Tears Again Liquid Gel Drops—An Assessment

a report by
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It has been estimated that there are almost five million American men and women over 50 years of age who experience dry-eye symptoms. This conservative estimate will correspondingly rise due to the anticipated growth of the 'baby boomer' age group, as well as the growth of refractive surgery. Numerous studies have reported not only a loss in quality of life but also a loss in work-related performance due to the visual detriment caused by dry-eye syndrome (DES), also known as dysfunctional tear syndrome (DTS).[1–3] Patients will present with myriad symptoms, ranging from foreign body sensation, burning, and tearing to impairment of vision.

Collaboration between researchers and clinicians has provided evidence-based recommendations for identifying and treating DES. For the most effective intervention to manage a dry-eye condition, it is imperative to accurately diagnose the underlying cause of DES. The report from the International Dry Eye Workshop (DEWS) group established the multifactorial pathophysiology of DES.[4] The treatment algorithm for DES and DTS is constructed in a stepwise fashion, with the initial treatment options including topical lubricants and allowing for environmental factors that may contribute to DES. This is well recognized and accepted by the International Task Force (ITF) Delphi Panel on Dry Eye.[5]

Tear supplementation is the universally prescribed initial method for treating DES. Topical lubricants have evolved to include not only demulcents but also emulsifiers, surfactants, and viscosity agents. The combination of these ingredients has resulted in expanded availability and use of numerous over-the-counter (OTC) products. It is not uncommon for patients to present for evaluation having attempted to self-medicate using OTC lubricants only to experience a progression of their symptoms.[6] Instituting a stepwise regimen for effective therapy is now recommended by the Delphi Panel. More importantly, establishing the stage of the DES is essential for customizing therapy. This article is limited to therapy for the initial stages of DES.

After appropriately addressing environmental factors that potentially contribute to DES, tear supplementation is essential. Although patients achieve some reduction in their symptoms, two problems prevail. First, the duration of action of most artificial tears is short, requiring frequent administration of drops.[7] Second, preservatives such as benzalkonium chloride have been identified as risk factors for continued compromise of the health of the ocular surface. Depending on the frequency of administration, preserved tears have been recognized to be toxic to the cornea and conjunctiva.[8] When a patient is in need of frequent dosing, preservative-free artificial tears (PFATs) are utilized. It is quite common for patients who use PFATs to report an increase in cost and environmental waste. In addition, the elderly patient with arthritis, for example, can have a difficult time administering from the individualized container due to the thin finger-like vial.

Traditionally, tear substitutes have contained solutions that have a low viscosity and, primarily, a liquid consistency. They come in a range of formulations, and typically contain polyvinyl alcohol, cellulose, methyl-cellulose, or hydroxypropyl methylcellulose. Newer agents have been developed to prolong the lubricating effect of tear substitutes without compromising visual acuity. They are available in a gel form, having more viscosity than artificial tears and more fluidity than petroleum-based ointments.[9] Compared with liquid-based lubricants, more viscous gel agents have reduced the frequency of dosing and increased patient satisfaction.[7]

Tears Again Liquid Gel (OCuSOFT) is an agent that has relieved the symptoms of dry-eye sufferers who require frequent dosing of tears but desire minimal disturbance in their vision. The gel contains 0.7% carboxymethylcellulose sodium as its active ingredient. The mid-viscosity gel provides adequate coating of the ocular surface with a reduction in its clearance compared with liquid lubricants. This additional viscosity helps prolong the lubricating effect of the gel and delays the need for re-administration. Petroleum-based ointments have a more prolonged clearance time; however, due to the added thickness in the tear film, they cause visual distortion and, therefore, are more suitable for bedtime dosing. Tears Again Liquid Gel has a transient blur in vision upon administration to which the patient can adapt and tolerate given the benefit of less frequent dosing.

Preservative toxicity is a risk factor for progression of DES; therefore, every effort should be made to eliminate preservatives from tear substitutes. Tears Again Liquid Gel is formulated with Dissipate, a preservative that hydrolyzes upon contact with the ocular surface. Once on the corneal surface, the gel increases the thickness of the tear film and disperses throughout the ocular surface. The heat from the globe and eyelids warms the gel into a more liquid-like state, minimizing the transient visual blur. The gel integrates with the tear film and undergoes a transformation from a cohesive mass of long-chain polymers to dispersive smaller chains of polymer. The mid-viscosity gel moisturizes the ocular tissue and has been shown to promote revitalization of denuded epithelial cells.[10] The effect can last for up to four to six hours following administration and, therefore, patients can maintain comfort and visual clarity for longer than with liquid tears.

Refractive surgery has been known to trigger DES, and this subset of patients need to be carefully managed throughout the post-operative course. Few reports have been published supporting the notion that carboxymethylcellulose is superior to hydroxypropyl methylcellulose in maintaining ocular surface health post-laser-assisted *in situ* keratomileusis (LASIK).[11]

These patients tend to be younger and desire tear substitutes that have a long duration of action and easy administration. Tears Again Liquid Gel is provided in a large bottle, rather than a tube, which allows for controlled and uniform dosing. Gels that are packaged in a tube are difficult to dose due to the uncontrolled expulsion of the product when the tube is pressed. This results in an excess amount of the product being delivered to the ocular surface that often spills out onto the peri-ocular surface and increases visual blur.

Given the unique system of preservation, longer duration of ocular hydration, and convenience of dispensing from a bottle, Tears Again Liquid Gel has filled a void that traditional tear substitutes cannot satisfy. Certainly, the continuum of DES requires ongoing stepwise graduation in therapy should the tear substitutes not curtail the symptoms. This may include the use of cyclosporine and tetracyclines. In addition, prolonging the residence time of the tear film can be achieved through punctal plugs. Regardless of the interventions, tear substitution remains the hallmark of treatment of DES. ■

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Editor's Recommendations—Healthcare Economics of Dry Eye

The Annual Cost of Dry Eye Syndrome in France, Germany, Italy, Spain, Sweden and the United Kingdom Among Patients Managed by Ophthalmologists

Clegg J, et al., Ophthalmic Epidemiol, *2006;13(4):263–74.*

This paper aimed to estimate the annual cost associated with the management of dry-eye patients by ophthalmologists in France, Germany, Italy, Spain, Sweden, and the UK from the perspective of the healthcare systems in the respective countries. Published epidemiological and healthcare resource use data attributable to dry-eye syndrome were supplemented with information obtained from interviewing ophthalmologists in the six countries. The estimated prevalence of dry-eye syndrome among patients reporting to ophthalmologists was less than 0.1% in all six countries.

The total annual healthcare cost of 1,000 dry-eye syndrome sufferers managed by ophthalmologists ranged from $0.27 million (95% confidence interval [CI] $0.20, $0.38 million) in France to $1.10 million (95% CI:US $0.70, $1.50 million) in the UK. A large proportion of dry-eye patients either self-treat or are managed by their general practitioner. Hence, our analysis reflects the prevalence and costs of those patients with severe enough symptoms to warrant treatment by an ophthalmologist. Given the limitations of the available economic evidence and our data sources, dry eye syndrome does not appear to impose a direct burden to healthcare expenditure in the countries investigated. However, given that many dry-eye sufferers self-treat with over-the-counter artificial tears and other medications—data that our study did not capture—the true societal costs of dry-eye syndrome borne by both patient and government are likely to be higher. ■

The Relative Burden of Dry Eye in Patients' Lives: Comparisons to a US Normative Sample

Mertzanis, et al., Invest Ophthalmol Vis Sci, *2005;46(1):46–50.*

This paper aimed to assess the relative burden of dry eye in daily life by comparing Short Form-36 (SF-36) responses from individuals with and without dry eye against US norms. Two hundred and ten people were assessed: 130 with non-Sjögren's keratoconjunctivitis sicca (non-SS KCS), 32 with Sjögren's syndrome (SS), and 48 control subjects. The study population data and published normative SF-36 data were compared. Dry eye severity was assessed by recruited severity (control, non-SS KCS, SS), patient self-report (none, very mild/mild, moderate, severe/extremely severe), and clinician-report (none, mild, moderate, severe). Age- and gender-matched norms were compared with all defined severity groups.

Compared with the norms, control subjects scored higher on all SF-36 scales. Effect size (ES) ranged from 0.15 to 0.52. Non-SS KCS patients had lower role-physical (ES -0.07), bodily pain (ES -0.08), and vitality (ES -0.11) scores, indicating more dry eye impact on those areas versus the norm. All SF-36 scale scores except mental health (ES = 0.12) were lower in the SS group than the adjusted norm (ES range -0.16 to -0.99). Regardless of severity classification, mild patients consistently had lower role-physical and bodily pain scores than the norm, suggesting an impact on daily roles (ES <0.2). Patients with moderately severe disease also experienced less vitality and poorer general health. The group with severe disease scored lower than the norm across all domains (ES range -0.14 to -0.91) except role-emotional (ES 0.13) and mental health (ES 0.23). These results indicate the negative impact of dry eye on everyday life, particularly in daily activities. ■