Comparison between the Effectiveness of Topical Cyclosporine 0.05% and Artificial Tears eye drops in Treatment of Moderate Dry Eye in Egypt

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List of Abbreviations

Abb.	Full term
AIDS	*Acquired Immune Deficiency Syndrome*
ATD	*Aquous Tear Deficiency Dry Eye*
CD4	*Cluster of Differentiation 4*
CD8	*Cluster of Differentiation 8*
CMC	*Carboxymethyl Cellulose*
CsA	*Cyclosporine A*
Da	*Dalton*
DED	*Dry Eye Disease*
DEWS	*Dry Eye Workshop*
EDE	*Evaporative Dry Eye*
FK	*Filamentry Keratitis*
GvHD	*Graft-Versus-Host Disease*
HPLC	*High-Performance Liquid Chromatography*
HSV	*Herpes Simplex Virus*
IDEEL	*Impact of Dry Eye on Everyday Life*
IFN	*Interferon*
IL	*Interlukin*
IOP	*Intraocular Pressure*
ITF	*International Task Force*
KCS	*Keratoconjunctivitis Sicca*
Kg	*Kilogram*
LASIK	*Laser-Assisted in Situ Keratomileusis*
LIPCOFs	*Lid-Parallel Conjunctival Folds*
mg	*Milligram*

List of Abbreviations (Cont...)

Abb.	Full term
MGD	*Meibomian Gland Dysfunction*
ml	*Milliliter*
MMP-9	*Matrix Metalloproteinase-9*
MUC	*Mucin*
NF-AT	*Nuclear Factor of Activated T*
ng	*Nanogram*
NSDE	*Non-Sjögren Syndrome Dry Eye*
OSDI	*Ocular Surface Disease Index*
SD	*Standard Deviation*
SS	*Sjögren's Syndrome*
SSDE	*Sjögren Syndrome Dry Eye*
TBUT	*Tear Breakup Time*
TGF	*Transforming Growth Factor*
TNF	*Tumor Necrosis Factor*
WHO	*World Health Organization*
MG	*Microgram*

Abstract

Comparing the two groups, the study found that there was no statistically significant difference found between the two studied groups regarding Schimer 1 score at baselineand at 1 month while there was statistically significant increase in Schirmer 1 score at 2 months and a highly statistically significant increase at 3 months in CsA group more than the preservative free artificial tears group.

The study also found that there was no statistically significant difference found between the two studied groups regarding TBUT at baseline, at 1 month and at 2 months while there was highly statistically significant increase in TBUT at 3 months in the CsA 0.05% group more than the perservative free artificial tears group.

This study compared the effectiveness of topical CsA 0.05% eye drops and preservative free artificial tears as regards Schirmer 1 score and TBUT and found a statistically significant increase in the CsA 0.05% group more than the preservative free artificial tears group as regards the Schirmer 1 score starting from the second month and also the TBUT starting from the third month.

Keywords: Tear Breakup Time, Transforming Growth Factor, Tumor Necrosis Factor, World Health Organization, Microgram

INTRODUCTION

Dry eye is a multifactorial disorder of the ocular surface involving the tear film and the reflex control of tear homeostasis. There are two major forms of dry eye: aqueous tear deficient dry eye (ATD) and evaporative dry eye (EDE) [(1)].

The ATD is subdivided into two categories: Sjogren syndrome tear deficiency and non-Sjogren tear deficiency depending upon whether there are associated systemic signs and symptoms [(2)].

The EDE can be caused by: Meibomian gland dysfunction (MGD) , lagophthalmos (facial nerve palsy, severe proptosis, defective blinking), contact lens wear or environmental factors [(3)].

The main symptoms include intermittent blurred vision and a dry gritty sensation in the eye. Additional symptoms can include burning or itching in the eyes, excessive tearing, pain and redness, and in some instances a stringy discharge [(4)].

Methods of diagnosis:

- *Schirmer test*
- *Tear film breakup time (TBUT)*
- *Other tests:* Tear film osmolarity, impression cytology, tear constituent, tear meniscometry [(3)].

Management:

The management of dry eye disease *(DED)* encompasses both pharmacologic and nonpharmacologic approaches, including avoidance of exacerbating factors, eyelid hygiene, tear supplementation, tear retention, tear stimulation, and anti-inflammatory agents.

Artificial tears are the mainstay of DED therapy but, although they improve symptoms and objective findings, there is no evidence that they can resolve the underlying inflammation in DED. *Topical corticosteroids* are effective anti-inflammatory agents, but are not recommended for long-term use because of their adverse-effect profiles. *Topical cyclosporine* currently the only pharmacologic treatment approved by the US Food and Drug Administration specifically for DED. It is disease-modifying rather than merely palliative. Treatment selection is guided primarily by DED severity. Recently published guidelines propose a severity classification based on clinical signs and symptoms, with treatment recommendations according o severity level [(4)].

AIM OF THE WORK

To compare between the effectiveness of topical Cyclosporine A (CsA) 0.05% and preservative free artificial tears eye drops in treatment of Moderate Dry Eye in Egypt.

Chapter 1
ANATOMY AND PHYSIOLOGY OF THE TEAR FILM

Tear film overview

The tear film overlays the ocular surface, which is comprised of the corneal and conjunctival epithelia. The tear film is essential for the health and protection of the ocular surface and for clear vision as the tear film is the first refractive surface of the eye [5].

Some authors provided a description of the tear film as a three-layered structure comprising an outer lipid (oil) layer, an aqueous (water) layer and an inner mucus layer over the corneal epithelium [6].

Others described the tear film as a complex mixture of secretions from multiple tissues and epithelia and consists of four layers (Fig. 1). The innermost layer is a glycocalyx that extends from the superficial layer of the ocular surface epithelia. The second is a mucous layer that covers the glycocalyx and may mix with the third aqueous layer. The outermost layer contains lipids. Similarly to mucous and aqueous layers, aqueous and lipid layers may mix [7].

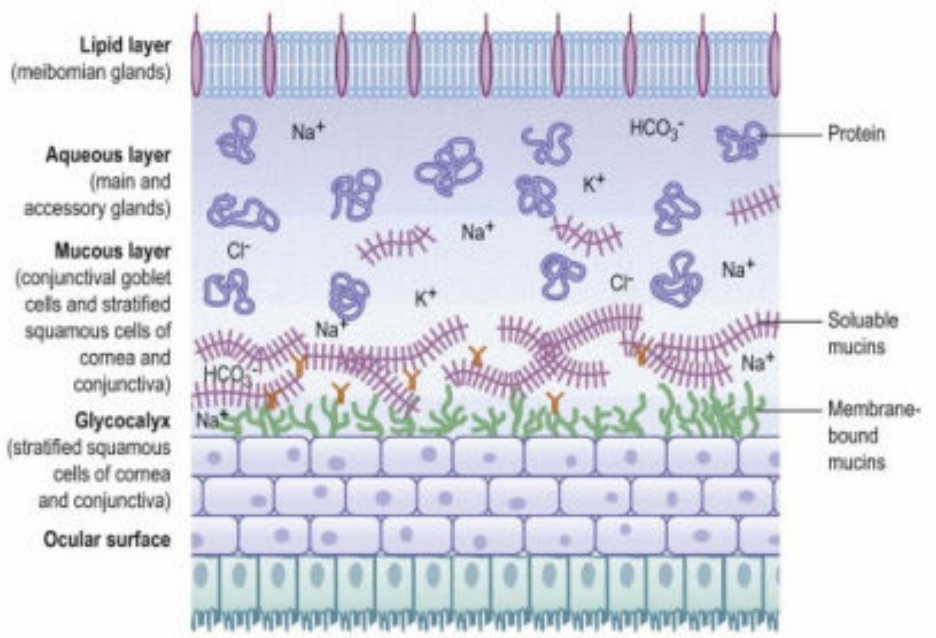

Fig. (1): Schematic of the tear film [7].

Components of the Film

A. Glycocalyx

- **Structure**

The glycocalyx is a network of polysaccharides that project from cellular surfaces. In corneal and conjunctival epithelia, the glycocalyx can be found on the apical portion of the microvilli that project from the apical plasma membrane of the superficial cell layer (Fig. 1).

Mucins are a critical component of the glycocalyx. Mucins consist of a protein core of amino acids linked by O-glycosylation to carbohydrate side chains of varying length and