E-Eye

Dry-eye syndrome treatment using intense pulsed light technology

MADE IN FRANCE

CE MEDICAL

IRPL technology

ESW Vision

"Meibomian gland dysfunction has been identified to be the main cause of dry eye syndrome around the world"

These are first report about Meibomian Gland Dysfunction (MGD) from the ARVO (the association for Research in Vision and Ophthalmology) conference organized in 2010. The gathering of more than 50 members included the most recognised ophthalmology and optometry experts around the globe.

Since then, an efficient treatment of the Meibomian Gland Dysfunction, radically different from existing treatments, has been developed and clinically tested with exceptional results.

The pathology

The dry-eye syndrome is a common pathology affecting - depending on the areas - between 5 to 15% of the population with symptoms increasing with age. Conditions of a modern lifestyle (including working on computer screens, driving cars, artificial lights, air pollution, wearing eye contact lenses…) make dry-eye syndrome a more and more frequent nuisance.

Generally speaking, dry-eye conditions are a result of a lacrymal layer issue, either caused by insufficient tears or an excessive evaporation.

It is recognised that a large majority of cases are caused by the evaporation form, mainly due to an insufficiency of the external lipid layer of the lacrymal film secreted by the Meibomian glands.

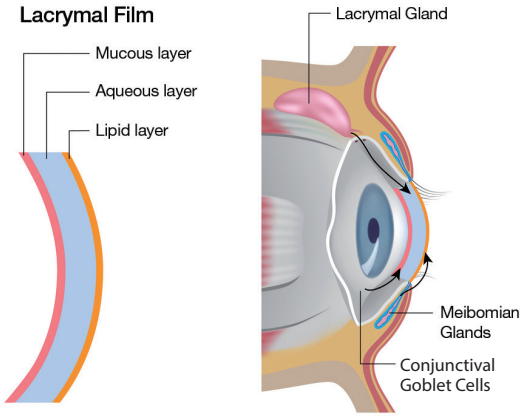
There are 80 meibomian cells located on the upper and lower eyelids.

These cells produce a fat phase, avoiding tear evaporation, adapting the tears to the irrigularities of the eye surface and a perfectly convex dioptre.

Lipids are made of polarised fat acids. Their fluidity is ensured by the body temperature. They are non-polarised on the surface, giving the stability of the lacrymal fluid and allowing the lubrification of the palpebral conjonctival plan. The contraction of the Riolan muscle allows the lacrymal film to spread out.

The lacrymal film, necessary to the eye function, is made of 3 layers:

- The mucous layer, in contact with the ocular globe, secreted by the conjonctival mucous cells.
- The aqueous layer, secreted by lacrymal glands.
- The lidip layer, secreted by meibomian glands.



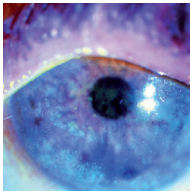
Meibomian Gland Dysfunction (MGD)

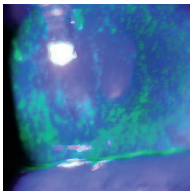
The affection of the lipid phase produced by these cells – the meibum – will lead to an excessive evaporation of tears, an unstable lacrymal film and an inflammatory reaction of the conjonctiva.

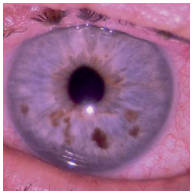
The result is an increase in vision disorders during long periods of short-distance tasks (work on computer screens...) with a feeling of "eye burning" stopping any visual work.

If this process accelerates, the discomfort becomes permanent creating a paradoxal tear increase; wearing contact lenses becomes impossible.

Anatomical modifications can occur with an atrophy of the meibomian glands orifices with episodical infections, sties, conjunctival secondary infections, chalazion and in more serious cases, apparition of micro-ulcerations of the epithelium cornea.







Current Treatments

Everyday dysfunctional signs of patients generate multiple therapeutic treatments. Treatments currently available are mainly substitutions and are often insufficient to overcome the discomfort felt by patients.

E-Swin innovates...

E-Eye treatment:
A new pulsed light technology servicing the ophthalmology industry - **IRPL**®

(Intense Regulated Pulsed Light).

E-Eye is a device that generates a new type of polychromatic pulsed light by producing perfectly calibrated and homogenously sequenced light pulses. The sculpted pulses are delivered under the shape of regulated 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.

- Medical CE (European Standard) certified in 2013.
- TGA registration approved in 2013.
- Certificate of compliance for cBVus in 2016.

CE MEDICAL

Australia Goverment
Department of Health and Ageing
Therapeutic Goods Administration

c US

Simple & fast

- Session treatment only takes a few minutes.
- Patients are comfortably seated on a treatment chair, preferably tilted. The metal eyewear protection are adjusted on the patients eyes. Then optical gel is applied on the cheekbone and the temporal areas.
- A series of 5 flashes are applied under one eye, starting from the inner canthus uo to the temporal area, using the nominal power.
- The same process is then repeated under the other eye.

Instant improvements

- The stimulation leads to the meibomian glands returning to their normal function in a very short time (a couple hours) following the treatment.
- The full success of treatment depends on the compliance with a specific protocol. This protocol consists of 3 sessions as follows:

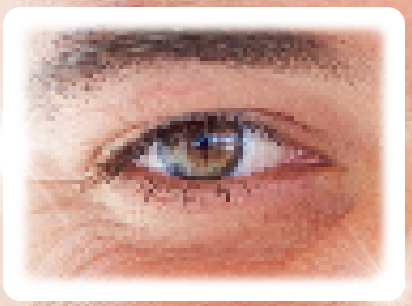
  - Day 0
  - Day 15
  - Day 45
  - Day 75 (optional)

E-Eye
treatment results

The efficiency is nearly constant on all forms of Meibomian Gland Dysfunctions.

On the other hand, it does not improve pathologies linked to aqueous or mucous phase or if there is a secondary infection that would need to be treated first.

Quantified efficiency



Clinical studies have been conducted in France, New Zealand and China. These studies have shown:

- A considerable improvement in the symptoms perceived by patients with a 90% satisfaction rate on the first 2 treatments. This improvement has been acknowledged from the patient's opinion about the discomfort levels before and after the treatment and the improvement of the fixation time while reading or watching television. This improvement is clearly felt from the initial session for the first couple of days and is increasing in time after the second and following treatments.

- A correlation between this perception and clinical measurement executed. 45% of patients originally classified as level 2 (Oxford classification) have, after instillation of fluoresceine, been improved by one or two levels. 81% of patients from level 1 have improved by 1 level.

We have obtained these remarkable results 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.

Patients suffering from a more severe pathology, classified on the 3rd and 4th level, will need to treat both inferior and superior eyelids. The ocular globe would need to be protected by a haptic contact lens. Here as well, improvement by one to two levels is expected.

E-Eye

IRPL® (Intense Regulated Pulsed Light) technology servicing the ophthalmology industy.

Simplicity

E-Eye is dedicated to the treatment of dry-eye using an intuitive and simple software. This program is controlled from a LCD touch screen.

Security

1. Medical CE Certification (European Standard) TGA registration approved in 2013.
2. Warranty (2 years).
3. New IRPL® technology (Intense Regulated Pulsed Light).
4. Made in France.

100% developed and made in France by E-Swin, the world largest medical intense pulsed light manufacturer certified ISO 9001 and ISO 13485.

Easy to use, fast and tailor-made for ophthalmologists.

- Start in a few seconds.
- No pre-heating required.
- Compact - It will fit in any practice space.

Technical specifications

Technology	IRPL® (Intense Regulated Pulsed Light)
Dimensions (Length x Width x Height)	345 x 320 x 440 mm
Weight	11,5 kg
Dimensions with packaging (Length x Width x Height)	740 x 460 x 610 mm
Weight with packaging	17,5 kg
Noise level	55 dBA
Power consumption	540 VA
Warranty	2 years

E-Eye: a French innovation

www.esw-vision.com

E-EYE, designed and manufactured by E-Swin (France), is a class IIb regulated health care device carrying the CE mark (issued by the organization CE 0197). This device is used for the treatment of meibomian blepharitis. Conditions for use described in these instructions must be observed.

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