Effect of Face Mask on Tear Film Stability in Eyes With Moderate-to-Severe Dry Eye Disease

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Purpose: The purpose of this study was to evaluate whether tear film stability worsens with the use of masks in patients with dry eye disease, objectively analyzing the tear film stability using noninvasive tear film breakup time (NITBUT) with and without a face mask.

Methods: A cross-sectional study including patients with moderate or severe dry eye disease was conducted. Tear stability was measured using an Oculus Keratograph 5M (Oculus, Wetzlar, Germany), which records NITBUT, both first and average NITBUT. Two measurements were taken: an initial measurement with a mask and a second measurement after 10 minutes without wearing the face mask.

Results: Thirty-one patients were included with a mean age of 57.6 ± 11.7 years (range 31–80) and 30 being female (97%). Mean first NITBUT with face mask was 6.2 ± 3.8 seconds (range 2.0–19.8), which increased to 7.8 ± 5.6 seconds (range 2.3–24.0) without the use of mask ($P = 0.029$), differences being −1.6 ± 0.7 seconds (CI 95% −3.1075 to −0.1770). Mean average NITBUT with a face mask was 12.3 ± 4.8 seconds (range 4.0–19.4) and increased to 13.8 ± 5 seconds (range 5.5–24.0) without the use of mask ($P = 0.006$), mean difference being −1.5 ± 0.5 seconds (CI 95% −2.5290 to −0.4458).

Conclusions: Face mask use decreases tear film stability in patients with moderate-to-severe dry eye.

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Dry eye disease (DED) is a multifactorial disease characterized by a loss of homeostasis of the tear film, with an estimated prevalence of up to one-third of the global population. Most common symptoms include ocular discomfort, dryness, pain, foreign body sensation, and visual disturbance.[1] Diagnosis includes evaluation of signs and symptoms and conventional diagnostic tests such as the fluorescein tear film breakup and the Schirmer test offering unsatisfactory reliability and reproducibility.[2,3]

Because of the current coronavirus disease 2019 (COVID-19) pandemic, there is an increase in face mask use globally to decrease transmission.[4] There have been several reports describing ocular irritation and dryness associated with regular mask use.[5,6] However, there are no objective data to prove alterations in the tear film in this context. The likely continued use of masks in the near future and the high number of patients with dry eye who could see their condition worsened make the study of the tear film in mask users mandatory.

The development of multiple imaging devices has enabled visualization and evaluation of the tear film and ocular surface objectively. In this regard, noninvasive tear breakup time (NITBUT) can be objectively measured, reflecting the stability and quality of the tear film with excellent repeatability and reproducibility while overcoming the limitations of fluorescein tear breakup time measurements.[7–9]

This study was designed to investigate whether tear film stability worsens with the use of masks in patients with DED, objectively analyzing tear film stability using NITBUT with and without a face mask.

METHODS

This cross-sectional study was conducted at the Hospital Clinico San Carlos in Madrid. Patients from the Dry Eye Unit who had been classified as having moderate or severe DED were recruited. Written informed consent was obtained from all the patients, and the study had the approval of the Clinical Research Ethics Committee at the Hospital Clinico

San Carlos. The study was performed in accordance with the tenets of the Declaration of Helsinki.

Patients with moderate or severe DED according to the TFOS DEWS 2 report[10] were included. Exclusion criteria were patients under 18 years of age, use of contact lenses, previous ocular surgery, and use of topical treatment other than DED treatment. The medical records of the patients were thoroughly revised to identify the selection criteria.

The patient's age, sex, ophthalmological history, and topical treatment were noted. Every patient underwent an ophthalmic examination including best-corrected visual acuity and slit-lamp biomicroscopy to confirm the inclusion and exclusion criteria.

Tear stability analysis was measured using an Oculus Keratograph 5M (Oculus, Wetzlar, Germany). This device consists of a keratometer with placid rings projected onto the cornea and a color camera optimized for external imaging, which records noninvasive tear film breakup time (NITBUT), among other measurements. To measure tear stability, the instrument is aligned at the pupil center and NITBUT measurement starts when the patient blinks. The video recording lasts up to a maximum of 25 seconds, or until the patient blinks, whichever occurs first. NITBUT is measured as the time in seconds between the last complete blink and the first perturbation of the placid rings projected onto the surface of the cornea, which the device automatically detects. The device displays 2 values generated automatically by the digital imaging software: first NITBUT (the time at which the first breakup of the tear film occurs) and average NITBUT (the average time of all the breakup incidents), which were both included for analysis.

In this study, 2 measurements were taken: an initial measurement with the patient wearing a face mask and a second measurement without wearing the mask. Patients confirmed to have been wearing the mask for at least 30 minutes before the examination and ten-minute intervals without masks between measurements ensured subsidence of effects for each examination. Testing was conducted under ambient conditions of temperature (20°C) and humidity (40%–50%) in an isolated room, with the appropriated health care conditions being considered. The room was ventilated between patients. The right eye of each patient was included for analysis, unless it did not meet the above inclusion-exclusion criteria in which case the left eye was selected. No drops were placed before examination. Patients with cloth or taped masks were not included. Data collection comprised first NITBUT and average NITBUT of both with-mask and without-mask measurements.

The sample size calculation was performed using GRANMO (7.2 software, Barcelona, Spain). To achieve a power beta of 0.8 with an alpha of 0.5 and a P value of 0.05, a sample of 18 patients was estimated to detect a difference of equal to or greater than 1 unit, assuming a standard deviation of 1.5 units. Statistical analysis was performed using SPSS v22.0 (SPSS, Chicago, IL). Study parameters were represented by their mean, along with their standard deviation (SD), and range. Differences between the groups were investigated using the paired t test, considering $P < 0.05$ as statistically significant.

RESULTS

Forty patients with DED were initially included, but 9 patients were excluded after written consent had been given because of insufficient NITBUT or poor-quality analysis, leaving a final sample of 31 patients with DED (30 women, 97%). The mean age of the patients was 57.6 ± 11.7 years (range 31–80).

Regarding treatment for DED, all patients were on lubricating eye drops, 5 patients (16%) were on topical cyclosporine, and 24 patients (77%) were on autologous serum. All patients were classified as having a moderate or severe form of DED.

Keratograph 5M analysis revealed a mean first NITBUT with face mask of 6.2 ± 3.8 seconds (range 2.0–19.8), which increased to 7.8 ± 5.6 seconds (range 2.3–24.0) without the use of mask (P= 0.029). The mean average NITBUT with face mask was 12.3 ± 4.8 seconds (range 4.0–19.4), and it increased to 13.8 ± 5 seconds (range 5.5–24.0) without the use of mask, differences being statistically significant (P= 0.006) (Fig. 1). The mean difference in first NITBUT was −1.6 ± 0.7 seconds (CI 95% −3.1075 to −0.1770), whereas the mean difference in average NITBUT was −1.5 ± 0.5 seconds (CI 95% −2.5290 to −0.4458). Figure 2 illustrates the changes of first NITBUT and average NITBUT with and without a face mask in one of the patients included.

DISCUSSION

This study aimed to assess whether the use of masks produces an alteration in the tear film by means of the NITBUT analysis using the Oculus Keratograph 5M, which provides a simple, noninvasive screening test for dry eye. Our results revealed that mask use decreases both first NITBUT and average NITBUT in patients with moderate-to-severe DED.

There is increasing evidence that during the COVID-19 pandemic, the prevalence of ocular discomfort symptoms has

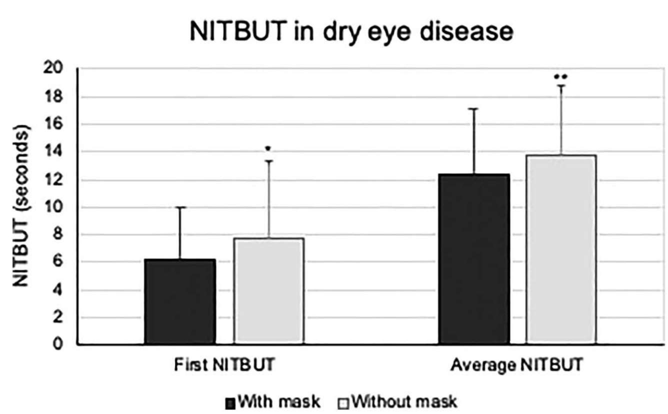

FIGURE 1. First NITBUT and average NITBUT in patients with dry eye disease with and without wearing a face mask. Significant differences were noted between the values of first NITBUT and average NITBUT depending on the use of mask. *$P < 0.05$ compared to with the mask on, whereas **$P < 0.01$ compared to with the mask on.

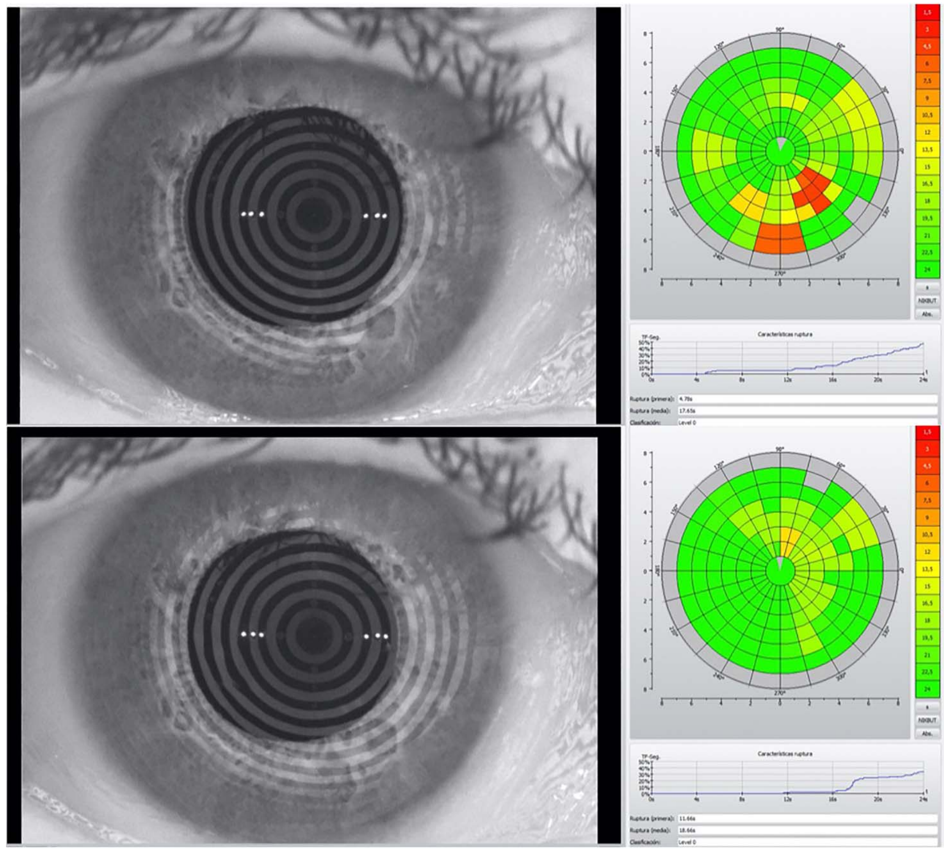

FIGURE 2. A representative Keratograph 5 (Oculus, Wetzlar, Germany) report of the NITBUT measurements of the right eye of a patient included in this study. Real-time images of the first breakup time were obtained with face mask (A) and without wearing a face mask (B). The report includes a video showing the distortion of the mire patterns over time, a color-coded polagraphic grid showing breakup time progression, and NITBUT (both first and average) by tear film segment against time plot with tear film stability classified by levels 0, 1, and 2 according to the average breakup value. Level 0 represents a stable tear film of greater than or equal to 14 seconds. Level 1 represents a critical tear film of greater than 7 seconds but less than 14 seconds, and level 2 represents an unstable tear film of less than 7 seconds. (The full color version of this figure is available at www.corneajrnl.com.)

increased, being in some cases related to the use of masks. In fact, regular mask wearers have reported more eye irritation, tearing, and red eye, with a subjective worsening in symptoms assessed in the Ocular Surface Disease Index. A deterioration in corneal staining and an increase in dryness reported by cataract patients on postoperative day 1 have also been considered by Moshirfar et al[5] to prove these changes. In a survey among 107 healthy students (mean age 28.5 years; 64.5% women), 72 (67.3%) reported to use face mask for more than 6 hours daily. Eleven participants (10.3%) described appearance or worsening of ocular discomfort symptoms, and 21 (19.6%) reported the need for daily use of tear substitutes.[6] However, no objective data have been reported.

This study shows that the use of face masks reduces both first NITBUT and average NITBUT by 1.6 ± 0.7 seconds and 1.5 ± 0.5 seconds, respectively, measured using the Keratograph 5M. NITBUT presents a good correlation with dry eye symptoms and represents a good diagnostic value for DED and for treatment response.[10,11] NITBUT measured using the Keratograph 5M presents good repeatability and reproducibility. Hong et al reported an intraclass correlation (ICC) ≥ 0.75 for all keratograph measurements, intraexaminer repeatability for NITBUT being better in DED compared with healthy patients. Hong et al noted good ICC values of NITBUT for intraobserver (0.93) and interobserver repeatability (0.88).[8,9] Therefore, keratograph offers simple noninvasive and repeatable measurements, and this is the first report in the literature to quantify the effect that the use of face masks in the COVID-19 pandemic is having in patients with DED.

These alterations in the tear film stability because of the use of masks may be caused by different mechanisms. First, the air that is exhaled rises and may leave the upper part of the mask if it is displaced or incorrectly fitted, being able to reach the ocular surface, which some mask users refer.[5] This movement of air over the surface helps the tear film to evaporate, leaving a poorly lubricated ocular surface. Giannaccare et al[6] suggested a similarity with continuous positive airway pressure users but to a lesser extent. Continuous positive airway pressure therapy has proven to cause increased ocular irritation, epiphora, tear evaporation, and conjunctival squamous metaplasia, which can lead to ocular complications.[12–14] The use of powered air-purifying respirators and protective integrated hood/mask also associates increased perceptions of eye dryness and epithelial, punctate keratopathy probably because of how the full facepiece directs air upward toward the eyes.[15,16] Therefore, there are many studies suggesting that increased air convection affects the eye, but this has not been firmly established in the context of face mask use.

Furthermore, the use of taped masks to prevent air convection toward the eyes may interfere with the normal lower eyelid position, possibly inducing mechanical ectropion and tear evaporation. The tape may cause tension in the eyelid, causing lagophthalmos or reducing blinking and risking exposure keratopathy because of altered tear stability.[5] In addition, an increase in the ventilation of closed spaces could aggravate further these phenomena.

The key role of the tear film and its stability as a barrier against pathogens should also be considered. Increased tear evaporation because of mask use, along with increased eye rubbing and face touching behaviors because of discomfort symptoms, may alter the ocular surface and worsen tear film breakdown.[17] Dry eye disease may exacerbate in these patients, increasing the risk of secondary infections, keratitis, exposure keratopathy, and other potential epithelial breakdown consequences to prolonged face mask wearing.[18] In fact, lactoferrin plays an important role against microbial and viral infections and exerts anti-inflammatory effects; Campione et al[19] suggested that it could even could counteract the SARS-CoV-2 infection. This is especially concerning given that the novel coronavirus has proved to spread through this route.[20] Hence, a thorough analysis of tear film changes in the COVID-19 era in these patients is mandatory.

Some limitations of this study should be acknowledged. Only patients with moderate-to-severe dry eye who attended the Dry Eye Unit have been studied, and examination was only performed with a mask to avoid risk of contagion. Although initially planned, controls were finally not included as a precaution to avoid healthy people's unnecessary visits to the hospital in the current pandemic. Moreover, there are more variables that determine DED and dry eye symptoms, but they are difficult to reproduce and to use to analyze changes with and without masks; therefore, only NITBUT was selected. Further studies may include a wider spectrum of measurements related to DED to investigate more thoroughly the effect of mask use on the ocular surface. Nevertheless, evidence of alterations in the ocular surface with prolonged mask use is absent from the literature, and this is the first study to date in the COVID-19 era to objectively analyze tear film changes with the use of masks.

In conclusion, awareness among ophthalmologists of DED worsening associated with COVID-19 measures should be increased. Emphasis should be made to avoid mask displacement or incorrect fitting that contributes to air leaking among patients with DED and consider increasing treatment for long-term mask users if there is previous history of DED, recent ophthalmic surgery, or other surface inflammatory diseases. Notwithstanding, the use of face mask is still crucial in this pandemic, and patients with moderate-to-severe dry eye should not be dissuaded from wearing face masks.

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