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Original Article

Effectiveness of a 3D-printed mask fitter in an ophthalmology setting during COVID-19

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Objective: To assess the effectiveness of a 3D-printed custom mask fitter in lieu of N95 respirators among ophthalmologists and other eye care professionals who may not be prioritized to receive N95 respirators amidst the coronavirus disease 2019 pandemic.

Methods: This was a proof-of-concept study from a tertiary eye care center in Oakville, Canada. All participants underwent the N95 Qualitative Fit Test with a custom mask fitter secured over an American Society for Testing and Materials Level 3 face mask. Participants answered a 10-point Likert scale questionnaire on comfort, ease of use, and feasibility of the custom mask fitter, as well as comfort of a regular face mask.

Results: Twenty participants were recruited. Of the 20 recruited, 18 (90%) successfully passed the fit test. The median scores for comfort, ease of use, and everyday feasibility for the custom mask fitter were 3.5, 4.5, and 3, respectively, whereas the median score for comfort of a regular face mask was 8.5.

Conclusion: A reusable, low-cost, 3D-printed custom mask fitter is a potential effective alternative to an N95 respirator among eye care professionals but may require improvement in its design and comfort. This is especially relevant in the context of a limited supply of N95 respirators amidst a global pandemic.

Objectif: Évaluer l'efficacité d'un ajusteur de masque personnalisé imprimé en 3D en remplacement des masques respirateurs N95 à l'intention des ophtalmologistes et autres professionnels de la vision qui n'ont peut-être pas la priorité en matière d'accès aux masques respirateurs N95 dans le contexte de la pandémie de maladie à coronavirus 2019.

Méthodes: Il s'agissait d'une étude de validation du concept réalisée dans un centre de soins oculaires tertiaires situé à Oakville, en Ontario, au Canada. On a fait passer à tous les participants un essai d'ajustement qualitatif pour un masque respirateur N95 (*N95 Qualitative Fit Test*) lors du port d'un masque chirurgical de niveau 3 selon l'American Society for Testing and Materials avec un ajusteur de masque personnalisé. Les participants ont répondu à un questionnaire Likert (10 questions) pour évaluer le confort, la facilité d'utilisation et la valeur pratique de l'ajusteur de masque personnalisé, de même que le confort d'un masque chirurgical ordinaire.

Résultats: Des 20 sujets qui ont pris part à l'étude, 18 (90 %) ont réussi le test d'ajustement. Les scores médians pour le confort, la facilité d'utilisation et la valeur pratique au quotidien de l'ajusteur de masque personnalisé s'élevaient à 3,5, à 4,5 et à 3, respectivement, tandis que le score médian pour le confort d'un masque chirurgical ordinaire se chiffrait à 8,5.

Conclusion: Si un ajusteur de masque personnalisé imprimé en 3D réutilisable et peu coûteux peut constituer une solution de remplacement efficace au masque respirateur N95 chez les professionnels de la vision, son design et son confort auraient besoin d'être améliorés. Voilà qui est particulièrement pertinent dans le contexte d'un approvisionnement limité en masques respirateurs N95 pendant une pandémie planétaire.

Eye care professionals (ECPs) face the challenge of protecting themselves and patients during the coronavirus disease 2019 (COVID-19) pandemic. To prevent transmission of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus, guidelines from the Centers for Disease Control and Prevention (CDC) encourage the usage of National Institute for Occupational Safety and Health-approved N95 respirators during in-person interactions or high-risk procedures.[1] Although N95 respirators are ideal owing to their airtight seal and ability to filter out 95% of all airborne viral particles, they can be difficult to obtain and are typically reserved for those involved in aerosol-generating procedures or for those working with high-risk patient groups. Unfortunately, ECPs do not fall into these categories. Owing to their limited supply, the CDC has recommended the use of a regular face mask for other health care providers when N95 respirators are unavailable.[1]

The use of a regular face mask can be unsettling for many ECPs as the SARS-CoV-2 virus has been shown to stay viable in aerosols.[2] Aerosolized particles cannot be filtered out by a regular face mask owing to its suboptimal seal and is particularly concerning for health care workers who consistently work in close proximity to patients. Efforts have been made to improve infection control in ophthalmologist

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offices, including the full use of personal protective equipment (PPE) and installation of barrier shields.[3,4] However, this is not an ideal solution given the possible transmission of SARS-CoV-2 via mucous membranes.[5]

A mask fitter is a reusable plastic frame placed on top of a regular face mask. The frame has a custom shape, which follows the contour of an individual's nose, midface, and chin, and is secured using elastic straps. Once in place, the mask fitter provides an airtight seal around the edges of the frame. In the context of a limited supply of N95 respirators, a mask fitter could be used to meet the demand for appropriate PPE among ECPs. This study aims to assess the effectiveness of a custom mask fitter compared with an N95 respirator and describes its implementation in a large, academic, tertiary eye care centre.

Methods

This was a proof-of-concept study to test the feasibility of a new type of PPE. Institutional Review Board approval was obtained from Trillium Health Partners and the protocol adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from each participant in the study. Statistical analysis was conducted on SPSS version 24 (IBM, Armonk, NY).

Participants were recruited from Prism Eye Institute, a tertiary ophthalmology centre in Oakville, Ontario. Participants included technicians, front-facing administrative staff (such as front desk staff and surgical booking assistants), optometrists, ophthalmologists, and medical students. The Bellus3D (Campbell, CA) smartphone application was used on an iPhone XS (Apple, Cupertino, CA) smartphone to capture a 3D image of each person's face.[6] The standard size mask fitter frame was selected, and custom designed to the 3D shape of each participant's face. Each mask fitter design was exported as an STL file and printed by a Prusa i3 MK3S 3D Printer (Prusa Research, Prague, Czech Republic) using polyactic acid filament, a plant-based biodegradable plastic. Perforated 2-cm elastic sewing bands were used as straps to secure the mask fitter over the regular face mask. To simulate the N95 respirator, the custom mask fitter was placed on top of an American Society for Testing and Materials (ASTM) Level 3 fluid-resistant face mask with ear loops (Halyard, Alpharetta, GA; Fig. 1). Each participant had only one mask fitter created, which was printed from the first successful 3D image capture.

Fig. 1—Mask fitter frame shown with anterior (A) and posterior (B) view along with elastic sewing band (C) fastened to the mask fitter as a strap (D). Mask fitter worn showing frontal (E), left (F), right (G), and inferior (H) view.

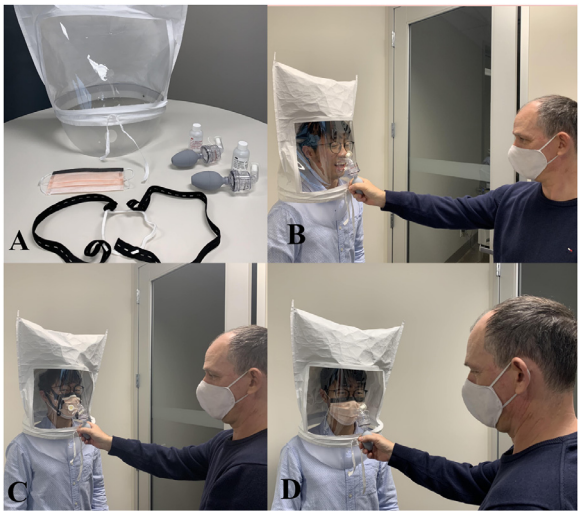

Fig. 2—Fit Test materials (A) and Fit Test steps, showing initial sensitivity test (B), Fit Test with custom mask fitter (C), and Fit Test with ASTM Level 3 regular facemask and no mask fitter (D).

To assess the mask fitter efficacy compared with N95 respirators, each participant underwent a standardized N95 Qualitative Fit Test (QLFT), consistent with protocols from the Occupational Safety and Health Administration standard 1910.134 App A (3M, St. Paul, MN; Fig. 2).[7] According to the test protocols, if an individual passes either on their first or second try, it is considered a pass overall. If they fail on their second try, then they have failed the test overall.

For this study, each participant wore their custom mask fitter over a Level 3 mask and underwent the QLFT. Additionally, all participants who passed the QLFT on the first try underwent the QLFT with only the Level 3 face mask and no custom mask fitter, to assess whether wearing the mask fitter made any difference. The same individual (J.L.) administered the QLFT to almost all participants to ensure consistency between administrations. One participant had their N95 QLFT administered at a hospital N95 testing centre.

At the conclusion of the QLFT, all participants answered a confidential Likert-scale questionnaire on comfort, ease of use, and everyday feasibility of the custom mask fitter, along with a question that allowed participants to leave comments and suggestions about the custom mask fitter. The questionnaire is shown in Figure 3.

Results

Table 1 outlines the participants who were enrolled in the study along with comments about the comfort level of the

The following questions will be asked after a participant completes the Fit Test with a 3D Printed Custom Mask Fitter.

Name: _____

Date of Birth (YYYY-MM-DD): _____

1. On a scale of 1 to 10, with 1 being not comfortable at all, and 10 being extremely comfortable, how comfortable would you say a regular surgical facemask feels? (Please circle a number).

1 2 3 4 5 6 7 8 9 10

2. On a scale of 1 to 10, with 1 being not comfortable at all, and 10 being extremely comfortable, how comfortable would you say the custom mask fitter feels? (Please circle a number).

1 2 3 4 5 6 7 8 9 10

3. On a scale of 1 to 10, with 1 being not easy to wear at all, and 10 being extremely easy to wear, how easy do you find it is to properly wear the custom mask fitter? (Please circle a number).

1 2 3 4 5 6 7 8 9 10

4. On a scale of 1 to 10, with 1 being not likely at all, and 10 being extremely likely, how likely would you be to wear the custom mask fitter on a daily basis? (Please circle a number).

1 2 3 4 5 6 7 8 9 10

5. Any additional comments about the mask fitter?

Fig. 3—Questionnaire administered to all participants.

Table 1—Participant Demographics and Comments Regarding Mask Fitter

Sex	Number of Participants
Male	8
Female	12
Mean age (years)	38.2
Health care role	
Technician	3
Optometrist	3
Ophthalmologist	4
Medical student	2
Front-facing administrative staff	8
Comments	
Participants describing some level of discomfort from mask fitter	13
• Elastic straps mentioned as an issue (easily slip off or are difficult to adjust)	7
• Mask fitter pushes on/squeezes eyes	6
• Mask fitter pushes on the chin or lower lip	3
Participants describing mask fitter comfort level as the same as an N95 respirator	1

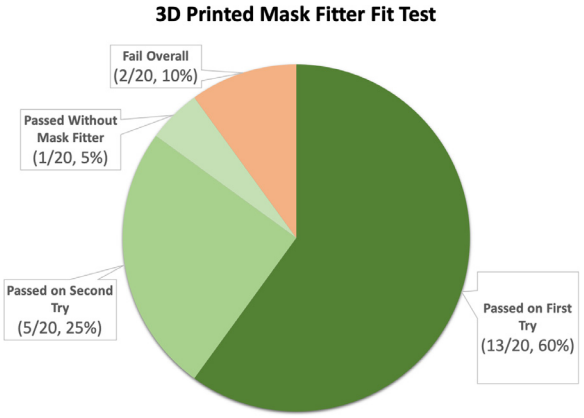

Fig. 4—Fit Test results for 3D-printed custom mask fitter.

mask fitter. Of 20 participants, 18 (90%) passed the QLFT, 13 of whom (65%) passed on the first attempt (Fig. 4). One female ophthalmologist passed the QLFT on the first try but also passed the QLFT when it was re-administered with only the fluid-resistant face mask. Among the 5 individuals who failed on the first try, 4 were female. A higher proportion of male participants passed on their first try (7 of 8) compared with female participants (6 of 12), although this was not statistically significant on χ^2 test ($p = 0.085$). There was no statistically significant association between age and the likelihood of passing the QLFT on the first try.

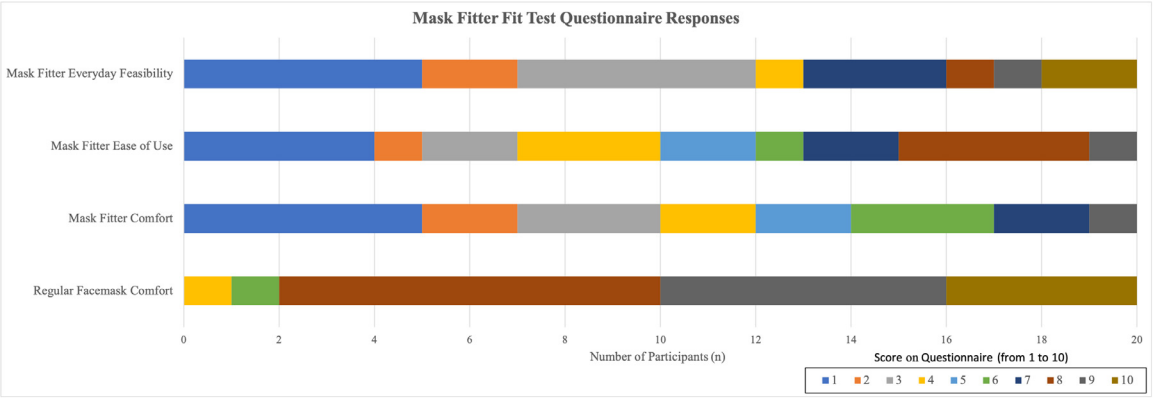

Fig. 5—Questionnaire responses for 3D-printed custom mask fitter.

Among all questionnaire responses (Fig. 5), the median scores on the Likert scales for comfort, ease of use, and everyday feasibility were 3.5, 4.5, and 3, respectively. A regular face mask had a median comfort score of 8.5, representing a median difference of 5 between the mask fitter and a regular face mask. None of the participants rated the mask fitter as more comfortable than the regular face mask, although 1 participant rated them at the same level of comfort. When stratifying by sex, there was a noticeable difference for everyday feasibility, with male participants assigning a higher median score for feasibility than female participants (7 vs 3), although this was not significant on Mann–Whitney U test ($p = 0.135$). No significant associations were found with questionnaire scores and age.

Discussion

In the context of a global pandemic and limited PPE supplies, health care workers have been encouraged to reuse disposable N95 respirators.[8] However, given N95 respirators are designed for 8 hours of use with the failure rate reported at 46% after 4 days of use,[9] this poses a significant risk to both health care providers and patients. There has also been discussion about the reuse of N95 respirators after sterilization with ionizing radiation. However, doing so causes their measured particular filtering efficiency to decline significantly, and is therefore not recommended.[10] Ideally, health care workers in true need of N95 respirators should be using them as they are designed and disposing of them when appropriate.

A 3D-printed custom mask fitter presents a possible PPE resource for health care providers who are in regular close contact with patient's faces but are not involved with aerosol-generating procedures or do not come into contact with confirmed or suspected COVID-19–positive patients. Ophthalmologists and other ECPs are examples of this population niche. Use of the custom mask fitter by this population can preserve the limited N95 respirator supply for higher-risk health care workers while maintaining adequate protection for ECPs. A mask fitter or brace is also mentioned by the CDC as a way to prevent air from leaking around the edges of the mask.[11] Our proof-of-concept study demonstrates promising results for the implementation of a 3D mask fitter in an outpatient setting. Ninety percent of participants' custom mask fitters performed at the appropriate standard of an N95 respirator based on the QLFT. Sixty percent of participants passed on the first try, whereas an additional 25% passed on their second attempt after modifying their seal. A study with N95 respirators similarly demonstrated that 44.2% of untrained health care workers passed the QLFT on their first try, with an additional 30.2% passing on a subsequent attempt after receiving proper donning instructions.[12]

The role of 3D printing to enhance PPE supplies amidst the COVID-19 pandemic has been discussed previously.[13] Custom mask fitters printed using the Bellus3D smartphone application have been informally demonstrated to enhance a peripheral seal on Level 2 and Level 3 surgical masks. However, to the best of our knowledge, this was the first study to formally investigate the effectiveness of 3D-printed custom mask fitters compared with N95 respirators while exploring its feasibility. There has also been formal investigation of the use of 3D-printed mask frames to prolong the life span of N95 respirators.[14] However, unlike the present study, those mask frames were not custom-fitted to an individual's face.

The influence of facial features on the fit of N95 respirators has been previously studied; the unique contours of a face alter how a face mask or respirator creates a seal.[15] Because the custom mask fitter is specifically designed for an individual's face, it eliminates issues associated with a "one-size-fits-all" solution. Additionally, the custom mask fitter is secured using adjustable, notched elastic straps, which allows for customization of the fit (Fig. 1). Five of the 7 participants who failed the Fit Test on the first try passed the test after the mask fitter was readjusted and tightened using the elastic straps. N95 respirators do not offer the same type

Fig. 6—Mask fitter elastic straps looped on top of a woman's hair ponytail to ensure a tighter seal.

of customization as there are only a few different models, which come in a single size and have nonadjustable elastic bands. However, participants in this study did comment on the difficulty of "fiddling around" with the straps and described them as "cumbersome." Although this was not a factor directly measured in our study, spectacle-wearing participants mentioned how wearing the mask fitter prevented fogging of their glasses. Furthermore, ophthalmologists noted that the mask reduced fogging while using the slit lamp and microscope oculars.

A higher proportion of women failed the QLFT on their first try compared with men in this study. This finding is similar to previous studies demonstrating that females were more likely to fail the Fit Test.[9] One recurring issue seen in female participants was the difficulty in securing the elastic straps when their hair was tied back. This was resolved by looping the lower elastic strap from the mask fitter on top of their ponytail (Fig. 6).

The most common comment regarding the mask fitter was discomfort in wearing it. Twenty-five percent of participants rated the mask fitter as a 1 out of 10 on comfort, and 60% rated it as 4 out of 10 or less. The most common area of discomfort was the mask fitter pushing up against the wearer's eyes, affecting one participant's ability to read. The discomfort was also felt where the frame overlay bony structures, such as the nasal bridge. Although loosening the straps could increase comfort, this also could compromise the seal. Improvements in design could include a thinner plastic frame around the sensitive area under the eyes, or a stronger hold around the chin to prevent the mask fitter from sliding up to the eyes. Although N95 respirators have generally been shown to be comfortable,[16] a direct comparison of the custom mask fitter and N95 respirator comfort level would be useful to study in the future.

The mask fitter's discomfort may be its most significant limitation as it effects feasibility. On the questionnaire, everyday feasibility was the only question to receive scores on both extremes of the spectrum although most scores were low. Two participants rated feasibility as 10 out of 10, while 13 participants rated it as 4 out of 10 or less. The 2 individuals who rated feasibility as 10 out of 10 were already using their custom mask fitters on a day-to-day basis for several months. Both acknowledged that the mask fitter was initially very uncomfortable, but they became accustomed to wearing it every day.

An additional limitation to using the custom mask fitter involves the type of regular face mask required. Although the seal around a mask is an important aspect of preventing aerosol transmission, the mask's physical material is another factor. In this study, the mask fitter was placed over an ASTM Level 3 facemask. The specific ASTM Level 3 facemask used in this study has an advertised particle filtration efficiency (PFE) of ≥99% at 0.1 microns and bacterial filtration efficiency (BFE) of ≥99% at 3 microns.[17] A National Institute for Occupational Safety and Health-approved N95 respirator sold by the same manufacturer has the exact same PFE and BFE.[18] Before commencing the study, the authors tested the mask fitter over an ASTM Level 1 mask and found it would fail the QLFT. Thus, ASTM Level 3 masks are required to successfully mimic an N95 respirator with the mask fitter, which are more costly than ASTM Level 1 masks. ASTM Level 2 masks were not tested and present an opportunity for further investigation.

Finally, there are imitations of the QLFT itself, which has not been shown to be an accurate representation of the respirator's ability to filter all particles.[14] Furthermore, as participants were aware of the goals of this study, there could be an element of participant bias. Additionally, the Likert scales provided in this study ranged from 1 to 10. A 0 to 10 scale would have been more useful, as Likert scales typically have an odd number of selections to allow a midpoint selection. Finally, with its small sample size of only 20 participants, these results are not generalizable to large populations and should be interpreted within its scope as a proof-of-concept study.

Overall, the 3D-printed custom mask fitter is a potential option for ECPs seeking more robust PPE given the current limited N95 respirator supply. As it is reusable, cost-effective, and custom-designed to each individual, it offers advantages over N95 respirators and may even be further investigated a new form of PPE after the COVID-19 pandemic resolves. However, the custom mask fitter requires further investigation to test its effectiveness through quantitative means, and further design adjustments to improve its comfort, user-friendliness, and everyday feasibility. In its current state, it cannot replace the N95 respirator, but may provide an alternative PPE solution when N95 supplies are limited.

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Footnotes and Disclosure

The authors have no proprietary or commercial interest in any materials discussed in this article.

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