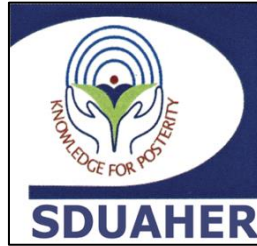


**“EVALUATION OF EFFICACY AND SAFETY OF TORIC INTRAOCULAR
LENS IMPLANTATION IN CATARACT PATIENTS WITH PRE EXISTING
ASTIGMATISM”**

By

DR. BORRA HARISH LAXMAN



Dissertation submitted to the
**SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND
RESEARCH CENTRE KOLAR**

In partial fulfillment of the requirements for the degree of

**MASTER OF SURGERY
IN
OPHTHALMOLOGY**

Under the guidance of

DR. K. KANTHAMANI, MBBS., MS.,



**DEPARTMENT OF OPHTHALMOLOGY
SRI DEVARAJ URS MEDICAL COLLEGE
TAMAKA, KOLAR**

April 2019

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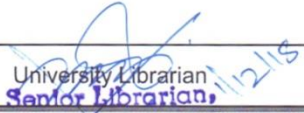


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LIST OF ABBREVIATIONS

SL NO	ABBREVIATIONS	FULL FORM
1	ICCE	Intra capsular cataract extraction
2	ECCE	Extra capsular cataract extraction
3	SICS	Small incision cataract extraction
4	IOL	Intraocular lens
5	D	Diopter
6	PAK	Photo-aastigmatic-keratectomy
7	WTR	With the rule astigmatism
8	ATR	Against the rule astigmatism
9	SIA	Surgically induced astigmatism
10	UDVA	Uncorrected distant visual acuity
11	CDVA	Corrected distant visual acuity
12	PMMA	Polymethylmethacrylate
13	RCT	Randomized control trial
14	LRI	Limbal relaxing incision
15	ORA	Optiwave Refractive Analysis
16	LASIK	laser-assisted <i>in situ</i> keratomileusis
17	SRK-T	Sanders –Retzlaff –Kraff
18	FLACS	Femtosecond assisted cataract surgery
19	KV	Vertical corneal curvature
20	KH	Horizontal corneal curvature
21	IOP	Intraocular pressure
22	AL	Axial length

ABSTRACT

TITLE: “EVALUATION OF EFFICACY AND SAFETY OF TORIC INTRAOCULAR LENS IMPLANTATION IN CATARACT PATIENTS WITH PRE EXISTING ASTIGMATISM”

NEED FOR THE STUDY: The cataract surgery has evolved from a mere visual rehabilitation to a refractive procedure. This is due to precise preoperative biometry, intraocular lens (IOL) power calculations and improved surgical techniques. Postoperative spectacle independence is the expectations of both the patients as well as surgeons. In patients undergoing cataract surgery, the prevalence of pre-existing astigmatism of >1.5D is 20%, which is one of the important cause of low vision postoperatively. ¹

This astigmatism can be treated by various procedures like Incision on steep meridian axis, Limbal relaxing incision and Corneal relaxing incision performed either alone or in combination, but predictability of correction is variable and shortlived.²

Toric IOL designed to replace the cataractous lens of an eye and to correct astigmatism in achieving emmetropia, but there are many studies about the efficacy and safety of toric IOL with variable results³ So we intended to do a study on efficacy and safety of toric IOL in correcting pre existing astigmatism.

OBJECTIVES:

1. To evaluate the efficacy of toric IOL in terms of visual and refractive outcome.
2. To evaluate the safety of toric IOL in terms of rotational stability and other complications.

RESULTS: The present study comprises of 42 eyes of 42 patients divided randomly into 2 groups, comprising 21 patients in each group. The mean age of patients in group 1 was 65.14 yrs (ranged from 50-75 years) and in group 2 was 59.19 (ranged from 45-75 years). Majority of patients in group 1 and group 2 were in the range of 61-70 years, comprising 71.4% and 38.1% respectively.

Group 1 had 9 (42.9%) male patients and 12 (57.1%) female patients and group 2 had 12 (57.1%) male and 9 (42.9%) female. The mean preoperative astigmatism in group 1 was 1.94 +/-0.38 and group 2 was 1.83 +/- 0.33.

After 6 months of post-operative period, the total mean astigmatism is in the range of 0.76 +/-0.51 with group 1 patients having mean astigmatism of 0.40 +/- 0.12 and group 2 patients having astigmatism of 0.76 +/- 0.51.

The mean preoperative UDVA in our study group 1 is 1.71+/-0.50 log MAR improved to 0.06+/-0.09 logMAR, Which was statistically significant. In group 2 is 1.76+/-0.47 logMAR improved to 0.24+/-0.05log MAR.

In our study, we did not encounter any IOL misalignment of more than 5 degrees which we considered significant. No patient underwent any IOL re-dialing. No other complications related to phacoemulsification are encountered in the study.

CONCLUSION:

With the inferences drawn from the study we conclude that,

- The final visual outcome in patients with pre-existing astigmatism who underwent phacoemulsification with Toric IOL implantation was significantly better when compared to Patients in non-Toric IOL group.
- It also reduces the mean preoperative astigmatism compared to non-Toric IOL.

- The Toric IOL gives best un-corrected visual acuity by eliminating preoperative astigmatism. But the results depend on accurate preoperative assessment of astigmatism, precise marking under the slitlamp, perfect alignment of IOL and thorough removal of visco-elastic substance at the end of surgery is essential in maintaining the rotational stability of the IOL.
- In our study we conclude that, Toric IOL is better in correcting preoperative corneal astigmatism and provides best un-corrected visual acuity when compared to non-Toric IOL, thus making patients independent of spectacles.

KEYWORDS: cataract, phacoemulsification, astigmatism and Toric IOL.

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Introduction



Objectives

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Review of Literature



Materials and methods

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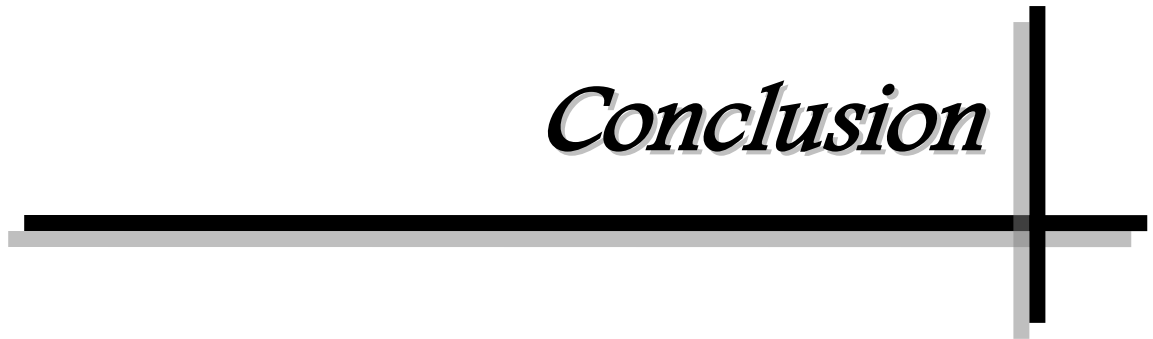
Results



Discussion

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Conclusion



Summary



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INTRODUCTION

Cataract, an opacification of crystalline lens or its capsule, whether developmental or acquired is the leading cause of avoidable blindness in India and other developing country accounting for about three quarters of the blindness. The World Health Organization estimates that the current global prevalence of blindness is 0.57% (range: 0.2%–1%), with more than 82% of all blindness occurring in individuals aged 50 and older. Cataract accounts for 41.8% of the world's roughly 37 million blind individuals.⁽¹⁾ In India cataract has been reported to be responsible for 50-80% of the bilaterally blind individuals.

Cataract surgery had advanced from Sushruta's couching method, Intracapsular cataract extraction (ICCE), conventional Extracapsular cataract extraction (ECCE), Small incision cataract surgery (SICS), phacoemulsification to most recent femtosecond cataract surgery.

Phacoemulsification with foldable IOL implantation is the treatment of choice for cataract patients. The spherical power of the patient is completely treated with implantation of IOL, but the astigmatism after the surgery is left untreated.

The cataract surgery has evolved from a mere visual rehabilitation to a refractive procedure. This is due to precise preoperative biometry, intraocular lens (IOL) power calculations and improved surgical techniques. Postoperative spectacle independence is the expectations of both the patients as well as surgeons. In patients undergoing cataract surgery, routine spherical lenses will not reduce the astigmatism. The prevalence of pre-existing astigmatism of >1.5D is 20%, which is one of the important causes of low vision postoperatively.¹ Significant astigmatism may be visually disabling causing diminution in visual acuity, glare, monocular diplopia, asthenopia and distortion.

Treating astigmatism is the biggest challenge that ophthalmologists are facing. the pre-existing corneal astigmatism can be managed by various methods such as the following which can be used alone or in combination:

1. Incision on steep meridian axis in cases with corneal astigmatism between 0.5–1D
2. Limbal relaxing incision and Corneal relaxing incision were proposed by Muller-Jensen et al to treat regular corneal astigmatism between 1–1.5D.²
3. Toric intraocular lenses – are commercially available & effective in treating > 1.5D of corneal astigmatism at the IOL plane.
4. Photo-astigmatic keratectomy(PAK) – reported to be effective in the correction of residual refractive errors in pseudophakic eyes. PAK is more effective than LRI in the control of pre-existing manifest astigmatism, whereas the shortcomings of PAK include accentuation of the spherical high-order aberrations, additional surgery, and high costs.

Patients with significant amount of preoperative astigmatism can benefit from the above-mentioned options. Hence, we have undertaken this study to determine the prevalence of preoperative corneal astigmatism to plan for an appropriate method to eliminate the same to achieve emmetropic vision.

The length of incision, site of incision, type of suture and material used are modified over years, these are used to reduce the astigmatism postoperatively, but the results are varied. so Toric IOL was designed.

The Toric IOL has been used clinically to correct astigmatism. Initially plate haptic Toric IOL was used, but failed to correct astigmatism because of poor rotational stability. 'Newer Toric IOLs are made of acrylic' material and with haptic having better rotational stability. These IOLs are of made up of hydrophilic and hydrophobic material. Toric IOL was designed to replace the cataractous lens of an eye and to

correct astigmatism in achieving emmetropia.³ So we intended to conduct a study on efficacy and safety of Toric IOL in correcting preexisting astigmatism.

OBJECTVES OF STUDY

1. To evaluate the efficacy of toric IOL in terms of visual and refractive outcome.
2. To evaluate the safety of toric IOL in terms of rotational stability and other complications.

REVIEW OF LITERATURE

Cataract means “clouding of lens”. The vision will depend on cornea, anterior chamber, lens, refractive media, vitreous and retina. Among them cornea and lens are the major contributors.

ANATOMY OF CORNEA AND LENS CORNEA

The cornea is an avascular structure with a convex surface and inner concave surface. It is smooth and transparent structure with optical function. It has refractive power of 40-45 D and refractive index of 1.376. The Horizontal diameter of anterior surface of cornea is 11.7mm and vertical diameter is 10.67mm. The cornea is usually more steeper in vertical meridian than horizontal meridian, leading to ‘with the rule’ astigmatism. In adults the radius of curvatur

e of anterior surface is 7.8mm and posterior surface is 6.5mm.⁴

Histology: Cornea has six layers from anterior to posterior:

1. Epithelium
2. Bowman’s layer
3. Stroma
4. Dues layer
5. Descements membrane
6. Endothelium

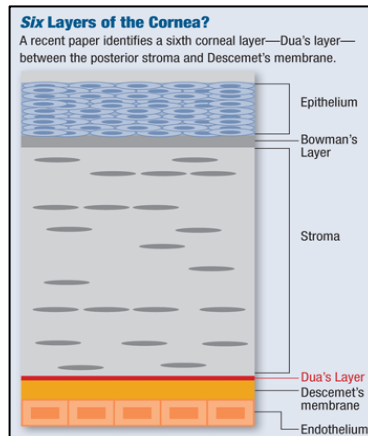


Fig 1: Layers of Cornea

EPITHELIUM:

The corneal epithelium is composed of stratified squamous epithelium which is non-keratinized. It consists of 5-6 layers of nucleated cells with 5090um thickness. The germinative layer of the epithelium is the layer of basal cells, which is made up of columnar cells with rounded heads & flat bases. Wing or umbrella cells forms the second epithelium layer, made up of polyhedral cells, they cap the basal cells and send processes. The other 2-3 layers are composed of polyhedral cells, they become flatter and wider towards the surface. In periphery, the surface cells have the largest surface area than the centre. In the epithelium, 70% of the wet weight is due to the water, whereas nitrogen and total lipids forms 11.9% and 5.4% respectively. The necessary enzymes for Embden-Mayerhoff and Pentose shunt pathways of the glucose metabolism and also the kreb's cycle for oxidation of pyruvic acid.⁴

BOWMAN'S LAYER:

It is the layer just beneath the corneal epithelium and is a narrow layer with acellular homogenous zone of 8-14um thick. Bowman's layer is resistance to infection & injury, but if damaged will not regenerate.⁵

STROMA:

Stroma is the thickest layer of about 500 um thick, contains regularly arranged lamellae of collagen bundles. water is the major constituent of stroma forming 75-80% and rest is made up of collagen and glycosoaminoglycans. The concentration of glycosoaminoglycans is more in stroma, in the form of keratin sulphate, chondroitin sulphate and chondroitin. These are responsible for swelling of stroma by imbibing water into it. Stroma is mainly made up of type 1 collagen, type 5 and 6 are also found in lesser quantity. In central stroma, fibrils are arranged parallelly and extends to the periphery and forms a concentric configuration at limbus. This gives strength to the peripheral cornea and maintains its curvature for optical function.⁵

PRE-DESCEMETS MEMBRANE/DUA'S LAYER:

It was discovered in 2013 by Dr. Harinder Dua. It is located anterior to the descemets membrane and 15 micrometer thick acellular structure. It is a tough layer.

DESCEMENTS MEMBRANE:

In adults, it is 10-12um thick and it is the basal lamina of corneal endothelium. Descemet's membrane forms a strong homogenous basement membrane of the endothelium. It is made up of collagen and glycoproteins. It cannot regenerate and shows resistance to chemical agents and trauma. It continues anteriorly as schwalbe's line, which is the anterior limit of trabecular meshwork.⁵

ENDOTHELIUM:

In this layer, flat polygonal epithelial cells appear as a Mosaic. Normally, Endothelial cell count in young adults is 3000 cells/mm², with increasing age count decreases.

The endothelial cells do not proliferate & contain 'active pump' mechanism to keep cornea hydrated.⁵

OPTICAL PROPERTIES OF CORNEA:

Cornea is major contributor for the optical activity of eye. Its structural properties are:

1. Surface is smooth
2. Asphericity
3. Transparency

Three optical zones are present

1. A spherical central optical zone 3-4 mm.
2. An aspherical, less steep, mid peripheral zone (5.0 - 7.0mm)
3. A still flatter limbal zone.

Hence the central cornea is optically crucial.^{4,5,8}

LIMBUS:

Limbus is wider vertically than horizontally and varies from 1-2mm. There is an anterior bluish zone, above the clear cornea & posterior to schwalbe's line forming the surgical limbus. Limbus is relatively avascular zone.⁹

LENS:

Lens is a biconvex, transparent structure placed in a saucer shaped depression, the patellar fossa. Thickness varies with age from 3.5mm – 5mm and has a diameter of 9-10mm. There are two surfaces anterior surface and posterior surface of which anterior is less convex than posterior surface. It has refractive index of 1.39 and refractive power of 16-17D.^{5,10}

The lens has:

1. Lens capsule
2. Anterior epithelium
3. Lens fibres.

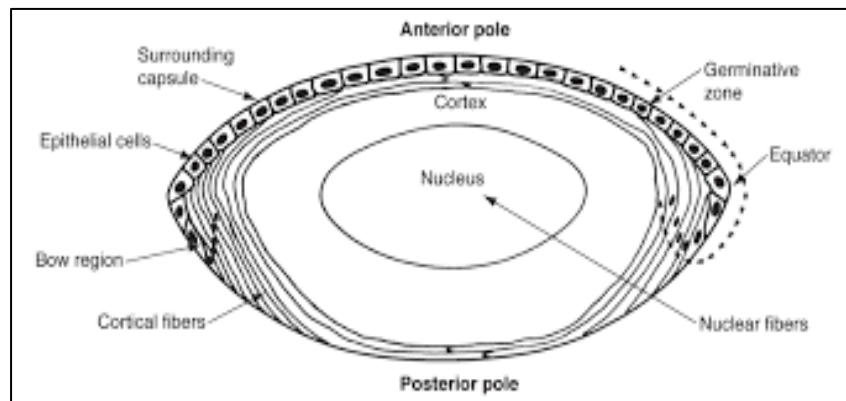


Fig 2: Parts of the human crystalline lens

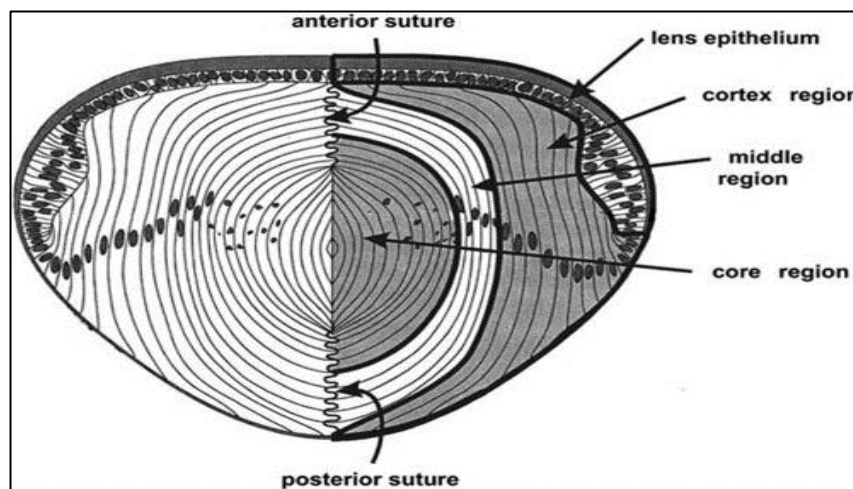


Fig 3: Lens fibres with equatorial germinal cells

LENS CAPSULE:

The capsule is a transparent, thin, hyaline collagenous membrane around the lens. Anterior capsule is secreted by the anterior basal cells and posterior capsule by the basal area of elongating fibres. Anterior capsule is thicker than posterior. It is made up of type 4 collagen & 10% glycosaminoglycans.^{5,10}

EPITHELIUM OF LENS:

Just beneath the anterior capsule, single layer of cuboidal epithelium cells form the anterior lens epithelium. These cuboidal cells become columnar cells in the equatorial region and actively forms lens fibres throughout the life. It is divided into 3 zones:

- a) Central zone
- b) Intermediate zone
- c) Germinative zone

The posterior capsule is devoid of epithelium .^{5,10}

LENS FIBRES CONSISTING OF CORTEX AND NUCLEUS:

At equator, epithelial cells multiply & differentiate to form the lens fibres. Lens fibres are about 10mm long, forms hexagonal prism. The older fibres forms the centre/nucleus and newly formed fibres forms the cortex. The lens fibres are tightly packed with lesser intercellular spaces.¹¹

ZONAL ARRANGEMENT OF THE LENS FIBRES:

The lens fibres will be formed throughout the life and based on development of lens they are arranged in zones.

- a) Nucleus: It contains older fibres, they are arranged from inner to outer as embryonic nucleus, fetal nucleus, infantile nucleus and the adult nucleus.
- b) Cortex: It forms the peripheral part, made up of youngest fibres.⁵

BIOCHEMICAL PROPERTIES IF LENS:

Lens contain 65% of water and highest protein content than any organ in the body. Lens proteins are divided into albuminoids & crystallins. Crystallins are made up of

over 90% of proteins which are water soluble. There are 3 types of crystallins in human eye i.e. **a,b & Y**, these forms the soluble and high molecular weight aggregates that pack lens fibres tightly. So this increases the refractive index of lens. **a** crystallins are found in the others parts of the eye and the body, **b & Y** are only found in lens. These belong to superfamily of chaperone proteins. The chaperone maintain the lens protein which last the entire life.¹² The lens transparency is maintained by the absence of organelles such as endoplasmic reticulum, nucleus & mitochondria within the mature lens fibres. The shape of the lens fibres is maintained by cytoskeleton, disruption/mutations of this leads to loss of transparency.⁵

THE CILIARY ZONULES: (zonules of zinn/suspensory ligaments of lens)

These run from ciliary body to the outer layer of lens capsule in the equatorial zone. This will hold the lens in position & ciliary muscles will act on them.⁵

HISTORY OF CATARACT:

The formation of cataract concept is of full of interest. The first record of cataract came from ancient Hindu medicines. Sushruta (6th century BC) was the first surgeon of Indian origin who described early cataract surgery. The Indian tradition of cataract surgery was performed with a special tool called the jabamukhi salaka, a curved needle used to loosen the lens and push the cataract out of field of vision. The first description says,

He [the surgeon] scratches the eyeball [lens] with the point of a lancet which has been wrapped in hemp [a marker to determine how deep to plunge the lancet into the eye].... If the patient then recognizes forms, the lancet is slowly withdrawn and molten butter is put on the eye....¹³

These surgeries in India were performed by physicians. The removal of cataract by surgery was introduced from India to china.

The term '*cataract*' was introduced by **Constantinus Africanus** (AD 1018)¹⁴ who was a monk. He translated Arabic suffusion to Latin.

Early surgeons had no idea what they were trying to push away from behind the pupil. It was in the 18th century, Antoine maitre-jan and Michel Pierre Brisseau (1708)¹⁵ identified it as Lens.

1747 – **Jacques Daviel**, French ophthalmologist is credited with first Extracapsular Cataract Extraction. This technique uses a small incision to remove the lens and minimize the wound.^{17,18}

1753 – **Samuel sharp**, London surgeon was the first surgeon to perform Intracapsular Cataract Extraction, a technique that uses a large incision to remove the entire natural lens and capsule.¹²

1949 – **Sir Harold Ridley** in London was the first surgeon to introduce the Intraocular lenses. These manmade lenses are made up of polymethylmethacrylate.^{7,11}

1950 – The first foldable IOL's made up of hydrogel are introduced and allow for smaller incisions and faster healing time.

1967 – **Dr. Charles Kelman**, first introduced the phacoemulsification surgery. It uses ultrasonography to break the cataract into small pieces, so that it can be aspirated and replaced with an IOL.¹⁹

1978 – **Kai-yi Zhou** invented the world's first foldable IOL made up of silicone.

1997 – FDA approves first multifocal IOL. These IOL's provide good quality vision for

multiple distances.²⁰

1998 – Toric IOLs were invented to correct astigmatism. The Toric IOLs will have different powers in different meridians of the lens to correct the Astigmatism power of the eye.

2004 – Aspheric IOLs are those which closely match the shape and optical quality of natural eye.²¹

2010 – FDA approved Femtosecond laser for cataract surgery. It replaces and supports the

phacoemulsification.²²

In the 20th century phacoemulsification is the greatest innovation. In this nucleus can be removed through a 3mm incision by eliminating complications. Dr. Charles Kelman quoted in his book as **“those of us who perform the technique become enamoured of the procedure, elated by the white, quite post of eyes, proud of the work as an artist is proud and empathetic with the patient who go back at work the next day proclaim that he had a cataract removed the day before and has no physical limitation”**. The ultimate goal of ideal cataract is very close.

PHACOEMULSIFICATION

The cataract removal is done by using ultrasound fragmentation and aspiration of lens material. The probe tip is made up of hollow 1mm titanium needle, it transmits the vibrations at rate of 27,000-60,000 cycles/sec for emulsifying the cataract. The phaco

tip varies from 0° to 60° , with 15° tip having more holding power and 60° tip has more cutting power. This phaco tip is connected to phaco machine called as console. ²³

THE PHYSICS OF PHACO:

Brief overview:^{24,25,26}

The titanium tip accelerates at 27,000 to 60,000 Hz connected to a transducer which changes electrical energy to mechanical energy. This allows surgeons to overcome the inertia and emulsifies the nucleus.

PHACO HAND PIECE:

The phaco tips have variable beveled angles varying from 0° , 15° , 30° , 45° , 60° . Sharper tip bevels are better for cutting nuclear material, where as lower angled tips are better for engaging nuclear material.

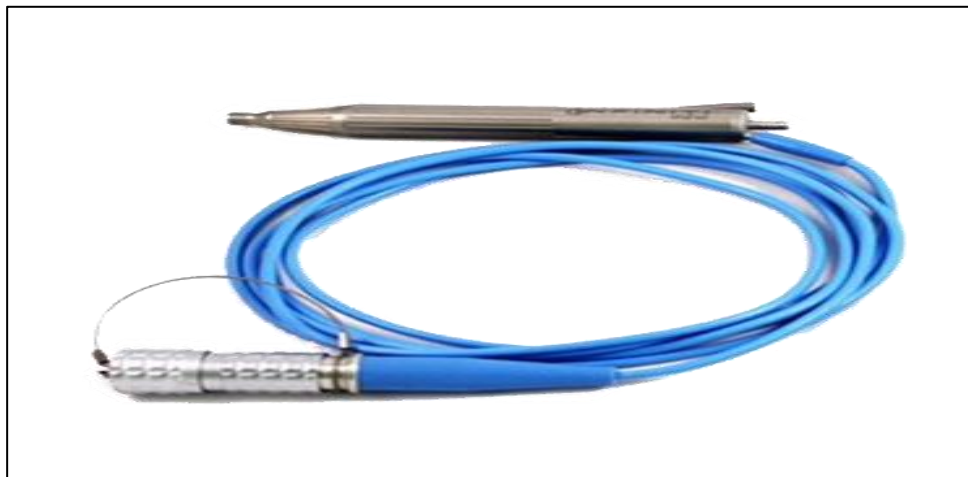


Fig 4: Phaco hand piece

PHACO TIP/NEEDLES:

Phaco needle is made up of titanium.

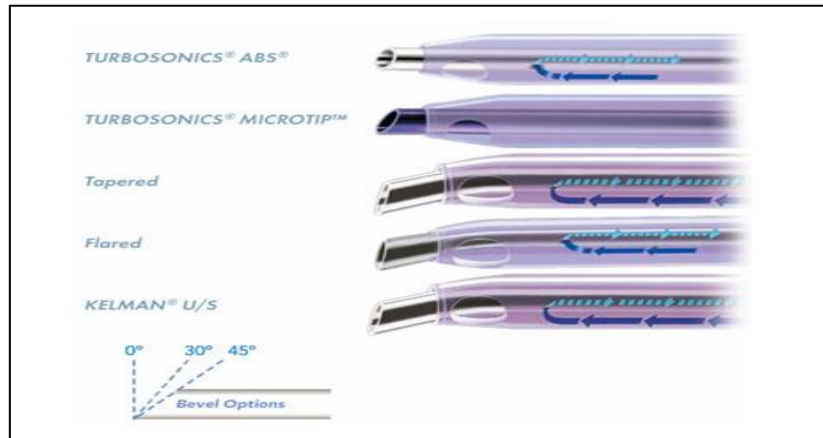


Fig 5: Phaco needle tip

FOOT PEDAL:

There are four modes in phaco machine- 0,1,2 and 3.

Position 'O' refers to resting, fully upright point of foot pedal.

The others three positions 1,2 and 3 refer to the range of foot pedal.

In position 1, irrigation is present.

In position 2, irrigation and aspiration are present.

In position 3, irrigation, aspiration and phaco power are present.



Fig 6: Foot pedal

PHACODYNAMICS:

Phaco Power: The ability of hand piece to emulsify or cut the cataract. It is directly related to stroke length, frequency and efficiency of phaco hand piece.

Stroke length: The distance by which phaco tip moves to and pro. It is important factor in deciding phaco power.

Frequency: The number of times the tip moves, this is fixed for a particular phaco hand piece and measured in KHz.

Continuous Vs Pulse Phaco Power: In pulse mode phaco power is delivered at preset intervals. In a continuous mode, power is delivered Continuously and it can be linear or panel controlled.

Maximum Phaco Power: The maximum obtainable ultrasonic energy, when foot pedal is fully depressed.

Actual Phaco Power: It depends on foot pedal position and represents the actual power being delivered at a given time.

Effective Phaco Time: it is defined as total phaco time at 100% phaco power.

IRRIGATION AND ASPIRATION SYSTEMS:

The main function of this system is to maintain stable anterior chamber during phacoemulsification. It helps in preventing damage to corneal endothelium, iris and posterior capsule.

IRRIGATION VALUES:

1. Bottle height is 22-30 inches above the eye.
2. Inflow port is fixed at 1mm.

ASPIRATION VARIABLES:

1. Aspiration rate – volume of fluid aspirated per unit time.

2. Aspiration level – occlusion of aspiration tip shows the amount of vacuum generated

3. Aspiration pump types:

a) Peristaltic pump:

- Vacuum is created by rotating cans sequentially compressing plastic tubing.
- Aspiration level (vacuum) and aspiration rate (flow) are independent variable.

In a peristaltic pump, vacuum is not created until aspirated is occluded. The development of vacuum to the preset level is usually slower.

The speed of peristaltic pump increases by depressing the foot pedal.

b) Venturi pump:

- Compressed air passing through venturi tube creates vacuum.
- Exquisite control of vacuum level is present.

c) Diaphragmatic pump:

- Vacuum pump creates vacuum
- Aspiration level (vacuum) is fixed with relationship to flow
- Occlusion of aspiration port is not necessary to create vacuum.
- Increasing depression of the foot pedal increases the amount of vacuum.
- The rate of development of vacuum is rapid.

PHACO VARIABLES:

- Pump flow: The pump flow or aspiration is preset by the surgeon. It is a measure of rotational speed of the peristaltic pump head, it determines the aspiration flow rate.

-
- Maximum vacuum: It is preset by surgeon. The maximum amount of vacuum obtained during complete occlusion of aspiration port.
 - The settings vary based on surgeon's preference and type of cataract.
 - Actual vacuum: the real time vacuum pressure at the aspiration port depends on position of foot pedal, maximum preset pump flow, degree of tip occlusion.

FLUIDICS OF PHACO SURGERY:^{24,25,26}

Fluidics has four components, they are:

- Inflow
- Aspiration
- Vacuum
- Energy

All the four parameters will play a role in Phaco Dynamics.

a) Fluid in (Infusion flow):

It is the rate of fluid entering the eye. It maintains the intraocular pressure, removes the particles and cools the hand piece. The fluid will enter the eye from bottle kept at about 65 cm above the patient head.

b) Fluid out: It occurs because of fluid leaks or fluid is pumped out.

- Fluid by leakage: It occurs in main incision site or side port. The leakage will depends on wound size, configuration and the way instruments are held.
- Fluid by pump action: Aspiration rate means the rate at which fluid is pulled out by pump action. Aspiration flow rate controls the movement of the phaco tip. It is called as followability.

c) Vacuum:

It is the negative pressure which is generated at the phaco tip and usually measured in mmHg.

Rise time: the time taken for vacuum to reach the level once the occlusion occurs to reach the preset value.

d) Phaco Energy: It is measured in joules. This is generated by tip vibration and cavitation. The tip vibrates and forms like mini jack hammer. The ability of the phaco energy to emulsify the cataract depends on the following factors:

- The direct impact of the tip on the lens at the end of its stroke.
- Cavitation – the process by which heat energy causes tiny bubbles to implode among them to create an energy wave, which destroys the nucleus of cataract.
- An acoustic wave is delivered through the fluid from the tip.
- Impact of fluid and lens particles which are pushed forward in front of the tip with a velocity of up to 72 Km/hr.

FACTORS CONTROLLING THE SURGICAL OUTCOMES:

1. Stable anterior chamber depth and intra ocular pressure – maintained by height of irrigation bottle, control of leakage, aspiration flow rate, Anti-surge mechanisms.
2. Followability – by control of aspiration flow rate.
3. Hold ability – control of vacuum.
4. Release of materials from tip – venting mechanisms.
5. Emulsification – phaco energy, frequency, design of top.

The incision site and size varies.^{25,26}

1. According to the size: size varies from 0.9-3mm.

-
2. According to the site:
 - a) Direct limbal
 - b) Limbal with scleral flap
 - c) Sclero-corneal
 - d) Clear corneal

The various technique used in the nucleus management are:^{7,26}

- Divide and conquer
- Four quadrants divide
- Phaco chop
- Stop and chop
- Chip and flip
- Spring surgery
- Choo-choo chop and flip

The technique used depends on the grading of cataract and surgeon's choice.²⁶

COMPLICATIONS OF PHACOEMULSIFICATION SURGERY:^{27,28,29}

Intraoperative complications:

1. Wound construction
 - a. Groove and limbal/scleral dissection too shallow
Wound will macerate and be difficult to close.
 - b. Groove and dissection too deep
May result in increased bleeding.
Possible damage to underlying uveal tissue.
 - c. Internal incision too posterior.

Likely iris prolapse

Injury to ciliary body

Bleeding

d. Internal incision too anterior.

Stripping of descemet's membrane

Corneal striae

e. Incision too tight

Leads to shallow anterior chamber due to crimping of silicon sleeve

'Oar-lock' of instruments

Corneoscleral burn

f. Incision too loose

Severe outflow

Increased endothelium damage

Shallow anterior chamber

2. Capsulotomy:

a. Too large

Difficulty in stabilizing nucleus for phaco techniques

Difficult to put IOL

b. Too small

Difficult to access nucleus and cortex

c. Anterior radial tears

Causes posterior capsule

3. Positive vitreous pressure:

a. It is seen by shallowing of anterior chamber. If the eye is

b. Soft: should rule out mechanical factors

-
- c. Firm: aqueous deviation syndrome Vs choroidal effusion.
 4. Posterior capsule tear with or without vitreous loss.
 5. The dropped nucleus.
 - a. Nucleus loss into anterior vitreous
 - b. Nucleus loss into posterior vitreous
 - Bleeding and hyphaema:
 - a. During incision
 - b. During closure
 - c. Internal wound margin

Post-operative complications:

A. Anterior segment:

1. Corneal complications
 - a. Edema: Due to
 - a) Mechanical trauma
 - b) Ultrasonic emissions
 - c) Endothelial damage – Bullous keratopathy
 - b. Astigmatism
2. Iris complications:
 - a) Trauma
 - b) Atrophy
 - c) Peaked pupil
 - d) Synechiae
 - e) Iridocyclitis
3. Glaucoma:

-
- a) Secondary to viscoelastic substances
 - b) Pupillary block glaucoma
 - c) Steroid induced glaucoma
 - d) Secondary to inflammation
4. Residual lens material: nuclear or cortical fragments
 5. Hyphaema
 6. IOL related complications
 7. Posterior capsular opacification

B. Posterior segment complications:

- Cystoid macular edema: most common following posterior capsular rupture and vitreous loss.
- Endophthalmitis

ADVANTAGES OF PHACOEMULSIFICATION:^{25,30}

- Less wound healing time
- Faster visual rehabilitation
- Less astigmatism due to small incision size.
- Reduced spectacle dependence
- Implantation of foldable IOL's

ASTIGMATISM AND CATARACT SURGERY³¹

1727 – Astigmatism was first considered by Sir Isaac Newton.

1811 – Thomas young considered lens as its cause.

1827 – Airy first to correct astigmatism with cylindrical lens.

1856 – Von Helmholtz described optics of aphakic eye.

1864 – Donders described that Against the Rule (ATR) follows cataract surgery.

1869 – Von Reuss measured astigmatism after cataract surgery with keratometer.

Astigmatism is a type of refraction, the condition of eye where a point focus of light cannot be formed on retina. The prevalence of astigmatism in general population is around 20- 40%.³² In patients undergoing cataract surgery, prevalence of astigmatism of more than 1.5D is 15-20%.³³ Astigmatism can occur due to change in curvature of cornea or refractive index.

Difference in the corneal curvature is responsible for the astigmatism of the eye. Astigmatic aberration also present on the posterior surface of the cornea and the lens, these contribute very less amount of astigmatism compared to anterior surface of cornea.

Types of astigmatism:

1. Regular astigmatism: In this two principal meridians are right angles to each other's.
 - a) Simple astigmatism: where one meridian falls upon the retina and other may fall in-front or behind the retina.

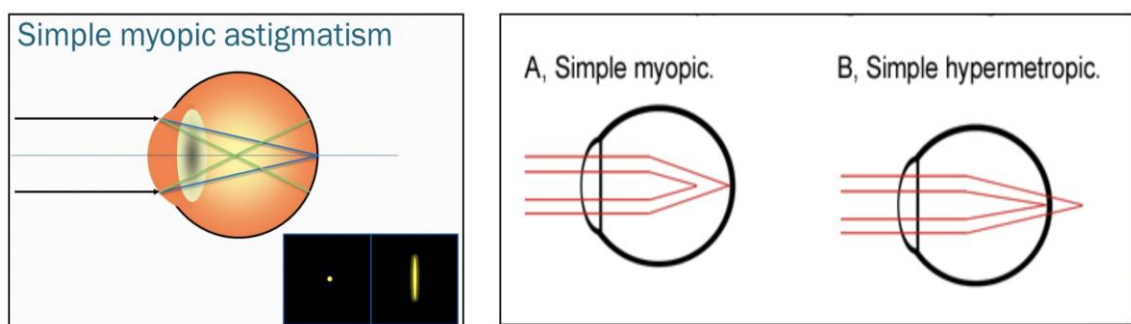


Fig 7: Simple myopic and hyperopic astigmatism

With the rule astigmatism – in this vertical meridian is steepest than the horizontal meridian.

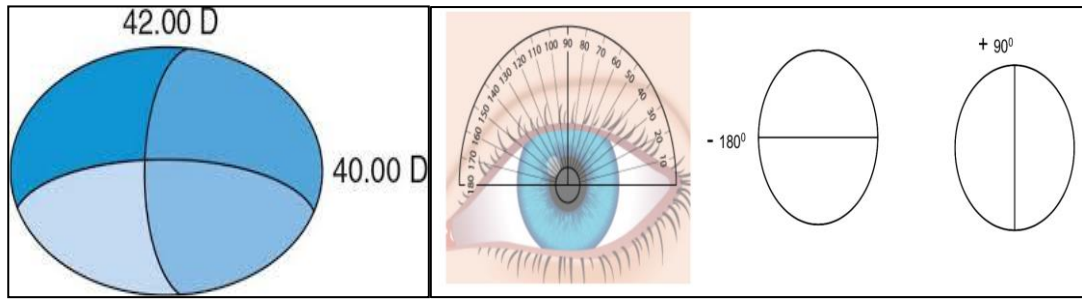


Fig 8: With the rule astigmatism

Against the rule astigmatism – in this horizontal meridian is steepest than the vertical meridian.

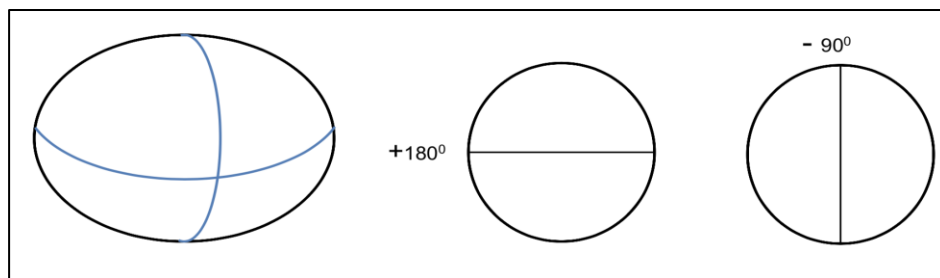


Fig 9: Against the rule astigmatism

Oblique astigmatism

- The two principal meridians are not the horizontal and vertical though these are at right angles to one another (e.g., 45° and 135°).
- Oblique astigmatism is often found to be symmetrical (e.g., cylindrical lens required at 30° in both eyes) or complementary (e.g., cylindrical lens required at 30° in one eye and at 150° in the other eye).

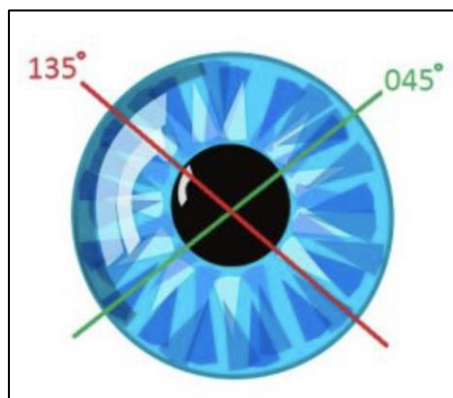


Fig 10: Oblique astigmatism

Optics of astigmatism: In regular astigmatism the parallel rays of light are not focused on a point but form two focal lines. The configuration of rays refracted through the astigmatic surface (toric Surface) is called *sturm's conoid* and the distance between the two focal lines is known as *focal interval* of sturm. The length of this focal interval is the measure of astigmatism.

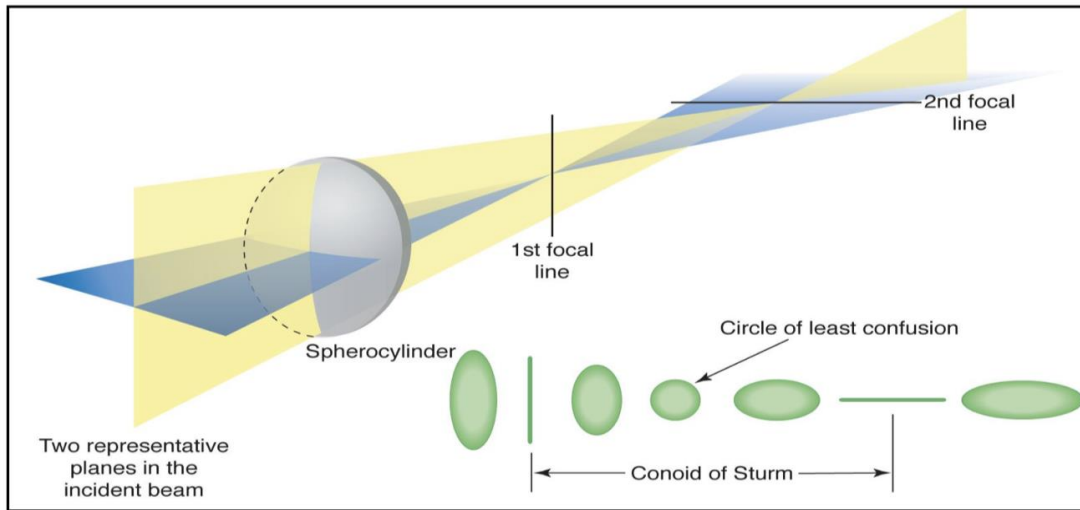


Fig 11: Optics of astigmatism

b) Compound astigmatism: The two foci does not lie on retina but both are placed either in-front or behind the retina.

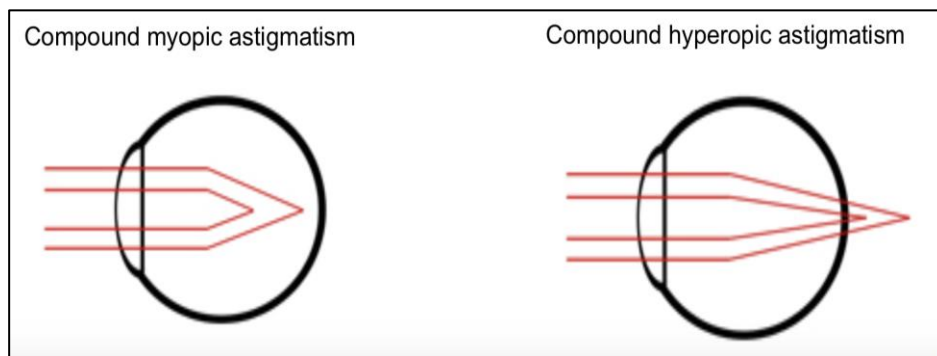


Fig 12: Compound myopic and hyperopic astigmatism

c) Mixed astigmatism: where one focus is in front and the other focus is behind the retina, so refraction is hypermetropia in one direction and myopia in other.

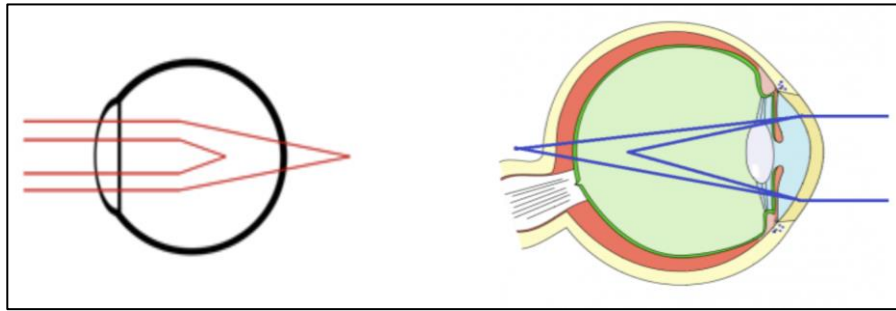


Fig 13: Mixed astigmatism

Factors Affecting Astigmatism After Cataract Surgery ³⁴

A. Preoperative factors

1. Native astigmatism
2. Corneal changes
 - Undetected keratoconus
 - Corneal scarring
 - Corneal thinning
 - Corneal vascularization
 - Contact lens wear
3. Scleral changes
 - Scleral thinning
 - Scleral surgery, i.e., buckle

B. Intraoperative factors

1. Incision: a) Length
 - b) Location
2. Suture: a) Technique
 - b) Material
 - c) Tension

d) Intraocular pressure

3. Cautery

4. Intraocular lens tilt

C. Postoperative Factors

1. Wound healing: a) General health, nutrition

b) Topical steroids

2. Wound dehiscence

3. Suture slippage, hydrolysis

4. Suture cutting

5. Intraocular pressure

POSTOPERATIVE CORNEAL ASTIGMATISM:

SURGICAL INDUCED ASTIGMATISM (SIA):

Corneal astigmatism is the result of cataract surgery after the start of limbal incision. In earlier days, after the extraction of cataract, astigmatism observed is ATR variety, which is caused by steepening of the corneal meridian at the right angles of the incision, it is called as "*surgically induced astigmatism*".³⁵ This is dependent on size of incision and proximity to the centre of cornea. The change in the external wound lip will not affect the SIA, whereas the internal lip of incision causes the SIA.³⁶ To patient's emmetropic status depends on preoperative astigmatism and SIA.

The following factors induces greater SIA:

- Longer incision
- Corneal incision
- Limbus parallel incision
- Uniplanar incision

-
- Sutural incision

POSTOPERATIVE EMMETROPIA:

It can be achieved with modifying surgical incisions. The following factors play role.

Principles of wound construction in cataract surgery:

Wound construction and closure is a crucial role in maintaining postoperative astigmatism. The two incision i.e., the external and the internal incision are important in correcting astigmatism.

External Incision:

The astigmatism is influenced by following factors:

- Length
- Shape
- Location and
- Cross sectional area of external incision

The incision is 2-3 mm behind the limbus, and the length varies with the type of cataract.

- 5 to 6 mm for cortical cataract
- 7 to 8 mm for nuclear sclerotic grade 4 cataract

The size of the incision depends on the grade of cataract and type of surgery not on the IOL used.³⁷

The External incision types:³⁷

- Straight
- Smiling
- Frown
- Straight with back cuts

-
- Inverted 'V' chevron's incision

INTERNAL INCISION:

Internal incision is the entry in to the anterior chamber. This incision is responsible is responsible for corneal instability and astigmatism. The internal corneal lip in scleral flap is self-sealing by the anterior chamber pressure, it forces the flap to close. It avoids wound separation.

Advantages of self-sealing incision: ³⁸

1. Prevents iris prolapse during surgery
2. Prevents iris root tears
3. Reduces hyphema
4. Decreases postoperative inflammation
5. Prevents hypotony
6. Avoids suture related complications
7. Avoids suture induced astigmatism
8. Increases postoperative comfort for the patient
9. Reduces surgical time

Richart kratz was the first surgeon to change the cataract incisions from limbus to sclera to have better wound healing and less astigmatism.²³ Due to better understanding of surgically induced astigmatism it has been possible to actually plan for better incisions to reduce postoperative astigmatism.

To minimize the high preexisting against the rule astigmatism, incision was put temporally or supero-temporally thereby improving the visual outcome. This incision also had the advantage of causing less distortion of central corneal curvature. Moreover, the supero-temporal incision has better wound strength due to minimal separation force of the lid pressure and gravity. These forces are neutralized well with

temporally placed incisions because the incision is parallel to the vector forces. Temporal incision has an advantage as it induces with the rule astigmatism in elderly cataract patients who had preoperatively against the rule astigmatism.

TORIC INTRAOCULAR LENS:

Historical overview

Shimizu et al. in 1992 first developed Toric IOL. It was a three piece IOL made up of non-foldable poly-methyl methacrylate (PMMA), implantation requires 5.7mm incision. These were available in cylinder powers of 2.0 D or 3.0 D. Postoperatively, residual refractive astigmatism and UDVA outcomes were not described, but CDVA was better in 77% of eyes. But, 50% of IOLs rotated more than 10 degrees and 20% of the IOLs rotated 30 degrees or more.³⁹

The first foldable Toric one-piece IOL became available in 1994. This was made up of silicone and can be implanted from a much smaller incision of 3.2 mm. the clinical results of this IOL showed UDVA of 20/25 in 23% patients when compared with standard IOL was only 4%. But main demerit of this IOL was high postoperative rotation. Since 1994, many advancements have been made in toric IOL technology, including improvements in IOL material and design and refinements in surgical technique. These advances have led to an improved postoperative rotational stability and consequently improved visual outcomes following toric IOL implantation.

TORIC IOL MATERIALS⁴⁰

Nowadays different types of Toric IOL models are available which includes monofocal and multifocal Toric IOL's. These are made of either hydrophobic acrylic, hydrophilic acrylic, silicone or PMMA biomaterial.

The postoperative rotation depends on the material made. After implantation in the capsular bag, the anterior and posterior capsules fuse with the IOL, thereby preventing IOL rotation. Adhesion of the IOL to the capsular bag was thought to prevent IOL rotation.

Several studies were conducted to study the interaction between different IOL materials and the capsular bag. Lombardo et al. used atomic force microscopy to determine IOL optic surface adhesiveness of different IOL biomaterials and found that hydrophobic acrylic IOLs showed the highest adhesive properties, followed by hydrophilic acrylic IOL, PMMA IOLs and finally silicone IOLs.

A study conducted on rabbits who underwent phacoemulsification with IOL implantation showed the strongest IOL-capsular bag adhesions for acrylic IOLs, followed by PMMA and silicone IOLs. Linnola et al. hypothesized that IOL biomaterials show differences in IOL adhesion due to a different affinity to proteins in the capsular bag. Extracellular matrix proteins, such as fibronectin, vitronectin and collagen type IV, are available in the aqueous humor following cataract surgery and may be involved in IOL adhesion to the capsular bag. Especially fibronectin is thought to play a major role in IOL-capsular bag adhesion. Acrylic IOLs taken from human autopsy eyes contained significantly more fibronectin compared to silicone or PMMA eyes. These results indicate that acrylic IOLs generally form the strongest adhesions with the capsular bag.

IOL DESIGN⁴¹

The IOL design is important in achieving stability in the capsular bag and avoiding postoperative IOL rotation. The overall IOL diameter and haptic design have been shown to be a major factor in the prevention of IOL rotation. Chang et al. compared

two different sizes of the same silicone toric IOL: a smaller model with a diameter of 10.8 mm and a longer model with a diameter of 11.2 mm.

The longer model was found to have a much better rotational stability compared to the smaller model: 10% of the longer IOLs rotated more than 10 degrees compared to 45% for the smaller IOLs. Currently available toric IOLs have a total IOL diameter ranging from 11.0 mm to 13.0 mm. Regarding the IOL haptics design, two different haptic designs are available: plate haptic and loop haptic.

A randomized controlled trial (RCT) has been performed to compare postoperative rotation of plate and loop haptic silicone IOLs. Postoperative rotation was significantly higher in loop haptic IOLs compared to plate haptic IOLs: 6.8 degrees versus 0.6 degrees. Patel et al. hypothesized that loop haptic IOLs may be more susceptible to rotation due to an asymmetric fusion of the capsular bag with the IOL haptics.

However, Prinz et al. recently compared plate and loop haptic acrylic IOLs and did not find a significant difference in postoperative rotation. This indicates that plate and loop haptics acrylic IOL demonstrate equally good rotational stability.

CURRENTLY AVAILABLE TORIC IOL :⁴²

At present, different types of toric IOL are available for correcting corneal astigmatism.

Staar Surgical Intraocular Lens – In 1998, it was the first toric IOL which was approved by FDA in united states. It was available in two forms, to correct distant vision. One will correct up to 2.00 diopters (D) and other corrects up to 3.5D astigmatism. These are plate haptic toric IOLs, and not gained popularity.

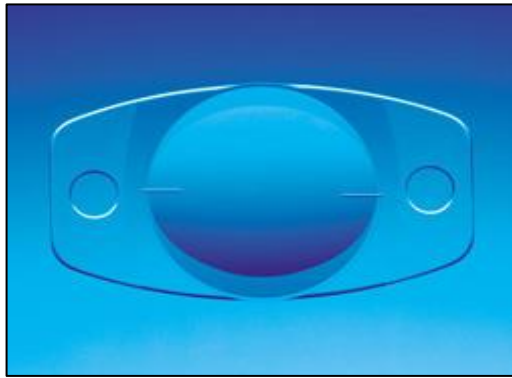


Fig 14: Staar intraocular lens

AcrySof IQ Toric IOL (Alcon Labs, USA)

It was approved in September 2005 by the FDA. It is available in aspheric model for crisper vision. The FDA also approved the AcrySof toric IOL in September 2005. It can filter damaging UV or blue light. It is based on the AcrySof Natural single-piece platform (Alcon Laboratories, Inc.) and is a foldable lens with a fully functional, 6-mm toric optic and Stable force haptics (Alcon Laboratories, Inc.). The lens' acrylic material is highly biocompatible and has adhesive properties that, along with the haptic design, help to prevent rotation of the IOL after its implantation in the capsular bag. The posterior surface of the lens has added cylindrical power and axis markings to help the surgeon align the IOL after implanting it in the capsular bag.

Newly AcrySof IQ ReSTOR Toric IOL is also available. The AcrySof IQ ReSTOR Multifocal Toric IOL combines the technologies of AcrySof IQ ReSTOR +3 add multifocal IOL and the AcrySof Toric IOL. The AcrySof IQ ReSTOR Multifocal Toric IOL have ability to deliver excellent visual outcome with independence from glasses in majority of cases.

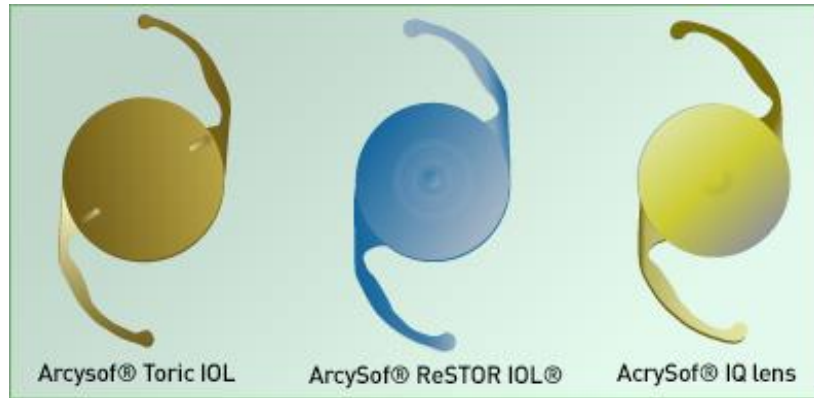


Fig 15: Acrysof toric, multifocal toric and multifocal with near add

Acri.Comfort 646TLC and Acri.LISA toric 466TD (Carl Zeiss Meditec):

Two main models of toric IOLS: Acri.Comfort 646TLC and Acri.LISA toric 466TD marketed by Carl Zeiss Meditec. The Acri.Comfort 646TLC is an aspherical bitoric IOL.

It was designed to insert IOL from incision less than 2mm as it decreases surgically induced astigmatism(SIA).

Its technical features are: hydrophilic acrylic polymer containing 25% water, Hydrophobic surface, Plate design with square edges in haptic and optic, Total diameter 11 mm, Optic diameter 6.0 mm, A-constant of 118.0, spherical powers from -10.0 to +32.0D and cylindrical powers from +1.00 to +12D .

The Acri. LISA toric 466TD is a multifocal toric IOL also designed for MICS to correct presbyopia in cataract patients with a distinct astigmatism.

Rayner T-flex Aspheric Toric IOLs:

Rayner T-flex aspheric Toric IOLs are better alternative to Toric IOLs having restricted torus and it offers a precise, better alternative to incisional keratotomy and Limbal Relaxing Incisions (LRIs) for the treatment of pre-existing corneal astigmatism. Aspheric Toric IOLs, the torus (cylinder) is implemented on the anterior surface of the optic and the Amon-Apple Enhanced Square Edge on the posterior surface.

It is useful in patients where incisional methods provide inadequate astigmatic correction. Aspheric Toric IOL leads to more precise surgical results, especially for cases of severe astigmatism: patients with a history of corneal pathology, keratoconus with penetrating keratoplasty (corneal grafts) and patients with burns and corneal scarring. It has inherent better rotational stability.

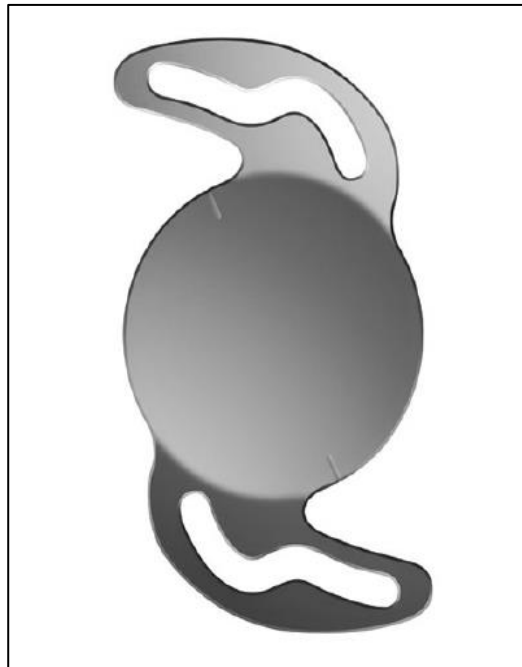


Fig 16: Rayner T-flex Aspheric Toric IOL

Rayner Sulcoflex toric 653T (Piggy back sulcus lens):

It is used for correcting post-surgical or residual ametropia. It was designed by Rayner for supplementing pseudophakic IOLs by piggy-back techniques for correcting refractive cylindrical power. It has following features:

- One piece foldable design
- Large optical zone to reduce contact between lens with round optic edge.
- Cylindrical power in 0.5 incremental ranging from +1.00 to +6.00D.



Fig 17: Rayner Sulcoflex toric 653T

Holland et al., (*Ophthalmology* 2010;117:2104-11) carried out a randomized study on 517 subjects, 256 – toric group and 261 -control group. They concluded that arcysot toric IOL(alcon laboratories,FW,Tx) showed favourable safety, efficacy, rotational stability and spectacle freedom.⁴³

Bauer et al., (*J Cataract Refract Surg.* 2008;34:1483-8) presented clinical data from a single –center prospective clinical trial of the AcrySof® toric (IOL)fifty-three eyes (43 patients) had implantation of an AcrySof® toric IOL. Three toric models were evaluated in cylinder powers of 1.50 diopters (D) (SN60T3; T3 group, $n=16$), 2.25 D

(SN60T4; T4 group, $n=14$) and 3.00 D (SN60T5; T5 group, $n=23$) at the IOL plane. They concluded that implantation of the AcrySof ® toric IOL proved to be an effective, safe, and predictable method of managing corneal astigmatism in cataract patients.⁴⁴

Kersey *et al.*, (*Cornea* 2007;26:133-5) studied the change in visual acuity and refraction after cataract surgery using a toric posterior chamber intraocular lens in patients with astigmatism after penetrating keratoplasty. Seven consecutive patients with all sutures removed were included. A marked improvement in both unaided visual acuity and astigmatism was shown after the procedure. The average preoperative cylinder was 10.12D (range, 3.40-17.89D); postoperatively, which decreased to 2.75D (range, 0.75-4.25). They concluded that cataract surgery with toric intraocular lens allows the correction of high degrees of regular corneal astigmatism.⁴⁵

Visser *et al.*, (*Cornea* 2011;30:720-3) reported 2 cases in which cataract extraction with foldable acrylic toric IOL implantation was used to correct corneal astigmatism (irregular) in patients (age > 60 years) with keratoconus and cataract. Refractive astigmatism decreased by 70% in both eyes. No IOL misalignment or other complications occurred. They concluded that cataract extraction with toric IOL implantation can be used to correct (irregular) astigmatism and to improve visual functioning in patients with mild to moderate amounts of stable keratoconus and cataract.⁴⁶

AUROLAB TORIC IOL:⁴⁷(No financial interest)

About design

The optic of Auroflex Toric IOL has been carefully designed with toricity on the anterior surface of the IOL.

Rotational stability

The success of a Toric IOL can be judged by its ability to maintain a stable position in the capsular bag as every degree of IOL rotation results in a loss of 3.3% of IOL cylinder power.

Auroflex toric with the dual haptic design offers the rotational stability on axis and clear optic for post-surgical vision.

Optic Diameter	6.0 mm
Overall Diameter	12mm
Optic Design	Anterior Toric surface
Haptics Design	Dual Haptic
Edge	360° Square edge
Angulation	Zero Degree Angulation
A Constant	118.0
ACD	5 mm
Dioptr range	Sphere powers from 10D to 30D, with each sphere power having cylinder power ranging from 1.5 D to 6.0 D in 0.5 increments

Table 1: Auroflex toric IOL specifications

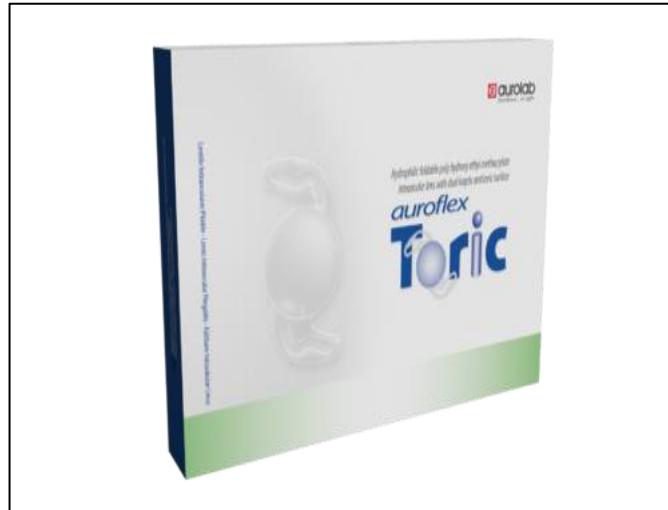


Fig 18: Auroflex Toric IOL

INTRAOCULAR LENS POWER CALCULATION:

There are many formulas and calculators to determine the axis and the power of toric IOL to be implanted. An ideal formula will consider Surgically Induced Astigmatism (SIA), posterior curvature of cornea and also effective lens position (ELP). The operating surgeon should calculate his SIA by using standard procedures.^(48,49) The most widely used toric IOL calculators does not take posterior corneal curvature into account for IOL power calculation. Another error is using only a single conversion factor for converting the cylindrical power from corneal plane to the IOL plane without considering the anterior chamber depth and pachymetry. This causes error in calculating the cylindrical power in patients with extremes of axial length.⁵⁰

The AcrySof online toric calculator and the iTRACE calculator uses a fixed ratio to convert power from corneal plane to IOL plane.⁵¹ The TECNIS calculator uses the anterior chamber depth which is based on the axial length and keratometry values and Holladay formula uses the ELP for its calculations.⁵²

The Baylor nomogram uses the posterior corneal curvature in its measurements and it is more precise than Holladay and Alcon toric calculators. The Barrett toric calculator will take both the ELP as well as the posterior corneal astigmatism into account and has better predictability than the Baylor nomogram as well as Holladay and Alcon toric calculators.⁵⁴

The online calculators were revised to incorporate corrections for posterior corneal astigmatism. The revised AcrySof toric calculator incorporates the Barrett toric algorithm, and the Tecnis calculator received FDA approval in 2016 to incorporate posterior corneal astigmatism compensation.

Intraoperative wavefront aberrometry is increasingly being used to estimate the toric IOL power and axis of placement based on the aphakic refraction, especially in postrefractive surgery cases. A retrospective analysis observed a mean prediction error of 0.43 ± 0.33 D with Optiwave Refractive Analysis (ORA) in post laser- assisted *in situ* keratomileusis (LASIK) cases undergoing toric IOL implantation. The results were more accurate than those obtained by the standard SRK- T formula and the online ASCRS calculator.⁵⁵

INTRAOCULAR LENS SELECTION:

Various toric IOLs are available commercially, with different material, design, and range of toric power. The choice of IOL depends on the surgeon comfort, patient expectations, financial considerations and availability. A monofocal or multifocal toric IOL may be selected based on patient's preference and preoperative assessment.

Marking Techniques:

Accurate alignment of toric IOL is a prerequisite to achieve successful outcomes. Various methods have been described to place the preoperative reference and axis marks and may be broadly categorized as manual methods, iris fingerprinting techniques, image- guided systems, and intraoperative aberrometry- based methods.

Manual techniques:

The three- step technique is commonly used for toric IOL alignment, which involves the preoperative marking of the reference axis, intraoperative alignment of the reference marks with the degree gauge of the fixation ring and intraoperative marking of the target axis.⁵⁶

The reference marks are commonly placed in the 3'O, 6'O, and 9'O clock positions to improve predictability, though some surgeons may prefer to mark only the horizontal 3'O and 9'O clock positions, or only the inferior 6'O clock position. The marking may be performed with a skin - marking pen in a free- hand manner, or with the help of various devices such as a thin slit- beam, weighted thread, pendulum marker or Nuijts- Solomon bubble marker.

This is followed by the intraoperative alignment of these reference marks to the degree gauge on a fixation ring, and the target axis is then marked with a corneal meridian marker. One- step axis marking may be done with the help of various devices such as tonometer markers, electronic toric markers, Neuhann one- step toric bubble marker, and Geuder- Gerten Pendulum marker.^{57,58}

A change in patient position from sitting to supine may induce significant cyclotorsion, and up to 28° of cyclotorsion has been observed in 68% cases.⁵⁶ Hence,

the patient should be sitting erect with the back resting against a wall and a straight- ahead gaze while marking the reference axis to avoid inadvertent errors. The cornea should be dry, and adequate topical anesthesia should be administered to improve patient comfort during marking.

The three- step marking method is fairly accurate, and a mean error of $2.4^{\circ} \pm 0.8^{\circ}$ has been observed during axis marking with a bubble marker, with a total error of $4.9^{\circ} \pm 2.1^{\circ}$ in toric IOL alignment.⁴⁶ Both bubble marker and pendulum marker are easy and reproducible techniques with fairly accurate results.⁶⁰ A comparative evaluation of four different marking techniques including coaxial slit beam, bubble marker, pendular marker, and tonometer marker observed minimum rotational deviation with the pendular marker and least vertical misalignment with the slit lamp marking technique.⁶¹

The least accurate results were observed with the tonometer marker, whereas the other three methods provided fairly accurate results. Slit- lamp assisted pendular marker has been observed to give more accurate results than using a horizontal slit- beam alone or a direct non pendular marker.⁵⁸

The manual marking methods have inherent sources of errors, such as smudging of the dye, irregular, and broad marks.

Moreover, they are associated with a significant learning curve, and intersurgeon variability may be observed in the accuracy of marking.

Osher ThermoDot Marker (Beaver- Visitec International, BVI, Waltham, Mass.) has been developed to eliminate the ink- associated problems in reference axis marking.

It employs a bipolar cautery to create an ink- free, precise reference mark during surgery. Anterior stromal puncture using a 26- gauge bent needle stained with sterile blue ink has been described for reference axis marking, to obtain precise reference marks with no smudging.⁶²

IMAGE- GUIDED TECHNIQUES

The concept of iris- fingerprinting was introduced by Osher in 2010, wherein the iris crypts, nevi, brush fields, etc., were used as landmarks to place the axis marks.^{63,64} It formed the basis for the development of various image- guided systems, such as CALLISTO Eye and Z align, VERION image- guided system and the TrueVision 3D Surgical System .⁶⁶⁻⁶⁹

The iris and limbal landmarks may be captured by the iTRACE system, and the Zaldivar Toric Caliper tool can be used to calculate the location of these marks and their distance in degrees from the target IOL axis. A final surgical plan is generated that provides simple angular directions from each reference mark to the desired axis of IOL placement with regard to surgeon's position and view.⁷⁰

The image- guided systems involve the capture of a preoperative reference image followed by intraoperative image registration wherein the limbal landmarks are used to match the two images with respect to each other. A graphic overlay is then superimposed on the surgical field along the target axis, which provides a guide for toric IOL alignment. The VERION image- guided system utilizes the scleral blood vessels, limbus, and iris details as reference landmarks to determine the extent of cyclotorsion.

In addition to aiding the alignment of the toric IOL, the image- guided systems also provide a step- by- step guidance during the various surgical steps including the placement of corneal incisions, the size and centration of the capsulorhexis as well as IOL centration.

Significantly more precise alignment has been observed with VERION- image guided marking as compared to manual slit lamp- assisted preoperative marking using pendulum- attached marker.^{57,69} The accuracy of CALLISTO Eye and Z align is similar to VERION.⁶⁷

The eye tracker in these systems may disengage during surgery, and a repeat registration may be required. Conjunctival chemosis, ballooning and bleeding may interfere with intraoperative registration. Registration may also not be possible in extremely uncooperative patients or difficult orbital anatomy including extremely deep- set eyes or narrow palpebral apertures. In addition to these limitations, the high financial cost involved may limit the widespread usage of this technology.

Intraoperative aberrometry:

Intraoperative aberrometry devices such as ORA (ORA; WaveTec Vision Systems Inc., CA, USA) and Holos IntraOp (Clarity Medical Systems, CA, USA) perform a real- time assessment of the phakic, aphakic, or pseudophakic refraction to provide feedback for toric IOL alignment.

ORA utilizes the principle of Talbot- Moire interferometry to perform real- time calculation of IOL power as well as the axis, based on the aphakic refraction. It employs a modified refractive vergence formula for accurate IOL power calculation even in complicated postrefractive surgery cases. Moreover, it permits refinement of

the axis by providing the direction as well as magnitude of rotation required to achieve minimum residual astigmatism. VerifEye has been incorporated in ORA with a fast imaging processor that confirms the stability of the system before measurements are taken.

Holos IntraOp provides continuous real-time refraction throughout the surgery. Although it does not provide the spherical IOL power to be implanted, the axis of the toric IOL can be refined based on the continuous feedback provided by this system.

Cases undergoing toric IOL implantation assisted with intraoperative aberrometry are 2.4 times more likely to have 0.50D or less residual astigmatism compared with other standard methods.⁷¹ Wavefront aberrometry significantly affects the intraoperative decision –making, with the cylinder power changed 24% of the time, the spherical power changed 25% of the time, and three or fewer rotations needed 92% of the time.⁷²

Intraoperative aberrometry is also superior to conventional methods in patients with prior myopic keratorefractive surgery.⁵⁵ However, a recent study comparing Callisto eye and Z align with ORA observed more precise alignment with less residual astigmatism in cases using Callisto image-guided system.⁶⁸

INTRAOPERATIVE TORIC INTRAOCULAR LENS ALIGNMENT

In cases with manual marking, the target axis is marked at the beginning of surgery after aligning the preoperatively placed reference marks with a degree gauge. In addition to intraoperative alignment of the toric IOL along the desired corneal

meridian, the clear corneal incisions, capsulorhexis and IOL centration also play a significant role in achieving optimal outcomes. Self-sealing clear corneal incisions that are astigmatically neutral or induce minimal astigmatism should be created. Uniformity of corneal incisions in terms of location and size is essential to prevent variations in SIA. Image-guided systems compensate for cyclotorsion and assist in the precise placement of incisions.

A well-centered circular continuous capsulorhexis providing adequate IOL coverage of around 0.5 mm is essential to ensure IOL stability in the postoperative period. Posterior capsular rent is a relative contraindication for in-the-bag toric IOLs, as there is a high risk of IOL tilt as well as rotation. The IOL should be centered along the coaxially sighted corneal light reflex, as represented by the first Purkinje image while the patient is fixating on the microscope light. Perfect centration is especially significant in cases undergoing toric multifocal IOLs to prevent the occurrence of dysphotopic visual symptoms.

During IOL alignment, the IOL should be left about 3°–5° anticlockwise of the final desired lens position. The final alignment should be done after complete OVD removal and hydration of the wounds, as most open-loop IOLs can be rotated only clockwise and a complete re-rotation will be needed if the IOL rotates further clockwise of the target axis during these maneuvers.

The precise capsulotomy created in FLACS may further improve the outcomes of toric IOL implantation. A significant decrease in higher order aberrations has been observed with FLACS as compared to standard phacoemulsification with toric IOL implantation.⁷³

FACTORS AFFECTING TORIC IOL ROTATION

Misorientation can occur for a number of reasons, for example surgical error resulting in inaccurate positioning of the IOL at the time of surgery (Watanabe et al., 2012) or post-operative rotation of the implanted IOL within the capsular bag (Ale et al., 2012a; Shah et al., 2012). When implanting a toric IOL, reference markers, usually on opposite sides of the pupil, must be determined to ensure correct placement of a toric IOL during surgery (Buckhurst et al., 2010a).

However these must be established prior to rather than during surgery, since low to moderate amounts of eye rotation have been reported to occur when changing from a seated to supine position (Chernyak, 2004). Techniques to apply these markers include using ink (Graether, 2009) or specific toric axis marking instruments (Buckhurst et al., 2010a). A commonly used 3 step ink-marker system (Ma et al., 2008; Visser et al., 2011a) for toric IOL implantation was found to have a mean alignment error rate of approximately 5° (Visser et al., 2011a). In this system the horizontal 0° to 180° axis of the eye is marked pre-operatively with the patient sitting upright. The desired alignment axis for the toric IOL is ascertained and then marked intra-operatively using a device with angular graduations. Following this the toric IOL is implanted and rotated until the IOL and reference markers match (Ma et al., 2008; Visser et al., 2011a). Precisely orientating the toric IOL during surgery is therefore essential in order to achieve optimum correction of astigmatism.

The majority of IOL rotation is thought to occur within the first month of surgery (Mingo- Botin et al., 2010) due to factors such as capsular bag size, capsulorhexis size and capsular fusion (Shimizu et al., 1994; Prinz et al., 2011). There is a gradual reduction in capsular bag size in the weeks following surgery.

While this shrinkage can help to secure the IOL, it is also possible for lens rotation to occur as a result of this contraction because of the compressive effect on the IOL haptics.

Capsular bag shrinkage is the most commonly reported source of late IOL rotation in uncomplicated cataract cases, with most of the resulting rotation occurring in the first three months after surgery (Kim et al., 2010;Prinz et al., 2011). Capsular fibrosis, which normally occurs in the weeks after surgery (Mamalis et al., 1996) can also help to anchor the IOL.

However it is possible for lens rotation to occur before this fibrosis stabilises the IOL (Buckhurst et al., 2010a). The presence of certain ocular or systemic diseases, such as glaucoma or diabetes, are thought to influence capsular fibrosis leading to a greater likelihood of rotation in these patients (Ale et al., 2012a).

Interestingly, there appears to be a refractive element to lens rotation with myopes being more susceptible to early toric IOL rotation (Shah et al., 2012). This effect may occur as a result of the correlation between increased axial lengths and a greater capsular bag diameter, which is thought to cause greater IOL instability (Novis, 2000) as a result of reduced equatorial friction (Shah et al., 2009).

Hence, maximising the resistance between the IOL haptic and capsular bag can help to reduce lens rotation soon after surgery; IOL material is crucial for this (Kim et al., 2001b). Polymethylmethacrylate (PMMA) has been found to be the best in terms of creating the most friction with the capsular bag and silicon the worst (Oshika et al., 1998;Yoshida et al., 1998;Taketani et al., 2004).

IOL size is also important as smaller IOLs have less contact and therefore less resistance with the capsular bag which can lead to increased lens rotation (Buckhurst

et al., 2010a). IOL haptic design can also impact upon the degree of rotation (Kim et al., 2010;Prinz et al., 2011). Plate haptic IOLs are more stable in the long term as they seem to be less vulnerable to the effects of capsular bag compression, whereas open loop haptic lenses show good rotational stability initially, but are more likely to rotate later on with capsular compression (Patel et al., 1999;Buckhurst et al., 2010a).

Early research into closed loop haptics indicates better overall rotational stability with this IOL haptic as a result of good initial friction between the IOL and capsular bag coupled with greater resistance to capsular compression (Buckhurst et al., 2010b). Surgical factors can also influence IOL rotation as discussed earlier, therefore ensuring accurate IOL alignment at the time of implantation as well as careful wound construction is imperative (Buckhurst et al., 2010a).

MATERIALS AND METHODS:

SOURCE OF DATA:

A total of 42 eyes fulfilling the inclusion criteria were selected and randomly divided into two groups of 21 eyes in each group for this study from ophthalmology inpatient department at R.L.J. HOSPITAL AND RESEARCH CENTRE, TAMAKA, KOLAR attached to SRI DEVARAJ URS MEDICAL COLLEGE between December 2016 and May 2018.

STUDY DESIGN: Randomised control study.

INCLUSION CRITERIA:

Patients with Senile cataract with regular corneal astigmatism of 1.5D - 3.0D

EXCLUSION CRITERIA:

- Astigmatism of <1.5 and >3.0D.
- Presence of pterygium.
- Severe dry eyes.
- Corneal scarring, dystrophies or degeneration.
- Pseudoexfoliation.
- Complicated cataract.
- History of trauma.
- Subluxated lens.
- Glaucoma.

- Retinal and macular disorders.

METHOD OF COLLECTION OF DATA

A total of 42 eyes fulfilling the inclusion criteria were included in this study. All patients underwent similar protocol for standard cataract evaluation, which consists of history of previous ocular surgery, recording of visual acuity, intraocular pressure, slit lamp examination, fundus evaluation and intraocular lens calculation by Sanders – Retzlaff –Kraff 2 method. Preoperative astigmatism was measured by using a standard calibrated Bausch and Lomb keratometer. Analysis of astigmatism will be performed by subtraction method.

SAMPLE SIZE ESTIMATION

Sample size was estimated by using the mean UDVA (Logmar) between the Toric IOL and Non –Toric IOL as 0.27 ± 0.20 and 0.54 ± 0.22 respectively from the study by Mohammed I. Khan et al. Using these values at 99% Confidence limit and 90% power sample size of 19 was obtained in each group. With 10% non response sample size of $19+2=21$ cases were included in each group.

Sample size estimation formula

$$\text{Sample size} = \frac{2SD^2 (Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

SD – Standard deviation = from previous studies or pilot study.

$Z_{\alpha/2} = Z_{0.05/2} = Z_{0.025} = 1.96$ (From Z table) at type 1 error of 5%.

$Z_{\beta} = Z_{0.20} = 0.842$ (From Z table) at 80% power

d = effect size = difference between mean values.

So now formula will be

$$\text{Sample size} = \frac{2SD^2(1.96+0.84)^2}{d^2}$$

RANDOMIZATION: The patients were randomized into two groups by simple randomization method. A total 42 eyes were selected, patients allotted even number were kept in study group and patient allotted odd number were kept in control group.

GROUP I (21 eyes) – These patients underwent phacoemulsification with Toric IOL implantation. Cylindrical power and axis of IOL placement was calculated using online calculator of the company.

GROUP II (21 eyes) – These patients underwent phacoemulsification with standard IOL implantation which was the control group and IOL power was calculated by biometry.

All patients were on oral tab Ciprofloxacin 500mg twice daily & Ciprofloxacin 0.3% eye drops hourly one day before the surgery. Preoperatively pupils were dilated with tropicamide/phenylephrine 0.5% or 1% drops along with flurbiprofen 0.03% drops. All surgeries were performed by an experienced surgeon.

GROUP I: TORIC IOL implantation

IOL power calculation: The toric IOL power and axis was derived from the online program of lens manufacturer. The data that have to be entered in the program includes the patient's data, manual keratometry and axis, IOL spherical power and average surgically reduced astigmatism of the surgeon. The output screen gave toric IOL axis, power and the model to be used.

Surgical technique:

1. Reference and axis marks: The reference marks were made with the reference marker at the limbus at 0 and 180 degrees. This was done in sitting position under the slit-lamp to account for cyclotorsion.
2. The Toric axis marks were made out just before starting. The incision with the reference marks acted as a guideline for using the toric axis marker.
3. All surgeries were done by phacoemulsification through a temporal corneal tunnel. A careful well centered capsulorrhexis of 5 to 5.5 mm was made. After phacoemulsification of the nucleus and complete cortical wash, the toric IOL was inserted in a controlled fashion and aligned appropriately with the axis marks.
4. After complete viscoelastic removal, the final accurate alignment of the IOL with the axis was done and the IOL was gently tapped into the place.

GROUP II: Standard IOL implantation

All surgeries were performed through a temporal clear corneal tunnel after 5 to 5.5 mm capsulorrhexis, phacoemulsification of the nucleus, complete removal of cortex, the standard IOL will be implanted.

Postoperative medications include an antibiotic steroid eye drops that was used for 6 weeks in a tapering dose. All patients were followed from 1st day, 1st week, 1st month, 3rd month and 6th month, and at each visit patient were evaluated for best corrected visual acuity, k1 k2 and postoperative complications. Rotational stability was assessed after 6 months using slit lamp beam.

OBSERVATION AND RESULTS⁷⁴⁻⁷⁷

Statistical analysis:

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. **Chi-square test** was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. **Independent t test or Mann Whitney U test** was used as test of significance to identify the mean difference between two quantitative variables and qualitative variables respectively.

Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as bar diagram, Pie diagram and Scatter plots.

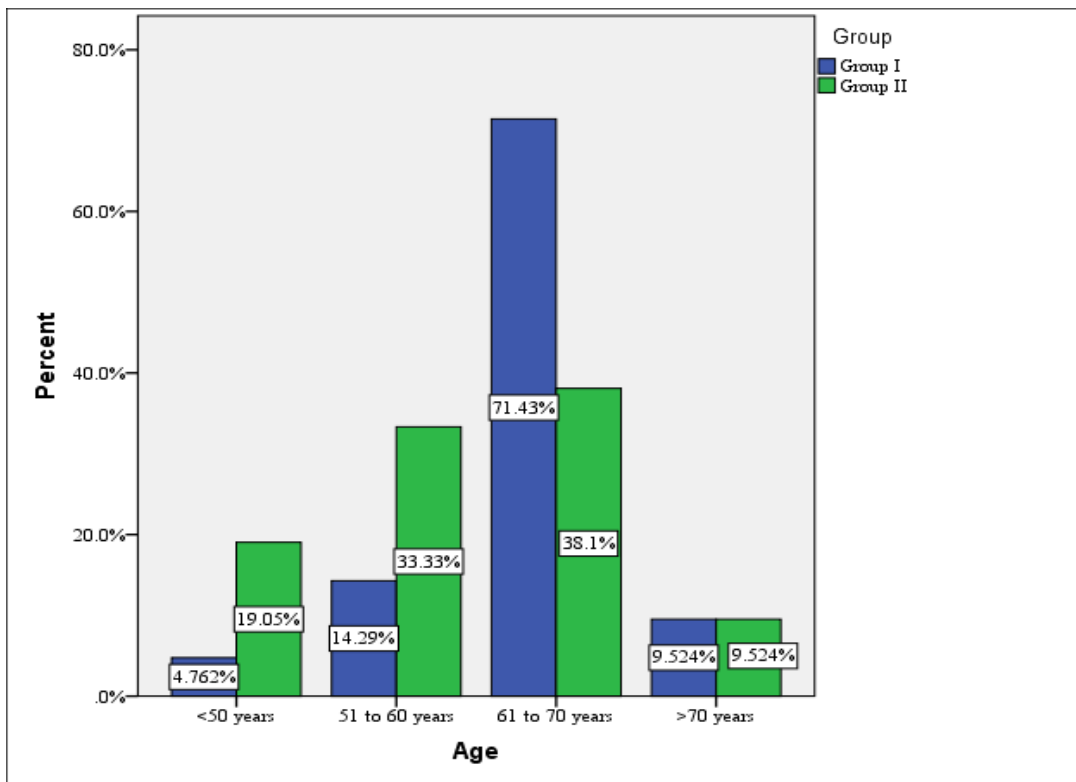
p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

Age in years	Group I		Group II		Total	
	N	%	N	%	N	%
<50	1	4.8	4	19.0	5	11.9
51 to 60	3	14.3	7	33.3	10	23.8
61 to 70	15	71.4	8	38.1	23	54.8
>70	2	9.5	2	9.5	4	9.5
Total	21	100	21	100	42	100

Table 2: Age distribution comparison between two groups

In Group I and Group II, majority of subjects were in the age group 61 to 70 years (71.4% and 38.1% respectively). There was no significant difference in age distribution between two groups. $\chi^2 = 5.53$, $df = 3$, $p = 0.137$

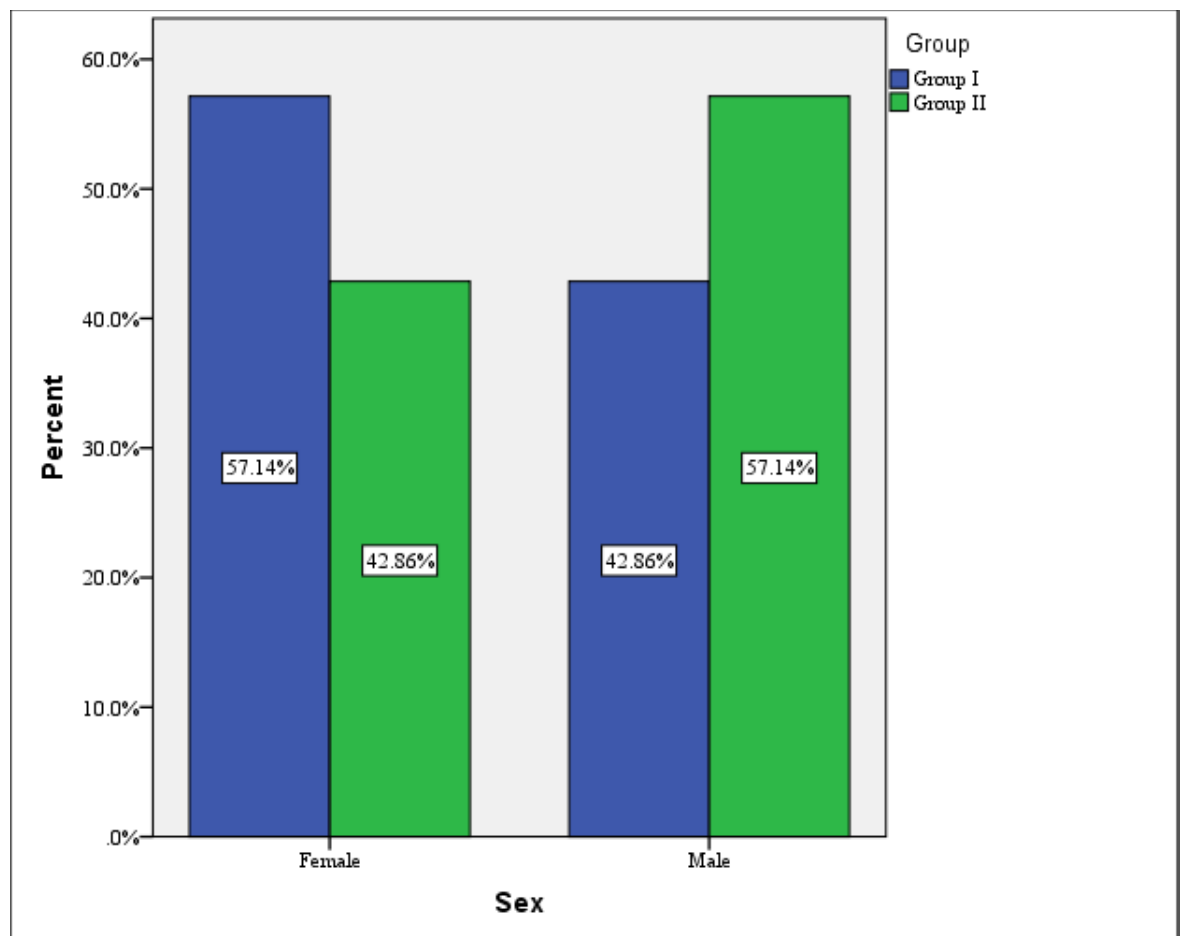


Graph 1: Bar diagram showing Age distribution comparison between two groups

Sex	Group I		Group II		Total	
	N	%	N	%	N	%
Female	12	57.1	9	42.9	21	50
Male	9	42.9	12	57.1	21	50
Total	21	100	21	100	42	100

Table 3: Sex distribution comparison between two groups

In Group I, 57.1% were females and 42.9% were males. In group II, 57.1% were males and 42.9% were females. There was no significant difference in sex distribution between two groups. $\chi^2 = 0.857$, $df = 1$, $p = 0.355$.

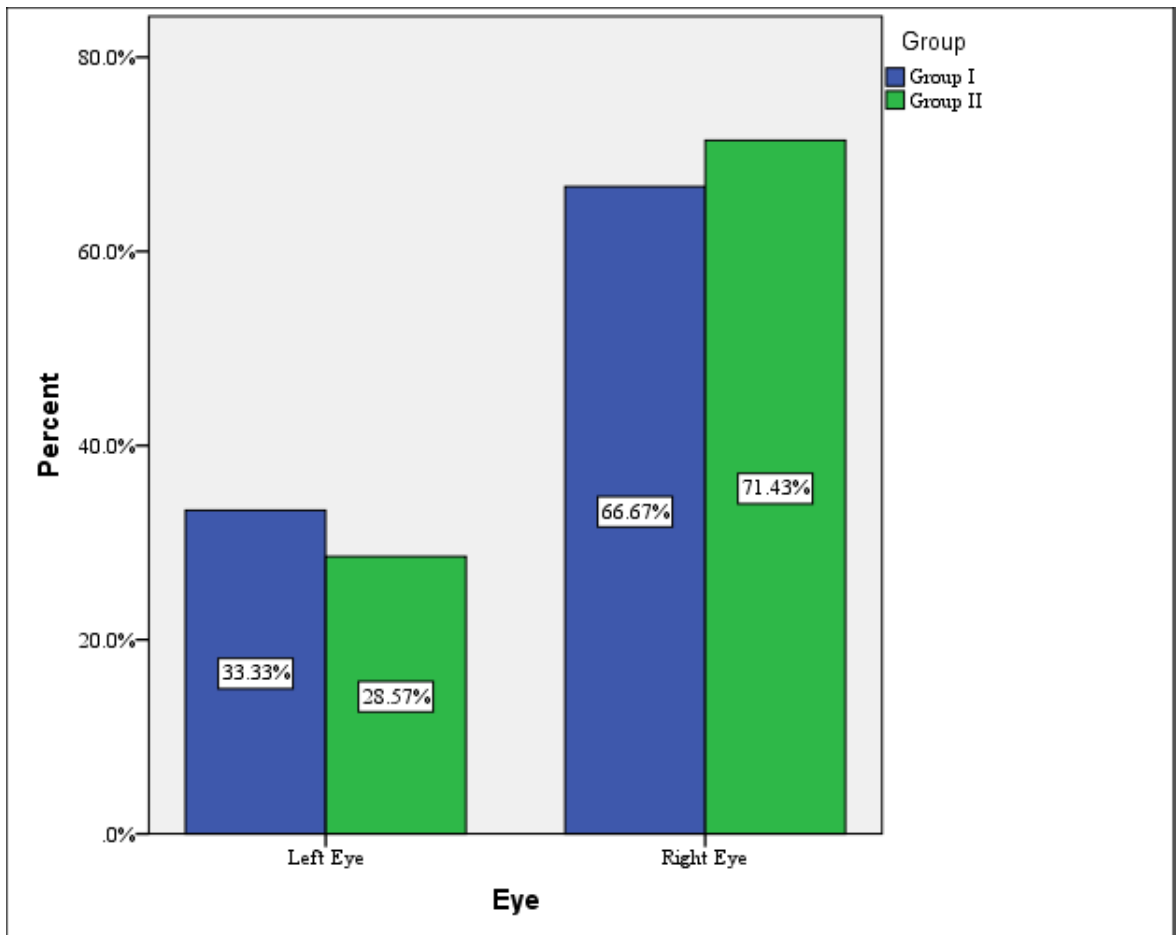


Graph 2: Bar diagram showing Sex distribution comparison between two groups

LATERALITY	Group I		Group II		Total	
	N	%	N	%	N	%
Left Eye	7	33.3	6	28.6	13	31
Right Eye	14	66.7	15	71.4	29	69
Total	21	100	21	100	42	100

Table 4: Side of Eye distribution comparison between two groups

In Group I, 66.7% were right eye and 33.3% were left eye. In Group 2, 71.4% were right eye and 28.6% were left eye. There was no significant difference in age distribution between two groups. $\chi^2 = 0.111$, $df = 1$, $p = 0.739$.

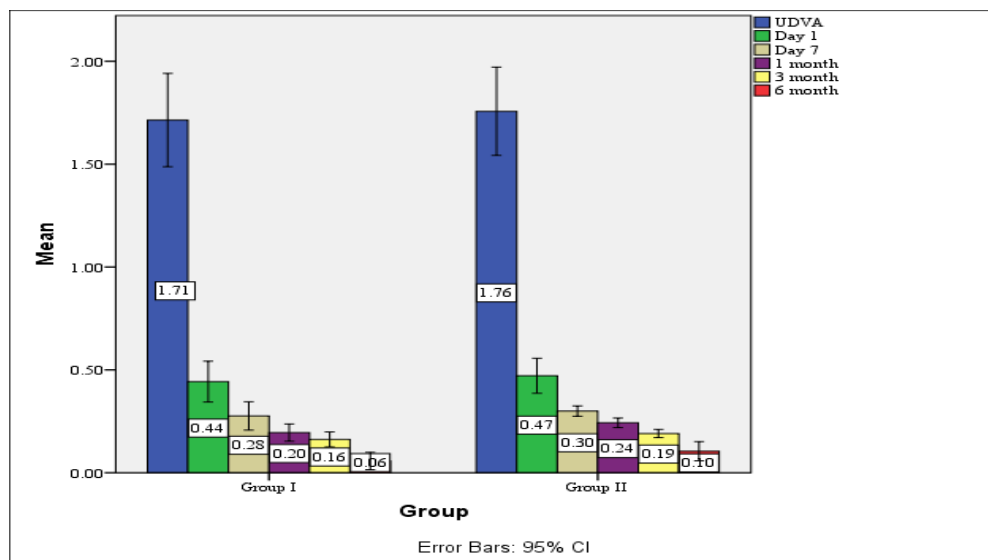


Graph 1: Bar diagram showing Side of Eye distribution comparison between two groups

UDVA in log MAR	Group I		Group II		Total		P value
	Mean	SD	Mean	SD	Mean	SD	
Pre OP	1.71	0.50	1.76	0.47	1.74	0.48	0.776
Day 1	0.44	0.22	0.47	0.19	0.46	0.20	0.651
Day 7	0.28	0.15	0.30	0.05	0.29	0.11	0.502
1 month	0.20	0.09	0.24	0.05	0.22	0.08	0.044*
3 month	0.16	0.08	0.24	0.05	0.20	0.07	0.032*
6 month	0.06	0.09	0.24	0.05	0.15	0.05	0.012*

Table 5: Comparison of postoperative uncorrected distant visual acuity between the two groups, at different intervals.

In the study there was significant difference in mean UDVA between two groups at 1 month, 3 months and 6 months. At 6 month, mean UDVA in Group I was 0.06 ± 0.09 and in Group II was 0.24 ± 0.05 . There was significant difference in UDVA between two groups at 1 month, 3months and 6months of follow up.

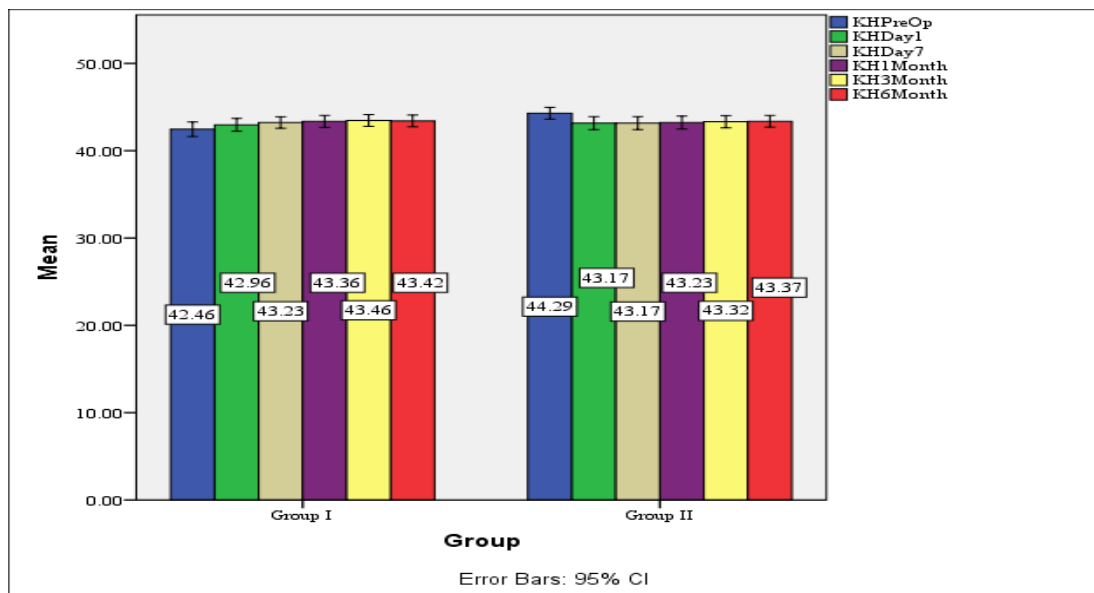


Graph 2: Bar diagram showing UDVA distribution comparison between two groups at different intervals of followup

KH	Group I		Group II		Total		P value
	Mean	SD	Mean	SD	Mean	SD	
Pre OP	42.46	1.84	44.29	1.48	43.38	1.89	0.001*
Day 1	42.96	1.61	43.17	1.63	43.07	1.61	0.688
Day 7	43.23	1.46	43.17	1.63	43.20	1.53	0.901
1 month	43.36	1.49	43.23	1.62	43.29	1.54	0.787
3 month	43.46	1.47	43.32	1.52	43.39	1.48	0.758
6 month	43.42	1.49	43.37	1.48	43.39	1.47	0.918

Table 6: KH distribution comparison between two groups at different intervals of followup.

In Group I, Mean KH at Pre Op was 42.46 ± 1.84 and in Group II was 44.29 ± 1.48 . There was significant difference in Mean Pre Op KH between two groups. There was no significant difference in Mean KH at Day 1, Day 7, 1 month, 3 months and 6 months between two groups.

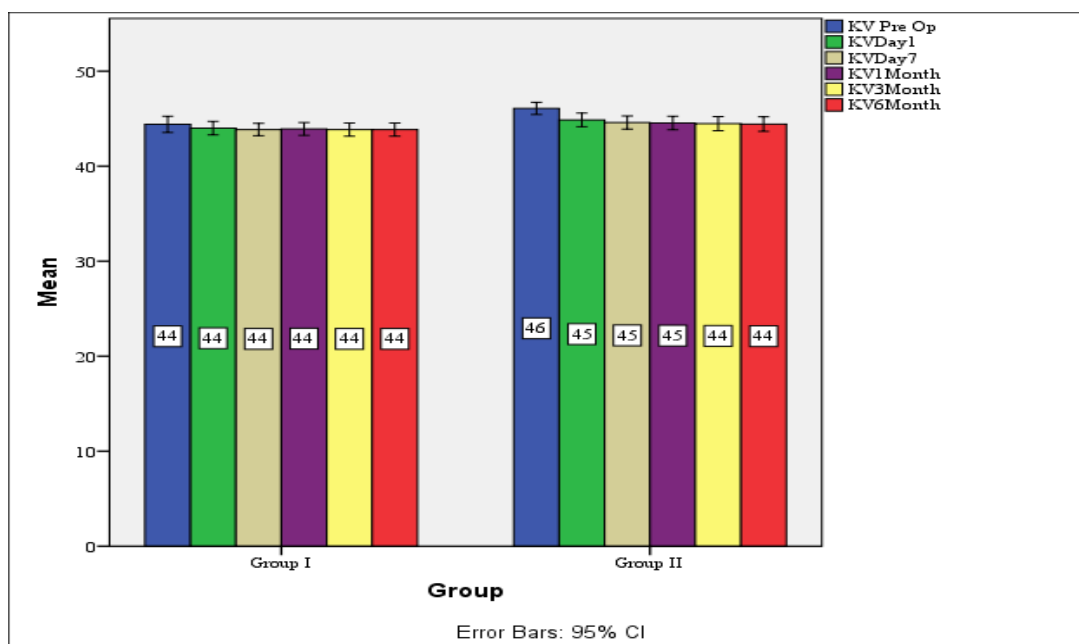


Graph 3: Bar diagram showing KH distribution comparison between two groups at different intervals of follow up.

KV	Group I		Group II		Total		P value
	Mean	SD	Mean	SD	Mean	SD	
Pre OP	44.40	1.87	46.08	1.41	45.24	1.84	0.002*
Day 1	44.00	1.56	44.87	1.58	44.43	1.61	0.081
Day 7	43.86	1.43	44.60	1.54	44.23	1.51	0.115
1 month	43.92	1.48	44.55	1.56	44.23	1.54	0.186
3 month	43.86	1.53	44.48	1.63	44.17	1.59	0.211
6 month	43.86	1.53	44.43	1.69	44.14	1.62	0.257

Table 7: KV distribution comparison between two groups at different intervals of follow-up

In Group I, Mean KV at Pre Op was 44.40 ± 1.87 and in Group II was 46.08 ± 1.41 . There was significant difference in Mean Pre Op KV between two groups. There was no significant difference in Mean KV at Day 1, Day 7, 1 month, 3 months and 6 months between two groups.

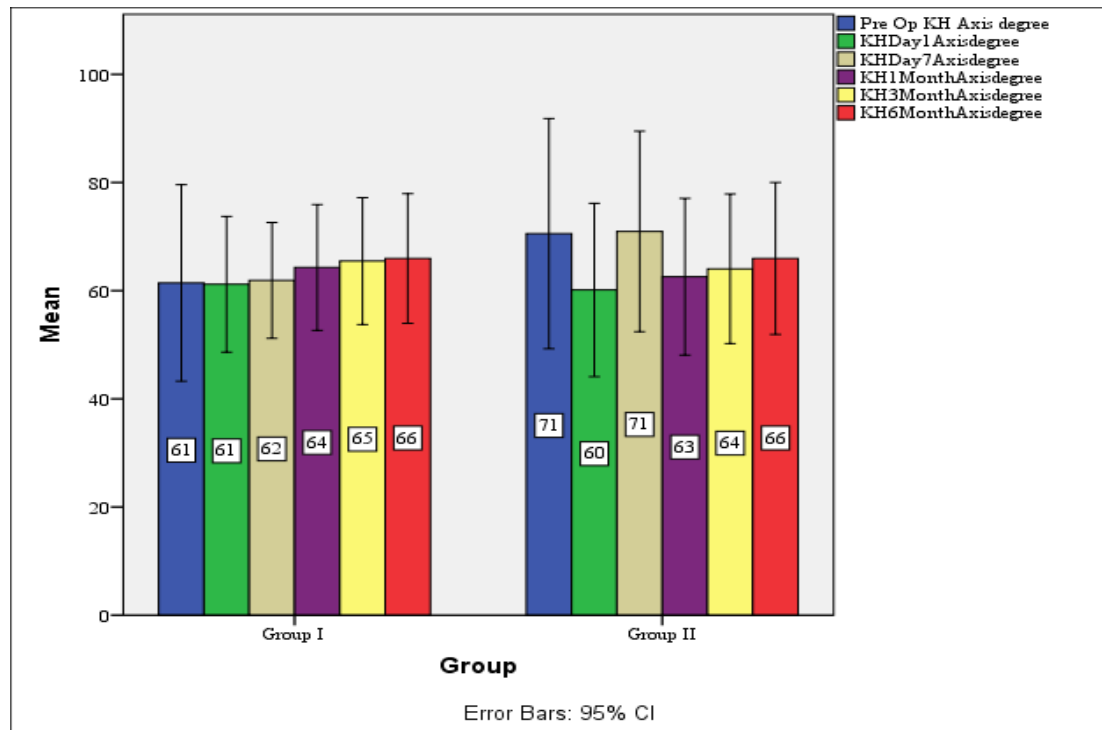


Graph 6: Bar diagram showing KV distribution comparison between two groups at different intervals of followup.

KH Axis Degree	Group I		Group II		Total		P value
	Mean	SD	Mean	SD	Mean	SD	
Pre OP	61.43	39.93	70.55	46.72	65.99	43.17	0.500
Day 1	61.19	27.56	60.14	35.20	60.67	31.23	0.915
Day 7	61.90	23.53	70.95	40.73	66.43	33.17	0.383
1 month	64.29	25.56	62.57	31.83	63.43	28.53	0.848
3 month	65.48	25.78	64.05	30.40	64.76	27.85	0.870
6 month	65.95	26.34	65.95	30.89	65.95	28.35	1.00

Table 8: KH Axis degree distribution comparison between two groups at different intervals of followup

There was no significant difference in Mean KH Axis degree at Pre OP, Day 1, Day 7, 1 month, 3 months and 6 months between two groups.

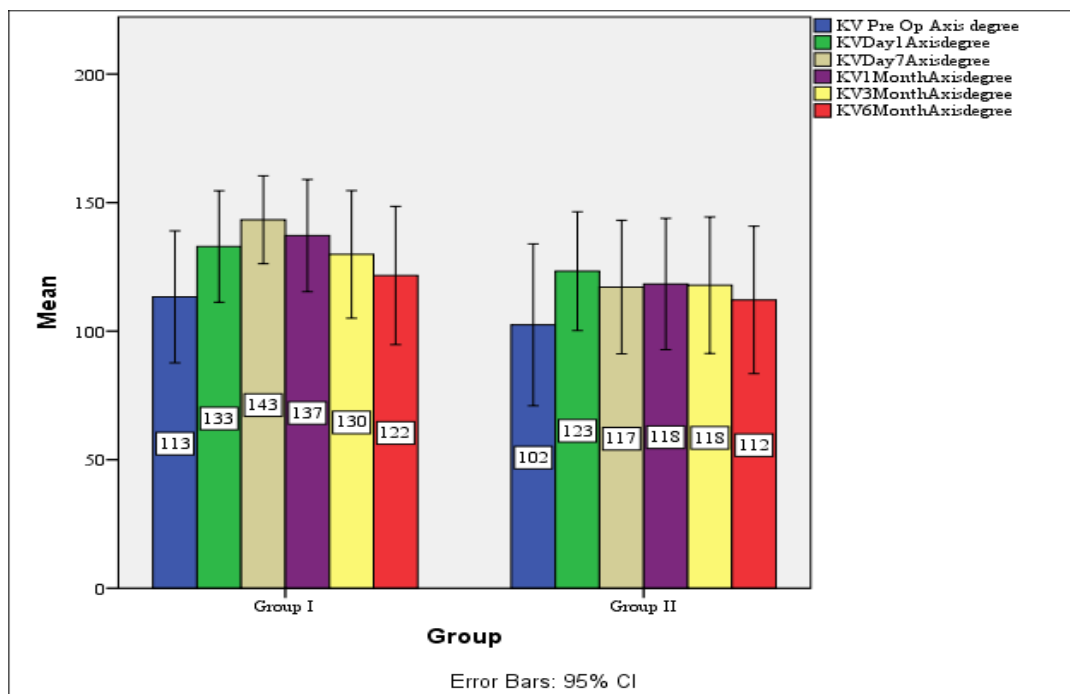


Graph 7: Bar diagram showing KH Axis degree distribution comparison between two groups at different intervals of followup

KV Axis Degree	Group I		Group II		Total		P value
	Mean	SD	Mean	SD	Mean	SD	
Pre OP	113.33	56.37	102.48	69.13	107.90	62.54	0.580
Day 1	132.90	47.66	123.33	50.74	128.12	48.86	0.532
Day 7	143.33	37.56	117.14	57.02	130.24	49.50	0.086
1 month	137.19	47.97	118.33	56.15	127.76	52.46	0.249
3 month	129.86	54.52	117.86	58.28	123.86	56.07	0.495
6 month	121.67	59.06	112.14	62.98	116.90	60.50	0.616

Table 9: KV Axis degree distribution comparison between two groups at different intervals of followup

There was no significant difference in Mean KV Axis degree at Pre OP, Day 1, Day 7, 1 month, 3 months and 6 months between two groups.



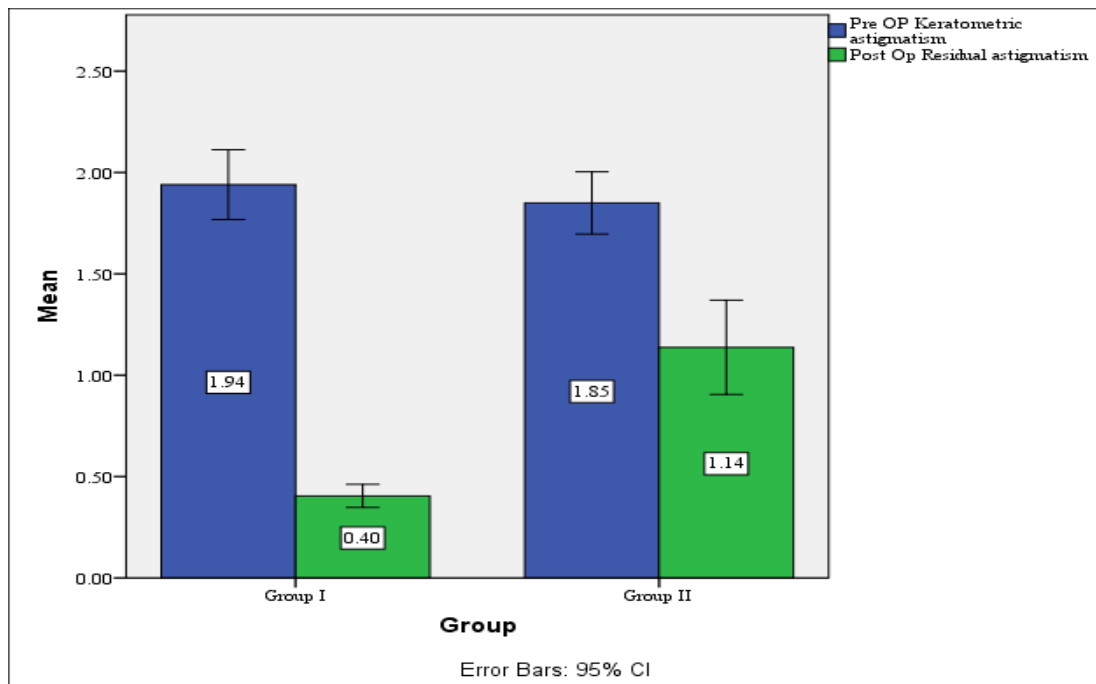
Graph 4: Bar diagram showing KV Axis degree distribution comparison between two groups at different intervals of followup.

Residual Astigmatism	Group I		Group II		Total		P value
	Mean	SD	Mean	SD	Mean	SD	
Pre Op	1.94	0.38	1.83	0.33	1.89	0.35	0.333
Post Op	0.40	0.12	1.14	0.50	0.76	0.51	<0.001*
Pre Op Axis degree KA	113.33	56.37	59.57	65.92	86.45	66.41	0.007*
Post Op Axis Degree RA	121.67	59.06	112.14	62.98	116.90	60.50	0.616

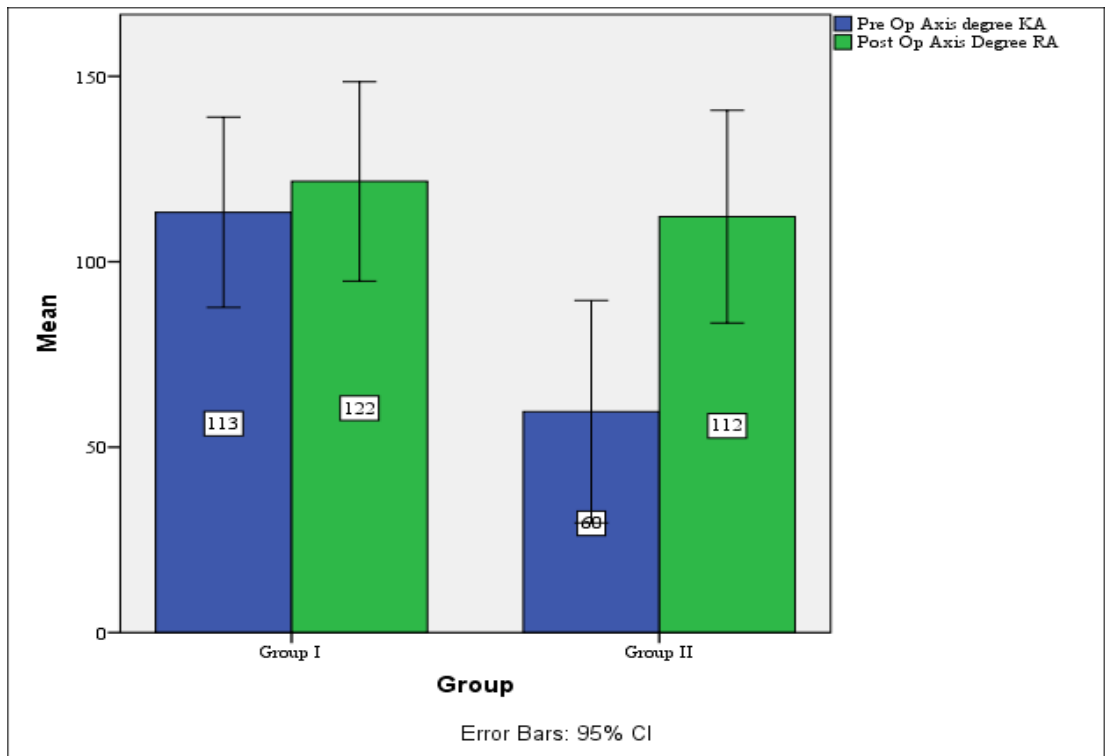
Table 10: Residual Astigmatism distribution comparison between two groups at Pre Op and Post OP

In the study there was significant difference in mean Residual astigmatism at Post Op b/w Group I and Group II. Mean Residual astigmatism in Group I at Post Op was 0.40 ± 0.12 and in Group II was 1.14 ± 0.50 .

Mean Pre Op Axis degree residual astigmatism in Group I was 113.33 ± 56.37 and in Group II was 59.57 ± 65.92 . There was significant difference in mean Pre Op Axis degree KA between two groups.



Graph 5: Bar diagram showing Residual Astigmatism distribution comparison between two groups at Pre Op and Post OP



Graph 6: Bar diagram showing Residual Astigmatism Axis degree distribution comparison between two groups at Pre Op and Post OP

Parameters	Group I		Group II		Total		P value
	Mean	SD	Mean	SD	Mean	SD	
IOP	14.29	2.31	14.05	1.80	14.17	2.05	0.711
Axial length	22.48	1.00	22.52	.91	22.50	.95	0.893
IOL	21.07	1.08	22.45	1.94	21.76	1.70	0.007*

Table 11: IOP, Axial length and IOL comparison between two groups

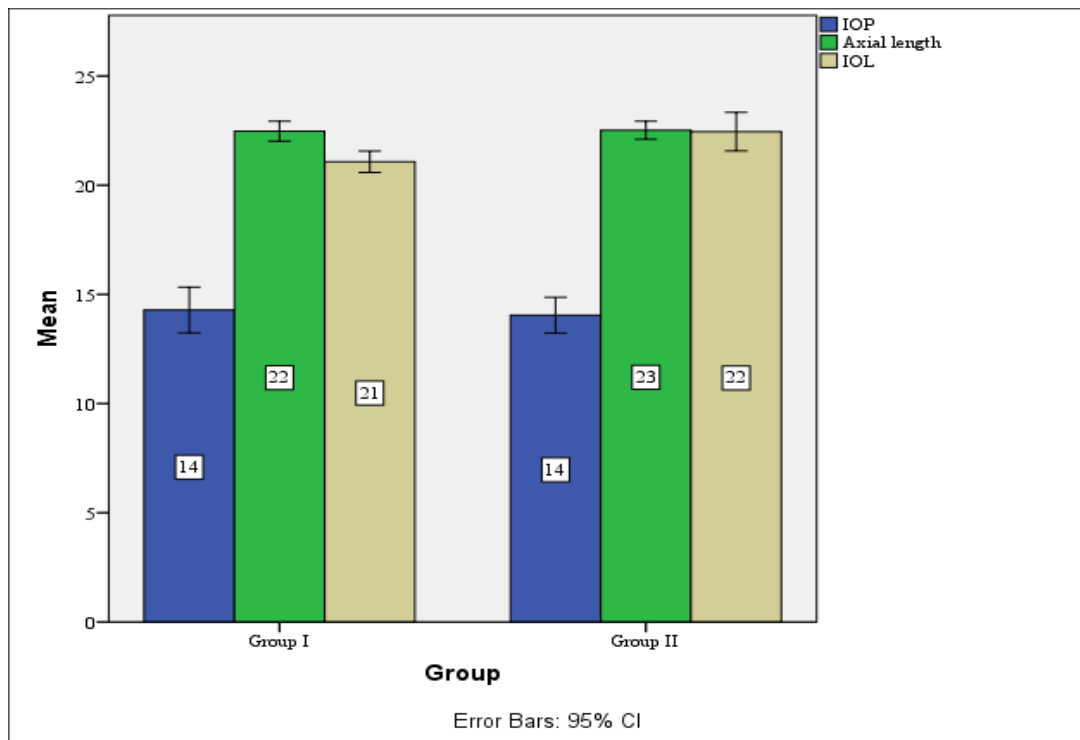
In Group I, mean IOP was 14.29 ± 2.31 and in Group II, mean IOP was 14.05 ± 1.80 .

There was no significant difference in IOP between two groups.

In Group I, mean Axial Length was 22.48 ± 1.00 and in Group II, mean IOP was 22.52 ± 0.91 . There was no significant difference in Axial Length between two groups.

In Group I, mean IOL was 21.07 ± 1.08 and in Group II, mean IOP was 22.45 ± 1.94 .

There was significant difference in IOL between two groups.



Graph 7: Bar diagram showing IOP, Axial length and IOL comparison between two groups

Toric IOL Rotation and Complications:

Mean degree of IOL rotation in our study was 1.95 ± 0.22 . IOL rotation of more than 5 degrees was considered significant. None of the subjects in our study had IOL misalignment of more than 5 degrees. None of the subjects in both the groups had experienced Glare and Halo

DISCUSSION

The present study comprises of 42 eyes of 42 patients divided randomly into 2 groups, comprising 21 patients in each group.

In group 1, patients underwent phacoemulsification with toric IOL implantation and in group 2, phacoemulsification with foldable IOL implantation. Both the surgeries are performed under peribulbar block by an experienced surgeon. All patients were followed up meticulously without any dropout. The duration of follow up was 6 months.

The two groups were compared in terms of postoperative visual acuity, residual astigmatism, complications and rotational stability.

DEMOGRAPHY:

The mean age of patients in group 1 was 65.14 yrs (ranged from 50-75 years) and in group 2 was 59.19 (ranged from 45-75 years). Majority of patients in group 1 and group 2 were in the range of 61-70 years, comprising 71.4% and 38.1% respectively.

There was no statistically significant difference between two groups in terms of age.

Group 1 had 9 (42.9%) male patients and 12 (57.1%) female patients and group 2 had 12 (57.1%) male and 9 (42.9%) female. There was no significant difference in sex distribution between two groups using chi-square test.

In group 1, 14 (66.7%) patients underwent surgery to right eye and 7 (33.3%) for left eye. In group 2, 15(71.4%) to right eye and 6(28.6%) left eye. There was no statistical significant difference between two groups.

ASTIGMATISM AND VISUAL ACUITY:

The preoperative astigmatism ranged from 1.5D – 3.0D in both the groups. The mean preoperative astigmatism in group 1 was 1.94 +/-0.38 and group 2 was 1.83 +/- 0.33.

There was no significant statistical difference in both the groups.

After 6 months of post-operative period, the total mean astigmatism is in the range of 0.76 +/-0.51 with group 1 patients having mean astigmatism of 0.40 +/- 0.12 and group 2 patients having astigmatism of 0.76 +/- 0.51. There was a statistically significant difference in mean residual astigmatism between two groups.

The mean preoperative UDVA in our study group 1 is 1.71+/-0.50 log MAR improved to 0.06+/-0.09 logMAR, Which was statistically significant. In group 2 is 1.76+/-0.47 logMAR improved to 0.24+/-0.05log MAR, which was statistically significant.

Venkataraman A, Kalpana their study compared the visual outcome and rotational stability of Toric IOL in 120 eyes showed the mean post-operative residual cylinder was reduced from 1.92 D +/- 0.30 to 0.36D +/- 0.57¹. This results are comparable to our study.

Khan I M et al., in their study compared the visual and refractive outcomes of toric intraocular lens implantation with foldable IOL implantation in patients with pre-existing astigmatism of >2.5D. The mean postoperative refractive cylinder values were 1.2 D +/- 0.68 in toric group and 3.23D+/-1.41 in non-toric group⁷⁸. The difference between two groups showed a statistical significance which is comparable to our study.

Holland et al., compared acrysof Toric IOL and an acrysof foldable IOL. The mean absolute residual refractive cylinder was 0.59D in Toric group and 1.22D in non-toric group⁴³. This results are comparable to our study.

Ahmad et al., evaluated the outcomes of bilateral toric intraocular lens implants in 117 patients (234 eyes). The mean residual refractive astigmatism was $0.4D \pm 0.4D^{79}$. Binocular UDVA was 20/40 or better in 99% of the patients which is comparable to our study.

Jung N Y et al conducted a randomised control trial with different types of toric IOLS in which Technis group has a residual refractive cylinder of $0.41 \pm 0.33D$ and precizon group had $0.31D \pm 0.29 D$ which was comparable to our study⁸⁰. The visual acuity at the end of 6 months in technis group was $0.08 \pm 0.12 \logMAR$ where as in precizon group it was $0.09 \pm 0.09 \logMAR$. However visual acuity at the end of 6 months in our study was better when compared to this study.

A study conducted by **Ferreira TB , Berendschot TT, Ribeiro FJ** on 51 eyes to evaluate the the clinical outcomes with a new transitional toric intraocular lens showed that mean UDVA was $0.06 \pm 0.1 \logMAR^{81}$ which was comparable to our study.

Gayton et al in a retrospective study compared the residual astigmatism in both uncomplicated and complex eyes after implanting acrysof toric IOL⁸². They concluded that residual cylinder reduced and UDVA improved in both the groups.

Thomas BC et al., in their study on clinical outcome after implantation of transitional conic toric surface toric IOL showed that UDVA increased from median $0.5 \logMAR$ preoperatively to median $0.6 \logMAR$ at three months postoperatively⁸³. This study was not comparable to our study.

Visser et al., in their study on visual outcomes after implantation of multifocal toric IOL showed mean UDVA was $0.04 \pm 0.15 \logMAR$ which was better than our study. Residual refractive astigmatism was $-1.0 D$ or less in 90% of the patients⁴⁶.

Entabi et al., evaluated the efficacy and the rotational stability of hydrophilic acrylic toric IOL and showed that mean UDVA was $0.28 \pm 0.23 \logMAR$ at the end of four months⁸⁴. Mean postoperative refractive astigmatism was $0.41 \pm 0.23 D$.

IOL ROTATIONAL STABILITY

Chang et al., in their study compared the rotational stability of acrysof SN60T toric IOL with AA4203 toric IOL. The mean IOL rotation was 5.56 +/- 8.49 degrees in the AA4203 group and 3.35 +/- 3.41 degrees in the acrysof SN60T toric IOL group. The study concluded that acrysof SN60T had better rotational stability.⁴¹

Visser et al., in their review article assessed the rotational stability of various Toric IOLs. It showed misalignment of more than 10 degrees was 20% ,13% , 9% and 3% for Staar, Rayner, microsil and Acrysof respectively. However there was no misalignment in Acri comfort and light adjustable lenses.⁴⁶

In our study, we did not encounter any IOL misalignment of more than 5 degrees which we considered significant. No patient underwent any IOL re-dialing. No other complications related to phacoemulsification are encountered in the study.

CONCLUSION

With the inferences drawn from the study we conclude that,

- The final visual outcome in patients with pre-existing astigmatism who underwent phacoemulsification with Toric IOL implantation was significantly better when compared to Patients in non-Toric IOL group.
- It also reduces the mean preoperative astigmatism compared to non-Toric IOL.
- The Toric IOL gives best un-corrected visual acuity by eliminating preoperative astigmatism. But the results depend on accurate preoperative assessment of astigmatism, precise marking under the slitlamp, perfect alignment of IOL and thorough removal of visco-elastic substance at the end of surgery is essential in maintaining the rotational stability of the IOL.
- In our study we conclude that, Toric IOL is better in correcting preoperative corneal astigmatism and provides best un-corrected visual acuity when compared to non-Toric IOL, thus making patients independent of spectacles.

SUMMARY

A total of 42 eyes fulfilling the inclusion criteria were selected and randomly divided into two groups of 21 eyes in each group for this study from ophthalmology inpatient department at R.L.J. HOSPITAL AND RESEARCH CENTRE, TAMAKA, KOLAR attached to SRI DEVARAJ URS MEDICAL COLLEGE between December 2016 and May 2018.

The present study comprises of 42 eyes of 42 patients divided randomly into 2 groups, comprising 21 patients in each group.

In group 1, patients underwent phacoemulsification with toric IOL implantation and in group 2, phacoemulsification with foldable IOL implantation. Both the surgeries are performed under peribulbar block by an experienced surgeon. All patients were followed up meticulously without any dropout. The duration of follow up was 6 months.

After 6 months of post-operative period, the total mean astigmatism is in the range of 0.76 +/-0.51 with group 1 patients having mean astigmatism of 0.40 +/- 0.12 and group 2 patients having astigmatism of 0.76 +/- 0.51. There was a statistically significant difference in mean residual astigmatism between two groups.

The mean preoperative UDVA in our study group 1 is 1.71+/-0.50 log MAR improved to 0.06+/-0.09 logMAR, Which was statistically significant. In group 2 is 1.76+/-0.47 logMAR improved to 0.24+/-0.05log MAR. The final visual outcome in patients with pre-existing astigmatism who underwent phacoemulsification with Toric IOL implantation had better outcome compared to non-Toric IOL.

The Toric IOL gives best un-corrected visual acuity by eliminating preoperative astigmatism. But the results depend on accurate preoperative assessment of

astigmatism, precise marking under the slitlamp, and perfect placement of IOL during surgery.

In our study we conclude that, Toric IOL is better in correcting preoperative corneal astigmatism and provides best un-corrected visual acuity when compared to non-Toric IOL, thus making patients spectacle independent.

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STUDY PROFORMA

Case no:

Date:

Name:

OP no:

Age:

IP no:

Sex:

DOA:

Occupation:

DOS:

Address:

Brief history:

Past history:

Family history:

Personal history:

GPE:

Vital signs:

Pulse –

RR –

BP –

Temp –

Systemic examination:

a) Cardiovascular system –

b) Respiratory System –

c) Per Abdominal examination –

Central Nervous System-

OCULAR EXAMINATION		
<u>TESTS</u>	<u>RE</u>	<u>LE</u>
1. HEAD POSTURE 2. OCULAR POSTURE 3. FACIAL SYMMETRY		
4. EXTRAOCULAR MOVEMENTS a) Ductions b) Versions		
5. <u>VISUAL ACUITY:</u> a) Distant b) Near		
6. <u>ANTERIOR SEGMENT</u> a. Lids and Adnexa b. Conjunctiva c. Cornea d. Anterior chamber e. Iris f. Pupil g. Lens h. Anterior Vitreous		
7. <u>FUNDUS</u> a. Distant direct ophthalmoscopy b. Direct ophthalmoscopy		

c. Indirect ophthalmoscopy		
8. <u>IOP</u> (mm Hg AT)		
9. <u>B – SCAN ULTRASONOGRAPHY</u>		
10. <u>KERATOMETRY</u> (diopter) K1 K2 Astigmatism		
11. AXIAL LENGTH (mm)		
12. INTRAOCULAR LENS POWER		
13. <u>DRY EYE EVALUATION</u> a) Schirmer’s test 1(mm) b) Schirmer’s test 2 (mm) c) Tear breakup time (Sec)		

POSTOPERATIVE ASSESSMENT:

POST OP DAY	1 WEEK	1 MONTH	3 MONTH	6 MONTH
VISUAL ACUITY				
KI				
K2				
COMPLICATIONS				
ROTATIONAL STABILITY				

**SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND
RESEARCH, TAMAKA, KOLAR - 563101.**

INFORMED CONSENT FORM

Case No:

IP No:

PREVALENCE OF ASTIGMATISM IN CATARACT PATIENTS

I, the undersigned, agree to participate in this study and authorize the collection and disclosure of my personal information as outlined in this consent form.

I understand the purpose of this study, the risks and benefits of assessment of astigmatism in cataract surgery and the confidential nature of the information that will be collected and disclosed during the study. The information collected will be used only for research.

I have had the opportunity to ask questions regarding the various aspects of this study and my questions have been answered to my satisfaction.

I understand that I remain free to withdraw from this study at any time and this will not change my future care.

Participation in this study does not involve any extra cost to me.

Name	Signature	Date	Time
Patient:			
Witness:			
Primary Investigator/ Doctor:			

ಭಾಗವಹಿಸಲು ಸಮ್ಮತಿ

ನಾನು, ರುಜುಮಾಡಿರುವ, ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಮತ್ತು ಈ ಒಪ್ಪಿಗೆ ರೂಪದಲ್ಲಿ ಅಂಶಗಳಂತೆ ನನ್ನ ವೈಯಕ್ತಿಕ ಮಾಹಿತಿಯ ಸಂಗ್ರಹಣೆ ಮತ್ತು ಡಿಸ್ಕೋಸರ್ ಅಧಿಕೃತಗೊಳಿಸಲು ಒಪ್ಪುತ್ತೀರಿ.

ಈ ಅಧ್ಯಯನದ ಉದ್ದೇಶ, ಬಳಸಲಾಗುತ್ತದೆ ಎಂದು ಕಾರ್ಯವಿಧಾನಗಳು, ಅಧ್ಯಯನ ಮತ್ತು ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಸಂಗ್ರಹಿಸಿದ ಮತ್ತು ಬಹಿರಂಗ ನಡೆಯಲಿದೆ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯ ಪ್ರಕೃತಿಯಲ್ಲಿ ನನ್ನ ಒಳಗೊಳ್ಳುವಿಕೆ ಸಂಬಂಧಿಸಿದ ಅಪಾಯಗಳನ್ನು ಮತ್ತು ಲಾಭಗಳನ್ನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.

ನಾನು ವಿವಿಧ ಈ ಅಧ್ಯಯನದ ಅಂಶಗಳು ಮತ್ತು ನನ್ನ ಪ್ರಶ್ನೆಗಳಿಗೆ ನನ್ನ ತೃಪ್ತಿಕರ ಉತ್ತರಗಳನ್ನು ಮಾಡಲಾಗಿದೆ ಸಂಬಂಧಿಸಿದ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವಕಾಶ ಹೊಂದಿದ್ದರು.

ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಈ ಅಧ್ಯಯನದಿಂದ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವಂತೆ ಮತ್ತು ಈ ನನ್ನ ಮುಂದಿನ ಆರೈಕೆ ಬದಲಾಗುವುದಿಲ್ಲ ಉಚಿತ ಉಳಿಯಲು ಎಂದು ಅರ್ಥ.

ವಿಷಯದ ಹೆಸರು ಮತ್ತು ಸಹಿ / ಹೆಬ್ಬೆಟ್ಟಿನ ಗುರುತು

ದಿನಾಂಕ:

ಪೋಷಕ / ಪೋಷಕರು ಹೆಸರು ಮತ್ತು ಸಹಿ

ದಿನಾಂಕ:

ಒಪ್ಪಿಗೆ ಪಡೆದ ವ್ಯಕ್ತಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ

ದಿನಾಂಕ

**SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND
RESEARCH, TAMAKA, KOLAR - 563101.**

PATIENT INFORMATION SHEET

Case no:

IP no:

This information is to help you understand the purpose of the study “**Evaluation of efficacy and safety of Toric intraocular lens implantation in Cataract patients With pre-existing Astigmatism.**” You are invited to take part voluntarily in this research study, it is important that you read and understand the purpose, procedure, benefits and discomforts of the study.

1. What is the purpose of this study?

To determine the prevalence, amount and type of astigmatism in cataract patients.

2. What are the various investigations being used? Are there any associated risks?

Absolutely no risks are associated with various investigations involved in this study such as manual keratometer, dry eye tests and routine ocular examination.

3. What is the benefit for me as a participant?

The identification of astigmatism in cataract individuals would be of importance in the determination of the intervention needed to reduce the postoperative diminished vision due to astigmatism by improving the services provided. Our observation may also be of importance in interpreting and/or planning clinical trials on various treatment options that help in achieving the near emmetropic vision.

Participation in this research study may not change the final outcome of your eye condition. However, patients in the future may benefit as a result of knowledge gained from this study. You will not be charged extra for any of the procedures

performed during the research study. Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at any time, without a penalty or loss of any benefits to which you were otherwise entitled before taking part in this study.

CONFIDENTIALITY

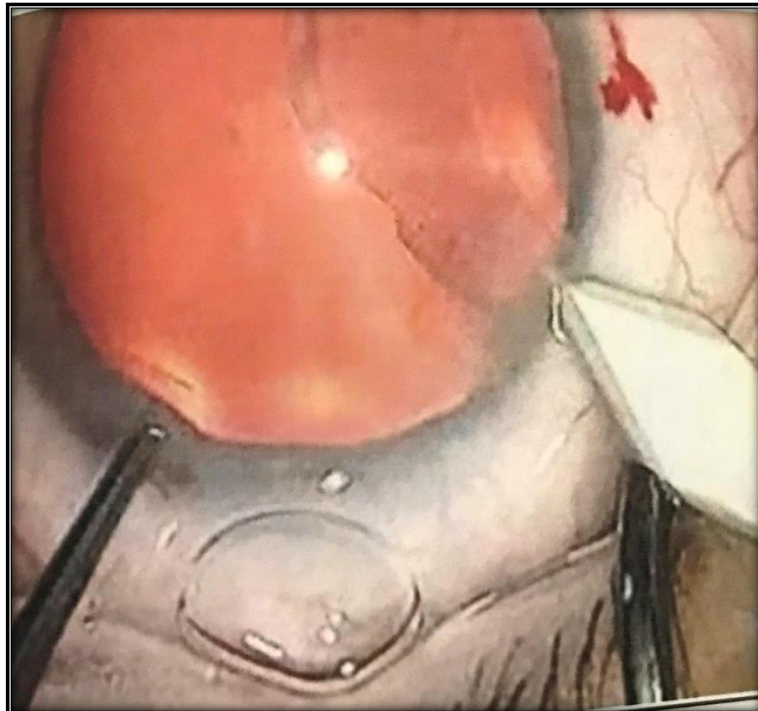
Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available. Your original records may be reviewed by your doctor or ethics review board. For further information/ clarification please contact Dr. KANTHAMANI. K, SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR - 563101.

Contact no: 9886416261

PHOTOGRAPHS



Photograph 1:preoperative slit lamp examination



Photograph 2: clear corneal incision



Photograph 3:phacoemulsification



Photograph 4:toric IOL insertion

KEY TO MASTER CHART

1. SI No: Serial number
2. IP No: In patient number
3. RE: Right eye
4. LE: Left eye
5. SIMC: Senile immature cataract
6. SMC: Senile mature cataract
7. PPC: Posterior polar cataract
8. SHMC: Senile hypermature cataract
9. PSP: Pseudophakia
10. DV: Distant vision
11. NV: Near vision
12. BCVA: Best corrected visual acuity
13. IOP: Intra Ocular Pressure

