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THE CHEDLY PUNCTAL OCCLUDER: A NEW TREATMENT MODALITY FOR DRY EYES

Chedly Bouzouaya and Peter Raus discuss the treatment options available to treat dry eye syndrome—a common condition treated by ophthalmologists

ABSTRACT

Objective
Dry eye syndrome is a common disorder, generally occurring in those over 40 years of age. The management of this condition is related to the severity of the symptoms. Permanent punctal occlusion is indicated for those patients experiencing severe dry eye syndrome.

Methods
With the use of a high-frequency, low-temperature surgical device and electrode specifically designed to cauterise and close the punctum, a large number of patients were treated and relieved from the symptoms of dry eye syndrome. The Chedly Puncial Occluder (CPO) electrode is designed to both dilate the punctum and be inserted in the lumen of the lacrimal duct to seal it.

Results
When there is an indication for a permanent punctal occlusion, the CPO, with the use of a high frequency device, seals the punctum permanently. There are no cases of reopening of the punctum and no lid notch as seen with the use of electrocautery or lasers.

Conclusions
Permanent punctal occlusion in severe dry eye syndrome using silicone plugs, argon laser, diode laser or cautery have drawbacks, are not cost-effective, and showed lower success rates in comparison with an easy-to-use and cost-effective punctal occludier electrode.

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KEYWORDS
dry eye syndrome, Chedly Punctal Occluder, radiofrequency, safety, cost-effective

DRY EYE SYNDROME IS ONE OF THE most common problems treated by ophthalmologists. It is estimated that over 10 million Americans suffer from dry eye syndrome (also known as keratoconjunctivitis sicca), and especially those older than 40 years of age. It is estimated that nearly 75% of people over age 65 years will experience dry eye syndrome[1]. Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, and tear film instability with potential damage to the ocular surface[1].

Dry eye is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface, and has been classified into two main categories by the US National Eye Institute[2]:

- Aqueous tear deficiency (ATD)
- Evaporative dry eye.

Tear-deficient dry eye can be further separated into Sjögren's syndrome-related dry eye, an autoimmune disorder affecting the lacrimal and salivary glands, and non-Sjögren's syndrome dry eye, which encompasses the range of other causes of tear deficiency.

Evaporative dry eye is caused by deficiency and/or alterations in lipid secretions as a result of meibomian gland dysfunction (MGD). Although differentiating patients according to the main causative factor is useful for diagnosis and therapy, clinical presentation is often a mixture of both pathogenic pathways[3,4].

Severe forms of dry eye syndrome associated with Sjögren's syndrome or skin diseases such as rosasea, can lead to vision-threatening complications, such as keratitis, corneal scarring, and vision disruption; therefore, early differential diagnosis is important. Most cases of dryness develop gradually over many years, with decreasing tear production and ocular surface damage as the final stages. Non-Sjögren's syndrome dry eye seems to deteriorate more slowly and less profoundly than dry eye associated with primary and secondary Sjögren's syndrome[5]. Owing to its intractable development, therapy of dry eye syndrome is often frustrating for patients and unrewarding for ophthalmologists. This makes the assessment of prognosis and patient counselling difficult. Therefore, it is paramount to find the most efficient therapeutic solutions to assist patients—even surgical solutions such as the salivary gland transplantation[6].

Diagnosing dry eye syndrome

The signs of dry eye can include conjunctival pleating, conjunctival vascular dilation, irregular corneal surface, increased debris in the tear film, and epithelial keratopathy. Rose bengal staining is an indicator of ▷

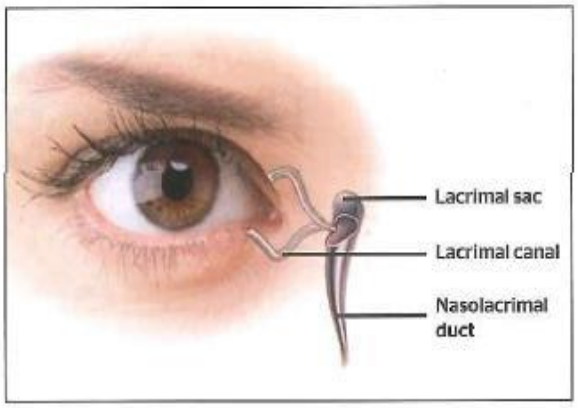

Figure 1 Anatomy of the lacrimal drainage system in frontal view

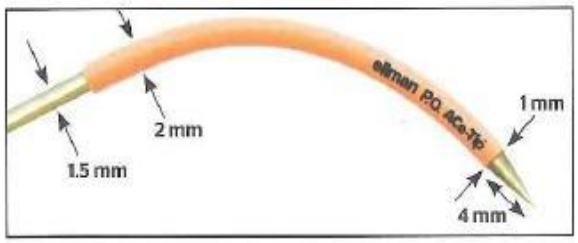

Figure 2 The Chedly Punctal Occluder

▷ early or mild cases of dry eye syndrome. It will stain the epithelial cells that are not protected by mucin tear coating. Other indicators include:

- The tear meniscus is less than 1 mm thick and is losing its convex shape
- The tear break-up time (BUT) with fluorescein stain is less than 10 seconds (the tear BUT is the time measured from a blink to the appearance of tear film defect)
- Schirmer's test shows unanaesthetised measures of basal and reflex tearing (the norm would be more than 15 mm at 5 minutes)
- Anaesthetised measures of basal tearing only (the norm is greater than 10 mm at 5 minutes).

The authors prefer to use anaesthetised methods to assess the patient's condition.

Figure 3 Chedly Punctal Occluder in the canaliculus lumen

Surgical anatomy of the lacrimal system

Tears in the marginal tear strip enter the lacrimal drainage system through the punctal opening of both eyelids (*Figure 1*). The puncta are located on the medial lid margin at the apex of small mounds of soft tissue. The papillae appear pale in contrast to the surrounding tissue as they contain more connective tissue and less vasculature. They are centred on the eyelid margin in line with the mucocutaneous junction. The upper papillae are located approximately 6 mm from the medial canthal angle and the lower papillae are 6.5 mm from the medial canthus. The punctal opening measures 0.2-0.3 mm in diameter and is surrounded by a ring of dense connective tissue that normally maintains a patent entrance. The aperture is round or oval in youth, but often collapses into a slit configuration with age. The puncta are normally directed somewhat posterior towards the globe and do not become visible unless the lid is slightly everted. For each punctum, a canaliculus passes perpendicular to the lid margin at a distance of 2 mm, where it dilates to form the ampulla, an irregular sac 2 mm in diameter. From the ampulla, the canaliculi turn horizontally and run medially, parallel to the lid margin for a distance of approximately 8 mm. In 90% of individuals[7], the two canaliculi join at an angle of approximately 25 degrees to form a common canaliculus 3-5 mm in length[8]. In the remaining 10%, the two canaliculi join the lacrimal sac independently.

The lacrimal sac passes inferiorly into the bony canal

> **"Thermal cautery has a higher success rate than laser, but also has severe drawbacks. The energy cannot be adjusted easily in order to provide the right amount."**

12 mm in length and 3-5 mm in width. Intranasally, the canal forms the lacrimal ridge, which runs in front of the middle turbinate and the medial wall of the ethmoid labyrinth.

Management strategies for severe dry eye syndrome

The management strategy for dry eye syndrome will often depend on the severity of symptoms. The mainstay is the use of tear substitutes, such as artificial tears. Pharmacologic stimulation of tear secretion, such as with topical cyclosporine, has been tried with only minimal success[9,10].

Permanent punctal occlusion is indicated for severe dry eye syndrome and minimal tear secretion. It is possible to achieve punctal occlusion using collagen or silicone plugs[9]. However, one of the drawbacks of punctal plugs is migration into the nasolacrimal system. This migration can cause canaliculus and lacrimal sac ▷

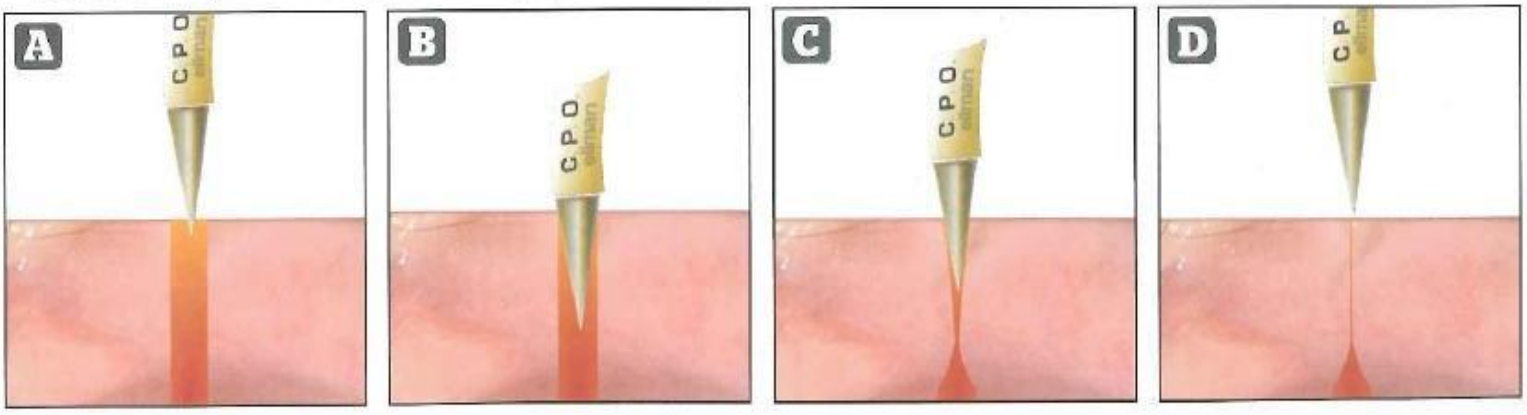

Figure 4 Four-step diagram of insertion and retrieval of CPO

Figure 5 Local anaesthesia on conjunctival side

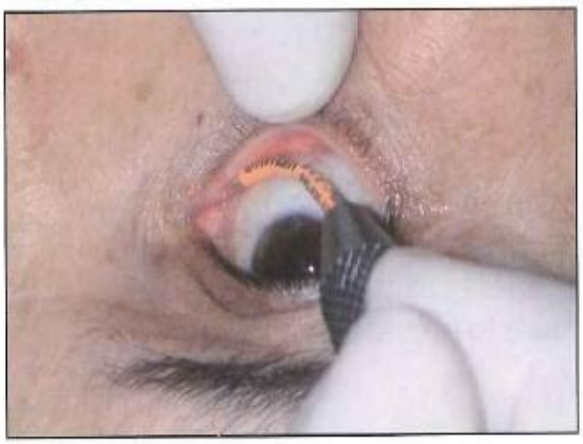

Figure 6 CPO inserted in the lumen of lower canaliculus

Figure 7 CPO in the lumen of the lower canaliculus

Figure 8 RF activated with CPO in the canaliculus lumen

▷ inflammation and infection (canaliculitis and dacryocystitis), caused by bacterial adherence to the silicone plug. They can also cause irritation, epiphora or extrusion[12, 13]. Prior to permanent punctal occlusion, collagen plugs can be used as diagnostic adjuncts; but the collagen may dissolve within days. Permanent punctal occlusion[14, 15, 16, 17] can be performed using the Argon laser, diode laser, electrocautery, or by using a high-frequency, low-temperature device[18].

In a study by Hutnic and Probst[19], comparing the use of Argon laser to electrocautery, the laser-treated patients reported a reduction in symptoms by 14% at 6 months, while symptoms in the electrocautery group were reduced by 64%. Therefore, it can be said that Argon laser punctal closure has a low success rate and is not cost-effective; thermal cautery has a higher reported success rate, but it is difficult to precisely control the depth of cauterisation and the exact temperature, often resulting in tissue burn, lid notch, and deformity.

> "Thermal cautery has a higher success rate than laser, but also has severe drawbacks. The energy cannot be adjusted easily in order to provide the right amount of energy. High energy will cause tissue destruction, a burn and a lid notch."

For the use of a diode laser, the canalicular area needs to be first stained with gentian violet, promoting absorption of the laser energy (532nm wavelength). The cornea needs to be protected with a metal corneal shield. It takes 2-3 weeks to have a complete closure with a slight opening of the punctum at 4-5 months[20]. With the use of the high-frequency radiosurgical device and the Chedly Punctal Occluder (CPO), the punctal closure was immediate, permanent and right into the lumen of the canaliculus (*Figures 2-4*). As a result, there is no tissue burn, no lid notch, and no additional precautions are needed, as is the case with lasers.

For the past 5 years the authors have been using the high-frequency, low-temperature Surgitron Dual radiofrequency (RF) device (Ellman International, Inc.)[21,22,23] with a higher success rate than that of laser[24] or thermal cautery. The RF device is more cost-effective than laser and has no side-effects in comparison with thermal cautery. Although thermocautery is not costly and has a reasonable success rate, the aforementioned drawbacks make the intervention with the RF device, together with the CPO, a much better treatment option. In addition to the low success rate, lasers can cost 20-30-times more than the price of a RF unit.

Thermal cautery has a higher success rate than laser, but also has severe drawbacks. The energy cannot be adjusted easily in order to provide the right amount of energy. High energy will cause tissue destruction, a burn and a lid notch.

In conjunction with the Surgitron, the authors use an electrode specifically designed to cauterise and close the punctum. The CPO, made from an alloy material, is designed to both dilate the punctum and be inserted in the lumen of the horizontal portion of the lacrimal ▷

Key points

- Using the Chedly Punctal Occluder and radiofrequency is a safe, quick and cost-effective treatment modality for dry eye syndrome
- The procedure can be carried out in an office environment
- Studies have shown that the procedure allows for a greater comfort among patients compared with traditional treatment methods

Figure 9 Postoperative result. Sealed lower punctum on the lower right lid

> When there is an indication for permanent punctal occlusion, RF with the use of the CPO was more efficient and more cost-effective than any of the other modalities.

▷ duct. The CPO is the cone-shaped Ellman RF electrode TNAEE287, patented and approved by the US Food and Drug Administration (FDA). With the CPO, a very effective treatment modality has been added to the treatment methods that are available for dry eye syndrome.

Technique

The eyelid is infiltrated with Xylocaine from the conjunctival side (*Figure 5*). The CPO – mounted on the Ellman handpiece – is inserted in the lumen of the canaliculus (*Figures 6* and *7*). The Surgitron is set on 'cut/coag' mode, the unit is activated for a few seconds (*Figure 8*), and then the CPO is pulled out. If the punctum is still visible, the tip of the CPO is applied on the lumen to seal it. At the end of the procedure, an antibiotic ointment is applied and used for a few days. No patches are necessary following treatment. This is a safe, fast, successful and cost-effective technique. One eye is treated at a time, addressing the lower punctum (*Figures 9* and *10*). If dry eye symptoms do not resolve, the upper punctum is occluded in the same manner. With the punctum completely sealed, the patient is relieved from the risk of irritation, inflammation, foreign body sensation, and light sensitivity for example.

Figure 10 Postoperative result. Sealed lower punctum on both sides

Discussion

When there is an indication for permanent punctal occlusion, RF with the use of the CPO was more efficient and more cost-effective than any of the other modalities. The RF unit operates at a high frequency of 4.0Mhz. The patented microprocessor circuit matches the wattage, waveform, alloy and patient's impedance to the optimum 4.0 Mhz. As the thicker diameter electrode produces slightly higher temperatures in tissue, the CPO has a thick cone-shaped design, eliminating the need to use a punctum dilator.

The CPO is 5mm long and is inserted nearly 4mm into the lumen. The punctum is sealed permanently. The authors have not experienced a reopening of the punctum or a lid notch as sometimes seen with cautery or lasers (*Figures 11* and *12*).

Conclusions

In the experience of the authors, surgical punctal occlusion using the Argon laser has a very low success rate in comparison with the diode laser. Both lasers were not cost-effective and showed a lower success rate compared with the Ellman RF unit.

When there is an indication for permanent punctal occlusion, RF with the CPO has been more efficient and cost-effective than other treatment modalities that

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Figure 11 One-year postoperative result

Figure 12 Two-year postoperative result

the authors have tried. It is also reusable. Laser punctal occlusion should be discouraged because it is less effective and more expensive than other methods of treatment.

This technique is again easy to use, with no great deal of time needed to learn the technique. It is an office procedure which takes only a few minutes to complete, and with no drawbacks or experience of reopening. All these advantages make the technique suitable to the growing numbers of dry eye patients following the widely used excimer laser refractive surgery.

▶ ***Declaration of interest*** *Dr. Bouzouaya has no direct financial or any other interest in the products mentioned in the article, nor is he a paid consultant for any companies mentioned.*

▶ ***Figures 1-12*** *© Chedly Bouzouaya*