Dry Eye Management Symposia
Post-Market
Clinical Follow-up Study
of Dry Eye Analyses

Validation of the Interpretation Grading Scale for
Examination of Dry Eye Disease

The study outcome was presented at
1st ESW Vision Dry Eye Symposia
ESCRS 2023 Vienna

10th September 2023

Participating Sites: 7 Centers / 1706 Patients / 6 Countries / 3 Continents / Mixed Demographics

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PURPOSE:

The purpose of this study was to evaluate the effectiveness of using the Interpretation Grading Scale for examination of Dry Eye Syndrome in outcomes of Post-Marketing Clinical Follow-up Study of Dry Eye Analyses and the use of E-Eye IRPL® to treat periorbital area of patients with MGD and/or DED. Evaluating and improving both subjective (Eye Fitness Questionnaire) and objective (tearcheck®) findings.

PATIENT ENROLLMENT PROTOCOL:

2021 Enrollment of Patients / 2021-2022 DED Measurement tearcheck® and (4) Treatment Sessions Performed with the IRPL® / 2023 Analyses Presentation – 1706 Patients Assessed and 818 Patients Completed Treatment Sessions.

INCLUSION PATIENT CRITERIA:

The study included individuals with Lacrimal and Meibomian Gland Dysfunction (DED and MGD) eligible for IRPL therapy.
Individuals with documented lacrimal dysfunction or different levels of DED in its various forms were enrolled. Patients with at least mild MGD (eyelid margin or mucocutaneous junction abnormalities, MG orifice capping, and/or decreased expressed meibum quality, [15] tearcheck® EFT (Eye Fitness Test)/Dry Eye Questionnaire score > 13, Age: 18 years or older.

EXCLUSION CRITERIA:

Previous ocular surgery, pregnancy or breastfeeding, presence of corneal degenerations, and other ocular diseases that could influence the ocular examination. Individuals with major comorbidities, such as diabetes and collagen-related diseases, were also excluded. The diagnosis of DED/MGD was based on an anamnesis comprehensive eye examination and other ocular assessments/measurements. Injured, burnt, or infected skin, sunbathed skin that has healed in the last month, had high UV radiation in the past ten days, Self-tanning products (creams, dietary supplements) in the past two weeks, Epilepsy, Porphyria Cutanea Tarda Skin Disease)

Relative contraindications: History of allergic reaction to sunlight, abnormal skin lesions, use of photosensitizing medication, pacemaker, or cardiac defibrillator.

Analysis tearcheck®

Examination of Dry Eye syndrome of patients 1600 (N=770) Participants following baseline (BL) evaluation. In addition to dry eye examination, on tearcheck®: NIBUT/TFSE®, Eye Redness, Meibography, Abortive Blinking, Tear Meniscus, OSIE®, Demodex, and Schirmer's test. Lissamine Green Staining of the bulbar and palpebral conjunctivae was carefully measured in both eyes. The subjects answered the Eye Fitness Test (EFT/Dry Eye Questionnaire) with the findings accessed at baseline on day 1 (Pre) and the latest. For optimal results, we require a minimum of 180 days from Pre to Post, along with the necessary results from other tests. This timeframe is crucial to ensure accuracy and effectiveness in achieving your desired outcome.

Treatment E-Eye/IRPL®
Intense Regulated Pulse Light

- The IRPL® (E-Eye by E-SWIN, Houdan, France) treatment was performed within a short protocol over a period of 3 to 4 treatment sessions: Days 1, 15, 45, and Day 75 (optional).The treatment only takes a few minutes per session.
- Patient's eyes are protected with opaque goggles, and treatment gel is applied around the periorbital area.
- A series of 5 flashes is applied around each eye: four flashes in the lower zone – starting at the inner canthus and one flash in the temporal zone. The same treatment application is applied to the other eye.
- Energy settings ranged from 9 to 13 J/cm, based on the Patient's Fitzpatrick skin-type.

METHODS:

The technology and principle of Meibomian gland stimulation in IRPL® have been explained. Contraindications have been discussed with the patient with a compatibility checklist. The requirement to avoid any make-up around the eyes or other cosmetic products on the skin on the face have been explained on the day of treatment. It has been explained that the skin can be some-what red after treatment and that sunscreen is necessary to protect treated skin areas from sunlight. It has been explained that the treated skin should not be further treated with other therapies during the entire period of treatment with IRPL®. **The patient has given informed consent to proceed with the IRPL® treatment.**

RESULTS – KEY MEASUREMENTS
STATISTICAL ANALYSIS

The data collected was organized in an Excel 4® spreadsheet (Microsoft Corporation, Redmond, WA, USA), and after a critical analysis of the observations, a total of 1706 patients (N=1706) were used in this study. Quantitative variables are listed in tables with statistical measurements (among other things, percentages in the given scale), and the qualitative average is listed in the table. A paired test was used to compare TCHEK, TO1 & TO2, and EFT before and after treatment: comparisons and calculations and p-values min. <0.08 % indicated statistical significance of measured values before treatment and after treatment.

RESULTS:

A total of **1706 patients** were measured preoperatively, and 818 were evaluated after the IRPL treatment, of whom 1342 were females (82%), and 293 were **males 18 (%)**. The mean ± standard deviation age was 52 ± 1 years (range: 18-85 years; median: 51 years).

Conclusions:

- 55% of patients discontinued the use of eye drops after the E-Eye Treatment
- 80% Patient Satisfaction
- High efficacy, easy, and smart system for evaluation of the DED by Grading Scale
  - 1706 measured / 818 patients treated in a period of 1 year / 7 centers
- The percentage of Symptomatic patients increased to 47%
  - DED – second most common eye disease in the world
- Comparison between other tests showed similarity in the improvement of the patients.
  - Schirmer test 75%
  - TFSE test 77% and NIBUT test 75%
  - EFT (Eye Fitness Test) 73%
- Ocular surface inflammation improved for 90% of patients.
- The risk of inflammation decreased for 95% of patients.
- 100% improvement in eradicating Demodex and increased lachrymal gland tear production.
- Increased patient satisfaction and treatment efficacy based on Asymptomatic and Symptomatic selection criteria. Asymptomatic Grade 1 / Symptomatic Grades 2,3 and 4
  - Improved practice workflow and efficiency for high-volume clinics with the tearcheck® assessments to E-Eye/IRPL® treatments
  - Educated staff decreased patient chair time.
- 0 Adverse Events reported in the data collection.

Conclusions Summary:

- Comparison between other tests showed similarity in the improvement of the patients.
  - Schirmer test 75%
  - TFSE test 77% and NIBUT test 75%
  - EFT (Eye Fitness Test) 73%
- Increased patient satisfaction and treatment efficacy based on Asymptomatic and Symptomatic selection criteria. Asymptomatic Grade 1 / Symptomatic Grades 2,3 and 4
  - Improved practice workflow and efficiency for high-volume clinics with the tearcheck® assessments to E-Eye/IRPL® treatments
  - Educated staff decreased patient chair time.
- Intense Regulated Pulse Light technology is recognized as a solution for dry eye treatment.
- More than 2500 sessions of treatments done with the E-Eye® (IRPL - ESW vision) technologies in the data collection
- 0 Adverse Events reported.
- 96% of patients recommend the IRPL® treatment.
- 80% Confirmed improvement of symptoms.
- 55% Stopped using eye drops after the treatment.

This Document was compiled by:

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