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Rapid Prototyping of Reusable 3D-Printed N95 Equivalent Respirators at the George Washington University

Destie Provenzano MS* [1], Yuan James Rao MD* [2], Konstantin Mitic[1], Sofian N. Obaid[1], Dominique Pierce[4], James Huckenpahler[5], Jeffrey Berger MD[3], Sharad Goyal MD[2], Murray H. Loew PhD[1]

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* These authors contributed equally to this work.
1 Biomedical Engineering, George Washington University School of Engineering and Applied Science, Washington, DC
2 Radiation Oncology, George Washington University School of Medicine and Health Sciences, Washington, DC
3 Anesthesiology, George Washington University School of Medicine and Health Sciences, Washington, DC
4 Libraries and Academic Innovation, The George Washington University, Washington, DC
5 Corcoran School of the Arts and Design, The George Washington University, Washington, DC

Correspondence should be directed to:
Murray H. Loew, PhD
Biomedical Engineering
George Washington University School of Engineering and Applied Science
Science and Engineering Hall
800 22nd St., N.W., Suite 5000
Washington, DC 20052 USA
+1-202-994-5910 (T)
loew@gwu.edu

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Abstract:
The 2019 Novel Coronavirus (COVID-19) has caused an acute reduction in world supplies of personal protective equipment (PPE) due to increased demand. To combat the impending shortage of equipment including N95 masks, the George Washington University Hospital (GWUH) developed a 3D printed reusable N95 comparable respirator that can be used with multiple filtration units. We evaluated several candidate prototype respirator models, 3D printer filaments, and filtration units detailed here. Our most recent working model was based on a respirator found on an open source maker website and was developed with PLA (printer filament), a removable cap, a removable filtration unit consisting of two layers of MERV 16 sandwiched between MERV 13, and removable elastic bands to secure the mask. Our candidate mask passed our own suction test protocol to evaluate leakage and passed a qualitative Bitrix N95 fit test at employee health at GWUH. Further efforts are directed at improving the current model for seal against face, comfort, and sizing. The 3D model is available upon request and in the supplement of this paper. We welcome collaboration with other institutions and suggest other facilities consider mask fit for their own population when exploring this concept.

1.0 Background:

The 2019 Novel Coronavirus (COVID-19) has caused an acute reduction in world supplies of personal protective equipment (PPE) due to increased demand. The DC area has faced an extreme shortage of equipment including N95 masks. Our group at the George Washington University School of Engineering and Applied Science and Hospital chose to tackle this problem of a deficiency of N95 masks by 3D printing reusable respirators. We tested a series of different prototype models, filaments, filter materials, 3D printers, and sealant material to determine an optimal protocol for rapid prototyping of a reusable 3D printable N95 equivalent respirator for the hospital. This study details the results of our preliminary trials that produced a reusable mask that passed a qualitative hospital Bitrix fit test. We seek to provide guidance and suggestions for methods to implement a rapid prototype and development of a similar 3D printed mask at additional healthcare systems and facilities.

2.0 Methods:

2.1 Overview:

Our study sought to evaluate prototype modules that would be sufficient to replace N95 masks should they become unavailable due to the COVID-19 pandemic. Each 3D model was created to act as a respirator that supported a filtration cartridge as well as allowed for a seal around the lower face of the provider. Each design requires a filtration unit, and should not be used without adequate filtration materials. The 3D printed respirators were designed to direct airflow through a smaller filtration area on the front of the mask to reduce size of filtration material required. This approach allows for reduced use of filtration material by standard N95 masks and allows for use of multiple filtration cartridges.

2.2 Mask Prototype:

3D printing passes a digital file to an additive manufacturing device such as a 3D printer to create a three dimensional solid object layer by layer. Digital files are often made available to the general community in the maker space in stl, .obj or even CAD formats. Digital files were processed, modified, and prepared in GrabCAD[i], Meshmixer[ii], Slic3r,[iii] and Meshlab[iv]. We evaluated prototype respirator digital files for testing based on popularity, preliminary evaluation of feasibility by physician, and use by other developers and clinics. Selected initial candidate prototypes were all publicly available on Thingverse[v] or elsewhere (Table 1).

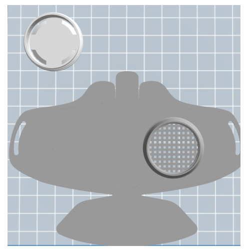
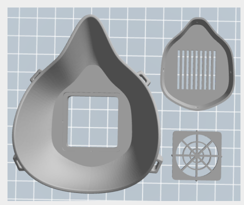
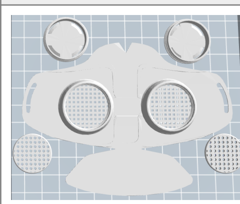
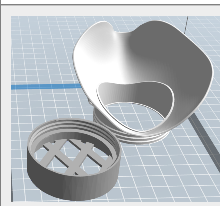
Option	Name	Source	Image	Criteria for selection:
Option 0	Nanohack Mask by Copper 3D	https://copper3d.com/hackthepandemic/		Selected due to popularity, media presence, and ease of design
Option 1	Covid-19 Mask by Lafactoria3d and the Billings Clinic in Montana	https://www.thingiverse.com/thing:4225667 https://lowellmakes.com/3d-printed-masks/ https://www.billingsclinic.com/foundation/3d-printed-surgical-mask/		Selected due to popularity, use in prior clinic, and ease of design
Option 2	Nanohack 2 filter design (Multiple Sources)	https://www.youmagine.com/designs/dual-filter-respirator-mask-covid19-coronavirus-etc https://www.thingiverse.com/thing:4240735 https://www.thingiverse.com/thing:4235063 https://www.thingiverse.com/thing:4236928		Selected due to popularity and feasibility when compared to Copper 3D Nanohack mask, and ease of design
Option 3	Single Filter Face Mask with Smaller Surface Area	https://www.dropbox.com/sh/k4-to3tve0y10uil/AAD1sjqyZk0VkYOii-Yfn50c6a?dl=0&fbclid=IwAR2wr-DGJug0hYZiC4g8BChFLyKTBiadzRhvh-PGuEb7YGesVx63kUH6B5dCQ https://www.thingiverse.com/thing:4230287 https://www.thingiverse.com/thing:4193939 https://www.thingiverse.com/thing:4244778		Selected due to popularity, potential shorter print time, and ease of design.

Table 1: 3D digital sources and files of respirator prototypes evaluated and ultimately printed by this study. All mask prototypes were evaluated and ultimately selected for initial printing based on Biomedical Engineer and Physician feedback.

A 2004 NIOSH study based on 3997 heads[vi], and 2005 study based on a half-piece respirator study that suggested a Simulated Workplace Protection Factor (SWPF) for respirator masks, together found that there were substantial and significant differences between the effectiveness of one-size-fits all face masks[vii]. Regression analysis of SWPF found the most important of 12 facial dimensions to be bigonial breadth, face width (bizgomatic breadth), face length (menton-sellon length) and nose protrusion. (Figure 1) Though not formally tested, the 2005 data was nearly normally distributed and suggested a basis for three potential sizes of masks[viii] (Table 2). For this preliminary trial we opted for a mask in between a medium and large size for testing. (Menton-Sellion=132 mm, Bigonial=96mm, Nose=43 mm).

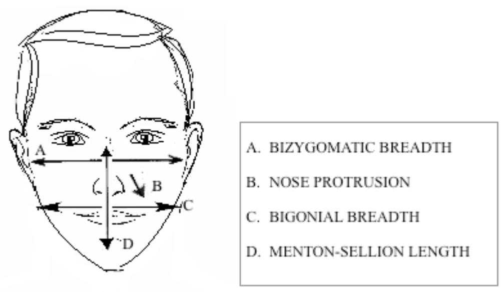


Figure 1: Diagram of 4 most important facial measurements for mask fit

Size, mm Dimension	Small	Medium	Large
Bigonial breadth	98	115	137
Bizygomatic breadth (face width)	126	140	152
Menton-Sellion length (face length)	102	118	137
Nose protrusion	25	25	25

Table 2: Suggested facial measurements for respirator mask fit.

2.3 3D Filaments:
A 3D filament is a plastic that is used in conjunction with a 3D printer to create a layer-by-layer three dimensional physical model of a digital file. 3D filaments may come in plastic form in addition to other materials. The two most popular materials are Acrylonitrile Butadiene Styrene (ABS) and Polylactic Acid (PLA)[ix]. We evaluated a series of filaments for our 3D printing purposes. Initial review was conducted of ULTEM 1010, PC-ISO, Nylon PA, ABS-M30i, PPSF/ PPSU, PEEK, MED610, ABS, PLA, and TPU. (Table 3) Standard 3D printing protocol for medical devices typically seeks to use filaments that are able to be autoclaved to assist in sterilization.[x] We anticipated that materials used could be disinfected with soap and water or alcohol per CDC guidance.[xi] Thus readily available plastics that were not heat resistance were also considered. Preliminary masks were printed from TPU, ABS, and PLA filaments due to their immediate availability at the George Washington University. Due to the difference in melting temperature and difficulty in printing, TPU was not used in a first edition prototype. Results are presented for tests from ABS and PLA. A 1 kg roll of PLA can produce roughly 12 masks in the medium - large range, suggesting cost of materials to be around $1 - 2 USD per mask.

Material	Heat Resistant	Tensile Strength, Yield	Tensile Modulus	HDT
ULTEM 1010	X	64 MPa (XZ Axis) and 42 MPa (ZX Axis)	2770 MPa (XZ Axis) and 2200 MPa (ZX Axis)	216 °C
PC-ISO	X	57 MPa	2000 MPa	133 °C
Nylon PA	X	43 MPa	1586 MPa	180 °C 95 °C
ABS-M30i	X	31 MPa	2,180 MPa	96 °C
PPSF/ PPSU	X	55 MPa	2100 MPa	230 °C
PEEK	X	98 MPa	4000 MPa	152 °C
MED610	X	50-65 MPa	75-110 MPa	45-50°C
TPU		60-80 MPa	0.483 - 5.50 GPa	51.0 - 199 °C
ABS	X	27 MPa	2.1 - 7.6 GPa	98°C
PLA		37 MPa	4 Gpa	49-52°C

Table 3: Overview of 3d printer filaments evaluated.

2.4 Equipment - 3D Printers:
Respirator prototypes were printed on a series of 3D printers available to the George Washington University through the School of Engineering and Applied Science, Library, Corcoran School of the Arts, and home printers of faculty and students. Our study was able to scale production based on crowd-sourcing and inclusion of home-printers and other resources throughout the university. Four Original Prusa i3 MK3 printers and two Prusa i3 MK2 printers[xii],

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five Stratasys F370 3D Printers[xiii], 10 Makerbot Replicator printers[xiv], and one Flashforge Adventurer 3 Lite[xv] were used to print initial prototype models.

2.5 Filtration Capabilities

N95 masks and respirator designation is defined by the United States National Institute for Occupational Safety and Health (NIOSH, regulation 42 CFR Part 84) as filtration of at least 95% of 0.3 micron particles[xvi]. The N-series are tested against a mildly degrading aerosol of sodium chloride (NaCl). The R-series filters are tested against a highly degrading aerosol of dioctylphthalate (DOP). Examples of efficiency of N95 and related NIOSH filter designations are included below (Table 4):

Filter Designation	Minimum Efficiency	Test Agent	Maximum Test Challenge Loading
N100	99.97%	NaCl	200 mg filter loading
N99	99%	NaCl	200 mg filter loading
N95	95%	NaCl	200 mg filter loading
R100	99.97%	DOP	200 mg filter loading

Table 4: Filter Designations as defined by the United States National Institute for Occupational Safety and Health (NIOSH).

As N95 and related filters are becoming difficult to source during the COVID-19 pandemic, alternative filtration materials are being investigated at the George Washington University. A possible candidate are air filters under the designation of American National Standards Institute and American Society of Heating, Refrigerating and Air-Conditioning Engineers (ANSI/ASHRA Standard 52.2-2017).[xvii] The efficiency of these air filters are classified using the Minimum Efficiency Reporting Value (MERV). MERV is expressed on a 16 point scale and is derived from the particle size efficiency (PSE) of filtration. Examples of MERV designations, air filter uses, and filtration efficiencies are listed below (Figure 2):

Based on the above specifications, it is conceivable that MERV16 filters may be a candidate replacement for the N95 filter, and filters of MERV 11-16 material may also be viable filters if enough layers of material are used. We considered four initial potential filter material components of a MERV 16, MERV 13, Smaller piece of an original N95 mask, and multiple layers of cotton for this study. We ultimately evaluated a filter cartridge consisting of two layers of MERV 16 sandwiched between two layers of MERV 13 material at a fit test. The reason for the MERV 13 sandwich is that some MERV16 filters might contain fiberglass, which is a potential health hazard, and the MERV13 filter will reduce the hazard of fiberglass inhalation. In contrast, MERV13 filters do not typically contain fiberglass. We assumed that the filter material performed according to the claims of the manufacturer. A sheet of MERV 16 combined with a sheet of MERV 13 can produce about 1,000, 40 mm x 40 mm (on average) squares of respirator material. This brought out cost per filter to be about $0.10 USD.

2.6 Sealant Material:

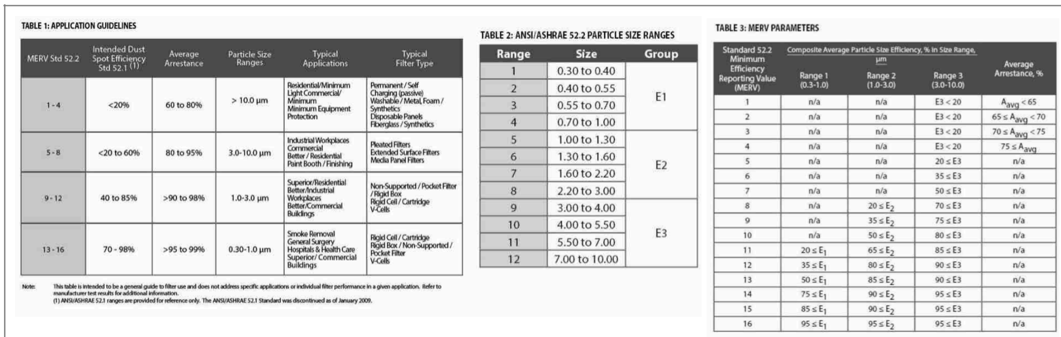

TABLE 1: APPLICATION GUIDELINES

MERV Std 52.2	Intended Dust Spot Efficiency Std 52.1 (1)	Average Arrestance	Particle Size Ranges	Typical Applications	Typical Filter Type
1 - 4	<20%	60 to 80%	> 10.0 µm	Residential/Minimum Light Commercial/ Minimum Minimum Equipment Protection	Permanent / Self Charging (passive) Washable / Metal, Foam / Synthetics Disposable Panels Fiberglass / Synthetics
5 - 8	<20 to 60%	80 to 95%	3.0-10.0 µm	Industrial Workplaces Commercial Better / Residential Paint Booth / Finishing	Pleated Filters Extended Surface Filters Media Panel Filters
9 - 12	40 to 85%	>90 to 98%	1.0-3.0 µm	Superior/Residential Better/Industrial Workplaces Better/Commercial Buildings	Non-Supported / Pocket Filter / Rigid Box Rigid Cell / Cartridge V-Cells
13 - 16	70 - 98%	>95 to 99%	0.30-1.0 µm	Smoke Removal General Surgery Hospitals & Health Care Superior/ Commercial Buildings	Rigid Cell / Cartridge Rigid Box / Non-Supported / Pocket Filter V-Cells

Note: This table is intended to be a general guide to filter use and does not address specific applications or individual filter performance in a given application. Refer to manufacturer test results for additional information.
(1) ANSI/ASHRAE 52.1 ranges are provided for reference only. The ANSI/ASHRAE 52.1 Standard was discontinued as of January 2009.

TABLE 2: ANSI/ASHRAE 52.2 PARTICLE SIZE RANGES

Range	Size	Group
1	0.30 to 0.40	E1
2	0.40 to 0.55	
3	0.55 to 0.70	
4	0.70 to 1.00	
5	1.00 to 1.30	E2
6	1.30 to 1.60	
7	1.60 to 2.20	
8	2.20 to 3.00	
9	3.00 to 4.00	E3
10	4.00 to 5.50	
11	5.50 to 7.00	
12	7.00 to 10.00	

TABLE 3: MERV PARAMETERS

Standard 52.2 Minimum Efficiency Reporting Value (MERV)	Composite Average Particle Size Efficiency, % in Size Range, µm			Average Arrestance, %
	Range 1 (0.3-1.0)	Range 2 (1.0-3.0)	Range 3 (3.0-10.0)	
1	n/a	n/a	E3 < 20	$A_{avg} < 65$
2	n/a	n/a	E3 < 20	$65 \le A_{avg} < 70$
3	n/a	n/a	E3 < 20	$70 \le A_{avg} < 75$
4	n/a	n/a	E3 < 20	$75 \le A_{avg}$
5	n/a	n/a	20 ≤ E3	n/a
6	n/a	n/a	35 ≤ E3	n/a
7	n/a	n/a	50 ≤ E3	n/a
8	n/a	$20 \le E_2$	70 ≤ E3	n/a
9	n/a	$35 \le E_2$	75 ≤ E3	n/a
10	n/a	$50 \le E_2$	80 ≤ E3	n/a
11	$20 \le E_1$	$65 \le E_2$	85 ≤ E3	n/a
12	$35 \le E_1$	$80 \le E_2$	90 ≤ E3	n/a
13	$50 \le E_1$	$85 \le E_2$	90 ≤ E3	n/a
14	$75 \le E_1$	$90 \le E_2$	95 ≤ E3	n/a
15	$85 \le E_1$	$90 \le E_2$	95 ≤ E3	n/a
16	$95 \le E_1$	$95 \le E_2$	95 ≤ E3	n/a

Figure 2: Example MERV specifications from ANSI/ASHRA Standards.

Special mention should be made of the difference between a 3D printed surgical mask and 3D printed N95 mask. Both masks are classified as respiratory protective barriers. A surgical mask is a loose fitting disposable device between the face and mask. FDA guidance for N95 masks suggests masks must have a close fit, and seal around the edges of the face and nose.[xviii] We tested a series of methods to seal the mask around the face. Various elastic and rubber bands were evaluated for comfort against the face and weather stripping foam as is available from common hardware stores was placed inside the mask to seal the mask against the face. Due to the thermal properties of PLA masks were also placed in warm water and molded against wearer's faces to evaluate fit and seal.

There is opportunity for inconstancy between masks produced on different types of 3D printers. Shellac[xix] and most polyurethane finishes once cured[xx] are food safe approved by the FDA and can be used to coat masks to create an additional seal for quality control and to prevent further viral or bacterial growth. Shellac in particular is commonly used in the pharmaceutical industry and can be purchased for about $7 USD for an aerosolized can.[xxi]

2.7 Fit testing Protocol
Fit testing of N95 masks and equivalent masks can be accomplished by qualitative and quantitative testing according to the United States Occupational Safety and Health Administration (OSHA, regulation 1910.134)[xxii] There are four qualitative methods accepted by OSHA including Isoamyl acetate, which smells like bananas; Saccharin, which leaves a sweet taste in the mouth; Bitrex (denatonium benzoate), which leaves a bitter taste in the mouth; and Irritant smoke, which can cause coughing. There are also three quantitative methods that are accepted including generated aerosol, ambient aerosol, and controlled negative pressure.

At the George Washington University, prototype 3D-printed respirators are initially tested for a basic negative pressure seal test by asking the user to place the respirator on the face, with the filter cap off, placing a hand over the filter opening. The user is then asked to inhale. A positive test is achieved if a tight seal is placed around the respirator and no leaks are detected. A negative test is achieved if leaks are felt around the edge of the mask during inhalation.

If the basic negative pressure seal test is successful, the user and fitted mask is sent to George Washington University Hospital employee health for a Bitrex qualitative fit test. This includes a sensitivity screening followed by mask fit testing under several use conditions. The sensitivity testing involves asking the subject to place a hood without a respirator, and Bitrex solution is aerosolized with a nebulizer, and the test is positive if the subject can taste the bitter taste of Bitrex. If the fit test is positive, the subject is instructed to put on the mask and Bitrex is regularly aerosolized in the hood. During this time, the subject is asked to undergo several use conditions including (a) normal breathing (b) deep breathing, (c) turning head side to side, (d) moving head up and down, (e) reciting a passage, (d) jogging in place, and (g) normal breathing. The test is completed and passed if the subject does not detect a bitter taste at any time during the test. If at any point the subject detects a bitter taste, the fit of the respirator to the subject is judged inadequate.

Masks were distributed amongst 9 GW faculty makers including radiation oncologists and anesthesiologists for preliminary evaluation. Three masks were brought to on-site fit test at the George Washington University Hospital.

2.8 Cleaning Protocol
3D Printed respirators can be cleaned according to hospital protocol for COVID-19. We tested soap and warm water, and alcohol. UV sterilization may also be effective[xxiii]. Light heat (70 degrees Celsius for 30 minutes) would require testing as special caution is advised to ensure 3D printed respirator filament doesn't deform.

3.0 Results:
3.1 Mask Prototype and Filament Comparison:
First models were printed on the Prusa i3 MK3 in PLA (Figure X), TPU (Not pictured) and ABS (Figure 3). Option 1 was determined to be similar to Option 3 and provided less room to breathe, so it was discarded from further consideration. ABS produced a result that was very porous and had toxic fumes, so it too was discarded from further consideration. Option 3 required extensive post processing to even test fit against the face and was discarded after print from further consideration. Option 4 fit, however didn't cover a large portion of the face and physician wearer didn't feel the mask had adequate facial coverage, as such it was discarded from further consideration. Option 1 was selected as the best prototype to continue with further testing due to its fit, ability to consistently pass a suction test, and overall positive feedback from preliminary test with physicians. PLA regardless of initial settings printed masks of similar fit test quality as long as it fit the printer according to printer specifications.

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Option 1 - PLA
Print time: 3 hours 15 minutes
3 per tray

Option 3 - PLA
Print time: 2 hours 45 minutes
1 per tray

Option 4 - PLA
Print time: 1 hour 45 minutes
4 per tray

Option 4 - ABS
Print time: 1 hour 45 minutes
4 per tray

Figure 3: Preliminary prototype results of options 2, 3, and 4.

3.2 3D Printer, Sealant, and Filtration Capabilities Comparison and Fit Test Results

Respirator prototypes were tested across printer, sealant method, and filtration capability. All masks fit to an individual were able to eventually pass the suction test. 3D printer settings were modified for different infill and qualities. It was found that infill could be varied down to as little as 5% without loss of respirator function. Models painted on the Stratsys (Figure 4) were more porous than other printers types and were more difficult to eventually fit.

Prusa i3 MK3 - PLA 15% infill	Prusa i3 MK3 - PLA 5% infill	Stratasys F370 15% infill	Flashforge Adventurer 3 Lite 5% infill

Figure 4: Comparison of respirators printed across various printers. Multiple versions of each were printed, three are depicted here.

Different types of mask sealant were also evaluated. Type of elastic or rubber material used to secure the mask to the face did not matter for suction or fit test, as long as the mask was secure. (Figure 5) Masks fit with warm water and pressed to face were ultimately the most comfortable based on preliminary feedback. Mask fit with foam was able to be worn around a clinic and hospital meeting for about an hour with minimal discomfort from the user. Mask not fit with warm water also passed the suction test and had only minimal discomfort to the user.

Mask dipped in warm water and fit to face.	Mask equipped with rubber weather stripping foam.	Mask sealed with duct tape worn during healthcare facility fit test.

Figure 5: Comparison of different sealants. Thermal properties of PLA allow fit by placement in warm water then suctioned to face. Masks were also fit using foam weather stripping material commonly available at a local hardware store. Mask with no additional modifications was fit with duct tape.

Masks were disinfected and sterilized with multiple rounds of rubbing alcohol then soap and water before distribution at hospital with no visible ill effects. Due to physician's schedule and lack of time, masks were not individually fit on site and duct tape was used as a last minute modification for comfort and seal. Of ten surveyed individuals, three were able to pass a suction test with no additional fitting, and two more passed with duct tape.

Mask was fit tested with MERV 16 filtration material layered in MERV 13 filtration material to absorb particulate matter and prevent transmission to physician. (Figure 6) A qualitative mask fit test was performed with Bitrix in GWUH Employee Health. The mask fit with duct tape adjustments passed the hospital fit test and the wearer reported lack of taste of Bitrix substance. This demonstrated that it is feasible for the 3D-printed N95 equivalent respirator to pass a qualitative fit test that is in clinical use at a healthcare facility.

Figure 6: Fit test and filtration packet. MERV 16 material (Darker colored) was wrapped with MERV 13 material to create a filtration packet. Special caution should be taken to ensure all air that enters the mask is passed through the filter.

3.3 Further Work

We incorporated feedback from physicians to create a George Washington University Hospital Model that passes the suction test that features a wider nose bridge and mask material that covers a larger portion of wearer's faces (Figure 7). Continued development will focus on sizing, fitting, filtration testing, and scalability of production. Facilities that seek to implement this model should take into consideration fit to their population and and do a test process prior to rollout. We seek collaborators from additional institutions and recommend other facilities contact corresponding author if they wish to participate. Our most recent iteration of the STL files will be uploaded to preprint and are available upon request.

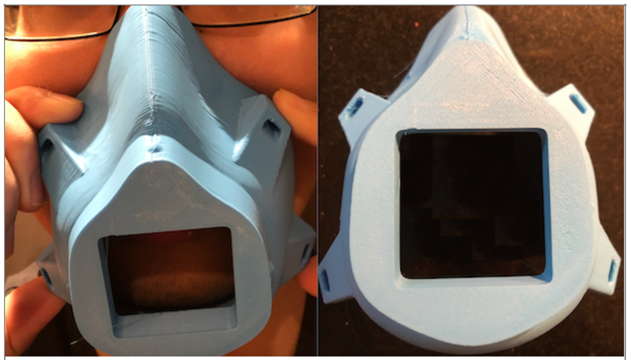

Figure 7: Sample Mask Developed for George Washington University Hospital. Pictured without filtration to show fit. Mask fit may need to be adjusted for other facilities based on population of users.

4.0 Discussion:

This study produced a 3D printed reusable respirator that was able to pass hospital Bitrix fit test for the N95 mask. The advantages of this method are the respirators are easy to produce, easy to clean, can be individually fit to an individual, and can be cleaned with UV, light heat, alcohol, or soap and water between each use. The filtration packets made of MERV 16 and MERV 13 material can be sterilized of COVID-19 and reused. As the filtration materials are used in furnaces, they can sterilized through heat or UV light without additional damage. Three masks can be produced roughly every three hours on the larger printers, as such scaling to production of 70 - 100 masks a day on local printers at the George Washington University Hospital is feasible. These masks would provide a viable alternative should supplies run out as 1,000+ filter cartridges can be produced from a single MERV 16 air filter. Each mask costs between $2 - 4 USD depending on source materials and can be reused multiple times assuming adequate cleaning.

The disadvantages of this method are the masks, similar to the N95 mask, have to be individually fit. Users that could not pass the suction test reported difficult fitting the mask around the nose and cheeks. Mask can be heated to mold to a users' face, so if protocols are not put in place to safely do this, individuals could burn themselves or have other adverse effects. This device could also function as a surgical mask, however for N95 feasibility fit needs to be ensured to users face through suction test and fit test before use. Extra thought into fit of the mask to an end user's population should be considered before this prototype is placed into mass production. The filtration qualities of the MERV material as stated by the manufacturer have not been independently validated at this time and this in particular requires additional investigation. Further research will evaluate if a 3D printed mask could provide an airtight fit to the majority of users through modification of design. Future efforts will focus on printing masks in three different suggested sizes. Additional research into use of rubber around the edges or other sealant could produce a better fit for all faces from generalized masks. Using a medical safe coating is also recommended to account for differences in mask creation such as the porous mask we developed on the Stratasys printer.

5.0 Conclusion:

3D printed N95 reusable respirators could provide a viable alternative to N95 masks should a facility deplete their supply of PPE. Extra caution when printing the model should be given to fit to the individual such that there are no leaks and all air has to pass through the filter to reach the wearer's face. The combination of a 3D printed respirator from our study made with PLA and a two layer-MERV 16 filter cartridge sandwiched between two layers of MERV 13 provided a reusable mask that passed a hospital Bitrix qualitative fit test once fit to the user's face.

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