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Reports

Face Masks and Bacterial Dispersion Toward the Periorcular Area

During the coronavirus disease 2019 pandemic, patients wear face masks, creating unique airflow toward the ocular surface that may complicate ocular procedures such as intravitreal injections. It has been hypothesized that oropharyngeal droplets from either the patient or physician increase the risk of postinjection infectious endophthalmitis. Prior studies have demonstrated reduced bacterial growth on culture media with simulated injections when the physician uses a face mask1,2 and when implementing a no-talking policy.3 In this study, we set out to determine how a patient wearing a mask affects bacterial dispersal in the direction of the eye because this may be a factor for intravitreal injection-related endophthalmitis.

Using schlieren imaging, we qualitatively evaluated air currents with a face mask on. When focusing on the superior aspect of a participant wearing a mask, schlieren imaging showed air escaping from the superior aspect of the mask. The same mask with tape covering the superior aspect showed no significant airflow toward the eye (Fig 1).

Next, to determine if the redirected air toward the ocular surface contained more bacteria, we used blood agar plates and counted the colony-forming units (CFUs) with different methods of mask wearing. Institutional review board approval was obtained through the University of Wisconsin, and all research conducted adhered to the tenets of the Declaration of Helsinki. Consenting participants were all older than 18 years.

Blood agar plates with 5% sheep blood in tryptic soy agar base were incubated at 37°C in 5% carbon dioxide for 48 hours. Plates were brought to room temperature from their storage temperature of 4°C to eliminate variability in organism recovery rate based on initial incubation temperatures.4 Participants used a standard face mask with elastic earloops and a wire-containing nasal bridge (3M Company).

Control plates were held uncovered and perpendicular to the floor for 2 minutes away from the individual. In the subsequent groups, a blood agar plate was placed at each inferior orbital rim perpendicular to the floor. We enrolled 54 participants, and each performed the 5 scenarios below, in which they were instructed to speak or count aloud for 2 minutes (Fig S2, available at www.aaojournal.org): (1) control; (2) no face mask worn; (3) face mask fully covering the mouth, but placed just below the nose (inappropriate use); (4) face mask covering the mouth and nose (recommended use); and (5) face mask covering the mouth and nose, with paper adhesive tape applied to seal the superior portion of the mask.

The mean CFUs for each group were as follows: control, 0.24 (95% confidence interval [CI], 0.14–0.42); no mask, 1.93 (95% CI, 0.54–6.86); mask below the nose, 0.67 (95% CI, 0.34–1.30); mask appropriately worn, 0.35 (95% CI, 0.16–0.78); and taped mask group, 0.13 (95% CI, 0.06–0.29; Table S1 and Fig S3, available at www.aaojournal.org).

The taped mask group showed 81% (95% CI, 48%–93%; \( P = 0.001 \)) fewer CFUs than the group wearing a mask inappropriately below the nose. Fewer CFUs also were observed when the group appropriately wearing masks was compared with the group wearing masks below the nose (47% reduction; incidence rate ratio, 0.53; 95% CI, 0.32–0.87; \( P = 0.011 \)). Some suggestion (\( P = 0.08 \)) was found that taped masks showed a lower mean CFU compared with when masks are worn normally (incidence rate ratio, 0.37; 95% CI, 0.12–1.13). Taped masks also showed 73% fewer CFUs (95% CI, 26%–90% fewer; \( P = 0.011 \)) than the average CFUs for other nontaped forms of wearing a mask (appropriate and inappropriately worn grouped together).

We did not find taping the superior aspect of a mask to decrease bacterial dispersal toward the ocular surface when compared with an appropriately worn mask. Even more importantly, this study looked at only bacterial dispersal toward the ocular surface and did not evaluate for endophthalmitis; this would be extremely difficult owing to its low prevalence. We hypothesize that taping the superior aspect of a mask decreases dispersal of bacteria toward the eye based on the statistical trend and schlieren imaging taken together. Further studies are needed to evaluate bacterial dispersal.

During the planning stage of the study, we anticipated greater separation between these groups. Based on current best estimates, and still intending to detect at least a 2-fold separation between mean CFUs, a replication study involving only these 2 groups would need 72 participants to have an approximately 81% chance of identifying such an effect at the 0.05 level, assuming separation of at least that size genuinely exists.

Many recommend a no-talk policy, by both the physician and patient, during intravitreal injections to help prevent excessive bacterial dispersal toward the ocular surface. After a small pilot study, we chose to have the patients speak for 2 minutes because this did improve culture yields. But for our intravitreal injections performed in clinic, we have everyone in the room maintain a no-talk policy unless essential information needs to be relayed. Additional limitations of this study include not controlling for facial shape, anatomic features, or hair. We also did not determine what species of bacteria grew on these plates.

Other benefits may exist for taping face masks, because condensation often forms on glasses during acuity checks and on examination lenses during slit-lamp and indirect examination. Also, when the mask is taped to the patient’s face, it reduces the temptation for the patient to lower or remove the mask during the visit.

Overall, we did not show less bacteria being dispersed toward the ocular surface when comparing appropriately worn masks with masks with the superior edge taped. However, inappropriately worn masks direct more bacteria toward the ocular surface, and taping the superior aspect of masks redirects air away from the eye, as shown with schlieren imaging, but the clinical significance could not be determined in this study. These data should serve for hypothesis generation and should help to guide future directions for examining how taping the superior aspect of a mask affects bacterial dispersal.
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HUMAN SUBJECTS: Human subjects were included in this study. The Institutional Review Board at the University of Wisconsin approved the study. All research adhered to the tenets of the Declaration of Helsinki. All participants provided informed consent.

No animal subjects were included in this study.

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Figure 1. Schlieren imaging showing postimaging processing of a participant wearing (A, C) a facemask without tape and (B, D) a facemask with tape (outlined by dashed red lines) covering the superior aspect of the mask. The control with (A, B) no breathing and (C, D) breathing are shown. C, Wearing a mask without tape redirects air movement towards the eye. D, Having the mask taped prevents air from being directed toward the eye, and air is seen passing through the face mask away from the eye (arrow).
The Descemet Endothelial Thickness Comparison Trial (DETECT) was a randomized, controlled, 2-surgeon, patient- and outcome assessor-masked clinical trial comparing ultrathin Descemet stripping automated endothelial keratoplasty (UT-DSAEK) with Descemet membrane endothelial keratoplasty (DMEK). It found visual acuity of approximately 1.5 lines better among those randomized to DMEK at 6 and 12 months; however, some evidence also suggested that endothelial cell loss (ECL) and complication rates were higher among DMEK patients. Currently, it is not known how these differences might affect long-term surgical outcomes, thereby modifying the comparative assessment of risks and benefits between the 2 surgical techniques. Herein, we report on the 24-month outcomes of the DETECT.

The full methods of the DETECT (ClinicalTrials.gov identifier: NCT02373137) have been reported previously in detail. Briefly, patients with isolated endothelial dysfunction resulting from Fuchs endothelial dystrophy or pseudophakic bullous keratopathy seeking treatment at the Casey Eye Institute, Oregon Health and Science University, and the Byers Eye Institute, Stanford University, were randomized in a 1:1 fashion to DMEK or UT-DSAEK. Surgical techniques and postoperative drops were standardized.

The main outcome for this prespecified secondary analysis was 24-month best spectacle-corrected visual acuity. Other secondary outcomes included change in endothelial cell density (ECD) from baseline and complication rates. Best spectacle-corrected visual acuity was recorded at 4 m by a certified, masked refractionist, using previously described methods. A calibrated slit-lamp biomicroscope was used to assess both recipient and donor corneal clarity, graft attachment, and complications.

The Cornea Image Analysis Reading Center determined the ECD at baseline and 24 months. Three images of the central corneal endothelium were obtained by the eye bank (Lions VisionGift) on the Konan KSS EB10 (Konan Medical USA). Similarly, 3 images of the central corneal endothelium were obtained at 24 months on the Nidek CEM 530 (Nidek, Inc) at Oregon Health and Science University and on the Topcon SP-2000P (Topcon Corp) at Stanford University. Calibrated eye bank and clinical images were transmitted to the Cornea Image Analysis Reading Center. In a masked fashion, ECD was determined by 2 certified readers (B.A.B. and S.M.D.). A 5% difference or more in ECD between readers was adjudicated by a third reader.

The prespecified primary analysis compared best spectacle-corrected visual acuity (BSCVA) between groups at the 24-month visit using linear regression with covariates for treatment arm and baseline BSCVA and a 2-sided \( P \) value of 0.05. Best spectacle-corrected visual acuity was analyzed using an intention-to-treat analysis including all eyes regardless of subsequent surgery or graft failure. Sensitivity analyses looking at clustered regression by study site and comparing BSCVA with the last observation carried forward for patients with primary graft failure also were performed. Endothelial cell density change from baseline and total adverse events were compared between groups using a \( t \) test.

Ethical approval was obtained from the human research committees at all institutions (University of California, San Francisco, Stanford University, Case Western Reserve University, and Oregon Health & Science University). Written informed consent was obtained from all participants, and the trial conformed to the tenets of the Declaration of Helsinki. The Data Safety Monitoring Committee performed 1 interim review.

A total of 216 patients were screened, and 50 eyes from 38 patients were randomized to UT-DSAEK or DMEK. Follow-up at 24 months was available for 46 of 50 eyes (92%). The baseline clinical characteristics are outlined in Table S1 (available at www.aaojournal.org). Figure 1 demonstrates the 24-month BSCVA and ECD compared with baseline. Eyes in the DMEK arm showed a mean visual acuity of 0.05 logMAR of the minimum angle of resolution (logMAR; Snellen equivalent, approximately 20/22) compared with the UT-DSAEK arm, which was 0.16 logMAR (Snellen equivalent, approximately 20/29). Therefore, eyes that had undergone DMEK showed an approximately 1.3-logMAR better visual acuity on average (95% confidence interval, 0.5–2.0 logMAR better; \( P = 0.001 \)). Sensitivity analyses, including removing baseline visual acuity as a covariate, excluding the patients who experienced primary graft failure, longitudinal analysis, and clustering by site or patient (linear mixed-effects models), did not change the analysis appreciably.