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LOW LEVEL LIGHT THERAPY FOR EVAPORATIVE DRY EYE

DISSERTATION SUBMITTED TO DR. D.Y.PATIL VIDYAPEETH, PUNE, IN FULFILLMENT OF FOUR YEARS FULL-TIME DEGREE PROGRAMME



B. OPTOM 4TH YEAR

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Institute of Optometry and Visual Science

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CERTIFICATE

This is to certify that the dissertation titled,

LOW LEVEL LIGHT THERAPY FOR EVAPORATIVE DRY EYE

Submitted to Dr. D. Y. Patil Institute of Optometry and Visual Sciences for the academic year 2017-2021, is a bonafide record of the original work done by GAJANAN J. INGALE, under my guidance.

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CERTIFICATE

This is to certify that GAJANAN J. INGALE student of Bachelor of Clinical Optometry (Institute of Optometry and Visual Sciences) for the academic year 2017-2021 has completed this study project on,

'LOW LEVEL LIGHT THERAPY FOR EVAPORATIVE DRY EYE'



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RESEARCH CENTER, MUMBAI.

CERTIFICATE

This is to certify that **GAJANAN J. INGALE**, student of Bachelor of Optometry (Institute of Optometry and Visual Sciences) for the academic year 2017-2021 has completed this study project on,

'LOW LEVEL LIGHT THERAPY FOR EVAPORATIVE DRY EYE'



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SIGNATURE OF THE GUIDE MRS SUSHMITA BANERJEE

SIGNATURE OF EXTERNAL EXAMINER

UNDERTAKING

I confirm that this record drawn up by me is an accurate record of the work I have undertaken.

Student GAJANAN J. INGALE

Date:

I confirm that I have examined the placement record and approved it as being an accurate record to the best of my knowledge



I confirm that I have examined the record and approved.

PRASHANT KUMAR SINGH ATTRE

Date:

.....

Co-Guide

ACKNOWLEDGEMENT

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ABSTRACT

AIM: study the effectiveness of low level light therapy for evaporative dry eye and to assess the improvement in meibomian gland function.

MATERIALS AND METHODS:

This study was conducted at Surya Eye Institute and Research Centre, Mulund. The study included 74 eyes of 37 subjects aged 25 years and above attending the ophthalmology outpatient department. All patients selected had a diagnosis of MGD of poor quality of secretion and having symptoms of dryness, foreign body sensation and burning sensation. Patients with uncontrolled systemic disease, contact lens wear, pregnancy, skin treatment within 2 months and history of any ocular trauma and surgeries were excluded from the study. The ophthalmological record included objective ocular tests such as Schirmer's test and TBUT.

RESULT:

74 eyes from 37 subjects were reviewed after 2 sittings of LLLT. A clinical record of 37 treated patients was available for analysis. The average age was 56.03 ± 15.29 with a range of 25 to 83 years. The majority of patients were females about 70% (26 out of 37). Schirmer's test and TBUT improved significantly from baseline to day 28 (15.38 \pm 7.47mm vs. 19.66 \pm 7.98mm) and (5.72 \pm sec vs. 9.14 \pm 4.67 sec) respectively.

CONCLUSION:

LLLT therapies in a single treatment produced significant improvement in tear break up time and schirmer's test with an associated improvement in the patient's subjective satisfaction after treatment. LLLT could be considered as an effective treatment for evaporative dry eye. More research is needed with more patients and longer follow-up time to assess the long-term outcomes of LLLT treatment.

KEYWORDS: Low Level Light therapy, Meibomian Gland Dysfunction, Dry Eye Disease, MeCheck machine

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AIMS & OBJECTIVES

Aim: study the effectiveness of low level light therapy for evaporative dry eye.

Objective: To check the effectiveness of low level light therapy for evaporative dry eye. To check the schirmer test and TBUT test before and after treatment.

HYPOTHESIS

Null Hypothesis (H0): There is no statistically significant difference before and after LLLT treatment for evaporative dry eye.

Alternative Hypothesis (H1): There is a statistically significant difference before and after LLLT treatment for evaporative dry eye.

INTRODUCTION

The dry eye per se is not a disease entity, but a symptoms complex occurring as sequelae to deficiency or abnormalities of the tear film. According to International Dry Eye Workshop Report (DEWS), the causes of the dry eye can be classified as below.

Aqueous deficiency dry eye.

2. Evaporative dry eye.

It is caused by the condition which decreases tear film stability and thus increases evaporation.

Causes -MGD (meibomian gland dysfunction, defective blinking rate, vitamin A deficiency. The dry eye is the tear film disorder due to reduced production of excessive evaporative of tears, causes damages to the exposed ocular surface and is associated with Eye comfort.

Dry eye disease is a multifocal disease of the tear and ocular surface that afflicts hundreds of millions around the world.

Excessive evaporation of tears (causes of 86% of dry eye causes) is induced by the obstruction of the meibomian gland located in the eyelid, and responsible for producing the lipid layer.

When not working properly the meibomian gland does not produce enough oily components for the tear film which consequently evaporates quicker. Absent lipid layer can cause tear evaporation up to 16 times faster.

Evaporative dry eye disease is the one of the most common types of the dry eye. It is often the result of chronic meibomian gland dysfunction (MGD) and associated ocular rosacea. Evaporative dry eye and MGD significantly reduce patient's quality of life. Traditional treatments, such as artificial eye tears, warm compresses, and medications, such as topical cyclosporine, azithromycin and oral doxycycline, provide some relief. However many patients still suffer from dry eye symptoms Low level light therapy, which has been used extensively in

dermatology to treat chronic skin condition, is a relatively new treatment in Ophthalmology for patient with evaporative dry eye disease.

LIGHT MODULATION (LLLT) is the unique technology of photobiomodulation used for many years in various fields of medicine. The emission of the particular light -to a certain wavelength- triggers an endogenous heating of the eyelids. This treatment eases the spill - from the meibomian gland of the tear film oily component, stabilizing the lipid layer of the tear film

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REVIEW OF LITERATURES

In the study outcome of the intense pulse light therapy for evaporative dry eye disease by vineet and seema in total 100 patient with MGD, they found that there was significant decrease in scoring of lid margin edema, meibum viscosity and OSDI score all with p < 0.001 there was a significant increase oil Flow score and TBUT. No significant changes in IOP were noted and no case of adverse ocular effects. Thus they concluded that the IPL for evaporative dry eye is the safe procedure.

In another study "Intense pulse light therapy: a promising complementary treatment for dry eye disease " by L.F Mejia and J. Gil purpose of the IPL therapy as a helpful supplementary treatment in patients with DED.50 eyes from 25 subjects were reviewed . the media of the symptoms scale they found was 8 and 3 before and after the therapy respectively (p<0.05) they median of TBUT was 4 and 10, schirmer test was 13 and 15 and Van Bisterveld score was 3 and 2 before and after the therapy respectively (p<0.05) they concluded the IPL treatment has an excellent result regarding both dry eye symptoms improvement and tests such as TBUT, Schirmer Test, Van Bijsterveld score, thus it could be considered as an effective adjunct for dry eye disease

The study "Prospective trial of low level light therapy and intense pulse light therapy for the treatment of meibomian gland dysfunction by Karl Stone Ciphar and Thomas G. Abell. A total 230 patients were identified for inclusion in the data set. Mean OSDI score were significantly lower after treatment; 70.4% of the patient had pre-treatment OSDI scores indicative of dry eye; this dropped to 29.1% of patients after treatment. A 1 step or greater reduction of MGD grading was observed in 70% of eyes, with 28% of eyes having a 2 steps or greater reduction. Tear break up time was <6 second in 86.7% of eyes pre-treatment dropping to 33.9% of eyes after treatment. There was no ocular and facial adverse events or side effects related to the light therapy.

In a "Prospective Trial of Intense Pulse Light for the Treatment of Meibomian Gland Dysfunction "by Jennifer Craig et al. 28 subjects underwent IPL treatment in one eye

and placebo treatment to partner control eye at 1, 15 and 45 days following baseline (BL) evaluation. Lipid Layer Grade (LLG), NIBUT, Tear Evaporation Rate (TER), Tear Meniscus Height (TMH) & SPEED were compared to BL and control value at each visit, they found that LLG & NIBUT improved significantly form BL to Day 45 in treated eye (p<0.001) but not in control eye.

A study " Combination Therapy of IPL & Meibomian Gland Expression (MGX) Can Improve Dry Eye Symptoms and Meibomian Gland Dysfunction in Patients With Refractory Dry Eye : A Retrospective Analysis" by Sravanthi Venguta et al. Medical records of 81 patients with dry eye treated with serial 1-4 IPL/MGX sittings were retrospectively examined, after reviewing ocular histories, SPEED 2 symptoms survey score, slit lamp examination and meibomian gland evaluation they determined that combination of IPL and MGX can significantly improve dry eye symptoms (in 89% patients) & meibomian gland function (in 77% of patients in at least 1 eye.)

A study "Intense Pulsed Light Treatment for Dry Eye Disease Due to Meibomian Gland Dysfunction ; A 3-Year Retrospective Study" by Rolando

Toyos, MD et al. to determine the clinical benefits of IPL treatment, this retrospective study gave primary outcomes which included change in TBUT, self-reported patient satisfaction, and adverse events. Physician-judged improvement in dry eye TBUT was found in 68 patients (87%) and 93% of patients reported post-treatment satisfaction with degree of dry eye symptoms. Overall, a statistically significant mean improvement was found (paired t test; p = 0.000) in TBUT from initial to the end of treatment. The results suggest that IPL holds promise as an option for treatment of evaporative DED caused by MGD^{.[7]}

A study "Long-Term Effects of Intense Pulsed Light Combined with

Meibomian Gland Expression in the Treatment of MGD" by Bei Rong, MD et al.

MGYS of both the upper eyelids and lower eyelids and TBUT improved at 1, 3, 6 months after treatment (p<0.01) the percentage improvement in the MGYS of lower eyelids after treatment was higher than that of upper lid

In a study "Combined low level light therapy and intense pulsed light therapy for the treatment of meibomian gland dysfunction" by Karl

Stonecipher et al. to evaluate the effects of combined LLLT and IPL therapy a total 460 eyes of 230 patients were included. 70.4% of patients had pre-treatment OSDI scores indicative of dry eye; this dropped to 29.1% of patients after treatment. A 1-step and 2-step or greater reduction in MGD grading observed in 70% and 28% of eyes respectively. TBUT was \leq 6 seconds in 86.7% of eyes pre-treatment, dropping to 33.9% of eyes after treatment. They concluded that this combination therapy seems beneficial in patients who have failed topical and/or systemic therapy



MATERIALS AND METHODOLOGY

STUDY SITE: Surya Eye Institute and Research Centre, Mulund

STUDY DESIGN: Prospective cross-sectional study

SAMPLE SIZE: 37 subject (74 eyes)

	Inclusion criteria	Exclusion criteria
1.	Patients complaining of following	Uncontrolled systemic disease.
	symptoms -dryness, foreign body	
	sensation, burning sensation.	
2.	Diagnosis of MGD with poor	Skin treatment within two month
	quality of secretion.	
3.	Patient aged 23 to 83	Pregnancy/nursing mother
4.		Patients treated with additional
		dry eye therapies
5.		History of ocular trauma and
		surgery.

METHODOLOGY

The Prospective study was connected at Surya Eye Institute and Research Centre, Mulund. The study included 74 eyes of 37 patients aged 23 years and above. All patients selected had a diagnosis of MGD of poor quality of secretion and having symptoms of dryness, foreign body sensation and burning sensation patients with uncontrolled systemic disease, contact lens wear, pregnancy, skin treatment within 2 months and history of any ocular trauma and surgeries were excluded from the study. The ophthalmological record included objective ocular tests such as Schrirmer's test and TBUT. The materials used in this study are as follows:

	Material Name	Material Name Company &		
		Model No.		
		C		
(1)	Me-check	Eye light line rev	Dry eye	
	Machine	2.1	Screening	
(2)	TBUT Machine	Make - ALCON	Dry eye	
		Model - CE0051	Screening	
(3)	LLLT Mask	My mask - (red	Low Level Light	
		center gross)	Therapy	
		44050 funo		
		ITALY		
(4)	Schirmers Strips		Measure the	
			quantity of tears	

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CLINICAL EXAMINATION

All the patients underwent comprehensive eye examinations. After doctor consultation, the dry eye workup was performed on all the dry eye suspected patients.



DRY EYE WORK UP

Dry eye suspected patients underwent Schirmer's test-1 and the tear volume was noted followed by the Tear Break-up Time (TBUT) it is Non-invasive Technique. Photographs of meibomian glands of both upper and lower lids were taken using the Mecheck machine and the grading was done to check the severity of dryness.

Aeiboscale – Lower Lid	Area of Loss	Meiboscale – Upper Lid	Area of Loss
	Degree 0 Store	-) 💽 🦰	Degree 0 =0%
	Degree 1 \$25% 80000	a 🖾 🦰	Degree 1 \$25%
	Degree 2	3 🚳 🦰	Degree 2 26% - 50%
	Degree 3 00000	2 🥯 🥂	Degree 3 51% - 75%
Ser V	Degree 4		Degree 4

fig.1.2 Grading system



Fig.1.3Me check machine

Once the grading was done and the reports were analysed, LLLT sittings to be given to the patients were decided. It may require about 2 or 3 sittings of LLLT as per the degree of dryness present.

TREATMENT PROTOCOL



1. Before starting the therapy patients should wash their face and remove any type of make-up that is applied on the face.

Total duration of the procedure is about 20 minutes.

Patients were placed in either a prone or supine position.

No protective eyewear is indicated during the treatment; the mask treats only the periorbital area and the patient is instructed to keep their eyes closed, to ensure the light therapy acts fully on the upper and lower lid.

Same procedure was repeated for next sittings. After that the values of Pre and Post treatment of objective tests (schirmer test and TBUT) were noted.

FOLLOW UP

In all the follow-ups the schirmer's test and TBUT were repeated for each and every patient and the readings were noted and accordingly ophthalmologists suggested further treatment.



RESULTS

All data is expressed as mean ± SD for statistical analysis of the data. Kolmogrov-smirnov test, student's paired't' test and Wilcoxon Matched -pairs signed-ranks test were used. GraphPad InStat (www.graphpad.com) software was used for statistical analysis of data.

A clinical record of 37 treated patients was available for analysis. The average age was 56.03 ± 15.29 with a range of 25 to 83 years. The majority of patients were females about 70% (26 out of 37). There was a significant difference between both Schirmer's test and TBUT values pre and post LLLT treatment which were found to be (15.38 \pm 7.47 mm vs. 19.66 \pm 7.98 mm) and(5.72 \pm 3.99 sec vs. 9.14 \pm 4.67 sec) Respectively.

Table 1: Assessment of the	Schirmer's test-1 Pre and	Post LLLT Treatment
----------------------------	---------------------------	----------------------------

(Pre LLLT treatment	Post LLLT treatment	Difference		
Mean	15.38 ± 7.47	19.66 ± 7.98	4.28 ± 5.72		
Median	13.500	18.000	-3.000		

Table 1 shows the distribution of schirmer's test-1 before treatment 15.38 ± 7.47 mm and aftertreatment 19.66 \pm 7.98. This change was statistically significant.



Fig. 1.5: Assessment of Schirmer's Test BT and AT

Table 2: Assessment of TBUT Pre and Post LLLT Treatment.

	Pre LLLT treatment	Post LLLT treatment	Difference		
Mean	15.38 ± 7.47	19.66 ± 7.98	4.28 ± 5.72		
Median	13.500	18.000	-3.000		

Table 2 shows the distribution of TBUT before and after treatment the mean break up time

 nearly doubled after treatment the changes was statistically significant



Fig. 1.6: Assessment of NITBUT (in sec) BT and AT.

Table 3: Sex-wise Distribution of Patients:

Sex	No. of Patients	Percentage			
Males	11	30%			
Females	26	70%			
Total	37	100%			



Fig. 1.7: Sex-wise Distribution of Patients

In the 74 eyes treated here, there were no reported facial or ocular side effects or adverse effects reported by any physicians. The sex -wise distribution of patients is shown in the **table 3**.

DISCUSSION

Evaporative dry eye is the most common cause of dry eye disease. Quality-of-life is significantly adversely affected by dry eye disease. The typical referral dry eye clinic treats patients who have had the disease for many years and have failed multiple modalities of dry eye treatment. In our experience, as shown in this study,

100% of respondents to the LLLT treatment improved over all two tests used to evaluate the evaporative dry eye and MGD. The leading cause of MGD is evaporative DED: a disease in which meibum production is more viscous than usual and from which patients can experience severe inflammation and bacterial overgrowth that exacerbates abnormal meibum production. The current study demonstrated significant improvement in the severity of dry eye and MGD in all patients when LLLT was applied. The application of LLLT to be an upper lid and periorbital area are not typically treated with IPL therapy. It may be an additional factor to the improvement in dry eye disease.

Comparisons with others studies are difficult because of differences in the methodologies used to measure changes to subjective and objective signs and symptoms. However the improvements reported here are similar to those reported with combined low level light and intense pulsed light therapy in previous studies. The TBUT test was extremely improved after treatment. The average TBUT test was higher after treatment and MGD grade was also significantly lower after treatment was reported by Karl Stone cipher.

CONCLUSION

LLLT therapies in a single treatment produced significant improvement in tear break up time and schirmer's test with an associated improvement in the patient's subjective satisfaction after treatment. LLLT could be considered as an effective treatment for evaporative dry eye. More research is needed with more patients and longer follow-up time to assess the long-term outcomes of LLLT treatment

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ANNEXURE

CONSENT FORM

I have been hereby informed; the data will be used for the study titled **Low Level Light Therapy for Evaporative Dry Eye**. The records of the study will be kept strictly confidential. Any information will not be collected or retained about my identity. My identity will not be disclosed in the material that is published.

Patient's Name:

Signature:

Date

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			PRE LLLT EVALUATION				POST LLLT EVALUATION					
PATIEN T NO.	AG E	GENDE R	SCHRI m	MERS(in nm)	TB se	UT in c	ME GRA	IBO .DE	SCHRIN n m	1ERS(i m)	TBUT(i	n sec)
			RIGH T EYE	LEFTEY E	RIGH T EYE	LEF T EYE	RIGH T EYE	LEF T EYE	RIGHT EYE	LEFT EYE	RIGH T EYE	LEF T EYE
1	26	F	8	5	3	5	G2	G2	12	9	10	10
2	36	F	10	9	8	8	G2	G2	15	10	12	11
3	50	М	15	13	10	9	G3	G3	15	15	10	10
4	45	F	13	11	10	10	-	-	14	16	12	11
5	25	F	18	15	11	11	G4	G3	18	20	16	16
6	54	F	22	12	9	10	G2	G3	25	19	16	17
7	36	М	19	9	14	12	-	-	19	15	8	11
8	34	F	20	15	12	10	G4	G4	22	20	14	13
9	29	F	5	3	9	9	G4	G4	5	6	9	9
10	24	М	3	5	5	4	G2	G2	8	9	9	9
11	25	F	6	9	10	11	G3	G3	9	13	15	15
12	28	М	14	13	10	9	G4	G4	15	22	15	16
13	43	F	12	11	6	5	G4	G3	12	26	15	15
14	54	М	18	18	2	9	G4	G3	18	24	12	12
15	25	F	17	15	9	6	G1	G2	19	15	15	15
16	23	F	18	13	11	10		-	19	13	15	14
17	29	М	2	5	6	8	G4	G4	6	6	9	9
18	30	F	1	3	3	2	G4	G3	5	9	9	10
19	32	М	3	5	5	5	G3	G3	5	10	14	15
20	23	F	5	2	5	9	G2	G3	9	9	12	13
21	28	F	4	9	12	12	G4	G4	10	22	19	19
22	27	F	7	8	4	5	G3	G2	35	15	9	9
23	23	М	18	15	8	4	-	-	22	15	10	15
24	40	М	16	17	11	11	-	-	20	20	15	15
25	26	F	12	10	13	10	G2	G2	19	13	12	16
26	28	F	13	9	10	15	G2	G3	16	9	16	16
27	32	М	11	9	5	8	G4	G3	12	12	15	15
28	30	F	17	15	9	9	G4	G4	35	15	13	11
29	41	F	18	13	6	5	G4	G4	35	15	14	12
30	29	F	14	11	3	6	G3	G4	18	14	12	12
31	25	F	12	10	10	13	G2	G2	12	10	11	17
32	27	F	2	5	9	8	G2	G3	2	35	12	15
33	26	F	7	8	9	6	G2	G2	10	20	10	10
34	30	М	15	15	6	10	-	-	15	16	9	9
35	35	F	18	17	12	9	G4	G4	16	19	15	14
36	30	F	17	13	11	10	G4	G4	35	15	16	12
37	26	F	20	18	6	12	G2	G2	10	20	15	13