ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

Effect of Glycemic Control Duration on Tear Film Quantity and Quality in Diabetic Patients: A Comparative Study

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Dissertation Submitted to the

Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore.

In Partial Fulfillment of the Requirements for the Degree of

Bachelor of Science in Optometry Under the Guidance of

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Publication Date: 2026/02/06

How to Cite: Aishwaryav; A. P. Nishad Begum (2026) Effect of Glycemic Control Duration on Tear Film Quantity and Quality in Diabetic Patients: A Comparative Study. *International Journal of Innovative Science and Research Technology*, 11(1), 3074-3113. https://doi.org/10.38124/ijisrt/26jan799

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

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I hereby declare this dissertation/thesis entitled "EFFECT OF GLYCEMIC CONTROL DURATION ON TEAR FILM QUANTITY AND QUALITY IN DIABETIC PATIENTS: A COMPARATIVE STUDY" is a bonafide and genuine research work carried out by me under the guidance of Mrs. A.P. NISHAD BEGUM (M. OPTOM)

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(Reg. no: 22O0372)

Date:

Place: Tumkur

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ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

CERTIFICATION

Dissertation submitted in partial fulfillment for the award of degree of

Bachelor in Optometry (B.Sc. Optometry)

Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore.

2022-2025

By

Ms. AISHWARYA.V. (Reg No. 22O0372)

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Designation: Designation:

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

ACKNOWLEDGMENTS

I am overwhelmed in all humbleness and gratefulness to acknowledge my depth to all those who have helped me put these ideas, well above the level of simplicity and into something concrete.

Foremost, I would like to express my sincere gratitude to RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES for providing me this opportunity to carry out the research study as a partial fulfilment of B.Sc. Optometry. Next, I would like to express my sincere gratitude to the Principal, Dr. KRISHNA MC and Professor DR. LAVANYA RAMAN department of ophthalmology for helping me grasp more knowledge about the research.

My deepest gratitude to my guide Mrs. A.P. NISHAD BEGUM for guiding me throughout this research work. I am incredibly grateful for his patience, time, and mentorship throughout this project. With her own passion for research that were important to me.

I also extend my gratitude to Ms. MUSKAN KOUSAR and other faculties from Shridevi Institute of Allied Health Sciences who worked actively to provide me motivation to complete my project.

I also thank all the students who have participated in my study for their co- operation and sincerity towards the current study.

It is impossible to extend enough thanks to my family, especially my parents, who gave me the encouragement I needed throughout this process. I would also like to thank all my friends for their support and help throughout this project.

Thank you very much, everyone !!

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

LIST OF ABBREVIATIONS USED

- DM- diabetic mellitus
- NDM-non diabetic
- DES/DED- dry eye syndrome/ dry eye disease
- TBUT- tear break up time
- F-Staining – fluorescein stain
- HbA1c- haemoglobin A1c (measure of blood sugar control)
- Min- minutes
- Mm - Millimetre
- Sec-seconds
- DO- Direct Ophthalmoscope
- TS-Tear secretion
- ST-Schirmer test
- DE-Dry eye
- DR-diabetic retinopathy
- OD- Ocular Dexter (right eye)
- OS- Ocular Sinister (left eye)
- OU- Ocular Uterque (both eyes)
- INS-Insulin
- GLU-Glucose

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

ABSTRACT

- ***Background:***

Diabetes can affect the tear film due to chronic hyper glycemia and reduced corneal sensitivity, leading to dry eye symptoms. Poor glycemic control and longer duration of diabetes further worsen tear quantity and quality. Assessing tear film changes helps in early detection and better ocular management in diabetic patients.

- ***Aim:***

To evaluate tear film quantity and quality in diabetic patients compared to non-diabetics, with reference to duration of diabetes.

- ***Methodology:***

This comparative study was conducted at Shridevi Institute of Allied Health Sciences from March to November 2025, including 56 participants—28 diabetics and 28 age-matched non-diabetic controls selected through systematic random sampling. After consent, each subject underwent Schirmer's test, TBUT, and fluorescein staining to assess tear film quantity and quality. Results were compared between diabetic groups based on HbA1c and duration, and with non-diabetic control.

- ***Result:***

Diabetic participants showed significantly lower Schirmer's and TBUT values compared to non-diabetics, indicating reduced tear quantity and stability. Higher HbA1c levels were associated with poorer tear film function, showing that diabetes negatively affects the tear film.

- ***Conclusion:***

Diabetes significantly reduces tear film quantity and stability, increasing the risk of dry eye. Poor glycemic control further worsens these changes, highlighting the need for regular tear film quantity and quality evaluation in diabetic patients.

Keywords: *Diabetes Mellitus, Glycemic Control, HbA1c, Tear Film, Schirmer's Test, Tbut, Fluorescein Staining, Dry Eye***.**

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CHAPTER ONE
INTRODUCTION

- *Eye*

The eye is a highly specialized sensory organ responsible for vision .Because of its complex structure and rich blood supply the eye is sensitive to both internal body changes and external environmental factors .Even small disturbance in the body, such as metabolic changes ,nerve damage ,or vascular abnormalities ,can effect normal eye function .Therefore ,maintaining ocular health is essential for overall well being and quality of life

- *Diabetes Mellitus:*

Diabetes mellitus is a long-term health condition in which the body cannot properly control the level of sugar in the blood. Normally, the pancreas produces a hormone called insulin that helps glucose move from the bloodstream into the body's cells, where it is used for energy.[3] In diabetes, either the pancreas does not make enough insulin or the body does not use insulin properly. As a result, glucose stays in the blood instead of entering the cells, leading to high blood sugar levels.[1,4] There are mainly two types of diabetes: Type 1, where the body completely stops producing insulin, and Type 2, which is much more common and occurs when the body becomes resistant to insulin or gradually produces less of it over time, Type 3, gestational diabetes which occurs in pregnancy and can cause some complications during the pregnancy, and at birth and increases the risk of type 2 diabetes in the mother and obesity in the offspring.[3,2] Diabetes can cause many symptoms like increased thirst, frequent urination, tiredness, and slow wound healing. If it remains uncontrolled for many years, it can affect different parts of the body, including the eyes, kidneys, nerves, heart, and blood vessels.[4] In the eyes, diabetes can reduce corneal sensitivity, affect tear secretion, and disturb the tear film, making diabetic individuals more likely to develop dry eye disease. Good control of blood sugar through diet, medication, exercise, and regular checkups is important to prevent these complications and maintain overall health[5].

- *HbA1c*

HbA1c, also known as Glycated Haemoglobin, is a clinical marker used to assess long-term blood glucose control in individuals with diabetes. Haemoglobin is a protein found inside red blood cells, and when glucose circulates in the bloodstream, a portion of it attaches to haemoglobin through a process called glycation[6-7]. The percentage of haemoglobin that becomes glycated is measured as the HbA1c value. Unlike random blood sugar or fasting blood glucose, which show immediate sugar levels, HbA1c reflects the average blood glucose level over the past 2–3 months[2,5].This is because red blood cells have a lifespan of about 120 days[1]. As a result, HbA1c is considered the most reliable indicator of long-term glycemic control in diabetic patients[7,6]. Higher HbA1c levels indicate poor blood sugar control, which increases the risk of systemic complications such as neuropathy, nephropathy, retinopathy, and cardiovascular disease[9]. It also affects the ocular surface, contributing to reduced tear secretion, tear film instability, and increased dry eye severity[5,7].

- *Risk Factors:*

Type 1 occurs most frequently in children, adolescents, and young adults. The cause or causes are not known[2].A combination of genetic susceptibility and environmental factors is believed to lead to type 1 diabetes[1,2]. Despite extensive research into potential biological, chemical, nutritional, and behavioral causes, none has as yet been identified as the cause of a significant number of cases beyond reasonable doubt[8]. The risk factors for type 2 diabetes are better known. Although the genetic component is substantial, the majority of cases occur in the presence of risk factors - age, overweight and obesity, and physical inactivity[10]. Smoking has also been shown to increase the risk of diabetes, but by far the strongest risk factor is increased body fat. Some ethnic groups, such as people of Southeast Asian origin are more sensitive than others to the diabetogenic effect of excess body fat. Several dietary practices, such as a high sugar and fat intake have also been linked to increased risk of type 2 diabetes[7]. The risk factors for gestational diabetes are not only similar to those for type 2 diabetes - family history, age, overweight and obesity, physical inactivity but also include excessive weight gain during pregnancy[9].

- *Complication:*

Diabetes, when not properly controlled, can cause long-term damage to various organs because high blood sugar harms blood vessels and nerves over time. This can lead to complications such as eye problems (diabetic retinopathy), kidney disease, nerve damage, heart disease, poor circulation, and delayed wound healing. HbA1c is an important test that shows the average blood sugar level over the past 2–3 months. A high HbA1c value indicates poor diabetes control, which increases the risk of all these complications.[9,10]

- *Preventing Diabetes:*

Diabetes can be prevented by eating healthy, staying active, maintaining a normal weight, and avoiding smoking and excess sugar. Regular checkups and a balanced lifestyle greatly reduce the risk.[6]

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➢ *Managing Diabetes:*

- *Diagnosis and Early Detection*

Even in high-income countries, a substantial proportion of cases of type 2 diabetes are undiagnosed because of a lack of pronounced symptoms. Diabetes is diagnosed by measuring glucose in a blood sample taken in the fasting state or 2 h after a 75 g oral glucose load.[9] Glycated hemoglobin A1c (HbA1c) can also be used to diagnose diabetes but is more costly than blood glucose measurement.[1] Basic diagnostic testing should be available in primary healthcare settings.[3] The decision to put in place or not put in place systems for early detection of diabetes should be based on whether the local healthcare resources are sufficient to cope with the extra workload.[7-10]

➢ *Components of Diabetic Management:*

Managing diabetes involves taking consistent steps to keep blood sugar levels within a healthy range and prevent long-term complications. A balanced diet plays a key role and includes choosing whole grains, vegetables, lean proteins, and foods low in sugar and unhealthy fats.[3] Regular physical activity, such as walking, cycling, or exercise for at least 30 minutes a day, helps the body use insulin more effectively and improves overall health.[6] Many individuals need oral medications or insulin therapy to control their blood sugar, and taking these medicines correctly is essential for good management. Regular monitoring of blood glucose and periodic testing of HbA1c help track how well the diabetes is controlled.[1,4] Maintaining a healthy weight, managing stress, getting enough sleep, and avoiding smoking also contribute to better diabetes control. Routine checkups with doctors, eye specialists, and other healthcare providers help detect complications early.[2] By combining lifestyle changes, medication, and regular monitoring, people with diabetes can manage the condition effectively and lead a healthier life. [1,5,6]

➢ *Tear Secretion:*

Tears are the fluid secreted by the eyes to nourish them by maintaining a balance of the ingredients of the eyes and moisture content of the eye. Precorneal (tear) film is spread across the eye and it has three layers namely, the lipid layer, aqueous layer, and mucous layer.[7,8] The lipid layer (secretes lipid) acts as a hydrophobic barrier and prevents the overflow of tears.[7] The aqueous layer (which contains water and tear proteins) acts as a physiological barrier and controls infection of the eyes.[4,3]The mucous layer (secrete mucin) acts as a hydrophilic layer.[8] In a day, 0.75-1.1 grams of tears are secreted which decreases with age. The tears are secreted by the lacrimal gland situated laterally.[8]

➢ *Tear Film:*

Tear film is the thin layer of tear fluid secreted continuously by the lacrimal glands. The tear film is important as the relation between the air and the tear film is responsible for two-thirds of the total refractory power of the eye.[1,5] Tear film covers an area of 1-3 square cm and has a thickness of2.7-11micro.[7] Tear film break-up time is used to check the stability of the tear film in case of dry eye and other eye disorders.[4] It is seen that lithium carbonate and sodium valproate help in decreasing the time taken for tear film break up.[5] Cortisol and dehydroepiandrosterone are some stress biomarkers present in tear secretion.[4] Thickness of the tear film is contributed mainly by the aqueous secretions of the eye and it contributes nearly 60% of the total value.[6] The tear film is a smooth layer formed during blinking and finally breaks up during evaporation. Thus the images become blurred with an increase in time. Irregular tear films cause visual problems.[8]

➢ *Tear Function in Diabetic Patients:*

Diabetes mellitus significantly affects normal tear function due to chronic hyperglycemia, which leads to microvascular damage, autonomic neuropathy, and dysfunction of the lacrimal functional unit.[2] Persistent elevated blood glucose levels, reflected by increased HbA1c values, are strongly associated with reduced tear secretion and greater ocular surface changes.[3,8] Higher HbA1c indicates poor long-term glycemic control, which worsens lacrimal gland impairment, decreases corneal sensitivity, and promotes inflammatory changes on the ocular surface.[5] These factors collectively result in decreased tear production, disturbed meibomian gland function, and reduced tear film stability, ultimately leading to increased evaporation and shortened tear film break-up time.[7] Consequently, individuals with poorly controlled diabetes (higher HbA1c levels) are more likely to experience symptoms of dry eye disease, such as burning, irritation, foreign body sensation, and fluctuating vision.[10] Therefore, evaluating tear function through Schirmer's test, TBUT, and fluorescein staining, along with monitoring HbA1c levels, is important for understanding the severity of tear film abnormalities in diabetic patients.[1]

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CHAPTER TWO
REVIEW OF LITERATURE

- Fanhua Meng et al. (2025) ss conducted a study title Impact of Hyperglycemia on Tear Film & MGD / Cross-sectional study with sample size of 56. This study concluded that Hyperglycemia damages tear film and meibomian glands; good glucose control helps protect ocular surface. [1]

- Bilal Khan et al. (2025) conducted a study title Comparative analysis of dry eye syndrome among diabetic versus nondiabetic patients presenting to tertiary care hospital, Peshawar/A case–control study with sample size of 100. This study concluded that Dry eye syndrome is significantly associated with diabetes mellitus; early screening in diabetics is necessary for timely intervention. [2]

- Vennila Selvaraj et al. (2023) conducted a study title Comparative study of dry eye status in normal healthy individual and type-II diabetes mellitus/Cross-sectional study with sample size of 350. This study concluded that Diabetes is associated with higher prevalence of dry eye, especially in older age groups and females. [3]

- Yu-Kai Kuo et al. (2022) conducted a study title Tear function in patients with diabetes mellitus: A systematic review and meta-analysis/Systematic review and meta-analysis with sample size of 7,234 eyes. This study concluded that Patients with type 1 or 2 DM have poorer tear function; good glycemic control is important to maintain tear film stability. [4]

- Nilesh Parekh et al. (2021) conducted a study title A Comparative Study of Tear Film Tests in Diabetic and Non-diabetic Patients – A Cross-Sectional Study/Cross-sectional observational study with sample size of 150. This study concluded that Dry eye is more common in diabetics; tear film tests showed significant reduction and should be considered in examinations. [5]

- Yash Hada, Shashank Banait (2020) conducted a study title A Comparative Clinical Study of the Precorneal Tear Film in Diabetic and Nondiabetic Person/Cross-sectional comparative study with sample size of 126. This study concluded that Diabetes is associated with reduced tear film amount and stability, indicating higher prevalence of dry eye. [6]

- Aljarousha et al. (2016) conducted a study title Comparison of Dry Eye Parameters between Diabetics and Non-Diabetics in District of Kuantan, Pahang / Retrospective study with sample size of 643. This study concluded that Diabetes is associated with higher prevalence of dry eye; regular screening is important. [7]

➢ *Need of Study:*

This study is needed to establish how glycemic control (HbA1c) affects tear film quantity and quality, enabling early detection and better ocular care in diabetic patients.

➢ *Hypothesis*

- *Null Hypothesis (H0):*

There is no significant association between diabetes (including HbA1c levels and duration) and tear film quantity or quality.

- *Alternate Hypothesis (H1):*

There is a significant association between diabetes (and its control/duration) and tear film abnormalities — specifically, poorer glycemic control (higher HbA1c) and longer duration of diabetes are associated with reduced tear quantity and worse tear quality.

➢ *Aim & Objectives*

- *Aim:*

✓ To evaluate tear film quantity and quality in diabetic patients compared to non- diabetics, with reference to duration of diabetes.

- *Objectives:*

✓ To assess tear film quantity in diabetic and non-diabetic individuals using Schirmer's test.
✓ To evaluate tear film stability and ocular surface integrity using TBUT and fluorescein staining.
✓ To correlate tear film abnormalities with HbA1c levels in diabetic patients.(<5, 5–10, 10–15, >15 years).
✓ To compare tear film parameters between diabetic and age-matched non-diabetic controls

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CHAPTER THREE
MATERIALS & METHODOLOGY

➢ *Methodology:*

- Study of site: Shridevi Institute of Allied Health Sciences, Tumkur.
- Source of data: OPD patients of Shridevi Institute of Medical Sciences and Research Hospital, Tumkur.
- Study design: A comparative study.
- Sampling method: Systematic Random Sampling Method
- Study duration: From March 2025 to November 2025.
- Sample size: 56 Samples
- Justification for sample size: The sample size was calculated using study conducted in India by Sabarwal S et al., in 2025. In this study shows that the prevalence rate of dry eye disease was 25%. At 95% confidence level with 5% allowable marginal error, the sample size calculation using below formula,

$$\text{Sample size (n)} = \quad n = \frac{Z^2 \cdot p(1-p)}{e^2} \quad 50.74 + 10\% \text{ non-response rate} = 55.814$$

= 56 participants Where, n = Sample size,

Z = Z-Statistics for a level of confidence

P = Prevalence rate of dry eye disease patients e = Marginal error

Therefore, total 56 suspected samples should be included in this study (28 participants in each group).

➢ *Materials Used:*

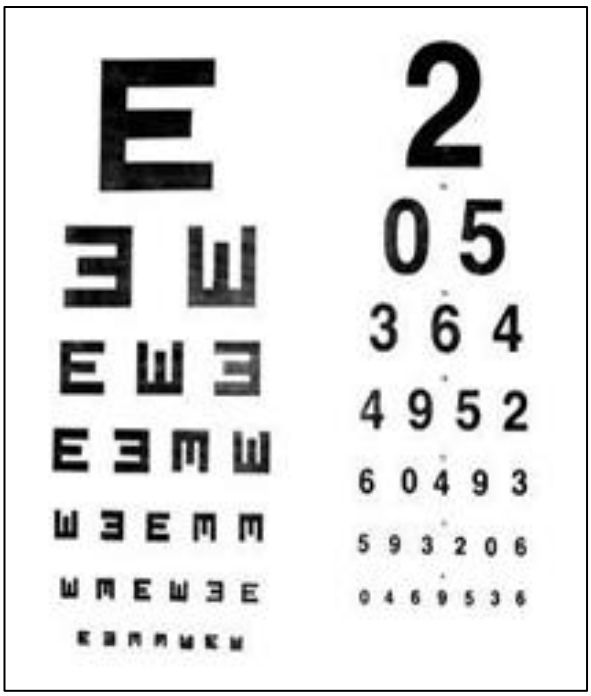

Fig 1 Snellen's Chart
(https://images.app.goo.gl/MgMuLwkk48wouAh7)

Fig 2 Trial Set
(Self-Image)

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Fig 3 Retinoscope & Direct Ophthalmoscope
https://images.app?GwNPSgC1gk1f9STPA)

Fig 4 Slit Lamp
https://www.zeiss.com/slit-lamps.html)

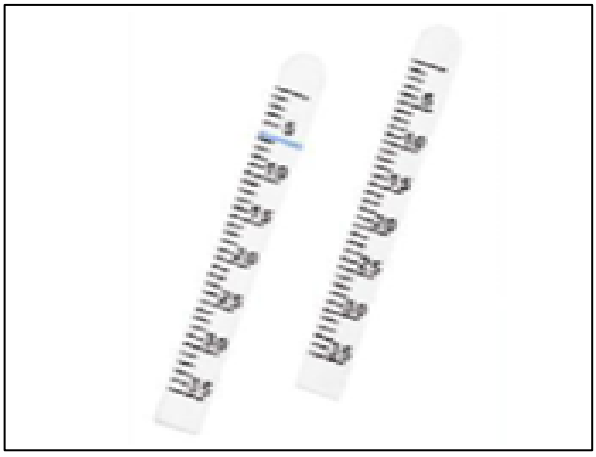

Fig 5 Schirmer Strip
(https://www..figure/Tear-test-strips-in-Schirmer)

Fig 6 Fluorescein Strip
(Self-image)

Fig 7 Paracain (0.5%)
(Self-Image)

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➢ *Inclusion Criteria:*

- *Case Group (Diabetic Participants)*

✓ Patients of age more than 40-70 years of both genders

✓ Patients of both type1 and type2 diabetes mellitus

✓ Patients who have a history of diabetic more than 3 years

✓ HbA1c reports available within the last 3 months.

✓ Patients on regular diabetic treatment (oral hypoglycemic agents and/or insulin)

✓ Patients giving written and informed consent for the study

- *Control Group (Non Diabetic Participants)*

✓ Age and gender-matched healthy individuals without diabetes.

✓ No history of systemic diseases known to affect tear production or ocular surface health.

✓ Normal fasting and postprandial blood glucose levels

✓ Willing and able to provide written informed consent.

✓ No history of ocular surgery, ocular trauma, or use of topical ocular medications

➢ *Exclusion Criteria:*

- *(For Both Case and Control Groups)*

✓ People who wear contact lenses

✓ Patients allergic to fluorescein dye.

✓ People below age of 40.

✓ Systemic diseases known to affect tear secretion (e.g., Sjögren's syndrome, rheumatoid arthritis, thyroid disorders).

✓ Media opacities restricting posterior segment evaluation

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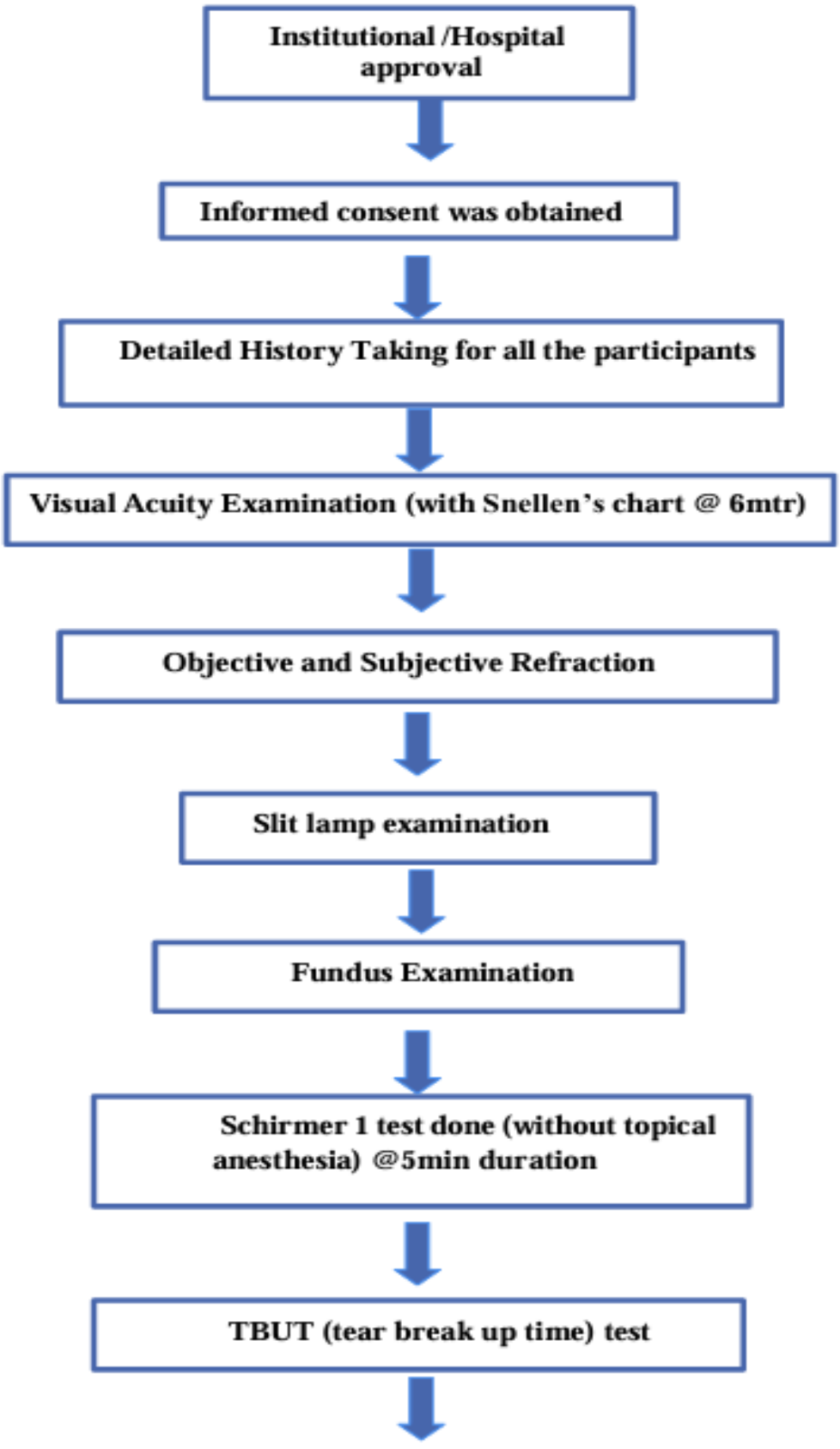
METHODOLOGY



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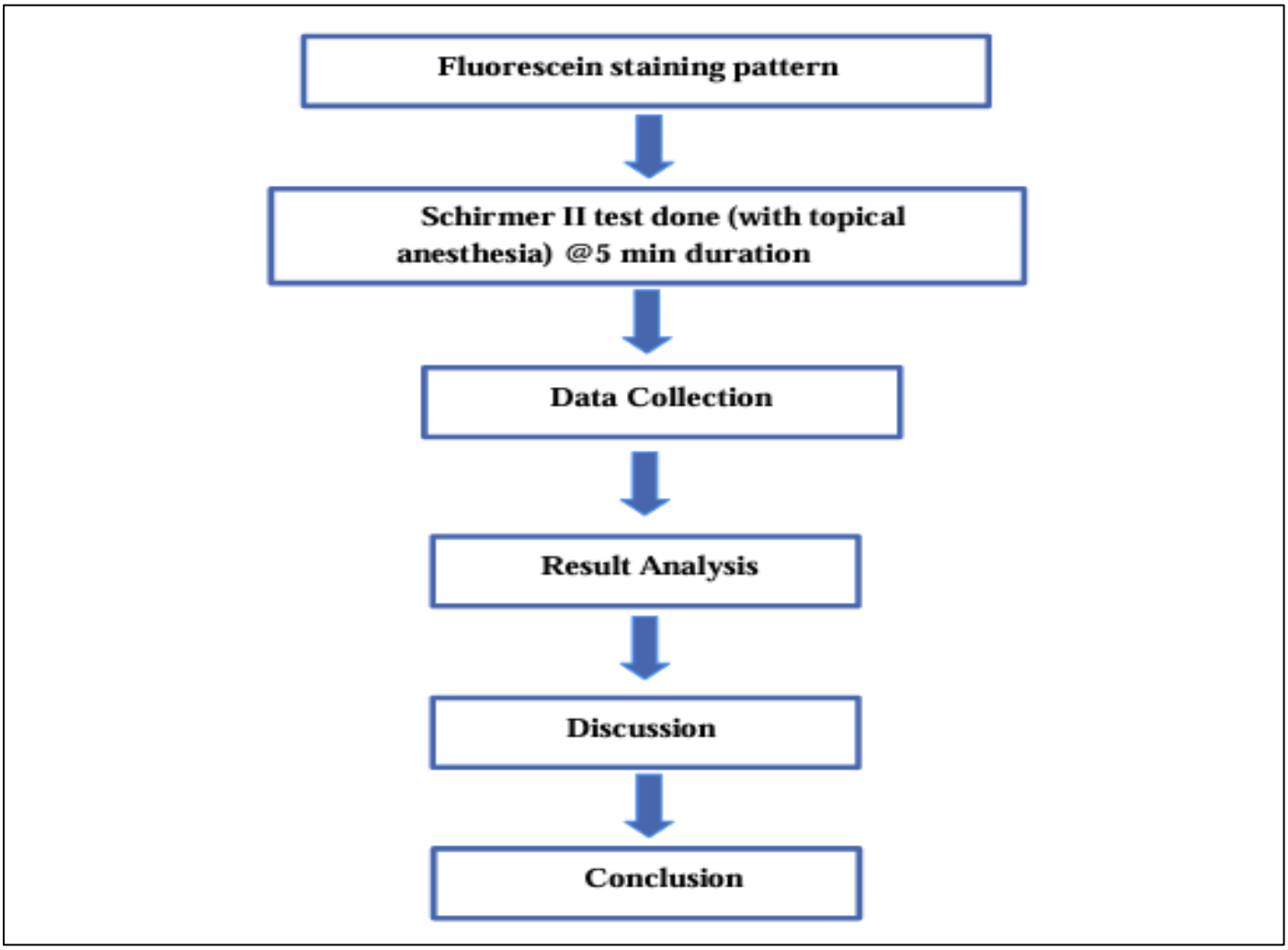

Fig 8 Flow Chart of "Procedure/Methodology."

Participants were selected from Shridevi Institute Of Allied Health Science of Tumkur from 2025. The purpose of the study was explained and informed, consent was taken from them.

All the participants had to undergo a comprehensive ocular examination. Eyes that fulfilled the inclusion criteria were selected for further assessment and 40 participants were selected for this study. Visual Acuity, Subject Refraction, Objective Refraction, Slit Lamp Examination, Fundus Examination, Schirmer 1&2, TBUT, F-staining. The detailed procedure performed in the study is explained below:

➢ *History Taking:*

History taking was the step to evaluate participants eye health by recording their Demographic History such as Name, Age, Gender, Address, Occupation, Contact Info proceeded by Chief Complaints, Ocular History, Systemic History, Medical History, Family History, Social History was documented.

➢ *Visual Acuity:*

- *Distant Visual Acuity:*

A Snellen's chart was used to evaluate Distant Visual Acuity from distance of 6 meter.[13] The participants was asked to sit comfortably and read with each eye separately. Then the Visual Acuity was recorded (Aided & Unaided).[13]

Each line on the chart corresponds to a certain level of vision and is labelled with a fraction such as 6/6, 6/9, 6/12, and so on.

- *Near Visual Acuity:*

Near visual acuity was tested with the help of Reduced snellen's chart at 40 cm.[14] The participants was asked to read the chart kept at 35 - 40cm with the good illumination.[14] Each eye was tested separately and recorded.[14]

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➢ *Refraction:*

- *Objective & Subjective Refraction:*

The participant was made to sit at the distance of 1m from the examiner & instructed to focus on a distance target 6/60.[15] Now the examiner, through retinoscope observe the red reflex in the participant eye.[15] If the reflex moves 'with the movement' a plus lens was used and if it moves 'against the movement' a minus lens was used to Neutralise.[17] This procedure was repeated for both the vertical & horizontal meridian to measure the astigmatism. Same procedure was repeated to other eye. [15,17] Then we subtract the Working Distance from the neutralising lens by which we get value of subjective refraction. [15,17]

- *Slit-Lamp Examination:*

The slit-lamp was used as comprehensive eye exam to visualise the Anterior Segment of the eye.[16] The participant was made to seat comfortably in front of the slit-lamp with the chin placed at the chin rest & forehead against head rest to keep it steady.[16] Diffused illumination was used to examine the Lid Margin, Conjunctiva, Iris pattern. Pupil regularity was observed by changing the intensity of illumination.[10] Cornea, Anterior Chamber depth and Crystalline Lens was observed using optical section.[10,16]

- *Fundus Examination:*

Fundus examination was performed using Direct Ophthalmoscope (DO). Participant was informed about the procedure.[10,17] The participant was asked to sit comfortably and to look at distant point. [10] Slowly the DO is moved closer to participants eye from 15 inches to 1 or 2 inches, particularly the Retina, Optic Disc, Macula & Blood Vessels were observed and recorded monocularly.[10,17]

- *Schirmer Test:*

The patient was explained about the entire procedure. The strip was shown to the patient. The patient was seated comfortably at the slit lamp. The test was performed by using a Schirmer's strip (Whatman filter paper no.41,5mm wide and 35 mm long). The strip was first folded at the 5mm mark and placed in the lower lid at the junction of the middle and outer third. Care must taken not to touch the cornea. Both eyes were examined simultaneously After 5 minutes both the strips were removed from the fornices and the wetting of the filter paper strip was measured from the fold. Wetting of less than 10mm was considered abnormal. Values of 5-10mm are suggestive of moderate to mild dry eye and less than 5mm are suggestive of suggestive of severe dry eye.

Fig 9 Schirmer Test
(Self-Image)

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

- *Tear Film Break-Up Time:*

The patient has explained the procedure. After a fluorescein strip moistened with sterile saline has been applied to the tarsal conjunctiva in the lower fornix and the patient asked to blink a few times, the strip is removed. The patient was comfortably seated at the slit lamp and the tear film is evaluated using a broad beam of the slit lamp with cobalt blue illumination. The patient asked to blink a few times and then asked not to blink and observed the slit lamp. The time lapse between the last blink and the appearance.

Fig 10 TBUT
(Self-Image)

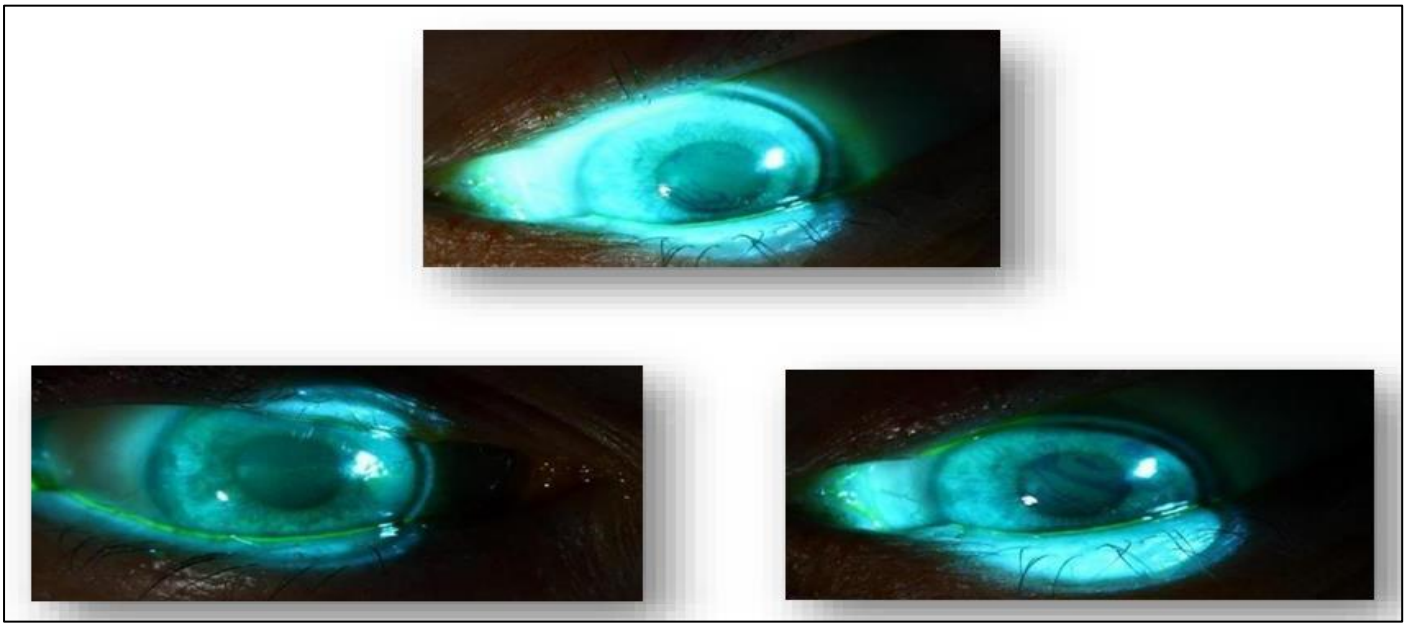


Fig 11 TBUT Images
(Self-Image)

The first randomly distributed dry spot on the cornea is the TBUT. The appearance of dry spots in less than 10 seconds is considered abnormal.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

- *Fluorescein Staining:*

Fluorescein staining helps identify different patterns of corneal epithelial damage based on how the dye pools in areas of epithelial loss. The most common pattern is punctate epithelial erosions, which appear as small, bright dots indicating mild surface damage, often seen in dry eye or contact lens irritation. When these dots become denser and grouped, they form punctate epithelial keratopathy, commonly associated with viral or toxic causes. Linear staining occurs as straight lines and usually suggests mechanical trauma from a foreign body or lid abnormalities. More extensive epithelial loss produces geographic or map-like staining, seen in severe dry eye or post-herpetic lesions. A characteristic dendritic, branching pattern with terminal bulbs is typical of active herpes simplex keratitis. In negative staining, the dye outlines elevated lesions, making abnormal areas appear dark. Filament staining occurs when mucus filaments adhere to the cornea, seen in severe dry eye conditions. These staining patterns help clinicians diagnose the underlying pathology and assess the severity of ocular surface disease.

Fig 12 Fluorescein Staining
(Self-Image)

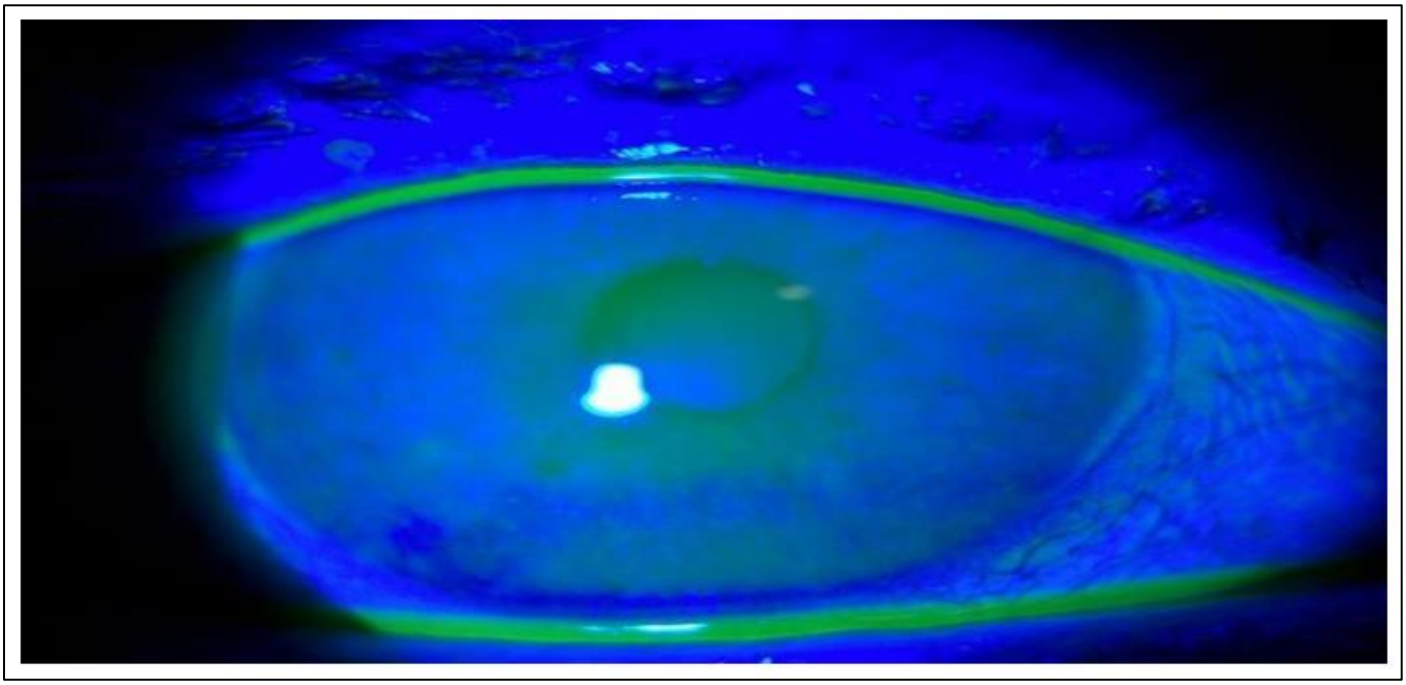


Fig 13 Fluorescein Staining Pattern
(Self-Image)

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

- *Statistical Analysis:*

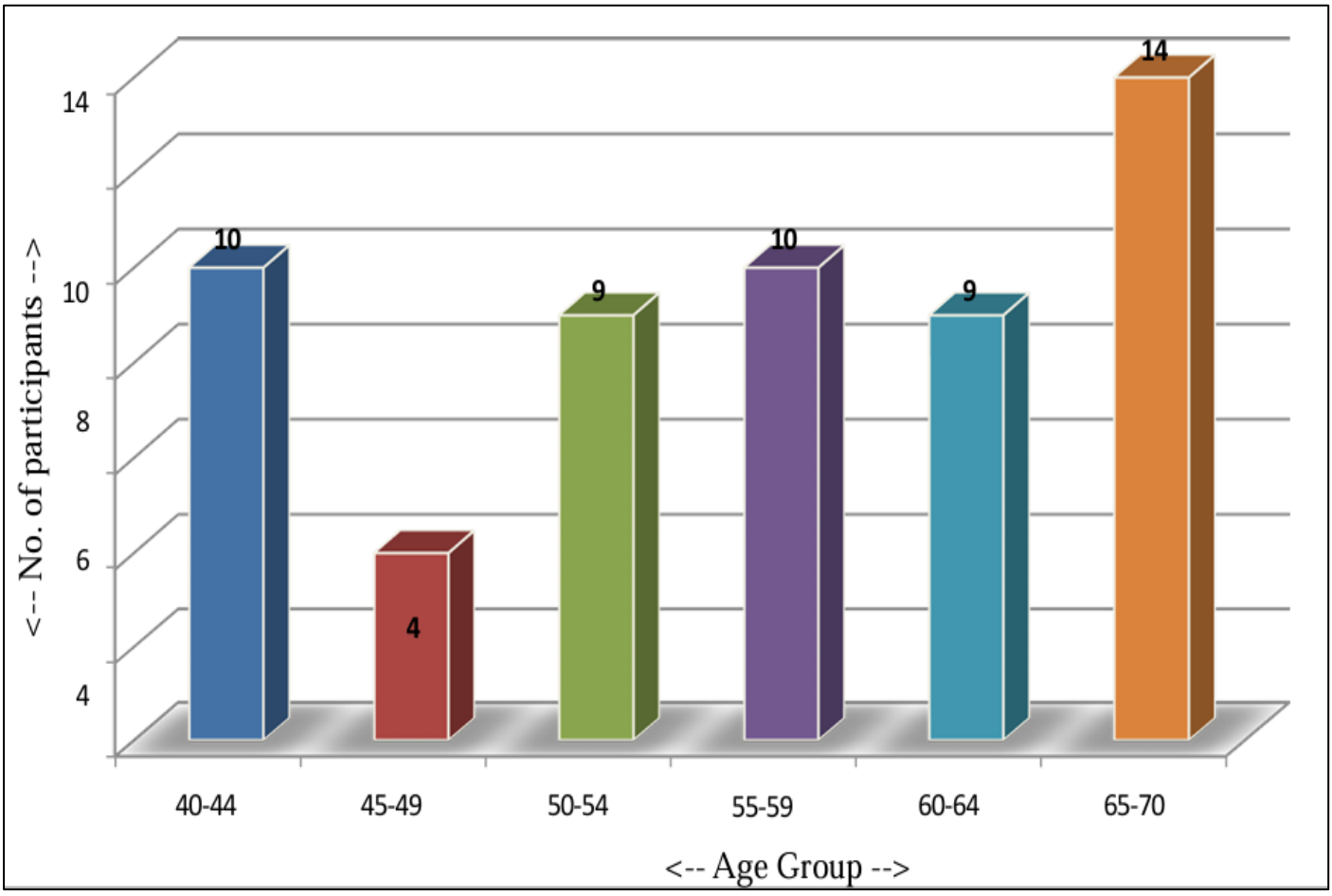
Data will be analysed using SPSS software. Continuous variables such as Schirmer's test, TBUT, and HbA1c will be expressed as mean ± SD, and categorical variables as percentages. Normality will be tested using the Shapiro–Wilk test. Comparison between groups based on glycemic control and duration will be done using independent t-test or ANOVA. Chi-square test will be used for categorical variables. Correlation between HbA1c and tear film parameters will be assessed using Pearson or Spearman correlation. A p-value<0.05 will be considered statistically significant.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

CHAPTER FOUR
RESULT

Table 1 Age (in Years) Distribution of Participants

Age group (in years)	No. of participants	Percentage
40 - 44	10	17.86
45 - 49	4	7.14
50 - 54	9	16.07
55 - 59	10	17.86
60 - 64	9	16.07
65 - 70	14	25.00
Total	**56**	**100.00**



X Axis Represents Age Group
Y Axis Represents No of Participants
Graph 1: Participant Demographics: Age Profile

The above table 1 and graph 1 shows that the comprised 56 participants, with the majority (25%) in the 65-70 age group, followed by 17.86% in both the 40-44 and 55- 59 age groups. The 45-49 age group had the lowest representation (7.14%). The distribution suggests an increasing trend in participation with advancing age, with the highest proportion of participants in the oldest age category (65-70 years), indicating potential age-related bias in the study sample or a higher prevalence of the condition being studied among older adults

Table 2 Gender-Wise Distribution of Participants

Gender	No. of participants	Percentage
Female	27	48.21
Male	29	51.79
Total	**56**	**100.00**

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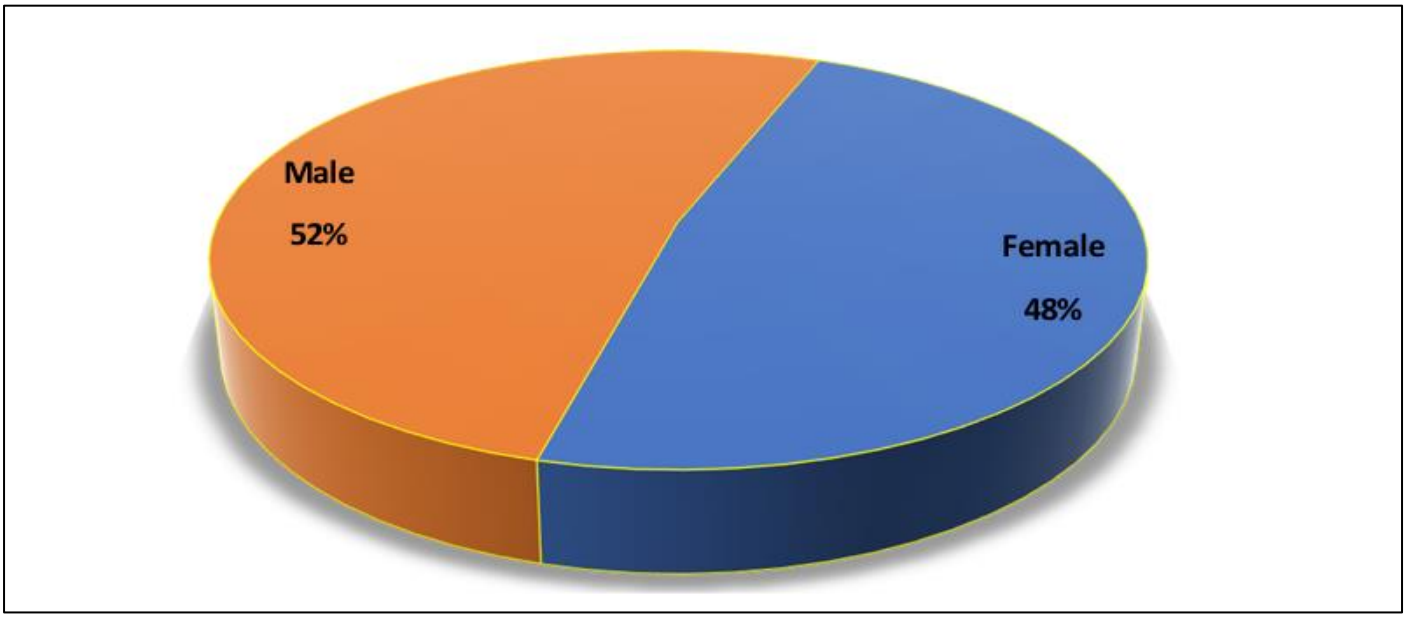
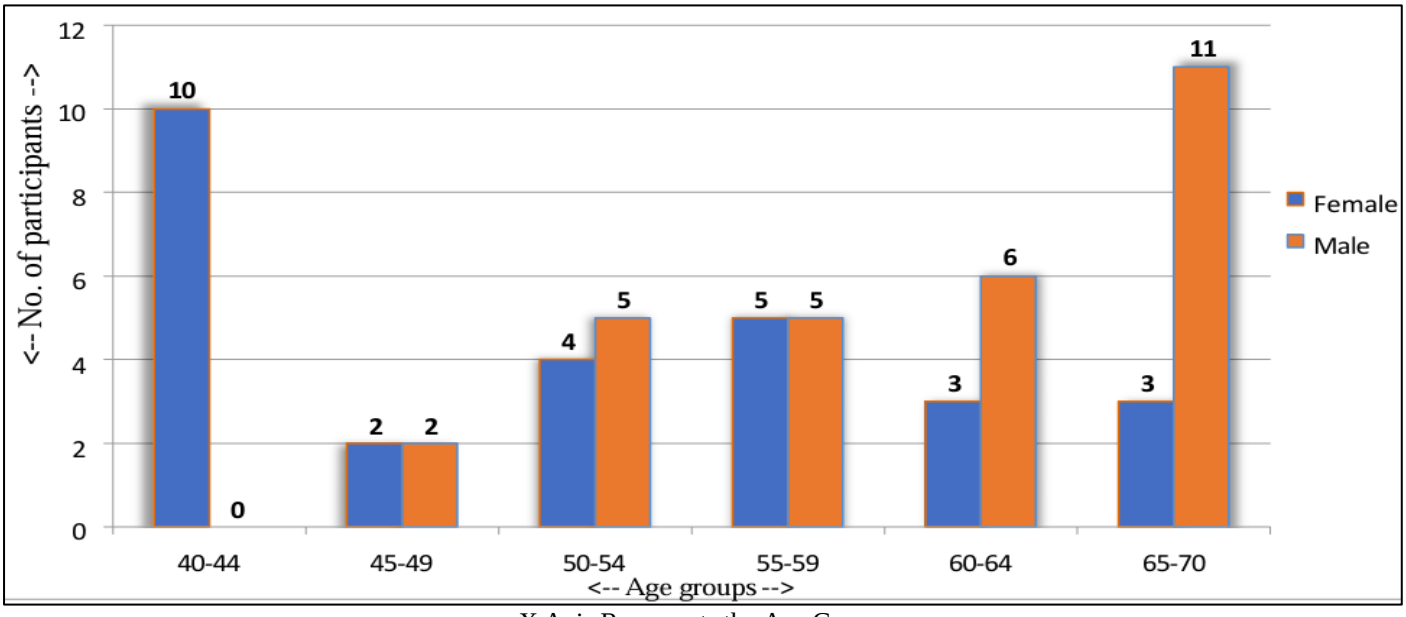


Graph 2 Participant Demographics: Gender Profile

The above table 2 and graph 2 show that the study comprised 56 participants with a relatively balanced gender distribution. Males accounted for 51.79% (29 participants), while females accounted for 48.21% (27 participants). The near-equal representation of both genders indicates that the study sample was fairly balanced in terms of gender, thereby minimizing potential bias and allowing for more robust comparisons between male and female subgroups.

Table 3 Age and Gender Distribution of Participants

Age group (in years)	Gender				Total
	Female	Percentage	Male	Percentage	
40 - 44	10	37.04	0	0.00	10
45 - 49	2	7.41	2	6.90	4
50 - 54	4	14.81	5	17.24	9
55 - 59	5	18.52	5	17.24	10
60 - 64	3	11.11	6	20.69	9
65 - 70	3	11.11	11	37.93	14
Total	**27**	**100.00**	**29**	**100.00**	**56**



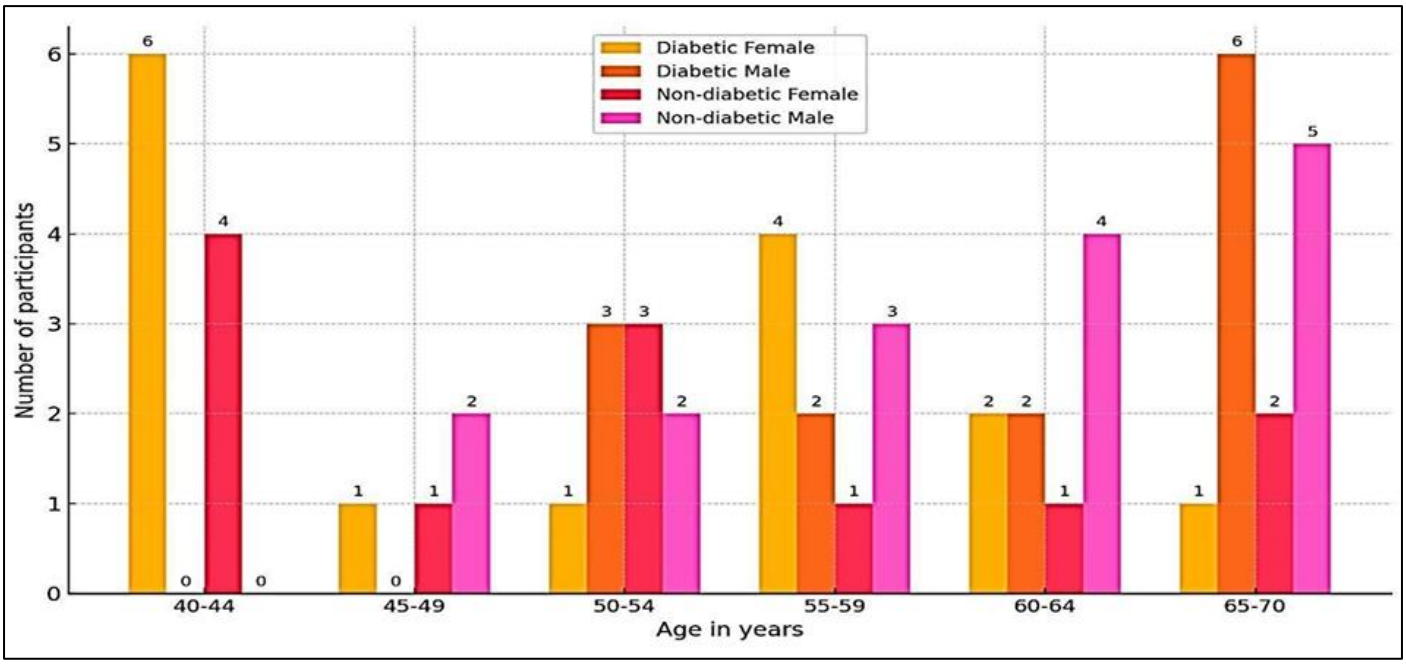
X Axis Represents the Age Group
Y Axis Represent the No of Participants
Graph 3 Age and Gender Distribution of Participants

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

The above table 3 and graph 3 shows that the age and gender distribution of participants reveals a diverse representation across various age groups. The majority of female participants (37.04%) fall within the 40 - 44 age group, whereas the majority of male participants (37.93%) are in the 65 - 70 age group. The distribution suggests a higher proportion of males in older age groups (60 - 64 and 65 - 70 years), while females are more represented in the younger age groups (40 - 44 and 45 - 49 years). This disparity highlights potential gender-specific trends in the study population, warranting further investigation into the underlying factors contributing to these differences.

Table 4 Age- and Gender-Wise Distribution of Diabetic and Non-Diabetic Participants

Age in years	Diabetic			Non-diabetic			Total
	Female	Male	Total	Female	Male	Total	
40 - 44	6	0	6	4	0	4	10
45 - 49	1	0	1	1	2	3	4
50 - 54	1	3	4	3	2	5	9
55 - 59	4	2	6	1	3	4	10
60 - 64	2	2	4	1	4	5	9
65 - 70	1	6	7	2	5	7	14
Total	**15**	**13**	**28**	**12**	**16**	**28**	**56**



X Axis Represents Age in Years
Y Axis Represents No of Participants
Graph 4 Age- and Gender-Wise Distribution of Diabetic and Non-Diabetic Participants

The above table 4 and graph 4 shows that the highest number of participants belonged to the 65–70 years age group (25%)**,** followed by the 40–44 years and 55– 59 years groups (each 17.86%). Both diabetic and non-diabetic participants were equally represented (n = 28 each). Among diabetics, females were slightly more prevalent (53.6%) than males (46.4%), whereas among non-diabetics, males were marginally higher (57.1%) than females (42.9%). Overall, the data indicate that the study population was predominantly composed of middle-aged to elderly individuals**,** with a fairly balanced distribution across gender and diabetic status.

Table 5 Distribution of Study Participants According to HbA1c (%) Levels

HbA1c Range (%)	Status	No. of participants
< 5.7	Normal (Non-diabetic)	28
5.7 – 6.4	Pre-diabetes	1
≥ 6.5	Diabetes	27
Total		**56**

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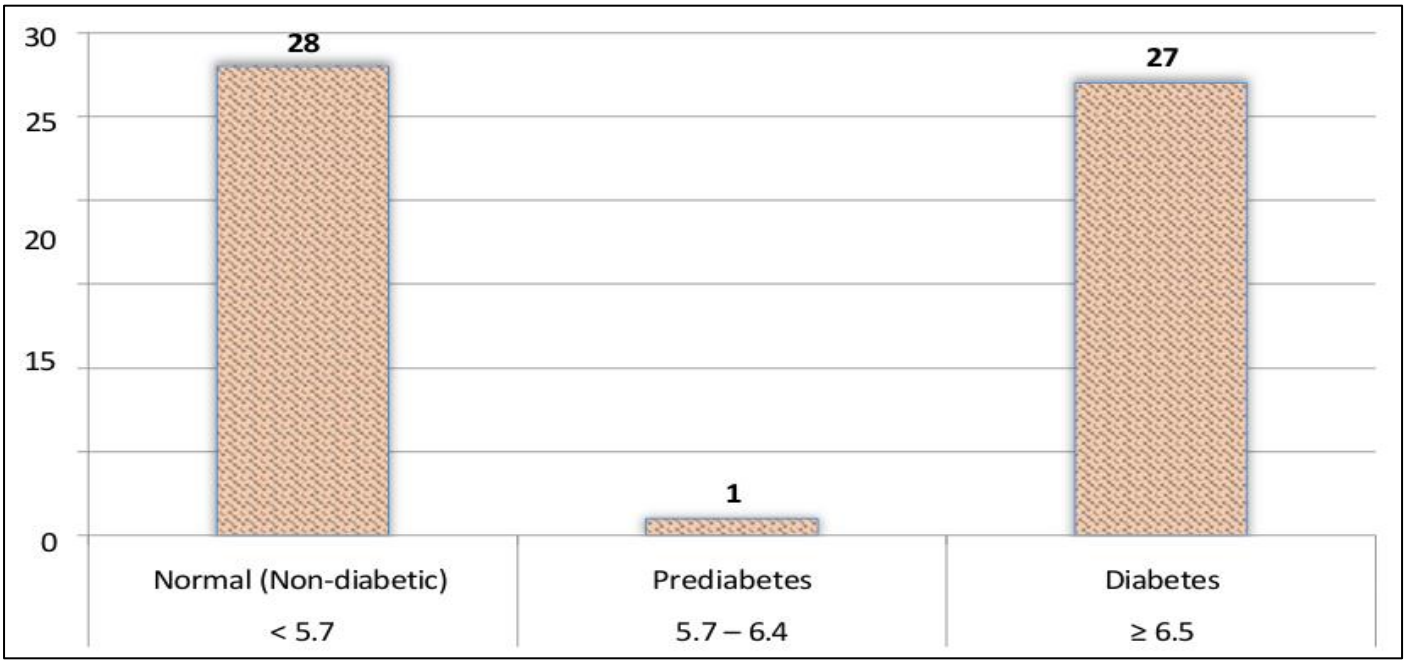


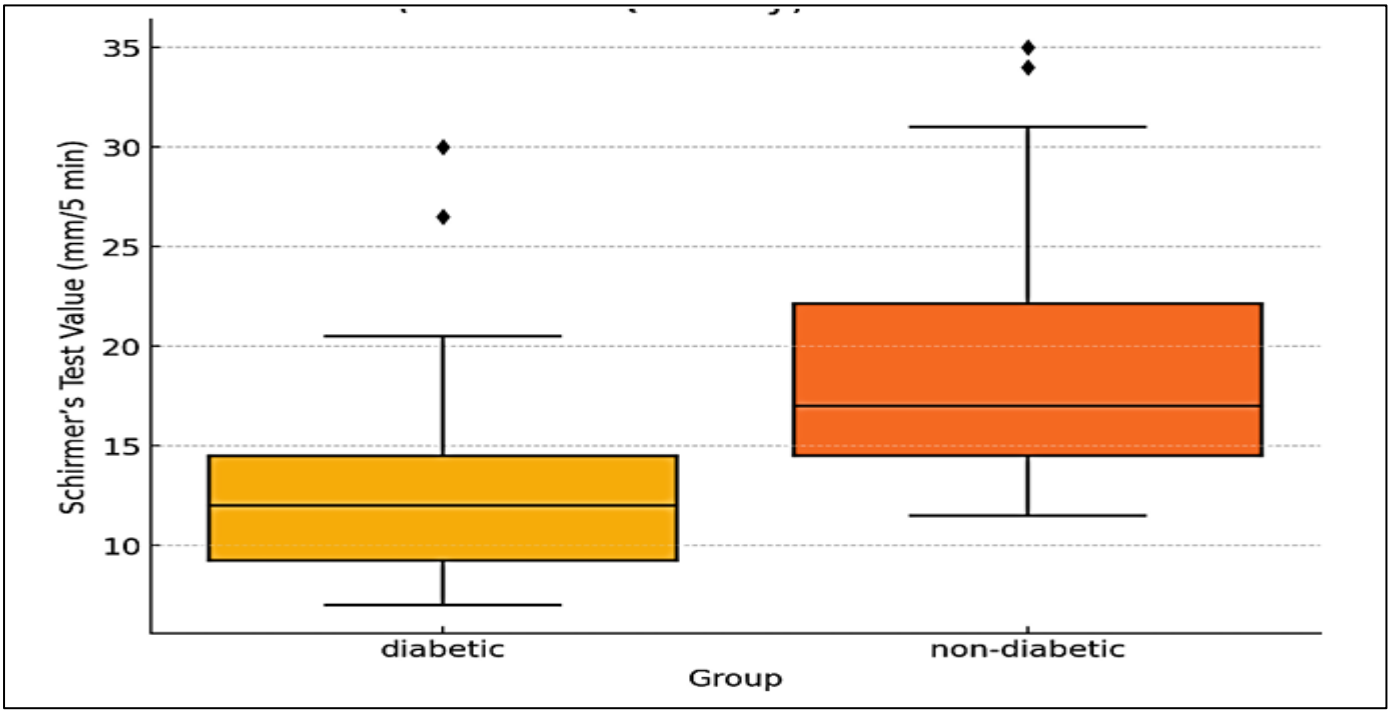
Graph 5 Distribution of Study Participants According to HbA1c (%) Levels

HbA1c levels (< 5.7%)**,** accounting for 50% of the total sample, while 48.2% (n = 27) were in the diabetic range (≥ 6.5%). Only one participant (1.8%) fell within the pre-diabetic range (5.7–6.4%). This distribution indicates a clear distinction between diabetic and non-diabetic groups in the study, with nearly half of the population demonstrating diabetic glycemic levels.

Table 6 Comparison of Schirmer's Test (Tear Film Quantity) between Diabetic and Non-Diabetic Groups

Groups	N	Mean (mm/ 5 min)	SD	Median	Min	Max	U Statistic	p- value	Interpretation
Diabetic	28	13.35	5.62	12	7	30	140.5	0.001	Highly significant
Non-Diabetic	28	19.7	6.76	17	11.5	35			

*U Statistic - Mann–Whitney U test



Graph 6 Comparison of Schirmer's Test (Tear Film Quantity) Between Diabetic and Non- Diabetic Groups

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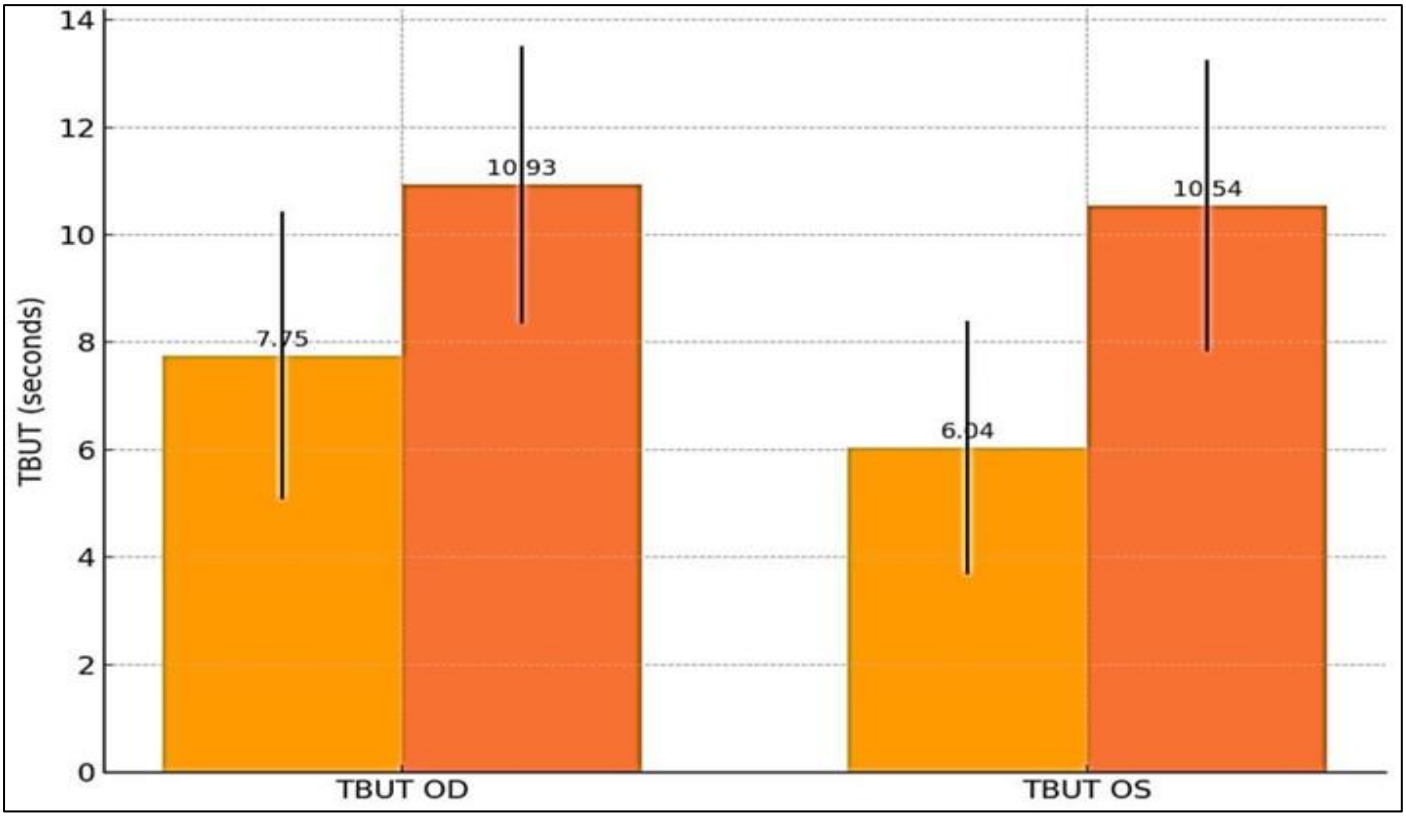
The above table 6 and graph 6 shows that the average Schirmer's test score for diabetic participants (13.35 mm/5 min) was significantly lower than that of non-diabetic participants (19.70 mm/5 min), with a statistical significance of $p < 0.001$. This indicates that diabetes mellitus negatively impacts tear film production, potentially due to autonomic neuropathy or microvascular changes.

Table 7 TBUT Comparison Between Groups

Parameter	Diabetic Mean ± SD (sec) n = 28	Control Mean ± SD (sec) n = 28	t-test	P-value	Interpretation
TBUT OD	7.75 ± 2.68	10.93 ± 2.59	- 4.51	0.0000347	Highly significant
TBUT OS	6.04 ± 2.36	10.54 ± 2.71	- 6.63	0.0000167	Highly significant



Graph 7 Comparison of TBUT Between Diabetic and Control Group

The above table 7 and graph 7 shows that the TBUT was significantly reduced in diabetic participants compared with healthy controls in both eyes. For the OD, diabetics showed a mean TBUT of 7.75 ± 2.68 seconds versus 10.93 ± 2.59 seconds in controls, yielding a highly significant difference ($t = -4.51$, $p = 0.0000347$). Similarly, in the OS, diabetic subjects demonstrated a markedly lower TBUT of 6.04 ± 2.36 seconds compared to 10.54 ± 2.71 seconds in controls, with a highly significant difference ($t = -6.63$, $p = 0.0000167$). These findings indicate that individuals with diabetes have substantially poorer tear film stability, consistent with an increased risk of dry eye disease.

Table 8 Correlation Between TBUT OD and TBUT OS in Study Participants

Correlations			
		TBUT OD	TBUT OS
TBUT OD	Pearson Correlation	1	0.704**
	Sig. (2-tailed)	--	0.000
	N	56	56
TBUT OS	Pearson Correlation	0.704**	1
	Sig. (2-tailed)	0.000	--
	N	56	56

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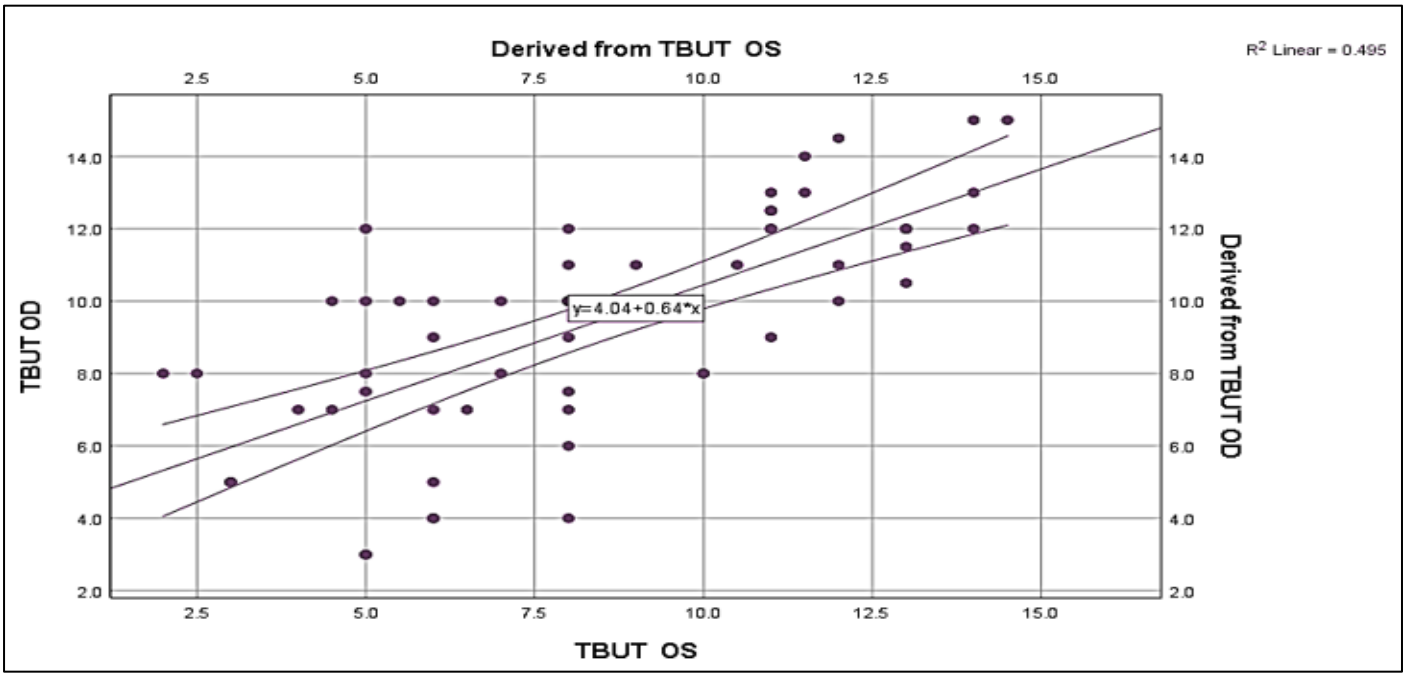
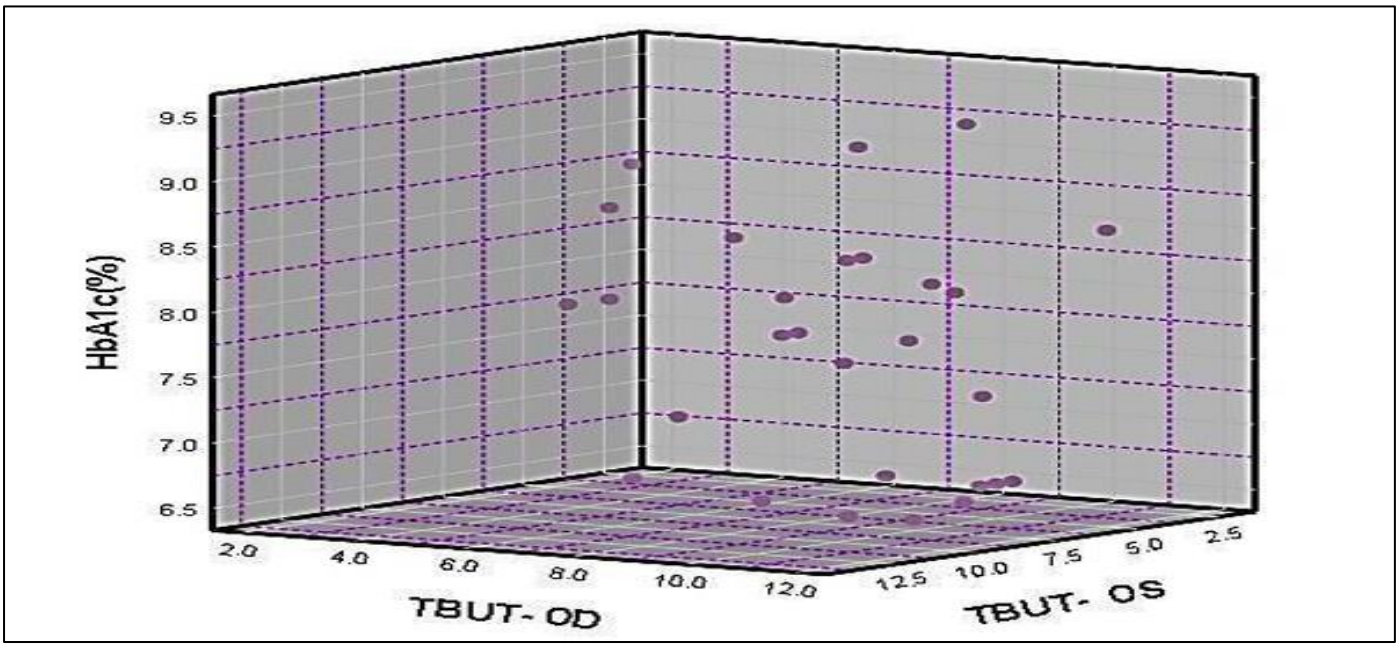


Graph 8 Correlation Between TBUT OD and TBUT OS in Study Participants

The above table 8 and graph 8 shows that a strong positive correlation was found between TBUT OD and TBUT OS (r = 0.704**,** p < 0.001), indicating that tear film stability is highly symmetrical between both eyes. The regression line (y = 4.04 + 0.64x) and $R^2 = 0.495$ show that nearly half of the variability in one eye's TBUT can be predicted from the other. This highlights the bilateral nature of tear film dysfunction and the importance of evaluating both eyes during clinical assessment.

Table 9: Correlation Between HbA1c with TBUT OD and TBUT OS in Study Participants

Correlations					
		TBUT- OD	**TBUT- OS**	**HbA1c (%)**	**Interpretation**
TBUT- OD	Pearson Correlation	1	0.329	-0.287	
	Sig. (2-tailed)		0.088	0.138	Weak negative correlation
TBUT- OS	Pearson Correlation	0.329	1	-0.290	
	Sig. (2-tailed)	0.088		0.134	Weak negative correlation
HbA1c (%)	Pearson Correlation	-0.287	-0.290	1	
	Sig. (2-tailed)	0.138	0.134		Weak negative correlation



Graph 9 Correlation Analysis of TBUT and HbA1c in Study Participants

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

The above table 9 and graph 9 shows that the correlation analysis reveals weak negative correlations between TBUT (OD and OS) and HbA1c levels, indicating that higher HbA1c levels are associated with lower tear stability. The correlations are not statistically significant ($p > 0.05$). A moderate positive correlation ($r = 0.329$) exists between TBUT-OD and TBUT-OS, suggesting consistency in tear function between the two eyes. These findings suggest a potential link between glycemic control and dry eye metrics, warranting further investigation.

Table 10 Mean TBUT by Duration of Diabetes

Duration Group	Mean TBUT OD (sec)	Mean TBUT OS (sec)
< 5 years	7.33	6.17
5 - 10 years	**8.2**	6
10 - 15 years	7.36	6.18
> 15 years	10	4

The above table 10 shows that the analysis of TBUT values across different duration groups reveals varying trends. Mean TBUT-OD is highest (10 sec) in the >15 years group and lowest in the < 5 years group (7.33 sec). In contrast, mean TBUT-OS values are relatively consistent, ranging from 4 - 6.18 sec, with the > 15 years group showing the lowest value (4 sec), indicating potential ocular surface changes with prolonged diabetes duration.

Table 11 TBUT Comparison Between Groups

Parameter	Diabetic Mean (sec)	Control Mean (sec)
TBUT OD	7.75	10.93
TBUT OS	6.04	10.54

The above table 11 shows that the comparison of tear film stability between diabetic patients and age- matched non-diabetic controls shows a marked reduction in TBUT values among diabetics. TBUT OD was significantly lower in the diabetic group (7.75 sec) compared to controls (10.93 sec), and a similar decrease was observed in TBUT OS (6.04 sec vs. 10.54 sec). These findings indicate that diabetes is associated with substantial impairment of tear film stability, reflecting early ocular surface changes and a higher likelihood of dry eye disease in diabetic individuals. This emphasizes the importance of routine tear film assessment in diabetes management to detect and address ocular surface dysfunction at an early stage.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

CHAPTER FIVE
DISCUSSION

➢ *Discussion:*

- Fanhua Meng et al. (2025) in his study concluded that he has discussed regarding Hyperglycemia damages tear film and meibomian glands; good glucose control helps protect ocular surface but our findings show that diabetic patients, especially those with poor glycemic control and longer disease duration, have significantly reduced Schirmer values, shorter TBUT, and more frequent fluorescein staining patterns compared to non- diabetic controls. These results indicate that both tear production and tear film stability are negatively affected in diabetes.[1]

- Bilal Khan et al. (2025) in his study concluded that he explained about Dry eye syndrome is significantly associated with diabetes mellitus; early screening in diabetics is necessary for timely intervention but our study outcomes indicate that diabetic participants show marked reductions in tear production, reinforcing that diabetes affects not only systemic health but also exerts a significant impact on ocular surface physiology. [2]

- Vennila Selvaraj et al. (2023) study concluded that Diabetes is associated with higher prevalence of dry eye, especially in older age groups and females. Hence our study shows clear association was observed between duration of diabetes and worsening tear film parameters, underscoring the importance of early screening and timely ophthalmic evaluation in all diabetic patients. [3]

- Yu-Kai Kuo et al. (2022) study concluded that Patients with type 1 or 2 DM have poorer tear function; good glycemic control is important to maintain tear film stability. Hence our study demonstrated that results emphasize the value of incorporating routine dry eye assessments such as Schirmer's test, TBUT, and fluorescein staining into regular diabetic check-ups to prevent long-term complications. [4]

- Nilesh Parekh et al. (2021) study concluded that Dry eye is more common in diabetics; tear film tests showed significant reduction and should be considered in examinations our study suggested that the comparison between diabetic and non-diabetic groups revealed a consistent pattern of compromised tear stability in diabetics, supporting the hypothesis that metabolic imbalance directly contributes to tear film dysfunction. [5]

- Yash Hada, Shashank Banait (2020) concluded that Diabetes is associated with reduced tear film amount and stability, indicating higher prevalence of dry eye. We found that the findings highlight that unaddressed tear film abnormalities may progress to symptomatic dry eye disease in diabetic individuals, indicating the need for proactive management strategies and patient education. [6]

- Aljarousha et al. (2016) concluded that Diabetes is associated with higher prevalence of dry eye; regular screening is important. Our study showed the results provide compelling evidence that maintaining optimal blood glucose levels may help preserve tear film stability and reduce the risk of chronic ocular surface changes in diabetic patients. [7]

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

CHAPTER SIX
CONCLUSION

The comparison of tear film stability between diabetic and non-diabetic participants provides important insights into the ocular surface alterations associated with diabetes mellitus. The findings from Table 12 demonstrate that individuals with diabetes exhibit substantially reduced Tear Break-Up Time (TBUT),Schirmer I&II in both eyes when compared with age-matched non-diabetic controls. Specifically, the diabetic group showed mean TBUT values of 7.75 seconds in the right eye (OD) and 6.04 seconds in the left eye (OS), whereas the control group demonstrated significantly higher averages of 10.93 seconds (OD) and 10.54 seconds (OS),where as in Schirmer means shows (13.35 mm/5 min) was significantly lower than that of non-diabetic participants (19.70 mm/5 min), with a statistical significance of $p < 0.001$. This indicates that diabetes mellitus negatively impacts tear film production, potentially due to autonomic neuropathy or microvascular changes.

The decreased TBUT & schirmer in diabetic participants can be attributed to several diabetes-related pathophysiological mechanisms, including autonomic neuropathy, microvascular compromise affecting the lacrimal gland, metabolic alterations, and chronic inflammatory processes. These factors collectively diminish the quality and stability of the tear film, making diabetic individuals more susceptible to symptoms such as ocular dryness, irritation, fluctuating vision, and increased risk of epithelial breakdown.

The findings align with previous research indicating that diabetes adversely affects both tear film quantity and quality, even in those with moderate glycemic control. Moreover, the observed bilateral nature of TBUT& Schirmer reduction highlights the systemic and symmetrical impact of diabetes on ocular structures. The significant differences between diabetic and non-diabetic groups underscore the need for routine tear film assessment as part of comprehensive diabetic eye care. Early detection of tear film abnormalities allows for timely management, which may include lubricants, anti-inflammatory agents, lifestyle modifications, and improved glycemic control to mitigate long-term ocular complications. In summary, the results clearly demonstrate that diabetic individuals experience significantly compromised tear film stability compared to non-diabetics. This emphasizes the importance of integrating regular tear film evaluation into diabetes management protocols to preserve ocular surface health, enhance patient comfort, and prevent progression to more severe forms DED.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

CHAPTER SEVEN
LIMITATION

- Small sample size limits generalized
- Conducted in a single hospital setting, reducing population diversity.
- A limitation of the current research is the lack of gender specific analysis within diabetes group.
- Environmental factors (humidity, temperature, airflow) were not controlled.
- Did not include advanced diagnostic tools like tear osmolarity or meibography.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

FUTURE SCOPE

- In future this study can be conducted as longitudinal studies to observe tear film changes over time with varying glycemic control.
- In future the sample size can be increased and carry out multi-centre studies for better Representation.
- In future advanced diagnostic tools (meibography, confocal microscopy, tear osmolarity) can we used for further deeper analysis.
- Perform subgroup analysis based on type of diabetes, treatment modality, and duration.
- Explore preventive strategies for ocular surface complications in long-standing diabetes.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

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ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

ANNEXURE

Effect of glycemic control duration on tear film quantity and quality in diabetic patients: A comparative study"

Patient consent to take part in research

Consent form No: Phone Number:

I.....Voluntarily agree to participate in this research study.

I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.

I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.

I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.

I understand that participation involves performing a procedure for **"Effect of glycemic control duration on tear film quantity and quality in diabetic patients: A comparative study."**
I understand that I will not benefit directly from participating in this research.

I understand that all information I provided for this study will be treated confidentially.

I understand that in any report on the result of this research my identity will remain anonymous.

I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities – they will discuss this with me first but may be required to report with or without my permission.

I understand that signed consent forms and data will be retained safely until the study is over.

I understand that under freedom of information legalization I am entitled to access the information I have provided at any time while it is in storage as specified above.

I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Name: Miss. Aishwarya.v.

Phone Number: 9980588406/ Email ID: aishwaryaraj390@gmail.com

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COLLEGE NAME: SHRIDEVI INSTITUTE OF ALLIED HEALTH SCIENCES

GUIDE: Mrs. A.P. Nishad Begum (8073577268), Lecturer, Dept. of Ophthalmology, SIAHS, Tumkur

Signature of research participant:

_____ _____
Signature of participant Date

Signature of researcher:
I believe the participant is giving informed consent to participate in this study

_____ _____
Signature of researcher Date

_____ _____
Signature of researcher Guider Signature

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jan799

PROFOMA

➢ *Demographic Data:*

- Name:
- Age/Gender:
- Contact No.:
- Occupation:

➢ *History:*

CHIEF COMPLAIN	
OCULAR HISTORY	
SYSTEMIC HISTORY	
MEDICAL HISTORY	
FAMILY HISTORY	
SOCIAL HISTORY	

➢ *Visual Acuity:*

Eye	**DISTANCE VISION @ 6m**		**NEAR VISION @ 40cm**
	UNAIDED	**AIDED**	
OD			
OS			

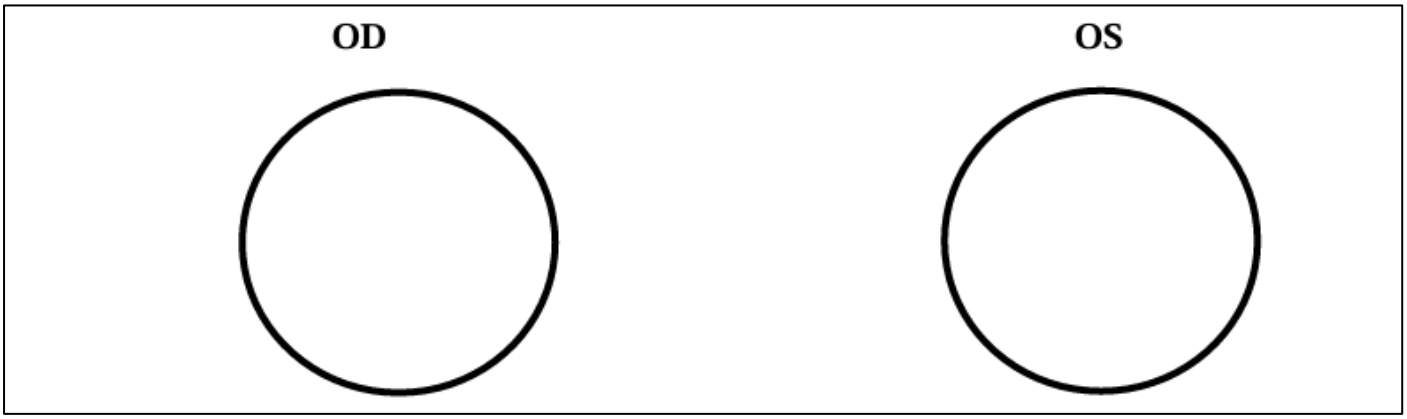
➢ *Refraction:*

	OD					**OS**				
	Sph	**Cyl**	**Axis**	**VA Dist.**	**Near**	**Sph**	**Cyl**	**Axis**	**VA Dist.**	**Near**
OBJ										
SUB										

➢ *Slitlamp Examination:*

EYE	**OD**	**OS**
EYELID		
CORNEA		
CONJUCTIVA		
SCLERA		
IRIS/PUPIL		

➢ *Fundus Examination: (Direct Ophthalmology)*



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OD	FUNDUS FINDINGS	OS
	CUP/DISC RATIO	
	AV RATIO	
	FOVEAL REFLEX	
	MACULA	
	VITREOUS	
	PERIPHERY	

- *Test Performed*

(----------duration)

TESTS	OD	OS
SCHIERMER I @ 5MIN (without topical anaesthesia)	mm	mm
SCHIERMER II @ 5MIN (with topical anaesthesia)	mm	mm
TBUT (TEAR BREAK UP TIME)	sec	Sec
FLUOROCEINSTAINING PATTERN