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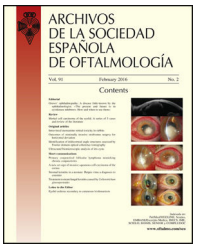

Original article

Effect of pulsed laser light in patients with dry eye syndrome☆,☆☆

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ABSTRACT

Objectives: The objective of this study was to determine the clinical benefits of pulsed light therapy for the treatment of Dry Eye Syndrome (DES) due to the decrease in aqueous tear production (aqueous deficient DES) and/or excessive tear evaporation (evaporative DES) due to Meibomian Gland Dysfunction (MGD).

Methods: A study was conducted on 72 eyes corresponding to 36 patients with DES. Out of these 72 eyes, 60 underwent refractive surgery (48 with femtosecond laser, 6 were operated with a mechanical microkeratome, and 6 with refractive photo-keratectomy[RPK], 6 treated with phacoemulsification, and 6 with no previous surgical treatment. Pulsed laser light (Intense Pulsed Light Regulated [IRPL®]) was use to stimulate the secretion of the Meibomian glands during 4 sessions, one every 15 days.

Results: Patients with aqueous deficient DES did not show any improvement. Eyes with no previous surgery and those treated with phacoemulsification and PRK had a favorable outcome. On the other hand, less conclusive results were observed in the eyes treated with excimer laser.

Conclusions: This treatment could be very helpful to treat evaporative DES produced by MGD. On the other hand, it is not helpful for those cases related to an isolated damage in the aqueous phase, or the mucin phase.

Efecto del láser de luz pulsada en pacientes con síndrome de ojo seco

Palabras clave:
Síndrome de ojo seco
Disfunción de las glándulas de Meibomio

RESUMEN

Objetivos: El objetivo de este estudio fue determinar los beneficios clínicos de la terapia de luz pulsada para el tratamiento del síndrome de ojo seco (SOS) consecuencia de la disminución de la producción de lágrima acuosa (SOS acuodeficiente) y/o de la evaporación lagrimal excesiva (SOS evaporativo) por la disfunción de las glándulas de Meibomio (DGM).

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Láser de luz pulsada
Tiempo de rotura de la película lagrimal
Meniscometría

Métodos: Estudiados 72 ojos correspondientes a 36 pacientes con SOS, de los cuales 60 ojos fueron intervenidos de cirugía refractiva (48 con láser de femtosegundo, 6 con microqueratomo mecánico y 6 con fotoqueratectomía refractiva [PRK]), 6 intervenidos con facoemulsificación y 6 sin intervención quirúrgica previa. Utilizamos un láser de luz pulsada (Intense Regulated Pulsed Light [IRPL®], E-Swin, Adainville, Francia) para estimular la secreción de las glándulas de Meibomio, realizando 4 sesiones, una cada 15 días.
Resultados: Los pacientes con SOS acuodeficiente no presentan mejoría alguna. Tanto los ojos no intervenidos quirúrgicamente, como los operados con facoemulsificación y los tratados con PRK, evolucionaron muy favorablemente. Por otro lado, observamos unos resultados menos concluyentes en los ojos tratados con láser excimer.
Conclusiones: El láser de luz pulsada puede ser de gran ayuda como tratamiento para el SOS evaporativo producido por la DGM, al contrario no lo es en las formas relacionadas con un daño aislado de la fase acuosa, o de la fase mucínica.

Introduction

The dry eye syndrome (DES) is a common pathology affecting between 10 and 20% of the population,[1–3] the frequency of which is correlated with age.

The importance of functional signs and daily discomfort of patients have given rise to a range of therapeutic actions. However, currently available treatments are mostly substitutions and frequently insufficient to diminish patients discomfort.

The Intense Regulated Pulsed Light (IRPL®) treatment (E-Swin, Adainville, France) is a pulsed polychromatic light generator that produces perfectly regulated and homogeneous light pulses. Sculpted impulses are released in the form of pulse sequences having a distance, energy and spectrum precisely determined to stimulate Meibomium glands to recover their normal function.[4–6] This article describes the personal experience of the authors, in view of the small amount of publications in current literature about the effectiveness of pulsed light laser for treating Meibomium gland dysfunction (MGD).

Subjects, material and methods

The present study was carried out in accordance with the guidelines of the Helsinki declaration and informed consent for IRPL® treatment given by each patient.

Eligibility for treatment: eligible candidates for IRPL® should have skin phototype I, II and III, as darker skins (phototype IV) exhibited a relative propensity to side effects such as pigmentation loss.[7] All patients with previous ocular or systemic pathology, subjects with a history of allergy to sunlight exposure, pregnant females, patients with skin exposed to the sun or UVA light during the month before treatment date, as well as having skin lesions of unusual appearance were excluded from treatment with IRPL®.

Treatment procedure: the intensity of the IRPL® treatment ranges from low power of 8 J/cm^2, which sequentially increases to a high power of 20 J/cm^2. Power must be regulated with each subsequent session according to the impression of the patients, the severity of the disease and the obtained results.[4,6]

In the present study, as the patients belonged to phototypes II and III of the Fitzpatrick scale, the intensity applied in the first session was 11.4 J/cm^2, while in the second session it was increased to 12.2 J/cm^2 and in the third and fourth session it was raised to 13.0 J/cm^2.

When the physician has selected the adequate match of power and type of skin, the patient is ready for treatment as described below: (1) the skin of all patients was inspected to make sure it was clean and dry, free of cosmetics; (2) eventual moles, dark spots or freckles were covered with self-adhesive patches; (3) ocular protection was placed on the patient and verified for adequate placement; (4) gel was generously applied (at least 1 cm thick), taking care to prevent gel from making contact with the eyes; (5) protective goggles were put on the operator; (6) 5 flashes were made in the left middle face, starting from internal canthus of the eye and finishing in the temporal area; (7) the operation was repeated in the right middle face, and (8) the gel was withdrawn and the skin cleansed.

The efficacy of said treatment depends on the application of a specific protocol. For the present study, the treatment was carried out in 4 sessions with a time interval of 15 days between each, a total of 45 days for all patients (day 0/day 15/day 30/day 45). It is convenient to consider additional sessions if necessary to maintain the obtained clinic benefits. These additional sessions must be carried out 6 months after the treatment and for this reason there are no sufficient data to verify whether they are necessary or not.

Procedure of the study: overall, the study comprised 72 eyes of 36 patients of 43 ± 25 years of age and predominantly female (58.33%). Of these, 60 eyes underwent refractive surgery (48 with femtosecond laser [FS], 6 with mechanical microkeratome [MM] and 6 with refractive photokeratectomy [PRK]), 6 with phacoemulsification and 6 without previous surgeries.

The patients who had undergone surgery exhibited a residual refraction of $+0.50 \pm 0.50$ sphere and -0.75 ± 0.25 cylinder, with visual acuity (VA) of 0.8 ± 0.2 measured with the Snellen test, while patients who had not undergone surgery exhibited

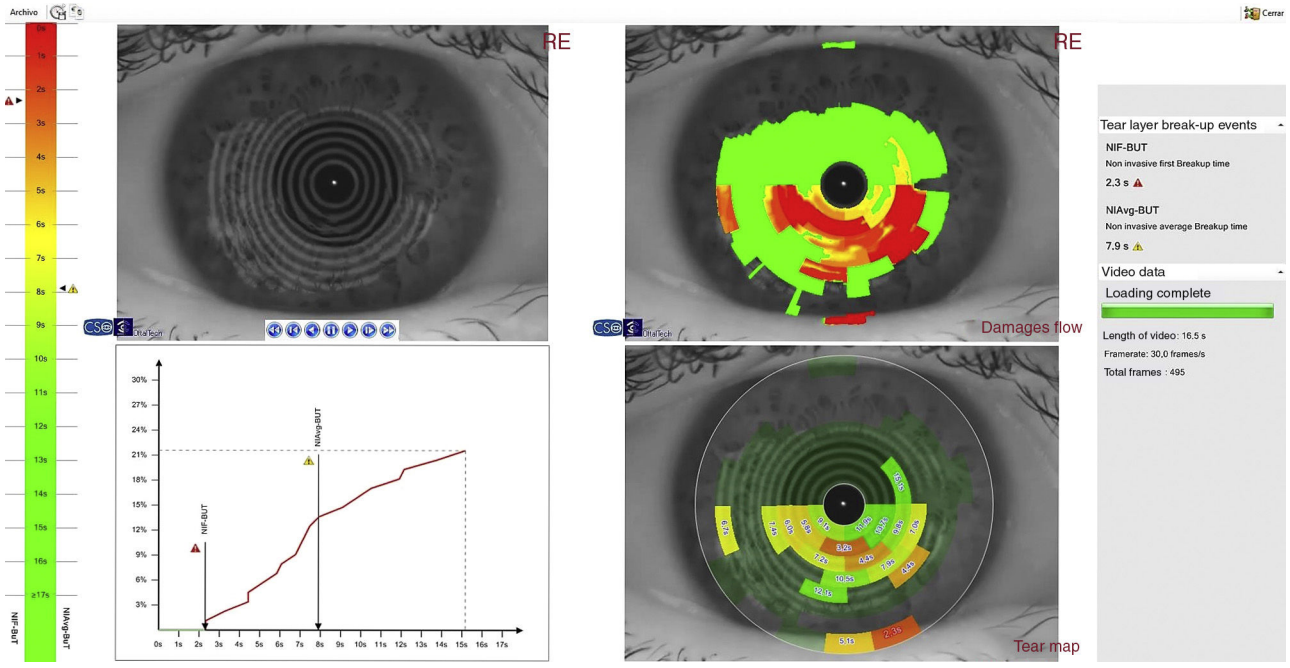

Fig. 1 – BUT measurement prior to treatment with the Sirius® topograph.

refraction of –3.00 ± 2.00 sphere and –1.25 ± 0.50 cylinder with corrected VA of 1.

All the patients had been previously treated with ocular lubricants, lacrimal occlusion agents or food supplements with omega-3 fatty acids that were maintained during said treatment.

None of the patients exhibited ocular or systemic diseases or took medicaments that could produce DES.

The tear breakup time (BUT) was measured with the Sirius® CSO topograph (Florence, Italy) (Figs. 1–3). In addition, the Schirmer II test was carried out and the lacrimal meniscus was assessed with Ivue® Optovue optical coherence tomography (Fremont, USA) (Figs. 4 and 5) for all patients prior to each treatment in order to objectively verify the existence of changes in these parameters.

The evolution of said treatment can be verified with the described images. The first breakup time (Fig. 1) went from 2.3 s to 5.6 s (Fig. 2) and to 5.6 s (Fig. 3). The mean breakup time went from 7.9 s (Fig. 1) to 9.9 s (Fig. 3). Placidus rings can be seen at the upper left side of the images, showing

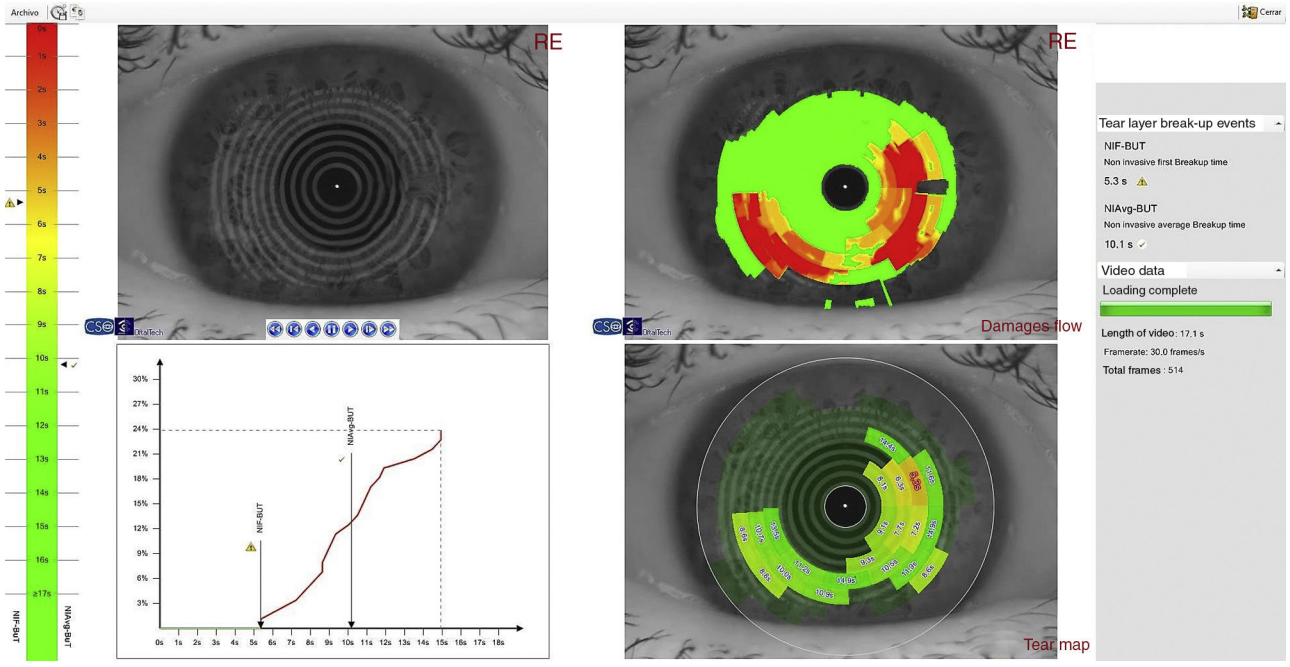

Fig. 2 – BUT measurement with the Sirius® topograph after the first IRPL® treatment session.

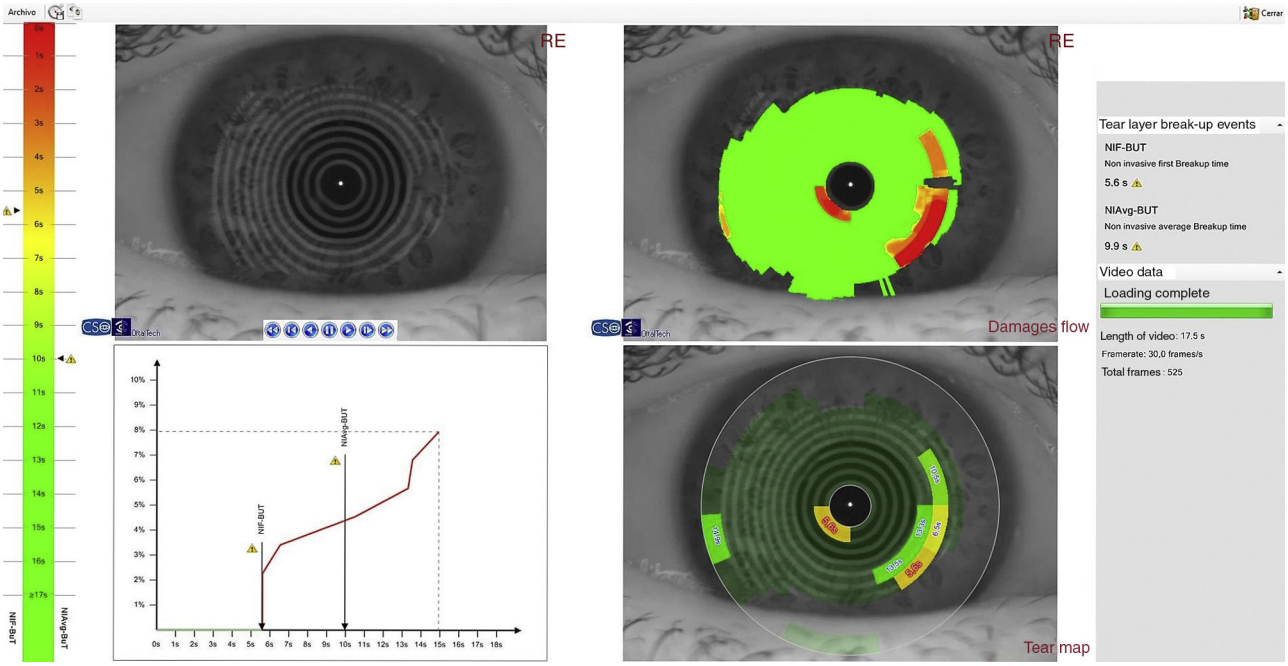

Fig. 3 – Image of BUT measurement with the Sirius® topograph after the second IRPL® treatment session.

the evolution and clearing up to a clear and sharp image (Fig. 3).

The present study was initiated March one, 2016 and completed 45 days later at the *Clínica Vistalaser Oftalmología* clinic of Malaga. All the treatments followed the same protocols and sequence: anamnesis, BUT measurements, lacrimal meniscus measurement and Schirmer II test. The BUT and lacrimal meniscus assessments involved three measurements for each, with a mean value chosen in all cases. The consulting room where the tests and the treatments were performed was almost the same, with low lighting and an ambient temperature of 23 °C.

All the patients received a file with treatment information and recommendations to be followed, but without mentioning the pre- or post-treatment tests, their condition or evolution. In all cases, any information that could interfere in the final results was not provided.

Data were processed with the IBM SPSS Statistics 22 (USA) application.

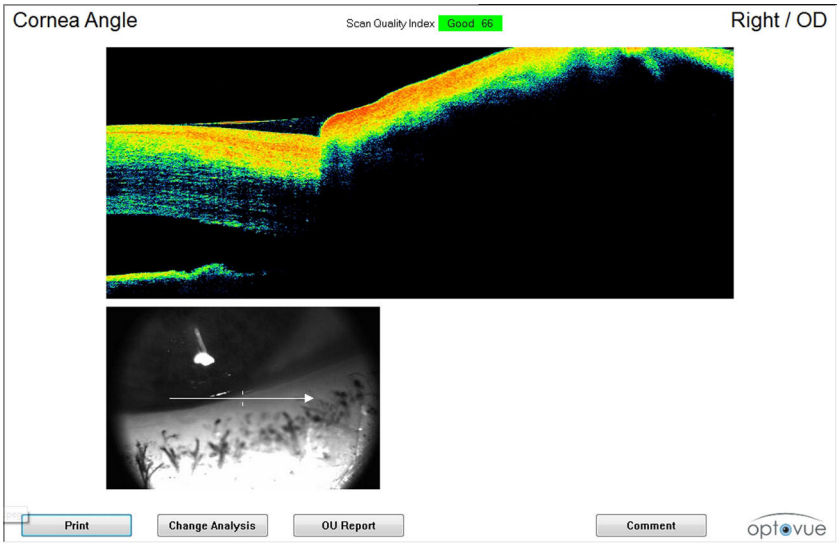

Fig. 4 – lacrimal meniscus evaluation with OCT Ivue®. The image shows the lacrimal meniscus, and the lower left picture shows the location of the anterior segment OCT scan utilized in all patients for measuring said meniscus.

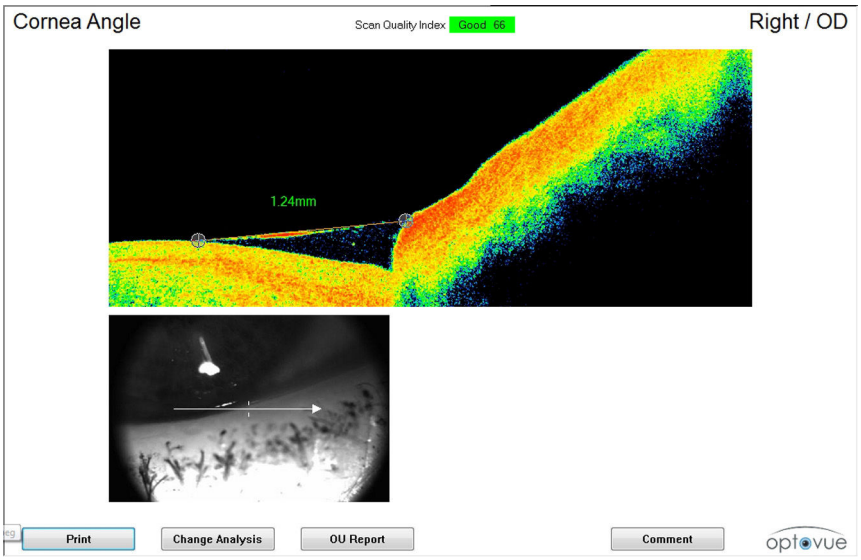

Fig. 5 – This image zooms in the area to measure said meniscus with greater precision and with a line segment or "caliper" or presenting meniscus height (1.24 mm).

Results

In general, increased BUT was observed from the first up to the last treatment session in 54.17% of patients, even though only 29.17% was for increases above 3 s. Fig. 6 illustrates the variations in BUT per control group and time period.

The patients who did not undergo surgery as well as those who underwent phacoemulsification and PRK treatment exhibited BUT improvements as from the initial treatment session (BUT: 5.85) up to the last one (BUT: 7.7), with an increase above 1 s (Fig. 1). On the other hand, patients who were operated with refractive surgery either with FS or MM, exhibited stable BUT from the first treatment session (BUT: 6.47) to the last one (BUT: 6.68).

As regards the Schirmer II test, improvements were obtained in 62.5% of patients, although at the quantitative level a substantial improvement was observed in only 37.5%. Fig. 7 illustrates the variations in said test for each control group and check-up.

Overall, the lacrimal meniscus was observed to increase in these patients, measured from the first to the last treatment session. In addition, subjective comparative evaluations related to improvements, stabilization or worsening of patients at the end of the treatment, obtaining very positive results: 51% of patients reported satisfaction with the treatment.

Only 2 of the 36 patients experienced an adverse event such as reddening in the face and light sensitivity, which resolved within a week without requiring treatment.

Following the classification of the International Workshop on Meibomian Gland Dysfuntion (IWMGD), half of the patients of this study exhibited hypo-secretory MGD due to the reduced release of sebaceous secretion called by anomalies

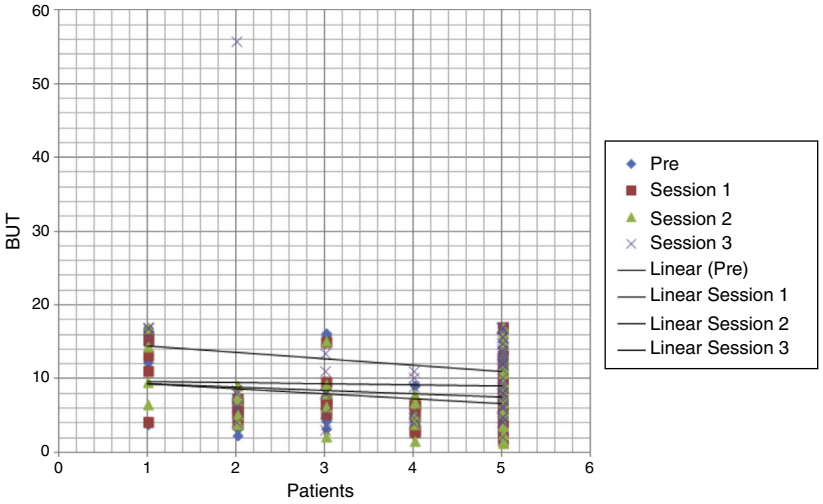

Fig. 6 – Comparison of BUT measurements.

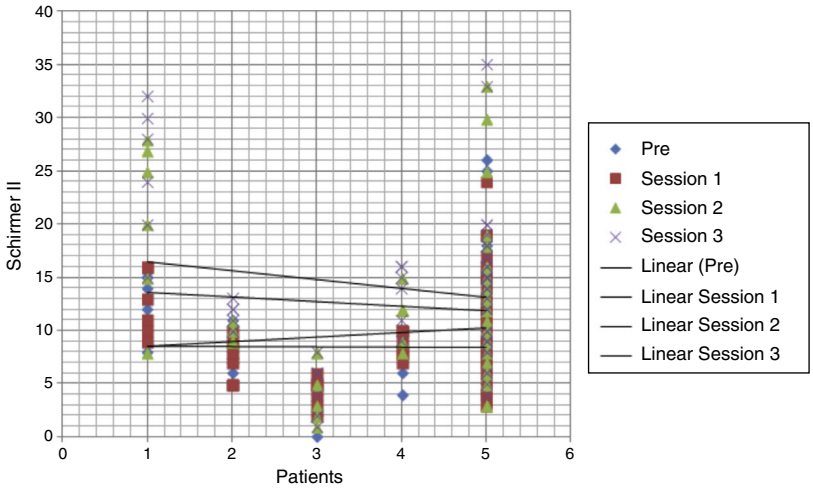

Fig. 7 – Comparison of Schirmer II test measurements.

in meibomian glands without significant obstruction, while the other half exhibited obstructive MGD. Both groups had non-cicatricial MGD.

Following the classification of corneal involvement proposed by IWMGD, the majority of the patients would be included in phase 3 and 4 of the disease, with 21% of patients of the study having the plus disease.

Discussion

Generally, ocular dryness is the result of damaged lacrimal film due to insufficient production of tears or excessive evaporation. It is known that the vast majority of cases are evaporative, with MGD in the main cause of DES in the world.[8,9] This form is mainly due to the absence or insufficiency of the lipidic external layer of the lacrimal tear secreted by the meibomian glands.

It is important to obtain a precise diagnostic of each patient and to analyze in depth all the characteristics that enable the differentiation of the disease and its progression stage in order to provide adequate advice about the best treatment that can be offered as well as for controlling the evolution and improvement thereof.

The IRPL® treatment is a new pulsed light technology for ophthalmology based on the stimulation of the meibomian glands that induces their recovery and normal function with the ensuing improvement for patients.[6]

Benefits were obtained for the 36 patients treated with IRPL® regarding BUT measurements. When the patients were assessed on the basis of the previous treatments they had received, significant differences were found in BUT, obtaining more benefits for patients who had not undergone surgery as well as for those who underwent phacoemulsification and PRK treatment (from 5.85 s to 7.7 s) compared to patients who underwent refractive surgery with FS and MM (from 6.47 s to 6.68 s). In fact, these results evidenced a close relationship between the quality and quantity of lipids secreted by the meibomian glands and the stability of tears on the ocular surface.

Accordingly, greater benefits were observed with the IRPL® treatment both for patients who had not undergone surgery as well as those who underwent phacoemulsification and PRK because in the latter the DES is a consequence of MGD and therefore laser stimulation induces a recovery of their normal activity, with the result of improved lacrimal film stability.[10,11]

On the other hand, patients who underwent refractive surgery either with MM or with FS did not exhibit significant improvements because in these patients DES is due to the corneal response induced by stromal ablation with excimer laser.

As regards subjective patients discomfort, considerable improvement of symptoms were referred as from the first session during a few days, which later increased in length after the second and subsequent applications. A correlation of said subjective impression with the clinical measurements was observed.

The limitations of the present study concern the absence of a control group, which means that the effectiveness of the IRPL® cannot be compared with that of other optional treatments. Additional limitations relate to the absence of objective measurements to assess patient satisfaction after treatment as well as the subjectivity of physicians while performing the treatment and evaluating its efficacy.

Conclusions

Overall results indicate that the IRPL® pulsed light technology is a promising option for treating evaporative DES caused by MGD, with a very limited profile of adverse events. In contrast, due to the nature of this treatment, IRPL® is not an adequate option in DES forms related to isolated aqueous or mucinic phase damage or in the presence of associated infection that must be treated first. In addition, it would be necessary to study larger numbers of patients with a control group and random treatment allocation in order to make a better assessment of the efficacy of said therapeutic technique as well as the range and frequency of adverse events.

Conflict of interests

No conflict of interests was declared by the authors.

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