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Effectiveness of eye-light therapy in improving dry eye symptoms

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ABSTRACT

Objectives: We aimed to examine the effectiveness of eye-light therapy in improving the dry eye symptoms.
Materials and Methods: The retrospective case series where patients who underwent eye-light therapy between March 2019 to May 2020 were analyzed. Twenty patients aged ≥18 years with dry eyes were included. Patients with ocular infections, complications, contact lens users and missing data were excluded. OSDI scores and tear parameters such as noninvasive break up time (NIBUT), lipid layer thickness (LLT), tear meniscus height, meibography of upper and lower lid were evaluated pre and post one month Eye-Light therapy.
Results: Twenty patients with mean±SD age of 43.55±20.53 years and mean spherical equivalent refractive error of 0.69±1.79 diopters were analyzed. OSDI was significantly associated with NBUT (r=-0.50, P = 0.02), lipid layer thickness (r=-0.45, P=0.047) and tear height (r =-0.45, P=0.046). OSDI was positively associated with upper lid meibography (r=0.74, P=<0.001) and lower lid meibography (r=0.45, P=0.045). Post-therapy, reduction in OSDI score post-therapy was present, NBUT was similar, lipid layer thickness and tear height were increased, meibography of upper lid was reduced, and meibography of lower lid did not alter much.
Conclusion: Eye-light therapy is effective in reducing dry eye related symptoms with minimal immediate effect on tear film parameters post therapy. Eye-light therapy acts as an adjunct to ameliorate MGD. MGD being a chronic disease requires sustained therapy with environmental changes. Long term evaluation is required to assess the tear film changes and the pattern of efficacy of light therapy.

1. Introduction

Dry eye disease (DED) is a multifactorial ocular surface disease that is characterized by symptoms of discomfort, irritation, and visual disturbance. DED is becoming common as the world is becoming digital. DED is a disease which is more symptomatic with or without clinical signs. Its prevalence around the world varies from 5% to 34%, which increases significantly with age.[1–3] DED causes significant effects on individuals, including impairment in social functioning, occupational functioning, and reduced quality of life, irrespective of the severity of symptoms.[3,4] DED has been broadly demarcated into aqueous-deficient and evaporative type with major cause being meibomian gland dysfunction.[2,5] DED can be episodic with transient signs and symptoms or chronic with persistent signs and symptoms which include foreign body sensation, stinging, pruritus, burning, and photophobia, lower tear meniscus, conjunctival redness, punctate epithelial erosion, meibomian gland dysfunction with thickened eyelid margins and telangiectasia.[4,6–9]

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Concepts and treatment modalities of dry eye disease are evolving with dry eye being not just a tear deficiency but associated with inflammation. Recently introduced intense pulse light (IPL) is a non-laser high-intensity light which stimulates the meibomian gland and thus helps treat the meibomian gland dysfunction and improves the subjective and objective measures of DED. IPL uses a wavelength ranges between 500-1200nm. Intense pulse light therapy is delivered by various instruments such as Lumenis M22 (Lumenis Ltd., Yokneam, Israel),[10] Dermamed Quadra 4 IPL (Lenni, PA),[11] Diamond Q4 (DermaMed Solutions),[12] E>Eye (E-swin),[13] Pulsed laser light (Intense Pulsed Light Regulated [IRPL®]),[14] Solari (Lutronic, Ilsan, Korea).[15] Although it is safe and effective in treating the dry eye it causes the hypopigmentation, skin burn and blistering of the skin.[16] However recently introduced Eye-Light® provides Low-level light therapy (LLLT) in addition to optimize pulsed energy (OPE®).

Eye-Light® simultaneously treats the upper and lower lid without application of any gel during the treatment process. Low level light therapy is a patented photobiomodulation technology (Light Modulation®) which has a strong metabolic enhancer that increases cellular action which emphasizes cell activity. LLLT is delivered through as face mask, which contains a LED matrix at specific wavelength, triggering endogenous heating of both upper and lower eyelid with temperature attaining 42ºC and given for 15 minutes duration. However to the best of our knowledge there is no previous study has been conducted on Eye-Light® treatment in treating dry eye or MGD. Thus in the present study we evaluated the effectiveness of Eye-Light® therapy in dry eye patients.

2. Materials and Methods

The retrospective non comparative observational case series where medical records of subjects who had undergone Eye-light® therapy between March 2019 to May 2020 were analyzed. The study was approved by an institutional ethics committee (ECR/1088/Inst/MH/2018, Protocol No. 2020/02, and Date of Approval 22^{nd} February, 2021) and adheres to the tenets of declaration of Helsinki. Since this was retrospective study, informed consent was not obtained.

A total of 20 patients aged ≥ 18 years with dry eyes who presented with symptoms such as burning sensation, sandy grity feeling, foreign body reaction, photophobia, and heavy lids as classified byy OSDI score ≥ 13, cllinically significant signs of MGD[17] were included. Patients with history of alkali burns, trachoma, ocular trauma, chronic uveitis, glaucoma, increased mucoid discharge and watery secretion suggestive of vernal keratoconjunctivitis, and ocular surgery within the last 6 months; those with acute ocular infection, corneal opacity or degeneration, impaired eyelid function such as in Bell's palsy, nocturnal lagophthalmos, ectropion, and contact lens users were excluded from the study.

Demographic characteristics, OSDI scores, MGD grades, tear parameters such as NIBUT, lipid layer thickness, tear height of all patients were noted. An OSDI questionnaire was administered to all participants to assess the symptoms of dry eye. OSDI scale was included for subjective evaluation, so as to have a better subjective understanding of the symptoms in relation to its effect on the quality of life.

2.1. Assessment of tear film parameters and meibomian gland

Idra Ocular surface analyzer (OSA) (SBM Sistemi, Italy) was used assess tear film parameter. The Instrument automatically provide measuerments such as non-invasive break up time (NIBUT), Lipid layer thickness, tear height, upper and lower lid meibography. NIBUT evalautes the tear film stability and regularity by measuring the time between the last complete blink and the appearance of the first discontinuity of the tear film in seconds. Interferometry test assesses the quality and quantity of lipid layer of tear film. It measures the lipid layer thickness using the international grading scale of Dr Guillon and colour coded map. Tear Meniscus height is non invasive measurement related to tear secretion rate and stability, providing infromation about tear volume. Small tear volume may result in dry eye symptoms especailly aqeuous tear deficiency. Infrared meibography automatically analyses the images of the both upper and lower lid, providing the percentage of extension and percentage of loss of the meibomian glands.

We also used ME-CHECK® (Espansione Group, Italy) which is a Non Invasive MGD screening module that grade the MGD on a scale of 0-4 and classified the patients as normal, mild, moderate, severe and very severe. It takes the infrared images of the meibomian gland and compared the capture images with a scale developed by Dr Heiko Pult.

2.2. Light therapy

Eye-light® (Espansione Group, Italy) therapy was given to all dry eye patients. All patients were given combined OPE and LLLT for 5 and 15 minutes respectievly for each session. We used manufacturer protocol for providing the treatment which is described in Table 1. For example if patients has grade 1 MGD then patients were given one session of eye-light® therapy.

All tear parameters measurements before and after eye-light therapy were noted.

2.3. Statistical analysis

Data were entered in MS Excel (Microsoft Corporation) and analyzed using Minitab 17 Software (Minitab LLC, State University, PA, USA). Means and standard deviation were calculated for continuous variables and proportions for the

categorical variables. Paired t test was used for comparison of OSDI and other parameters before and after the light therapy. Further, patients were also divided in to different grades based on meibography grading scale developed by Dr Heiko Pult and sub group data was analyzed using Mann-whiteney test. Fisher's exact test was also used to compare the change in different meibography before and after light therapy.

3. Results

40 eyes of 20 Subjects with Mean ± SD age of 43.55±20.53 years and spherical equivalent refractive error of - 0.69 ± 1.79 diopters were included. The mean ± SD IOP was 15.26 ± 3.03 mmHg.

Pre light therapy, we assessed the association between OSDI score and tear parameters. The average of both eyes was taken to evaluate this association. We noted significant negative association between OSDI and NBUT (r = -0.50, P = 0.02). We also noted borderline significant negative association of OSDI with lipid layer thickness (r = -0.45, P = 0.047) and tear height (r = -0.45, P = 0.046). OSDI was positively associated with upper lid meibography (r=0.74, P=<0.001) and lower lid meibography (r= 0.45, P=0.045)

We noted reduction in OSDI score post therapy however it did not reach statistical significance (P = 0.11). NBUT was similar post therapy (P = 0.92). The lipid layer thickness (P = 0.14) and tear height (P = 0.35) was found to increase post light therapy however the difference was not statistical significant. Meibography of upper lid was reduced post therapy (P = 0.12) however meibography of lower lid did not alter much (P = 0.91). Table 2 describes the mean and standard deviation of all parameters.

3.1. Sub group analysis

10 eyes of 5 patients had grade 1 MGD, 22 eyes of 11 patients had grade 2 MGD and 8 eyes of 4 patients had grade 3 MGD. Mann Whitney test was done to compare tear characteristics pre and post therapy in different groups. Mann Whitney test revealed in grade 1 NBUT significantly improved (p = 0.002) however LLT, tear height and meibography of upper and lower lid were similar (p >0.05)

In grade 2 there was significant improvement in tear height (P = 0.03) however did not found any significant changes in NBUT, LLT, meibography of Upper and lower lid (P >0.05). In grade 3, we did not find significant improvement in any of the parameters (P >0.05). Table 3 describes the median and IQR of all parameters.

4. Discussion

Dry eye causes eye irritation and affects the overall quality of life. If treatment is delayed for dry eye, it can develop ocular surface complications, like blepharitis, epithelial break-down, ulceration of the cornea, and in severe cases, may also lead to thinning, scarring and even perforation of the cornea.[18] We have studied OSDI and tear film parameters pre and post eye-light therapy (photobiomodulation) in patients with dry eye. We have noted improvement in OSDI scores and tear film parameters however it was not statistically significant. In grade 1 and 2, we noted symptomatic relief and improvement in OSDI score however grade 3 we did not find improvement in any of the parameter. This could be attributed minimal or no meibomian gland reservoir.

The effects of light therapy on OSDI and tear film parameters:

4.1. OSDI

OSDI is valid and reliable parameter which provides assessments of symptoms related to dry eye disease and its effect on vision related quality of life.[19] We noted improvement in OSDI scores after eye-light therapy compared to baseline, which is in agreement with previous studies.[13,20]

4.2. Non-invasive tear break up time

Fluorescein tear breakup time (TBUT) and Schirmer strips are standard, common and widely use test to assess tear film stability and volume/production respectively. Although these tests remain vital components of the ocular surface exam, they are subjective and are affected by various factors, including fluorescein volume, reflex tearing etc. It has been reported that TBUT is significantly associated with NIBUT.[21] In our study, we assessed NIBUT which was similar post therapy (P=0.92). However previous studies of light treatment have reported improvements in measures of tear film stability with serial intense pulsed light treatment.[22] Craig, Chen and Turnbull[23] reported significant improvement in NIBUT after 3 (at 45 days) treatment sessions in the treated eye versus control eye (14.1 ± 9.8 seconds versus 8.6 ± 8.2 seconds, P< 0.001). Previous studies have reported significant improvement in tear film break up time after a series of monthly intense pulsed light and MGX treatments.[24,25]

4.3. Lipid layer thickness

Continuous lipid layer is important to retard excessive aqueous tear evaporation. Thus lipid layer thickness forms the important parameter in evaluating tear film stability. Although lipid layer thickness correlates well with symptoms as well as signs of MGD, it does not necessarily reflect quality of the lipid layer.[26]In the present study we noted increase in lipid layer thickness however it was not statistically significant. Previous studies have also reported no changes in lipid grade after 1 (at day 1) or 2 (day 15) treatment sessions however an improvement was noted after

Table 1: Describesthe eye-light® treatment protocol based on meibography grading developed by Dr Heiko Pult

Grades	Dry eye Severity	Eyelight Protocol OPE+ LLLT	Meibography Grading % of Loss
1	Reduced	1 Sessions	Degree 1: ≤25%
2	Medium	2 Sessions	Degree 2: 26-50%
3	Medium to high	3 Sessions	Degree 3: 51-75%
4	High	4 Sessions	Degree 4: >75%

Table 2: Mean±SD tear parameter pre and post eye-light therapy

	Pre	Post	P Value
OSDI	24.34 ± 10.79	19.68 ± 14.66	0.19
NBUT	8.67 ± 0.84	8.647± 1.557	0.91
LLT	32.35 ± 28.43	39.15 ± 32.13	0.14
Tear Height	0.29 ± 0.16	0.31 ± 0.11	0.34
Meibography Upper Lid	34.67 ± 13.84	30.45 ± 13.83	0.12
Meibography Lower Lid	19.15 ± 15.18	19.43 ± 17.72	0.92

Table 3: Median (IQR) of tear parameters among different grades of MGD pre and post eye-light therapy

		Pre	Post	P Value
Grade 1	OSDI	25.0 (9.58)	12.0 (16.04)	0.21
	NBUT	8.4 (0.6)	9.0 (1.5)	0.002
	LLT	30.0 (41)	15.0 (18.5)	0.89
	Tear Height	0.41(0.22)	0.40 (0.19)	0.65
	Meibography Upper Lid	30.0 (11.5)	28.0 (15.5)	0.45
	Meibography Lower Lid	12.0 (12)	12.0 (14.5)	1.0
Grade 2	OSDI	29.17 (14.96)	20.83 (16.67)	0.49
	NBUT	8.8 (0.95)	8.7 (1.3)	0.72
	LLT	15.0 (37.5)	39.0 (32.5)	0.60
	Tear Height	0.23 (0.09)	0.25 (0.10)	0.03
	Meibography Upper Lid	36.0 (22.50)	32.0 (20.50)	0.39
	Meibography Lower Lid	23.0 (20.50)	20.0 (28.0)	0.75
Grade 3	OSDI	21.88 (15.52)	11.04 (17.28)	0.19
	NBUT	8.7 (1.07)	8.8 (0.50)	0.81
	LLT	15.0 (5.75)	28.50 (38.75)	0.34
	Tear Height	0.24 (0.22)	0.35 (0.18)	0.20
	Meibography Upper Lid	35.50 (8.75)	34.50 (11.5)	0.69
	Meibography Lower Lid	24.50 (11.25)	17.0 (14.75)	0.42

3 (at day 45) treatment sessions.[23] This suggests that the effect of light therapy is slow and gradual.

4.4. Tear meniscus height

Tear meniscus height is a non-invasive measure which provides quantification of the tear volume. In our study tear height (P=0.35) was found non-significant increase in tear meniscus height post light therapy, which is in agreement with Craig JP et al which depicted Tear meniscus height did not change from BL in either eye (P> 0.05).[23]

4.5. Upper and lower lid meibography

Meibomian gland dysfunction is common in DED. Clinical diagnosis is often curtailed to examination of the lid margin through slit lamp to measure the degree of inspissations and telengiectasia. Also information about the integrity of the glands within the tarsus has usually been more difficult to ascertain using older meibography methods.[27] Non-contact Infrared meibography images upper as well as lower lids. The assessment of Meibomian gland dropout by infrared meibography correlates well with signs and symptoms of dry eye disease.[26]Non-significant reduction in MGD of upper eye lid meibography was noted however MGD of lower eyelid was similar.

5. Instrument consideration

In the present study we used the Eye-Light LLLT module as this provides low level light therapy. The device uses xenon light (600nm) and LED (630 nm) which gets converted in to metabolic energy with subsequent modulation of the biological functioning of the cells. Most modern devices

generate light pulses generated by bursts of electrical current travelling through a xenon gas-filled chamber.[28] Selective photo thermolysis forms the working principle of the IPL, in which thermally mediated radiation damage is limited to have selected epidermal and dermal pigmented targets at the tissue structure or cellular levels and its use has been recorded in cosmetic dermatology.[29] IPL employs electromagnetic waves of desired wavelengths to dilate the capillaries, making them to involute [30]. This causes suppression of the leaked inflammatory mediators, which in turn interrupt the vicious cycle of inflammation and improving symptoms of dry eye. It also works with the aid of thermal pulsation for various patients.[31] This meibum clogs the glands rather than melting into the tear film's lipid layer as it should. Thermal pulsation therapy entails a combination of sustained heat and pressure to liquefy the meibum and thus clear the glands. Expressing the glands manually proves less effective, uncomfortable for patients, and could potentially cause scarring. Thermal pulsation, besides being gentle, is an effective method as well.[32] Eye-Light therapy is combination therapy of sustained low level light therapy and optimized pulse energy delivered together.

Since dry eye is multifactorial disease, its improvement is dependent on various factors such as duration of treatment, frequency of treatment and combination of IPL with other treatments along with various extrinsic and intrinsic environmental factors.[23,33] In the present study we did not find any significant changes in tear film parameters since we studied the immediate effect of the therapy and our patients had undergone limited treatment session.

There are various limitations to our study. Since this was retrospective analysis, we were not able to assess the repeatability of the instrument as well as inter-observer and intra-observer variability. Thus we suggest need the future studies that can be undertaken to evaluate repeatability of the Idra ocular surface analyzer. Secondly, the study design was single arm and was based on both eyes of a small quantum of patients. More studies with a larger number of patients and a control group are required. Thirdly, after the final treatment, the duration of follow-up was also limited. Longer follow-up periods will be required to measure the safety and long-term effectiveness of IPL treatment. Lastly, current medications were continued by all the patients during their course of treatment. For future studies it would be preferable to have a more controlled experimental design.

6. Conclusion

Eye-light therapy is effective in reducing dry eye related symptoms with minimal immediate effect on tear film parameters post therapy. Eye-light therapy acts as an adjunct to ameliorate MGD, which being a chronic disease requires sustained topical medication with environmental changes. Long term evaluation is required to assess the tear film changes and the pattern of efficacy of light therapy.

7. Source of Funding

None.

8. Conflict of Interest

The author declares no conflict of interest.

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