"A RANDOMIZED CLINICAL TRIAL TO EVALUATE SURGICALLY INDUCED ASTIGMATISM AFTER PHACOEMULSIFICATION WITH TEMPORAL SCLERAL INCISION AND SUPERIOR SCLERAL INCISION"

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Date: **Dr. Priyanka Katnalli**

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ABSTRACT

Background

Cataract is opacity in the lens capsule or its substance. The mainstay of management of cataract is surgery and with the advent of foldable intraocular lens and Remarkable development in phacoemulcification it is possible to implant lens through an incision small as 2.2mm, which helps in significantly reducing post operative astigmatism.

Aims and Objectives of this study were

To evaluate the outcome of surgically induced astigmatism by comparing the superior sclera incision and temporal sclera incision in phacoemulcification with foldable lens.

To compare the pre operative and post operative astigmatism in superior and temporal scleral incisions.

Methods:

The prospective study was conducted at B.L.D.E.U'S Shri B.M .Patil medical college, Hospital and Research Centre, Vijayapur from December 2014- May 2016.

A total of 116 patients were included in the study clinically diagnosed of immature senile cataract. All patients were evaluated in detail regarding grading of cataract, visual acuity, keratometry, slit lamp examination, fundus and detailed evaluation was done.

Patients were divided into "WITH THR RULE" and "AGAINST THE RULE" groups based on keratometry readings.

Results:

The present student was done among 116 patients and evaluated surgically induced astigmatism.

Patients divided into two Groups (Group 1- Superior scleral incision) and (Group 2- Temporal scleral incision) . 53.4% patients in Group 1 had with the rule and 25.9% patients had against the rule astigmatism. In Group 2 34.4% patients had with the rule and 48.3% patients had ATR astigmatism.

34.4% patients in group 1, developed WTR astigmatism after phacoemulsification. 60.3% patients developed ATR astigmatism. 56.9% patients of group 2 developed WTR astigmatism while 37% patients developed ATR astigmatism. in Group 1, 27.6% patients developed WTR astigmatism, with a mean astigmatism of 0.72D and 62.1% patients developed ATR astigmatism with a mean astigmatism of 1.00D. in Group 2, 53.4% patients developed WTR astigmatism with a mean astigmatism of 0.79D and 31.1% patients developed ATR astigmatism having a mean of 0.46D. the average surgical induced astigmatism in patients who underwent phacoemulsification with superior scleral incision and temporal scleral incision was 0.83D and 0.54D respectively.

Interpretation & Conclusion:

The current study shows that temporal scleral incisions seem to achieve the goal of minimizing surgically induced astigmatism. Temporal scleral incision is evidently better than superior scleral incision in minimizing surgically induced astigmatism.

Key Words: Phacoemulsification, Keratometry, With the Rule, Against the Rule Astigmatism, Foldable lens, Scleral incision.

LIST OF ABBREVIATIONS

χ^2	Chi_square
ATR	Against The Rule
WTR	With the Rule
KH	Horizontal Keratometry
KV	Vertical Keratometry
PCIOL	Posterior Chamber Intraocular Lens
VA	Visual Acuity
IMSC	Immature Senile Cataract

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INTRODUCTION

Cataract is defined as “Opacity in the lens capsule or its substance”. It is the commonest cause 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. The visual outcome of surgery is mainly attributed to degree of postoperative astigmatism, which in turn depends on the type, length, and position of incision and also 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.

Intracapsular cataract extraction was introduced in 1753 which resuted in Aphakia. Then came extracapsular cataract extraction with intraocular lens, which corrected the Aphakia, but postoperative astigmatism was significant with large incisions.

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 intraocular lens, it is possible to implant the lens through an incision as small as 2.2 mm, which helps in significantly reducing postoperative astigmatism.

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. Thus in the present study we have endeavoured to evaluate surgically induced astigmatism after phacoemulsification with temporal and superior scleral incisions using foldable intraocular lens.

AIMS AND OBJECTIVES

- To evaluate the outcome of surgically induced astigmatism by comparing the superior scleral incision and temporal scleral incision in phacoemulcification with foldable intraocular lens.
- To compare the pre operative and post operative astigmatism in superior and temporal scleral incisions.

REVIEW OF LITERATURE

HISTORICAL PRESPECTIVE

Cataract means “Waterfall”. Any congenital or acquired opacity in the lens capsule or substance causing visual impairment is called cataract.

Management of cataract is ‘surgery’, which is indicated only if and when cataract develops to a degree sufficient to cause difficulty in performing daily essential activities.

The cataract extraction started with couching or depression in 1000 BC by the great exponent Sushruta.

In 1745 Daniel performed cataract surgery by a limbal section of 180° in lower half.

Samuel Sharp introduced intracapsular cataract extraction in 1753. Vangrafe in 1865, made a section in upper half and advanced iridectomy.

1867 Nucleus extraction was done by indenting the cornea infront of limbus.

Later on the incision size reduced to about 120° and then 8–12 mm in planned extracapsular cataract extraction.

In 1951 Ridley introduced and placed acrylic intraocular lens (IOL) behind pupil. A cryosurgical probe was first employed by Krawauritz in 1961.

In 1967 Kelman introduced the technique of phacoemulsification. Postoperative emmetropia and early visual rehabilitation, elimination of postoperative complications of large incision cataract surgery and reduction of surgically induced astigmatism were important parameters which determined the success of phacosurgery.

SELF SEALING CATARACT INCISIONS – HISTORICAL MILESTONES

Dr.Richard Kratz (1980) was the first surgeon to move the cataract incision from limbus to sclera increasing the surface of the apposed wound edges. This was expected to enhance the wound healing there by control surgically induced astigmatism.

In 1983, Gerald t. Keener JR, pioneered the alternative method of small incision cataract extraction which combined the advantages of a standard phacoemulsification with those of a conventional extracapsular cataract extraction.

Phacodynamics :

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

Ultrasound power which is produced by piezoelectric crystal oscillating between

20,000–60,000 times/sec. Axial oscillations through its stroke length results in Jackhammer effect which mechanically breaks lens material (microcavitation).

A irrigating fluid bottle which supplies fluid volume and pressure to maintain anterior chamber. It is placed 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 phacotip occlusion.

Flow–rate is adjusted to clear anterior camber of the emulsate and to cool phaco–tip i.e. 18–25 cc/min. Vacuum pump indirectly controls flow i.e. 200–250 mmHg.

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 is prefixed. Also handpieces like for irrigation, aspiration and ultrasonic handpiece used respectively intraoperatively. The piezoelectric handpiece uses electric current to reorient piezoelectric crystal which is translated into linear movement.

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°).

Phacopower is the ability of the phaco–handpiece to emulsify cataract i.e. 50–70%.

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.

Advantages of Phacoemulsification over extra capsular cataract extraction :

- Fast visual recovery.
- Small and sutureless self–sealing incision.
- Minimal astigmatism.
- Decentration of intraocular 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 quiet being sutureless.
- Photophobia and foreign body sensation is minimal.
- Hospitalization and suture removal not needed.
- Chances of vitreous loss and cystoid macular edema is 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 (1991), in a study comparing astigmatism after phacoemulsification and conventional extracapsular cataract extraction concluded that phacoemulsification group induced less astigmatism than conventional extracapsular cataract extraction group[1].

Neuman AC, ***et al*** (1989), presented a comparison of surgically induced astigmatism between phacoemulsification with silicone foldable lens implantation and phacoemulsification with rigid PMMA IOL through 6mm incision and conventional extracapsular cataract extraction through10 mm incision. In phacoemulsification series mean induced astigmatism was significantly less than conventional extracapsular cataract extraction and PMMA IOL (6 mm incision) at the end of 3 and 6 month postoperatively[2].

Müller–Jensen K, ***et al*** (1996), in their comparative study of astigmatism after 4 mm sutureless versus 12 mm sutured clear corneal incision concluded that mean surgically induced astigmatism was 1D in 4 mm sutureless incision and 1.75D in 12 mm sutured incision group[3].

Advantages of temporal clear corneal incision :

- Surgeon positioned on the side, working at the temporal periphery, there is no need to turn eye down, as when working over the brow, and therefore the bridle sutures ar 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".

Basics of Astigmatism :

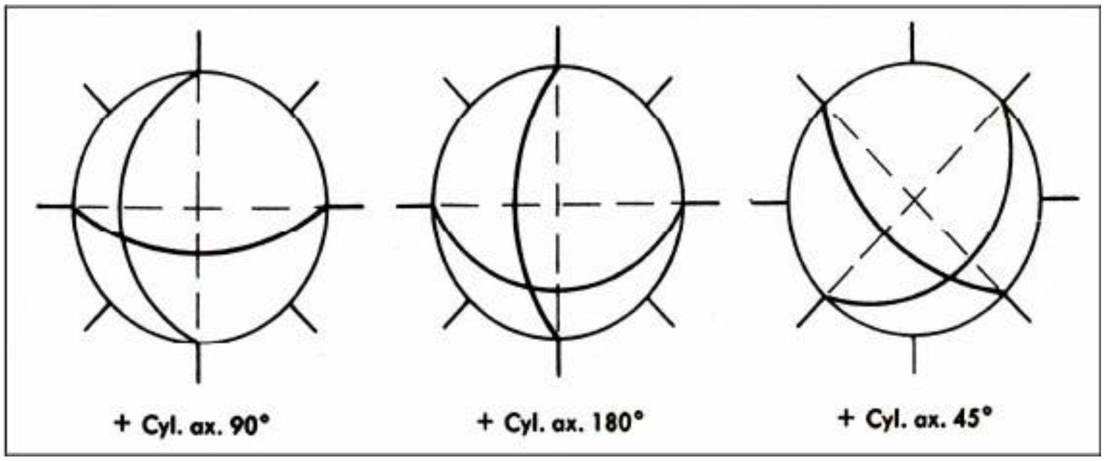
The term astigmatism is derived from Latin word "Stigma" (meaning a point). Thus astigmatism means "without a point".

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 (1990), 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[4].

Generally one meridian exhibits the greatest and the other the least power. These are known as "principal meridians".

Classification :



Figure–1 : Corneal Astigmatism.

A) Regular Asigmatism

i) With the rule

ii) Against the rule iii) Oblique

iv) Bioblique

B) Irregular 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 infront of retina.

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

Is physiological type where 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 less than 30° with vertical plane or the meridian with greatest refractive power is near horizontal in orientation or close to 180°.

iii) Oblique Astigmatism :

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

Irregular Astigmatism :

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

This exists when the distribution of refracting power over the cornea is irregular.

That prevents the cornea from forming a single point focus. This cannot be corrected with spherocylindrical spectacles.

Types :

- Macro irregular Astigmatism : Occurs when the corneal curvature along a given meridian is different for each semi–meridian. A common example is keratoconus in which inferotemporal corneal steepening occurs.
- Micro irregular Astigmatism : Exists when small regions of the corneal surface show variable refracting power i.e. 1 mm as in the faceting of contact

lens wrapage or as small as a few epithelial cells as in keratoconjunctivitis sicca with superficial punctate keratitis. This is easily detected where mires become wavy and irregular and crisp superimposition is impossible.

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

The astigmatism produced by the contraction of scar of cataract surgery results in flattening of cornea in the meridian at right angles to the wound[5]. This change in corneal curvature continues to alter for some weeks after surgery. So final spectacles should be ordered after at least 6 weeks postoperatively.

ASTIGMATISM IN PHACOEMULSIFICATION :

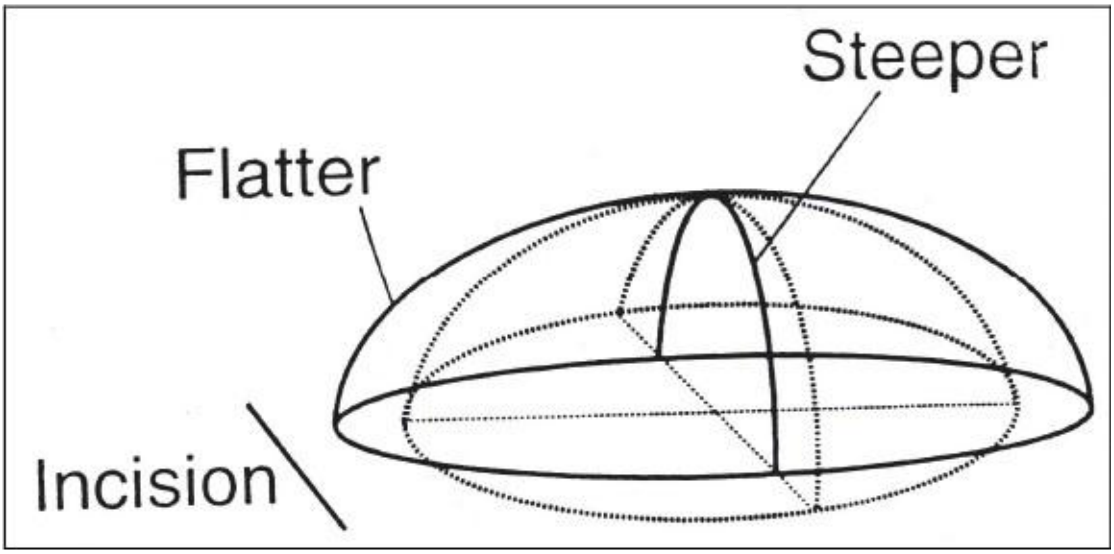
Manual small–incision cataract surgery Vs. Phacoemulsification

Extracapsular extraction by phacoemulsification offers the advantage of cataract removal through a smaller wound which decreases the surgically induced astigmatism compared to MSICS.

Zhang JY, *et al* (2013), compared phacoemulsification versus manual small–incision cataract surgery for age–related cataract, a meta–analysis study where a total of 1315 eyes were studied. They found that PE is superior to MSICS in UCVA and causes less SIA, but there were no significant differences in visual rehabilitation, ECC loss and complication rates between the two techniques[6].

Wound length with suture closure :

Sutures cause corneal steepening in the meridian of the suture. However, greater surgically induced astigmatism results in a long wound even when the same numbers of sutures are used. In a longer wound more tissue can be affected by suture tension. Small wounds have less surgical edge surface area and therefore are more resistant to the mechanical forces of the sutures.



Figure–2 : Postoperative Corneal Changes.

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.

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.

i) Incision :

a. Location

b. Length

c. Construction

Location :

- Both proximity to the visual axis and meridonal 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, obliquely 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. Oblique incisions have been shown to have an intermediate effect.

Roman S and Ullern M (1997), 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 against the rule, in superior approach for WTR astigmatism. The postoperative surgically induced astigmatism was 0.98D with superior and 0.58D with temporal incisions. The superior corneal incision rarely allows reaching a minimum postoperative astigmatism as with a temporal incisions[7].

Simsek S, *et al* (1998), 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[8].

Ermiss SS, *et al* (2004), evaluated SIA after small 3.5 mm superotemporal and superonasal clear corneal incision phacoemulsification in 56 eyes of 28 patients. SIA after superonasal incision was statistically significantly higher than superotemporal incision[9].

Barequet IS, *et al* (2004), compared astigmatism outcomes after temporal and nasal clear corneal incision in phacoemulsification with foldable intraocular lens.

Postoperatively temporal incisions yielded 0.74D and nasal 1.65D at 12 months. Temporal incisions induced significantly less astigmatism than nasal[10].

Length :

- Incision length has been known to affect astigmatism.
- The long incision used in intracapsular cataract extraction and extracapsular 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.

Vasavada V, *et al* (2013), studied Incision integrity and postoperative outcomes after micro coaxial phacoemulsification performed using 2 incisions–dependent systems. Eyes were randomized to have phacoemulsification using a 1.8 mm clear corneal incision (CCI) system (Group 1, Stellaris system) or a 2.2 mm CCI system (Group 2, Intrepid Infiniti system). Incision enlargement at end of surgery was measured. Conclusion – At the end of surgery, it is not the initial incision size alone but also the distortion of the incision during subsequent stages of surgery that determine the integrity of the CCI[11].

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 the most 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.

The disadvantage 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 surgically induced astigmatism.

Greater flattening is seen with longer corneal incisions. Clear corneal entries do not induce equal and opposite coupling in curvature especially in the periphery.

Astigmatic influence of clear corneal incision disproportionately affects the tempora meridian.

Martin who compared 3.2 mm incision cases receiving foldable intraocular lens with 6 mm incision cases receiving a PMMA intraocular lens and found that there was less induced astigmatism with the small incisions used with foldable intraocular lens than with the longer incisions used with PMMA intraocular lens.

Jacobs BJ, *et al* (1999), 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 doest not induce a clinically important amount of astigmatism[12].

Small incision sutureless cataract surgery by phaco has allowed for the creation of a potentially astigmatically neutral incision with less postoperative against the rule shift. Cataract incisions centered around the superior position usually result in a degree of against the rule shift. Thus many surgeons prefer placing the corneal incision temporally which helps to reduce preexisting against the rule astigmatism. The temporal approach is thought to induce regular astigmatism 90° from the incision (with the rule type). The studies and literature reports that a temporal incision can reduce and quickly stabilize surgically induced astigmatism.

Fine IH (1991), developed a systematic approach to cataract surgery from temporal aspect of the clear cornea[13].

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.
2) Radial corneal incision flattens the adjacent cornea and the cornea 90° away.
3) The flattening effect of incision and the cornea increases as incision approaches the visual axis.
4) The cornea flattens directly over any sutured incision.
5) The cornea flattens adjacent to loose limbal suture, flatterns 180° away and steepens 90° away
6) Cornea steepens adjacent to tight limbal sutures, steepens 180° away and flattens 90° away.

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

Oshima Y, *et al* (1997), compared astigmatism of phaco with foldable intraocular lens through 3 mm temporal clear corneal and 3 mm superior scleral tunnel incision on 78 patients, with preexisting ATR astigmatism. The preexisting keratometric cylinder decreased in the temporal clear corneal incision group and increased in superior scleral tunnel group. 0.56D at 3rd month postoperative scleral tunnel group, 0.65D at 3rd month postoperatively in temporal clear corneal group[14].

Lesiewska–Junk H, *et al* (2002), evaluated postoperative astigmatism in 135 patients.

Group I – 75 ECCE with 12 mm corneoscleral incision.

Group II – 30 phaco with 3.5 mm corneal incision.

Group III – 30 patients phaco with 3.5 mm tunnel incision.

Results :

Mean Astigmatism 4.19D – group I

2.50D – Group II

1.79D – Group III

The difference between all the groups were statistically significant[15].

Course of Postoperative Astigmatism :

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

1) Wound compression
2) Wound dehiscence

Factors that appear to increase wound compression are :

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

Wound compression in superior incisions lead to a reduction of vertical circumference of the globe and thus a steepened vertical meridian. It also caused an increase in the vertical circumference of the globe, which resulted in a flattened vertical meridian.

Jaffe GF reports that these changes are because of ocular rigidity and shape of cornea.

Foldable Intraocular 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 intraocular lens fulfill a prerequisite of the ophthalmic surgeon – extraction of cataractous lens and implantation of intraocular 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 compatability **:**
    - 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 Intraocular Lens :

1. Helps to retain the smallness of the phacoincision which decreases postoperative astigmatism, increases wound stability and allows more rapid visual rehabilitation.
2. Increased protection to corneal endothelium.
3. Gentle to the uveal tissue, thus reduces risk of inflammation. Reduce risk of cellular precipitates on the lens surface.
4. 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.
5. Ease of explantation because of the absence of perilenticular fibrosis with these lenses.
6. 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 a 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 intraocular lens.
8. Foldable lenses are also expensive.

The surgically induced astigmatism is found less with foldable intraocular lens than conventional rigid intraocular lens because of small incision.

Liu Y and Li S (1998), 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[16].

Ruhswurm I, *et al* (2000), studied astigmatism correction with a foldable toric intraocular lens in cataract patients i.e. foldable toric single piece silicone intraocular 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 intraocular lens[17].

Measuring the corneal curvature :

1. Keratoscopes :

Placidos 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. Placido in 1880 and Gullstrand in 1896 who developed the mathematical theory necessary for quantitative analysis invented the photokeratoscope.

It provides information about corneal topography by photographing the imaged placidos disc and measuring the distortion and displacement of each ring at many points.

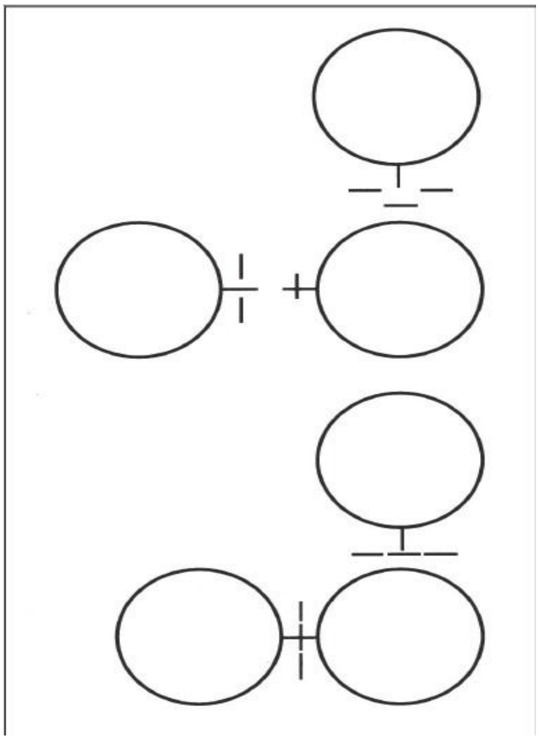
Earlier instruments had flat targets, but these produced an image curvature, which prevented all of the images from being in focus at once. Modern instruments have spherical, ellipsoidal or cylindrical target planes.

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. It can reduce postoperative astigmatism.

2. Keratometers (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.



Non–aligned mires

Aligned mires

Figure–3 : Mires of Keratometer.

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 newer automated Keratometer :

The instrument comprises 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, its 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 ellipse.

Terry was the first to develop a quantitative surgical keratometer. While some studies have shown intraopertive 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 colour maps, where cooler colours represent flatter areas and warmer colours steeper areas.

In 1998 while comparing phacoemulsification cataract surgery with a 3.2mm vs a 5.5mm sutureless incision, Olson & Crandall found that over the long term, phacoemulsification with a 3.2mm incision is associated with a significantly less astigmatic shift & better uncorrected visual acuity than in phacoemulsification with a 5.5mm incision.[18]

In 2000 in a comparison of regular & irregular astigmatism after superior versus temporal scleral incision cataract surgery, Oshika & co-researchers[19] found that postoperatively, the superior group showed slight ATR astigmatic changes, whereas slight WTR astigmatism was seen with the temporal incision group. There was no significant difference in the uncorrected & corrected visual acuity between both groups postoperatively.

In 2004 a study of surgically induced astigmatism after superotemporal & superonasal clear corneal incisions in phacoemulsification by Ermis & co-workers[9] concluded that although SIA did not differ significantly between the 2 incision groups, decomposition of vectors showed that the horizontal component of SIA after superonasal incision was statistically significantly higher than superotemporal incision throughout the study. Vertical components of SIA & the incision size after IOL implantation between the 2 incision groups were not significantly different.

Barequet IS et al[10] in 2004 their analysis of astigmatic outcomes of horizontal temporal versus nasal clear corneal incision cataract surgery noted that a significant shift toward WTR astigmatism occurred postoperatively. Vector analysis revealed a mean SIA of 1.17 D at 6 weeks & 1.04 D at 12 months. Also the side of incision affected SIA. At 6 weeks; Temporal- 0.74 D & Nasal- 1.65 D. This trend persisted at 12 months; Temporal- 0.71 D & Nasal- 1.41 D.

Susie et al[20] in 2007 their analysis of postoperative corneal astigmatism after phacoemulsification through a clear corneal incision, concluded that the mean surgically induced corneal astigmatism was 0.23 D. The vertical component of astigmatism was significantly lower postoperatively than preoperatively. There was no significant difference in the horizontal component of astigmatism preoperatively and postoperatively.

A study by Yongqi HE et al in 2009 showed that clear temporal corneal incision Phacoemulsification will not increase more keratometric corneal astigmatism than superior scleral incision after three months of operation[21].

A study by Malik VH et al in 2012 showed that Small Incision Cataract Surgery with temporal approach provides better stabilization of refraction with a significantly less surgically induced astigmatism than superior approach[22]

Magdum RM et al in 2012 did a prospective randomized comparative study and evaluated the amount and type of surgically induced astigmatism in superior and temporal scleral incision in Manual Small Incision Cataract Surgery (MSICS). The study revealed that temporal approach MSICS produces less postoperative astigmatism and has manifold advantages over superior incision MSICS with excellent visual outcome.[23]

Patil P et al in 2013 compared the incidence, amount, type, and course of surgically induced astigmatism and visual acuity in temporal 5.5-mm clear corneal phacoemulsification and 6-mm superior scleral incision in Small incision cataract surgery (SICS). The authors concluded that surgically induced astigmatism was higher in the 5.5-mm temporal clear corneal group than in the superior scleral group. Clinical outcome of both surgeries was same, as there was no significant difference in the uncorrected postoperative visual acuity in between the groups.[24]

Al Mahmood AM et al in 2014 in a case report reviewed the advantages and disadvantages of clear corneal incisions in cataract surgery and summarised that since the introduction of sutureless clear corneal cataract incisions, the procedure has gained increasing popularity worldwide because it offers several advantages over the traditional sutured scleral tunnels and limbal incisions. Some of these benefits include lack of conjunctival trauma, less discomfort and bleeding, absence of suture-induced astigmatism, and faster visual rehabilitation. However, an increasing incidence of postoperative endophthalmitis after clear corneal cataract surgery has been reported. Different authors have shown a significant increase up to 15-fold in the incidence of endophthalmitis following clear corneal incision compared to scleral tunnels.[25]

Bhavani MV et al in 2015 did a prospective, randomized, comparative study of astigmatism induced by superior & temporal sections in manual SICS. The authors in the study observed that the decay of astigmatism from third to sixth week in temporal scleral incision was negligible (0.068 D) implying early wound stabilization. Therefore, early spectacle correction by third week possible in temporal scleral group. Superior scleral incision shows a significant post-operative ‘against the rule’ drift as compared to temporal scleral incision. Therefore, superior scleral incision should not be done in patients with ‘ATR’ astigmatism. Surgically induced astigmatism of < 1D was seen in 62% in temporal scleral as compared to only 42% in superior scleral incision. This implies that, temporal scleral incision induces less astigmatism when compared to superior scleral incision. Temporal scleral incision give a substantial improvement in surgical exposure, especially in patients with deep set eyes or prominent eyebrows. Temporal scleral incision is more advantageous than superior scleral incision in astigmatically neutral patients, patients with ‘Against the rule’ astigmatism, patients with ‘with the rule’ astigmatism upto < 1D and superior scleral incision is preferred only if ‘with the rule’ astigmatism is > 1D.[26]

Khokhar S et al in 2016 did a retrospective analysis described an improved surgical technique for the creation of surgical incisions during phacoemulsification in eyes with cataract associated with microcornea. All eyes were operated using the scleral pocket incision for phacoemulsification. This scleral pocket incision was tangential to the limbus and created approximately 2.5 mm behind limbus through which phacoemulsification probe was inserted. Because of the posterior placement of incision, the anterior chamber crowding was minimized. There was no incidence of port-site peripheral corneal edema. Fifty percent eyes developed transient central corneal edema, the intraocular lens in bag was implanted in 5/8 eyes, and none developed Descemet's membrane detachment. Mean best-corrected visual acuity improved from 1.85 ± 0.38 logarithm of minimum angle of resolution (LogMAR) to 1.26 ± 0.70 LogMAR postoperatively (P = 0.01; paired t-test). The authors concluded that posterior incision placement during phacoemulsification in microcornea helps achieve favorable postoperative outcomes in contrast to outcomes using clear corneal approach.[27]

MATERIALS & METHODS

The present study was a Prospective study done on Patients undergoing phacoemulcification in Department of Ophthalmology.

Study period: December 2014-May 2016.

SAMPLE SIZE:

At 10% level of significance(a), Power of test 80%, The Anticipated mean difference of surgically induced astigmatism between two groups is 0.38D and Anticipated standard deviation between 2 groups hs 0.7D9, The minimum sample size was 58 per arm, therefore total sample size was 116 i.e., n = 116.

Formulal2

-a Z/3 X2X SD2

MD2

a= level of significance=10%

Power of one sided test 1-13=80%

Z= value of z statistic at different a 0 SD=Standard Deviation

MD=Mean Difference

STATISTICAL ANALYSIS:

Data was analyzed using following statistical method

1. Mean + SD
2. x2 test of association
3. t test for difference of mean

METHOD OF COLLECTION OF DATA

All cases of clinically diagnosed senile cataract, undergoing phacoemulcification during the study period was included in the study after taking informed consent.

A standardized performa was completed for each patient after dividing them into group one and group two, group one undergoing superior scleral incision and group two undergoing temporal scleral incision, by alternative method, with age and sex matching documenting sociodemographic information as well as clinical findings. Clinical findings included measurement of visual acuity (by Snellen's chart), 111ft-a ocular pressure measurement, pre operative astigmatism by (K) readings, patency of lacrimal passages.

Associated systemic and local factors was identified. Previous treatment history and use of topical corticosteroids was also noted. Any other preexisting ocular problem contributing to defective vision was also documented.

INCLUSION CRITERIA:

Patients of uncomplicated immature senile cataract with less than Grade III Nuclear sclerosis undergoing phacoemulcification with foldable lens implantation...

EXCLUSION CRITERIA:

Patients having:

1. Hard brown cataract.
2. Chronic uveitis.
3. Previous history of ocular trauma.
4. Complicated cataract.
5. History of use of corticosteroids.

6. Collagen disease.
7. Any corneal, conjunctival and scleral diseases.
8. History of previous ocular surgeries.

INVESTIGATIONS:

Pre operative investigations:

1. CBC
2. Random blood sugar levels
3. HIV TEST
4. HbsAG
5. Urine Examination
6. BT CT

THE STUDY REQUIRES ANY INVESTIGATION OR INTERVENTION TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS.

Yes

ETHICAL CLEARANCE HAS BEEN OBTAINED FROM YOUR INSTITUTE.

Sample size calculation

At 10% level of significance(a), Power of test 80%, The Anticipated mean difference of surgically induced astigmatism between two groups is 0.38D and Anticipated standard deviation between 2 groups has 0.7D, The minimum sample size is 58 per arm, therefore total sample size is 116 i.e. n = 116.

Formula

$$\frac{{}^{-}a\ Z/3\ X^{2}X\ SD^{2}}{MD^{2}}$$

a= level of significance=10%

Power of one sided test 1-13=80%

Z= value of z statistic at different a

SD=Standard Deviation

MD=Mean Difference

STATISTICAL ANALYSIS

Quantitative data is presented with the help of Mean and Standard deviation. Comparison among the study groups is done with the help of unpaired t test as per results of normality test. Qualitative data is presented with the help of frequency and percentage table. Association among the study groups is assessed with the help of chi-Square test. ‘p’ value less than 0.05 is taken as significant.

Pearson's chi-squared test

$$X^2 = \sum_{i=1}^{n} \frac{(O_i - E_i)^2}{E_i}$$

Where,

X2 = Pearson's cumulative test statistic.

Oi = an observed frequency;

Ei = an expected frequency, asserted by the null hypothesis;

n = the number of cells in the table.

Results were graphically represented where deemed necessary.

Appropriate statistical software, including but not restricted to MS Excel, SPSS ver. 20 will be used for statistical analysis. Graphical representation will be done in MS Excel 2010.

OBSERVATIONS AND RESULTS

Distribution of patients according to Age

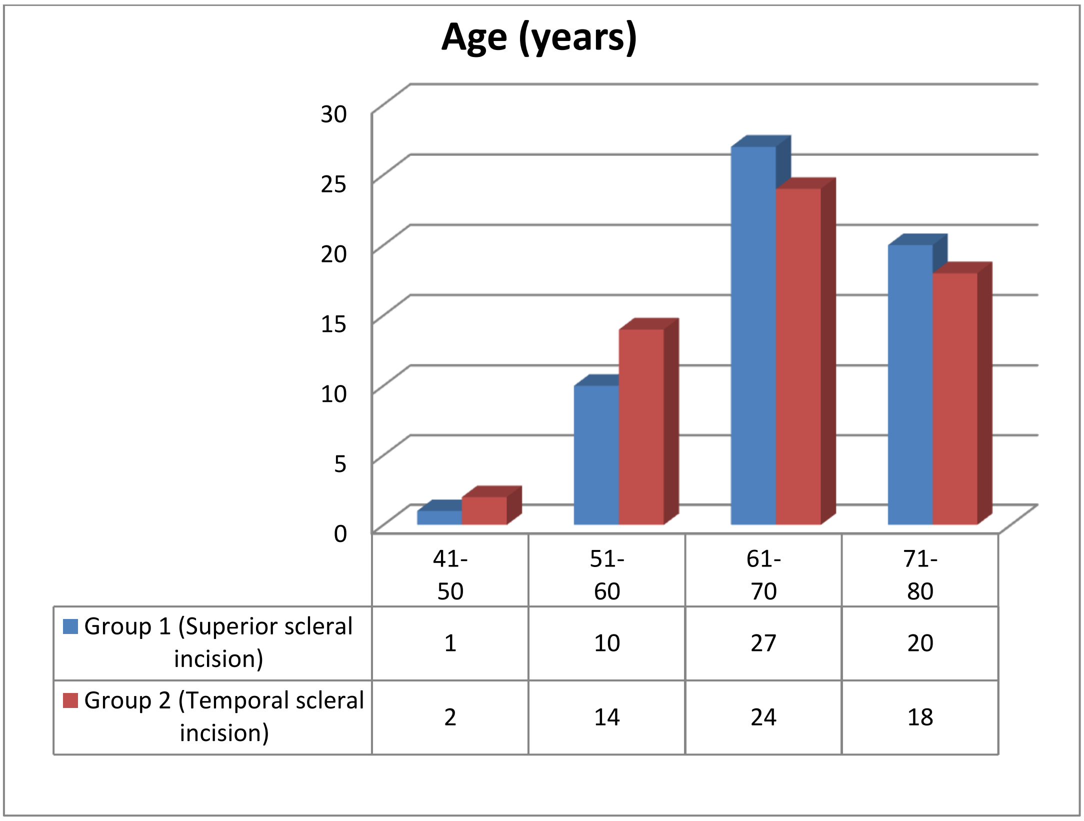
Majority of the patients in Group 1 (Superior scleral incision) and Group 2 (Temporal scleral incision) were in the range of 61–70 years i.e. 27 (46.7%) and 24 (41.4%) patients respectively. The Chi-square test showed that the distribution of patients in both the groups was statistically not significant and there was a comparable distribution based on the age group.

Table 1: Distribution of patients according to Age

Age (yrs)	Group 1 (Superior scleral incision)		Group 2 (Temporal scleral incision)	
	N	%	N	%
41-50	1	1.7%	2	3.4%
51-60	10	17.2%	14	24.1%
61-70	27	46.7%	24	41.4%
71-80	20	34.4%	18	31.1%
Total	58	100%	58	100%
Mean ± SD	**67.41 ± 7.42**		**66.02 ± 8.43**	
p Value	p>0.05			

***p<0.05 - Statistically Significant**

Graphs 1 : Distribution of patients according to Age



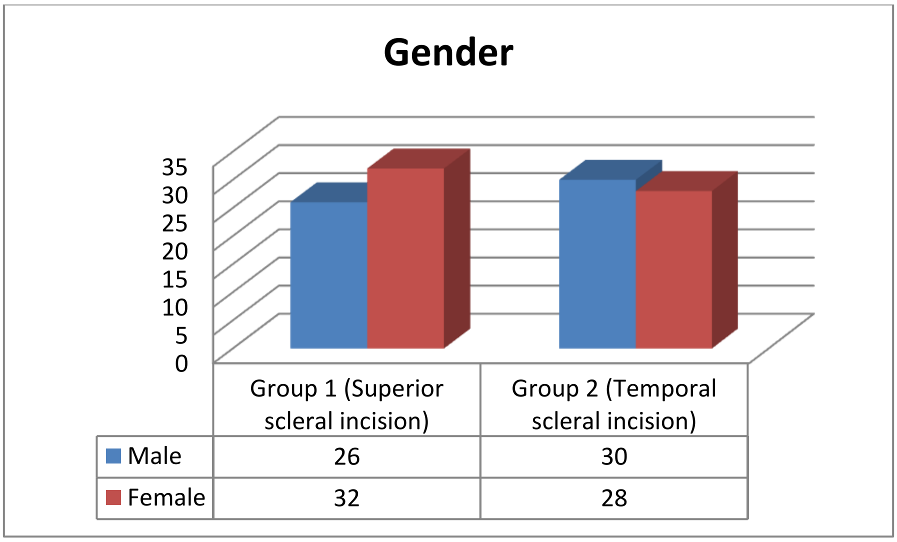
Distribution of patients according to Gender

There was Female predominance in Group 1 (Superior scleral incision) 32 (55.2%) patients whereas most patients in Group 2 (Temporal scleral incision) were male 30 (51.7%) patients.

Table 2: Distribution of patients according to Gender

Gender	Group 1 (Superior scleral incision)		Group 2 (Temporal scleral incision)	
	N	%	N	%
Male	26	44.8%	30	51.7%
Female	32	55.2%	28	48.3%
Total	58	100%	58	100%

Graphs 2 : Distribution of patients according to Gender



Distribution of patients according to Preoperative Visual Acuity

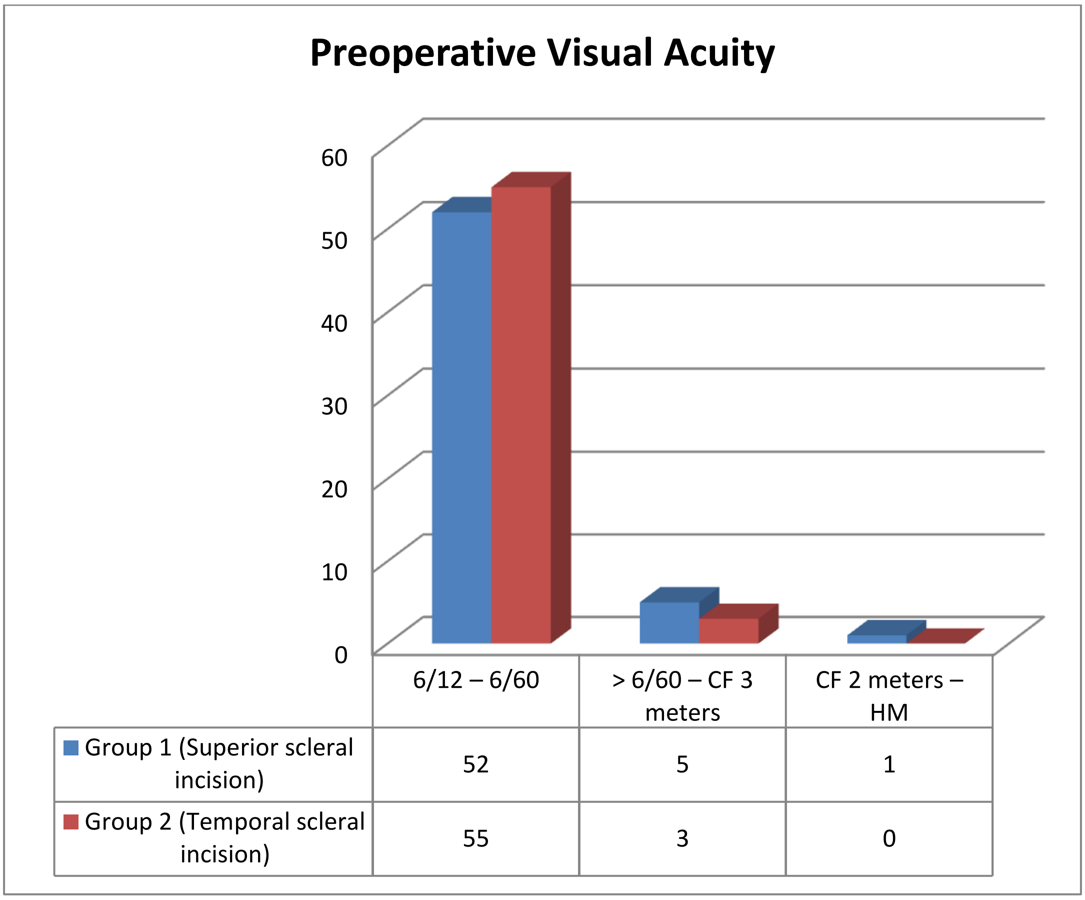
In Group 1 (Superior scleral incision), 52 (89.7%) patients had visual acuity of 6/12–6/60. 5 (8.67%) patients had vision from CF 3 metres to 6/60. 1 (1.7%) patient had visual acuity from CF 2 metres to hand movement close to face.

In Group 2 (Temporal scleral incision), 55 (94.8%) patients had visual acuity of 6/12–6/60. 3 (5.2%) patients had vision from CF 3 metres to 6/60.

Table 3: Distribution of patients according to Preoperative Visual Acuity

Preoperative Visual Acuity	Group 1 (Superior scleral incision)		Group 2 (Temporal scleral incision)	
	N	%	N	%
6/12 – 6/60	52	89.7%	55	94.8%
> 6/60 – CF 3 meters	5	8.6%	3	5.2%
CF 2 meters – HM	1	1.7%	0	-
Total	58	100%	58	100%

Graph 3: Distribution of patients according to Preoperative Visual Acuity



Distribution of patients according to Preoperative Astigmatism

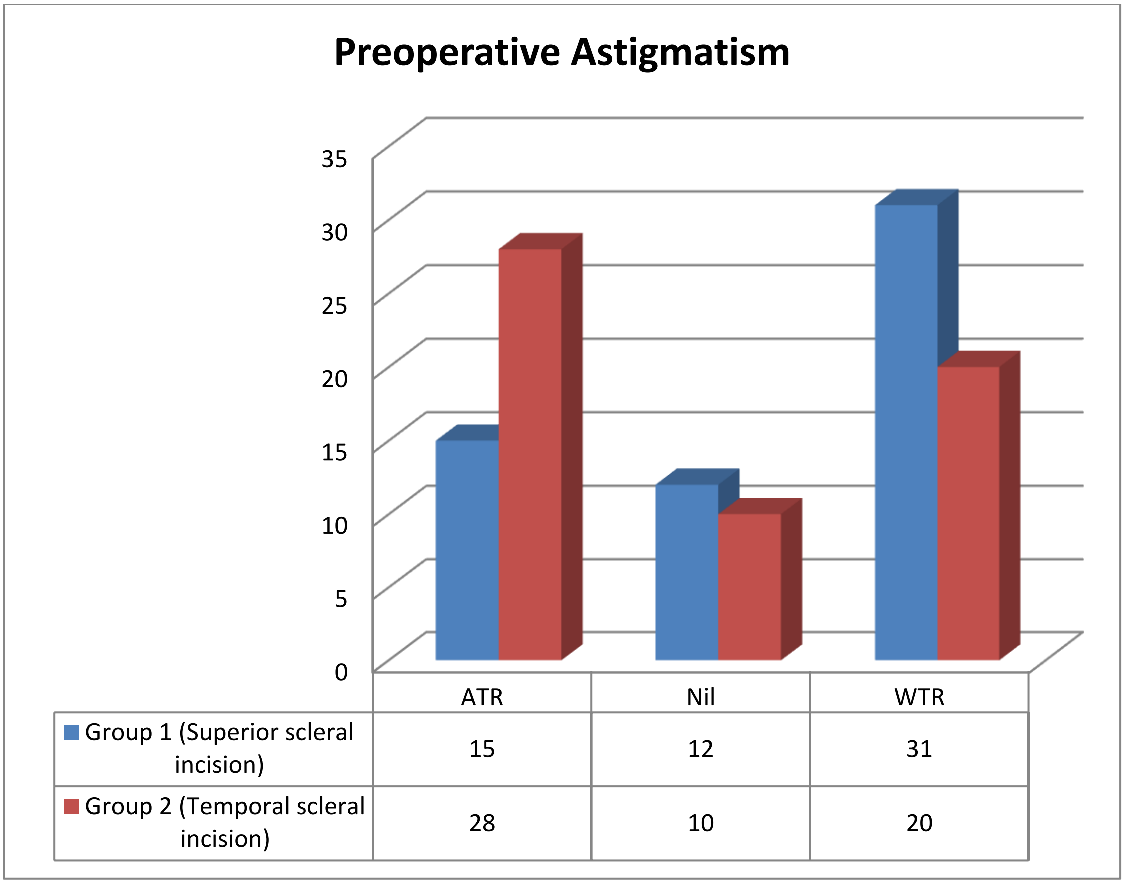
31 (53.4%) patients in Group 1 (Superior scleral incision) had with the rule and 15 (25.9%) patients had ATR astigmatism. 12 (20.7%) patients had nil preoperative astigmatism.

In Group 2 (Temporal scleral incision), 20 (34.4%) patients had with the rule and 28 (48.3%) patients had ATR astigmatism. 10 (17.3%) patients had nil preoperative astigmatism.

Table 4: Distribution of patients according to Preoperative Astigmatism

Preoperative Astigmatism	Group 1 (Superior scleral incision)		Group 2 (Temporal scleral incision)	
	N	%	N	%
ATR	15	25.9%	28	48.3%
Nil	12	20.7%	10	17.3%
WTR	31	53.4%	20	34.4%
Total	58	100%	58	100%

Graph 4: Distribution of patients according to Preoperative Astigmatism



Distribution of patients according to Postoperative Astigmatism

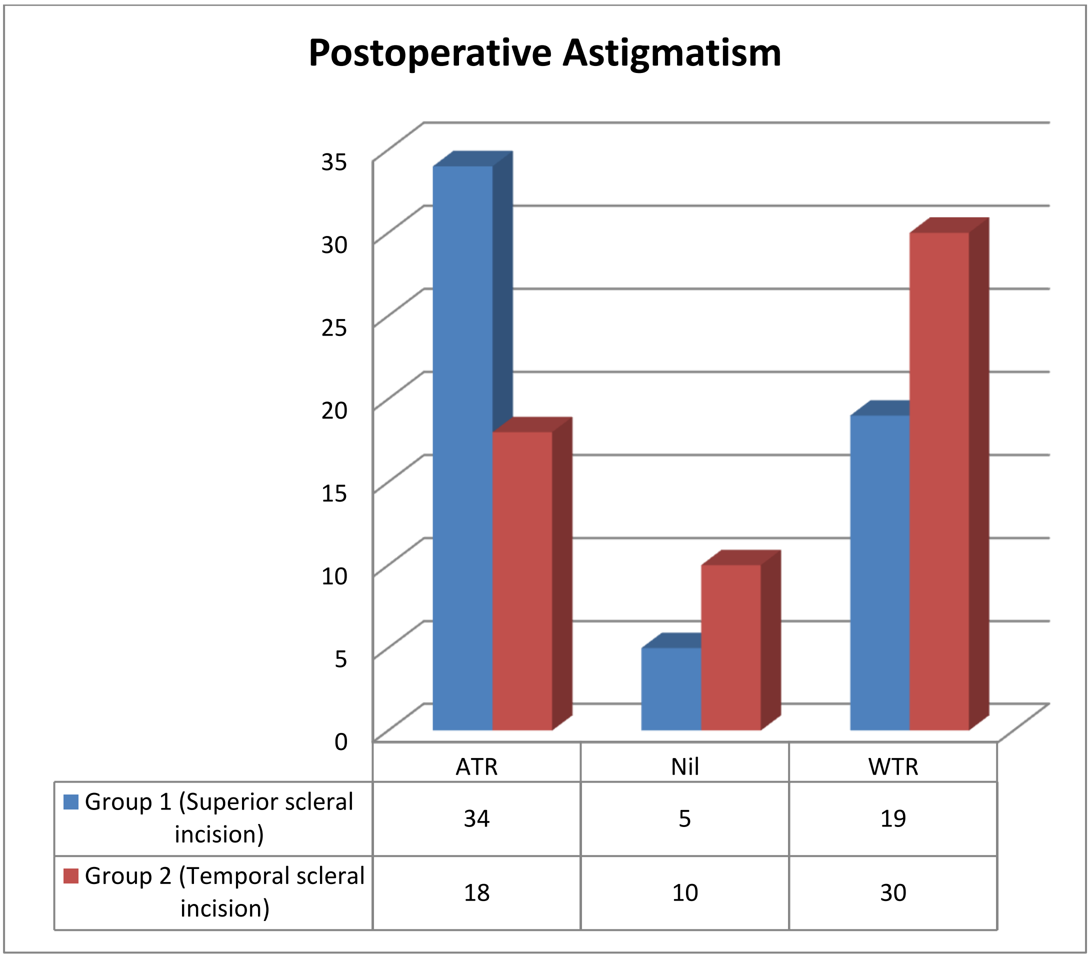
In Group 1 (Superior scleral incision), 19 (32.8%) patients developed WTR astigmatism after phacoemulsification. 34 (58.6%) patients developed ATR astigmatism. 5 (8.6%) patients had no astigmatism postoperatively.

30 (51.5%) patients of Group 2 (Temporal scleral incision) developed WTR (with the rule) astigmatism after phacoemulsification, while 18 (31.3%) patients developed against the rule astigmatism. 10 (17.2%) patients had nil postoperative astigmatism.

Table 5: Distribution of patients according to Postoperative Astigmatism

Postoperative Astigmatism	Group 1 (Superior scleral incision)		Group 2 (Temporal scleral incision)	
	N	%	N	%
ATR	34	58.6%	18	31.3%
Nil	5	8.6%	10	17.2%
WTR	19	32.8%	30	51.5%
Total	58	100%	58	100%

Graph 5: Distribution of patients according to Postoperative Astigmatism



Comparison of Astigmatic Change from Preoperative to Postoperative state between Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)

Of the patients having a preoperative WTR astigmatism, 6 (10.3%) patients of Group1 (Superior scleral incision) and 9 (15.5%) patients of Group 2 (Temporal scleral incision) continued to remain so postoperatively. 16 (27.6%) patients of Group1 (Superior scleral incision) and 3 (5.2%) patients of Group 2 (Temporal scleral incision) showed a postoperative ATR drift. 3 (5.2%) patients of Group1 (Superior scleral incision) and 5 (8.6%) patients of Group 2 (Temporal scleral incision) showed no astigmatism postoperatively.

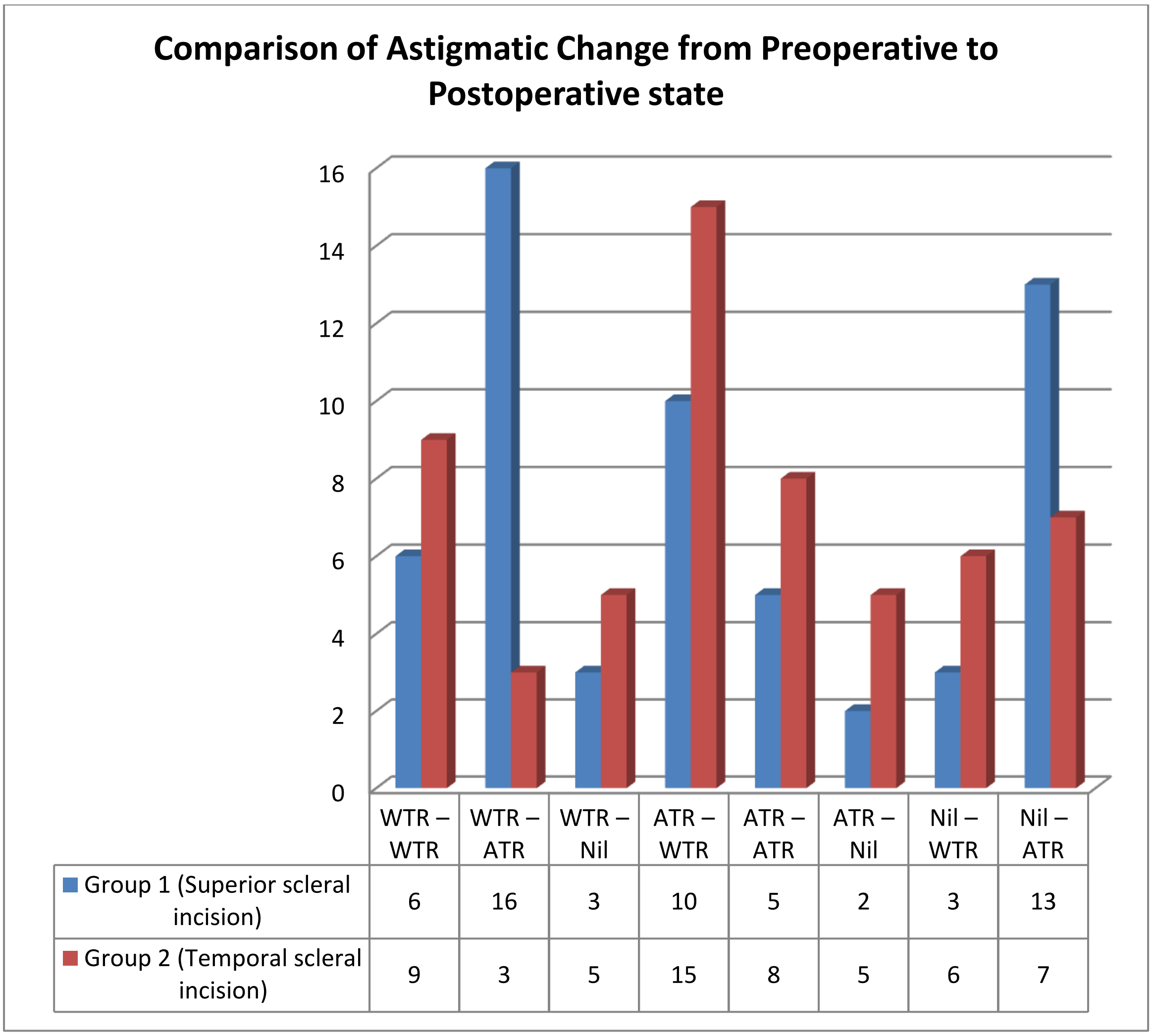
Of the patients having ATR astigmatism preoperatively, 10 (17.2%) patients of Group1 (Superior scleral incision) and 15 (25.9%) patients of Group 2 (Temporal scleral incision) shifted towards WTR astigmatism. 5 (8.6%) patients of Group1 (Superior scleral incision) and 8 (13.8%) patients of Group 2 (Temporal scleral incision) continued to remain ATR even after surgery. 2 (3.5%) patients of Group1 (Superior scleral incision) and 5 (8.6%) patients of Group 2 (Temporal scleral incision) shifted to nil atygmatism and developed shift to nil astigmatism.

Of the patients having no astigmatism preoperatively, 3 (5.2%) patients of Group1 (Superior scleral incision) and 6 (10.3%) patients of Group 2 (Temporal scleral incision) developed WTR astigmatism postoperatively. Also, 13 (22.4%) patients of Group1 (Superior scleral incision) and 7 (12.1%) patients of Group 2 (Temporal scleral incision) developed a ATR astigmatism after surgery.

Table 6: Comparison of Astigmatic Change from Preoperative to Postoperative state between Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)

Postoperative Astigmatism	Group 1 (Superior scleral incision)		Group 2 (Temporal scleral incision)	
	N	%	N	%
WTR – WTR	6	10.3%	9	15.5%
WTR – ATR	16	27.6%	3	5.2%
WTR – Nil	3	5.2%	5	8.6%
ATR – WTR	10	17.2%	15	25.9%
ATR – ATR	5	8.6%	8	13.8%
ATR – Nil	2	3.5%	5	8.6%
Nil – WTR	3	5.2%	6	10.3%
Nil – ATR	13	22.4%	7	12.1%
Total	58	100%	58	100%

Graph 6: Comparison of Astigmatic Change from Preoperative to Postoperative state between Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)



Preoperative kH and kV of Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)

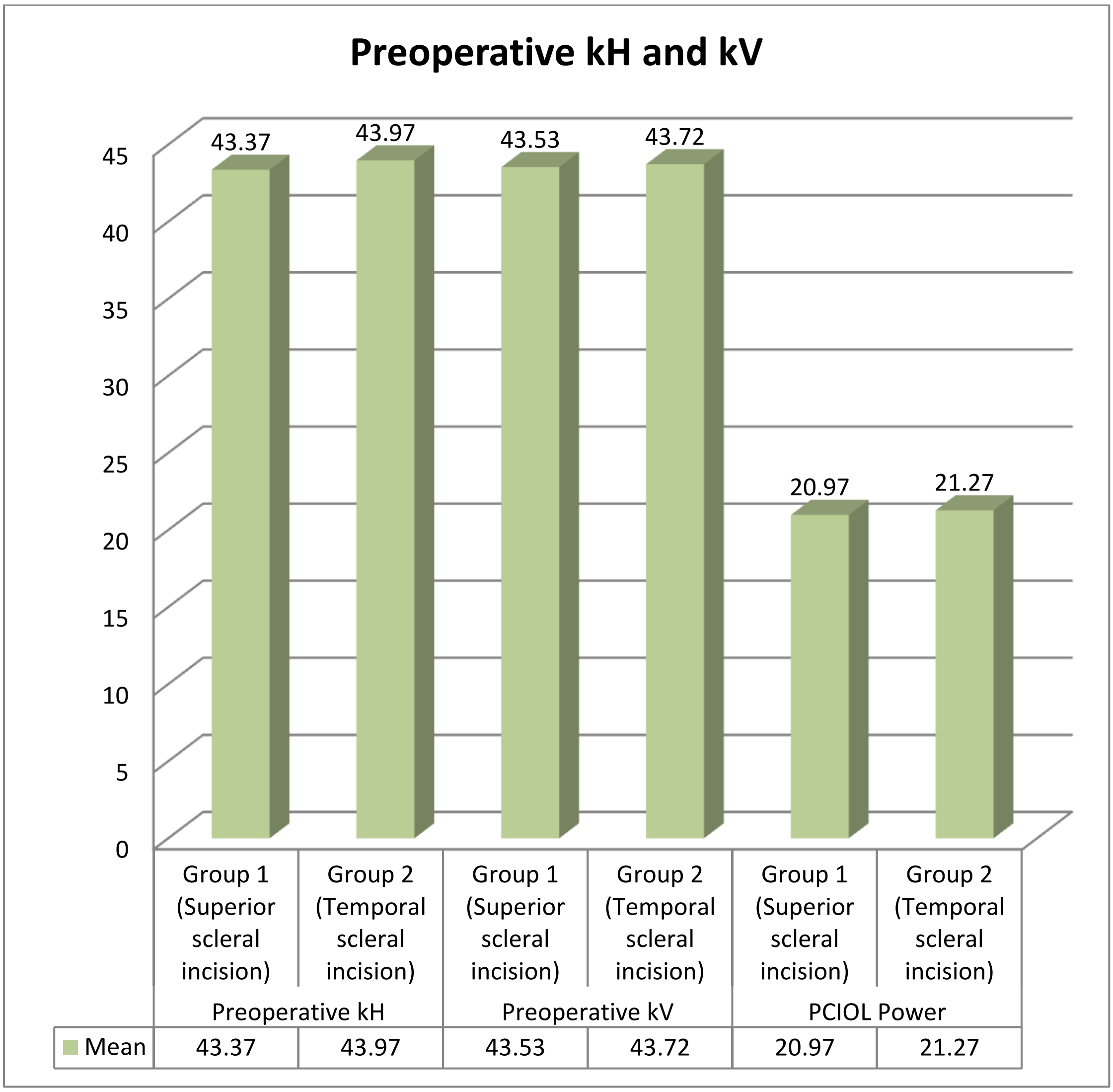
The preoperative kH, kV and PCIOL power did not show statistically significant change between both the groups. Fisher's test was done for the statistical analysis.

Table 7: Preoperative kH and kV of Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)

	Type	N	Mean	Std. Deviation	p value
Preoperative kH	Group 1 (Superior scleral incision)	58	43.37	1.41	p>0.05
	Group 2 (Temporal scleral incision)	58	43.97	1.19	
Preoperative kV	Group 1 (Superior scleral incision)	58	43.53	1.36	p>0.05
	Group 2 (Temporal scleral incision)	58	43.72	1.13	
PCIOL Power	Group 1 (Superior scleral incision)	58	20.97	2.08	p>0.05
	Group 2 (Temporal scleral incision)	58	21.27	2.00	

***p<0.05 - Statistically Significant**

Graph 7: Preoperative kH and kV of Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)



Postoperative kH and kV of Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)

There were no statistical significant changes in the postoperative kH and kV parameters between both the groups when evaluated over a period of 2 days to 3 months. Fisher's test was done for the statistical analysis.

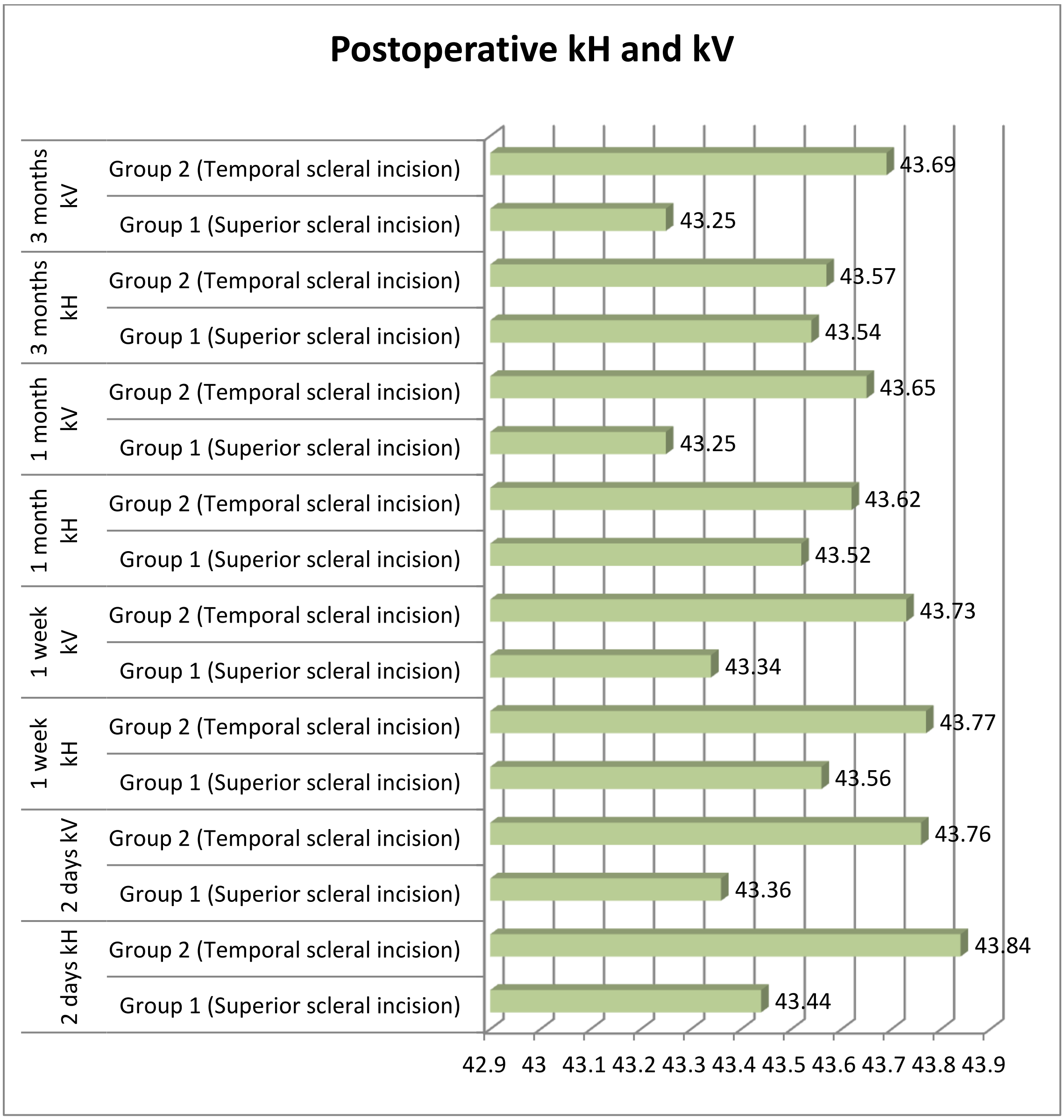
Table 8: Postoperative kH and kV of Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)

	Type	N	Mean	Std. Deviation	'p' value
2 days kH	Group 1 (Superior scleral incision)	58	43.44	1.39	p>0.05
	Group 2 (Temporal scleral incision)	58	43.84	1.21	
2 days kV	Group 1 (Superior scleral incision)	58	43.36	1.38	p>0.05
	Group 2 (Temporal scleral incision)	58	43.76	1.18	
1 week kH	Group 1 (Superior scleral incision)	58	43.56	1.38	p>0.05
	Group 2 (Temporal scleral incision)	58	43.77	1.21	
1 week kV	Group 1 (Superior scleral incision)	58	43.34	1.39	p>0.05
	Group 2 (Temporal	58	43.73	1.18	

	scleral incision)				
1 month kH	**Group 1 (Superior scleral incision)**	58	43.52	1.46	p>0.05
	Group 2 (Temporal scleral incision)	58	43.62	1.18	
1 month kV	**Group 1 (Superior scleral incision)**	58	43.25	1.46	p>0.05
	Group 2 (Temporal scleral incision)	58	43.65	1.64	
3 months kH	**Group 1 (Superior scleral incision)**	58	43.54	1.44	p>0.05
	Group 2 (Temporal scleral incision)	58	43.57	1.11	
3 months kV	**Group 1 (Superior scleral incision)**	58	43.25	1.43	p>0.05
	Group 2 (Temporal scleral incision)	58	43.69	1.24	

***p<0.05 - Statistically Significant**

Graph 8: Postoperative kH and kV of Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)



Distribution of patients according to Range of Surgically–induced Astigmatism

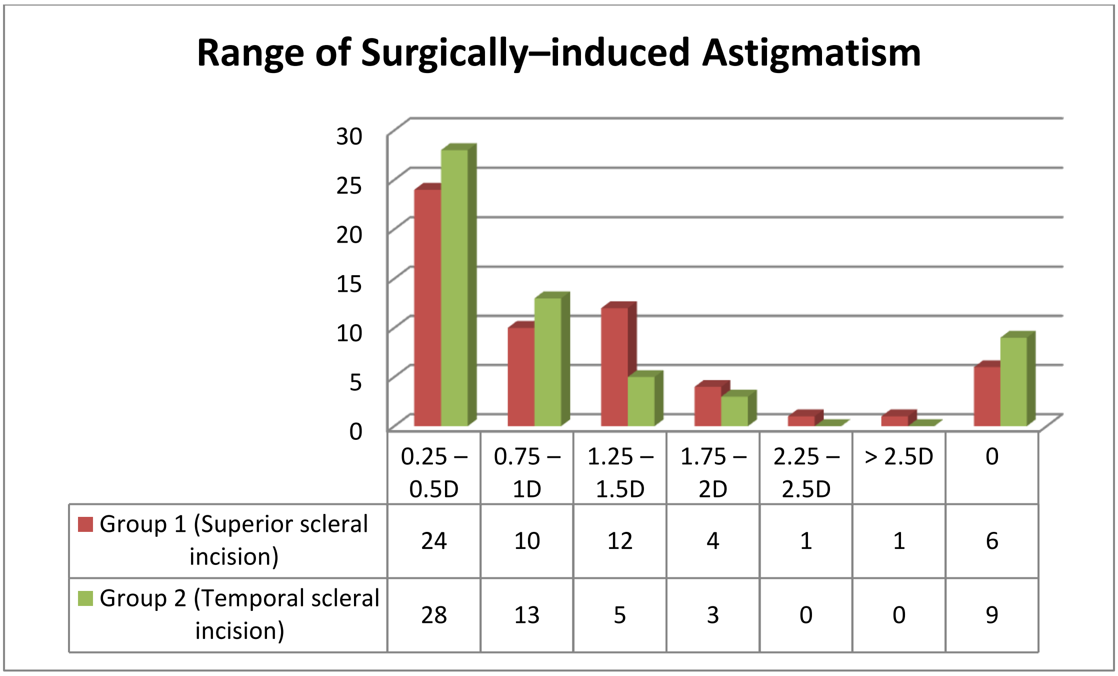
In Group 1 (Superior scleral incision), 24 (41.3%) patients had astigmatism in the range 0.25 to 0.5D, 10 (17.2%) patients had induced astigmatism in range of 0.75 to 1D, 12 (20.7%) patients had astigmatism in the range of 1.25 to 1.5D, 4 (6.9%) patients had astigmatism in the range 1.75 to 2D and 1 (1.7%) patient each had astigmatism in the range of 2.25 to 2.5D and greater than 2.5D range. 6 (10.5%) patients had no surgically induced astigmatism.

In Group 2 (Temporal scleral incision), 28 (48.3%) patients had astigmatism in the range 0.25 to 0.5D, 13 (22.4%) patients had induced astigmatism in range of 0.75 to 1D, 5 (8.6%) patients had astigmatism in the range of 1.25 to 1.5D, 3 (5.2%) patients had astigmatism in the range 1.75 to 2D and no patients in the range of 2.25 to 2.5D and greater than 2.5D range. 9 (15.5%) patients had no surgically induced astigmatism.

Table 9: Distribution of patients according to Range of Surgically–induced Astigmatism

Range	Group 1 (Superior scleral incision)		Group 2 (Temporal scleral incision)	
	N	%	N	%
0.25 – 0.5D	24	41.3%	28	48.3%
0.75 – 1D	10	17.2%	13	22.4%
1.25 – 1.5D	12	20.7%	5	8.6%
1.75 – 2D	4	6.9%	3	5.2%
2.25 – 2.5D	1	1.7%	0	-
> 2.5D	1	1.7%	0	-
0	6	10.5%	9	15.5%
Total	58	100%	58	100%

Graph 9: Distribution of patients according to Range of Surgically–induced Astigmatism



Mean and Std. Deviation of Surgically–induced Astigmatism

In Group 1 (Superior scleral incision), 16 (27.6%) patients developed WTR astigmatism, with a mean astigmatism of 0.72D and 36 (62.1%) patients developed ATR astigmatism with a mean astigmatism of 1.00D. 6 (10.3%) patients had no surgically induced astigmatism.

In Group 2 (Temporal scleral incision), 31 (53.4%) patients developed WTR astigmatism with a mean astigmatism at 0.79D and 18 (31.1%) patients developed ATR astigmatism having a mean of 0.46D. 9 (15.5%) patients had no surgically induced astigmatism.

Table 10: Mean and Std. Deviation of Surgically–induced Astigmatism

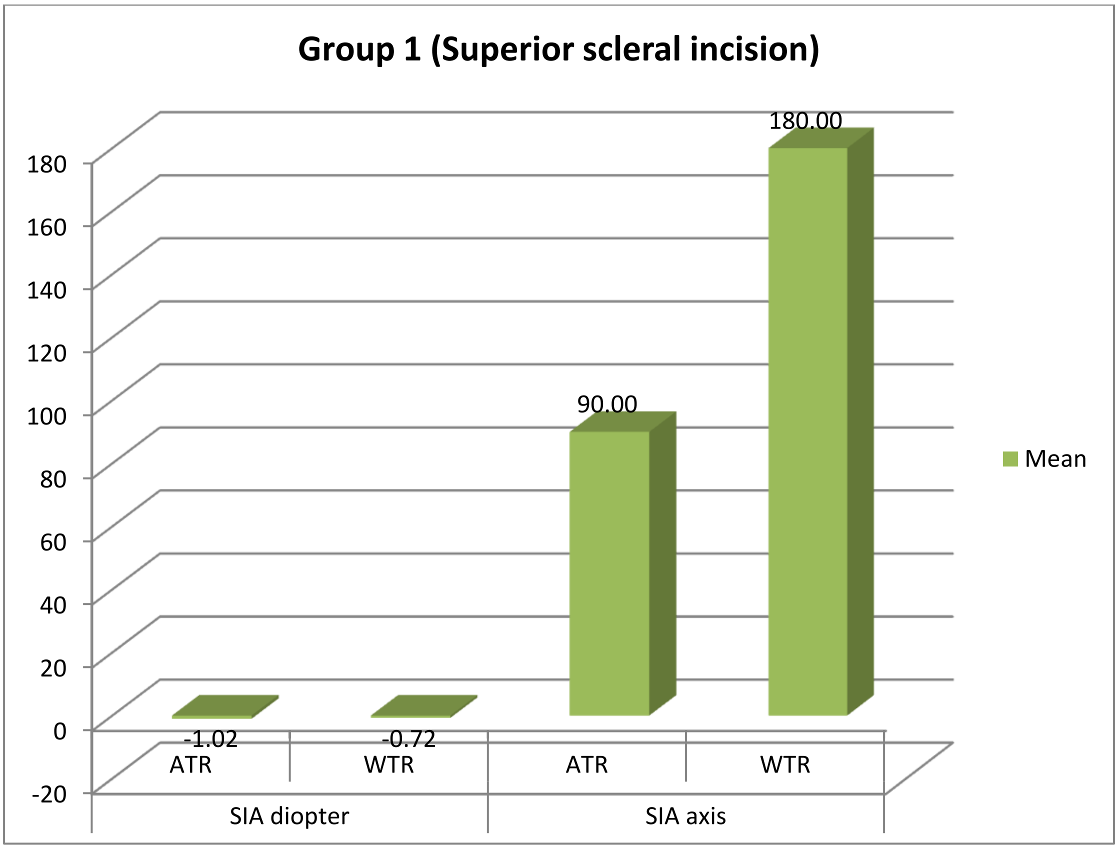
Group 1 (Superior scleral incision)

		N	Mean	Std. Deviation
SIA diopter	**ATR**	36	–1.02	0.595
	WTR	16	–0.72	0.523
SIA axis	**ATR**	36	90	0
	WTR	16	180	0

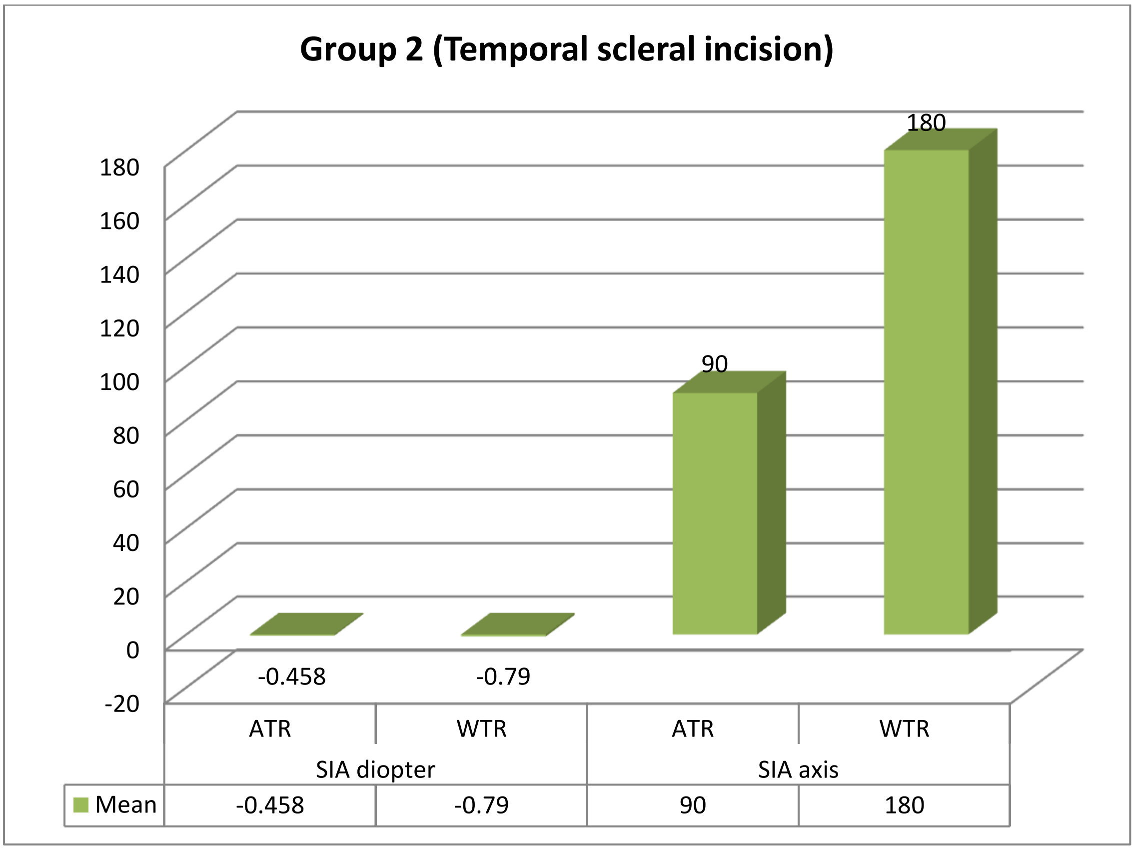
Group 2 (Temporal scleral incision)

		N	Mean	Std. Deviation
SIA diopter	ATR	18	–0.458	0.214
	WTR	31	–0.790	0.517
SIA axis	ATR	18	90	0
	WTR	31	180	0

Graph 10 : Group 1 (Superior scleral incision)



Group 2 (Temporal scleral incision)



Comparison of Amount of Surgically–induced Astigmatism between Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)

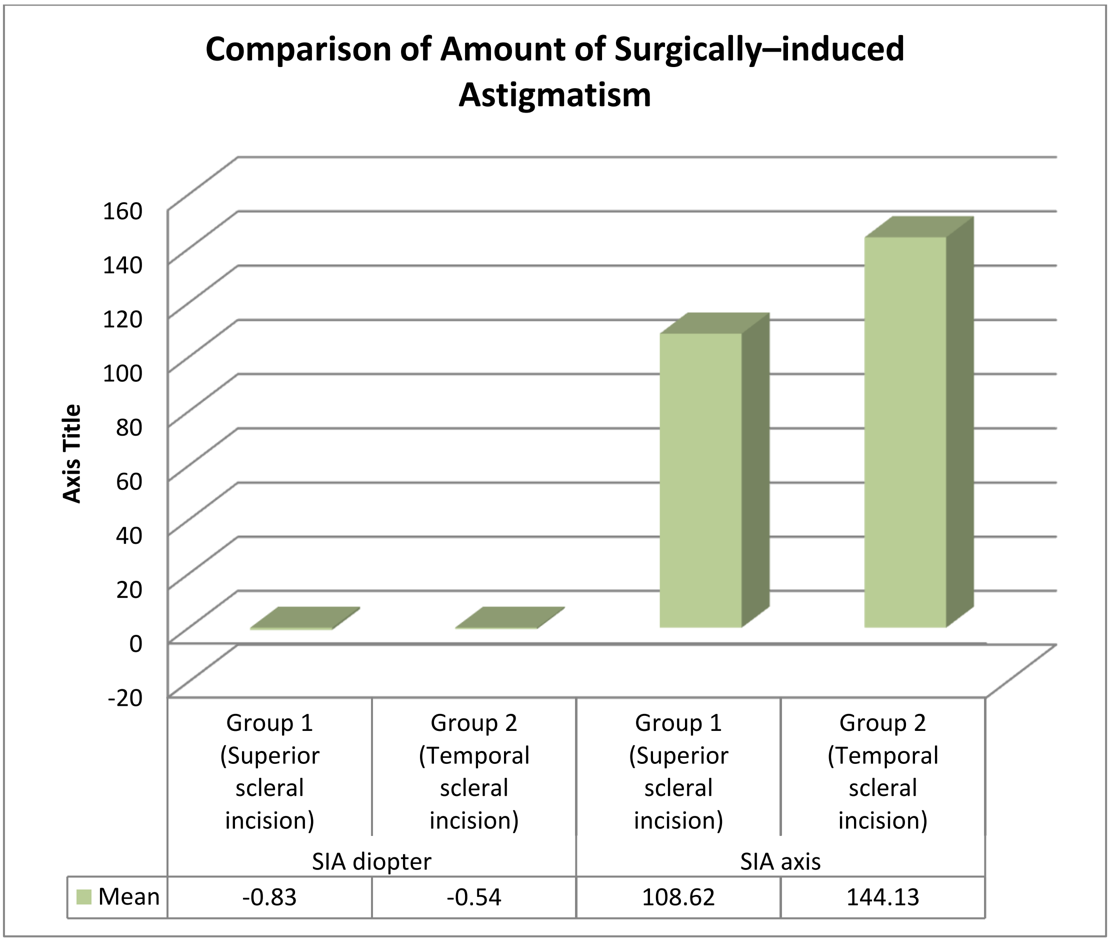
The average surgically induced astigmatism in patients who underwent phacoemulsification with superior clear corneal incision and temporal clear corneal incision was 0.83D and 0.54D respectively. Hence the average surgically induced astigmatism was less with temporal clear corneal incision as compared to superior clear corneal incision phacoemulsification with foldable intraocular lens implantation. Fisher's test was done for the statistical analysis.

Table 11: Comparison of Amount of Surgically–induced Astigmatism between Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)

	Type	N	Mean	Std. Deviation	p value
SIA diopter	**Group 1 (Superior scleral incision)**	58	–0.83	0.623	**p<0.05***
	Group 2 (Temporal scleral incision)	58	–0.54	0.442	
SIA axis	**Group 1 (Superior scleral incision)**	58	108.62	49.89	**p<0.05***
	Group 2 (Temporal scleral incision)	58	144.13	67.07	

***p<0.05 - Statistically Significant**

Graph 11: Comparison of Amount of Surgically–induced Astigmatism between Group1 (Superior scleral incision) and Group 2 (Temporal scleral incision)



DISCUSSION

Cataract is defined as "Opacity in the lens capsule or its substance". It is the commonest cause of preventable blindness in the world. The mainstay of management of cataract is surgery and the aim of cataract surgery is to provide early visual rehabilitation. With the advent of foldable intraocular lens, it is possible to implant the lens through an incision as small as 2.2 mm, which helps in significantly reducing postoperative astigmatism. There are two approaches, i.e. through superior clear corneal and temporal clear corneal incision. The present study was done among 116 patients and evaluated surgically induced astigmatism after phacoemulsification with temporal and superior clear corneal incisions.

In both groups, majority of patients were in the age group of 61–70 years. There was Female predominance in Group 1 (Superior scleral incision) 32 (55.2%) patients whereas most patients in Group 2 (Temporal scleral incision) were male 30 (51.7%) patients.

In Group 1 (Superior scleral incision), 52 (89.7%) patients had visual acuity of 6/12–6/60. 5 (8.67%) patients had vision from CF 3 metres to 6/60. 1 (1.7%) patient had visual acuity from CF 2 meters to hand movement close to face. In Group 2 (Temporal scleral incision), 55 (94.8%) patients had visual acuity of 6/12–6/60. 3 (5.2%) patients had vision from CF 3 meters to 6/60.31 (53.4%) patients in Group 1 (Superior scleral incision) had with the rule and 15 (25.9%) patients had ATR astigmatism. 12 (20.7%) patients had nil preoperative astigmatism. In Group 2 (Temporal scleral incision), 20 (34.4%) patients had with the rule and 28 (48.3%) patients had ATR astigmatism. 10 (17.3%) patients had nil preoperative astigmatism.

The study by Anders N et al[28] confirmed that age and preoperative astigmatism were found to influence induced astigmatism significantly. Tadros A et al[29] evaluated the effect of an axis opposite clear corneal incision in phacoemulsification. They showed that there was a weak association between the surgically induced astigmatism and the patients age and axis of preoperative astigmatism.

In Group 1 (Superior scleral incision), 19 (32.8%) patients developed WTR astigmatism after phacoemulsification. 34 (58.6%) patients developed ATR astigmatism. 5 (8.6%) patients had no astigmatism postoperatively. 30 (51.5%) patients of Group 2 (Temporal scleral incision) developed WTR (with the rule) astigmatism after phacoemulsification, while 18 (31.3%) patients developed against the rule astigmatism. 10 (17.2%) patients had nil postoperative astigmatism.

Simsek S et al[8] evaluated the effect of superior and temporal clear corneal incisions on astigmatism after phacoemulsification in 40 eyes of 20 patients. A superior clear corneal incision was used in all right eyes and temporal clear corneal incision in all left eyes. Temporal incision group showed significantly lower astigmatism. Upper lid pressure on the superior corneal incisions led to fluctuating against the rule astigmatism that was significantly higher than that induced by temporal incisions.

Roman SJ, et al[7] evaluated surgically induced astigmatism, postoperative astigmatism and uncorrected visual acuity after phacoemulsification with superior, clear corneal, superior scleral and temporal corneal incisions in 90 patients with preoperative WTR astigmatism. It was observed that superior clear corneal incision produced significant surgically induced astigmatism (SIA) than scleral and temporal incisions.

In another study conducted by Barequet IS, et al[10], in 178 eyes with temporal clear corneal incision in right eyes and nasal incision left eyes after phacoemulsification.

They compared short and long term astigmatism outcome. They found that cataract surgery using a horizontal clear corneal incision induced WTR astigmatism and temporal incision induced significantly less astigmatism than nasal incisions.

In this study, we compared preoperative and postoperative astigmatism between Group 1 (Superior scleral incision) and Group 2 (Temporal scleral incision). Of the patients having a preoperative WTR astigmatism, 6 (10.3%) patients of Group1 (Superior scleral incision) and 9 (15.5%) patients of Group 2 (Temporal scleral incision) continued to remain so postoperatively. 16 (27.6%) patients of Group1 (Superior scleral incision) and 3 (5.2%) patients of Group 2 (Temporal scleral incision) showed a postoperative ATR drift. 3 (5.2%) patients of Group1 (Superior scleral incision) and 5 (8.6%) patients of Group 2 (Temporal scleral incision) showed no astigmatism postoperatively.

Of the patients having ATR astigmatism preoperatively, 10 (17.2%) patients of Group1 (Superior scleral incision) and 15 (25.9%) patients of Group 2 (Temporal scleral incision) shifted towards WTR astigmatism. 5 (8.6%) patients of Group1 (Superior scleral incision) and 8 (13.8%) patients of Group 2 (Temporal scleral incision) continued to remain ATR even after surgery. 2 (3.5%) patients of Group1 (Superior scleral incision) and 5 (8.6%) patients of Group 2 (Temporal scleral incision) shifted to nil atygmatism and developed shift to nil astigmatism.

Of the patients having no astigmatism preoperatively, 3 (5.2%) patients of Group1 (Superior scleral incision) and 6 (10.3%) patients of Group 2 (Temporal scleral incision) developed WTR astigmatism postoperatively. Also, 13 (22.4%)

patients of Group1 (Superior scleral incision) and 7 (12.1%) patients of Group 2 (Temporal scleral incision) developed a ATR astigmatism after surgery.

By knowing a preexisting astigmatism preoperatively, one can reduce postoperative astigmatism by selecting a appropriate incision i.e. astigmatism is decreased by taking incision closure to steeper cornea and neutralized by taking incision on steeper area. Instead postoperative astigmatism increases by taking incision on opposite axis.

Beltrame G, et al[30] compared astigmatic and topographic changes induced by different oblique incisions i.e. total of 168 eyes.

60 eyes – 3.5 mm clear corneal incision

54 eyes – 5.5 mm sutured clear corneal incision

54 eyes – 5.5 mm scleral incision

Postoperatively astigmatism and topographical changes were assessed. Wound–related flattening was seen at the incision site in all the groups and less significant in scleral tunnel group and more with 5.5 mm clear corneal incision group. Steepening effect at opposite axis was seen which is higher in 5.5 mm clear corneal incision group and least in scleral tunnel group.

In Group 1 (Superior scleral incision), 24 (41.3%) patients had astigmatism in the range 0.25 to 0.5D, 10 (17.2%) patients had induced astigmatism in range of 0.75 to 1D, 12 (20.7%) patients had astigmatism in the range of 1.25 to 1.5D, 4 (6.9%) patients had astigmatism in the range 1.75 to 2D and 1 (1.7%) patient each had astigmatism in the range of 2.25 to 2.5D and greater than 2.5D range. 6 (10.5%) patients had no surgically induced astigmatism.

In Group 2 (Temporal scleral incision), 28 (48.3%) patients had astigmatism in the range 0.25 to 0.5D, 13 (22.4%) patients had induced astigmatism in range of 0.75 to 1D, 5 (8.6%) patients had astigmatism in the range of 1.25 to 1.5D, 3 (5.2%) patients had astigmatism in the range 1.75 to 2D and no patients in the range of 2.25 to 2.5D and greater than 2.5D range. 9 (15.5%) patients had no surgically induced astigmatism.

In Group 1 (Superior scleral incision), 16 (27.6%) patients developed WTR astigmatism, with a mean astigmatism of 0.72D and 36 (62.1%) patients developed ATR astigmatism with a mean astigmatism of 1.00D. 6 (10.3%) patients had no surgically induced astigmatism.

In Group 2 (Temporal scleral incision), 31 (53.4%) patients developed WTR astigmatism with a mean astigmatism at 0.79D and 18 (31.1%) patients developed ATR astigmatism having a mean of 0.46D. 9 (15.5%) patients had no surgically induced astigmatism.

These results are in conformity with some of the following studies :

Xie L et al[31] in their study of 34 cases of phacoemulsification proved that the postoperative astigmatism showed a tendency of change from WTR shifting to ATR. Azar DT, et al[32] proved in their study of 131 patients treated with phacoemulsification with three, one, and no sutures. Sutureless group had the greatest proportion of patients with significant ATR shift and lowest with significant WTR shift. They therefore concluded that sutureless and 1 suture surgery resulted in a low percentage of WTR induced astigmatism postoperatively i.e. upper lid pressure on the superior clear corneal incisions led to fluctuating ATR astigmatism.

A similar study conducted by Lyhne N, et al[33] showed that the postoperative keratometric cylinder and induced keratometric cyclinder were significantly higher in

ATR group with 0.76D and 0.69D respectively. They concluded that these differences were significantly in favour of patients with preoperative WTR astigmatism. The findings support using temporal incision in cases with a preoperative ATR axis of astigmatism.

Latha NV et al[34] did a study to determine and compare the surgically induced astigmatism in patients who have undergone phacoemulsification with clear corneal and corneoscleral incisions made superiorly and temporally. Surgically induced astigmatism calculated with SIA Calculator using Holladay's method was as follows; Superior corneoscleral 0.79D, Temporal corneoscleral 0.52D, Superior clear corneal 0.60D, Temporal clear corneal 0.73D. A higher incidence of against the rule astigmatism was seen pre-operatively (45%) and post-operatively (42%). The authors concluded that no significant difference was seen in the surgically induced astigmatism following phacoemulsification in all four incisions though the least SIA value was obtained with Temporal corneo-scleral. Temporal corneo-scleral incisions being farther away from the visual axis has minimal effect on the corneal curvature with near astigmatic neutrality.

Simsek S et al[8] showed that 3 months postoperatively mean astigmatism was 1.60 ± 0.37D in superior incision group and 0.83± 0.19D in temporal incision group. Induced analysis calculated by vector analysis was 1.44 ± 0.31D and 0.62 ± 0.28D respectively. They concluded that ATR astigmatism was significantly higher than that induced by temporal incisions.

Roman SJ et al[7] showed in their study the superior corneal incision produced significant surgically induced astigmatism leading to high postoperative astigmatism. The scleral and temporal incisions produced minimal surgically induced astigmatism.

Anwar MS et al[35] did a prospective study to evaluate the difference between pre and postoperative astigmatism in patients undergoing cataract extraction by phacoemulsification with intraocular lens implantation through 3.2 mm superotemporal clear corneal incision. They were divided into two groups depending upon, "With the Rule" (Group A) or "Against the Rule"(Group B), pre-operative astigmatism. Before surgery, mean astigmatism in group A patients was -0.83 D (Diopter) and in those of group B was -0.76 D. After the surgery, mean astigmatism in group A patients was -1.10 D and in those of group B was -1.10 D. The mean increase in astigmatism post operatively in the two groups was 0.27 D and 0.34 D respectively. The authors concluded that superotemporal clear corneal incision of 3.2 mm size is favourable in terms of wound stability and the final optical outcome. When followed up over a long time, the post-operative astigmatism approaches almost the preoperative value although there may be a negligible increase in it.

A study conducted by Liu Y et al[16] investigated the therapeutic effects, advantages and disadvantages of phacoemulsification and foldable lens implantation through a temporal clear corneal incision. With 812 patients who underwent phacoemulsification and foldable lens implantation 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 convenient and effective.

Superior incision being closer to visual axis, gravity and eyelid blink create drag on the incision, impart more corneal changes postoperatively with significant postoperative astigmatism, whereas temporal incision being away from visual axis, and more stable, also flattening around the wound is less likely to effect corneal curvature, hence results into least astigmatism.

In the present study the average surgically induced astigmatism in patients who underwent phacoemulsification with superior clear corneal incision was 0.83D and 0.54D with temporal clear corneal incisions.

A study by Cillino S et al[36] compared temporal versus superior approach phacoemulsification interm of postoperative astigmatism i.e. temporal clear corneal with PMMA IOL and superior corneoscleral incision. They found a positive WTR surgically induced astigmatism in the temporal approach and ATR in superior approach group.

Bhavani MV et al[26] studied to show that the decay of astigmatism from third to sixth week in temporal scleral incision was negligible (0.068D) implying early wound stabilization. Superior scleral incision showed a significant post-operative 'against the rule' drift as compared to temporal scleral incision. Therefore, superior scleral incision should not be done in patients with 'ATR' astigmatism. Surgically induced astigmatism of <1D was seen in 62% in temporal scleral as compared to only 42% in superior scleral incision. This implies that, temporal scleral incision induces less astigmatism when compared to superior scleral incision. Temporal scleral incision gives a substantial improvement in surgical exposure, especially in patients with deep set eyes or prominent eyebrows. Temporal scleral incision is more advantageous than superior scleral incision in astigmatically neutral patients, patients with 'Against the rule' astigmatism, patients with 'with the rule' astigmatism upto <1D and superior scleral incision is preferred only if 'with the rule' astigmatism is >1D.

SUMMARY

The present study was done among 116 patients and evaluated surgically induced astigmatism after phacoemulsification with temporal and superior clear corneal incisions. Based on the observations, the following conclusions were drawn:

In both groups, majority of patients were in the age group of 61–70 years. There was Female predominance in Group 1 (Superior scleral incision) (55.2%) patients whereas most patients in Group 2 (Temporal scleral incision) were male (51.7%) patients.

1. In Group 1 (Superior scleral incision), 89.7% patients had visual acuity of 6/12–6/60 whereas in Group 2 (Temporal scleral incision), 94.8% patients had visual acuity of 6/12–6/60.
2. 53.4% patients in Group 1 (Superior scleral incision) had with the rule and 25.9% patients had ATR astigmatism. In Group 2 (Temporal scleral incision), 34.4% patients had with the rule and 48.3% patients had ATR astigmatism.
3. 34.4% patients in Group 1 (Superior scleral incision) developed WTR astigmatism after phacoemulsification. 60.3% patients developed ATR astigmatism. 56.9% patients of Group 2 (Temporal scleral incision) developed WTR (with the rule) astigmatism after phacoemulsification, while 37.9% patients developed against the rule astigmatism.
4. Of the patients having a preoperative WTR astigmatism, 10.3% patients of Group1 (Superior scleral incision) and 15.5% patients of Group 2 (Temporal scleral incision) continued to remain so postoperatively. 17.2% patients of Group1 (Superior scleral incision) and 25.9% patients of Group 2 (Temporal scleral incision) having ATR astigmatism preoperatively shifted towards WTR astigmatism.

5. The preoperative and post-operative kH, kV and PCIOL power did not show statistically significant change between both the groups.
6. In Group 1 (Superior scleral incision), 41.3% patients had astigmatism in the range 0.25 to 0.5D and in Group 2 (Temporal scleral incision), 48.3% patients had astigmatism in the range 0.25 to 0.5D.
7. In Group 1 (Superior scleral incision), 27.6% patients developed WTR astigmatism, with a mean astigmatism of 0.72D and 62.1% patients developed ATR astigmatism with a mean astigmatism of 1.00D. In Group 2 (Temporal scleral incision), 53.4% patients developed WTR astigmatism with a mean astigmatism at 0.79D and 31.1% patients developed ATR astigmatism having a mean of 0.46D.
8. The average surgically induced astigmatism in patients who underwent phacoemulsification with superior scleral incision and temporal scleral incision was 0.83D and 0.54D respectively.

CONCLUSION

It is a prospective study on astigmatic changes in 116 cataract patients underwent phacoemulcification by 2 approaches i.e superior scleral incision and temporal scleral incision with foldable lens implantation with incision as small as 2.2 mm which helps in reducing post operative astigmatism.

In our study we observed that in group 1(superior scleral incision) , 31 patients had WTR and 15 patienta had ATR astigmatism pre operatively, who underwent superior scleral incision and post operative astigmatism for WTR patients was 0.72D and ATR patients had 1.00D astigmatism.

In group 2 , 20 patients had WTR and 28 patients had ATR astigmatism preoperatively, all of which underwent temporal scleral incision and post operatism astigmatism for WTR astigmatism was 0.79D and ATR astigmatism was 0.46D.

Hence we observed in pre operative WTR patients superior scleral incision is better and in pre operative ATR patients temporal scleral incision is better as it causes less post operative astigmatism.

The average surgically induced astigmatism was 0.54D with temporal scleral incision as compared to superior scleral incision of 0.83D post operatively.

In patients with pre operative NIL astigmatism temporal scleral incision is preferred as it causes WTR astigmatism in post operative period which stabalises early postoperatively.

With the comparison of temporal and superior scleral incisions there is no significant surgically induced astigmatism amplitude but a different surgically induced astigmatism axis orientation. The discrepancy in surgically induced astigmatism is attributable to difference in incision location.

In conclusion temporal scleral incision seem to achieve the goal of minimizing surgically induced astigmatism. Temporal scleral incision is slightly better than superior scleral incision in minimizing surgically induced astigmatism.

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ANNEXURES

ETHICAL CLEARANCE CERTIFICATE

Institutional Ethical Committee
BIJAPUR-586 103.
OUTWARD
No. 541/14
Date 24/11/14
B.L.D.E. U's Shri B.M. Patil Medical College

B.L.D.E. UNIVERSITY'S
SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR-586 103
INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 22-11-2014 at 3:30 pm. to scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected & revised version synopsis of the Thesis has been accorded Ethical Clearance.

Title "A Randomised clinical Trial to Evaluate Surgically Induced Astigmatism after Phacoemulsification with Temporal Scleral incision and Superior Scleral incision"

Name of P.G. student Dr. Priyanka. H. Katnalli
Dept of Ophthalmology

Name of Guide/Co-investigator Dr M. H. Patil, Professor
Dept of Ophthalmology

for

DR.TEJASWINI. VALLABHA
CHAIRMAN
INSTITUTIONAL ETHICAL COMMITTEE
BLDEU'S, SHRI.B.M.PATIL
MEDICAL COLLEGE, BIJAPUR.

Following documents were placed before E.C. for Scrutinization
1) Copy of Synopsis/Research project.
2) Copy of informed consent form
3) Any other relevant documents.

INFORMED CONSENT FOR PARTICIPATION IN DISSERTATION/RESEARCH

I undersigned the ______________________________________, S/O, D/O, W/O ____________________________, aged years, ordinarily resident of do hereby state/declare that Dr. Priyanka Katnalli of Shri. B. M. Patil Medical College Hospital and Research Centre - has examined me thoroughly on at (place) and it has been explained to me in my own language that I am suffering from disease (condition) and this disease/condition mimic following diseases. Further Dr. Priyanka Katnalli informed me that he/she is conducting dissertation/research titled "A Randomised Clinical Trial To Evaluate Surgically Induced Astigmatism After Phacoemulcification With Temporal Scleral Incision And Superior Scleral Incision" under the guidance of Dr. M. H. Patil requesting my participation in the study. Apart from routine treatment procedure, the pre-operative, operative, post-operative and follow-up observations will be utilized for the study as reference data.

Doctor has also informed me that during conduct of this procedure like adverse results may be encountered. Among the above complications most of them are treatable but are not anticipated hence there is chance of aggravation of my condition and in rare circumstances it may prove fatal in spite of anticipated diagnosis and best treatment made available. Further Doctor has informed me that my participation in this study help in evaluation of the results of the study which is useful reference to treatment of other similar cases in near future, and also I may be benefited in getting relieved of suffering or cure of the disease I am suffering.

The Doctor has also informed me that information given by me, observations made/ photographs/ video graphs taken upon me by the investigator will be kept secret and not assessed by the person other than me or my legal hirer except for academic purposes.

The Doctor did inform me that though my participation is purely voluntary, based on information given by me, I can ask any clarification during the course of treatment / study related to diagnosis, procedure of treatment, result of treatment or prognosis. At the same time I have been informed that I can withdraw from my participation in this study at any time if I want or the investigator can terminate me from the study at any time from the study but not the procedure of treatment and follow-up unless I request to be discharged.

After understanding the nature of dissertation or research, diagnosis made, mode of treatment, I the undersigned Shri/Smt under my full conscious state of mind agree to participate in the said research/dissertation.

Signature of patient:

Signature of doctor:

Witness: 1.

2.

Date:

Place

CLINICAL PROFORMA

TITLE : A RANDOMISED CLINICAL TRIAL TO EVALUATE SURGICALLY INDUCED ASTIGMATISM AFTER PHACOEMULCIFICATION WITH TEMPORAL SCLERAL INCISION AND SUPERIOR SCLERAL

PATIENT DETAILS

Name :	Address
Age	Income
Sex:	O.P. / I.P. No:
Occupation	D.O.A :
Phone No	D.O.D :

HISTORY OF PRESENTING ILLNESS:

PAST RIO:

1. Any Ocular Surgeries
2. Any long term use of Ocular or Systemic medication
3. History of any Ocular trauma
4. History of DM / HT / TB / Bronchial Asthma / IHD

PRE OPERATIVE EVALUATION

EXAMINATION:

General Examination

	RIGHT EYE	LEFT EYE

EYEBROW

EYELASHES :

EYE LIDS

CONJUNCTIVA :

SCLERA •

CORNEA ·

AC •

Depth Contents

IRIS PUPIL

Size

Shape

Reaction (Direct / Indirect):

LENS •

•

Position

Shape Color Transparency :

Grade

IOP (Applanation Tonometry):

VISUAL ACUITY (Suellen's chart)

Unaided:

Pin hole:

RIGHT EYE LEFT EYE **NASOLACRIMAL DUCT PATENCY**

EXTRA OCULAR MOVEMENTS

FUNDUS EXAMINATION

K reading :

Horizontal

Vertical

A SCAN

IOL POWER

DIAGNOSIS

PROCEDURE

EARLY POST-OP EVALUATION (DAY-1)

RIGHT EYE **LEFT EYE**

VISUAL ACUITY (Snellen's chart)

U n a i d e d

Pin hole :

Conjunctiva :

Scleral incision

Suture

Gaping / Wound leak

Fish Mouthing ± Iris

Prolapse ±

Security of the Wound

(Apposition)

Cornea:

Transparency

SK

Edema

K reading

Horizontal

Vertical

Anterior Chamber:

Depth

Contents

Flare

Cells

Iris: Colour

Pupil:

Size

Shape

Reaction

IOL: Centration

POST OPERATIVE EVALUATION DAY — 7:

RIGHT EYE LEFT EYE

VISUAL ACUITY (Snellen's chart)

Un aided

Pin hole

Wound:

Security of the Wound

(Apposition)

Cornea K reading:

Horizontal

Vertical

Pupil:

Size

Shape

Reaction

IOL: Centration

FUNDUS:

POST OPERATIVE EVALUATION — 30 DAYS: VISUAL ACUITY (Snelien's chart)

Un aided •

Wound: •

Security of the Wound (Apposition)

Cornea K reading: Horizontal

Vertical

Pupil: Size

Shape Reaction

IOL: Centration

FUNDUS:

IOP (Applanation Tonometry):

POST OPERATIVE EVALUATION —1 $^1/_2$ MONTHS: VISUAL ACUITY (Snellen's chart)

Un aided Pin hole

Cornea K reading: Horizontal

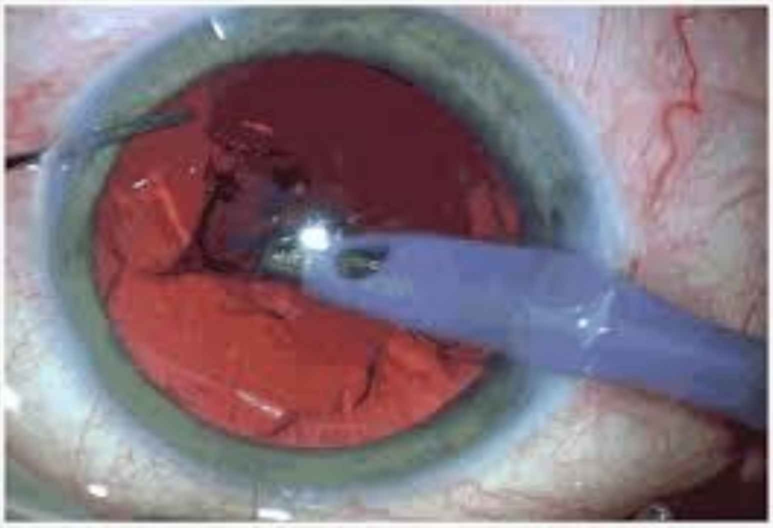
Vertical

IOL: Centration

IOP (Applanation Tonometry):

Signature of PG student

PHOTO GRAPHS



PCIOL INSERTION

KEY TO MASTER CHART

V/A	:	VISUAL ACUITY
kH	:	HORIZONTAL KERATOMETRY
kV	:	VERTICAL KERATOMETRY
D	:	DIOPTERS
ATR	:	Against The Rule
WTR	:	With The Rule
Rt	:	Right
Lt	:	Left