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Effect of Taping Face Masks on Quantitative Particle Counts Near the Eye: Implications for Intravitreal Injections in the COVID-19 Era

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• PURPOSE: To determine the effect of taping the top of face masks on air particle counts directed toward the eye during simulated intravitreal injections.
• DESIGN: Prospective observational crossover study.
• METHODS: Thirteen healthy subjects were recruited. Each wore a cloth, surgical, or N95 mask in randomized order. The number of air particles were quantified by using a particle counter suspended over the right eye while each subject breathed normally, deeply, or spoke using a standardized script. Particle counts were obtained with the top of each mask taped and not taped. The main outcome measurements were particle counts of 0.3, 0.5, 1, 3, 5, and 10 μm and total particle counts.
• RESULTS: Taping cloth masks while subjects were speaking significantly reduced particle counts for the 0.3- (P = .03), 0.5- (P = .01), and 1-μm (P = .03) particles and total particle counts (P = .008) compared to no taping. Taping the top of cloth masks during normal or deep breathing did not significantly affect particle counts compared to no taping. Taping the top of surgical or N95 masks did not significantly alter particle counts for any breathing condition tested.
• CONCLUSIONS: Taping the top of cloth masks prior to simulated intravitreal injections significantly reduced air particle counts directed toward the eye when subjects were speaking compared to no taping. This may have implications for decreasing air particles reaching the eye during intravitreal injections, including aerosolized droplets from a patient's mouth that may carry oral pathogens. (Am J Ophthalmol 2021;225: 166–171. © 2021 Elsevier Inc. All rights reserved.)

Endophthalmitis is a feared complication of intravitreal injections, with high morbidity, including blindness.1 The post-injection endophthalmitis rate in published studies ranges from 0.021% to 0.1%, with one meta-analysis of 43 studies that found an overall rate of 0.056%.2-7 The increased use of intravitreal injections to treat age-related macular degeneration, diabetic retinopathy, and macular edema due to retinal vein occlusion have made it a common procedure, with more than 5.9 million injections delivered as of 2016.8 This high number of injections yields a significant number of endophthalmitis cases, even though this complication is relatively rare. Multiple studies have concluded that oral flora increase the risk of poor outcomes from endophthalmitis, although how often the flora come from the injecting physician versus the patient is currently unknown.5,9 Some studies have demonstrated decreased rates of oral flora-associated endophthalmitis with either a “no talking” policy or physician use of a face mask.10,11 Euretina Expert Consensus established guidelines in 2018 of a “no talking” policy and use of a surgical mask for physicians during injections to protect patients from physician flora.6

The coronavirus disease 2019 (COVID-19) pandemic has led to patients and physicians wearing masks during office visits, including during intravitreal injections. Although one might expect that universal masking would decrease the risk of oral flora contamination during the injection procedure, anecdotal reports of oral flora-related endophthalmitis during the COVID-19 pandemic have emerged. It is possible that a patient’s mask may direct aerosolized breath particles containing oral flora upward toward the eyes, thereby increasing the risk of oral flora-associated endophthalmitis. A previous study measured warm air flowing over the eyes with a thermal camera and found that surgical masks frequently directed airflow toward the eyes, heightening these concerns.12 One recommendation to reduce droplets is to tape the top of the mask to block airflow toward the eyes.12

The purpose of this study was to investigate the effect of taping the top of a face mask on quantitative air particle counts near the eyes. A reduction in air particle counts with taping may lend support to the premise that this simple, cost-effective intervention may reduce the risk of post-injection oral flora-associated endophthalmitis.
METHODS

This prospective, observational cohort study was conducted in accordance with the tenets of the Declaration of Helsinki and conformed to the Health Insurance Portability and Accountability Act. Institutional Review Board approval was obtained prior to initiation of the study from Wills Eye Hospital. Participants were required to be healthy adults from 18 to 80 years of age who were fit tested with an N95 mask and provided informed consent.

The study was conducted in an ophthalmic examination room within an outpatient retina clinic that had no specialized air filtration equipment, no positive or negative pressure ventilation systems, and no open windows. Each participant was seated on an ophthalmic examination chair that was reclined to 45 degrees, simulating the position used for an intravitreal injection procedure. A single investigator wearing an N95 mask and remaining silent was present in the room standing behind the examination chair for the duration of each experiment. The room door was closed during the experiment. During the study, each participant was asked to alternate wearing 3 types of masks in randomized order: 1) a 3-ply melt blown fabric, ear-loop surgical mask (Jiangyin City, Jiangsu Province, China) containing an internal malleable metal insert across the top of the mask allowing it to be molded around the nose for a snug fit; 2) a 3-layered cotton cloth mask with ear loops (model MASKN2; Hanes, Winston-Salem, North Carolina, USA) that did not contain any malleable insert to adjust the top of the mask around the nose; and 3) an N95 health care particulate respirator (model 1860; 3M, St. Paul, Minnesota, USA). In addition, measurements were taken with the masks taped and not taped for a total of 6 mask scenarios per individual. Masks were placed above the nostrils and centered on the nose. For the taped mask scenario, an 11-cm piece of paper tape (16-47310; McKesson, Irving, Texas, USA) was placed along the superior edge of the masks, straddling the mask and the participant’s skin in order to seal any gaps. For each mask scenario, 3 respiratory modes were tested. Each participant was asked to breathe normally, breathe deeply, or speak normally using a standardized script. Therefore, data for a total of eighteen permutations of varying mask scenarios and respiratory modes were collected per participant. For each participant, the order of respiratory mode for each mask was also randomized.

An AeroTrak handheld particle counter (HPC) (model 9306; TSI, Shoreview, Minnesota, USA) was used to quantify the number of particles for each mask scenario and respiratory mode permutation. This HPC is typically used for air quality measurements in clean rooms and measures the disruption of a laser beam by variably sized air particles passing through the inlet.13 The HPC was positioned on a tray table so that its air sampling inlet was aligned with the inferior border of the right supercil-}


typical arch of the participant and above the skin by <5 mm. Each participant was instructed to remain completely still during each trial. The HPC quantified the total number of particles and categorized the particle counts by set sizes (0.3, 0.5, 1, 3, 5, and 10 μm). A flow rate of 2.83 L/min was used, and each trial consisted of 1 minute of data collection. After each mask scenario trial, 1 minute was allowed to transpire before conducting the next and 5 minutes before each new subject in order to allow washout of ambient particles. Particle counts were zeroed before each new mask scenario began so that the counts reflected that mask scenario only rather than the sum of several trials. A zero check, ensuring a zero-particle count after sampling air after passing through a dense filter, was performed using the HPC prior to initiating the study.

• STATISTICAL METHODS: The Wilcoxon signed rank test was used, due to non-normally distributed particle counts, to test for paired differences between taped and non-taped particle counts for each combination of mask type and respiratory mode, at each particle size. All statistical analyses were carried out using SAS version 9.4 software (Cary, North Carolina, USA). A two-sided P value <.05 was considered statistically significant. Based on preliminary data from this study, with a 5% error rate and an 80% power, we would need 13 pairs of observations (taped vs. non-taped, effect size = 0.75) for each experiment.

RESULTS

Thirteen healthy adults volunteered for this study: 10 men and 3 women with a median age of 26 (range, 24-35 years). None of the subjects had significant amounts of facial hair, such as a beard or mustache, and all had passed N95 fit testing.

• CLOTH MASKS: The Table shows the differences in particle counts of taped versus non-taped cloth masks by respiratory mode. Taping the top of cloth masks resulted in a mean decrease in total particles measured over a 1-minute period by 1,275.3 during normal breathing (P = .34) and 5,712.9 during talking (P = .008). A mean increase in total particles of 1,076.2 was found with taping during deep breathing (P = .41). As for specific particles sizes, taping the top of cloth masks during talking resulted in a significant decrease in 0.3-μm particles by 4,840.8 (P = .03); 0.5-μm particles by 488.7 (P = .01); and 1-μm particles by 112.5 (P = .03). No significant changes in particle counts were observed after taping cloth masks for larger particle classes or for other respiratory modes (normal and deep breathing).

• SURGICAL MASKS: Supplemental Table 2 shows the differences in particle counts with taped versus non-taped surgical masks by respiratory mode. Taping the top of
surgical masks resulted in a mean decrease in total particles measured over a 1-minute period by 3,210.7 particles during normal breathing (P = .89); 796.2 particles during deep breathing (P = .41); and 408.4 particles during talking (P = .89). Regarding specific particle sizes, taping the top of surgical masks resulted in no significant changes in particle counts for any of the particle classes or respiratory modes.

- **N95 MASKS**: Supplemental Table 3 shows the differences in particle count with taped versus non-taped N95 masks by respiratory mode. Taping the top of N95 masks resulted in a mean decrease in total particles measured over a 1-minute period by 2,381.5 particles during normal breathing (P = .38); 2,858.9 particles during deep breathing (P = .85); and 695.3 particles during talking (P = .41). Regarding specific particle sizes, taping the top of N95 masks resulted in no significant changes in particle counts for any of the particle classes or respiratory modes.

**DISCUSSION**

This study examined the effect of taping the top of various types of face masks on particle counts directed toward the eye. Results indicate that taping significantly reduced particle counts emitted from the top of cloth masks particularly for particles of ≤1μm during talking but did not appear to have a significant effect with the surgical or N95 mask during any of the tested respiratory modes.

Several studies have explored the effect of taping around masks but have not specifically explored airflow being redirected toward the eyes. A recent study found that the success rate of qualitative fit testing for N95 respirators can be increased by adding adhesive around the entire periphery of the mask, which suggests that taping may decrease counts of droplets directed toward the eyes, contrary to our findings. However, in that study, multiple pieces of adhesive were applied to the nose piece. The authors also used double-sided waterproof tape which might have created a more robust seal than the single-sided paper tape used in our study. In addition, it is not clear how success in qualitative fit testing translates to a reduced number of particles.
directed toward the eyes as that type of fit testing relies on subjective detection of aerosols entering around the mask rather than an exploration of the release of particles from the mask wearer. Subjects in that study also had previously failed qualitative fit testing, whereas all subjects in our study passed qualitative N95 fit testing. Another study used particle counters inside and outside various masks to measure particles entering behind the mask from the ambient air. The authors found that taping around the masks significantly reduced particle counts entering behind the masks. Although that study may suggest the inverse finding that taping should also decrease the number of particles escaping around the mask, it was not specifically designed to explore that. Finally, a recent qualitative video using a camera that detected carbon dioxide demonstrated that placing a surgical adhesive drape around the eye appeared to reduce the exhalation air jets directed toward the eye. Although the authors implied that taping the top of masks should have similar effects, they did not provide any direct evidence for that claim in the study.

The theory that patient face mask wear during the COVID-19 pandemic may be increasing the risk of oral flora-associated endophthalmitis by directing aerosolized particles toward the eyes is supported in a more quantitative manner by our study. Taping the top of cloth face masks significantly reduced air particles that were ≤1 μm. One study found that most exhaled bacterial flora come in aerosolized particles ranging from 0.5 μm to 1 μm in size, suggesting that this simple maneuver may be an effective deterrent. Another study demonstrated that higher counts of air particles in the 0.3, 0.5, and 5 μm sizes correlated with bacterial and fungal contamination in various room environments at a tertiary care hospital. One specific finding was that 0.3-μm particle counts >9,000/14.1 L of air sampled (212.77 particles/L) correlated with room contamination. Our study demonstrated a decrease in 0.3 μm particle counts of 4,840.85/2.83 L of air sampled (1,710.55 particles/L) with taping the top of cloth masks, which suggests that reducing air particle counts may have a clinically meaningful reduction in microbiological contamination. A third study found fewer colony-forming units on blood agar plates attached to subjects’ foreheads when the subjects wore a taped versus a non-taped mask. The fact that our study only found a significant decrease in particle counts with taping versus no taping when subjects were instructed to talk is clinically relevant in the setting of intravitreal injections. In some clinics, a technician will prepare a patient’s eye for injection prior to the physician entering the room to perform the procedure. Patients may converse with the technician or family members after the topical anesthetic and antiseptic drops have been applied and before receiving the injection, potentially leading to contamination of the conjunctival surface. Instead of taping the top of cloth masks, another option might be to request that the patient not speak after being prepared for injection as our study did not find a significant difference between taping and not taping with breathing alone. In addition, it may be less important to tape a properly fitted surgical or N95 mask. However, clinicians need to be mindful that patients may often not be wearing the surgical or N95 masks properly and may not have been properly fit tested for the N95 masks.

Several of the findings from our study were somewhat unanticipated. We did not detect any differences between taping and not taping the top of cloth masks when subjects were asked to breathe normally or deeply. Individual differences in breathing and changes in the ambient environment may have contributed to the observed high variations, especially given that the HPC is aspirating the air samples rather than passively quantifying what is passing over the sensor. In addition, by taping only the top of the masks, it is conceivable that air particles escaping from the sides of the mask may have still been detectable near the eyes. It is also possible that the tape itself may have influenced the results because the paper type that was used is described by the manufacturer as being air and moisture permeable. Perhaps, a less porous tape would have blocked air particles better, yielding a more significant difference between taping and not taping. Some of those factors may also explain why particle counts decreased for certain particle sizes and not others. In addition, there were significantly fewer counts in the larger size classes, which may have led to our study being underpowered to detect a difference. Another unexpected finding was that taping the top of surgical masks did not significantly decrease the detected particle counts. We suspect that the metal nasal bridge strip on the surgical mask allows it to conform better to the user’s facial anatomy thereby limiting air flow toward the eyes and making the difference in air particle counts between taping and not taping fairly similar. As expected, no significant difference was seen between taping and not taping N95 masks, likely due to the tighter seal.

Our study has several important limitations. Because each subject’s depth and frequency of ventilation was not controlled for during the various respiratory modes, this may have contributed to the observed high variations in particle counts. We attempted to mitigate this by giving each participant the same instructions on what constituted normal breathing, deep breathing, and talking. By collecting air samples for 1 minute and therefore allowing multiple breaths, the likelihood that 1 abnormal breath would bias the results should have been reduced. Another limitation was that the HPC was open to ambient air in the room, which was a standard clinic procedure room without special air filtration or ventilation systems. As a result, the ambient air in the room might have influenced the particle counts. We tried to reduce this risk by closing the door and using the same room for the entire study, which theoretically should have produced similar background levels of ambient air particles. It is also important to note that we only tested 3 specific mask types. Therefore, it may not be accurate to extrapolate the results to all masks, even those in the same class as materials and manufacturing likely vary by brand.
In addition, subjects involved in this study were healthy adults and generally younger than patients who typically receive intravitreal injections. Although we are unaware of any studies that have demonstrated differences in aerosol production by younger versus older subjects, it is possible that older individuals with specific medical conditions (e.g., chronic obstructive pulmonary disease with chronic cough) may generate different levels of aerosols. Finally, although it is reasonable to associate increased particle counts directed toward the eye with an increased risk of endophthalmitis, our study is not intended to prove this relationship. As a result, although our findings indicate that taping a cloth mask may reduce the aerosolized droplets that are directed toward the eyes when talking, it is not clear if this will truly reduce the risk of endophthalmitis.

In summary, this study demonstrated that taping the top of cloth masks appeared to reduce quantitative air particle counts reaching the eyes while subjects were speaking compared to no taping. However, no statistically significant reduction was detected during normal or deep breathing. Taping the top of surgical and N95 masks did not appear to have a significant effect on air particle counts. Theoretically, exhaled air particles and aerosols that are being directed toward the eyes due to the use of a patient mask during the COVID-19 pandemic may increase the risk of endophthalmitis after intravitreal injections or even intracocular surgery. As a result, taping the top of cloth masks, which appear to be one of the more common types worn by patients in the U.S., may help mitigate this infection risk. In addition, the type of tape used may also have an impact as more porous types may not provide as effective a barrier. However, additional larger studies comparing taping versus not taping of patients’ masks with various types of tape in a clinical setting will be needed to determine if this simple intervention actually has a meaningful impact on reducing endophthalmitis risk, particularly from oral flora.

TOC

Taping the top of cloth masks prior to simulated intravitreal injections significantly reduced quantitative air particle counts reaching the eye when subjects were speaking compared to no taping. This simple maneuver may have implications for decreasing air particles directed toward the eye during intravitreal injections, including aerosolized droplets from a patient’s mouth that may carry oral pathogens.

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