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Dry Eye Disease and Intense Pulsed Light Technology

The search for the panacea in dry eye treatment proceeds in an unrelenting manner. This is because dry eye disease in some clinical settings is present in well over 50 per cent of the patient cohort.¹

WRITER Dr. Jim Kokkinakis

"Dry eye disease is a multifactorial and potentially very complex condition"

Dry eye disease (DED) is particularly frustrating to patient and practitioner, as it often interferes with the overall management and perceived satisfaction of the patient. There are significant symptoms, which are either not treated effectively or ignored by the eye care practitioner, usually because there is not enough time or it is perceived that the complaint is insignificant or untreatable. This is because in a typical eye consultation the practitioner must prescribe accurate optical correction, provide comfortable binocular vision and rule out blinding eye disease. The correction must complement the patient's individual lifestyle. Most importantly we need to rule out, treat or refer potentially blinding eye diseases such as macular degeneration and glaucoma. These common eye diseases have NO symptoms (as far as the patient

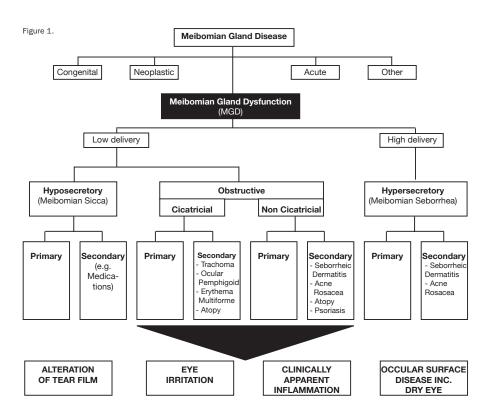
is concerned) until very late in the disease process. Dry eyes on the other hand can cause significant irritation to debilitating corneal pain.

The typical eye examination takes approximately 20 minutes. This is because our health system remunerates for this time frame. Proper dry eye management in this context just does not get a look in. Yet dry eyes are something the patient complains about, feels and perceives a reduction in their quality of life.²

Dry eye disease is a multifactorial and potentially very complex condition. To be managed properly it requires a thorough workup that could include:

- Patient questionnaires. There are quite a few available patient questionnaires. Some worth considering are ODSI score,³ SPEED questionnaire or the McMonnies questionnaire;
- Aqueous assessment using Schirmers, Phenol Red Thread, tear prism observation or a combination of these;
- Lipid assessment using invasive or noninvasive tear break up time, Tearscope and now the far more sophisticated LipiView Ocular Surface Interferometer;⁴
- Mucous assessment using conjunctival impression cytology (this is not readily done due to its complexity);

- Corneal and conjunctival assessment using biomicroscopy with fluorescein and lissamine green staining;
- meibomian gland assessment using infrared meibography, manual expression or new MGE (meibomian gland evaluator);
- Lid wiper assessment using biomicroscopy and lissamine green staining;
- Eye lid margin and eyelash assessment looking for anterior and posterior blepharitis, and especially telangiectatic vessels. This is often a sign of ocular rosacea;
- Blinking assessment looking for frequency, completeness and ruling out lagophthalmos especially during sleep;
- Medical and medication history. Autoimmune disease, previous eye surgery, oral medication such as roaccutane (even many years ago) or antihistamines etc. all must be accounted for;
- Work and home environment assessment. This needs careful consideration as digital device use in airconditioning is the most common denominator today;
- Past and current treatments can be major contributors to chronic dry eye disease, especially use of vasoconstrictors and eye drops containing preservatives;



• Contact lens use particularly around cleaning systems containing preservatives often requires re-education. This is a major issue that few pay attention to, yet is probably a major cause of contact lens dropout and often a stimulus into chronic dry eye disease.

When you look at the above possible workup for dry eye disease, is it any wonder that few eye care practitioners will involve themselves in this very frustrating condition? Twenty minutes is just not enough.

"McCulley classified blepharitis into six categories, which make sense from a treatment perspective"

Once the dry eye workup has been completed, the eye care practitioner is now in a position to develop some sort of treatment strategy. Again the options are extensive, complex and can be frustrating if the underlying contributing factors are not clearly discovered.

In cases that involve mainly aqueous deficiency we should consider:

- Preservative free aqueous replacement such as Thera Tears, Blink, BION Tears etc.
- Cyclosporine and 0.5 per cent Prednisolone phosphate can be used in tandem if there are signs of inflammation.
- A major consideration here is Sjogrens syndrome. This frustrating condition is sometimes best managed with immunosuppression and or scleral contact lenses.⁵

Currently meibomian gland dysfunction (MGD) is considered the most common cause of dry eye syndrome.⁶ MGD can be broken down into hyper-secretors and hypo-secretors. Both of these entities are common and equally frustrating to manage.

HYPER-SECRETING MEIBOMIAN GLANDS

This condition is associated with anterior blepharitis, ocular rosacea and inflamed eyelid margins that have significant telangiectatic vessels. Ocular irritation, which is perceived as gritty, scratchy eyes, is not really "dry" in the early stages of this disease process. The meibum that is secreted by the meibomian glands is complex and not well understood. It is made up of both polar and non-polar lipid phases, which can easily be disrupted7 and lead to evaporative and inflammatory issues. Combined with this in the presence of anterior blepharitis there seems to be an overabundance of lid bacteria such as staphylococcus epidermidis, etc. which also probably contribute toxins and waste products to the tear film.8

Blepharitis over the years has been studied in great detail. McCulley classified blepharitis into six categories, which make sense from a treatment perspective.⁹ Of particular concern is the comment "these entities be recognised as chronic diseases requiring control and ones for which there is no 'cure'."

The six categories are:

- Staphylococcal blepharitis
- · Seborrheic blepharitis
- Mixed seborrheic with staphylococcal
- Seborrheic with meibomian seborrhoea
- Seborrheic blepharitis with secondary meibomianitis
- Primary meibomianitis.

Keeping it under control is important as over time apart from the ongoing irritation there can also be changes in eyelid margin morphology leading to notching, pouting of the meibomian gland orifices, and eventual blockage of the glands. Of late demodex infestation is believed to be involved in many cases of blepharitis.¹⁰

Figure 2.



Figure 3.



Whether the demodex mite is the primary cause or is able to colonise in greater number due to a favourable environment in the presence of significant blepharitis is still not understood.

HYPO-SECRETING MEIBOMIAN GLANDS

This entity can be broken down into two groups - obstructive and real hypo-secreting.

Trying to avoid obstructive MGD is possibly a matter of early diagnosis of the underlying conditions, which might include; rosacea, dermatitis, psoriasis, trachoma, pemphigoid etc. Aggressive treatment of these conditions possibly might limit the obstruction of the meibomian gland orifices. Obstructive MGD implies a normal to near normal production of meibum which cannot reach the ocular surface due to keratinisation and therefore blockage of the meibomian gland orifices.

True hypo-secreting meibomian glands can be associated with menopause and medications such as roaccutane.

To date the definitive publication on meibomian gland dysfunction has been sponsored by the Tear Film and Ocular Surface Society (TFOS) in 2011. Anyone interested in dry eye disease should become familiar with this exhaustive piece of medical literature. A comprehensive classification tree summarises what is currently understood about MGD (Figure 1).

In 2007 the TFOS also sponsored the DEWS report, which outlined, Definition and Classification; Epidemiology; Diagnosis; Research; Clinical Trials, and Management and Therapy of Dry Eye. This year the society organised a report about contact lens discomfort. This report and the above two papers can be downloaded at: www.tearfilm.org.

TREATMENT OF MEIBOMIAN GLAND DYSFUNCTION

This is where things get interesting and frustrating. Because most cases of dry eye have some form of MGD contributing to patient discomfort (Lemp e al.),11 it becomes important to treat this multifactorial entity by whatever means we have.

For mild cases simply adding lipid based eye drops such as Systane Balance and Artelac could be enough to return the ocular surface to normality. Unfortunately many cases will progress beyond mild at which stage more aggressive treatments are required.

Some examples of more aggressive management include non-preserved topical steroids, oral tetracyclines such as doxycycline, LIPIFLOW (discussed in detail in *mivision* last year), manual expression, meibomian gland probing and a procedure called BlephEx (specifically for anterior blepharitis).

The latest addition to our armamentarium for the treatment of some forms of meibomian gland dysfunction is Intense Pulsed Light (IPL). This novel treatment recently received TGA approval in Australia, which implies evidence of efficacy and safety.

INTENSE PULSED LIGHT

Intense pulsed light (IPL) systems are high intensity light sources that emit polychromatic, non-coherent light over a broad spectrum. Cut out filters are used to limit the wavelengths to specific treatments.12

IPL was first developed for treating skin lesions in the 1990s.¹³ Wavelengths between 550-1200nm are used. Most of us are aware of the use of IPL for hair removal at beauty parlours.

The treatment of dry eye disease using IPL can be traced to Dr. Ronaldo Toyos (MD) in Memphis USA. He admits accidentally discovering this application of IPL in 2002 after adding an aesthetic clinic to his already established ophthalmology practice and using IPL to treat facial rosacea.14 IPL treatment for rosacea and telangiectatic vessels is well documented¹⁵ and because rosacea and ocular rosacea is known to be associated with significant dry eye type symptoms, it made sense to Dr. Toyos that this could be a viable treatment. Many of his rosacea patients came back not only looking better but also telling him that their eyes felt better.

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Dr. Toyos describes IPL for MGD as brief, powerful bursts of light at specific wavelengths that cause changes in blood vessels near the surface of the skin, raise skin temperature and eliminate problematic flora on the skin and eyes, all of which may have a beneficial effect on meibomian

Figure 4.



Figure 5.



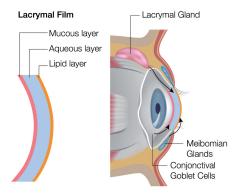


Figure 6.

gland dysfunction. There are currently around 40 eye clinics in the USA offering IPL to treat dry eye.

Some practitioners express the meibomian glands immediately following an IPL treatment. This practice is not necessary, but can help improve the results.

"Patients often experience a relief within minutes following the treatment"

IPL IN AUSTRALIA

IPL has been used for years in Australia and has TGA approval for permanent hair reduction, skin pigmentation and collagen stimulation. It is only recently that it has also received TGA registration for the treatment of dry eye.

France Medical – Australian distributor of E-Swin world leader in IPL technology for all purposes – this year received approval for their IPL device called E>Eye for meibomian gland dysfunction through a TGA process which took about 12 months.

The E-eye is supported by two clinical studies from France carried out on 150 patients. Their results indicate that, 45 per cent of patients originally classified as level two (Oxford classification) have improved by one or two levels. Eighty one per cent of patients from level one have improved by one level. These results were obtained two months (on average) after the third E-Eye treatment. Non-invasive, affordable with fast results, E-Eye is a revolution in lots of different aspects.

This is now being followed by another treatment study for our dry eye patients

in Australasia. Dr Jennifer Craig (University of Auckland, Department of Ophthalmology) and her student Amy Chen are currently conducting a prospective, randomised, investigator and participant-masked trial to evaluate the effect of intense pulsed light (IPL) on tear film and ocular surface characteristics and on subjective comfort.

The study was due to be completed by the end of March and the report available shortly after.

As this study is "double-masked", no results are available yet. Prior to this clinical study, a preliminary open label trial was conducted, which showed encouraging results.

The following clinical measurements and assessments were made during the course of this comprehensive study:

- Lipid grade (measured with the Tearscope from 0 to 5)

- NIBUT (non-invasive tear break-up time, measured with the Tearscope in seconds)

- Tear meniscus height (Digital imaging, measured in mm)

- Tear osmolarity (measured with the TearLab)

- Evaporation rate (Delphin vapometer)

An evaluation has also been done with three questionnaires (OSDI, SPEED and VAS comfort) and hyperemia has also been

assessed (BHVI / CCLRU grading scale).

ABOUT THE E-EYE

E-Eye is a device that generates a polychromatic pulsed light by producing perfectly calibrated and homogenously sequenced light pulses. The sculpted pulses are delivered under the shape of train pulses. The energy, spectrum and time period are precisely set to stimulate the meibomian glands in order for them to return to their normal function.

THE IPL PROTOCOL

Pre-treatment

To make sure that the safety and the efficacy of the treatment is maximised it is important to determine the skin phototype and the skin condition of the patient.

Treatment

After the first treatment patients have to wait 15 days before a second session. Then, each treatment has to be spaced by 30 days until the symptoms subside.

Always clean the skin before each treatment (no make-up, no foundation and no spray tans). The patient should always wear the opaque safety goggles during the treatment, while the E>Eye operator and every other person in the room should wear

IPL Technology in General

The Intense Pulsed Light (IPL) technology was initially developed to treat skin conditions in the 1990s. Over decades, its field of application has been extended to other treatments such as the well-known permanent hair removal, skin pigmentation or collagen stimulation in skin clinics.

An IPL device emits a polychromatic light, i.e. a multitude of wavelengths. This wavelength spectrum can be extended from 515 to 1,200nm allowing a great variety of treatment adapted to different needs and skins.

Each kind of treatment requires a specific intensity of light. A machine used for permanent hair reduction will not emit the same wavelength than one used for skin rejuvenation. There is a wide spectrum of potential combination of wavelength, pulse duration and frequency with the IPL.

IPL is different from laser. The flash is longer and less intense during IPL treatments, which allows treatments on most skin types with less risk of burning. For skin treatments, the heat emitted by the light will target a specific molecule, called chromophore, that needs to be destroyed or modified to obtain the expected results. (E.g: pigment in the skin for hair removal, water or fibroblast for collagen stimulation, pigment in the skin for pigmentation treatments, hemoglobin for vascular and acne treatment)

Each year, new treatments using IPL are discovered extending the field of application of the technology. Today skin clinics are not the only one to use this technology. Other professionals such as dermatologists are using it for acne or vascular treatments and now eye care professionals to treat dry eyes.

By distributing medical grade IPL devices made in France by the world leader E-Swin, France Medical, based in Brisbane, is providing professional machines that have been clinically tested and certified. The E-Eye machine distributed by France Medical is registered with the TGA (Australian certification).

E-Eye safety glasses. Always use E-Eye conductive gel for E>Eye treatments. A 5mm thickness should at least be applied in between the skin and the E>Eye head. The gel should be applied after fitting the opaque goggle. (To prevent the gel migrating beneath the opaque goggles and conducting light inside them).

"Luckily with the progress of technology and clinical understanding we are now in a position to improve our patient's quality of life"

It is very important to never direct the flash of the E>Eye to unprotected eyes as this can result in serious eye injury.¹⁶ At least four flashes inferior to each eyelid are recommended (Figure 2). Overlapping flashes are advisable to achieve full coverage.

Further Treatment Considerations

For more severe cases of dry eye, it is recommended to flash both the lower eyelid as well as the upper eyelid using metal corneal shields that are placed in the eye similar to a haptic contact lens. This would allow the operator to approach the eyelids and therefore the meibomian glands more effectively.

Post-Treatment Protocol

For the first 24 hours after treatment, the patient should adhere to the following guidelines:

- No excessive perfumed products or make-up on the treated area
- No excessive heat (e.g.: sauna or steam room)
- No touching, picking or scratching the area.

Aloe Vera can be used by the patient to soothe the area if any skin reaction occurs. Patients often experience a relief within minutes following the treatment.

CONTRAINDICATIONS

There are patient categories considered unsuitable for IPL treatment, such as those:

• taking photosensitive drugs (e.g. doxycycline)

- taking anti-coagulant medication
- taking the acne drug Roaccutane,
- fitted with a pacemaker
- with cancer, heart disease, kidney disease, diabetes, epilepsy, HIV/AIDS, haemophilia or Lupus disease
- with keloid scarring, vitiligo or xeroderma on treated area
- · suffering from porphyria
- · who have had a gold injection
- · with spray tans on treated area
- · who are pregnant

SKIN PHOTOTYPES

This is a very important topic in the context of IPL treatment. There are six categories that skin types can be classified. The most common way of skin phototype classification is by using the Fitzpatrick Skin Type Chart.¹⁹ The only skin type that is contraindicated is the very dark skin type VI. Skin types I through to V are suitable for meibomian gland dysfunction treatment using the E>Eye IPL technology. Counterintuitively the lighter the skin colour, the more suitable for IPL treatment. This is because IPL stimulates not only blood cells but also melanin. The darker the skin tone, the more melanin.

CONCLUSION

In summary, chronic dry eye disease management can be a very frustrating clinical entity that is ignored by eye care practitioners due to its complex nature.

Luckily with the progress of technology and clinical understanding we are now in a position to improve our patient's quality of life like never before.

Intense Pulsed Light for meibomian gland dysfunction has finally become available in Australasia with the TGA approval of the E>Eye by France Medical. It will add another tool to our extensive armamentarium of dry eye treatments, which our patients are eagerly looking for.

Dr. Jim Kokkinakis is a therapeutically qualified optometrist, who specialises in Keratoconus and complex contact lens fittings, Dry Eye disease and computer vision syndrome. He is a member of a number of Australian Optometrical Associations, a Fellow of the American Academy of Optometry and was elected one of 40 full members of The International Society of Contact Lens Specialist. He is an international speaker and part-time Senior Lecturer at the University of NSW Optometry School, lecturing to students at both an undergraduate and post-graduate levels.

To earn your points from this article, answer the assessment available at www.mivision.com.au /intense-pulsed-light-technology



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