Does continuous wear of a face mask affect your tear film?

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Abstract---The study's objective was to assess the effect of type of mask wear and duration, including short-term wear of mask on TBUT. This was a cross-sectional, comparative study. A total of 90 subjects were categorized into three groups, each comprising 30 subjects. Either the groups were given a surgical, cloth, or N95 masks to wear. Baseline TBUT was collected after 30 mins without mask wear; subsequently after 1 min of mask wear and after every 30 mins for 3.5 hours among all the three groups. TBUT changes within the groups and between the groups were compared using Friedman ANOVA and the Kruskal Wallis test. TBUT was stable among N95 wearers for first 30 minutes and declined among cloth & surgical mask users. A continuous significant difference was evident only from 2 hours among surgical and cloth mask users and at 3.5 hours within N95 users. N95 wearers have a higher TBUT, and surgical having the least. Surgical mask wears significantly influence tear film stability, followed by cloth mask wear because of air leak from nose wire. TBUT is minimally affected by N95 wear.

Introduction

A thin tear film covers the ocular surface. *The tear film* is a trilaminar structure compactly arranged with superior lipid, middle aqueous, and inferior mucin layers. This trilaminar structure abides with a complex interaction and provides lubrication to the ocular surface. It also protects the cornea from microbes, promotes metabolic functions and corneal transparency [1, 2, 3]. Aqueous and mucin layer is considered a single layer due to lack of clear boundaries differentiating between two, hence referred to as mucoaqueous layer or mucoaqueous pool (Map) [4]. The boundaries and real thickness of tear film are varied greatly in the literature and range between 3 µm to 6.5 µm [5, 6].

Abnormalities in tear constituents or meibomian gland dysfunction will lead to Dry eye abnormality [7, 8]. Exposure Dry eye is much higher among the patients with mechanical ventilation [9]. Similarly, any lid anatomical disturbances such as ectropion will also induce exposure related dry eye [10]. Since the onset of the pandemic, wearing masks has become a new normal in addition to the other safety precautions. Ocular irritation and dryness are the major concerns of PPE (personal protective equipment), the masks especially [11]. The symptoms of dryness and irritation worsened after prolonged mask usage. Clinical symptoms such as irritation and dryness after prolonged mask use are well known [12]. The mask usage creates an effect analogous to mechanical ventilation by creating a fog formation, especially among the spectacle wearers with the mask.

Aims

The earlier studies evidenced the incidence of dry eyes and ocular irritation with mask usage. The magnitude of tear stability with continuous increase in mask wear time is unknown within the short period and among the different mask users. The current study aims to find the association of tear film stability with prolonged mask usage in short intervals, effects of different mask type and precept a wearing schedule for mask usage.

Materials and Methods

The current study is a prospective cross-sectional study. A sample of 180 student participants from Centurion University of Technology and Management was involved. The participants included were 18 years or older, with no history of contact lens wear, not using any topical medications, and having normal corneal and anterior segment findings. All the participants with any ocular surface diseases and irregularities, positive fluorescein corneal staining, Schirmer's with less than 5mm, met with any ocular trauma, glaucoma, infections, underwent any ocular surgery in past two years, anyone with any systemic illness and or constitutional symptoms are excluded from the study. This study is conducted in accordance with the guidelines of the Declaration of Helsinki. Each participant is given informed consent before enrolling in the study.

A preliminary examination including Distance and Near Visual Acuity, Objective and Subjective Refraction is performed prior to the slit lamp examination. The quantity of tears was evaluated using Schirmer's 1 B (using Tear strips, 35 mm x 5mm). Following the COVID19 safety protocols, continuous mask wear is ensured during all these procedures except while collecting baseline values. Before collecting baseline measurements, the study ensured that each participant would remain without a face mask for 30 minutes to make that the TBUT was free from the mask impact. We ensured that participants maintained an appropriate social distance, by asking the participants to sit in a waiting room and kept under video surveillance. After collecting the baseline data, each participant was asked to wear either a cloth mask, surgical mask, or N95 (NIOSH-approved respirators). We make sure that each mask is multi-layered and the wear has a nose wire to ensure a proper fit over the nose and mouth to prevent air leaks. Masks that have exhalation vents or with thin fabrics are omitted. After collecting baseline TBUT, every 30 participants are provided with any of the masks as mentioned above and asked to wear them continuously for 3.5 hours. TBUT is measured initially after 1 minute of mask wear and after every 30 minutes periodically till 3.5 hours. Data is collected independently by two different examiners, MS & SM or SG, to assess the inter-observer agreement. All the measurements were repeated thrice, and an average of three readings was considered.

Statistical analysis

The normality of the data was assessed using the Shapiro-Wilk test. The TBUT changes with mask usage and increased time were assessed using Friedman ANOVA. Accordingly, we performed a post hoc analysis to identify the TBUT changes with increased wear time in detail. The reproducibility of the data is statistically analyzed using the Bland-Altman method. We used the Kruskal-Wallis 1- way analysis of variance test to assess the effect on TBUT with different mask use.

Results

A total of 90 (180 eyes) subjects (76 females) were involved in this study, with a mean & SD subject age was 21.2 years ±3.6 years. A total of 30 subjects were asked to wear Surgical masks, other 30 cloth masks, and another 30 participants N95 masks; the TBUT is assessed before 30 minutes of mask wear as a baseline, immediately after 1 minute of mask wear, and after every 30 minutes of mask wear for continuous three and half hours. TBUT of nine measurements obtained from each mask wear type user. See table **1**. Each participant is recruited for 4 hours.

Table 1: TBUT measurements made at time intervals mentioned

TBUT measurement number	Timelapse
Baseline TBUT	After 30 mins without mask wear
2nd TBUT	After 1 min of mask wear

3rd TBUT	After 30 mins of mask wear
4th TBUT	After 1 hour of mask wear
5th TBUT	After 1.5 hours of mask wear
6th TBUT	After 2 hours of mask wear
7th TBUT	After 2.5 hours of mask wear
8th TBUT	After 3 hours of mask wear
9th TBUT	After 3.5 hours of mask wear

The Bland-Altman for the inter-observer agreement indicated a high reproducibility of all nine consecutive TBUT measurements among the three types of mask wearers. With an increase in mask wear duration, there is a significant decrease in TBUT. Freidman's ANOVA test revealed a statistically significant effect of duration of mask wear on TBUT among all the mask types; Post hoc analysis with Wilcoxon signed-rank tests was conducted with a Bonferroni correction applied, resulting in a significance level set at $p < 0.005$. Within the surgical mask users have a chi-square value of $x2$ $(8, n= 60) = 156.67$, $=0.000$. Compared to baseline TBUT Median (used as Md hereafter) value Md 6 sec; TBUT declined to Md 5 sec, p= 0.001 after 30 mins, and maintained the same at 2 hours and 2.5 hours with p = 0.000. TBUT further declined to Md 4sec, p=0.000 after 3 hours and Md 3 sec p =0.000 after 3.5 hours (see table 2).

A similar effect is observed among cloth mask users as well. Chi-square showed $x2$ $(8, n= 60) = 60.81$, $=0.000$. Compared to the baseline value Md 6sec, TBUT declined to Md 5 seconds after 30 mins, p =0.000, then rocketed with Md 7 sec after 2 hours, p = 0.000. In contrast after 2 hours, TBUT progressively waned to Md 6 sec at 2.5 hours, Md 5 sec at 3 hours, and Md 4 sec at 3.5 hours with p=0.000 (see table 2). On the other hand, among N95 mask users, TBUT is much more stable. Chi-square showed $x2$ $(8, n= 60) = 26.39$ $=0.000$. TBUT declined from baseline Md 7 sec to Md 6 sec only after 3.5 hours with p= 0.003(see table 2).

Table 2: Trend of TBUT with increased duration of mask wear

Baseline compared to time at which TBUT measured	Surgical Mask			Cloth Mask			N95 Mask		
	Md (x to y)	P Value	x2 ANOVA (8 ; 60) & Overall Significance P<0.05	*Md (x to y)*	P Value	x2 ANOVA (8 ; 60) & Overall Significance P<0.05	*Md (x to y)*	P Value	x2 ANOVA (8 ; 60) & Overall Significance P<0.05
Baseline v/s 1 min	6 to 6.5	0.519		6 to 6	0.519		7 to 7	0.711	
Baseline v/s 30mins	6 to 5	0.000		6 to 5	0.000		7 to 6.5	0.325	
Baseline v/s 1 hour	6 to 6	0.092		6 to 6	0.092		7 to 7	0.378	

Baseline v/s 1.5 hours	6 to 6	0.017	156.67	6 to 5	0.017	60.81	7 to 7	0.593	26.39
Baseline v/s 2 hours	6 to 5	0.000	&	6 to 7	0.000	&	7 to 7	0.342	&
Baseline v/s 2.5 hours	6 to 5	0.000	P=0.000	6 to 6	0.000	P=0.000	7 to 7	0.824	P=0.001
Baseline v/s 3 hours	6 to 4	0.000		6 to 5	0.000		7 to 7	0.117	
Baseline v/s 3.5 hours	6 to 3	0.000		6 to 4	0.000		7 to 6	0.003	

*Md = median in seconds *x= baseline TBUT, *y= TBUT with increased mask time, *x2 ANOVA = Chi-square Analysis of variance, *8= degrees of freedom, *60= sample size, *in P values bold indicates significant values (≤0.005) after Bonferroni correction

Among all the three mask wearers, Kruskal-Walli's test revealed no significant differences for TBUT measurements till 1.5 hours. However, there was a subsequent continuous significant difference after 2 hours of mask wear (p=0.002), and (P = 0.000) after 2.5 hours to 3.5 hours. Among Surgical, Cloth, and N95 mask wearers, N95 wearers have a higher TBUT, and surgical have the least TBUT. See Table **3**.

Table 3: Median TBUT in seconds among different mask wearers with P values

Time period of mask wear	Median TBUT in Sec			P value
	Surgical Mask	Cloth Mask	N95 Mask	
1 minute	6.5	6	7	0.678
30 minutes	5	5	6.5	0.611
1 hour	6	6	7	0.004
1.5 hours	6	5	7	0.177
2 hours	5	7	7	0.002*
2.5 hours	5	6	7	0.000*
3 hours	4	5	7	0.000*
3.5 hours	3	4	6	0.000*

*Bold indicates significant values ≤0.05

Discussion

Wearing a mask for long hours has a significant influence on TBUT. The impact of TBUT is more seen among cloth mask users and surgical mask users. In contrast, the impact of TBUT on N95 mask usage is much lesser. Friedman ANOVA showed a decline of TBUT from Md 6 sec to Md 4 sec among the cloth mask wearers and from Md 6.5sec to Md 3 sec in surgical mask wearers, whereas, N95 wearers TBUT showed a slight shift from Md7 sec to Md6 sec only after 3.5hours of mask wear. A significant difference is noted only after 30 mins of mask wear among surgical and cloth mask users and after 3.5 hours in N95 users. In a study, among moderate to severe dry eye patients, the mean NITBUT measured with mask showed 6.2 ± 3.8 seconds, which improved to 7.8 ± 5.6 seconds after 10 mins of mask removal [13]. In the current study, we did not find any significant difference from the baseline TBUT measured after 30 mins without mask wear to TBUT measured immediately after 1 min of mask wear, which could be probably due to the lesser influence of mask on tear film within 1 minute.

Mask usage is made mandatory with the onset of novel coronavirus. Dry eye symptoms among the regular mask wearers have become frequent. Few cases with corneal erosions post mask wear induced dryness have been reported [14]. Higher incidence of dry eye and greater OSDI scores are prevalent among healthcare workers who wear masks for more than 6 hours [15]. Higher OSDI scores were commonly reported among continuous mask users. It is higher among women than men, higher with existing dry eye disease, and higher among 3 to 6 hours of mask wearers [16, 17]. Reduced tear quantity after wearing respiratory PPE, including facemasks and respirators, is also seen. Schirmer's values reduced by 3mm after 8 hours of PPE usage [18].

Exacerbations of symptoms are also self-reported during the mask use and shown mask associated dry eye [19]. Mask usage also significantly impacts contact lens users during the pandemic. Contact lens wear hours have declined among the mask users due to experienced dry eye symptoms [20]. Dendritic cell quantification and corneal nerve morphological changes are some of the typical cellular indicators of inflammation in DED (Dry eye disease hereafter) [21]. The face mask users who had an earlier diagnosis of DED showed an increase in DCD (dendritic cell density) and HLA-DR (Human Leukocyte Antigen – DR isotype). DCD & HLA-DR has also significantly increased among healthy individuals wearing masks for more than 6 hours a day. It also has an impact on quality of life. This evidence that the facemask will induce inflammatory changes leading to dry eye [22]. Widespread use of mask wear is also associated with an increased incidence of chalazion. The disruption in hydration of meibomian glands and evaporative dry eye could be the common cause among the mask wearers [23].

In comparing TBUT among the three different masks from Kruskal-Wallis, N95 has shown superior tear film stability with Md 6 sec after 3.5 hours, whereas surgical mask wearers have greater instability of tear film with tear film TBUT Md 3sec after 3.5 hours. Improper usage of masks will impact TBUT and dry eye symptoms. We subjectively asked about the watering and fog formation on the glasses in which most of the cloth mask and surgical mask users reported the presence of tearing initially after mask wear and fogging of glasses. Additionally, on visual inspection, we identified that the nose wire is not accurately bound to the nose causing the air to flow out, especially among the cloth and surgical mask users, and this is minimal or nil among the N95 users in which nose wire is accurate to sit on the nose & mouth without air leaks. In a study, increased mask wear showed a significant effect on TBUT, baseline TBUT of 13.03±2.18 seconds(s) and varied to 9.12±1.85 sec post 8 hours of mask wear. Schirmer's baseline of 16.87±3.01 mm at baseline varied to 12.97±2.74 mm after 8 hours of mask wear. When the subjects were taped their masks properly at the nose and reassessed TBUT after 15 days of mask wear, TBUT improved to 12.78±2.05 sec and Schirmer's to 17.01±2.95 mm [24]. Similarly, in a questionnaire study, dry eye symptoms are predominantly seen only among single mask wearers compared to double mask wearers [25].

The mask wear essentially controls the spread of the virus. Dry eye symptoms are solely due to air leakage or blowing up air from the leaks affecting the tear film directly among the mask users. The proper usage of masks can minimize dry eye symptoms. All the masks should be appropriately bound to the nose without any

leaks. Superior designs of masks such as N95 are best to control the virus spread and to minimize dry eye symptoms.

Conclusion

With Pandemic onset, mask usage has become mandatory to restrict the virus expansion. Although mask wear is an effective way to restrict virus spread, it also negatively influences ocular health in the form of dry eyes and early tear break up. The primary cause is due to the air blown up from the masks. Surgical mask users are highly prone to have lesser TBUT with more significant air leaks than cloth and N95 masks. Better mask designs without leaks will reduce the influence of TBUT, thereby reducing the symptoms of Dry eye.

Acknowledgement

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List of Abbreviations used:
ANOVA = Analyses of Variance
DCD = Dendritic Cell Density
DED = Dry Eye Disease
HLA – DR = Human Leukocyte Antigen – DR isotype
OSDI = Ocular Surface Disease Index
PPE = Personal Protective Equipment
TBUT = Tear Film Break Up Time

Authors contributions:

1) First Author: Sony Gunaganti – Data collection, Data analysis and interpretation, critical revision of manuscript
2) Co-first & Corresponding author: Manisai Koduri – Conceptualization and design of research, Data collection, critical revision and final approval
3) Second Author: Sravani Mereddy – Data collection