"EFFECT OF MANUAL SMALL INCISION CATARACT SURGERY ON PRE- CORNEAL TEAR FILM AT TERTIARY CARE CENTRE"

By

DR.KRUTHIKA.S , M.B.B.S

Dissertation submitted to

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, CENTRE, TAMAKA, KOLAR

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY IN OPHTHALMOLOGY

Under the guidance of

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JUNE/JULY 2023

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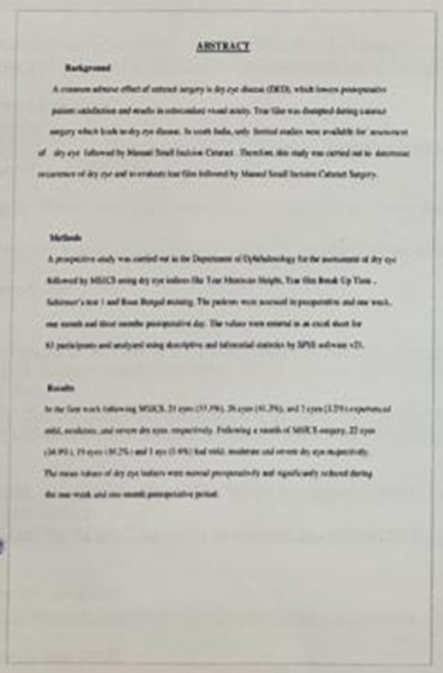

ABSTRACT

Background

A common adverse effect of cataract surgery is dry eye disease (DED), which lowers postoperative patient satisfaction and results in corneoconjunctival visual acuity. Tear film was disrupted during cataract surgery which leads to dry eye disease. In south India, only limited studies were available for assessment of dry eye followed by Manual Small Incision Cataract. Therefore, this study was carried out to determine occurrence of dry eye and to evaluate tear film followed by Manual Small Incision Cataract Surgery.

Methods

A prospective study was carried out in the Department of Ophthalmology for the assessment of dry eye followed by MSICS using dry eye indices like Tear Meniscus Height, Tear film Break Up Time , Schirmer's test I and Rose Bengal staining. The patients were assessed in preoperative and one week, one month and three months postoperative day. The values were entered in an excel sheet for 82 participants and analysed using descriptive and inferential statistics by SPSS software v21.

Results

In the first week following MSICS, 21 eyes (37.5%), 26 eyes (41.3%), and 7 eyes (12.5%) experienced mild, moderate, and severe dry eyes, respectively. Following a month of MSICS surgery, 22 eyes (34.9%), 19 eyes (30.2%) and 1 eye (1.6%) had mild, moderate and severe dry eye respectively. The mean values of dry eye indices were normal preoperatively and significantly reduced during the one week and one month postoperative period.

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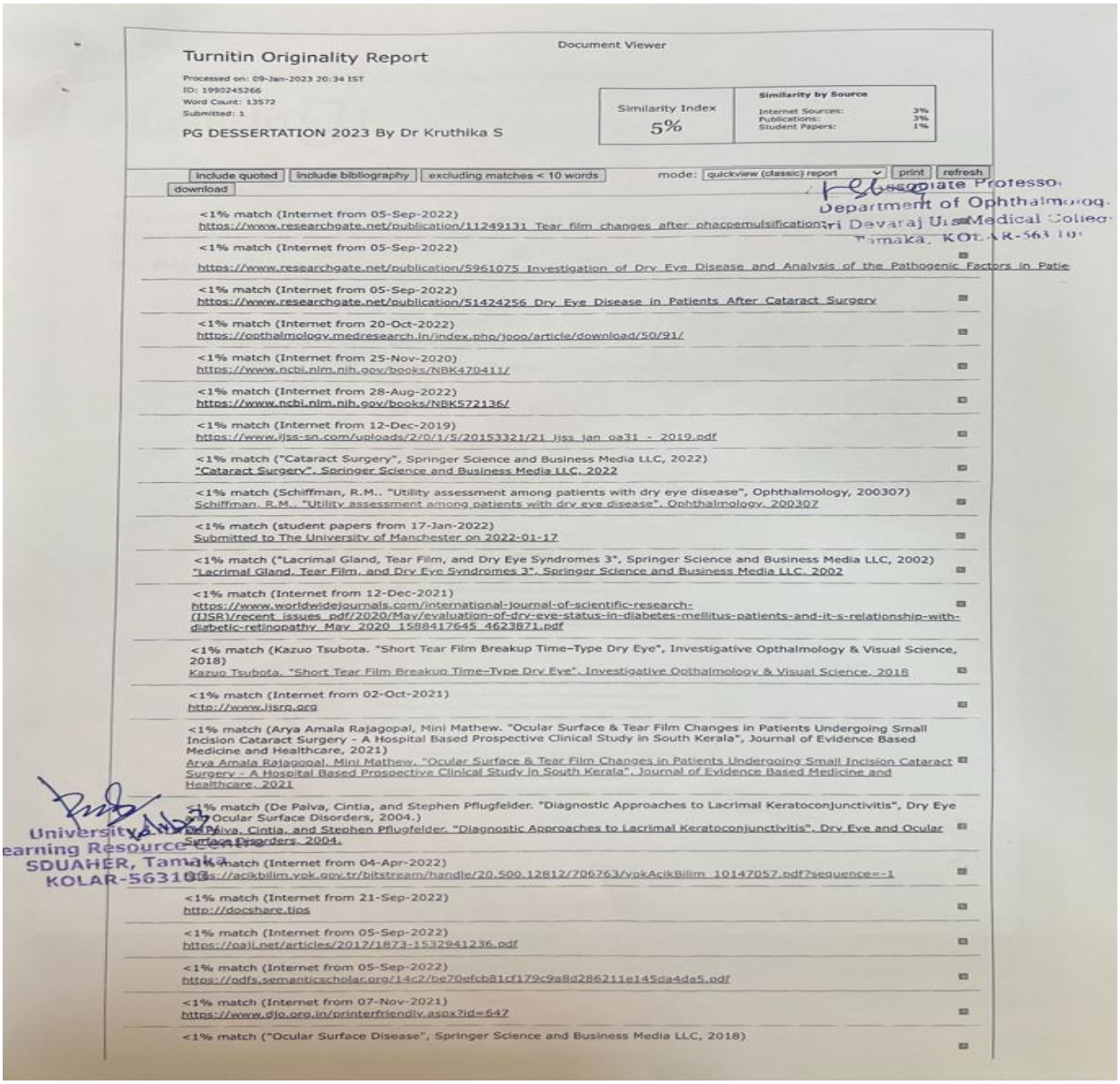

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LIST OF ABBREVIATIONS

DED	Dry Eye Disease
MSICS	Manual Small Incision Cataract Surgery
ECCE	Extra Capsular Cataract Extraction
TMH	Tear meniscus Height
TBUT	Tear film Break up time
ST1	Schirmer's test
RB	Rose Bengal staining
SD	Standard deviation

ABSTRACT

Background:

A common adverse effect of cataract surgery is dry eye disease (DED), which lowers postoperative patient satisfaction and results in substandard visual acuity. Tear film was disrupted during cataract surgery which leads to dry eye disease. In south India, only limited studies were available for assessment of dry eye followed by Manual Small Incision Cataract . Therefore, this study was carried out to determine occurrence of dry eye and to evaluate tear film followed by Manual Small Incision Cataract Surgery.

Methods:

A prospective study was carried out in the Department of Ophthalmology for the assessment of dry eye followed by MSICS using dry eye indices like Tear Meniscus Height, Tear film Break Up Time , Schirmer's test 1 and Rose Bengal staining. The patients were assessed in preoperative and one week, one month and three months postoperative day. The values were entered in an excel sheet for 63 participants and analyzed using descriptive and inferential statistics by SPSS software v21.

Results:

In the first week following MSICS, 21 eyes (33.3%), 26 eyes(41.3%), and 2 eyes (3.2%) experienced mild, moderate, and severe dry eyes, respectively. Following a month of MSICS surgery, 22 eyes(34.9%), 19 eyes (30.2%) and 1 eye (1.6%) had mild, moderate and severe dry eye respectively. The mean values of dry eye indices were normal preoperatively and significantly reduced during the one-week and one-month postoperative period.

Conclusion and interpretation:

The dry eye illness began to manifest right away following cataract surgery and peaked on day seven. Over time, symptoms of dry eye can lessen. Despite strong visual recovery, dry eye illness is a typical post-cataract surgery complaint that negatively impacts patient satisfaction and must be assessed and treated promptly.

Keywords: Cataract Surgery, Tear film, dry eye, Prospective study

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INTRODUCTION

1.INTRODUCTION

A near- or distance vision impairment affects a minimum of 2.2 billion individuals worldwide. [1] The cause of vision loss and blindness were cataract and refractive errors. A cataract is impairment of lens transparency brought on by the lens' opacification.[2] Globally 94 million people were addressed with vision loss due to cataract.[1] In 2020, cataract (15 million) instances was the main cause of blindness in 50 years old. [3]

The prevalence of cataract in India was 62.6% based on the survey by "National Programme for Control of Blindness and Visual Impairment".[4] Over the age of 50 year India's population started increasing between 2001 and 2020 ,despite a decline in the occurrence of cataract blindness, which resulted in a rise in number of cataract patients from 7.75 million in 2OO1 to 8.25 million in 2O2O.[5]

With significant improvements in activities of daily living, lower mortality, and immediate increases in visual acuity, cataract operation is most important clinical management. Some of the methods used in cataract surgery include intracapsular cataract extraction, manual extracapsular cataract extraction, Manual small incision cataract surgery, Phaco-emulsification, femto-second laser assisted cataract surgery, and refractive lens exchange. Even though cataract surgery can improve visual acuity in up to 95% of patients, there are still risks involved.[6]

A common adverse effect of cataract surgery is dry eye disease (DED), which lowers postoperative patient satisfaction and results in substandard visual acuity.[7] One significant elements impacting old individuals quality of life is dry eye. [8]

“Dry eye disease was anticipated to affect 11.59% of the world's population, and the estimated prevalence of symptoms was 9.12%, with women accounting for 9.5% and males for 6.8%. [9] In Asia, the estimated pooled prevalence of DED was 20.1%, and the incidence was 16.7%, according to a systematic review and meta-analysis by Cai Y et al. Males and females, respectively, had a prevalence rate of DED of 16.4% and 21.7%.[10] According to a meta-analysis by Kitazawa et al[11], DED affects 9.2% of people 60 years and older, and the odds ratio of ageing compared to younger age is 1.313 and concluded that ageing has a significant impact on the ocular surface microenvironment, which contributes to DED.”

Cataract surgery being an intraocular procedure, ocular surface damage occurs microscopically, which may exacerbate any ocular surface diseases already present or result in dry eyes.[12] The association of Cataract surgery with dry eye had 1.8 odds of risk. [13]A dry eye is a disorder is brought on by inadequate or disproportionate evaporation of tears, by which interpalpebral ocular surface is damaged and accompanied by symptoms of ocular discomfort. [14] Many more dry eye symptoms, including a sense of a foreign body in the eye, blurring of vision, sensitivity to light and eye redness, may be experienced by those who are affected.[15]

These symptoms commonly appear after cataract surgery and in some cases, they last until a successful remedy is found. [8]

The procedure of performing cataract surgery causes ocular inflammation, which may have a negative impact on patients' tear-film integrity and formation.[16]This postoperative dry

eye might have an adverse influence on visual acuity results and the length of visual recovery duration. [17]

The continued use of eye drops, reduced tear film breakup time at the incision site due to surface irregularities , dropped mucin production from the conjunctiva as a result of incision placement, reduced corneal sensation which interrupts the corneal-lacrimal gland loop as a result of surgical incision resulting in poor tear film production ,reduced tear secretion, and poor stabilisation owing to surgical inflammation are aspects that allow to the occurance of dry eye after cataract surgeries. [18]

A meta-analysis and systematic review by Miura et al reported that 37.4% of patients developed dry eye followed by cataract surgery and stated risk factors for dry eye after cataract surgery includes, female sex, systemic illnesses, age ,systemic drugs, psychological issues, previous DED, MGD, eye drops containing preservatives , operating procedures, and lifestyle. Following cataract surgery, DED severity peaked 1 POD continued to last for 1 to 12 months. As a result, regular DED follow-up is advised for at least 1 month.[19]

Tear film was disrupted during cataract surgery which leads to DED. Limited studies were available for assessment of eye dryness followed by MSICS among South India . Hence, this study was an opportunity to determine the prevalence of dry eye and to evaluate tear film followed by Manual Small Incision Cataract Surgery.

AIMS
AND
OBJECTIVES

2.AIMS & OBJECTIVES

AIM

- To determine the effect of manual small incision cataract surgery on pre corneal tear film for the diagnosis of dry eye among cataract patients admitted for surgery in a tertiary care centre.

OBJECTIVES

- To estimate the prevalence of dry eye following manual small incision cataract surgery.
- To evaluate the precorneal tear film following manual small incision cataract surgery.
- To assess the severity of dry eyes following manual small incision cataract surgery.

HYPOTHESIS

Alternate hypothesis

- There was a change in the pre-corneal tear film following manual small incision cataract surgery and the incidence of dry eye was high.

REVIEW

OF

LITERATURE

3.REVIEW OF LITERATURE

The literature reviewed and discussed in the following headings

- Manual Small- Incision Cataract Surgery
- Dry eye disorders
- Tear film and Evaluation of pre-corneal tear film
- Prevalence of dry eye followed by Cataract surgery

MANUAL SMALL INCISION CATARACT SURGERY

The most prevalent easily treatable cause of blindness worldwide is cataract, or opacity of the eye's lens.[20] The Opacification or clouding of the eye's normally clear lens or its capsule (the transparent membrane surrounding the lens) is defined as cataract , which prevents light from passing and onto the retina of the eye through the lens. [21]

One of following techniques is utilised to retrieve the lens from mature cataracts because their nuclei are extremely hard:

- Extracapsular cataract removal: a preferred procedure
- Intracapsular cataract extraction is a dated procedure that is rarely utilised because of its drawbacks.
- Manual Small Incision Cataract Surgery

- Phaco-emulsification is an ECCE modification that results in quicker visual recovery and reduced astigmatism.

- Recent innovation now being tested: laser phacolysis

MSICS

A small incision method of ECCE, which is of low cost known MSICS sometimes known as SICS or SECCE, is mostly used in underdeveloped nations. The benefit of a self-sealing sutureless wound is seen in MSICS over conventional ECCE. [(22)] 12.O mm incision size for ICCE, 1O.O mm for extracapsular cataract extraction (ECCE), 6-7 mm for MSICS, and roughly 2.2-2.8 mm for phacoemulsification. Over time there has been sturdy decrease in incision size for a cataract extraction. [23]

Technique

Peribulbar anesthesia was given after achieving sufficient mydriasis with hemostasis being performed with bipolar diathermy cautery , bridle suture applied to superior rectus , and a fornix-based flap in conjuctiva is established for creating a sclero corneal tunnel.

1.5 mm posterior to the limbus, a curvilinear partial-thickness scleral incision of size 6.5mm to 7mm is created. There have been several types of incisions mentioned, including the straight, frown, smile, and chevron shapes. A soft cataract requires a smaller incision, but a hard, dense cataract requires a larger one.

For a cortical cataract, the incision is typically large for(6 to 7 mm)for dense cataract (such as 4+ nuclear sclerosis), it is 7 to 8 mm long. The depth ought to be about 0.3 mm. [24]

For easier additional intraocular manipulation, a side port was made. Tryphan blue was used to stain the anterior capsule. continuous curvilinear capsulorexhesis done followed by hydro dissection. Above and behind the nucleus, viscoelastic should be injected, causing it to prolapse into the anterior chamber. With the help of wire Vectis and sinskeys hook nucleus was delivered out by sandwich technique. Cortical was done using Simcoe cannula. Posterior chamber Intra Ocular Lens was placed in capsular bag. Anterior Chamber wash should be given. Subconjuctival Injection of dexona with gentamycin should be given. Scleral pocket incision which was unsutured was verified to be watertight .[25]

DRY EYE DISORDERS

"Dry eye is one of the most emblematic reasons for an visit to the eye doctor, which is also known as dry eye disease, dry eye syndrome, and keratoconjunctivitis sicca (KCS). [26]Dry eye disease or dry inflammation of the cornea and conjunctiva is referred to by the Latin phrase "keratoconjunctivitis sicca." Swedish ophthalmologist Henrik SC Sjogren originally invented the phrase, which Andrew De Roetth revived as "dry eye" in 1950. [27]Inadequate or excessive tear evaporation affects the interpalpebral ocular surface, causing dry eye, a tear film disorder that is associated with ocular discomfort."

Definition

"The recent definitionby Dry Eye Workshop II (DEWS II) of the Tear Film and Ocular Surface Society (TFOS) defined that Dry eye is a multifactorial condition of thetears andocular surface that causes symptoms of pain, blurred vision, and tear film instability as well as the risk for ocular surface injury. Along with it, the ocular surface becomes inflamed and the tear film's osmolarity increases.[14] According to the Asia Dry Eye Society, dry eye is a

multifactorial condition marked by an unstable tear film that can result in a variety of symptoms, including vision loss, and may also be coupled by ocular surface defects. [28] Depending on the diagnostic standards used, the prevalence of dry eye illness has varied from roughly 5 to 50% in population-based research." [29]

Types

Evaporative dry eye disease which is also known as aqueous deficiency are the 2 traditional classifications for the condition. [26] The causes such as Sjogren syndrome, obstruction in lacrimal glands , or systemic drugs that affect tear production results in insufficient tear production, known as aqueous tear deficit. The most common cause of evaporative dry eye is MGD,which is characterised by increased tear film evaporation. Vision blurriness, a persistent feeling of a foreign body in the eye, and chronic ocular irritation are all signs of dry eye disease (DED). [30] Gritty sensations, paradoxical tearing ,discomfort, photophobia, burning, tired eyes, fluctuating vision, stinging, and are some of the initial signs of aqueous deficiency dry eye (ADDE). Artificial tears do not properly relieve the burning that evaporative dry eye patients typically experience.

TEAR FILM

The precorneal film is thin liquid film covering cornea. [31] The second ocular defence surface next to eyelids is tear film.Cornea Goblet cells, Meibomian glands, eyelids, conjunctiva, and sensory and motor neurons which is the integrated lacrimal functional unit (LFU), that connect them, controls tear film. [32] The most vulnerable area exposed to the environment is the ocularsurface. A normally functioning tear film is essential maintain the health of epithelial cells and also maintain a smooth surface for light refraction and provide comfort ocular surface.

The functions of tear film are [33]

i. It gives protection to the most environmentally exposed mucosal ocular – surface

ii. Through reflex tearing it flushes out the, potential pathogens, irritants, allergens, , and pollutants.

iii. Providing a smooth ocular surface through continuous lubrication for refraction.

iv. The crucial factors for protecting the health of the conjunctiva and cornea and for promoting wound healing are antimicrobial elements, including lactoferrin, lysozyme, peroxidase, and immunoglobulins.

v. It also provides electrolytes, growth factors and glucose and eliminates free radicals from epithelium of the cornea.

vi. Main physiochemical properties of tear film are described as follows: [34]

Physiochemical properties of the Tear film	
Properties	**Values**
Volume	7–9 µl
Basal secretion rate	1-2 µl
Thickness	6.5 µm
pH	7.3 to 7.7
Osmolarity	296 to 308 mOsm/l
Refractive Index	1.3361 to 1.3361 to 1.3379
Viscosity	1 to 100 cps
Evaporation rate	10.1 x 10-7 gm/cm2/s

Several studies have shown that the steady volume of tears in an un-anaesthetized eye is 7.4 and for an anaesthetized eye, it is around 2. 6µl. Tears are also highly concentrated in proteins than other body fluids which help in wound healing.[35]

Layers of Tear- film:

A three-layered structure of the pre corneal tear film in 1946 was identified by Wolff initially. [36]The tear film is heterogeneous consists of three main layers such as

1. Outer layer - lipid
2. Middle layer - aqueous
3. Inner layer - mucin

Lipid layer (The meibomian oil layer)

The secretions from the meibomian glands, released from margins of the lids and dispersed across pre corneal tear film with subsequent blink forms the tear films lipid layer. It is around 1OO nm thick, composed of, free fatty acids, phospholipids and cholesterol. Precorneal tear film's surface tension is reduced by the action of the surfactant, which maintains stability between blinks and delays tear evaporation. When the glycocalyx is contaminated with too much lipid, the outcome is tear film instability, but when there is an insufficient lipid, fast evaporation occurs. [37]

Middle aqueous layer

The aqueous layer, a mucogel composed primarily of water (98%), proteins, growth factors and salts, makes up more than 90% of the tear film. The lacrimal and auxiliary lacrimal glands has the functions of lubrication, and infection prevention which is secreted by mid layer. By draining tears and turning them over while blinking, the ocular surface is cleansed and other dangerous compounds are eliminated. Because of toxic substances on the surface an excess of tears brought on by inadequate drainage might promote inflammation on the surface, hyperosmolarity may result due to lack of tears and hinder many actions.[38]

Inner mucin layer

Glucose, immunoglobulins, proteins, and urea,which are the primary components of the aqueous layer, a mucogel composed primarily of water (98%),growth factors , salts, proteins, makes up more than 90% of the tear film. By draining tears and turning them over while blinking, the ocular surface is cleansed and other dangerous compounds are eliminated. Hyperosmolarity may be due to retentionof toxic substances on the surface.[38] By the goblet cells of the conjunctival epithelium and, to a lesser extent, by the acinar cells ofthe

lacrimalglands these toxins are released. [39] By making up the glycocalyx, the mucins membrane associated are in charge of preserving the wettability of the ocular surface. Their attachment to the epithelial cells of cornea ' microplicae raises the tension of adhesion factor for water, which makes it easier for tears to travel across the ocular surface.[40] They also provide epithelial cells with a physical defence against harm and infection. The mucin layer ranges in thickness from 0.02 to 0.05 m. This layer's primary function is to keep the aqueous layer stable.This layer adheres to the glycocalyx to anchor the middle aqueous layer and maintain stability and surface tension.

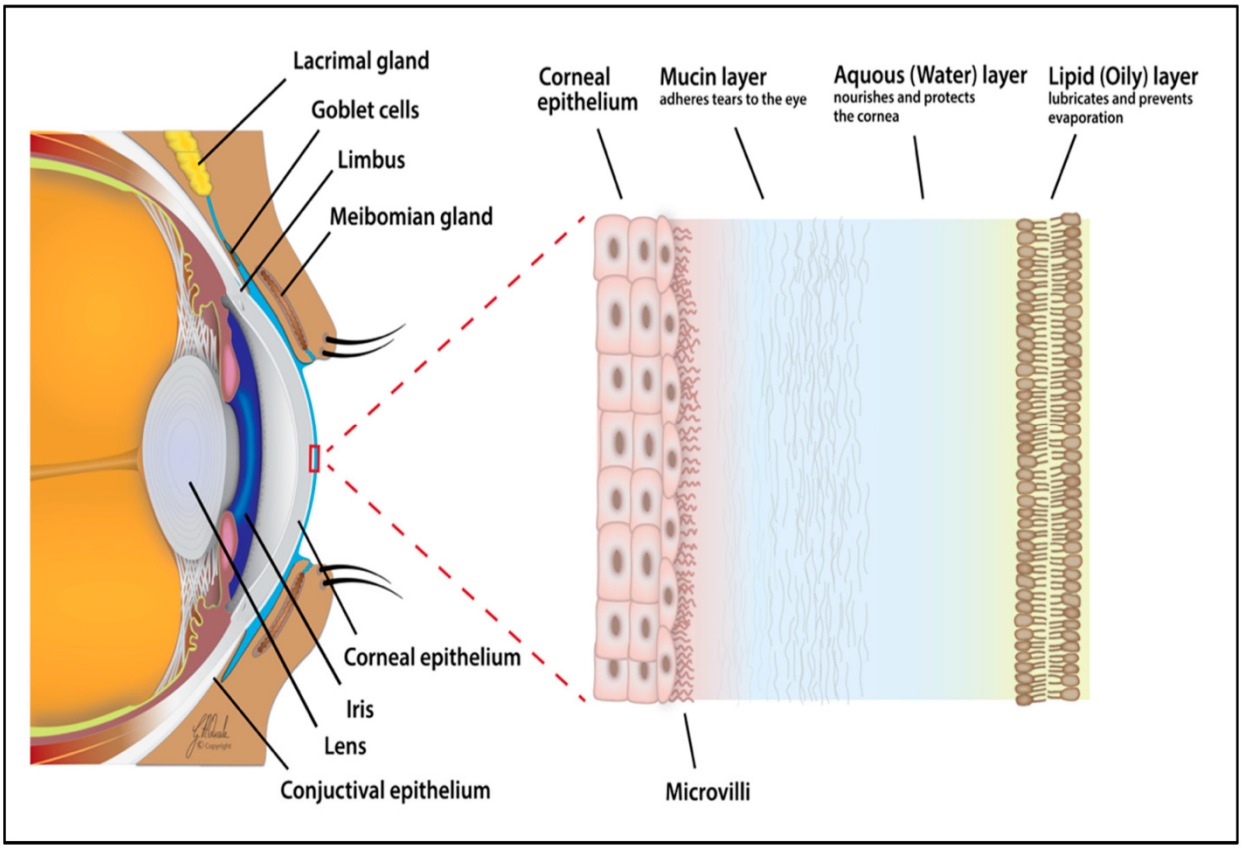


figure 1:TEAR FILM LAYER

The tear formation is well regulated by innervation of both parasympathetic and sympathetic in lacrimal and meibomian glands and goblet cells. Trigeminal afferent nerves deeply innervate the ocular surface. These nerves' impulses serve asthe building blocks of a

reflex circuit that causes the production of tears. [41] The menisci, which lie in-between the globe and lid margins permit the tears to move towards the lacrimal puncta and canaliculi and finally drain into the nasolacrimal system. pain, irritation, and temperature activates the parasympathetic response and leads to increase tear production whereas the sympathetic impulse is mainly from the conjunctival epithelial cells.

Types of tears

The tears are classified into three types which are

- Basal tears – nutrients to the ocular surface are given by, present on the ocular surface and act as a constant shield between the eye and environment.
- Reflex tears – mainly secreted in response to irritants or any stimuli. This mainly helps in washing away of harmful irritants. Because of that, it is secreted more than basal tears[42]

EVALUATION OF TEAR FILM

The assessment of dry eye illness cannot be made solely based on one "gold standard" symptom or sign. It is recommended to evaluate both symptoms and signs of dry eye illness because threre can be signs without symptoms and vice versa.

"The Outcomes Research Group at Allergan (Irvine, CA, USA) created the OSDI, a 12-item survey that assesses vision-related functionality. Subjective dry eye symptoms were rated quantitatively from 0 to 4 using the OSDI score, and the sum of these scores was included in the analyses. Three subscales make up this questionnaire: the ocular symptoms scale (three questions), the vision-related functions scale (six questions), and the environmental triggers scale (three questions). On a five-point scale,"None of the time" receives zero points, "All ofthe time" receives four points, and "N/A" is selected when a

question is irrelevant.[43] The total OSDI score ranges from 0 (no symptoms) to 100 (maximal symptoms) after each item is given a 5-point rating. [44]A score ≥ 13 indicates of dry eye disease based on OSDI.[45]"

Standard Patient Evaluation of Eye Dryness Questionnaire (SPEED)

"SPEED questionnaire was also used to assess dry eye based on subjective symptoms and signs. [46] SPEED assesses both the frequency and seriousness of symptoms in just eight questions,. On a measure of zero to four, the patient rates the severity of her symptoms, with zero denoting no symptoms and four denoting severe symptoms. Each response's numerical value is added, with scores ranging from 0 to 28. The questionnaire is designed to ask patients about their symptoms in the last three months and the present because of the unpredictability of time. [47]"

TBUT

TBUT was assessed with observation of lipid layer of tear film traditionally.[48,49].The interval between a full blink and the emergence of the first dry spot is TBUT. Fluorescein dye has been injected into the conjunctival sac and the patient's eye opened and subjected to cobalt blue light from a slit lamp, the time to tear breakup is evaluated during the TBUT test.[50] It's common knowledge that dry eye illness is associated with a cut-off time of less than 10 seconds.

The Keratograph M device was recently used to create a non-invasive TBUT test to detect the tear breakup time without the use of fluorescein dye (K5M; Oculus Optikgerate, Wetzlar, Germany) [51]

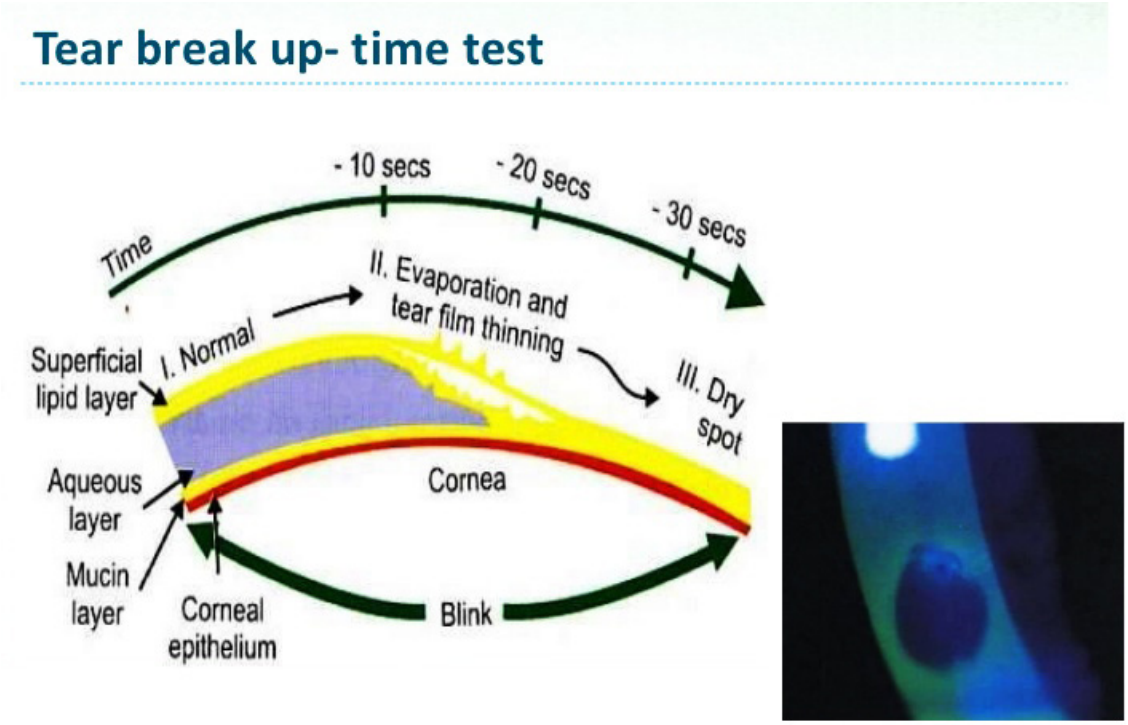


figure 2: TBUT

Blinking tolerance time test

The room's humidity and temperature were carefully maintained at 40% to 60% and 23° to 26°, respectively. Electric fans and air conditioners were not in operation when the inspection was taking place. Subjects are made to sit on examination chair with eyes closed for the BTT testing. The investigator directed each subject to fix their eyes on a visual object that was 3 metres distant as well as to maintain them open.Using a stopwatch, researcher assessed duration of time untill eyes were open without blinking, or the period between the previous blink and the inevitable next blink, to an accuracy of 0.1 seconds. The participant's next inevitable blink was caused by annoyance or pain. Test was carried out with eyes as open as possible participants were advised not to open their eyes. Results were calculated based on 3 successive measures taken by the examiner in order to assess the intra-examiner

repeatability. To provide reliable and repeatable data, the participants were given a rest for at least 30 seconds in between each measurement. [50]

Tear volume assessment

Schirmer's test

Tear volume is assessed by schirmers test. [49]This test, which Schirmer first introduced in 1903, is still one of the utmost widely used indicators of tear formation. [52]The ST I assesses reflex and basal tears. The Schirmer II test is a variant that exclusively evaluates reflex tears with topical anaesthetic. The lower lid margin's temporal third is covered with a short paper strip with rulers, with the folded end placed within the inferior conjunctival fornices. After five minutes, the strips are removed, and the number of tears that were created during that period is determined by counting down the millimetres of soaking. This test can be done under anaesthesia or without, and there are several ways to interpret the results, but typically, less than 10mm of tear production in 5 minutes is indicative of dry eye.[53]

figure 3: ST

Tear function index

Another procedure for examining production of tears similar to the anaesthetized ST is tear function index. The intensity and length of the wetted area are matched with roughly like a standard colour strip five minutes just after injection of a 10 drop of fluorescein and assessed. The pace at which the fluorescein dye's colour diminishes determines the tear clearance rate. The ST with anaesthesia value, which represents tear drainage, is then separated by the clearance rate of tear to get the index.[54] An index score of less than 96,indicated as dry eye while Sjogren's syndrome is indicated by an index score < than 34. [55]

Tear Meniscus Assessment

The tear quantity laying at intersection of the lower eyelid and bulbar conjunctiva, sometimes known as the tear lake is defined as meniscus. The presence or absence of dry eye is assessed by measurements of height and curvature of tear meniscus. [56]The inferior tear film meniscus height is examined and used to assess the tear meniscus which is a tear volume assessment. Despite being straightforward to use, this method has poor intervisit repeatability.[57] Tearscope-Plus (Keeler Ltd, Windsor, UK) measures are more consistent than slit-lamp biomicroscopy, which can accurately detect lower tear meniscus height without staining.[58] Regardless of technique used to measure tear lake, a healthy patient's tear meniscus height ranges from O.2 to O.5 millimetres, however in cases of dry eye, it is typically less than 0.2 millimetres. [59]

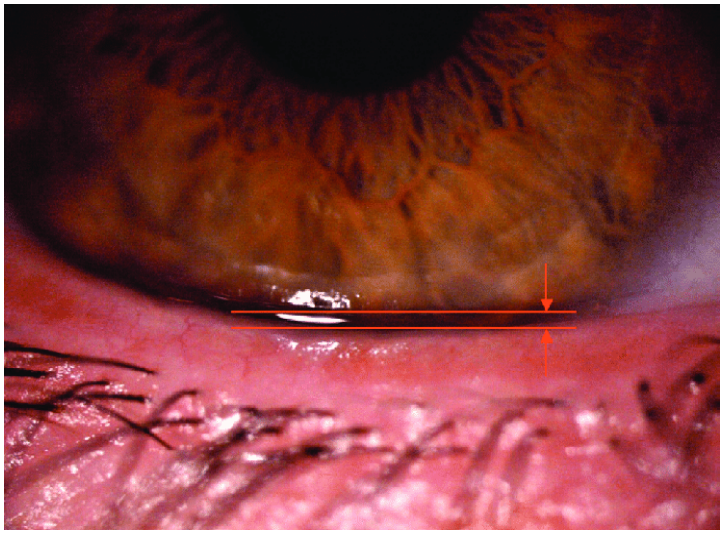


figure 4: Tear Meniscus Height assessment

Phenol red test

A cotton thread stained with phenol red looped over the eyelid temporally and into the sulcus. This procedure is similar to Schirmer testing. Clinical cut-off values range from less than 1O to 2Omm, and the thread appears red when wet.

Fluorescein staining

The evaluation of corneal injury and ocular surface assessment is possible with fluorescein staining. The best viewing occurs after application of the fluorescein into the tear film one to three minutes later. [60] There are several grading methods utilised, including the Oxford grading scale, and more than 5 staining spots are regarded as a positive result. [61]

Lissamine green staining

Lisssamine green staining is an ocular surface assessment in which lissamine used in the evaluation of lid margin, cornea and, to a lesser extent, conjunctival injury. Positive results are those with more than 9 spots. Lid wiper epitheliopathy, also knownas, staining of the lid margin can be diagnosed if there is staining of at least 2 mm length.

Rose Bengal test

Rose Bengal is a mildly poisonous brilliant red stain that adheres to damaged epithelium cells, mucus, and fibrous tissue and absorbs them. [62]Areas of the cornea or conjunctiva without membrane-associated mucins exhibit rose-bengal (RB) staining. [63]It serves as a metric for evaluating ocular surface damage. The inferior fornix was stained with sterile, commercially available Rose Bengal strip that had been soaked with 4% xylocaine. After 15 seconds, the eye was inspected under slit lamp to check for staining of the cornea and conjunctiva. Based on a scale of 0 to 3 in three areas—the nasal conjunctiva, temporal conjunctiva, and cornea. To rate the staining of the cornea and conjunctiva the VanBijsterveld scoring system employed. A positive test result was known as an additive range of 4 or higher. [64]

figure 5: Rose Bengal staining

Tear film osmolarity

Greater variability of osmolarity and elevated osmolarity of the tears defines the dry eye. With illness, severity comes an increase in osmolarity readings. There have been reported to be a number of cut-off values, with 3O8mOsm/L being cutoff to assess mild - moderate disease and 316mOsm/L being used for more severe disease.[45]

Matrix metalloproteinase – 9

Matrix metalloproteinase-9 (MMP-9) levels can be determined in people who have dry eye. [65]

Emerging technologies[27]

- Reflective meniscometry
- Optical Coherance Tomography
- Tear film stability analysis test
- Interferometery
- Tear normalization test

Management[26]

- Treatment of dry eye syndrome depends on how severe the condition is in a step-by-step manner. [66]
- Initial approaches are explaining about the condition, environment modification (reducing screen time, eliminating direct high airflow/fans), topical tear substitutes, lid hygiene (warm compresses and lid scrubs),identifying the causative topical or systemic agents , and oral essential fatty acids are some of initial approaches.
- The options for the next stage of treatment include intense pulsed light therapy, expression of the meibomian glands, preservative-free ocular lubricants, nighttime ointment or moisture goggles, reversible punctual occlusion (punctal plugs), topical corticosteroids, cyclosporine, and oral antibiotics macrolide or tetracycline.
- Amniotic membrane grafting, therapeutic contact lenses, serum eye drops, surgical punctal occlusion, reversible punctual occlusion (punctal plugs), and tarsorrhaphy are other treatment options include.

CATARACT SURGERY AND DRY EYE

A dry eye is due to a drawback of surgical treatments, where the sensory nerves found on the surface of the eye may unavoidably sustain injury. The corneal sensation is decreased in the absence of accurate sensory detection, which reduces basal and reflex tearing as well as blinking frequency. Additionally, sensory denervation will prevent the lacrimal gland from producing tears, which will result in less tear secretion.[(32)] The lipid layer of the tear film might become thinner after cataract surgery and become unstable, leading to dry eyes. Corneal nerve injury sustained after surgery might be the reason for decreased tear production. The human body's largest concentration of sensory nerve endings is found in the cornea. The loss of cytoskeletal structures, increased permeability, lower metabolic activity, and impaired epithelial wound healing are all possible side effects following the transection of these nerves. Clinically, we can see a decline in corneal sensitivity followed by a decline in tear production, which results in dry eyes with insufficient aqueous tears.[67]

The mucinous portion of the tear film is created by goblet cells. Therefore, it seems sensible that a decrease in mucin-producing cells could undermine the tear film's integrity and result in an evaporative dry eye. There is an ongoing discussion on how the density of goblet cells decreases following cataract surgery, according to studies.[(67)]Goblet cells, which lubricate the eye, may be diminished by exposure to a narrow beam of microscope used by ophthalmic surgeons. [68]

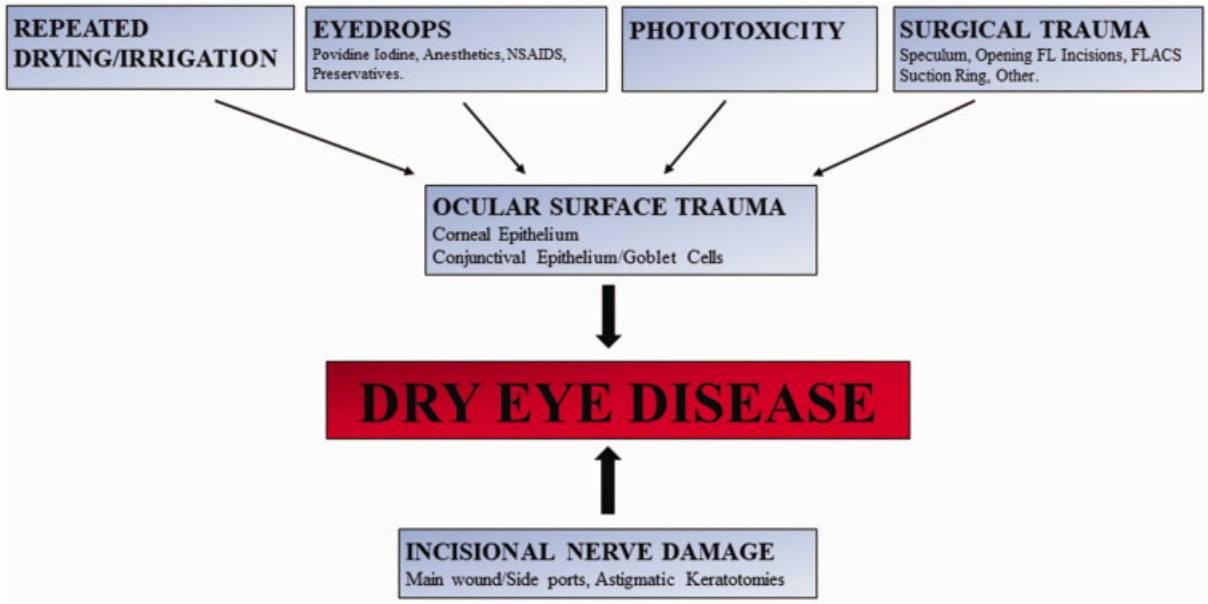


figure 6: Factors Dry eye disease due to cataract surgery

The eye drops which are applied before, throughout, and after surgery may have adverse consequences on the ocular surface, including damage to goblet cells, conjunctival epithelial cells, and corneal epithelial cells. After cataract surgery ocular surface was exposed and is susceptible to repeated cycles of drying followed by irrigation to maintain postoperative optical clarity. The corneal and conjunctival surfaces could thereby sustain injury. Both laboratory and clinical research have proven the working microscope's light has phototoxic effects on the ocular surface. [69]

Following surgery, pre-existing dry eye is also known to get worse, which increases the risk of problems and has less favourable visual outcomes. [70]

Age, female gender, chronic illnesses, chronic drugs, psychiatric problems, previous DED, MGD, preservatives added in eye drops, surgical methods, were risk factors for DED after cataract surgery. Following cataract surgery, DED severity peaked at 1 day after the procedure and continued for at least 1 to 12 months. As a result, regular DED follow-up is advised for at least 1 month. [19]

PREVALENCE OF DRY EYE FOLLOWED BY CATARACT SURGERY

Li X et al in China studied fifty cataractous eyes that underwent surgery and found that the mean ST1 values were 9.87 5.62, 8.20 4.84, 5.67 4.32 and 7.93 4.96 during preoperative, postoperative at one week, post-operative at one month and post-operative three months period.[8]

The mean Schirmer test value was 32.1±3.005 mm preoperatively and it was reduced to 21.12±6.448 mm in a one-week post-operative period. Further, the values were tested during 4 weeks (19.64 ± 6.691) and 12 weeks (18.80 ± 7.393) of a post-operative period which shows reduction after MSICS among cataract patients by Bista B et al research in Nepal.[71]

Lakshmi PS et al in Andhra Pradesh conducted a study among 100 eyes of cataract patients and found that the preoperative TMH (Tear Meniscus Height) study revealed that all individuals had normal TMH values. At 0ne week, 0ne month, and 3 months after Manual SICS (Manual Small Incision Cataract Surgery) respectively, 23%, 29%, and 24% of patients had low TMH, which was statistically significant. All of the participants exhibited normal TBUT (Tear film break-up time measurement**)** values before surgery, according to the TBUT analysis. 6%, 23%, and 8% of patients had low TBUT readings at 0ne week, 0ne m0nth, and three months after surgery, respectively. In the 3-month follow-up period, 92% of the patients had returned to normal values, which was statistically significant. Prior to surgery, ST **(Schirmer test)** analyses were entirely normal in all patients. At post op 0ne week, 0ne month, and 3 months in 0%, 3%, and 0%, there will be low Schirmer values respectively. All patients recovered ST1 values of greater than 10 after 3 months following surgery, which was statistically significant. During the postoperative period at one week 22%, 6% and 1% of

patients were found to have mild, moderate and severe dry eye based on the RBstaining .29%,15% and 7% of them had mild, moderate and severe dry eye based on the RB test at one month of post-operative period. 23%, 11% and 3% of them were diagnosed with mild, moderate and severe dry eye based on the RB test.[72]

Gupta V et al from Jammu and Kashmir evaluated precorneal tear film after Manual SICS among fifty patients and found that at pod 0ne week, 0ne month, and 3 months, MH analysis revealed that 22 (44%), 38 (76%), and 31 (62%) had low TMH, that was significant statistically. The TBUT analysis revealed that low TBUT values (less than 10 seconds) were present at 0ne week, 0ne month, and 3 months following surgery in 18 (36%), 23 (46%), and 18 (36%) respectively. At 0ne week, 0ne month, and three months following surgery, 21-42%, 26 -52%, and 9 -18% patients, respectively, had low ST1 (less than 10) values. At 0ne week, 0ne month, and three months following surgery, RB test examination revealed that, correspondingly, 21 (42%), 26 (52%), and 9 (18%) patients exhibited aberrant values (score more than four).[73]

Ishrat S et al in a study in Madhya Pradesh among hundred eyes undergone Manual SICS (64 eyes) and phacoemulsification (36 eyes) described that 53.1% and 22.2% of them had dry eyes at one-week postoperative period respectively in SICS and phacoemulsification group. Compared to preoperative observations, the TBUT values were significantly lower at one week into the early postoperative phase (mean 8.7, SD 0.48 sec vs. Mean 15, SD 0.31 seconds and a p value of 0.001). At 1-month follow-up, the substantial difference was still discernible (mean 11.2, SD 0.39 seconds vs. Mean 15.8, SD 0.31 seconds and a p value of 0.001). Anyhow, as TBUT continued to improve, this difference ceased to be significant at three months (mean 14.3±O.37 sec vs. 15.8 ±O.31 sec p = O.O89). Preoperative results when compared, all patients' early postoperative ST-1 scores at one week were lower (mean 15.2,

SD 0.64 mm vs. mean 24.5, SD 0.59 mm and a p value of 0.001). The substantial relationship was still present at the 1-month (19.7± 0.60 versus 24.5± 0.59 mm, mm p value - 0.001. and 3-month (21.8± 0.64 vs. 24.5± 0.59 mm, p 0.001) follow-up visits. 27%, 11% and 4% of eyes had a mild, moderate and severe dry eye at one week of the postoperative period respectively. 12% and 3% of eyes had a mild and moderate dry eye at one month of the postoperative period respectively. 7.1% and 3.5% of eyes had a mild and moderate dry eye at 3 months post-surgical period respectively.[18]

Dry eyes affected 92.9% of participants who underwent SICS after one week and 26.8% of them after a month of the procedure. The mean ST value was 27.22±4.4 mm during preoperative but it was reduced during one week (12.91±2.95) and one month (24.61±6.32) of post operative period. The mean TBUT value was 13.5±1.89 seconds during preoperative but it was reduced during one week (9.64±2.2) and becomes the same during one month (13.16±2.45) of post-operative period in a study done by Garg P. et al. in Lucknow with 176 cataract patients[74]

81 cataract patients who underwent SICS at Bagalkot, it was discovered that the Schirmer's test mean value was 18.21 mm, with an Standard deviation of 6.15 mm, and that the lowest and highest values were 8 mm and 30 mm, respectively, during a preoperative session. The ST1 mean value dropped to 10.14mm with an Standard deviation of 4.09mm one week after surgery, with the lowest result being 2mm and the highest being 18mm. The mean ST measurement at one month postoperatively was 14.62 mm a SD of 4.15 mm, with the lowest value of 7 mm and a maximum value of 25 mm. Before surgery, the TBUT was 11.10 seconds with a SD of 5.40, with the least value of 5 seconds and a max value of 25 seconds. On the first postoperative day, it was 5.82 with a standard deviation of 3.96, and one week after surgery, it had further decreased to 3.43 with a standard deviation of 2.79, either a

maximum level of 15 seconds or minimum value of 0 seconds. It reached 10.40sec with SD 4.5 after the postoperative month, with a lower limit of 3 seconds and a higher limit of 15 seconds in a study by Jayshree et al.[75]

In Karnataka with 68 patients who underwent cataract surgery using SICS, Venugopal K et al. discovered that 66.2% of patients experienced dry eyes. They were classified as mildly dry (53.32%), moderately dry (26.6%), and severely dry (20%).[76]

In Chengalpet, Tamil Nadu, among 100 patients who underwent MSICS cataract surgery, it was discovered that 69% of patients had a dry eye condition. 13%, 33%, and 23% of patients had mild, moderate, or severe dry eye illness, respectively. The mean Schirmer's test value was 21.168±0.327 mm during preoperative but it was reduced during one week (10.20±0.515) and three weeks (12.252±0.478) of post operative period. The mean TBUT value was 17.374±0.406 seconds during preoperative but it was reduced during one week (8.705±0.373) and during three weeks (10.961±0.386) of post operative period conducted by Patil M. et al.[77]

In a study conducted in Jhansi, India with 110 cataract patients who had MSICS, Kumar J et al reported that TMH analysis revealed that all individuals had normal TMH levels prior to surgery. At postoperative 0ne week, 0ne month, and three months, respectively, 29%, 34%, and 30% had low TMH, was statistically significant. All of the participants exhibited normal TBUT values before to surgery, according to the TBUT analysis. 8%, 26%, and 9% of patients had low TBUT readings at 0ne week, 0ne month, and 3 months during postoperative period. In 3-month follow-up period, 92% of the patients returned to normal values,was significant. ST1 analysis was all normal in the patients prior to surgery, Low ST1 values were present at POD 1 week, 0ne month, and 3 months in 0%, 5%, and 0%, respectively. All patients had statistically significant ST1 values of >10 after 3

months postoperatively. A statistically significant change in RB stain grading between preoperative, POD 0ne week, 0ne month, and 3 months was revealed by Rose Bengal stain analysis. [64]

According to a study by Kanfade et al. at Wardha, 100 patients who underwent cataract surgery showed signs of dry eye (89%) on the first postoperative day. Preoperatively, the Schirmer's 1 mean value was 16.78 mm, with an SD of 5.54 mm. The Schirmer's mean test result dropped to 7.03 with SD 5.17 after the first day of surgery. The Schirmer's test mean was increased to 7.15 mm with an SD of 5.08 mm 0ne week after surgery. The mean ST measurement was 10.45 mm with an SD of 5.97 mm, ranging from 4 mm to 30 mm, one month after surgery. Schirmer's test results from before surgery and those from the first day, first week, and the first month after surgery show a significant difference with a p-value less than 0.0001. The mean tear breakup time (TBUT) before surgery was 17.89 seconds with an SD of 6.98 in the TBUT trial. On the first postoperative day, the mean TBUT dropped to 7.24 seconds with an SD of 5.40, and after one week, it rose to 7.84 seconds with an SD of 5.22. The mean TBUT increased again one month after surgery to 13.23 seconds with an SD of 7.48. The mean TBUT had a maximum value of 28 seconds and the lowest value of 2 seconds. The mean TBUT values show a significant difference between pre-operative TBUT values and those of the first day, first week, and the first month following surgery with a p-value of 0.0001.[78]

According to a study by Shrivastava et al. in Maharastra, there was a substantial difference ($P < 0.05$) in the preoperative results (26.44±3.53)of the Schirmer's I test compared with the day 7 (17.3±5.28) and day 21 (18.14±4.39 mm) postoperative values in cataract patients with MSICS. However, there was no appreciable variation between the preoperative and day 90 (26.56±3.19) postoperative values ($P>0.05$).The preoperative values (11.12±0.96)

of TBUT also differed significantly from the day 7 (10.16±2.05)and day 21 (10.38±1.75 sec) postop values (P 0.05), whereas the day 90 postoperative values (11.2±0.90) were similar to the values before surgery and showed no statistical significant difference P value- > 0.05.[79]

MATERIALS AND METHODS

4.MATERIALS AND METHODS

5.1 Study Design:

- Prospective study

5.2 Study Area:

- Department of Ophthalmology, SRI DEVARAJ URS MEDICAL COLLEGE, TAMAKA, KOLAR

5.3 Study Duration:

- January 2021 – June 2022

5.4 Study Population:

- Patients with senile cataracts.

5.5 Inclusion Criteria:

- All grades of senile cataract irrespective of gender
- Patients with comorbid illnesses like Diabetes and Hypertension
- Pateinet who underwent uneventful cataract surgery.

5.6 Exclusion Criteria:

- Patients with ocular problems like dry eyes, glaucoma, uveitis, corneal dystrophy, corneal degeneration, lid disorders, nasolacrimal pathway disorders, pterygium, blepharitis, pseudoexfoliation, and ocular allergy.
- Patients underwent previous ocular surgery and refractive surgeries.
- Patients with a systemic illness like Sjogren's syndrome.
- Patients with a history of contact lens usage
- Patients on treatment with anticholinergic drugs, antidepressant drugs and antihistaminics and other drugs causing dry eyes.

5.7 Sampling Technique:

- Simple random sampling. The sampling frame was prepared based on cataract patients admitted for surgery and patients were selected randomly meeting the criteria from the sampling frame.

5.8 Sample Size:

- Sample size was calculated using the formula with 80% of power and 95% confidence intervals.

$$n = \frac{\sigma_d^2 (Z_\beta + Z_{\alpha/2})^2}{\text{difference}^2}$$

- Based on the mean difference in Mean tear film breakup time (TBUT) between pre-op and post-op from the research conducted by Lakshmi PS et al (pre-op TBUT value was 20.72 ± 5.37 and post-op it was 17.71 ± 5.02) with 10% nonresponse rate the estimated sample size was 63.

- n = 63

5.9 Study Instruments:

- Direct and Indirect ophthalmoscope
- Slit lamp biomicroscopy
- Goldmann applanation tonometer
- Ultrasound B scan
- Keratometry
- Schirmer's test – Schirmer's test strips, watch, clear adhesive tape and pen
- Rose Bengal strips
- Fluorescein strips

5.10 Operational Definition:

- Dry eye

    - Ocular surface multifactorial condition is known as dry eye disease (DED), an ocular surface disorder, also known by the names dry eye syndrome (DES), keratoconjunctivitis sicca (KCS), and keratitis sicca, is brought on by a loss of the tear film's homeostasis. Due to underlying tear film instability, ocular surface inflammation and injury, and neurosensory anomalies, it frequently causes ocular discomfort and visual disruption.[80]

5.11 Data Collection:

- Data was collected in the outpatient department of Ophthalmology among patients with senile cataracts.

- Pilot study was done by using 10% of the sample size. 6 patients were undergone a pilot study and they were excluded from the analysis.

- Evaluation of the patient with detailed history regarding their complaints to be taken.

Pre-assessment

- Thorough pre-operative evaluation was done on the day of admission with an emphasis of Refraction and uncorrected or best corrected visual acuity.

- Slitlamp biomicroscopy with emphasis cataract type, grading of the nucleus, pupil size, TMH, TBUT, ST ,RB staining was done.

- Posterior segment was evaluated using DO and IDO and IOP was recorded using the Goldmann applanation tonometer.

- Lacrimal syringing, blood pressure, and blood sugars were undergone in all cases. For the invisibility of the fundus, a B scan was performed.

- Preoperative keratometry value was done using TOPCON KR 800 keratometer and Intraocular lens power calculation by Sanders –Retzalff2(SRK method) Sight accutome. From all the participants informed oral consent was taken before surgery. The patient was advised to instill antibiotic drops and a xylocaine test dose.

Preoperative

- Lid lashes both upper and lower were trimmed before operation and using tropicamide -0.8% plus phenylephrine -5% eye drops eye was dilated .

- 1 drop of FBN was given for prophylaxis for the prevention of cystoid macular edema and miosis

- Under local anaesthesia-2% Lignocaine with adrenaline 1:1000 plus Hyalase used. Hyalase helps in spreading local anaesthetic in tissue spaces.

- After local anesthesia digital massaging was given to spread 5ml of it to achieve mild ocular hypotony. After drapping the eyelid ,placing wire speculum , superior rectus bridle suture applied .

- Conjunctival peritomy done superiorly .Hemostasis was achieved with bipolar cautery and a scleral incision was made with size of 6 to 6.5mm with 15 number blade.

- sclero corneal tunnel was made and paracentesis done at 9 o clock position a 15° side port entry blade in a clear cornea about 1 mm from the limbus. Air was injected into the AC.

- After diluting trypan blue -0.06% under the air bubble, the anterior capsule (AC) was stained. A bent 26G needle was used to execute a capsulorrhexis with a diameter of approximately 6 mm, replacing the air with 2% Hydroxypropyl methyl cellulose (HPMC), followed by mild hydro dissection.

- Visco expression caused the nucleus prolapsed into the AC and delivered out. Simcoe's cannula was used for cortical cleaning. In a capsular bag, a 6 mm optic size of single-piece Poly Methyl Methacrylate IOL with a was then implanted.

- Enough viscoelastic material (2% HPMC) was used at each intraocular phase to maintain the anterior chamber and safeguard corneal endothelium. An eye was given a subconjunctival injection of gentamicin with dexamethasone 0.4 ml at the conclusion of the surgery, and the AC was created with a balanced salt solution.

- Any intraoperative complication occurring during surgery was recorded.

Postoperative

- All patients should have their snellens vision and examinations performed on POD, and any changes in the cornea should be noted.

- Milflodex eye drops 0.5%, to be used hourly for 1 week, were given to all patients; the dosage was decreased over a period of 3 weeks. Followingsurgery, patients were examined one week, one month, and three months later.

- BCVA were measured each visit, along with corneal condition, intraocular lens position, postop inflammation, and posterior segment status, all of which were noted using a slit lamp examination. ST 1, Tear Meniscus Height , TBUT, and Rose Bengal staining were performed.

- The normal TMH is 0.2 – 0.5 mm. A TMH less than 0.2 was considered a low TMH (dry eye).

- After the application of 2% fluorescein dye the readings were taken using a cobalt blue filter under a slit lamp.The time between the full blink and the appearance of first dry spot is noted. TBUT dry eye was defined as lasting fewer than 10 seconds.

- Whatman N0.41 filter paper strips of five mm by thirty five mm were to determine dry eye by Schirmer's test. From the sterile packet, two Schirmer test strips were removed and marked "R" (to the right) and "L." (left). By placing a Schirmer paper strip at intersection of middle 2/3 rd and lateral 3rd of lower cul de sac for 5 minutes, ST1 was assessed.

- Strip was bent to a 90-degree angle and the patient was advised to look up and gently pull down the lower eyelid with their index finger. The patient was told to open both eyes, and the strip was taken out after 5 minutes.Dry eyes are those that have < 10mm of wetting.

Rose Bengal staining

- The inferior fornix was stained with RB strip that had been soaked with 4% xylocaine.

- Three sections of the conjunctiva—the nasal conjunctiva, the temporal conjunctiva, and the cornea—were scored using the Van Bijsterveld grading system on a scale of 0 to 3. Rose Bengal stain is graded as follows: O for absence, 1 for barely noticeable staining, 2 for moderate staining, and 3 for severely noticeable staining.

- A positive test result was defined as an eye cumulative rating of four or higher.

5.12 Measurement of Variables:

- Age was a continuous variable included in numbers

- Tear meniscus height,ST1,TBUT,RB staining was recorded as a continuous variable during the preoperative period, 0ne-day after surgery, 0ne-week after surgery, and three months after surgery.

- TMH was considered to be normal/low

- TBUT dry eye was defined as lasting fewer than 10 seconds. (Normal/dry eye)

- Based on Schirmer's test 1, Dry eyes are those that have less than 10 mm of wetting. (Normal/dry eye)

- An additive score of more than four in Rose Bengal stain was taken into account as dry eye.
- Presence of dry eye and their categorization was represented as categorical data. "Mild, moderate, and severe categories of dry eye were used.
    - Mild dry eye were ST1 less than 10 mm in 5 min, TBUT less than 10 s, and less than 1 quadrant of RB staining on the cornea were considered to have.

- The definition of moderate dry eye includes ST1 of 5–10 mm in 5 min and TBUT of 5–10 s with punctate staining of more than one corneal epithelial quadrant by RB.

- The conjunctival epithelium was described as diffuse punctate or confluent staining with ST1 less than 5 mm in 5 minutes and TBUT less than 5 seconds in cases of severe dry eye. The corneal epithelium was described as diffuse punctate or confluent staining (with RB), usually with filaments."

5.13 Data Analysis:

- In Microsoft excel data was recorded using 2019 version was analyzed using "SPSS (Statistical Package of Social Sciences) 21 version software."

- Categorical data and Continuous data were represented in the form of Frequencies (Mean ± Standard deviation) and proportions respectively.

- The paired values (pre-op and post-op) were analyzed for association using paired T-test for continuous variables.

- Test of association was tested by chi-square test (categorical variables) and independent T-test (continuous variables).

- P value <O.O5 was considered statistically significant.

5.14 Ethical Issues:

- Ethical approval was obtained from the Institutional Ethics Committee of SRI DEVARAJ URS MEDICAL COLLEGE, TAMAKA, KOLAR

- Patients were informed about the procedure of surgery, precorneal tear film evaluation and follow-up visits and their consent were obtained from them.

RESULTS

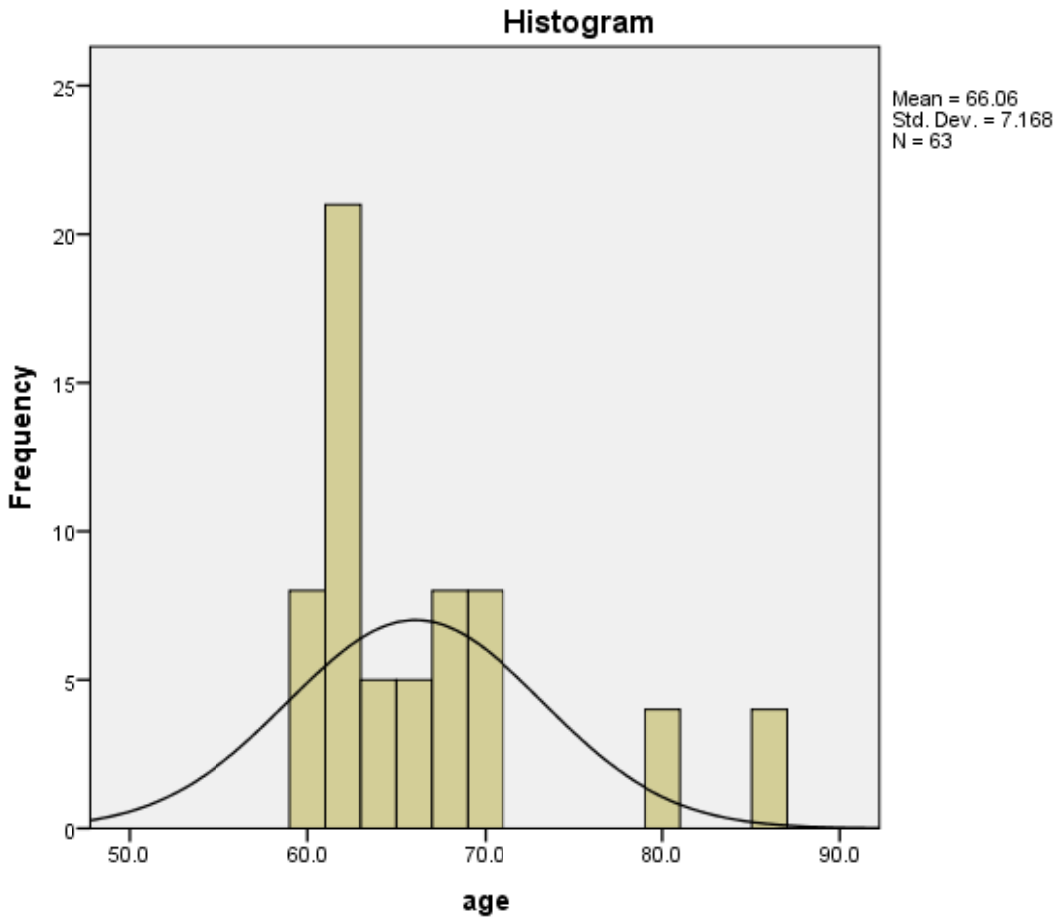
5.RESULTS

This study was conducted among 63 patients with cataract posted for manual small incision surgery to assess precorneal tear film.

DESCRIPTIVE STATISTICS

Age distribution

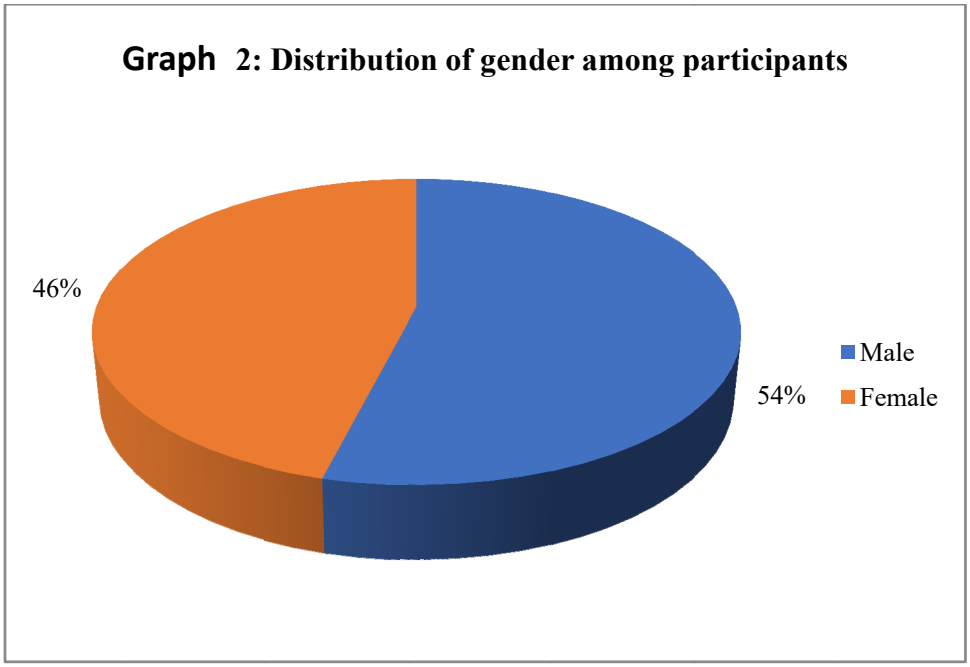
The mean age of participants was 66.06 ± 7.1681 ranging from 61 – 85 years. Age group follows normal distribution.



Graph 1: Distribution of age group among participants

Gender distribution

54% of men and 46% of women participated in this study.



Tear Meniscus height

The normal tear meniscus height ranges from 0.2 – 0.5. The mean TMH values varies from 0.215±0.143, 0.294±0.144 and 0.363±0.153 respectively during one week, one month and three months after post operative day.

Table 1: Descriptive Statistics of Tear Meniscus height

TMH	n	Minimum	Maximum	Mean	SD
TMH preoperative	63	0.20	0.80	0.410	0.118
TMH postoperative	63	0.02	0.56	0.215	0.143

after a week					
TMH postoperative after a month	63	0.05	0.50	0.294	0.144
TMH postoperative after three months	63	0.05	0.60	0.363	0.153

Schirmer's test

The mean Schirmer's test values vary from 11.35±4.820, 13.52±6.701 and 26.78±4.531 respectively during one week, one month and three months after post operative day.

Table 2: Descriptive Statistics of Schirmer test results

Schirmer's test	n	Minimum	Maximum	Mean	SD
Schirmer's preoperative	63	25	30	28.06	2.094
Schirmer's post-operative one week	63	7	25	11.35	4.820
Schirmer's post-operative one month	63	7	30	13.52	6.701

Schirmer's post-operative three months	63	8	30	26.78	4.531

Tear film break up time

The mean tear film break up time values vary from 8.25±1.606, 8.33±2.155 and 21.22±3.594 respectively during one week, one month and three months after post operative day.

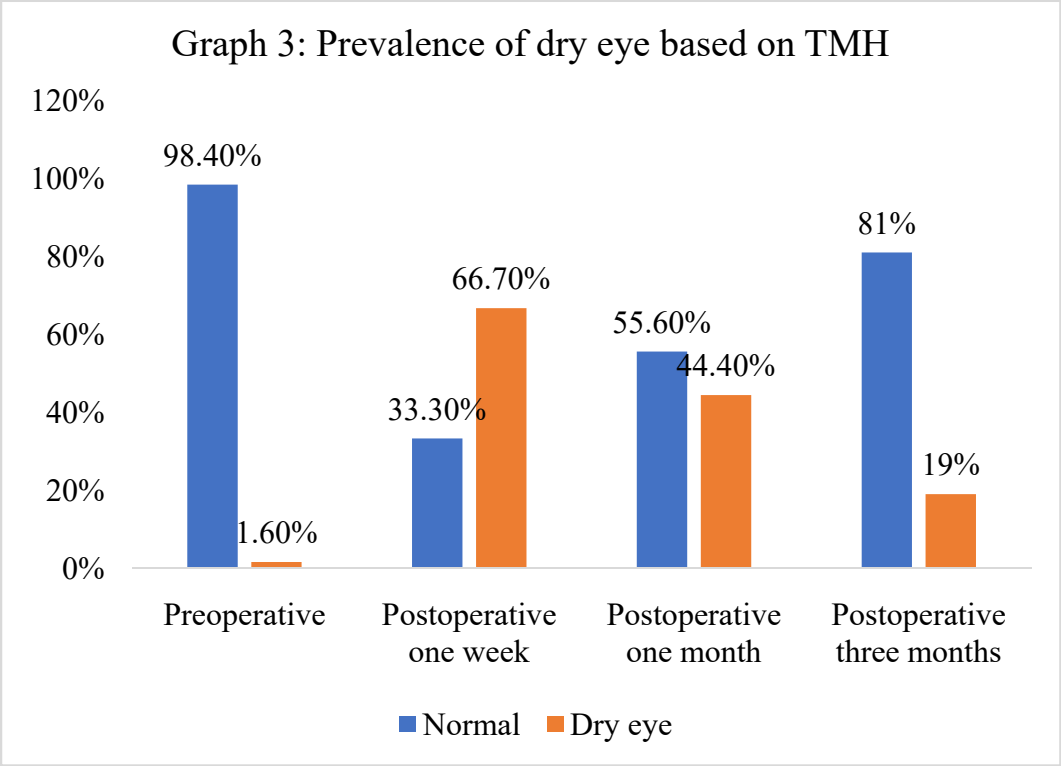
Table 3: Descriptive Statistics of TBUT test results

TBUT	n	Minimum	Maximum	Mean	SD
TBUT preoperative	63	18	28	22.49	2.078
TBUT post operative one week	63	5	10	8.25	1.606
TBUT post operative one month	63	5	20	8.33	2.155
TBUT post operative three months	63	7	26	21.22	3.594

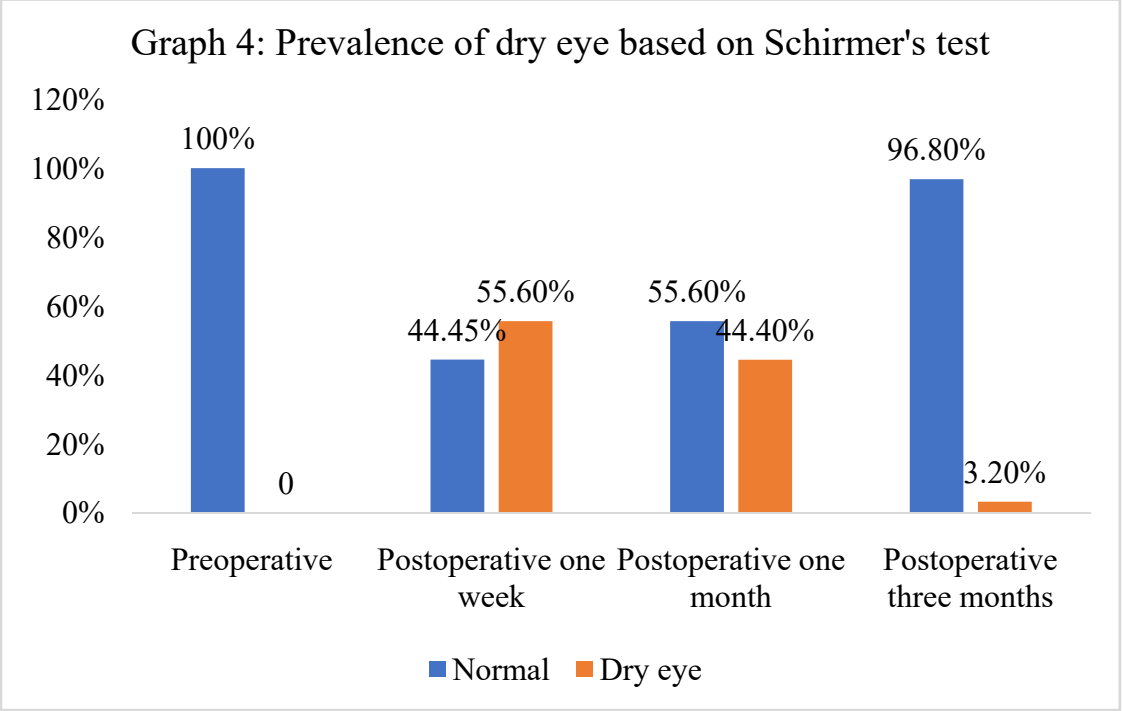
INFERENTIAL STATISTICS

Prevalence of dry eye

66.7%, 44.4%, 19% of patients had dry eye based on Tear Meniscus height (< 0.2) during one week, one month and three months after post operative period.

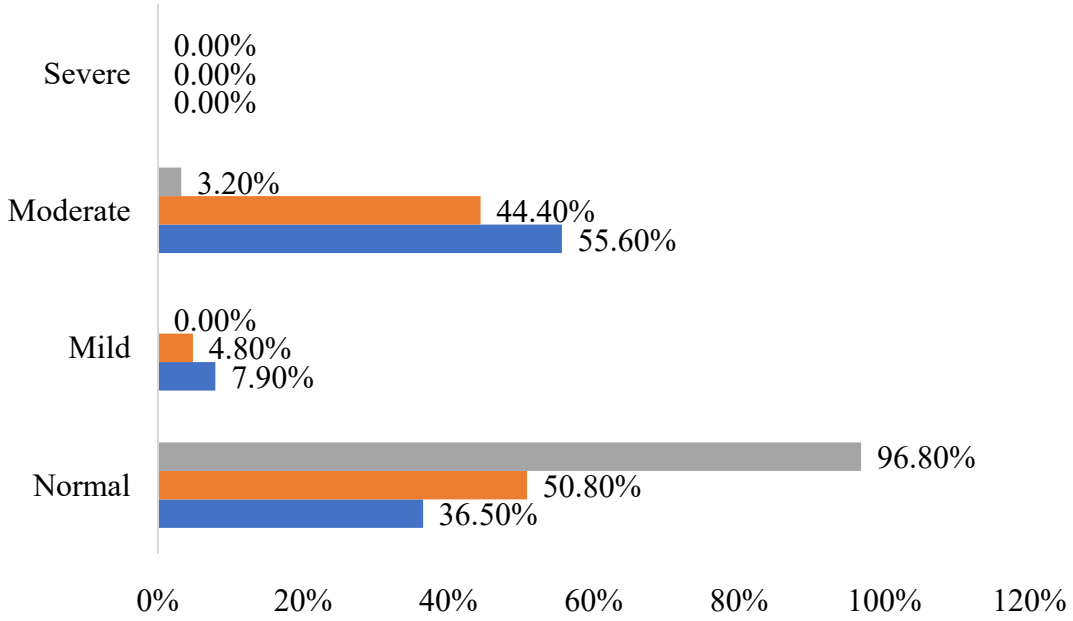


55.6%, 44.4%, 3.2% of patients had dry eye based on Schirmer's test1 (less than 10mm) during one week, one month and three months after post operative period.



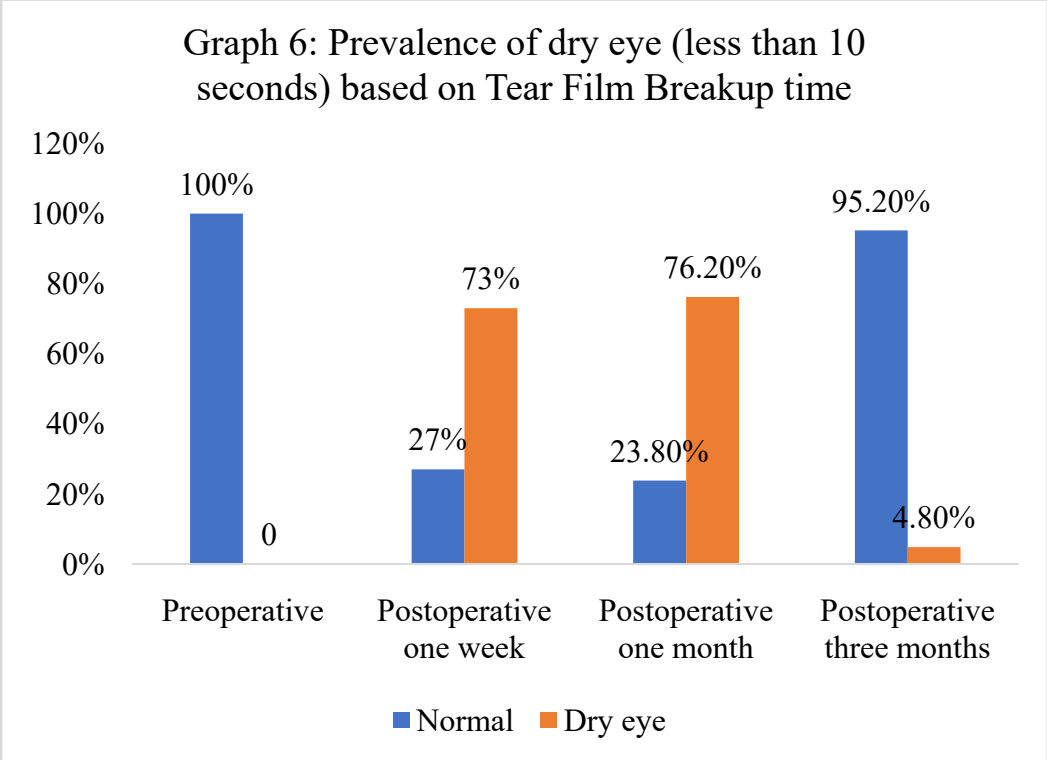
The dry eye was categorized into mild (less than 10 mm), moderate (5 – 9 mm) and severe (less than 5 mm) based on Schirmer's test. 7.9% and 4.8% of patients had mild dry eye during one week and one month of post operative period. 55.6%, 44.4% and 3.2% of patients had moderate dry eye during one week one month and three months of post operative period.

Graph 5: Categorization of dry eye based on Schirmer's test



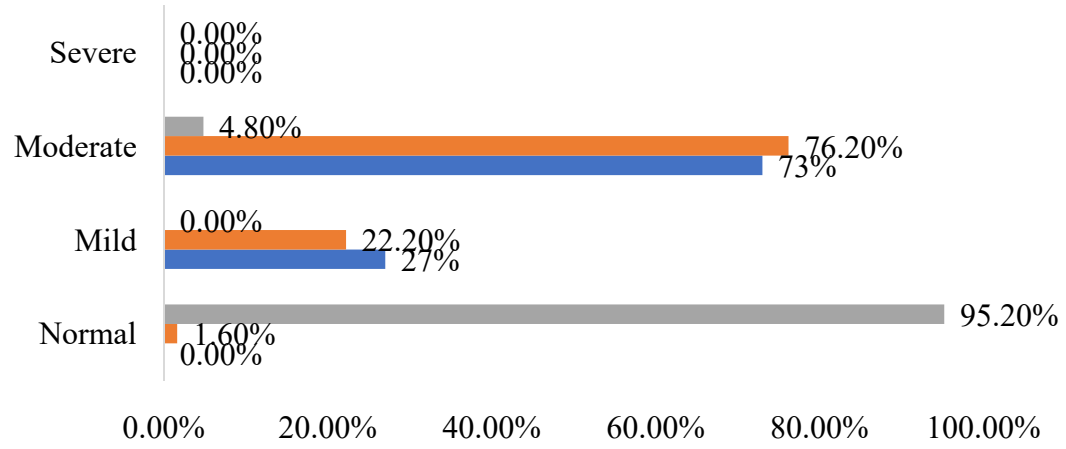
	Normal	Mild	Moderate	Severe
Three months	96.80%	0.00%	3.20%	0.00%
One month	50.80%	4.80%	44.40%	0.00%
One week	36.50%	7.90%	55.60%	0.00%

73%, 76.2%, 4.8% of patients had dry eye based on Tear film break up time (less than 10 seconds) during one week, one month and three months after post operative period.



The dry eye was categorized into mild (less than 10 seconds), moderate (5 – 9 seconds) and severe (less than 5 seconds) based on Tear film break up time. 27% and 22.2% of patients had mild dry eye during one week and one month of post operative period. 73%, 76.2% and 4.8% of patients had moderate dry eye during one week one month and three months of post operative period.

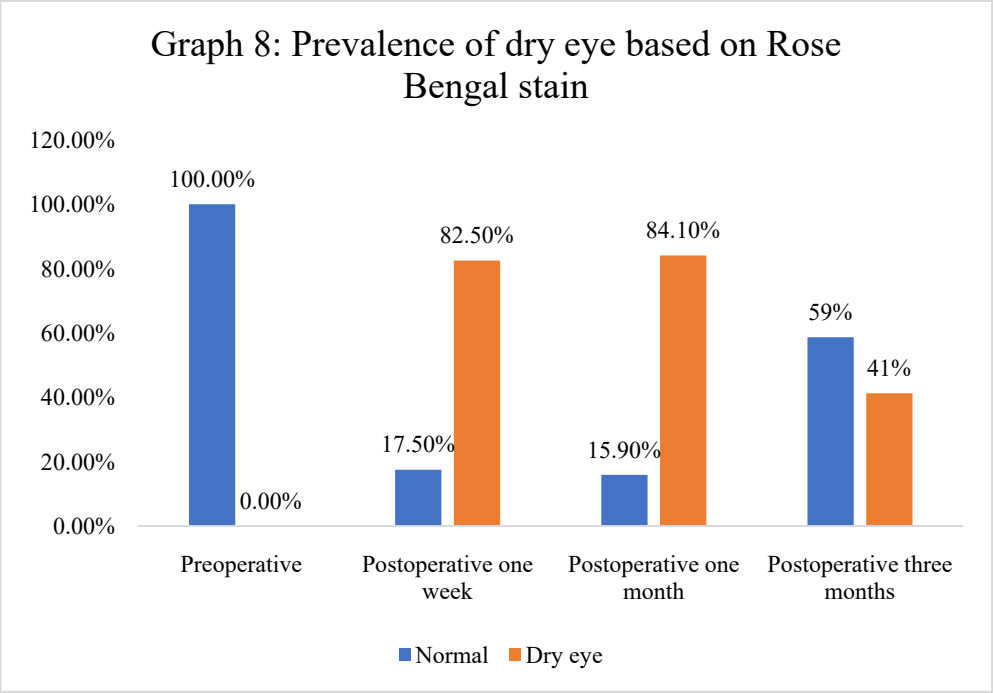
Graph 7: Categorization of dry eye based on Tear film break up time



	Normal	Mild	Moderate	Severe
Three months	95.20%	0.00%	4.80%	0.00%
One month	1.60%	22.20%	76.20%	0.00%
One week	0.00%	27%	73%	0.00%

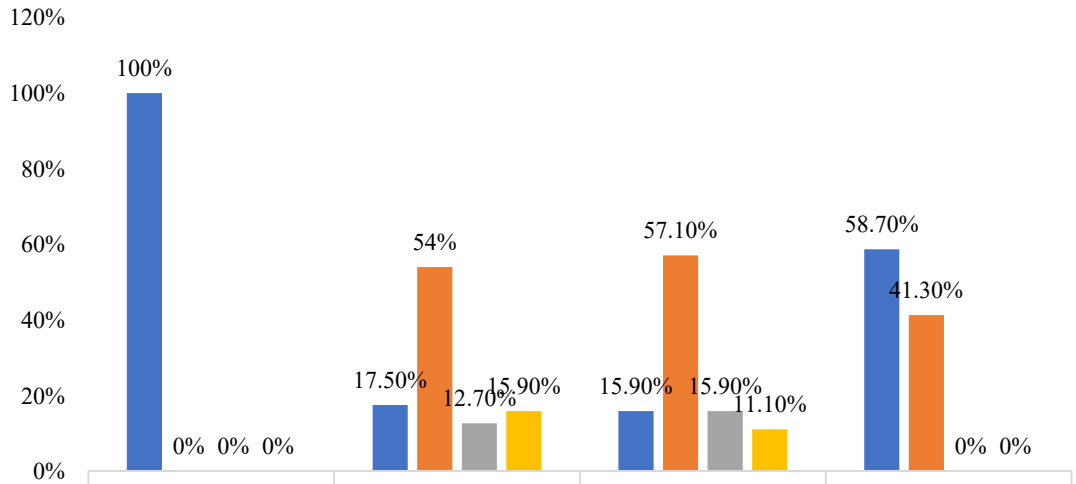
Rose Bengal test

82.5%, 84.1% and 41% of eyes had dry eyes in the postoperative period of one week, one month and three months respectively.



Preoperatively the total eyes (n = 63) had normal Rose Bengal stain (n = 100). During one week after the postoperative period, 34 eyes (54%) had mild dry eye, 8 eyes (12.7%) had moderate dry eye and 10 eyes (15.9%) had severe dry eyes based on Rose Bengal staining. 36 eyes (57.1%), 10 eyes (15.9%) and 7 eyes (11.1%) had a mild, moderate and severe dry eye in a one-month follow-up post-operative period graded by Rose Bengal staining. 26 eyes (41.3%) had mild dry eye even after three months of the postoperative follow-up period.

Graph 9: Categorization of Rose Bengal test



	RB preop	RB post op - one week	RB post op - one month	RB post op - three months
Normal	100%	17.50%	15.90%	58.70%
Mild	0%	54%	57.10%	41.30%
Moderate	0%	12.70%	15.90%	0%
Severe	0%	15.90%	11.10%	0%

Normal Mild Moderate Severe

Comparison of Pre operative and post operative findingsp

Tear meniscus height

The mean value tear meniscus height was reduced on one week after post operative day (0.215±0.143), and one month after post operative day (0.294 ±0.144) and this value was significant statistically. It was also reduced on three months after post operative day (0.363 ±0.153) but the value was not statistically significant.

Table 4: Comparison between preoperative and post operative findings of TMH

S No	Variables	Mean (SD)	P value
1	Preoperative	0.4102 (0.118)	**0.001**
	Post operative one week	0.215 (0.143)	
2	Preoperative	0.4102 (0.118)	**0.001**
	Post operative one month	0.294 (0.144)	
3	Preoperative	0.4102 (0.118)	0.055
	Post operative 3 months	0.363 (0.153)	

Schirmer test

The mean value of Schirmer's test results was reduced on one week after post operative day (11.35 ±4.820), one month after post operative day (13.52±6.701) and this value was significant. It was also reduced on three months after post operative day (26.78 ±4.531) and the value was significant.

Table 5: Comparison between preoperative and post operative findings

S No	Variables	Mean (SD)	P value
1	Preoperative	28.06 (2.094)	**0.001**
	Post operative one week	11.35 (4.820)	
2	Preoperative	28.06 (2.094	**0.001**
	Post operative one month	13.52 (6.701)	
3	Preoperative	28.06 (2.094)	0.022
	Postoperative 3 months	26.78 (4.531)	

Tear Film Break up time

The mean value of tear film break up time results was reduced on one week after post operative day (8.25±1.606), and one month after post operative day (8.33±2.155) this value was significant. It was also reduced on three months after post operative day (21.22±3.594) and the value was significant.

Table 6: Comparison between preoperative and post operative findings

S No	Variables	Mean (SD)	P value
1	Preoperative	22.49 (2.078)	**0.001**
	Post operative one week	8.25(1.606)	
2	Preoperative	22.49 (2.078)	**0.001**
	Post operative one month	8.33(2.155)	
3	Preoperative	22.49 (2.078)	**0.010**
	Post operative three months	21.22(3.594)	

Rose Bengal test

The mean score of Rose Bengal test had a statistical significant difference in one week and one month of the postoperative period. The scores were significantly higher compared with the preoperative period.

Table 7: Comparison between preoperative grade and post-operative grade findings

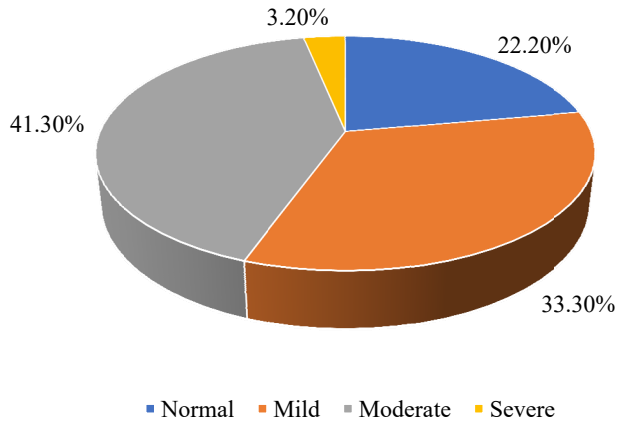
S No	Variables	Mean (SD)	P value
1	Preoperative	0.24(0.429)	**0.001**
	Postoperative one week	1.27 (0.937)	
2	Preoperative	0.24(0.429)	**0.001**
	Postoperative one month	1.22(0.851)	
3	Preoperative	0.24(0.429)	**0.027**
	Postoperative 3 months	0.41(0.496)	

PREVALENCE OF DRY EYE BY COMBINING TESTS

Dry eye was defined as patients who had two positive clinical tests (TBUT = 10 seconds, ST1 score = 10 mm, RB statin score of > four). Patients with ST1 less than 10 mm in 5 minutes, TBUT less than 10 seconds, and less than one quadrant of staining of the cornea by RB are considered to have mild dry eyes. A ST1 of 5 to 10 mm in 5 minutes, a TBUT of 5 to 10 seconds, and punctate staining of more than one corneal epithelial quadrant by RB are considered signs of moderate dry eye. Diffuse punctate or confluent staining (with RB) of the

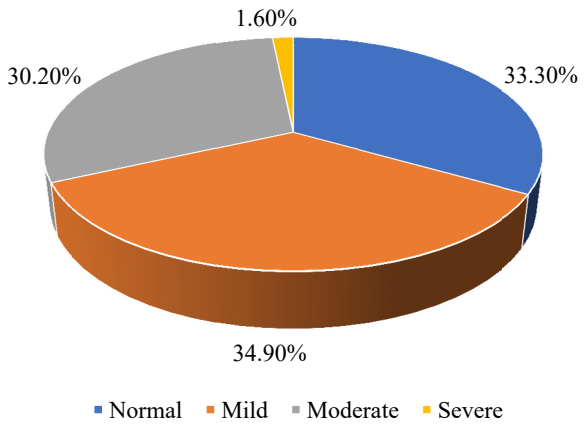
corneal epithelium, frequently with filaments, with ST1 less than 5 mm in 5 minutes and TBUT less than 5 seconds is considered to be severe dry eye.

Graph 10: Prevalence of dry eye in one week of postoperative period

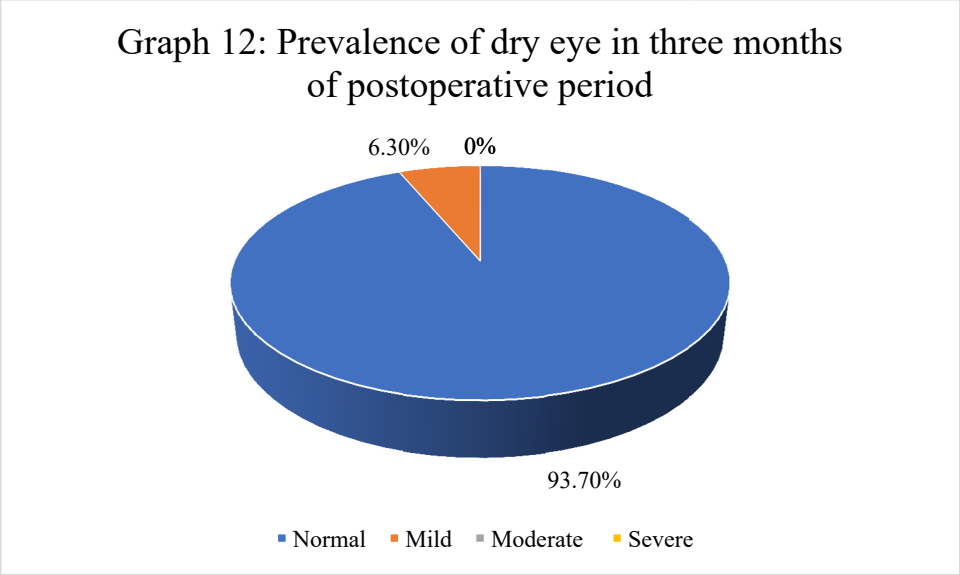


In the first week following MSICS, 21 eyes (33.3%), 26 eyes (41.3%), and 2 eyes (3.2%) experienced mild, moderate, and severe dry eyes, respectively.

Graph 11: Prevalence of dry eye in one month of post operative period



Following a month of MSICS surgery, 22 eyes (34.9%), 19 eyes (30.2%) and 1 eye (1.6%) had mild, moderate and severe dry eye respectively



5 eyes (6.3%) had mild dry eye during three months of postoperative day.

GENDER AND TEAR FILM ASSESSMENT

Association between gender and TMH

There was no difference in the mean value of Tear meniscus height among male and female patients

Table 8: Association between gender and TMH

TMH	Male		Female		p-value
	Mean	Std. Deviation	Mean	SD	
TMH preoperative	0.42	0.13	0.39	0.097	0.334
TMH postoperative after a week	0.21	0.13	0.21	0.15	0.891

TMH postoperative after a month	0.28	0.13	0.30	0.157	0.480
TMH postoperative after three months	0.386	0.146	0.337	0.159	0.213

There was no difference in the mean value of Schirmer's test among male and female patients

Association between gender and Schirmer's test

Table 9: Association between gender and Schirmer's test

Schirmer's test	Male		Female		p-value
	Mean	SD	Mean	SD	
Schirmer's preoperative	28.18	2.052	27.93	2.17	0.647
Schirmer's postoperative after a week	11.59	5.147	11.07	4.48	0.674
Schirmer's postoperative after a month	13.18	6.157	13.93	7.377	0.660
Schirmer's postoperative after three months	26.97	4.31	26.55	4.845	0.718

Association between gender and Tear Film break up time

There was no difference in the mean value of Tear break up time among male and female patients

Table 10: Association between gender and TBUT test					
TBUT	Male		Female		p value
	Mean	SD	Mean	SD	
TBUT preoperative	22.59	1.86	22.38	2.336	0.694
TBUT postoperative after a week	8.38	1.498	8.1	1.739	0.497
TBUT postoperative after a month	8.18	1.623	8.52	2.668	0.536
TBUT postoperative after three months	20.59	4.439	21.97	2.079	0.131

Association between gender and Rose Bengal test

There was no difference in the mean value of Rose Bengal test among male and female patients

Table 11: Association between gender and RB test					
Rose Bengal test	Male		Female		p-value
	Mean	SD	Mean	SD	

RB preoperative	0.24	0.431	0.24	0.435	0.956
RB postoperative after a week	1.21	0.978	1.34	0.897	0.562
RB postoperative after a month	1.15	0.857	1.31	0.85	0.452
RB postoperative after three months	0.50	0.508	0.31	0.471	0.132

DISCUSSION

6.DISCUSSION

This study was conducted to evaluate tear film followed by MSICS among 63 patients.

Dry eye prevalence followed by cataract surgery

Prevalence of dry eye varies across the studies. Patients who underwent MSICS experienced dry eye in one week, one month and three months of postop day.

Studies	0ne week	0ne month	Three months
Our study	21 eyes (33.3%), 26 eyes (41.3%), and 2 eyes (3.2%) experienced mild, moderate, and severe dry eyes	22 eyes (34.9%), 19 eyes (30.2%) and 1 eye (1.6%) had mild, moderate and severe dry eye	5 eyes (6.3%) had mild dry eye
Ishrat S et al[19]	27%, 11% and 4% of eyes had mild, moderate and severe dry eye	12% and 3% of eyes had mild and moderate dry eye	7.1% and 3.5% of eyes had mild and moderate dry eye
Garg P. et al.[74]	92.9% dry eye	26.8% dry eye	-
Venugopal K et l.[76]	-	Mild -dry eye (53.32%), Moderate- dry eye (26.6%), and severe- dry (20%).	-

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Patil M. et al.[77]	-	13%, 33%, and 23% of patients had mild, moderate, or severe dry eye illness	-

Evaluation of tear film after MSICS

Schirmer's test

Studies	Preoperative	One week	One month	Three months
Our study	28.06 ±2.094	11.35 ±4.820	13.52±6.701	26.78 ±4.531
Li X et al[8]	9.87±5.62	8.20±4.84	5.67±4.32	7.93±4.96
Bista B et al[71]	32.1±3.005	21.12±6.448	19.64 ± 6.691	18.80 ±7.393
Ishrat S et al[18]	24.5± 0.59	15.2 ±0.64	19.7± 0.60	21.8± 0.64
Garg P et al[74]	27.22±4.4	12.91±2.95	24.61±6.32	-
Jayshree et al[64]	18.21±6.15	10.14±4.09	14.62±4.15	-
Patil M et al.[77]	21.168±0.327	10.20±0.515	12.252±0.478	-
Kanfade et al.[78]	16.78±5.54	7.15±5.08	10.45±5.97	-
Shrivastava et al.[79]	26.44±3.53	17.3±5.28	18.14±4.39	26.56±3.19

Above mentioned studies showed that the mean ST1 values were decreased during 0ne week and 0ne month of the postoperative period and becomes near normal during three months of the postoperative period. Our study results also described a significant reduction in mean Schirmer's values in the postoperative follow up period.

Our study showed that 55.6%, 44.4%, 3.2% of patients had dry eye based on ST1 (less than 10mm) during one week, one month and three months after post operative period.

Lakshmi PS et al found low Schirmer Test 1 values were present at POD 0ne week, 0ne month, and 3 months in 0%, 3%, and 0%, respectively. All patients recovered ST1 values of greater than 10 after 3 months following surgery, which was statistically significant. The prevalence was higher in our study might be due to population characteristics and surgical techniques. [72]

Gupta V et al found that at on week, one month, and three months following surgery, 42%, 52%, and 18% patients, respectively, had low ST1 (less than 10) values. This result was near similar to our study results.[73]

Kumar J et al Jhansi, India Prior to surgery, ST1 analysis was all normal in the patients. 0%, 5%, and 0%, had low ST1 values at post-op 0ne week, 0ne month, and 3 months in respectively. The prevalence was higher in our study might be due to population characteristics and surgical techniques. All patients had statistically significant ST1 values of >10 after 3 months postoperatively which was similar to our study results.[64]

Tear Meniscus Height

Our study depicted that 66.7%, 44.4%, 19% of patients had low TMH based on (< 0.2) during one week, 0ne month and three months after post operative period. **Lakshmi PS et al** in Andhra Pradesh conducted a study among 100 eyes of cataract patients and found that

during 0ne week, 0ne month, and three months after Manual SICS (Manual Small Incision Cataract Surgery) respectively, 23%, 29%, and 24% of patients had low TMH, which was statistically significant. The proportion was higher during one week and month postoperative period in our study compared with Lakshmi PS et al. This variation might be due to larger sample size in **Lakshmi PS etal** research (n =100).[72]

Gupta V et al from Jammu and Kashmir evaluated precorneal tear film after Manual SICS among fifty patients and found that at pod one week, one month, and 3 months, respectively, TMH analysis revealed that 44%, 76%, and 62% had low TMH, that was significant statistically.[73] Kumar J et al reported that at postoperative 0ne week, 0ne month, and three months, respectively, 29%, 34%, and 30% had low TMH, which was statistically significant.[64] There was a variation in prevalence of dry eye might be due to surgical techniques.

Tear Film Break up time

Studies	Pre operative	One week	One month	3 months
Our study	22.49 ±2.078	8.25±1.606),	8.33±2.155	22.49 ±2.078
Garg P. et al.[74]	13.5±1.89	9.64±2.2	13.16±2.45	-
Jayshree et al.[64]	11.10±5.40	3.43±2.79	10.40±4.5	-
Patil M et al.[77]	17.374±0.406	8.705±0.373	10.961±0.386	-
Ishrat S et al[18]	15.8±0.31	8.7±0.48	11.2 ±0.39	14.3±0.37
Kanfade et al.[78]	17.89±6.98	7.84±5.22	13.23±7.48	
Shrivastava et al.[79]	11.12±0.96	10.16±2.05	10.38±1.75	11.2±0.90

Above mentioned studies showed that the mean TBUT values were decreased during one week and one month of postoperative period and becomes near normal during three months of postoperative period. Our study results also described significant reduction in mean TBUT values in postoperative follow up period.

Our study described that 73%, 76.2%, 4.8% of patients had dry eye based on Tbut (low TBUT < 10 sec) during 0ne week, 0ne month and three months after post operative period.

Lakshmi PS et al in Andhra Pradesh conducted a study among 100 eyes of cataract patients and found that 6%, 23%, and 8% of patients had low TBUT readings at 0ne week, 0ne month, and 3 months after surgery, respectively. In the 3-month follow-up period, 92% of the patients had returned to normal values, which was statistically significant.[72]**Gupta V et al** from Jammu and Kashmir evaluated precorneal tear film after Manual SICS among fifty patients and found that the TBUT analysis revealed that low TBUT values were present at 0ne week, 0ne month, and 3 months following surgery in 36%, 46% and 36% respectively.[73]

Kumar J et al [64] found that All of the participants exhibited normal TBUT values before to surgery, according to the TBUT analysis. 8%, 26%, and 9% of patients had low TBUT readings at 0ne week, 0ne month, and 3 months postoperatively. In the 3-month follow-up period, 92% of the patients returned to normal values, which was statistically significant.

Our study described that 73%, 76.2%, 4.8% of patients had dry eye based on TBUT (low TBUT < 10 sec) during 0ne week, 0ne month and three months after post operative period.

Lakshmi PS et al in Andhra Pradesh conducted a study among 100 eyes of cataract patients and found that 6%, 23%, and 8% of patients had low TBUT readings at 0ne week, 0ne month, and 3 months after surgery, respectively. In the 3-month follow-up period, 92% of the patients had returned to normal values, which was statistically significant. Gupta V et al from Jammu and Kashmir evaluated precorneal tear film after Manual SICS among fifty patients and found that the TBUT analysis revealed that low TBUT values were present at 0ne week, 0ne month, and 3 months following surgery in 36%, 46% and 36% respectively.[72]

Rose Bengal stain

Our study showed that during one week after the postoperative period, 54% had mild dry eye, 12.7% had moderate dry eye and 15.9% had severe dry eyes based on Rose Bengal staining. 57.1%, 15.9%, and 11.1% had mild, moderate and severe dry eye in a one-month follow-up post-operative period graded by Rose Bengal staining. 41.3% had mild dry eye even after three months of the postoperative follow-up period.

Lakshmi PS et al found that during the postoperative period at one week 22%, 6% and 1% of patients were found to have mild, moderate and severe -dry eye based on the RB test. 29%, 15% and 7% of them had mild, moderate and severe dry eye based on the Rose Bengal test at one month of post-operative period. 23%, 11% and 3% of them were diagnosed with mild, moderate and severe dry eye based on the RB test.[72]

At one week, one month, and 3 months after surgery, **Gupta V et al.** from Jammu and Kashmirinvestigated precorneal tear film after Manual SICS in fifty patients and discovered that 21 (42%), 26 (52%), and 9 (18%) patients, respectively, had abnormal results (score more than four).[73]

The prevalence was higher in our study compared with Lakshmi PS et aland Gupta V et al might be due to population characteristics and surgical techniques.[72,73]

Therefore, the alternate hypothesis was accepted that there was a change in tear film following manual small incision cataract surgery and the incidence of dry eye was high.

CONCLUSION

7.CONCLUSION

This study was conducted among sixty-three cataract patients who underwent MSICS for the assessment of dry eye indices using ST1,Tear Meniscus Height, Tear Break Up Time , and Rose Bengal staining.

The mean values of dry eye indices were normal preoperatively and becomes lower during the follow-up postoperative period. The mean values of TMH, TBUT, ST1 and RB staining were significantly reduced during one week, and one month of the postoperative period. After ninety days of surgery, many participants regain their tear film within normal limits and some had dry eyes.

Even though mild - moderate dry eye may not impair vision, more severe cases might result in a loss of vision. Preoperative evaluation should be carried out adequately using tests for tear film formation and stability as well as questionnaires about symptoms of dry eyes. Artificial tears eye drops can be provided after surgery if dry eye is discovered beforehand. We conclude that dry eye symptoms can appear right away following cataract surgery, peak on day 7, and become better over time. However, in order to guarantee that the patients receive the right care, have good vision, and have a high quality of life, ophthalmologists must evaluate dry eye both before and after cataract surgery.

SUMMARY

8. SUMMARY

This study was conducted among 63 patients with cataract posted for MSICS to determine the prevalence of dry eye.

Prevalence of dry eye

- 66.7%, 44.4%, 19% had dry eye on Tear Meniscus height (< 0.2) during 1 week, 0ne month and 3 months after post operative period.
- 55.6%, 44.4%, 3.2% of patients had dry eye based on Schirmer's test1 (less than 10mm) during 0ne week, 0ne month and three months after post operative period.
- 73%, 76.2%, 4.8% of patients had dry eye based on TBUT (less than 10 seconds) during 0ne week, 0ne month and 3 months after post operative period.
- 82.5%, 84.1% and 41% of eyes had dry eyes in the postop period of 0ne week, 0ne month and three months respectively based on Rose Bengal staining

Precorneal tear film evaluation preoperative and post operative findings

- The mean value tear meniscus height was reduced on one week after post operative day (0.215±0.143), and one month after post operative day (0.294 ±0.144) from pre operative value (0.4102 ±0.118) and this value was significant statistically. It was also reduced on three months after post operative day (0.363 ±0.153) but the value was not statistically significant.
- The mean value of ST1 results was reduced on one week after post operative day (11.35 ±4.820), and one month after post operative day (13.52±6.701) from pre operative value (28.06 ±2.094) and this value was significant. It was also reduced on three months after post operative day (26.78 ±4.531) and the value was significant.

- The mean value of tear film break up time results was reduced on one week after post operative day (8.25±1.606), and one month after post operative day (8.33±2.155) from pre operative value (22.49 ±2.078) and this value was significant. It was also reduced on three months after post operative day (21.22±3.594) and the value was significant.
- The mean score of Rose Bengal test had a statistically significant difference in 0ne week, 0ne month and 3 months of postoperative period. The scores were significantly higher compared with the preoperative period.

Severity of dry eyes

- The dry eye was categorized into mild (less than 10 mm), moderate (5 – 9 mm) and severe (less than 5 mm) based on Schirmer's test. 7.9% and 4.8% of patients had mild dry eye during one week and one month of post operative period. 55.6%, 44.4% and 3.2% of patients had moderate dry eye during 0ne week 0ne month and 3 months of postoperative period.
- Dry eye was categorized into mild < 10 seconds, moderate 5 – 9 seconds and severe < than 5 seconds based on TBUT. 27% and 22.2% of patients had mild dry eye during one week and one month of post operative period. 73%, 76.2% and 4.8% of patients had moderate dry eye during one week one month and three months of postoperative period.
- During one week after the postoperative period, 54% had mild- dry eye, 12.7% had moderate dry eye and 15.9% had severe dry eyes based on Rose Bengal staining. 57.1%, 15.9%, and 11.1% had mild, moderate and severe dry eye in a one-month follow-up post-operative period graded by Rose Bengal staining. 41.3% had mild dry eye even after three months of the postoperative follow-up period

LIMITATIONS

9.LIMITATIONS

- The sample size was smaller (n = 63), it is better to be larger for generalizing results.

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ANNEXURES

11.ANNEXURE-1

CASE PROFORMA

Name:	Date:
Age:	IP no:
Sex:	DOA:
Occupation:	DOS:
Address:	

Chief complaints:

History of Presenting illness:

Past history:

DM / HTN / BA / Epilepsy

Family history:

Personal history:

Appetite – Sleep – Bowel –

Diet – Habits – Bladder –

GPE:

Pallor / Edema /Icterus / Cyanosis / Clubbing / Lymphadenopathy

Vital signs:

a. Pulse – c) RR –

b. BP – d) Temp –

Systemic examination:

a. CVS – c. RS –

	b. PA –	d. CNS –

OCULAR EXAMINATION			
TESTS	**RE**	**LE**	
1. HEAD POSTURE 2. OCULAR POSTURE 3. FACIAL SYMMETRY			
4. EXTRAOCULAR MOVEMENTS a) Ductions b) Versions			
5. VISUAL ACUITY: a) Distant • Without spectacles • With spectacles b) Near			
6. KERATOMETRY READINGS- K1 K2			
7. FUNDUS a) Direct ophthalmoscopy b) Indirect ophthalmoscopy			
8. Tear Meniscus Height			
9. Tear Film Break Up Time			
10. Schirmers Test			

11. Rose Bengal staining			
12.Post operative test	Post operative one week	Post operative After one month	Post operative after 3 months
Tear meniscus height			
Tear Film Break up time			
Schirmers test 1			
Rose Bengal staining			

ANNEXURE-2

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

INFORMED CONSENT FORM

Case no:

IP no:

TITLE: EFFECT OF MANUAL SMALL INCISION CATARACT SURGERY ON PRE CORNEAL TEAR FILM AT TERTIARY CARE CENTRE.

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

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

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

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

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

Name	Signature	Date	Time
Patient:			
Witness:			
Doctor			

ಶ್ರೀ ದೇವರಾಜ್ ಉರ್ಸ್ ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನೆ ಅಕಾಡೆಮಿ, ತಮಕ,

ಕೋಲಾರ - 563101 .

ಮಾಹಿತಿ ನೀಡಿದ ಒಪ್ಪಿಗೆ ನಮೂನೆ

ಪ್ರಕರಣ ಸಂಖ್ಯೆ:

IP ಸಂಖ್ಯೆ:

ಶೀರ್ಷಿಕೆ: ತೃತೀಯ ಆರೈಕೆ ಕೇಂದ್ರದಲ್ಲಿ ಪ್ರೀ ಕಾರ್ನಿಯಲ್ ಟಿಯರ್ ಫಿಲ್ಮ್‌ನಲ್ಲಿ ಹಸ್ತಚಾಲಿತ ಸಣ್ಣ ಛೇದನದ ಕಣ್ಣಿನ ಪೊರೆ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ಪರಿಣಾಮ.

ನಾನು, ಕೆಳಗೆ ಸಹಿ ಮಾಡಿದ್ದೇನೆ, ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪುತ್ತೇನೆ ಮತ್ತು ಈ ಸಮ್ಮತಿ ನಮೂನೆಯಲ್ಲಿ ವಿವರಿಸಿದಂತೆ ವೈಯಕ್ತಿಕ ಮಾಹಿತಿಯ ಸಂಗ್ರಹಣೆ ಮತ್ತು ಬಹಿರಂಗಪಡಿಸುವಿಕೆಯನ್ನು ಅಧಿಕೃತಗೊಳಿಸುತ್ತೇನೆ.

ಈ ಅಧ್ಯಯನದ ಉದ್ದೇಶ, ತಂತ್ರಜ್ಞಾನದ ಅಪಾಯಗಳು ಮತ್ತು ಪ್ರಯೋಜನಗಳು ಮತ್ತು ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಸಂಗ್ರಹಿಸಿದ ಮತ್ತು ಬಹಿರಂಗಪಡಿಸುವ ಮಾಹಿತಿಯ ಗೌಪ್ಯ ಸ್ವರೂಪವನ್ನು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ. ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಸಂಶೋಧನೆಗೆ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ.

ಈ ಅಧ್ಯಯನದ ವಿವಿಧ ಅಂಶಗಳ ಬಗ್ಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ ಮತ್ತು ನನ್ನ ಪ್ರಶ್ನೆಗಳಿಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ.

ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಈ ಅಧ್ಯಯನದಿಂದ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಹಿಂಪಡೆಯಲು ನಾನು ಮುಕ್ತನಾಗಿರುತ್ತೇನೆ ಮತ್ತು ಇದು ಭವಿಷ್ಯದ ಕಾಳಜಿಯನ್ನು ಬದಲಾಯಿಸುವುದಿಲ್ಲ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯು ನನಗೆ ಯಾವುದೇ ಹೆಚ್ಚುವರಿ ವೆಚ್ಚವನ್ನು ಒಳಗೊಂಡಿರುವುದಿಲ್ಲ.

ಹೆಸರು	ಸಹಿ/ಹೆಬ್ಬೆಟ್ಟಿನಗುರುತು	ದಿನಾಂಕ	ಸಮಯ
ರೋಗಿಯಹೆಸರು			
ಸಾಕ್ಷಿಗಳಹೆಸರು			
ಪ್ರಾಥಮಿಕಸಂಶೋಧಕರು/ ವೈದ್ಯರು			

ANNEXURE-3

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

PATIENT INFORMATION SHEET

TITLE : EFFECT OF MANUAL SMALL INCISION CATARACT SURGERY ON PRE CORNEAL TEAR FILM AT TERTIARY CARE CENTRE.

You are invited to take part voluntarily in this research study, it is important that you read and understand the purpose, procedure, benefits and discomforts of the study.

1. What is the purpose of this study?

   To compare pre and post operative tear film abnormality.

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

   Absolutely no risks are associated with various investigations involved in this study such as

   1. Visual acuity by Snellens chart for distant vision.
   2. Near vision – Jaeger chart.
   3. Automated Keratometry readings.
   4. Tear Meniscus Height .
   5. Tear Film Break Up Time.
   6. Schirmers Test 1.
   7. Rose Bengal Staining .

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

   Participation in this research study may not change the final outcome of your eye condition. However, patients in the future may benefit as a result of knowledge gained from this study. You will not be charged extra for any of the procedures performed during the research study. Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at any time, without a penalty or loss of any benefits to which you were otherwise entitled before taking part in this study.

CONFIDENTIALITY

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available. Your original records may be reviewed by your doctor or ethics review board.

For further information/ clarification please contact Dr.USHA B.R , SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR - 563101.Contact no:9980983829 9597183562 to Dr KRUTHIKA S

ಶ್ರೀ ದೇವರಾಜ್ ಉರ್ಸ್ ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನೆ ಅಕಾಡೆಮಿ, ತಮಕ,

ಕೋಲಾರ - 563101.

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಶೀರ್ಷಿಕೆ : ತೃತೀಯ ಆರೈಕೆ ಕೇಂದ್ರದಲ್ಲಿ ಪ್ರೀ ಕಾರ್ನಿಯಲ್ ಟಿಯರ್ ಫಿಲ್ಮ್‌ನಲ್ಲಿ ಹಸ್ತಚಾಲಿತ ಸಣ್ಣ ಛೇದನದ ಕಣ್ಣಿನ ಪೊರೆ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ಪರಿಣಾಮ.

ಈ ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಪಾಲ್ಗೊಳ್ಳಲು ನಿಮ್ಮನ್ನು ಆಹ್ವಾನಿಸಲಾಗಿದೆ, ಅಧ್ಯಯನದ ಉದ್ದೇಶ, ಕಾರ್ಯವಿಧಾನ, ಪ್ರಯೋಜನಗಳು ಮತ್ತು ಅನಾನುಕೂಲಗಳನ್ನು ನೀವು ಓದುವುದು ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಳ್ಳುವುದು ಮುಖ್ಯವಾಗಿದೆ.

1. ಈ ಅಧ್ಯಯನದ ಉದ್ದೇಶವೇನು?

   ಪೂರ್ವ ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ಕಣ್ಣೀರಿನ ಫಿಲ್ಮ್ ಅಸಹಜತೆಯನ್ನು ಹೋಲಿಸಲು.

2. ಯಾವ ವಿವಿಧ ತನಿಖೆಗಳನ್ನು ಬಳಸಲಾಗುತ್ತಿದೆ? ಯಾವುದೇ ಸಂಬಂಧಿತ ಅಪಾಯಗಳಿವೆಯೇ?

   ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಒಳಗೊಂಡಿರುವ ವಿವಿಧ ತನಿಖೆಗಳೊಂದಿಗೆ ಸಂಪೂರ್ಣವಾಗಿ ಯಾವುದೇ ಅಪಾಯಗಳು ಸಂಬಂಧಿಸಿಲ್ಲ

   1. ದೂರದ ದೃಷ್ಟಿಗಾಗಿ 스넬렌스 ಚಾರ್ಟ್‌ನಿಂದ ದೃಷ್ಟಿ ತೀಕ್ಷ್ಣತೆ.
   2. ಸಮೀಪ ದೃಷ್ಟಿ - ಜೇಗರ್ ಚಾರ್ಟ್.
   3. ಸ್ವಯಂಚಾಲಿತ ಕೆರಾಟೋಮೆಟ್ರಿ ವಾಚನಗೋಷ್ಠಿಗಳು.
   4. ಕಣ್ಣೀರಿನ ಚಂದ್ರಾಕೃತಿ ಎತ್ತರ .
   5. ಟಿಯರ್ ಫಿಲ್ಮ್ ಬ್ರೇಕ್ ಅಪ್ ಸಮಯ.
   6. ಸ್ಕಿಮರ್ಸ್ ಟೆಸ್ಟ್ 1.
   7. ರೋಸ್ ಬೆಂಗಾಲ್ ಸ್ಟೇನಿಂಗ್ .

3. ಭಾಗವಹಿಸುವವನಾಗಿ ನನಗೆ ಏನು ಪ್ರಯೋಜನ?

   ಈ ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯು ನಿಮ್ಮ ಕಣ್ಣಿನ ಸ್ಥಿತಿಯ ಅಂತಿಮ

ಫಲಿತಾಂಶವನ್ನು ಬದಲಾಯಿಸದಿರಬಹುದು. ಆದಾಗ್ಯೂ, ಈ ಅಧ್ಯಯನದಿಂದ ಪಡೆದ ಜ್ಞಾನದ ಪರಿಣಾಮವಾಗಿ ಭವಿಷ್ಯದಲ್ಲಿ ರೋಗಿಗಳು ಪ್ರಯೋಜನ ಪಡೆಯಬಹುದು. ಸಂಶೋಧನಾ ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ನಡೆಸಿದ ಯಾವುದೇ ಕಾರ್ಯವಿಧಾನಗಳಿಗೆ ನಿಮಗೆ ಹೆಚ್ಚುವರಿ ಶುಲ್ಕ ವಿಧಿಸಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನೀವು ಭಾಗವಹಿಸುವುದು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ನಿರಾಕರಿಸಬಹುದು ಅಥವಾ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವ ಮೊದಲು ನೀವು ಅರ್ಹರಾಗಿದ್ದ ಯಾವುದೇ ಪ್ರಯೋಜನಗಳ ದಂಡ ಅಥವಾ ನಷ್ಟವಿಲ್ಲದೆಯೇ ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದನ್ನು ನಿಲ್ಲಿಸಬಹುದು.

<u>ಗೌಪ್ಯತೆ</u>

ನಿಮ್ಮ ವೈದ್ಯಕೀಯ ಮಾಹಿತಿಯನ್ನು ಅಧ್ಯಯನ ವೈದ್ಯರು ಮತ್ತು ಸಿಬ್ಬಂದಿ ಗೌಪ್ಯವಾಗಿಡುತ್ತಾರೆ ಮತ್ತು ಸಾರ್ವಜನಿಕವಾಗಿ ಲಭ್ಯವಾಗುವಂತೆ ಮಾಡಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಮೂಲ ದಾಖಲೆಗಳನ್ನು ನಿಮ್ಮ ವೈದ್ಯರು ಅಥವಾ ಎಥಿಕ್ಸ್ ರಿವ್ಯೂ ಬೋರ್ಡ್ ಪರಿಶೀಲಿಸಬಹುದು.

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ/ಸ್ಪಷ್ಟೀಕರಣಕ್ಕಾಗಿ ದಯವಿಟ್ಟು ಡಾ.ಯುಶಾ ಬಿ.ಆರ್, ಶ್ರೀ ದೇವರಾಜ್ ಯುಆರ್ಎಸ್ ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನೆ ಅಕಾಡೆಮಿ, ತಮಕ, ಕೋಲಾರ - 563101 ಅನ್ನು ಸಂಪರ್ಕಿಸಿ.ಸಂಪರ್ಕ ಸಂಖ್ಯೆ:9980983829 , 9597183562 ಅವರಿಗೆ ಡಾ ಕೃತಿಕಾ ಎಸ್

ANNEXURE-IV

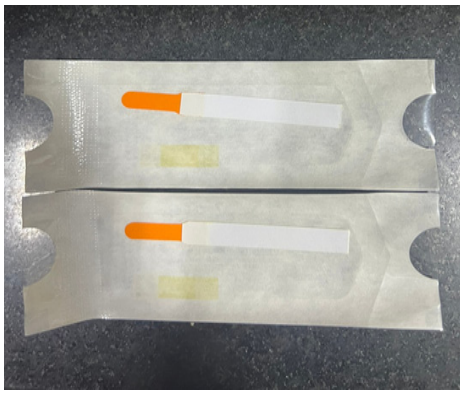

Photo 1: FLUROSCEIN STRIPS SRTIPS

Photo 2: ROSE BENGAL

Photo 3:SCHIRMERS TEST

Photo 4:Slit lamp assessing TBUT

Photo 4:slit lamp measuring TMH

ANNEXURE-5

KEY TO MASTER CHART

S NO	TERMS	ABBREVATION
1	TMH	Tear Meniscus Height
2	ST1	Schirmers test
3	TBUT	Tear film break up time
4	RB	Rose Bengal staining test
5	PRE OP	Pre operative
6	PO	Post op
7	1w	One week
8	1M	One Month
9	3M	Three Month

`

MASTER CHART

`

12.MASTER CHART

UHID	age	gender	TMH preop	TMH po 1w	TMH po 1m	TMH po 3m	st 1 preop	st 1 po 1w	st 1 po 1m	st 1 po 3m	preop tbut	tbut po 1w	tubut po 1m	tbut po 3m	rb preop	rb po 1w	rb po 1m	rb po 3m
88750	56	F	0.3	0.05	0.05	0.3	25	25	25	8	20	9	9	20	0	2	1	1
888060	65	F	0.3	0.06	0.06	0.3	30	15	15	30	22	8	8	22	1	3	2	1
888057	67	M	0.26	0.1	0.1	0.4	25	9	9	25	20	10	10	9	2	4	1	2
887758	60	F	0.22	0.05	0.07	0.3	30	10	10	15	25	5	5	25	1	3	2	3
890565	54	M	0.6	0.06	0.12	0.2	30	8	8	30	23	6	6	23	1	4	1	1
890571	70	M	0.4	0.2	0.2	0.05	30	12	12	30	22	6	6	8	2	4	2	3
892126	70	M	0.36	0.11	0.12	0.5	30	8	8	9	24	7	7	24	1	2	4	1
897554	85	M	0.36	0.16	0.2	0.5	25	8	8	25	20	9	9	20	1	2	1	1
895204	62	M	0.3	0.05	0.05	0.06	25	18	18	25	23	10	10	7	3	2	2	2
896866	58	M	0.5	0.18	0.18	0.06	30	25	25	28	25	9	9	20	2	3	4	2
896883	56	F	0.24	0.07	0.07	0.06	30	9	9	24	18	9	9	18	1	4	2	2
899842	60	F	0.4	0.08	0.16	0.06	30	7	7	30	18	8	8	18	2	4	3	0
901736	67	F	0.5	0.16	0.18	0.05	28	12	28	28	22	9	9	23	2	4	1	3
901733	80	F	0.4	0.12	0.16	0.5	28	12	28	28	22	9	8	25	2	3	2	1
908782	63	M	8	0.3	0.4	0.5	25	9	25	25	20	10	10	18	2	3	0	3
927103	56	F	0.3	0.14	0.4	0.06	30	9	30	30	20	9	5	18	2	2	1	1
926999	65	F	0.3	0.3	0.4	0.06	25	10	25	25	22	8	6	22	1	4	3	2
93001	67	M	0.62	0.16	0.5	0.06	25	8	8	25	20	10	6	22	1	6	2	1
930013	60	F	0.44	0.3	0.4	0.4	30	12	12	30	25	5	7	20	1	3	1	3
930391	54	M	0.3	0.2	0.16	0.4	30	8	8	30	23	6	9	20	1	3	4	2
928028	70	M	0.3	0.18	0.14	0.4	30	8	8	30	22	6	10	22	1	2	2	2
931013	70	M	0.5	0.1	0.3	0.4	28	18	18	28	24	7	9	20	1	1	1	2
931739	85	M	0.5	0.22	0.4	0.5	28	25	25	28	20	9	9	25	2	1	4	3
931736	62	M	0.4	0.06	0.26	0.4	25	9	9	25	20	10	8	23	2	1	1	2
933387	58	M	0.4	0.4	0.2	0.5	30	7	7	30	22	9	7	22	2	1	2	2
933374	56	F	0.4	0.4	0.2	0.3	30	12	12	30	20	9	9	24	2	2	4	2
933387	60	F	0.4	0.4	0.4	0.3	25	12	12	25	25	8	10	20	1	1	4	2
935016	67	F	0.5	0.5	0.5	0.4	25	9	9	25	23	10	9	20	2	4	1	1
934951	80	F	0.4	0.22	0.4	0.3	30	8	8	30	22	9	9	22	1	2	1	1
934961	63	M	0.5	0.5	0.4	0.2	30	12	12	30	24	8	8	20	2	2	4	1
934948	56	M	0.3	0.2	0.4	0.2	30	8	8	30	20	10	9	25	1	0	1	1
934942	65	F	0.3	0.16	0.4	0.5	28	8	8	28	23	5	9	23	1	1	2	1
934951	67	M	0.4	0.5	0.4	0.5	28	18	18	28	25	6	10	22	2	1	4	1
936902	60	F	0.3	0.5	0.5	0.4	25	25	25	25	20	6	9	24	1	1	4	1

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UHID	age	gender	TMH preop	TMH po 1w	TMH po 1m	TMH po 3m	st 1 preop	st 1 po 1w	st 1 po 1m	st 1 po 3m	preop tbut	tbut po 1w	tubut po 1m	tbut po 3m	rb preop	rb po 1w	rb po 1m	rb po 3m
936932	54	M	0.2	0.06	0.18	0.4	30	9	9	30	22	7	8	20	1	2	1	1
938589	70	M	0.26	0.56	0.5	0.4	30	7	7	30	20	9	10	23	2	1	2	1
938589	70	M	0.5	0.16	0.3	0.4	28	12	12	28	25	10	5	25	2	0	4	1
937230	85	M	0.5	0.4	0.3	0.5	28	12	12	28	23	9	6	20	2	0	1	2
939237	62	M	0.4	0.18	0.4	0.4	25	9	9	25	22	9	6	22	1	1	1	1
948423	58	M	0.4	0.14	0.16	0.5	30	12	12	30	24	8	7	20	2	4	4	2
948399	56	F	0.4	0.14	0.2	0.4	25	9	9	25	22	10	8	23	3	1	1	2
948388	60	F	0.4	0.18	0.18	0.5	28	9	18	25	20	7	8	21	3	2	2	2
948388	67	F	0.5	0.16	0.5	0.3	26	9	10	26	25	9	10	22	3	1	1	1
952146	80	F	0.4	0.02	0.5	0.4	30	10	12	25	23	10	10	25	1	4	4	1
947202	63	M	0.5	0.3	0.4	0.3	28	9	25	25	22	7	8	20	2	1	1	1
945224	56	F	0.5	0.5	0.4	0.5	26	8	9	30	23	10	10	22	2	1	1	1
951024	65	F	0.44	0.18	0.18	0.26	30	18	7	25	23	5	8	22	3	0	0	1
951025	67	M	0.6	0.07	0.5	0.5	30	25	12	30	22	6	10	20	2	0	4	1
951051	60	F	0.6	0.08	0.3	0.5	25	9	12	30	24	6	5	23	1	1	2	1
950223	54	M	0.5	0.16	0.3	0.4	25	7	9	28	22	7	6	21	3	4	4	1
950228	70	M	0.4	0.12	0.4	0.4	30	12	12	30	20	9	6	22	2	1	3	1
950238	70	M	0.5	0.3	0.16	0.4	30	12	9	30	25	10	7	25	1	2	4	1
948388	85	M	0.4	0.14	0.2	0.4	30	9	12	30	23	9	9	20	2	1	5	2
893835	62	M	0.22	0.3	0.18	0.5	28	12	9	28	22	9	10	22	2	3	1	2
893844	58	M	0.36	0.16	0.5	0.4	28	9	9	28	23	10	9	20	3	1	2	1
893849	56	F	0.32	0.3	0.5	0.5	25	9	9	25	24	8	9	22	3	1	5	1
893836	60	F	0.5	0.2	0.4	0.5	30	9	10	30	22	6	8	24	3	4	3	2
893833	67	F	0.5	0.56	0.4	0.44	30	10	9	30	26	10	7	20	2	3	1	1
893849	80	F	0.32	0.16	0.14	0.6	28	9	8	28	22	10	20	22	2	1	4	2
893848	65	M	0.34	0.4	0.4	0.6	30	9	20	20	24	10	10	26	2	2	5	1
54850	56	M	0.22	0.18	0.4	0.5	28	9	26	28	26	8	8	25	2	1	1	2
50656	63	F	0.56	0.14	0.5	0.4	28	9	20	30	28	8	6	22	1	4	4	2
50649	64	M	0.6	0.14	0.2	0.5	26	10	18	18	26	10	10	24	1	1	1	1