"EFFICACY OF PUPIL EXPANSION DEVICE IN SMALL PUPIL CATARACT SURGERY: A ONE YEAR PROSPECTIVE INTERVENTIONAL STUDY IN A TERTIARY CARE CENTRE"

By

REG NO: BK0121005

Dissertation

Submitted to the KLE Academy of Higher Education and Research, Belagavi, Karnataka

In Partial Fulfilment

of the Requirements for the Degree of

MASTER OF SURGERY IN

OPHTHALMOLOGY

DEPARTMENT OF OPHTHALMOLOGY,

JAWAHARLAL NEHRU MEDICAL COLLEGE,

BELAGAVI, KARNATAKA.

DECEMBER-2024 / JANUARY -2025

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ABBREVIATIONS

Continuous Curvilinear Capsulorhexis	=	CCC
Diabetes Mellitus	=	DM
Pseudoexfoliation	=	PXF
Intraoperative Floppy Iris Syndrome	=	IFIS
Pupil Expansion Devices	=	PEDs
Bhattacharjee Pupil Expansion Ring	=	B-HEX
Acetylcholine	=	ACh
Pupillary Light Reflex	=	PLR
Midbrain	=	MB
Edinger Westphal	=	EW
Total afferent pathway defect	=	TAPD
Relative afferent pathway defect	=	RAPD
Marcus Gunn Pupil	=	MGP
Argyll Robertson pupil	=	ARP
Peripheral Anterior Synechiae	=	PAS
Anterior Chamber	=	AC
Nonsteroidal Anti-Inflammatory Drugs	=	NSAIDS
Ophthalmic Viscosurgical Device	=	OVD
Graether 2000 Pupil Expander	=	GPE
Assia pupil expander	=	APX

ABSTRACT

Introduction:

Cataract is identified as the leading cause of moderate or severe vision impairment globally. The small, poorly dilated pupil is one of the most common difficulties faced by cataract surgeons. Literature states that small pupil cataracts accounted for about 11 percent of all cataract operations. Small pupil makes the surgery more difficult to perform and causes more postoperative damage response. The incidence of complications such as capsular rupture and vitreous loss increases remarkably. Numerous pharmacologic and mechanical strategies have been developed to increase pupil size and optimize surgical visualization. Newer Pupil expansion device provide increased points of pupillary margin fixation to provide uniform pupil dilation, resulting in a better intraoperative visualization as well as less postoperative pupil distortion

Objective Of the Study:

To determine the efficacy and safety of Pupil expansion device in small pupil cataract surgery undergoing phacoemulsification.

Methodology:

The present study was conducted at the Department of Ophthalmology, KLE'S Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi during the period of August 2023 to July 2024.

Pupil diameter at baseline was 3.1 ± 1.1mm and post-operative 1 month was 3.6 ± 0.8mm. Considering similar result in our study, at 5% level of significance and

85 % power, minimum sample size required is 44 subjects. Considering 10% follow-up loss, the minimum sample size required is 48 subjects.

All patients, attending the Ophthalmology OPD, meeting the inclusion and exclusion criteria were enrolled in the study after taking informed and written consent. All the demographic data was noted in a predesigned proforma. Intraoperatively, the eyes were enrolled into the study after failure to achieve pupil dilation of 5 mm or more with pharmacologic and mechanical maneuvers such as administration of topical and intracameral mydriatic agents and subsequently pupil expansion device was inserted. Pupil Diameter in the various stages of the surgery and at the 1-month follow-up visit, and the postoperative pupil shape and irregularity were evaluated. Pupil Diameter will be measured using Castroviejo calipers at 7 pre-defined time- points: (1) preoperative baseline, (2) after maximal preoperative dilation with topical mydriatics, (3) after intracameral dilation with epinephrine and Ophthalmic viscoelastic devices, (4) following application of the pupil expansion ring (5) at the end of the surgery, following withdrawal of the ring, (6) post of day 1 and (7) at 1month postoperative visit (4 weeks).

Results:

The mean patient age was 66.54 ± 9.22 years. The B HEX PED was successfully applied in all eyes . In our study, we found that 47.67% had diabetes while pseudo exfoliation was seen in 29.17 % concluding diabetes as major cause of small pupil. With the use of intracameral epinephrine the mean pupil diameter was
5.42 ± 0.3 while with the use of PEDs the mean was 6.52 ± 0.25 mm after insertion. On Post operative day 1 the mean pupil diameter was 4.78 ± 0.44 mm and postoperative day 28 it was 3.55 ± 0.43. 62.5% of cases had round pupil

postoperatively on day 28. Major complication noted with PEDs was corneal edema in 35.42 % followed by iris bleeding and floppy iris while 52.08% had no complications. There was no significant difference in IOP on POD 1 and POD 28 compared to pre operative IOP.

Conclusion:

Small pupil is of the most important causes of intraoperative complications during cataract surgery. The PEDs safely and effectively provided and maintained adequate pupil expansion and surgical visualization in eyes with significant reduction in the chance of complications and increase in the success rate of small pupil cataract surgery.

Key words: small pupil , pupil expansion device, cataract surgery, B hex ring

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INTRODUCTION

Cataract is the primary factor responsible for significant visual impairment worldwide.[1] One of the most frequent challenges encountered by cataract surgeons is the presence of a small, inadequately dilated pupil. According to literature, cataracts with small pupils constituted approximately 11 percent of all cataract surgeries.[1] Typically, a pupil diameter smaller than 5 mm is considered small, according to scientific standards. Nevertheless, a study has established that a smaller pupil characterized by a diameter of 4 mm or less. A study has indicated that cataracts with such pupils were responsible for approximately 11 percent of all cataract surgeries.[2] In order to utilize modern procedures effectively, it is necessary to have a clear and direct view of the lens capsule, covering a region that is as large as the size of continuous curvilinear capsulorhexis (CCC), along with the nucleus.[3]

There are multiple factors that can lead to the occurrence of a less pupil diameter during cataract surgery. Common and significant factors leading to small pupil size include pseudoexfoliation syndrome (PXF), diabetes mellitus (DM), intraoperative floppy iris syndrome (IFIS), and iridoschisis. Pseudo exfoliative material present in the iris stroma in PXF leads to mechanical blockage, resulting in restricted dilation of the pupil, in addition to hypoxia caused by vascular anomalies.[4] Diabetic individuals frequently exhibit unusually constricted pupils that are unresponsive to mydriatics. The reason for such pupils in individuals with diabetes mellitus are neuropathy of the dilator muscle, which leads to resistance to mydriatics, as well as anomalies in the iris muscles and blood vessels.[5] IFIS, or Intraoperative Floppy Iris Syndrome, is a condition characterized by three main factors: the iris

stroma swelling in response to normal irrigation currents, the floppy iris having a tendency to protrude through the incisions, and the gradual narrowing of the pupil.

Most occurrences are linked to alpha-1 antagonists, specifically tamsulosin.[6] Additional factors contributing to the condition include previous injuries or surgical procedures, uveitis (inflammation of the uvea), and long-term use of mitotic treatment for treating glaucoma.

A diminutive pupil complicates the surgical procedure and elicits a heightened postoperative damage reaction. Small pupil can lead to severe consequences that pose a risk to vision, including tears in the anterior and posterior capsules, iris damage, displacement of the nucleus or intraocular lens, cystoid macular oedema, and retinal detachment.[6] Performing phacoemulsification through a small pupil is a difficult task for surgeons and is known to be linked with additional difficulties. Small pupils may hinder the visibility of loose zonules and hard nuclei. Additionally, the risk of problems is increased when the surgeon has to navigate in the capsular bag beneath the iris, where visibility is limited.

A multitude of pharmacologic and mechanical approaches have been devised to enhance the size of the pupil and maximize surgical visibility. Introduction of iris hooks was a significant advancement in the development of mechanical pupil enlargement.[7] Sleeve of the hook is modified to enlarge the pupil to the preferred size. Some disadvantages of using an iris hook are the potential for tears in the iris sphincter and the danger of hemorrhage. It has the potential to cause a pupil dilation of 5.0 mm in order to reduce the likelihood of postoperative irregular and atonic pupils caused by excessive stretching of the iris tissue.

Pupil expansion devices (PEDs) are composed of several materials, each offering distinct flexibilities. These devices can be placed through the primary incision. They offer uninterrupted expansion and also safeguard the edge of the iris sphincter, preventing any ripping or harm to the iris. Three The Malyugin ring is the most widely used pupil expansion ring. The new ring is thinner than the previous one, which facilitates safer and more convenient manipulation within the eye.[7] Subsequently, the Visitec i-Ring Pupil Expander was developed. This innovative gadget, constructed from pliable polyurethane, is designed for one-time usage and facilitates the formation of a circular aperture measuring 6.3 mm in diameter. The I- Ring device keeps the pupil's round shape during the treatment and might be able to protect it from any mechanical damage.[8] A pupil expander made of 5-0 black monofilament nylon (Nylon) is called the Bhattacharjee Pupil Expansion Ring (B- HEX).

It comes in both square and hexagonal shapes, with notches on the sides that face inward. The purpose of these cuts is to make the pupillary margin wider. The XpandNT iris speculum is constructed from a titanium alloy known as memory metal. This material is round in shape and consists of an even number of alternate side elements that are joined by arches. Both single-use and multiuse versions are available.

A small, inadequately dilated pupil is a frequently encountered issue for cataract surgeons, which is linked to several issues both before and after cataract surgery. The incidence of tiny pupil in cataract cases is rising with time.

Lack of proper usage of equipment required for small pupil surgery as well as insufficient guidelines on how to utilize them signifies the need to undertake this study. Studies are also lacking on cataract in small pupil and the pupil expansion devices. This study emphasizes on the efficacy of pupil expanders on small pupil in a phacoemulsification cataract surgery.

OBJECTIVE OF THE STUDY

- To determine the efficacy and safety of Pupil expansion device in small pupil cataract surgery undergoing phacoemulsification.

REVIEW OF LITERATURE

The pupil is a circular opening that is located in the iris's centre. Gerard of Cremona is credited with coining the term "pupil".[9] The primary purpose of the structure is to regulate the quantity of light that enters the retina, as well as manage the levels of chromatic and spherical aberration in the retinal image. Each eye normally has one pupil, but if there are several pupils, it is a congenital condition known as polycoria. The pupil is typically positioned in the centre of the iris. However, if it is naturally off-center, this condition is referred to as correctopia. The average diameter of the pupil ranges from 3 to 4 mm, which is influenced by the level of illumination. Pupil diameter is determined by a complicated interplay of hormonal, circulatory, and neurological variables that affect the muscles of the iris. They exhibit a tiny size after birth, reach their maximum size during adolescence, and subsequently display a diminishing trend as they age. Isocoria refers to the normal condition when both pupils are of equal size, while anisocoria is the term used to describe a disparity in size between the two pupils.[10] The colour of pupils is typically a shade of greyish black, however in cases with aphakia, they develop a deep black colour. Leucokoria, also known as a white-colored pupil, is the reflection of white light that is observed when the fundus is directly illuminated through the pupil. This is different from the normal red glow and is commonly seen in retinoblastoma, congenital cataract, Coats disease, and various other eye diseases.[11]

The size of the pupil is determined by the smooth muscles in the iris: the Sphincter pupillae muscle and the Dilator pupillae muscle. The sphincter pupillae muscle consists of a flat strip of smooth muscle fibers that originate from the ectoderm and receive innervation from parasympathetic fibers via the third cranial

nerve. Contraction of the sphincter pupillae causes the iris to constrict, resulting in a decrease in the size of the pupil. The dilator pupillae, located in the posterior region of the stroma of the ciliary zone of the iris, is responsible for pupil dilation when it contracts. This contraction is initiated by the cervical sympathetic. The muscles in question are commonly known as the intrinsic muscles of the eye.

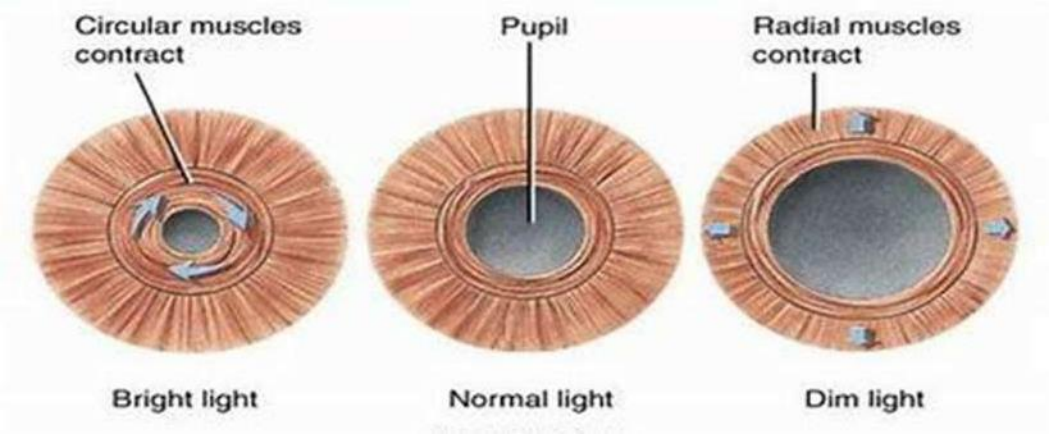


Figure 1 : Intrinsic muscles of the eye

Drugs can either cause the pupil to dilate or constrict. Miotics are drugs that cause pupil constriction. Miotics can be categorized into two groups: Parasympathomimetic medicines, which stimulate the sphincter, and Sympatholytic, which prevent dilation.

Parasympathomimetic medications mimic or enhance the effects of acetylcholine (ACh) by causing the sphincter pupillae and ciliary muscles to contract.[12] These are classed based on their manner of actions –

- Cholinergic medicines, such as pilocarpine, have a similar structure to acetylcholine (ACh) and directly affect the muscarinic receptors on the muscular membrane.

- Anticholinesterases are substances that hinder or eliminate the activity of cholinesterase, resulting in an extended buildup of naturally occurring ACh. These medications are categorized into two subcategories:

  - ❖ Physostigmine is an example of a reversible cholinesterase inhibitor.

  - ❖ Irreversible cholinesterase inhibitors, such as echothiopate iodide, demecarium, and diisoprophyl fluorophosphate, are substances that permanently suppress the activity of the enzyme cholinesterase.

- This substance is a parasympathomimetic with dual activity, meaning it affects both.

Sympatholytic drugs exert their effects on the dilator pupillae muscle. The inhibition of Dilator Pupillae can be achieved by either blocking the release of neurotransmitters at the neuromuscular junction or by preventing the neurotransmitter from affecting the dilator fibers. Alpha-adrenergic blocker medications such as thymoxamine, phenoxybenzamine, and dibenamine bind to alpha receptors on the iris dilator muscle and cause constriction of the pupil by inhibiting its contraction. Guanethidine is a frequently employed sympatholytic medication that inhibits the release of norepinephrine from nerve endings. Prolonged use of this medicine can lead to the development of Horner's syndrome, which is defined by drooping of the upper eyelid (ptosis), constriction of the pupil (miosis), and heightened sensitivity to adrenergic medications. Mydriatics are drugs that cause pupil dilation. There are two main types of medicines that are often utilized as mydriatics.

1. Pharmaceuticals that mimic or enhance adrenaline's effects, causing pupils to enlarge but without cycloplegia, are known as sympathomimetic mydriatics. There are three ways in which these medications enhance dilator activity:

    - ❖ Raising the secretion of norepinephrine
    - ❖ Keeping it from being taken up by the presynaptic vescia
    - ❖ By acting directly on the dilator fibers

The commonly available sympathomimetic mydriatics include:

- One of the most popular sympathomimetic mydriatics is adrenaline (epinephrine), which is a weak mydriatic when injected into a healthy eye but can dilate the pupil after four drops of a 1 in 1000 solution. Simple glaucoma is one of its indications. Solutions containing 1% to 2% reduce water output and enhance effluent discharge. Other indications include clearing the
- conjunctiva, helping patients who are on long-acting anticholinesterases (1- 2%) avoid developing iris cysts, in case of Horner's Syndrome and local anesthetic absorption is reduced (1:50,000 or 1:100,000).[13]
- An analogue of epinephrine, phenylephrine (Neo-synephrine) stimulates the typical dilator at concentrations of 5 to 10%. One of its uses is in ophthalmoscopy. (a) Dissolving synovial bridges in the back (b) Using long- acting anticholinesterases to prevent iris cysts in patients in the time leading up to a cataract extraction procedure.[13]

- Norepinephrine is quickly released from peripheral terminals when hydroxy amphetamine is administered. Within 40 minutes, it causes mydriasis and is usually used for ophthalmoscopy.[10]

- Norepinephrine is released from the nerve and activates the dilator fibres because cocaine, when taken at a concentration of 2-4 percent, acts as a local anesthetic and blocks its absorption at the presynaptic terminal. Mydriasis and partial cycloplegia set in approximately 20 minutes and last for two hours. Ophthalmoscopy is one of the indications. (b) Time before surgery to remove a cataract. (c) Anesthesia locally.[13]

2. Parasympatholytic mydriatics result in the dilation of the pupils by interfering with acetylcholine at the myoneural junction, effectively inhibiting sphincter activity.

Some of the drugs used in this context are:

- Atropine is a potent mydriatic and cycloplegic that has the ability to fully paralyses the sphincter pupillae and ciliary muscle. It is available in the form of 1% drops or ointment, which leads to dilation within 30-40 minutes and cycloplegia within 2 hours. Temporary reversal can be achieved through the use of 1:100 intracameral acetylcholine. One of its uses is for the treatment of anterior uveitis. Examining children under 5 years of age**.** Using a dosage of 0.01% atropine has been found to be effective in slowing the progression of myopia in children. Common side-effects include difficulties with accommodation, as well as issues with papillae and follicles.

- Homatropine (2% drops) has a faster onset of action compared to atropine. It induces cycloplegia and mydriasis within approximately 45 minutes to 1 hour, and the effects last for around 48 hours. It does not induce full paralysis of the eye muscles in children, and therefore it is enhanced by cocaine and can be reversed by eserine. It is frequently used in ophthalmoscopy and before cataract extraction surgery.

- This medication, known as cyclopentolate, is a mydriatic and cycloplegic that has a short duration of action. It begins to take effect within one hour and its impact can last for a duration of 6 to 12 hours.[13] It is evident in the phenomenon of refraction. The maximum level of cycloplegia is achieved after 45 minutes and lasts for a duration of 30 minutes. Full recovery typically takes place within 24 hours, although it can be shortened to 6 hours with a 2 percent reduction. Maximize pupil dilation within 30 minutes. Especially beneficial for individuals with heavily pigmented irises. Before undergoing cataract extraction surgery, it is important to be aware of the side effects. These can include sensitivity to light, blurry vision, irritation, conjunctivitis, and in certain instances, an increase in intraocular pressure.

- Tropicamide (1%) is a fast-acting mydriatic and cycloplegic that reaches its peak activity in just 20 minutes and remains effective for 6 hours. Uses include assessing vision in adults. The duration of maximal cycloplegia is limited to 20 minutes. Before undergoing cataract extraction surgery. Most patients experience a brief stinging sensation and a temporary increase in intraocular pressure when using tropicamide. Additional side effects may include temporary redness and blurring of near vision following application. In

extremely rare instances, the use of Tropicamide can potentially lead to an episode of acute angle-closure glaucoma.[15]

- Ox phenonium is a highly potent mydriatic agent with a long-lasting effect of up to 4 days. It also exhibits cycloplegic action that can last for up to 12 days. It serves as a valuable alternative to atropine for patients with sensitivity.

- Hyoscine (Scopolamine) (0.25 and 0.5 per cent.) is known for its ability to cause significant dilation of the pupil and paralysis of the ciliary muscle, which can last for up to 5 days. It is often prescribed for the treatment of anterior uveitis in individuals who are sensitive to atropine.

- This medication, known as Eucatropine (Euphthalmine), is a mydriatic that has a relatively short duration of action, lasting only 4 hours. It has the advantage of causing minimal cycloplegia. Uses: (a) Ophthalmoscopy. (b) examination for individuals with suspected closed-angle glaucoma**.**

Understanding the pupillary light reflex (PLR) is crucial for comprehending how the pupil size is regulated in response to different levels of light. This reflex plays a vital role in helping our vision adjust to varying degrees of brightness and darkness by affecting the retinal ganglion cells in the retina. When light is directed into one eye, the pupils of both eyes will constrict simultaneously. When light is shone on the pupil, it constricts in what is known as the direct light reflex. Conversely, the other pupil constricts as well, which is referred to as the consensual (indirect) light reflex. Typically, the light reflexes exhibit identical characteristics in terms of timing, progression, and intensity. The initiation of the light reflex is attributed to the activity of rods and cones. The pupillary response during dark

adaptation is influenced by the level of light intensity. When the intensity of light exceeds 9 log units, the pupillary response reaches a plateau and the latency period is between 0.2 and 0.5 seconds.[15]

The pupillary light reflex involves a neural pathway that includes an afferent limb and two efferent limbs on each side. The afferent limb consists of nerve fibres that pass through the optic nerve (CN II). The oculomotor nerve (CN III) consists of nerve fibers that extend along each efferent limb, just like a neuroscientist would observe.

- Fibers that carry information from the retina to the midbrain's pretectal nucleus are called afferent fibers (MB).Bipolar cells get information from rods and cones, which convert light stimuli into neural impulses. This information then travels centrally along the optic nerve to the chiasma via interactions with ganglion cells. After passing through the optic chiasma, the retinal fibers from the nose will continue on the other side of the optic tract, while the fibers from the temporal region will continue on the same side. Thus, the right optic tract will house the right eye's temporal retinal fibers in addition to the left eye's nasal retinal fibers. After passing via the superior colliculus's brachium, impulses reach the MB's pretectal area via the optic tracts.[16]

- Each pretectal nucleus is linked to the Edinger-Westphal (EW) nucleus on either side by internuncial fibers. Every pretectal area communicates with the preganglionic parasympathetic nuclei in the medial border to the extra ventricular nuclei in a bilateral fashion.[16]

- The parasympathetic fibers that make up the effective pathway originate in the MB's EW Nucleus and extend down the oculomotor nerve. Through the inferior oblique nerve, the preganglionic fibers join the ciliary ganglion and the third nerve's inferior division. The sphincter pupillae is innervated by postganglionic fibers that go down the short ciliary nerves. Pupil constriction is caused by the iris sphincter muscles contracting.[17]

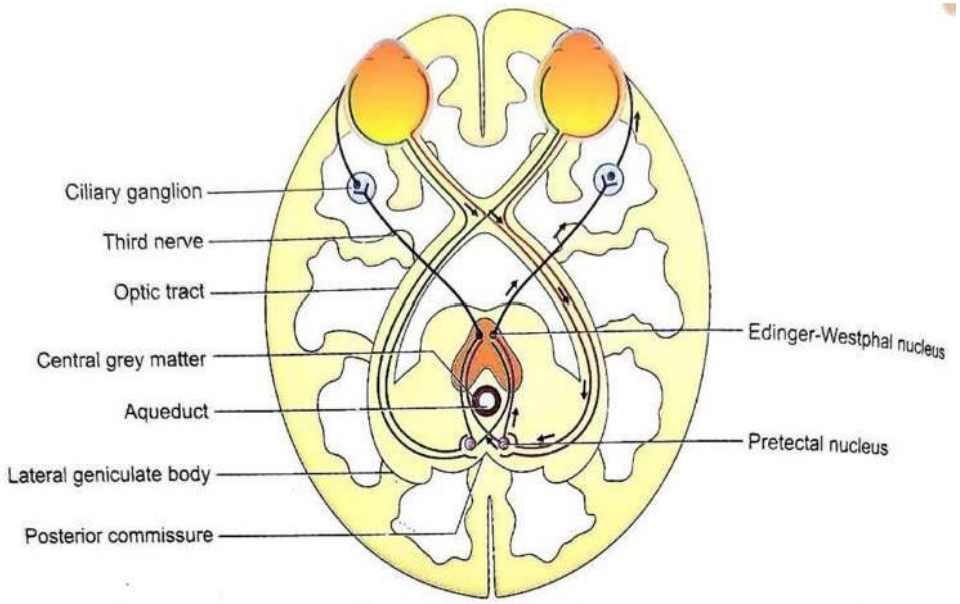


Figure 2: Pathway of light reflex

Psychosensory stimuli, like a loud noise, a pinch on the back of the neck, or even just letting the pupil relax can heighten the pupillary dark reflex, which causes the pupil to dilate in reaction to dark, as part of a generalized sympathetic response to physical stimuli. Upon detection of darkness, messages are transmitted from the optic tract and retina to neurons in the hypothalamus. These signals then reach the lateral horn segments T1–T3 of the spinal cord. The iris dilator muscle receives its impulses from sympathetic postganglionic axons transmitted via the long ciliary nerve from

sympathetic preganglionic neurons in the lateral horn segments, which in turn send their fibers to the superior cervical ganglion.

Focusing on nearby things triggers a visual reaction known as the accommodation reflex, accommodation-convergence reflex, or close reflex. The regions of the brain that surround the visual cortex and the frontal eye fields are part of the supranuclear regulatory system for the near reflex. The following is the pathway of the accommodation reflex:

- Impulses originating from the retina travel to the prestriate cortex via the optic nerve, chiasma, optic tract, lateral geniculate body, optic radiations, and striate cortex.

- The internuncial fibers transmit signals from the parastriate cortex to the EW nucleus on both sides through the occiput mesencephalic tract and the pontine centre.

- Efferent fibers transmit signals from the Edinger-Westphal nucleus through the third cranial nerve to the sphincter pupillae and ciliary muscle.[10]

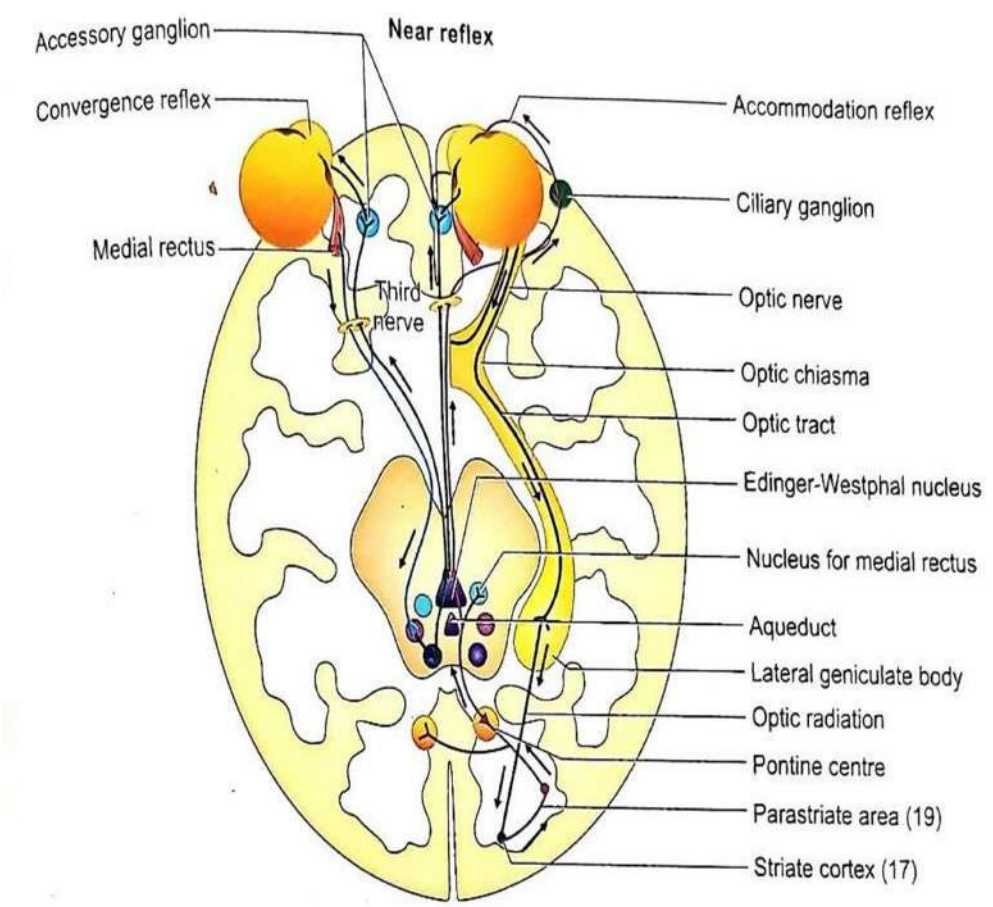


Figure 3: Pathway of near reflex

The accommodation reflex involves three responses:

1. **The convergence**: The near object is brought into focus as a result of the two eyes converging, which helps project the image onto the fovea. To accomplish this, one must abduct both eyes by contracting their medial rectus muscles and relaxing their lateral recti.

2. **Constriction**: The sphincter pupillae muscles constrict, causing the pupils to constrict and increasing the depth of focus. Distant objects' rays don't reach the fovea because they diverge and bounce off the cornea's periphery.

3. **Contraction**: The contraction of both ciliary muscles causes the lens to become thicker, resulting in a shorter focal length and an increase in its refractive power.

4. When these three processes are in sync, the eye's power is transformed, enabling the shift of focus from faraway objects to those closer by, or vice versa.[18]

The abnormalities of pupillary reflexes are following:

- Malfunctions in the pathway that carries sensory information towards the central nervous system.
- Efferent pupillary deficiencies
- Pupillary light-near dissociation refers to a condition where the pupils of the eyes do not respond appropriately to light but do respond appropriately to close vision.
- Anisocoria
- Sympathetic pupillary defect

1) <u>AFFERENT PATHWAY DEFECTS</u>

a) Total afferent pathway defect (TAPD) or Amaurotic pupil:

The occurrence of full blindness in the affected eye is attributed to a lesion in either the optic nerve or the retina. The damaged side will lack a direct light reflex, while the normal side will lack a consensual light reflex. The normal eye will exhibit the presence of both the light reflex and the near reflex.

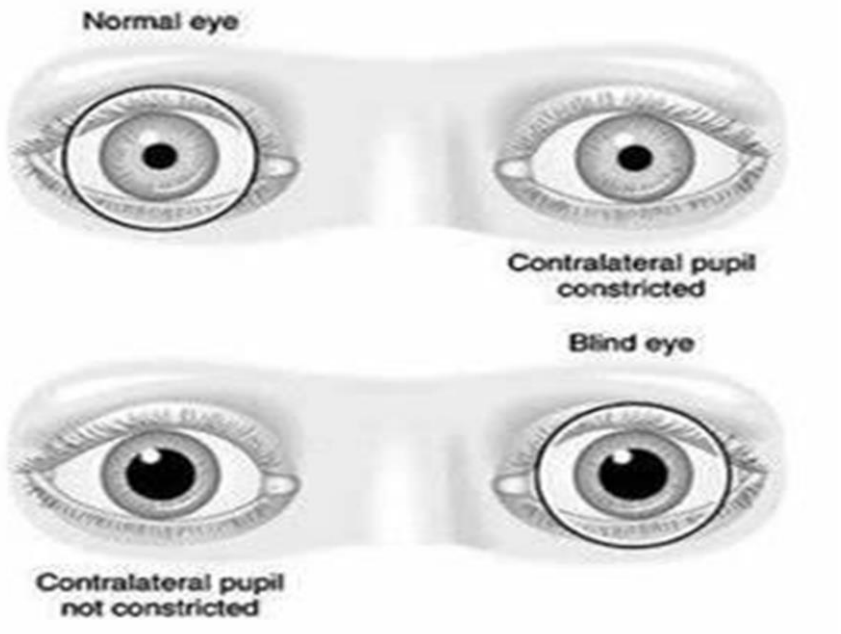


Figure 4: TAPD or Amaurotic Pupil

b) Relative afferent pathway defect (RAPD) or Marcus Gunn Pupil (MGP):

Anomalous pupil behavior can be observed in some eye conditions, resulting in an atypical pupillary response. Following exposure to intense light, a typical pupil contracts. However, in the case of MGP, there is a reduced responsiveness of the sensory pathway of the pupillary light reflex in comparison to the other eye. Consequently, when light is quickly shifted from the normal eye to the eye with MGP, the pupil of the MGP eye expands instead of contracting.[19] The Swinging torch test is the most effective way to evoke it. A unilateral afferent sensory abnormality or bilateral asymmetric vision loss is characterized by the presence of a RAPD (Relative Afferent Pupillary Defect).

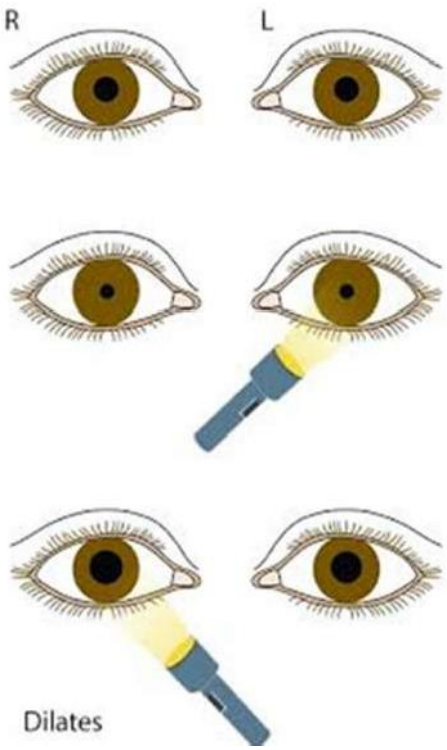


Figure 5: RAPD or MGP

c) Wernicke's hemianopic pupil:

The contralateral homonymous hemianopia is caused by the division of the optic tract. In this condition, the absence of the light response occurs When light is directed towards the temporal half of the retina on the affected side and the nasal half of the retina on the contralateral side. Conversely, when light is focused on the affected side's nasal half and the opposite side's temporal half, the light reflex is observed. Another telltale sign is a lowering of the eyelid on the same side as the hemianopia. Pupils are also noticeably larger in one eye than the other. likewise on the same side as the hemianopia. Wernicke's hemianopic pupil occurs as a result of a lesion in the optic tract in an area that precedes the splitting of the two types of fibers.

2) EFFERENT PUPILLARY DEFECTS:

a) Adie’s tonic pupil:

It's not known what causes Adie's pupil, which is also known as steady pupil. It happens when the postganglionic supply of the sphincter pupillae and ciliary muscle is cut off. Some of its defining traits are:

- Unilaterality
- affects healthy women more than men
- Impacts women who are in good health more significantly than males. Linked to the absence of the knee jerk reaction.
- The affected pupil is enlarged and has an uneven shape. The response to light is either absent or delayed.
- The near reflex is sluggish and sustained. This condition is known as accommodative paresis.
- associated mild regional impairment of corneal sensations

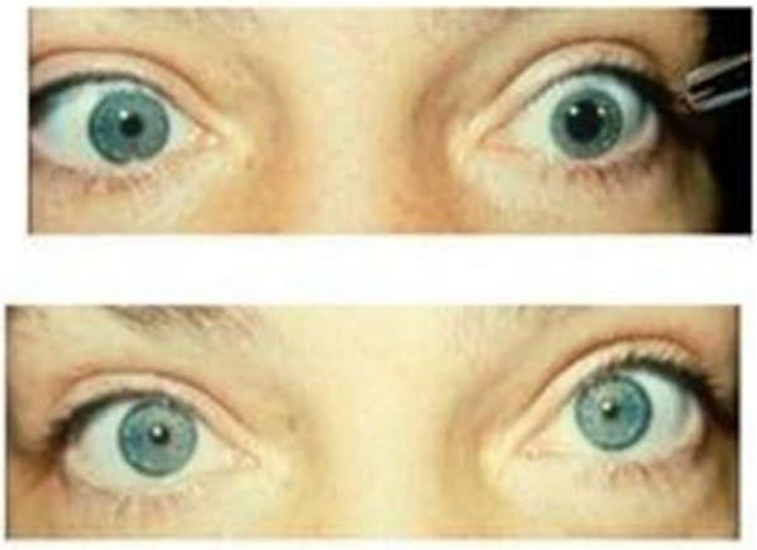


Figure 6: Adie’s tonic pupil in left eye

b) Oculomotor nerve palsy:

It manifests as either complete or partial paralysis, with or without involvement of the pupil, or entire or partial drooping of the eyelid, which may hide the double vision. Compressive third nerve lesions usually have pupillary involvement. Pupil is mid dilated, light, consensual and near reflexes are affected. On pilocarpine test -there will be constriction with 1% pilocarpine while no constriction with 0.25% pilocarpine.

c) Iris Trauma:

Iris damage secondary to previous surgery or grossly elevated intraocular pressure. A patient who has suffered from traumatic iris sphincter damage will exhibit ripped pupillary margin or iris illumination deficiencies that can be observed during biomicroscopic inspection.

d) Drugs:

A fixed dilated pupil is caused by exposure to a mydriatic substance, like atropine. For dilated pupils produced by neurological lesions, pilocarpine 1% will constrict them; however, for dilated pupils caused by mydriatic agents, it will have no effect.

3. PUPILLARY LIGHT -NEAR DISSOCIATION

a) Argyll Robertson pupil (ARP):

ARP Anisocoria with light-near dissociation is characterized by the presence of unequal pupil sizes that constrict when focusing on a nearby object, but do not respond to bright light by constricting. These symptoms are indicative of neurosyphilis, although they might also be indicative of diabetic neuropathy. Typically, when students are able to adjust but do not respond, it is referred to as light-near dissociation.[21]Characteristic features include:

- Typically, involvement is characterized by bilateral yet asymmetrical participation.
- The retinae have light sensitivity, yet the pupils are both tiny and irregularly shaped.
- The pupillary light reflex is not present, but the near reflex is present. The dilation of the pupil is not effective when using mydriatics such as Atropine. The use of Physostigmine may lead to additional constriction of the pupil.

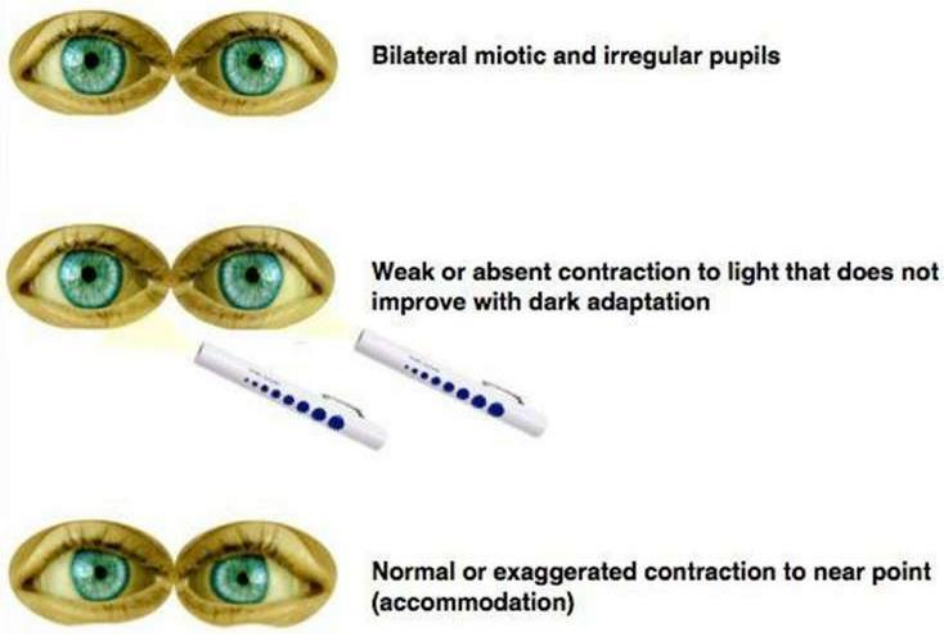


Figure 7: Argyll Robertson Pupil

4. SYMPATHETIC PUPILLARY DEFECT

Horner's Syndrome

Damage to a network of nerves called the sympathetic trunk can cause a constellation of symptoms that are collectively known as Horner's syndrome or oculosympathetic paresis. [22] Clinical features of Horner's syndrome include:

- The condition of ptosis is caused by the paralysis of Muller's muscle in the upper eyelid.
- Upside down ptosis is caused by the weakening of the inferior tarsal muscle.

- Miosis occurs when the sphincter pupillae muscle contracts without any opposition from the dilator pupillae muscle, which is paralyzed.

- The pupillary responses to light and close stimuli are within the usual range.

- Dilation lag: Dilatation of Horner's pupil occurs more slowly than that of a normal pupil does because it lags the pull of dilator pupillae

- Facial Anhidrosis: reduced sweating on the ipsilateral face and neck is characteristic of preganglionic Horner's syndrome

- Heterochromia iridis occurs due to interrupted sympathetic ocular innervation causes failure of the pigment of the iris stroma to develop.

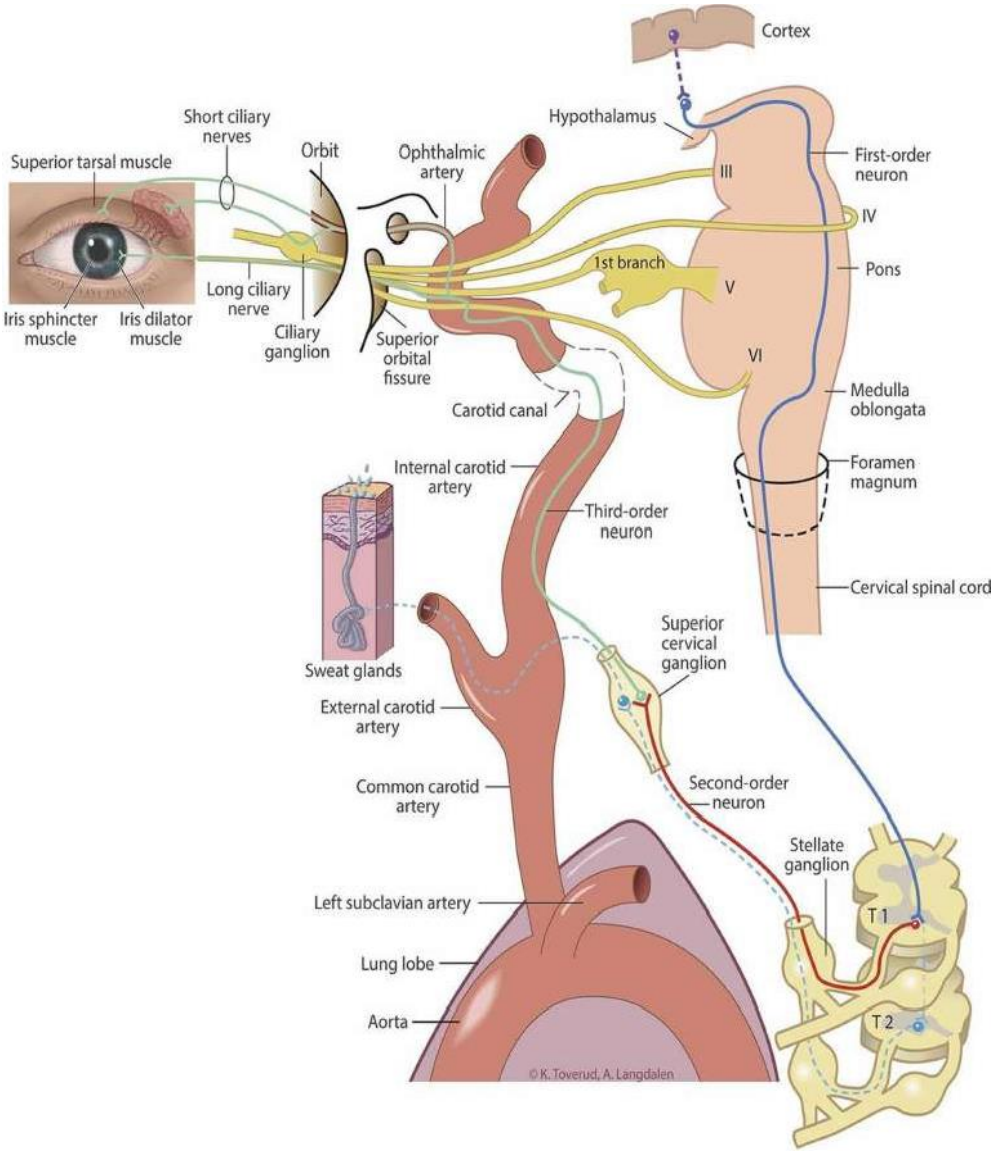


Figure 8: Sympathetic supply of the eye

Cataract surgeries attributed to small pupil cataracts constituted around 11 percent of the total number of cataract operations.[23] Usually, a pupil diameter of less than 5 mm is thought to be small. However, one study thought that a pupil diameter of 4 mm or less was also small.[3] A small pupil is a widely recognized risk factor linked to several problems during and following cataract surgery. Small pupils are not just a geometric problem that restricts access to the surgical field.

They also result in poor pupil dilation due to systemic diseases, the use of certain drugs, and local conditions such as glaucoma, ocular trauma, previous eye surgery, and uveitis. These eyes are generally more susceptible to increased permeability of the blood-aqueous barrier, which leads to inflammation after surgery.[24] There are two types of small pupils:

- Rigid or inelastic small pupils or non-IFIS type: in such pupils, sphincters are rigid.eg: uveitis and senile miotic pupil.
- Elastic small pupil or IFIS type: e.g.: Intraoperative floppy iris syndrome.

The various causes of small pupil include:

- Pseudo exfoliation Syndrome (PXF)
- Diabetes Mellitus (DM)
- Intraoperative Floppy Iris Syndrome (IFIS)
- Iridoschisis
- Chronic Uveitis
- Senile or age related

1) PSEUDO EXFOLIATION SYNDROME:

Pseudo exfoliation syndrome is a condition that occurs with age and is characterized by the gradual buildup and deposition of exfoliation material in the front part of the eye and other tissues in the body.[25]Poor pupillary dilation and zonular weakness are the two most common issues in cataract surgery in eyes with PXF . Poor

pupillary dilatation is due to peri pupillary atrophy due to which there is a poor response to mydriatics. There is infiltration of iris stroma with PXF material which causes mechanical impediment to mydriatrics. Adding to this there are also adhesions of Material for exfoliation onto the iris pigment epithelium and anterior lens capsule which also impairs pupillary dilation.[26]It has been postulated that abnormal deposition of PXF material and abnormality in vessels led to degeneration and atrophy of muscle cells which explains poor pupil dilation in PXF eyes.[27]

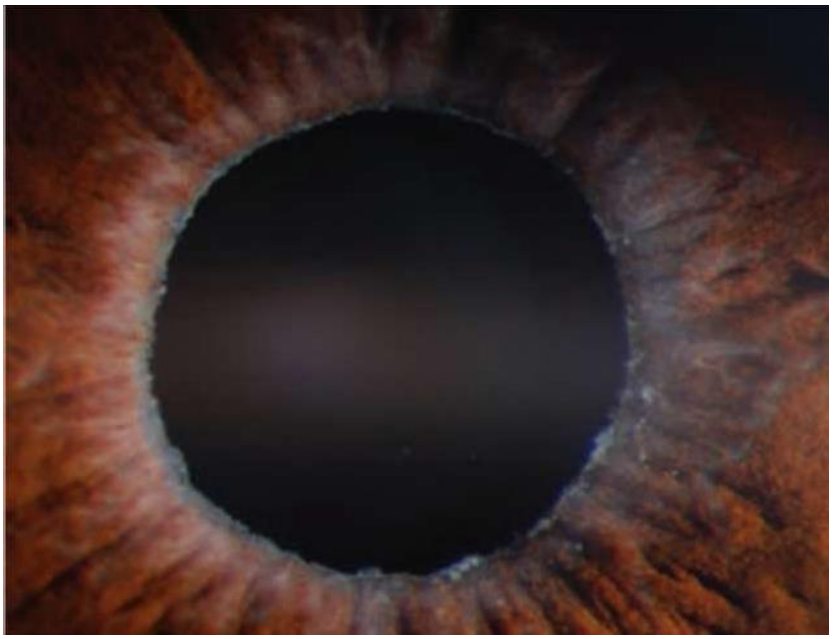


Figure 9: A small pupil with pseudoexfoliation deposits on the crystalline lens and iris

2) DIABETES MELLITUS:

Diabetic patients frequently exhibit unusually constricted pupils that can be resistant to mydriatics. The reason for this is a condition called autonomic neuropathy, which affects the sphincter and dilator muscles by partially reducing their nerve supply[29]. Additional pupillary

abnormalities observed in the eye of individuals with diabetes include a slow response to light or a decrease in the rhythmic dilation and constriction of the pupil with prolonged exposure to light. The pupil of a person with diabetes does not dilate well in response to antimuscarinic medicines, but shows increased sensitivity when treated with sympathomimetic agents. This increased sensitivity is caused by sympathetic denervation. Diabetic individuals also exhibit morphological abnormalities, such as the buildup of glycogen in the pigment epithelium of the iris.

3) INTRAOPERATIVE FLOPPY IRIS SYNDROME(IFIS)

IFIS, or Intraoperative Floppy Iris Syndrome, is a medical condition marked by inadequate widening of the pupil in response to the application of eye- dilating medications before surgery:

- This floppy iris has a tendency to protrude towards the phaco and side port incision sites.
- The patient had persistent and unyielding constriction of the pupil during surgery, despite the implementation of routine measures to prevent this.
- The traditional intraoperative triad consists of a flaccid iris that tends to billow in response to normal intraocular fluid currents during phacoemulsification.

IFIS is classified as:

- Mild IFIS is defined by a preoperative pupil that is well dilated and mild postoperative iris billowing.
- Moderate intraoperative floppy iris syndrome (IFIS) is marked by a preoperative mid-dilated pupil and a modest inclination of the iris to protrude through surgical incisions.
- Severe IFIS: Patients with significant intraoperative iris prolapse and tiny, non-dilatable pupils prior to surgery are considered.

IFIS has been linked to tamsulosin, a medication used to treat benign prostatic hyperplasia (BPH) symptoms in the urinary tract. In addition to relaxing the smooth muscles of the bladder and prostate, the iris dilator muscle is also relaxed by tamsulosin, a selective alpha blocker, because it binds to the postsynaptic nerve ends of that muscle.[30] Use of alpha 1a blocker leads to relaxation of the dilator iris muscle and poor pupillary dilation.

4) IRIDOSCHISIS:

Iridoschisis is a rare iris disease characterized by the division of the iris stroma into two halves, resulting in the separation of the anterior and posterior iris stroma. The anterior layer divides into filaments, and the unattached tips remain suspended in the anterior chamber.[31] Iridoschisis can occur as a result of either age-related changes, physical trauma, or as a secondary condition following glaucoma. Angle-closure glaucoma refers to the narrowing of the angle in the eye, which can lead to a sudden closure of the angle. This condition is often linked with iridoschisis causes peripheral anterior synechiae causing small pupil. Peripheral laser iridotomy is usually done to relieve the pupillary block.

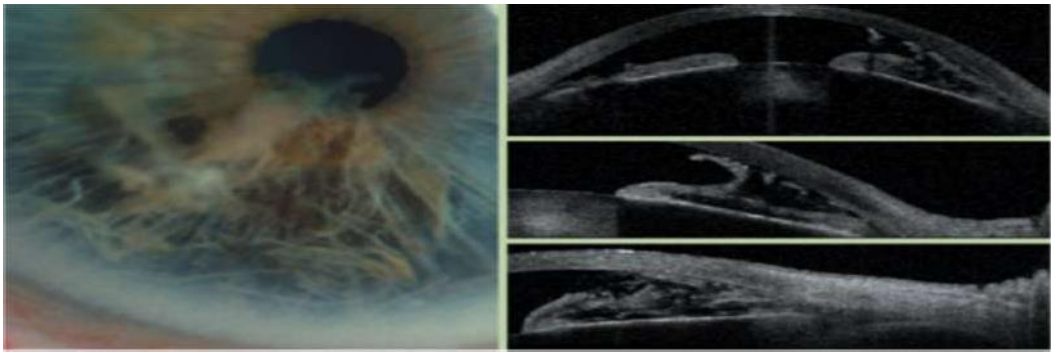


Figure 10: OCT of an iridoschisis patient shows cross-sections with associated shredded appearance of the iris

5) CHRONIC UVEITIS:

When inflammation returns to the anterior segment, it might leave behind sequelae of the small pupil, which can be linked to synechiae on the back of the eye and the membrane that lines the pupil. When in doubt, use visco-dissection to expand the angles and release the peripheral anterior synechiae (PAS) first. Only then should the posterior synechiae be released. To immediately dilate a completely occluding pupil, one must first remove the band of fibrotic tissue that surrounds the pupil's edge. Sphincterotomies can be done more than once if the pupil size remains less than 4 mm.[32]

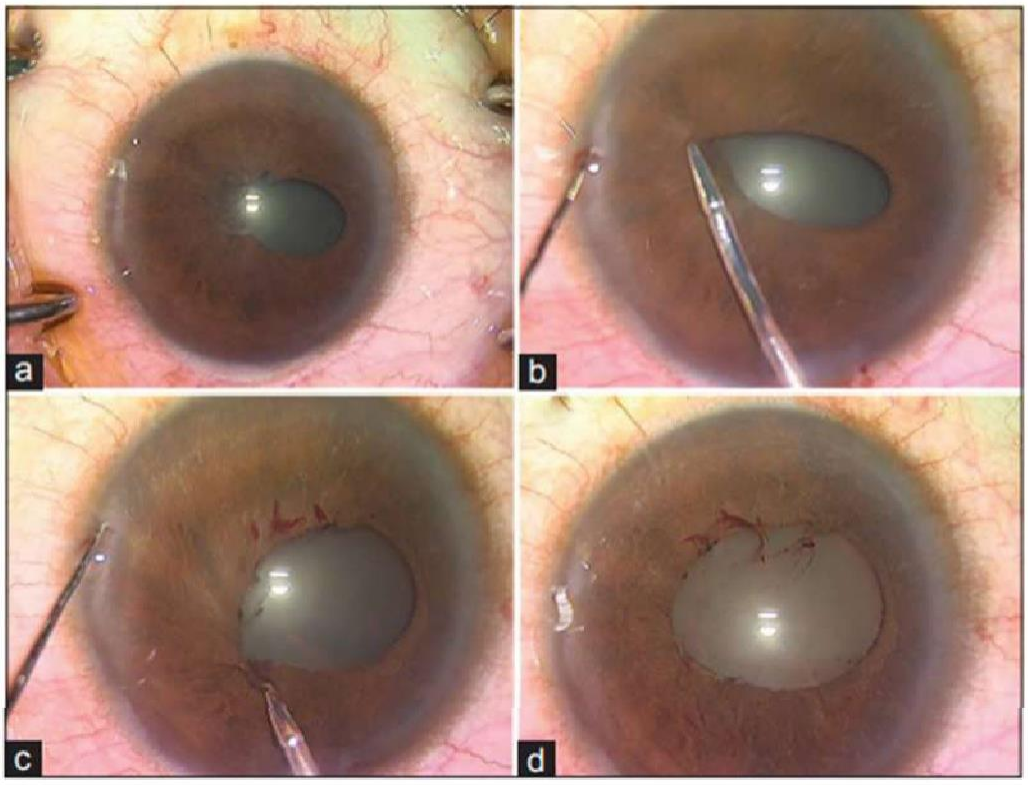


Figure 11: Removal of pupillary membrane and PAS

MANAGEMENT STRATEGIES FOR SMALL PUPIL CATARACT SURGERY

Multiple strategies may be needed to accomplish a safe cataract surgery in case of small pupil. Preoperative evaluation includes detailed dilated slit lamp examination including status of cornea for corneal guttae, Anterior Chamber (AC) depth, degree of pupil dilation preoperatively, condition of pupil sphincter, presence of PXF material, presence of and extent of posterior synechiae, cataract grading, zonular weakness and retinal evaluation. Also detailed systemic history including history of hypertension, DM and benign prostatic hypertrophy and medications especially oral alpha blockers such as prazosin, tamsulosin etc.

1) PHARMACOLOGICAL MANAGEMENT FOR PUPILLARY EXPANSION:

Several pharmacological agents are available for pupillary dilation and for maintenance of pupillary dilation throughout surgery.

- **MYDRIATICS OR CYCLOPLEGICS:**

Combination of tropicamide 1% and phenylephrine 2.5% is usually used for pupillary dilation prior to cataract surgery. Cyclopentolate 1% should be avoided for dilating the pupil the day before surgery to prevent pupillary fatigue on the day of surgery. Mydriatic agents may be administered either via topical eye drops or directly into AC (intracamerally) or via depot delivery system such as Mydriasert or a sponge/wick. Mydriasert is a long acting, insoluble ophthalmic insert meant for mydriasis prior to cataract surgery which contains phenylephrine hydrochloride and tropicamide. It is applied in the lower fornix 1 hour before surgery.[33]

- **NONSTEROIDAL ANTI-INFLAMMATORY DRUGS(NSAIDS):**

NSAIDS drugs such as ketorolac, Nepafenac, bromfenac are used to maintain mydriasis throughout surgery and counter miosis. They act by blocking the cyclooxygenase (COX) enzymes thus reducing or blocking the release of prostaglandins which cause pupillary miosis during cataract surgery. These are usually given 1-2 days before surgery.

- **MYDRICAINE:**

The subconjunctival injection consists of a single vial containing 1.3 mg of atropine sulphate, 0.12 mg of adrenaline, and 8.4 mg of procaine hydrochloride, all

mixed together in a volume of 0.4 ml. Preoperatively, it can be utilized to disrupt posterior synechiae in instances of chronic uveitis. It is advisable to use caution while using it in patients with reduced cardiac function, such as those with cardiac arrhythmias or myocardial infarction.

- **INTRACAMERAL EPINEPHRINE:**

Epinephrine relaxes the sphincter pupillae, hence is added in irrigating solution during cataract surgery to maintain mydriasis intraoperatively. It is used in concentration of 1:100000 which is prepared by diluting 0.1 ml of 0.01% adrenaline hydrochloride in 0.9 ml of BSS to form 0.001%.

- **EPI-SHUGARCAINE:**

It is a combination of epinephrine 0.025% and buffered lidocaine 0.075% in fortified BSS plus. It is used intracamerally for mydriasis for cataract surgery and for increasing the iris tone in case of IFIS.[34]It is prepared by mixing 3 cc preservative free lidocaine and 4 cc of 1:1000 preservative free bisulfite free epinephrine with 9 cc of BSS or BSS Plus. In case of IFIS, injection of this solution leads to significant reduction in flaccidness or floppiness of iris in a few seconds.

- **OMIDRIA:**

It is a combination of phenylephrine 1% and ketorolac 0.3% which is preservative free and bisulfite free. This solution is infused in the irrigation solution before cataract surgery. In this way an NSAID and a mydriatic can act constantly on the pupil.

2) SURGICAL MANAGEMENT OF THE SMALL PUPIL

Surgical management of small pupils consist of:

- Viscomydriasis
- Stretching the pupil using non sharp forceps to break adhesions or synechiae or remove pupillary membrane
- Use of pupillary expansion devices

VISCOMYDRIASIS

Pupillary dilatation is achieved by the injection of and ophthalmic viscosurgical device (OVD) in AC. Usually Healon 5 is injected in to AC which is a high molecular weight sodium hyaluronate.[35]It helps small pupil cataract surgery by following mechanisms:

- Mechanically moves the iris tissue towards the angle and helps to deepen AC
- Mechanically dilate the pupil
- Keeps the iris flat against the anterior lens capsule preventing iris prolapse through incision
- Aids capsulorhexis construction and helps control peripheral extension

Healon 5 produces mydriasis in almost all patients and is extremely useful in pediatric cataract since in newborn or infants the pupils are poorly dilating because of poorly developed dilator pupillae muscle. But it is necessary to repeatedly inject

into AC to maintain its effect since the OVD may be aspirated or may leak through the incision site.

STRETCHING THE PUPIL

A) SYNECHIOLYSIS:

In cases where small pupils are due to posterior synechiae between iris and anterior capsule can be tackled by breaking these adhesions. These are broken either using visco cannula fixed to the OVD syringe or with the help of an iris repositor. Broad synechial adhesions require dissection with a sharp instrument like curved vannas scissors.[26]

B) SPHINCTERECTOMY:

The procedure is performed on individuals with constricted sphincter muscles and tiny pupils. Fine was the first to describe the method of doing numerous sphincterotomies and stretching them to widen a pupil that is not suitably dilated for phacoemulsification surgery.[36] In this procedure, after injection of OVD such as Healon 5 into AC the posterior synechiae are released. Fibrosed tissue or membrane around or at the pupil is removed with the help of Endo forceps or endoscissors in case of dense tissue. After complete removal of all fibrosed tissue, iris sphincter may be cut to further enlarge the pupil. Sphincterotomies are efficient and uncomplicated procedures that ensure a consistent dilation of the pupil, enabling consistent visibility during surgery. The likelihood of experiencing complications after surgery is minimal, and can be affected by the presence of a predisposing factor such as glaucoma, uveitis, or a macular disease.[37]

C) IRIS STRETCH:

A two-instrument iris stretch is the stretching of the pupil using two instruments, such a Kuglen hook or Y hook. While one instrument is placed through paracentesis, the other is placed through the phaco wound. To dilate the pupil, the devices are progressively pushed 180 degrees apart towards the limbus after being hooked on to the iris.[26] However, when comparing pupil dilating devices, it is typically seen that the final pupil size is generally smaller and there may be some degree of intraoperative miosis.[38]

FIGURE 12: 2-Instrument Stretch

D) IRIS STRETCH-BEEHLER DEVICE:

The Beehler pupil dilator has three retractable prongs or micro fingers which is inserted through a 3.0 mm incision to enable the hook to pass into AC. Next, the instrument's splines are elongated and carefully adjusted to connect with the edges of the pupil. Subsequently, the iris is gradually drawn towards the incision, causing it to expand in three or four different orientations. It is highly beneficial in situations where there are small pupils accompanied by heightened stiffness of the iris sphincter. A drawback of this surgery is that it can result in iris tears and leave the iris flaccid after the operation.[26]

FIGURE 13: Beehler Pupil Dilator

E) IRIS RETRACTORS OR HOOKS:

Iris hook is the most important invention in cases of small pupil cataract surgery. It consists of a hook and an adjustable silicone stopper which are introduced through multiple short paracentesis parallel to the iris plane. They are used for conditions like iridoschisis, IFIS, and small pupils, but they can also be used to support the internal region of lenses that have moved out of place.[39] The hook's sleeve is modified to enlarge the pupil towards the limbus

to the desired dimension. The approach has the benefit of universal accessibility to iris hooks and simplicity of insertion. Drawbacks of this procedure encompass the occurrence of iris sphincter rips and the potential for hemorrhage. Iris sphincter tears can lead to a semi dilated pupil postoperatively. Also the process of implantation and removal is time consuming

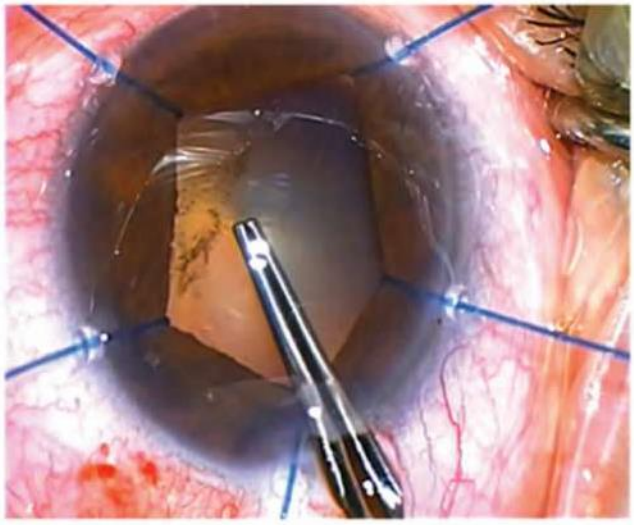


FIGURE 14: Iris Retractor Hooks

PUPIL EXPANSION DEVICES(PEDs)

The role of PEDs is

- Maximize mydriasis for safer or more comfortable cataract surgery
- Stabilize the pupil sphincter
- Center the eccentric pupil as in iris coloboma
- Protect iris from surgical trauma

A) MALYUGIN RING:

One of the most well-known PED is the Malyugin ring, which was created by Boris Malyugin.It's a square device that can be folded up and is made of polypropylene. It has four circular scrolls that engage the pupil at equal distances, giving it a controlled stretch. The device's main trait is that it fixes the pupillary margin in eight places, which is the same as implanting eight iris hooks.25The latest version, called Malyugin ring 2.0, can be put in through a 2 mm cut using a syringe that has been changed. The new model has a thinner material (5-0 polypropylene), a bigger coil gap, and a material that is softer and more stretchy. The new ring comes in sizes 6.25 mm and 7.0 mm and is lighter and more flexible. The advantages of the device are:[39]

- Gentler to iris tissue when compared to iris hooks
- No additional paracentesis is required for insertion
- Equidistant position of the loops provides well distributed stretching force on iris tissue
- Chances of iris aspiration during phacoemulsification are reduced since the iris rim is fixed safely in the loops of the ring

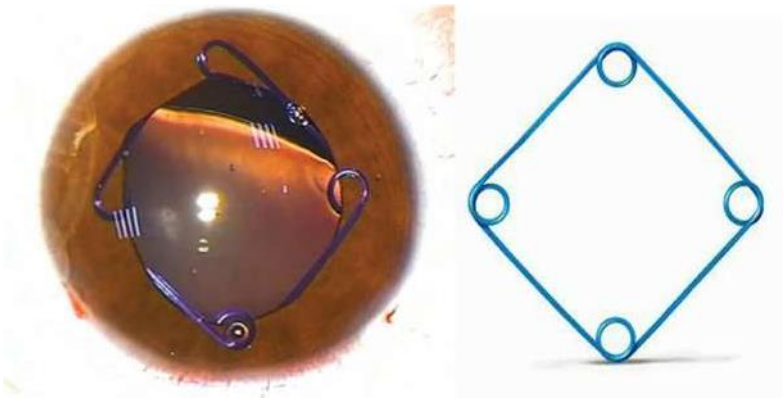


FIGURE 15: Malyugin ring

B) B HEX PUPIL EXPANDER:

Flexible and without joints, the B-HEX Pupil Expander is a third- generation Bhattacharjee Ring. Its hexagonal plastic profile is 0.075 mm and it has notches and flanges arranged in a single plane. Each sanitary 6.5 mm B-HEX has an extended pupil of 5.5 mm and comes preloaded in a see-through, one-time use container with an ergonomic grip that ensures sterility at the site of incision. A dull-tipped micro Sinskey hook manipulator is included in the package for inserting and removing the device from the pupil margin.41The resilient flanges prevent buckling when subjected to the compressive stress of the nondilating pupil, and the flexible notches enable maneuverability. For one-time usage only, it has been sterilized using ethylene oxide. Reuse or autoclaving changes the shape and elasticity, which impacts performance.[40] The advantages of the B HEX device include:

- Available preloaded and can be implanted and removed through an incision of even 1 mm

- Has a thin and uniplanar design which allows unrestricted instrument movement during phacoemulsification, aspiration of cortex and IOL implantation

- Can be implanted safely after capsulorhexis for lens implantation considering that one can see the narrow uniplanar notches clearly

- Useful in MICS and femtosecond laser-assisted cataract surgery (FLACS)[25]

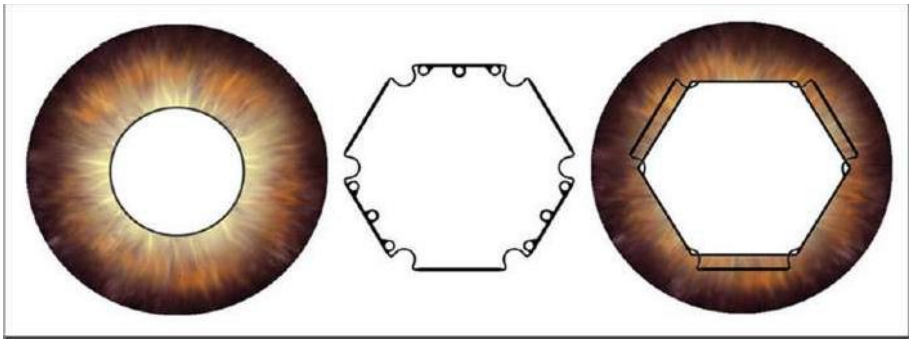


FIGURE 16: B HEX Pupil Expander

C) GRAETHER 2000 PUPIL EXPANDER(GPE):

GPE was designed by John M Graether for mechanical dilation of pupil. The gadget is made up of three parts: the iris glide-retractor, a disposable insertion tool, and the pupil expander. The silicone ring that acts as the pupil expander has grooves cut onto it to fit snugly around the iris sphincter. Among the issues with this gadget are[42].

- Challenges in activating the iris sphincter.
- Pupil block can cause an increase in intraocular pressure, leading to shallowing of the anterior chamber.
- The movement of the expander away from the sphincter due to the phaco tip or sleeve can be prevented by lengthening the strap before inserting the phaco tip.

FIGURE 17: Graether Pupil Expander

D) ASSIA PUPIL EXPANDER (APX):

The APX device was designed by Ehud I Assia. Designed for mechanically enlarging the pupil during intraocular surgery, this device is meant for a single usage only. The spring-loaded tool resembles little, blunt scissors. Distinct forceps are used to introduce two devices through two 19-gauge incisions that are opposite to each other.[43]When both the devices are placed ,a rectangular pupil opening is created of around 6x6mm.The earlier version was APX 100 which was made of stainless steel ,now second generation APX 200 is used.

The advantages of the device include:[25]

- No intraocular manipulation required
- The orientation of the two devices can be changed to create a trapezoidal opening
- In case of PC rent the device is unlikely to fall into vitreous cavity
- Scissors like device provides good surgical view.

FIGURE 18: The APX DEVICE

E) VISITEC I RING PUPIL EXPANDER:

Soft polyurethane makes up the Visitec i-Ring Pupil Expander, a disposable device. A 6.3 mm diameter circular hole is made by it. In addition to providing additional stability during surgery, the four corners of the device form four channels that secure the iris in place. A device that may be inserted and removed using an injector is part of the assembly.[7]

The device engages the iris completely and enlarges it 360 degrees enabling a pupil expansion of 6.3mm. Each corner contains a positioning hook through which a sinskey hook can be engaged. The device is made available along with an attached inserter. The surgeon retracts the slider on the inserter which causes the ring to fold inside as it is pulled inside the inserter which is then positioned with Sinskey hook.[2] The advantages of the device is that it is more gentle and atraumatic to the iris, cornea and lens.

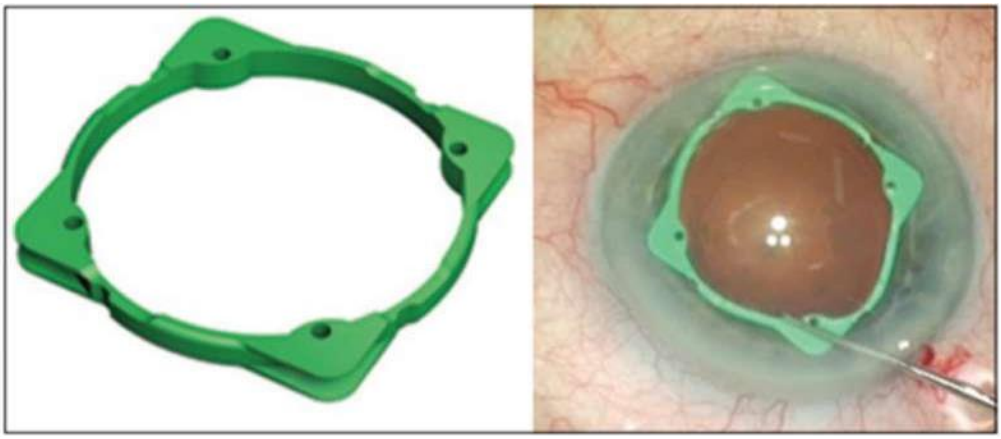


FIGURE 19: Visitec I Ring Pupil Expander

F) CANABRAVA RING:

This device was designed by Sergio Canabrava and is the first intraocular ophthalmological device produced by 3 D printer. It is made of PMMA and consists of an incomplete ring with ultralight tab like parts which are oriented either up or down along the ring. The parts which are "up" are oriented over the pupil edge and the parts which are "down" are oriented below the pupil edge.[44]It can also be used in iris coloboma and damaged iris.

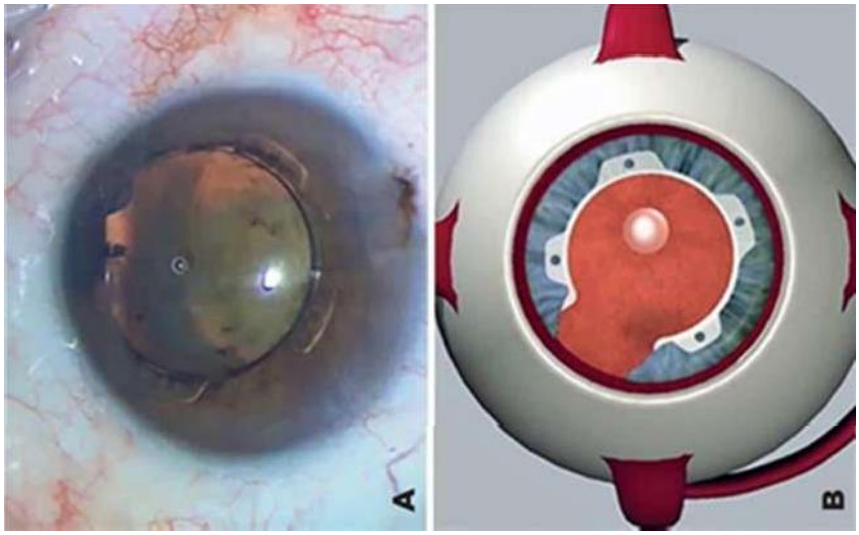


FIGURE 20: Canabrava Ring

F) OASIS IRIS EXPANDER:

The OASIS Iris Expander is a disposable surgical device designed to improve visualization during cataract surgery in patients with small pupils or IFIS. This ring-shaped device, made of polypropylene, measures 6.25 millimeters in diameter.

The OASIS Iris Expander offers several advantages:

- **Improved Pupil Dilation:** It helps gently expand the pupil, providing better access and visibility for the surgeon throughout the cataract procedure.
- **Ease of Use:** The disposable design simplifies operation, and the included injector facilitates insertion and removal.
- **Tissue Gentleness:** The soft polypropylene material minimizes potential damage to delicate iris tissue.

Availability:

The OASIS Iris Expander comes packaged with five sterile, single-use units per box, each pre-loaded in a disposable injector for convenient use during cataract surgery.

FIGURE 21: Oasis Iris Expander

G) PERFECT PUPIL DEVICE:

The Perfect Pupil device is an expansion device for small or medium sized pupil developed by John Milverton. The device is made of soft flexible polyurethane and has a small arm that remains externalized and hence provides space for phaco probe. It provides pupil expansion of 7-8 mm. The advantages are that it does not damage following surgery, the iris sphincter and the pupil return to their natural dimensions, size, and function.[25]

H) MORCHER PUPIL DILATOR:

The Morcher pupil dilator is a semicircular elastic ring made of polymethyl methacrylate for pupil expansion during phacoemulsification. The device is either implanted manually or with the help of Geuder pupil injector system. It is indicated in Intraoperative floppy iris syndrome.[25]

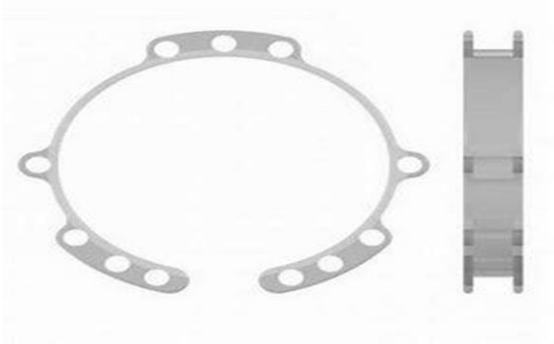


FIGURE 22: Moecher Pupil Dilator

I) XpandNT SPECULUM:

It is a new generation device which is like an implantable iris speculum consisting of a ring made of nitinol and has an aperture 6.7 mm. The device is inserted with an injector through a 2.4 mm or wider incision.

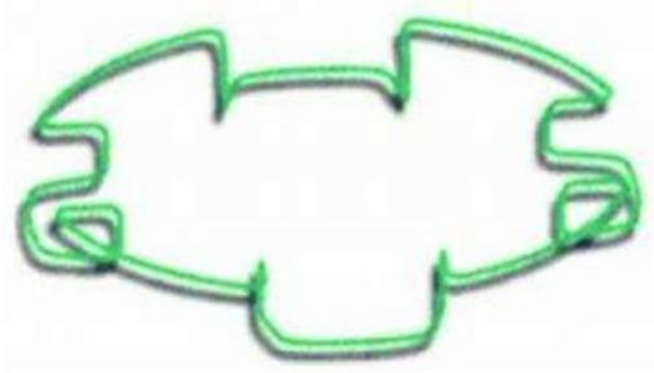


FIGURE 23: XpandNT speculum

COMPLICATIONS OF PUPIL EXPANSION DEVICES

- Sphincter tears: device which stretch the iris can lead to sphincter tears and also it can make iris flaccid and floppy and also may lead to iris prolapse.
- Rough implantation and explantation of device may snag the wound site.
- Injury to corneal endothelium, iris, angle, anterior capsule and lens can happen in implantation or explantation of the device.
- Intraoperative disengagement or dislodgement of device which can increase the risk of iris aspiration
- Iridodialysis may happen while explantation of device
- Damage of iris may cause bleeding and release of iris pigments intraoperatively
- Pupil irregularity, deformity or atony may occur postoperatively.
- Increased chances of inflammation in the postoperative period especially in cases of uveitis and diabetes
- In case of PCR, dislocation of the device into vitreous cavity must be taken care off.

MATERIALS AND METHODS

This research was undertaken by the Department of Ophthalmology at KLE Dr. Prabhakar Kore Hospital and Medical Research Centre in Belagavi, India, between August 2023 and July 2024.

Study Goal

The primary aim of this investigation was to assess the effectiveness and safety of pupil expansion devices during cataract surgery with phacoemulsification in patients with small pupils.

Methods

- **Participants:** The study involved patients visiting the ophthalmology outpatient department (OPD) at the KLE Dr. Prabhakar Kore Hospital and Medical Research Centre.
- **Study Design:** A prospective, interventional, non-comparative design was followed for the study, spanning one year.
- **Study Duration:** The data collection period lasted one year, from August 2023 to July 2024.
- **Sample Size:** A total of 48 participants were enrolled in the study.

Sampling Procedure:

The formula used for sample size calculation is,

$$n = \frac{\sigma_d^2 \left(Z\underline{\alpha} + Z_\beta\right)^2}{\frac{2}{(\mu_1 - \mu_2)^2}}$$

$$\sigma_d^2 = 2 \times (1 - \rho)\, \sigma^2$$

$$d = \frac{|\mu_1 - \mu_2|}{\sigma_d}$$

Where μ_1 is the mean of the pre-test, μ_2 is the mean of the post-test, for 95% confidence level, $Z\underline{\alpha}$ values are 1.96 and for 85% power the $Z\beta$ value is 1.036.

Pupil diameter at baseline was 3.1 ± 1.1mm and post-operative 1 month was 3.6 ± 0.8mm. Considering similar results in our study, at 5% level of significance and 85 % power, the minimum sample size required is 44 subjects.

- **Sample Selection:** A standard sample size calculation formula was employed to determine the appropriate number of participants.

Selection criteria:

Inclusion Criteria:

Subjects undergoing cataract surgery with small pupil of < 5mm.

Exclusion Criteria:

People who have had iris surgery, zonular weakness, a very shallow anterior chamber depth, a history of iris trauma, a history of using a pupil enlargement device, or a history of using medicines that can affect pupil size (such as pilocarpine or amphetamine) are all at risk.

We acquired ethical clearance from the local institutional ethical committee. After thoroughly explaining the study's methodologies and procedures in the patients'

native language, we obtained their informed written consent.

At the initial visit, the investigator recorded demographic data on a predesigned proforma, including age, sex, occupation, and address.

An in-depth evaluation of the patient's medical history and eyes were carried out. The eyes that were examined for preoperative inclusion/exclusion criteria had surgical cataracts and non-dilating pupils less than 5 mm. The eyes were included in the study during surgery when pharmacologic and mechanical manoeuvres, such as topical and intracameral mydriatic agent administration, failed to dilate the pupils to 5 mm or more. PEDs were then placed. We measured the pupil size before, during, and after surgery, as well as during the 1-month checkup, and we looked for signs of irregularity or form in the pupils.

At seven specified intervals, we shall use Castroviejo callipers to measure the pupils' diameters:

1. Initial measurement before surgery
2. Measurement after the eyes have been dilated as much as possible using eye drops
3. Measurement after the eyes have been dilated using epinephrine and viscoelastic devices injected into the eye
4. Measurement taken after a ring has been placed to expand the pupil
5. Measurement taken at the end of the surgery, after the ring has been removed
6. Measurement taken one day after the surgery
7. Measurement taken at the one-month follow-up visit after the surgery.

In this study B-Hex was used as the pupil expansion device. It arrives at the incision in a sterile state, already loaded inside a see-through, single-use container with an ergonomic grip.

SURGICAL TECHNIQUE:

A) PREPARATION:

Two side-port incisions, spaced at right angles to each other, flanked a 1.5 mm or bigger incision made on the steep axis. It is common practice to inject viscoelastic under the pupil margin and maintain the anterior chamber underfilled. The ability to tuck flanges is made possible by the anterior vaulting of the iris. Be careful not to fill the chamber to the brim. This reduces the likelihood of anterior capsular injury and enhances the safety profile. Another component of the B-HEX housing is viscoelastic injection.

B) NSERTION:

The ring was introduced into the anterior chamber while being grabbed at the median placement hole on a flange using 23 G forceps. The iris was delicately placed on top of the B-Hex ring. The notches have been straightened, resulting in an extended design that makes passing easier. During insertion, the flanges are not tucked in any way.

C) ENGAGEMENT TO THE PUPIL MARGIN:

Underneath the iris are the corresponding flanges that contain the holes. One option is to use a 23-gauge forceps to draw the flange centrally and tuck it under the pupil margin, while another is to engage the manipulator in a mid-

flange hole. When necessary, access is gained through main and side port incisions. Be careful not to tilt the device by pronating your hand; instead, maintain the gadget perpendicular to the iris while using it. It is possible that this angle will only engage one notch.

D) PHACOEMULSIFICATION AND INTRAOCULAR LENS IMPLANTATION:

A 5 mm capsulorhexis was performed and the nucleus was fragmented into little pieces. Removing a large, solid piece from the protective sac surrounding the lens might potentially cause damage to the circular rip in the sac or cause the ring to become loose. Viscoelastic substances are used to maintain the shape of the anterior chamber when the phaco or I/A probes are removed from the eye. Subsequently, a monolithic hydrophobic acrylic intraocular lens (IOL) was inserted into the capsular bag.

E) REMOVAL:

The anterior chamber is filled with viscoelastic substance. A pair of forceps with a force of 23 G was utilized to separate a notch, after which the ring was seized and extracted from the primary incision. The viscoelastic substance was completely removed and antibiotics were administered through an intracameral injection. The primary surgical cuts and auxiliary openings were moisturized.

Following the surgery, a slit lamp assessment was conducted on the day after the operation, and then repeated one week and one month later. Topical corticosteroids were provided at an initial dosage of 6 drops per day and gradually

reduced over time, following the standard tapering protocol. We also evaluated the intraocular pressure and pupil diameter.

Data processing and analysis/statistical analysis:

Data is analyzed with the use of Excel and the statistical programme R, version 4.3.2. Tables showing the frequency of certain categorical variables. The Mean ± SD / Median (Min, Max) form is used for continuous variables. Max Stuart Use this test to see how your visual acuity has changed over the years. The QQ plot and Shapiro-Wilk test are used to verify if the variables are normal. The distribution of variables over time can be compared using the Friedman test. Post hoc analysis is performed using a pairwise Wilcoxon test with a Bonferroni adjustment. A p-value of 0.05 or less suggests statistical significance

RESULTS

The present study was conducted at KLE's Dr Prabhakar Kore Hospital and Medical Research Centre, in the duration of one year from August 2022 to July 2023. 48 patients were enrolled in the study. Data was analyzed using statistical software R version 4.3.2. and Microsoft Excel. The results acquired are tabulated as follows.

The collected sample were seen in age ranged from 47 to 85 years with mean age of 66.54 ± 9.22 years. The following table gives the distribution of subjects according to demographic details.

Table 1: Distribution of subjects according to demographic details.

Variables	Sub Category	Number of subjects (%)
Age (years)	Mean ± SD Median (Min, Max)	66.54±9.22 65 (47, 85)
Sex	Male	26 (54.17%)
	Female	22 (45.83%)

In the present study, the number of males were more than females,26 (54.17%) was male and 22 (45.83%) were females.

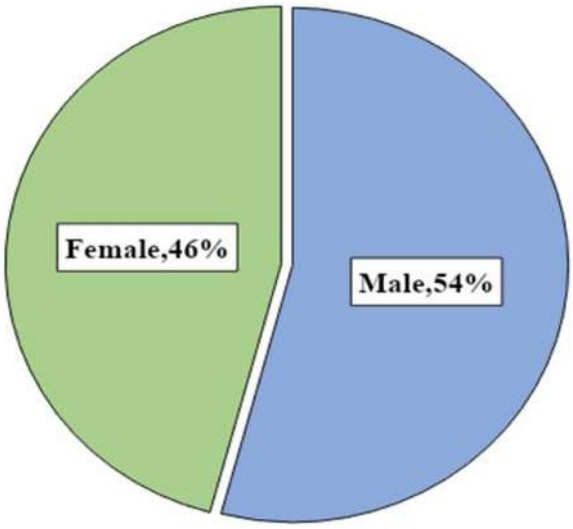


Figure 24: Distribution of subjects according to sex.

The following table gives the distribution of subjects according to comorbidities. Out of 48 subjects, 20 (41.67%) had diabetes and 24 (50%) had HTN.

Table 2: Distribution of subjects according to comorbidities.

Variables	Sub Category	Number of subjects (%)
Diabetes	No	28 (58.33%)
	Yes	20 (41.67%)
HTN	No	24 (50%)
	Yes	24 (50%)

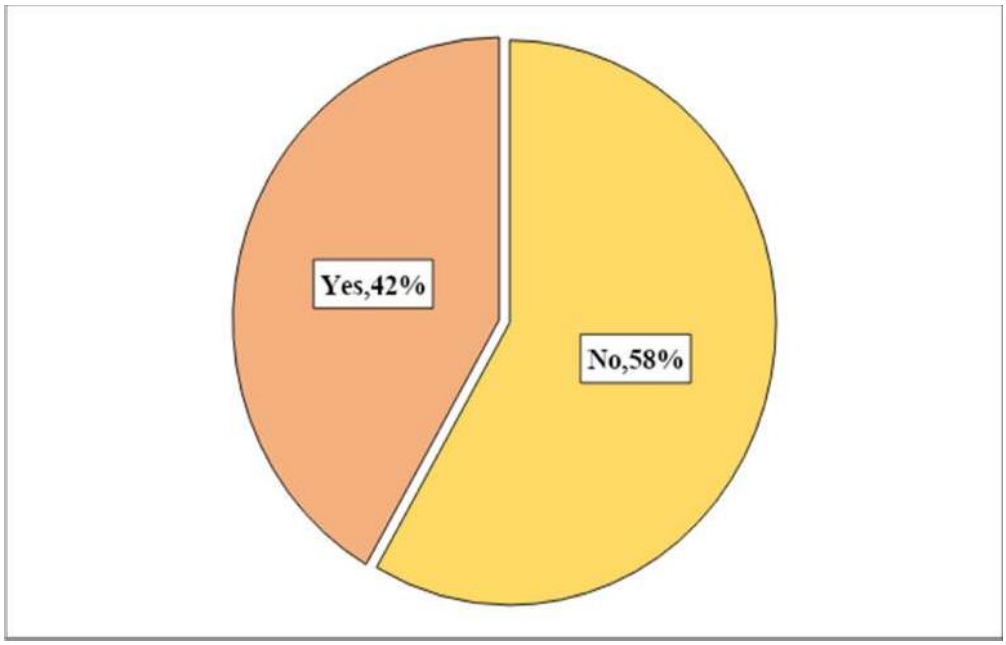


Figure 25: Distribution of subjects according to diabetes.

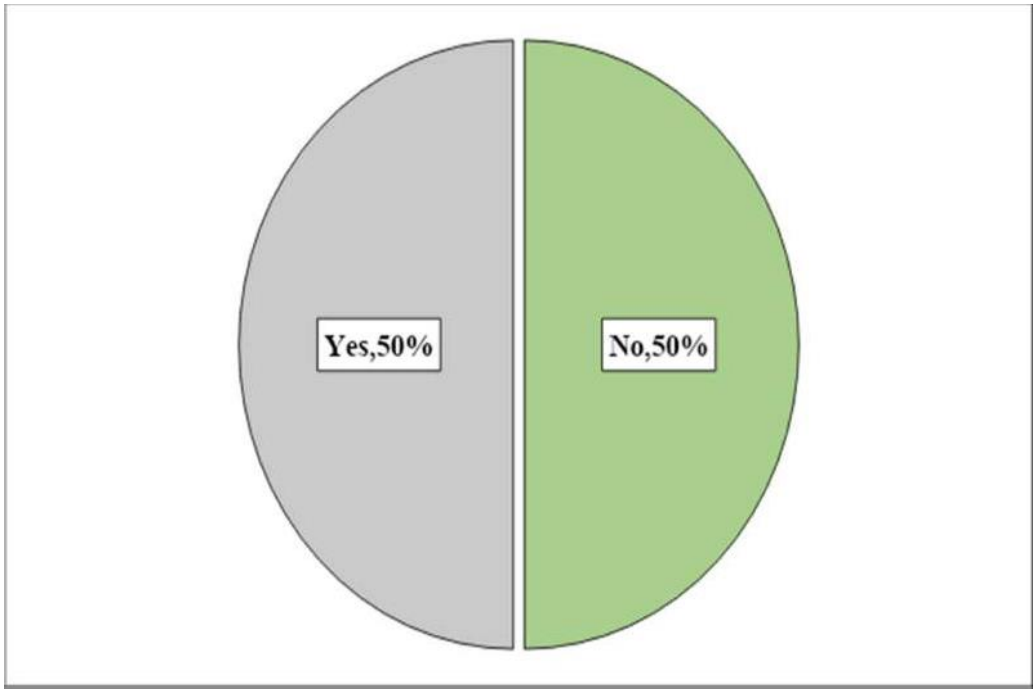


Figure 26: Distribution of subjects according to HTN.

Out of 48 subjects, 23 (47.92%) had diminution of vision in right eye and 25 (52.08%) had diminution of vision in left eye out of which Senile immature cataract (SIMC) was present in 35 (72.92%) subjects and Senile mature cataract (SMC) in 10 (20.83%) subjects and remaining contributed to 3 cases which included 1 Hypermature cataract (HMC), 1 Posterior polar cataract (PPC) and 1 posterior subcapsular cataract (PSC).

Table 3: Distribution of subjects according to clinical diagnosis

Variables	Sub Category	Number of subjects (%)
Diminution of vision (RE/LE)	Left eye	25 (52.08%)
	Right eye	23 (47.92%)
Diagnosis	SIMC	35 (72.92%)
	SMC	10 (20.83%)
	HMC	1 (2.08%)
	PPC	1 (2.08%)
	PSC	1 (2.08%)

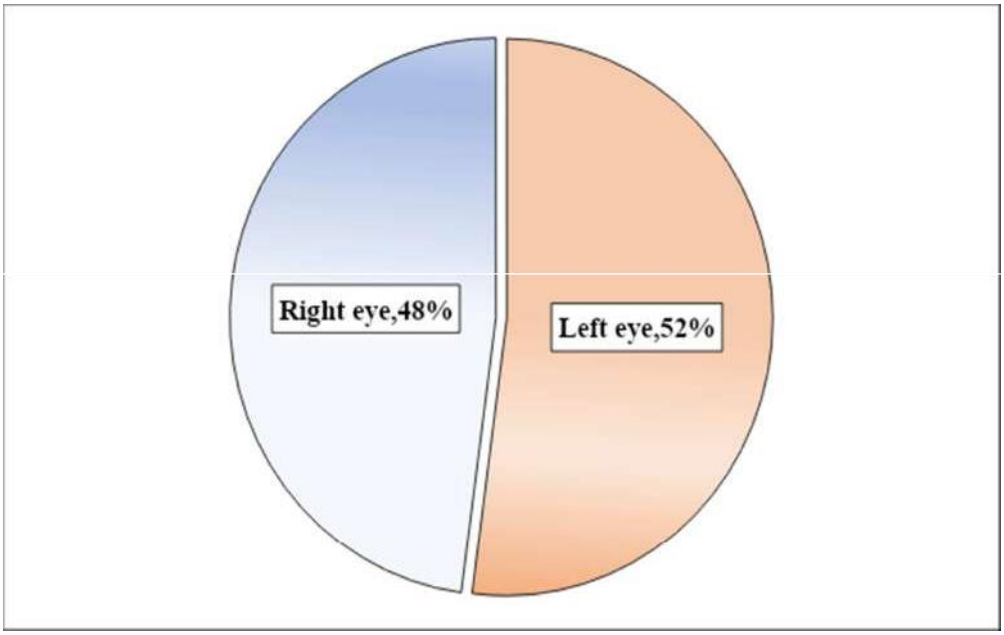
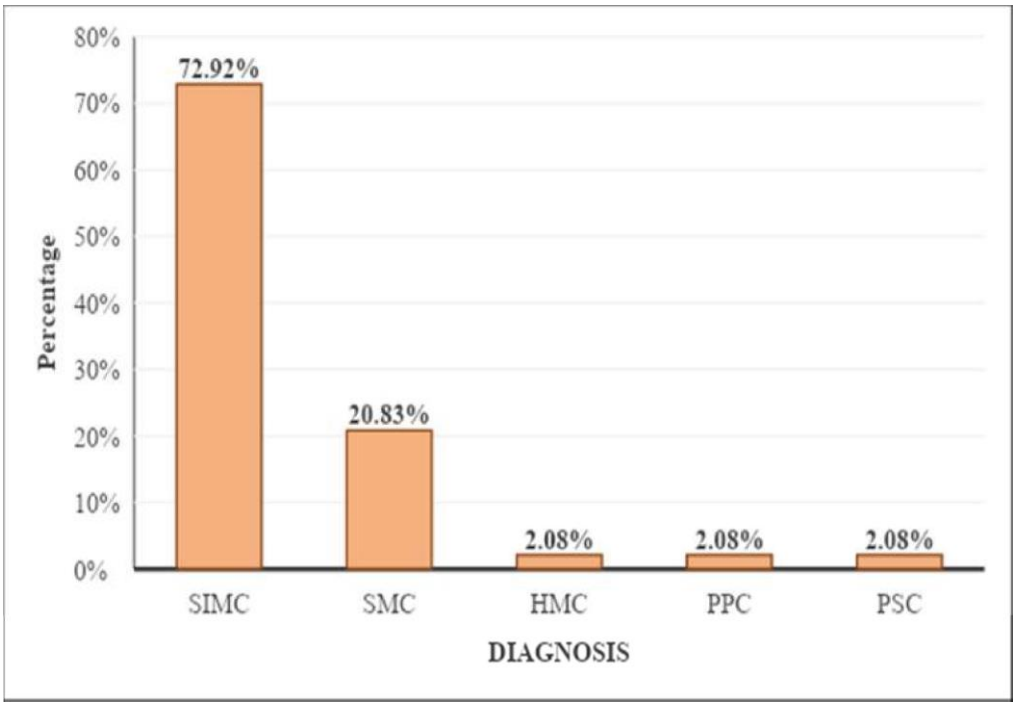


Figure 27: Distribution of subjects according to Diminution of vision



Graph 1: Distribution of subjects according to diagnosis.

Table 4: Distribution of subjects according to pseudo exfoliation

Pseudo exfoliation was observed in 14 (29.17%) out of 48 subjects.

Variables	Sub Category	Number of subjects (%)
Pseudo exfoliation	No	34 (70.83%)
	Yes	14 (29.17%)

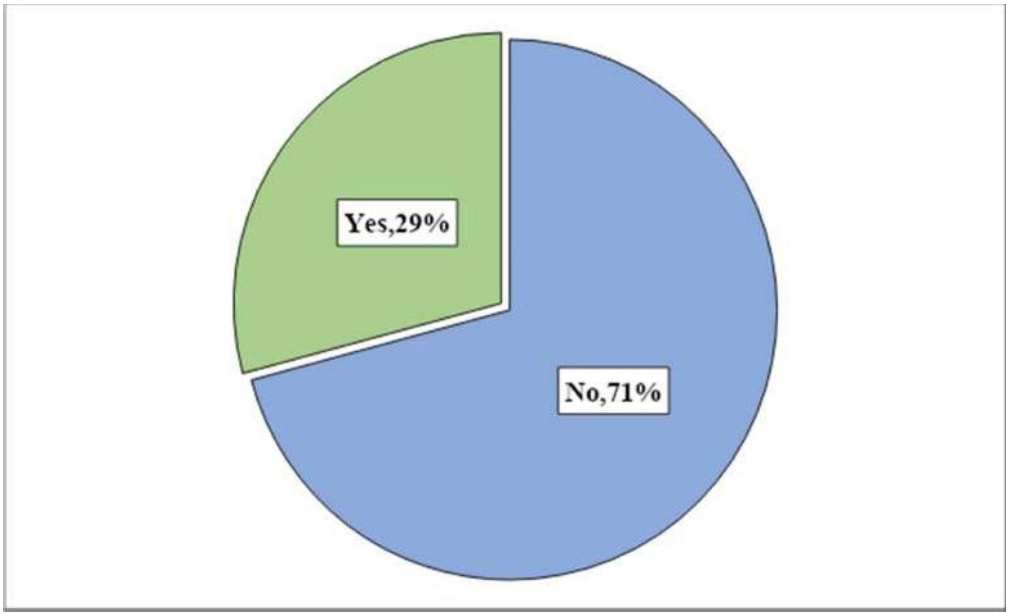
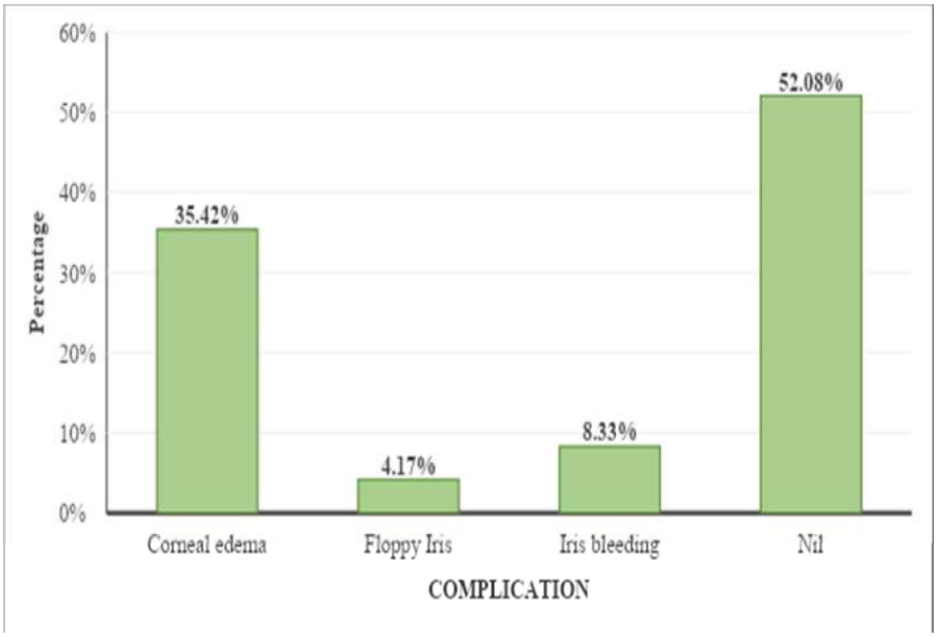


Figure 28: Distribution of subjects according to pseudo exfoliation.

No complication was observed in 25 (52.08%) subjects while 17 (35.42%) had corneal edema, 4 (8.33%) had iris bleeding and 2 (4.17%) had floppy iris.

Table 5 : Distribution of subjects according to complications

Variables	Sub Category	Number of subjects (%)
Complications	Corneal edema	17 (35.42%)
	Floppy Iris	2 (4.17%)
	Iris bleeding	4 (8.33%)
	Nil	25 (52.08%)

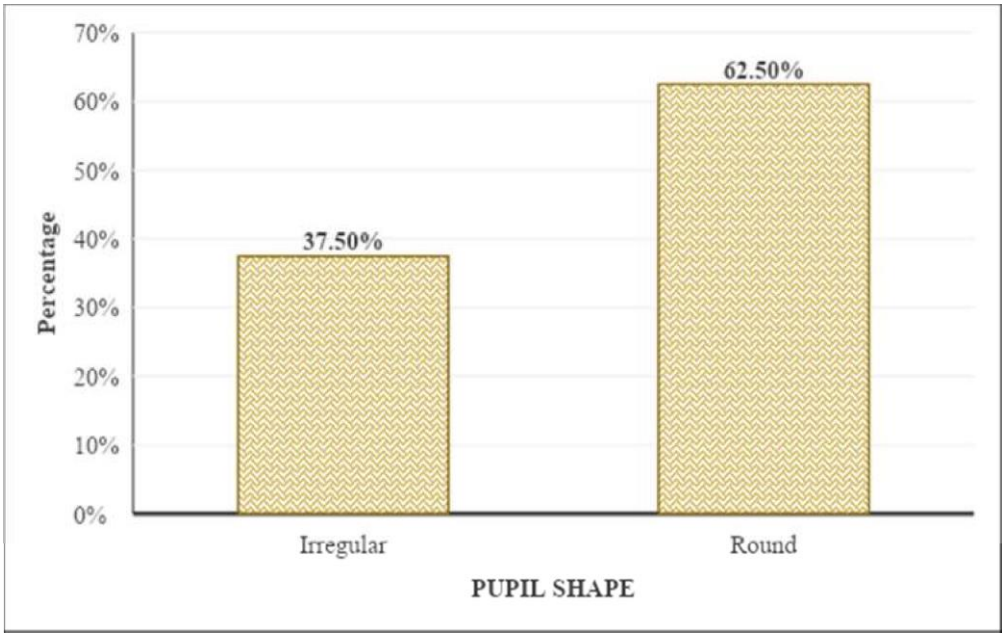


Graph 2: Distribution of subjects according to complications.

Out of 48 subjects, the pupil shape was irregular in 18 (37.5%) subjects and round in 30 (62.5%) subjects.

Table 6: Distribution of subjects according to pupil shape.

Variables	Sub Category	Number of subjects (%)
Pupil shape	Irregular	18 (37.5%)
	Round	30 (62.5%)



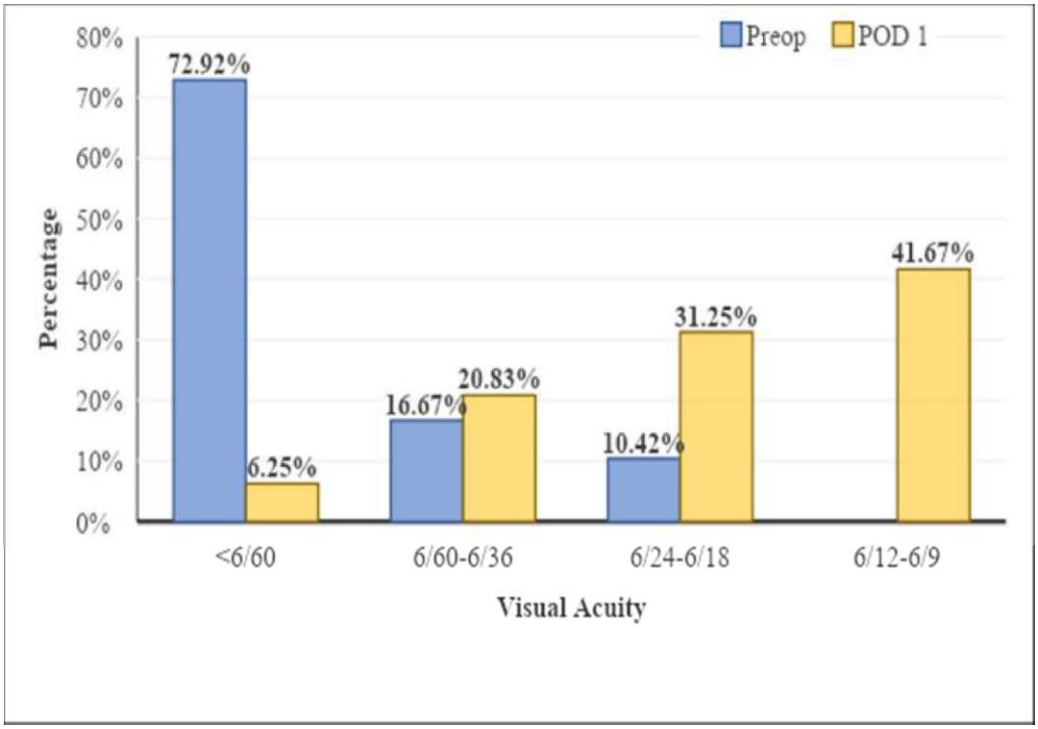
Graph 3: Distribution of subjects according to pupil shape.

The following table gives the distribution of Visual acuity over time.

Table 7: Distribution of Visual acuity over time.

Visual Acuity	Preop	POD 1	p-value
<6/60	35 (72.92%)	3 (6.25%)	**<0.001^{SM*}**
6/60-6/36	8 (16.67%)	10 (20.83%)	
6/24-6/18	5 (10.42%)	15 (31.25%)	
6/12-6/9	0	20 (41.67%)	

During the pre-operative assessment, 35 participants (72.92%) had visual acuity that was less than 6/60. Additionally, 8 subjects (16.67%) had visual acuity ranging from 6/60 to 6/36, and 5 subjects (10.42%) had visual acuity between 6/24 and 6/18. On the first day after the operation, only 3 out of the total patients (6.25%) had a visual acuity lower than 6/60. 10 subjects (20.83%) had a visual acuity between 6/60 and 6/36. 15 subjects (31.25%) had a visual acuity between 6/24 and 6/18. Lastly, 20 subjects (41.67%) had a visual acuity between 6/12 and 6/9. Stuart Maxwell's test reveals a notable disparity in the distribution of visual acuity as time progresses. Evidently, there is a discernible enhancement in visual acuity subsequent to the treatment.



Graph 4: Distribution of visual acuity over time.

The Friedman test reveals a statistically significant variation in the distribution of intraocular pressure (IOP) across time, with a p-value of 0.0008. Additionally, based on post hoc research, it has been found that there is a notable disparity in the distribution of pre-op IOP and POD 1 IOP (p-value = 0.0009). However, no significant differences are observed in the distribution of IOP on POD 28 compared to preop IOP (p-value = 0.1148) and POD 1 IOP (p-value = 0.1148). The following table gives the comparison of IOP over timepoints.

Table 8: Comparison of IOP over timepoints.

ime	IOP		p-value
	Mean ± SD	**Median (Min, Max)**	
Pre-op	14.46 ± 4.15	14.6 (7.1, 23.4)	
POD 1	16.97 ± 5.28	17.55 (10.2, 43)	**0.0008[F]***
POD 28	15.79 ± 2.72	15.85 (10.2, 20.3)	

The table above presents a comparison of pupil diameter at different timepoints. The Friedman test reveals a statistically significant variation in the distribution of pupil diameter with time, with a p-value of less than 0.0001. Additionally, based on post hoc analysis, it has been noted that there is a significant difference in the distribution of all pairs, except for Mydriatics and POD1, as well as Device removal and Intracameral epinephrine. The p-values for these exceptions are greater than 0.9999.

Table 9: Comparison of pupil diameter over timepoints

Time	Pupil diameter		p-value
	Mean ± SD	**Median (Min, Max)**	
Pre-op	2.35 ± 0.55	2 (1.5, 3)	**<0.0001[F]***
Mydriatics	4.92 ± 0.21	5 (4, 5)	
Intracameral epinephrine	5.42 ± 0.3	5.5 (4.5, 6)	
Device insertion	6.52 ± 0.25	6.5 (6, 7)	
Device removal	5.4 ± 0.52	5.5 (4, 6.5)	
POD 1	4.78 ± 0.44	5 (4, 5.5)	
POD 28	3.55 ± 0.43	3.5 (3, 4)	

DISCUSSION

There are a lot of potential problems that can arise during and after cataract surgery if the pupil is small.[7] In order for cataract surgery to yield desirable anatomical and functional outcomes, it is essential to achieve the correct mydriasis. Every cataract surgeon needs to be well-versed in techniques to reduce the risk of complications and maximize patient results when dealing with small pupils, as this is a common and complex circumstance.[3] The likelihood of complications is greatly enhanced in situations when there is insufficient dilatation of the pupils and/or inadequate assistance from the capsules.[45] Iris trauma and photophobia can occur if the mydriasis before surgery is inadequate and the miosis during surgery is also inadequate. Assistive pupil expansion devices are a tool in the toolbox of contemporary cataract surgeons. The days of small pupils having to endure sphincterotomies and key-hole iridectomy along with the pain and discomfort that came with it are over.[46] Topical and intraocular mydriatics, a well-chosen viscosurgical device, and mechanical dilatation using tools, iris hooks, and/or pupil expanders should all be part of the surgical strategy for handling patients involving small pupils.[7]

Patients with tiny pupils have additional challenges beyond those associated with surgical procedures. Iris, lens capsule, and zonular fiber biomechanical property loss, disruption of the blood-aqueous barrier, and inadequate pupil dilation are symptoms of multiple systemic and local comorbidities.[47] Patients whose pupils did not dilate more than 5 mm following pharmacologic treatments were included in our investigation. When pharmacological dilation fails to produce a pupil size more than

3.5 mm, mechanical dilation may be necessary for cataract surgery, according to Akman et al.[37]

Due to the increased prevalence of alpha-adrenergic antagonist agents, which cause intraoperative floppy iris syndrome (IFIS) and inadequate pupillary dilation, PEDs have emerged as crucial surgical tools for small pupil cataract surgery during the last 20 years.2So far, various PEDs have been developed and are now on the market. Some examples are the 5S Iris Ring, Perfect Pupil, Graether Expander, Malyugin Ring, APX 200, Canabrava Ring, Bhattacharjee B-HEX Pupil Expander, I- Ring, and many more.

The participants' ages ranged from 47 to 85 years old, with a mean age of 66.54 years, among the 48 patients who participated in the study. Males made up 54.17% of the sample and females 45.83%. The ratio of males to females was not significantly different ($p = 0.67$).

Although small pupils are a common symptom of diabetes, only 41.67% of patients in our study had a history of diabetes as a systemic condition, while 50% had a history of hypertension. Almost half of the eyes with tiny pupils had PXF, making it the most common cause of inadequate pupillary dilatation.48 It should be noted that only 29.17% of patients in our PXF patient cohort had inadequate pupil dilation. Drolsum et al. found that tiny pupils occurred in 47% of their patient group with PXF and cataract, which contradicts the present study. They did not, however, define a "small pupil" according to their criteria.49Poor vision and zonular instability are prominent symptoms of PXF, which is characterised by inflexible and weakly dilating pupils. Based on the potential for late decentration and tilt, which would severely diminish visual quality in both multifocal and toric lenses, PXF is deemed an absolute

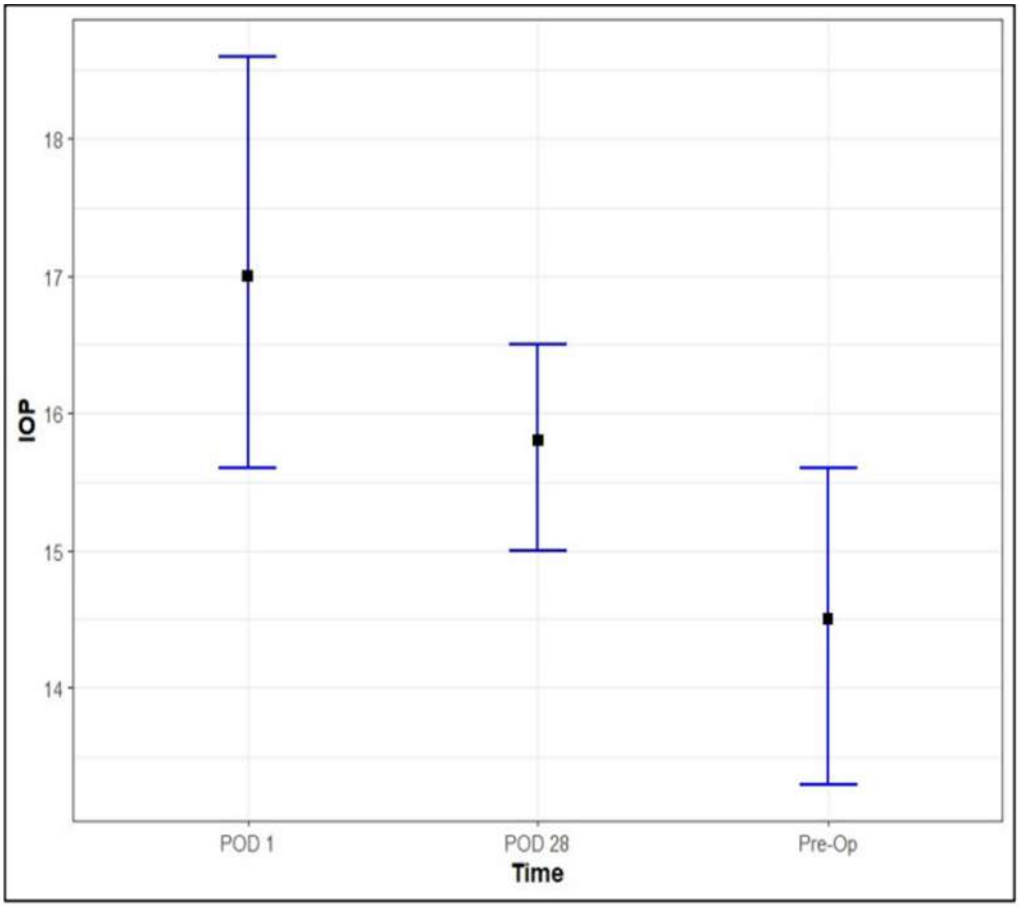
contraindication for multifocal lenses and a relative contraindication for toric lenses in a literature review by Anastasopoulos E et.al.50

In our study, 35.4% of patients experienced postoperative corneal edema, making it the most prevalent complication. Careful removal of the device should be emphasized due to the higher incidence of endothelium injury with pupil expansion devices.

Intraoperative problems such as a floppy iris can occur when the iris is slightly manipulated during the insertion or removal of a pupil expansion device. The PEDs did not appear to have significantly distorted the iris following surgery; in 62.5% of instances, the pupil shape remained round, and the mean eccentric index was close to that of a perfectly circular pupil. After therapy, most patients' best corrected visual acuity improved to over 6/18, indicating a statistically significant improvement. The use of the I-Ring in small-pupil cataract surgery reduced pupil distortion compared to using a Malyugin ring in the other eye of the same patient, according to a case study by Tian et al.8According to research by Harvey S. Uy et al. and others using different PEDs, postoperative pupil size increases ranged from 0.64 to 1.1 mm, meaning that the pupil size cannot go back to its preoperative size following PED use.2 The researchers found that patients' postoperative pupils remained about the same size as their preoperative pupils, with an average increase of just 0.5 mm. Unwanted glare and unfavorable dysphotopsias might result from postoperative pupils that are too large.

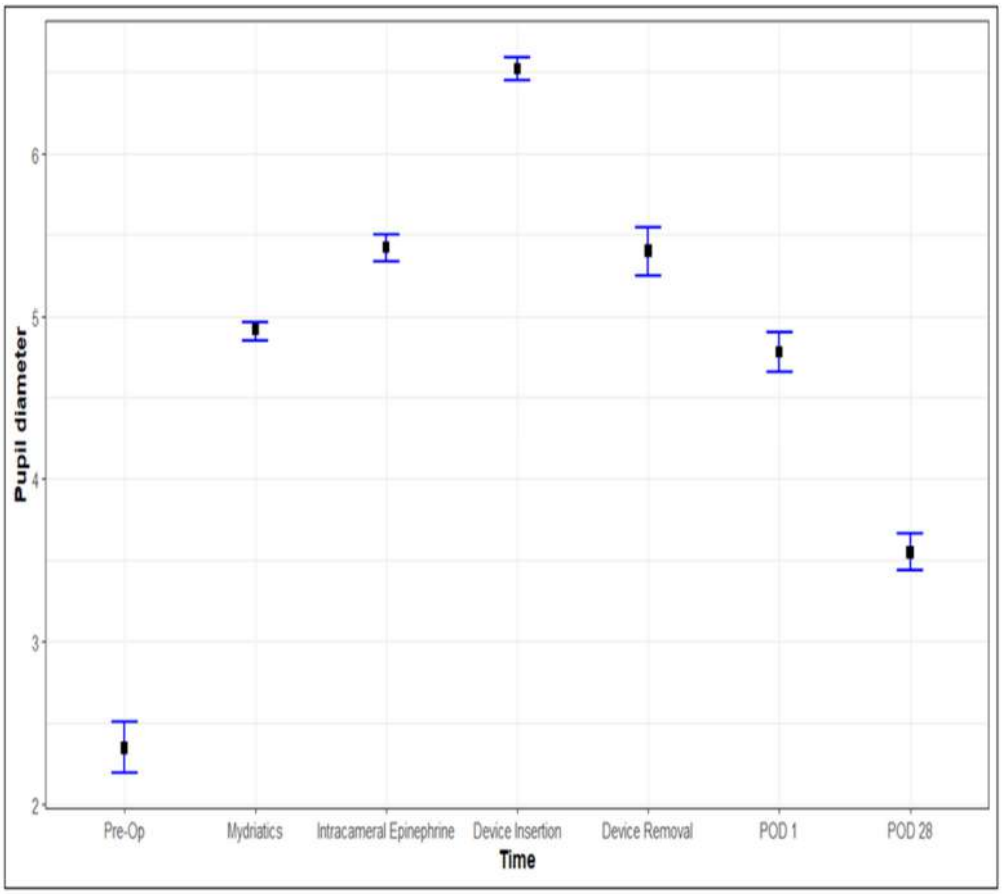
The distribution of intraoperative hemostatic pressure (IOP) before surgery and one day after surgery varied significantly ($p = 0.0009$). There were no notable

variations in the distribution of intraocular pressure (IOP) between preoperative and postoperative days (POD) 1 and 28, nevertheless.



Graph 5: Comparison of IOP over timepoints

The average pupil size before surgery was 5 mm with mydriatic agent, however it grew to 5.5 mm with intracameral epinephrine and 6.5 mm following device implantation in this specific trial. According to research by Salviat et al., using a B Hex ring caused pupils to dilate to 4.8 mm after a viscoelastic injection and 5.8 mm after insertion.[51]



Graph 6: Comparison of pupil diameter over timepoints.

With the use of PEDs, there was improvement in best corrected visual acuity with no significant difference in IOP values and less complications noted during the study. Besides determining the device's overall efficacy and safety, this study thoroughly examined critical intraoperative and postoperative variables in addition to visual outcomes.

CONCLUSION

The findings of this study suggest that:

- DM and PXF was the main causes for small pupil.
- The average pupil dilatation after intracameral epinephrine was 5.5mm while after device insertion it was 6.5mm.
- After the follow up of 1 month average pupil diameter was observed to be 3.5 mm.
- Furthermore, the intraocular pressure pre operatively and postoperatively was within normal limits signifying the use the PEDs are safe in small pupil cataract surgery.
- The main complication observed was corneal edema followed by iris bleeding while majority of patients didn't have any complications.
- Postoperatively most of the patients had round pupil adding more to the efficacy of PEDs.

SUMMARY

Smaller pupils in cataract surgery can often be challenging to manage and may lead to higher rates of complication. Impaired visualization through a small pupil and poor tissue stabilization increases the chance of tissue damage, retained nuclear material, and vitreous loss. Preoperative, intraoperative, and postoperative care for individuals with small pupils undergoing cataract surgery is complicated. Adequate mydriasis and its maintenance during the surgery are the best ways to prevent complications arising from a small pupil. Improvements in patient safety and the identification of novel treatment paradigms may result from innovations in surgical tools and techniques. It is crucial to identify patients at risk for miosis or with small pupils before surgery so that compensatory measures can be taken to obtain great visual outcomes with a low complication rate. When it comes to PEDs, cataract surgeons have a lot of options. Their design, ease of insertion and removal, and stability during the process are key differentiators. Pupil expansion devices may require the recruitment of additional skills, instruments, and potential costs. In order to perform cataract surgery safely and effectively, the majority will offer wide and unimpeded access to the lens. The latest innovations significantly reduced the chance of complications and increased the success rate of small pupil cataract surgery.

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ANNEXURE -I

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed to-be-University)
Accredited 'A+' Grade by NAAC in (3rd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC INSTITUTIONAL ETHICS COMMITTEE
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref No.MDC/JNMCIEC/ 88 **Date: 27/09/2022**

To.

REG NO: BK0121005
PG Student in Ophthalmology,
J. N. Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"EFFICACY OF PUPIL EXPANSION DEVICE IN SMALL PUPIL CATARACT SURGERY: A ONE YEAR PROSPECTIVE INTERVENTIONAL STUDY IN A TERTIARY CARE CENTRE."** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

(Dr. Smita Sonoli)
Member Secretary
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi.

(Dr. Harsha Hegde)
Chairman,
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi

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ANNEXURE -II

INFORMED CONSENT

Title of Research study :

"EFFICACY OF PUPIL EXPANSION DEVICE IN SMALL PUPIL CATARACT SURGERY: AONE YEAR PROSPECTIVE INTERVENTIONAL STUDY IN A TERTIARY CARE CENTRE."

Objective: To determine the efficacy and safety of Pupil expansion Device in small pupil cataract surgery undergoing phacoemulsification

Introduction: Small pupil cataracts accounted for about 11 percent of all cataract Operations [1]. Most commonly pupil diameter less than 5 mm is considered as small however, there is a study that considered pupil diameter of 4 mm or less as small pupil [3]. Pupil expansion devices [PED] such as iris hooks and the Malyugin ring are innovative solutions for controlling intraoperative pupil size.

Explanation of procedure: Subject with cataract who will undergo routine workup for surgery which include pupillary dilatation and subjects whose pupil dilatation <5mm is evaluated and during surgery pupil expansion device is inserted and removed just before the surgery is over there is 0.5% complications during the procedure.

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact: Dr Harsha Hegde, Chairperson, J.N.M.C., IEC & Scientist D, ICMR, National Institute of Traditional Medicine, Belagavi – 10 Ph No 9480422500

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study "**EFFICACY OF PUPIL EXPANSION DEVICE IN SMALL PUPIL CATARACT SURGERY: A ONE YEAR PROSPECTIVE INTERVENTIONAL STUDY IN A TERTIARY CARE CENTRE**". My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURE III:

PROFORMA

Hospital ID: Study ID:

NAME: _____

AGE:_____Years_____

GENDER: MALE FEMALE

ADDRESS: _____

_____

_____

CONTACT NUMBER:

DATE OF EXAMINATION: / /

IS THE PATIENT ELIGIBLE FOR STUDY? YES NO

HAS INFORMED CONSENT BEEN GIVEN? YES NO

CHIEF COMPLAINTS:

DIMINUTION OF VISION: YES NO

RE: DURATION _____Days/Months/Years

LE: DURATION _____Days/Months/Years

GRADUAL PROGRESSIVE SUDDEN NON-PROGRESSIVE

PAST HISTORY:

1. DIABETES: PRESENT ABSENT
   DURATION OF DIABETES: _____Months/Years
2. HYPERTENSION: PRESENT ABSENT
   ANY MEDICATION: _____
3. OCULAR TRAUMA: PRESENT ABSENT
4. OCULAR SURGERY: YES NO

A.OCULAR EXAMINATION:	RIGHT EYE	LEFT EYE
VISUAL ACUITY		
PINHOLE		
WITH GLASSES		
NEAR VISION		

A. ANTERIOR SEGMENT:	RIGHT EYE	LEFT EYE
ADNEXA		
CONJUNCTIVA		
CORNEA		
ANTERIOR CHAMBER		
IRIS		
PUPIL		
LENS		

C. FUNDUS EXAMINATION

GLOW		
MEDIA		
DISC		
B/V		
B/G		
MACULA		

D. INTRAOCULAR PRESSURE (BY NCT)

PRE OPERATIVE IOP	POST OPERATIVE IOP	
	POD 1	**POD 28**

E. SAC: RIGHT EYE LEFT EYE

F. BP:

G. DIAGNOSIS :

I. VISUAL ACUITY POSTOPERATIVE:

H. PUPIL DIAMETERS (RIGHT EYE / LEFT EYE)

PREOPERATIVE		INTRAOPERATIVE			POSTOPERATIVE	
BASELINE	**AFTER MYDRIATIC**	**AFTER INTRACAMERAL EPINEPHRINE**	**AFTER INSERTING PUPIL EXPANSION DEVICE**	**AFTER REMOVAL OF PUPIL EXPANSION DEVICE**	**POD-1**	**POD-28**

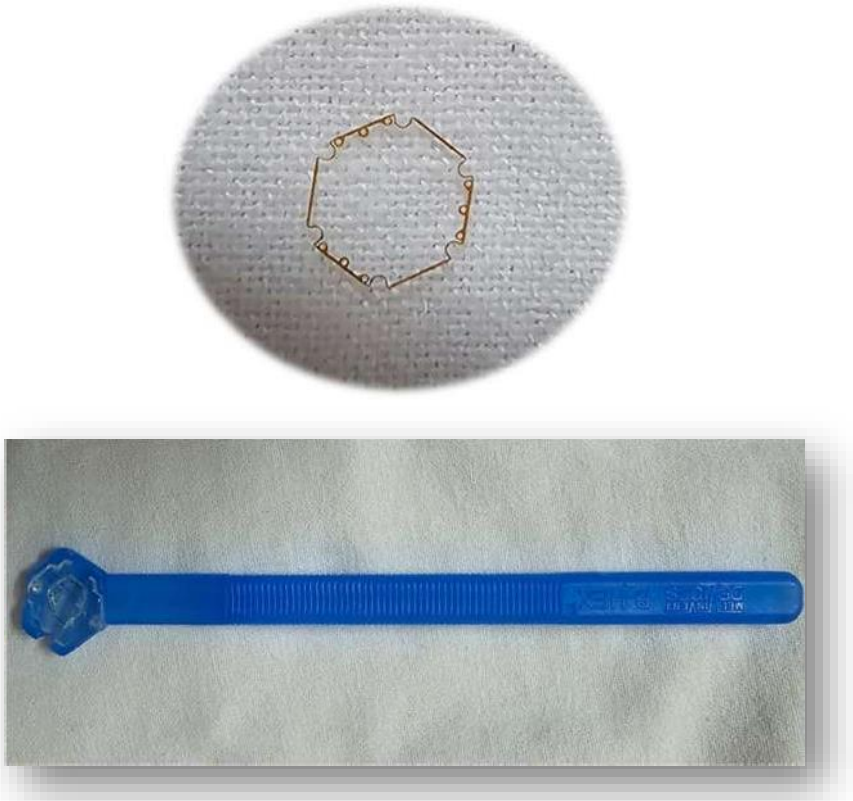
NAME OF THE INVESTIGATOR:

SIGNATURE : _____

NAME OF THE GUIDE

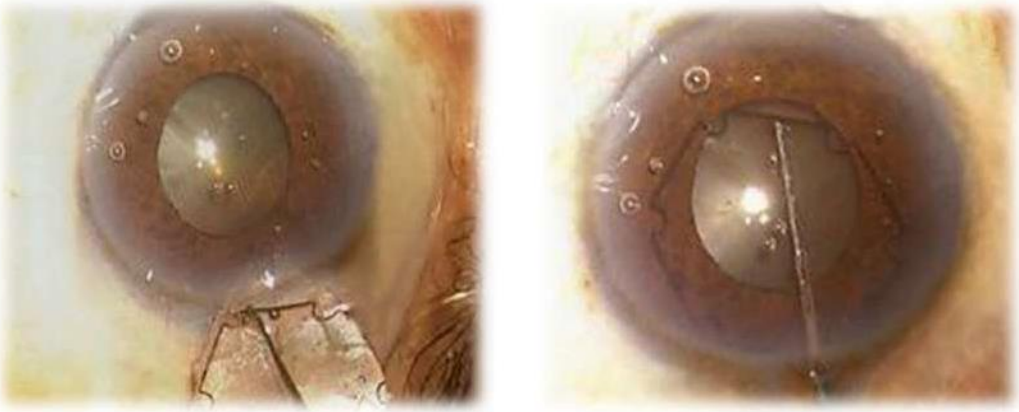
SIGNATURE : _____

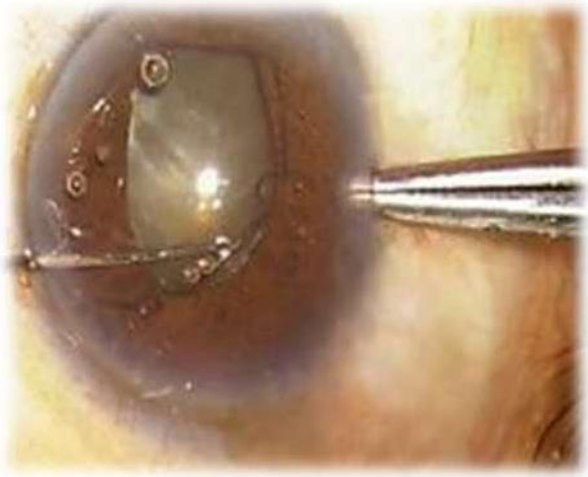
ANNEXURE IV : PHOTOGRAPHS



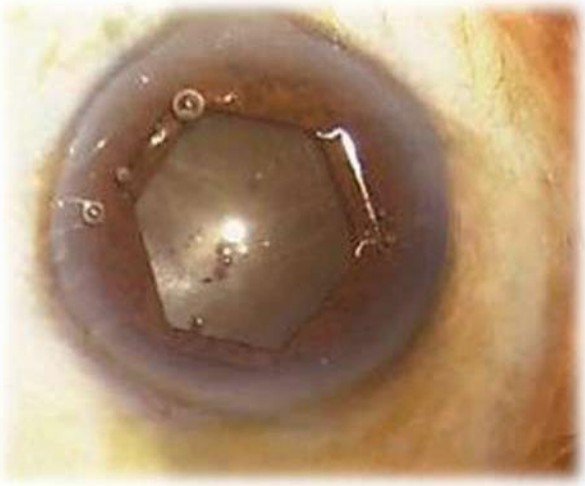
B HEX Pupil Expansion device

Castroviejo Caliper

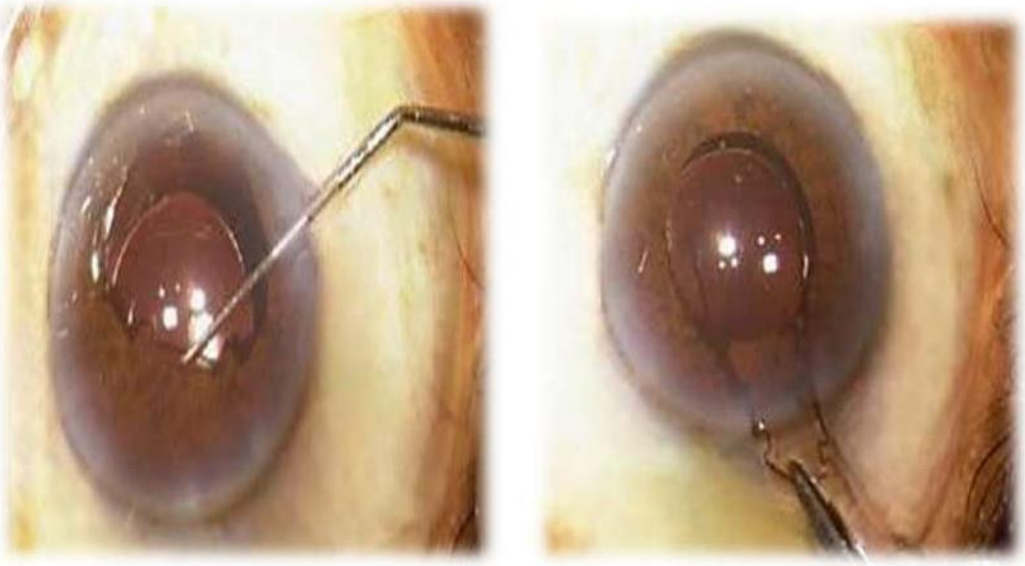




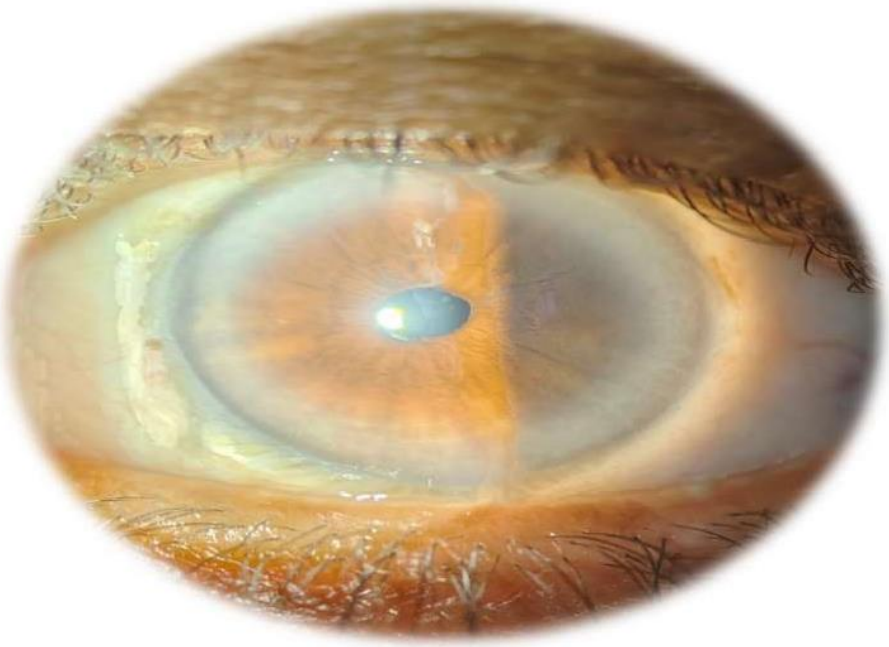
Device Insertion



Device In Situ Pupil



Device Removal



Postoperative Pupil Shape

ANNEXURE V: KEY TO MASTER CHART

Male	=	M
Female	=	F
Diabetes Mellitus	=	DM
Hypertension	=	HTN
Left Eye	=	LE
Right Eye	=	RE
Diminution of vision	=	DOV
Visual Acuity	=	VA
Senile Immature Cataract	=	SIMC
Senile Mature Cataract	=	SMC
Hypermature Cataract	=	HMC
Posterior supcapsular cataract	=	PSC
Posterior Polar Cataract	=	PPC

ANNEXURE VI :MASTERCHART

SL .NO	AGE	SEX	DM	HTN	DOV (RE/LE)	VA	PXF	DIAGNOSIS	PRE OP IOP	POD 1 IOP	POD 28 IOP	PREOP	MYDRIATIC	INTRACAMERAL EPINEPHRINE	DEVICE INSERTIN	DEVICE REMOVAL	COMPLICATIONS	POD 1	POD 28	PUPIL SHAPE
1	70	M	NO	NO	LE	PL +PR ACC	NO	LE SMC	12.1	11.6	10.3	1.5MM	5MM	5.5MM	7MM	5MM	CORNEAL EDEMA	4MM	3MM	ROUND
2	59	M	NO	NO	LE	6/36	NO	LE SIMC	11.8	17.8	17.3	2MM	5MM	5MM	6.5MM	4MM	CORNEAL EDEMA	4MM	3.5MM	IRREGULAR
3	54	M	YES	NO	LE	PL +PR ACC	NO	LE SMC	10.8	43	19.2	2MM	5MM	5.5MM	6.5MM	4MM	IRIS BLEEDING	5MM	3MM	IRREGULAR
4	56	M	YES	YES	RE	CFCF	NO	RE SIMC	16.3	18.7	15.4	3MM	5MM	5.5MM	6.5MM	5MM	NIL	4MM	3MM	ROUND
5	65	F	NO	NO	RE	PL +PR ACC	YES	RE HMC	9.5	11.2	10.2	3MM	5MM	5.5MM	6.5MM	5MM	CORNEAL EDEMA	5MM	3.5MM	ROUND
6	64	M	NO	NO	LE	CF 1M	NO	LE SIMC	8.8	10.5	11.3	2MM	4MM	4.5MM	6MM	5.5MM	FLOPPY IRIS	5MM	3MM	IRREGULAR
7	60	F	YES	NO	RE	CF 1M	NO	RE SIMC	23.4	20.7	19.6	3MM	5MM	5.5MM	6.5MM	5.5MM	NIL	4.5MM	4MM	ROUND
8	60	M	NO	YES	RE	6/60	YES	RE SIMC	14.6	10.2	13.6	3MM	5MM	5.5MM	6.5MM	6MM	CORNEAL EDEMA	5MM	3MM	ROUND
9	85	M	YES	NO	RE	CF 1M	NO	RE SIMC	8.5	13.2	17.9	1.5MM	4.5MM	5MM	6.5MM	6MM	NIL	5.5MM	4MM	ROUND
10	72	F	YES	YES	RE	6/36	NO	RE SIMC	13.8	14.2	13.7	2MM	5MM	5MM	6.5MM	5MM	NIL	4MM	3MM	IRREGULAR
11	65	F	NO	NO	LE	CF 2M	NO	LE SIMC	8.5	12.2	10.5	2MM	4.5MM	5.5MM	6.5MM	6.5MM	CORNEAL EDEMA	5MM	4MM	IRREGULAR
12	61	F	NO	NO	LE	6/60	NO	LE SIMC	14.6	13.2	17.8	1.5MM	5MM	5.5MM	7MM	6MM	IRIS BLEEDING	4.5MM	3.5MM	ROUND
13	71	F	YES	YES	RE	CF 1.5M	YES	RE SIMC	14.6	13.5	19.2	2MM	4.5MM	5MM	6.5MM	5MM	CORNEAL EDEMA	4MM	4MM	ROUND
14	65	M	NO	YES	RE	PL +PR ACC	NO	RE SMC	14.6	12.3	11.2	2MM	4.5MM	5MM	6.5MM	6MM	NIL	5MM	3MM	IRREGULAR
15	55	M	NO	NO	LE	PL +PR ACC	YES	LE SMC	16.8	13.5	17.3	1.5MM	4.5MM	5.5MM	6.5MM	5.5MM	NIL	5MM	3.5MM	ROUND
16	70	F	NO	YES	LE	6/24	YES	LE SIMC	12.5	13.2	15.6	2MM	5MM	5.5MM	6.5MM	6MM	NIL	5MM	4MM	IRREGULAR
17	84	M	NO	YES	RE	6/36	NO	RE SIMC	11.2	10.3	14.5	3MM	5MM	5.5MM	6.5MM	5.5MM	CORNEAL EDEMA	5MM	3MM	ROUND
18	75	F	NO	NO	LE	CFCF	NO	LE SIMC	15.2	17.9	15.3	3MM	5MM	5.5MM	6.5MM	5MM	NIL	5MM	3.5MM	ROUND
19	70	F	NO	YES	RE	6/24	YES	RE PPC	12.2	18.5	13.4	2MM	5MM	5.5MM	6MM	5MM	NIL	5MM	4MM	ROUND
20	76	M	YES	YES	LE	CF 1M	NO	LE SIMC	17	15.6	13.8	2MM	5MM	5MM	7MM	5MM	IRIS BLEEDING	4MM	3.5MM	IRREGULAR
21	78	F	NO	NO	LE	CF1/2M	YES	LE SIMC	16.9	17.9	13.4	3MM	5MM	5.5MM	6.5MM	5MM	NIL	4MM	3MM	IRREGULAR
22	60	F	NO	NO	LE	CF 2M	YES	LE SIMC	10.2	16.9	14.7	2MM	5MM	5.5MM	7MM	5MM	CORNEAL EDEMA	4MM	3MM	ROUND
23	60	F	YES	NO	RE	CF 1M	YES	RE SIMC	10.2	15.7	13.6	2MM	5MM	5.5MM	6.5MM	5MM	CORNEAL EDEMA	4.5MM	3MM	ROUND
24	55	F	NO	YES	RE	6/18	NO	RE PSC	13.3	15.4	13.8	3MM	5MM	5.5MM	6.5MM	6MM	NIL	5MM	3.5MM	IRREGULAR
25	50	F	YES	NO	LE	CF 2M	NO	LE SIMC	12.3	16.5	12.8	2MM	5MM	5.5MM	6MM	5MM	NIL	5MM	4MM	ROUND
26	65	M	NO	NO	LE	6/36	YES	LE SIMC	7.1	12.4	17.5	2MM	5MM	5MM	6.5MM	5.5MM	CORNEAL EDEMA	5MM	4MM	ROUND
27	80	F	NO	NO	RE	CF 1.5M	NO	RE SIMC	15.3	20.3	17.3	3MM	5MM	5.5MM	6.5MM	5MM	NIL	4MM	3MM	ROUND
28	72	F	YES	NO	RE	CF 2M	NO	RE SIMC	17.8	20.4	18.4	3MM	5MM	6MM	7MM	6MM	NIL	5MM	3.5MM	ROUND
29	59	M	YES	YES	LE	PL +PR ACC	YES	LE SMC	18.1	20.1	17.8	2MM	5MM	5.5MM	6.5MM	5.5MM	FLOPPY IRIS	5MM	4MM	IRREGULAR
30	76	M	YES	YES	LE	CF 1M	NO	LE SIMC	18.7	20.1	17.3	3MM	5MM	5.5MM	7MM	6MM	CORNEAL EDEMA	5MM	3MM	ROUND
31	74	F	YES	YES	LE	CF 1M	NO	LE SIMC	21.7	19.8	18.7	2MM	4.5MM	5MM	6MM	5MM	NIL	5MM	3.5MM	ROUND
32	76	F	NO	YES	RE	CF 1M	NO	RE SIMC	16.1	19.3	17.5	3MM	5MM	6MM	6.5MM	6MM	CORNEAL EDEMA	5.5MM	3.5MM	IRREGULAR
33	65	M	NO	YES	LE	6/24	NO	LE SIMC	11.3	17.9	17	3MM	5MM	5.5MM	6.5MM	5.5MM	NIL	5MM	4MM	ROUND
34	70	M	YES	NO	LE	CFCF	NO	LE SIMC	20.2	19.7	16.1	2MM	5MM	5MM	6.5MM	5MM	NIL	5MM	3MM	ROUND
35	48	F	NO	YES	LE	6/60	YES	LE SIMC	17.3	19.3	17.9	2MM	5MM	5.5MM	6.5MM	6MM	NIL	5MM	4MM	ROUND
36	47	F	YES	YES	LE	CFCF	NO	LE SMC	13.5	19.3	19	3MM	5MM	5.5MM	6.5MM	6MM	IRIS BLEEDING	5MM	3.5MM	IRREGULAR
37	82	M	NO	YES	LE	CF 2M	NO	LE SIMC	14.2	10.2	11.7	3MM	5MM	5MM	6.5MM	5MM	NIL	5MM	3.5MM	ROUND

38	65	M	NO	NO	RE	HMCF	NO	RE SMC	7.3	15.6	15.1	3MM	5MM	6MM	7MM	5.5MM	CORNEAL EDEMA	5MM	4MM	ROUND
39	60	F	NO	YES	RE	PL +PR ACC	NO	RE SMC	9.8	15.3	14.1	3MM	5MM	5.5MM	6.5MM	5MM	CORNEAL EDEMA	4MM	3MM	IRREGULAR
40	73	M	YES	YES	RE	HMCF	NO	RE SIMC	9.7	17.3	15.3	3MM	5MM	6MM	6.5MM	5.5MM	NIL	5MM	4MM	IRREGULAR
41	78	M	YES	NO	RE	CF 2M	NO	RE SIMC	19.5	21.3	18.1	2MM	5MM	5.5MM	6.5MM	5.5MM	NIL	5MM	4MM	ROUND
42	75	M	NO	YES	RE	PL +PR ACC	NO	RE SMC	20.8	20.1	17.3	2MM	5MM	5.5MM	6.5MM	5.5MM	CORNEAL EDEMA	5MM	4MM	ROUND
43	65	M	NO	YES	LE	HMCF	NO	LE SMC	20.1	19.3	17.4	2MM	5MM	5.5MM	6.5MM	6MM	NIL	5MM	3.5MM	ROUND
44	71	M	NO	NO	LE	CF 2M	YES	LE SIMC	11.8	10.3	15.4	2MM	5MM	5.5MM	6.5MM	5.5MM	CORNEAL EDEMA	5MM	4MM	IRREGULAR
45	63	F	YES	YES	RE	HMCF	NO	RE SIMC	17.8	19.7	20.1	2MM	5MM	5.5MM	6.5MM	5.5MM	NIL	5MM	4MM	ROUND
46	69	M	YES	NO	RE	CF 2M	YES	RE SIMC	21.5	23.2	20.3	3MM	5MM	5.5MM	6MM	5.5MM	CORNEAL EDEMA	5MM	4MM	IRREGULAR
47	61	M	NO	YES	LE	6/24	NO	LE SIMC	15.4	18.7	15.3	2MM	5MM	5.5MM	6.5MM	5MM	NIL	5MM	4MM	IRREGULAR
48	60	M	YES	NO	RE	6/60	NO	RE SIMC	19.5	21.3	18.1	2MM	5MM	5.5MM	6.5MM	5.5MM	NIL	5MM	4MM	ROUND