"A LONGITUDINAL STUDY TO EVALUATE EFFECT OF SURGICALLY INDUCED ASTIGMATISM AFTER PHACOEMULSIFICATION CLEAR CORNEAL INCISION PLACED IN THE STEEPEST MERIDIAN ON EYES WITH PRE EXISTING ASTIGMATISM AT KLES HOSPITAL, BELAGAVI"

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Endorsement by the Head Of Department, Principal/ Head of the Institution

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LIST OF ABBREVIATIONS USED

ATR	–	Against the rule
BCVA	–	Best Corrected Visual Acuity
BSS	–	Balanced salt solution
CCC	–	Continuous curvilinear capsulorrhexis
CCTI	–	Clear Corneal Temporal Incision
CCOI	–	Clear Corneal On-axis Incision
D	–	Diopters
ECCE	–	Extracapsular cataract extraction
IOL	–	Intraocular lens
IOP	–	Intraocular pressure
K_H	–	Horizontal Meridian
K_V	–	Vertical Meridian
LASIK	–	Laser assisted in situ keratomileusis
LRI	–	Limbal relaxing incision
PEA	–	Pre-existing Astigmatism
PCIOL	–	Posterior chamber intraocular lens
PMMA	–	Polymethyl Methacrylate
SIA	–	Surgically Induced Astigmatism
SICS	–	Small Incision Cataract Surgery
SIRCs	–	Surgically induced refractive changes
UCVA	–	Uncorrected visual acuity
VA	–	Visual acuity
WTR	–	With the rule

ABSTRACT

Background and objectives

Of the total estimated 38 million blind people in the world, about 9 - 12 million are in India. 50-80 % of these people are blind due to cataract. The technique of ECCE became popular; but surgically induced astigmatism was very high due to sutures and longer incision length. Then came into picture manual SICS which proved better than ECCE but still there was little surgically induced astigmatism. After the introduction of phacoemulsification through small clear corneal incision induction of surgically induced astigmatism was very less. Thus, it has been proposed that by placing the incision on the steepest meridian by marking the magnitude of pre-existing astigmatism we can cause further reduction in surgically induced astigmatism. The purpose of the study is to see the beneficiary effect of an incision placed on the steepest meridian in controlling/ lowering the astigmatic outcome in eyes with pre-existing astigmatism and comparing effect of incisions at different sites.

1. To evaluate the effect of Surgically Induced Astigmatism (SIA) after phacoemulsification clear corneal incision in the steepest meridian on the magnitude of the Pre-existing astigmatism (PEA).
2. To map the magnitude of surgically induced astigmatism by incisions in positions Superior (S) and Temporal (T).

Methodology

The present one year longitudinal study was conducted in the Department of Ophthalmology, KLES Dr. Prabhakar Kore hospital and Medical Research Centre, Belagavi on patients undergoing cataract surgery during the period of 1st January 2014

– 31st December 2014. The study was approved by the Ethical and Research Committee of Jawaharlal Nehru Medical College, Belagavi. The patients undergoing phacoemulsification with pre-existing astigmatism ranging from 0.5 D – 1.5 D were selected for the study to evaluate surgically induced astigmatism after phacoemulsification clear corneal incision in the steepest meridian on the magnitude of the pre-existing astigmatism.

Results

In the present study the mean age was 60 years with majority of the patients in the range of 50-70 years. 56% patients were males and 44% patients were females.

In the present study, 32% patients had 0.5 D of pre-existing astigmatism followed by 51% patients in the range of 0.5 – 1D and 17% patients had pre-existing astigmatism in the range of 1- 1.5 D. 93 % patients had post-operative astigmatism in the range of 0.0 - 0.5 D followed by 07 % patients in the range of 0.5 – 1D. 30% patients were reported to have no post-operative astigmatism.

In the study, 54 % patients had SIA in the range of 0.0 - 0.50 D followed by 39% patients who had SIA in the range of 0.5 – 1 D and 05% in the range of 1 -1.5D. The result showed that the average SIA recorded was 0.54 D $\pm$ 0.34 with $p < 0.001$ (Statistically significant). It was concluded using the paired‘t’ test.

The SIA through the temporal incision was 0.70 D with standard deviation of 0.35. The SIA through the superior incision was 0.84 D with standard deviation of 0.49. But, this difference of SIA comparison between temporal and superior incision was not statistically significant ($p = 0.145$)

In the temporal incision, pre-operatively 22 patients (54%) had pre-operative astigmatism in the range of 0.00 – 0.5 D whereas post-operatively 40 patients (98%) had post-operative astigmatism in the range of 0.00 – 0.5 D In the superior incision, pre-operatively 20 patients (49%) had pre-operative astigmatism in the range of 0.00 – 0.5 D, whereas post-operatively 36 patients (88%) had post-operative astigmatism in the range of 0.00 – 0.5 D.

On taking temporal incision, the mean keratometric difference was 1.03 $\pm$ 0.96 which was statistically significant ($p<0.001$). On taking superior incision, the mean keratometric difference was 0.92 $\pm$ 0.95 which was statistically significant ($p<0.001$)

The visual rehabilitation was good. 90% patients had UCVA in the range of 6/12 -6/6 and 95 % patients had BCVA in the range of 6/12 – 6/6.

Conclusion and interpretation

Choosing the clear corneal incision site based on the preoperative steepest meridian significantly decreased the keratometric astigmatism at the temporal and superior locations. As well as, temporal incision is evidently better than superior incision in minimizing surgically induced astigmatism.

Key Words

Phacoemulsification, Pre-existing Astigmatism, Surgically Induced Astigmatism

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

LIST OF PHOTOGRAPHS

INTRODUCTION

Of the total estimated 38 million blind people in the world, about 9 - 12 million are in India. 50-80 % of these people are blind due to cataract. In addition to the backlog, around 3.8 million people become blind each year due to cataract. [(1)]

Cataract is defined as an "Opacity in the lens capsule or its substance". It is one of the commonest causes of preventable blindness in the world. The mainstay of management of cataract is surgery, as medical treatment has not proved beneficial.

The aim of cataract surgery is to provide early visual rehabilitation. Intracapsular cataract extraction was introduced in 1753 which ends with aphakia. Then came extra capsular cataract extraction with intra ocular lens which corrected aphakia but post-operative astigmatism was significant with large incisions. The visual outcome of uncomplicated surgery is mainly attributed to degree of postoperative astigmatism which in turn depends on the type, length and position of incision and also on the method of wound closure.

The advent of microsurgery with operating microscope, better quality of instruments, invention of intraocular lens have remarkably improved the result of cataract surgery. The most remarkable development in cataract surgery during the 20^{th} century was the technique of phacoemulsification introduced by Kelman in 1967.The main advantage of this technique being small incision, least postoperative morbidity in terms of tissue injury, pain, inflammation and surgically induced astigmatism.

With the advent of latest foldable intraocular lens as a deviation from conventional rigid intra ocular lens, it is possible to implant the lens through an incision as small as 3 mm or even low, which helps in significantly reducing post-operative astigmatism.

The present day cataract surgery aims at not only removal of cataract but also correction of pre-existing spherical as well as cylindrical component of the refraction, and so is rightly called as 'Refractive Cataract Surgery'. The spherical refractive error can be eliminated through a meticulously performed accurate IOL power calculation, while control of final post-operative astigmatism during cataract surgery involves management of 2 important aspects:

- Pre-existing astigmatism
- Surgically induced astigmatism

  By assessment of corneal topographic changes by keratometer helps in correcting the surgically induced astigmatism with refraction.

There are two approaches, i.e. through superior clear corneal and temporal clear corneal incision. Placing the incision on the steepest meridian in eyes with pre-existing astigmatism leads to a significant amount of corneal flattening in that meridian and a corresponding steepening in the opposite meridian. [(2)]

There are various modalities of correcting astigmatism which include on axis cataract incision, Corneal relaxing incision, Limbal relaxing incision/Opposite clear corneal incision, Toric IOLs.

The purpose of the study is to see the beneficiary effect of an incision placed on the steepest meridian in controlling/ lowering the astigmatic outcome in eyes with pre-existing astigmatism and comparing effect of incisions at different sites.

AIMS AND OBJECTIVES

1. PRIMARY:

To evaluate the effect of Surgically Induced Astigmatism after phacoemulsification clear corneal incision in the steepest meridian on the magnitude of the pre-existing astigmatism.

2. SECONDARY:

To map the magnitude of Surgically Induced Astigmatism by incision in Superior (S) and Temporal (T) positions.

REVIEW OF LITERATURE

Cataract means "Waterfall". Any congenital or acquired opacity in the lens capsule or its substance is called cataract. Management of cataract is 'surgery', which is indicated only if and when cataract develops to such a degree that is sufficient to cause difficulty in performing daily essential activities [(3)].

Cataract surgery in antiquity

Cataract surgery has been performed since centuries. Over the period, cataract surgery has evolved from couching to the latest femtosecond laser-assisted micro incision cataract surgery (MICS) [(4)].

- Era of couching (600 B.C to 18th century)
- Era of early Extracapsular cataract extraction (1745 – 1877)
- Era of Intracapsular cataract extraction (1877 – 1980)
- Evolution of modern Extracapsular cataract extraction :

- Planned ECCE
- Manual Small Incision Cataract Surgery (MICS)
- Phacoemulsification [(4)]

Sushruta practiced couching as early as 600 B.C. The word couching derived from the French word 'couche' which means 'to put to bed' refers to displacement of abnormal material obstructing vision. The technique involved making a hole (sclerotomy) posterior to the corneo-scleral junction followed by pushing the cataractous lens inferiorly with the help of the so-called couching needle [(4)].The proof of success was the ability of the patient to see forms and figures again.

Cataract surgery developed from couching to modern day Manual Small Incision Cataract Surgery and Phacoemulsification after the development of Intra Ocular Lens (IOL) by Ridley [(4)].

- In 1745 Daviel performed cataract surgery by a limbal section of 180° in the lower half with a triangular knife.
- Samuel Sharp in 1773, introduced intracapsular cataract extraction, through a limbal incision using pressure from his thumb.
- Von Graefe in 1865 made a section in the superior limbus and advocated iridectomy to prevent pupillary block glaucoma.
- Williams in 1867 was the first to use corneal sutures.
- Pagenstecher in 1877, advocated the delivery of the lens complete in its capsule by indenting the cornea in front of the limbus.
- Later on the incision size reduced to about 120° and then 8-12 mm in planned extra capsular cataract extraction.
- In 1951 Ridley introduced and placed acrylic intraocular lens (IOL) behind the pupil.
- A cryosurgical probe was first employed by Krawauritz in 1961.
- Richard Kratz first developed the scleral tunnel incision in 1980.
- In 1982 Kratz and Sanders proved that smaller incisions were better than larger, producing less early induced astigmatism and less late healing astigmatic shift.
- Michael McFarland published the development of a sutureless incision in March 1990.

- Ernest later recognized that the corneal lip of this sclerocorneal tunnel acted as a one way valve which imparted self sealing property to this incision.
- Blumenthal described hydro expression of nucleus in 1992 [(4)].

In the era of early Extracapsular cataract extraction (ECCE), due to increased incidence of lens matter induced inflammation, pupillary membrane (after cataract) formation and rise of IOP (Secondary glaucoma) effort started to remove the lens in entirety.

In modern ECCE techniques which have improved with the availability of newer instruments, use of microscopes, better techniques of anterior capsulotomy and improved infusion/aspiration modalities has gained popularity.

Although this technique of conventional ECCE became popular, surgically induced astigmatism was very high due to the sutures and longer incision length. So, SICS came into picture which proved better than conventional ECCE as it had many advantages.

Advantages of manual small incision cataract surgery over conventional Extracapsular cataract surgery

- Fast visual recovery.
- Small and sutureless incision, no photophobia and foreign body sensation.
- Self sealing tunnel incision.
- Minimal astigmatism.
- Patient rehabilitation is faster and early rehabilitation is possible.

SICS is still a popular technique in many places but the surgically induced astigmatism was still a problem. So, the latest technique which is now popular is phacoemulsification through a small incision which gave an advantage of less surgically induced astigmatism.

Charles D.Kelman introduced the concept of phacoemulsification as early as 1948, but it was accepted in 1967. The original equipment was known as Cavitron-Kelman Phacoemulsifier Mark I. A significant breakthrough in the surgical removal of cataracts occurred with the introduction of clear corneal incisions by I. Howard Fine, M.D., in 1992 [(4)].

Merits of Phacoemulsification

- Topical anesthesia
- Post-operative congestion is minimal as performed through clear corneal incision
- Small incision (2.8 - 3.2 mm)
- Less corneal complications
- Visual rehabilitation is comparatively quicker
- Post-operative astigmatism is less as foldable IOLs are implanted through a smaller incision
- The use of clear corneal wounds has transformed cataract surgery by reducing surgical time, offering faster postoperative recovery and lowering the rate of induced astigmatism in comparison to the once-dominant traditional scleral tunnel incision.

- Complications associated with scleral tunnel incisions, such as conjunctival manipulation and hyphemas, have been virtually eliminated with the utilization of clear corneal incisions.

Nowadays, after the introduction of phacoemulsification through a small clear corneal incision induction of surgically induced astigmatism generated by ECCE was almost solved. So, cataract surgery today is seen as a **'refractive cataract surgery'**. Thus, it has been proposed that by placing the incision on the steepest meridian by marking the magnitude of pre-existing astigmatism, we can cause reduction in surgically induced astigmatism. The making of the incision in the steepest meridian causes corneal flattening in that meridian to reduce astigmatism. Although small, the magnitude of astigmatism caused by incision depends on the size and its location [(5)].

Snellen suggested that a corneal incision running perpendicular to the steepest meridian would induce an opposite astigmatism that would neutralize the first; although he made no mention of the effect of such an incision might have on the opposite meridian – a process called coupling [(6)].

Any surgical incision placed on the cornea, results in a change of the corneal curvature. This induces a flattening in the axis of incision and steepening 90 degrees away. Based on the Gauss's law for a perfectly elastic dome any change in one axis, results in an equal or comparable change in the opposite axis [(7)].

In 1885, Schiotz confirmed Snellen's hypothesis that significant degree corneal flattening occurred in a cataract patient after the placement of a corneal incision tangential to the steep meridian [(8)].

Bates had set down few basic principles of astigmatic surgery –

- A corneal incision lengthens the radius of curvature of that meridian which is at right angles to the line of the incision and does not flatten any other meridian
- The immediate result is greater than the ultimate result
- The astigmatism produced is permanent after a length of time – at least a month after the cornea has healed
- The amount of astigmatism produced is greater near the centre of the cornea
- He recognized the ability of relaxing incisions to produce flattening of steep curvature. [(6)]

Lans showed that flattening in the meridian perpendicular to a transverse incision would be associated with steepening in the opposite meridian [(6)]. Astigmatism today following cataract surgery is less common with the smaller incision being used. So, keeping all these aspects we have tried to reduce the surgically induced astigmatism post-cataract surgery by a few modifications like steepest meridian incision. The concept is that flattening force has to be applied to the steeper meridian with less force being applied to the flatter meridian [(6)].

Advantages of Phacoemulsification over extra capsular cataract extraction:

- Fast visual recovery.
- Small and sutureless self sealing incision.
- Minimal astigmatism.
- Decentration of intra ocular lens is less as it is in the bag.
- Less chances of iris injury intraoperatively.
- Less chances of wound leak, flat anterior chamber and infection.
- Eye remains quite being sutureless.

- Photophobia and foreign body sensation is minimal.
- Hospitalization and suture removal not needed.
- Chances of vitreous loss and cystoid macular edema are less.
- Postoperative retinal examination is possible soon after surgery because of clear cornea.
- Patient rehabilitation is faster as stay is not required and early return to work is possible.

Pallin SL has done a study comparing astigmatism after phacoemulsification and conventional extra capsular cataract extraction concluded that phacoemulsification group induced less astigmatism than conventional extra capsular cataract extraction group.[(9)]

Dr.Fine IH developed the clear corneal incision which had obvious advantages over scleral tunnel incisions like less bleeding, prevention of cautery and induced astigmatism, view during surgery is unhampered by conjunctival flap and a good visualization of intraocular structures during surgery. [(10)]

Neuman AC presented a comparison of surgically induced astigmatism between phacoemulsification with silicone foldable lens implantation and phacoemulsification with rigid PMMA IOL through 6 mm incision and conventional extra capsular cataract extraction through 10 mm incision. In phacoemulsification series mean induced astigmatism was significantly less than conventional extra capsular cataract extraction and PMMA IOL (6 mm incision) at the end of 3 and 6 month post operatively. **[(11)]**

Muller Jenson K in his comparative study of astigmatism after 4 mm sutureless versus 12 mm sutured clear corneal incision concluded that mean surgically induced astigmatism was 1 D in 4mm suture less incision and 1.75 D in 12 mm sutured incision group. [(12)]

Advantages of temporal clear corneal incision:

- Surgeon positioned on the side, working at the temporal periphery, there is no need to turn eye down. Therefore the bridle sutures are not necessary.
- With the iris plane parallel to the light of microscope, the red reflex is enhanced and there is marked improvement in visualization of intraocular structures.
- This location allows greater access to the incision than when working over the brow.
- At this location, the lateral canthal angle is directly beneath the incision, the irrigation fluid drains naturally.
- The temporal location is farthest from the visual axis, and thus the endothelial damage postoperatively is much less than superiorly placed incisions, and any flattening around the wound is less likely to affect the corneal curvature at the visual axis.
- Incisions at this location are more stable with respect to against the rule drift.
- When incision is located superiorly, both gravity and eyelid blink tend to create drag on the incision. With temporal location, these forces are better neutralized.
- At this location, the astigmatism induced is “with the rule”, which is advantageous for the aged patients whose preoperative astigmatism was ‘against the rule’.

Stan J.Roman et al studied surgically induced astigmatism with superior and temporal incisions in cases of WTR pre-operative astigmatism. They concluded

superior clear corneal incision produced significant SIA leading to high post-operative astigmatism and poor UCVA. The temporal incision produced minimal SIA and good UCVA. [13]

Advantages of superior clear corneal incision:

- Safety – Due to the incision under the eyelid.
- Patient comfort - A superior incision is almost completely away from the blink of an eyelid, so theoretically reducing post-operative discomfort and foreign body sensation.
- Patients who do not have deep set eyes are preferably taken for superior incision if the patient has WTR astigmatism.
- Easier to abandon and convert to large section surgery should the need arise
- Lesser incidence of post-operative endophthalmitis

The incision has a relaxing effect on the meridian where it is placed. The SIA is against the rule for a superior location and with the rule for a temporal location. The superior corneal incision rarely allows reaching a minimum postoperative astigmatism as with a temporal location [14].

ANESTHESIA IN PHACOEMULSIFICATION:

Most surgeons prefer peribulbar anesthesia. However, other techniques which are being used are topical anesthesia with 4% paracaine drops, subconjunctival injection of 2% xylocaine with sensorcaine, sub-tenon perfusion with a canula, application of a wet cotton plaque dipped in xylocaine at the wound site, intracameral preservative free xylocaine.

PHACODYNAMICS:

Phacodynamics refers to the study of the main functions of phacomachine which include phaco power delivery and irrigation-aspiration and their inter-relationship. Phacodynamics include:

- Fluidics
- Phaco power modulation
- Surge and its prevention [15]

Phacoemulsification comprised of two elements, i.e. the ultrasound energy which is used to emulsify the cataractous nucleus and fluidic circuit to remove the emulsified nucleus through small incision.

Phacomachine has three basic functions i.e. irrigation, aspiration and ultrasonic fragmentation which is operated by depressing foot pedal (0, 1, 2, 3) or foot switch which is prefixed. Phaco-tip made of titanium is hollow with the distal opening aspiration port. The phaco-tip bevel angles ranges from 0° to 60° [0°, 15°, 30°, 40° and 60°].

Power is generated by the vibrating piezo-electric crystals. The individual crystal vibrates at a frequency of 28,000 – 60,000 Hz which is the domain of the ultrasonic. Axial oscillations through its stroke length results in Jackhammer effect which mechanically breaks lens material (microcavitation). Power delivery is controlled by the foot pedal. In position three, power generated is proportional to the amount of foot pedal depression (linear control). The actual mode of delivery of power may be continuous or pulsed [16]

Phacopower is the ability of the phaco-handpiece to emulsify cataract i.e. 30-70%. Its increased if the cataract is dense i.e. up to 80% stroke length is the distance by which the titanium phaco-tip moves to and fro. Frequency is the number of times the tip moves. Pulse power in constant mode – is delivered continuously by panel. Aspiration by peristaltic pump, which controls aspiration and produce negative suction pressure.

Irrigation System - Gravity is the primary determinant of the hydrostatic pressure . The pressure involved is proportional to the height of the irrigation bottle above the patient's eye level [(16)].An irrigating fluid bottle which supplies fluid volume as well as pressure to maintain anterior chamber. It is placed usually between 65 - 75 cm above the eyelevel. This fluid maintains anterior chamber, while clears the emulsate from anterior chamber, attracts nuclear fragments when phaco-tip is unoccluded by a current in anterior chamber.

Flow-rate depends on the degree of phaco-tip occlusion. Flow-rate is adjusted to clear anterior chamber of the emulsate and to cool phaco-tip i.e. 18-25 cc/min. Vacuum pump indirectly controls flow i.e. 200-250 mm of Hg.

There are 2 types of pump system i.e peristaltic pump and venturi pump. Peristaltic pump can independently control vacuum and Aspiration Flow Rate (AFR). Venturi pump cannot independently control vacuum and AFR.

Applied anatomy of cornea for wound healing [(17)]

The cornea is a transparent, avascular, watch glass like structure forming anterior one sixth of the outer fibrous coat of the globe.

The anterior surface of cornea is elliptical with an average horizontal diameter of 11.7 mm and vertical diameter of 11 mm. The posterior surface of cornea is circular with an average diameter of 11.5 mm. It is 0.52 mm thick in the centre and 0.67 mm thick at the periphery. The central 3 - 5 mm of cornea "the optical zone" has an anterior radius of curvature of 7.8 mm and a posterior radius of curvature of 6.5 mm. The total refractive power of cornea is 45 D which is $3/4^{th}$ of the total refractive power of the eye. Its refractive index is 1.37.

Microscopically the cornea has five layers. These is an anterior epithelium of 5 to 90µ thickness, the Bowman's membrane which is 8 to 14µ thick, the stroma which forms 90% of corneal thickness and is 0.5 mm in thickness, a 40µ thick Descemets membrane and a single layer of endothelium facing the anterior chamber.

The epithelium of cornea continues across the limbus as the conjunctival epithelium and the stroma of cornea continues across the limbus as the stroma of sclera. Stroma is the main supporting tissue. Any injury and incision, healing affects the stromal layer more.

Collagen arrangement in cornea

The collagen lamellae in the cornea are oriented orthogonal to each other in the stroma with regular spacing in between them. These lamellae run from limbus to limbus across the cornea. The fibers near the limbus are all oriented tangential to the limbus and the limbal fibers are in the form of a well defined annulus which extends 1 mm into the sclera. This annulus varies in width with position around the cornea. It being 1.5 mm wide superiorly, 2 mm wide inferiorly and maximum value midway between superior and nasal and superior and temporal cornea [(17)].

Clear Corneal Incision – Biomechanics of wound healing

Once the wound is created, the wound edges become quite edematous and opaque due to fluid imbibitions by the corneal layers. Anterior and posterior apices are formed corresponding to the superficial and deep edges of the wound respectively. Healing of the anterior triangle is brought by two mechanics. Firstly, epithelial cells surrounding the area migrate to cover the defect. Secondly, there is increased mitotic activity of the epithelial cells. Healing of the posterior triangle is by filling the defect with endothelial cells that rearrange themselves by sliding, mitosis and thinning. In stromal healing, there is a gradual increase in collagen formation and subsequent increase in tensile strength. The new connective tissue formed pushes out the epithelial plug outwards and also fills in the posterior triangle such that the normal layering of the cornea is restored [(18)]. By placing a clear corneal incision at the steepest meridian causes flattening of the cornea in that meridian and steepening of the opposite meridian.

HISTORY OF ASTIGMATISM

- In 1801, Thomas Young was the first to describe about ocular astigmatism.
- However, it was some years later that Airy in 1827 corrected astigmatism using cylindrical lens.
- Corneal astigmatism was characterized by Knapp and Donders in 1862.
- In 1864 Donders describes regular astigmatism.
- Donders also described astigmatism after cataract surgery and soon after Snellen in 1869 suggested that placing the incision on steep axis would reduce corneal astigmatism. [(19)]

Basics of Astigmatism:

The term astigmatism is derived from Latin word “Stigma” (meaning a point). Thus astigmatism means “without a point”. Irwin and Borigh (1970) defined astigmatism as a refractive condition in which a variation of power exists in the different meridians of the eye.

Miller Stephen J defined astigmatism as an “error of refraction in which a point of light cannot be made to produce a punctate image upon the retina by a correcting spherical lens”. **(20)** Generally one meridian exhibits the greatest and the other the least power. These are known as “principal meridians”.

Classification:

A) Regular Astigmatism

i) With the rule

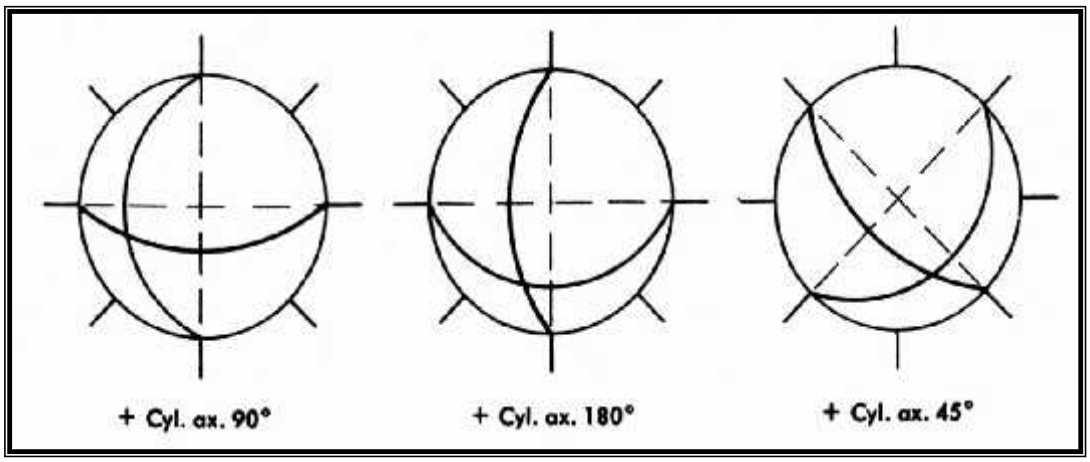
ii) Against the rule

iii) Oblique

iv) Bi-oblique

B) Irregular Astigmatism

FIGURE NO – 1 : CORNEAL ASTIGMATISM



With the rule **Against the Rule** **Oblique**

Regular Astigmatism:

Here, the two principal meridians i.e. direction of greatest and least curvatures of cornea lies at right angles to one another. This is determined by manifest refraction and manual keratometry.

Simple Astigmatism:

Where one of the foci falls upon the retina and the other focus may fall infront or behind the retina i.e. –

a) Simple hypermetropic astigmatism: Where one of the foci falls on retina and the other falls behind the retina.

b) Simple myopic Astigmatism: One of the foci falls on retina and the other falls in front of the retina.

Compound Astigmatism:

Neither of the two foci lies upon the retina but both are –

a) Compound hypermetropic astigmatism where both foci are placed infront of the retina.

b) Compound myopic astigmatism where both foci are placed behind the retina.

Mixed Astigmatism:

Where one focus is in front of the retina and the other behind the retina so that refraction is hypermetropic in one direction and myopic in the other.

i) With the Rule (Direct) (WTR):

It is a physiological type where in the vertical curve is greater than the horizontal i.e. the meridian with the greatest refractive power is near vertical in orientation or close to 90° or the meridian of least curvature makes an angle of less than 30° with horizontal plane.

ii) Against the Rule (ATR):

The meridian of least curvature makes an angle of less than 30° with vertical plane or the meridian with greatest refractive power is near the horizontal in orientation or close to 180°.

iii) Oblique Astigmatism:

The principle meridians are greater than 30° from the vertical or horizontal meridian but still at right angles to each other.

Irregular Astigmatism:

Refraction in different meridians conforms to no geometrical plane and the refracted rays have no planes of symmetry. This is found only in pathological conditions of the cornea i.e. irregular healing following any injury, inflammation or ulceration.

This usually exists when distribution of the refracting power over the cornea is irregular and prevents the cornea from forming a single point focus. Instead it forms a line focus. This refractive error cannot be corrected with sphero-cylindrical spectacles.

Types:

- Macroirregular Astigmatism: It occurs when the corneal curvature along a given meridian is different for each semi meridian. A common example is keratoconus in which the inferotemporal corneal steepening occurs.

- Microirregular Astigmatism: It exists when small regions on the corneal surfaces show variable refracting power i.e. 1 mm as seen in the faceting of contact lens warpage or as small as a few epithelial cells seen in keratoconjunctivitis sicca with superficial punctate keratitis. This can be easily detected where in mires become wavy and irregular due to which crisp superimposition is impossible.

The importance of astigmatism lies in the fact that it is particularly liable to cause the worst form of asthenopic symptoms. It usually results in headache, eye ache due to blurring of vision.

The astigmatism produced by the contraction of scar post cataract surgery results in flattening of the cornea in the meridian at right angles to the wound. [(10)] This change in the corneal curvatures continues to alter for some weeks after the surgery. So, the final spectacle correction should always be done after at least 6 weeks postoperatively.

Prevalence of astigmatism and changes with age

In first months of life, infants show a high prevalence of high (6D average) ATR astigmatism (corneal). The steepest most astigmatic corneas occur in newborns with the lowest birth weight and lowest post conception age. As infants grow, emmetropisation of astigmatism occurs. Astigmatism shifts to low levels of WTR after four years age and pressure from eyelids on cornea over time has been suggested as a cause. Children typically display WTR astigmatism. Young adults typically display small degrees of WTR astigmatism and in older adults shift occurs and ATR astigmatism becomes more prevalent. Internal astigmatism remains stable throughout life and changes in astigmatism throughout life are primarily due to changes in corneal curvature.

Causes of astigmatism

1. Both genetic and environmental influences have a role in development of astigmatism.
2. Eye lid pressure has been proposed as a cause of WTR astigmatism by Grosvenor.
3. Nystagmus – people with nystagmus usually have high degrees of corneal WTR astigmatism.

4. Visual tasks – Certain visual tasks like prolonged reading habit in down gaze have a potential for inducing ATR astigmatism.
5. Surgically induced astigmatism occurs after surgeries for cataract, trabeculectomy, ptosis, scleral buckling, pterygium excision.

Effect of astigmatism on vision

Astigmatism induces distortion of image. The retinal images in astigmatism are distorted because of a differential magnification in the two principal meridians. There is 0.3% image distortion per diopter of astigmatism [(21)].

In WTR astigmatism, the weaker principal meridian power produces a vertical line focus. In printed matter the vertical strokes of the letter are more important for recognition for example b, d, h, also there is less space between letters than between lines. Hence it is useful to have a better focus in vertical meridian as is there in myopic WTR astigmatism, resulting in better Snellen's visual acuity.

Another benefit of WTR astigmatism is that less cylinder is required in spectacle correction than ATR astigmatism of same magnitude. In corrected, astigmatic eye, retinal image distortion arises due to unequal spectacle magnification in the two principal meridians, representing 1.6% distortion per diopter cylinder correction.

More over spectacle cylinder will be less than the ocular astigmatism when the spherical equivalent is positive and greater than the ocular astigmatism when spherical equivalent is negative. So in general myopic ATR astigmatism will result in proportionally larger spectacle correction, which will produce more distortion. A

certain degree of myopic astigmatism is useful as it may produce a situation of pseudo accommodation in psuedophakic patient [22].

Uncorrected astigmatism causes blurred image, glare, monocular diplopia. Even with appropriate spectacle correction the meridional magnification may create distortion. The patients having preoperative astigmatism may experience difficulty adapting to axis shift induced by surgery. Any of these effects may create not only dissatisfaction with visual outcome, but also discomfort with an otherwise uneventful surgery.

Refraction

Refraction evaluates the entire optical system of the eye and includes any aberrations of the lens, posterior cornea, IOL or posterior capsule. Retinoscopy can determine both the magnitude as well as the axis of cylinder in astigmatism with remarkable precision.

Refractions are normally performed at the spectacle plane and not at the corneal plane. For surgically induced refractive changes (SIRCs) determined by refraction to be compared with SIRCs determined by keratometry or topography, they must be vertexed to corneal plane. Spectacle vertex distance is usually 12 mm. When correctly vertexed to cornea, astigmatism at corneal plane is almost $1/4^{th}$ D less. This relationship is always true for compound myopia. For compound hypermetropia it is just opposite, that is astigmatism is always more by $1/4^{th}$ D at corneal plane than at spectacle plane [23]. If there is zero residual spherical equivalent refraction, the cylinder will be equal to corneal astigmatism [24].

The main refractive media of the eye are the cornea and the lens. The refractive state of the lens can be variable, particularly with cataract development. Hence retinoscopy does not give an accurate refractive status of the eye in cataract patients as well as in patients with pseudophakia [25].

Measuring the corneal curvature:

1. Keratoscopes:

Placido's disc: Invented by Gode in 1847. This instrument is 20 cm in diameter and forms an erect, virtual image of concentric rings a few millimeters behind the cornea after light from an attached or external source is reflected from the rings onto the cornea to be examined. The examiner views the image through a central hole usually with the aid of a positive lens to reduce accommodation and provide some magnification.

Photokeratoscope:

This involves photographically recording the ring patterns for later measurement and review. The photokeratoscope was invented by Placido in 1880 and Gullstrand in 1896 developed the mathematical theory necessary for quantitative analysis.

It provides information about corneal topography by photographing the imaged placido's disc and measuring the distortion and displacement of each ring at many points. Earlier instruments had flat targets, but these produced an image curvature, which prevented all of the images from being in focus at once. Modern instruments have spherical, ellipsoidal or cylindrical target planes.

FIGURE NO – 2 : PLACIDO'S DISC

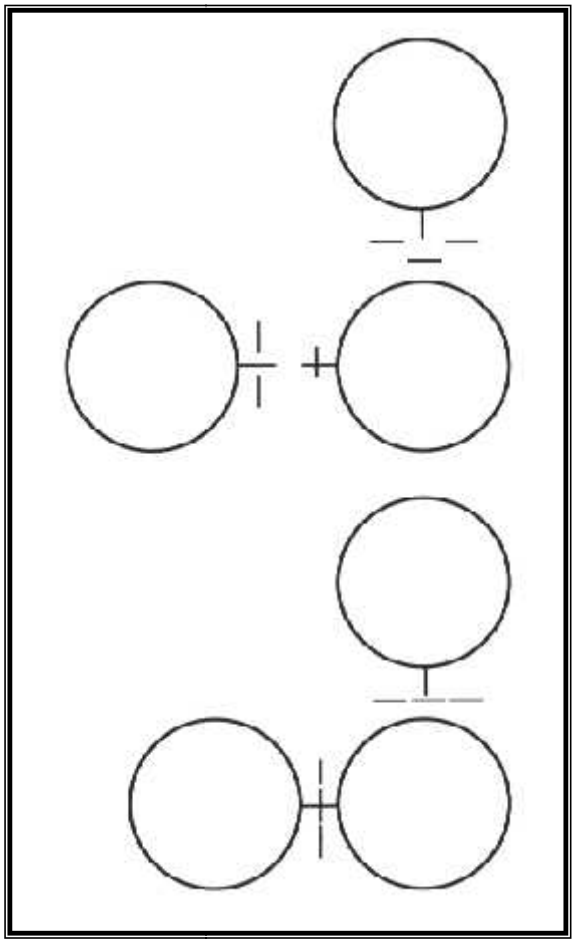
Astigmometer:

Manufactured by Keeler to control corneal astigmatism during suturing. A ring of light emitting diode is mounted on the operating microscope in the focal plane of one eyepiece and the image formed by the cornea is viewed through the eyepiece. An astigmatic cornea produces an ellipsoidal image of lights. By tilting the ring of lights, the image can be made circular and the angle of tilt can be used to estimate the amount of astigmatism. The instrument can reduce postoperative astigmatism.

2. Keratometer (Ophthalmometers):

The first keratometer was devised by Helmholtz in 1854. The instrument uses an image doubling technique to measure the radius of curvature and location of refracting surfaces of the eye. Javal and Schoitz in 1881 simplified the Helmholtz instrument by restricting its use to measurement of the curvature of the cornea and included the ability to measure surface astigmatism.

Figure No – 3 : Mires of Keratometer



Non-aligned mires

Aligned mires

Following the Javal-Schoitz keratometer, the micrometer and the Bausch and Lomb keratometers have come into vogue. Although techniques were available to measure the radius of curvature by reflection, measurements on the eye were difficult

because of image movement. Doubling the image, which involves separating the image beam into two parts and measuring the distance between the two images, eliminated this problem since the two images move together when the eye moves.

The Bausch and Lomb Keratometer:

The instrument comprises of a lamp system that illuminates the mires by a diagonal mirror. Light from the mire strikes the cornea producing an image behind it. The mire having fixed dimensions, image size depends on the corneal radius. The image formed now acts as an object for the optical system.

Light from the object is gathered by an objective lens and focused to a plane farther along the central axis. A four aperture diaphragm is located near the objective lens. Beyond the diaphragm are two doubling prisms, one with base up and the other with base out. The prisms can be moved independently, parallel to the central axis of the instrument. Light passing through the left aperture of the diaphragm is deviated by the base up prism to place one image above the control axis. Light passing through the right aperture is deviated by the base out prism placing a second image to the right of the control axis.

Light through the upper and lower apertures does not pass through either prism and an image is produced on the axis. The total area of upper and lower apertures is equal to the area of each of the apertures, making the brightness of all three images equal. The upper and lower apertures also act as a Scheiner's Disc, doubling the central image when the instrument is not properly focused on the corneal mire image. The eye piece lens gives a magnified view of the double images.

Automated Keratometry:

Here, the reflected image of a target is focused onto a photodetector which measures the image size and the radius of curvature is computed. The target mires are illuminated with infrared light and an infrared photodetector is used. The image is measured in many meridians and the power and axis of the major meridians are computed. As the performance here is quicker than ocular movements, no doubling device is needed.

Intraoperative Keratometry:

Barraquer was the first surgeon to advocate the use of keratometer during a surgical procedure. Troutman developed a qualitative device that projects a series of dots onto the cornea in the form of a circle. In the presence of astigmatism, the circle is seen as an eclipse. Terry was the first to develop a quantitative surgical keratometer. While some studies have shown intraoperative keratometry to reduce suture induced astigmatism, some have found a poor correlation between intraoperative keratometric readings and final postoperative astigmatism.

3. Computed Corneal Topography:

A computed screen simulates a piece of graph paper divided into many small squares or pixels. Video camera signals are put into the computer resulting in an image on the screen. The curvature of the cornea that corresponds to the rings in every location is determined. A detailed map of the cornea is obtained in which values of corneal curvature at each location of the ring appear. These numerical values can be represented as color maps, where cooler colors represent flatter areas and warmer colors represent steeper areas.

SURGICALLY INDUCED ASTIGMATISM FOLLOWING CATARACT SURGERY

Since Donder's first description, it is well recognized that the wound performed during cataract surgery produces astigmatism. With the advent of sutured cataract sections and IOL implantation induced astigmatism became more of a concern.

SURGICALLY INDUCED ASTIGMATISM IN PHACOEMULSIFICATION:

Extra capsular cataract extraction Versus Phacoemulsification

Extracapsular cataract extraction by phacoemulsification gives an advantage of cataract extraction through a smaller wound/incision which decreases the surgically induced astigmatism as compared to conventional extra capsular cataract extraction. The longer the size of the incision and increased number of sutures in extra capsular cataract extraction definitely results in greater degree of surgically induced astigmatism.

Wound length with suture closure:

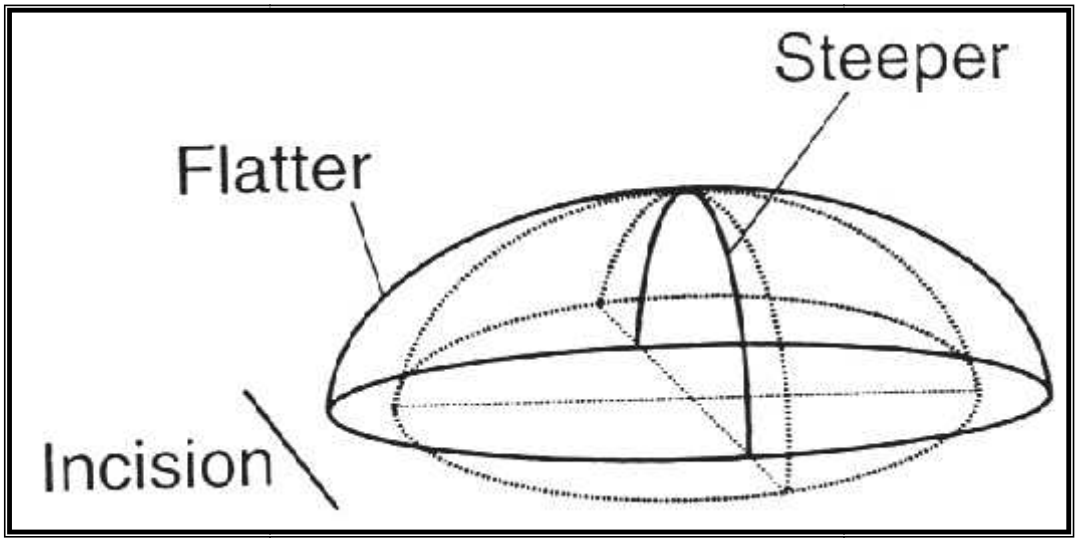
Sutures usually cause a corneal steepening in the meridian of the suture. But, SIA is greater in a larger wound even though the same number of sutures are used. In a long wound, more number of tissues can be affected by suture tension. Smaller wounds usually have less surgical edge surface area. Therefore, they are more resistant to the mechanical forces of the sutures.

Larger wounds produce greater amount of WTR astigmatism, in addition the astigmatism by these wounds decays faster over a time and requires more time for stabilization.

Post-operative Astigmatism:

The astigmatism after cataract surgery is generally of “against the rule” type which is caused by some degree of flattening of the corneal meridian at right angles to the direction of the incision. That is when the incision is made above, a postoperative flattening of cornea in the meridian right angles to the wound.

FIGURE NO – 3 : POST OPERATIVE CORNEAL CHANGES



Factors responsible for postoperative astigmatism after phacoemulsification with posterior chamber intraocular lens implantation:

This procedure offers sutureless, very small incision with early visual rehabilitation and least postoperative astigmatism.

Incision:

a) Location

b) Length

c) Construction

d) Site of incision depending on pre-existing astigmatism

Location:

- Both proximity to the visual axis and meridional location are important to control astigmatism.
- Incision in the cornea or sclera causes flattening of the cornea immediately adjacent to it and at the meridian perpendicular to it. The meridian 90° away is steepened as a result of the coupling effect.
- Closer the incision is to the central cornea, the greater its astigmatic effect.
- For incisions of the same size, scleral incisions induce less astigmatism than limbal incisions.
- In clear corneal surgery, the placement of incision in the steep axis, whether superiorly or temporally or obliquely. Usually it can help to reduce the astigmatism within that meridian.
- Incisions placed vertically resulted in greater drift than those placed horizontally. A horizontal incision is away from central cornea.

- Superior corneal incisions have nearly twice the astigmatic impact of temporal incisions. This is probably due to the fact that the temporal limbus is farther from the visual axis than superior limbus.

Roman S, Ullern M. compared induced astigmatism with superior and temporal incisions with foldable IOL. The incision was placed according to the preexisting astigmatism i.e. temporal approach in case of ATR and superior approach for WTR astigmatism. The postoperative SIA was 0.98D with superior and 0.58D with temporal incisions. The superior corneal incision rarely allows to reach a minimum postoperative astigmatism as with a temporal incisions. [(14)]

Simsek S, Yasar T, Demirok A, Cinal A, Yilmazo F. compared superior and temporal clear corneal incisions in 40 eyes of 20 patients. Mean postoperative astigmatism was 1.60D in superior group and 0.83D in the temporal group. The temporal incision group had significantly lower astigmatism. [(26)]

Ermiss SS, Inan UU, Ozturk F. evaluated SIA after small 3.5mm superotemporal and superonasal clear corneal incision phacoemulsification in 56 eyes of 28 patients. SIA after superonasal incision was statistically significantly higher than superotemporal incision. [(27)]

Barequet ,Vitale S, Cassard S, Azar DT, Stark WJ compared astigmatism outcomes after temporal and nasal clear corneal incision in phacoemulsification with foldable intra ocular lens. Postoperatively temporal incisions yielded 0.74D and nasal 1.65D at 12 months. Temporal incisions induced significantly less astigmatism than nasal. [(28)]

Length:

- Incision length has been known to affect astigmatism.
- The long incision used in intra capsular cataract extraction and extra capsular cataract extraction has a tendency to produce significant unwanted postoperative astigmatism.
- Some authors have advocated merely varying the incision length as a means of reducing postoperative astigmatism.

Construction:

- Architecture of the wound also can influence its astigmatism effect. Wounds can be constructed in a single plane "Stab incision" configuration, or they can be grooved or hinged.
- Single plane incisions are usually astigmatically neutral, especially when placed in the horizontal meridian. This type of incision is best used to prevent surgically induced astigmatism in a spherical cornea.
- The grooved incision has similar architectural characteristics to a transverse relaxing keratotomy and hence a greater astigmatic effect than the single plane incisions.
- Corneal astigmatism is directly proportional to the length of incision and is irreversibly proportional to the distance, the incision is placed from the limbus.

McFarland and Ernest introduced an incision architecture that allowed phacoemulsification and implantation of lens without the need for suturing. Besides lengthening the scleral tunnel, this incision terminated in a decidedly corneal entrance and the posterior tip of the incision, the so-called corneal lip, acted as a one way valve imparting to the incisions its self sealing characteristics. **(29)**

The disadvantages of scleral tunnel incisions in the need for conjunctival incision and scleral dissection, both of which produce bleeding. The use of cautery to control bleeding contributes to creating SIA.

Longer is the corneal incision, greater is the flattening. Clear corneal incisions do not induce equal and opposite coupling effect in curvature especially in the periphery. Astigmatic influence of clear corneal incision disproportionately affects the temporal meridian.

Brian J Jacobs, Bruce I Gaynes, OD, Thomas A, Deutsch MD studied astigmatism after clear corneal phaco incision, i.e. 52 eyes of 52 patients, whose keratometer reading was taken preoperatively and 1^{st}, 3^{rd} and 6^{th} months postoperatively. A fourier method of vector analysis was used and concluded that superior position clear corneal incision does not induce a clinically important amount of astigmatism. **(30)**

Small incision sutureless cataract surgery by phacoemulsification has allowed for the creation of a potentially astigmatically neutral incision with less postoperative against the rule shift. Cataract incisions taken in the superior position usually results in a degree of against the rule astigmatism. So, most surgeons prefer placing the clear corneal incisions temporally, which helps to reduce the preexisting against the rule

astigmatism. The temporal approach is thought to induce regular astigmatism 90° from the incision i.e WTR type. The studies and literatures report, that a temporal incision can reduce as well as quickly stabilize SIA.

Dr. I.H. Fine developed a systematic approach towards the cataract surgery through the temporal aspect of the clear cornea. **(10)**

Site of incision

Nowadays, cataract surgery is also seen a refractive surgery. So, we should choose the best location of clear corneal incision in phacoemulsification depending on the pre-existing astigmatism. The site of incision can be superior, temporal, supero-temporal or nasal.

Principles of clear corneal incision:

Appreciation of the physical dynamics of the cornea is the key to understand surgically induced astigmatism.

1) The normal cornea flattens over any incision site.
2) Radial corneal incision flattens the adjacent cornea as well as the cornea 90° away from the site.
3) The flattening effect of incision site as well as the cornea increases as the incision approaches the visual axis.
4) Cornea will flatten directly over any of the sutured incision.
5) Cornea flattens adjacent to lose limbal suture, flattens 180° away and steepens 90° away.

6) Cornea usually steepens adjacent to the tight limbal sutures. It steepens 180° away and flattens 90° away.

Hence incision area flattens, sutures steepen. Also pre-existing astigmatism with steeper cornea and incision on opposite axis increase the postoperative astigmatism and incision when it is nearer to steep cornea post-operative astigmatism reduces or the astigmatism is totally neutralized.

Oshima Y, Tsujikawa K, Oh A, Harino S. compared astigmatism of phacoemulsification with foldable intra ocular lens through 3mm temporal clear corneal and 3mm superior scleral tunnel incision on 78 patients with preexisting ATR astigmatism were taken for study. The preexisting keratometric cylinder decreased in the temporal clear corneal incision group and increased in superior scleral tunnel group. 0.65 D at 3rd month postoperative scleral tunnel group, 0.56 D at 3rd month postoperatively in temporal clear corneal group [(31)].

Lesiewska Junk H, Kaluzny J, Malukiewicz-Wisniewska G. (2002) evaluated postoperative astigmatism in 135 patients.

Group I – 75 ECCE with 12 mm corneoscleral incision

Group II – 30 phacoemulsification with 3.5 mm corneal incision

Group III – 30 patients phacoemulsification with 3.5 mm tunnel incision

Results: Mean Astigmatism

4.19 D – group I, 2.50 D – Group II, 1.79 D – Group III

The difference between all the groups were statistically significant. **[(32)]**

James Tejedor and Juan Murube studied the best location of clear corneal incision in phacoemulsification, depending on pre-existing astigmatism. It concluded that in patients without corneal astigmatism, corneal changed induced were greater in superior than temporal incision. The study concluded, superior incision is recommended with atleast 1.5 diopters of astigmatism and steep axis at 90 degrees. Temporal incision is recommended with astigmatism < 1.5 dioptre and steep axis at 90 degrees, negligible astigmatism or astigmatism < 0.75 dioptre and steep axis at 180 degrees. (33)

Pistarini Fernando Goncalves,Antonia Carios Rodrigues Lottelli, studied phacoemulsification using clear corneal incision in steepest meridian. They concluded that by knowing the pre-existing astigmatism is in which meridian, can reduce surgically induced astigmatism. (34)

Ken Hayashi, Motoaki Yoshida, Koichi Yoshimura, studied the effect of steepest-meridian clear corneal incision for reducing pre-existing corneal astigmatism using a meridian –marking method or surgeon's intuitions. The study concluded, the mean meridian misalignment of the steepest-meridian CCIs was significantly smaller in meridian marking group (4.4 degree $\pm$ 2.8 SD) than in surgeon's intuition group. (35)

Edmonda Borasia et al, studied Surgically induced astigmatism after phacoemulsification. They concluded at the first follow up, the difference in SIA between the 2 incision types was 0.15 D and it was not statistically significant. At the second follow up, the difference was 0.29 D which was statistically significant. Seven weeks after small incision phacoemulsification, the CCTI induced less SIA than the CCOI. (36)

Course of Postoperative Astigmatism:

Cornea is nearly spherical before surgery. At the time of surgery with relation to incision site, sutured or sutureless and length of incision contributes to post operative astigmatism by way of

1) Wound compression
2) Wound gape.

Factors that appear to increase wound compression are:-

- Deeply inserted sutures
- Wide suture bites
- Tightly tied sutures
- Greater number of sutures

Nakada S, Tanuka M, Nakajima A. in a study of 137 patients found an initial with the rule astigmatism for 6 months. Slowly over a period of 2-4 yrs after surgery most patients had against the rule astigmatism. [(37)]

Masket S, Tennon DG has found that these incisions skip with the rule phase and demonstrate against the rule astigmatism even on the first postoperative day i.e. unsutured and sutured incisions more in the direction of against the rule astigmatism over time. **[(38)]**

Wound compression in superior incisions led to a reduction of vertical circumference of the globe and thus a steepening of the vertical meridian. Wound gape caused an increase in the vertical circumference of the globe, which resulted in a flattening of the vertical meridian. Gary F. Jaffe reports that these changes are because of ocular rigidity and shape of cornea [(24)]. Ken Hayashi, Akira Hirata, Shin-

Ichi Manabe and Hideyuki Hayashi studied long term change in corneal astigmatism after suturless cataract surgery.

The study concluded corneal astigmatism after sutureless cataract surgery shows a long term against-the-rule astigmatism change with advancing age, and this change is similar to that of normal cornea, suggesting that ATR change that occurs subsequently should be taken into consideration at the time of cataract surgery. [39]

During the evolution of change in astigmatism following cataract surgery, the patient's actual spherical equivalent remains constant. According to Gauss's law of elastic domes, 'For every change in the curvature of one meridian there is an equal and opposite change 90° away'. This corneal behavior is known as the coupling effect. Thus the corneal curvature changes not as if a single spherocylinder was placed at a single axis, but as if a plus cylinder was placed in the steeper meridian and a minus cylinder of equivalent magnitude was placed in the flatter meridian [40].

Management of postoperative astigmatism:

The various methods are spectacles, contact lens, compression and relaxation procedures. For aphakic patients, spectacles are the main stay of treatment. The typical magnitude of astigmatism is not more than 3D after 6 weeks, which is correctable by aphakic spectacles. Major failure of spectacles is distortion caused by meridional magnification. The binocular distortion because of astigmatic correction can lead to marked asthenopia. The other mode of management is by surgery i.e. either by compressive or relaxation procedures which alter the corneal curvature.

Compressive procedures are semilunar crescentic resection, wedge resection, wound revision and compressive sutures. Compressive and steepening procedures

compress the long flat corneal meridian and steepen the central cornea. Compressive sutures placed across the flattest corneal meridian achieve a spherical cornea. These compressive suturing procedures were developed by Jose Baraquer for the control of congenital astigmatism.

Wedge resection was developed by Troutman for astigmatism caused by penetrating keratoplasty. He found that astigmatism cannot be permanently corrected by compressive sutures alone since most sutures loosen biodegrade and cause loss of effect. So, recent attempts are to correct astigmatism by suture induced compression with or without any incision. High astigmatism following cataract surgery can be corrected by repairing ectatic cataract wound, this is called wound revision. Compression sutures steepen the cornea sufficiently to convert minus axis to plus axis in the same meridian.

Relaxation Procedures:

Various relaxation procedures are suture release or suture adjustment, parallel keratotomy, arcuate keratotomy and transverse keratotomy.

By relaxing procedures, the steep corneal meridian relaxes. The effects produced by corneal flattening directly over the area of incision, e.g. if parallel incision are used to flatten the steep meridian, perpendicular meridian also flattens, the same happens with trapezoidal keratotomy.

Atkins and Roper Hall did suture adjustment 6-8 weeks after surgery which resulted in a decrease in the final cylindrical power and only a small shift in cylindrical axis. [(34)]

Sparrow and Brown (1988) in a study of 9 eyes, found a large reduction in with the rule astigmatism after suture removal [(41)].

Bansal RK, Gupta A, Grewal SP in a study of 38 patients, found a reduction of astigmatism from 5.42 D to 3.3 D one week after suture removal. Some of the patients showed a change from with the rule astigmatism to an against the rule astigmatism. **(42)**

A study called "Surgically tailored astigmatism reduction (STAR)" was based on a review of 4000 consecutive cataract extractions for gaining a spherical eye postoperatively. Neumann et al. found that a T-incision with interrupted radial incision was most effective in flattening the meridian with least amount of axis deviation. **(11)**

Modifications of astigmatism

1. Astigmatic keratotomy: In this technique, arcuate shaped corneal relaxing incisions (CRIs) are used, either single or paired, placed concentric to the visual axis, at 99% of peripheral pachymetry measurements. But these have limited predictability and often result in over correction. Moving the relaxing incision off the cornea to the limbus creates limbal relaxing incisions (LRI). These can be used with any type of cataract incision and result in smoother corneal topography and are quiet effective in astigmatism = 3 D.

2. Toric IOLs: These are foldable, toric, silicone IOLs which are implanted along with spherical IOLs in cataract patients with pre-existing astigmatism. Their limitations are that they are available in only two powers of 2 D or 3.5 D with an effective correction at corneal plane of 1.5 D or 2.25 D respectively. Moreover they have a tendency to rotate and studies show that 18 to 25%

cases rotate by more than 20°, moreover they are not effective for astigmatism > 3 D.

3. Piggyback toric lenses: These are used in cases with high astigmatism Problem here is that even a small amount of rotation affects the cylinder correction seriously. To prevent this, plate haptic lenses are used. This is a good method to reduce high preoperative astigmatism.

4. Toric lenses with LRIs: This method can be used to correct larger amounts of astigmatism. The advantage of using a toric lens is the reduction in the amount of incisional surgery required.

5. Spectacle: An astigmatic error of = 0.5 D usually requires correction. Uncorrected, the Snellen visual acuity (VA) may reduce to 6/9 to 6/18 by an error of 1 - 2 D. Patients who have adapted to a life time of cylinder axis may not tolerate spectacle correction of a surgically induced axis change. Moreover spectacle correction may produce meridional aniseikonia, which becomes problematic with binocular vision.

6. Contact lenses may be satisfactory for many patients but superior wound gape with horizontal steepening may cause inferior ride of lens.

7. Other methods to reduce astigmatism are photorefractive keratotomy (PRK), wedge resection and laser assisted in situ keratomileusis (LASIK).

CALCULATION AND ANALYSIS OF SURGICALLY INDUCED ASTIGMATISM

To estimate the effect on corneal curvature induced by cataract surgery, the difference between preoperative and postoperative keratometry needs to be calculated. Various methods are used to calculate SIA.

The vector method: The vector method described by Jaffe is based on a variation of a technique of finding the sum of oblique cylinders in which the cylinder is represented on a graph by a vector. Vector gives information regarding both amplitude and direction. The sum of two obliquely crossed cylinders can be found by treating the component powers of the two cylinders as vector in a vector diagram, but while doing so the vectors representing cylinder powers are directed at angles twice the actual angle of orientation before the eye. To calculate SIA after cataract surgery the preoperative and postoperative astigmatism values are treated as vectors and represented a vector diagram at twice their axis angles. If K1 is preoperative astigmatism at axis Φ1 and K3 is postoperative astigmatism at axis Φ3 then K1 and K3 are represented in a diagram at axis 2Φ, and 2Φ3. The ends of K1 and K3 are joined together which gives K2 (SIA). A line is plotted parallel to baseline so the direction of K2 can be measured around the end of K1.

The resultant angle is then halved to get the axis of SIA. In these calculations, it makes no difference whether one uses positive or negative cylinders as the signs are kept the same in each calculation [(24)].

Foldable Intra Ocular Lens:

Sir Harold Ridley's invention of intraocular lens over five decades ago has been one of the most stellar achievements of modern medicine. The foldable lens from a conventional relatively rigid implant is its ability to undergo deformation and also reformation after insertion. These foldable intra ocular lenses fulfill a prerequisite of ophthalmic surgeon – Extraction of cataractous lens through smallest incision and implantation of intra ocular lens through a smallest incision.

Intraocular implant material should have the following properties:-

- Biocompatibility:
  - Chemically inert
  - Does not react with ocular tissue to incite inflammation, infection.
  - Have no carcinogenic potential
  - Does not degrade in the in-vivo environment
- Optical compatibility:
  - Transparent
  - Have high optical resolution
  - Filters off ultraviolet radiation
  - Focuses for variable distances
- Mechanical compatibility
  - Resist mechanical strains
  - Flexible
  - Good memory for deformation and reformation.

Properties of Phaco IOL components:

Optical component:

Acrylic

Rigid PMMA:

- Hydrophobic
- Incite mechanical irritation
- May damage endothelial cells
- Refractive index 1.49

Flexible Acrylic:

- Viscoelastic properties – temperature dependent
- Three dimensional stability
- Refractive index 1.55

Silicone :

- Elastomers are polymers capable of large and reversible deformation i.e. biocompatibility
- UV chromophores
- Refractive index 1.46

Hydrogel:

- These swell significantly on contact with water but do not dissolve in it.
- Hydrophilic (hence retard cellular and microbial adhesion)
- Hard and rigid in dehydrated state (soft and rubbery in hydrated state)
- Refractive index 1.48 (HEMA)

Haptic Component:

- Polymide (Nylon). It undergoes fragmentation due to hydrolysis.

- Polypropyelene (prolene). Has high elasticity and tensile strength. It is preferred because of its memory and resistance to biodegradation.
- PMMA
- Polymide

Advantages of Foldable Intra Ocular Lens:

1) Helps to retain the smallness of the phacoincision which decreases post operative astigmatism, increases wound stability and allows more rapid visual rehabilitation.
2) Increased protection to corneal endothelium because they are hydrophobic.

   Gentle to the uveal tissue, thus reduces risk of inflammation

   Reduce risk of cellular precipitates on the lens surface.
3) Reduced glare is possible because of the superior qualities of the injection moulded and tumble polished silicone lenses. Lathe cut hydrogel lenses, cryopolished flexible acrylics.
4) Ease of explanation because of the absence of perilenticular fibrosis with these lenses.
5) Better YAG laser compatibility.

   Increased resistance to biodegradation

   Lesser strain on zonules because of their reduced weight.

Disadvantages:

1) Sizing and design of these lenses is more critical, when it is used in a region other than the capsular bag.
2) Prone to damage during implantation because of tensile strength. Permanent fold marks, creases from holding, folding and inserting may produce disturbance in vision.

3) Lens discolouration (original STAAR silicone polymer), microvacuole formation (Acrysof) and formation of a liquefied after cataract that resolves spontaneously.
4) Cannot be used in the presence of a rent in the posterior capsule.
5) If vitreoretinal surgery becomes necessary in an eye with a silicone implant – silicone oil cannot be used as a vitreous substitute. Because of the development of a close interface between the implant and silicone oil.
6) Edge glare – this is true in people with large pupil who complain of dazzling of light.
7) Negative dysphotopsia:- A few patients complain about seeing a scotoma in the temporal field of vision. This could be due to destructive interference as well as internal reflection due to the high refractive index of intra ocular lens.

Foldable lenses are also expensive. The SIA is found less with foldable intra ocular lens than conventional rigid intra ocular lens because of small incision.

Liu Y, Li S. studied the therapeutic effects, advantages and disadvantages of phacoemulsification and foldable lens implantation through a temporal clear corneal incision i.e. 812 patients underwent phaco and showed postoperatively temporal flattening near the incision in the early stage, mild corneal astigmatism, reduced endothelial cell loss (8.23%). Conclusion – The phacoemulsification and foldable lens implantation through a temporal clear corneal incision is convenient and effective. [(43)]

Yusuke Oshima, Tsujikawa K, Oh A, Harino S. compared the clinical outcome of phacoemulsification and foldable silicone intra ocular lens through 3.0 mm temporal clear corneal incision and 3.0 mm superior scleral tunnel incision. Eighty eyes of 78 patients assigned to one of the two groups. Mean astigmatism was

0.56 D at 3rd month with temporal clear corneal incision group. 0.65 D at 3rd month with scleral tunnel incision group. Conclusion – Both incisions offered satisfactory clinical results with minimal keratometric change in both groups. **(44)**

Ruhswarm I, Scholz U, Zehetmayer M, Hanselmayer G, Vass G, Skorpik C. studied astigmatism correction with a foldable toric intraocular lens in cataract patients i.e. foldable toric single piece silicone intra ocular lens implanted in 37 eyes. Phacoemulsification was performed through a scleral or corneal sutureless self sealing incision. Conclusion: Early postoperative and long term follow-ups showed effective and stable correction of astigmatism after implantation of a toric foldable posterior chamber silicone intra ocular lens. **(45)**

On axis cataract incision alone can correct the pre-existing astigmatism (PEA). 3.2 mm phacoemulsification incision placed on the steep axis is reported to correct 0.5D OF PEA. Enlarging the phacoemulsification incision at the end of the surgery to 4.5 and 5.5 mm can approximately correct up to 1 D and 1.5 D of PEA[(2)].

METHODOLOGY

The present study was conducted in the department of Ophthalmology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi on patients to evaluate surgically induced astigmatism after phacoemulsification clear corneal incision in the steepest meridian on the magnitude of the pre-existing astigmatism.

Source of Data: All the patients with cataract and pre-existing astigmatism of 0.5 D – 1.5 D undergoing phacoemulsification surgery with foldable IOL, at KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

METHOD OF COLLECTION OF DATA

STUDY DESIGN :

A LONGITUDINAL STUDY (one year study)

STUDY PERIOD:

One year – 1st January 2014 to 31st December 2014.

SAMPLE SIZE:

A sample size of 82 cases

SAMPLING PROCEDURE :

Sample size for the study is calculated by following formula:

$$n = \frac{(Z\ alpha + Z\ beta)2}{d2}$$

Mean difference = 0.1

Assumed SD of mean difference = 0.5

Effect size = Mean difference/ SD

= 0.1/0.5

=0.34

Type of error is 0.05

Power = 0.8 or 80%

Z alpha = 1.96

Z beta = 0.84

Selection criteria:

Inclusion criteria

- Patients with cataract and pre-existing astigmatism of 0.5D – 1.5 D undergoing phacoemulsification surgery with foldable posterior chamber IOL implantation at KLES Hospital, Belagavi.
- Age group between 30 to 80 years.
- Patients with cataract up to grade 3 nuclear sclerosis.
- Pre-existing astigmatism of 0.5 D to 1.5 D
- Patients willing to give informed consent.

Exclusion criteria

- Patients having hard brown cataract.
- Patients with corneal opacities, complicated cataracts, cataract with chronic uveitis, traumatic cataract, congenital cataract, cataract with pterygium.

METHODOLOGY PROPER

All the patients who satisfy the inclusion criteria were included in the study. The patients were enrolled into the study and written informed consent was taken from them by the investigator.

Data regarding demographic parameters such as age, sex, occupation and address were noted on a predesigned proforma by the investigator at the time of first visit.

Detailed history of following symptoms was noted:

- H/O Diminution of vision RE/LE
    - ✓ Duration
    - ✓ Gradual/Sudden
    - ✓ Progression/static
    - ✓ Distant/Near vision
    - ✓ Visual improvement with bright light or dim light
    - ✓ Painful/ Painless
- Diplopia/Polyopia
- Photophobia
- Flashes of light
- Coloured halos
- Floaters
- Watering
- Redness
- Discharge

- Black spots in front of the eye
- H/O Curtain falling in front of the eyes
- H/O wearing glasses
- H/O Diabetes Mellitus, Hypertension.

History was followed by ocular examination that included :

- Visual Acuity with Snellen's chart
- Ocular examination proper (Adnexa,conjunctiva,cornea,Anterior chamber,iris,pupil and lens).
- Detailed slit lamp biomicroscopy to grade the cataract as:-
  - Cortical Cataract
  - Nuclear Sclerosis
  - Posterior Subcapsular Cataract
- Schiotz tonometry
- Best corrected Visual Acuity
- Retinoscopy
- Ophthalmoscopy.
- **Pre operative Keratometry (Manual Bausch and Lomb Keratometer)**
- A scan biometry(SRK II Formula)
- Blood Pressure

Routine laboratory investigations included are:-

- ❖ Routine haemogram
- ❖ Diabetic Status

The study included 82 patients who underwent clear corneal phacoemulsification by taking either superior or temporal incision depending on the magnitude of pre-existing astigmatism.

Clear Corneal Phacoemulsification:

- Preoperative measures like consent for surgery, antibiotic eye drops, dilatation of pupil was done.
- The steepest meridian was marked with the surgical marking pen before anesthesia.
- Peribulbar block was given
- The eye was painted and draped.
- Eyelids retracted with speculum.
- Side ports made with 1.2 mm side-port blade depending on the incision site.
- Anterior chamber was filled with visco-elastic material
- Continuous curvilinear capsulorrhexis was carried out with a modified cystitome.
- A clear corneal self-sealing incision was made with a 3.2 mm keratome.
- Astigmatic ring is placed over the cornea.
- Depending on the markings and the axis, superior incision is marked or temporal incision is marked.

- For superior clear corneal incision, surgeon sits at the head end and incision taken at 12.00 o'clock position.
- For temporal clear corneal incision surgeon, sits at the temporal side and takes incision according to the astigmatic ring axis.
- Hydrodissection and hydro delineation was performed to separate the capsule and nucleus and free rotation of nucleus was ensured.
- Phacoemulsification was done by chip and flip or by stop and chop procedure.
- Bimanual irrigation and aspiration was performed to remove the cortex.
- Following this, capsular polishing done.
- A foldable intraocular lens was inserted through a 3.2 mm incision with the help of an injector. Intra ocular lens inserted within the capsular bag.
- Residual visco-elastic was removed.
- The clear corneal wound was sealed by hydration.
- Eye was padded and bandaged after installing antibiotic eye drops.

Postoperatively, all patients received –

- Topical antibiotic with steroid 6 times x 1 week tapering the dosage every week for one month.
- Systemic antibiotics i.e. Oral Ciprofloxacin 500 mg BD given for 5 days.
- Postoperative assessment of the patient was carried out on 2^{nd} day, 3 week and 6 weeks.

Ocular examination during follow-up involved assessing:-

- Visual acuity
- Wound sealing

- Corneal clarity
- Intra ocular lens placing
- Fundus visibility
- Keratometry readings were taken on 3 and 6 weeks postoperative visit.

The amplitude of preoperative astigmatism and postoperative astigmatism will be calculated from the difference in keratometric values in the steeper meridian and flatter meridian. The amplitude of Surgically Induced Astigmatism was also calculated from pre and post operative vectors using the vector method.

Statistical analysis

Paired 't' test was used to calculate mean Surgically Induced Astigmatism.

Introduction

Objectives

Review of Literature

Methodology

Results

Discussion

Conclusion

Summary

Bibliography

Annexure – I

Annexure – II

Annexure – III

Annexure – IV

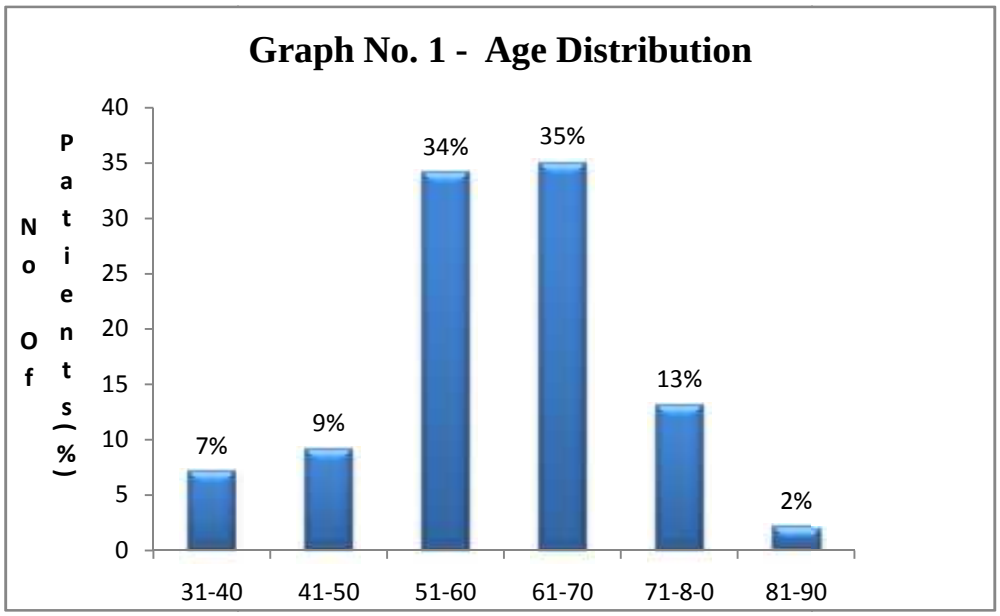
RESULTS

The present study was conducted on 82 eyes that underwent Phacoemulsification at Department of Ophthalmology, KLES Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi during study period. The patients underwent Phacoemulsification by either Superior or Temporal incision depending on the magnitude of pre-existing astigmatism.

Pre-operative and post-operative keratometric readings and refraction were used for analysis. All calculations were performed using SIA calculator version 2.1, a free software programme.

TABLE NO 1: Age Distribution

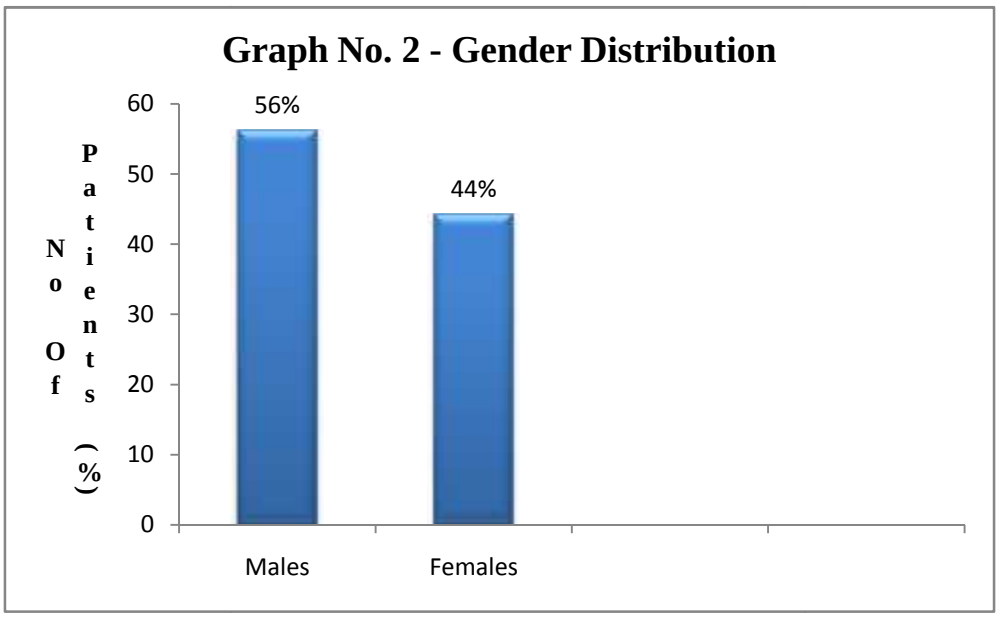
AGE (in years)	NO. of patients	Percentage (%)
31-40	06	7 %
41-50	07	9 %
51-60	28	34 %
61-70	29	35 %
71-80	11	13 %
81-90	01	2 %
TOTAL	82	100 %



In the present study the mean age was 60 $\pm$ 2 years. Majority of the patients were in the range of 50-70 years that is 69%.

Table no 2: Gender Distribution

GENDER	No. of patients	Percentage (%)
MALES	46	56 %
FEMALES	36	44 %
TOTAL	82	100 %

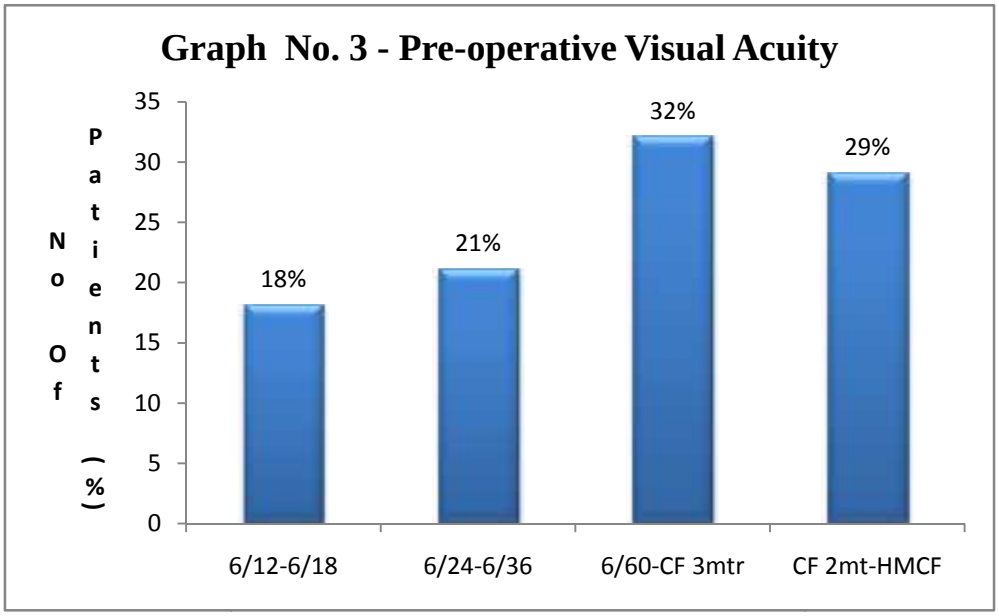


In this study 56% patients were males and 44% patients were females.

Ratio of male : female is 1.3: 1

Table No 3: Pre-operative Visual Acuity

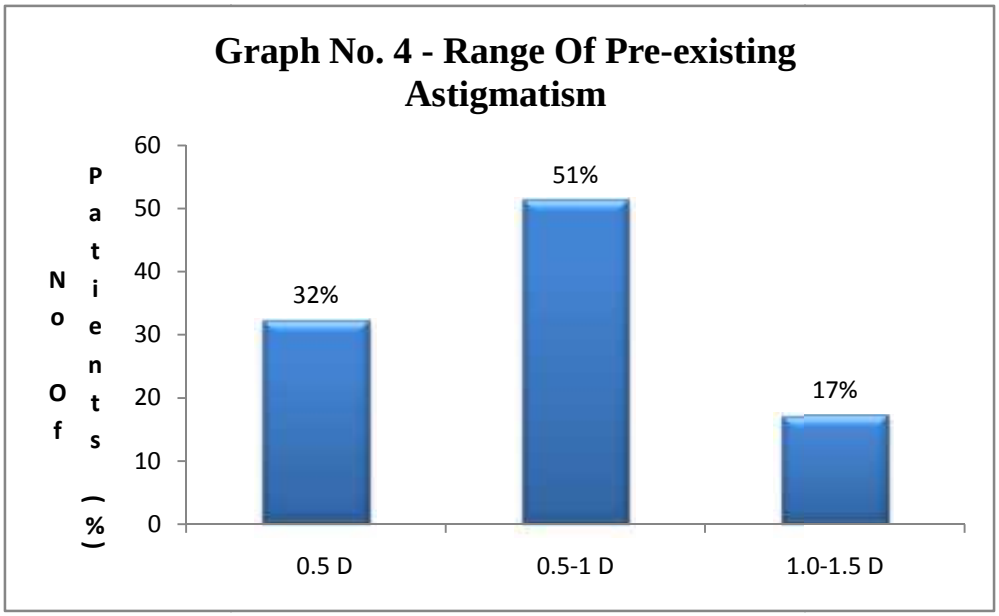
Pre-op visual acuity	NO. of patients	Percentage (%)
6/12 -6/18	15	18 %
6/24 -6/36	17	21 %
6/60 –CF 3mt	26	32 %
CF 2mtr – HMCF	24	29 %



Majority of patients that is 32% had pre-operative visual acuity in the range 6/60 to CF 3 meters followed by 29% patients with visual acuity in the range of CF 2 meters to HMCF.

Table no 4 : Range of Pre-existing astigmatism

Pre-existing astigmatism	No of patients	Percentage (%)
0.5 D	26	32%
0.5 -1 D	42	51 %
1 -1.5 D	14	17 %
TOTAL	82	100 %

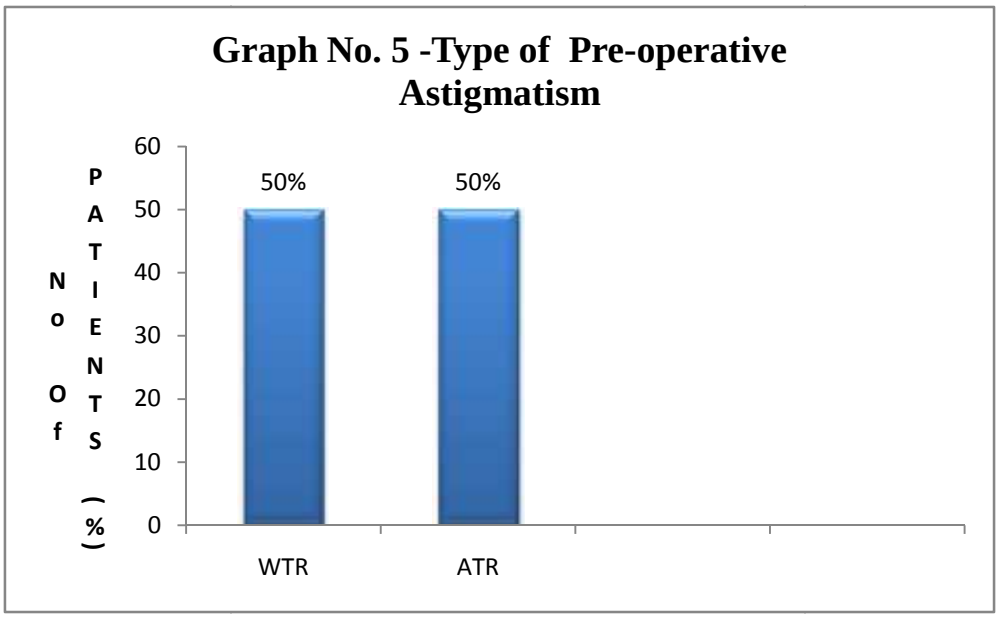


In this study, 32% patients had 0.5 D of pre-existing astigmatism followed by 51% patients in the range of 0.5 – 1D of pre-existing astigmatism.

17% of patients had pre-existing astigmatism in the range of 1- 1.5 D.

Table no 5: Type of Pre-operative astigmatism

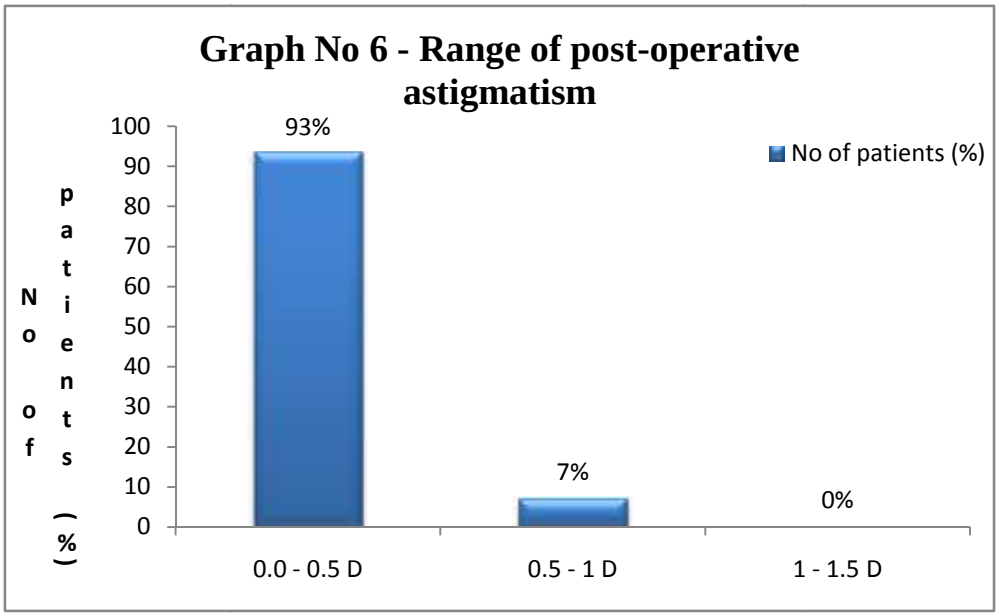
Pre-operative astigmatism	NO. of patients	Percentage (%)
WTR	41	50 %
ATR	41	50 %
TOTAL	82	100 %



In this study 50% patients had WTR astigmatism and 50% had ATR astigmatism.

Table No 6 – Range of post-operative astigmatism

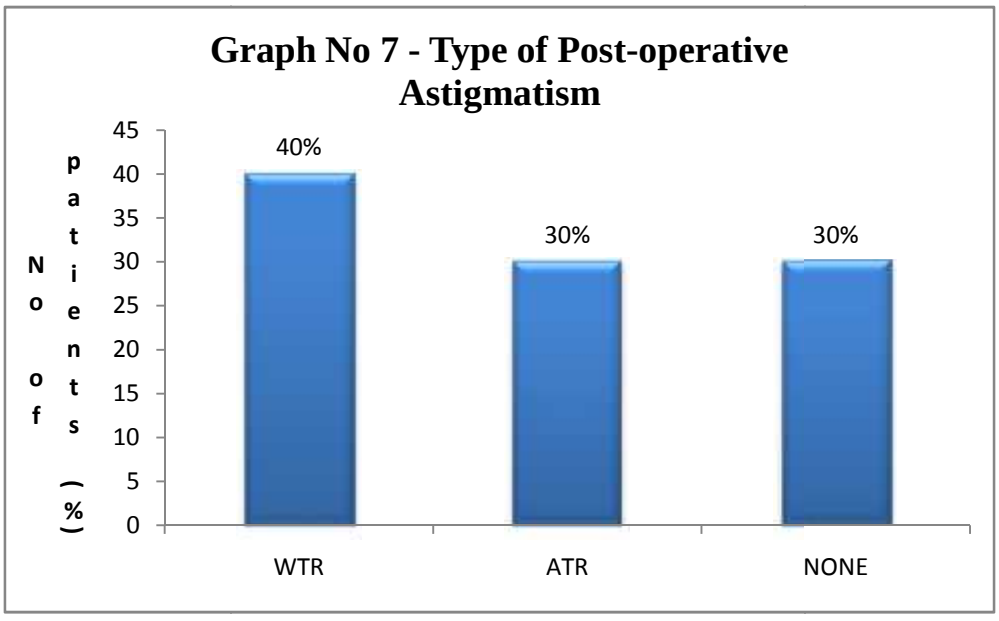
Post – operative astigmatism	No of patients	Percentage (%)
0.0 - 0.5 D	76	93%
0.5 -1 D	06	07 %
1 -1.5 D	00	00 %
TOTAL	82	100 %



In this study, 93 % patients had post-operative astigmatism in the range of 0.0 - 0.5 D followed by 07 % patients in the range of 0.5 – 1D of post-operative astigmatism. No patient had post-operative astigmatism in the range of 1- 1.5 D.

Table no 7: Type of Post-operative astigmatism

Post-operative astigmatism	NO. of patients	Percentage (%)
WTR	33	40 %
ATR	25	30 %
NONE	24	30 %
TOTAL	82	100 %

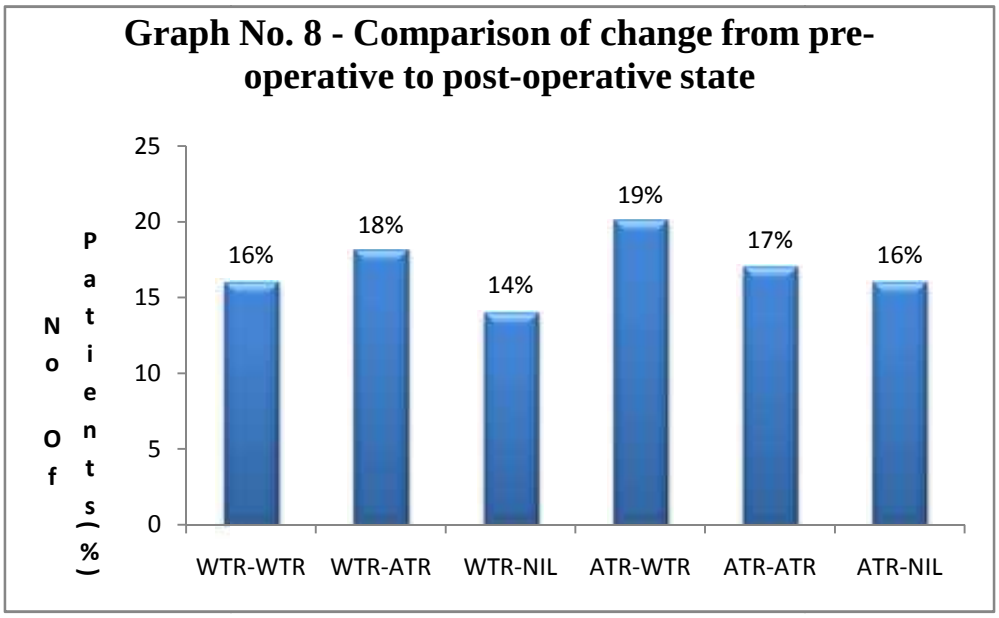


In this study 40% patients had post-operatively WTR astigmatism followed by 30% with post-operative ATR astigmatism.

30% were reported to have no post-operative astigmatism.

Table no 8: Comparison of change from pre-operative to post-operative state

Change of Astigmatism	NO. of patients	Percentage (%)
WTR –WTR	13	16 %
WTR –ATR	15	18 %
WTR-NIL	11	14%
ATR-WTR	16	19%
ATR-ATR	14	17%
ATR-NIL	13	16%
	82	100%



Of the 41 patients having pre-operative WTR astigmatism, 13 patients (16%) continued to remain so post-operatively.

15 patients (18%) showed a post-operative ATR drift.

11 patients (14%) showed no astigmatism post-operatively.

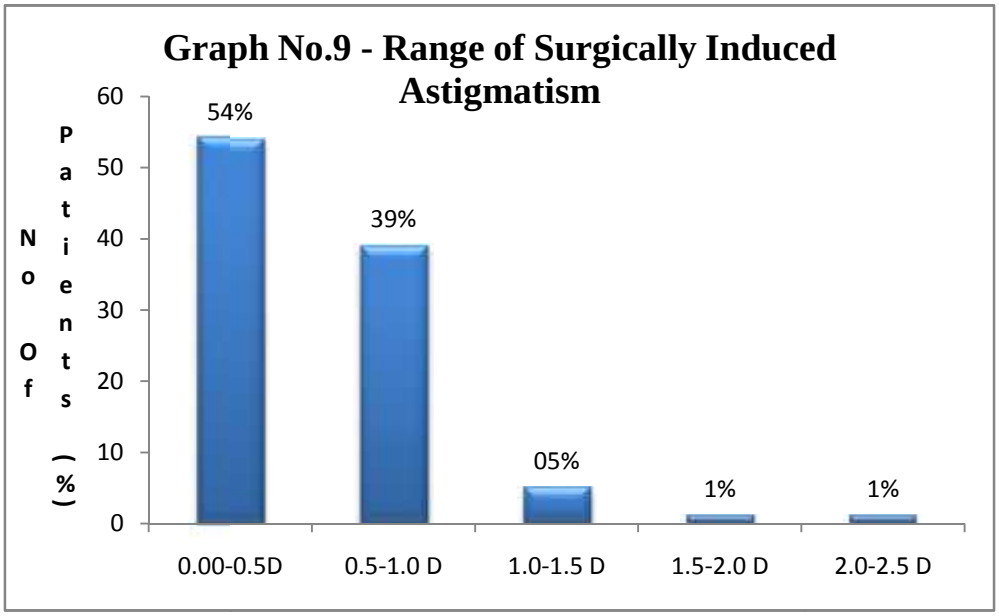
Of the 41 patients having pre-operative ATR astigmatism, 16 patients (19%) continued to remain so post-operatively.

14 patients (17%) showed a post-operative WTR drift.

13 patients (16%) showed no astigmatism post-operatively.

Table no 9: Range of Surgically Induced Astigmatism

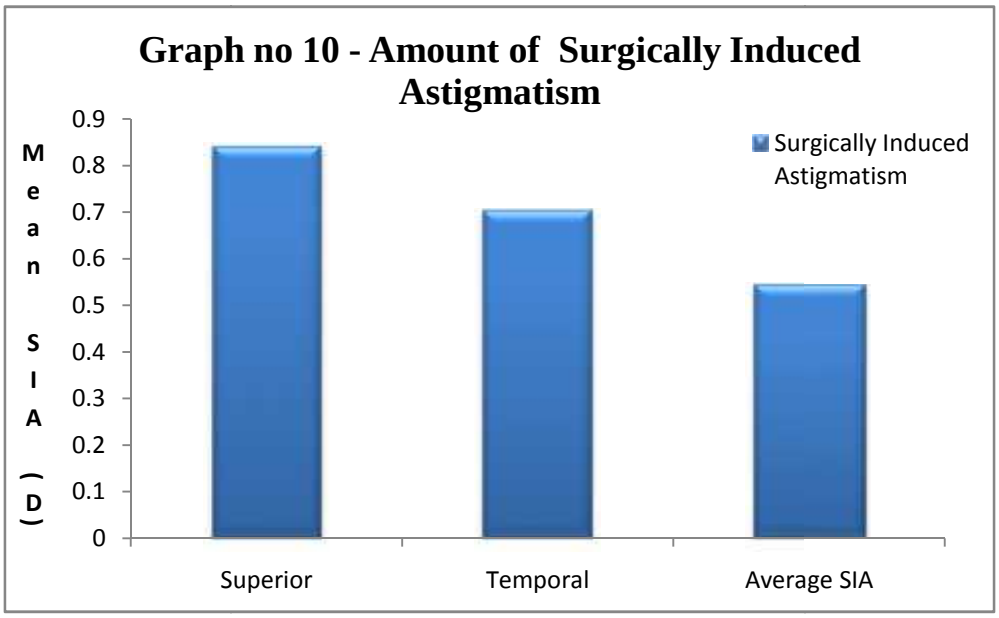
Surgically induced astigmatism	NO. of patients	Percentage (%)
0.00-0.5 D	44	54%
0.5 -1 D	32	39 %
1 -1.5 D	04	05 %
1.5 -2.0 D	01	01 %
2.0 -2.5 D	01	01 %
TOTAL	82	100 %



54% of the patients had SIA in the range of 0.0 – 0.5D followed by 39% in the range of 0.5 – 1 D, 05% in the range of 1 -1.5D, 1% in the range of 1.5- 2D and 1% in the range of 2 – 2.5D.

Table no 10 : Amount of Surgically Induced Astigmatism

TYPE OF SIA	Mean	SD
Superior	0.84	0.49
Temporal	0.70	0.35
Average SIA	0.54	0.34



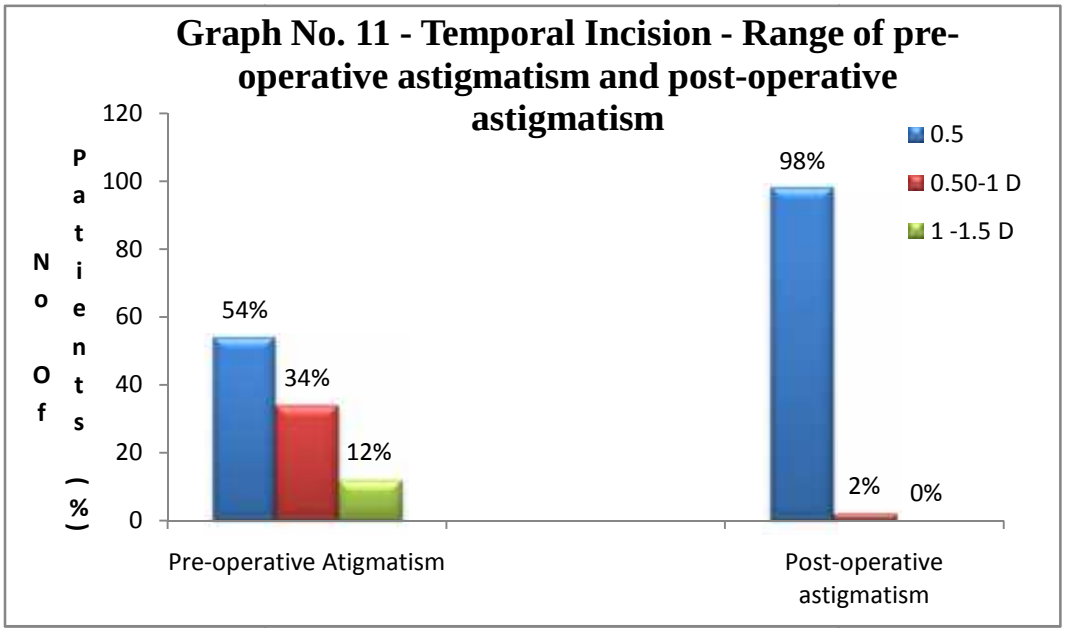
In the present study, the average Surgically Induced Astigmatism recorded was 0.54 D $\pm$ 0.34 with $p<0.001$ (Statistically significant)

The average SIA induced by superior incision was 0.84 D $\pm$ 0.49 with $p = 0.145$ (Not statistically significant)

The average SIA induced by temporal incision was 0.70 D $\pm$ 0.35 with $p = 0.145$ (Not statistically significant)

Table no 11: Temporal Incision - Range of pre-operative astigmatism and post-operative astigmatism

	Range of Pre-operative Astigmatism (No. of patients)	Percentage (%)	Range of Post-operative Astigmatism (No. of patients)	Percentage (%)
0.50 D	22	54%	40	98 %
0.50 – 1 D	14	34%	01	2%
1 -1.5 D	05	12%	0	0 %



Pre-operative

22 patients (54%) had pre-operative astigmatism in the range of 0.00 – 0.5 D,

14 patients (34%) had pre-operative astigmatism in the range of 0.50 – 1 D

05 patients (12%) had pre-operative astigmatism in the range of 1 – 1.5 D

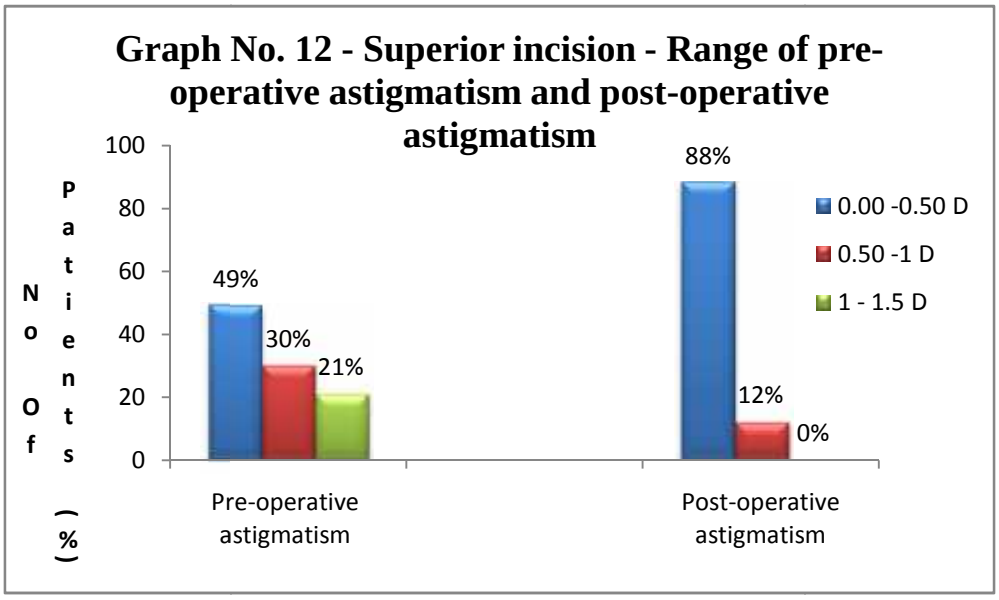
Post-operative

40 patients (98%) had post-operative astigmatism in the range of 0.00 – 0.5 D,

01 patient (02%) had post-operative astigmatism in the range of 0.50 – 1 D

Table no 12: Superior incision - Range of pre-operative astigmatism and post-operative astigmatism

	Range of Pre-operative Astigmatism(No. of patients)	Percentage (%)	Range of Post-operative Astigmatism (No. of patients)	Percentage (%)
0.50D	20	49%	36	88 %
0.50 – 1 D	12	30%	05	12%
1 -1.5 D	09	21%	0	0 %



Pre-operative

20 patients (49%) had pre-operative astigmatism in the range of 0.00 – 0.5 D,

12 patients (30%) had pre-operative astigmatism in the range of 0.50 – 1 D

09 patients (21%) had pre-operative astigmatism in the range of 1 – 1.5 D

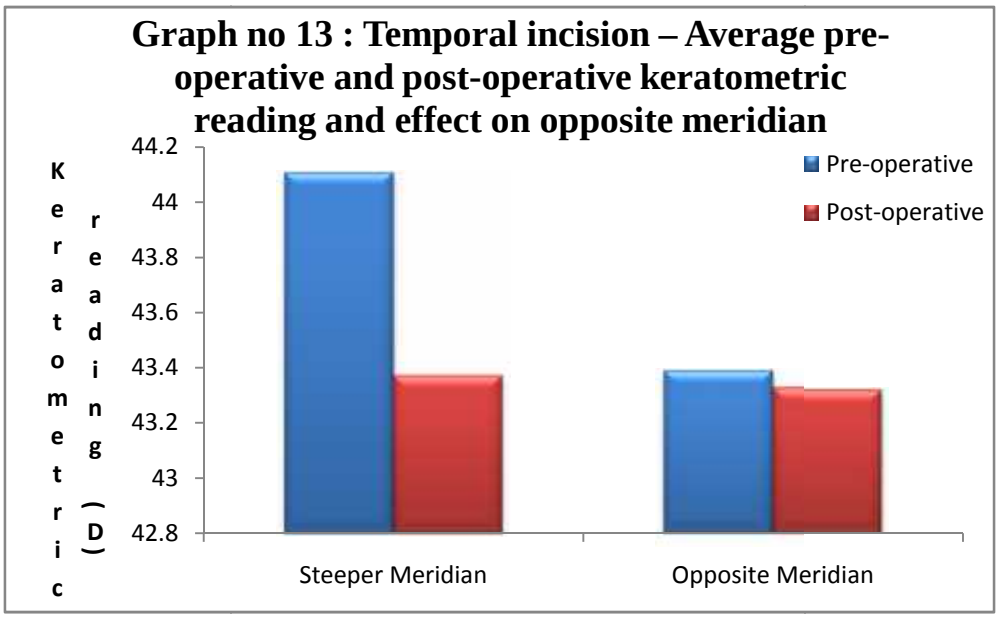
Post-operative

36 patients (88%) had post-operative astigmatism in the range of 0.00 – 0.5 D,

05 patients (12%) had post-operative astigmatism in the range of 0.50 – 1 D

Table No 13: Temporal incision – Average pre-operative and post-operative keratometric reading and effect on opposite meridian

	Pre-operative Average Keratometric reading	Post-operative Average Keratometric reading
Steeper Meridian	44.10	43.07
Opposite Meridian	43.38	43.32

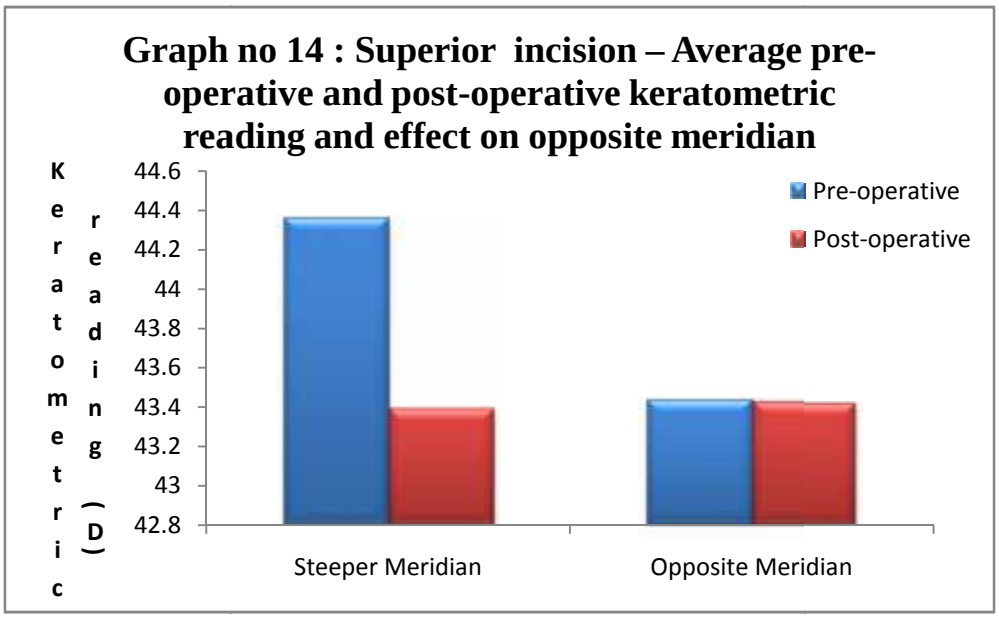


In this study, by taking the incision on the temporal side on the basis of pre-existing astigmatism, which is the steeper meridian the average pre-operative keratometric reading is 44.10 D and the average post-operative keratometric reading is 43.07 D. The difference was 1.03 + 0.96 with $p < 0.001$ (Statistically significant)

The effect on the opposite meridian is as follows, the average pre-operative keratometric reading is 43.38 and the average post-operative keratometric reading is 43.32.

Table no 14 : Superior incision – Average pre-operative and post-operative keratometric reading and effect on opposite meridian

	Pre-operative Average Keratometric reading	Post-operative Average Keratometric reading
Steeper Meridian	44.35	43.43
Opposite Meridian	43.43	43.42

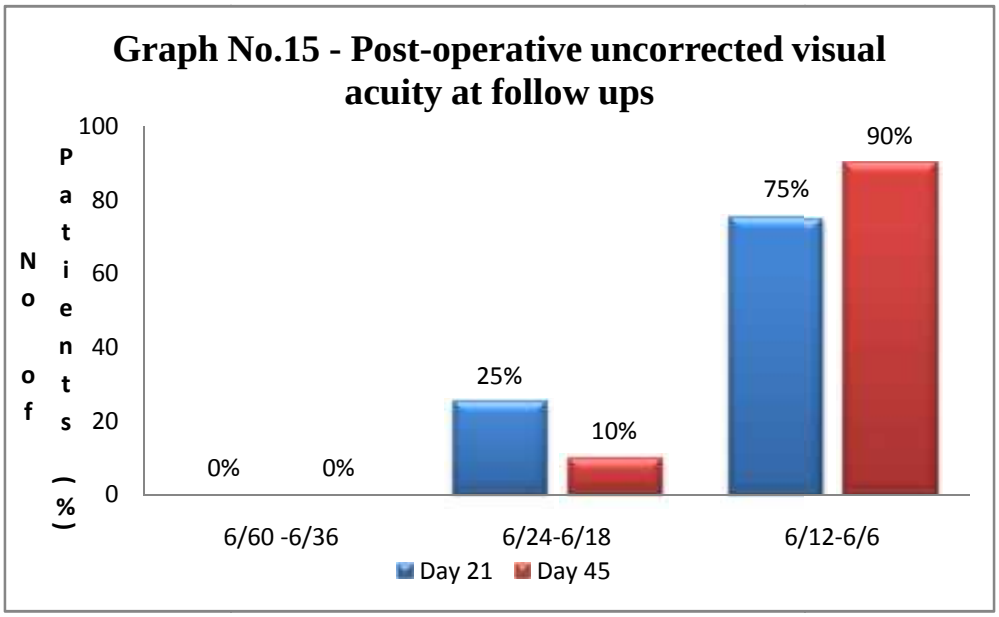


In this study, by taking the incision on the superior side on the basis of pre-existing astigmatism, which is the steeper meridian the average pre-operative keratometric reading is 44.35 and the average post-operative keratometric reading is 43.43. The difference was 0.92 + 0.95 with $p < 0.001$ (Statistically significant).

The effect on the opposite meridian is as follows, the average pre-operative keratometric reading is 43.43 and the average post-operative keratometric reading is 43.42

Table no 15 : Post-operative uncorrected visual acuity at follow ups

Range of visual acuity	Follow up day	NO. of patients	Percentage (%)
6/60 -6/36	Day 21	0	0 %
	Day 45	0	0 %
6/24 – 6/18	Day 21	20	25 %
	Day 45	09	10 %
6/12 – 6/6	Day 21	62	75 %
	Day 45	73	90 %



On day 21, post-operatively 25% patients had uncorrected visual acuity in the range of 6/24 – 6/18.

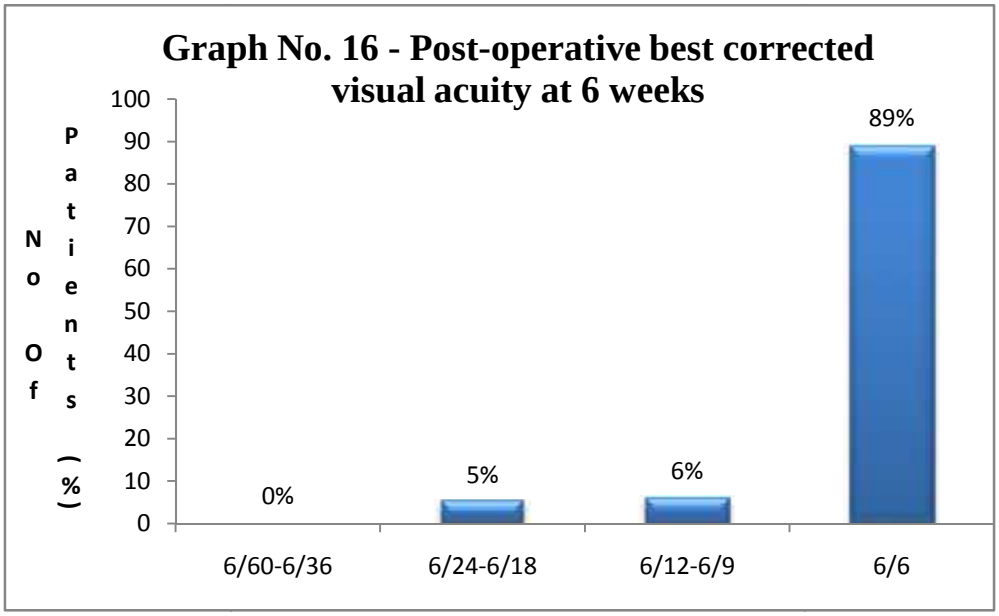
75% patients had uncorrected visual acuity in the range of 6/12 – 6/6.

On day 45, post-operatively 10% patients had uncorrected visual acuity in the range of 6/24 – 6/18.

90% patients had uncorrected visual acuity in the range of 6/12 – 6/6.

Table no 16: Post-operative best corrected visual acuity at 6 weeks

Range of visual acuity	NO. of patients	Percentage (%)
6/60 – 6/36	0	0%
6/24 – 6/18	4	5%
6/12 – 6/9	5	6%
6/6	73	89%



In this study, the best corrected visual acuity was maximum in the range of 6/9 – 6/6.

73 patients (89.02%) had BCVA of 6/6

5 patients (6.09%) had BCVA in the range of 6/12 – 6/9

4 patients (4.87%) had BCVA in the range of 6/24 – 6/18

So, 95% patients has BCVA in the range of 6/12-6/6

DISCUSSION

The present study was conducted on 82 eyes that underwent Phacoemulsification at Department of Ophthalmology, KLES Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi during study period of 1 year from 1st January 2014 – 31st December 2014. The patients underwent Phacoemulsification by either Superior or Temporal incision depending on the magnitude of pre-existing astigmatism.

Cataract surgery has been there since 20 centuries. It has evolved from couching in ancient times to modern day manual Small Incision Cataract Surgery (SICS) and phacoemulsification. Phacoemulsification has become the most favoured procedure for cataract surgery in industrialized countries. Nowadays, after the introduction of phacoemulsification through a small clear corneal incision induction of SIA generated by ECCE was almost less. Thus, it has been proposed that by placing the incision on the steepest meridian by marking the magnitude of pre-existing astigmatism, we can cause reduction in surgically induced astigmatism. The making of the incision in the steepest meridian causes corneal flattening in that meridian to reduce astigmatism. Thus, cataract surgery today can be modified as a **'Refractive Cataract Surgery'.**

The major cause of poor unaided visual acuity following cataract surgery is surgically induced astigmatism. The goal of modern cataract surgery is to minimize corneal curvature changes postoperatively. This requires an exact pre-operative evaluation of corneal curvature and astigmatism.

Hence, modern cataract surgery, in its quest for providing the best uncorrected visual acuity to the patient and minimizing surgically induced astigmatism has become a refractive surgery today. With the goal not only to remove the cataract but also to minimize astigmatism induced by surgery and to reduce the preoperative astigmatism, if any, in the patient.

The results of this study show that there is minimal astigmatism in phacoemulsification and that surgically induced astigmatism can be modified by modification of the incision location by knowing the steepest meridian of the pre-existing astigmatism. Any surgical incision placed on the cornea, results in a change of the corneal curvature. This induces a flattening in the axis of incision and steepening 90 degrees away.

In the present study, the mean age was 60 $\pm$ 2 years. Majority of the patients were in the range of 50 – 70 years that is 69% as cataract is more common in this age group. In the present study, 56% patients were male and 44 % patients were female with male : female ratio of 1.3 : 1.

In the present study, majority of the patients that is 32 % had pre-operative visual acuity in the range of 6/60 to CF 3 meters, followed by 29 % patients with pre-operative visual acuity in the range of CF 2 meters to HMCF.

A study conducted by Ninn Pedersen K proved that the most important predisposing factor for rapid changes in the postoperative astigmatism were large preoperative astigmatism, young age and preoperative intraocular pressure [(46)].

A study conducted by Anders N et al. confirmed that age and preoperative astigmatism were found to influence induced astigmatism significantly [(47)].

In the present study, we had included patients in a range of pre-existing astigmatism from 0.5 D to 1.5 D who underwent either superior or temporal clear corneal incision based on the pre-existing astigmatism. In this study, 32 % patients had 0.5 D of pre-existing astigmatism. 51% in the range of 0.5 D – 1D of pre-existing astigmatism and 17 % in the range of 1 D – 1.5 D of pre-existing astigmatism.

In a study conducted by Jaime Tejedor, which was based on choosing the location of the corneal incision based on pre-existing astigmatism in phacoemulsification. He also considered the range of pre-existing astigmatism from 0.5 D -1.5 D to choose the incision site as corneal incision causes flattening of the incised meridian. This study considered the amount and the axis of pre-existing astigmatism [(33)].

WTR astigmatism is when the vertical meridian of the corneal curvature is steeper and ATR astigmatism is when the horizontal meridian is steeper [(48)].

Out of the total 82 eyes, 41 eyes had pre-operative WTR astigmatism ($K_V > K_H$) and so underwent phacoemulsification through superior incision. Another 41 eyes had pre-operative ATR astigmatism who underwent phacoemulsification through temporal incision ($K_H > K_V$).

Similar profile of pre operative astigmatism was observed in a study by Roman S, Ullern M which evaluated SIA post operative and uncorrected visual acuity with superior and temporal incision among 90 patients with pre operative astigmatism [(14).]

A study conducted by Salvatore Cillino, who studied temporal versus superior approach phacoemulsification and determined short term post-operative astigmatism.

In this study, 40 patients had pre-operative WTR astigmatism and 40 patients had pre-operative ATR astigmatism which was similar to our study [(49)].

In the present study, the type of post-operative astigmatism was 40 % WTR, 30% ATR and 30 % of patients with no post-operative astigmatism. This result helps us to conclude that, by taking the incision on the steepest meridian based on pre-existing astigmatism is helpful in reducing Surgically Induced Astigmatism.

Postoperative astigmatism after cataract surgery is of ATR type which is caused by flattening of the corneal meridian at right angles to the direction of the incision. When incision is taken closer to the steeper axis, preoperative astigmatism reduces and if incision is taken on the steeper axis the astigmatism totally neutralizes [(50)] whereas pre-existing astigmatism with steeper cornea and incision taken on opposite axis – post-operative astigmatism increases. A temporal incision shows WTR type of postoperative astigmatism in majority of patients probably due to the incision being away from visual axis. When incision is taken superiorly which is closer to central cornea will have nearly twice the astigmatic effect than horizontal incision [(50)].

Simsek S, Yasar T, Demirok A, Cinal A, Yilmaz conducted a study to evaluate the effect of temporal and superior clear corneal incisions on astigmatism after phacoemulsification in 40 eyes. Temporal incision group showed significantly lower astigmatism. Upper eyelid pressure on the superior clear corneal incisions led to ATR astigmatism that was significantly higher than that was induced by the temporal incisions [(26)].

In the present study we compared the change from pre-operative to post-operative astigmatism. We concluded 41 patients had WTR pre-operative astigmatism. The post-operative results were 13 patients that is 16 % continued to have WTR astigmatism of less magnitude. 15 patients (18%) showed a post-operative ATR drift whereas 11 patients (14 %) showed no post-operative astigmatism. Of the 41 patients having pre-operative ATR astigmatism, 16 patients (19%) continued to remain so post-operatively with less magnitude. 14 patients (17%) showed a post-operative WTR drift and 13 patients (16%) showed no post-operative astigmatism.

Superiorly placed incisions induce ATR type astigmatism and temporal incisions induced WTR astigmatism [(51)]. By knowing a preexisting astigmatism preoperatively, one can reduce postoperative astigmatism by selecting an appropriate incision i.e. astigmatism is decreased by taking incision closure to steeper cornea and neutralized by taking incision on steeper meridian. Instead postoperative astigmatism increases by taking incision on opposite axis [(52)].

In the present study, all the patients underwent phacoemulsification through either superior or temporal incision depending on the pre-existing astigmatism. The range of post-operative SIA was evaluated. Pre-operative and post-operative keratometric readings and refraction were used for analysis. All calculations were performed using SIA calculator version 2.1, a free software programme.

In the present study, 44 patients (54 %) had surgically induced astigmatism in the range of 0.0 – 0.5 D. 32 patients (39%) had surgically induced astigmatism in the range of 0.5 – 1 D. 4 patients (05%) had surgically induced astigmatism in the range of 1D – 1.5 D. 1 patient (1%) had surgically induced astigmatism in the range of 1.5D – 2 D. 1 patient (1%) had surgically induced astigmatism in the range of 2D – 2.5 D.

In the present study, the average Surgically Induced Astigmatism recorded was 0.54 D $\pm$ 0.34 with $p<0.001$ (Statistically significant). In the present study, we concluded that pre-operatively 32% patients had pre-existing astigmatism of 0.5 D, whereas post-operatively 93% patients had post-operative astigmatism in the range of 0.0 – 0.5 D. 51% patients had pre-existing astigmatismin the range of 0.5 – 1 D while 07 % patients had post-operative astigmatism in the range of 0.5 – 1D. Lastly, 17% patients had PEA in the range of 1 – 1.5 D whereas no patient had post-operative astigmatism in the range of 1 – 1.5 D.

The above results indicate that choosing the clear corneal incision based on the preoperative steepest meridian has significantly decreased the post-operative keratometric astigmatism at the temporal and superior locations. So, it is desirable to take the corneal incision on the steeper meridian in eyes with pre-existing corneal astigmatism higher than 0.50 D [(53)].

In this present study, 41 patients had WTR astigmatism pre-operatively. So, underwent phacoemulsification though superior incision. The amount of surgically induced astigmatism through the superior incision was 0.84 D with standard deviation of 0.49. Pre-operatively 41 patients had ATR astigmatism. So, underwent phacoemulsification though temporal incision. The amount of surgically induced astigmatism through the temporal incision was 0.70 D with standard deviation of 0.35. But, this comparison of difference of surgically induced astigmatism between temporal and superior incision was not statistically significant ($p=0.145$).Although, clinically it showed that temporal incision induces less surgically induced astigmatism compared to superior incision whenever the incision is placed on the steepest meridian.

In a study conducted by Chang Rae Rho, who studied the effects of steeper meridian incision on pre-existing corneal astigmatism in phacoemulsification. This study included patients with pre-existing corneal astigmatism more than 0.50 diopter (D). Patients were grouped according to the incision site (temporal, supero-temporal, superior [53].

This study evaluated 95 patients (30 eyes temporal incision, 32 eyes supero-temporal incision and 33 eyes superior incision). Two months postoperatively,the SIA changed significantly in the temporal group, supero-temporal group and superior group. The SIA was 0.28 D $\pm$ 79 in the temporal group, 0.40D $\pm$ 85 in the supero-temporal group and 0.46 D $\pm$ 92 in the superior group [53].

This study concluded that choosing the corneal incision based on the preoperative steepest meridian significantly decreased keratometric astigmatism at the temporal, supero-temporal and superior locations. So, it is wise to place the corneal incision on the steepest meridian in eyes with corneal astigmatism greater than 0.50 D which is similar to our study [53].

A similar study conducted by Lyhne N et al showed that there was a reduction in induced keratometric cylinder in the clear corneal incision group. The findings support using temporal incision in cases with a preoperative ATR type of astigmatism reduces surgically induced astigmatism [54].

A study conducted by Liu Y, Li S (1998) investigated the therapeutic effects, advantages and disadvantages of phacoemulsification through a temporal clear corneal incision. With 812 patients who underwent phacoemulsification through a temporal clear corneal tunnel incision. Topographical changes displayed temporal

flattening near incision in early stage with mild surgically induced astigmatism and endothelial cell loss was 8.23% postoperatively. They concluded that temporal clear corneal incision is effective and convenient [43].

In the present study, the range of pre-operative astigmatism and post-operative astigmatism through the temporal incision was calculated. 22 patients (54%) had pre-operative astigmatism of 0.5 D. 14 patients (34%) had pre-operative astigmatism in the range of 0.5 D – 1 D. 05 patients (12%) had pre-operative astigmatism in the range of 1 D – 1.5 D. Post-operatively, 40 patients (98%) had astigmatism in the range of 0.0–0.5 D. 01 patient (02%) had astigmatism in the range of 0.5 – 1 D. This result concludes that there is a reduction in post-operative astigmatism by taking the temporal incision in patients with ATR astigmatism.

In the present study, the range of pre-operative astigmatism and post-operative astigmatism through the superior incision was calculated. 20 patients (49%) had pre-operative astigmatism of 0.5 D. 12 patients (30%) had pre-operative astigmatism in the range of 0.5 D – 1 D. 09 patients (21%) had pre-operative astigmatism in the range of 1 D – 1.5 D. Post-operatively, 36 patients (88%) had astigmatism in the range of 0.0–0.5 D. 05 patients (12%) had astigmatism in the range of 0.5 – 1 D.

Naturally occurring (idiopathic) astigmatism is frequent, with up to 95% of eyes having detectable astigmatism [55]. It is estimated that approximately 70% of the general cataract population has at least 1.00 D of astigmatism and approximately 33% of patients undergoing cataract surgery are eligible for treatment of pre-existing astigmatism [56].

Ferrer-Blasco et al studied prevalence of corneal astigmatism before cataract surgery and found that in 13.2 % of eyes no corneal astigmatism was present; in 64.4 %, corneal astigmatism was between 0.25 – 1.25 diopters(D) and in 22.2%; it was 1.50 D or higher [(57)]. This finding implies that, when planning a surgery, both spherical and the astigmatic components should be taken in to account to achieve post-operative outcomes as close to emmetropia as possible [(58)].

In this study, by taking the incision on the temporal side on the basis of pre-existing astigmatism, which is the steeper meridian the average pre-operative keratometric reading is 44.10 and the average post-operative keratometric reading is 43.07. The difference was 1.03 + 0.96 with $p< 0.001$ (Statistically significant). So, our study shows that there is a 1D reduction in the keratometric reading after the cataract surgery performed by taking incision on the steepest meridian on the temporal side.

The effect on the opposite meridian is as follows, the average pre-operative keratometric reading is 43.38 and the average post-operative keratometric reading is 43.32. There was not much difference on the opposite meridian by taking incision on the steepest meridian (Not statistically significant).

In this study, by taking the incision on the superior site on the basis of pre-existing astigmatism, which is the steeper meridian the average pre-operative keratometric reading is 44.35 and the average post-operative keratometric reading is 43.43. The difference was 0.92 + 0.95 with $p< 0.001$ (Statistically significant). Our study shows that there is a 0.92D reduction in the keratometric reading after the cataract surgery performed by taking incision on the steepest meridian.

The effect on the opposite meridian is as follows, the average pre-operative keratometric reading is 43.43 and the average post-operative keratometric reading is

43.42. There was not much effect on the opposite meridian (Not statistically significant).

This study proves that firstly by taking the incision on the steepest meridian depending on the pre-existing astigmatism there was flattening in that meridian. On comparison between superior and temporal incision, our study showed that the temporal incision induces more flattening. There is less SIA. Such a comparison is not done in any other study.

Jaime Tejedor in his study concluded that superior incision is recommended with at least 1.5 diopters of astigmatism and steep axis at 90 degrees. Temporal incision is recommended with astigmatism < 2.5 D and steep axis at 90 degrees, negligible astigmatism or astigmatism <0.75 D and steep axis at 180 degrees [(33)].

Edmondo Borasio, conducted a study to compare between 2 types of clear corneal incisions used in phacoemulsification: the temporal and the on-axis clear corneal incision. At the second follow-up, the difference was 0.29 D and it was statistically significant (0.63 D in CCOI; 0.34 D in CCTI; PZ.0004). Seven weeks after small-incision phacoemulsification, the CCTI induced less SIA [(59)].

In another study conducted by Muhammad Asif Sadiq et al, to study effect of 5.5 millimeters clear corneal temporal versus steepest meridian phacoemulsification incision on pre-existing astigmatism. It was a randomized control trial which included 100 cases divided in 2 groups. In group A, incision was made on steepest meridian. In group B, incision was made on uniformly selected temporal site (irrespective of steepest meridian). On 12 weeks post-operatively, corneal astigmatism of group A (0.46 $\pm$ 0.377) was significantly less than pre-operative astigmatism. In group B, the corneal astigmatism was 0.98 $\pm$ 0.44. So, in group B also

the difference was statistically significant but the effect of phaco-incision in reducing pre-existing astigmatism was much superior in group A than in group B. This study concluded that steepest meridian phaco-incision results in significant decrease in pre-operative astigmatism [(60)].

In a study conducted by Edmondo Borasio, which was a study on 62 eyes with cataract and corneal astigmatism (<2.60 diopters [D]) having phacoemulsification with a temporal CCI (temporal group) or on-axis CCI (on-axis group).Three weeks after surgery, the on-axis CCI induced slightly more flattening of the meridian of the incision (mean _0.63 G 0.57 D [SD]) than the temporal CCI (mean _0.50 G 0.44 D). However, the differences were not statistically significant. In eyes with preoperative astigmatism less than 2.60 D, on-axis CCI phacoemulsification induced slightly more flattening along the incision meridian than temporal CCI phacoemulsification, although the differences were not significant [(61)].

Pistarini Fernando Goncalves conducted a study to evaluate the effect of phacoemulsification with clear corneal incision in the steepest meridian on the magnitude of the pre-operative astigmatism. The mean SIA was 0.61 D $\pm$ 0.25 through the temporal incision [(34)].

Randall J conducted a study, to report the result of sutureless cataract surgery by phacoemulsification. The comparison was between a 3.2 mm and 5.5 surgical incision. There were statistically significant differences in favour of the 3.2 mm incision group associated with less astigmatic shift [(62)].

Stephan Kohnen MD, Ralph Neuber MD, Thomas Kohnen MD stated that for superior clear corneal incision surgeon sits at the head end. This results in a steeper

angle of approach, mostly during the use of incision keratome and phacohandpiece. The steeper access of the phacohandpiece resulted in a more wound stress and causing stretching of the corneal tissue. Both should result in a more unstable wound and would explain the higher induced astigmatism [(63)].

In the present study, on day 21 post-operatively 25% patients had uncorrected visual acuity in the range of 6/24 – 6/18. 75% patients had uncorrected visual acuity in the range of 6/12 – 6/6. On day 45, post-operatively 10% patients had uncorrected visual acuity ranging from 6/24 – 6/18. 90% patients had uncorrected visual acuity ranging from 6/12 – 6/6.

In this study, the best corrected visual acuity was maximum in the range of 6/9 – 6/6. 73 patients (89.02%) had BCVA of 6/6. 5 patients (6.09) had BCVA in the range of 6/12 – 6/9. 4 patients (4.87%) had BCVA in the range of 6/24 – 6/18. So, 95% patients have BCVA in the range of 6/12-6/6.

Deng G and Liu R in their study found that there was a mean increase in corneal refractivity in phacoemulsification group which was significantly less ($p<0.05$) and the best corrected visual acuity was better than that in conventional extracapsular extraction group at postoperative ½ month, 3 months and 6 months. [(64)]

Minassian DC, et al. in their randomized trial compared extracapsular cataract extraction with phacoemulsification. The mean comparative outcomes were visual acuity, refraction and complication rates. They found a higher proportion achieved on unaided visual acuity of 6/9 or better in the phacoemulsification group. Thus phacoemulsification shows earlier visual rehabilitation. [(65)]

Due to new developments in phacoemulsification devices, changes in operation techniques and the use of small incisions in cataract surgery which reduce the operation-induced astigmatism or make an inconsiderable change in the existing corneal astigmatism, the general aim of cataract surgery has gone from simple cataract extraction to ensuring the best visual acuity and quality without spectacle dependence. During cataract surgery, it is possible to reduce the pre-existing astigmatism by modifying the length, shape, type and the localization of the incision [(66)].

A study by Giasanti et al, indicated that a clear corneal incision of 2.75 mm for a cataract surgery induced little change in astigmatism in eyes with low pre-operative corneal cylinder, regardless of the incision site. But later a retrospective study was done, which concluded that larger changes were induced by superior rather than temporal 2.8 mm incision [(67)].

So the present study concluded that, by placing the incision in the steepest meridian depending on the magnitude of pre-existing astigmatism, the surgically induced astigmatism was less. On comparison between temporal and superior incision site, the SIA was less with temporal as compared to superior incision.

CONCLUSION

The present study was conducted on 82 eyes that underwent Phacoemulsification at Department of Ophthalmology, KLES Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi during study period of 1 year. The patients underwent Phacoemulsification by either Superior or Temporal incision depending on the magnitude of pre-existing astigmatism.

In this study, we performed phacoemulsification through clear corneal incision and the site of incision was determined by the magnitude of pre-existing astigmatism which was determined by the keratometric readings. Then we evaluated the SIA.

The following conclusions were drawn from the study.

- The average surgically induced astigmatism was low and statistically significant by taking the incision on the steepest meridian. The making of the incision in the steepest meridian causes corneal flattening in that meridian to reduce astigmatism.
- The incidence of post-operative astigmatism following phacoemulsification with foldable intra ocular lens implantation with both temporal clear corneal incision and superior clear corneal incision was low as the site of incision was on the steepest meridian of corneal curvature.
- The average surgically induced astigmatism was less with temporal clear corneal incision as compared to superior clear corneal incision phacoemulsification with foldable intraocular lens implantation.

- The average surgically induced astigmatism was 0.54 with the standard deviation of 0.34. This was concluded using the paired‘t’ test and was statistically significant ($p < 0.001$).
- The average surgically induced astigmatism with the temporal incision was 0.70 with standard deviation of 0.35. The average surgically induced astigmatism with the superior incision was 0.84 with standard deviation of 0.49
- In the study, 54 % patients had surgically induced astigmatism in the range of 0.0 – 0.5 D.
- In the study, 30 % of patients had no post-operative astigmatism.
- On taking temporal incision, the mean keratometric difference was 1.03 ± 0.96 which was statistically significant ($p<0.001$). On taking superior incision, the mean keratometric difference was 0.92 ± 0.95 which was statistically significant ($p<0.001$)
- In the present study the visual rehabilitation was good. 90 % patients had UCVA in the range of 6/12 – 6/6 and 95 % patients had BCVA in the range of 6/12 – 6/6.

In conclusion, choosing the clear corneal incision site based on the preoperative steepest meridian significantly decreased the keratometric astigmatism at the temporal and superior locations.

As well as, temporal incision is evidently better than superior incision in minimizing surgically induced astigmatism.

SUMMARY

Cataract surgery has been there since 20 centuries. It has evolved from couching in ancient times to modern day manual SICS and phacoemulsification. Nowadays, after the introduction of phacoemulsification through a small clear corneal incision induction of surgically induced astigmatism was less. Thus, it has been proposed that by placing the incision on the steepest meridian by marking the magnitude of pre-existing astigmatism, we can cause further reduction in surgically induced astigmatism. The purpose of the study is to see the beneficiary effect of an incision that is placed on the steepest meridian in controlling/ lowering the astigmatic outcome in eyes with pre-existing astigmatism and comparing effect of incisions at different sites.

The present one year longitudinal study was conducted in the department of Ophthalmology, KLES Dr. Prabhakar Kore hospital and Medical Research Centre, Belagavi on patients undergoing cataract surgery during the period of 1st January 2014 – 31st December 2014. The patients undergoing Phacoemulsification with pre-existing astigmatism in the range of 0.5D – 1.5 D were selected for the study to evaluate surgically induced astigmatism after phacoemulsification clear corneal incision in the steepest meridian on the magnitude of the pre-existing astigmatism.

In the present study the mean age was 60 $\pm$ 2 years with majority of the patients in the range of 50-70 years. In this study 56% patients were males and 44% patients were females. In this study, 32% had pre-operative visual acuity in the range 6/60 to CF 3 meters followed by 29% patients with visual acuity in the range of CF 2 meters to HMCF.

In the present study, 32% patients had 0.5 D of pre-existing astigmatism followed by 51% patients in the range of 0.5 – 1D of pre-existing astigmatism. Whereas, 17 % of patients had pre-existing astigmatism in the range of 1- 1.5 D.

In this study, 93 % patients had post-operative astigmatism in the range of 0.0 - 0.5 D followed by 07 % patients in the range of 0.5 – 1D of post-operative astigmatism. 30% were reported to have no post-operative astigmatism.

In the present study, 54 % patients had surgically induced astigmatism in the range of 0.0 -0.50 D followed by 39% patients who had surgically induced astigmatism in the range of 0.5 – 1 D and 05% in the range of 1 -1.5D. The result showed that the average surgically induced astigmatism recorded was 0.54 D $\pm$ 0.34 with $p<0.001$ (Statistically significant). It was concluded using the paired‘t’ test.

The surgically induced astigmatism through the temporal incision was 0.70 D with standard deviation of 0.35. The surgically induced astigmatism through the superior incision was 0.84 D with standard deviation of 0.49. But, this difference of surgically induced astigmatism comparison between temporal and superior incision was not statistically significant ($p=0.145$)

In the temporal incision, pre-operatively 22 patients (54%) had pre-operative astigmatism in the range of 0.00 – 0.5 D whereas post-operatively 40 patients (98%) had post-operative astigmatism in the range of 0.00 – 0.5 D. In the superior incision, pre-operatively 20 patients (49%) had pre-operative astigmatism in the range of 0.00 – 0.5 D, whereas post-operatively 36 patients (88%) had post-operative astigmatism in the range of 0.00 – 0.5 D.

On taking temporal incision, the mean keratometric difference was 1.03 $\pm$ 0.96 which was statistically significant ($p<0.001$). On taking superior incision, the mean keratometric difference was 0.92 $\pm$ 0.95 which was statistically significant ($p<0.001$)

The visual rehabilitation was good. 90 % patients had UCVA in the range of 6/12 – 6/6 and 95 % patients had BCVA in the range of 6/12 – 6/6.

Clear Corneal incision placed at the steepest meridian causes flattening of the incised meridian and steeping of the opposite meridian. So, by pre-determining the incision site, the surgically induced astigmatism can be reduced.

Temporal incision creates less astigmatic effect than superior due to the fact that temporal limbus is farther from the visual axis. Along with this, the pressure the eyelid exerts on the superior incision increases astigmatism on that localization.

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CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

ID NO. | | | |

Mr/Mrs/Ms_____ You are invited to participate in our research study titled **"A longitudinal study to evaluate the effect of Surgically Induced Astigmatism after phacoemulsification clear corneal incision placed in the steepest meridian on eyes with pre-existing astigmatism at KLES Hospital, Belgaum."**

Respected Sir/Madam we request you to enroll yourself to participate in our study as you are eligible for doing so.Your participation in the study is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If u decide to participate you are free to withdraw at any time.

Purpose of the study :- The purpose of the research is to evaluate the beneficiary effect of Surgically Induced Astigmatism after Phacoemulsification clear corneal incision in the steepest meridian on eyes with pre-existing Astigmatism.

Procedure Involved :- If you agree to enroll yourself in this study, you will be asked to give detailed history. Then you will be clinically examined in detail by slit-lamp examination, fundoscopy, tonometry for measurement of intraocular pressure. Syringing for patency of the lacrimal sac, keratometry and A scan ultrasonography and investigations like Blood Pressure measurement, Random Blood sugar will be done. Then you will be undergoing Phacoemulsification cataract surgery where the incision

will be placed on the steepest meridian. The steepest meridian will be identified using an corneal astigmatic marker before giving the block for surgery. You will be asked to follow up on specified dates when your progress would be monitored and documented.

Risks and Benefits :- Rare complications of cataract surgery includes endophthalmitis, vitreous loss, globe perforation, retro bulbar hemorrhage, expulsive choroidal hemorrhage for which all necessary precautions will be taken.

Your participation may benefit you and others and others suffering from same ailment in future, by helping us learn more about the disease process and better treatment modalities.

Alternatives :- If you are not willing to participate you will be treated according to the existing protocol & it will not affect your relationship with this hospital.

Costs for participating in this research :- There will not be any extra cost incurred by the participant. The participant will however have to pay for the investigations which are the part of the existing management protocol for this ailment. There is no commitment for any reimbursement or any other compensation for the participant.

Privacy and Confidentiality:- The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to others without your written permission.

Authorization to Publish Results :- When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Compensation :- In the event of injury related to the study, treatment will be made available through KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law. The doctors and the staff will provide facilities and medical attention to you.

Consent for participation in research trial

I, Mr./Ms./Mrs _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up ant of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Signature or the Left Thumb Print of Subject: _____

Witness Name: _____

Signature of Witness: _____

Investigators Name: _____

Signature of Investigator: _____

Name of the Guide :-

Signature of the guide :- _____

Date: _____

Place: _____

Witness Name: _____

Signature of Witness: _____

Investigators Name: _____

Signature of Investigator: _____

Date: _____

Place: _____

PROFORMA

PATIENTS ID NO: | | | |

NAME: | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | |

AGE: | | | Years

SEX: | | (1-Male; 2-Female)

ADDRESS: | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | |

CONTACT NUMBER :- | | | | | | | | | | |

OP NUMBER: | | | | | | | | |

IP NUMBER: | | | | | | | | |

DATE OF ADMISSION: | | / | | / | | | | |

DATE OF DISCHARGE: | | / | | / | | | | |

IS THE PATIENT ELIGIBLE FOR STUDY? (1-YES; 2-NO) | |

HAS INFORMED CONSENT BEEN GIVEN? (1-YES; 2-NO) | |

FINAL RESULT INFORMATION | |

1- INELIGIBLE
2- ELIGIBLE- REFUSAL
3- ELIGIBLE- PARTICIPATING

SURGEON'S NAME: | | | | | | | | | | | | | | | |

SURGEON'S SIGNATURE: _____

DATE: | | / | | / | | | | |

CHIEF COMPLAINTS:

DIMINUTION OF VISION RE ☐

Duration: _____ days/ months/years

LE ☐

Duration: _____ days/ months/years

HISTORY OF PRESENT ILLNESS:

1 .DIMINUTION OF VISION 1- Gradual; 2- Sudden ☐

1- Progressive; 2- Static ☐

1- Painless; 2- Painful ☐

1- For distance; 2- For near ☐

2. DIPLOPIA/POLYOPIA 1- Present; 2- Absent ☐

3. COLOURED HALOS 1- Present; 2- Absent ☐

4. BLACK SPOTS BEFORE THE EYES 1- Present; 2 - Absent ☐

5. WATERING 1- Present; 2 - Absent ☐

6. REDNESS 1- Present; 2 - Absent ☐

7. DISCHARGE 1- Present; 2 - Absent ☐

8. H/O WEARING GLASSES (1-Distance; 2-Near; 3-Both) ☐

Duration: ☐☐onths/years

PAST HISTORY:

TRAUMA TO THE EYE: 1- Present; 2- Absent ☐

OCULAR SURGERY: 1- Present; 2- Absent ☐

Type of surgery: _____

Duration: ☐☐ months/years

DIABETES: 1- Present 2- Absent ☐

Duration: ☐☐ months/years

HYPERTENSION: 1- Present 2- Absent ☐

Duration: ☐☐ months/years

ANY OTHER MEDICAL DISORDERS: _____

PERSONAL HISTORY:

SMOKING: 1- Present; 2- Absent ☐

Duration: ☐☐ months/years

ALCOHOLISM: 1- Present; 2- Absent ☐

Duration: ☐☐ months/years

ANY OTHER ADDICTIONS: _____ ☐

Duration: ☐☐ months/years

GENERAL PHYSICAL EXAMINATION:

General Appearance:

1- Well built ,2- Moderately built, 3- Poorly built, 4- emaciated ☐

Pallor: 1- Present 2- Absent ☐

If present 1- Mild 2- Moderate 3- Severe ☐

Pulse: ☐☐☐ /minute

BP:- ☐☐☐ / ☐☐☐ mm of hg

Temperature: ☐☐☐ degree Fahrenheit

Respiratory rate: ☐☐ /minute

SYSTEMIC EXAMINATION:

CVS: 1- Normal 2- Abnormal ☐
if 2, specify :_____

RS: 1- Normal 2- Abnormal ☐
if 2, specify: _____

CNS: 1- Normal 2- Abnormal ☐
if 2, specify :_____

Per Abdomen: 1- Normal 2- Abnormal ☐
if 2, specify :_____

OCULAR EXAMINATION:

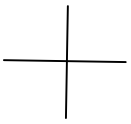
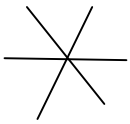
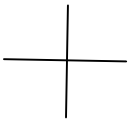
☐

Head posture: 1- Erect ,2- Tilted

Visual Axis: 1- Parallel, 2- Deviated ☐

Facial Symmetry: 1- Symmetrical, 2- Asymmetrical ☐

Extraocular movements:

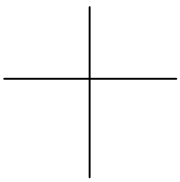
RE-  Binocular :-  LE- 

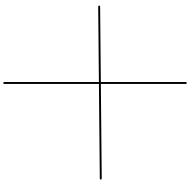
(N- Normal, R- Restricted) ☐

1) Visual Acuity:

	RE	LE
DISTANT		
PINHOLE		
NEAR		
AIDED		

REFRACTION/RETINOSCOPY:





Prescription	Spherical	Cylindrical	Axis	BCVA
RE				
LE				

2. Adnexa (1- Normal; 2-Abnormal)	☐	☐
3. Sclera (1- Normal; 2- Congested)	☐	☐
4. Conjunctiva (1-normal; 2-conjunctival congestion; 3-ciliary congestion; 4-chemosis)	☐	☐
5. Cornea (1- normal; 2-opacity; 3-vascularisation)	☐	☐
6. Anterior chamber (1- normal depth; 2-shallow; 3-deep)	☐	☐
7. Iris (1-normal colour & pattern; 2-Abnormal)	☐	☐
8. Pupil: Size- ____ in mm Shape- 1- Round & Regular; 2-Abnormal Reaction: Direct (1. Present, 2. Absent) Indirect (1. Present, 2. Absent) Near reflex (1. Present, 2. Absent)	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐

9. Lens Clarity- 1. Clear, 2. Opaque Cataract - (1) , PCIOL - (2) Cataract if present- 1.immature 2.mature 3. hyper mature A) CORTICAL- (1.Present, 2. Absent)		☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
B) NUCLEAR SCLEROSIS- 1. PRESENT, 2- ABSENT If present- 1. Grade-1 2. Grade-2 3.Grade-3 4. Grade-4		☐ ☐	☐ ☐
(C) POSTERIOR SUBCAPSULAR CATARACT 1. PRESENT, 2. ABSENT		☐	☐

FUNDUS	RE	LE
GLOW		
MEDIA		
DISC		
C:D RATIO		
BLOODVESSELS		
BACKGROUND		
MACULA		

DIAGNOSIS:-

IMPRESSION:-

INVESTIGATIONS:

1. Ocular

A) Lacrimal patency

(1-Patent , 2- regurgitation: 2A- Clear fluid, 2B- Mucopurulent ,

3- blocked)

RE ☐

LE ☐

2 IOP:

RE: ☐ mm of hg

LE : ☐ mm of hg

3 Blood sugar: _____mg%

4 Blood Pressure:_____mm of hg

PREOPERATIVE KERATOMETRY:

EYE: ☐ (1-Right eye; 2- Left eye)

KH (Diopters)	Axis (degree)	KV (Diopters)	Axis (degree)	Preoperative astigmatism(A) A= KH-KV	Axis (degree)

A SCAN BIOMETRY : SRK II FORMULA

	RE	LE
KH		
KV		
AXL		
AC DEPTH		
PCIOL		

OPERATIVE PROCEDURE: PHACOEMULSIFICATION CATARACT SURGERY WITH INCISION ON STEEPEST MERIDIAN WITH FOLDABLE IOL IMPLANTATION.

DATE:_____/_____/_____

OPERATING EYE : _____

ANAESTHESIA: PERIBULBAR BLOCK/ TOPICAL

INCISION: 1. Superior ☐

2.Temporal ☐

INTRAOCULAR LENS TYPE: _____

Operative Complications: 1. Present, 2. Absent ☐

If present- specify

Post- operative complications: 1. Present, 2. Absent ☐

If present- specify

FOLLOW UP PLAN: 3 week post-operatively

1. Conjunctiva (1-normal; 2-conjunctival congestion; 3-ciliary congestion; 4-chemosis)	☐
2.Section/suture site (1-edges opposed; 2- edges gaping)	☐
3.Cornea (1-clear; 2-hazy/descemets fold)	☐
4. Anterior chamber (1- normal depth; 2-shallow; 3-deep)	☐
5. Pupil: Size- ____ in mm Shape- 1- Round & Regular; 2-Abnormal IF 2 (Specify) :	☐
6.Intraocular Lens (1-in situ, 2-decentred)	☐

VISUAL ACUITY	RE	LE
DISTANT		
PINHOLE		

POSTOPERATIVE KERATOMETRY:

3 weeks

EYE: ☐ (1-Right eye; 2- Left eye)

KH (Diopters)	Axis (degree)	KV (Diopters)	Axis (degree)	Postoperative astigmatism(A) A= KH-KV	Axis (degree)

FOLLOW UP PLAN: 6 week post-operatively

1. Conjunctiva (1-normal; 2-conjunctival congestion; 3-ciliary congestion; 4-chemosis)	☐
2.Section/suture site (1-edges opposed; 2- edges gaping)	☐
3.Cornea (1-clear; 2-hazy/descemets fold)	☐
4. Anterior chamber (1- normal depth; 2-shallow; 3-deep)	☐
5. Pupil: Size- ____ in mm Shape- 1- Round & Regular; 2-Abnormal IF 2(Specify) :	☐
6.Intraocular Lens (1-in situ, 2-decentred)	☐

VISUAL ACUITY	RE	LE
DISTANT		
PINHOLE		

POSTOPERATIVE KERATOMETRY:

6 weeks

EYE: ☐ (1-Right eye; 2- Left eye)

K1 (Diopters)	Axis (degree)	K2 (Diopters)	Axis (degree)	Postoperative astigmatism(A) A= KH-KV	Axis (degree)

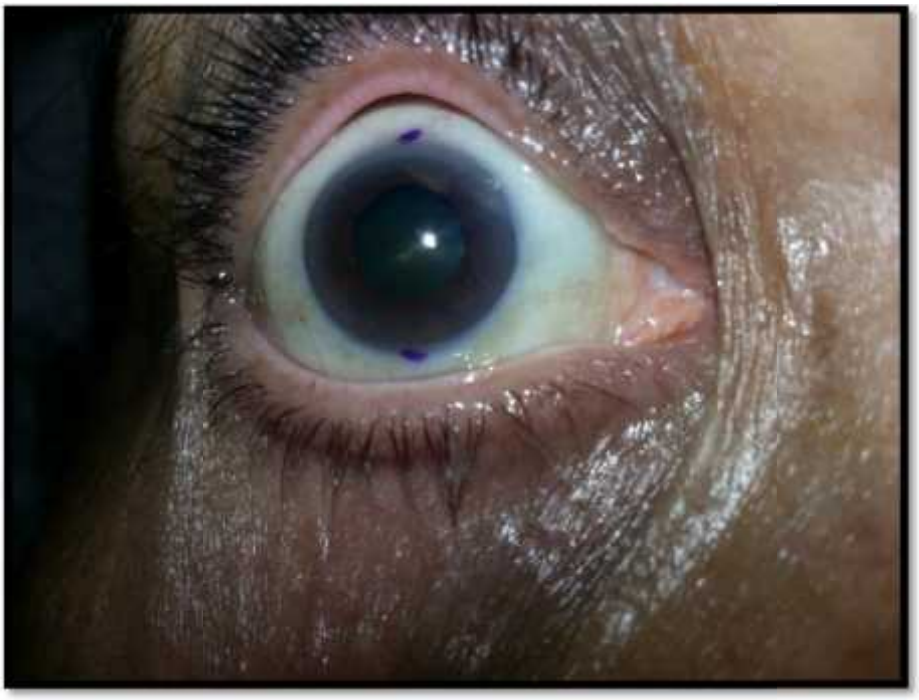
Prescription	Spherical	Cylindrical	Axis	BCVA
RE				
LE				

SURGICALLY INDUCED ASTIGMATISM:

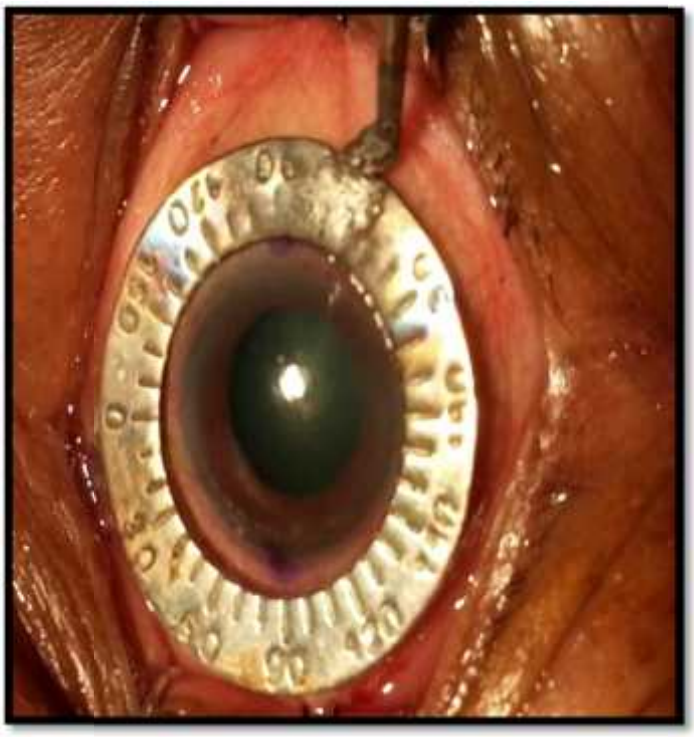
	Astigmatism in diopters	AXIS in degrees
3 WEEKS		
6 WEEKS		

ANNEXURE III – PHOTOGRAPHS

Photograph 1 - Keratometry



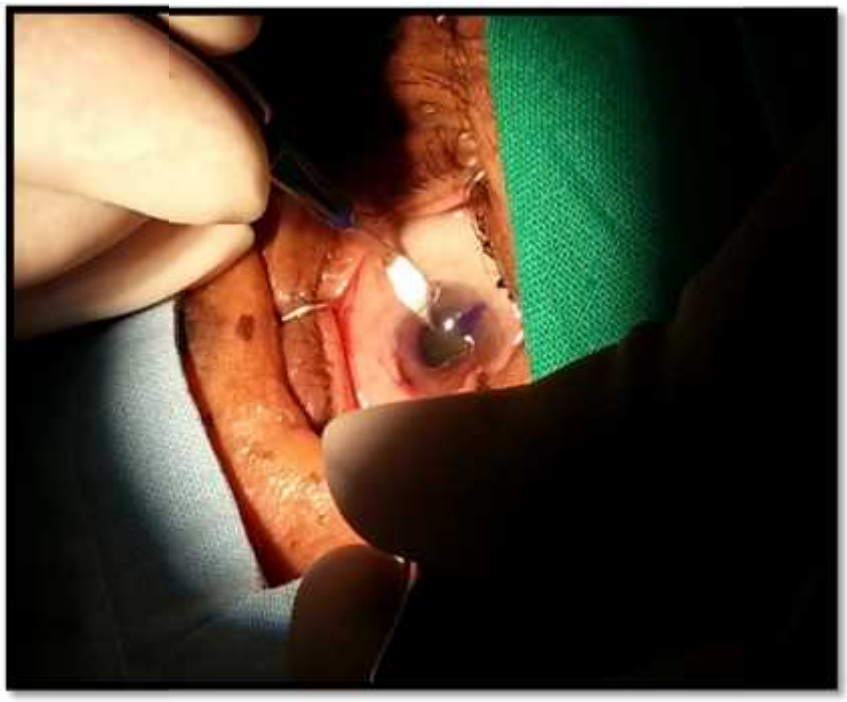
Photograph 2 – Axis marking with surgical marker



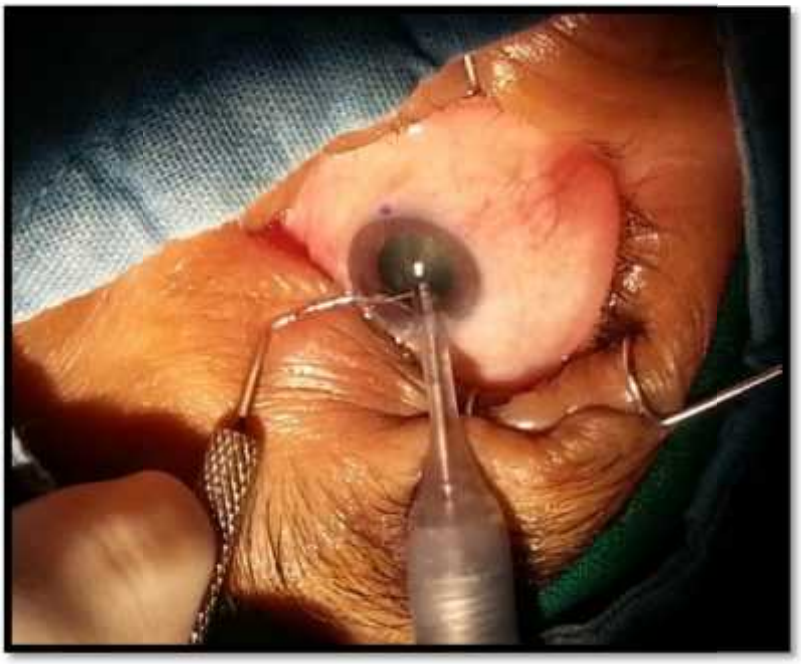
Photograph 3 – Mendez protractor for axis

Photograph 4 – Bausch & Lomb Phacoemulsification machine with OT setup

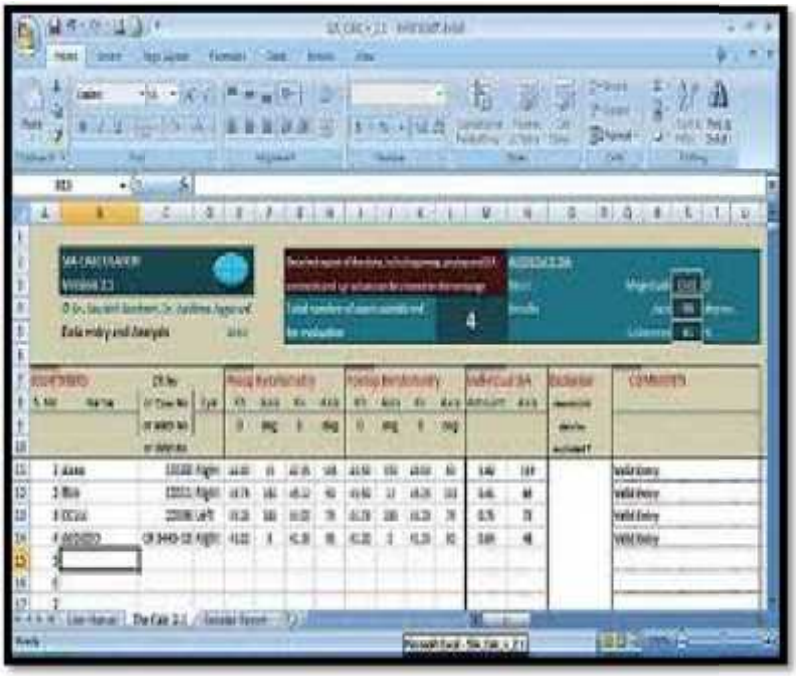
Photograph 5 – Superior clear corneal incision



Photograph 6 - Temporal clear corneal incision



Photograph 7 – ongoing phacoemulsification



Photograph 8 – SIA software 2.1 version

SR. NO	OP NO	Gender	Age (Years)	Eye	PRE OPERATIVE							POST OPERATIVE												
						Keratometry			Astigmatism			UCVA		Astigmatism			SIA				Refraction			
					Visual Acuity	KH	KV	PCIOL Power	Diopters (K1)	Axis (A1)	TYPE	DAY 21	DAY 45	Diopters (K3)	Axis (A3)	TYPE	K2	A2	Intended Angle	Angle of error	Sphere	Cylinder	Axis	Near
1	2766227	M	69	Left	CF 3 M	44.50	43.75	19.5	0.75	180	ATR	6/6	6/6	1	180	ATR	0.25	180	90	90		-1	90	3
2	2766227	M	69	Right	6/18	44.50	43.25	17	1.25	180	ATR	6/6	6/6	0	0	NIL	1.25	0	90	-90		-1.3	90	3
3	2604075	M	55	Right	CF 2 M	44.00	43.50	16	0.5	180	ATR	6/6	6/6	0.5	180	ATR	0	0	90	-90		-0.5	60	2.5
4	2279811	M	75	Left	CF 2 M	42.00	41.25	19	0.75	180	ATR	6/9	6/6	0.25	90	WTR	1	90	90	0		-1.3	90	3
5	568452	M	39	Right	6/24	43.75	44.50	21.5	0.75	90	WTR	6/6	6/6	0	0	NIL	0.75	90	180	-90		-1	90	
6	2810303	M	61	Right	CF 2 M	42.75	43.50	21	0.75	90	WTR	6/24	6/9	0.25	180	ATR	1	180	180	0	-2	-0.5	150	3
7	1603677	M	65	Right	6/18	42.25	41.75	20.5	0.5	180	ATR	6/24	6/9	0	0	NIL	0.5	180	90	90	-2			3
8	2631455	F	60	Left	CF 1 M	44.00	44.75	22	0.75	90	WTR	6/12	6/9	0.25	90	WTR	0.5	90	180	-90	-1	-0.5	90	3
9	2824470	M	52	Right	6/60	41.75	42.50	22.5	1.25	90	WTR	6/24	6/9	0.5	180	ATR	1.25	180	180	0		-1.3	180	2
10	2737026	F	75	Left	6/36	43.75	44.50	21.5	0.75	90	WTR	6/9	6/9	0.25	90	WTR	0.5	90	180	-90		-1	90	3
11	2856482	F	60	Right	6/24	43.00	42.25	20.5	0.75	180	ATR	6/9	6/6	0	0	NIL	0.75	180	90	90	0.3			3
12	2856486	M	65	Right	6/12	42.50	42.00	21	0.5	180	ATR	6/12	6/6	0	0	NIL	0.5	180	90	90	0.3			3
13	833571	M	38	Left	6/36	44.75	45.25	20	0.5	90	WTR	6/9	6/6	0	0	NIL	0.5	90	180	-90	-1			
14	2020242	M	68	Left	6/36	44.50	43.50	20.5	1	180	ATR	6/9	6/6	0.25	180	ATR	0.75	180	90	90	-0	-0.3	90	3
15	2598548	M	60	Right	6/12	41.25	42.25	24	1	90	WTR	6/12	6/9	0.25	90	WTR	0.75	90	180	-90	-2	-1.5	90	3
16	2863513	F	65	Left	CF 1 M	48.00	47.50	23	0.5	180	ATR	6/9	6/9	0	0	NIL	0.5	180	90	90	-0			3
17	2896659	M	69	Left	CF 3 M	42.00	41.25	19.5	0.75	180	ATR	6/9	6/9	0.5	180	ATR	0.25	180	90	90	0.3	0.5	180	3
18	2723006	M	56	Right	CFCF	43.50	44.00	21.5	0.5	90	WTR	6/9	6/6	0.25	180	ATR	0.75	180	180	0	0.3			2.5
19	2932785	F	48	Left	HMCF	43.00	43.50	21.5	0.5	90	WTR	6/6	6/6	0	0	NIL	0.5	90	180	-90	0.3			2
20	1522436	M	54	Right	6/60	44.75	44.25	19.5	0.5	180	ATR	6/6	6/6	0.25	90	WTR	0.75	90	90	0	0.3			2.5
21	1139391	M	58	Left	CF 3 M	39.25	40.25	19.5	1	90	WTR	6/6	6/6	0	0	NIL	1	90	180	-90	-1			2.5
22	1394659	M	50	Left	HMCF	43.50	44.00	19.5	0.5	90	WTR	6/18	6/9	0	0	NIL	0.5	90	180	-90	-1			2
23	2792284	F	75	Left	6/36	48.00	47.50	25	0.5	180	ATR	6/9	6/6	0.25	90	WTR	0.75	90	90	0	0.3			3
24	2972838	M	65	Left	CF 3 M	43.50	44.50	20.5	1	90	WTR	6/6	6/6	0.75	180	ATR	1.75	180	180	0	0.5	0.5	180	3
25	29806250	F	32	Right	6/60	42.50	43.00	23	0.5	90	WTR	6/9	6/6	0.25	180	ATR	0.75	180	180	0	0.3			
26	2956417	M	75	Right	CF 3 M	44.25	45.00	21	0.75	90	WTR	6/6	6/6	0.5	90	WTR	0.25	90	180	-90		-1	90	3
27	3074619	M	60	Left	6/18	42.75	42.00	22.5	0.75	180	ATR	6/9	6/9	0.25	90	WTR	1	90	90	0	0.5	0.5	180	3
28	3026158	F	30	Left	6/12	43.75	44.75	19.5	1	90	WTR	6/9	6/6	1	180	ATR	2	180	180	0		0.5	180	2.5
29	2014207	F	64	Right	CF 3 M	44.00	44.75	21.5	0.75	90	WTR	6/18	6/12	0	0	NIL	0.75	90	180	-90	1.5			3

SR. NO	OP NO	Gender	Age (Years)	Eye	PRE OPERATIVE							POST OPERATIVE												
						Keratometry			Astigmatism			UCVA		Astigmatism			SIA				Refraction			
					Visual Acuity	KH	KV	PCIOL Power	Diopters (K1)	Axis (A1)	TYPE	DAY 21	DAY 45	Diopters (K3)	Axis (A3)	TYPE	K2	A2	Intended Angle	Angle of error	Sphere	Cylinder	Axis	Near
30	3001141	M	53	Right	6/36	43.00	44.50	23	1.5	90	WTR	6/9	6/9	1	180	ATR	2.5	180	180	0	-1	-0.5	90	2.5
31	2979908	M	82	Right	6/60	41.75	40.75	21.5	1	180	ATR	6/18	6/12	0	0	NIL	1	180	90	90		-1	90	2.5
32	2913112	F	62	Left	CF 2 M	47.50	47.00	9.5	0.5	180	ATR	6/12	6/9	0.25	180	ATR	0.25	180	90	90	-3	-1	50	3
33	593887	F	57	Left	CF 1 M	44.00	42.75	23	1.25	180	ATR	6/9	6/9	0.25	180	ATR	1	180	90	90	-0	-0.8	70	2.8
34	2961919	F	60	Left	6/36	44.75	45.25	20.5	0.5	90	WTR	6/9	6/6	0.5	90	WTR	1	90	180	-90		-0.3	70	2.5
35	1521433	F	50	Left	6/60	43.50	44.00	23.5	0.5	90	WTR	6/6	6/6	0.25	180	ATR	0.75	180	180	0		-1	90	2.5
36	1521433	F	50	Right	6/24	44.50	44.00	24.5	0.5	180	ATR	6/9	6/9	0.25	90	WTR	0.75	90	90	0	1			2.5
37	1817475	F	75	Right	CF 1 M	44.75	43.75	21.5	1	180	ATR	6/9	6/6	0	0	NIL	1	180	90	90	0.3			3
38	1593925	M	73	Right	6/24	42.50	41.25	26	1.25	180	ATR	6/9	6/6	0.25	180	ATR	1	180	90	90	-0	-0.3	180	3
39	2979971	F	70	Left	HMCF	46.25	45.50	19	0.75	180	ATR	6/24	6/9	0.5	180	ATR	0.25	180	90	90		-0.5	180	3
40	1045584	F	59	Right	6/24	46.25	45.00	20	1.25	180	ATR	6/9	6/9	0.25	180	ATR	1	180	90	90				3
41	1311106	F	50	Left	CF 2 M	43.75	43.00	21.5	0.75	180	ATR	6/9	6/9	0.25	90	WTR	1	90	90	0	-0	-0.5	140	3
42	3025943	M	58	Right	6/24	41.00	40.00	19	1	180	ATR	6/9	6/9	0.25	180	ATR	0.75	180	90	90	0.5	0.5	180	2.5
43	3018096	M	75	Right	6/36	42.00	43.25	21	1.25	90	WTR	6/9	6/9	0	0	NIL	1.25	90	180	-90	-1			3
44	2967558	F	60	Right	6/60	41.50	40.50	20.5	1	180	ATR	6/12	6/12	0.5	180	ATR	0.5	180	90	-90	1.5	0.8	180	2.5
45	594674	F	67	Left	CF 1 M	44.50	45.00	20	0.5	90	WTR	6/18	6/12	0.25	90	WTR	0.25	90	180	-90		0.8	180	3
46	3080562	M	55	Right	CF 2 M	45.75	46.25	20.5	0.5	90	WTR	6/9	6/9	0.25	90	WTR	0.25	90	180	-90	2.5	-1	110	2
47	2992310	F	75	Left	CF 1 M	46.25	45.50	21.5	0.75	180	ATR	6/9	6/9	0.25	180	ATR	0.5	180	90	90	-1	-0.8	90	3
48	2933501	M	46	Left	6/18	43.50	43.00	21	0.5	180	ATR	6/9	6/9	0.25	180	ATR	0.25	180	90	90	0.3			2.8
49	2950019	M	62	Left	6/60	44.50	44.00	23	0.5	180	ATR	6/9	6/6	0.25	90	WTR	0.75	90	90	0	0.3	0.3	90	3
50	3043962	F	75	Right	6/24	43.00	43.50	18.5	0.5	90	WTR	6/9	6/9	0	0	NIL	0.25	90	180	-90		-2.5	30	3
51	2983688	M	65	Left	CF 2 M	45.00	44.50	20	0.5	180	ATR	6/9	6/9	0.25	180	ATR	0.25	180	90	90	0.3			3
52	975847	F	65	Right	6/60	42.00	42.50	19.5	0.5	90	WTR	6/24	6/12	0.5	180	ATR	1	180	180	0	1.5	1	160	3
53	2258158	F	65	Right	6/60	44.50	46.00	21	1.5	90	WTR	6/9	6/9	0	0	NIL	1.5	90	180	-90		0.5	180	3
54	3074365	M	65	Left	6/60	43.50	44.75	21	1.25	90	WTR	6/9	6/6	0.25	90	WTR	1.5	90	180	-90	-2	-2	70	3
55	1988584	M	53	Right	6/18	41.50	43.00	22	1.5	90	WTR	6/9	6/6	0	0	NIL	1.5	90	180	-90	0.8			2
56	3062678	M	68	Left	CF 2 M	47.50	48.00	27	0.5	90	WTR	6/18	6/12	0.5	180	ATR	1	180	180	0	-3	-1	80	3
57	3057733	F	60	Right	CF 3 M	46.50	46.00	20	0.5	180	ATR	6/18	6/12	0.25	180	ATR	0.25	180	90	90	-3	-0.5	90	3
58	3080198	M	68	Right	CF 3 M	46.00	44.50	22	1.5	180	ATR	6/12	6/12	0.5	90	WTR	2	90	90	0	-2			3

SR. NO	OP NO	Gender	Age (Years)	Eye	PRE OPERATIVE							POST OPERATIVE												
						Keratometry			Astigmatism			UCVA		Astigmatism			SIA				Refraction			
					Visual Acuity	KH	KV	PCIOL Power	Diopters (K1)	Axis (A1)	TYPE	DAY 21	DAY 45	Diopters (K3)	Axis (A3)	TYPE	K2	A2	Intended Angle	Angle of error	Sphere	Cylinder	Axis	Near
59	2940493	F	60	Right	6/18	45.50	45.00	22.5	0.5	180	ATR	6/9	6/9	0	0	NIL	0.5	180	90	90	-1	-0.5	90	3
60	2353777	M	68	Left	CF 1 M	43.50	44.00	22.5	0.5	90	WTR	6/9	6/6	0.5	180	ATR	0.75	180	180	0	-1	-0.5	180	3
61	1969767	M	68	Right	6/18	43.75	43.25	19.5	0.5	180	ATR	6/9	6/6	0.25	90	WTR	0.75	90	90	0		-0.5	90	3
62	2922025	M	60	Right	6/18	41.25	41.75	22	0.5	90	WTR	6/18	6/12	0	0	NIL	0.5	90	180	-90	0.5	-1	180	3
63	3157139	F	54	Left	CF2 M	41.50	43	26	1.5	90	WTR	6/12	6/9	0.5	90	WTR	1	90	180	-90	1	1	160	3
64	3151904	M	61	Right	CF 2 M	43.00	44	22	1	90	WTR	6/24	6/18	0	0	NIL	1	90	180	-90				3
65	3168114	F	67	Left	CF 1 M	44.50	44	20.5	0.5	180	ATR	6/9	6/6	0.25	180	ATR	0.25	180	90	90	-1	-0.5	180	3
66	2792593	M	70	Right	CF 2M	44.50	44	21.5	0.5	180	ATR	6/9	6/6	0.25	180	ATR	0.75	180	90	90	-1	-0.5	180	3
67	3097255	M	55	Left	6/60	44.50	45	20.5	0.5	90	WTR	6/9	6/6	0.25	90	WTR	0.25	90	180	-90		-0.3	100	2
68	3178794	M	64	Right	6/18	42.75	42.25	17	0.5	180	ATR	6/6	6/6	0.25	90	WTR	0.75	90	90	0		-0.3	90	2.5
69	3151014	M	31	Right	6/12	41.50	42	20	0.5	90	WTR	6/9	6/6	0	0	NIL	0.5	180	0	180	1.8			
70	3096956	M	60	Left	6/24	42.50	42	22	0.5	180	ATR	6/9	6/6	0	0	NIL	0.5	0	90	-90	0.3			3
71	3138589	M	65	Right	CF 5 M	40.75	40.25	20	0.5	180	ATR	6/9	6/6	0.25	90	WTR	0.75	90	90	0		-0.3	90	3
72	3150932	F	55	Left	6/60	43.50	44	20.5	0.5	90	WTR	6/9	6/6	0.5	180	ATR	1	180	180	0	-0	-0.3	180	2.5
73	3167582	F	58	Right	CF 1 M	44.75	45.25	21.5	0.5	90	WTR	6/6	6/6	1	180	ATR	1.5	180	180	0	0.3	-1	90	2.5
74	2967562	F	65	Left	CF 3 M	45.50	45	20.5	0.5	180	ATR	6/9	6/9	0.25	90	WTR	0.75	90	90	0		-0.5	90	3
75	3014656	F	80	Right	6/24	42.50	42	20	0.5	180	ATR	6/9	6/6	0	0	NIL	0.5	0	180	180	-0			3
76	2377001	M	50	Left	6/18	43.75	43.25	18.5	0.5	180	ATR	6/9	6/6	0	0	NIL	0.5	0	180	180	-0			3
77	2999924	M	75	Left	6/60	44.00	44.5	22	0.5	90	WTR	6/9	6/6	0.25	90	WTR	0.25	90	180	-90	-0			4
78	2660403	M	70	Left	6/60	42.25	42.75	20	0.5	90	WTR	6/9	6/6	0.25	180	ATR	0.75	180	180	0	0.5			3
79	3107367	F	58	Left	CF 3 M	44.00	43	18	1	180	ATR	6/6	6/6	0.25	180	ATR	0.75	180	90	90	0.5			3
80	1779641	F	55	Left	6/60	46.00	47	22	1	90	WTR	6/6	6/6	0.25	90	WTR	0.75	90	180	-90	0.3			2.5
81	3108890	F	55	Left	6/36	48.25	49.5	21	1.25	90	WTR	6/9	6/6	0.75	90	WTR	0.5	90	180	-90	-0	-0.3		3
82	312877	F	40	Right	6/18	42.50	44	20	1.5	90	WTR	6/6	6/6	0.5	180	ATR	1	180	180	0	-0			2.5

SR. NO	OP NO	Gender	Age (Years)	Eye	PRE OPERATIVE							POST OPERATIVE											
						Keratometry			Astigmatism			UCVA		Astigmatism			SIA				Refraction			
					Visual Acuity	KH	KV	PCIOL Power	Diopters (K1)	Axis (A1)	TYPE	DAY 21	DAY 45	Diopters (K3)	Axis (A3)	TYPE	K2	A2	Intended Angle	Angle of error	Sphere	Cylinder	Axis	Near
1	2766227	M	69	Left	CF 3 M	44.50	43.75	19.5	0.75	180	ATR	6/6	6/6	1	180	ATR	0.25	180	90	90		-1	90	3
2	2766227	M	69	Right	6/18	44.50	43.25	17	1.25	180	ATR	6/6	6/6	0	0	NIL	1.25	0	90	-90		-1.3	90	3
3	2604075	M	55	Right	CF 2 M	44.00	43.50	16	0.5	180	ATR	6/6	6/6	0.5	180	ATR	0	0	90	-90		-0.5	60	2.5
4	2279811	M	75	Left	CF 2 M	42.00	41.25	19	0.75	180	ATR	6/9	6/6	0.25	90	WTR	1	90	90	0		-1.3	90	3
5	568452	M	39	Right	6/24	43.75	44.50	21.5	0.75	90	WTR	6/6	6/6	0	0	NIL	0.75	90	180	-90		-1	90	
6	2810303	M	61	Right	CF 2 M	42.75	43.50	21	0.75	90	WTR	6/24	6/9	0.25	180	ATR	1	180	180	0	-2	-0.5	150	3
7	1603677	M	65	Right	6/18	42.25	41.75	20.5	0.5	180	ATR	6/24	6/9	0	0	NIL	0.5	180	90	90	-2			3
8	2631455	F	60	Left	CF 1 M	44.00	44.75	22	0.75	90	WTR	6/12	6/9	0.25	90	WTR	0.5	90	180	-90	-1	-0.5	90	3
9	2824470	M	52	Right	6/60	41.75	42.50	22.5	1.25	90	WTR	6/24	6/9	0.5	180	ATR	1.25	180	180	0		-1.3	180	2
10	2737026	F	75	Left	6/36	43.75	44.50	21.5	0.75	90	WTR	6/9	6/9	0.25	90	WTR	0.5	90	180	-90		-1	90	3
11	2856482	F	60	Right	6/24	43.00	42.25	20.5	0.75	180	ATR	6/9	6/6	0	0	NIL	0.75	180	90	90	0.3			3
12	2856486	M	65	Right	6/12	42.50	42.00	21	0.5	180	ATR	6/12	6/6	0	0	NIL	0.5	180	90	90	0.3			3
13	833571	M	38	Left	6/36	44.75	45.25	20	0.5	90	WTR	6/9	6/6	0	0	NIL	0.5	90	180	-90	-1			
14	2020242	M	68	Left	6/36	44.50	43.50	20.5	1	180	ATR	6/9	6/6	0.25	180	ATR	0.75	180	90	90	-0	-0.3	90	3
15	2598548	M	60	Right	6/12	41.25	42.25	24	1	90	WTR	6/12	6/9	0.25	90	WTR	0.75	90	180	-90	-2	-1.5	90	3
16	2863513	F	65	Left	CF 1 M	48.00	47.50	23	0.5	180	ATR	6/9	6/9	0	0	NIL	0.5	180	90	90	-0			3
17	2896659	M	69	Left	CF 3 M	42.00	41.25	19.5	0.75	180	ATR	6/9	6/9	0.5	180	ATR	0.25	180	90	90	0.3	0.5	180	3
18	2723006	M	56	Right	CFCF	43.50	44.00	21.5	0.5	90	WTR	6/9	6/6	0.25	180	ATR	0.75	180	180	0	0.3			2.5
19	2932785	F	48	Left	HMCF	43.00	43.50	21.5	0.5	90	WTR	6/6	6/6	0	0	NIL	0.5	90	180	-90	0.3			2
20	1522436	M	54	Right	6/60	44.75	44.25	19.5	0.5	180	ATR	6/6	6/6	0.25	90	WTR	0.75	90	90	0	0.3			2.5

SR. NO	OP NO	Gender	Age (Years)	Eye	PRE OPERATIVE							POST OPERATIVE											
						Keratometry			Astigmatism			UCVA		Astigmatism			SIA				Refraction			
					Visual Acuity	KH	KV	PCIOL Power	Diopters (K1)	Axis (A1)	TYPE	DAY 21	DAY 45	Diopters (K3)	Axis (A3)	TYPE	K2	A2	Intended Angle	Angle of error	Sphere	Cylinder	Axis	Near
21	1139391	M	58	Left	CF 3 M	39.25	40.25	19.5	1	90	WTR	6/6	6/6	0	0	NIL	1	90	180	-90	-1			2.5
22	1394659	M	50	Left	HMCF	43.50	44.00	19.5	0.5	90	WTR	6/18	6/9	0	0	NIL	0.5	90	180	-90	-1			2
23	2792284	F	75	Left	6/36	48.00	47.50	25	0.5	180	ATR	6/9	6/6	0.25	90	WTR	0.75	90	90	0	0.3			3
24	2972838	M	65	Left	CF 3 M	43.50	44.50	20.5	1	90	WTR	6/6	6/6	0.75	180	ATR	1.75	180	180	0	0.5	0.5	180	3
25	29806250	F	32	Right	6/60	42.50	43.00	23	0.5	90	WTR	6/9	6/6	0.25	180	ATR	0.75	180	180	0	0.3			
26	2956417	M	75	Right	CF 3 M	44.25	45.00	21	0.75	90	WTR	6/6	6/6	0.5	90	WTR	0.25	90	180	-90		-1	90	3
27	3074619	M	60	Left	6/18	42.75	42.00	22.5	0.75	180	ATR	6/9	6/9	0.25	90	WTR	1	90	90	0	0.5	0.5	180	3
28	3026158	F	30	Left	6/12	43.75	44.75	19.5	1	90	WTR	6/9	6/6	1	180	ATR	2	180	180	0		0.5	180	2.5
29	2014207	F	64	Right	CF 3 M	44.00	44.75	21.5	0.75	90	WTR	6/18	6/12	0	0	NIL	0.75	90	180	-90	1.5			3
30	3001141	M	53	Right	6/36	43.00	44.50	23	1.5	90	WTR	6/9	6/9	1	180	ATR	2.5	180	180	0	-1	-0.5	90	2.5
31	2979908	M	82	Right	6/60	41.75	40.75	21.5	1	180	ATR	6/18	6/12	0	0	NIL	1	180	90	90		-1	90	2.5
32	2913112	F	62	Left	CF 2 M	47.50	47.00	9.5	0.5	180	ATR	6/12	6/9	0.25	180	ATR	0.25	180	90	90	-3	-1	50	3
33	593887	F	57	Left	CF 1 M	44.00	42.75	23	1.25	180	ATR	6/9	6/9	0.25	180	ATR	1	180	90	90	-0	-0.8	70	2.8
34	2961919	F	60	Left	6/36	44.75	45.25	20.5	0.5	90	WTR	6/9	6/6	0.5	90	WTR	1	90	180	-90		-0.3	70	2.5
35	1521433	F	50	Left	6/60	43.50	44.00	23.5	0.5	90	WTR	6/6	6/6	0.25	180	ATR	0.75	180	180	0		-1	90	2.5
36	1521433	F	50	Right	6/24	44.50	44.00	24.5	0.5	180	ATR	6/9	6/9	0.25	90	WTR	0.75	90	90	0	1			2.5
37	1817475	F	75	Right	CF 1 M	44.75	43.75	21.5	1	180	ATR	6/9	6/6	0	0	NIL	1	180	90	90	0.3			3
38	1593925	M	73	Right	6/24	42.50	41.25	26	1.25	180	ATR	6/9	6/6	0.25	180	ATR	1	180	90	90	-0	-0.3	180	3
39	2979971	F	70	Left	HMCF	46.25	45.50	19	0.75	180	ATR	6/24	6/9	0.5	180	ATR	0.25	180	90	90		-0.5	180	3
40	1045584	F	59	Right	6/24	46.25	45.00	20	1.25	180	ATR	6/9	6/9	0.25	180	ATR	1	180	90	90				3

SR. NO	OP NO	Gender	Age (Years)	Eye	PRE OPERATIVE							POST OPERATIVE												
						Keratometry			Astigmatism			UCVA		Astigmatism			SIA				Refraction			
					Visual Acuity	KH	KV	PCIOL Power	Diopters (K1)	Axis (A1)	TYPE	DAY 21	DAY 45	Diopters (K3)	Axis (A3)	TYPE	K2	A2	Intended Angle	Angle of error	Sphere	Cylinder	Axis	Near
41	1311106	F	50	Left	CF 2 M	43.75	43.00	21.5	0.75	180	ATR	6/9	6/9	0.25	90	WTR	1	90	90	0	-0	-0.5	140	3
42	3025943	M	58	Right	6/24	41.00	40.00	19	1	180	ATR	6/9	6/9	0.25	180	ATR	0.75	180	90	90	0.5	0.5	180	2.5
43	3018096	M	75	Right	6/36	42.00	43.25	21	1.25	90	WTR	6/9	6/9	0	0	NIL	1.25	90	180	-90	-1			3
44	2967558	F	60	Right	6/60	41.50	40.50	20.5	1	180	ATR	6/12	6/12	0.5	180	ATR	0.5	180	90	-90	1.5	0.8	180	2.5
45	594674	F	67	Left	CF 1 M	44.50	45.00	20	0.5	90	WTR	6/18	6/12	0.25	90	WTR	0.25	90	180	-90		0.8	180	3
46	3080562	M	55	Right	CF 2 M	45.75	46.25	20.5	0.5	90	WTR	6/9	6/9	0.25	90	WTR	0.25	90	180	-90	2.5	-1	110	2
47	2992310	F	75	Left	CF 1 M	46.25	45.50	21.5	0.75	180	ATR	6/9	6/9	0.25	180	ATR	0.5	180	90	90	-1	-0.8	90	3
48	2933501	M	46	Left	6/18	43.50	43.00	21	0.5	180	ATR	6/9	6/9	0.25	180	ATR	0.25	180	90	90	0.3			2.8
49	2950019	M	62	Left	6/60	44.50	44.00	23	0.5	180	ATR	6/9	6/6	0.25	90	WTR	0.75	90	90	0	0.3	0.3	90	3
50	3043962	F	75	Right	6/24	43.00	43.50	18.5	0.5	90	WTR	6/9	6/9	0	0	NIL	0.25	90	180	-90		-2.5	30	3
51	2983688	M	65	Left	CF 2 M	45.00	44.50	20	0.5	180	ATR	6/9	6/9	0.25	180	ATR	0.25	180	90	90	0.3			3
52	975847	F	65	Right	6/60	42.00	42.50	19.5	0.5	90	WTR	6/24	6/12	0.5	180	ATR	1	180	180	0	1.5	1	160	3
53	2258158	F	65	Right	6/60	44.50	46.00	21	1.5	90	WTR	6/9	6/9	0	0	NIL	1.5	90	180	-90		0.5	180	3
54	3074365	M	65	Left	6/60	43.50	44.75	21	1.25	90	WTR	6/9	6/6	0.25	90	WTR	1.5	90	180	-90	-2	-2	70	3
55	1988584	M	53	Right	6/18	41.50	43.00	22	1.5	90	WTR	6/9	6/6	0	0	NIL	1.5	90	180	-90	0.8			2
56	3062678	M	68	Left	CF 2 M	47.50	48.00	27	0.5	90	WTR	6/18	6/12	0.5	180	ATR	1	180	180	0	-3	-1	80	3
57	3057733	F	60	Right	CF 3 M	46.50	46.00	20	0.5	180	ATR	6/18	6/12	0.25	180	ATR	0.25	180	90	90	-3	-0.5	90	3
58	3080198	M	68	Right	CF 3 M	46.00	44.50	22	1.5	180	ATR	6/12	6/12	0.5	90	WTR	2	90	90	0	-2			3
59	2940493	F	60	Right	6/18	45.50	45.00	22.5	0.5	180	ATR	6/9	6/9	0	0	NIL	0.5	180	90	90	-1	-0.5	90	3
60	2353777	M	68	Left	CF 1 M	43.50	44.00	22.5	0.5	90	WTR	6/9	6/6	0.5	180	ATR	0.75	180	180	0	-1	-0.5	180	3

SR. NO	OP NO	Gender	Age (Years)	Eye	PRE OPERATIVE							POST OPERATIVE											
						Keratometry			Astigmatism			UCVA		Astigmatism			SIA				Refraction			
					Visual Acuity	KH	KV	PCIOL Power	Diopters (K1)	Axis (A1)	TYPE	DAY 21	DAY 45	Diopters (K3)	Axis (A3)	TYPE	K2	A2	Intended Angle	Angle of error	Sphere	Cylinder	Axis	Near
61	1969767	M	68	Right	6/18	43.75	43.25	19.5	0.5	180	ATR	6/9	6/6	0.25	90	WTR	0.75	90	90	0		-0.5	90	3
62	2922025	M	60	Right	6/18	41.25	41.75	22	0.5	90	WTR	6/18	6/12	0	0	NIL	0.5	90	180	-90	0.5	-1	180	3
63	3157139	F	54	Left	CF2 M	41.50	43	26	1.5	90	WTR	6/12	6/9	0.5	90	WTR	1	90	180	-90	1	1	160	3
64	3151904	M	61	Right	CF 2 M	43.00	44	22	1	90	WTR	6/24	6/18	0	0	NIL	1	90	180	-90				3
65	3168114	F	67	Left	CF 1 M	44.50	44	20.5	0.5	180	ATR	6/9	6/6	0.25	180	ATR	0.25	180	90	90	-1	-0.5	180	3
66	2792593	M	70	Right	CF 2M	44.50	44	21.5	0.5	180	ATR	6/9	6/6	0.25	180	ATR	0.75	180	90	90	-1	-0.5	180	3
67	3097255	M	55	Left	6/60	44.50	45	20.5	0.5	90	WTR	6/9	6/6	0.25	90	WTR	0.25	90	180	-90		-0.3	100	2
68	3178794	M	64	Right	6/18	42.75	42.25	17	0.5	180	ATR	6/6	6/6	0.25	90	WTR	0.75	90	90	0		-0.3	90	2.5
69	3151014	M	31	Right	6/12	41.50	42	20	0.5	90	WTR	6/9	6/6	0	0	NIL	0.5	180	0	180	1.8			
70	3096956	M	60	Left	6/24	42.50	42	22	0.5	180	ATR	6/9	6/6	0	0	NIL	0.5	0	90	-90	0.3			3
71	3138589	M	65	Right	CF 5 M	40.75	40.25	20	0.5	180	ATR	6/9	6/6	0.25	90	WTR	0.75	90	90	0		-0.3	90	3
72	3150932	F	55	Left	6/60	43.50	44	20.5	0.5	90	WTR	6/9	6/6	0.5	180	ATR	1	180	180	0	-0	-0.3	180	2.5
73	3167582	F	58	Right	CF 1 M	44.75	45.25	21.5	0.5	90	WTR	6/6	6/6	1	180	ATR	1.5	180	180	0	0.3	-1	90	2.5
74	2967562	F	65	Left	CF 3 M	45.50	45	20.5	0.5	180	ATR	6/9	6/9	0.25	90	WTR	0.75	90	90	0		-0.5	90	3
75	3014656	F	80	Right	6/24	42.50	42	20	0.5	180	ATR	6/9	6/6	0	0	NIL	0.5	0	180	180	-0			3
76	2377001	M	50	Left	6/18	43.75	43.25	18.5	0.5	180	ATR	6/9	6/6	0	0	NIL	0.5	0	180	180	-0			3
77	2999924	M	75	Left	6/60	44.00	44.5	22	0.5	90	WTR	6/9	6/6	0.25	90	WTR	0.25	90	180	-90	-0			4
78	2660403	M	70	Left	6/60	42.25	42.75	20	0.5	90	WTR	6/9	6/6	0.25	180	ATR	0.75	180	180	0	0.5			3
79	3107367	F	58	Left	CF 3 M	44.00	43	18	1	180	ATR	6/6	6/6	0.25	180	ATR	0.75	180	90	90	0.5			3
80	1779641	F	55	Left	6/60	46.00	47	22	1	90	WTR	6/6	6/6	0.25	90	WTR	0.75	90	180	-90	0.3			2.5
81	3108890	F	55	Left	6/36	48.25	49.5	21	1.25	90	WTR	6/9	6/6	0.75	90	WTR	0.5	90	180	-90	-0	-0.3		3
82	312877	F	40	Right	6/18	42.50	44	20	1.5	90	WTR	6/6	6/6	0.5	180	ATR	1	180	180	0	-0			2.5

KEY TO MASTER CHART

A1 – Axis of preoperative astigmatism

A2 – Axis of surgically induced astigmatism

A3 – Axis of postoperative astigmatism

ATR – Against the rule astigmatism

BCVA – Best corrected visual acuity

CFCF – Counting Fingers close to face

F – Female

HMCF – Hand movements close to face

K1 – Preoperative astigmatism in diopters

K2 – Surgically induced astigmatism in diopters

K3 – Postoperative astigmatism in diopters

KH – Keratometry reading in horizontal meridian

KV – Keratometry reading in vertical meridian

M – Male

SIA – Surgically induced astigmatism

UCVA – Uncorrected Visual Acuity

WTR – With the rule astigmatism

CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

ID NO. | | | |

Mr/Mrs/Ms_____

You are invited to participate in our research study titled **"A longitudinal study to evaluate the effect of Surgically Induced Astigmatism after phacoemulsification clear corneal incision placed in the steepest meridian on eyes with pre-existing astigmatism at KLES Hospital, Belgaum."**

Respected Sir/Madam we request you to enroll yourself to participate in our study as you are eligible for doing so.Your participation in the study is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If u decide to participate you are free to withdraw at any time.

Purpose of the study :- The purpose of the research is to evaluate the beneficiary effect of Surgically Induced Astigmatism after Phacoemulsification clear corneal incision in the steepest meridian on eyes with pre-existing Astigmatism.

Procedure Involved :- If you agree to enroll yourself in this study, you will be asked to give detailed history. Then you will be clinically examined in detail by slit-lamp examination, fundoscopy, tonometry for measurement of intraocular pressure. Syringing for patency of the lacrimal sac, keratometry and A scan ultrasonography and investigations like Blood Pressure measurement, Random Blood sugar will be done. Then you will be undergoing Phacoemulsification cataract surgery where the incision will be placed on the steepest meridian. The steepest meridian will be identified using an corneal astigmatic marker before giving the block for surgery. You will be asked to follow up on specified dates when your progress would be monitored and documented.

Risks and Benefits :- Rare complications of cataract surgery includes endophthalmitis, vitreous loss, globe perforation, retro bulbar hemorrhage, expulsive choroidal hemorrhage for which all necessary precautions will be taken.

Your participation may benefit you and others and others suffering from same ailment in future, by helping us learn more about the disease process and better treatment modalities.

Alternatives :- If you are not willing to participate you will be treated according to the existing protocol & it will not affect your relationship with this hospital.

Costs for participating in this research :- There will not be any extra cost incurred by the participant. The participant will however have to pay for the investigations which are the part of the existing management protocol for this ailment. There is no commitment for any reimbursement or any other compensation for the participant.

Privacy and Confidentiality:- The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to others without your written permission.

Authorization to Publish Results :- When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Compensation :- In the event of injury related to the study, treatment will be made available through KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law. The doctors and the staff will provide facilities and medical attention to you.

Consent for participation in research trial

I, Mr./Ms./Mrs _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up ant of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Signature or the Left Thumb Print of Subject: _____

Witness Name: _____

Signature of Witness: _____

Investigators Name: _____

Signature of Investigator: _____

Name of the Guide :-

Signature of the guide :- _____

Date: _____

Place: _____

Witness Name: _____

Signature of Witness: _____

Investigators Name: _____

Signature of Investigator: _____

Date: _____

Place: _____