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Quantitative Fit Tested N95 Respirator-Alternatives Generated With CT Imaging and 3D Printing: A Response to Potential Shortages During the COVID-19 Pandemic

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Rationale and Objective: Three-dimensional (3D) printing allows innovative solutions for personal protective equipment, particularly in times of crisis. Our goal was to generate an N95-alternative 3D-printed respirator that passed Occupational Safety and Health Administration (OSHA)-certified quantitative fit testing during the COVID-19 pandemic.

Materials and Methods: 3D printed prototypes for N95 solutions were created based on the design of commercial N95 respirators. Computed tomography imaging was performed on an anthropomorphic head phantom wearing a commercially available N95 respirator and these facial contour data was used in mask prototyping. Prototypes were generated using rigid and flexible polymers. According to OSHA standards, prototypes underwent subsequent quantitative respirator fit testing on volunteers who passed fit tests on commercial N95 respirators.

Results: A total of 10 prototypes were 3D printed using both rigid (n = 5 designs) and flexible materials (n = 5 designs). Prototypes generated with rigid printing materials (n = 5 designs) did not pass quantitative respirator fit testing. Three of the five prototypes with flexible materials failed quantitative fit testing. The final two prototypes designs passed OSHA-certified quantitative fit tests with an overall mean fit factor of 138 (passing is over 100).

Conclusion: Through rapid prototyping, 3D printed N95 alternative masks were designed with topographical facial computed tomography data to create mask facial contour and passed OSHA-certified quantitative respirator testing when flexible polymer was used. This mask design may provide an alternative to disposable N95 respirators in case of pandemic-related shortages. Furthermore, this approach may allow customization for those that would otherwise fail fit testing on standard commercial respirators.

Key Words: 3D printing; N95 respirator; COVID-19; 3D printing COVID-19; personal protective equipment; 3D printed mask.

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INTRODUCTION

The Coronavirus Infectious Disease 2019 (COVID-19) pandemic is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which can be spread via virus-containing airborne particles (1). Healthcare workers are particularly vulnerable to infection given their occupational exposures, including respiratory droplets and aerosol generated by patients infected with SARS-CoV-2, which can remain infectious for hours after becoming airborne (2). Early in the COVID-19 pandemic, there were personal protective equipment (PPE) shortages, particularly N95 respirators, and concerns that there may be long-term shortages (3). N95 respirators are certified by the National
Institute of Occupational Safety and Health, and their low cost and high functionality have helped them become the most common particulate-filtering facepiece respirator (4) and are certified by the National Institute of Occupational Safety and Health. Filtration depends on a close facial fit that is verified via standardized fit testing (5). When properly used, at least 95% of airborne particles are filtered when tested against a difficult particle size to filter (approximately 0.3 microns) (hence the “95” in N95), including pathogen-containing particles (5). Thus, concerns of limited masks during the COVID-19 pandemic (6, 7) prompted an investigation of viable alternatives, including those generated with 3D printing technology. A number of 3D-printed N95 alternative designs have been published (8–12) or are freely available online (13–17); however, standardized fit test performance data to ensure protection from aerosolized particles is lacking (18). The purpose of this study was to generate a 3D printed N95 respirator alternative that passed an Occupational Safety and Health Administration (OSHA)-certified quantitative fit test.

MATERIALS AND METHODS

Our institutional review board designated this project as non-human research as no personal or identifying information was collected. Computed tomography (CT) examinations of commercial N95 respirators were performed to design a novel 3D printed N95 alternative and were tested on healthcare professional volunteers. This study was conducted during the early COVID-19 pandemic period, March 19–May 25, 2020.

Institutional N95 Task Force

Iterative generation of a 3D printed N95 alternative was facilitated by serial rapid prototyping and feedback provided by a multidisciplinary task force. An N95 task force was formed at our institution, a subgroup of a larger initiative (institutional maker task force) to manufacture or secure other forms of personal protective equipment (e.g., face shields, surgical gowns, cleansing wipes, and other items). This task force was generated to address the potential shortage projected during the early COVID-19 pandemic period. At the onset of the study period (March 2020), we were prototyping N95 alternative solutions at the initiative of institutional efforts to address an anticipated shortage of N95s along with surgical masks. Within the N95 alternative task force team, there were over 40 physicians, scientists, engineers, and other experts. This team worked together to form a testing solution to test ad hoc N95 respirators from 3D printed and cloth solutions. Although named an N95 task force, the aim was also to manufacture or secure other mask solutions that would offer some level of filtration and liquid barrier protection. Members of the directed task force were given access to OSHA-certified qualitative and quantitative respiratory fit testing equipment with direct supervision by institutional occupational health personnel. This culminated in the testing and validation of several N95 solutions, including the 3D printing efforts presented in this work. Prototypes, including the ones presented in the current study, were discussed in twice weekly task-force affiliated multidisciplinary videoconference calls. During these meetings, mask designs and results of the respiratory fit testing were discussed.

CT of Commercial N95 Respirators

To aid in designing 3D-printed N95 respirators, CT acquisitions of commercial N95 respirators were acquired both alone and donned on an anthropomorphic head CT phantom (Fig 1). CT imaging was performed (kVp 120, mAs 200, slice thickness of 0.6 mm) was performed with a Siemens Biograph TruePoint PET/CT (Siemens, Munich, Germany). Both small and regular-sized commercial N95 respirators (disposable 3M 1860 Health Care Particulate N95 FFR Respirators [3M, St. Paul, MN]) were imaged. Using 3D Slicer (Kitware, Inc., New York, NY) (19), CT data was processed to match the contours of the scanned mask, these data were imported to Blender v2.81 (Blender Foundation, Amsterdam) to design the N95 respirator. To further aid in 3D-printed mask designs, another CT examination was performed with the same protocol with a mid-iteration 3D printed mask both in isolation and fitted on the anthropomorphic head CT phantom.

Prototype Iterations and 3D Printing

Using data from CT images of the N95 mask and the anthropomorphic head CT phantom, an N95 respirator mask conforming to facial contours was created. Initial prototypes (Fig 2) allowed a filter to be contained between the mask’s skin-facing side and an inner rigid perforated plate.

![Figure 1. CT acquisition of a commercial N95 respirator to aid in generation of a 3D printed mask. Photographs and computed tomography (CT) acquisition images of a commercial N95 respirator in isolation (A, B) and positioned on an anthropomorphic head CT phantom (C, D). (Color version of figure is available online.)](image-url)
Subsequent prototypes allowed a filter to be contained in an outer circular chamber(s) of the mask (Figs 3 and 4). Non-3D printed materials required for assembly of all 3D-printed mask prototypes included elastic bands, flexible metal for nasal bridge securement, and the filter material (tested using a small section of N95 filter material) (Fig 1). Different iterations of prototypes throughout this study are detailed in Supplementary Table 1. STL (standard tessellation language) files of the final prototype designs are provided in Supplementary Files 1 and 2.

3D printing was performed on multiple printers using multiple materials. 3D printers included Makerbot 5th generation (Makerbot, Brooklyn, NY), Fusion3 F410 (Fusion 3D, Greensboro, NC), Form 2 (FormLabs, Somerville, MA) and Stratasys J750 (Stratasys, Eden Prairie, MN) 3D printers. Initial prototypes were printed with Makerbot and Fusion3 printers using low cost rigid and semirigid polymers, polylactic acid, and thermoplastic polyurethane. Mask printed with the Form 2 and Stratasys J750 used materials constructed from each 3D printing company's proprietary polymers: FormLabs elastic and flexible (V2) resins (20, 21) for the Form 2 3D printer and Agilus30, Biocompatible Clear MED610, Tango, and Vero for the Stratasys J750 3D printer (22–25). For masks printed with a Form 2, a Makerbot 5th generation was used to print the inner rigid piece using polylactic acid filaments. The Stratasys J750 printer could print constructs with multiple densities and a second printer was not required for masks printed using this 3D printer.

Fit Testing
A 7-minute quantitative respiratory fit testing was performed according to OSHA standards (26) on healthcare professional
volunteers. The quantitative fit test was performed using a PortaCount Respirator Fit Tester Model 8048 and TSI Model 8026 Particle Generator with TSI FitPro Ultra software (TSI incorporated, Shoreview, Minnesota, USA). A 4 mm metal grommet was punched through each prototype to connect to the PortaCount device’s 4-mm tubing (Fig 5).

Briefly, the OSHA-certified quantitative respiratory fit test is a supervised examination of an individual wearing an N95 respirator after optimizing it for fit. In the current study, quantitative respirator fit testing was directly supervised and facilitated by our institutional occupational health service, who routinely perform and supervise thousands of annual respirator fit testing for all healthcare workers at our institution. The N95 respirator is connected by tubing to the commercial PortaCount device, which in real-time measures particle concentration around/outside of an individual’s respirator along the particle concentration leak into the respirator. The ratio of the particles around/outside of an individual’s respirator compared to the concentration inside the respirator is the fit factor, which is the reported real-time measurement of the PortaCount device (Fig 5). A fit factor of >100 is required for an individual to pass the respirator quantitative fit test for an N95 respirator (or half mask or quarter facepiece respirator). A fit factor of 100 means the particle concentration around/outside the respirator is 100 times greater than within. With the device recording real-time dynamic measurements, the quantitative respiratory fit test consists of eight prompted and standardized exercises where the individual follows the computer prompt. These include normal breathing, deep breathing, two variations of head movement (side-to-side and up-and-down), while talking (reading from a prompt), grimace facial expression, bending over, normal breathing. Fit factors are generated for each of these exercises and the overall fit factor for the test is calculated from the number of exercises divided by the inverse values of each individual exercise final mean fit factor.

Fit testing was performed on four individuals who passed the OSHA 7-minute standardized fit test for a regular size N95 respirator ($n = 5$) and a small size N95 respirator ($n = 2$). The healthcare professional volunteers gave direct feedback on subjective characteristics, specifically degree of comfort, along with identifying points of fit test failure (e.g., if there were obvious or perceptible air gaps from the mask not being tightly opposed to the individual’s face) and the ease of breathing (scaled from labored, uncomfortable, acceptable, and comparable to normal breathing).

RESULTS

3D printed N95 masks were generated through multiple iterations facilitated through our institutional task force. Twenty-five 3D prints of 10 prototype mask designs were tested, with each prototype undergoing direct feedback from the fit testing participants along with a discussion with engineering and occupational health experts. In line with our goal of generating a N95 equivalent, we required use of standard fit testing equipment. Quantitative fit testing instrumentation requires tubing to be in communication with the internal chamber of the mask; this requires generation of a hole within the mask. The fit testing was facilitated by a grommet hole punch device (same as used for standard N95s). In initial prototypes, the generation of a hole fractured the mask around the whole punch device (Fig 5). In next iterations, a similar diameter defect was 3D printed to simulate the grommet, but this also caused fracture of the material around the mask. A final successful modification was to insert the
grommet hole punch device into the filter material rather than the printed component (Fig 5).

The CT examinations of the commercial N95 respirators had the topography of the uniformly flexible and filter-containing N95 design in its baseline state and conformed to the anthropomorphic head CT phantom (mannequin head) with the nasal bridge fixation device conformed to the mannequin’s nasal protrusion. The CT examination of the commercial N95 on the phantom helped the initial 3D-printed mask design with the surface area in contact with the skin along with the morphology of the skin-opposing portion of the 3D-printed mask. The commercial N95 design had the advantage of having a large portion of its design being filter material compared to the 3D-printed N95 alternative masks that did not provide sufficient space to secure filter material. The CT examination of the mid-iteration 3D-printed prototype (which itself and previous versions failed quantitative fit testing) highlighted persistent design flaws while fitted on the anthropomorphic head CT phantom including too short distance between the face and filter fixation area and poor fit of the prototype on the nasal bridge. Comparative CT images of the commercial N95 respirator and a mid-iteration 3D-printed mask prototype made with flexible materials are demonstrated in Figure 6.

Masks were generated from different rigidity polymers, and in this work, we used both rigid (n = 5 designs) and flexible materials (n = 5 designs) (Supplementary Table 1), with a total of 25 total 3D-printed masks of the 10 prototypes. None prototype masks that were 3D printed using rigid materials for the proximal facial component (n = 5 designs), passed the quantitative respirator fit tests (mean fit factor of 0). The rigid prototypes had volunteer feedback of discomfort and obvious air gaps and were highly uncomfortable with the rigid polymer indenting individual’s skin. An early flexible polymer prototype (Fig 2) passed a qualitative fit test (the prototype first to pass any type of fit testing), but failed a quantitative fit test with a mean fit factor of 15 (passing is 100) (26). Intermittent flexible prototype designs had a mean fit factor of 23 (range 6–36). For early and intermittent prototypes, the diameter of the outer chamber where the filter was situated was 4 cm and ease of breathing was rated as “uncomfortable” to “acceptable.” Increasing the outer chamber to 6 cm for the final prototype designs improved the ease of breathing to consistent levels of “acceptable.” The two final prototype designs (Figs 3 and 4) printed with flexible polymers (primarily Biocompatible Clear MED610 and Agilus30) passed an OSHA-certified quantitative fit testing with a mean fit factor of 138 (range 108–168 [passing is 100]) (26). Additional fit testing data is noted in Supplementary Table 2. The comfort level was noted as similar to commercial N95 respirators.

Mean print time for rigid material masks that did not pass respiratory fit testing was 6 hours. Mean print time for early

![Figure 6](image-url)

Figure 6. CT examination of the commercial N95 respirator (A-C, top row) and a mid-iteration 3D printed N95 respirator alternative printed with flexible materials (D-F, bottom row) both fitted on an anthropomorphic head CT phantom. Comparison 3D rendering oblique images (A and D), axial (B and E) and sagittal (C and F) CT images. Contours and most proximal boundaries of the commercial N95 respirator (black dashed line in A, yellow dashed line in B) were more superficial compared to 3D printed alternative, which required more surface area contact at the face and deeper extension (thick yellow arrows in D and E show deep extension compared to the reference point where the commercial N95 respirator stops). A design flaw of the imaged iteration of the 3D printed mask is highlighted in F, where there is <5 mm between the mouth and inner portion of the filter securement chamber (F) compared to 20 mm of space with the commercial N95 respirator (C) (yellow arrow in C and F shows the 20 mm of space for the commercial N95 respirator; dashed transparent yellow line in F represents overlay of the commercial N95 respirator). Identification of this flaw, among others, helped improve subsequent designs. (Color version of figure is available online.)
flexible material masks that did not pass quantitative respiratory fit testing, printed with the FormLabs Form 2, was 11.5 hours; the platform for this printer allows for a maximum 1 mask per print. For the final flexible material mask that passed respiratory fit testing, printed with Stratasys J750 3D printer, had an individual mask mean print time of 10.5 hours. The build platform for J750 allows for 10 masks to be printed in 24 hours. The disconnect in mean time between one versus 10 masks is due to the logistics of the build platform of a single 3D printer used for the final prototype.

DISCUSSION

In March 2020, challenges related to airway PPE shortages during the COVID-19 pandemic (27) drove us to generate an N95-equivalent 3D-printed respirator that could be used in the hospital setting. The rapid prototyping afforded by 3D printing allowed multiple mask prototypes and iterations, ultimately leading to a 3D-printed N95 alternative that passed OSHA-certified quantitative respirator fit tests and was optimized for user experience. Further, given the rapid prototyping and flexibility afforded by 3D augmentation of the design allowed incorporation of multiple filter ports and sizes of the filter fixation sites, to increase surface area for filtration.

A survey undertaken in March 2020 revealed that nearly half of all reporting US healthcare facilities were nearly or completely out of N95 respirators (27). At the time of development, we did not know if our institution or others would have an adequate supply and N95 level protection. Shortages were predicted at our institution for various PPE, including N95 level respiratory protection. Therefore, we created an ad hoc task force centered around the creation of the 3D-printed mask in the current study. We aimed to manufacture these masks with the goal of a design that could be rapidly-disseminated, mass-produced, and pass quantitative respiratory fit testing.

For the 3D-printed mask design in the current study, several designs and materials were considered and we found the greatest comfort and fit test pass rate was with flexible polymers. Initially prototypes were printed with rigid polymers, including polyactic acid and thermoplastic polyurethane. Rigid polymers carry the advantages of low cost and compatibility with most desktop 3D printers, namely using fused deposition modeling (28). However, masks made with rigid materials were uncomfortable and did not pass the respirator fit testing. On the other hand, masks made with silicone-like consistency polymers passed respirator fit testing and had better user comfort. Although we did not formally measure approximation of mask with skin, fit testing assumes adequate approximation. Rigid materials had obvious air gaps at their facial contours.

In this study, we rapidly generated 3D-printed masks that were not specifically tailored to the individuals undergoing fit testing—masks were generated from CT images from an anthropomorphic “mannequin” head. Had 3D-printed models been generated using imaging of the individuals undergoing testing, we suspect fit testing would have been optimized, although that would have exposed the individual to a finite dose of ionizing radiation. However, radiation exposure could be avoided with other techniques to record facial geometry such as laser scanning or photogrammetry. Along these lines, we also speculate that 3D printing may provide alternatives for respiratory PPE in those that do not pass-fit testing with standard commercially available N95 respirators due to size or anatomical variation. Many essential healthcare workers fail initial N95 fit testing (29, 30) due to variations in face morphology. Tailored 3D printed masks may overcome these limitations using imaging data contoured specifically to the user. Others have reported using facial scans molding for 3D-printed N95 alternatives manufactured with rigid materials (8, 9), but have not described fit testing results (18). Facial scanning to allow customization to pass fit testing could have utility in unique situations, but may not be practical as a method used for everyone.

Customized 3D-printed masks may have advantages over traditional airway PPE, such as N95 masks. Degesys et al (31) reported that individuals that passed standard N95 respirator fit testing within the last 1–2 years, experienced failure with both duckbill and dome-shaped masks with extended use; increased failure rate was associated with increased donning/doffing, and total hours used. Maranhao et al (32) reported higher probability of fit testing failure with commercial disposable N95 respirators when reused and sterilized after 4 days of continuous use. Further, activities in close approximation to patients, such as cardiopulmonary resuscitation, reduce efficacy of N95 in those that would otherwise pass fit testing (33).

The 3D printing community response was unlike anything we have seen with 3D printing rising to a challenge. The digital nature of 3D printing and associated decentralized production allows rapid response in times of crisis. During the early COVID-19, traditional supply chains could not meet the healthcare demands, and in some cases 3D printing was used to fill these needs (12, 34). Compared to the H1N1 2009 pandemic, now in the COVID-19 pandemic 3D printers are more widely used, cheaper, and integrated into aspects of medicine and rapid prototyping of medical devices. This is in part because in 2009 key 1989 intellectual property for 3D printers’ designs expired, which in turn allowed for more 3D printing companies to produce printers, ultimately driving down the cost (35). In the case of COVID-19, both the scale of the pandemic and printer availability drive this response, which manifested in N95 mask alternatives, face shield production, nasal swabs, ventilator part supplements, and mask extenders (8–12, 34, 36–40). As the COVID-19 pandemic progressed, traditional N95 supply methods were able to meet demands at our institution. Nonetheless, these digital blueprints can be used in future times of need. The National Institutes of Health has hosted many 3D printed PPE designs on the NIH 3D Printing Exchange (13).

There are several limitations with 3D printed respirators. An advantage of commercial N95 respirators is that they have a relatively large area of air exchange, which decreases air resistance and, therefore, potentially work of breathing. The
surface area of filter material required to maintain N95 filtration will be dependent upon the filter material used. In later iterations we increased the surface area two double that of initial prototypes. Thus, the overall effectiveness of the mask in the healthcare setting may vary. We offer a design that passed standardized OSHA-certified quantitative fit testing and strongly recommend centers perform such testing on any 3D-printed prototype. The fit testing was successful on a small number of volunteers and it is unknown if fit testing would be successful over a wide range of individuals. The mask that was generated was based on the contours of a mannequin head, we suspect that customized masks generated from contour maps of individuals would have even better fit tests results and comfort. With the implementations of institutional reuse of disposable N95s, limiting on-site personnel, and with our institutional burden of COVID-positive and suspected patients, we did not reach a point where the clinical use of this mask in a widespread manner was required. However, 3D printing resources at our institution were prepared and worked towards the goal of rapidly producing a design that passed OSHA-certified quantitative fit testing. In the case that individuals were to wear 3D-printed masks that would approximate the skin, confirmation of biocompatibility is recommended according to the FDA document on technical considerations for additive manufactured devices (41). We suspect rates would be low with the inert compounds and the polymers used in this study do have safety and chemical data sheets available from the manufacturer (22–25). In the event that there are adverse skin reactions, different polymers could be used. In this work, we do not objectively report comparisons with other available designs, although we have printed a number of these (five designs) and none passed a fit test, primarily due to rigid materials, and it is likely that soft polymers substantially aid in achieving adequate fit along the contours of variable facial anatomy. A limitation of this work is that it was not compared to published (8–12) or freely available N95 alternatives (13–17); however, at the early onset of this work, there was only one freely available 3D-printed N95 alternative. No comparison group in this work was partly driven by this 3D-printed mask development was a potential need with anticipated N95 respirator shortages, therefore, it was expedited to achieve a model that passed quantitative respirator fit testing. The 10 mask per 24 hours mean print time for the 3D printer used in the final prototype’s production may not be favorable for a mass production standpoint. In considering this and if these masks would have been required for clinical use, the task force in the current study had industry collaboration to make a mold of the mask design for higher volume production.

In conclusion, we developed an ad hoc 3D-printed N95 mask solution during the COVID-19 early pandemic period. Although several designs for 3D-printed N95 alternatives have been published (8–12) or freely available (13–17) in response to and during the COVID-19 pandemic, the vast majority do not pair the design with respiratory fit testing data (18). The current study provides a 3D-printed N95 respirator alternative design that passed quantitative respirator fit testing. In different iterations of the mask prototypes in this study, flexible polymers provided a better fit of 3D-printed masks modeled as N95 respirator alternatives and provided better comfort compared to rigid materials. From our available resources and data, rigid 3D-printed N95 respirator alternatives were less expensive and printed faster compared to flexible N95 alternative; however, rigid N95 3D-printed alternatives did not pass respiratory fit testing according to OSHA standards. A highlight of this study was that it used rapid prototyping and iteration to generate a potentially viable N95 alternative. Fortunately, we never reached a point where we were required to use the masks we generated, but we suspect this process of rapid prototype/iteration facilitated by 3D printing is translatable to future urgent needs in healthcare.

**Supplementary File 1.** “MIR mask” – STL (standard tessellation language) file of single filter design that passed quantitative respiratory fit testing in the current study.

**Supplementary File 2.** “MIR mask” – STL (standard tessellation language) file of double filter design that passed quantitative respiratory fit testing in the current study.

**Supplementary Table 1.** Different iterations of the 3D printed mask design through the course of this study.

* – rigid prints of the mask base itself were abandoned at this point in the study as none showed any potential to pass fit testing. Est is estimated time and cost if those components were printed.

**Supplementary Table 2.** Comparison of mean fit factor from quantitative respiratory fit testing analyzed with non-Gaussian ANOVA comparisons. Note that the commercial device only gave the >200 value for the commercial N95 respirators rather than their actual values precluding analysis compared to the 3D printed N95 respirator alternatives.

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