

DRY EYE REVOLUTIONS

THE SMARTPLUG AND RESTASIS™

THE EYE NEWSLETTER • VOLUME XXVII • SUMMER 2003

ROBERT M. SCHARF, M.D. • 972-596-3328

What is keratoconjunctivitis sicca (KCS)?

Keratoconjunctivitis sicca (KCS) - also known as Dry Eye Disease - is a condition caused by many factors that result in inflammation of the eye and the tear-producing glands (see Figures 1 and 2). Inflammation can decrease the eye's ability to produce normal tears that protect the surface of the eye and keep it moist and lubricated.

The symptoms of Dry Eye Disease include a dry, gritty feeling in the eyes that is often accompanied by burning, redness, and the sensation of a foreign object in the eye. If left untreated, Dry Eye Disease can damage the delicate tissues of the eye's surface and disrupt the cornea of the eye, which may lead to impaired vision, pain and constant irritation.

What are the causes of Dry Eye Disease?

Onset of Dry Eye Disease may be the result of hormonal changes associated with aging, menopause, and autoimmune diseases such as arthritis, lupus, and Sjogren's syndrome or medical

conditions such as diabetes or lacrimal gland dysfunction. The incidence of dry eye syndrome has increased substantially as a consequence of LASIK procedures and cosmetic eyelid surgery, such as blepharoplasty.

Also, keep in mind that environmental, occupational, and lifestyle factors, such as smoke, dry air, dust, the wearing of contact lenses for extended periods of time, and prolonged reading, can all exacerbate Dry Eye Disease.

How do I know if I have Dry Eye Disease?

We can check your eyes for the signs and symptoms of dry eye. Several quick and painless tests are available to measure visual clarity, tear production, ocular surface

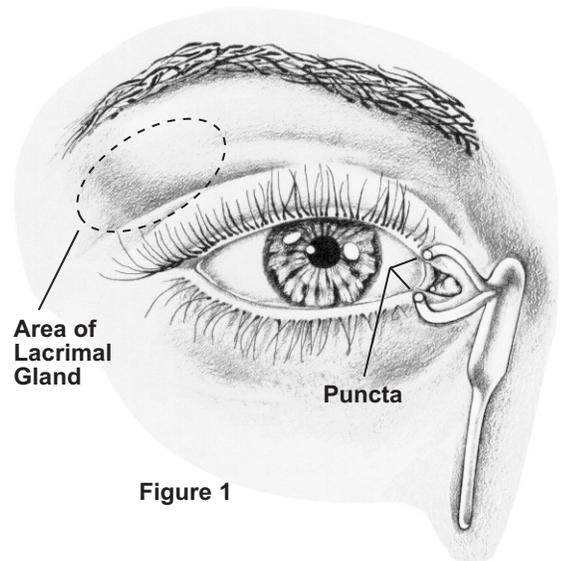


Figure 1

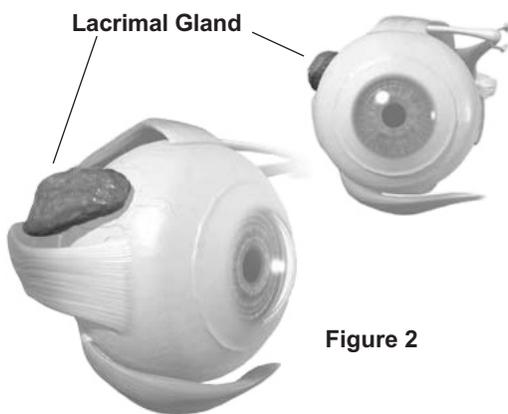


Figure 2

dryness, and damage to the cornea or conjunctiva. The conjunctiva is a membrane that lines the eyelids.

These tests will help determine the severity of your condition. If you use artificial tears 4 or more times a day and are still experiencing dry eye symptoms, you may be a candidate for one or both of two revolutionary treatments - **Restasis** (cyclosporine ophthalmic emulsion) 0.05% and the **SmartPlug**.

How is Dry Eye Disease treated?

Two of the most common treatments for the dry eye are using artificial tears and plugging the opening in the inner corner of the eyelid (punctum - Figure 1) that allows tears to drain away. The use of artificial tears is limited by patient compliance and the punctum plug has been plagued by spontaneous extrusion and direct irritation of the eye.

The traditional punctal plug (Figure 3) is made of silicone. The lower portion is pointed and guides the plug into the opening of the punctum (Figure 1). The top of the plug is flat, slightly elevated and works as an anchor so the plug won't fall beneath the surface of the punctum. If a plug doesn't stay in the punctum, you may then try a larger plug, which would fit more snugly.

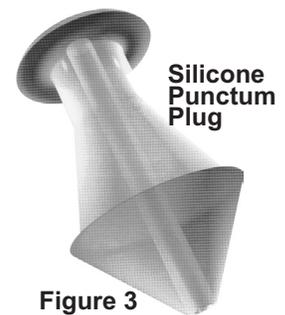


Figure 3

The first revolution: The SmartPlug

A “smart” material is defined as one that alters its physical properties in response to an outside stimulus. A particular polymer, a thermosensitive, hydrophobic acrylic developed by scientists at Medennium, Inc., changes from a rigid solid to a soft, cohesive gel when its temperature changes from room temperature to body temperature.

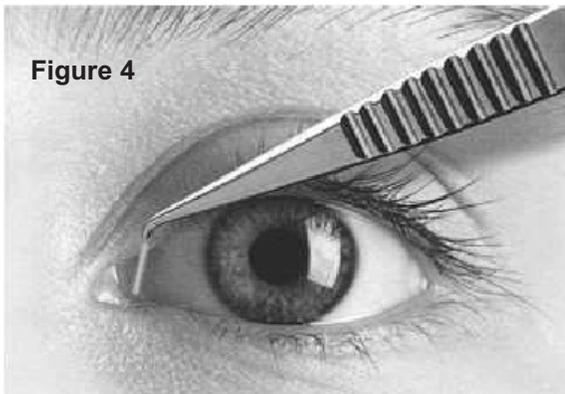


Figure 4

Outside the punctum, at room temperature, the SmartPlug is a rigid rod about 0.4 mm in diameter and 9 mm long. Specially designed grooved forceps (Figure 4) are used to insert two-thirds of the SmartPlug into the punctum, leaving one-third protruding (Figure 5).

As the material inside the punctum rapidly warms, it shortens and expands in diameter, turning from a rigid rod into a gel-like plug, conforming to the size and shape of the punctum. Meanwhile, the shortening length draws the remainder of the rod down into the punctum. When the transition is complete, the SmartPlug is totally contained inside the lower vertical punctum.

Removal, if necessary, is accomplished with irrigation. A syringe of saline solution, introduced using a cannula, causes the plug to become slippery and pushes it out through the lacrimal system. Because the plug is tiny and has a gel-like consistency, it usually leaves the body unnoticed.

SmartPlug vs. traditional silicone plug

The SmartPlug has numerous advantages over traditional silicone plugs:

- Because it adapts to the size of the individual punctum, we don't have to measure or stretch the punctum before insertion.
- We don't need to keep an inventory of multiple plug sizes in stock. One size fits all.
- Once inserted, the SmartPlug doesn't protrude from the punctum to potentially irritate your cornea.
- Unlike silicone plugs, the SmartPlug has an extremely high retention rate, and is nearly impossible to rub out.
- Eyes treated with SmartPlugs have less burning and stinging, foreign body sensation, tearing, discharge and light sensitivity symptoms.
- Forty to fifty per cent of silicone plugs were extruded in most studies.
- If a SmartPlug has to be removed, all patients were found to have a normal lacrimal system.



Figure 5

You can see the transformation of the rod in Figure 5 as it is placed into the punctum. **This is revolutionary.**

The second revolution: Restasis™

The FDA has approved Restasis (cyclosporine ophthalmic emulsion) 0.05% for the following indication: to increase tear production in patients whose tear production is suppressed due to ocular inflammation associated with chronic dry eye. Increased tear production was not apparent in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Reports about cyclosporine indicate that it acts by reducing inflammatory cells in the conjunctiva and lacrimal gland (Figure 2). It also acts by increasing the number of mucin-secreting goblet cells. These cells create a substance that helps prevent the evaporation of tears.

The medication is suspended in a substance much like castor oil. This substance, by itself, has some beneficial effect in chronic dry eyes.

Unlike artificial tears, Restasis is the only treatment proven to effectively treat a cause of Dry Eye Disease rather than only temporarily alleviate symptoms.

How does Restasis work? While the exact mechanism of action is unknown, Restasis is presumed to treat inflammation, which is an underlying cause of Dry Eye Disease. It has been shown to increase tear production. This leads to a significant

improvement in ocular surface integrity and resolves dry eye symptoms. This returns the surface of the eye to a more normal state while providing relief of the symptoms associated with Dry Eye Disease.

How effective is Restasis? Restasis was proven to increase tear production in patients with Dry Eye Disease. Patients who used Restasis for 6 months saw a significant improvement in their symptoms. Over time, at least three to six months, this returns the surface of the eye to a more normal state.

How safe is Restasis? Restasis has an excellent safety profile. In fact, in clinical studies, there was no detectable systemic drug absorption in the blood in up to 12 months of treatment.

Are there any side effects I should know about? Restasis has no significant side effects. The most common side effect reported by 17% of patients was ocular burning. Other side effects reported by 1% to 5% of patients included conjunctival redness, discharge, tearing, eye pain, foreign-body sensation, itching, stinging, and visual disturbance or blurring.

Is Restasis safe to use with other prescription and over-the-counter medications? There is no known interaction with systemic drugs. However, be sure to mention any other medications you are taking as well as eye care products you are using.

What is the dosing requirement for Restasis? Restasis is formulated as an eye drop and the recommended dosage is 1 drop in each eye every 12 hours.

How long will I have to use Restasis? Keep in mind that Restasis treatment is not a cure. There is presently no cure for Dry Eye Disease. However, you will receive benefits from Restasis for as long as you continue its use.

Will I still need to use artificial tears? Restasis can be used with artificial tear products. As with some patients, you may require the addition of lubricant artificial tears along with Restasis therapy, but usage will drop off as your eyes improve.

Will Restasis be available over the counter? No. You will need to be evaluated in our office to obtain a prescription for Restasis.

What is the cost of Restasis? The cost of a box of thirty-two vials is about \$90. Legal necessities requires a label of “use one drop in each eye and then dispose of the vial.” With refrigeration, one vial will last two days. That lowers the cost to about \$45 per month.

The **SmartPlug** and **Restasis** are truly revolutionary treatments that allow us to greatly expand the number of tools we have available to treat dry eyes. The SmartPlug blocks the drainage of needed tears from leaving the eye and Restasis actually allows the lacrimal gland to produce more of the necessary tears to keep the eye healthy.

Please call our office at **(972) 596-3328** if you have any questions or interest in either of these two revolutionary products.



Figure 6