"THE VISUAL OUTCOMES AFTER CATARACT SURGERY WITH EXTENDED DEPTH OF FOCUS LENS AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI -A PROSPECTIVE INTERVENTIONAL STUDY".

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"THE VISUAL OUTCOMES AFTER CATARACT SURGERY WITH TRIFOCAL LENS AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI – A PROSPECTIVE INTERVENTIONAL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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ABBREVIATIONS

ACIOL	ANTERIOR CHAMBER INTRAOCULAR LENS
AS	ANTERIOR SEGMENT
D	DIOPTER
DV	DISTANT VISION
ECCE	EXTRA CAPSULAR CATARACT EXTRACTION
ICCE	INTRA CAPSULAR CATARACT EXTRACTION
IOL	INTRAOCULAR LENS
PHACO	PHACOEMULSIFICATION
PCIOL	POSTERIOR CHAMBER INTRAOCULAR LENS
PS	POSTERIOR SEGMENT
NV	NEAR VISION
SICS	SMALL INCISION CATARACT SURGERY
EDOF	EXTENDED DEPTH OF FOCUS

ABSTRACT

Background: This study with aimed to assess the visual outcomes after cataract surgery with Expanded Depth of Focus lens. Due to its capacity to deliver functional vision over a variety of distances, multifocal IOLs represent the first choice for many surgeons, and spectacle independence is anticipated to be attained.

Methodology: This one year prospective interventional study, included patients who underwent unilateral cataract surgery with EDOF lens at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. The source of data for the study were the patients diagnosed with cataract willing for phacoemulsification under topical anaesthesia and opted for the EDOF lens, attending the Out Patient Department of the Department of Ophthalmology

Result: Total of 30 participants fulfilling the inclusion criteria were included in the study after obtaining the informed consent. The mean age of participants was found to be 61.83±9.71yrs of age. Among them 60% were female patients and 40% were male patients with female to male ratio of 1.5:1 (female preponderance in the study was noted). The improvement of distant vision was seen in 90% of patients, improvement of intermediate vision was seen in 93.3% of patients and improvement of near vision was seen in 83.3% of patients at the 4^{th} week of follow-up with EDOF lens. In this study, day glare was noted in 13.3% of patients, night glare in 26.7% of patients and halos in 30% of patients at the end of 4 weeks.

Overall satisfaction of the patients was found to be very satisfied in 76.7% of patients, 16.7% of patients responded as satisfied and 6.7% of patients responded that they were not satisfied with the outcome.

Conclusion: The study demonstrated that EDOF lenses may be implanted in individuals undergoing cataract surgery safely and with satisfactory visual results. With EDOF lens lesser dysphotic symptoms were observed. The patient's satisfaction showed that majority of the patients were very satisfied at the 4^{th} week of follow-up.

Keyword: Lens, Cataract, Extended Depth of Focus, Intraocular lens.

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INTRODUCTION

According to the most recent WHO assessment, cataract is responsible for 51% of global blindness i.e around 20 million individuals are affected annually. Cataract continues to be the major cause of treatable blindness. The number of persons diagnosed with cataract is expected to rise as people live longer lives. Cataract is most common cause of vision loss in both developed and developing countries.

The demand for newer intraocular lenses (IOLs) has grown as the indications for cataract surgery have expanded. Patients seek treatment because of the loss of distant vision as well as progressive loss of lens accommodation as they age.

Monofocal IOLs correct only the distance vision but the intermediate and near vision are not corrected. The near vision in monofocal IOLs can be corrected by monovision correction but their will be loss of stereopsis and suppression. To overcome this presbyopic IOLs were used.

Multifocal (bifocal and trifocal), accommodative or pseudo-accommodative and EDOF IOLs are some of the different IOLs that are used to correct presbyopia.

Because multifocal IOLs are expected to provide functional vision at a wide range of distances and are predicted to be spectacle independent, many surgeons choose them over other IOLs. Modern bifocals have two portions. The upper portion of the lens is for long-distant vision while its lower portion is for near vision. In Trifocals three useful focal lengths are provided by newly developed diffractive technology (distant, intermediate and near).

There are a few drawbacks with multifocal IOLs. The influence of the light in an out-of-focus image reduces the contrast of the image because the design of the multifocal IOL divides the light rays into more than one focus. In comparison to the far and near distance ranges, traditional bifocal IOLs continue to impair the intermediate distance range. Along with reducing contrast sensitivity and modulation transfer function (MTF), bifocals also increases the likelihood of undesirable visual phenomena including glare and halos. The most common complaints with trifocals are halos, day glare and night glare.

Accommodating IOLs are different from standard IOLs because they are able to change focal distances. These IOLs have flexible "arms" called haptics. These haptics use the movements of the eye's muscles to change focus from distance to near. They have poor long-term visual outcomes as a result of the posterior capsular opacification (PCO) and asymmetric vaulting caused by capsular contraction and lens slant.

The extended range of focus IOL, also known as the EDOF IOL, is cutting-edge treatment modality for correcting presbyopia. In contrast to monofocal IOLs or MF IOLs, which focus light on a single spot, the basic optical principle is to generate a single, expanded focal point to improve depth of focus (which have two or three distinct points).[1]

EDOF IOLs had good visual outcomes with reduced contrast deterioration and less dysphotic phenomena, which are frequently linked with multifocal IOLs. The current prospective interventional study at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, sought to evaluate the visual results, dysphotic phenomenon and patient satisfaction following cataract surgery with an EDOF lens.

OBJECTIVES

Aim:

To evaluate the visual outcomes, dysphotic symptoms and patient satisfaction after cataract surgery with EDOF lens at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi

REVIEW OF LITERATURE

An opacity 0f the eye's lens known as a cataract can impair or distort vision, create glare problems, or, in extreme circumstances, result in blindness. The Latin word for "waterfall" is where the word "catarractes" originates. To the naked eye of the spectator,. The main cause of blindness in the globe is cataract.[3]

Cataracts occur commonly with increasing age and may be a typical aspect 0f ageing. On the other hand, their development can be sped up by metabolic insults, poor nutrition, trauma, excessive sun exposure or other radiation exposure, and some medications like cortisone. There are no medical treatments that have been demonstrated to work. In the vast majority 0f cases, modern microsurgical techniques when combined with intraocular lens implantation, it is possible to restore normal vision..[4]

Cataracts continue to be the main cause 0f blindness. There were 12.3 million cases of cataract-related blindness in 1990 and 20 million cases in 2010, with a regional variation 0f 42 percent in Southeast Asia compared to a global average 0f 12.7%.[3] Cataract surgery has grown in most parts 0f the world, while the proportion 0f cataract-related blindness has decreased- East Asia, tropical Latin America, and western Europe experienced the greatest declines, while Sub-Saharan Africa experienced the smallest decreases..

The pattern and rate of blinding illnesses differ by country, depending on whether dietary and viral causes of blindness are eradicated and resources for curable disorders like cataract are available.. Furthermore, there are discrepancies in how blindness is defined; for example, blindness according to international health standards converts to 10/200 by Snellen notation.

Lens protein

India has the highest number 0f blind people in the world. Cataracts and corneal opacities are responsible for 70% of blindness. Cataracts are more common in the eyes 0f the elderly and diabetics. Because the lens is avascular, it relies on the aqueous humour for oxygen and critical metabolites. The lens's uppermost region is composed of a monolayer of epithelial cells that proliferate and differentiate to become the lens's long fibre cells.. Proper lens cells (but not aged cells) have the normal protein synthesis machinery. The lens's proteolytic activity is quite low, which is due to the existence 0f endogenous protease inhibitors. Lens tissue has the highest levels of NADPH and a very active HMP shunt mechanism. Ascorbic acid is also abundant in the lens. They scavenge free radicals while keeping the lens transparent.[5]

Embryology

As was already mentioned, the lens is made of cells from the broad preplacodal region. Pax-6 has always delivered genetic instructions that are necessary for the development of the lens. Because Pax-6 activates and works with another transcription factor, Sox-2, it is necessary for the surface ectoderm to express itself in order for it to react to inductive signals (FGF and BMP) from the underlying optic vesicle. This causes the surface ectoderm to thicken and generate the lens placode. Additionally, other preplacodal region cells are prevented from growing into lens by signals produced by migrating neural crest cells that do not reach the area between the optic vesicle and the prospective lens. The lack of Pax-6 expression in these cells implies that they are unable to form lenses. Pax-6 expression remains as the lens placode invades to produce the lens vesicle, which eventually separates from the surface ectoderm. Pax-6 currently serves a unique role in regulating the activation 0f the genes that control the creation 0f lens crystallin proteins.

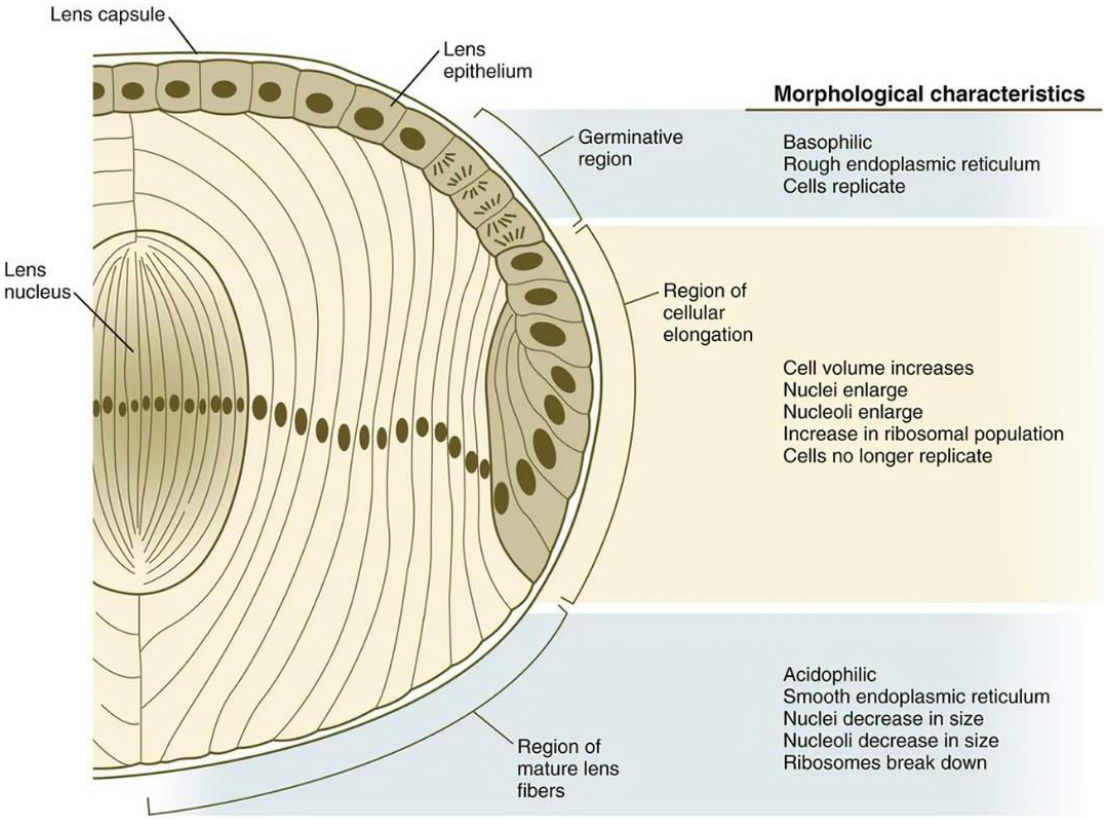


Figure 1: Human lens morphology

Alpha, beta, and gamma crystallins are the most important lens proteins. There are also small amounts 0f delta and epsilon variations described. They are not replaced during the individual's life. These proteins have no turnover. The proteins in the lens's centre are as old as the individual. The lens proteins are transparent because to the regular arrangement of the molecules. Alpha crystallin is found in practically all cells 0f the body, not just the lens.[5]

Optics of Human Eye[6–8]

Three chambers make up the eye. the aqueous humor- consisting of an anterior chamber between the cornea and the iris.

Aqueous humour is present in the posterior chamber between the lens,iris and ciliary body. Consisting of an anterior chamber between the cornea and the iris

Vitreous chamber, which contains clear gel known as viterous humour, is situated between the lens and the retina.

Image formation

The cornea allows light to enter the eye. The cornea and lens both refractively bend light.

The cornea has the greatest amount of power.

When a different distance is required for the eye to focus, the lens shape may be changed to modify its power (accommodation).

The iris, or aperture stop, 0f the system controls the beam diameter.

The pupil is the aperture 0f the iris.

Like a camera, the picture on the retina is reversed.

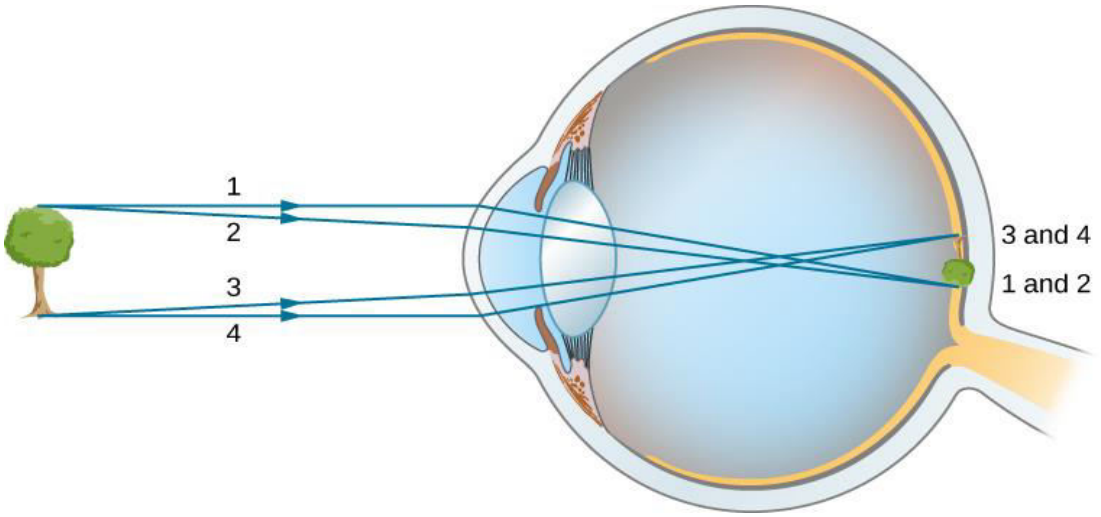


Figure 2: Principle 0f image formation by the eye

Eye power

The equivalent power 0f any optical system is one 0f its most significant functions.

The system's capacity to bend or divert the light ray.

The bigger the strength of the lens, the greater its capacity to divert the rays.

The eye's corresponding power F

F = n'/P'F'

As F'n' is the refractive index of the vitreous, light entering the eye from a great distance is imaged.

The average power 0f eye is $60m^{-1}$ or 60 diopter (D)

Binocular vision[9,10]

Using two eyes improves perception 0f the outside environment compared to using one eye alone.

With two eyes separated by around 60mm on either side, it is possible to see the world in three dimensions, including stereopsis, the feeling 0f depth.

In the horizontal plane, the overall field of view is about 210º

Binocular overlap is 120 º

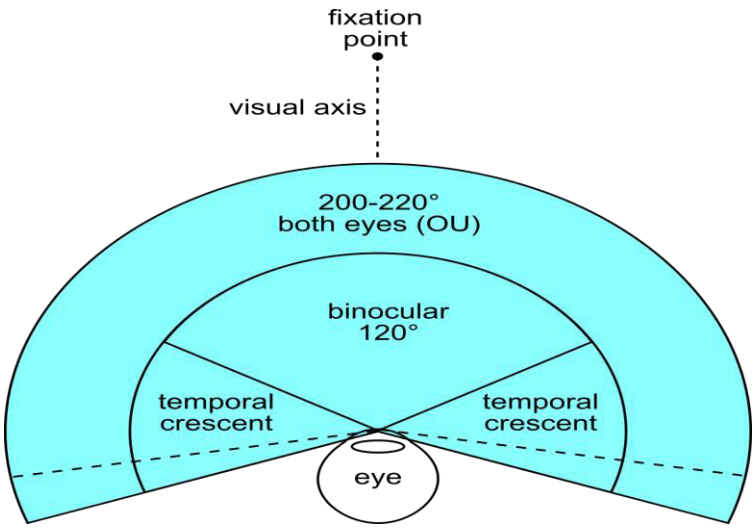


Figure 3: Binocular vision

Refractive components of the eye

The cornea provides 40 D (2/3rd power).

It contains several layers and supports the tear film.

In the middle, the thickness is around 0.5mm.

The posterior surface curves more than the anterior surface.

The power 0f the front surface (48D) is larger than that 0f the posterior surface.

Because the cornea and aqueous have a modest refractive index difference.

Curvature is frequently vary in various locations.

In general, the radius 0f curvature grows as one moves away from the surface apex.

Higher order aberrations are influenced by corneal surface asphericity.

Lens

It is a cellular tissue mass with a non-uniform refractive index.

Frequently found within the elastic capsule

There is no precise documentation 0f the lens's refractive index dispersion.

The majority 0f lens cells are lengthy fibres that have lost their nuclei.

Lenses continue to expand with age, as new fibres are deposited over the older fibres.

The anterior radius 0f curvature is around 12mm.

The posterior radius 0f curvature is approximately 6mm.

Shape changes as a result of accommodation and age, particularly at the front surface

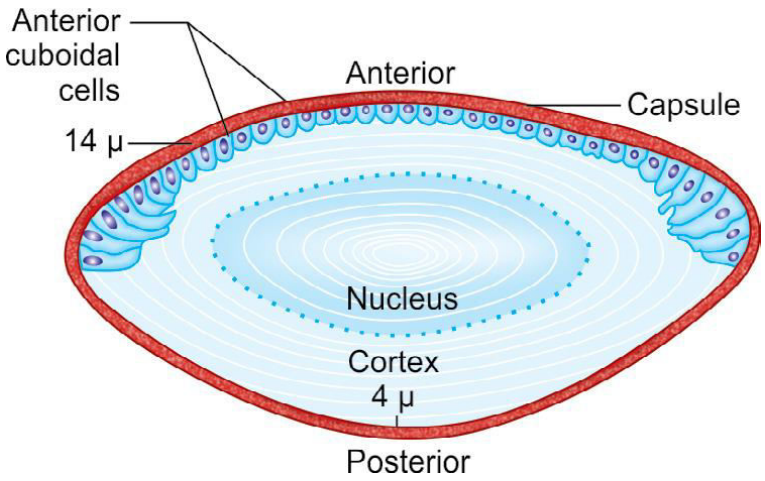


Figure 4: Structure 0f lens

Refractive errors[11]

These types 0f faults are more significant than similar power.

This can be interpreted as a length mistake caused by a mismatch with the corresponding power.

If length is excessively short, the picture is produced behind the retina, resulting in Hypermetropia.

If the length is greater than the power, the picture is produced in front 0f the retina, resulting in myopia.

Anomalies in refractive indices

The eye 0ptimally focuses on an item 0f interest, and the picture is finely focused 0n fovea.

An emmetropic eye is one that has a defined point 0f vision at infinity. This is considered a normal eye if it has an adequate range 0f accommodation. If the distant point is not at infinity, the refractive anomaly arises. Ametropic eyes are those whose distant point is not at infinity.

Types of refractive anomalies[11]

Myopia

Hypertmetropia

Astigmatism

Presbyopia

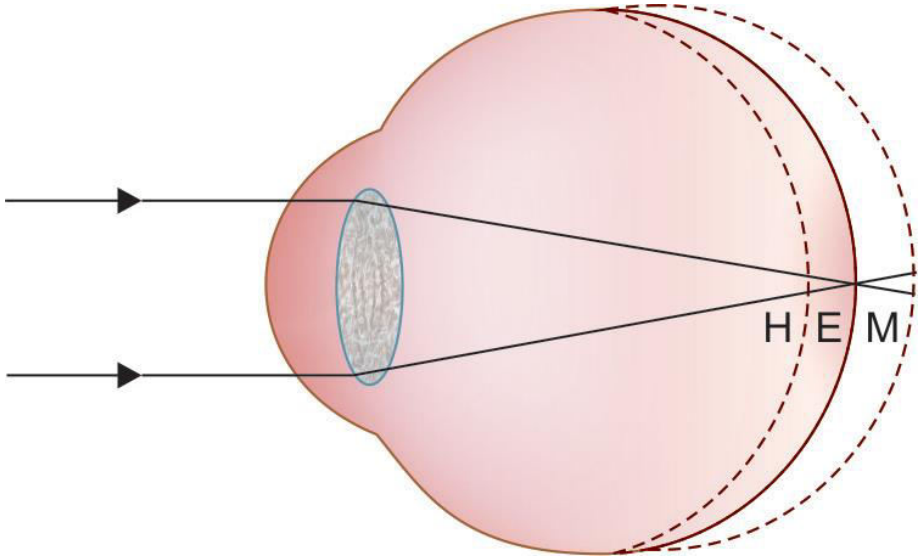


Figure 5: Hypermetropia (H), emmetropia (E) and Myopia (M)

When accommodation is at rest, the In emmetropia -the light-sensitive layer of the retina receives a perfect focus from incident parallel rays. (no refractive error).

When the accommodation is at rest, the parallel beams 0f light are not focused perfectly on the retina, resulting in ametropia (refractive error).

Myopia: [11]

Its far point is in front of the eye at a fixed distance.

By observing distant things through a negative powered lens with adequate power, this eye can focus clearly.

Hypermetropia: [11]

When the accommodation is at rest- It is a refractive error in which the retina's light-sensitive layer is focused posteriorly by incident parallel light beams.

Behind the eye is the furthest point 0f the eye.

If the amplitude 0f accommodation is sufficient, the eye may concentrate clearly 0n distant 0bjects.

By using a positive powered lens with the proper power.

Astigmatism[11]

The refractive system is uneven in different meridians, and there is no one focal focus on the retina.

The strength 0f the eye varies according to the meridian.

Usually as a result 0f one or more toroidal-shaped refracting surfaces.

This might be caused by surface displacement or tilting.

Typically associated with inaccuracies in the primary meridians 0f maximum and lowest power.

Myopia and hypermetropia may be associated with astigmatism.

As a result, it may exhibit myopic, hypermetropic, or mixed astigmatism.

Presbyopia: [11]

The selection of accommodation is limited, making it difficult to view nearby points of interest.

Aphakia: [11]

Aphakia meaning "absence of the crystalline lens of the eye.". Optically, it refers to the crystalline lens not being present in the pupillary region as it normally would be (patellar fossa).

Prior to the development of IOLs, the cataract was excised and the eye was left aphakic following ICCE and ECCE.

Because the lens is vital in refraction, its removal results in a significant drop in the eye's refractory power and causes it to become very hypermetropic.

The eye's power reduced from +60D to +44D.

The ability to accommodate has been gone, and the posterior focus point is now behind the eyeball.

Aphakia causes vision to be deficient owing to excessive hypermetropia and lack 0f accommodation, as well as some eryhropsia and cyanopsia. This might be owing to infrared and ultraviolet light entering the eye in the absence 0f a crystalline lens.

Aphakia requires correction due to poor eyesight and loss 0f accommodation.

Initially, spectacles were provided to address this poor vision.

Contact lenses gradually take their place, but they have significant drawbacks, such as high expense, more care required, and may not be suited for use in young children or elderly people. Contact lenses can cause issues such as infections.

With many of the difficulties and issues associated with glasses and contact lenses, IOLs have gained popularity.

Aging of eye[11]

Stable Refractive err0rs are quite common between the ages 0f 20 and 40, after which there is a shift in hypermetropic direction.

Many optical changes occur in adult eyes, resulting in a gradual decrease in visual ability.

The most noticeable age-related changes 0ccur in the lens's shape, size, and mass.

Its capacity to change form and light transmission decrease significantly.

The amplitude 0f accommodation peaks early in childhood and then steadily falls.

When most individuals in their 40s can no longer see clearly enough to complete the near task, this becomes a problem (presbyopia)

In the 1950s, accommodation is entirely lost.

In recent years, the cause 0f presbyopia has been debated. The majority 0f studies think that the lens loses its ability to change form as a result of changes inside the lens and capsule.

Pathogenesis 0f Cataract[12]

The eye's lens has a unique structure that renders it vulnerable to damage caused by ageing or other circumstances. It is composed 0f specialised cells that are arranged in a highly organised and intricate pattern and have a high concentration 0f cytoplasmic protein. Crystallin proteins, as well as the lens's complicated structure, contribute to its transparency. The lens, unlike other epithelia, is unable to shed nonviable cells, which over time press into the lens's centre and reduce its transparency.

Cataracts caused by ageing: Cataracts affect the vast majority 0f adults over the age of 50. Pathogenesis is associated to aging-related cell structural degradation. Although there are certain anatomic and ultrastructural correlations 0f lens opacity, the particular pathogenetic routes remain unclear. According to epidemiologic and experimental investigations, photo-oxidative damage, maybe aggravated by hazardous or sensitising substances, appears to play a role.

Non-age-related cataracts: Topical anticholinesterases, topical corticosteroids, certain phenothiazines, necrotizing scleritis, radiation of an intraocular tumour,

uveitis, scleritis, and trauma are the most frequent causes 0f non-age-related cataracts (toxic cataract).

The lens is composed 0f fibres (modified epithelial cells) which makes it clear and transparent and it is encased in a lens capsule which is membrane structure. The lens substance is divided into two parts:

• Cortex (superficial region) – made of younger fibres

• The nucleus fibres (the deeper section) are older.

Lens proteins are denatured and coagulated in many degenerative processes via diverse pathways, resulting in loss of clearness and, finally, cataract formation..[13] Following are the numerous mechanisms are involved:

- Congenital Cataract
- Subcapsular Cataract
- Cortical Cataract
- Nuclear Cataract
- All 0f leading to formation of cataract, which hampers the vision of patients.

Classification of cataract

No classification of cataract is entirely satisfactory. It may be classified as follows:

Congenital or developmental cataract

Acquired cataract

Senile

Traumatic

—— Irradiation

—— Mechanical

—— Electric shock

„ . Complicated (due to some other ocular disease)

- High myopia
- Anterior uveitis
- Retinitis
- Retinal detachment
- Glaukomflecken

„ . Secondary (due to some systemic disease)

- Hypocalcemia
- Diabetes mellitus
- Myotonic dystrophy
- Atopic dermatitis

„ . Toxic (due to drugs)

- Busulfan
- Corticosteroids
- Miotics (long-acting)
- Chlorpromazine
- Amiodarone
- Gold

Syndromes associate with cataract

- Treacher Collins
- Down's
- Wilson's disease
- Lowe's
- Fabry's disease

Senile cataract may be broadly divided into two types (though they may occur concurrently).

1. Cortical or s0ft cataract (75–80%): The classical features 0f hydration followed by coagulation 0f lens proteins, appear primarily in the cortex.

2. Nuclear or hard cataract (20–25%): The essential feature is a slow progressive sclerosis in the lens nucleus.

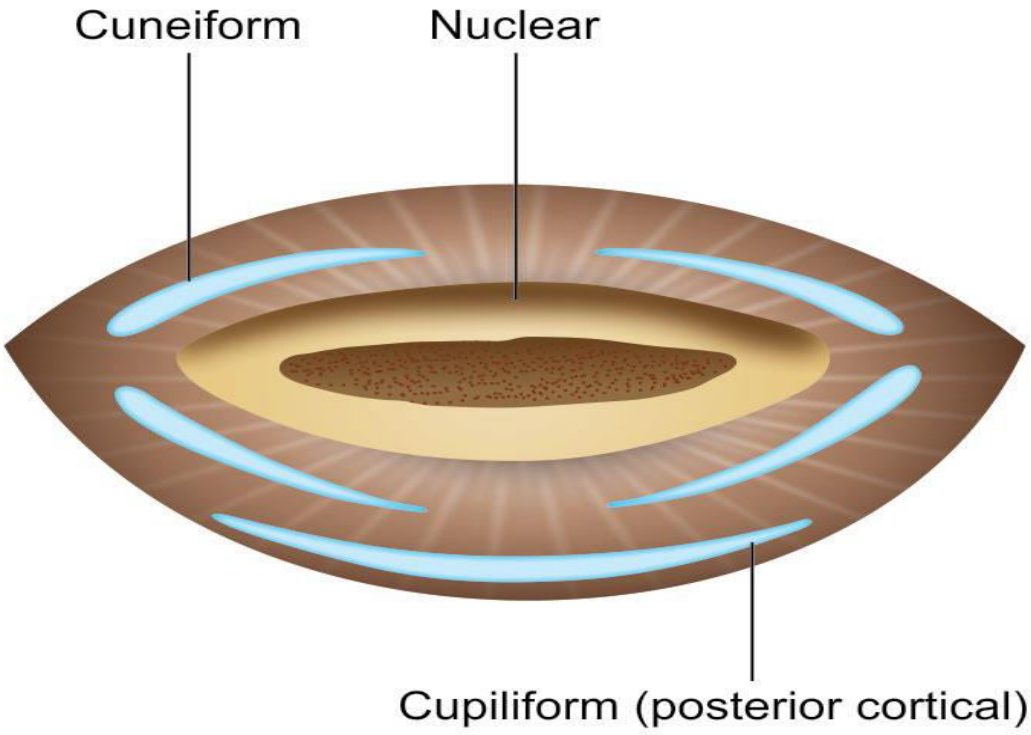


Figure 6: Types of senile cataract

Risk factors[12]

Several risk factors for cataract have been identified[14,15]:

- Age.
- Alcohol consumption.
- Smoking.
- Low education.
- Poor lifestyle habits, plus physical inactivity and malnutrition.[16]
- Sunlight exposure.
- Diabetes mellitus.
- Metabolic syndrome.
- HIV/AIDS.
- Electric shock
- Blunt trauma

The majority 0f these risk factors are environmental stressors that cause toxin production or antioxidant impairment. There is a dose-response association between ultraviolet B exposure in sunshine and smoking.[17,18] Smoking cessation may help some lens damage caused by smoking be repaired, but the majority 0f the cataract risk decrease is caused by reducing further dose-related lens damage. Additional environmental forces could exist as well. In the United States, adults' average cumulative low-level lead exposure levels appear to be linked to a higher risk of cataract development.[19,20]

Clinical presentation[12]

Cataract development is a painless, progressive process that varies greatly between individuals. Patients typically present with bilateral symptoms and report difficulties driving at night (particularly owing to glare from approaching headlights)

or reading road signs or fine print. The majority 0f occurrences occur in persons over the age 0f 60. Younger people with cataracts are more likely to have risk factors such as diabetes or systemic steroid usage. Cataracts can affect patients of all ages as a result of major eye trauma. Age-related and non-age-related cataracts have the same clinical appearance.

Investigation[12]

The following tests can aid in the diagnosis and management 0f the disease:

Intraocular pressure is measured t0 rule 0ut glaucoma.

Tests in a dark room: Direct Ophthalmoscope and Indirect Ophthalmoscope.

To rule out any vitreous pathology or retinal pathology, a fundoscopy is performed.

Biometry is used during surgery to insert intraocular lenses (IOLs).

Peripheral Retinal Assessment: evaluating light projection in all quadrants.

The cardboard test which is the two-point discrimination test, laser interferometry, the Maddox rod test, foveal electroretinogram, and the light stress-test are examples of macular function tests.

Ultrasound-scan: A B scan is recommended to assess for retinal detachment or any other vitreous disease.

Blood glucose levels, ECG, echocardiogram, and USG are all used to diagnose systemic illnesses.

Baseline testing includes a chest x-ray, liver function test, complete blood count, bleeding profile, renal function test, and screening for hepatitis B and C.

Treatment or Management

The treatment option is determined by the degree 0f opacity that makes performing important daily tasks difficult. The following therapy options are available:

Medically, surgery is not required if visual acuity is 6/24 or above since using refractive lenses or pupil dilation with 2.5 percent phenylephrine was adequate to do daily duties. Atropine, cyclopentolate can be helpful.

If the eye's vision is less than 6/24, or a medical indication (phacolytic-phacomorphic glaucoma, retinal detachment) that cataract is endangering that eye's health, typically, surgery is necessary.

Congenital Cataract: Over than 6/24 visual acuity and the patients can do their usual daily tasks, no treatment is required. F0r visual blurring or diplopia, refractive glasses may be recommended. If the patient's vision goes down from 6/24, surgery is required, and The surgeon has the option..[21]

Senile Cataract-

The following are treatment options: [22,23]:

Medical: Once the cataract has matured, no medical therapy is helpful. Mature cataracts have very hard nucleus, hence one of following procedures is utilised to remove the lens: Extracapsular cataract extraction: a preferred approach Intracapsular cataract extraction is an outdated procedure that is no longer performed owing to problems.

Phaco-emulsification is the modification of extracapsular cataract extraction (ECCE) that produces reduced astigmatism and faster vision recovery.

Laser-phacolysis is a noteworthy innovation that is currently being tested.

Indications for surgery

The various reasons for the surgery for the cataract in adult includes

- For optical reason
- Medical reasons
    - Phacolytic glaucoma
    - Secondary angle closure glaucoma due to intumescent cataract
    - Vitreoretinal disease
- Cosmetic reasons

Extracapsular Cataract Extraction[11]

It entails removing the centre part 0f the anterior capsule (anterior capsulotomy), followed by nucleus expression and cortical cleansing. The posterior capsule, equatorial area, and a portion of the anterior capsule's periphery are all kept intact.

Merits

The likelihood 0f vitreous loss is quite low.

The incidence of vitreous-related anterior segment complication is quite low. Because the posterior capsule is intact, there is a lower risk 0f cystoid macular edoema (CME).

There is a lower risk 0f retinal detachment. A PCIOL in the capsular bag is typically implanted in conjunction with ECCE, and it is a perfect IOL (Figs 15.27A and B).

An intact posterior capsule protects against infection (such as endophthalmitis) for an extended length of time.

Demerits

A demanding microsurgical procedure that is costly and time-consuming to master. Iridocyclitis and glaucoma are common side effects of lens particles. The posterior capsule becomes opaque (after cataract) occurs in a considerable number of cases, necessitating YAG-laser capsulotomy or needling.

Extracapsular cataract extraction is impossible in cases of dislocation and difficult in cases of lens subluxation.

Manual small incision cataract surgery

SICS (or manual SICS) is the variant 0f ECCE which is popular among underdeveloped nations. Manual SICS provides the advantage 0f stitchless self-sealing wounds and substantially speedier rehabilitation as compared to traditional ECCE.

In low-resource situations, manual SICS has various advantages over phacoemulsification, including quicker operative time, no requirement for advanced technology, and reduced cost. According to recent research, the results and complication rates 0f patients receiving phaco and manual SICS with PCIOL implantation are comparable. There are various manual SICS procedures and adjustments with comparable visual and surgical outcomes.

Phacoemulsification[11]

It is essentially an ECCE with the assistance of a highly complex equipment known as a phacoemulsifier. After being emulsified by ultrasonic vibration, the lens nucleus and cortical matter are simultaneously aspirated and controlled irrigated.

Finally, the entire posterior capsule and a portion 0f the anterior capsule are preserved as a capsular bag. In practically all forms of cataracts, it is a safe approach 0f doing ECCE with in-the-bag PCIOL implantation.

Merits

Sutureless cataract surgery is performed with a small incision and without the use of sutures. Faster wound healing Convalescence time is reduced. Early refraction stabilisation with little or no astigmatism.

Demerits

The equipment is pricey. The toughest technique. Beginners have a high risk 0f problems such as iris injury, corneal decompensation, posterior capsular rent, or nucleus drop into the vitreous. It is difficult to conduct in white mature cataracts and nuclear cataracts of grade 4+.

Differential diagnosis

The differential diagnosis for cataract include

Refractive errors

Diabetic retinopathy

Glaucoma

Macular degeneration

Optic atrophy

Corneal dystrophies and degenerations

Retinitis pigmentosa

Complications

Cataracts produce a number 0f problems, which are mentioned below:

C0ngenital cataract: [24]:

Include corneal ulcers, corneal perf0ration, and blindness. C0mplications 0f surgery include posterior capsular thickening, uveitis, aphakia following cataract surgery, refractive alterations which are growth-related, retinal detachment. and glaucoma.

Cataract development: These can be disease-related or surgical in nature:

Complications 0f the disease include acute congestive glaucoma, glaucoma of phacolytic type, iritis, subluxation 0f lens, glaucoma (hypermature stage), and loss of vision.

Complications from surgery are categorised as follows:

During surgery, the following complications occurred: posterior capsular rent, expulsive-haemorrhage, corneal-burn, and nucleus drop in the vitreous. Following surgery [25,26]: delayed anterior chamber formation, Iris prolapse, infection such as endophthalmitis or striate keratopathy, panophthalmitis, cystoid macular edoema, IOL malpositioning, dysphotopsia, ptosis, pseudophakic glaucoma, posterior capsular thickening, retinal detachment, and opacifications are some of the conditions that can occur.

INTRAOCULAR LENS IMPLANTATION[27]

Intraocular lens implantation is usually performed along with extraction 0f cataract at the same sitting (as a primary procedure), and it is called primary implantation. But, an implantation can also be done in selected cases any time after primary cataract surgery, it is then called secondary implantation.

Types 0f IOL

Depending on the placement 0f optics they are of two types

Anterior chamber IOL

Posterior chamber IOL

Single piece

Uniplaner

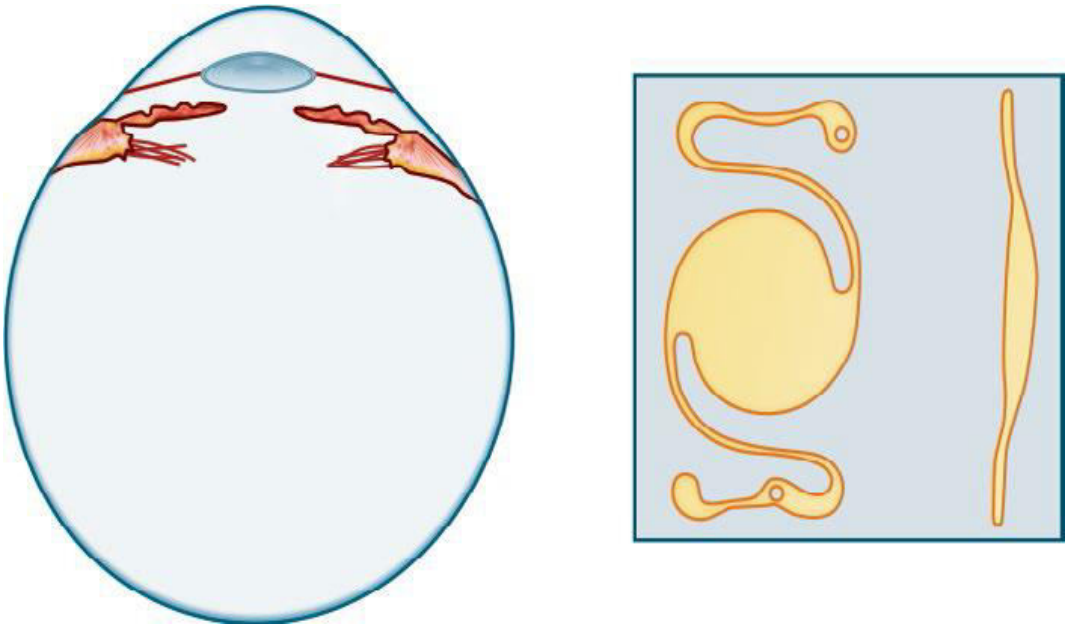


Figure 7: Anterior chamber IOL

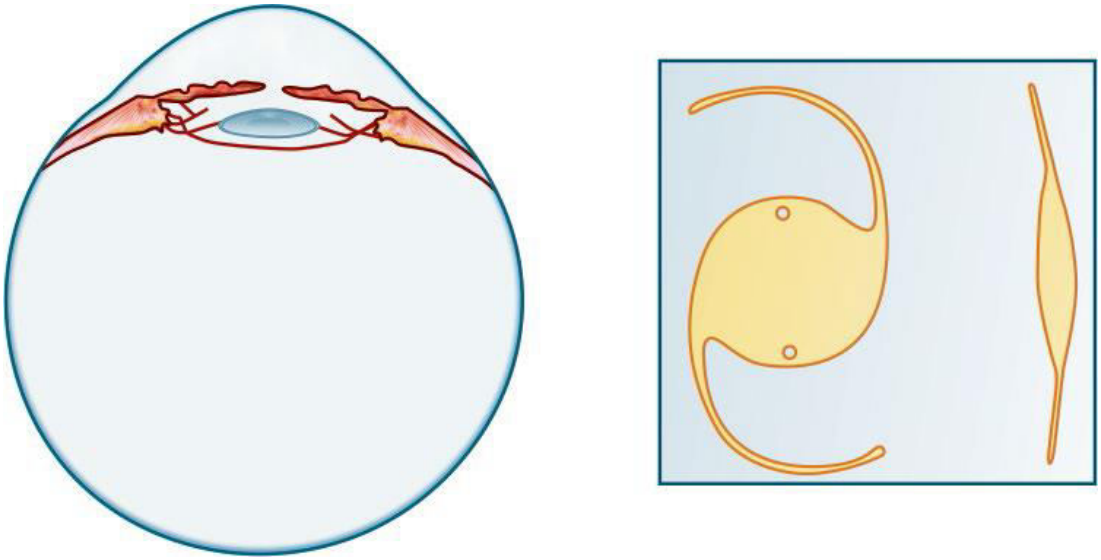


Figure 8: Posterior chamber IOL

Optics

It is made 0f PMMA, Silicone, or acrylic materials and it is about 5.5 to 6.5 mm in diameter. Optic may be planoconvex or biconvex. There may be 2–4 minute holes at the periphery of the optic, called dialing holes (some optics do not have holes). Power 0f the optic varies from –5.0 to +40D.

Types 0f IOL

Optics materials

Rigid IOL – PMMA material

Foldable IOL

Spherical or aspherical

Monofocal or multifocal

Accommodative IOLs

UV filtering violet shielding and blue blockers IOLs

Toric IOLs

Toric multifocal IOLs

Square edge IOL

Phakic IOLs

Anterior chamber type

Posterior chamber type

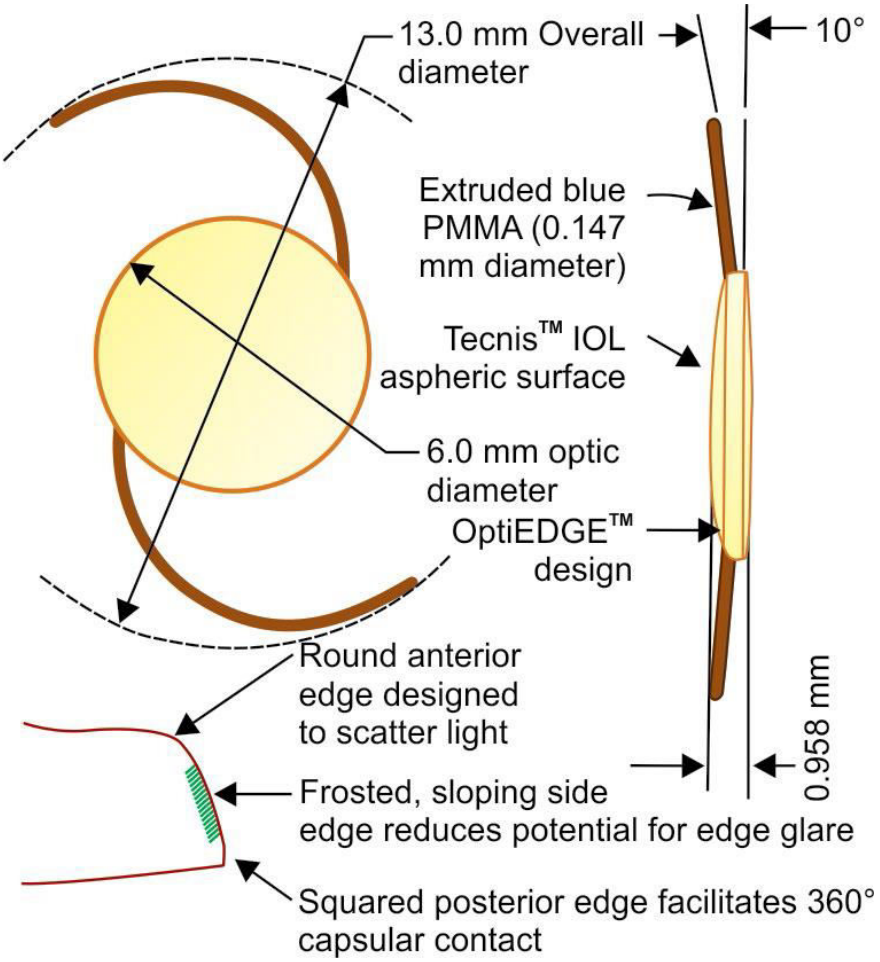


Figure 9: Parts of IOL

Multifocal IOLs[28–30]

Multiple powers are combined inside a single lens in multifocal intraocular lenses, enabling distinct focus points at various distances. This study will refer to multifocal IOLs rather than bifocal IOLs since they have optical designs that provide two separate focus locations.

Multifocal IOLs, according to the simultaneous vision idea, send both crisp and soft images to the retina at the same time. The function of the visual-neural system is to amplify the crisp component while ignoring or suppressing the blurring component, resulting in the best vision at varying distances. Additionally, compared to a monofocal IOL, which has an unresolvable near image, the multifocal IOL provides a considerably higher near image quality. Designers of multifocal IOLs work to reduce contrast loss and halos at varied object distances while enhancing field 0f vision.

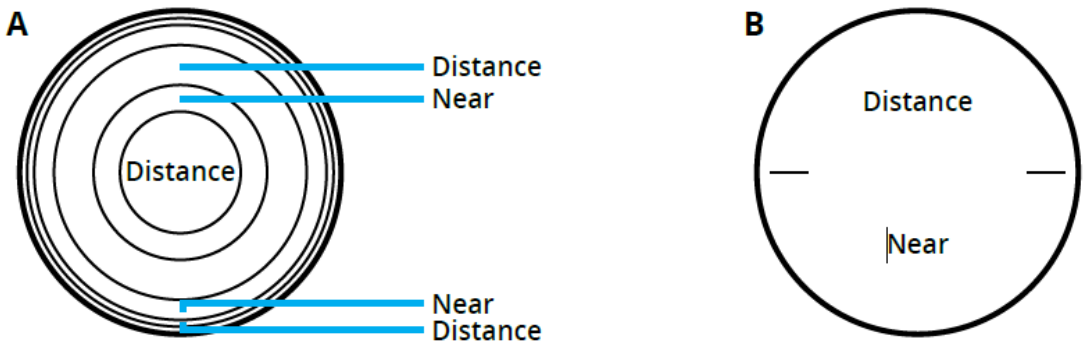


Figure 10: Examples 0f refractive multifocal 0ptic design. (A) Alternating zones 0f varying refractive power (zonal refractive lens). (B) Radial sectors that provide near and distance (sector refractive lens).

Figure 11A depicts the structure of a zonal refractive lens and the wavefront that passes through it. The wavefront is continuous, but it is locally twisted so that some parts of it conver on one of the two focal locations. A sector multifocal lens' profile is shown in Figure 11B. The bottom part 0f the lens' wavefront condenses to the near focus while the top part does the opposite.

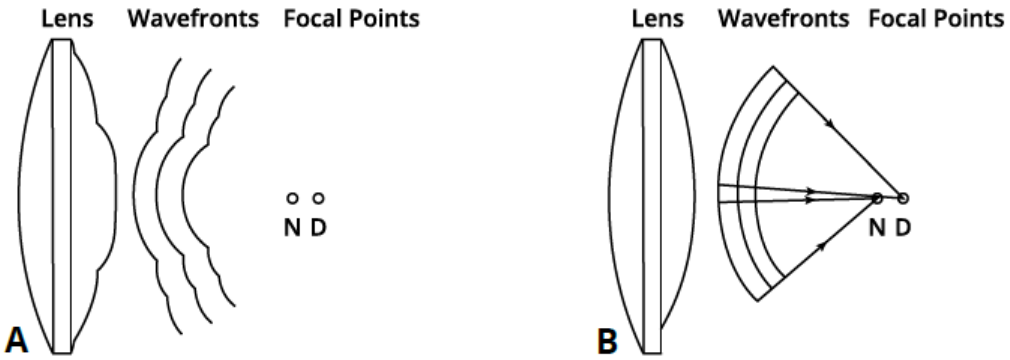


Figure 11: A continuous, but locally curved wavefront with waves convergent at two focal points passes through (A) a zonal refractive lens and (B) a radial sector refractive lens (N – near, D – distance).

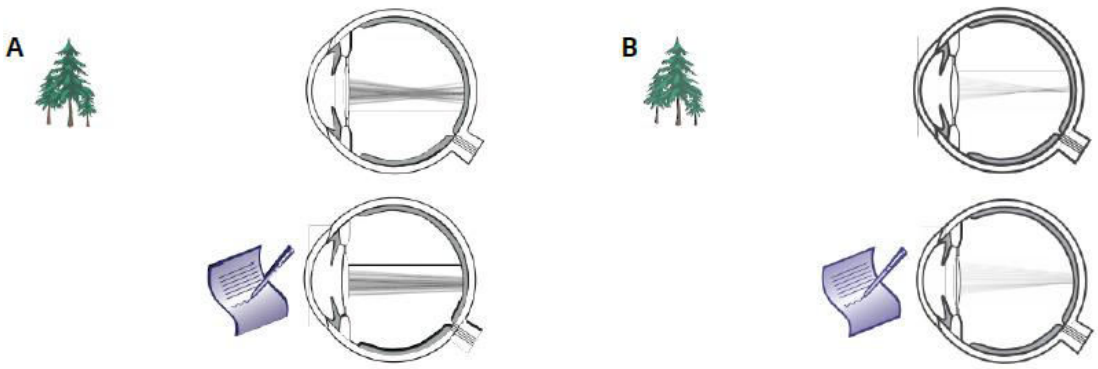


Figure 12: IOL light distribution of Multifocal. (A) Alternating zones (B) Radial sectors.

Because they differ from the simpler mathematical concept 0f light rays bending at the lens's surface, diffractive multifocal lenses are commonly misinterpreted. Instead, these lenses make use of light's wave pattern. Waves have the power to interfere with one another in general. (Figure 13) There are peaks and troughs in each wave. If the peaks 0f the waves coincide when they overlap, the waves combine to produce twice as high peaks. This is referred to as constructive interference. Similarly, if the peaks 0f two waves coincide, the combined wave is neutralised, resulting in a zero-height wave.

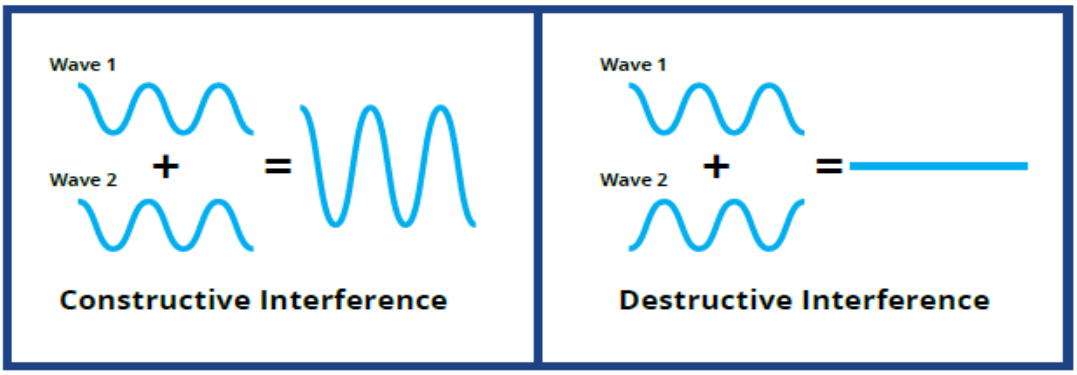


Figure 13: Wave pattern

In multifocal IOLs with diffractive vision, a structure is applied to the surface of lens with a shape intended to produce diffraction, resulting in waves that display constructive interference at two separate foci leaving the lens. On their surface, typical diffractive multifocal lenses have concentric circular zones. The width of each zone decreases as you get closer to the edge of the lens since the zone surface areas are equal. Each zone's intersection makes a sharp step (Figure 14B). The quantity of energy that flows into each focus is determined by the area of each zone and the height of the step.

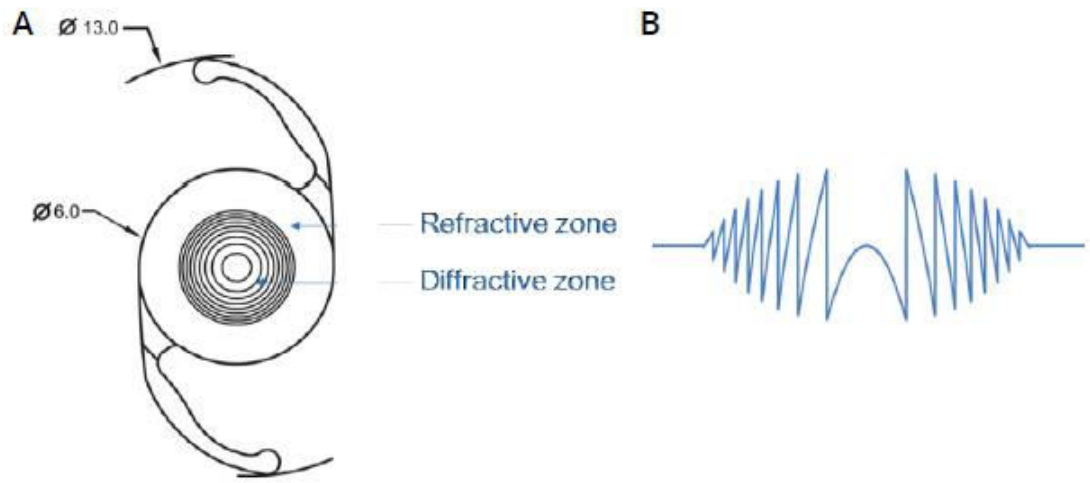


Figure 14: hybrid diffractive-refractive lens

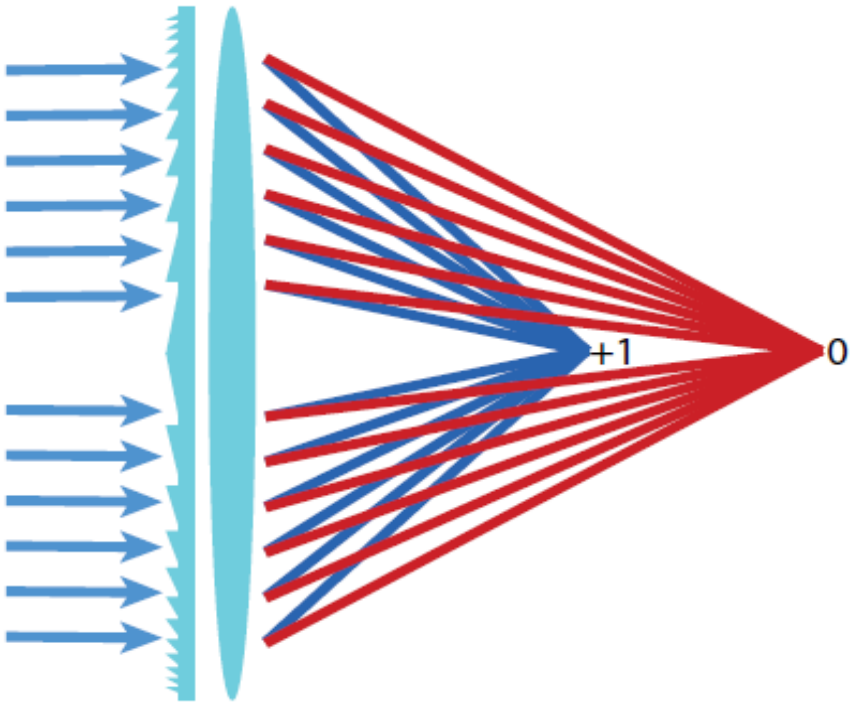


Figure 15: The diffraction pattern at two different points

The two-dimensional rotationally symmetric analogue 0f a linear grating is a diffractive multifocal lens. The triangle-shaped diffractive pattern divides the incoming light into two diffraction orders. The angle at which the diffracted light bends increases as the distance between the diffractive zones closes.The two beams can focus on two different spots because the diffractive structure is placed on top 0f a refractive base lens. In this case, the near focus corresponds to the +1st order, whereas the far focus corresponds to the 0th order.

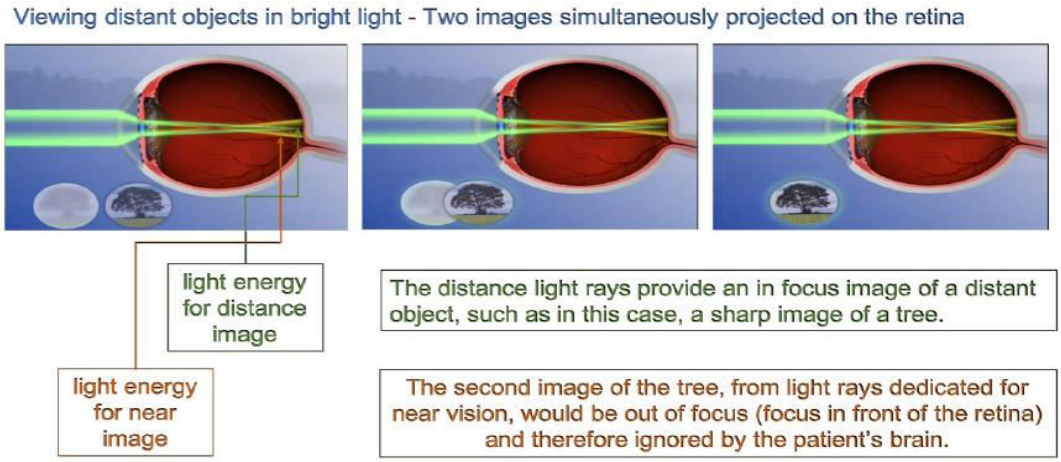


Figure 16: Distinct object Multifocal IOL Diffraction.

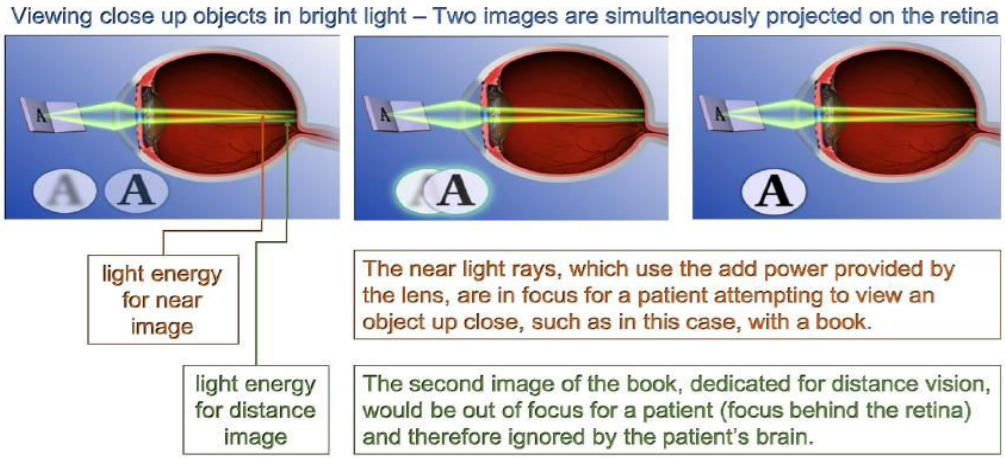


Figure 17: Close-up object Multifocal IOL Diffraction

Advantage of multifocal over monofocal IOL[30]

Spectacle independence in patients after multifocal IOL surgery for both distant and near vision

Spectacle independence in young adults with traumatic cataracts to improve binocularity at close range, especially if the companion eye has no refractive defect or is repaired by contact lenses.

Disadvantages of multifocal over Monofocal IOL: [30]

Reduced contrast sensitivity

Difficulty in driving especially at night

Subjective symptoms like Glare, halos and reduced depth perception

Advantages of monofocal over multifocal IOL: [30]

No difficulties with night driving

Best corrected distance visual acuity

Normal contrast sensitivity

No subjective symptoms like glare, halos etc.

Disadvantages of Monofocal over Multifocal IOL: [30]

Spectacle dependency for near vision post-operative

Unilateral traumatic cataract among young patients post operatively difficult to adapt to since they will lose their physiological accommodation completely and suddenly while undertaken for cataract surgery.

Extended-depth 0f focus (EDOF)[31,32]

Introduction- IOLs are used t0 replace the normal human lens and/0r correct refractive defects in b0th refractive correction in lens and cataract surgery.

A wide range have been created in recent years, and these IOLs have surpassed the performance compared to monofocal IOLs.

Furthermore, Individuals with presbyopia who cannot get laser eye surgery but prefer not to use reading glasses can have presbyopia-correcting intraocular lenses implanted as a kind 0f treatment.

MF IOLs (diffractive and refractive designs), EDOF IOLs, and accommodating IOLs are the three types of presbyopia-correcting IOLs available (intracapsular or sulcus placed).

Aberration influence on retinal image quality and depth 0f focus

Spherical aberration brought on by the disparity in focal length between the main and side rays at the entry of the lens. Average value of corneal spherical aberration with 6.0-mm pupil size is 0.31 0.135mm, however the Zernike coefficients differ significantly for each eye.

By opting for a negative spherical aberration IOL, you can reduce corneal aberration to a certain extent.

An IOL that corrects spherical aberrations provides a finer focus resulting vision improvement for given distance.

This is the main mechanism that permits pure EDOF IOLs to enhance their depth-0f-focus.

Chromatic Aberration- The result is that the focus lengths of the various colours of light in the visible spectrum vary.

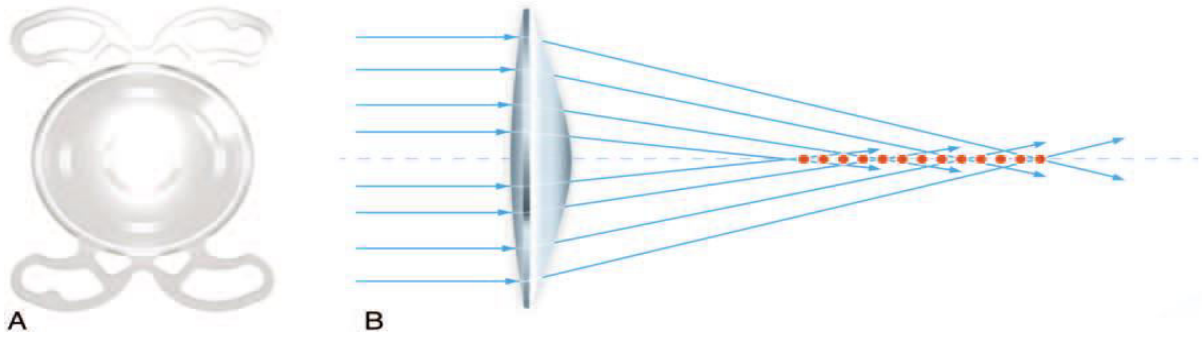
The human cornea distorts blue light more than red light, which leads to CAs.

Pure EDOF IOLs

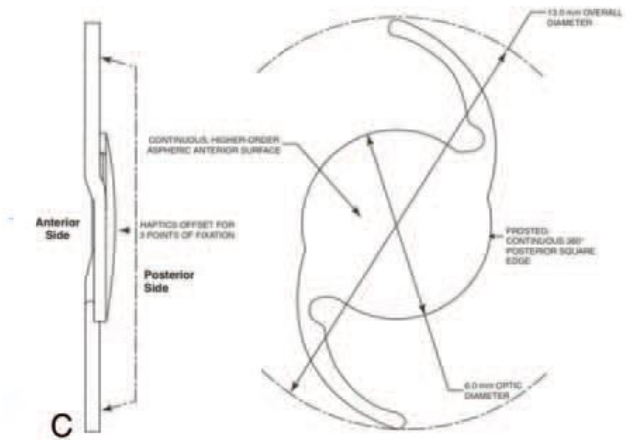
EDOF IOLs with a spherical aberration-Light waves entering EDOF lenses are lengthened in a longitudinal plane when spherical aberrations are added.

The stretched focus theoretically eliminates both the halo effect and the overlap of close and distant images.

The drawback is that when the visual quality declines, their performance is constrained due to the decline in retinal image quality. As a result, the range of near vision is often just about 1 D.



EDOF IOLs Spherical aberration



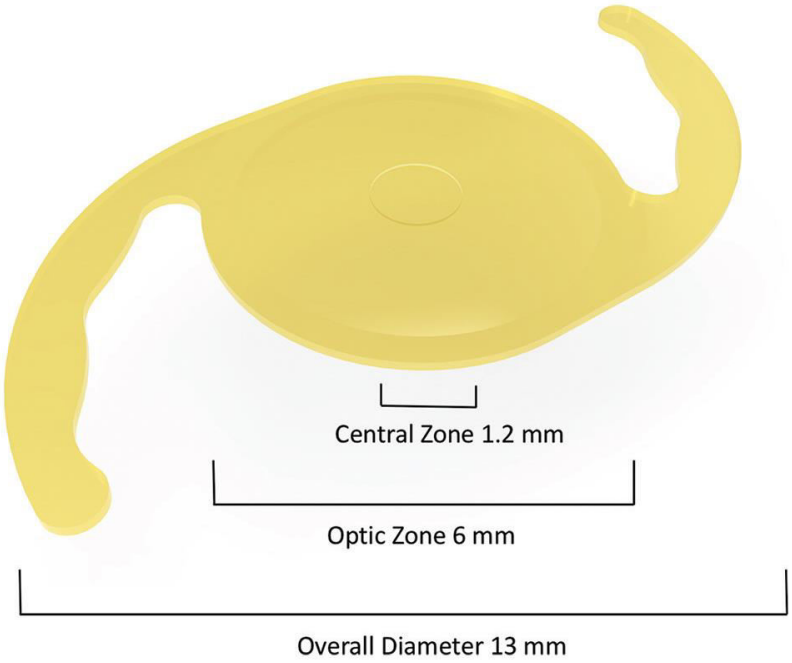
(C) TecnisEyhance ICB00.

The EDOF IOL, is a novel therapy option for presbyopia-correcting lenses. The fundamental optical concept is to generate a single extended focal point to increase depth of field, in contrast to MF IOLs or monofocal IOLs, which focus light on a single point (which have two or three independent points).[1]

This EDOF is intended in order to remove the halo effect induced from the overlap of near and distant imagery generated from normal Multi-focal IOLs; These IOLs ought to ideally enhance intermediate and near vision while having little to no impact on distance vision. Secondary out-of-focus image generation is constrained by the continuous range of focus and asymmetric IOL power distribution of EDOF lenses.[33,34]

It provides a smooth and continuous rise of its strength from the borders to the centre since there is no separating line.

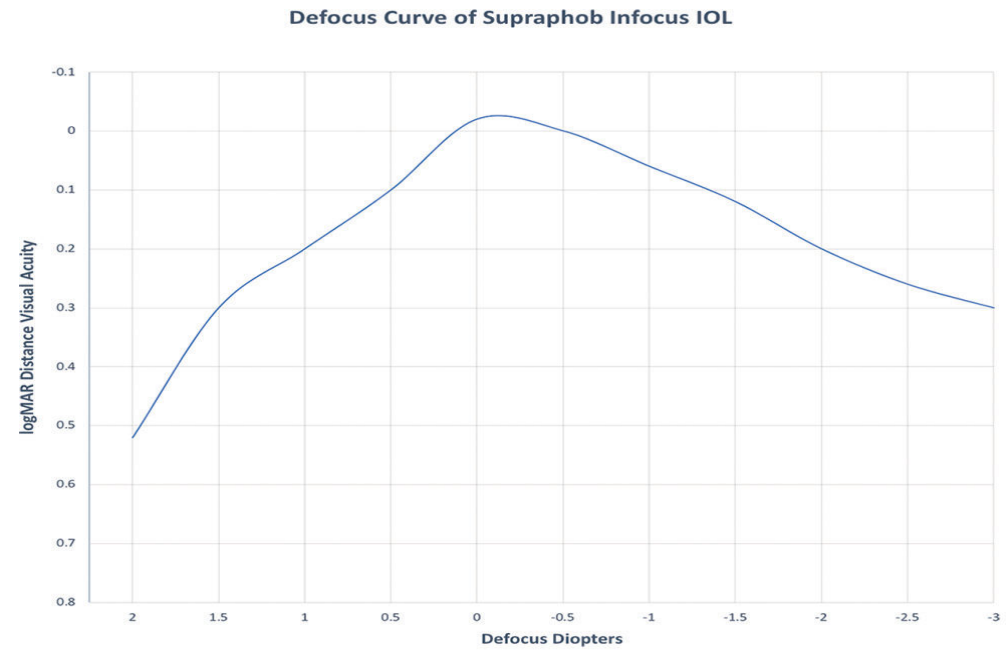
It promises to deliver 66 cm of intermediate vision, correct corneal spherical aberrations, and provide monofocal distance performance with little photic effects (ZCB00).Increasing depth of field may come at a cost in terms of visual quality. When the degree of the aberration is too severe, it results in a loss of distant picture quality, overlapping of perceptual pictures, and dysphotopsia.[35,36]



It is a hydrophobic acrylic EDOF IOL with a yellow chromophore. It features a refractive pinhole pattern on its anterior surface. The rear surface has an aspheric optic and a 360degree improved square edge design. It features a 13 mm overall diameter and a 6 mm optic size.

It has a 1.2 mm centre zone with nano diffractive 0ptics for near and intermediate vision, as well as an extra power of 3.5D to focus on objects between 33 cm and 80 cm.

A region 0.3 below the core zone's boundary causes light rays to bend inward, lowering the likelihood of glare. Good distance vision is provided by light beams passing through the optic between 1.21 mm and 4.75 mm from the centre, which are concentrated and travel through the optic. The haptic is angled at 0°. The refractive index of this material is 1.5045. The A constant is 118.8, and the IOL is accessible in increments of 0.5D from +7.0D to +30.0D.



Contrast sensitivity

Near activity questions indicated that 96 percent of the patients had no problem reading newspapers, while 90 percent had no difficulty reading the tiny type on pharmaceutical bottles. Brief reading was always observed to be independent of spectacles, while 4% of patients occasionally needed glasses to read books, newspapers, or magazines. [37]

The impact of produced aberrations on the clarity and depth of focus of retinal images:

Presbyopia correction involves balancing three interconnected factors depth of field, dysphotopsias, and visual quality. The following sections present the most significant optical models used in Extended depth Of Focus Lenses.

Spherical aberrations

Chromatic aberrations

The pinhole effect

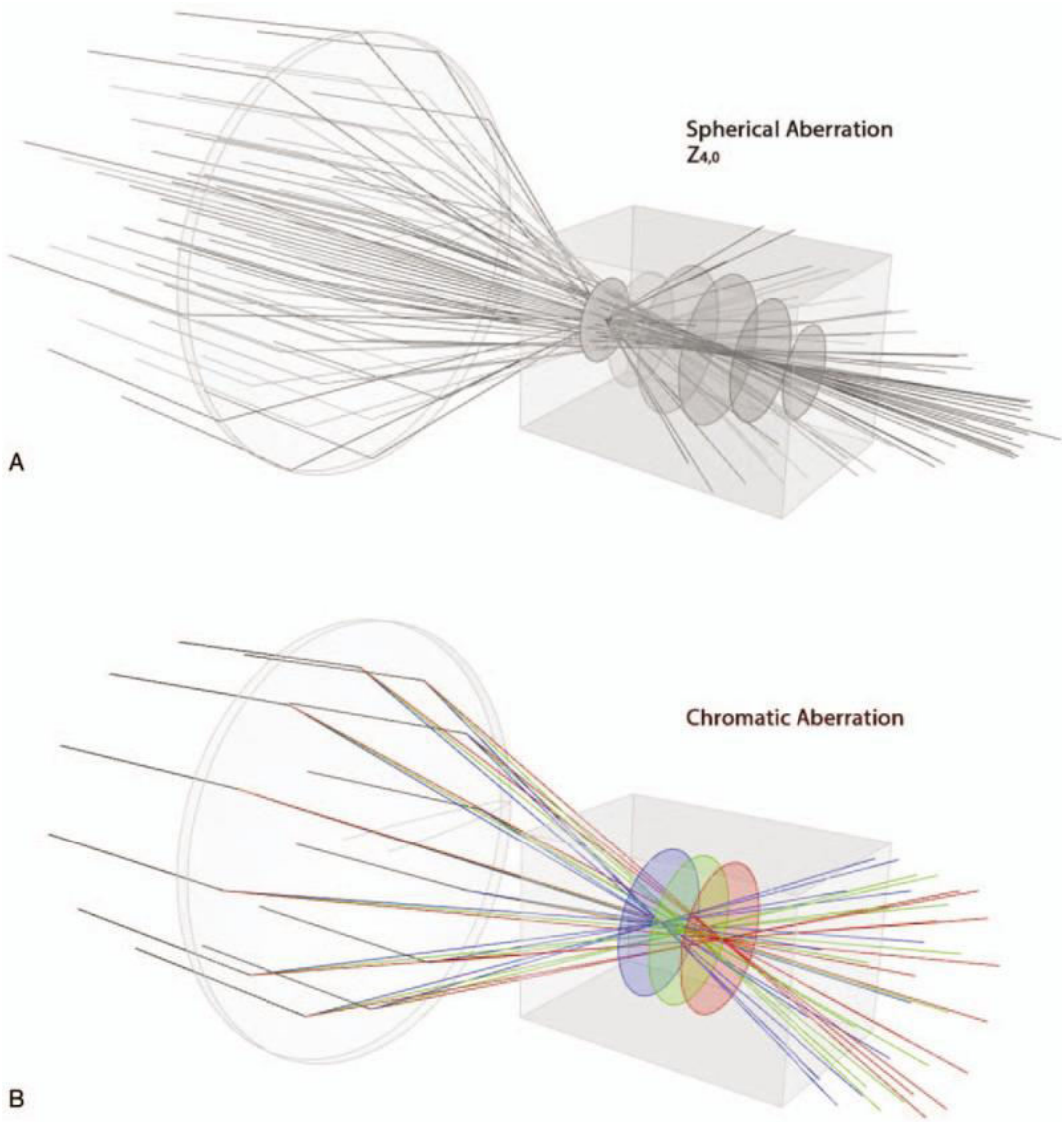


Figure 18: Showing spherical versus chromatic aberrations[1]

TESTING FOR VISUAL ACUITY[11]

Distance visual acuity

The Snellen'e test type is frequently employed to rate central visual acuity at a distance. The concept that two distant spots may only be recognised from one another when they are one minute apart at the nodal point of the eye forms the basis of Snellen's test kinds. It consists of a string of progressively smaller black capital letters organised in lines on a white board.

The chart's letters are designed to fit into squares with sides five times the component lines' width. At the nodal point of the eye at the designated distance, each letter subtends a 5 minute angle From a distance of 60 metres, the characters on Snellen's heart's top line should be visible.

Similarly, the letters in the next lines should be read from 36, 24, 18, 12, 9, 6, 5, and 4 metres away, correspondingly.

Evaluation:

To evaluate distant visual acuity, the patient is seated 6m away from the Snellen chart, such that the light rays are almost parallel and the patient exerts minimum accommodation.

The visual acuity is measured as a fraction, with the denominator being the smallest letter that can be seen accurately and the numerator being the patient's distance from the letters. The patient is instructed to read the chart with each eye individually. The patients are urged to read the chart with each eye separately, and their visual acuity is noted as a fraction, with the denominator being the smallest letter that can be read correctly and the numerator being the patient's distance from the letters.

Near visual acuity:

Near vision is assessed by having patients read the near vision chart, which is held at a distance of 35cm in excellent lighting, with each eye individually. A number of different sizes of printer types are stacked in ascending order and labelled in the near vision chart. The following are examples of commonly used near vision charts:

Jaeger's chart: On this chart, the prints are labelled 1–7, and the patient's acuity is indicated by the letter J1–J7 based on which print he or she can read.

Near vision is measured using the Roman test types N6, N8, N10, N18, and N36.

Type of Snellen near vision test.

Contrast sensitivity

In its most basic form, contrast sensitivity refers to the visual system's capacity to discriminate between an item and its backdrop. It indirectly analyses eyesight quality. The reciprocal value of the contrast threshold is the contrast sensitivity. A patient with poor contrast sensitivity requires a lot of contrast to view a target, and vice versa.

Blur is not the same as insufficient contrast sensitivity. People with vision worse than 6/6 on Snellen's letter chart will have hazy vision. A person with weak contrast sensitivity (for example, due to cataract) may nonetheless test well on the 6/6 letters on chart and experience foggy vision.

Contrast sensitivity tests solve Snellen's high contrast acuity's problem by altering two parameters: grating size and contrast level. It assesses functional vision, or how effectively people view ordinary visual objects or scenes (while driving or at work and play). The sensitivity to contrast changes with ageing. We lose contrast sensitivity as we age, initially at higher spatial frequencies and subsequently across the board.

Tests for Contrast Sensitivity

There are numerous test systems available (both for far and near); the primary distinction is the target type:

Low contrast letter charts with the same size are known as Pelli-Robson charts.

• A Regan chart is a low contrast, variable-size letter chart.

• The Functional Acuity Contrast Test (FACT) evaluates a particular visual channel. It offers a sine-wave grating curve that is more instructive.

Cambridge contrast sensitivity examination.

Glare

The ability to see objects of low and moderate contrast fails in high glare situations. Such as when driving into low sun or night on crowded roads, walking on a summer beach or even being in white walled bathroom.

Especially on roads, that is a potent cause of accidents. The problem is caused by the light scattering within the eye and thereby reducing the contrast of the retinal image.

Susceptibility can be quantified in term of glare susceptibility (GSR) defined as visual acuity with no glare source divided by visual acuity in the presence of standard glare source. This index provides a direct impression of the effect of glare.

Glare can render low-contrast objects invisible while having comparatively little effect on visual activity is no more than straight forward consequence of the function's structure for contrast sensitivity.

Lens opacities, light penetrating through the iris, and corneal scarring are the causes of glare susceptibility.

It is worth noting that the slit-lamp approach for studying lens opacities is based on light scattered back from the opacities, whereas glare is generated by light scattered forward into the retina.

As a result, a slit lamp test may not always reveal the level of glare handicap experienced by particular individuals.

Clinical applications of EDOF Lenses

According to IOL technology, we believe there should be two categories: pure EDOF IOLs and hybrid Multi-focal-Extended Depth OF Focus IOLs. The pinhole effect or spherical aberration optics are used only in pure EDOF IOLs. The three types of hybrid Multifocal-Extended Depth Of Focus lenses are diffractive-Extended Depth OF Focus Lenses, refractive-EDOF IOL and Combined diffractive-refractive-EDOF IOL.[1]

Following the insertion of a trifocal intraocular lens with EDOF IOL, McNeely RN et al., (2021), patient satisfaction was examined at 1 and 12 months. There were no statistically significant differences in UNVA, UDVA, or CDVA between the two groups three months after surgery. At one and three months, there was a statistically negligible change in the secondary outcome indicators. At 1 and 12 months following surgery, this IOL combination delivers acceptable unassisted visual acuity, as well as excellent functional vision and postoperative satisfaction However, at the 12-month evaluation, there was a considerable increase in overall nighttime quality of life. [38]

Moshirfar M et al. compared the visual results of a study using a trifocal lens and EDOF lens. Three months following surgery, UNVA did not alter in a statistically meaningful way. There was no variation in UDVA or CDVA between the

two groups. At one and three months, secondary outcome markers showed no statistically significant change. At one month postoperatively, Although the AcrySof IQ PanOptix trifocal intraocular lens and the TECNIS Symfony extended depth-of-focus intraocular lens both seem to provide higher UNVA, this difference was not apparent three months after surgery. There is no statistically significant difference in UDVA and CDVA between the two groups on postoperative day one, one month, or three months.[39]

In order to evaluate postoperative visual performance and patient-reported outcomes following the concurrent implantation of an EDOF intraocular lens and a trifocal intraocular lens, McNeely RN et al., (2020) did a sequential patient research. Good unaided far and near vision acuity is provided by the use of an EDOF IOL in conjunction with a trifocal IOL. Despite the great postoperative pleasure and functional vision that this IOL combination offers, certain early visual unfavourable effects have been seen.[40]

In 2020, Singh B et al. investigated the visual outcomes of bilateral implantation of a diffractive trifocal IOL and EDOF lens. Visual symptoms or quality did not differ across groups. In near VA, tri-focal IOLs clearly outperformed EDOF IOLs, whereas both IOLs performed well in distant and intermediate VA. Both IOLs delivered excellent spectacle independence and patient satisfaction while causing very moderate photic disturbances.[41]

Tarib I et al. carried out a prospective study to examine the visual outcome at various distances, depths of focus, and optical quality. Both groups reported successful restoration of visual acuity, together with outstanding visual quality and patient satisfaction. Mixed group performed better in terms of near visual acuity.[42]

The AcrySof IQ Panoptix intraocular lens was implanted in 52 eyes of 26 bi -

lateral patients at the Vissum Ophthalmological Corporation in Alicante, Spain., as part of this prospective sequential case-series study (2018). The near activity visual questionnaire, the defocus curve, contrast sensitivity (Pelli-Robson test), and internal aberrations were all assessed using Osiris. The therapy improved all visual acuities: corrected distance, corrected near, and uncorrected distance. The study's drawback is its demographics. Because the study was conducted in Europe, it does not provide any information regarding the outcomes that may be obtained in South East Asian countries such as India.[43]

Cochener B et al. analyzed the performance of two diffractive trifocal intraocular lenses and an EDOF lens (2018). 90% of patients were independent of their glasses overall. Visual symptoms and aberrometry did not vary between groups. All three IOLs provided acceptable visual acuity at all distances, a high degree of independence from glasses, and little to no disruption of everyday activities for the patients. The EDOF IOL was outperformed in near vision by both trifocal IOLs.[44]

IOLs were implanted in 66 of 33 human patients' eyes, according to the Vision Eye Institute (2017), Victoria-Avenue, Sydney, NSW 2067, Australia. This did not depart significantly from the desired refraction ($p = 0.841$). All patients had the intended correction within 0.50 D, and 65 percent of patients reached the goal SE refraction within 0.25 D. Early postoperative haloes were a complaint from five patients. The AcrySof IQ Panoptix IOL offers functional uncorrected visual acuity at a distance, intermediate distance, and near distance. [45]

MATERIALS AND METHODS

Source of data: Patients diagnosed with cataract and undergoing phacoemulsification under topical anaesthesia with EDOF lens at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi

Study Design: A One Year Prospective Interventional Study

Duration: January 2021 – December 2021

Study Population: The patients diagnosed with cataract who agreed to undergo phacoemulsification under topical anaesthesia and chose the EDOF IOL at the Department of Ophthalmology, Dr. Prabhakar Kore Hospital and Medical Research Center and who met the inclusion criteria served as the study population.

Sample Size —30

Sample size formula: Sample size is calculated by using **G*Power** software. Data was collected at 4 different time points (at preoperative, post operative day 1^{st} day,1^{st} week and 4^{th} week). By assuming medium **effect size within the subject as 0.2**, 5% level of significance, power 85%, non-sphericity correction ε taken as 1 and by assuming 0.7 correlations present between repeated measures, minimum sample size required is 25.

By assuming 20% of lost to follow-up cases, final **minimum sample** size required is **30**.

Larger the sample, better the precision.

Sampling method: Universal sampling

SELECTION CRITERIA:

Inclusion criteria

1. People having significant cataract that affect their vision
2. Patients having significant cataract with corneal astigmatism less than 2.00D.
3. Patients with normal visual potential post cataract surgery.
4. **Exclusion criteria**

1. People with other co-morbid diseases like diabetes, asthma and Ischaemic heart diseases.
2. Patients with amblyopia
3. Patients with neuro-ophthalmic diseases
4. Patients who have undergone prior corneal refractive surgery.
5. Corneal disease or opacity
6. Inadequate pupillary dilatation
7. Glaucoma
8. Pseudoexfoliation syndrome
9. Patients with active ocular disease such as uveitis.
10. Previous ocular trauma

METHODOLOGY:

The study included a total of 30 eyes from 30 consecutive cataract patients who matched the inclusion criteria. Study was conducted in the Department Of Ophthalmology at KLES Dr. Prabhakar Kore Hospital And Medical Research Centre, Belagavi

After obtaining informed written consent, the demographic information of the participants were recorded in a predesigned proforma, All patients underwent a thorough ophthalmic evaluation before surgery including distance visual acuity at 6 metres with the Snellen chart, intermediate vision at 66cm with Sloan vision chart and the near visual acuity at 33cm with the Snellen Reading Chart and refractive status of the patient was also assessed.

The anterior segment was examined with slit-lamp biomicroscopy, and dilated fundus examination was done with Indirect Ophthalmoscopy. The intraocular pressure was measured with Non contact Tonometer (Canon TX-20P Full auto tonometer). Keratometry readings were recorded with autorefractometer (Shin-Nippon) and IOL calculation was done with A Scan Biometry machine (Appascan MAX) and SRK-T formula was used for calculating the IOL implantation.

All patients underwent phacoemulsification under topical anaesthesia by a single surgeon with Stellaris-Bausch and Lomb phacoemulsification machine. The size of the incision was 2.2mm and it was enlarged to 2.8mm for IOL implantation.

Preoperatively, the patients were started with Moxifloxacin (0.5%w/v) eye drops 5 times a day, one day prior surgery. On the day of surgery, Tropicamide (5%w/v)- Phenylephrine (0.8%w/v) eye drops were instilled 3 times at an interval of 15 minutes 2 hours before the surgery on the operating eye.

During postoperative period the patient was started with Moxifloxacin (0.5%w/v)-Dexamethasone (0.1%w/v) eye drops 8 times a day, Moxifloxacin (0.5%w/v) eye drops 4 times a day, Tropicamide(5%w/v)-Phenylephrine (0.8%w/v) eye drops once in the night for 1 week.

Moxifloxacin (0.5%w/v) eye drops and Tropicamide(5%w/v)- Phenylephrine (0.8%w/v) eyedrops were stopped after 1 week and Moxifloxacin (0.5%w/v)-Dexamethasone (0.1%w/v) eye drops were tapered in 3 weeks gradually.

The patients were evaluated postoperatively on day 1, at the end of 1st week and lastly at the end of 4th week.

During each postoperative visit distant visual acuity, intermediate visual acuity and near visual acuity was assessed. The patient also underwent contrast sensitivity testing, slit lamp and fundus examination in the operated eye at each visit. The patients were asked to come for the evaluation at 1st day, at the end of 1st week and at the end of 4th week of postoperative day. Patient satisfaction evaluation was also done by National Eye Institute Refractive Error Quality of Life instrument-42(NEI RQL-42) visual function questionnaire at the end of 4th week.

STATISTICAL ANALYSIS

Excel was used to collect and store the data. Microsoft Excel and the statistical programme R were used to analyse the data. Continuous data were presented as mean, SD, and median (range). Categorical variables were represented by frequency Chi-square test was employed to examine the relationship between the attributes. T-test, ANOVA, Mann-Whitney test, and Kruskal-Wallis test were used to evaluate mean and distribution across groups. The paired t-test, repeated measures of the ANOVA, the Wilcoxon test, and the Friedman test were used to evaluate the mean to compare the paired nominal data at two timepoints within the group, Mc-Nemar's test was used. Shapiro-test Wilk's and the Quantile-Quantile (QQ) plot were used to determine whether the variables were normal. A P-value of 0.05 or less indicates statistical significance.

RESULTS

After receiving informed consent, 30 participants who met the eligibility criteria were recruited for the study.

The mean age of participants was found to be 61.83±9.71yrs of age.

Table 1: Showing the mean age of patients in the present study

	N	Minimum	Maximum	Mean	SD
Age	30	42	85	61.83	9.71

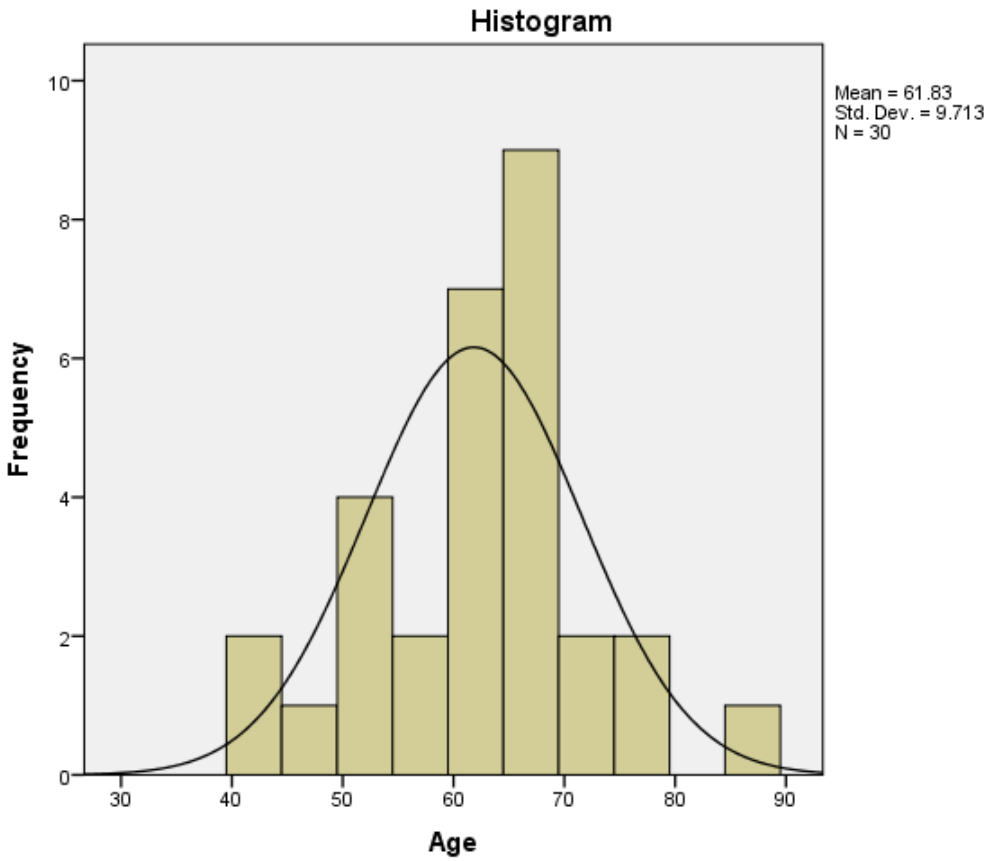


Figure 19: Histogram showing the mean age of patients

Out of 30 patients ,18 patients (60%) were female and 12(40%) patients were male.

Table 2: Showing the distribution of gender

		Frequency	Percent
Gender	Female	18	60.0
	Male	12	40.0
	Total	30	100.0

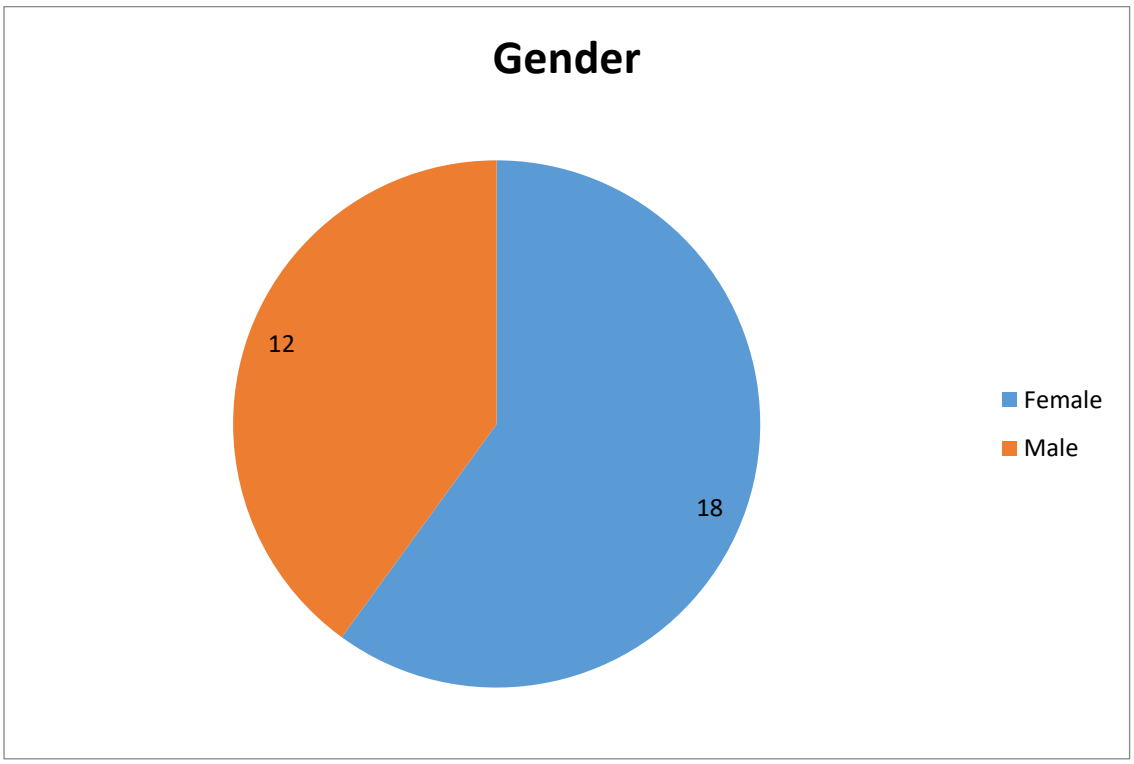


Figure 20: Showing the distribution of gender

Out of the 30 patients included in the study, cataract was seen in left eye in 17 patients (56.7%) and in right eye in 13 patients (43.3%)

Table 3: Showing the eye involved in the study

		Frequency	Percent
Eye	Left	17	56.7
	Right	13	43.3
	Total	30	100.0

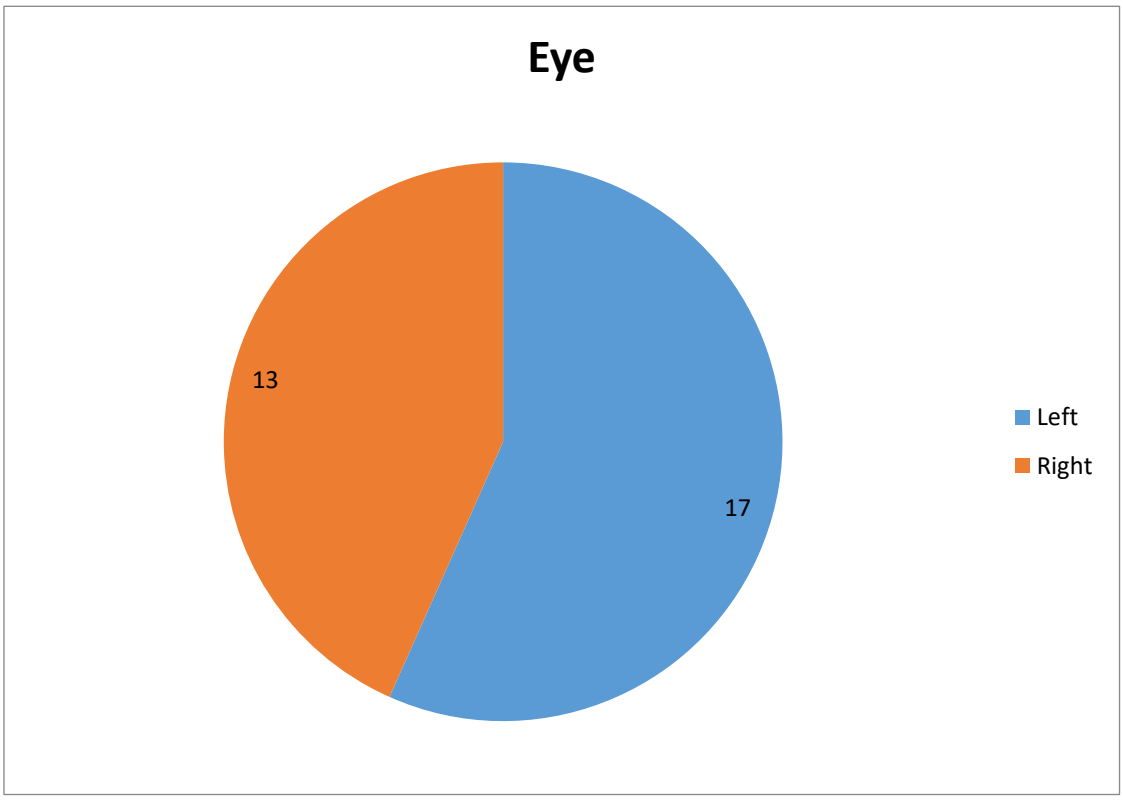


Figure 21: Showing the eye involved in the study

Majority 13(43.3%) of the patients had a preoperative distant vision of 6/60.

Table 4: Showing the findings of pre-operative distant vision

		Frequency	Percent
Distant vision pre-operative	6/36-6/24	2	6.7
	6/60	13	43.3
	CF 2-1M	3	10.0
	CF 3-2M	6	20.0
	HMCF PLRR	6	20.0
	Total	30	100.0

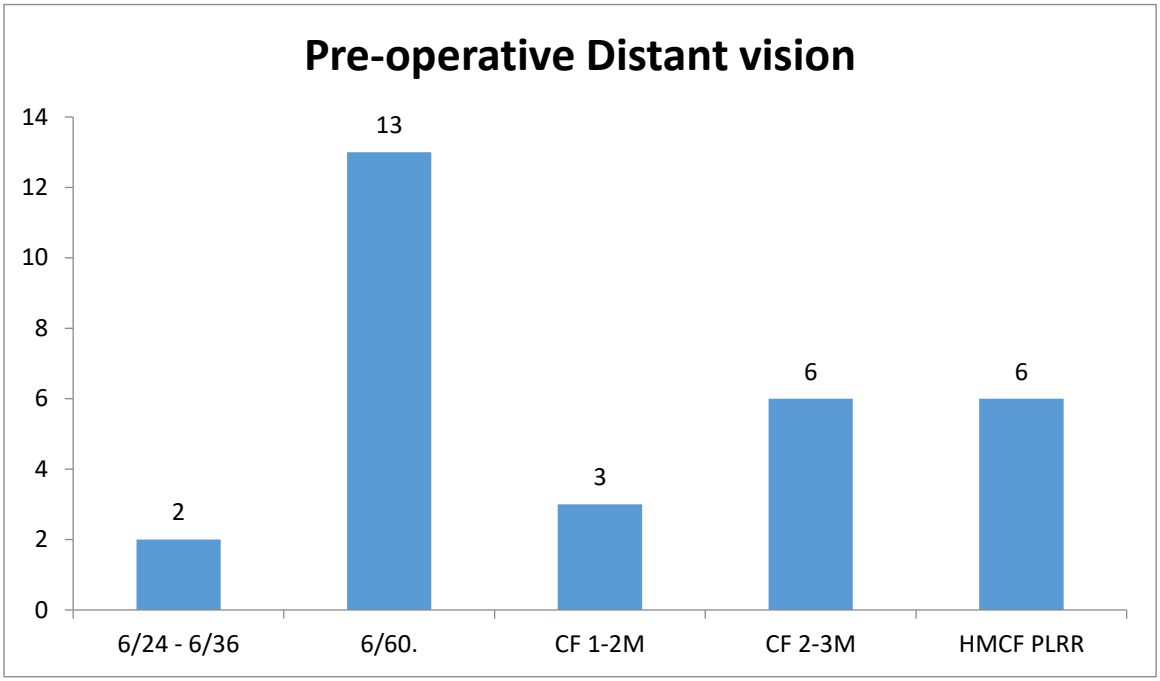


Figure 22: Showing the findings of distant vision pre-operative

Postoperatively on Day 1 ,17 (56.7%) patients had achieved vision of 6/36-6/24 whereas 13(43.3%) patients achieved vision of 6/18-6/12.

Table 5: Showing the findings of Distant vision of postoperative day 1

		Frequency	Percent
Distant vision Day 1 post-operatively	6/18 - 6/12	13	43.3
	6/36-6/24	17	56.7
	Total	30	100.0

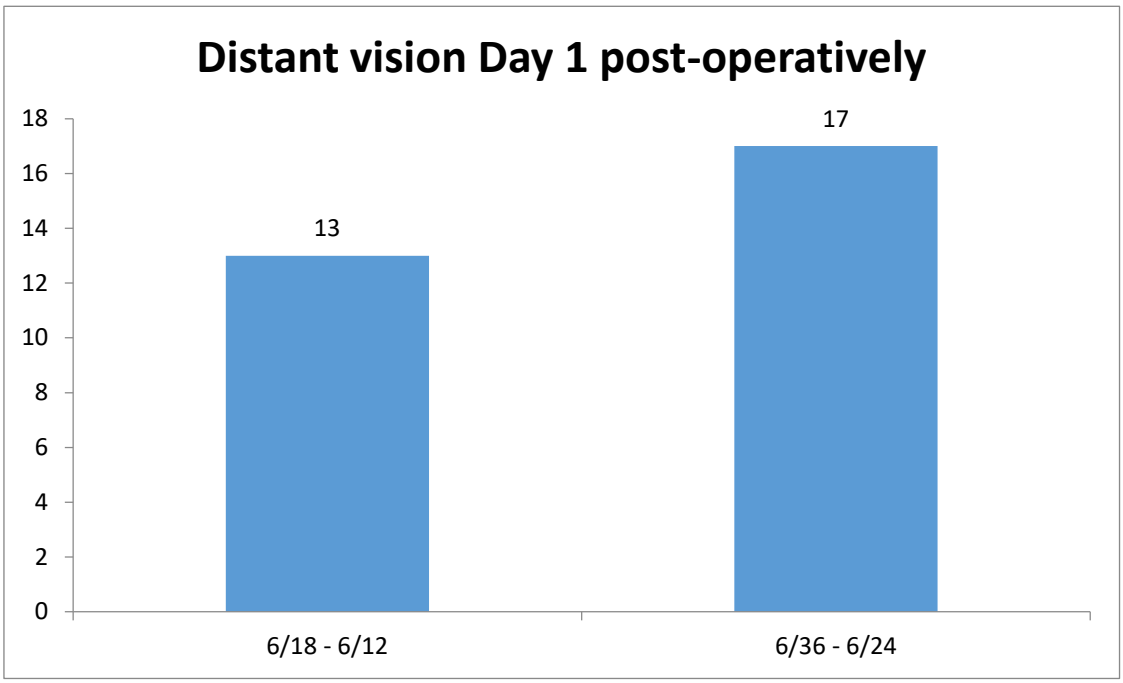


Figure 23: Showing the findings of Distant vision Day 1 post-operatively

Postoperatively at the end of 1st week follow up, 5(16.7%) patients had achieved vision of 6/9- 6/6 whereas 19 (63.3%) achieved vision of 6/18-6/12.

Table 6: Showing the findings of distant vision at 1st week post-operatively

		Frequency	Percent
Distant vision at 1st week post-operatively	6/9 - 6/6	5	16.7
	6/18 - 6/12	19	63.3
	6/36-6/24	6	20.0
	Total	30	100.0

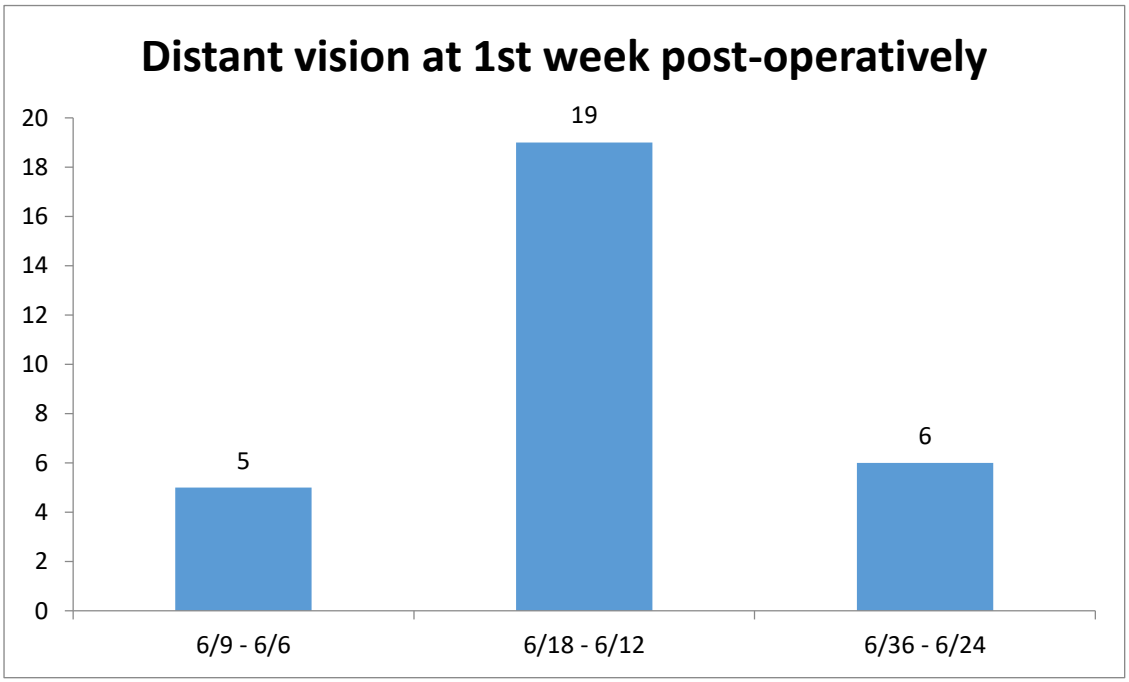


Figure 24: Showing the findings of Distant vision at 1st week post-operatively

27 (90%) patients had distant vision of 6/9 – 6/6 at the end of 4th week follow up.

Table 7: Showing the findings of Distant vision at 4th week post-operatively

		Frequency	Percent
Distant vision at 4th week post-operatively	6/9 - 6/6	27	90.0
	6/18 - 6/12	2	6.7
	6/36-6/24	1	3.3
	Total	30	100.0

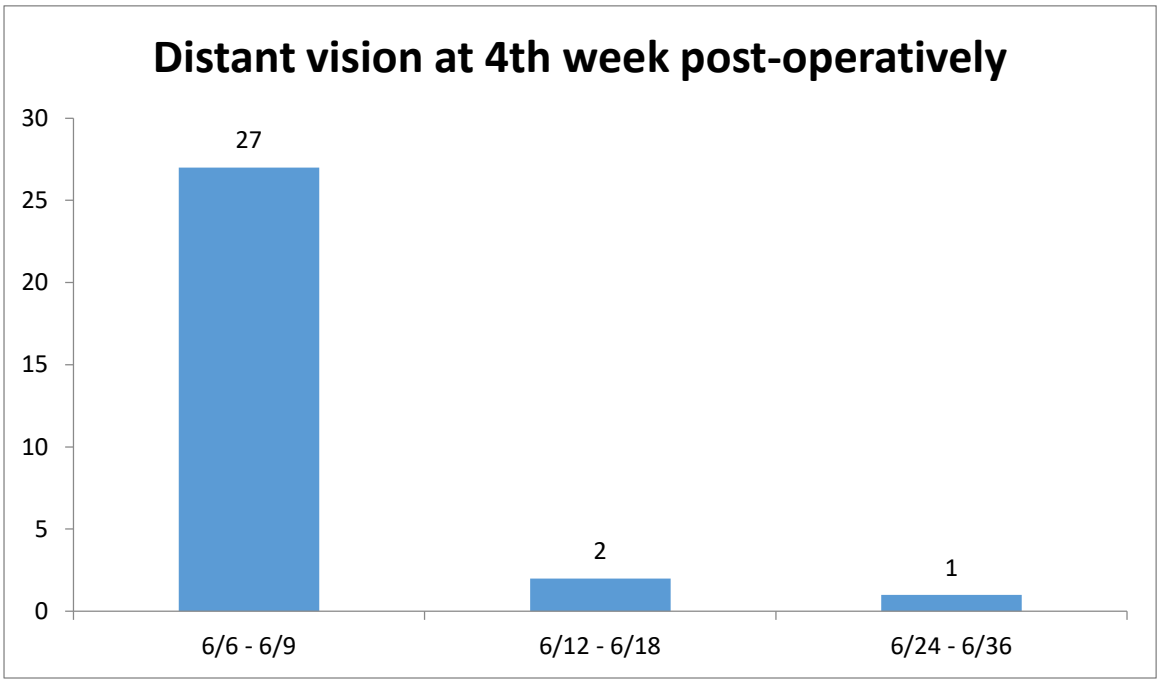


Figure 25: Showing the findings of Distant vision at 4th week post-operatively

20 (66.7%) patients were having preoperative intermediate vision of less than 6/60

Table 8: Showing the findings of Intermediate vision pre-operatively

		Frequency	Percent
Intermediate vision pre-operatively	<6/60	20	66.7
	6/48	4	13.3
	6/38	3	10
	6/30	1	3.3
	6/24	2	6.7
	Total	30	100.0

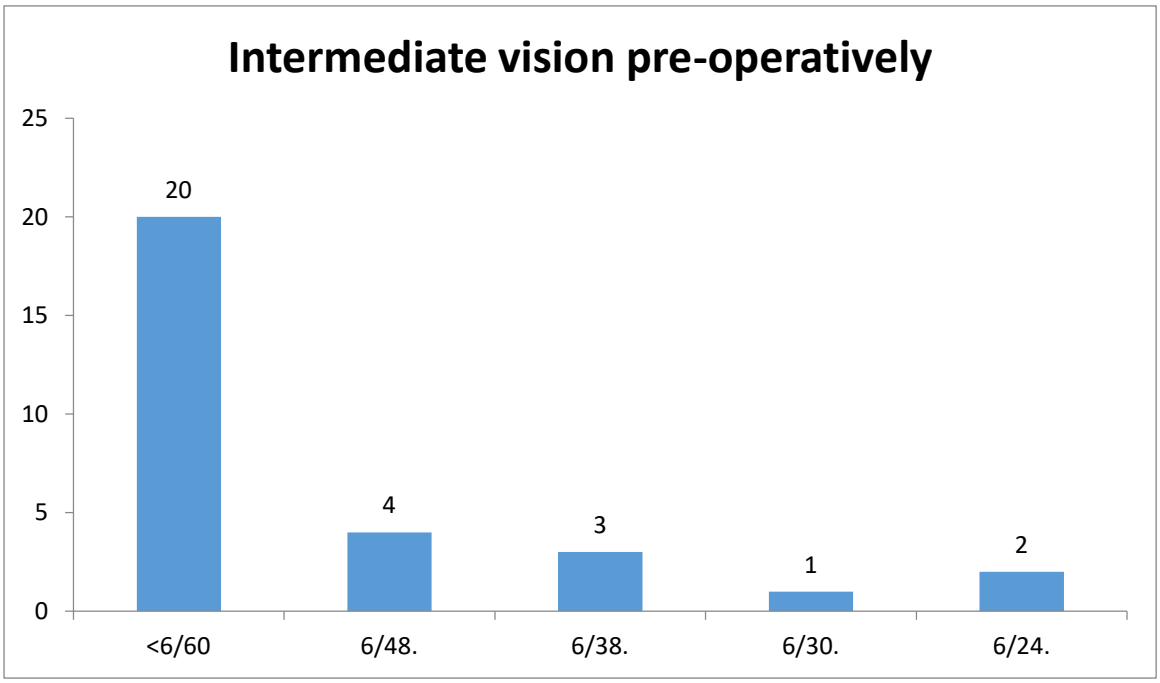


Figure 26: Showing the findings of Intermediate vision pre-operatively

9 (30%) patients were able to achieve 6/15 intermediate vision at the end of 1st day follow up

Table 9: Showing the findings of Intermediate vision day 1 post-operatively

		Frequency	Percent
Intermediate vision day 1 post-operatively	<6/60	1	3.3
	6/30.	2	6.6
	6/24.	6	20.0
	6/19.	4	13.3
	6/15.	9	30.0
	6/12.	6	20.0
	6/9.5.	1	3.3
	6/7.5.	1	3.3
	Total	30	100.0

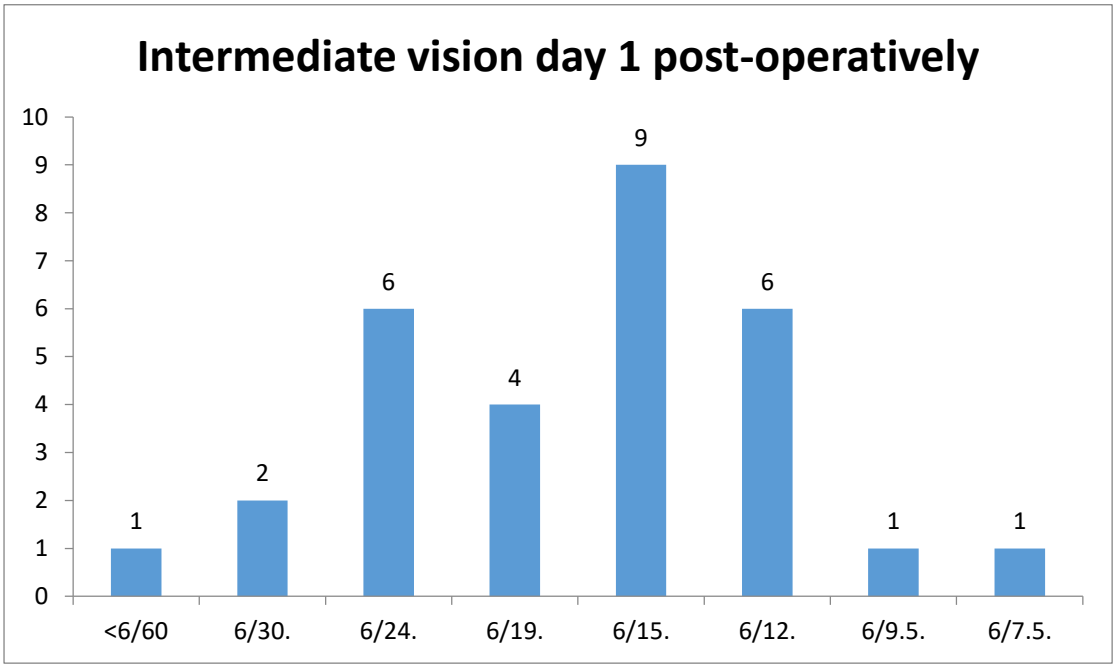


Figure 27: Showing the findings of Intermediate vision day 1 post-operatively

12(40%) patients were able to achieve 6/12 intermediate vision and2(6.7%) % patients were able to achieve 6/9 - 6/6 intermediate at the end of 1st week of follow up.

Table 10: Showing the findings of Intermediate vision 1st week post-operatively

		Frequency	Percent
Intermediate vision 1st week post-operatively	<6/60	1	3.3
	6/30.	4	13.3
	6/24.	9	30.0
	6/19.	3	10.0
	6/15.	5	16.7
	6/12.	12	40.0
	6/9.5.	2	6.7
	6/7.5.	1	3.3
	6/6.	1	3.3
	Total	30	100.0

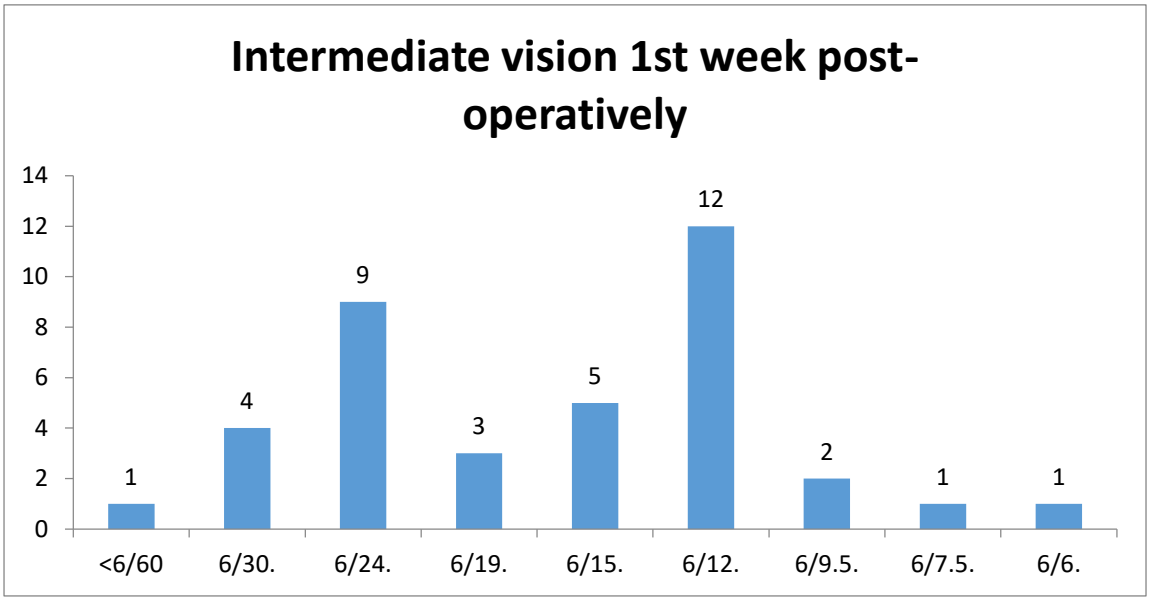


Figure 28: Showing the findings of Intermediate vision 1st week post-operatively

19 (63.3%) patients were able to achieve 6/6 intermediate vision at the end of 4th week of follow up

Table 11: Showing the findings of Intermediate vision 4th week post-operatively

		Frequency	Percent
Intermediate vision 4th week post-operatively	6/19.	3	10
	6/9.5.	3	10
	6/7.5.	5	16.7
	6/6.	19	63.3
	Total	30	100.0

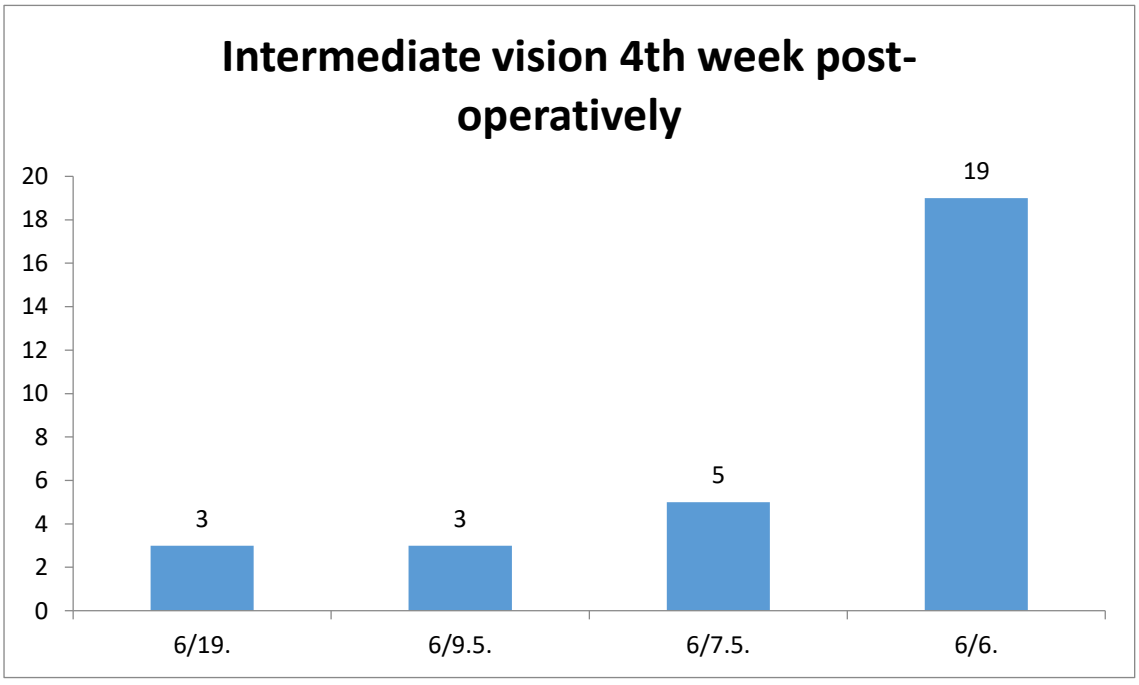


Figure 29: Showing the findings of Intermediate vision 4th week post-operatively

24(80 %) of the patients had <N36 of preoperative near vision.

Table 12: Showing the findings of Preoperative Near Vision

		Frequency	Percent
Preoperative Near Vision	<N36	24	80
	N36 – N18	6	20
	Total	30	100.0

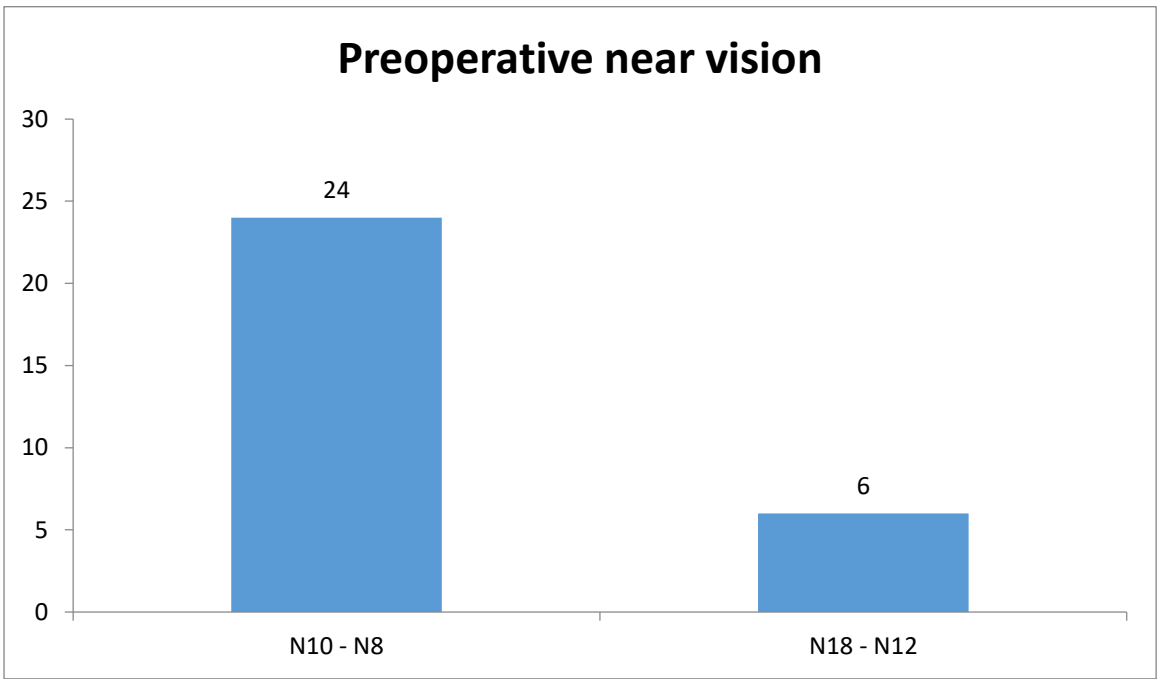


Figure30: Showing the findings of Preoperative Near Vision

18(60%) patients had N10 – N8 near vision whereas 12(40%) patients had N18 – N12 vision at 1st day follow up.

Table 13: Showing the findings of Near vision day 1 post-operatively

		Frequency	Percent
Near vision day 1 post-operatively	N10 - N8	18	60.0
	N18 – N12	12	40.0
	Total	30	100.0

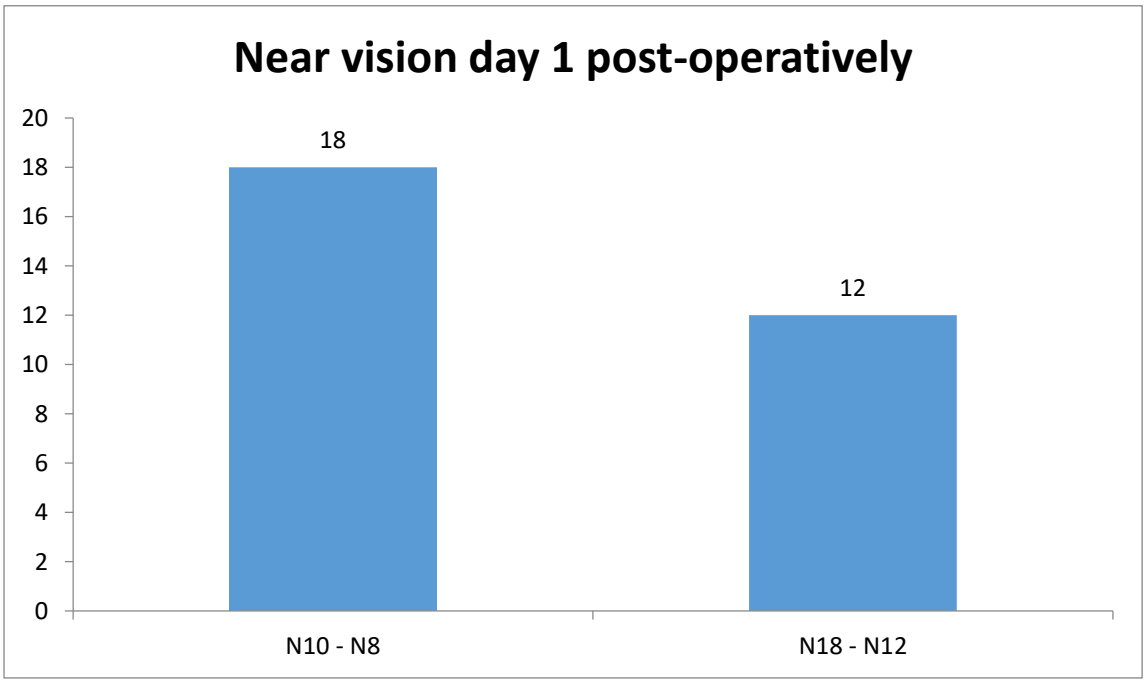


Figure 31: Showing the findings of Near vision day 1 post-operatively

26 (86.7%) patients achieved vision of N10 – N8 at the first week of follow up.

Table 14: Showing the findings of Near vision 1st week post-operatively

		Frequency	Percent
Near vision 1st week post-operatively	N10 – N8	26	86.7
	N18 – N12	4	13.3
	Total	30	100.0

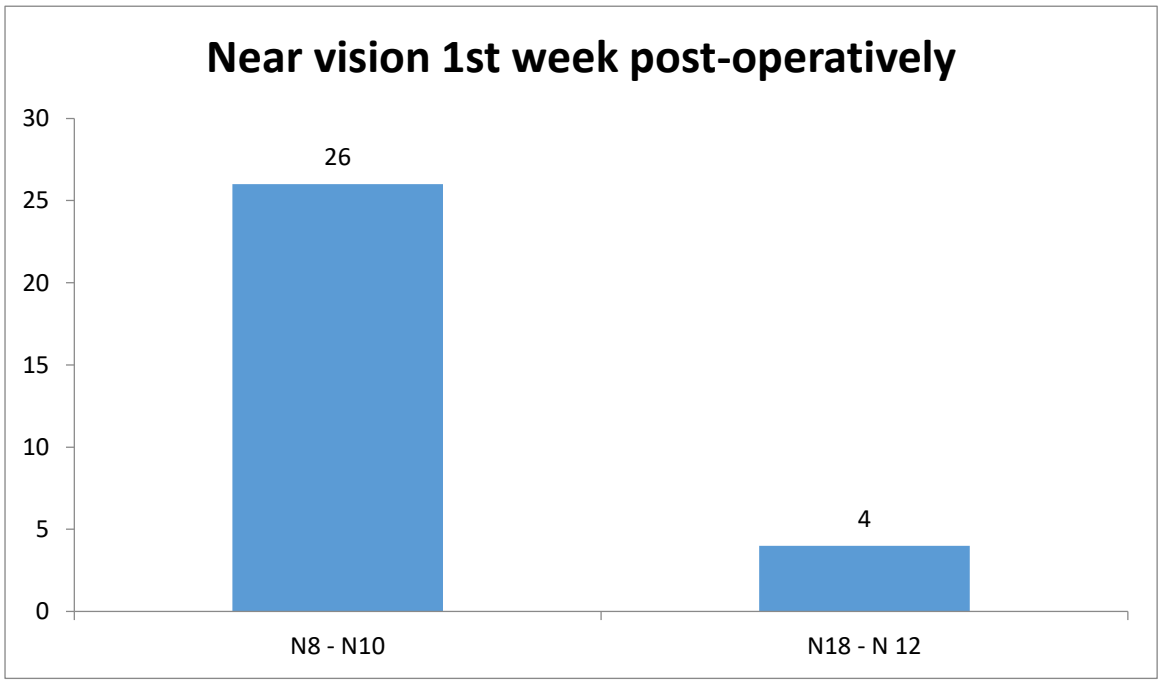


Figure 32: Showing the findings of Near vision 1st week post-operatively

21(70%) patients were able to achieve near vision of N8-N10 at the end of 4th week of follow up.

Table 15: Showing the findings of Near vision 4th week post-operatively

		Frequency	Percent
Near vision 4th week post-operatively	N6	8	26.7
	N10 – N8	21	70.0
	N18 – N12	1	3.3
	Total	30	100.0

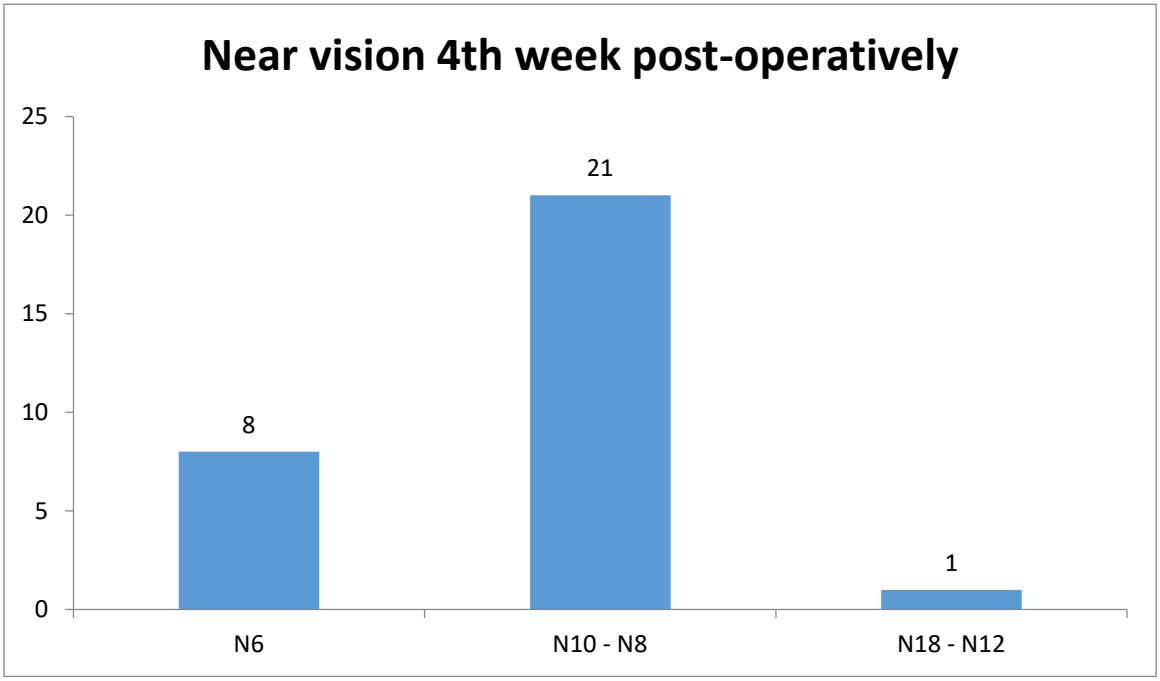


Figure 33: Showing the findings of Near vision 4th week post-operatively

27(90%) patients were able to achieve 6/9 – 6/6 vision at the end of 4th week of follow up

Table 16: Comparison of the distant vision findings before and after EDOF lens

Distant Vision	Pre-operative		Day 1 post-operative		1 week post operative		4 week post-operative		p-value
	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	
6/9 - 6/6	0	0.0%	0	0.0%	5	16.7%	27	90.0%	0.001**
6/18 - 6/12	0	0.0%	13	43.3%	19	63.3%	2	6.7%	
6/36-6/24	2	6.7%	17	56.7%	6	20.0%	1	3.3%	
6/60	13	43.3%	0	0.0%	0	0.0%	0	0.0%	
CF2- 1MT	3	10.0%	0	0.0%	0	0.0%	0	0.0%	
CF 2-3M	6	20.0%	0	0.0%	0	0.0%	0	0.0%	
HMCF PLRR	6	20.0%	0	0.0%	0	0.0%	0	0.0%	

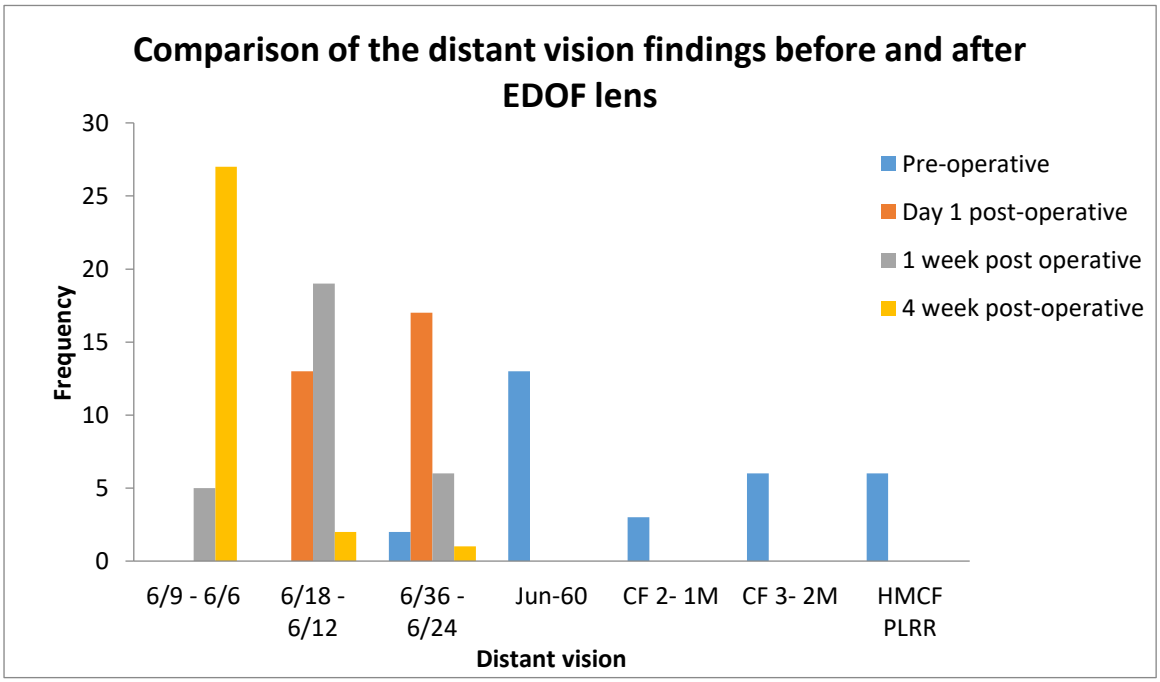


Figure 34: Comparison of the distant vision findings before and after EDOF lens

19(63.3 %) patients were able to achieve 6/6 intermediate vision and 5(16.7%) patients were able to achieve 6/7.5 intermediate vision at the end of 4th week follow up.

Table 17: Comparison of the intermediate vision findings before and after EDOF lens

Intermediate vision	Pre-operative		Day 1 post-operative		1 week post operative		4 week post-operative		p-value 0.001**
	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	
<6/60	20	66.7%	1	3.3%	1	3.3%	0	0	
6/48	4	13.3%	0		0		0	0	
6/38	3	10%	0		0		0	0	
6/30.	1	0.0%	2	6.6%	4	13.3%	0	0	
6/24	2	3.3%	6	20%	9	30%	0	0	
6/19.	0	6.7%	4	13.3%	3	10%	3	10%	
6/15	0		9	30%	5	16.7%	0	0	
6/12	0		6	20%	12	40%	0	0	
6/9.5	0		1	3.3%	2	6.7%	3	10	
6/7.5	0		1	3.3%	1	3.3%	5	16.7	
6/6	0		0		1	3.3%	19	63.3	

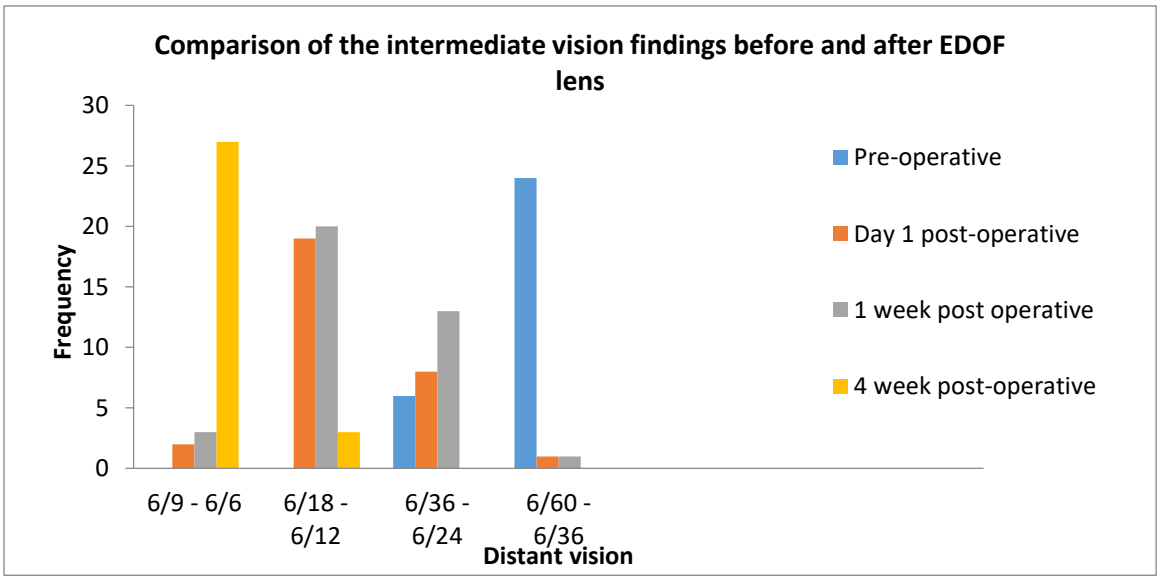


Figure 35: Comparison of the intermediate vision findings before and after EDOF lens

21 (70%) patients were able to achieve near vision of N10 – N8 and 18 (26.7%) were able to achieve near vision of N6 at the end of 4th week of follow up.

Table 18: Comparison of the near vision findings before and after EDOF lens

Near vision	Pre-operative		Day 1 post-operative		1 week post operative		4 week post-operative		p-value
	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	
N6	0	0.0%	0	0.0%	0	0.0%	8	26.7%	0.001**
N10 – N8	0	0.0%	18	60.0%	26	86.7%	21	70.0%	
N18 – N12	4	13.3%	12	40.0%	4	13.3%	1	3.3%	
N36 – N24	4	13.3%	0	0.0%	0	0.0%	0	0.0%	
<N36	22	73.3%	0	0.0%	0	0.0%	0	0.0%	

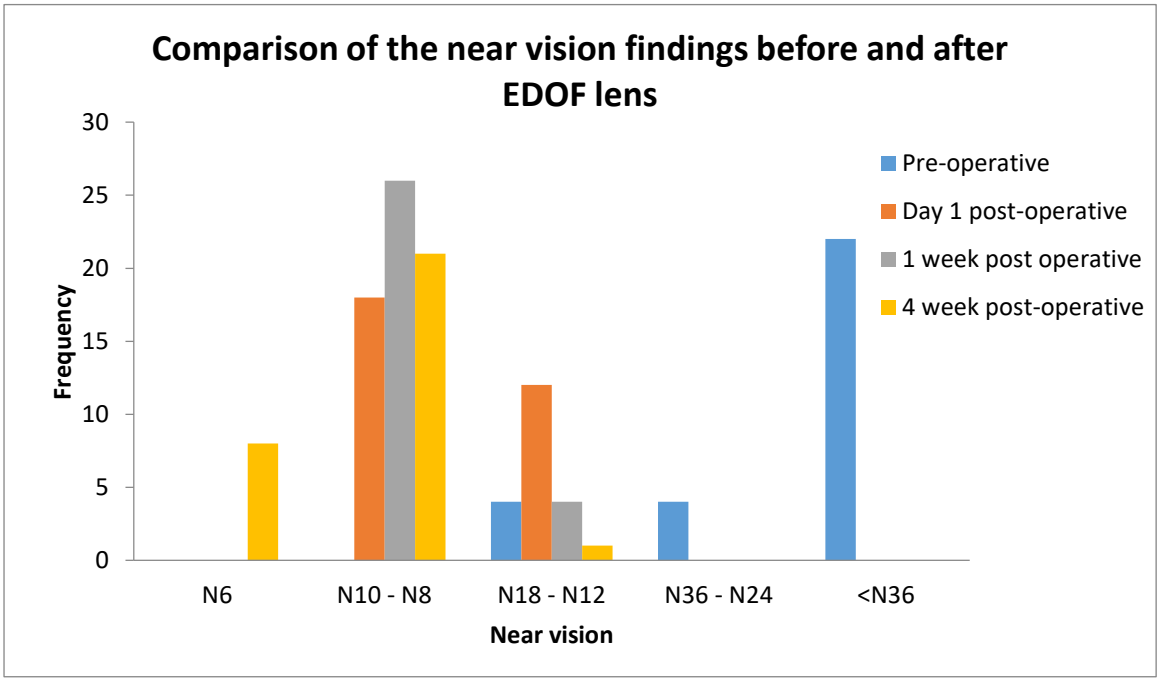


Figure 36: Comparison of the near vision findings before and after EDOF lens

The mean KH value was found to be 43.36 and KV was found to be 44.09.

The mean PCIOL value was found to be 20.63.

Table 19: Showing the mean level of KH, KV and PCIOL

	N	Minimum	Maximum	Mean	SD
KH	30	40.75	45.75	43.36	1.31
KV	30	41.00	47.50	44.09	1.62
PCIOL	30	17.0	23.5	20.63	1.58

The minimum high contrast sensitivity was found to be .1 and maximum was 0.4

The minimum low contrast sensitivity was found to be 0.2 and maximum contrast sensitivity was found to be 0.7

Table 20: Showing the mean level of CSH and CSL among study participants

	N	Minimum	Maximum	Mean	SD
CSH	30	.1	.4	0.233	0.0994
CSL	30	.2	.7	0.423	0.1455

In the present study, only 3(10%) of the patients reported of difficulty in night driving.

Table 21: Showing the distribution of DND at 4th week of follow-up

		Frequency	Percent
DND at 4th week	No	27	90.0
	Yes	3	10.0
	Total	30	100.0

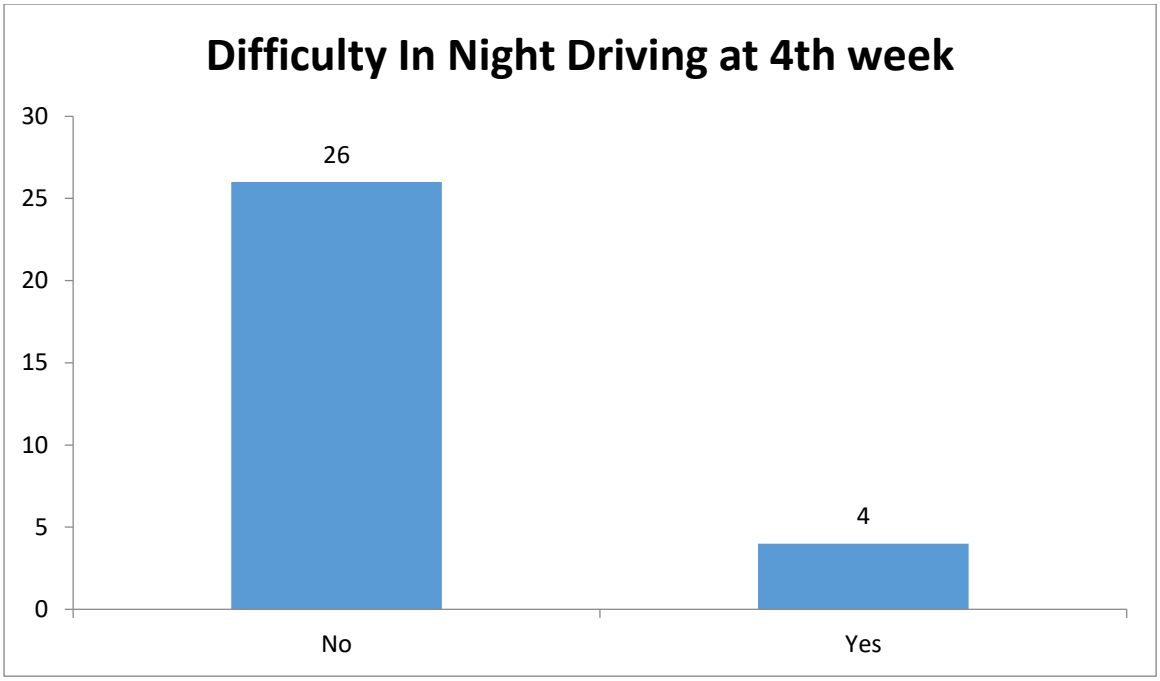


Figure 37: Showing the distribution of DND at 4th week of follow-up

Out of 30 patients, 4(13.3%) patients reported of day glare.

Table 22: Showing the distribution of day glare at 4th week of follow-up

		Frequency	Percent
Day glare at 4th week	No	26	86.7
	Yes	4	13.3
	Total	30	100.0

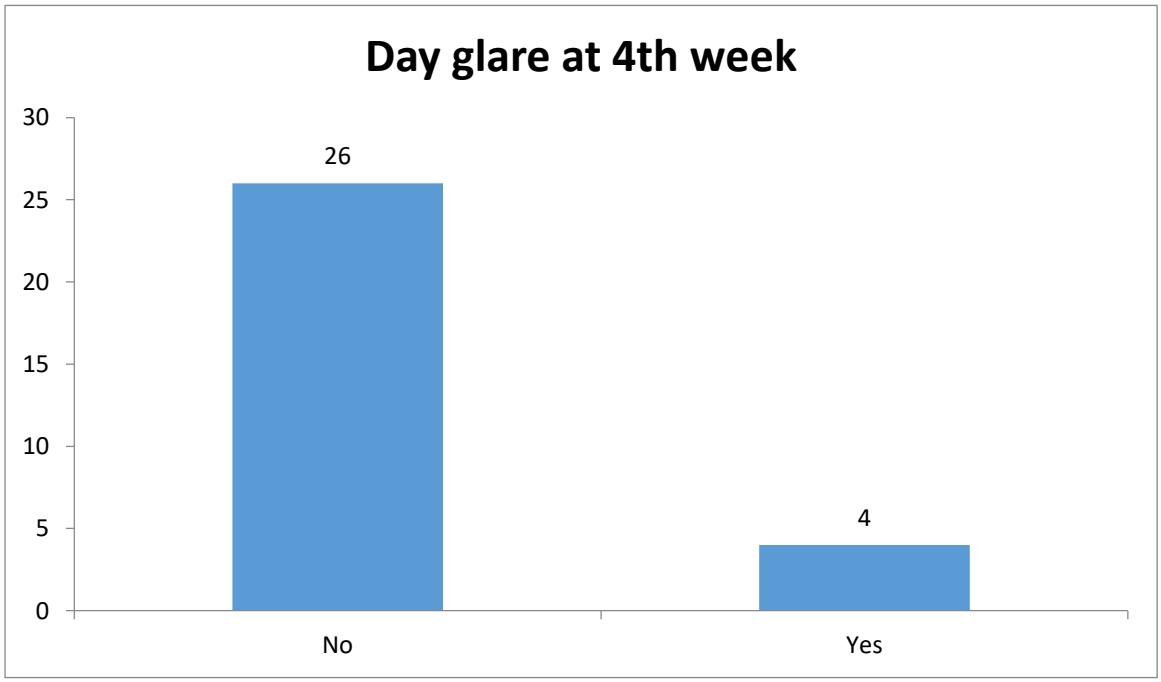


Figure 38: Showing the distribution of day glare at 4th week of follow-up

8(26.7%) patients reported of night glare at the end of 4th week follow up.

Table 23: Showing the distribution of night glare at 4th week of follow-up

		Frequency	Percent
Night glare at 4th week	No	22	73.3
	Yes	8	26.7
	Total	30	100.0

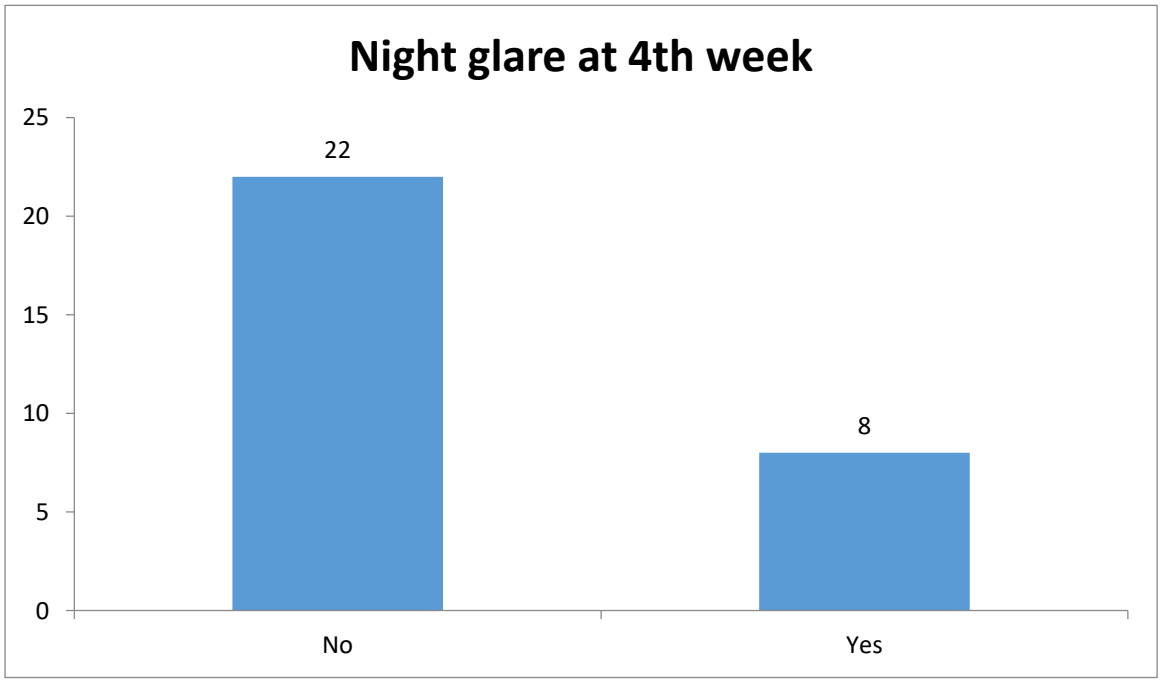


Figure 39: Showing the distribution of night glare at 4th week of follow-up

9(30%) of the patients reported of halos at the end of 4th week of follow up.

Table 24: Showing the distribution of Halo at 4th week of follow-up

		Frequency	Percent
Halo at 4th week	No	21	70.0
	Yes	9	30.0
	Total	30	100.0

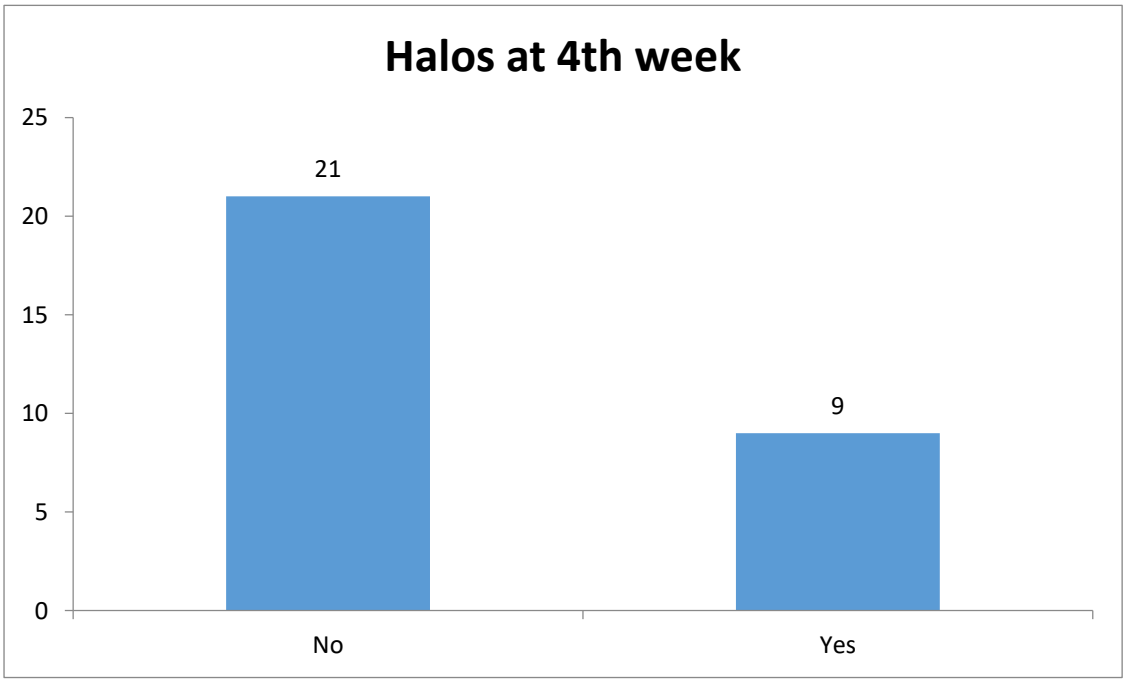


Figure40: Showing the distribution of Halo at 4th week of follow-up

1(3.3%) patient reported of tearing at the end of 4th week of follow up.

Table 25: Showing the distribution of tearing at 4th week of follow-up

		Frequency	Percent
Tearing at 4th week	No	29	96.7
	Yes	1	3.3
	Total	30	100.0

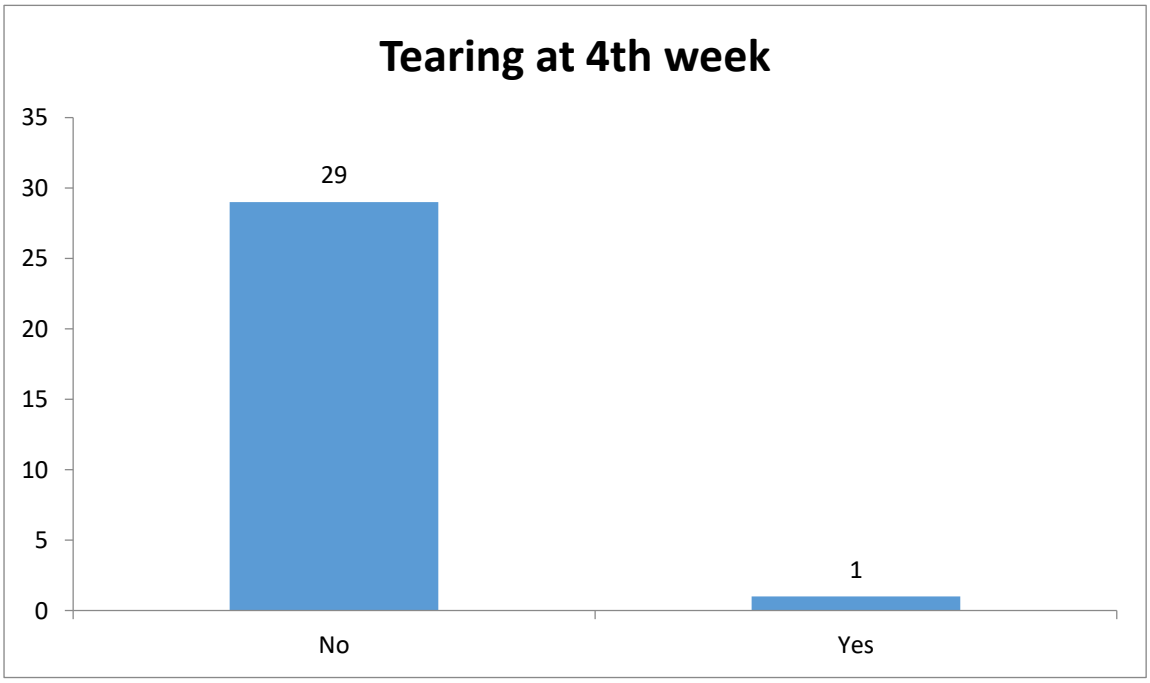


Figure 41: Showing the distribution of tearing at 4th week of follow-up

24(80%) of the patients had spectacle independence at the final follow up.

Table 26: Showing the distribution of spectacle independence at 4th week of follow-up

		Frequency	Percent
Spectacle Independence at 4th week	No	6	20.0
	Yes	24	80.0
	Total	30	100.0

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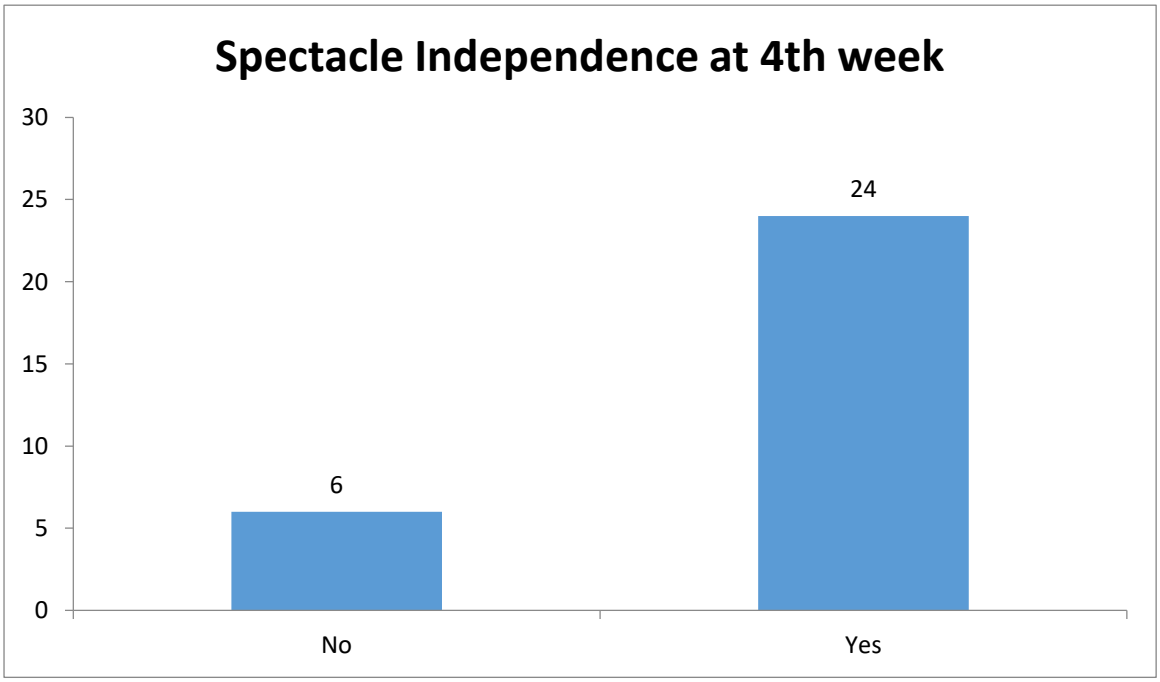

Figure42: Showing the distribution of spectacle independence at 4th week of follow-up

27(90%) patients were satisfied with the distant vision at the final follow up.

Table 27: Showing the distribution of satisfaction for distance vision

		Frequency	Percent
Satisfaction Distance vision	No	3	10.0
	Yes	27	90.0
	Total	30	100.0

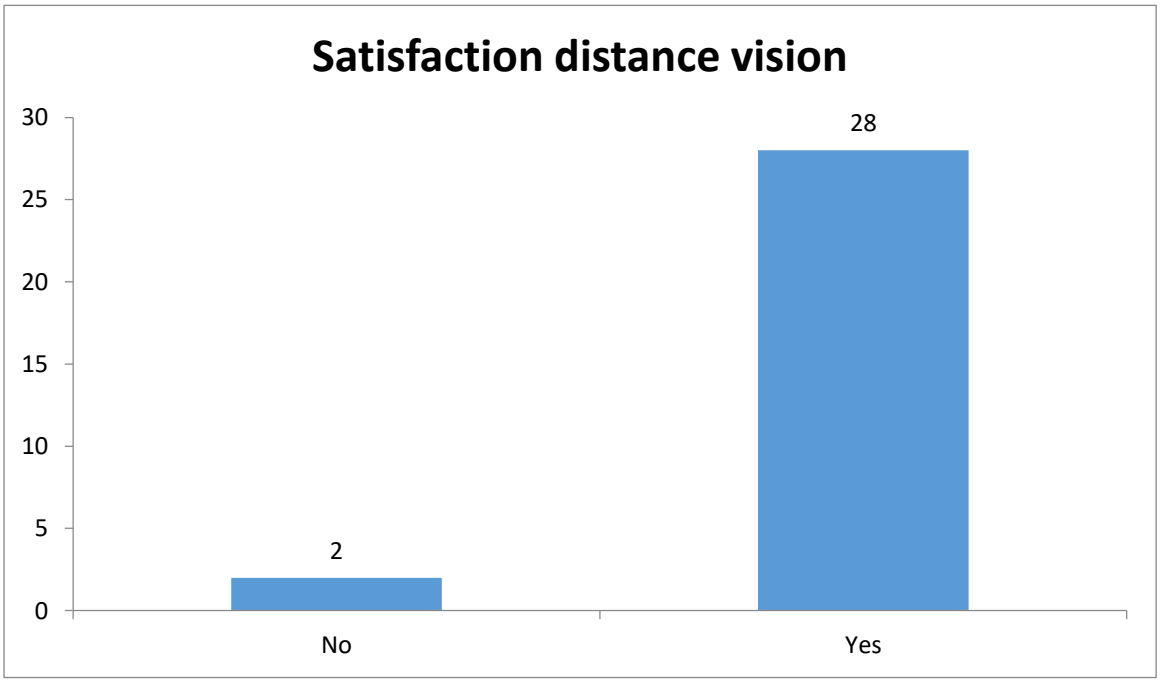

Figure 43: Showing the distribution of satisfaction for distance vision

28(93.3%) patients were satisfied with the intermediate vision at the final follow up.

Table 28: Showing the distribution of satisfaction for intermediate vision

		Frequency	Percent
Satisfaction Intermediate vision	No	2	6.7
	Yes	28	93.3
	Total	30	100.0

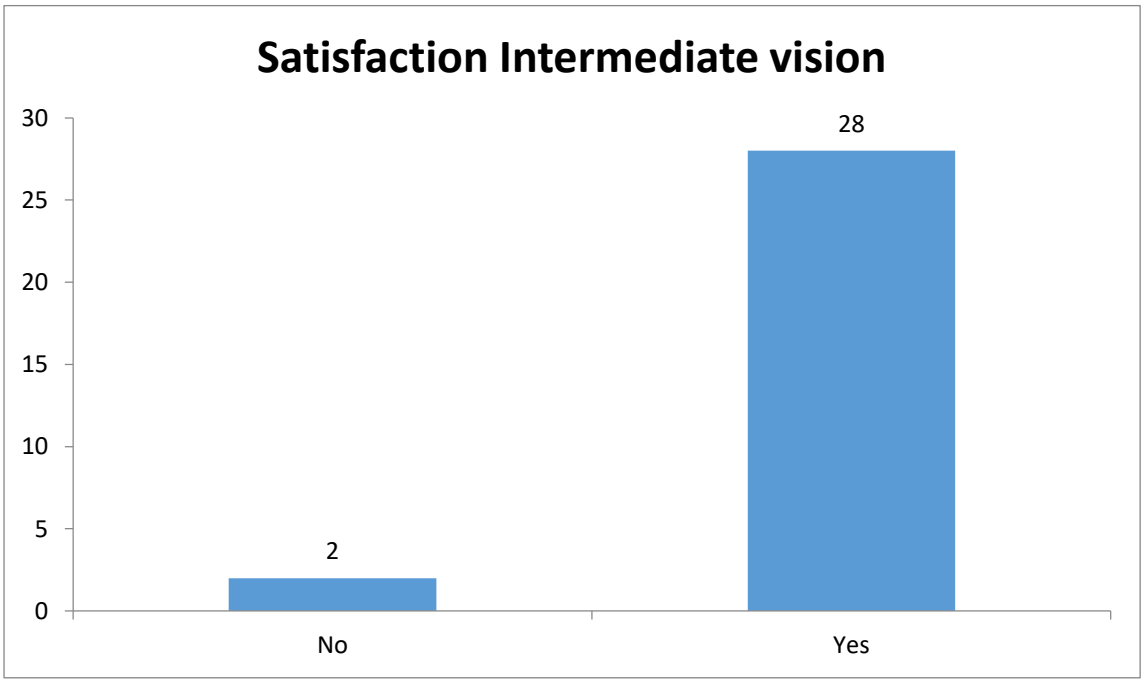

Figure 44: Showing the distribution of satisfaction for intermediate vision

Out of 30 patients in the study 25(83.3%) patients were satisfied with the near vision.

Table 29: Showing the distribution of satisfaction for near vision

		Frequency	Percent
Satisfaction Near vision	No	5	16.7
	Yes	25	83.3
	Total	30	100.0

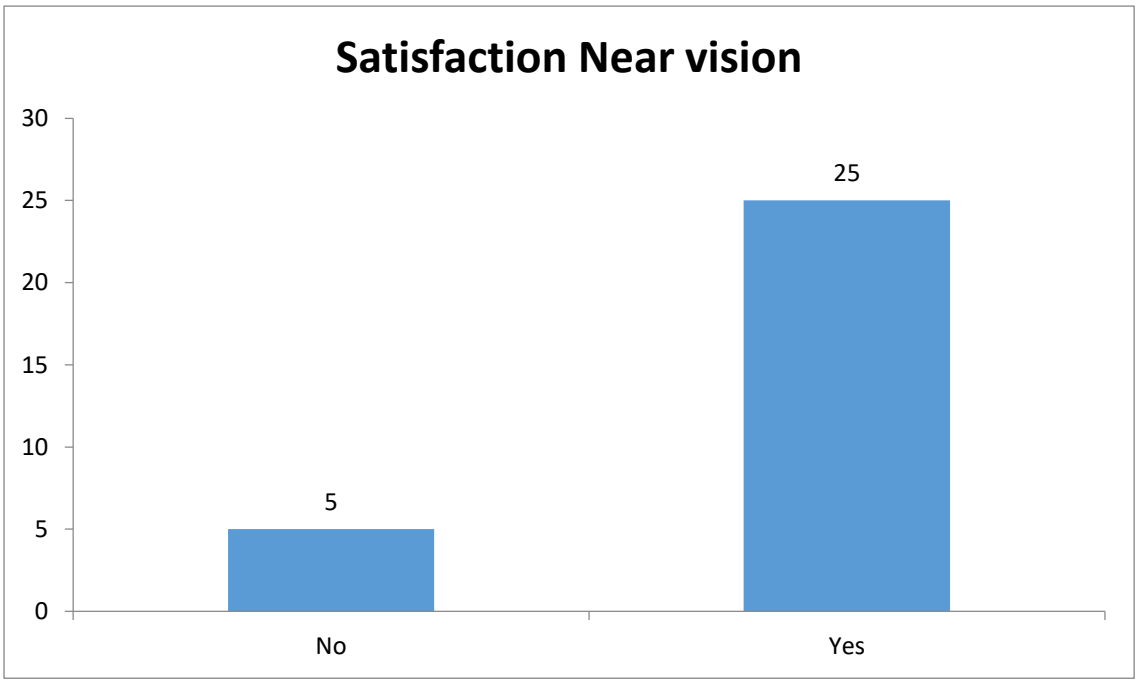

Figure45: Showing the distribution of satisfaction for near vision

In the overall satisfaction index of the patients,23 (76.7%) were very satisfied, 5(16.7%) were satisfied and 2(6.7%) were not satisfied.

Table 30: Showing the overall satisfaction of patients

		Frequency	Percent
Overall satisfaction	Very satisfied	23	76.7
	Satisfied	5	16.7
	Not satisfied	2	6.7
	Total	30	100.0

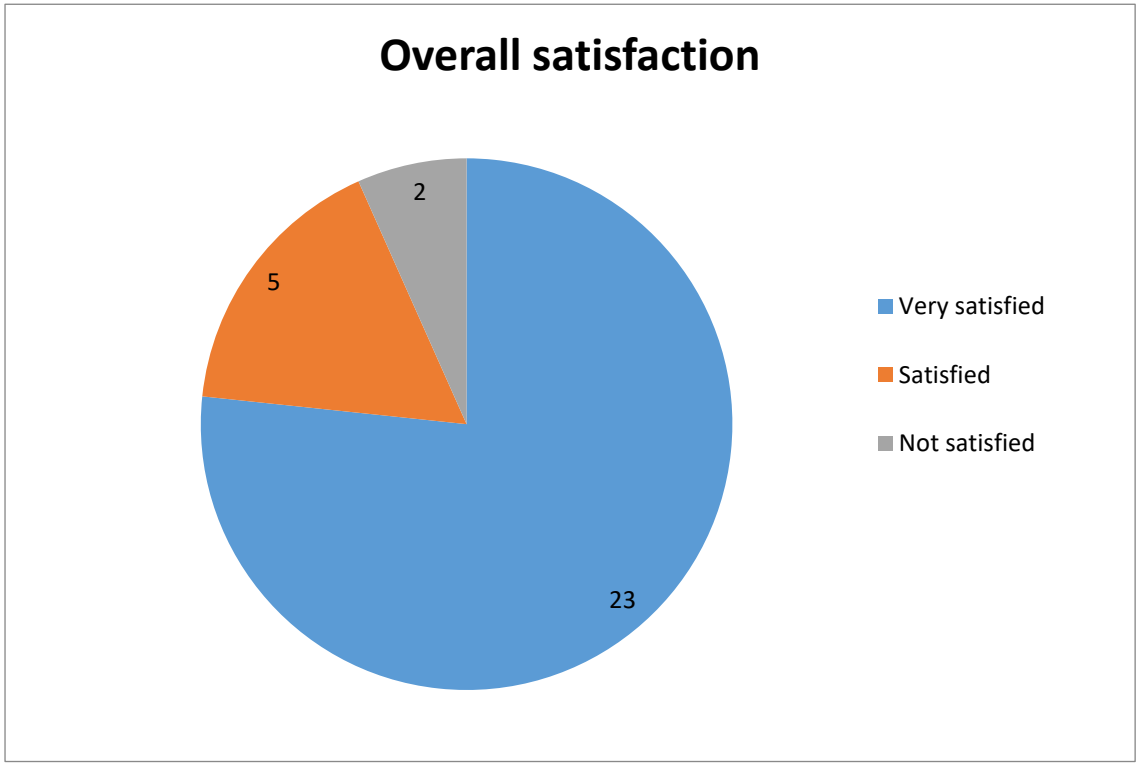

Figure 46: Showing the overall satisfaction of patients

DISCUSSION

For correction of presbyopia during cataract surgery multifocal, accommodative and EDOF lenses are being used. But due to the disadvantages associated with multifocal and accommodative IOLs, the EDOF IOLs are increasingly being used for achieving good vision at various distances.

The first EDOF IOL approved by USFDA was TECHNIS Symfony in the year 2016 which has gained immense popularity. There are various studies evaluating the distant, intermediate, near vision as well as contrast sensitivity and patient satisfaction associated with EDOF lens used during phacoemulsification surgery but the high cost of EDOF is the major limiting factor in developing countries.

This prospective interventional study was carried out to evaluate the visual outcomes following cataract surgery with EDOF lenses. The study was conducted for duration of 1yr from January 2021 to December 2021. The patients diagnosed with cataract who matched the inclusion criteria, attending the Ophthalmology OPD, Dr. Prabhakar Kore Hospital and Medical Research Centre, and who were willing to undergo phacoemulsification under topical anaesthesia using the Extended Depth of Focus intraocular lens were included in the study.

Preoperative evaluation involved a thorough ophthalmic examination, which included an assessment of distant, intermediate and near visual acuity, refractive status, slit- lamp biomicroscopy, dilated fundoscopy, non-contact tonometry, keratometry and A-Scan biometry. Snellen's chart was used to assess the distance visual acuity, Snellen Reading Chart was utilized to assess near visual acuity, whereas the Sloan chart analysed intermediate visual acuity. KH and KV were taken with

autorefractometer and PCIOL calculation was done with A-Scan Biometry. IOP was measured with non contact tonometer.

The patients underwent phacoemulsification under topical anaesthesia and were implanted with the intraocular EDOF lens by a single surgeon. Postoperatively detailed examination of distant visual acuity, intermediate vision and near visual acuity, contrast sensitivity testing, slit lamp and fundus examination was done for all the patients at every visit. The patients were asked to come for the postoperative evaluation at 1st day, at the end of 1st week and at the end of 4th week of follow up. Patient satisfaction evaluation was also done by visual function questionnaire at the end of 4th week.

The average age of patients was found to be 61.83 9.71 years. The cataract was found in left eye in 56.7% and in right eye in 43.3% of participants. In our study male to female ratio was 1:1.5 with female preponderance was noted. In the study conducted by Singh et al., the average patient age was 58.4 9.3 years, with an equal number of male and female distribution[37]

The patients data was noted by examination preoperatively and the same details were measured postoperatively on 1st day, at the end of 1st week and at the end of 4th week of follow up. The majority of patients had preoperative distant visual acuity of less than 6/60. On assessment of the distant vision in the postoperative period, 56.7% had distant vision of 6/36-6/24 on day 1, 63.3% had distant vision of 6/18-6/12 at the end of 1st week and 90% had distant vision of 6/9-6/6 at the end of 4th week follow up. This improvement seen in distant vision was found to be statistically significant. (p value of less than or equal to 0.05).

Majority of patients had a preoperative intermediate visual acuity of less than 6/60. After the operative procedure, 30% of patients had intermediate vision of 6/15 on day1, 40% of patients had intermediate vision of 6/12 at the end of 1st week follow up and 63.3% of patients had intermediate vision of 6/6 at the end of 4th week follow up. Similarly on assessment of near vision preoperatively majority (73.3%) of patients had near vision of <N36. In postoperative period, 60% of patients had near vision of N10-N8 on day 1, 86.7% had near vision of N10-N8 at the end of 1st week and 70% had improvement of near vision to N10-N8 at the end of 4th week follow up. The improvement in intermediate and near vision were found to be statistically significant (p value less than or equal to 0.05).

In a study done by Singh et al, the majority of the patients had postoperative good distance, intermediate and near visual acuity.96% of the eyes had UDVA of 20/20 or greater at the three month follow up. These findings correlated with our study.[41]

Another study done by Cochener B et al documented that at 6 month postoperatively, 60% of patients had UDVA of 20/20. 55% of patients achieved UIVA of better than 20/32 and 52.5% of patients had UNVA J2(>20/32) with EDOF IOL. This improvement in distant, intermediate and near vision was similar to the findings observed in our study.[38]

In study done by McNeely R N et al assessment of distant, intermediate and near vision was done at 1 month and 12 month postoperative period. There was improvement in UDVA of 20/20 in 94.8% of patients at 1 month follow up and 100% at the end of 12 month postop. Intermediate vison improved to 20/40 in 94.8% of patients at 1 month and 96.6% of patients had improvement in intermediate vision

upto 20/40 at 12 months of postoperative period. Near vision also improved significantly upto 20/40 in 94.8% of patients at 1 month and 20/40 in 98.3% of patients at 12 months follow up. These findings of improvement in distant, intermediate and near vision was similar to our study.[38]

In the current study, day glare was noted in 13.3% of patients, night glare in 26.7% of patients, halos in 30% of patients, tearing in 3.3% of patients and spectacle independence was noted in 80% of the patients with EDOF lens at the 4th week follow up. In study done by Singh et al, 10% of patients noted starburst, glare or halos which was similar to findings in our study.[41]

According to Cochener B et al, less than 1% of patients experienced glare, halos, dry eye which was very less compared to our study.[44]

Mc Neely RN et al documented low rate of bothersome side effects at both postoperative examinations done at 1 month and 12 month with majority vanishing by the second assessment.[38]

In the present study, spectacle independence was noted in 80% of the patients for both distant and near vision. In study done by Singh et al, 92.3% of patients had spectacle independence for near vision and 96.2% of patients had spectacle independence for distance vision. Cochener B et al documented 72% spectacle independence for near vision and 92% spectacle independence for distant vision in their study.[44] Another study by Titiyal et al observed that 62% of patients had spectacle independence for distance vision.[47] McNeely RN et al documented spectacle independence in 87% of the patients which was similar to our study.[38]

In the assessment of patient satisfaction done at the end of 4th week follow up, 90% of patients reported being satisfied with their distant vision, 93.3% of patients were satisfied with their intermediate vision and 83.3% of patients were satisfied with their near vision. In terms of overall patient satisfaction, 76.7% of patients reported being extremely satisfied,16.7% reported being satisfied and 6.7% reported not being satisfied with the results.

In a study done by Singh et al, 92% of the cases had complete satisfaction with the IOL whereas 8% had moderate satisfaction. The patient satisfaction Questionnaire revealed that more than 95% of patients were able to perform near tasks without the need for spectacles. These findings correlated with our study.[41]

In another study by McNeely et al, 91 % of patients reported being satisfied or extremely satisfied with surgery.[40]

The study demonstrated that EDOF lenses may be implanted in individuals having cataract surgery safely and with satisfactory visual results.

CONCLUSION

The study demonstrated that EDOF lenses may be implanted in individuals undergoing cataract surgery and with satisfactory visual results. In addition, there were few dysphotic symptoms related to IOL implantation. The patient's satisfaction showed majority were very satisfied at the 4^{th} week of follow-up.

SUMMARY

This prospective interventional study included patients undergoing phacoemulsification under topical anaesthesia with EDOF lens at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

The source of data for the study were the patients diagnosed with cataract willing for phacoemulsification and opted for the EDOF intraocular lens, attending the Ophthalmology OPD.

After obtaining the informed and written consent, a total of 30 people who met the eligibility criteria were included in the study.

The mean age of participants was found to be 61.83±9.71yrs of age.

Among them 60% were female patients and 40% were male patients.

The gender ratio was 1.5:1. (female preponderance was noted in the study).

In this study, cataract was seen in left eye in 56.7% of patients and in right eye in 43.3% of patients.

The patient's data was noted by examination pre-operatively and the same details were measured post cataract surgery at 1st day, at the end of 1st week and at the end of 4th week.

In this study during pre operative assessment majority of patients had distant vision of less than 6/60

On assessment of the distant vision in post-operative period,

- 56.7% had distant vision of 6/36-6/24 on day 1,
- 63.3% were having distant vision of 6/18-6/12 at the end of 1st week follow-up, and
- 90% had distant vision of 6/9-6/6 at the end of 4th week follow-up.

Similarly the Preoperative Intermediate vision was assessed, which was found to be 6/60 in majority of patients (66.7%).

After the operative procedure,

- The majority of patients were (30%) were having intermediate vision of 6/15 on day 1,
- 40.0% of patients were having intermediate vision of 6/12 at the end of 1st week of follow up and
- 63.3% had 6/6 intermediate vision at the end of 4th week follow up

Similarly the near vision was assessed pre-operatively which was found<N36 (73.3%) in majority of the patients.

In post-operative period,

- 60% patients had near vision of N10-N8 on day 1,
- 86.7% of patients had near vision of N10-N8 at the end of 1st week
- 70% of patients had N10-N8 near vision and 26.7% of patients had N6 near vision at the end of 4th week follow up.

In present study at the 4th week of follow-up with EDOF lens,

Day glare was found in 13.3% of the patients

- Night glare in 26.7% of patients,
- Halos in 30% of patients,
- Tearing in 3.3% and
- Spectacle independence was seen in 80% of the patients.

On assessment of patients satisfaction at the end of 4th week of follow-up, the patient's satisfaction for

- Distance was seen in 90%,
- For Intermediate vision was seen in 93.3% and
- For near vision was seen in 83.3% of patients.

Overall satisfaction of the patients was found to be

- Very satisfied in 76.7% of patients,
- 16.7% responded as satisfied and
- 6.7% responded that they were not satisfied with the outcome.

The study demonstrated that EDOF lenses may be implanted in individuals undergoing cataract surgery and with satisfactory visual results.

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ANNEXURE I:

INFORMED CONSENT

Title Of Research Study:

"THE VISUAL OUTCOMES AFTER CATARACT SURGERY WITH EXTENDED DEPTH OF FOCUS LENS AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI -A PROSPECTIVE INTERVENTIONAL STUDY"

Principal Investigator:

REG. NO: BK0120005

POST GRADUATE STUDENT,

DEPARTMENT OF OPHTHALMOLOGY,

JAWAHARLAL NEHRU MEDICAL COLLEGE,

BELAGAVI – 590010

Guide:

DR. _____

PROFESSOR

DEPT. OF OPHTHALMOLOGY,

JNMC, BELAGAVI.

Introduction and Purpose

The purpose of this study is to determine the visual outcomes after cataract surgery with Extended Depth Of focus lens at

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI

Procedure

If, you agree to be part of the research study, you will be asked the relevant history and will be subjected to relevant clinical examination and investigations.

BENEFITS

The aim of this study is to evaluate the clinical profile and visual outcomes, quality of near vision, the perception of light distortion, and intraocular optical quality of patients unilaterally implanted with a Extended Depth Of Focus lens. The knowledge about

Bifocal IOLs provide satisfactory visual acuities for near and far distances however compromise intermediate vision. The development of trifocal IOLs addresses this problem and provides good results that are reported by several authors

Risk

NIL

Alternatives

Taking part in this study is voluntary. You may choose not to take part in this study. If you decide to take part you can later change your mind and withdraw from the study. Your decision will not change the present or future health care or other services that you receive. The study doctor or sponsor may stop your participation in this study at any time. If you choose not to take part in the study, you will receive the standard treatment for patients with your condition.

Privacy and Confidentiality

All the information collected about you during the course of this study will be kept confidential to the extent permitted by law. The code numbers will identify you in this research record. Information from this study may be published but your identity will be confidential in any publication.

Institution / Sponsor's policy

Does not apply to this research

Financial incentives for participation

You will not be paid / offered any gifts /incentives for participating in the study.

Authorization to publish the results

The results of the study would be forwarded to the KLE University, Belgaum as part of requirement towards the completion of MS degree, review and publishing.

In case of the queries during study or in future you may contact following persons,

1. REG. NO: BK0120005
   Investigator,
   PG in Ophthalmology,
   J.N.M.C., Belagavi

2. Dr. _____
   Professor,
   Dept. of Ophthalmology
   J.N.M.C., Belagavi

3. Dr. Roopa Bellad MBBS MD DCH
   Chairman
   J.N.M.C. Ethical Committee
   for Human Research
   J.N.M.C., Belagavi

CONSENT FORM

I voluntarily agree to take part in this study by signing below. I may withdraw at any time. I am not giving up any of my legal rights by signing this form. My signature below indicates that I have read this consent form, or it has been read to me, and I have had all the questions answered. The study and the consent form has been explained to me in my language.

Participant's Name: ……

Name of the Legally Authorized Representative / Guardian: ……

Signature / Left Thumb print of the Participant

or Legally Authorized Representative

Witness' Name: ……

……

Signature / Left thumb Impression

Investigator's Name and Signature:

Signature / Left thumb Impression

DATE:

PLACE:

ANNEXURE II:

PROFORMA

GENERAL INFORMATION

IP NUMBER: OP NUMBER: PATIENT ID NUMBER:

NAME:
_____

AGE: _____ GENDER: F/M CONTACT NUMBER: _____

ADDRESS:
_____

_____

DATE OF ADMISSION: _____ DATE OF DISCHARGE: _____

Is the patient eligible for the study? YES/NO

Has informed consent been given? YES/NO

Final result information:

1. Ineligible
2. Eligible –Refusal
3. Eligible – Participating

CHIEF COMPLAINTS

Diminution of vision: RE/LE/BOTH EYES

Duration: RE: _____ days/months/years
LE: _____ days/months/years

HISTORY OF PRESENTING ILLNESS

Diminution of vision: Gradual/Sudden
Progressive/Static

Painless/Painful

For distance/For near/For both distance and near

Diplopia: Present/Absent

Coloured halos: Present/Absent

Black spots before the eyes: Present/Absent

Watering: Present/Absent

Redness: Present/Absent

Discharge: Present/Absent

Clear/Whitish

Serous/Mucoid

Spectacle use: Distance/Near/Both

Duration: _____ days/months/years

Last refraction done: _____ days/months/years

back

PAST HISTORY

Ocular surgery: Yes/No Type of Surgery:

_____

Duration: _____ days/months/years

Diabetes: Yes/No

Duration: _____ days/months/years

Hypertension: Yes/No

Duration: _____ days/months/years

Any other medical disorders:

_____

_____

PERSONAL HISTORY

Smoking: Yes/No

Duration: _____ days/months/years

Alcoholism: Yes/No

Duration: _____ days/months/years

Other addictions: Yes/No

Duration: _____ days/months/years

GENERAL PHYSICAL EXAMINATION

General appearance: Well-built/Moderately built/Poorly built/Emaciated

Pallor: Present/Absent If present: Mild/Moderate/Severe

Pulse: _____ beats/minute BP: _____ mmHg

Temperature: _____ ^{o}F Respiratory Rate: _____/minute

SYSTEMIC EXAMINATION

CVS: Normal/Abnormal
Specify:
_____

RS: Normal/Abnormal
Specify:
_____

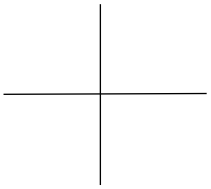
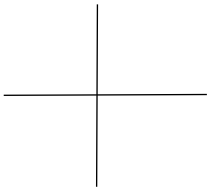
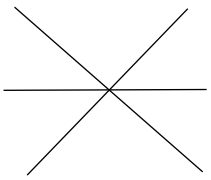
CNS: Normal/Abnormal
Specify:
_____

GIT: Normal/Abnormal
Specify:
_____

OCULAR EXAMINATION

Head posture: Erect/Tilted
Visual axis: Parallel/Deviated
Facial symmetry: Symmetrical/Asymmetrical

Extra-ocular movements: Normal/Restricted/Partially restricted

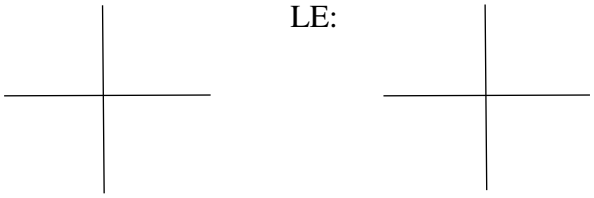
RE:  LE:  Binocular: 

VISUAL ACUITY:

	RE		LE	
DISTANT				
PINHOLE				
INTERMEDIATE				
NEAR				

REFRACTION/RETINOSCOPY:

RE: LE:



PRESCRIPTION	SPHERICAL	CYLINDRICAL	AXIS	BCVA

LE				

	OD	OS
LID		
ADNEXA		
CONJUNCTIVA		
SCLERA		
CORNEA		
ANTERIOR CHAMBER		
IRIS		
PUPIL A. Size B. Shape C. Direct D. Indirect E. Near reflex	_____ in mm Present/Absent Present/Absent Present/Absent	_____ in mm Present/Absent Present/Absent Present/Absent
LENS	Clear/Opaque	Clear/Opaque

	Aphakia/Pseudophakia Immature/Mature/Hypermature NS/CC/PSC Grade – I / II / III / IV	Aphakia/Pseudophakia Immature/Mature/Hypermature NS/CC/PSC Grade – I / II / III / IV

Fundus Examination	OD	OS
GLOW		
MEDIA		
DISC 1. Size 2. Shape 3. Colour 4. NRR 5. Vessels 6. Lamellar Dot Sign 7. Haemorrhagic Spots 8. Other Signs		
C:D RATIO		
BLOOD VESSELS		
BACKGROUND		
MACULA		

DIAGNOSIS:

_____
_____
_____

INVESTIGATIONS:

1. Lacrimal Patency:
2.

	Patent	Regurgitation		Blocked
		Clear Fluid	Regurgitation	
RE				
LE				

3. IOP:

	By NCT	By Schiotz		
		5.5g	7.5g	10.0g
RE				
LE				

4. Blood Sugar: _____ mg% (RBS/FBS)

5. A-Scan:

K_H EXTENDED DEPTH OF FOCUS LENS IOL

Calculation:

K_v

Axl:

ACD:

PCIOL:

OPERATIVE PROCEDURE:

Surgery: Phacoemulsification with EXTENDED DEPTH OF FOCUS LENS

Date:_____ Eye to be operated: Right/Left/Both

ANAESTHESIA: Peribulbar block/Topical

INCISION: Superior/Temporal/Supero temporal/Inferotemporal

OPERATIVE COMPLICATIONS: Present/Absent

If present, Specify-

_____

OPERATING SURGEON:

_____

SURGEON'S SIGNATURE:

FOLLOW UP PLAN: POST OPERATIVELY-OPERATED EYE

	1ST DAY	1ST WEEK	4TH WEEK
VISUAL ACUITY: (UNCORRECTED)			
DISTANT			
PINHOLE			
INTERMEDIATE			
NEAR			
VISUAL ACUITY(BEST CORRECTED)			
DISTANCE			
PINHOLE			
INTERMEDIATE			
NEAR			
ANTERIOR SEGMENT:			
LIDS			
ADNEXA			
CONJUNCTIVA			
SCLERA			
CORNEA			
ANTERIOR CHAMBER			
IRIS			
PUPIL			
LENS			
FUNDUS EXAMINATION			
GLOW			
MEDIA			
DISC			
C:D RATIO			

BLOOD VESSELS			
BACKGROUND			
MACULA			
IOP (BY NCT)			
REFRACTION/RETINOSCOPY			

LOGMAR	**HIGH CONTRAST (26%)**
0-0.1	
0.2-0.4	
0.5-0.7	

ETDRS contrast acuity chart

EYE

LOGMAR	**LOW CONTRAST(7%)**
0-0.1	
0.2-0.4	
0.5-0.7	

VISUAL FUNCTION QUESTIONNAIRE(VFQ)

1.Are you satisfied with your distance vision?

2.Are you satisfied with your intermediate vision?

3.Are you satisfied with your near vision?

4.Are glasses necessary for your near vision?

5.Are glasses necessary for your daily life activities?

6.Sunglasses required during day to decrease glare?

7.Daytime glare?

8.Night time glare?

9.Difficulty in night driving?

10.Any rings or halo around Light?

11.Excessive tearing?

OVER ALL PATIENTS SATISFACTION

VERY SATISFIED	
SATISFIED	
NOT SATISFIED	

ANNEXURE II:

PHOTOGRAPHS

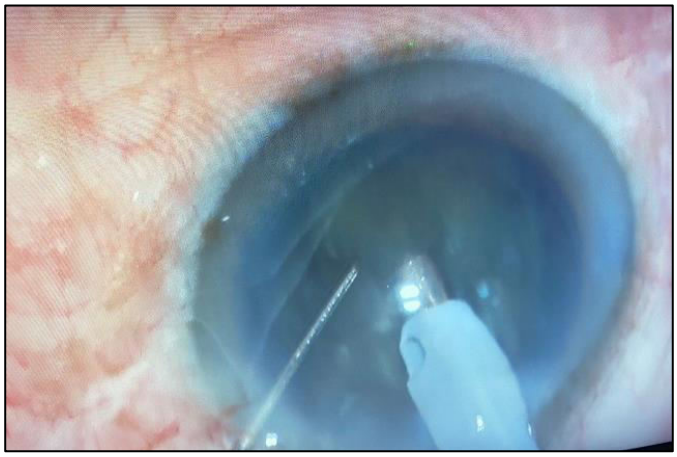
PREOP EVALUATION-

Slit Lamp Examination

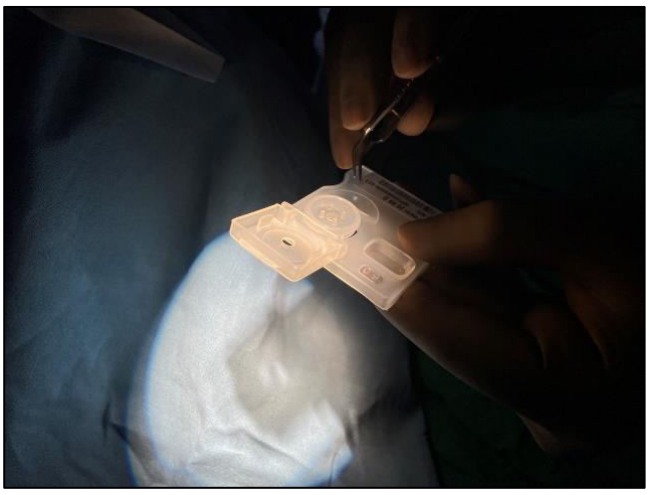
Keratometry with Auto-refractometer

Non Contact Tonometry

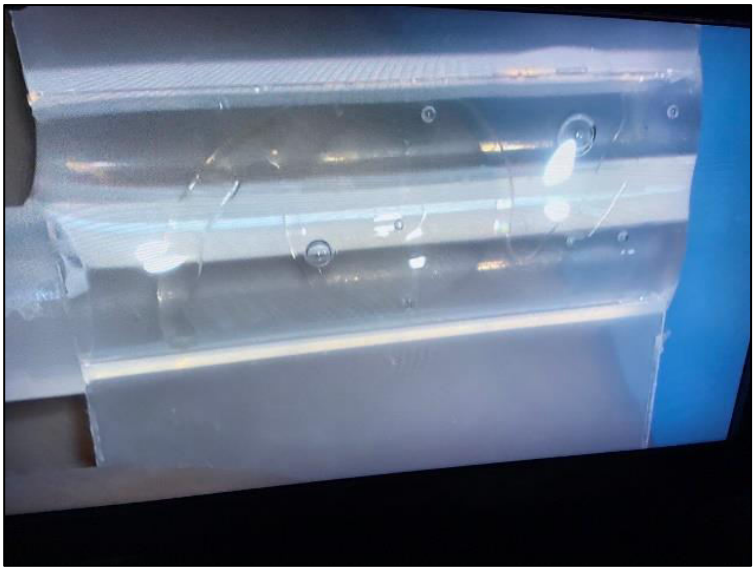
Intraoperative



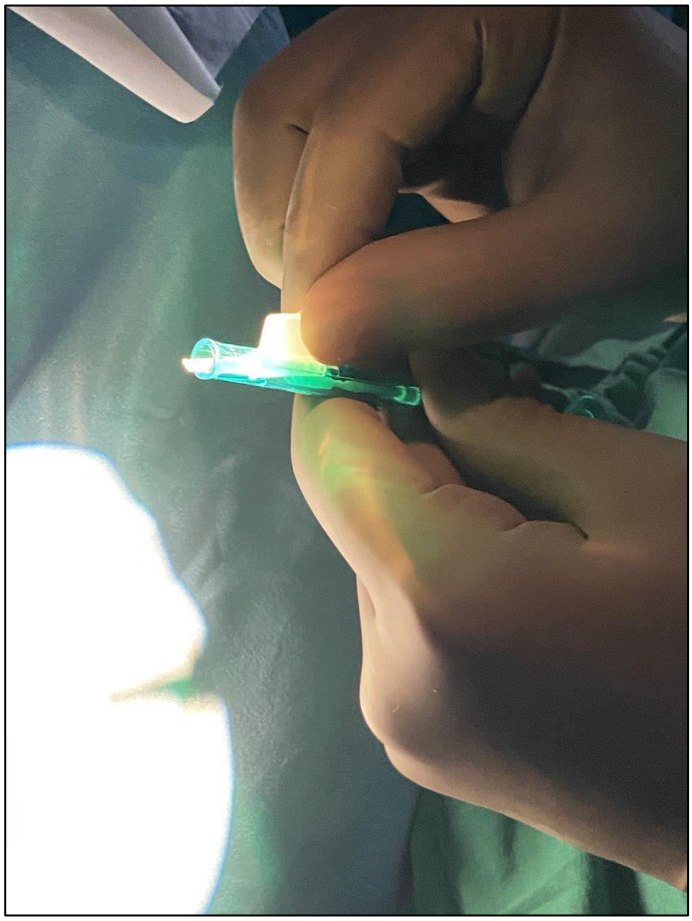
Phacoemulsification Of Nucleus



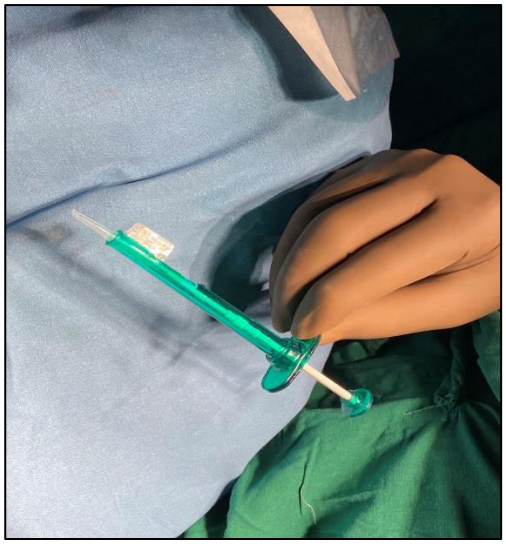
EDOF IOL



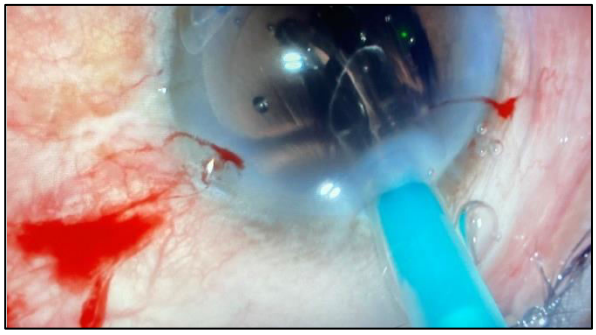
IOL in catridge



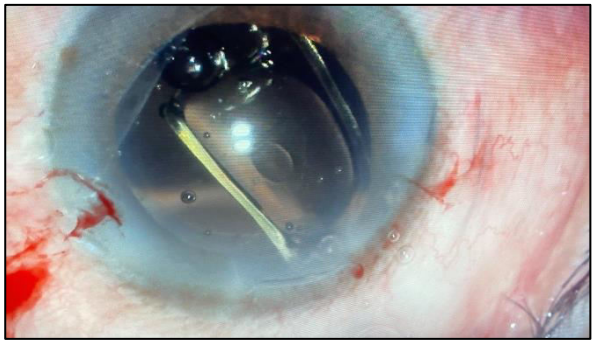
Loading of Cartridge on the injector

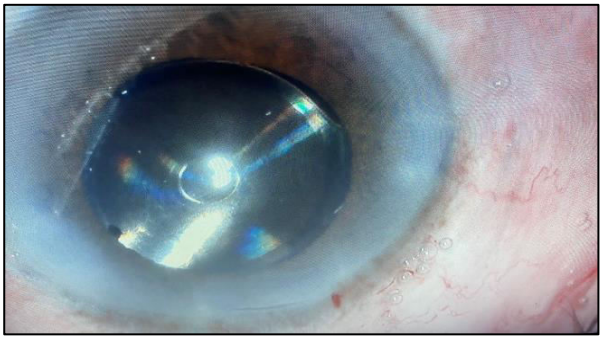


Injector loaded with IOL

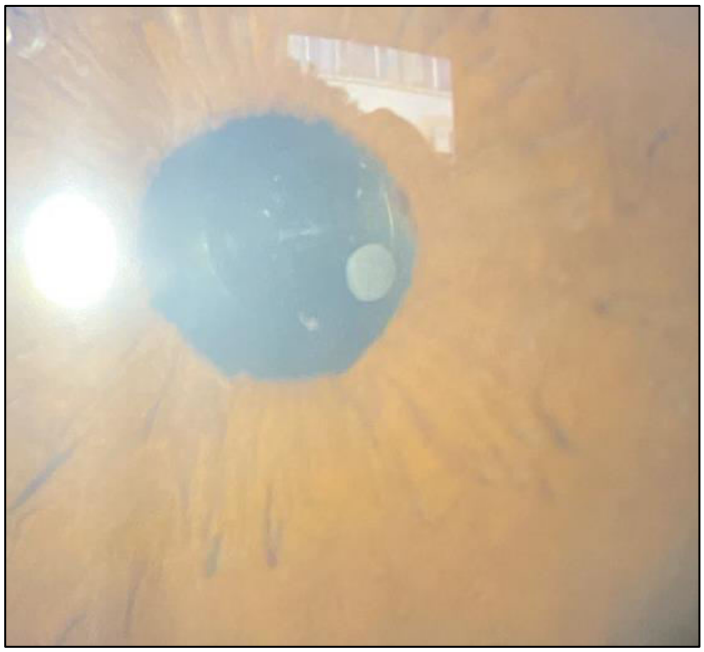


IOL injecting into the Bag





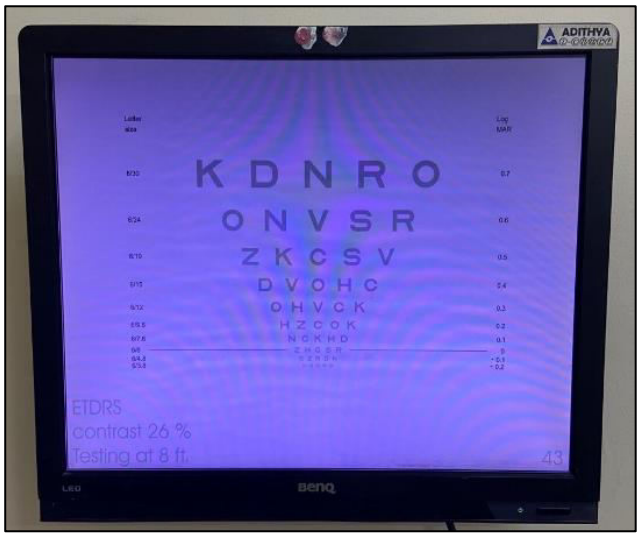
1 EDOF opening in the bag **2. Well centered IOL**



Post Operative Day 1

Postoperative Distant Vision testime

Postoperative Near Vision testime



ETDRS contrast sensitivity chart

ANNEXURE

DV-	Distant Visual Acuity
IV-	Intermediate Visual Acuity
NV-	Near Visual Acuity
KH-	Keratometry reading in horizontal meridian
KV-	Keratometry reading in Vertical Meridian
PCIOL-	Posterior chamber Intraocular lens
CSH-	High Contrast Sensitivity
CSL-	Low Contrast Sensitivity
G & H-	Glare and Haloes
DND-	Difficulty in Night Driving
CF-	Counting fingers
HMCF-	Hand movement Close to Face
M-	Male
F-	Female
NR-	Not Recordable
Y-	Yes
N-	No

'[																			
					PREOPERATIVE														
											1ST DAY			1st week/7 DAY					
S.NO.	OP NUMBER	Age	Gender	Eye	DV	Int V	Nv	KH	KV	PCIOL	DV	Int V	NV	DV	Int V	NV	CSH	CSL	DV
1	5946432	67	F	LEFT	PL+PR ACC	<6[60	<N36	44.75	45.25	20	6[36	6[15	N10	6[24	6[19	N8	0.3	0.6	6[9
2	5946408	75	M	LEFT	CF2.5MT	<6[60	<N36	44.5	45.5	20	6[24	6[24	N12	6[24	6[30	N12	0.5	0.7	6[18
3	5946672	64	F	LEFT	6[60	<6[60	<N36	44.75	45.25	21	6[36	6[24	N18	6[24	6[24	N12	0.3	0.7	6[24
4	1034551	75	F	LEFT	CF3MT	6[38	N18	43.75	45.25	20	6[24	6[24	N12	6[12	6[30	N10	0.5	0.7	6[9
5	5128256	65	F	LEFT	6[60	6[48	N36	44	45	22	6[12	6[24	N12	6[12	6[30	N10	0.3	0.4	6[6
6	6009518	50	F	LEFT	6[60	6[48	N18	42.75	43.75	23	6[60	<6[60	N18	6[60	6[60	N18	0.4	0.7	6[9
7	5946432	67	F	RIGHT	CF3MT	<6[60	<N36	44.5	44.5	20.5	6[18	6[19	N10	6[18	6[15	N8	0.6	0.5	6[9
8	1049596	65	F	RIGHT	6[60	6[38	N36	44.75	46.5	20	6[12	6[9.5	N8	6[9	6[6	N8	0.2	0.4	6[6
9	6067003	50	F	RIGHT	CF2MT	<6[60	<n36	41.75	42.75	20.5	6[24	6[15	N10	6[12	6[15	N10	0.4	0.6	6[9
10	6067834	42	F	LEFT	HMCFPLPR	<6[60	<N36	43	43.75	23	6[24	6[15	N10	6[9	6[24	N10	0.3	0.5	6[6
11	5224115	65	M	RIGHT	HMCFPLPR	<6[60	<N36	44.5	45.75	22	6[24	6[30	N10	6[12	6[24	N10	0.5	0.6	6[9
12	6069955	42	F	RIGHT	CF2.5MT	<6[60	<N36	44	44.25	20.5	6[18	6[15	N8	6[12	6[15	N8	0.4	0.6	6[9
13	6083965	65	F	LEFT	6[60	6[24	N36	44.75	46.5	20.5	6[24	6[15	N1O	6[12	6[12	N8	0.4	0.4	6]6
14	6079384	50	F	LEFT	6[60	<6[60	<N36	45.5	46.5	23.5	6[36	6[15	N12	6[18	6[19	N10	0.5	0.7	6[12
15	5350116	61	F	LEFT	CF3MT	<6[60	<N36	42.75	43	20	6[24	6[19	N12	6[18	6[19	N10	0.4	0.5	6[6
16	1057346	58	M	RIGHT	CF1MT	<6[60	<N36	42.75	43	22	6[36	6[30	N12	6[36	6[30	N12	0.3	0.6	6[9
17	6069955	65	F	LEFT	6[60	<6[60	<N36	43	43.75	22	6[12	6[12	N10	6[12	6[12	N8	0.4	0.5	6[6
18	6152083	67	M	RIGHT	CF3MT	<6[60	<N36	41.25	41.75	20.5	6[24	6[19	N12	6[12	6[15	N10	0.3	0.5	6[6
19	6151685	60	F	RIGHT	CF1MT	<6[60	<N36	44.25	44.75	17	6[12	6[7.5	N8	6[9	6[7.5	N8	0.2	0.4	6[6
20	6152083	67	M	LEFT	6[60	6[48	N36	41	41.5	20	6[24	6[19	N12	6[12	6[24	N10	0.4	0.5	6[9
21	3642424	72	M	LEFT	6[36	6[48	N18	43	43.5	20.5	6[18	6[15	N10	6[12	6[24	N8	0.4	0.6	6[6
22	6190553	62	M	LEFT	HMCFPLPR	<6[60	<N36	43.5	44	20	6[24	6[15	N10	6[12	6[24	N10	0.3	0.6	6[6
23	3642424	72	M	RIGHT	6[60	6[38	<N36	42.5	43.5	20	6[12	6[15	N10	6[12	6[24	N8	0.5	0.7	6[9
24	1079310	85	M	LEFT	CFCF	<6{60	<N36	45.75	47.5	17	6[24	6[24	N12	6[12	6[24	N10	0.3	0.5	6[6
25	6278787	49	M	LEFT	6[60	<6[60	<N36	40.75	41	21	6[36	6[24	N18	6[24	6[24	N10	0.5	0.7	6[9
26	6264015	60	F	RIGHT	6[60	<6[60	<N36	42	42	21	6[12	6[12	N10	6[9	6[15	N8	0.2	0.4	6[6
27	6290121	53	M	RIGHT	6[36	6[24	N18	43.5	44.25	21.5	6[12	6[12	N10	6[12	6[9.5	N8	0.4	0.4	6[6
28	6264015	60	F	LEFT	6[60	<6[60	<N36	42	42.25	21	6[12	6[12	N10	6[9	6[12	N8	0.3	0.6	6[6
29	4954014	59	M	RIGHT	PL+PR ACC	<6[60	<N36	43.5	44	17	6[18	6[12	N8	6[18	6[12	N8	0.4	0.5	6[6
30	6305111	63	F	RIGHT	6[60	6[30	<N36	42.25	42.5	22	6[12	6[12	N8	6[12	6[9.5	N10	0.2	0.4	6[6

POST-OPERATIVE

4th week

Int V	NV	CSH	CSL	DND	day-glare	night-glare	halo	tearing	Spect-Indepndence	Satisfaction			OVERALL		
										Distance	Intermediate	Near	VERY SATISFIED	SATISFIED	NOT SATISFIED
6[6	N8	0.1	0.4	N	N	N	N	N	Y	Y	Y	Y	YES		
6[9.5	N10	0.2	0.5	N	Y	Y	Y	N	N	N	N	N			YES
6[19	N12	0.2	0.4	Y	N	Y	Y	N	N	N	N	N			YES
6[9.5	N8	0.4	0.4	N	N	N	N	N	N	Y	Y	N		YES	
6[6	N8	0.1	0.2	N	N	N	N	N	Y	Y	Y	Y	YES		
6[9.5	N8	0.3	0.7	N	N	Y	Y	N	N	N	Y	Y		YES	
6[7.5	N6	0.1	0.3	N	N	N	N	N	Y	Y	Y	Y	YES		
6[7.5	N6	0.2	0.2	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N8	0.3	0.5	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N6	0.3	0.4	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N8	0.3	0.6	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N8	0.2	0.5	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N6	0.2	0.3	N	N	N	N	N	Y	Y	Y	Y	YES		
6[19	N10	0.4	0.7	Y	N	Y	Y	N	N	Y	Y	N	YES		
6[7.5	N8	0.3	0.3	N	N	Y	Y	Y	Y	Y	Y	Y	YES		
6[6	N8	0.2	0.4	N	Y	Y	Y	N	Y	Y	Y	Y		YES	
6[7.5	N8	0.1	0.3	N	N	N	N	N	Y	Y	Y	Y		YES	
6[6	N8	0.3	0.4	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N8	0.2	0.4	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N8	0.3	0.4	N	Y	Y	Y	N	Y	Y	Y	Y	YES		
6[6	N8	0.3	0.5	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N8	0.2	0.5	N	N	N	N	N	Y	Y	Y	Y	YES		
6[7.5	N6	0.4	0.7	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N8	0.2	0.4	N	N	N	N	N	Y	Y	Y	Y	YES		
6[19	N10	0.4	0.7	Y	Y	Y	Y	N	N	Y	Y	N		YES	
6[6	N6	0.1	0.3	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N6	0.1	0.2	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N8	0.2	0.4	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N8	0.3	0.4	N	N	N	N	N	Y	Y	Y	Y	YES		
6[6	N6	0.1	0.3	N	N	N	Y	N	Y	Y	Y	Y	YES		