

# **The Prevalence of Dry Eye Syndrome among Patients at the Eye Clinic in Nelson Mandela Academic Hospital**

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## ABSTRACT

**Introduction:** Dry eye syndrome (DES) is a multi-factorial disease of the tears and ocular surface that results in ocular discomfort, visual disturbance, and tear-film instability with potential damage to the ocular surface. The aim of the study was to determine the prevalence of dry eye syndrome among patients at the Eye Clinic in Nelson Mandela Academic Hospital (NMAH) in Mthatha. No study has been published on the prevalence of dry eye syndrome in the Eastern Cape Province.

**Method:** This is an observational descriptive study that looked at the prevalence of dry eye syndrome among patients at the eye clinic in Nelson Mandela Academic Hospital (NMAH). Dry eye syndrome was assessed using the Ocular Surface Disease Index (OSDI) questionnaire, Tear-Break Up Time (TBUT) and Schirmer 2 Test. The OSDI questionnaire was administered by a trained optical dispenser student to the participants that agreed to partake in the study. Following the completion of the OSDI questionnaire, the three clinical tests were performed in sequence. The researcher used the same slit lamp for all the participants and tests. The researcher started assessing for the Meibomian glands to determine whether the participant had Meibomian gland dysfunction or not. After the assessment of Meibomian glands, the TBUT was measured. The Schirmer 2 test was performed 5 minutes later after the TBUT was performed. When performing the Schirmer 2 test, novesin wander was used as a local anesthetic for all participants. The Schirmer strips were measured with a millimeter ruler after 5 minutes of inserting the strip in the lower lid of each eye. A stopwatch was used for timing when performing the TBUT and Schirmer 2 tests. The outcomes of each test were recorded on the data sheet that was marked uniquely using a code for each participant.

**Results:** One hundred and fifty participants took part in the study, and 72% of the participants were females. The prevalence of dry eye syndrome was determined to be 92.00% when using the OSDI. The OSDI determined the prevalence of severe dry eye syndrome to be 64.67%. The Tear Break-Up Time (TBUT) and Schirmer's 2 test determined the prevalence of dry eye syndrome to be 64.67% and 62.67% respectively.

**Conclusion:** There was high prevalence of DES among patients at the Eye clinic in NMAH. Females were predominantly affected more than males. An intervention from health authorities is required in order to curb the disease. Eye care personnel, such

as Ophthalmic nurses, Optometrists and Ophthalmologist should be made aware of the seriousness of the disease and its prevalence in order to encourage them to take precautions when managing other ocular disease to avoid turning a blind eye to the disease. The inclusion of tear osmolarity testing as a tool in assisting with the diagnosis of dry eye syndrome will be recommended for future studies.

Keywords: Prevalence; Dry eye syndrome (DES); Ocular Surface Disease Index (OSDI); Tear-Break Up Time (TBUT); Schirmer 2 Test; Nelson Mandela Academic Hospital (NMAH).

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## **LIST OF ACRONYMS**

OSDI – Ocular Surface Disease Index

DES – Dry Eye Syndrome

NMAH – Nelson Mandela Academic Hospital

TBUT – Tear Break-Up Time

DEWS – Dry Eye Workshop

AIDS – Acquired Immune Deficiency Syndrome

TV – Television

N/A – Not Applicable

ATM – Automated Teller Machine

Km – Kilometers

UFS – University of the Free State

HRT – Hormone Replacement Therapy

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# CHAPTER 1 INTRODUCTION

## 1.1 Introduction

This chapter will give an introduction to this study that sets out to determine the prevalence of Dry Eye Syndrome (DES) among Patients at the Eye Clinic in Nelson Mandela Academic Hospital (NMAH). An overview will be provided on the definition of the dry eye syndrome, causes, signs, symptoms and the management of the dry eye syndrome. The problem statement, aims and objectives of the study are detailed in this chapter.

## 1.2 Definition of dry eye syndrome

The evolution of dry eye research has seen dry eyes being defined in different ways, with one definition evolving from the other. Dry eye syndrome (DES) is a multi-factorial disease of the tears and ocular surface that results in ocular discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface (Utine *et al.*, 2011). Recently, dry eye has been defined as a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyper-osmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles (Craig *et al.*, 2017). The tear film is a three layered structure, comprised of the lipid, aqueous and mucin layers (Sahai & Malik, 2005). It is responsible for keeping the ocular surface moist at all times and is fundamental to the maintenance of a healthy ocular surface (Schaumberg *et al.*, 2009). Reduced tear production, possibly due to meibomian gland dysfunction or excessive tear evaporation causes deficiencies in the quality or quantity of tears. This reduction may result in an unstable tear film, persistent dryness of the conjunctiva and corneal ocular surfaces (Viso *et al.*, 2011; Schaumberg *et al.*, 2009; Clegg *et al.*, 2006).

## 1.3 Causes

The DES can primarily results from aqueous deficiency, excessive lacrimal tear film evaporation, or a combination of the two. Aqueous deficiency occurs as a result of the adversely affected lacrimal gland function, which consequently reduces the tear volume. In evaporative dryness, the tear film is abnormal due to rapid evaporation, whereas the tear volume is normal (Alhamyani *et al.*, 2017).

Dry eye disease can occur in a person with lagophthalmos, which is the inability to close the eyelids completely (Badawi, 2018). The dry eye results from a poor or incomplete lid closure or poor lid to globe apposition, thus resulting in a poor inter-blink tear film (Badawi, 2018).

Meibomian gland dysfunction has been noted as a leading contributor to evaporative dry eye (Badawi, 2018). DES can also be caused by aging, the impact of air conditioners or heaters or fans, humidity, wind, allergies, hormonal changes, illness such as arthritis, rosacea and lupus, fatigue, medications (especially antihistamines, antidepressants and oral contraceptives), sun and pregnancy (Clegg *et al.*, 2006). A number of studies (Bakkar *et al.*, 2016; Hashemi *et al.*, 2014; Viso *et al.*, 2009; Uchino *et al.*, 2008) have reported that females are greater sufferers of dry eye disease compared to males. From the list of causes of dry eye syndrome mentioned above, it that many people may be suffering from this condition.

#### **1.4 Signs and symptoms**

The symptoms of dry eyes are non-specific, and may be confused with ocular allergy and other symptoms of ocular infections. Symptoms of dry eye syndrome are common among the elderly population (Chia *et al.*, 2003). The symptom of discomfort has been noted as the principal symptomatic response that is associated with dry eye (Barlett *et al.*, 2015). There is a wider variation in symptoms of dry eyes, with a lack of a single reliable clinical assessment. This makes it challenging to accurately diagnose and classify dry eye disease (Barlett *et al.*, 2015). In most cases of diagnosing DES, the changes and severity of signs do not correspond to clinical symptoms of dry eye (Barlett *et al.*, 2015). The reason for low association between signs and symptoms of dry eye is that they can present independently of each other (Barlett *et al.*, 2015). Some patients who can present with symptoms may actually have minimal ocular surface disease, while others may show signs of dry eye disease in the absence of specific symptoms or show no symptoms altogether (Barlett *et al.*, 2015).

The signs of DES are accompanied by excessive lacrimation with increased osmolarity of the tear film and inflammation of the ocular surface, which results in conjunctival hyperemia or congestion which may range from mild to severe

conjunctival congestion (Utine *et al.*, 2011). A person with dry eye syndrome will have increased corneal sensitivity and reduced visual acuity (Clegg *et al.*, 2006).

Among the symptoms of DES a person may report discomfort of the eyes, burning and itchy sensation, and a desire to blink excessively, blurred vision, redness and sensitivity to light or sunlight (Clegg *et al.*, 2006). In cases where a person has severe dry eyes, corneal pain is experienced due to local loss of the outer layer of the corneal epithelium, resulting in exposure of the corneal nerves (Clegg *et al.*, 2006).

## **1.5 Classification of Dry Eyes**

According to a review by Stapleton *et al.* (2017) which was conducted under the auspices of the Tear Film and Ocular Surface Society International Dry Eye Workshop (TFOS DEWS), a subcommittee of the TFOS DEWS reviewed the prevalence, incidence, risk factors, natural history, morbidity, and questionnaires reported in epidemiological studies of dry eye disease.

DEWS II is a subcommittee of TFOS DEWS that summarized the available evidence on dry eye prevalence, incidence, risk factors, and its impact. It also reviewed the instruments for the diagnosis and assessment of dry eye disease (DED) in clinical trials (Stapleton *et al.*, 2017).

Dry eye has been classified under the two primary categories according to the DEWS II classification (Stapleton *et al.*, 2017). The primary categories are Aqueous-tear deficient dry eye and Evaporative dry eye.

### **1.5.1 Aqueous-tear deficient dry eye**

The aqueous-tear deficient dry eye occurs due to a failure of lacrimal tear secretion (Craig *et al.*, 2017). When dry eye is due to lacrimal dysfunction, it can either occur as a result of a reduced lacrimal tear secretion and/or tear volume. This cause tear hyperosmolarity, because dry eye in aqueous-tear deficient is from a reduced aqueous tear pool (Craig *et al.*, 2017). The aqueous-tear deficient dry has two major subclasses namely Sjogren syndrome dry eye and Non-Sjogren syndrome dry eye.

#### *1.5.1.1 Sjogren syndrome dry eye*

In Sjogren syndrome, lacrimal and salivary glands are targeted by an autoimmune process. The lacrimal and salivary glands are infiltrated by activated T-cells, which

cause acinar and ductular cell death and hyposecretion of the tears or saliva (Craig *et al.*, 2017).

There are two forms of Sjogren syndrome. These two forms are primary Sjogren syndrome and secondary Sjogren syndrome (Craig *et al.*, 2017). Primary Sjogren syndrome consists of the occurrence of aqueous-tear deficient in combination with symptoms of dry mouth, in the presence of autoantibodies, evidence of reduced salivary secretion and with a positive focus score minor salivary gland biopsy. Secondary Sjogren syndrome consists of the features of primary Sjogren syndrome together with the features of an overt autoimmune connective tissue, such as rheumatoid arthritis or systemic lupus erythematosus, polyarteritis nodosa, Wegener's granulomatosis, systemic sclerosis, primary biliary sclerosis, or mixed connective tissue disease (Craig *et al.*, 2017).

#### *1.5.1.2 Non-Sjogren syndrome dry eye*

In Non-Sjogren syndrome dry eye, the systemic autoimmune features characteristics of Sjogren syndrome dry eye are excluded (Craig *et al.*, 2017). The most common form of Non-Sjogren Syndrome dry eye is age-related dry eye (Craig *et al.*, 2017). There are four different forms of Non-Sjogren Syndrome Dry eye and they are primary lacrimal gland deficiencies, secondary lacrimal gland deficiencies, obstruction of the lacrimal gland ducts and reflex hyposecretion (Craig *et al.*, 2017).

#### **1.5.2 Evaporative Dry Eye**

Evaporative dry eye occurs due to excessive water loss from the exposed ocular surface in the presence of normal lacrimal secretory function (Craig *et al.*, 2017). The causes of evaporative dry eye have been described as intrinsic or extrinsic. The intrinsic causes are due to intrinsic disease affecting lid structures or dynamics. The extrinsic causes occur due to extrinsic exposure to the ocular surface disease (Craig *et al.*, 2017). The two forms of evaporative dry eye are summarized on Table 2 below.

#### **1.6 Ocular Surface Disease Index (OSDI) Questionnaire**

The Ocular Surface Disease Index (OSDI) questionnaire is a standardized valid and reliable instrument to evaluate the symptoms of dry eye subjectively as whether normal, mild to moderate, and severe, and also their effect on vision related function

(Schiffman et al., 2000). The OSDI score is assessed on a scale of 0 to 100 (Appendix C). The higher scores represent a greater disability of dry eye. The questionnaire demonstrates sensitivity and specificity in distinguishing between normal subjects and patients with dry eye disease.

It consists of 12 questions that are asked, with regard to signs and symptoms of dry eye syndrome (Appendix C).

The OSDI score is calculated using the following formula:

$$\text{OSDI} = ((\text{Sum of score for Q13, Q14 and Q15}) * 25)$$

Number of questions answered excluding questions answered N/A

The sum of score for question 13,14 and 15 is extracted for the OSDI score calculation from our master coding copy, which consists of 18 questions, inclusive of participant's demographics and clinic assessment data. The overall OSDI score is defined as normal if the score is between 0 and 12 points or as mild ocular surface disease if the score is between 13-22 points or moderate ocular surface disease if the score is between 23-32 points or severe ocular surface disease if the score is between 33-100 points.

Table 1: Causes of evaporative dry eye

<b>Intrinsic causes of evaporative dry ye</b>	<b>Extrinsic causes of evaporative dry eye</b>
Meibomian oil deficiency	Ocular surface disorders
Disorders of lid aperture and lid/globe congruity or dynamic	Contact lens wear
Low blink rate	Ocular surface disease
	Allergic conjunctivitis

Adapted from Crag *et al.* (2017).

## 1.7 Management

Dry eye is most often treated as a diagnosis of exclusion, because of its complexity and overlap with other ocular surface conditions. Some ocular surface conditions close mimic or masquerade as dry eye disease, and many occur concurrently with dry eye

disease (Craig *et al.*, 2017). There are low and inconsistent associations between the signs and symptoms of dry eye, which have implications for monitoring the response to treatment (Barlett *et al.*, 2015). The severity of dry eye determines the management options which eventually determine the response to treatment (Rathi & Sangwan, 2017).

The main goal in the management of dry eye disease is to restore the tear film homeostasis. The nature of the management of dry eye disease is complex, which remains a challenge to develop management and treatment strategies that are not overly complicated for our patients (Nelson *et al.*, 2017).

The dry eye that is primarily from the aqueous deficiency is managed with artificial tears and lubricating eye drops. In patients with a lipid deficiency, artificial tears that increase the tear volume may worsen dry eye symptoms (Rath and Sangwan, 2017). Warm compressors are highly recommended in managing dry eye that is due to lipid deficiency (Badawi, 2018; Rath and Sangwan, 2017). Meibomian gland dysfunction is best managed with warm compressors over closed eye lids, followed by the expression of the Meibomian secretions (Rath and Sangwan, 2017).

When the Schirmer's test score is less than 5mm with an ocular surface staining, tear retention using punctal plugs or the occlusion therapy is highly recommended. The tear retention with punctal occlusion can be achieved with cautery or punctal plugs that are either absorbable or non-absorbable (Badawi, 2018).

### **1.8 Problem statement**

The prevalence of dry eye syndrome (DES) varies with geographical locations. DES affects 1 out of every 2 elderly patients in countries such as the United States of America (USA) and China and also causes a financial burden on health systems (Lu *et al.*, 2008; Yu *et al.*, 2011). It has been found that there is an increased prevalence of DES in rural India compared to urban India (Sahai & Malik, 2005). Exposures to excessive wind, sunlight or high temperatures are significantly related to dry eye syndrome. Illiteracy and older age have also been noted as predictors of dry eye disease (Onwubiko *et al.*, 2014). Therefore, it is important to determine the prevalence of DES in different geographical areas. Only two studies have been published on the

prevalence of DES in South Africa; one in KwaZulu-Natal amongst students investigating the prevalence of dry eye using the Ocular Surface Disease Index (OSDI) questionnaire, tear thinning time, tear break-up time (TBUT) and Schirmer's 2 test and the other in Johannesburg among students and university staff and their relatives which used only the Ocular Surface Disease Index (OSDI) questionnaire to investigate the prevalence and severity of dry eye symptoms (Castelyn *et al.*, 2015; Gillan, 2009). There has been no study of this nature conducted in the Eastern Cape region, as the region has populations based in rural and urban areas.

### **1.9 Aim of the study**

To determine the prevalence of dry eye syndrome among patients at the Eye Clinic at Nelson Mandela Academic Hospital (NMAH) in Mthatha.

### **1.10 Objectives of the study**

- To determine the prevalence of dry eye by measuring the stability of the tear film using the tear break-up time (TBUT).
- To determine the prevalence of dry eye by evaluating the integrity of the lacrimal secretion system using Schirmer 2 test.
- To determine the prevalence and severity of dry eye symptoms by using the ocular surface disease index (OSDI) questionnaire.
- To document the prevalence of DES among patients at the Eye Clinic in NMAH

## CHAPTER 2: LITERATURE REVIEW

### 2.1 Introduction

Previous studies on the prevalence of dry eyes and associated symptoms will be discussed in this chapter. The reviewed studies were done in different countries.

### 2.2 Studies done in Australia

A population-based study in Australia was done to describe the epidemiology of dry eyes among adults aged 40 to 97 years (McCarty *et al.*, 1998). A questionnaire was administered to obtain the commonly experienced symptoms. The tear break-up time, Rose Bengal staining, fluorescein corneal staining and Schirmer's tests were used to determine the presence of dry eyes. The prevalence of dry eyes differed with the methods used to assess dry eye. The prevalence of dry eye was found to be 10.8% with Rose Bengal, 16.3% with Schirmer's test, 8.6% with tear film break-up time and 1.5% with fluorescein staining. Subjectively, using the questionnaire, the prevalence was 7.4% with two or more symptoms and 5.5% with any severe symptom not attributed to having fever. Women reported more severe symptoms of dry eye compared to that of men.

The Blue Mountains Eye Study in Australia determined the prevalence and associations of dry eye syndrome in an older population aged 50 to 90 years using a questionnaire (Chia *et al.*, 2003). One dry eye symptom was reported by 57.7% of the participants, with 16.6% of participants reporting moderate to severe symptoms. Three or more symptoms were reported by 15.3% of participants. The symptoms were more frequent in women compared to that of men. Arthritis, asthma, gout, use of corticosteroids, antidepressants and hormone replacement therapy were significantly associated with the dry eye syndrome.

### 2.3 Studies done in Iran

In an Iranian study of the prevalence of dry eye syndrome in type 2 diabetic patients, 54.3% of participants were diagnosed as having dry eye syndrome (Manaviat *et al.*, 2008). Dry eye syndrome was assessed objectively using Schirmer's test, fluorescein corneal staining and tear break-up time. It was also noted that dry eye syndrome was more common in older and female patients.

## 2.4 Studies done in China and Taiwan

A population based study was done to determine the prevalence of dry eye among an elderly Chinese population ( $\geq 65$  years) in Taiwan (Lin *et al.*, 2003). A questionnaire and the clinical examination consisting of Schirmer's test, slit-lamp assessment of the meibomian glands, fluorescein corneal staining and tear break-up time were used to assess the prevalence. One or more dry eye symptoms were reported by 33.7% of participants. Among those who were symptomatic, 78.9% had low tear break up time of equal or less than 10 seconds, 62.5% with Schirmer test results of equal or less than 5mm and 61.7% had abnormal meibomian glands. It was also noted that the dry eye syndrome was common among females. This study reported relatively higher prevalence of dry eyes in Asians as compared to other studies done among Whites (Lin *et al.*, 2003).

Another population based study was done in Beijing eye study to determine the prevalence of dry eye among adult Chinese ( $\geq 40$  years) using a questionnaire, the Schirmer's test, slit-lamp assessment of the meibomian glands, fluorescein corneal staining and tear break-up time. The prevalence of the dry eye was 21% based on the symptoms. There was no significant association between tests conducted such as tear break-up time, assessment of the corneal fluorescein staining, slit-lamp examination of the meibomian gland dysfunction and dry eye symptoms (Jie *et al.*, 2009).

In a Henan eye population based study, the prevalence of dry eye disease among Mongolians at high altitude in China was determined using a questionnaire and the clinical examination consisting of Schirmer's test, fluorescein corneal staining and tear break-up time. The prevalence of dry eye disease was 50.1% according to the symptoms. About 37.7% had low tear break up time of equal or less than 10 seconds, 19.9% with Schirmer's test results of equal or less than 5mm and 6% had a fluorescein staining score of equal or greater than 1. Dry eye signs were significantly associated with dry eye symptoms (Guo *et al.*, 2010).

In a study that was conducted among Chinese senior high school students in a county of Shandong Province, on the prevalence and risk factors associated with dry eye syndrome, the prevalence of dry eye syndrome was 23.7% (Zhang *et al.*, 2012). Dry eye syndrome was assessed subjectively using a questionnaire. Contact lens wear,

inadequate refractive correction, frequent self-administered topical ophthalmic medication and poor sleep quality were significantly associated with the dry eye syndrome.

### **2.5 Studies done in Jordan**

An ocular surface disease index (OSDI) questionnaire on dry eye symptoms was used to determine the prevalence of dry eyes among the general population of Jordan (Bakkar *et al.*, 2016). It was found that 59% of the participants whose ages ranged from 18 years to older than 45 years exhibited dry eye symptoms. Females showed higher prevalence than males. The prevalence was also higher in older participants (>45 years) and also in contact lens wearers.

### **2.6 Studies done in Saudi Arabia**

A study was conducted to determine the prevalence and risk factors of dry eye in a normal population in Jeddah, Saudi Arabia using a questionnaire and a clinical examination consisting of the tear break-up time, slit-lamp assessment of the lid margins and meibomian glands, fluorescein corneal staining and Schirmer test (Bukhari *et al.*, 2009). The prevalence of dry eye on the basis of the presence of one or more symptoms occurring most of the time and the presence of one or more clinical signs, was 93.2%. There was no statistical significant association between dry eye with advancing age or gender. Blepharitis and smoking were identified as the most common risk factors for dry eye syndrome.

### **2.7 Studies done in Nigeria**

A cross-sectional community based study on the prevalence and the factors associated with the dry eyes was conducted in Nigeria in adults aged 40 to 100 years (Olaniyani *et al.*, 2016). A questionnaire was administered to obtain the common symptoms of dry eyes. The tear break-up time, fluorescein corneal staining and Schirmer's test were used to determine the presence of dry eyes. The prevalence of dry eyes was 32.5% and the most common reported symptoms were grittiness (53.4%), burning/stinging sensation (48.3%) and a feeling of dryness (35.6%).

Another study was done in Nigeria among patients attending the eye clinic whose ages ranged from 18 to 94 years. Dry eye was assessed subjectively using the OSDI questionnaire. Schirmer's test and tear break-up time were used to determine the

presence of the dry eyes objectively. The prevalence of dry eyes was 19.2% and was more prevalent among older patients and those with no formal education.

A population based study was conducted in rural Niger Delta community, southern Nigeria, studying the prevalence of dry eye disease. The prevalence of dry eye disease was determined to be 27.4%. Ocular examination including the Schirmer test were performed to determine the prevalence of dry eye disease (Onua & Chukwuka, 2017).

### **2.8 Studies done in Southern Egypt**

A cross-sectional, observational, hospital-based study was conducted at the Ophthalmology Outpatient Clinic of the Sohag University Hospital, in Egypt. Dry eye disease was assessed subjectively using the Ocular Surface Disease Index (OSDI) questionnaire and objectively with the Schirmer's test, tear film break-up time (TBUT), and conjunctival/corneal staining. The prevalence of dry eye disease was 22.8% (Mostafa, 2016). Elderly patients and females were found to be more susceptible to dry eye disease.

### **2.9 Studies done in South Africa**

Prevalence of dry eye study was determined among University of KwaZulu-Natal students aged 18 to 30 years (Castelyn *et al.*, 2015). Dry eye symptoms were investigated using the OSDI questionnaire, tear thinning time, tear break-up time and Schirmer's 2 test. The prevalence of dry eye was 41% according to the OSDI questionnaire and 81% according to the clinical testing.

Another South African study was conducted at the University of Johannesburg on students, staff and their relatives whose ages ranged from 18-80 years. The prevalence and severity of dry eye symptoms were determined using the OSDI. The prevalence was 64%. Most of the participants had at least mild dry eye symptoms. However, in this study, more of the participants were younger than 40 years of age (Gillan, 2009).

### **2.10 Summary**

It was for the first to conduct a study of the prevalence of dry eye syndrome in a hospital based population in South Africa, particularly in the Eastern Cape region in

Mthatha. The study was conducted with a goal to inform health authorities in the province about the prevalence of dry eye syndrome, and to assist curb the disease by budgeting for medications that are used for treating dry eye syndrome.

The aim of the study was to determine the prevalence of dry eye syndrome among patients at the Eye Clinic at Nelson Mandela Academic Hospital (NMAH) in Mthatha. This was achieved by determining the prevalence of dry eye by measuring the stability of the tear film using the tear-break-up time (TBUT) and evaluating the integrity of the lacrimal secretion system using Schirmer 2 test. The ocular surface disease index (OSDI) questionnaire was used to determine the prevalence and severity of dry eye symptoms.

In summary, the prevalence of DES varies from 1.5% to 93%, which shows a great disparity. The variability depends on the methods used to collect the data and also the population tested.

## **CHAPTER 3: METHODOLOGY**

### **3.1 Introduction**

This chapter gives an overview of the methodology employed to address the purpose of the study. The study design, study site, population, sampling and sample size, inclusion and exclusion criteria used are also outlined. A procedure for data collection is provided. Thereafter, a discussion will follow on the data management, which explains how data was stored, as well as the statistical analysis. The chapter concludes by explaining how reliability and validity were ensured, as well as the ethical issues that were taken into consideration when conducting the study

### **3.2 Study design**

This study was a quantitative, observational descriptive cross-sectional study. A defined sample size for a defined population size was studied with clinical tools to determine the prevalence of dry eyes in a structured observation.

### **3.3 Ethical and legal considerations**

The research protocol was submitted to the evaluation committee of the School for the Allied Health Professions. After the approval, the protocol was submitted to the Health Sciences Research Ethics Committee of the University of the Free State (UFS) and was approved (Annexure E). Thereafter, the permission to commence the study was sought from the Eastern Cape Provincial department of Health, and the permission was granted (Annexure F). The hospital authorities were also informed and furnished with the relevant documentation to show that the study process to collect data was granted from different relevant departments.

### **3.4 Study site**

The study was conducted on patients at the Eye clinic at Nelson Mandela Academic Hospital (NMAH). NMAH is a tertiary hospital situated in Mthatha, in Oliver Regional (OR) Tambo District Municipality, in the Eastern Cape Province. The hospital is a referral hospital closely situated next to the Mthatha regional hospital. The Eye clinic currently has one consultant Ophthalmologist, two Ophthalmic registrars, five Ophthalmic medical officers, four Ophthalmic nurses, two professional nurses, three enrolled nursing assistants and one Optometrist.

### 3.5 Study population

The study was conducted on Eye clinic attendees that mainly lived in the rural Eastern Cape. The Eye clinic attendees are referred from the regional hospitals, district hospitals, healthcare centers and private practicing health care providers.

### 3.6 Study sample and size

There were 150 participants that took part in the study. The total number was chosen on the basis that approximately 60 patients are seen every day in the Eye clinic. Clinic days are Monday to Thursday, with new patients only seen on Mondays and Wednesdays. The total number of new patients per week is approximately 120. Participants for the study were those patients that came to the Eye clinic for their eye examination for the first time. The data collection was only conducted on Mondays and Wednesdays.

Convenience sampling method was applied, where in each day of data collection, the first participant was recruited by the researcher as the patients waited to be seen by the doctor for the day. The other participants in each day were recruited by an Optical dispenser student when the researcher was busy performing the tests in the consulting room. About 5 to 10 participants agreed to take part on the days of data collection.

### 3.7 Inclusion and exclusion criteria

The inclusion and exclusion criteria are tabulated in Table 2.

Table 2: Inclusion and Exclusion criteria.

Inclusion criteria	Exclusion criteria
<ol style="list-style-type: none"><li>1. Patients 18 years and older</li><li>2. Only new patients</li></ol>	<ol style="list-style-type: none"><li>1. Patients younger than 18 years</li><li>2. Patients who have been examined before at the NMAH</li><li>3. Patients with ocular surface pathologies i.e. corneal ulcers, traumatic corneal lacerations</li></ol>

### 3.8 Data collection tools (or measuring tests)

The slit-lamp biomicroscopy was used to assess the integrity of the cornea, conjunctiva, and the sclera. The integrity of the Meibomian glands and the measurement of the tear break-up time (TBUT) were accomplished using the slit-lamp biomicroscopy. The Schirmer's 2 test was performed using Schirmer's strips. The OSDI questionnaire was used to assess the symptoms related to dry eye disease and their effect on vision.

### **3.9 Pilot study**

A pilot study was conducted on the first five participants in a convenience sampling method. The results were included in the main study as there was no change to the procedure when collecting the data for the research study.

### **3.10 Data collection process and procedure**

Patients started their morning at the registration department of the hospital to open files for the day. As the patients waited for their turn into the doctor's consulting rooms in the Eye Clinic, they were recruited to participate in a research study. An information document (Annexure B) in the participant's language of choice were read and explained to them as a first step. Patients willing to partake in the study were asked to sign the consent form (Annexure C) and those that could not sign using a signature were asked to put an X next to the signature line. As prospective participants indicated their interest in taking part in the study, they were given a code that was unique to the participant e.g. 001. The same code was written on the consent, OSDI questionnaire (Annexure A) and data sheet (Annexure D) for that particular participant.

A 3<sup>rd</sup> year optical dispensing student who was trained by the researcher to administer the questionnaire, asked the participant to fill in the questionnaire form. The participant who could not understand what was on the questionnaire was assisted to complete the form. After the completion of the questionnaire, the participants were asked to go to a room that was dedicated for the three research tests to be done by the researcher. The same room was used throughout entire process of data collection.

The researcher assessed the participant in the following sequence: Meibomian gland evaluation, Tear-Break Up Time (TBUT) and after 5 minutes waiting period, then the Schirmer test 2 was done.

### **3.10.1 Meibomian Gland Evaluation**

The researcher used a Takagi slit-lamp SM-70N to assess the integrity of the meibomian gland. The same slit lamp was used for all the tests that required its use. The meibomian gland assessment was done under normal room illumination. The participant was asked to put the chin on the chin rest of the slit lamp. The target for fixation for the participant was the ear of the researcher, that is in line with the eye not examined. The researcher assessed the integrity of the meibomian gland using a white light and medium magnification to inspect the lower eyelid margins. The researcher looked for capping of the meibomian gland orifices (yellow mounds), notching of eyelid margins (indentations) and frothing of the tears on the eyelid margins. The researcher inspected the palpebral conjunctiva for concretions by pulling the lower eyelid down. The researcher exerted mild pressure by pressing on the eyelid margins near the eyelashes and watched for the meibomian gland orifices. If clear fluid was expressed that would indicate normal meibomian gland functioning. Capping of the orifices, a cheesy secretion on expression and frothing of the eyelid margins indicated meibomian gland dysfunction. The presence of concretions was associated with meibomian gland dysfunction. The findings were recorded on the data sheet (Annexure D).

### **3.10.2 Tear-Break-Up Time**

Following the meibomian gland assessment, fluorescein was instilled into the lower fornix of right eye of the participant for the measurement of the tear-break up time. The participant was asked to blink several times to ensure a widespread of fluorescein to the rest of ocular surface. A participant looking at the examiner's ear with the eye not examined, the tear film was examined with a broad slit lamp beam and a cobalt blue filter on the non-fixating eye. The examiner looked for dark spots or lines that appeared in the fluorescein stained film, which would indicate the formation of dry areas. The examiner counted the seconds it took for dark spots or lines to appear after the participant had been instructed to blink and try not to blink again. A tear break-up time was the interval between the last blink and the appearance of the first randomly distributed dry spot. Tear break-up time of less than 10 seconds was abnormal indicating dry eyes (Carlson & Kurtz, 2004). The procedure was repeated 3 times, with the findings recorded for each time. Then the fluorescein was instilled into the lower

fornix of left eye and the procedure was repeated. The average time it took for dry areas to appear in each eye was calculated and recorded on the data sheet (Annexure D)

### **3.10.3 Schirmer's 2 Test**

The Schirmer's 2 test was performed after 5 minutes, following the measurement of the tear break-up time. The test was performed under dim room illumination with the patient in the upright, seated position. The participant was asked to close his/her eyes to allow excess fluid to be out of the eyes. The closed lids of a participant were gently dried with a cotton bud. The round ends of the strips were folded before being removed from the cellophane wrapping, such that they were creased at the notch. The strips were removed from the cellophane wrapper, without touching the rounded ends. A single drop of a topical anaesthetic, novesin wander, was instilled in both eyes before removing the strips to be inserted in the eyes. The examiner waited for the reactive hyperaemia and reflex tearing to subside and gently blotted the excess fluid from the participant's inferior cul-de-sac. The participant was asked to look up whilst gently pulling the lower eyelid of the right eye. The folded, notched end of a Schirmer strip was placed over the lower lid margin at its lateral third whilst avoiding touching the cornea with the Schirmer strip. Another Schirmer strip was inserted in the left eye in the same manner. The participant was instructed to keep his/her eyes open and continue to look up. The Schirmer test strips were removed after 5 minutes, unless the entire strip got wet before the end of the time period. The wet portion of the strip was marked and the amount of wetting from the notch was measured in millimetres using a millimetre ruler. The data was recorded for each eye separately. A value of less than 5mm was suggestive of a true dry eye state (Carlson & Kurtz, 2004). A value of less than 10mm was significant to indicate the presence of dry eyes and lacrimal insufficiency (Carlson & Kurtz, 2004).

When the researcher was finished with data collection, each participant was thanked for taking part in the study and was asked to go back to the waiting room to wait for the doctor for a full eye examination.

### **3.11 Data management and analysis**

The data was safely kept in a locked cupboard. The coding system was used as patient names were not used in the questionnaire and data sheets in order to maintain

confidentiality. The data was entered on an excel spreadsheet. The questionnaire and clinical examination results were reported as frequencies with percentages. The scores were reported with ranges, means and medians. The data was analyzed with the help of the Biostatistics department of the University of the Free State. The data analysis was done using SAS software. Copyright, SAS institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

### **3.12 Reliability and validity**

The OSDI questionnaire that was used to determine the severity of dry eye symptoms is an international accepted and a valid questionnaire to determine the prevalence of dry eyes. The questionnaire has been assessed for validity and reliability (Schiffman *et al.*, 2000). It is an accepted questionnaire by the Food and Drug Administration. Clinical tests, the Tear Break-up Time (TBUT) and Schirmer 2 test provide reliable results and are considered valid test to assess for dry eyes (Mcmonnies, 2018).

## CHAPTER 4: RESULTS

### 4.1 Introduction

In this chapter, the results of the study are presented. Firstly, the demographic profile of the cohort is described, followed by the description outlining contact lenses usage, medications and smoking details of the cohort. The percentages highlighting the previous diagnosis of dry eye syndrome will be presented. Thereafter, the OSDI questionnaire, Meibomian gland, TBUT, and Schirmer 2 test results will be presented.

### 4.2 Demographics

A total of 150 participants completed the questionnaire and undergone the clinical evaluation for dry eye syndrome. Among the 150 participants that participated in the study, 72% of participants were females.

The median age of the participants was 58.5 years with a range from 20 to 87 years as shown in Figure 1.

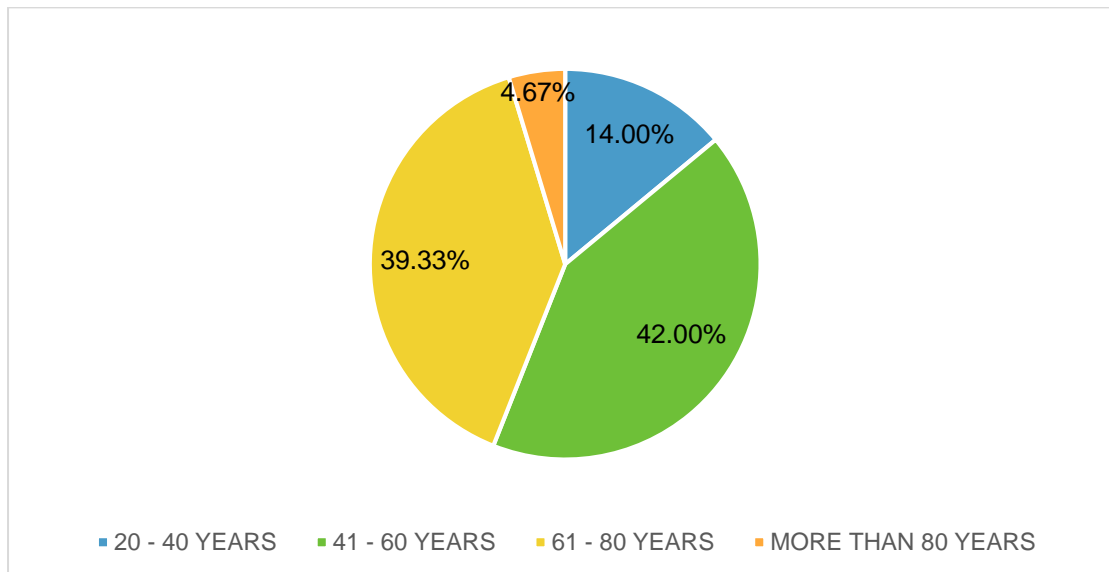


Figure 1: Age distribution of the participants

Most of the participants (49.33%) came from Mthatha with a least number of the participants from Ngcobo town as shown in Table 4. A total of about 27.33% of the participants indicated that they came from other towns than the ones that were listed in the questionnaire. These towns and distances from Mthatha in kilometers (km) were Mt Frere (104.5 km), Idutywa (84.9 km), Butterworth (119.8 km), Ntabankulu (156.0

km), Mt Ayliff (150.4 km), Lusikisiki (127.2 km), Bizana (233.3 km), Flagstaff (170.0 km), Port St John's (98.2 km), Elliotdale (59.2 km), Libode (33.8 km), Matatiele (233.8 km), Maclear (105.6 km), Ugie (87.2 km) and Mt Fletcher (166.0 km).

Table 3: Different towns with number of participants per town.

TOWN	NUMBER OF PARTICIPANTS	PERCENTAGE (%)
Mthatha	74	49.33
Tsolo	8	5.33
Ngqeleni	10	6.67
Mqanduli	6	4.00
Ngcobo	5	3.33
Qumbu	6	4.00
Others	41	27.33
TOTAL	150	100

### 4.3 Contact lens wearing

None of the participants wore contact lenses.

### 4.4 Medications and Smoking

Only 4% of the participants were smokers and were ALL males. About 69.33% indicated that they were taking medications. About 75% of the participants were taking medications for high blood pressure and 31.73% for diabetes as indicated in figure 2. There were few participants (0.96%) who were taking medications for eye problems. None were on birth control or menopause medications and none were having thyroid and stomach problems.

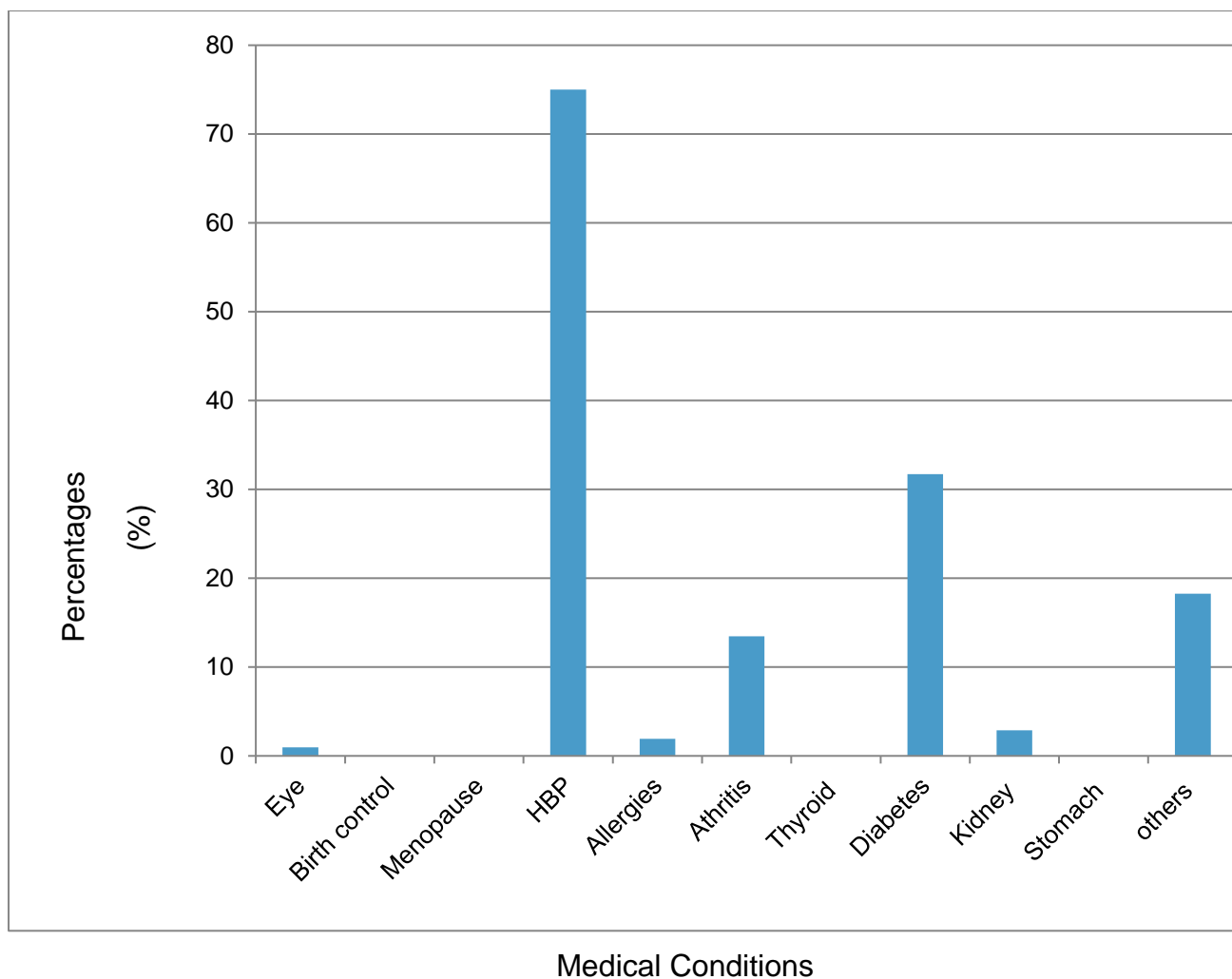


Figure 2: Percentages of participants that took medications for different medical conditions

#### 4.5 Previous Dry Eye Syndrome diagnosis

Participants were asked if any doctor had ever diagnosed them with dry eye syndrome. There were about 2.67% that reported to have been diagnosed previously with dry eye syndrome and 80.67% had never had a diagnosis of dry eye syndrome. Only 16.67% did not know if they had been previously diagnosed with dry eye syndrome.

#### 4.6 OSDI results

Participants were assessed on ocular symptoms, vision related functions and environmental triggers using the Ocular Surface Disease Index (OSDI) questionnaire.

##### 4.6.1 Sensitivity to light

The participants were asked whether they had experienced sensitivity to light in their eyes during the last week. There were about 33.33% of the participants that reported that their eyes were sensitive to light sometimes, 24.00% reported that eyes were sensitive to light most of the time, 22.67% reported that eyes were sensitive to light all of the time and 19.33% reported that the eyes were not sensitive to light as shown in Table 5.

#### **4.6.2 Grittiness in the eyes**

The participants were asked whether they had experienced grittiness in their eyes during the previous week. There were about 41.33% of the participants that reported that their eyes felt grittiness sometimes, 22.00% reported that eyes were gritty most of the time, 11.33% reported that eyes were gritty all of the time, and 24.67% reported that the eyes were not gritty as shown in Table 5.

#### **4.6.3 Painful or sore eyes**

The participants were asked whether they had experienced painful or sore eyes during the previous week. More than half of the participants (54.67%) reported that they did not have painful or sore eyes. About 34.67% reported that they felt painful or sore eyes some of the time, about 1.33% reported that they felt painful or sore eyes half of the time, 6.00% reported that they felt painful or sore eyes most of the time, and 3.33% reported that they felt painful or sore eyes all of the time (Table 5).

#### **4.6.4 Blurred vision**

Participants were also asked as to whether they had experienced blurred vision during the previous week. There were about 22.67% that had experienced blurred vision some of the time, about 0.67% reported that they experienced blurred vision half of the time, 37.33% reported that they experienced blurred vision most of the time and 22.67% experienced blurred vision all of the time (Table 5).

#### **4.6.5 Poor vision**

Participants were asked whether they experienced poor vision during the previous week, 38.67% reported that they had poor vision most of the time, about 26.67% reported that they had experienced poor vision all of the time, and 18,67% reported that they experienced poor vision some of the time (Table 5).

Table 4: OSDI questionnaire on ocular symptoms

Question	Percentage (%) 'All the time"	Percentage (%) 'Most of the time"	Percentage (%) 'Half of the time"	Percentage (%) 'Some of the time"	Percentage (%) 'None of the time"
Eyes that are sensitive to light	22.67	24	0.67	33.33	19.33
Eyes that feel gritty	11.33	22.00	0.67	41.33	24.67
Painful or sore eyes	3.33	6.00	1.33	34.67	54.67
Blurred vision	22.67	37.33	0.67	22.67	16.67
Poor vision	26.67	38.67	0.67	18.67	15.33

#### 4.6.6 Reading

Participants were asked whether their eyes limited them from reading during the previous week, and about 63.70% reported that they experienced limitations with reading all of the time, about 19.86% reported that they did not experience any limitations with reading as shown in table 6.

#### 4.6.7 Driving at night

Participants were asked whether they had experienced limitations with driving at night during the previous week, half of the participants (50.00%) reported that they did not have any limitations with driving during the last week, about 31.82% experienced limitations with driving at night most of the time as shown in table 6.

#### 4.6.8 Working with a computer or bank machine (ATM)

Participants were asked whether their eyes limited them from working with a computer or bank machine (ATM) during the previous week, 78.65% reported that there was none of the time that their eyes limited them from working on a computer or using a bank machine during the previous week, about 8.99% reported that they had experienced limitations with working on the computer or bank machine some of the time as shown in table 6.

#### **4.6.9 Watching television (TV)**

Participants were asked whether their eyes limited them from watching television (TV) during the previous week, 46.98% did not have limitations with watching TV during the last week, about 36.91% had experienced that their eyes limited them from watching TV some of the time, and 8.72% had experienced that their eyes limited them from watching TV most of the time during the last week as shown in table 6.

#### **4.6.10 Windy conditions**

Most of the participants (44.97%) had uncomfortable eyes in the windy conditions some of the time, 20.81% had their eyes feeling uncomfortable most of the time and only 1.34% had their eyes feeling uncomfortable half of the time during the last week as shown in table 7.

#### **4.6.11 Places or areas with low humidity (very dry)**

Participants were also asked whether their eyes felt uncomfortable when they were in places or areas with low humidity (very dry). There were about 9.82% that experienced uncomfortable eyes most of the time when they were in places or areas with low humidity, 8.93% that had experienced uncomfortable eyes some of the time, and 7.14% had experienced uncomfortable eyes all of the time as shown in table 7.

Table 5: OSDI questionnaire on vision related functions

Question	Percentage (%) 'All the time"	Percentage (%) 'Most of the time"	Percentage (%) 'Half of the time"	Percentage (%) 'Some of the time"	Percentage (%) 'None of the time"	Percentage (%) Not Applicable (N/A)
Eyes limited while reading	63.70	9.59	0	6.85	19.86	0
Eyes limited while driving at night	13.64	31.82	0	4.55	50.00	0
Eyes limited while working with computer or ATM	7.87	4.49	0	8.99	78.65	0
Eyes limited while watching TV	7.38	8.72	0	36.91	46.98	0

#### 4.6.12 Areas that are air-conditioned

Participants were asked if their eyes felt uncomfortable when they were in areas that were air-conditioned. There were about 35.20% of the participants that had uncomfortable eyes some of the time, 15.20% had uncomfortable eyes all of the time, 10.40% had uncomfortable eyes most of the time, and 0.80% had uncomfortable eyes half of the time. There were about 38.40% of the participants that did not have eyes that felt uncomfortable in areas that were air conditioned (Table 7).

Table 6: OSDI questionnaire on environmental triggers

Question	Percentage (%) 'All the time"	Percentage (%) 'Most of the time"	Percentage (%) 'Half of the time"	Percentage (%) 'Some of the time"	Percentage (%) 'None of the time"	Percentage (%) Not Applicable (N/A)
Eyes felt uncomfortable in windy conditions	18.12	20.81	1.34	44.97	14.77	0
Eyes felt uncomfortable low in humid or very dry places	7.14	9.82	0	8.93	74.11	0
Eyes felt uncomfortable in air conditioned areas	15.20	10.40	0.80	35.20	38.40	0

#### 4.6.13 OSDI score

The Ocular Surface Disease Index (OSDI) score was calculated and the participants were classified into the different categories as shown in Table 8. Eight percent (8%) of the participants were classified as having normal ocular surface and 92% had dry eyes. Among those who were classified with dry eyes, 10% had mild dry eye disease and 17.33% had moderate dry eye disease, whereas 64.67% of the participants had severe dry eye disease.

Table 7: OSDI score classification

OSDI score	Number of participants (n)	Percentages (%)
Normal (OSDI score 0-12)	12	8.00
Mild dry eye (OSDI score 13-22)	15	10.00
Moderate dry eye (OSDI score 23-32)	26	17.33
Severe dry eye (OSDI score 33-100)	97	64.67
Total	150	100.00

#### 4.7 Meibomian gland results

Most of the participants (73.33%) had normal meibomian function and only 26.67% of the participants had Meibomian gland dysfunction.

#### 4.8 TBUT results

Most participants (64.67%) had dry eyes with TBUT of less than 10 secs as shown in table 9.

#### 4.9 Schirmer 2 test results

There were about 16.67% of the participants that were classified as having true dry eyes, whilst 46% were classified as having dry eyes and lacrimal insufficiency. Therefore, from the Schirmer 2 test, 62.67% of participants had dry eyes, whereas about 37.33% of the participants were found to be having normal eyes on Schirmer 2 test as shown in table 10.

Table 8. Tear break-up Time (TBUT)

	Number of participants (n)	Percentage (%)
Normal (10 sec or more)	53	35.33
Dry eye (less than 10 sec)	97	64.67
Total	150	100

Table 9. Schirmer 2 test

	Number of participants (n)	Percentage (%)
Normal (10 mm or more)	56	37.33
Dry eye and lacrimal insufficiency (5-9mm)	69	46.00
True dry eye (less than 5mm)	25	16.67
Total	150	100

#### **4.10 Summary of the prevalence rates of dry eye syndrome using 3 measuring tools**

The prevalence of dry eye by measuring the stability of the tear film using the tear break-up time (TBUT) is 64.67%. The prevalence of dry eye by evaluating the integrity of the lacrimal secretion system using Schirmer test 2 is 62.67%. The prevalence and severity of dry eye symptoms by using the ocular surface disease index (OSDI) questionnaire is 92.00%.

## CHAPTER 5: DISCUSSION

### 5.1 Introduction

This chapter provides a discussion and analysis of the results obtained. The main results are given, the results are compared to previous studies and limitations are discussed.

The aim of the study was to determine the prevalence of dry eye syndrome among patients at the Eye Clinic at Nelson Mandela Academic Hospital (NMAH) in Mthatha. The four objectives were to determine the prevalence and severity of dry eye syndrome by administering the OSDI questionnaire; determining the prevalence of dry eye syndrome by measuring the stability of the tear film using the using the TBUT; determining the prevalence of dry eye syndrome by evaluating the integrity of the lacrimal secretion system using the Schirmer 2 test; and lastly to document the prevalence of DES among patients at the eye clinic in NMAH.

### 5.2 Demographics and the characteristics of the patients

The current study comprised of 150 adult outpatients aged 18 years and older, similar to the study that looked at the prevalence of dry eye disease in southern Egypt: a hospital-based outpatient clinic study (Mostafa, 2016). More than 90% of the participants were of Black race. It would have very nice to have other races, for example White, Indian etc. represented in numbers in the study, so as to make good comparison between ethnic groups. The median age for the participants was 58.5 years with the youngest being 20 years and the oldest 87 years. The majority of the participants (82.0%) were older than 40 years, and were likely to have systemic diseases as the symptoms of chronic eye irritation are common in an elderly population and frequently due to DES (Chia *et al.*, 2003). An increasing age has been seen as one of the risk factors for the development of DES (Gayton, 2009). A majority of the participants in the study were females, and hormonal changes, with a resultant oestrogen deficiency, could have resulted in high prevalence of DES in females than males. Previous studies reported high prevalence of dry eye in females than males (Mostafa, 2016; Nowak & Smigielski, 2016; Colligris *et al.*, 2014; Jie *et al.*, 2009; Schaumberg *et al.*, 2003). Thus there is a gender relation to the prevalence of dry eyes, with females being the greater sufferers of dry eyes. The etiology of dry eye is

associated or linked to hormonal changes that occur in females (Onua & Chukwuka, 2017). The oestrogen deficiency and change in the local hormonal milieu of the lacrimal gland is caused by menopause (Sahai & Malik, 2005). In as much as it is most notable to determine prevalence of dry eye syndrome to be greater in females than in males, one study indicated the prevalence of dry eye syndrome to be greater in males than females (Ranjan *et al.*, 2016). The reason for a higher prevalence in males than females has been attributed to the rural background of the patients that were used in the study, and emphasizing that males are more active in outside and get exposed to different exposure factors such as sunlight, high temperature and excessive wind (Ranjan *et al.*, 2016). Amongst other things, smoking, air pollution and drugs were suggested to be risk factors of dry eye in males (Ranjan *et al.*, 2016).

A greater number of the participants (49.33%) came from Mthatha. This is because Nelson Mandela Academic Hospital is situated in Mthatha and is much more easily accessible to local residents. None of the participants wore contact lenses. Contact lenses are still a rare option in managing refractive errors as spectacles are currently available for managing refractive errors in the Eastern Cape public sector hospitals where optometry services are rendered. Contact lenses are seen as precipitates or factors that would exacerbate the development of DES, due to the disturbance of the tear film they cause on wearing them and their ability to desensitize the cornea over time (Gayton, 2009).

Most of the participants (69.33%) were taking medications for different medical conditions. The common medications (75%) taken were for high blood pressure, followed by diabetic medications (31.73%). Only a small percentage of participants (0.96%) took medications for eye problems as compared to 13.46% for arthritis and 1.92% for allergies. None of the participants were taking medications for birth control, menopause, thyroid and stomach problems. It would have been interesting to have some females on hormone replacement therapy (HRT) so that a link could be made to HRT and DES in this study. In a study that was conducted on the prevalence of dry in diabetics, it was found that diabetics are more prone to suffering from dry eye than normal subjects (Kamel *et al.*, 2017). The drugs that are associated with dry eye disease are atenolol, chlorpheniramine, hydrocholothiazide, isetretinoin, ketorolac, ketotifen, levocabastine, levofloxacin, oxybutynin and tolterodine (Colligris *et al.*, 2014). In a study that was conducted in Saudi Arabia, on the prevalence of dry eye

symptoms and its risk factors among patients of King Abdulaziz Specialist Hospital (Taif), Saudi Arabia, there was a significant association between arthritis, hypercholesterolemia and dry eyes, but no significant effect of gender (Alhamyani *et al.*, 2017).

Only 4% of the participants, which were only males, reported that they were smoking. It is possible that the relatively low percentage of smoking was due to the fact that only males that reported to be smoking. Some participants might have been afraid to report some of negative healthy habits or behaviors such as smoking. Some of the male participants would report that they stopped smoking long time ago, when they were asked if they smoked. Smoking is a common thing amongst adult males in South Africa (Reddy *et al.*, 2015), even though there is no study pertaining to prevalence of smoking in the Eastern Cape Province. From previous studies (Mostafa, 2016; Ranjan *et al.*, 2016), male participants constituted a greater percentage of smokers than females. It is known that the direct irritants to the eyes from smoking increases the risk of DES (Chia *et al.*, 2003). For the present study, there is no direct link of smoking to DES that can be shown among males that were smokers.

### **5.3 Prevalence and severity of dry eye syndrome using OSDI**

The prevalence of dry eyes was 92% and the majority of the participants (64.67%) had severe dry eyes. Only 8% of the participants did not have some form of dry eyes. A greater percentage of the participants had a higher prevalence of severe dry eye symptoms from the OSDI questionnaire.

#### **5.3.1 Comparison with previous studies**

An ocular surface disease index (OSDI) questionnaire on dry eye symptoms was used to determine the prevalence of dry eyes among the general population of Jordan (Bakkar *et al.*, 2016). It was found that 59% of the participant whose ages ranged from 18 years to older than 45 years exhibited dry eye symptoms. There was a greater (more than 50%) prevalence of dry eye symptoms in the study of Jordan as in this study. A South African study that was conducted at the University of Johannesburg on students, staff and their relatives had participants with ages that ranged from 18-80 years. The prevalence and severity of dry eye symptoms were determined using the OSDI. The prevalence was 64%. Most of the participants had at least mild dry eye

symptoms whereas in this study most of the participants had severe dry eyes of about 64.67%.

This therefore indicates that there is a greater prevalence of dry eye amongst patients attended at NMAH, in the eye clinic. The OSDI questionnaire is subjective, but is a good tool to determine the prevalence of the symptoms of dry eyes.

From the most recent study that was conducted in Saudi Arabia using the OSDI questionnaire to determine the prevalence dry eye symptoms and its risk factors among patients of King Abdulaziz Specialist Hospital (Taif), about 24.07% of the patients were classified as normal. Out of 482 patients that were studied, 21.37% of the patients had mild dry eye, whereas about 12.86% of the patients had moderate dry eye and 41.70% of the patients had severe dry eye (Alhamyani *et al.*, 2017).

Comparing to the study conducted at NMAH to the one conducted in Saudi Arabia, both studies indicate a high prevalence of dry eye symptoms under those classified as having severe dry eye. This is because the majority of the participants in both studies were older than 40 years of age, with a likely possibility of having systemic medical conditions that are risk factors to dry eye syndrome.

#### **5.4 Prevalence of dry eye syndrome using TBUT**

From a second tool, the tear break-up time (TBUT) that was used to determine the prevalence of dry eye syndrome by measuring the stability of the tear film, the prevalence was 64.67%. TBUT of less than 5 seconds was prevalent in 38% of the participants and TBUT of less than 10 seconds but more than 5 seconds was prevalent in 26.67% of the participants.

##### **5.4.1 Comparison with previous studies**

The prevalence of dry eye syndrome determined using the TBUT, which is 64.67%, is high as in the study that was conducted in the University of KwaZulu-Natal, which was 81%. The TBUT of less than 10 seconds was prevalent in 44.7% of the cases in a hospital-based outpatient clinic study done in southern Egypt. The prevalence study in southern Egypt, a hospital-based outpatient clinic study, had a bigger number (3128) of the participants compared to our study of less participants (150).

The study that was conducted in Bangkok, Thailand, showed that 54.7% of the participants had a TBUT of less than 10 seconds, a percentage lesser than our study.

## **5.5 Prevalence of dry eye syndrome using Schirmer 2 test**

From the Schirmer 2 test, the prevalence of dry eye was determined by evaluating the integrity of the lacrimal secretion system. The prevalence was 62.67% on Schirmer 2 test. The results of the prevalence of dry eye using Schirmer 2 test, TBUT, and OSDI questionnaire were 62.67, 64.67% and 82% respectively.

### **5.5.1 Comparison with previous studies**

In a study that was conducted in Egypt, on the prevalence of dry eye in diabetics, Schirmer 1 test (without topical anesthesia) was used to measure the total tear secretion (Kamel, 2017) whereas in this study Schirmer 2 test (with topical anesthesia) was used to determine the prevalence of dry eye syndrome. The Schirmer 1 test values were lower among the patients with uncontrolled diabetes indicating a highly statistically significant relation between severity of dry eye and diabetes (Kamel, 2017).

In a study that was conducted in Southern Nigeria, on the prevalence of dry eye disease in a rural Niger Delta community, over 72% of the study population had normal Schirmer test results, 18.4% had mild dry eye syndrome, 6.8% had moderate dry eye syndrome and 2.2% had severe dry eye syndrome (Onua & Chukwuka, 2017). The results from the Schirmer test were classified as normal (>15mm), mild (9-14mm), moderate (4-8mm) and severe (<4mm) dry eye disease (Onua & Chukwuka, 2017). As of this study, the classification of dry eye syndrome using the Schirmer test was either normal (10mm or more), dry eye and lacrimal insufficiency (5-9mm) or true dry eye (<5mm).

## **5.6 Severity of dry eye syndrome**

In this study, the prevalence of dry eye syndrome is much more severe in elderly and female participants. The severity of dry eye syndrome is determined using the Ocular Surface Disease Index (OSDI) questionnaire, Tear Break-Up Time (TBUT) and Schirmer 2 test. The OSDI questionnaire determined the prevalence of severe dry eye syndrome to be 64.67%. The TBUT determined the prevalence of severe dry eye syndrome to be 38%, whereas the Schirmer 2 test determined the prevalence of severe dry eye syndrome to be 16.67%, much lesser than the OSDI and TBUT. Based

on the OSDI questionnaire, the dry eye syndrome is much more severe based on symptoms than the objective clinical testing.

### **5.6.1 Comparison with previous studies**

There is a lack of the gold standard for determining the severity of dry eye disease (Baudouin *et al.*, 2014). The OSDI questionnaire is a widely used tool to determine the severity of dry eye disease, as the OSDI score of around 30 or over is necessary for the diagnosis of severe dry eye disease (Baudouin *et al.*, 2014). For determining the severity, tear osmolarity has been seen as the best single marker for dry eye syndrome (Utine *et al.*, 2011).

### **5.7 Limitations**

There is no accepted grading system for meibomian gland dysfunction (Jie *et al.*, 2009), which is why the assessment of Meibomian glands was used as an adjunct in determining the prevalence of dry eye syndrome. The study on the prevalence of dry eye syndrome only determined the prevalence on patients as this is a hospital based study.

## **CHAPTER 6: CONCLUSION AND RECOMMENDATIONS**

The prevalence of dry eye among patients at the eye clinic in Nelson Mandela Academic Hospital differed according to the tests or measuring tools used. The OSDI questionnaire determined the prevalence of dry eye to be 92.00%. The Tear Break-Up Time (TBUT) and Schirmer's 2 test determined the prevalence of dry eyes to be 64.67% and 62.67% respectively. Female participants were predominant in the study with a high prevalence of dry eyes in females. There was a high prevalence of dry eye among patients examined at the Eye clinic in Nelson Mandela Academic Hospital in Mthatha. All the tools used to determine the prevalence showed an agreement in that the prevalence was more than 60%.

There are few of the tests that are performed as routine tests to diagnose dry eye syndrome (Sullivan *et al.*, 2014). With this in mind, the following recommendations can be made:

- study results will be made available to the departments of ophthalmology and optometry to encourage clinicians to perform a majority of clinical tests to diagnose dry eye syndrome, for a proper or improved management of the disease. The eyecare professionals that manage eye related conditions must be informed that dry eye syndrome is highly prevalent in Mthatha and must never be overlooked or remain undiagnosed as patients will continue to suffer from dry eyes.
  
- the department of health must also be informed of the high prevalence of dry eye syndrome in the area so that, the department can ensure that medications for managing dry eye syndrome are available in all facilities to aid in curbing the disease.
  
- The results of this study will be made available to health authorities in order to raise attention on the prevalence of DES and seek to see a widespread distribution of over the counter eye drops to local hospitals and health care centers for managing dry eye syndrome.

- Dry eye assessment lacks a gold standard for its diagnosis. With the new tear Osmolarity testing that is considered a gold standard for measuring dry eyes, future studies need to be conducted using the tear osmolarity test, even though it is widely accepted that there is no single test that is accepted as the gold standard for dry eye syndrome (Onua & Chukwuka, 2017).
- A hospital based population prevalence study on dry eye syndrome, that covers other hospitals in the Eastern Cape province, would be recommended for future studies with the inclusion of other dry eye tests such as tear osmolarity test.

## **CHAPTER 7: REFERENCES**

Alhamyani A.H., Kalakattawi R.M.N., Kalakattawi A.M.N., Alhamyani A.H., Alsuqati F.A., Al-Sheri L.A., Assery M.S. and Alzahrani A.A. Prevalence of dry eye symptoms and its risk factors among patients of King Abdulaziz Specialist Hospital (Taif), Saudi Arabia. *Saudi Journal Health Science*. 2017; 6:140-144.

Badawi D. A novel system. TearCare®, for the treatment of signs and symptoms of dry eye disease. *Clinical Ophthalmology*. 2018; 12:683-694.

Bakkar M.M., Shihadeh W.A., Haddad, M.F. and Khader Y.S. Epidemiology of symptoms of dry eye disease (DED) in Jordan: A cross-sectional non-clinical population-based study. *Contact Lens and Anterior Eye*. 2016; 39:197-202.

Barlett J.D., Keith M.S., Sudharshan L. and Snedecor S.J. Associations between signs and symptoms of dry eye disease: a systematic review. *Clinical Ophthalmology*. 2015; 9:1719-1730.

Baudouin C., Aragona P., Setten G.V., Rolando M., Irkec M., Castillo J.B.D., Geerling G., Labetoulle M., Bonini S. and ODISSEY European Consensus Group members. Diagnosing the severity of dry eye: a clear and practical algorithm. *British Journal of Ophthalmology*. 2014; 98:1168-1176.

Bukhari A., Ajlan R. and Alsaggaf H. Prevalence of Dry Eye in the Normal Population in Jeddah, Saudi Arabia. *Orbit*. 2009; 28:392-7.

Carlson N.B. and Kurtz D. (2004). *Clinical procedures for ocular examination*, 3rd Edition. 2004; McGraw-Hill Companies.

Castelyn B., Majola S., Motilal R., Naidu M.T., Ndebele S.A., Vally T.A. and Khan N.E. Prevalence of dry eye amongst Black and Indian university students aged 18-30 years. *African Vision and Eye Health*. 2015; 74(1),6 pages.

Chia E.M., Mitchell P., Rochtchina E., Lee A.J., Maroun R. and Wang J.J. Prevalence and associations of dry eye syndrome in an older population: The Blue Mountains Eye Study. *Clinical and Experimental Ophthalmology*. 2003; 31:229-232.

Clegg J.P., Guest J.F., Lehman A. and Smith A.F. The Annual Cost of Dry Eye Syndrome in France, Germany, Italy, Spain, Sweden and the United Kingdom among Patients Managed by Ophthalmologists. *Ophthalmic Epidemiology*. 2006; 13:263-274.

Colligris B., Alkozi H.A. and Pintor J. Recent developments on dry eye disease treatment compounds. *Saudi Journal of Ophthalmology*. 2014; 28:19-30.

Craig J.P., Nichols K.K., Akpek E.K., Caffery B., Dua H.S., Joo C.-K., Liu Z., Nelson J.D., Nichols J.J., Tsubota K. and Stapleton F. TFOS DEWS II Definition and Classification Report. *The Ocular Surface*. 2017; 15:276–283.

Dougherty B.E., Nicholas J.J. and Nichols K.K. Rasch Analysis of the Ocular Surface Disease Index (OSDI). *Investigative Ophthalmology and Visual Science*. 2011; 52:8630-8635.

Gayton J.L. Etiology, prevalence, and treatment of dry eye disease. *Clinical Ophthalmology*. 2009; 3:405-412.

Gillan W.D.H. A small-sample survey of dry eye symptoms using the Ocular Surface Disease Index. *African Vision and Eye Health*. 2009;68(4):188-191.

Guo B., Lu P., Chen X., Zhang W. and Chen R. Prevalence of dry eye disease in Mongolians at high altitude in China: The Henan eye study. *Ophthalmic Epidemiology*. 2010; 17:234-41.

Hashemi H., Khabazkhoob M., Kheirikhah A., Emamian M.H., Mehravaran S., Shariati M. and Fotouhi A. Prevalence of dry eye syndrome in an adult population. *Clinical and Experimental Ophthalmology*. 2014; 42:242-248.

Jie Y., Xu L., Wu Y.Y. and Jonas J.B. Prevalence of dry eye among adult Chinese in the Beijing Eye Study. *Eye*. 2009; 23:688-93.

Kamel S.S., Mohammed T.H., El Zankalony Y.A. and Saad A.H. Prevalence of dry eye in diabetics. *Journal of the Egyptian Ophthalmological Society*. 2017; 110:77-82.

Lu P., Chen X., Liu X., Yu L., Kang Y., Xie Q., Ke L. and Wei X. Dry eye syndrome in elderly Tibetans at high altitude: a population-based study in China. *Cornea*. 2008; 27:545-51.

Lin P.Y., Tsai S.Y., Cheng C.Y., Liu J.H., Chou P. and Hsu W.M. Prevalence of dry eye among an elderly Chinese population in Taiwan: The Shihpai Eye Study. *Ophthalmology*. 2003; 110:1096-101.

Manaviat M.R., Rashidi M., Afkhami-Ardekani M. and Shoja M.R. Prevalence of dry eye syndrome and diabetic retinopathy in type 2 diabetic patients. *Ophthalmology*. 2008; 8:10.

McCarty C.A., Bansal A.K., Livingston P.M., Stanislavsky Y.L. and Taylor HR. The epidemiology of dry eye in Melbourne, Australia. *Ophthalmology*. 1998; 105:1114-19.

Mcmonnies C.W. Tear instability importance, mechanisms, validity and reliability of assessment. *Journal of Optometry*. 2018;11: 203-210.

Mostafa E.M. Prevalence of dry eye disease in southern Egypt: a hospital-based outpatient clinic study. *Journal of the Egyptian Ophthalmological Society*. 2016; 109:32-40.

Nelson J.D., Craig J.P., Akpek E.K., Azar D.T., Belmonte C., Bron A.J., Clayton J.A., Dogru M., Dua H.S., Foulks G.N., Gomes J.A.P., Hammit K.M., Holopainen J., Jones L., Joo C., Liu Z., Nichols J.J., Nichols K.K., Novack G.D., Sangwan V., Stapleton F., Tomlinson A., Tsubota K., Willcox M.D.P., Wolffsohn J.S. and Sullivan D.A. TFOS DEWS II Introduction. *The Ocular Surface*. 2017; 15:269-275.

Nowak M.S. and Smigielski J. The Prevalence and Risk Factors for Dry Eye Disease among Older Adults in the City of Lodz, Poland. *Open Journal of Ophthalmology*. 2016; 6:1-5.

Olaniyana S.I., Fasina O., Bekibele C.O. and Ogundipe A.O. Dry eye disease in an adult population in South-West Nigeria. *Contact Lens and Anterior Eye*. 2016; 39:359-64.

Onua A.A. and Chukwuka I.O. Prevalence of dry eye disease in rural Niger Delta community, Southern Nigeria. *Open Journal of Ophthalmology*. 2017; 7:95-102.

Onwubiko S.N., Eze B.I., Udeh N.N., Arinze O.C., Onwasigwe E.N. and Umeh R.E. Dry eye disease: prevalence, distribution and determinants in a hospital-based population. *Contact Lens and Anterior Eye*. 2014; 37:157-61.

Ranjan R., Shukla S.S., Singh C.V., Mishra B.N., Sinha S. and Sharma B.D. Prevalence of Dry Eye and Its Association with Various Risk Factors in Rural Setup of Western Uttar Pradesh in a Tertiary Care Hospital. *Open Journal of Preventive Medicine*. 2016; 6:57-63.

Rathi V.M. and Sangwan V.S. Prevention, diagnosis & management of dry eye in South Asia. *Community Eye Health*. 2017;30(99): S3-S4.

Reddy P. Zuma K. Shisana O. Jonas K. and Sewpaul R. Prevalence of tobacco use among adults in South Africa: Results from the first South African National Health and Nutrition Examination Survey. *South African Medical Journal*. 2015;105(8):648-655.

Sahai A. and Malik P. Dry Eye: Prevalence and Attributable Risk Factors in a Hospital-Based population. India. *Indian Journal of Ophthalmology*. 2005; 53:87-91.

Schaumberg D.A., Dana R., Buring J.E. and Sullivan D.A. Prevalence of dry eye disease among US men: estimates from the Physicians' Health Studies. *Archives of Ophthalmology*. 2009; 127:763-768.

Schiffman R.M., Christianson M.D., Jacobsen G., Hirsch J.D. and Reis B.L. Reliability and Validity of the Ocular Surface Disease Index. *Archives of Ophthalmology*. 2000; 118:615-621.

Stapleton F., Alves M., Bunya V.Y., Jalbert I., Lekhanont K., Malet F., Na K.S., Schaumberg D., Uchino M., Vehof J., and Viso E. TFOS DEWS II Epidemiology Report. *The ocular surface*. 2017;15(3):334-65.

Sullivan B.D., Crews L.A., Messmer E.M., Foulks G.N., Nichols K.K., Baenninger P., Geerling G., Figueiredo F. and Lemp M.A. Correlations between commonly used objective signs and symptoms for the diagnosis of dry eye disease: clinical implications. *Acta Ophthalmologica*. 2014; 92:161-166.

Utine C.A., Bicakcigil M., Yavuz S. and Ciftci F. Tear Osmolarity Measurements in Dry Eye Related to Primary Sjogren's syndrome. *Current Eye Research*. 2011;36 (8):683-690.

Uchino M., Schaumberg D.A., Dogru M., Uchino Y., Fukagawa K., Shimmura S., Satoh T., Takebayashi T. and Tsubota K. Prevalence of dry eye disease among Japanese visual display terminal users. *Ophthalmology*. 2008; 115:1982-1988.

Viso E., Gude F. and Rodriguez-Ares M.T. The association of meibomian gland dysfunction and other common ocular diseases with dry eye: a population-based study in Spain. *Cornea*. 2011; 30:1-6.

Viso E., Rodriguez-Ares M.T. and Gude F. Prevalence and associated factors for dry eye in a Spanish adult population (the Salnes Eye Study). *Ophthalmic Epidemiology*. 2009; 16:15-21.

Yu J., Asche C.V. and Fairchild C.J. The economic burden of dry eye disease in the United States: a decision tree analysis. *Cornea*. 2011; 30:379-87.

Zhang Y., Chen H. and Wu X. Prevalence and risk factors associated with dry eye syndrome among senior high school students in a county of Shandong Province, China. *Ophthalmic Epidemiology*. 2012; 19:226-230.

## **ANNEXURES**

### **ANNEXURE A**

**OSDI questionnaire (Attachment)**

#### **ANNEXURE A1**

**OSDI questionnaire in isiXhosa (Attachment)**

#### **ANNEXURE A2**

**OSDI questionnaire template (Attachment)**

## **ANNEXURE B**

### **Information document**

The Prevalence of Dry Eye Syndrome among patients at the Eye Clinic in Nelson Mandela Academic hospital

Researcher: Monwabisi Nonkula

You are being invited to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The purpose of this study is to determine the number of patients with eyes that are dry, attending the eye clinic at Nelson Mandela Academic Hospital (NMAH).

At least, a minimum of about 150 individuals will take part in this study. All the people who partake in the study will have their eyes tested by a researcher to determine whether they have dry eyes or not. Testing will be done using a light that will be shone to your eyes. There will be a yellow dye that will be put into your eyes to assess dry eyes. An eye drop to numb your eyes will also be used when strips of papers are to be inserted into your eyes to assess dry eyes. There is no pain or harm from these tests. Those identified as having dry eyes will get the eye drops that help alleviate dry eyes. The testing by a researcher will not take more than 20 minutes. You will also be asked questions about your age, health, eyes, medications that you are taking and these will take about 5 minutes of your time.

There are no risks in partaking in the study. You can refuse to partake in the study without losing any benefits from the hospital and there are no costs involved to the participant.

All the information collected will be kept confidential and the research may be published.

Should you have any questions about the research or any related matters, please contact the researcher at 083 533 4370 during regular business hours of the day. For questions about your rights as a research participant and for reporting of complaints, contact the Secretariat of the Health Sciences Research Ethics Committee of the University of the Free State at 051 401 7795.

## ANNEXURE B1

### Information document in isiXhosa

### Ingcaciso ngophando lwesifundo

The Prevalence of Dry Eye Syndrome among patients at the Eye Clinic in Nelson Mandela Academic hospital

Umphandi: Monwabisi Nonkula

Sicela uthabathe ingxaxheba kuphando esilenzayo. Phambi kokuba uthathe isigqibo sokuthatha ingxaxheba koluphando, kubalulekile ukuba wazi ukuba oluphando silwenzela ntoni kwaye zintoni ezizakubandakanyeka. Sicela uthathe ixesha ufunde okulandelayo, ungoyiki ukubuza umphandi xa kukho ongakuqondiyo okanye xa ufuna ukucaciselwa ngakumbi.

Unobangela woluphando kukufumanisa nokubala inani labantu abanamehlo anengxaki yokoma abathi bandwendwele kwisibhedlela sase Nelson Mandela, kunyango lwamehlo.

Abantu abalinani elingange 150 bazawukuthatha uxanduva kwezizifundo. Bazawukudibana nomphandi, ozothi axilonge amehlo abo ukufumanisa ukuba, ingaba banazo na ingxaki zamehlo okanye abanazo. Kuzawukusetyenziswa ilayiti kunye namanzi anxengiweyo ukuxilonga amehlo akho. Kuza kusetyenziswa neyeza elenza amehlo abe bundindisholo xa kuzofakwa amaphepha mancinci apha emehlweni akho. Akhukho bungozi koluxilongo lwamehlo. Abo bathe bafunyaniswa benengxaki zamehlo omayo okanye omileyo, bawukuxhamla kunyango lwamehlo omileyo.

Umphandi uzawukuthatha imizuzu engagqithanga kwelishumi kuxilongo lwakhe. Kuzakubakho nephepha elinemibuzo ngawe, ngobume bempilo yakho, naleyo yamehlo ozothi uyiphendule ngokugcwalisa iphepha elo elinemibuzo.

Akukho bungozi kwezizifundo. Uvumelekile ukuba ungayeka ukuba yinxalenye nanini na ufuna. Akukho kuchaphazeleka uzawukufumana kuyango lwesibhedlela kuba uyeke ukuba nendima kwezizifundo zophando.

Xa unemibuzo ngezizifundo, uvumelekile ukutsalela umphandi kwezinombolo (083) 533 4370 ngamaxesha omsebenzi. Ngemibuzo okanye ngokuxela ngezikhhalazo onazo ngoluphando, ungatsalela kwibhodi yase Free State yezokhuselo zamalungelo abantu kwezinombolo (051) 401 7795.

## ANNEXURE C

### Consent Form

The Prevalence of Dry Eye Syndrome among patients at the Eye Clinic in Nelson Mandela Academic Hospital

Researcher: Monwabisi Nonkula

I hereby invite you to participate in a research study on the prevalence of dry eye syndrome. The purpose of the research is to see how many people are suffering from dry eyes.

There should be no risks or discomfort to you when you get tested for data collection. Your participation will mean that you will be asked questions and have your eyes examined by a researcher. A consecutive number will be assigned to you as your identity will not be revealed when the study is reported or published on data.

If you have any questions about the study or about participating in the study, please feel free to contact me (Monwabisi Nonkula). You may call me at (083) 533 4370 (cell) or at (047) 502 4670 (work).

Your participation in this study is totally voluntary, thus you are under no obligation to participate. You have a right to withdraw at any time if you feel like or want to, without any penalty, even in the middle of eye examination. The study and its procedures have been approved by relevant authorities. I have discussed the above points with the subject. It is my opinion that the subject understands the risks, benefits and obligations involved in participating in the research study.

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Date

I therefore freely and voluntarily agree to participate in the research study. I may refuse to participate or withdraw my consent and stop participating at any time without penalty. I hereby freely consent to take part in this research project.

\_\_\_\_\_  
Participant name and signature

\_\_\_\_\_  
Date

## ANNEXURE C1

### Consent form in isiXhosa

The Prevalence of Dry Eye Syndrome among patients at the Eye Clinic in Nelson Mandela Academic Hospital

Umphenyi: Monwabisi Nonkula

Esi sisimemo nesicelo sokuba uthathe uxanduva kwizifundo zophando ngamehlo omileyo. Koluphando sifundo, kubalwa abantu abanamehlo omileyo.

Ukuba uthe wafunyaniswa ungomnye wabo bantu, uyakuthi uzuze ngokufumana uncendo lokunyangwa kwesisifo samehlo omileyo. Akukho bungozi okanye luvavanyo lungakwenza ungazivi kamnandi xa kuthathwa iziphumela zamehlo akho. Xa uthatha uxanduva koluphando, kuzawufuneka ugqwalise impendulo kwimibuzo ethile, wakuba ugqibile udibane nomphandi ozothi axilonge amehlo, ajonge ukuba ingaba amahlo akho omile okanye hayi. Igama lakho alizusetyenziswa xapapashwa iziphumela zoluphando.

Uvumelekile ukuba ungayeka ukuzibandakanyeka nezizifundo nangaliphi na ixesha uziva njalo. Xa uthe wabe ufuna ukuyeka, awunakufumana sohlwayo ngalonto.

Imibuzo ngoluphando ungayijolisa kuMnu Monwabisi Nonkula, kwinombolo yomxebe 083 533 4370 okanye kweyase msebenzini 047 502 4670.

Ukuthatha uxanduva koluphando luqinisekisiwe ukuba likukuzikhethela kwakho.

Oluphando lucacisiwe lwagqitha nakubaphathi abafanelekileyo nqu nabesibhedlela.

---

Umphandi

---

Umhla

Ngokutyikitya kulomgca ungezantsi, ndiyavuma ukuba ndizawukuthatha uxanduva koluphando lwezifundo zamehlo omileyo. Ndiyayazi into yokuba ndingayeka ukuba yinxalenye yezizifundo nanini na ndifuna, kwaye akukho sohlwayo endothi ndisifumane kuba ndikhethe ukuzikhwebula kwezizifundo.

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Ozigqatsileyo

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Umhla

## ANNEXURE D

**Data sheet (Attached)**

## **ANNEXURE E**

**UFS ethics approval letter (Attached)**

## **ANNEXURE F**

**Eastern Cape Department of Health approval letter (Attached)**

# ANNEXURE A

## The Prevalence of Dry Eye Syndrome among patients at the Eye Clinic in Nelson Mandela Academic Hospital

### Instructions

Mark the appropriate block with a X or write your answer on the space provided.

STUDY ID NUMBER 

--	--	--

1. Date questionnaire is completed (dd/mm/yy) .... / ..... / .....

2. Gender

Male(1)	Female(2)
---------	-----------

3. Date of birth (dd/mm/yy)..... / ..... / .....

4. Age

.....year(s) .....month(s)

5. Town

Mthatha (1)	
Tsolo (2)	
Ngqeleni (3)	
Mqanduli (4)	
Ngcobo (5)	
Qumbu (6)	
Others, specify (7) _____	

6. Do you wear contact lenses?

Yes(1)	No(2)
--------	-------

**If yes go to 7; if no go to 8**

7. For how long you have been wearing contacts?

less than 1 year (1)
1 - 2 years (2)
more than 2 years (3)

8. Are you taking any medications?

Yes(1)	No(2)
--------	-------

**If yes go to 9, if no go to 10**

9. These are medications for:

**(Mark all the appropriate options)**

Eye problems (1)	
Birth control (2)	
Menopause (3)	
High blood pressure (4)	
Allergies (5)	
Arthritis (6)	
Thyroid problems (7)	
Diabetes (8)	
Kidney problems (9)	
Stomach problems (10)	
Any other (specify) (11) .....	

10. Do you smoke?

Yes(1)	No(2)
--------	-------

11. Have you ever been diagnosed by any Doctor as having dry eye syndrome?

Yes (1)	
No (2)	
Do not know (3)	

**SECTION B**

**OSDI questionnaire used to screen dry eye symptoms in the study population (Allergan Inc, 1995)**

**Mark the appropriate box for each question**

**A. OCULAR SYMPTOMS**

**Have you experienced any of the following during the last week?**

A1. Eyes that are sensitive to light?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)

A2. Eyes that feel gritty?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)

A3. Painful or sore eyes?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)

A4. Blurred vision?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)

A5. Poor vision?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)

**B. VISION RELATED FUNCTIONS:**

**Have problems with your eyes limited you in performing any of the following during the last week?**

B1. Reading?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)
N/A (5)

B2. Driving at night?

None of the time (0)
----------------------

Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)
N/A (5)

B3. Working with a computer or bank machine (ATM)?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)
N/A (5)

B4. Watching TV?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)
N/A (5)

**C. ENVIRONMENTAL TRIGGERS**

**Have your eyes felt uncomfortable in any of the following situations during the last week?**

C1. Windy conditions?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)
N/A (5)

C2. Places or areas with low humidity (very dry)?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)
N/A (5)

C3. Areas that are air conditioned?

None of the time (0)
Some of the time (1)
Half of the time (2)
Most of the time (3)
All of the time (4)
N/A (5)







# ANNEXURE A1

## The Prevalence of Dry Eye Syndrome among patients at the Eye Clinic in Nelson Mandela Academic Hospital

### Imiyalelo

Khetha ngokubhala u X okanye ubhale kwisithuba osinikiweyo

STUDY ID NUMBER 

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1. Umhla wokugcwalisa le mibuzo (dd/mm/yy) ...../...../.....

2. Isini

Indoda(1)	Umfazi(2)
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3. Umhla wakho wokuzalwa (dd/mm/yy)...../...../.....

4. Iminyaka

.....year(s) .....month(s)

5. Indolophu

Mthatha (1)	
Tsolo (2)	
Ngqeleni (3)	
Mqanduli (4)	
Ngcobo (5)	
Qumbu (6)	
Ezinye, cacisa (7)	

6. Uyazifaka i contact lenses?

Ewe(1)	Hayi(2)
--------	---------

**Ukuba ewe yiya ku 7; ukuba hayi yiya ku 8**

7. Sekulithuba elingakanani ufaka i contacts?

Ngaphantsi konyaka oyi 1 (1)	
1 - 2 yeminyaka (2)	
Ngaphezu kweminyaka emibini (3)	

8. Akhona amayeza owasebenzisayo?

Ewe(1)	Hayi(2)
--------	---------

**Ukuba ewe yiya ku 9; ukuba hayi yiya ku 10**

9. Lamayeza ngawe:

**(Khetha zonke ekuzizo)**

Ngxaki zamehlo (1)	
Ngawokucwangcwiswa (2)	
Menopause (3)	
Hay-hayi (4)	
I aleji (5)	
Ngxaki zamathambo (6)	
Dlala (7)	
Swekile (8)	
Ngxaki zezintso (9)	
Ngxaki zesisu (10)	
Ezinye (cacisa) (11) .....	

10. Uyatshaya?

Ewe(1)	Hayi(2)
--------	---------

11. Wakhe wafunyaniswa unengxaki zamehlo omayo ngu Gqirha?

Ewe (1)	
Hayi (2)	
Andazi (3)	

**ICANDELO B**

**OSDI questionnaire used to screen dry eye symptoms in the study population (Allergan Inc, 1995)**

**Khetha ibhokisi nganye kumbuzo ngamnye**

**A. IZIKHALAZO NGAMEHLO**

**Ingaba ubukhe weva enye kwezilandelayo kuleveki iphelileyo?**

A1. Amehlo aphantsi layiti?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)

A2. Amahlo antlaluzelayo?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)

A3. Amehlo aqaqambayo?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)

A4. Ukubona buthuzula?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)

A5. Ukungaboni kakuhle?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)

**B. INGXAKI EZIHAMBISANA NOKUBONA:**

**Ingaba ingxaki zamehlo bezikuchaphazela ekufezekiseni ezi zilandelayo kule veki iphelileyo?**

B1. Ekufundeni?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)
Akukho mpendulo (5)

B2. Xa uqhuba ebusuku?

Akukho xesha (0)
------------------

Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)
Akukho mpendulo (5)

B3. Xa usebenzisa I computha okanye umatshini webhangi (ATM)?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)
Akukho mpendulo (5)

B4. Ekubukeleni umabona kude?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)
Akukho mpendulo (5)

**C. INTSUSA NGOKWENDAWO**

**Ingaba amehlo akho akhe avakala ebuthakathaka kwemeko zilandelayo kuleveki iphelileyo?**

C1. Xa kunomoya?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)
Akukho mpendulo (5)

C2. Kwindawo ezomileyo?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)
Akukho mpendulo (5)

C3. Kwindawo ezinomoya ofakelweyo?

Akukho xesha (0)
Maxesha wambi (1)
Ihafu yexesha (2)
Ixesha elininzi (3)
Lonke ixesha (4)
Akukho mpendulo (5)







## Ocular Surface Disease Index<sup>®</sup> (OSDI<sup>®</sup>)<sup>2</sup>

Ask your patients the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

<b>Have you experienced any of the following <i>during the last week</i>?</b>	<b>All of the time</b>	<b>Most of the time</b>	<b>Half of the time</b>	<b>Some of the time</b>	<b>None of the time</b>
1. Eyes that are sensitive to light? . . .	4	3	2	1	0
2. Eyes that feel gritty? . . . . .	4	3	2	1	0
3. Painful or sore eyes? . . . . .	4	3	2	1	0
4. Blurred vision? . . . . .	4	3	2	1	0
5. Poor vision? . . . . .	4	3	2	1	0

Subtotal score for answers 1 to 5

<b>Have problems with your eyes limited you in performing any of the following <i>during the last week</i>?</b>	<b>All of the time</b>	<b>Most of the time</b>	<b>Half of the time</b>	<b>Some of the time</b>	<b>None of the time</b>	<b>N/A</b>
6. Reading? . . . . .	4	3	2	1	0	N/A
7. Driving at night? . . . . .	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)? . . . . .	4	3	2	1	0	N/A
9. Watching TV? . . . . .	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9

<b>Have your eyes felt uncomfortable in any of the following situations <i>during the last week</i>?</b>	<b>All of the time</b>	<b>Most of the time</b>	<b>Half of the time</b>	<b>Some of the time</b>	<b>None of the time</b>	<b>N/A</b>
10. Windy conditions? . . . . .	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)? . . . . .	4	3	2	1	0	N/A
12. Areas that are air conditioned? . . .	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12

Add subtotals A, B, and C to obtain D  
(D = sum of scores for all questions answered)

Total number of questions answered  
(do not include questions answered N/A)

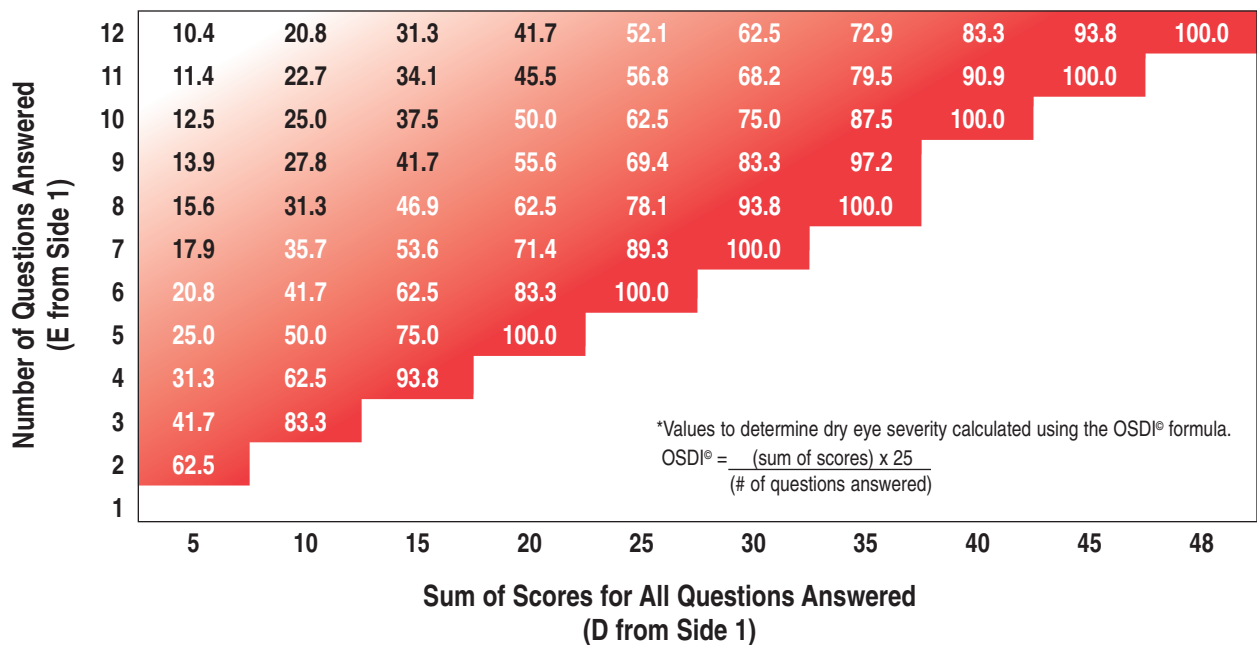
Please turn over the questionnaire to calculate the patient's final OSDI<sup>®</sup> score.

## Evaluating the OSDI® Score<sup>1</sup>

The OSDI® is assessed on a scale of 0 to 100, with higher scores representing greater disability. The index demonstrates sensitivity and specificity in distinguishing between normal subjects and patients with dry eye disease. The OSDI® is a valid and reliable instrument for measuring dry eye disease (normal, mild to moderate, and severe) and effect on vision-related function.

## Assessing Your Patient's Dry Eye Disease<sup>1, 2</sup>

Use your answers D and E from side 1 to compare the sum of scores for all questions answered (D) and the number of questions answered (E) with the chart below.\* Find where your patient's score would fall. Match the corresponding shade of red to the key below to determine whether your patient's score indicates normal, mild, moderate, or severe dry eye disease.



Normal                      Mild                      Moderate                      Severe

.....  
 Patient's Name: \_\_\_\_\_ Date: \_\_\_\_\_

How long has the patient experienced dry eye disease? \_\_\_\_\_

Eye Care Professional's Comments: \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

1. Data on file, Allergan, Inc.  
 2. Schiffman RM, Christianson MD, Jacobsen G, Hirsch JD, Reis BL. Reliability and validity of the Ocular Surface Disease Index. *Arch Ophthalmol.* 2000;118:615-621

# APPENDIX D

## The Prevalence of Dry Eye Syndrome among patients at the Eye Clinic in

### Nelson Mandela Academic Hospital

#### Instructions

Mark the appropriate block with an X or write your answer on the space provided.

STUDY ID NUMBER 

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1. Date Data sheet is completed (dd/mm/yy) .../.../.....

2. Slit-Lamp Examination

2.1 Meibomian Gland Dysfunction

Yes (1)	No (2)
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2.2 Tear Break-Up Time

OD				Average	
OS				Average	

1-5 sec (1)	6-9 sec (2)	10 sec and more (3)
-------------	-------------	---------------------

2.3 Schirmer 2 Test

OD	
OS	

1-4 mm (1)	5-9 mm (2)	10 mm and more (3)
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IRB nr 00006240  
REC Reference nr 230408-011  
IORG0005187  
FWA00012784

26 July 2017

MR MONWABISI NONKULA  
DEPT. OF OPTOMETRY  
FACULTY OF HEALTH SCIENCES  
UFS

Dear Mr Monwabisi Nonkula

**HSREC 94/2017 (UFS-HSD2017/0972)**

**PRINCIPAL INVESTIGATOR: MR MONWABISI NONKULA**

**SUPERVISOR: PROF TA RASENGANE**

**PROJECT TITLE: THE PREVALENCE OF DRY EYE SYNDROME AMONG PATIENTS AT THE EYE CLINIC IN NELSON MANDELA ACADEMIC HOSPITAL**

**CONDITIONAL APPROVAL**

1. You are hereby kindly informed that, at the meeting held on 25 July 2017, the Health Sciences Research Ethics Committee (HSREC) reviewed the above research project. Research may not be conducted before the following condition(s) has/have been met and the HSREC grants final approval for the project:

*1.1. Application:*

*1.1.1. Need Supervisor Adamjee's signature on the Conflict of Interest-form. Please submit*

*1.2. Documents:*

*1.2.1. Need proof of registration for both supervisors.*

*1.2.2. Eastern Cape authority permission outstanding.*

**PLEASE NOTE:** Upon receipt of the updated documentation/other request(s) from the HSREC in RIMS, the project will be re-considered.

2. Kindly use the **HSREC NR** as reference in correspondence to HSREC Administration.
3. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite); Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines; Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

DR SM LE GRANGE  
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE





Eastern Cape Department of Health

Enquiries: Madoda Xokwe

TelNo: 040 608 0710

Date: 25 August 2017

Fax No: 043 642 1409

e-mail address: madoda.xokwe@ehealth.gov.za

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Dear Mr. M. Nonkula

**Re: The Prevalence of Dry Eye Syndrome among Patients at the Eye Clinic in Nelson Mandela Academic Hospital (EC\_201708\_002)**

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE



*Kamva eliqagambileyo!*