

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

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## Abstract

The purpose of this study was to understand how the use of the light modulation LED mask MY MASK affects Contact Lens Discomfort (CLD).

Forty-two (42) soft contact lens wearers with dry eye symptoms were recruited for a 3-week descriptive observational study. Treatment using the light modulation LED mask was applied three times, each lasting 15 minutes; on day 1, day 3 and after one week. Symptoms of CLD were quantified with the help of a specific questionnaire (CLDEQ-8) before and after treatment. Ocular surface and tear film measurements were conducted at baseline and 1 week after the last treatment.

Visual acuity remained stable (0.00 LogMAR  $\pm$  0.10). The number of symptomatic contact lens wearers decreased by 43% (18 out of 42 subjects), as indicated by the CLDEQ-8 scores ( $t$ -test = 5.14;  $p < 0.001$ ) ( $R^2 = 0.218$ ). Non-invasive tear film breakup time (NIBUT) improved significantly. Before treatment, 70% of eyes (59 out of 84) showed a NIBUT of less than 10 s; after treatment, 26% had values below this cut-off ( $t$ -test = 3.06;  $p = 0.001$ ) ( $R^2 = 0.241$ ). Meibography values did not change ( $t$ -test = 1.17;  $p = 0.121$ ) ( $R^2 = 0.872$ ). TearScope showed considerable improvement in tear film lipid layer thickness and the data obtained through the Gland Evaluator also demonstrated an improvement.

Treatment using MY MASK light modulation LED could be an interesting option in improving the aspects that characterise CLD. Additional research is required to establish the reliability of the observed improvement and investigate the necessity of repeated treatments as a means of stabilising or sustaining satisfaction in contact lens wearers.

*Keywords: contact lens, dry eye, discomfort, meibomian glands*

## Introduction

Contact lens discomfort (CLD) due to dry eye is the most common complication in soft contact lens wearers: more than three out of five wearers report dryness during the day (Ramamoorthy et al., 2008). Several recent studies estimate that the frequency of contact lens induced dry eye is roughly 50–79% globally (Inomata et al., 2020), with an afflicted population of 17 million individuals in the United States and 1 million in the UK (Richdale et al., 2007).

Ocular discomfort and dry eye symptoms are the main reasons for contact lens wear intolerance and discontinuation. It is generally accepted that there is an inflammatory component to dry eye disorders, 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) (Nichols et al., 2013) termed this phenomenon Contact Lens Discomfort (CLD), which frequently leads to contact lens dropout.

As reported by McMonnies and Ho (1986), contact lens wear is a provocative factor in marginal dry eye, which is associated with hyper-evaporation of the tear film and friction between the contact lens and the ocular surface (Dumbleton et al., 2013).

In this context, dry eye and discomfort can be multifactorial, but the growing clinical impression suggests that physiological changes in the eyelid and meibomian glands (MGs) are involved (Craig et al., 2013; Kojima, 2018). Scientific research has highlighted the central role of blinking, the lipid phase of the tear film, and MGs in the aetiology of this condition (Arita et al., 2009; Rohit et al., 2014; Siddireddy et al., 2018).

Practitioners can improve tear evaporation rate by treating the MGs. Historically, treatment of MGs has ranged from warm compresses and lid scrubs to topical or systemic pharmaceutical therapy (Geerling et al., 2011), though in recent years, several new devices/procedures have been designed to promote improved outflow of meibum. The light modulation LED mask is based on Low-Level Light Therapy (LLLT), one of the most advanced non-contact, effective and non-invasive systems (Giannaccare et al., 2023). This technology is based on heat production and photo-biomodulation, which stimulates mitochondrial energy production. Increased mitochondrial activity and ATP (adenosine triphosphate) consumption result in endogenous heat growth (internal heat) (D'Souza et al., 2022).

Pult (2020b) suggested that LLLT had a significantly higher heat effect than warm compresses or the like, while still being within the range recommended for the treatment of MGD (meibomian gland dysfunction). This technology allows heat to penetrate deeper into the eyelids than when using external heat (warm compresses or similar). The use of this non-invasive technology resulted in the removal of gland blockages, which facilitated the flow of lipids to achieve a complete tear composition (Pult, 2020a).

In a study by Stonecipher et al. (Stonecipher & Potvin, 2019; Stonecipher et al., 2019), 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 medication. After the treatment, there was significant improvement in MG function, as well as in objective and subjective indicators of dry eye. The development of endogenous heat made the meibomian secretion less viscous, reducing inflammatory and neuropathic pain. Furthermore, it stimulated the parasympathetic nervous system and meibum production (Pult, 2020a; Stonecipher & Potvin, 2019; Stonecipher et al., 2019).

The proposed work evaluated how the light modulation LED mask can reduce discomfort due to dry eye (Gomes et al., 2017) during soft contact lens wear. In this descriptive observational study, patients using soft contact lenses and displaying associated dry eye symptoms underwent a cycle of treatments with the MY MASK light modulation LED mask. The impact on the CLD, tear film, and MGs was evaluated.

## Methods

This multicentre investigation was conducted at three different practices: two based in Italy ("Studio Optica di Pietro Gheller" and "VisionOptica Pavan") and one based in Spain (David Piñero, University of Alicante). Patients who had used soft contact lenses for at least 3 years were recruited in the study. The Declaration of Helsinki's requirements were fulfilled, and

each patient signed an informed consent form before the treatment was started. Forty-two subjects with CLD and a MG atrophy below stage 3 ( $\leq 3$ ) on the Pult scale (Pult & Riede-Pult, 2012) were included in the study. CLD was defined by a Contact Lens Dry Eye Questionnaire – 8 items (CLDEQ-8) (Garza-Leon et al., 2019; Zeri et al., 2023) score of 12 or more (Chalmers et al., 2016). The participants attended the clinic twice: at enrolment for baseline measurements, and 1 week after the last treatment for follow-up measurements. Between these two visits the subjects were treated with the MY MASK light modulation LED mask (Espansione Group) according to the instructions provided by the manufacturer: 15 min of treatment three times: on the first day, the third day and one week after enrolment (Stonecipher et al., 2020).

At the start of the enrolment visit, a clinician assessed the inclusion criteria and performed baseline measurements on both eyes of each participant before any treatment was administered. Following the treatment period, follow-up assessments were conducted at a time of day as close as possible to that of the initial enrolment visit to ensure consistency in the measurement conditions. To minimise the impact on tear film physiology for subsequent tests, measurements were performed in ascending order of invasiveness, always starting with the right eye.

Information about the participants' contact lens wear during the study was not recorded. Participants were permitted to wear their contact lenses regularly during the study period.

Monocular corrected visual acuity (VA) was assessed with a standard LogMAR chart.

The primary outcome measure was tear film lipid layer thickness employing the interferometer TearScope Polaris (CSO, Italy). The tear film lipid layer was graded according to the Guillon system (Mengher et al., 1985): grade 1: open meshwork; grade 2: closed meshwork; grade 3: wave or flow; grade 4: amorphous; grade 5: coloured fringes; grade 0: non-continuous layer (non-visible or abnormal coloured fringes) (cut-off 50–70 nm) (Guillon, 1998). Non-invasive tear film breakup time (NIBUT) was measured with the Placido disk topographer Antares (CSO, Italy) using automated detection of first breakup, while the subject maintained fixation and was requested to refrain from blinking. First breakup time was measured once (cut-off 10 s) (Wolffsohn et al., 2017). Infrared (IR) meibography was performed with the meibograph Me-check (Espansione Group, Italy), with the inferior eyelids everted in turn. From the captured image, the proportion of MGs visible within the tarsal area was graded according to the five-point Meiboscale (Pult classification, cut-off 3rd stage) (Pult & Riede-Pult, 2012) and the area of atrophy was automatically calculated by the software. The MG expression was evaluated using the MG evaluator Tear-Science Gland Evaluator (Johnson&Johnson, US). The flowing meibum was graded according to the 4-degree scale (cut-off 2nd stage) (Meadows, 2011).

### Data analysis

The results obtained were described and evaluated by calculating the averages, frequencies and probability distributions. A linear regression analysis was developed to determine the data's dependencies and their compatibility. Various *t*-tests were performed to study the probability for observing any differences. The measurements from the left and right eyes were recorded as independent variables. Statistical analysis, performed separately for right eye (OD) and left eye (OS), did not reveal any significant differences between the eyes. Consequently, data from both the left and right eyes were combined for the overall analysis.

## Results

The mean age  $\pm$  SD of the 42 enrolled participants (27 females, 15 males) was  $32 \pm 12$  years. Summary statistics of clinical measurements pre treatment, and 1 week post light modulation LED mask treatment are presented in Table 1.

Table 1: CLDEQ-8 and clinical measurements pre-treatment (Pre), and 1 week post Light Modulation LED mask treatment (Post). Data are presented as mean  $\pm$  SD or median (IQR). The *p*-values are reported.

Parameter	Day	Mean $\pm$ SD	Range	<i>p</i> -value
CLDEQ-8	Pre	21.5 $\pm$ 1.3	12.0–35.0	< 0.001
	Post	12.5 $\pm$ 1.1	3.0–28.0	
Best corrected visual acuity (logMAR)	Pre	0.00 $\pm$ 0.11	0.10–(–0.10)	1.000
	Post	0.00 $\pm$ 0.10	0.10–(–0.10)	
Non-invasive tear film breakup time (s)	Pre	8.2 $\pm$ 0.6	2.1–16.3	0.001
	Post	11.0 $\pm$ 0.7	3.2–19.0	
Inferior eyelid meibography grade (% atrophy)	Pre	42.8 $\pm$ 1.5	23.3–61.0	0.121
	Post	40.4 $\pm$ 1.5	20.0–61.0	
Tear film lipid layer grade (out of 5)	Pre	3 $\pm$ 0	2–4	< 0.001
	Post	4 $\pm$ 0	4–5	
Meibomian gland expression (out of 4)	Pre	3 $\pm$ 0	2–3	0.055
	Post	3 $\pm$ 0	2–3	

### Symptoms

When analysing the CLDEQ-8 questionnaire, a consistent trend of decreasing symptoms was observed when comparing the mean scores obtained for each individual question (items 1–8) pre and post treatment. Notably, there was a marked decrease in the overall mean score after treatment with the light modulation LED mask (see Figure 1).

To evaluate the total score on the CLDEQ-8, the average values and their associated standard deviations between the participants were calculated: pre treatment:  $21.5 \pm 1.3$  and post treatment:  $12.5 \pm 1.2$ . The distribution of outcomes by scoring band is depicted by the graphs in Figures 2a and 2b. The probability areas of our samples were very roughly described by Gaussian curves, as illustrated.

After the use of the light modulation LED mask, dryness-related complaints were reported by only 57% of the wearers (24 out of 42 subjects) compared to 100% before the treatment. This indicated a reduction in CLD symptoms for nearly half of the participants to below the cut-off threshold. None of the individuals examined reported a worsening of their symptoms, and dryness symptoms decreased. Subsequent to the therapy, the results (linear regression and *t*-test) showed a significant improvement in CLD symptoms, with a statistical likelihood indicator of 100% (*t*-test=5.14; *p* < 0.001) ( $R^2 = 0.218$ ). The linear correlation of CLDEQ-8 questionnaire score pre and post treatment are illustrated in Figure 3.

### Visual function and tear assessment

No effect on vision was noted as a result of the treatment and no adverse events were reported by participants during the study. No significant changes in visual acuity were observed following the light modulation LED mask sessions, with an average value of  $0.00 \text{ LogMAR} \pm 0.11$ .

The objective tests revealed enhanced quality of the tear film after the treatment. Initially, 70% of the eyes (59 out of 84) had a NIBUT of less than 10 seconds. Following the treatment cycle, only 26% of the eyes had reduced NIBUT values, with the remaining 74% demonstrating a normal NIBUT value. This observation was statistically significant, with a *t*-test value of 3.06 (*p*=0.001) and an  $R^2$  value of 0.240, as illustrated in Figure 4.

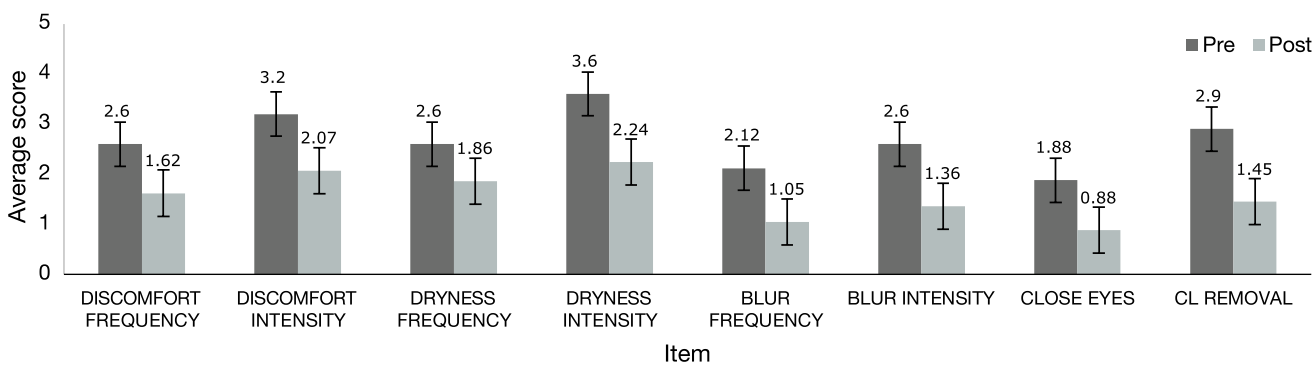


Figure 1: CLDEQ-8 questionnaire average score for each item at baseline and one week after the light modulation LED mask treatment cycle. Each bar represents the average score. Error bars represent the standard deviation.

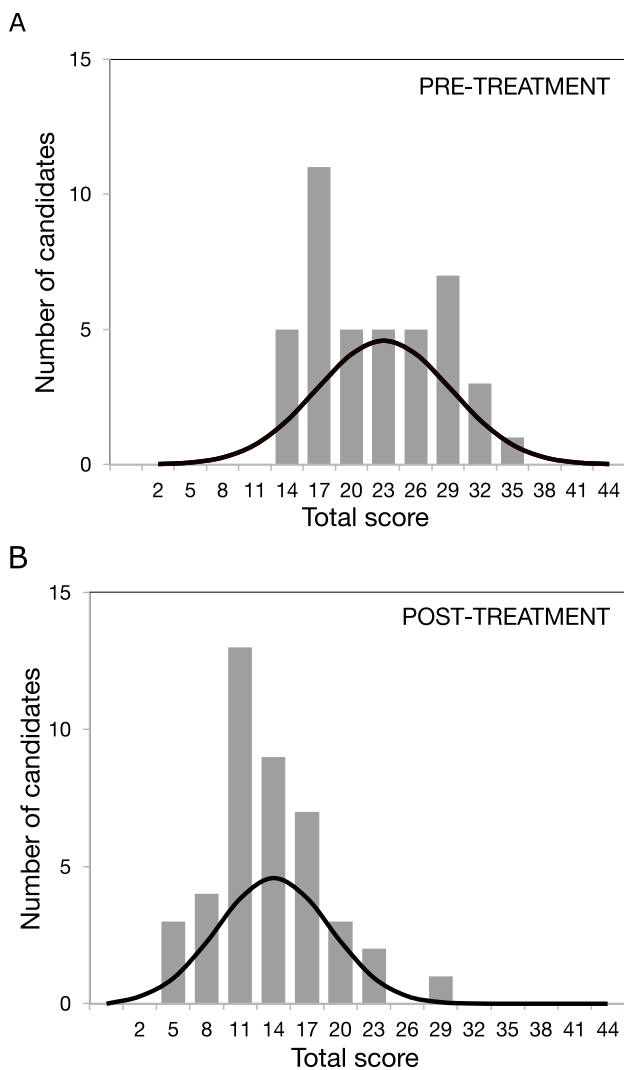


Figure 2: The distribution of CLDEQ-8 questionnaire score pre and post treatment. The scoring bands reflect the frequency of participants who obtained a particular score on the CLDEQ assessment, while the Gaussian curve depicts the probability distribution of the sample scores.

The TearScope data revealed variation among the participants with 26% of eyes having a lipid layer thinner than 50–70 nm before the treatment. However, post treatment every eye’s lipid layer showed significant increase of at least one degree on the Guillon scale, from  $3 \pm 1$  before to  $4 \pm 1$  after the treatment ( $t$ -test=10.90).

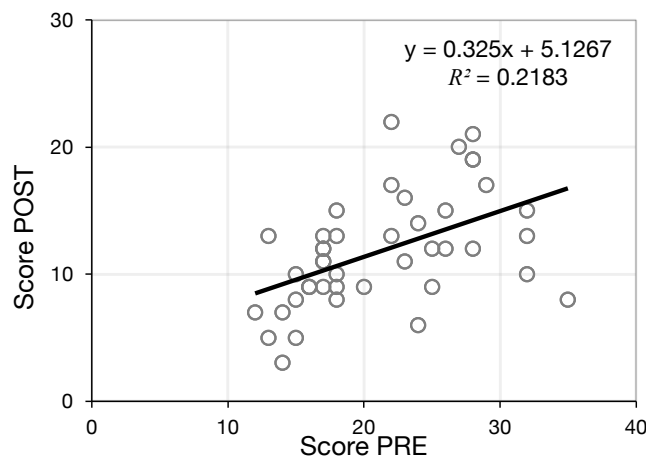


Figure 3: The linear correlation of CLDEQ-8 questionnaire score pre and post treatment. The graph relates the scores obtained from the questionnaire by each subject before (x-axis) and after (y-axis) the LLLT treatment. The slope of the line indicates the correlation between the CLDEQ-8 pre and post treatment.

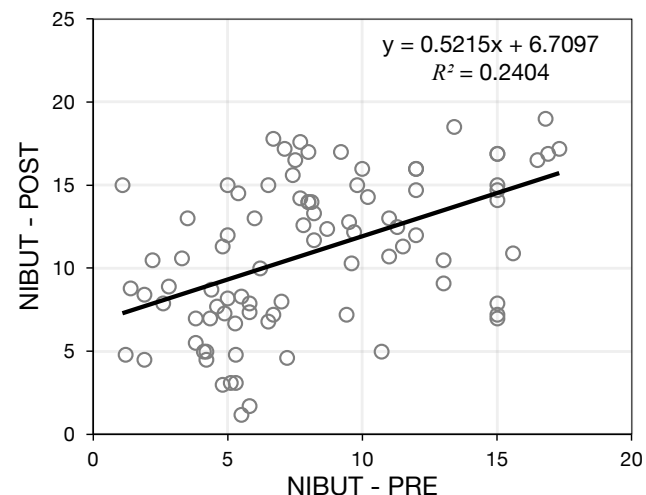


Figure 4: The linear correlation of NIBUT before and after treatment.

In the meibography analysis, the sample of eyes investigated showed an initial decrease of atrophy in the area of the MGs, to almost below the third degree on the Meiboscale (Pult classification, cut-off 3rd stage) (Meadows, 2011; Pult & Riede-Pult, 2012). The mean atrophy area post-treatment was calculated to be  $42.8 \pm 1.5$ . However, exposure to light modulation LED mask did not lead to a statistically significant change in meibography results, and changes were not always observed ( $t$ -test=1.17,  $p=0.121$ ) ( $R^2=0.872$ ) (see Figure 5).



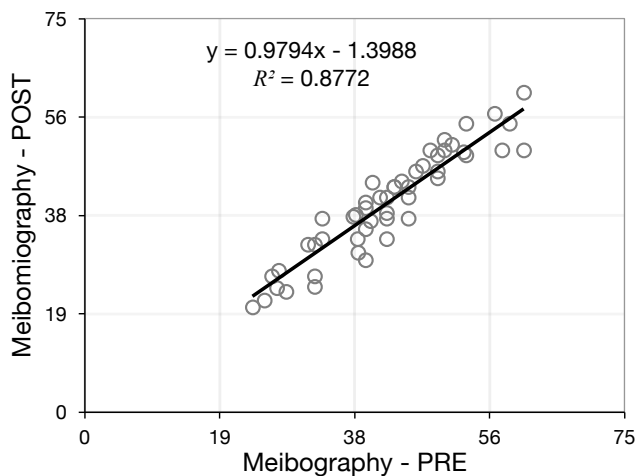


Figure 5: The linear correlation of meibography before and after treatment.

In the MG expression evaluation, all eyes were classed as grade 2 or 3 on the selected 4-degree scale (TearScience Gland Evaluator [Johnson&Johnson, US]). The majority of eyes (65%) presented normal secretion, which is characterised by a clear liquid secretion. Before the light modulation LED mask treatment, 35% of the observed glands (29 out of 84 eyes) showed slightly altered expressibility, which is characterised by opaque liquid. After treatment, this had decreased to 11% (9 out of 84) ( $t$ -test=1.61;  $p$ =0.055).

## Discussion

The results of the present study show that a two-week course of treatment with a light modulation LED mask led to a significant improvement in CLD symptoms and tear film measurements. The questionnaire responses indicated that almost half of the participants experienced a reduction in CLD and dry eye symptoms to below the cut-off level. All contact lens wearers reported improvement in symptoms such as dryness, burning, itching, and stability of vision. The overall trend of improvement observed in the study population suggested that there was better tolerance to the use of contact lenses after the treatment.

Within a short period of time, treatment with the light modulation LED mask improved tear stability, tear film lipid layer thickness, and MG expression. The treatment was even effective in tear film previously considered unstable due to the absence of homeostasis. Quantity and quality of flowing meibum was assessed following compression of the MGs (Chalmers et al., 2016). Despite most of the participants being within the normal range when entering the study, significant improvement in this parameter was observed after the treatment and an ideal condition was achieved. Furthermore, following the treatment, TearScope data indicated an increase of more than one degree in lipid layer thickness according to the Guillon scale. The expression of natural meibum is associated with improvement in tear film stability, as it strengthens the integrity of the surface lipid layer, which is necessary for inhibiting aqueous tear evaporation. Consequently, NIBUT values improved to above the cut-off of 10 s for almost all participants. The decrease of evaporation ensured the maintenance of the aqueous component of the tear film.

This data could also have included blink frequency and other factors to better understand their effect on contact lens comfort. This study cannot establish that improvement in tear film performance directly influences dryness symptoms associated with contact lens wear. We are also aware that CLD is affected not only by the quality of the tears but also by the chemical-physical

characteristics of the contact lens surface (Richdale et al., 2007).

Moreover, it is difficult to determine whether the effects detected in the current study might be due to the transient natural changes in tear film stability, which are recognised to be highly variable. The follow-up time of one week was also insufficient to demonstrate long-term effects.

Other limitations are that the study design can be subject to various sources of bias that can limit the interpretation of this findings. Furthermore, this study cannot establish causality. Unlike randomised controlled trials (RCT), observational studies do not involve randomly assigning participants to different treatment groups, so it is difficult to determine whether a particular exposure is truly responsible for an outcome (Pinqart, 2019). In addition, longer follow-up periods are required in future studies, further research is needed to determine the duration of improvements, and whether repeat treatments can stabilise or improve contact lens wear satisfaction.

However, based on this study, it is possible to argue that in the group of subjects analysed there was a general improvement such as to significantly reduce the CLD preliminary condition. LLLT treatment with the light modulation LED mask MY MASK device has proved to be an interesting option in improving the aspects that characterise CLD.

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## Behandling av ubehag i forbindelse med kontaktlinsebruk med MY MASK Light Modulation LED-maske

### Sammendrag

Målet med denne studien var å undersøke hvordan behandling med LED-maske (MY MASK) påvirker ubehag i forbindelse med kontaktlinsebruk.

Førtito mykлинsebrukere med symptomer på tørre øyne deltok i en tre uker lang studie. De ble behandlet med LED-masken tre ganger à 15 minutter; på dag 1, dag 3 og etter 1 uke.

Symptomer på ubehag i forbindelse med kontaktlinsebruk ble målt ved hjelp av et spørreskjema (CLDEQ-8) før og etter behandling. Øyets overflate, inkludert målinger av tårefilmen, ble undersøkt ved begynnelsen av studien og 1 uke etter siste behandling.

Visus var uendret ( $0.00 \log\text{MAR} \pm 0.10$ ). Antall symptoma-tiske linsebrukere var redusert med 43% (18 av 42 deltakere), i henhold til score på spørreskjemaet CLDEQ-8 ( $t\text{-test}=5.14$ ;  $p < 0.001$ ) ( $R^2 = 0.218$ ). Tårefilmstabilitet målt med "non-invasive tear film breakup time" (NIBUT) hadde signifikant bedring. Før behandling hadde 70% (59 av 84) av øynene NIBUT mindre enn 10 sek; etter behandling hadde 26% verdier lavere enn denne grenseverdien ( $t\text{-test}=3.06$ ;  $p = 0.001$ ) ( $R^2 = 0.241$ ). Meibografi viste ingen endring av øyelokkskjertlene ( $t\text{-test}=1.17$ ;  $p = 0.121$ ) ( $R^2 = 0.872$ ). TearScope viste betydelig økning tykkelsen på tårefilmens lipidlag og data fra Gland Evaluator viste også forbedring.

Behandling med LED-maske kan være et interessant alternativ for å redusere ubehag i forbindelse med kontaktlinsebruk. Det kreves ytterligere forskning for å fastslå grad av pålitelighet og undersøke nødvendigheten av gjentatte behandlinger for å stabilisere og sikre varighet av komfort hos linsebrukere.

*Nøkkelord: kontaktlinse, tørre øyne, ubehag, meibomske kjertler*

## Trattamento del Discomfort da Lenti a Contatto (CLD) con la Light Modulation LED mask MY MASK

### Riassunto

Lo scopo di questo studio è comprendere come l'uso della Light Modulation LED mask (MY MASK) influisca sul Discomfort da Lenti a Contatto (CLD).

Quarantadue (42) portatori di lenti a contatto morbide con sintomi di occhio secco sono stati reclutati per uno studio osservazionale descrittivo della durata di 3 settimane. Il trattamento con la Light Modulation LED mask è stato applicato tre volte, ciascuna sessione della durata di 15 minuti: il primo giorno, il terzo giorno e dopo una settimana. I sintomi di CLD sono stati quantificati mediante un questionario specifico (CLDEQ-8) prima e dopo il trattamento. Sono state inoltre effettuate misurazioni della superficie oculare e del film lacrimale all'inizio dello studio e una settimana dopo l'ultimo trattamento.

L'acuità visiva è rimasta stabile ( $0.00 \log\text{MAR} \pm 0.10$ ). Il numero di portatori di lenti a contatto sintomatici è diminuito del 43% (18 su 42 soggetti), come indicato dai punteggi CLDEQ-8 ( $t\text{-test}=5.14$ ;  $p < 0.001$ ) ( $R^2 = 0.218$ ). Il tempo di rottura del film lacrimale non invasivo (NIBUT) è migliorato in modo significativo. Prima del trattamento, il 70% degli occhi (59 su 84) presentava un NIBUT inferiore a 10 secondi; dopo il trattamento, solo il 26% aveva valori inferiori a questa soglia ( $t\text{-test}=3.06$ ;  $p = 0.001$ ) ( $R^2 = 0.241$ ). I valori della meibografia non hanno mostrato cambiamenti ( $t\text{-test}=1.17$ ;  $p = 0.121$ ) ( $R^2 = 0.872$ ). I dati ottenuti tramite TearScope hanno evidenziato un notevole miglioramento dello spessore dello strato lipidico del film lacrimale, e anche i dati ottenuti attraverso il Gland Evaluator hanno mostrato un miglioramento.

Il trattamento con la Light Modulation LED mask potrebbe rappresentare un'opzione interessante per migliorare gli aspetti che caratterizzano il CLD. Sono necessarie ulteriori ricerche per stabilire l'affidabilità del miglioramento osservato e indagare la necessità di trattamenti ripetuti come mezzo per stabilizzare o mantenere la soddisfazione nei portatori di lenti a contatto.

*Parole chiave: lenti a contatto, occhio secco, discomfort, ghiandole di Meibomio*