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Recommended Personal Protective Equipment for Cochlear Implant and Other Mastoid Surgery During the COVID-19 Era

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Objectives/Hypothesis: The overall aim of this study was to evaluate personal protective equipment (PPE) that may facilitate the safe recommencement of cochlear implantation in the COVID-19 era, with the broader goal of minimizing the period of auditory deprivation in prelingually deaf children and reducing the risk of cochlear ossification in individuals following meningitis.

Methods: The study design comprised 1) an objective assessment of mastoid drilling-induced droplet spread conducted during simulated cochlear implant (CI) surgery and its mitigation via the use of a protective drape tent and 2) an evaluation of three PPE configurations by otologists while performing mastoid drilling on ex vivo temporal bones. The various PPE solutions were assessed in terms of their impact on communication, vital physiological parameters, visual acuity and fields, and acceptability to surgeons using a systematic risk-based approach.

Results: Droplet spread during simulated CI surgery extended over 2 m, a distance greater than previously reported. A drape tent significantly reduced droplet spread. The ensemble of a half-face mask and safety spoggles (foam lined safety goggles) had consistently superior performance across all aspects of clinical usability. All other PPE options were found to substantially restrict the visual field, making them unsafe for microsurgery.

Conclusions: The results of this preclinical study indicate that the most viable solution to enable the safe conduct of CI and other mastoid surgery is a combination of a filtering facepiece (FFP)3 mask or half-face respirator with safety spoggles as PPE. Prescription spoggles are an option for surgeons who need to wear corrective glasses to operate. A drape tent reduces droplet spread. A multicenter clinical trial to evaluate the effectiveness of PPE should be the next step toward safely performing CI surgery during the COVID-19 era.

Key Words: COVID-19, coronavirus, otolaryngology, cochlear implant, mastoidectomy, ear, nose, and throat surgery, otology, personal protective equipment, safety.

Level of Evidence: 4

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INTRODUCTION

In January 2020, the World Health Organization declared the novel coronavirus outbreak, now known as COVID-19, a public health emergency of international concern.[1] The first case of COVID-19 was reported in Wuhan, Hubei Province, China, and has since spread worldwide.[2] Personal protective equipment (PPE) is critical for reducing viral transmission to healthcare workers (HCWs).[3] COVID-19 is thought to spread not only via droplets, but also through contamination of mucous membranes around the eye during aerosol-generating medical procedures (AGMPs).[3,4] A substantial number of otolaryngology procedures, including mastoidectomy, are considered aerosol generating,[5] and early reports from China and Italy indicate high rates of infection amongst otolaryngologists.[6–8]

The present study aimed to 1) measure the extent of droplet contamination during mastoid drilling in a preclinical model both with and without a novel commercially designed drape to create a tent over the surgical field, and 2) evaluate various PPE options including a full-face respirator, a modified full-face snorkel mask, and safety goggles or spoggles (foam-lined safety goggles) and a half-face mask. We evaluated communication (near field

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and far, in quiet and with drill-induced noise), vital physiological parameters, visual acuity, visual fields, and general acceptability to otologists.

MATERIALS AND METHODS

Study Design

The study design comprised 1) an objective assessment of mastoid drilling-induced droplet spread conducted during simulated cochlear implant (CI) surgery and 2) an evaluation of three PPE configurations by otologists while performing mastoid drilling on ex vivo temporal bones.

Visualization of Drill Induced Droplet Contamination

Contamination onto and around the operating surgeon was characterized with and without a the use of a novel barrier drape that creates a tent over the surgical field while drilling.[9] CI surgery was simulated on a human cadaveric temporal bone in a standard operating theater. Drilling of the temporal bone, without the microscope, was performed initially for 1 minute with a drill speed of 60,000 rpm. The contamination of the surgical field was visualized by replacing the irrigation fluid with fluorescent dye extracted from glow sticks.[10] The extent of droplet contamination was assessed, aided by a black light in a darkened operating theater, and the results photographically documented. These steps were subsequently repeated using the two microscope drape method[9] that creates a tent over the head of a patient.

Evaluation of PPE Solutions During Simulated CI Surgery

Three PPE configurations were evaluated by otologists while performing mastoid drilling on ex vivo temporal bones: 1) a full-face respirator (Promask; 3M Scott, Munroe, NC; n = 5 otologists), 2) a modified full-face snorkel mask[11] (n = 10 otologists), and 3) and the ensemble of a half-face mask (filtering facepiece [FFP]3 or FFP2) and safety goggles or spoggles (n = 5 otologists) (Fig. 1). The safety goggles (Coverall COVERSI; Bollé, Villeurbanne, France) and safety spoggles (BAXTER RX foam-lined safety glasses; Bollé) were chosen as they both meet safety standards to protect against liquid droplets or splashes, large dust particles >5 μm, and gas and fine dust particles <5 μm. CI surgery was again simulated in a standard operating theater with use of a surgical microscope and a cadaveric temporal bone. Study participants were each asked to operate for a period of 30 minutes while wearing the different PPE options.

The PPE evaluation included:

1. Ease of donning and doffing
2. Efficacy of communication
3. Participants' vital physiological parameters, including heart rate (HR), oxygen (O_2) saturations, fractional inspired carbon dioxide ($FiCO_2$), and end-tidal carbon dioxide ($ETCO_2$) levels
4. Participants' subjective comfort and breathability levels
5. Participants' visual acuity with and without the microscope and visual fields using the microscope

Communication was assessed by participants reading lists of monosyllabic words from the Arthur Boothroyd (AB) word test[12] at conversational level in addition to 10 sentences commonly used in theater such as "Can you pass me the drill?" Both the AB word and sentences lists were presented under two conditions, 1) with both the drill and suction off (57 dB LAeq average ambient noise level at a distance of 2 m) and 2) with both the drill and suctioned turned on (70 dB LAeq average ambient noise level at a distance of 2 m). Both a near listener located 1.2 m from the drill position, simulating the typical position of a scrub nurse, and a far listener located 1.5 m from the drill position, simulating the typical position of an anesthetist, were asked to record what they heard. A score of the percent correct was given for the AB words and sentence lists individually, and under each listening condition.

The assessment of vital physiological parameters consisted of taking measurements of HR), O_2 saturations, $FiCO_2$, and $ETCO_2$. HR and O_2 saturation recordings were achieved by attaching a pulse oximeter to the hallux of each participant on the foot opposite to that used for operating the drill pedal. $FiCO_2$ and $ETCO_2$ measurements were achieved by securing one end of an anesthetic gas sampling line to each participant's lower face underneath the respirator/face mask, approximately halfway between the upper lip and nostril in line with the oral commissure. Both the pulse oximeter and gas sampling line were attached to the anesthetic machine, and for each PPE option,

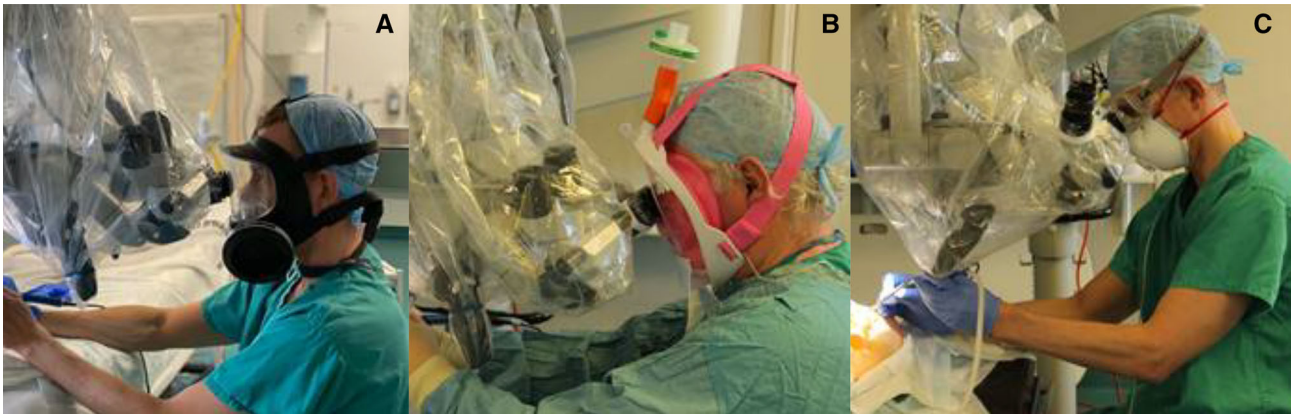

Fig. 1. PPE solutions subjected to an ergonomic evaluation. (A) Full-face respirator (Promask; 3M Scott, Monroe, NC). (B) Modified full-face snorkel mask that consists of a full-face mask, an appropriate medical-grade filter that captures viral particles, and a custom-made three-dimensional–printed adaptor that connects the two.[11] (C) FFP3 mask (3M 1863) and soft goggles (Bollé Coverall COVERSI) or spoggles (Bollé BAXTER RX) used as an ensemble. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

these measurements were continuously monitored and recorded at 5-minute intervals for 30 minutes.

Comfort and breathability parameters were recorded at 5-minute intervals while participants performed simulated CI surgery. Participants were asked to subjectively rate each parameter as either good (no perceived effect), adequate (perceived effect but with no effect on performance), or inadequate (perceived effect with detrimental effect on performance).

An objective assessment of visual acuity, without use of the microscope, and the visual field, with the use of the microscope, was also performed for each participant. Visual acuity testing was performed using the Peek Acuity Eye Testing App (Peek Vision, London, United Kingdom) at 0, 15, and 30 minutes.[13] For the evaluation of the visual field, participants (n = 5) were asked to draw the outline of their visual field onto a piece of graph paper while using the microscope, both with and without PPE.

Ergonomic Evaluation of PPE Solutions Over Longer Periods of Time

To assess the ergonomics of wearing the PPE over longer periods of time, all otologists who participated in the full-face respirator (n = 5) and full-face snorkel mask (n = 10) evaluations were asked to wear the mask at home while performing normal day-to-day activities for as long as they could. A questionnaire on the usability of each mask over longer periods of time was subsequently completed by these participants. A questionnaire sought opinions on the efficacy and clinical usability of all types of PPE utilized in this study.

Qualitative Fit Testing for Respiratory PPE Solutions

All of the participants who evaluated the full-face respirator (n = 5) and nine of the participants who evaluated the full-face snorkel mask (n = 10) underwent qualitative fit testing. One of the participants that completed an ergonomic assessment for the full-face snorkel mask declined fit testing due to concerns over a minor allergic skin reaction. Fit testing for both masks was carried out by an appropriately trained administrator and adhered to Nottingham University Hospitals National Health Service (NHS) Trust guidelines. All of the participants who evaluated the full-face respirator (n = 5) also formed five out of 10 participants for the full-face snorkel mask evaluation. Nine out of the 10 snorkel mask study participants had previously undergone a qualitative fit test for at least one type of FFP3 mask, the result of which was sought from each participant. We did not perform qualitative fit testing for the FFP2 mask, as this was not standard procedure for clinical practice at Nottingham University Hospitals NHS Trust.

RESULTS

Visualization of Drill- and Irrigation-Induced Droplet Spread

Droplet spread during simulated CI surgery extended in all directions from the drilling site (360°). The contamination extended for over 2 m from the drill site, which is further than previously reported spread (~1 m) during simulated mastoid drilling.[4,14] The extended reach of contamination in the present study may be attributable to the use of a fluorescent dye as irrigation fluid rather than impregnation into bone.[4] The extent of drilling-induced contamination was substantially reduced with use of the drape tent[9] (Fig. 2).

Ergonomic Assessments and Qualitative Fit Testing of PPE Solutions

Ease of donning and doffing. Donning and doffing instructions for the full-face respirator, the full-face snorkel mask, and half-face (FFP3/FFP2) mask with safety goggles and spoggles were all performed with ease and without any reported issues. All instructions were compliant with Nottingham University Hospitals NHS Trust guidelines.

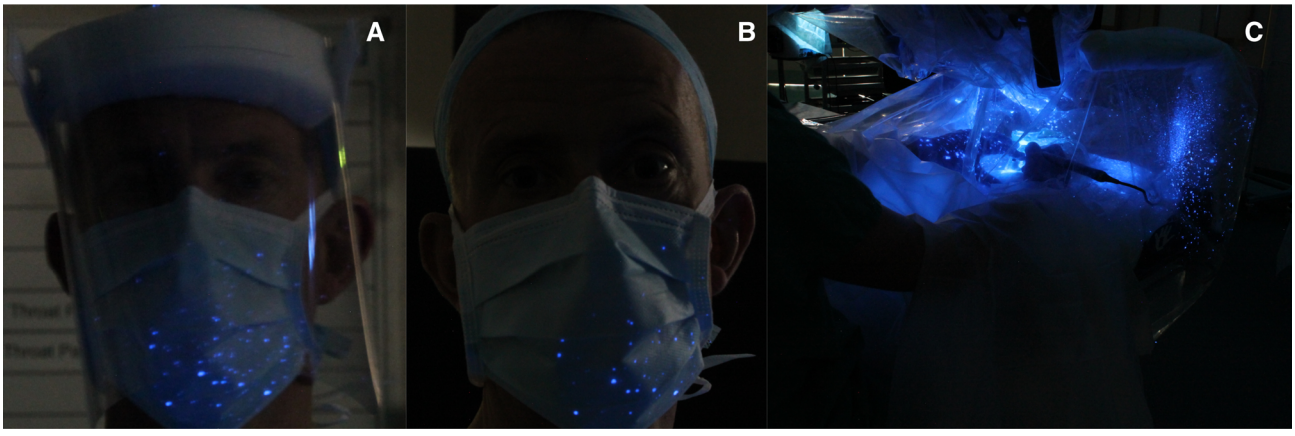

Fig. 2. Photographic illustration of the extent of mastoid drilling-induced droplet contamination. Following a period of drilling without the use of the drape tent, droplet contamination was visualized not only on the surgeon's visor (A), but also underneath it and directly onto the surgical mask (B). Contamination was also visualized on the floor of the operating theater, extending 2.2 m at its maximum distance to the back left and front right of the surgeon's drilling position. An assessment of droplet spread following a period of drilling with the drape tent in situ revealed the visualized contamination to be contained within the tent (C). Also, droplet contamination was not visualized on the surgical mask of the surgeon, nor on the floor of the operating theatre. Removal of the microscope tent was performed according to clinical guidelines.[9] [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

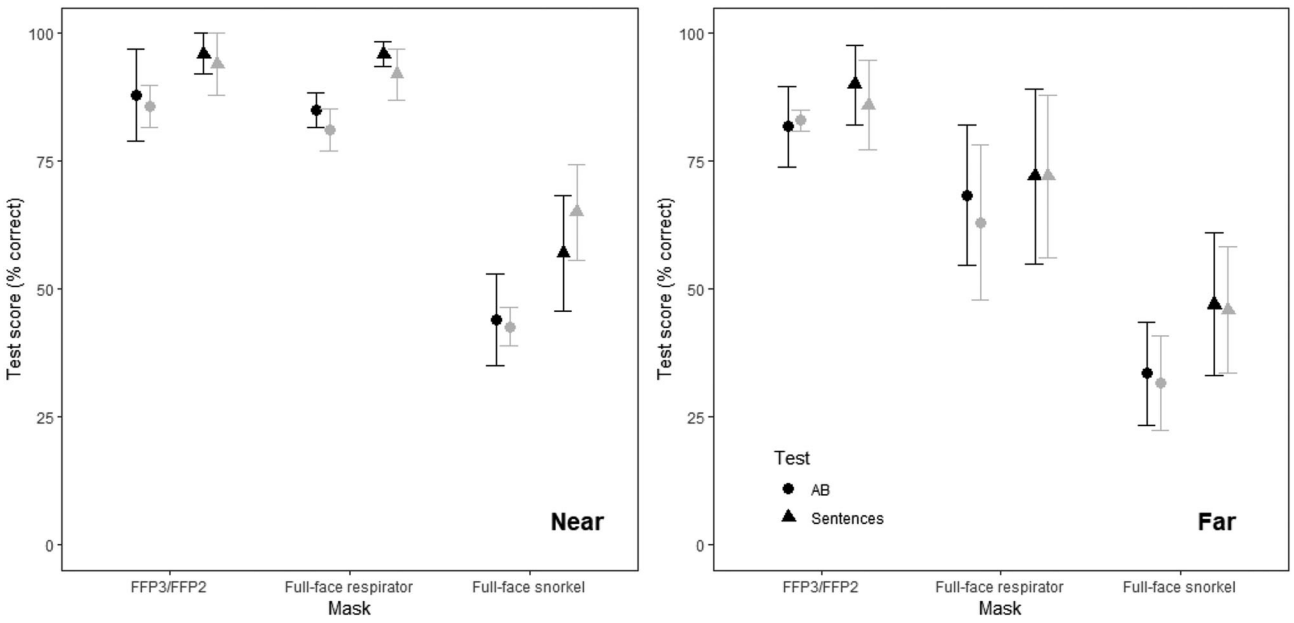

Fig. 3. The effectiveness of communication for the full-face respirator, full-face snorkel, and half-face FFP3/FFP2 mask under the various listening conditions. Results are displayed separately for both near and far listeners. The data points colored black represent the percent correct scores for the Arthur Boothroyd (AB) word (circle) and sentence (triangle) tests in the no-noise condition. The shaded data points represent results for the AB word (circle) and sentence tests (triangle) in the noise condition. Error bars show ±1 standard error of the mean. The efficacy of communication for both the full-face respirator and half-face FFP3/FFP2 mask was consistently higher than the full-face snorkel mask across all listening conditions for both near and far listeners.

Efficacy of communication. The mean percent correct score for both AB words and sentences, each with and without the added background noise of the drill and suction, was calculated across all listeners. The results for near and far listeners are displayed separately in Figure 3. Communication was most degraded using the full-face snorkel mask, with participants' performance around 50% correct across all conditions and listener

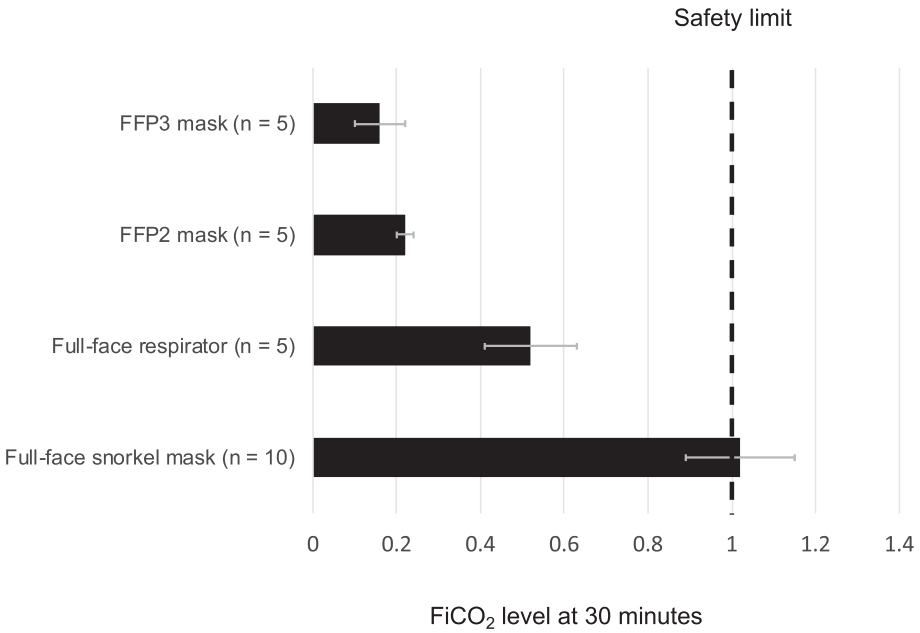

Fig. 4. Mean participant fractional inspired carbon dioxide ($FiCO_2$) levels after 30 minutes of wearing a full-face respirator, full-face snorkel, and half-face FFP3/FFP2 mask. The mean $FiCO_2$ level at 30 minutes was calculated for all participants wearing each type of mask. Error bars show ±1 standard error of the mean. The substantial increase in the $FiCO_2$ level for the full-face snorkel mask elevated above health and safety regulations (indicated by the vertical dashed line at 1%).[15–17]

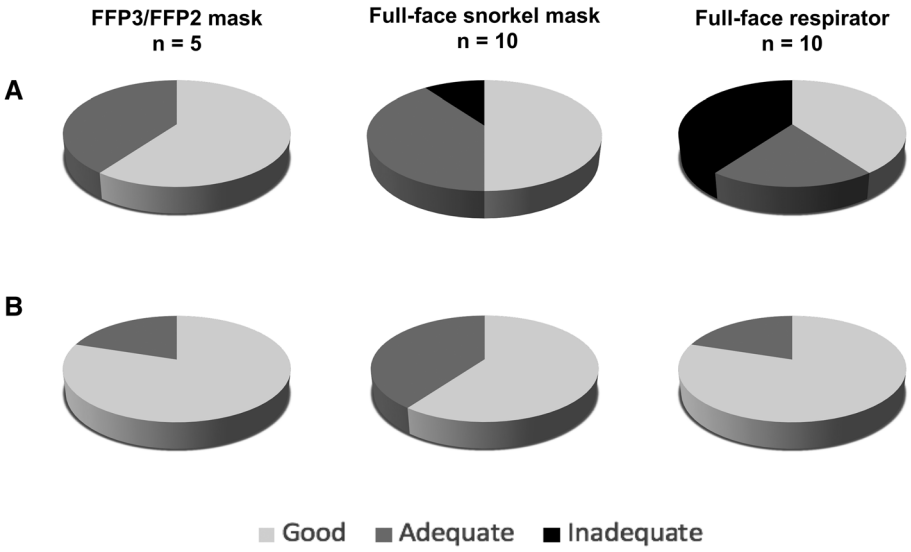

Fig. 5. Reported participant comfort (a) and breathability (b) after 30 minutes of simulated cochlear implant surgery. The half-face FFP3/FFP2 mask had consistently superior performance across both subjective parameters.

positions. The full-face respirator performed comparatively better than the full-face snorkel mask, particularly for the near listener position. On average, communication scores for the half-face mask (FFP2 or FFP3) were superior to both of the full-face mask options.

Physiological parameters. With respect to the physiological parameters, no concerning changes were observed in HR, O_2 saturations, or $ETCO_2$ levels across all participants for all mask types. Figure 4 demonstrates the mean $FiCO_2$ level after 30 minutes of wearing each mask type. The observed rise in the $FiCO_2$ level for the full-face snorkel mask was substantial, and breached current health and safety regulations for respiratory PPE, which state that inspired CO_2 levels should not rise above 1%.[15–17]

In terms of demographics, the age, gender, and ethnicity of participants evaluating the respiratory PPE options varied substantially. The age of participants ranged from 24 to 66 years old. There was an equal mix of male and female participants (n = 7 of each gender) and ethnicity included Asian British Indian (n = 5), white British (n = 5), white other (n = 2), Asian Indian (n = 1), and Arab (n = 1).

Subjective comfort and breathability. The results of participants' comfort and breathability after wearing the various types of PPE for 30 minutes are shown in Figure 5. Most participants rated the comfort associated with the half-face (FFP3 or FFP2) mask as good, a higher proportion than either of the full-face masks. Breathability was rated as good by the majority of participants for all types of PPE.

Visual acuity and visual field testing. With respect to visual acuity at 30 minutes (without use of the microscope), this was recorded as 0.00 LogMAR for PPE options, except in the full-face snorkel mask, where it was recorded as 0.01 LogMAR for n = 2 participants. Normal visual acuity is considered to be <0.1 LogMAR, which is equivalent to a Snellen score of 20/25 ft or 6/7.5 m. The effect of the various PPE solutions on the visual field is plotted in Figure 6, relative to the no-PPE condition (100%). The safety spoggles had a negligible effect upon the visual field (radius = 96%). The safety goggles, full-face snorkel mask, and full-face respirator all caused a substantial reduction of the radius of the visual field to 55%, 40%, and 18%, respectively.

Ergonomic evaluation of PPE solutions over longer periods of time. The majority of respondents that trialed the full-face respirator said they would not personally use it for the purpose of CI surgery, despite reporting that they could wear it for at least 2 hours. Most participants only tolerated wearing the full-face

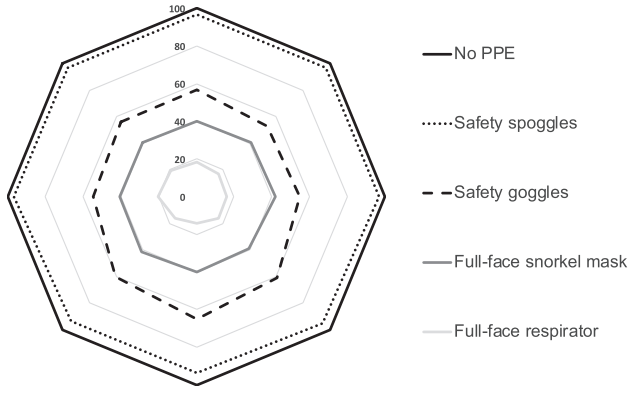

Fig. 6. The effect of the various personal protection equipment (PPE) options on participants' visual field while using the microscope. Each participant (n = 5) was asked to draw their visual field onto graph paper both with and without the various PPE options. The radar plot shows the mean relative reduction in the visual field caused by each type of eye PPE, in comparison to wearing no PPE (radius of visual field = 100%). The safety spoggles had a negligible effect on the visual field (radius = 96%), whereas the safety goggles, full-face snorkel mask, and full-face respirator reduced the radius of the visual field to approximately 55%, 40%, and 18%, respectively.

snorkel mask for less than 60 minutes and, again, the majority also stated that they would not personally use it for CI surgery. Most surgeons had similar concerns about performing cochlear implantation with the combination of an FFP3 mask and safety goggles. Restriction of the visual field and a lack of binocular vision were major concerns for all of these PPE options. The most popular choice of PPE was the combination of a FFP3 mask and spoggles, with all respondents saying they would use it for CI surgery.

Qualitative fit testing. Eight out of nine participants passed qualitative fit testing for the full-face snorkel mask. All five participants that underwent fit testing for the full-face respirator passed. All nine participants that had previously undergone fit testing for a FFP3 respirator passed with at least one type of mask.

DISCUSSION

A systematic risk-based approach to the evaluation of PPE in the healthcare setting has already been devised.[18] We therefore based our PPE assessment strategy on this evidence-based framework, which states that the categories of PPE performance that must be considered include 1) donning, doffing, and changing; 2) usability, and 3) fit for purpose.[18] We also ensured that we involved HCWs, specifically otolaryngologists, in the simulation of the activity for which the PPE was being assessed.[18] In terms of donning and doffing, all the PPE options that were subjected to a full ergonomic assessment were performed with ease.

We evaluated droplet spread during mastoid drilling, and found droplet contamination extended further (up to 2.2 m) from the drill site than has been previously reported for bone scatter[14] and particulate dispersion.[4,14] This is certainly within the range of not only the operating surgeon, but also the scrub nurse and anesthetist. Therefore, the present results indicate that adequate PPE should be considered essential for all these theater personnel during mastoid drilling, and that the total number of personnel in the theater be reduced to a minimum. Consistent with a previous report,[4] we also demonstrated that the use of a drape tent over the surgical field[9] substantially reduced droplet spread during simulated CI surgery.[4]

Although the COVID-19 pathogen spreads via airway-generated droplets, it is also present in the air in the form of aerosols.[19] Aerosols refer to the suspension of particles in a gas and include particles with a diameter of 10 μm or less, and form as a result of the desiccation of droplets.[20–22] Our study was designed to detect the spread of macroscopic droplet contamination only, and we are therefore unable to draw any conclusions on the extent of drill-induced aerosolization during simulated CI surgery. However, mastoidectomy is considered an AGMP.[5,9] Infectious agents, such as the COVID-19 pathogen, that are potentially transmitted by aerosols, require HCWs to wear PPE that creates a tight seal around the nasal and oral airways.[20] As transmission of the COVID-19 virus can also occur via the transcorneal route,[14] an airtight seal is also a requirement of any protective eyewear worn during CI surgery, which justified our evaluation of various PPE solutions, including full-face masks, and half-face mask and goggle or spoggle ensembles.

In terms of usability, out of the three PPE solutions that were subjected to an ergonomic evaluation during CI surgery, the ensemble of a half-face (FFP3 or FFP2) mask and safety spoggles had superior performance across all aspects of the evaluation. Communication was at least 80% effective across all listening conditions, even for words spoken in isolation of any contextual cues (Fig. 3). All participants reported comfort and breathability at 30 minutes to be good or adequate for this PPE (Fig. 5). Authors have previously reported that combining eye protection with the oculars of an operating microscope while wearing PPE presents a considerable challenge.[23] In our study, we found that the safety spoggles had a negligible effect on the visual field with the operating microscope (Fig. 6). Despite having no detrimental effect on visual acuity, the safety goggles caused a substantial reduction in the visual field, relative to the no-PPE condition. The full-face snorkel and respirator caused an even greater restriction, making all the aforementioned PPE options, aside from the spoggles, unsafe for microsurgery. For surgeons who need to use corrective glasses to operate, prescription spoggles are available.[24] It is possible to wear safety goggles over standard corrective glasses. However, this combination does substantially impair the surgeon's field of vision while using the operating microscope and, in some cases, may compromise the protective seal around the goggles.

No substantial changes were observed in the vital physiological parameters measured during use of the half-face FFP2 and FFP3 masks. Of notable concern was that despite all participants (n = 10) reporting breathability to be good or adequate for the full-face snorkel mask, a mean $FiCO_2$ level of over 1% was observed after 30 minutes (Fig. 4). Numerous health and safety standards for respiratory protective equipment state the level of CO_2 in the inspired air should not exceed 1%.[15–17] Therefore, HCWs considering use of the modified full-face snorkel mask should be aware that this option does not meet minimum safety standards for PPE, and may result in increased inspired CO_2 levels.

For PPE to be fit for purpose, it must be assessed for an adequate fit and seal to block the anticipated mode of transmission.[18] The current study found that qualitative fit testing was highly successful for all types of respiratory PPE assessed, with all participants passing for an FFP3 mask and the full-face respirator. For the purposes of this study, qualitative fit testing was not performed for the safety goggles or spoggles. However, the specific safety goggles (Bollé Coverall COVERSI) and spoggles (Bollé BAXTER RX) used in this study both have a CE marking that indicates they provide protection against gas particles <5 μm. Furthermore, equipment is available to objectively measure fit.[25]

There are limitations to this preclinical study. Due to the small number of participants, the acquired data could not be subjected to robust statistical analysis. In terms of the communication assessment for each mask, there was potential for the hearing level of individual listeners to affect the observed variability in percent correct

scores, as no formal hearing tests were performed. With respect to the analysis of vital physiological parameters, participants were not matched for demographics or comorbidities. Although the results of this study suggest that the recommended infection prevention and control measure and PPE for CI surgery should be a drape tent and the ensemble of a FFP3 mask (or half-face respirator) with safety spoggles, multicenter clinical trials will be essential to formally evaluate the effectiveness of PPE solutions at reducing transmission of COVID-19 to otologists and other operating theater staff. Qualitative testing for FFP3 or half-face respirator and safety spoggles as an ensemble would also be required.

CONCLUSION

Droplet spread during simulated CI surgery appears to extend further than previously reported for other mastoid drilling-induced particulate matter. The combination of an FFP3 mask, or half-face respirator with appropriate ocular PPE such as safety spoggles, could facilitate safe CI surgery while not unduly affecting communication in the operating room. The addition of a microscope tent reduces dispersal of droplets. Evaluation of inspired CO_2 levels is recommended for all novel full-face PPEs. The recommencement of CI and other mastoid surgery using these or similar PPE solutions should be accompanied by prospective trials evaluating transmission rates of COVID-19 to ensure patient benefit can be delivered while protecting those who deliver these important healthcare services.

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