

# Contact Lens Discomfort (CLD) Treatment with MY MASK Light Modulation® LED mask

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## *ABSTRACT*

**OBJECTIVE:** To understand how the use of the Light Modulation LED mask (MY MASK®) can influence dissatisfaction with the use of soft contact lenses due to dry eye (CLIDE – Contact Lens Induced DryEye).

## **MATERIALS AND METHODS**

Forty-two (42) soft contact lens wearers with dry eye symptoms were recruited in a 3-week descriptive observational study. Three treatments of Light Modulation LED mask lasting 15 minutes each were applied 1 day, 3 days and 1 week after. CLIDE symptoms were described with a specific questionnaire (CLDEQ-8) before and after treatment. Ocular surface and tear film measurements were conducted at baseline, and 1 week after the end of the cycle by a practitioner.

## *RESULTS*

The visual acuity values measured before and after the LLLT treatment do not differ from each other ( $10/10 \pm 1/10$ ). After 1 week upon conclusion of the treatment the percentage of symptomatic CL wearers is reduced by 43% (18 out of 42 subjects), showing at CLDEQ-8 a reduction in CLIDE symptoms below the cut-off value by almost half (43%) of the candidates ( $Z$  Test = 5.14;  $R^2 = 0.186$ ). Before treatment, 70% of the evaluated data (59 out of 84) sets a NIBUT value of less than 10s. Following the treatment, only 26% demonstrate values below the cut-off and the remaining 74% are characterized by higher values ( $Z$  Test = 4.09;  $R^2 = 0.315$ ). Following exposure to LLLT (Low Level Light Therapy), the obtained meibomyography values do not change ( $Z$  Test = 1.17;  $R^2 = 0.872$ ). Data surface were obtained by Tear Scope undergo considerable variations for all candidates who show an advancement of at least one degree in the classification of the pattern according to the Guillon scale. The data obtained through the Gland Evaluator also demonstrate an improvement.

## *CONCLUSIONS*

It is possible to argue that in the group of subjects analyzed there was a general improvement such as to significantly reduce the contact lens discomfort preliminary condition. LLLT treatment has proved to be an interesting option in improving the aspects that characterize CLIDE. Other studies will be necessary to

establish the persistence of the improvement and the possibility of treatment recalls to stabilize or maintain satisfaction in the use of contact lenses.

## 1. INTRODUCTION.

Contact lens-induced dry eye (CLIDE) is the most common complication in soft contact lens wearers: more than three out of five wearers report symptomatic dryness during the day<sup>1</sup>. Several recent studies estimate that the frequency of CLIDE is roughly 50-79% globally<sup>2</sup>, with an afflicted population of 17 million individuals in the United States and 1 million in the UK<sup>1,3</sup>.

Ocular discomfort and dry eye symptoms are the main factors for contact lens (CL) wear intolerance and discontinuation. It is generally accepted that there is an inflammatory component to a dry eye disorder, which indicates that the body is responding to the irritants and distresses of daily life. Already in 2013, the International Workshop TFOS (Tear Film Ocular Surface)<sup>4</sup> defined this phenomenon with the term CLD Contact Lens Discomfort, which frequently leads to contact lens dropout.

As reported by McMonnies and Ho<sup>5</sup>, contact lens wear is a provocative factor of marginal dry eye, which is associated with hyper-evaporation of the tear film and friction between the contact lens and ocular surface<sup>6</sup>.

In this context, dry eye and discomfort can be multifactorial, but the growing clinical impression suggest that physiological changes in the eyelid and meibomian glands (MG) are involved. Scientific research has highlighted the central role of blink, the lipid phase of the tear film, and meibomian glands in the etiology of this condition<sup>7-11</sup>.

Practitioners can improve tear evaporation rate by treating meibomian glands. Historically, treatment of MG has ranged from warm compresses and lid scrubs to topical or systemic pharmaceutical therapy<sup>12</sup>, though in recent years, several new devices/procedures have been designed to promote improved outflow of meibum. Low-Level Light Therapy (LLLT) is one of the most innovative non-contact, effective and non-invasive systems. This technology is based on heat production and photo-biomodulation, which urges the mitochondria of cells to increase energy production<sup>13,14</sup>.

Pult<sup>15,16</sup> suggested that the LLLT had a significantly higher heat effect, which was within the range recommended for the treatment of MGD with warm compresses or the like. This temperature can penetrate deeper into the eyelids than when using external heat (warm compresses or similar). This non-invasive technology removes blockage of the glands and allows lipids to flow to complete tear composition.

In a study by Stonecipher, Abell, Chotiner and colleagues<sup>17,18</sup>, a combination of LLLT and intense pulsed light therapy (IPL) was given to participants with dry eye who had previously failed with drops and oral medicines. Meibomian gland function, objective and subjective indicators of dry eye have significantly improved after the treatment. The development of endogenous heat makes the meibomian secretion less viscous and reduces inflammatory and neuropathic pain. It also stimulates the parasympathetic nervous system and the production of lipid liquid<sup>15-18</sup>.

The proposed work evaluated how the LED Light Modulation<sup>®</sup> (LLLT) mask can affect dissatisfaction with the use of soft contact lenses, due to dry eye<sup>13-19</sup>. In this descriptive observational study, patients using soft CL

and displaying the associated dryness symptoms undergo a cycle of treatments with the MY MASK<sup>®</sup>. The impact on the CLIDE symptoms, tear film, and meibomian glands have been discussed.

## 1. METHODS.

This multicentre investigation was conducted at 3 different practices: two based in Italy (“Studio Optica di Pietro Gheller” and at “VisionOttica Pavan”) and one based in Spain (David Piñero, University of Alicante). Patients who have used soft contact lenses for at least three years have been recruited in the study. The Declaration of Helsinki’s requirements were satisfied, and each patient signed an informed consent before the treatment was given. 42 participants were enrolled with inclusion criteria as follows: a level score on the CLDEQ-8 questionnaire (Contact Lens Dry Eye Questionnaire 8 items) equal to or above the cut-off (12 points)<sup>20</sup> and a meibomian gland condition below the 3rd stage (Pult scale)<sup>21</sup>.

Visual acuity (VA) was assessed for each candidate before and after treatment. Preliminarily the NIBUT (cut-off 10s)<sup>22,26</sup> value was performed by the placid disk topographer Antares (CSO, Italy). Succeeding the feature of the lipid tear film were measured. For these examinations were observed: Meibomyography (cut-off 3rd stage, Pult classification)<sup>21,26</sup> with the infrared (IR) meibomyograph MeCheck (Expansion Group, Italy), interferometry (cut-off 50-70nm, Guillon scale)<sup>22,27</sup> employing the interferometer TearScope Polaris (CSO, Italy), and meibomian gland expression (cut-off 2nd stageon, 4 degrees scale)<sup>23</sup> using the meibomian gland evaluator TearScience Gland Evaluator (Johnson&Johnson, US).

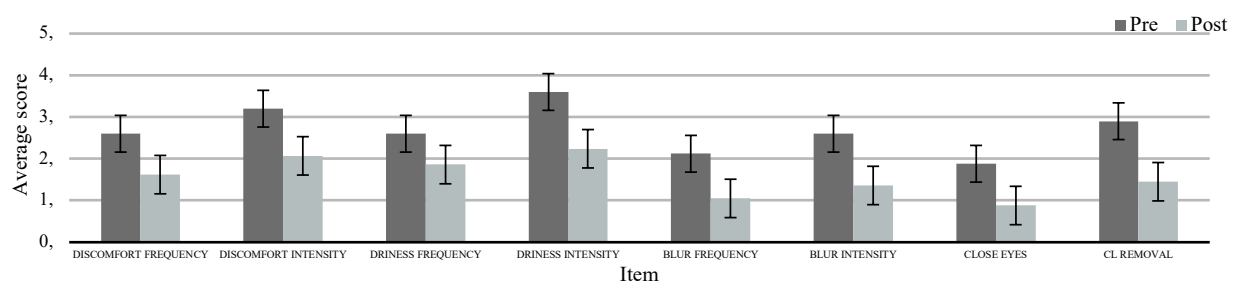
Successively, the candidates were treated with the low level light therapy (LLLT) mask “MY MASK” by Espansione Group according to the instructions provided by the company: three treatments of 15 minutes, the second three days following the first, and the last one a week later<sup>25</sup>. A follow-up examination for signs and symptoms was performed one week after the end of the cycle.

The results obtained from the tests carried out were described and evaluated by calculating the averages, frequencies and probability distributions. A linear regression analysis was developed to determine the data’s dependence and their compatibility. Various Z-tests were performed to study the probability for observing any differences.

## 3. RESULTS

### *Subjective Tests*

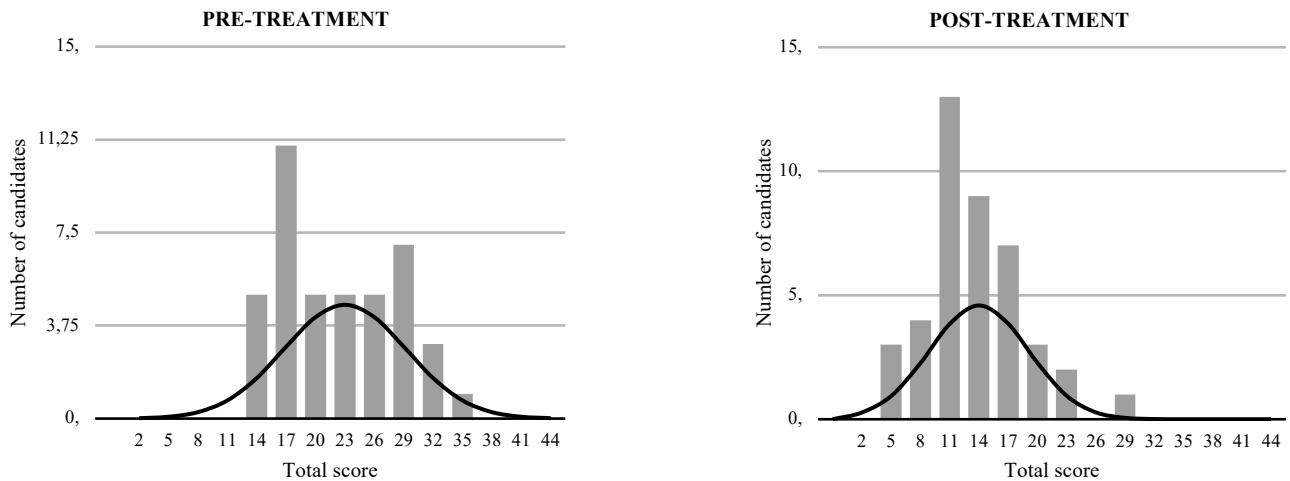
Considering CLDEQ-8 questionnaire, a similar statistical tendency was found by comparing the average scores obtained for each individual question (item 1-8) before and after treatment. It stood out by a widespread drop in the average value after the treatment with the LLLT mask device.



**Fig. 1.** CLDEQ-8 questionnaire average score for each item at baseline and one week after the LLLT cycle. Each bar

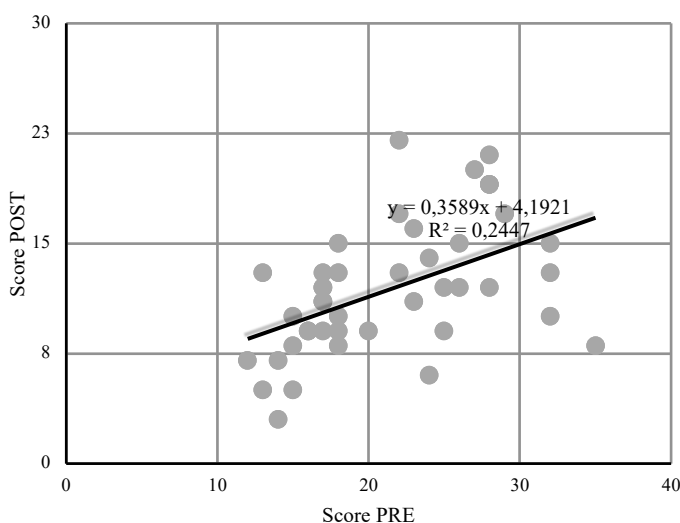
In order to evaluate the total score on the CLDEQ-8, the average values and their associated standard deviation between the participants were calculated: pre ( $22.1 \pm 1.36$ ) and post ( $13 \pm 1.15$ ) treatment. The distribution of outcomes by scoring band is depicted in the graph below. The probability area of our sample is described by the Gaussian curve of fit to the distributions, which is also illustrated.

Before treatment, the total scores obtained at CLDEQ-8 questionnaire described a percentage of 100% of subjects affected by CLIDE (42 of 42 subjects). After using the LLLT device, only 57% of wearers reported



**Fig. 2.** The distribution of CLDEQ-8 questionnaire score before and after treatment.

feeling dryness-related complaints (24 out of 42 subjects). This statistic showed a decrease in CLIDE symptoms for over half of the candidates below the cut-off threshold. None of the examined people developed worse symptoms and all symptom variations associated with dryness were ameliorative. Following therapy, the results of the statistical analysis tests (linear regression and Z test) showed a certain improvement in CLIDE symptoms: the statistical likelihood indicator was 100% ( $Z \text{ Test} = 5.14$ ). ( $R^2 = 0.218$ ).

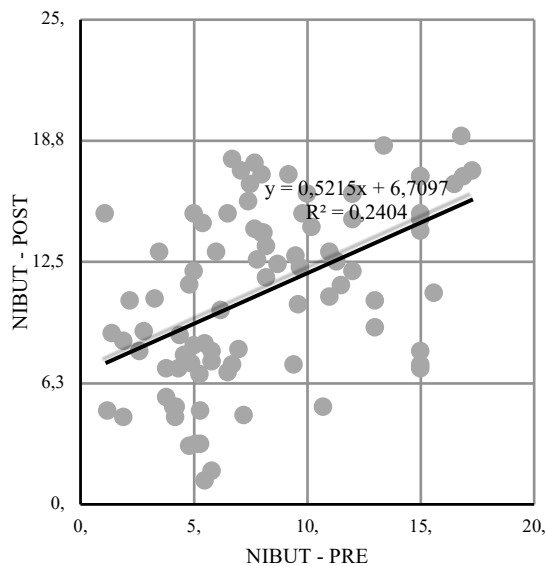


**Fig. 3.** The linear correlation of CLDEQ-8 questionnaire score before and after treatment.

### Objective Tests

The visual acuity values measured before and after the LLLT treatment do not differ from each other, positioning themselves around an average of 10/10 ± 1/10.. No alterations in eyesight were noted as a result of the sessions.

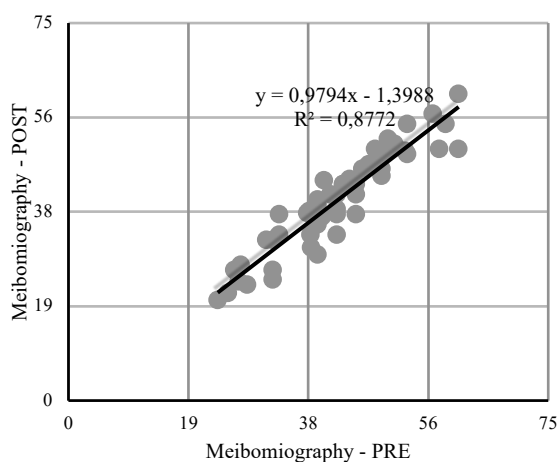
Comparing the results obtained with the objective tests showed improvements in the performance of the tear film before and after the low level light treatment. Initially, 70% of participants (59 of 84) established a NIBUT value of less than 10s. The number of individuals below the cut-off declined after LLLT cycle: just 26% had reduced values; A balanced situation characterized the remaining 74%. (Z Test=3.06) ( $R^2=0.240$ ).



**Fig. 4.** The linear correlation of Non-invasive break up time before and after treatment.

Tear Scope data was inconsistent across the different candidates prior to treatment, and only in 26% of patients lipid layer was smaller than the thickness of 50–70 nm. According to Guillon scale, each subject's lipid thickness exhibited an improvement of at least one degree in the classification after receiving the led light modulation treatment. (Z-test=10.90). The average values and their associated standard deviation between the participants were calculated: pre ( $3 \pm 1$ ) and post ( $4 \pm 1$ ) treatment.

At the meibomiography, the sample of participants investigated showed a decrease in the meibomian glands' area that was almost below the third degree. The mean area that was missing was  $42,8 \pm 1,5$ . The acquired meibomyography results did not significantly alter after exposure to LLLT technology, and changes were not always present (Z Test=1,17) ( $R^2=0,872$ ).



**Fig. 5.** The linear correlation of meibomiography before and after treatment.

Meibomian gland expression placed the candidates in groups 2 or 3 of the chosen scale (4 degrees). A normal secretion (clear liquid secretion) was present in most cases (65%). 35% of the glands observed (16 out of 46) exhibited barely altered expressibility (opaque liquid) before LLLT mask treatment (opaque liquid). After the cycle was completed, this percentage dropped to 11%. (5 out of 46). There was an 89.19% chance that the value would change.

#### 4. CONCLUSION

The results of the current study show that following two weeks of LLLT treatment, candidates exhibited a general improvement in symptoms and signs of contact lens-related dry eye. In the short period, the LLLT made it possible to determine the ideal tear evaporation rate, tear film lipid layer thickness and meibomian gland expression. Even in situations that seemed to be more unstable, they made a noticeable improvement. Significant changes in the interferometry, NIBUT, and glandular expressivity objective tests is seen, all of those performance were improving over time.

Compression of the meibomian glands evaluated quality and quantity of flowing meibum<sup>23</sup>. Despite the fact that none of the candidates appear to be in an unsatisfactory scenario based on the initial data, after the LLLT mask cycle, this parameter significantly improved and achieved an ideal condition. Following the treatment, the lipid layer's volume also increased, in fact tear scope data indicated that its thickness has increased by more than one degree, according to Guillon scale. The expression of natural meibum can be associated with improvements in tear film stability through fortifying the integrity of the surface lipid layer with a continuous lipid layer being necessary for inhibiting aqueous tear evaporation<sup>28</sup>. The non-invasive break-up time values improved, reaching above the cut-off of 10s for almost all candidates. The absence of evaporation guarantees the maintenance of the aqueous component of the tear. This could mean that the eye and contact lenses are more hydrated. Though this data should consider the blink frequency, its entirety and more to understand the influence on comfort with contact lenses and on friction with the CL. This study cannot establish that the improvement in tear film performance directly influence dryness symptoms associated with contact lenses.

We are also aware that CLIDE is affected not only by the quality of the tears but also by the chemical-physical characteristic of the contact lenses surface<sup>3</sup>. However, these data certainly give greater value to the initial hypothesis.

The questionnaire answers demonstrated that almost 50% improved below threshold dry eye symptoms. Half of CL wearers didn't feel more dryness, burning, itching, and bad vision. All of the samples exhibited the same general change who suggest a greater adherence to the use of lac.

Following two weeks LLLT mask cycle, no changes were observed in visual acuity, conjunctival hyperaemia, ocular surface staining, or meibomian gland dropout, and no adverse events were reported by participants during the study.

However, it is difficult to determine whether the presence of significant effects detected in the current study might be due to the transient nature of improvements in tear film stability, which is recognized to be a highly variable measurement, or suboptimal treatment adherence. The follow-up time of one week was also insufficient to demonstrate long-term effects to develop. Other studies will be necessary to establish the

persistence of the improvement and the possibility of treatment recalls to stabilize or maintain satisfaction in the use of contact lenses.

Anyway, it is possible to argue that in the group of subjects analyzed there was a general improvement such as to significantly reduce the CLD preliminary condition. LLLT treatment through the MY MASK ® device has proved to be an interesting option in improving the aspects that characterize CLIDE.

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