6 weeks majority (46%) had 6/6- 6/12 visual acuity and the remaining had visual acuity between 6/18-6/36 in 32% of cases and 6/60 - 4/60 in 22% cases. The improvement in visual acuity at 6 weeks is due to the treatment of complications.

The success of surgery was defined as visual acuity $\geq 6/18$. In our study 62% of patients have visual acuity of $\geq 6/18$. In the primary SFIOL group the success rate was 40% and 71% in the secondary SFIOL group. So from our study it is found that the visual acuity in the secondary group is statistically significant(p value 0.031). In Sanjeev kumar et al study, the success rate was ($\geq 6/18$) 100% in secondary implantation and 83.33% in primary implantation. This could be explained by small sample size in this study(10 patients)²³.

In Lee et al study the success rate was 56.6% in primary and 76% in secondary group. This can be attributed to the fact that there is increased

risk of post-operative inflammation in primary group as compared to presumably healthier group of eyes preselected in the secondary group²⁴.

Furthermore, the skilled and meticulous surgical technique may not be ideally performed under stressful situation associated with posterior capsular rupture. Post operative refraction is between -2.5 to 0 in 74% of patients in our study as in a study by Donaldson et al(- 1.32 ± 2.12) and is more towards myopic side for SFIOL³⁵.

LIMITATIONS OF THE STUDY

Longer follow up time is required to assess the long term post operative complications like suture related complications. Because of the small sample size, many of the factors assessed were not statistically significant.

CONCLUSION

In our study, males are predominantly affected. The age group 45-75 years formed the core group to get operated. Majority of the patients presented with post surgical aphakia.

The statistically significant factors associated with poor visual outcome are preoperative factors like chronic uveitis and trauma, intraoperative factors like prolonged duration of surgery and post-operative complications like iritis and striate keratopathy.

Results in this study reveal that the visual outcome following the secondary SFIOL implantation is better than primary SFIOL implantation which can be attributed to the increased rate of inflammation in the primary procedure. The success rate of the surgery was 62% .The post operative refraction is mostly towards myopic side in this study.

The final visual outcome depends on the preoperative, intraoperative and postoperative factors. So emphasis must be laid on thorough preoperative evaluation of the patient, meticulous surgical technique and treatment of the postoperative complications.

FUTURESCOPE

Future advances in this area include endoscope assisted suture fixation of PCIOL, described by Jurgens et al and Sasaharan et al could help ease the technical difficulty of implanting these lenses.UBM technology allows the surgeon to have proper visualisation of haptic position in regards to ocular anatomy. It is most useful as a postoperative diagnostic test when patient has signs of lens malposition. Foldable IOLs allow for insertion through smaller incisions therefore cutting operative time by possibly eliminating closure of limbal incision, reduced hypotony and minimising postoperative astigmatism.

In the future, the rate of secondary IOL implantation will decrease drastically because most IOL implantation will be done at the time of cataract removal. However there will be still a need for secondary procedure in cases with severe complications during cataract surgery, in IOL exchange, in children where congenital cataract removal is done before 1 year of age and in patients after ocular trauma where IOL implantation is postponed.

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PROFORMA

SFIOL IMPLANTATION

NAME:

AGE/SEX:

COMPLAINTS:

PAST HISTORY: CATARACT SURGERY/TRAUMA/COLLAGEN VASCULAR DISEASE/DM/HTN PRE-OP COMPLICATIONS Preoperative corneal opacity/striate keratopathy/chronic uveitis/cystoid macular edema/type & complications of cataract surgery done/mode of injury/duration between trauma/cataract surgery & SFIOL implantation/associated systemic diseases

DIAGNOSIS:

	RE	LE
VA with		
aphakic		
correction		
TENSION		
DUCT		
BP		
RBS		
A-SCAN		
K READING		
SLE		
FUNDUS		
B SCAN		
SPECULAR		
MICROSCOPY		
X-RAY ORBIT		
(if required)		
OCT		

SURGERY TECHNIQUE: DURATION:

SURGEON:

INTRA OPERATIVE COMPLICATIONS:

	RE	LE
VISION with PH		
TENSION		
FUNDUS		
SLE		
SPECULAR MICROSCOPY		
B SCAN		
ОСТ		
K Reading		
UBM		

POST OPERATIVE COMPLICATIONS: Striate keratopathy/iritis/corneal decompensation(<500 cells)/ cystoid macular edema(OCT thickness> 250μ)/retinal detachment/transient rise of IOP/endophthalmitis/ vitritis/IOL decentration.

AT DISCHARGE -VISION

RETINOSCOPIC REFRACTION:

SIGNIFICANT DETAILS:

KEY TO MASTER CHART

SEX

M- Male

F- Female

complaints

DV- Defective vision

PAST HISTORY

- 1. cataract surgery
- 2. trauma
- 3. collagen vascular diseases

4. spontaneous

DIAGNOSIS

- 1. Post surgical aphakia
- 2. Post tarumatic cataract
- 3. Post traumatic subluxation of lens
- 4. Post traumatic anterior dislocation oflens
- 5. Spontaneous subluxation /dislocation of lens due to CVD
- 6. Spontaneous subluxation /dislocation of lens due toPXF

SURGERY

- 1. Primary
- 2. secondary

NO PRE-OP FACTORS

- 1. yes
- 2. no

TYPE OF SURGERY

- 1. ECCE
- 2. SICS
- 3. PHACO
- 4. PPV with lens removal

TYPE OF INJURY

- 1. stick
- 2. blunt

VISUAL ACUITY

- 1.6/6-6/12
- 2.6/18-6/36
- 3. 6/60- 4/60
- $4. \leq 3/60$

FUNDUS

- 1. normal
- 2. abnormal
- 3. not visualised

B SCAN

- 1. Normal
- 2. PVD
- 3. Retinal detachment
- 4. Vitritis

ΙΟ

1. Normal

2. Raised

INTRAOPERATIVE COMPLICATIONS

1. No complications

OCT

- 1. Normal
- 2. CME

SL.No	NAME	AGE .	SEX	EYE	DIAGNOSIS	1.12*	N	co	SK	cu	CME	SPON DISL	TRAU DIS	· MO	HTN	TYPE of Surgery	MODE OF INJUR	Interval	PRE-OP VA	CORRECTION	TENSION	FUNDUS	B SCAN	SPEC. MIC	DUR OF SURIMIN	Time	PO VISION	PO TENSION	PO SPEC MIC	B SCAN	PO NORMAL	POST OPSK	IRITIS	8	IOL MAL	SUT. IRR	POST OP CME	IOP RAISE	ENDOPH	VITRITIS	UNV I	4 WK		6 WK	RETINOS REF		Success
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	iyaraman		m		2	-	_	_	-	1	0	0		0		0		6		660nip	1			152			3				_					0	0	-	0	-	0	_	_	2	_3.5ds	_	1
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	vadai selvi		ſ		-	_	_	0	-	0	_		0	0	1	2	0	3	-	260+11.5Ds 660	1			224		_	-	1			0	-		0	-	0	0	0	-		0 -			2	_1ds0.5dcy1@70	-	0
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