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## Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-039120
Article Type:	Original research
Date Submitted by the Author:	04-Apr-2020
Complete List of Authors:	Byrne, James; Brigham and Women's Hospital, Radiation Oncology; Massachusetts Institute of Technology, Koch Institute Wentworth, Adam; Brigham and Women's Hospital, Medicine / Division of Gastroenterology; Massachusetts Institute of Technology, Koch Institute Chai, Peter; Brigham and Women's Hospital, Emergency Medicine Huang, Hen-Wei; Massachusetts Institute of Technology, Koch Institute; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Babae, Sahab; Massachusetts Institute of Technology, Mechanical Engineering; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Li, Canchen; Massachusetts Institute of Technology, Koch Institute Becker, Sarah; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Tov, Caitlynn; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Min, Seokkee; Massachusetts Institute of Technology, Koch Institute Traverso, Giovanni; Massachusetts Institute of Technology, Mechanical Engineering; Brigham and Women's Hospital, Medicine / Division of Gastroenterology
Keywords:	PUBLIC HEALTH, RESPIRATORY MEDICINE (see Thoracic Medicine), Respiratory infections < THORACIC MEDICINE

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## Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection

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**Word count:** 3132

### Abstract

**Objective** To develop and test a new reusable, sterilizable N95-comparable face mask, known as the iMASC system, given the dire need for personal protective equipment (PPE) within healthcare settings during the COVID-19 pandemic

**Design** Single arm feasibility study

**Setting** Emergency department and outpatient oncology clinic

**Participants** Healthcare workers that have previously undergone N95 fit testing

**Interventions** Fit testing of new iMASC system

**Primary and secondary outcome measures** Primary outcome is success of fit testing, and secondary outcomes are user experience with fit, breathability, and filter replacement.

**Results** Twenty-four subjects were recruited to undergo fit testing, and the average age of subjects was 41 years (range of 21-65 years) with an average BMI of 26.5. The breakdown of participants by profession was 46% nurses (n=11), 21% attending physicians (n=5), 21% resident physicians (n=5), and 12% technicians (n=3). Of these participants, 4 did not perform the fit testing inability to detect saccharin solution on pre-mask placement sensitivity test, time, and general mask on her face. All participants (n=20) that performed the fit test successfully completed the fit test as part of the hospital annual policy. User experience with the iMASC system, as evaluated using a Likert scale with a score of 1 indicating excellent and a score of 5 indicating very poor, demonstrated an average fit score was 1.75, breathability was 1.6, and ease of replacing the filter on the mask was scored on average as a 2.05.

**Conclusions** The iMASC system was shown to successfully fit multiple different face sizes and shapes using an OSHA approved testing method.

## Article summary

### Strengths and limitations of this study

- Development of a new N95-comparable mask that can be sterilized and reused
- Mechanical testing of iMASC system determining stability under sterilization conditions
- Finite elemental analysis showcasing mask deformation and reaction forces from facial scans of twenty different wearers
- Testing of iMASC system in emergency department and outpatient oncology clinic healthcare workers with faces that were different sizes and shapes
- The iMASC system as an alternative sustainable solution to the dwindling supply of disposable N95 masks

## Introduction

Dwindling supplies of personal protective equipment (PPE) in hospitals is forcing healthcare workers to reuse and clean PPE using anecdotal strategies, which may weaken the effectiveness of PPE in protecting workers from acquisition of COVID-19 disease. In some places, the complete lack of PPE has resulted in healthcare workers using PPE that may have variable droplet protection.<sup>1</sup> Shortages of PPE have significant impact among healthcare workers who evaluate individuals with suspected and confirmed COVID-19 disease.<sup>1-2</sup> First, individuals using PPE acquired outside of the hospital may inadvertently be using PPE without droplet protection resulting in inadequate protection. Second, workers without PPE will acquire infections, including COVID-19, at greater rates than those with adequate PPE.<sup>3</sup> Infected healthcare workers may transmit disease to family members, worsening the pandemic.<sup>4</sup> Third, with increased COVID-19 infection among healthcare workers, the available workforce to address sick patients decreases, resulting in increasing morbidity and mortality.<sup>4</sup> There is therefore a critical need to develop innovative measures to generate safe, reusable PPE.

Thus, we have designed and fabricated an Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection with N95 material filters that can be inserted and replaced as needed. To understand the ability of our mask to conform to multiple face sizes and shapes, we have undertaken finite element analysis evaluating the deformability of the iMASC system. Lastly, we performed a prospective clinical trial for fit testing of our mask as well

1 as qualitative assessment of the mask compared to the current N95 masks. Our goal is to address  
2 the critical shortage of N95 face masks to maximally protect healthcare workers and provide an  
3 enduring supply chain of N95 face masks to reduce and prevent COVID-19 transmission among  
4 healthcare workers and patients.  
5  
6

## 7 **Methods**

### 8 *iMASC fabrication*

9  
10 Masks were designed in SolidWorks based upon current 3M 1860 N95 masks. Once  
11 optimized, the design was exported as a SolidWorks file. Reusable face masks were then generated  
12 by Protolabs through injection molding out of liquid silicone rubber. Elastic straps were used to  
13 secure the mask to the wearer's face. The mask utilized dual, replaceable filters consisting of virgin  
14 N95 filter media bonded to a rigid retaining ring which can easily press-fit into recessed areas of  
15 the mask. A 3-inch long, 5mm wide aluminum strip was bonded across the bridge of the nose  
16 section of the mask similar to traditional N95 masks.  
17  
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19

### 20 *Material selection and testing*

21  
22 As a material currently used in anesthesia masks, DOW QP1-250 LSR was selected as a  
23 proven injection molding material which enabled greater design freedom for the manufacturing  
24 process. Mechanical testing according to ASTM D412 was performed on samples cut directly from  
25 masks exposed to a variety of sterilization methods including 10 cycles of autoclaving, 10-minute  
26 soak in 10% bleach solution, and 10-minute soak in isopropanol.  
27  
28  
29

### 30 *Face scans*

31  
32 To obtain the 3D face geometry of the participants, we developed an IOS application (app)  
33 using the TrueDepth camera from an iPhone 11 to capture the face image of the participants. The  
34 app employs the ARKit developed by Apple for the use of face tracking in augmented reality to  
35 transform a 2D image with depth information into a 3D mesh. The output 3D mesh would then be  
36 converted into a solid model for finite element analysis.  
37  
38

### 39 *Deformation studies*

40  
41 The commercial FE package ABAQUS/standard 2017 was used for simulating the  
42 deformation response of elastic masks. The 3D FE models were constructed by importing the CAD  
43 model of the mask from SolidWorks and scanned images of the participant faces. In all the analyses,  
44 we discretized the mask using four-node 3D linear tetrahedron elements with hybrid formulation  
45 (C3D4H Abaqus element type). The material behavior of the elastomeric mask was captured using  
46 an almost incompressible Neo-Hookean hyperelastic model with Poisson's ratio of  $\nu_0 = 0.499$  and  
47 density of 1.12E3 kg/m<sup>3</sup>) with directly imported uniaxial test data described in "Material  
48 characterization of the medical-grade silicone elastomer". The scanned faces were imported as 3D  
49 Shell Discrete Rigid Element and meshed using three-node 3D rigid triangular elements (R3D3  
50 Abaqus element type). A simplified contact law ("surface to surface" type interaction) was assigned  
51 to the model with a penalty friction coefficient 0.2 for tangential behavior and a "hard" contact for  
52 normal behavior. The top-middle edge of the mask was positioned to the node at the center of the  
53 line connecting the eyes. The "Quasi-static" dynamic implicit solver (\*DYNAMIC module in  
54 Abaqus) was used. The mask was deformed by applying tensile forces along bands, shown in **figure**  
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1 **S1** using SMOOTH step amplitude curve, while completely constraining the motion of the face.  
2  
3 The reaction force of the mask against the face as well as contact pressures were recorded as a  
4 function of applied load.  
5

### 6 *Clinical studies*

7  
8 Institutional Review Board (IRB) approval was obtained prior to any work (Partners IRB  
9 2020P000852). Subjects were comprised of adult Partners Healthcare staff including physicians,  
10 residents, nurses, and technicians who were recruited on a voluntary basis. Subjects were enrolled  
11 by study staff. Subjects gave informed consent to participate in the study. Following enrollment  
12 and consent, subjects were briefed on the study procedure and then completed a baseline assessment  
13 to obtain general demographic information and ensure they had previously been fit tested  
14 successfully.  
15

16  
17 Subjects underwent fit testing in accordance with the protocol outline in the OSHA guidance  
18 in Appendix A of 1910.134 using the Gerson Respirator Fit Test kit (part # 065000). In brief, a  
19 demonstration was performed to show subjects how to put on a respirator, how it should be  
20 positioned on the face, how to set the strap tension and how to determine a proper fit. Subjects then  
21 selected a respirator from the two available sizes and adjusted the facepiece until it provided an  
22 acceptable fit and was comfortable. Fit was defined as proper placement of the chin; adequate strap  
23 tension; fit across the bridge of the nose; tendency of respirator to slip; and ensuring the respirator  
24 was of proper size to span between the bridge of the nose and the chin through self-observation in  
25 a mirror. Comfort was defined as the position of the mask on the nose, face, and cheeks; room for  
26 eye protection; and room to talk. Once the mask was deemed comfortable and of adequate fit, the  
27 subject performed a user seal check. To check positive pressure, subjects gently exhaled while  
28 wearing the mask to see if the facepiece bulged slightly. Similarly, to perform a negative pressure  
29 air check subjects took a deep breath in while wearing the mask and observed for areas of collapse.  
30 If air leaked between the subject's face and the face seal of the respirator or if bulging or collapse  
31 occurred during the user seal test, the subject removed the mask and began the procedure again  
32 with a new mask. If the subject passed, they proceeded to the fit test.  
33

34  
35 Subjects first ensured they could detect the taste of the Saccharine test solution. Without a  
36 mask on, subjects donned a hood with a fitted collar with a nozzle hole in front of the subject's  
37 mouth and nose. The subject was instructed to breathe through his or her nose and to report when  
38 a sweet taste was detected. An inhalation medication nebulizer containing the test solution was  
39 gently squeezed ten times while attached to the hood apparatus to aerosolize the test solution into  
40 the hood for an approximate volume of 1ml of aerosolized test solution in the hood. If the subject  
41 reported a sweet taste, the threshold test was considered complete. If the subject was unable to taste  
42 anything, ten more squeezes were administered. Again, if the subject reported a sweet taste the  
43 threshold test was considered complete and if not, another ten squeezes were administered (30  
44 total). If the subject was unable to taste the test solution after 30 squeezes, the subject was  
45 considered unable to taste the solution and was excused from the study. Study staff recorded the  
46 taste threshold indicated in the threshold test for each subject.  
47

48  
49 After successful completion of the threshold screening test, subjects donned the mask they  
50 had previously fitted for comfort and fit under a hood with a fitted collar and were instructed to  
51 report if they could taste the test solution. A nebulizer of odorous solution (Saccharin) was inserted  
52 into the hole in the front of the hood and sprayed at the same concentration (10, 20, or 30 squeezes)  
53

1 as the subject was able to taste in their initial threshold test. The subject was instructed to perform  
2 the following exercises while the aerosolized solution was replenished every 30 seconds: normal  
3 breathing, deep breathing, turning the head side to side, moving the head up and down, counting  
4 backwards from 100, grimacing, bending over, and finally normal breathing for a second time. If  
5 the subject at any time during the fit test was able to taste the solution, they indicated to the study  
6 staff and the test was considered failed. If the subject did not report tasting the solution the test was  
7 considered passed. Subjects who passed the fit test were introduced to how to properly replace the  
8 filter with a demonstration by study staff. Subjects were then asked to replace the filter and perform  
9 a user seal check to ensure an adequate fit. Subjects then performed a second fit test with the  
10 replacement filter. Finally, subjects completed an exit assessment where they ranked fit,  
11 breathability, and difficulty of replacing the filter according to a Likert scale. Subjects were also  
12 asked about their willingness to wear the mask compared to either a surgical mask and an N95  
13 mask. All testing was performed at Brigham and Women's Hospital.  
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## 19 Results

### 20 *Design and generation of injection molded liquid silicone rubber mask*

21 The iMASC system was designed to function as an N95-comparable mask (**figure 1**). The  
22 shape of the iMASC system was modeled from disposable regular N95 masks used in the hospital,  
23 which are amenable to many different face sizes and shapes. Medical grade liquid silicone rubber  
24 (LSR) was identified as an optimal material for mask fabrication due to its conformable capacity,  
25 sterilizability through multiple methods and compatibility with injection molding for fabrication  
26 scalability. The weight of the iMASC system was  $44.84 \pm 0.05$  grams ( $n = 3$ ) compared to  $10.41 \pm$   
27  $0.13$  grams ( $n = 3$ ) of current N95 masks. We employed a dual filter approach similar to half-mask  
28 elastomeric respirators to increase breathability and filtration area (5). A single regular N95 mask  
29 generated up to 5 filters for the iMASC system, thus extending the N95 material use. Furthermore,  
30 based upon the material selection of a medical grade LSR, the iMASC system is reusable after  
31 sterilization by cleaning with hospital grade bleach/alcohol wipes, autoclave and heating methods.  
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### 38 *Characterization of mask material after sterilization*

39 An advantage of the iMASC system over the half-mask respirators is the methods of  
40 sterilization (see **table S1**). We have performed tensile tests of the mask material after 10 autoclave  
41 cycles and 5 minutes in a 1:10 bleach solution and 70% isopropyl alcohol. We found that 10  
42 autoclave cycles make the mask slightly stiffer, while the bleach soak resulted in no change and the  
43 isopropanol alcohol soak makes the material less stiff (**figure S2**). Despite these small changes in  
44 tensile strength, there were no gross differences in the mask compared to the non-sterilized mask.  
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### 48 *Finite element analysis for mask deformation upon different face shapes and sizes*

49 We used non-linear finite element (FE) analyses (see "Deformation studies" in Methods) to  
50 evaluate the deformation response of the flexible mask frames while wearing and determine the  
51 forces required to keep the mask in place across a range of subject faces. In **figure 2A**, we reported  
52 the numerical snapshots of the face mask when subjected to the strap's tensile loads, denoted by  $T$   
53 shown in **figure S3**, and monitored the deformation of the mask at different levels of the reaction  
54 force exerted from the mask to the face,  $F = 0$  (undeformed), 4.5 (initial contact), and 10 (full  
55 contact) N. The color maps represent the distribution of displacement's magnitude,  $U$ , showing  
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1 relatively large deformation of the mask required to fit in to the subject face. We also calculated the  
2 normal contact forces,  $F^N$ , and contact pressures,  $P$ , as a function of  $F$  to evaluate the interaction  
3 between the mask and face. In **figure 2B**, the distribution of the  $F^N$  are shown at the different  $F$ . As  
4 expected, no  $F^N$  was recorded at  $F = 0$ . By pulling the straps, the mask starts to be engaged with  
5 the face, and at  $F = 4.5$  N the maximum  $F^N$  occurs around the cheek. Further pulling the straps ( $F$   
6 = 10 N) induces a relatively higher  $F^N$  along the edge of the mask in the cheek and chin (lower  
7 lips) rather than the nose and cheekbones. This is a signature of the need to the Aluminum strip to  
8 bond across the bridge of the nose to enhance the contact pressure.  
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12 Next, we estimated the reaction force required to achieve an average contact pressure of  $P$   
13 = 10 KPa (relatively uniformly distributed along the edge of the mask) as a higher limit of the  
14 contact pressure that results in a suitable fit between the mask and skin faces.<sup>6</sup> This reaction force  
15 is equivalent to the force applied through the straps. In **figure 2C**, we reported the reaction forces  
16 for twenty different subjects, ranging from 9.5 to 15 N. These variations are due to the difference  
17 in shape and size of the subject's faces especially in the jaw and cheekbone parts. Through  
18 application of these forces via the straps combined with the aluminum strip across the nose bridge,  
19 one can guarantee the mask will be tightly stayed in place.  
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### 23 24 *Clinical trial evaluating mask fitting*

25 In a prospective trial, we enrolled 24 healthcare workers at a large, urban, academic medical  
26 center who had been previously certified to wear a N95 respirator into our IRB-approved study. We  
27 excluded individuals with significant facial hair or those that had failed a N95 fit test. Consenting  
28 individuals were subject to a fit test as defined by the United States Occupational Safety and Health  
29 Administration (OSHA).<sup>7-8</sup> Briefly, participants first placed the iMASC system on their face and  
30 molded the nose piece to ensure an adequate seal. Next, the participant's head and face were placed  
31 in a plastic hood, and a saccharine solution was sprayed into the enclosed space as guided by  
32 OSHA.<sup>7</sup> Participants were asked to perform four maneuvers: 1) rotating head in the lateral plane,  
33 2) moving the head up and down, 3) verbally counting down backwards from 100 to 90 and 4)  
34 bending at the waist. A passing test was defined as no detection of saccharine solution by study  
35 participants. **Figure 3A** shows the demographics of the participants, and **figures S3** and **S4**  
36 showcase the 3D facial reconstructions demonstrating variability of facial sizes and shapes among  
37 the participants. The average age of participants was 41 years with a range of 21-65 years with an  
38 average BMI of 26.5. The breakdown of participants by profession was 46% nurses (n=11), 21%  
39 attending physicians (n=5), 21% resident physicians (n=5), and 12% technicians (n=3). Of these  
40 participants, 4 did not perform the fit testing (1 due to inability to detect saccharin solution on pre-  
41 mask placement sensitivity test, 2 due to time, and 1 due to fit of the mask on her face).  
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48 All participants (n=20) that performed the fit test successfully completed the fit test as part  
49 of the hospital annual policy. All participants passed their fit test and were also able to successfully  
50 replace the filter into the mask, resulting in a 100% success rate for both fit testing and filter  
51 exchange. User experience with the iMASC system was evaluated using a Likert scale with a score  
52 of 1 indicating excellent and a score of 5 indicating very poor. Of the 20 participants, the average  
53 fit score of the mask was a 1.75 (**figure 3B**). Participants on average scored the breathability of the  
54 mask as a 1.6 with a median of 1.5. Finally, ease of replacing the filter on the mask was scored on  
55 average as a 2.05 with a median score of 2. Participants' preference to wear the iMASC over a  
56 surgical mask or an N95 respirator was also assessed. Sixty percent of participants indicated they  
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would be willing to wear our mask instead of a surgical mask, with 20% indicating no preference between our mask and a standard surgical mask and 20% indicating they would prefer to wear a surgical mask (**figure 3C**). When asked about preference to wear our mask instead of an N95 respirator, 25% of participants indicated they would prefer to wear our mask and 60% indicated no preference between our mask and a standard issue mask, with only 15% indicating they would prefer to wear a standard issue N95 respirator (**figure 3D**).

## Discussion

During times of pandemics, it is essential to protect healthcare workers from infection and transmission of disease with adequate PPE.<sup>4,9</sup> As stocks of N95 face masks have reduced, healthcare workers are forced to find alternative strategies of protection, including re-sterilizing masks and using alternative mask materials that may result in less protection and higher disease transmission.<sup>9-10</sup> Our approach here was to develop a scalable, reusable face mask that can extend the amount of N95 material while providing the same droplet protection as standard N95 masks. The iMASC system was shown to successfully fit multiple different face sizes and shapes using an OSHA approved testing method. Based on the success of the iMASC system in fit testing, this approach could be scaled up for use across many locations. By selecting injection molding as the fabrication technique for the iMASC system, we believe we possess a fundamental advantage to other initiatives using three-dimensional (3D) printing techniques because injection molding is highly scalable and has decreased production time when compared to 3D printing.

These are initial proof-of-concept studies and have some limitations. First, the small sample size and single institutional nature of this prospective study limit generalizability and warrants evaluation in a larger cohort involving multiple institutions. As a result of the lack of availability of standard N95 masks, the iMASC system was not compared to standard of care N95 masks. For the iMASC system, filter replacement was noted to be slightly challenging and additional design changes, such as slight adjustments to dimensions and tolerances, would likely improve the fit and robustness. All post injection-molding manufacturing steps were completed in-house and in large scale production would be outsourced to contracted manufacturers with greater quality control of filter components.

Newer face masks, such as our iMASC system, have potential to resupply hospitals and clinics with effective N95-comparable masks. Furthermore, a 2018 consensus report from the National Academies of Engineering, Science, and Medicine recommended that the durability and reusability of elastomeric respirators made them desirable for stockpiling for emergencies.<sup>5</sup> This approach could be applicable to users outside of the healthcare setting, including people in the research, home improvement, and manufacturing settings.

## Author Statement

**Acknowledgments:** We thank Ania Hupalowska for her illustrations of the clinical workflow. We thank Prof. R. Langer for helpful discussions around mask development.

**Contributors:** J.D.B. and A.J.W. designed and fabricated the iMASC system, assisted with the clinical trial, analyzed and interpreted data, and wrote the manuscript. P.R.C. performed the clinical trial, analyzed and interpreted data, and wrote the manuscript. H.W.H. and S.B. designed the face scanning and performed FEA modeling, analyzed data, and wrote the manuscript. S.B., C.T., and

1 S.M. analyzed data and designed prototypes. G.T. supervised, reviewed the data and edited the  
2 manuscript.  
3

4  
5 **Funding:** J.D.B. was supported by the Prostate Cancer Foundation Young Investigator Award. G.T.  
6 was supported in part by the Department of Mechanical Engineering, MIT and Brigham and  
7 Women's Hospital. P.R.C was supported by NIHK23DA044874, and investigator-initiated  
8 research grants from e-ink corporation, Gilead Sciences, Philips Biosensing and the Hans and  
9 Mavis Lopater Psychosocial Foundation. Support for the materials and supplies was from  
10 discretionary funds to G.T. from Brigham and Women's Hospital and the Department of  
11 Mechanical Engineer, MIT.  
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16 **Competing Interests:** There are no competing interests related to the work described in the  
17 manuscript. Complete details of all other relationships for profit and not for profit for G.T. can  
18 found at the following link: [https://www.dropbox.com/sh/szi7vnr4a2ajb56/AABs5N5i0q9Aft1IqIJAE-  
19 T5a?dl=0](https://www.dropbox.com/sh/szi7vnr4a2ajb56/AABs5N5i0q9Aft1IqIJAE-T5a?dl=0)  
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22 **Patient and public involvement:** Patients and/or the public were not involved in the design, or  
23 conduct, or reporting, or dissemination plans of this research.  
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26 **Data Availability Statement:** The authors declare that the data supporting the findings of this  
27 study are available within the paper and its supplementary information files.  
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**Figures**

**Figure 1. iMASC system for aerosol-based protection.** (A) Front and (B) side images of the iMASC system. (C) Workflow for sterilization and reuse of iMASC system.

**Figure 2. Finite Element modeling of flexible masks.** (A) Numerical images showing the deformation of the elastomeric mask at different levels of reaction forces,  $F = 0, 4.5, \text{ and } 10 \text{ N}$  in two different views (top and bottom rows). The colors represent the magnitude of displacement field,  $U$ . (B) The corresponding distribution of the normal contact forces,  $F^N$ , between the mask and face. (C) Reaction forces for the subject numbers  $n=1,2,3,\dots, 20$  computed from simulations.

**Figure 3. Fit testing of iMASC system in healthcare workers and their user experience.** (A) Demographics of participants ( $N = 24$ ) enrolled in fit testing clinical trial. (B) User experience ( $N = 20$ ) with the mask based upon a Likert scale. User preferences ( $N = 20$ ) comparing the iMASC system to the (C) standard surgical mask and (D) N95 respirators.

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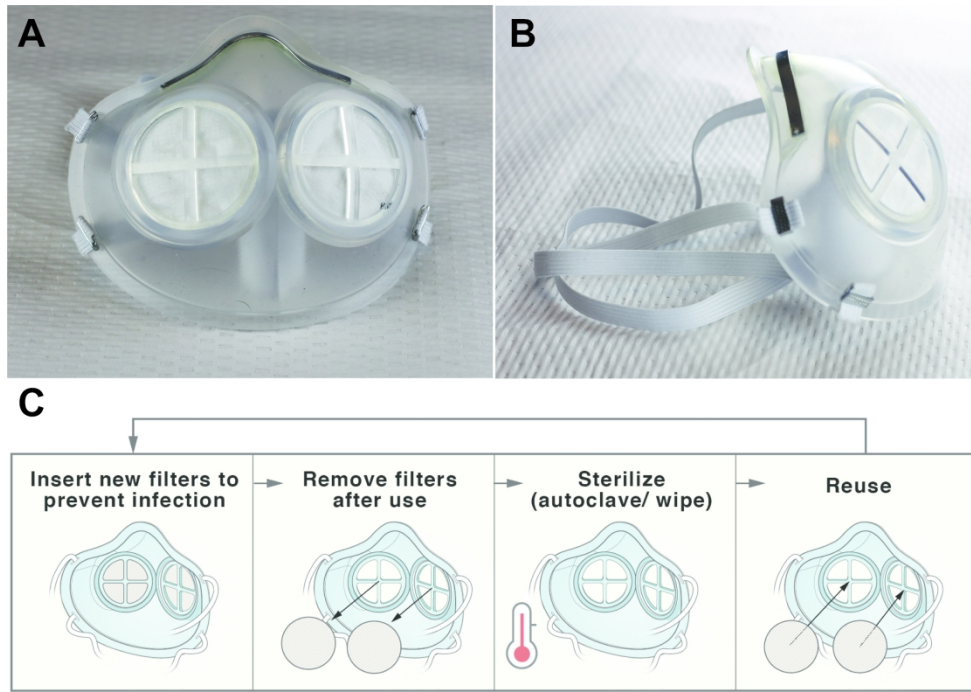


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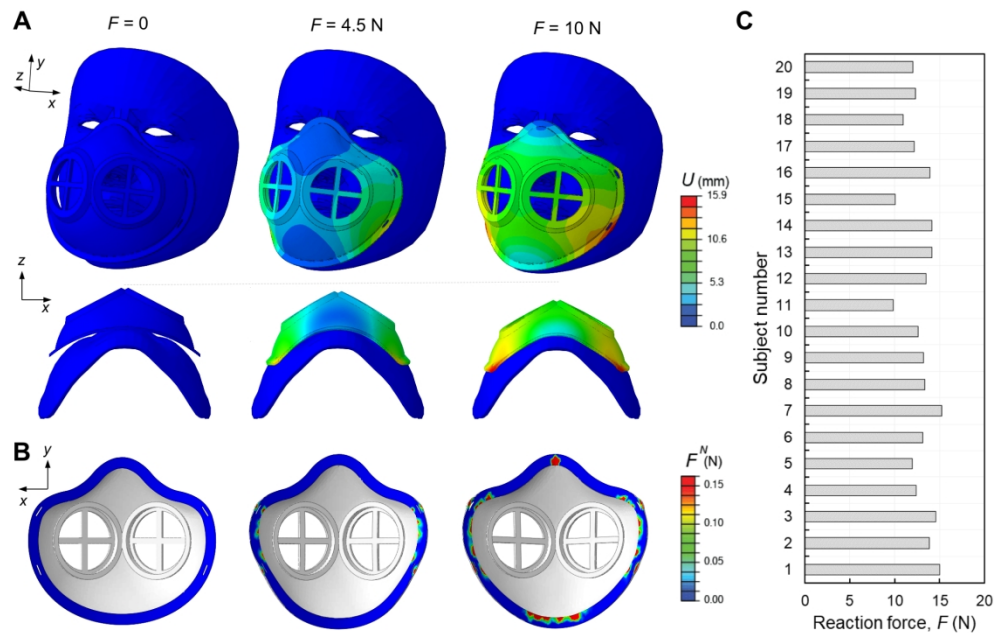


Figure 2. Finite Element modeling of flexible masks. (A) Numerical images showing the deformation of the elastomeric mask at different levels of reaction forces,  $F = 0, 4.5,$  and  $10$  N in two different views (top and bottom rows). The colors represent the magnitude of displacement field,  $U$ . (B) The corresponding distribution of the normal contact forces,  $F^N$ , between the mask and face. (C) Reaction forces for the subject numbers  $n=1,2,3,\dots, 20$  computed from simulations.

259x165mm (220 x 220 DPI)

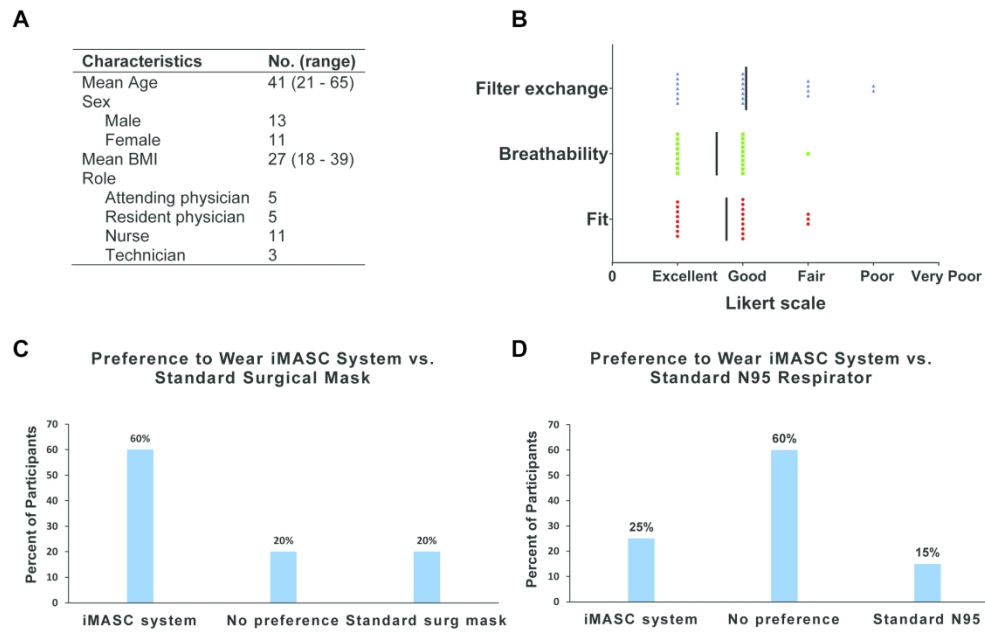


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## Supplementary Information

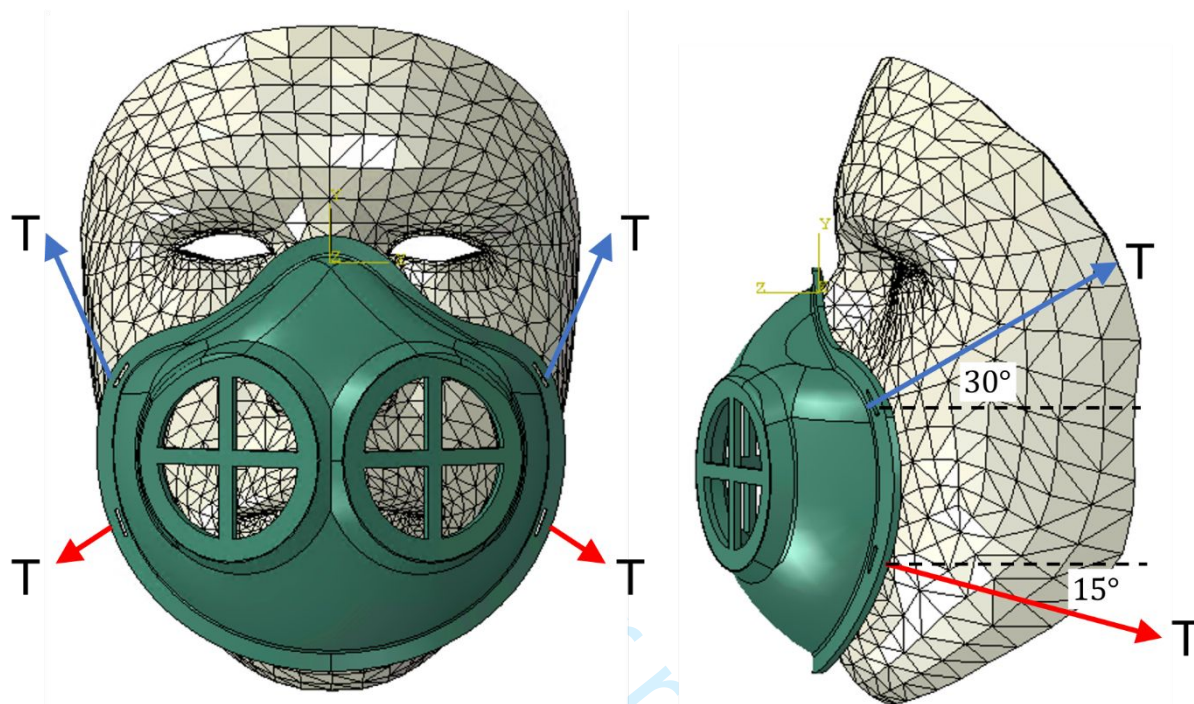
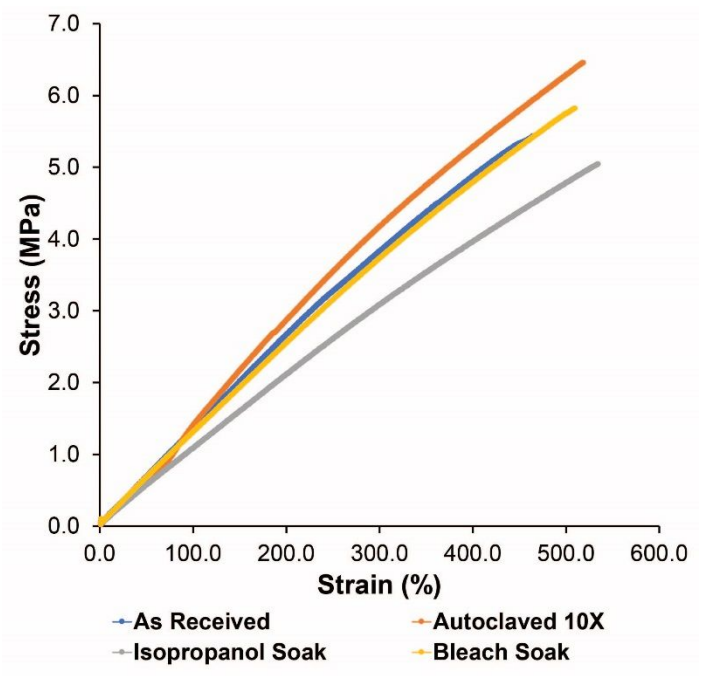


Figure S1. Illustration of the applied loads via mask straps.

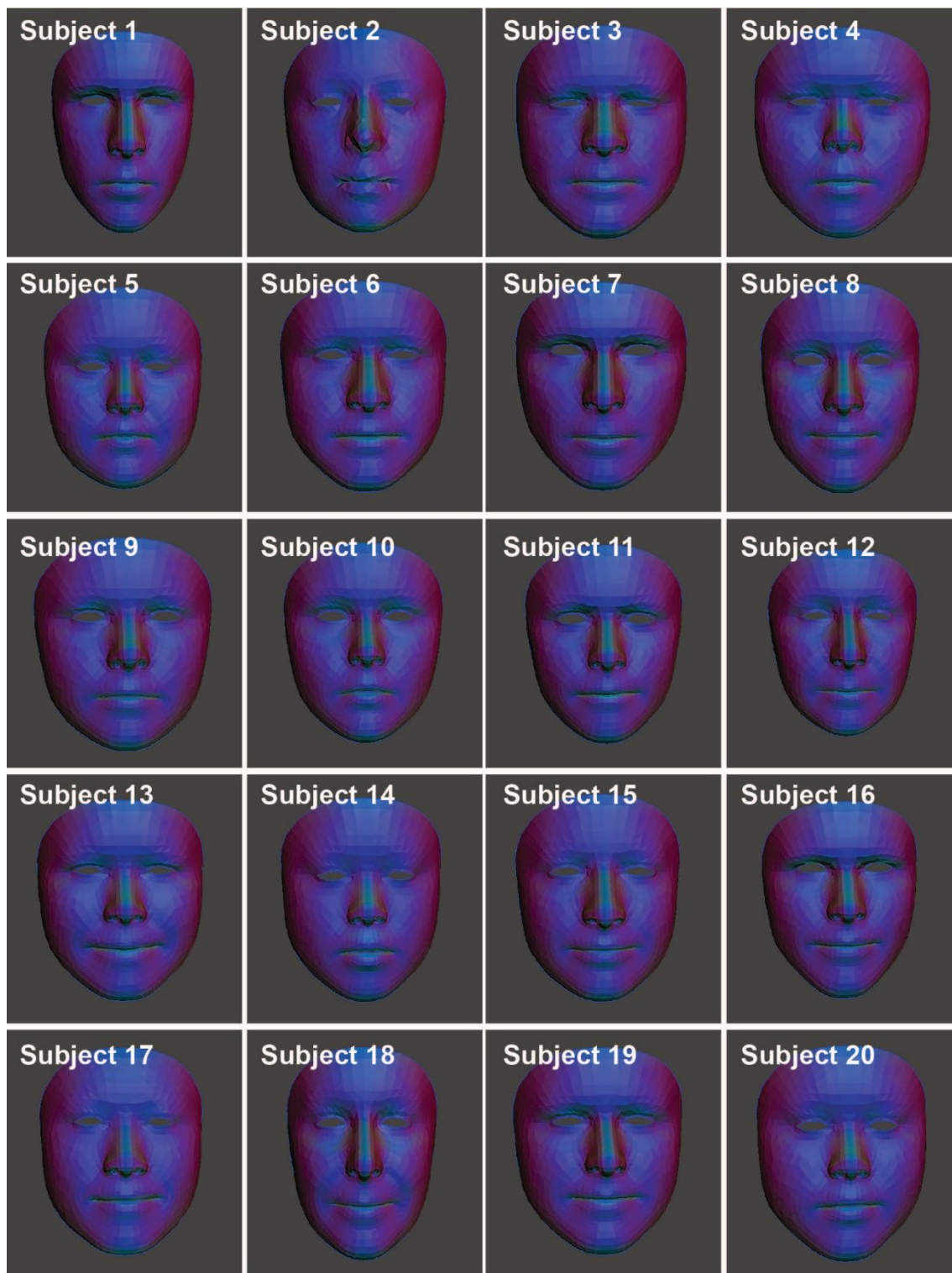


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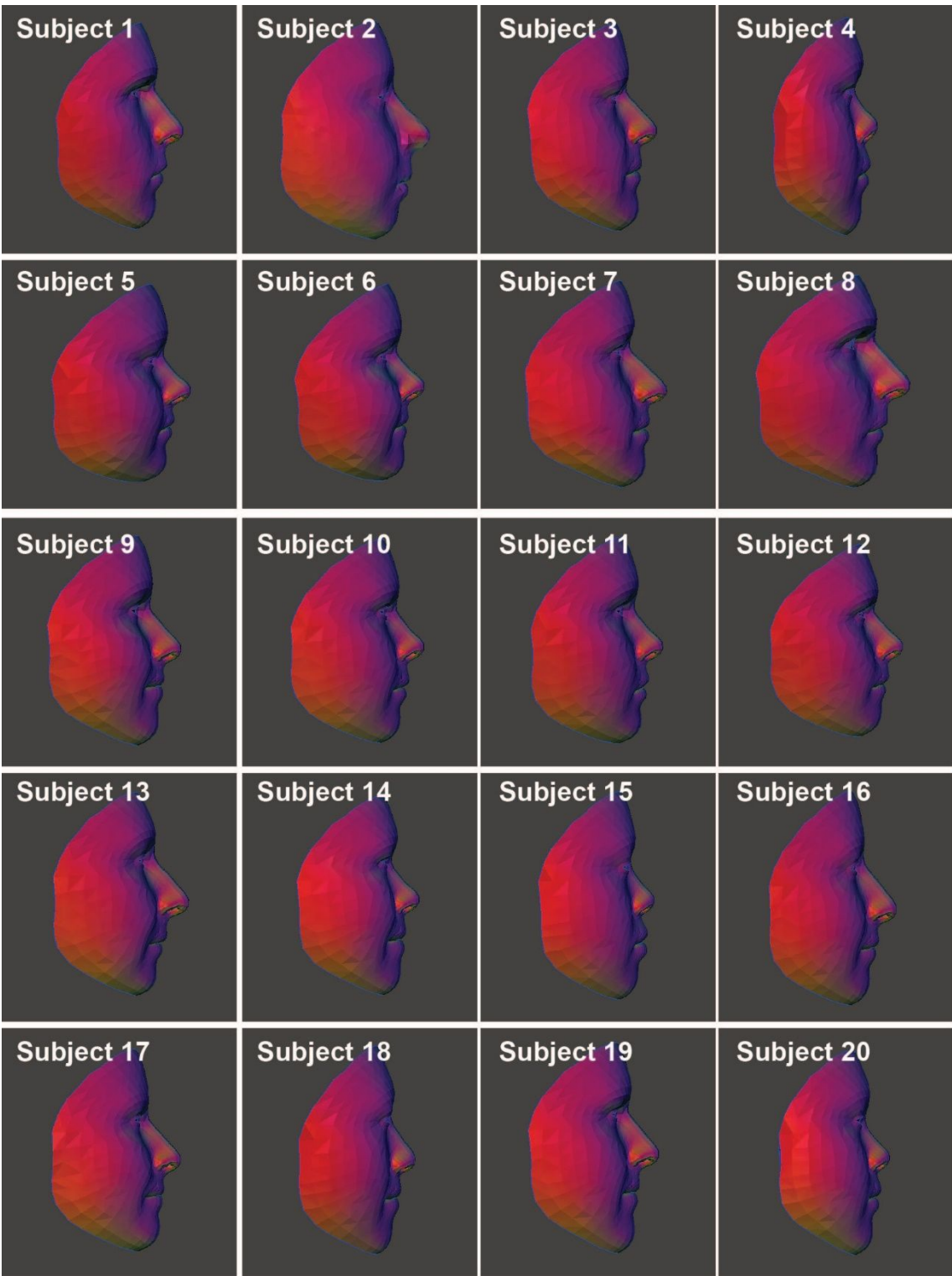
**Figure S2.** Mechanical testing on samples cut directly from masks exposed to a variety of sterilization methods including 10 cycles of autoclaving, 10-minute soak in 10% bleach solution, and 10-minute soak in isopropanol.

review only




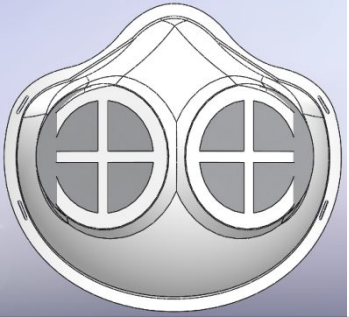


**Figure S3.** Front view of 3D facial reconstruction of participants faces in fit trial of the iMASC system.

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**Figure S4.** Side view of 3D facial reconstruction of participants faces in fit trial of the iMASC system.

**Table S1.** Array of N95 and N95-comparable technologies.

Type	Ex \$/Unit	Pros	Cons	Recommended Sterilization Method
Disposable FFR 	3M 8210 \$4.29	<ul style="list-style-type: none"> <li>Ease of fit/use</li> <li>Cheap per use compared to HFRR and FFRR</li> <li>Some models come with exhaust valve</li> </ul>	<ul style="list-style-type: none"> <li>Not reusable</li> <li>No eye protection</li> <li>If exhaust valve is available, it's not filtered</li> </ul>	N/A
iMASC system 	Mask: < \$2.00  Filter: TBD	<ul style="list-style-type: none"> <li>Cheap cost</li> <li>Ease/accessibility of manufacturing</li> <li>Potentially autoclavable</li> </ul>	<ul style="list-style-type: none"> <li>No eye protection</li> <li>No exhaust valve for humidity/ease of use relief</li> </ul>	Autoclave, Clorox wipe, IPA wipe, detergent and sterilization agent wash
Half-Face Reusable (HFRR) 	3M HFRR 6000 Mask: \$28.99  3M 2097 Cartridge: \$10.10/pair	<ul style="list-style-type: none"> <li>Powered air compatible with select models</li> <li>Exhaust valve reduces humidity and breathing resistance</li> <li>Flange/gusset provides comfortable seal skin</li> </ul>	<ul style="list-style-type: none"> <li>Expensive</li> <li>Exhaust valve not filtered</li> <li>No eye protection</li> </ul>	Detergent and sterilization agent wash
Full-Face Reusable (FFRR) 	3M FFRR 6000 Mask: \$149.52  3M 2097 Cartridge: \$10.10/pair	<ul style="list-style-type: none"> <li>Best coverage protection</li> <li>Powered air compatible with select models</li> <li>Exhaust valve reduces humidity and breathing resistance</li> <li>Flange/gusset provides comfortable seal to skin</li> </ul>	<ul style="list-style-type: none"> <li>Expensive</li> <li>Exhaust valve not filtered</li> <li>Potential visual obstruction due to fogging</li> </ul>	Detergent and sterilization agent wash

# BMJ Open

## Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection: a prospective single arm feasibility study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-039120.R1
Article Type:	Original research
Date Submitted by the Author:	21-May-2020
Complete List of Authors:	Byrne, James; Brigham and Women's Hospital, Radiation Oncology; Massachusetts Institute of Technology, Koch Institute Wentworth, Adam; Brigham and Women's Hospital, Medicine / Division of Gastroenterology; Massachusetts Institute of Technology, Koch Institute Chai, Peter; Brigham and Women's Hospital, Emergency Medicine Huang, Hen-Wei; Massachusetts Institute of Technology, Koch Institute; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Babae, Sahab; Massachusetts Institute of Technology, Mechanical Engineering; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Li, Canchen; Massachusetts Institute of Technology, Koch Institute Becker, Sarah; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Tov, Caitlynn; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Min, Seokkee; Massachusetts Institute of Technology, Koch Institute Traverso, Giovanni; Massachusetts Institute of Technology, Mechanical Engineering; Brigham and Women's Hospital, Medicine / Division of Gastroenterology
<b>Primary Subject Heading</b>:	Global health
Secondary Subject Heading:	Public health, Global health
Keywords:	PUBLIC HEALTH, RESPIRATORY MEDICINE (see Thoracic Medicine), Respiratory infections < THORACIC MEDICINE

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6 **Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for**  
7 **aerosol-based protection: a prospective single arm feasibility study**  
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9 James D. Byrne<sup>1,2,3†</sup>, Adam J. Wentworth<sup>2,3†</sup>, Peter R. Chai<sup>2,3,4,5,6†</sup>, Hen-Wei Huang<sup>2,3†</sup>, Sahab  
10 Babae<sup>2,3,7</sup>, Canchen Li<sup>3</sup>, Sarah L. Becker<sup>2,7</sup>, Caitlynn Tov<sup>2</sup>, Soekkee Min<sup>7</sup>, Giovanni  
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42 \*Corresponding author. E-mail: cgt20@mit.edu, ctraverso@bwh.harvard.edu (G.T.)  
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45 **Word count:** 3298  
46

47 **Abstract**

48 **Objective** To develop and test a new reusable, sterilizable N95-comparable face mask, known as  
49 the iMASC system, given the dire need for personal protective equipment (PPE) within healthcare  
50 settings during the COVID-19 pandemic  
51

52 **Design** Single arm feasibility study  
53

54 **Setting** Emergency department and outpatient oncology clinic

55 **Participants** Healthcare workers that have previously undergone N95 fit testing

56 **Interventions** Fit testing of new iMASC system  
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**Primary and secondary outcome measures** Primary outcome is success of fit testing, and secondary outcomes are user experience with fit, breathability, and filter replacement.

**Results** Twenty-four subjects were recruited to undergo fit testing, and the average age of subjects was 41 years (range of 21-65 years) with an average BMI of 26.5. The breakdown of participants by profession was 46% nurses (n=11), 21% attending physicians (n=5), 21% resident physicians (n=5), and 12% technicians (n=3). Of these participants, 4 did not perform the fit testing inability to detect saccharin solution on pre-mask placement sensitivity test, time, and placement over hair. All participants (n=20) that performed the fit test successfully completed the fit test as part of the hospital annual policy. User experience with the iMASC system, as evaluated using a Likert scale with a score of 1 indicating excellent and a score of 5 indicating very poor, demonstrated an average fit score was 1.75, breathability was 1.6, and ease of replacing the filter on the mask was scored on average as a 2.05.

**Conclusions** The iMASC system was shown to successfully fit multiple different face sizes and shapes using an OSHA approved testing method. These data support further certification testing needed for use in the healthcare setting.

## Article summary

### Strengths and limitations of this study

- Development of a new N95-comparable mask that can be sterilized and reused
- Mechanical testing of iMASC system determining stability under sterilization conditions
- Finite elemental analysis showcasing mask deformation and reaction forces from facial scans of twenty different wearers
- Testing of iMASC system in emergency department and outpatient oncology clinic healthcare workers with faces that were different sizes and shapes
- The iMASC system as a promising alternative sustainable solution to the dwindling supply of disposable N95 filtering facepiece respirators (FFRs)

## Introduction

Dwindling supplies of personal protective equipment (PPE) in hospitals is forcing healthcare workers to reuse and clean PPE using anecdotal strategies, which may weaken the effectiveness of PPE in protecting workers from acquisition of COVID-19 disease. In some places, the complete lack of PPE has resulted in healthcare workers using PPE that may have variable droplet protection.<sup>1</sup> Shortages of PPE have significant impact among healthcare workers who evaluate individuals with suspected and confirmed COVID-19 disease.<sup>1-2</sup> First, individuals using PPE acquired outside of the hospital may inadvertently be using PPE without droplet protection resulting in inadequate protection. Second, workers without PPE will acquire infections, including COVID-19, at greater rates than those with adequate PPE.<sup>3</sup> Infected healthcare workers may transmit disease to family members, worsening the pandemic.<sup>4</sup> Third, with increased COVID-19 infection among healthcare workers, the available workforce to address sick patients decreases, resulting in increasing morbidity and mortality.<sup>4</sup> There is therefore a critical need to develop innovative measures to generate safe, reusable PPE.<sup>5</sup>

Thus, we have designed and fabricated an Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection with N95 material filters that can be inserted and replaced as needed. To understand the ability of our mask to conform to multiple face sizes and shapes, we have undertaken finite element analysis evaluating the deformability of the



1 iMASC system. Lastly, we performed a prospective clinical trial for fit testing of our mask as well  
2 as qualitative assessment of the mask compared to the current N95 FFRs. Our goal is to address the  
3 critical shortage of N95 FFRs to maximally protect healthcare workers and provide an enduring  
4 supply chain of N95 FFRs to reduce and prevent COVID-19 transmission among healthcare  
5 workers and patients.  
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## 8 **Methods**

### 9 *Materials*

10 The mask material was DOW Corning QP1-250 liquid silicone rubber (LSR) sourced to  
11 Protolabs (Maple Plain, Minnesota, USA). The nasal bridge and elastic holders were 5mm wide by  
12 1 mm thick aluminum sheets obtained from Amazon, and nylon elastic bands were obtained from  
13 a local fabric store. Adhesive for the nasal bridge was 3M Scotch-Weld (PR40). Filters were laser  
14 cut from 3M 1860 N95 FFRs. The filters were adhered to laser cut acrylic sheeting (3.2 mm thick,  
15 46 mm diameter) (McMaster Carr, Product 8560K257) using fabric adhesive obtained from a local  
16 fabric store.  
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### 19 *iMASC fabrication*

20 Masks were designed in the three-dimensional (3D) computer aided design (CAD) software  
21 SolidWorks (Dassault Systems) based upon current 3M 1860 N95 FFRs that were in use at the  
22 hospitals in the Partners Healthcare network. Once optimized, the design was exported as a  
23 SolidWorks file. Reusable face masks were then generated by Protolabs through injection molding  
24 out of liquid silicone rubber. Elastic straps were used to secure the mask to the wearer's face. The  
25 mask utilized dual, replaceable filters. The filters were laser cut from unused N95 FFRs bonded to  
26 a rigid retaining ring which can easily press-fit into recessed areas of the mask. A 7.6 cm long, 5  
27 mm wide aluminum strip was bonded across the bridge of the nose section of the mask similar to  
28 traditional N95 FFRs.  
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### 31 *Material selection and testing*

32 As a material currently used in anesthesia masks, DOW QP1-250 LSR was selected as a  
33 proven injection molding material which enabled greater design freedom for the manufacturing  
34 process. To evaluate sterilization, the masks (n = 4 per group) were exposed to a variety of  
35 sterilization methods including 10 cycles of autoclaving (dry cycle - 121 Celsius for 15 minutes),  
36 10-minute soak in 1:10 bleach solution, or 10-minute soak in 100% isopropanol. These solutions  
37 were selected to simulate on shift sterilization by healthcare workers using standard hospital  
38 cleaning solutions. Mechanical testing according to ASTM D412 (Standard Test Methods for  
39 Vulcanized Rubber and Thermoplastic Elastomers) was performed on samples cut directly from the  
40 sterilized masks. Unpaired t-test was performed on tensile stress at maximum force between groups  
41 to evaluate for statistical differences.  
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### 44 *Face scans*

45 To obtain the 3D face geometry of the participants, we developed an IOS application (app)  
46 using the TrueDepth camera from an iPhone 11 to capture the face image of the participants. The  
47 app employs the ARKit developed by Apple for the use of face tracking in augmented reality to  
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1 transform a 2D image with depth information into a 3D mesh. The output 3D mesh would then be  
2 converted into a solid model for finite element (FE) analysis.  
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#### 4 *Deformation studies*

5  
6 The commercial FE package ABAQUS/standard 2017 was used for simulating the  
7 deformation of the iMASC system. The 3D FE models were constructed by importing the CAD  
8 model of the mask from SolidWorks and scanned images of the participant faces. In all the analyses,  
9 we discretized the mask using four-node 3D linear tetrahedron elements with hybrid formulation  
10 (C3D4H Abaqus element type). The material behavior of the elastomeric mask was captured using  
11 an almost incompressible Neo-Hookean hyperelastic model with Poisson's ratio of  $\nu_0 = 0.499$  and  
12 density of  $1.12E3 \text{ kg/m}^3$  with directly imported stress-strain curves from mechanical testing. A  
13 simplified contact law ("surface to surface" type interaction) was assigned to the model with a  
14 penalty friction coefficient 0.2 for tangential behavior and a "hard" contact for normal behavior,  
15 and the top-middle edge of the mask was positioned to the node at the center of the line connecting  
16 the eyes. The "Quasi-static" dynamic implicit solver (\*DYNAMIC module in Abaqus) was used.  
17 The mask was deformed by applying tensile forces along bands, shown in **figure S1** using  
18 SMOOTH step amplitude curve, while completely constraining the motion of the face. The reaction  
19 force of the mask against the face as well as contact pressures were recorded as a function of applied  
20 load. Multiple levels of the reaction forces were exerted from the mask to the face, including  $F=0$   
21 (undeformed), 4.5 (initial contact), and 10 (full contact) N.  
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#### 29 *Clinical studies*

30 Partners Healthcare Institutional Review Board (IRB) approval was obtained prior to any  
31 human testing of the iMASC system (Partners IRB 2020P000852). Subjects were comprised of  
32 adult Partners Healthcare staff including physicians, residents, nurses, and technicians who were  
33 recruited on a voluntary basis and had undergone Occupational Safety and Health Administration  
34 (OSHA)-approved fit testing over the past year. Healthcare workers with facial hair were excluded  
35 from enrollment. Subjects were enrolled by study staff and gave informed verbal consent to  
36 participate in the study. Verbal informed consent was obtained due to non-invasive nature and short  
37 duration of the study. Following enrollment and consent, all subjects were briefed on the study  
38 procedure by the same member of the research team and then completed a baseline assessment to  
39 obtain general demographic information and ensure they had previously been fit tested successfully.  
40

41 Subjects underwent fit testing in accordance to the Saccharin Solution Aerosol Protocol per  
42 OSHA §1910.134 using the Gerson Respirator Fit Test kit (Gerson part # 065000, Middleboro,  
43 Massachusetts.) with the saccharin solution. The fit testing was performed by a member of the study  
44 staff. This fit test system was the same system used for fit testing healthcare workers at the hospitals  
45 in the Partners Healthcare system. After successful completion of the threshold screening test,  
46 subjects donned the iMASC system and a hood with a fitted collar. They were instructed to report  
47 if they could taste the test solution. A nebulizer of the saccharin solution was inserted into the hole  
48 in the front of the hood and sprayed at the same concentration (10, 20, or 30 squeezes) as the subject  
49 was able to taste in their initial threshold test. The subject was instructed to perform the following  
50 exercises while the aerosolized solution was replenished every 30 seconds: normal breathing, deep  
51 breathing, turning the head side to side, moving the head up and down, counting backwards from  
52 100, grimacing, bending over, and finally normal breathing for a second time. If the subject at any  
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1 time during the fit test was able to taste the solution, they indicated to the study staff and the test  
2 was considered failed. If the subject did not report tasting the solution the test was considered  
3 passed. Subjects who passed the fit test were introduced to how to properly replace the filter with a  
4 demonstration by study staff. Subjects were then asked to replace the filter and perform a user seal  
5 check to ensure an adequate fit. This procedure allowed us to simulate the replacement of filters by  
6 healthcare workers prior to the start of a workday. Finally, subjects completed an exit assessment  
7 where they ranked fit, breathability, and difficulty of replacing the filter according to a Likert scale.  
8 Subjects were also asked about their willingness to wear the mask compared to either a surgical  
9 mask or an N95 mask. All testing was performed at Brigham and Women's Hospital.  
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## 14 Results

### 15 *Design and generation of injection molded liquid silicone rubber mask*

16 The iMASC system was designed to function as an N95-comparable mask (**figure 1**). The  
17 shape of the iMASC system was modeled from disposable regular N95 FFRs used in the hospital.  
18 Medical grade liquid silicone rubber (LSR) was identified as an optimal material for mask  
19 fabrication due to its conformable capacity, sterilizability through multiple methods and  
20 compatibility with injection molding for fabrication scalability. The weight of the iMASC system  
21 was  $44.84 \pm 0.05$  grams ( $n = 3$ ) compared to  $10.41 \pm 0.13$  grams ( $n = 3$ ) of current N95 FFRs. We  
22 employed a dual filter approach similar to half-mask elastomeric respirators to increase  
23 breathability and filtration area (5). A single regular N95 mask generated up to 5 filters for the  
24 iMASC system, thus extending the N95 material use.  
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### 30 *Characterization of mask material after sterilization*

31 An advantage of the iMASC system over the half-mask respirators is the methods of  
32 sterilization (see **table S1**). We have performed tensile tests of the mask material after 10 autoclave  
33 cycles and 5 minutes in a 1:10 bleach solution and 70% isopropyl alcohol. We found that 10  
34 autoclave cycles make the mask slightly stiffer, while the bleach soak resulted in no change and the  
35 isopropanol alcohol soak makes the material less stiff (**figure S2**). Evaluation of the tensile stress  
36 at maximum forces between groups were found to not be significantly different ( $p > 0.05$ ). Despite  
37 these small changes in tensile strength, there were no gross differences in the mask compared to the  
38 non-sterilized mask.  
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### 43 *Finite element analysis for mask deformation upon different face shapes and sizes*

44 We used non-linear finite element (FE) analyses (see "Deformation studies" in Methods) to  
45 evaluate the deformation response of the flexible mask frames while wearing and determine the  
46 forces required to keep the mask in place across a range of subject faces. In **figure 2A**, we reported  
47 the numerical snapshots of the face mask when subjected to the strap's tensile loads, denoted by  $T$   
48 shown in **figure S1**, and monitored the deformation of the mask at different levels of the reaction  
49 force exerted from the mask to the face. The color maps represent the distribution of displacement's  
50 magnitude,  $U$ , showing relatively large deformation of the mask required to fit in to the subject  
51 face. We also calculated the normal contact forces,  $F^N$ , and contact pressures,  $P$ , as a function of  
52  $F$  to evaluate the interaction between the mask and face. In **figure 2B**, the distribution of the  $F^N$   
53 are shown at the different  $F$ . As expected, no  $F^N$  was recorded at  $F = 0$ . By pulling the straps, the mask  
54 starts to be engaged with the face, and at  $F = 4.5$  N the maximum  $F^N$  occurs around the cheek.  
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1 Further pulling the straps ( $F = 10$  N) induces a relatively higher  $F^N$  along the edge of the mask in  
2 the cheek and chin (lower lips) rather than the nose and cheekbones. This is a signature of the need  
3 to the Aluminum strip to bond across the bridge of the nose to enhance the contact pressure.  
4

5 Next, we estimated the reaction force required to achieve an average contact pressure of  $P$   
6  $= 10$  KPa (relatively uniformly distributed along the edge of the mask) as a higher limit of the  
7 contact pressure that results in a suitable fit between the mask and skin faces.<sup>6</sup> This reaction force  
8 is equivalent to the force applied through the straps. In **figure 2C**, we reported the reaction forces  
9 for twenty different subjects, ranging from 9.5 to 15 N. These variations are due to the difference  
10 in shape and size of the subject's faces especially in the jaw and cheekbone parts. Through  
11 application of these forces via the straps combined with the aluminum strip across the nose bridge,  
12 the mask should remain in place.  
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### 16 *Clinical trial evaluating mask fitting*

17 In a prospective trial, we enrolled 24 healthcare workers at a large, urban, academic medical  
18 center who had been previously certified to wear a N95 respirator into our IRB-approved study. We  
19 excluded individuals with facial hair or those that had failed an N95 fit test. Consenting individuals  
20 were subject to a fit test as defined by OSHA.<sup>7-8</sup> **Figure 3A** shows the demographics of the  
21 participants, and **figures S3** and **S4** showcase the 3D facial reconstructions demonstrating  
22 variability of facial sizes and shapes among the participants. The average age of participants was  
23 41 years with a range of 21-65 years with an average BMI of 26.5. The breakdown of participants  
24 by profession was 46% nurses ( $n=11$ ), 21% attending physicians ( $n=5$ ), 21% resident physicians  
25 ( $n=5$ ), and 12% technicians ( $n=3$ ). Of these participants, 4 did not perform the fit testing (1 due to  
26 inability to detect saccharin solution on pre-mask placement sensitivity test, 2 due to time, and 1  
27 due to the inability to get the elastic straps over her hair and face).  
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33 All participants ( $n=20$ ) that performed the fit test successfully completed the fit test as part  
34 of the hospital annual policy. All participants passed their fit test and were also able to successfully  
35 replace the filter into the mask, resulting in a 100% success rate for both fit testing and filter  
36 exchange. User experience with the iMASC system was evaluated using a Likert scale with a score  
37 of 1 indicating excellent and a score of 5 indicating very poor. Participants scored the fit of the  
38 iMASC system as excellent (8 participants), good (9 participants), or fair (3 participants) (**figure**  
39 **3B**). Participants scored the breathability of the iMASC system as excellent (9 participants), good  
40 (10 participants), or fair (1 participants). Finally, participants scored the filter replacement of the  
41 iMASC system as excellent (7 participants), good (7 participants), fair (4 participants), or poor (2  
42 participants). Participants' preference to wear the iMASC over a surgical mask or an N95 respirator  
43 was also assessed. Sixty percent of participants indicated they would be willing to wear our mask  
44 instead of a surgical mask, with 20% indicating no preference between our mask and a standard  
45 surgical mask and 20% indicating they would prefer to wear a surgical mask (**figure 3C**). When  
46 asked about preference to wear our mask instead of an N95 FFR, 25% of participants indicated they  
47 would prefer to wear our mask and 60% indicated no preference between our mask and a N95 FFR,  
48 with only 15% indicating they would prefer to wear a standard issue N95 FFR (**figure 3D**).  
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### 55 **Discussion**

56 During times of pandemics, it is essential to protect healthcare workers from infection and  
57 transmission of disease with adequate PPE.<sup>4,9</sup> As stocks of N95 FFRs have reduced, healthcare  
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workers are forced to find alternative strategies of protection, including re-sterilizing masks and using alternative mask materials that may result in less protection.<sup>9-10</sup> Our approach here was to develop a scalable, reusable face mask that can extend the amount of N95 material. The iMASC system withstood decontamination using three methods and was shown to successfully fit multiple different face sizes and shapes using an OSHA approved testing method. The iMASC system could be scaled up for use across many locations once additional certification testing has been completed. By selecting injection molding as the fabrication technique for the iMASC system, we believe we possess a fundamental advantage to other initiatives using three-dimensional (3D) printing techniques because injection molding is highly scalable and has decreased production time when compared to 3D printing.

These are initial proof-of-concept studies and have some limitations. First, the small sample size and single institutional nature of this prospective study limit generalizability and warrants evaluation in a larger cohort involving multiple institutions. As a result of the lack of availability of standard N95 FFRs, the iMASC system was not compared to standard of care N95 FFRs. Previous studies have demonstrated that a respirator user gains experience with subsequent donnings and may result in improved fit-test pass rate biasing our results<sup>11-13</sup>; thus, it will important to assess fit testing in inexperienced subjects. While Bitrex is the preferred choice for fit test solution as a leak detection<sup>14</sup>, saccharin was chosen due to availability and use in OSHA approved qualitative fit tests. Additional development for smaller face sizes and shapes are warranted since the iMASC system was modeled from the 3M 1860 model. Furthermore, all testing was performed in North America, and it is possible face shapes and sizes may differ for workers outside of this region. Modifications to the filter system and elastic straps would likely improve the fit and robustness of the mask. All post injection-molding manufacturing steps were completed in-house and in large scale production would be outsourced to contracted manufacturers with greater quality control of filter components. Further, the testing of mechanical properties after combinations of different sterilization techniques could provide a better representation of what would be used in the hospital. Additional quantitative fit testing, extended wearer testing, and certification testing, including NIOSH 42 CFR part 84 (or equivalent), will be needed to validate the iMASC system for use in the healthcare setting as qualitative fit testing is unable to verify the protection factor of the respirator. To source additional filter materials in the future, we will plan to perform filter efficiency testing on these materials, such as the NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059.

Newer face masks, such as our iMASC system, have potential to resupply and sustain hospitals with effective N95-comparable masks. Furthermore, a 2018 consensus report from the National Academies of Engineering, Science, and Medicine recommended that the durability and reusability of elastomeric respirators made them desirable for stockpiling for emergencies.<sup>5</sup> This approach could be applicable to users outside of the healthcare setting, including people in the research, home improvement, and manufacturing settings.

## Author Statement

**Acknowledgments:** We thank Ania Hupalowska for her illustrations of the clinical workflow. We thank Prof. R. Langer for helpful discussions around mask development.

**Contributors:** J.D.B. and A.J.W. designed and fabricated the iMASC system, assisted with the clinical trial, analyzed and interpreted data, and wrote the manuscript. P.R.C. performed the clinical

1 trial, analyzed and interpreted data, and wrote the manuscript. H.W.H. and S.B. designed the face  
2 scanning and performed FEA modeling, analyzed data, and wrote the manuscript. S.B., C.T., and  
3 S.M. analyzed data and designed prototypes. G.T. supervised, reviewed the data and edited the  
4 manuscript.  
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7  
8 **Funding:** This work was supported in part by the Prostate Cancer Foundation. J.D.B. was supported  
9 by the Prostate Cancer Foundation Young Investigator Award. G.T. was supported in part by the  
10 Department of Mechanical Engineering, MIT and Brigham and Women's Hospital. P.R.C was  
11 supported by NIHK23DA044874, and investigator-initiated research grants from e-ink corporation,  
12 Gilead Sciences, Philips Biosensing and the Hans and Mavis Lopater Psychosocial Foundation.  
13 Support for the materials and supplies was from discretionary funds to G.T. from Brigham and  
14 Women's Hospital and the Department of Mechanical Engineer, MIT.  
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18 **Competing Interests:** There are no competing interests related to the work described in the  
19 manuscript. Complete details of all other relationships for profit and not for profit for G.T. can  
20 found at the following link: <https://www.dropbox.com/sh/szi7vnr4a2ajb56/AABs5N5i0q9AfT1IqIJAE-T5a?dl=0>  
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25 **Patient and public involvement:** Patients and/or the public were not involved in the design, or  
26 conduct, or reporting, or dissemination plans of this research.  
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29 **Data Availability Statement:** The authors declare that the data supporting the findings of this  
30 study are available within the paper and its supplementary information files.  
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## Figures

**Figure 1. iMASC system for aerosol-based protection.** (A) Front and (B) side images of the iMASC system. (C) Workflow for sterilization and reuse of iMASC system.

**Figure 2. Finite Element modeling of flexible masks.** (A) Numerical images showing the deformation of the elastomeric mask at different levels of reaction forces,  $F=0, 4.5, \text{ and } 10 \text{ N}$  in two different views (top and bottom rows). The colors represent the magnitude of displacement field,  $U$ . (B) The corresponding distribution of the normal contact forces,  $F^N$ , between the mask and face. (C) Reaction forces for the subject numbers  $n=1,2,3,\dots, 20$  computed from simulations.

**Figure 3. Fit testing of iMASC system in healthcare workers and their user experience.** (A) Demographics of participants ( $N = 24$ ) enrolled in fit testing clinical trial. (B) User experience ( $N = 20$ ) with the mask based upon a Likert scale. User preferences ( $N = 20$ ) comparing the iMASC system to the (C) standard surgical mask and (D) N95 respirators.

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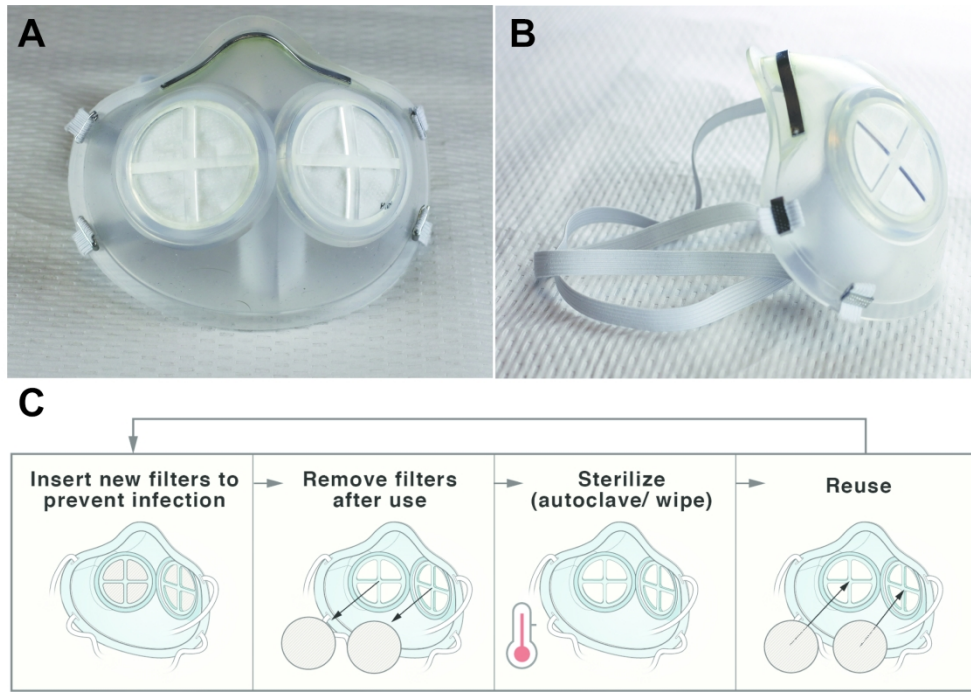


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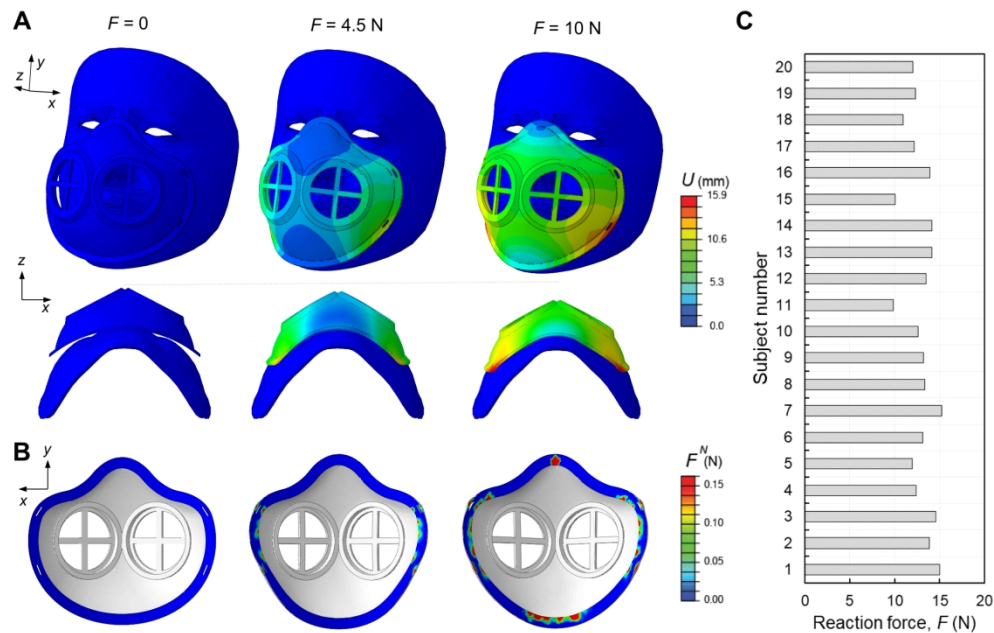


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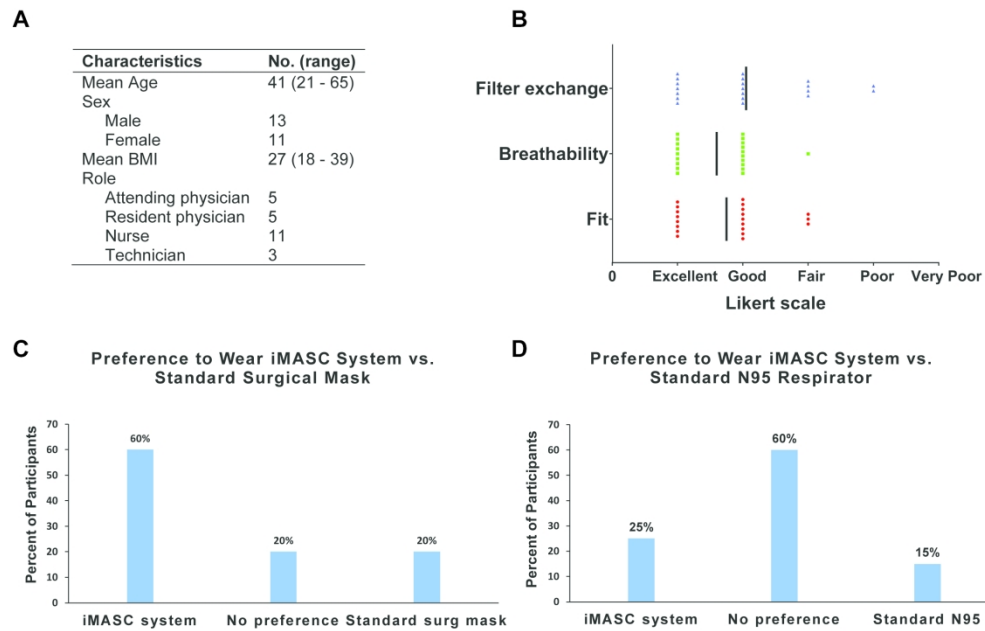


Figure 3. Fit testing of iMASC system in healthcare workers and their user experience. (A) Demographics of participants (N = 24) enrolled in fit testing clinical trial. (B) User experience (N = 20) with the mask based upon a Likert scale. User preferences (N = 20) comparing the iMASC system to the (C) standard surgical mask and (D) N95 respirators.

## Supplementary Information

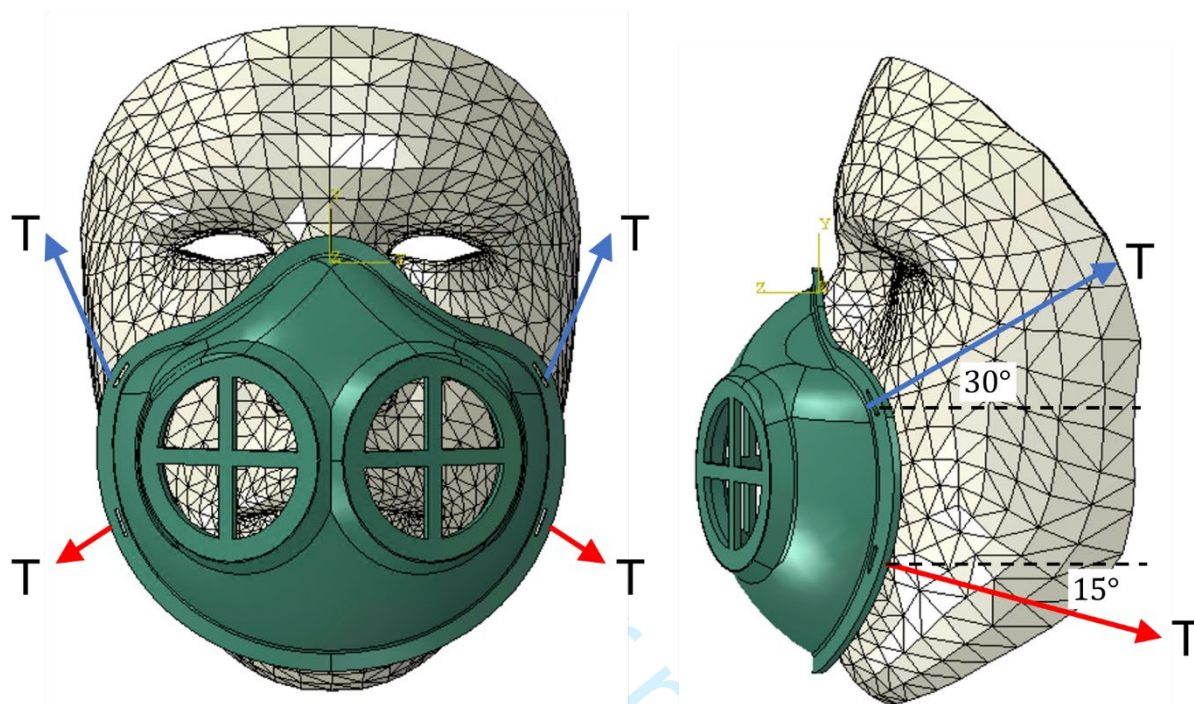
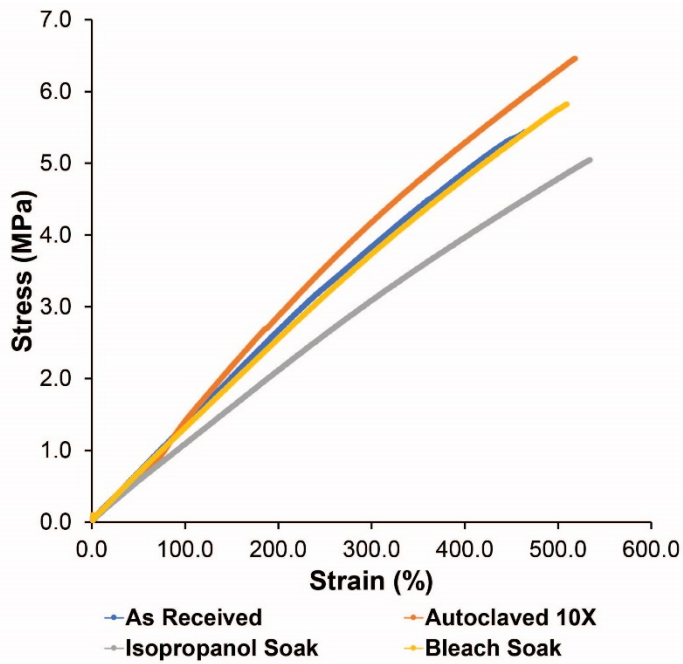
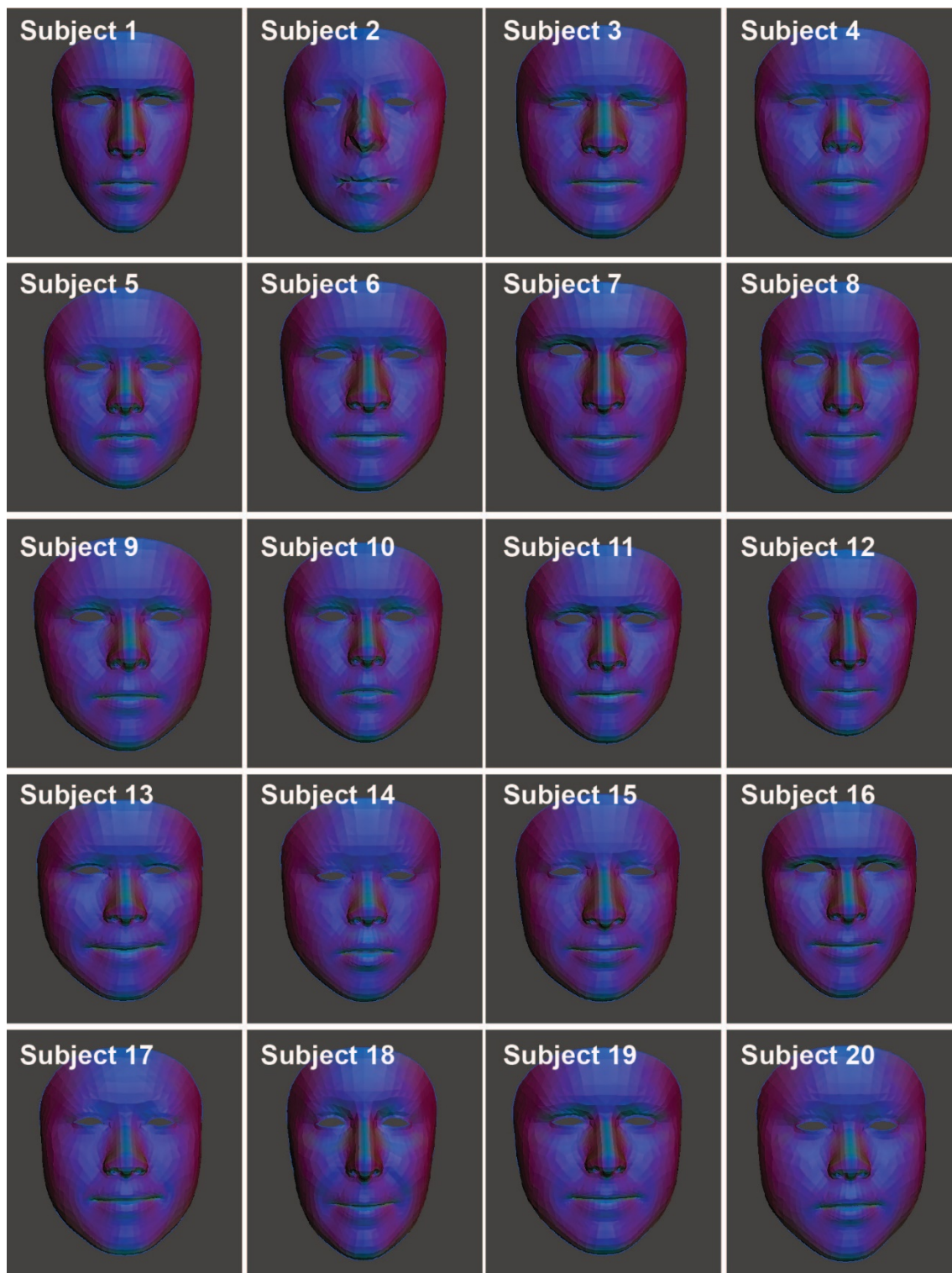


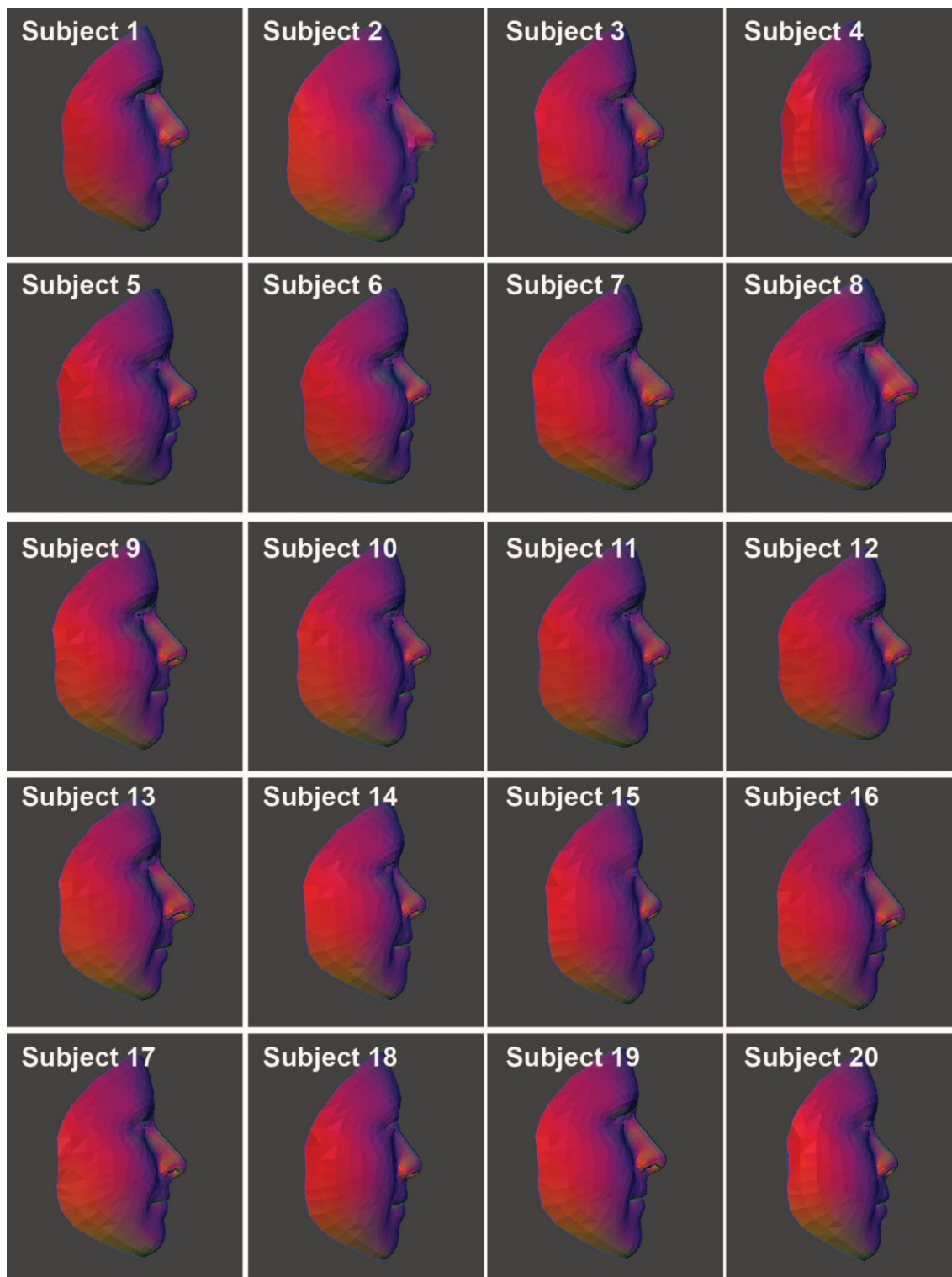
Figure S1. Illustration of the applied loads via mask straps.



**Figure S2.** Mechanical testing on samples cut directly from masks exposed to a variety of sterilization methods including 10 cycles of autoclaving, 10-minute soak in 10% bleach solution, and 10-minute soak in isopropanol.


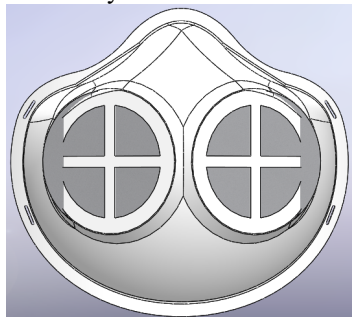




**Figure S3.** Front view of 3D facial reconstruction of participants faces in fit trial of the iMASC system.



**Figure S4.** Side view of 3D facial reconstruction of participants faces in fit trial of the iMASC system.

**Table S1.** Array of N95 and N95-comparable technologies.

Type	Ex \$/Unit	Pros	Cons	Recommended Sterilization Method
Disposable FFR 	3M 8210 \$4.29	<ul style="list-style-type: none"> <li>Ease of fit/use</li> <li>Cheap per use compared to HFRR and FFRR</li> <li>Some models come with exhaust valve</li> </ul>	<ul style="list-style-type: none"> <li>Not reusable</li> <li>No eye protection</li> <li>If exhaust valve is available, it's not filtered</li> </ul>	N/A
iMASC system 	Mask: < \$2.00  Filter: TBD	<ul style="list-style-type: none"> <li>Cheap cost</li> <li>Ease/accessibility of manufacturing</li> <li>Potentially autoclavable</li> </ul>	<ul style="list-style-type: none"> <li>No eye protection</li> <li>No exhaust valve for humidity/ease of use relief</li> </ul>	Autoclave, Clorox wipe, IPA wipe, detergent and sterilization agent wash
Half-Face Reusable (HFRR) 	3M HFRR 6000 Mask: \$28.99  3M 2097 Cartridge: \$10.10/pair	<ul style="list-style-type: none"> <li>Powered air compatible with select models</li> <li>Exhaust valve reduces humidity and breathing resistance</li> <li>Flange/gusset provides comfortable seal skin</li> </ul>	<ul style="list-style-type: none"> <li>Expensive</li> <li>Exhaust valve not filtered</li> <li>No eye protection</li> </ul>	Detergent and sterilization agent wash
Full-Face Reusable (FFRR) 	3M FFRR 6000 Mask: \$149.52  3M 2097 Cartridge: \$10.10/pair	<ul style="list-style-type: none"> <li>Best coverage protection</li> <li>Powered air compatible with select models</li> <li>Exhaust valve reduces humidity and breathing resistance</li> <li>Flange/gusset provides comfortable seal to skin</li> </ul>	<ul style="list-style-type: none"> <li>Expensive</li> <li>Exhaust valve not filtered</li> <li>Potential visual obstruction due to fogging</li> </ul>	Detergent and sterilization agent wash

## Exit assessment

Version 1.0

March 24, 2020

Thank you for participating in the study. After you have completed your fit test, we would like for you to answer the following questions:

1. How would you rate the fit of the mask you tried today?

Excellent	Good	Fair	Poor	Very Poor
(1)	(2)	(3)	(4)	(5)

2. How would you rate the breathability of the mask?

Excellent	Good	Fair	Poor	Very Poor
(1)	(2)	(3)	(4)	(5)

3. How would you rate the difficulty of replacing the filter on the mask?

Excellent	Good	Fair	Poor	Very Poor
(1)	(2)	(3)	(4)	(5)

4. Would you be willing to wear this mask compared to a surgical mask?

- I would prefer to wear the mask I tried today
- I would prefer to wear the surgical mask
- I have no preference

5. Would you be willing to wear this mask compared to a regular N95 mask?

- I would prefer to wear the mask I tried today
- I would prefer to wear the N95 mask
- I have no preference



# BMJ Open

## Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection: a prospective single arm feasibility study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-039120.R2
Article Type:	Original research
Date Submitted by the Author:	05-Jun-2020
Complete List of Authors:	Byrne, James; Brigham and Women's Hospital, Radiation Oncology; Massachusetts Institute of Technology, Koch Institute Wentworth, Adam; Brigham and Women's Hospital, Medicine / Division of Gastroenterology; Massachusetts Institute of Technology, Koch Institute Chai, Peter; Brigham and Women's Hospital, Emergency Medicine Huang, Hen-Wei; Massachusetts Institute of Technology, Koch Institute; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Babae, Sahab; Massachusetts Institute of Technology, Mechanical Engineering; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Li, Canchen; Massachusetts Institute of Technology, Koch Institute Becker, Sarah; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Tov, Caitlynn; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Min, Seokkee; Massachusetts Institute of Technology, Koch Institute Traverso, Giovanni; Massachusetts Institute of Technology, Mechanical Engineering; Brigham and Women's Hospital, Medicine / Division of Gastroenterology
<b>Primary Subject Heading</b>:	Global health
Secondary Subject Heading:	Public health, Global health
Keywords:	PUBLIC HEALTH, RESPIRATORY MEDICINE (see Thoracic Medicine), Respiratory infections < THORACIC MEDICINE

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6 **Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for**  
7 **aerosol-based protection: a prospective single arm feasibility study**  
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9 James D. Byrne<sup>1,2,3†</sup>, Adam J. Wentworth<sup>2,3†</sup>, Peter R. Chai<sup>2,3,4,5,6†</sup>, Hen-Wei Huang<sup>2,3†</sup>, Sahab  
10 Babae<sup>2,3,7</sup>, Canchen Li<sup>3</sup>, Sarah L. Becker<sup>2,7</sup>, Caitlynn Tov<sup>2</sup>, Soekkee Min<sup>7</sup>, Giovanni  
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42 \*Corresponding author. E-mail: cgt20@mit.edu, ctraverso@bwh.harvard.edu (G.T.)  
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45 **Word count:** 3298  
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47 **Abstract**

48 **Objective** To develop and test a new reusable, sterilizable N95 filtering facepiece respirator (FFR)-  
49 comparable face mask, known as the iMASC system, given the dire need for personal protective  
50 equipment (PPE) within healthcare settings during the COVID-19 pandemic  
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52 **Design** Single arm feasibility study  
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54 **Setting** Emergency department and outpatient oncology clinic

55 **Participants** Healthcare workers that have previously undergone N95 fit testing

56 **Interventions** Fit testing of new iMASC system  
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**Primary and secondary outcome measures** Primary outcome is success of fit testing using an Occupational Safety and Health Administration (OSHA)-approved testing method, and secondary outcomes are user experience with fit, breathability, and filter replacement.

**Results** Twenty-four subjects were recruited to undergo fit testing, and the average age of subjects was 41 years (range of 21-65 years) with an average BMI of 26.5. The breakdown of participants by profession was 46% nurses (n=11), 21% attending physicians (n=5), 21% resident physicians (n=5), and 12% technicians (n=3). Of these participants, 4 did not perform the fit testing due to the inability to detect saccharin solution on pre-mask placement sensitivity test, lack of time, and inability to place mask over hair. All participants (n=20) that performed the fit test were successfully fitted for the iMASC system using an OSHA-approved testing method. User experience with the iMASC system, as evaluated using a Likert scale with a score of 1 indicating excellent and a score of 5 indicating very poor, demonstrated an average fit score was 1.75, breathability was 1.6, and ease of replacing the filter on the mask was scored on average as a 2.05.

**Conclusions** The iMASC system was shown to successfully fit multiple different face sizes and shapes using an OSHA-approved testing method. These data support further certification testing needed for use in the healthcare setting.

## Article summary

### Strengths and limitations of this study

- Development of a new N95-comparable mask that can be sterilized and reused
- Mechanical testing of iMASC system determining stability under sterilization conditions
- Finite elemental analysis showcasing mask deformation and reaction forces from facial scans of twenty different wearers
- Testing of iMASC system among physicians, nurses, and technicians with faces that were different sizes and shapes
- The iMASC system as a promising alternative sustainable solution to the dwindling supply of disposable N95 FFRs

## Introduction

Dwindling supplies of personal protective equipment (PPE) in hospitals is forcing healthcare workers to reuse and clean PPE using anecdotal strategies, which may weaken the effectiveness of PPE in protecting workers from acquisition of COVID-19 disease. In some places, the complete lack of PPE has resulted in healthcare workers using PPE that may have variable droplet protection.<sup>1</sup> Shortages of PPE have significant impact among healthcare workers who evaluate individuals with suspected and confirmed COVID-19 disease.<sup>1-2</sup> First, individuals using PPE acquired outside of the hospital may inadvertently be using PPE without droplet protection resulting in inadequate protection. Second, workers without PPE will acquire infections, including COVID-19, at greater rates than those with adequate PPE.<sup>3</sup> Infected healthcare workers may transmit disease to family members, worsening the pandemic.<sup>4</sup> Third, with increased COVID-19 infection among healthcare workers, the available workforce to address sick patients decreases, resulting in increasing morbidity and mortality.<sup>4</sup> There is therefore a critical need to develop innovative measures to generate safe, reusable PPE.<sup>5</sup>

Thus, we have designed and fabricated an Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection with N95 material filters that can be inserted and replaced as needed. To understand the ability of our mask to conform to multiple face

1 sizes and shapes, we have undertaken finite element analysis evaluating the deformability of the  
2 iMASC system. Lastly, we performed a prospective clinical trial for fit testing of our mask as well  
3 as qualitative assessment of the mask compared to the current N95 FFRs. Our goal is to address the  
4 critical shortage of N95 FFRs to maximally protect healthcare workers and provide an enduring  
5 supply chain of N95 FFRs to reduce and prevent COVID-19 transmission among healthcare  
6 workers and patients.  
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## 10 **Methods**

### 11 *Materials*

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13 The mask material was DOW Corning QP1-250 liquid silicone rubber (LSR) sourced to  
14 Protolabs (Maple Plain, Minnesota, USA). The nasal bridge and elastic holders were 5mm wide by  
15 1 mm thick aluminum strips obtained from Amazon, and nylon elastic bands were obtained from a  
16 local fabric store. Adhesive for the nasal bridge was 3M Scotch-Weld (PR40). Filters were laser  
17 cut from 3M 1860 N95 FFRs. The filters were adhered to laser cut acrylic sheeting (3.2 mm thick,  
18 46 mm diameter) (McMaster Carr, Product 8560K257) using fabric adhesive obtained from a local  
19 fabric store.  
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### 24 *iMASC fabrication*

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26 Masks were designed in the three-dimensional (3D) computer aided design (CAD) software  
27 SolidWorks (Dassault Systems) based upon current 3M 1860 N95 FFRs that were in use at the  
28 hospitals in the Partners Healthcare network. Reusable face masks were then generated by Protolabs  
29 through injection molding out of liquid silicone rubber. Elastic straps were used to secure the mask  
30 to the wearer's face. The mask utilized dual, replaceable filters. A 7.6 cm long aluminum strip was  
31 bonded across the bridge of the nose section of the mask similar to traditional N95 FFRs.  
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### 35 *Material testing*

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37 To evaluate sterilization of the iMASC system, the masks (n = 4 per group) were exposed  
38 to a variety of sterilization methods, including 10 cycles of autoclaving (dry cycle - 121 Celsius for  
39 15 minutes), 10-minute soak in 1:10 bleach solution, and 10-minute soak in 100% isopropanol.  
40 These sterilization methods were performed mutually exclusively. These solutions were selected to  
41 simulate on shift sterilization by healthcare workers using standard hospital cleaning solutions.  
42 Mechanical testing according to ASTM D412 (Standard Test Methods for Vulcanized Rubber and  
43 Thermoplastic Elastomers) was performed on samples cut directly from the sterilized masks.  
44 Unpaired t-test was performed on tensile stress at maximum force between groups to evaluate for  
45 statistical differences.  
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### 50 *Face scans*

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52 To obtain the 3D face geometry of the participants, we developed an IOS application (app)  
53 using the TrueDepth camera from an iPhone 11 to capture the face image of the participants. The  
54 app employs the ARKit developed by Apple for the use of face tracking in augmented reality to  
55 transform a 2D image with depth information into a 3D mesh. The output 3D mesh would then be  
56 converted into a solid model for finite element (FE) analysis.  
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### *Deformation studies*

The commercial FE package ABAQUS/standard 2017 was used for simulating the deformation of the iMASC system. The 3D FE models were constructed by importing the CAD model of the mask from SolidWorks and scanned images of the participant faces. In all the analyses, we discretized the mask using four-node 3D linear tetrahedron elements with hybrid formulation (C3D4H Abaqus element type). The material behavior of the elastomeric mask was captured using an almost incompressible Neo-Hookean hyperelastic model with Poisson's ratio of  $\nu_0 = 0.499$  and density of  $1.12E3 \text{ kg/m}^3$  with directly imported stress-strain curves from mechanical testing. A simplified contact law ("surface to surface" type interaction) was assigned to the model with a penalty friction coefficient 0.2 for tangential behavior and a "hard" contact for normal behavior. The top-middle edge of the mask was positioned to the node at the center of the line connecting the eyes. The "Quasi-static" dynamic implicit solver (\*DYNAMIC module in Abaqus) was used. The mask was deformed by applying tensile forces along bands, shown in **figure S1** using SMOOTH step amplitude curve, while completely constraining the motion of the face. The reaction force of the mask against the face as well as contact pressures were recorded as a function of applied load.

### *Clinical studies*

Partners Healthcare Institutional Review Board (IRB) approval was obtained prior to any human testing of the iMASC system (Partners IRB 2020P000852). Subjects were comprised of adult Partners Healthcare staff including physicians, residents, nurses, and technicians who were recruited on a voluntary basis and had undergone OSHA-approved fit testing over the past year. Healthcare workers with facial hair were excluded from enrollment. Subjects were enrolled by study staff and gave informed verbal consent to participate in the study. Verbal informed consent was obtained due to non-invasive nature and short duration of the study. Following enrollment and consent, all subjects were briefed on the study procedure by the same member of the research team and then completed a baseline assessment to obtain general demographic information and ensure they had previously been fit tested successfully.

Subjects underwent fit testing in accordance to the Saccharin Solution Aerosol Protocol per OSHA §1910.134 using the Gerson Respirator Fit Test kit (Gerson part # 065000, Middleboro, Massachusetts.) with the saccharin solution. The fit testing was performed by a member of the study staff. This fit test system was the same system used for fit testing healthcare workers at the hospitals in the Partners Healthcare system. After successful completion of the threshold screening test, subjects donned the iMASC system and a hood with a fitted collar. They were instructed to report if they could taste the test solution. A nebulizer of the saccharin solution was inserted into the hole in the front of the hood and sprayed at the same concentration (10, 20, or 30 squeezes) as the subject was able to taste in their initial threshold test. The subject was instructed to perform the following exercises while the aerosolized solution was replenished every 30 seconds: normal breathing, deep breathing, turning the head side to side, moving the head up and down, counting backwards from 100, grimacing, bending over, and finally normal breathing for a second time. If the subject at any time during the fit test was able to taste the solution, they indicated to the study staff and the test was considered failed. If the subject did not report tasting the solution the test was considered passed. Subjects who passed the fit test were introduced to how to properly replace the filter with a demonstration by study staff. Subjects were then asked to replace the filter and perform a user seal check to ensure an adequate fit. This procedure allowed us to simulate the replacement of filters by

1 healthcare workers prior to the start of a workday. Finally, subjects completed an exit assessment  
2 where they ranked fit, breathability, and difficulty of replacing the filter according to a Likert scale.  
3 Subjects were also asked about their willingness to wear the mask compared to either a surgical  
4 mask or an N95 mask. All testing was performed at Brigham and Women's Hospital.  
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## 7 **Results**

### 8 *Design and generation of injection molded liquid silicone rubber mask*

9 The iMASC system was designed to function as an N95 FFR-comparable face mask (**figure**  
10 **1**). The shape of the iMASC system was modeled from disposable regular N95 FFRs used in the  
11 hospital. Medical grade liquid silicone rubber (LSR) was identified as an optimal material for mask  
12 fabrication due to its conformable capacity, sterilizability through multiple methods and  
13 compatibility with injection molding for fabrication scalability. The weight of the iMASC system  
14 was  $44.84 \pm 0.05$  grams ( $n = 3$ ) compared to  $10.41 \pm 0.13$  grams ( $n = 3$ ) of current N95 FFRs. We  
15 employed a dual filter approach similar to half-mask elastomeric respirators to increase  
16 breathability and filtration area.<sup>5</sup> A single regular N95 FFR generated up to 5 filters for the iMASC  
17 system, thus extending the N95 material use.  
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### 23 *Characterization of mask material after sterilization*

24 An advantage of the iMASC system over the half-mask respirators is the methods of  
25 sterilization (see **table S1**). We have performed tensile tests of the mask material after 10 autoclave  
26 cycles and 5 minutes in a 1:10 bleach solution and 70% isopropyl alcohol. We found that 10  
27 autoclave cycles make the mask slightly stiffer, while the bleach soak resulted in no change and the  
28 isopropanol alcohol soak makes the material less stiff (**figure S2**). Evaluation of the tensile stress  
29 at maximum forces between groups were found to not be significantly different ( $p > 0.05$ ). Despite  
30 these small changes in tensile strength, there were no gross differences in the mask compared to the  
31 non-sterilized mask.  
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### 37 *Finite element analysis for mask deformation upon different face shapes and sizes*

38 We used non-linear finite element (FE) analyses (see "Deformation studies" in Methods) to  
39 evaluate the deformation of the flexible mask frames while wearing and determine the forces  
40 required to keep the mask in place across a range of subject faces. In **figure 2A**, we reported the  
41 numerical snapshots of the face mask when subjected to the strap's tensile loads, denoted by  $T$   
42 shown in **figure S1**, and monitored the deformation of the mask at different levels of the reaction  
43 force exerted from the mask to the face. The color maps represent the distribution of displacement's  
44 magnitude,  $U$ , showing relatively large deformation of the mask required to fit in to the subject  
45 face. We also calculated the normal contact forces,  $F^N$ , and contact pressures,  $P$ , as a function of  
46  $F$  to evaluate the interaction between the mask and face. In **figure 2B**, the distribution of the  $F^N$  are  
47 shown at the different  $F$ . As expected, no  $F^N$  was recorded at  $F = 0$ . By pulling the straps, the mask  
48 starts to be engaged with the face, and at  $F = 4.5$  N the maximum  $F^N$  occurs around the cheek.  
49 Further pulling the straps ( $F = 10$  N) induces a relatively higher  $F^N$  along the edge of the mask in  
50 the cheek and chin (lower lips) rather than the nose and cheekbones. This is a signature of the need  
51 to the Aluminum strip to bond across the bridge of the nose to enhance the contact pressure.  
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57 Next, we estimated the reaction force required to achieve an average contact pressure of  $P$   
58  $= 10$  KPa (relatively uniformly distributed along the edge of the mask) as a higher limit of the  
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1 contact pressure that results in a suitable fit between the mask and skin faces.<sup>6</sup> This reaction force  
2 is equivalent to the force applied through the straps. In **figure 2C**, we reported the reaction forces  
3 for twenty different subjects, ranging from 9.5 to 15 N. These variations are due to the difference  
4 in shape and size of the subject's faces especially in the jaw and cheekbone parts. Through  
5 application of these forces via the straps combined with the aluminum strip across the nose bridge,  
6 the mask should remain in place.  
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### 10 *Clinical trial evaluating mask fitting*

11 In a prospective trial, we enrolled 24 healthcare workers at a large, urban, academic medical  
12 center who had been previously certified to wear a N95 respirator into our IRB-approved study. We  
13 excluded individuals with facial hair or those that had failed an N95 fit test. Consenting individuals  
14 were subject to a fit test as defined by OSHA.<sup>7-8</sup> **Figure 3A** shows the demographics of the  
15 participants, and **figures S3** and **S4** showcase the 3D facial reconstructions demonstrating  
16 variability of facial sizes and shapes among the participants. The average age of participants was  
17 41 years with a range of 21-65 years with an average BMI of 26.5. The breakdown of participants  
18 by profession was 46% nurses (n=11), 21% attending physicians (n=5), 21% resident physicians  
19 (n=5), and 12% technicians (n=3). Of these participants, 4 did not perform the fit testing (1 due to  
20 inability to detect saccharin solution on pre-mask placement sensitivity test, 2 due to time, and 1  
21 due to the inability to get the elastic straps over her hair and face).  
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26 All participants (n=20) that performed the fit test successfully completed the fit test as part  
27 of the hospital annual policy. All participants passed their fit test and were also able to successfully  
28 replace the filter into the mask, resulting in a 100% success rate for both fit testing and filter  
29 exchange. User experience with the iMASC system was evaluated using a Likert scale with a score  
30 of 1 indicating excellent and a score of 5 indicating very poor. Participants scored the fit of the  
31 iMASC system as excellent (8 participants), good (9 participants), or fair (3 participants) (**figure**  
32 **3B**). Participants scored the breathability of the iMASC system as excellent (9 participants), good  
33 (10 participants), or fair (1 participants). Finally, participants scored the filter replacement of the  
34 iMASC system as excellent (7 participants), good (7 participants), fair (4 participants), or poor (2  
35 participants). Participants' preference to wear the iMASC over a surgical mask or an N95 respirator  
36 was also assessed. Sixty percent of participants indicated they would be willing to wear our mask  
37 instead of a surgical mask, with 20% indicating no preference between our mask and a standard  
38 surgical mask and 20% indicating they would prefer to wear a surgical mask (**figure 3C**). When  
39 asked about preference to wear our mask instead of an N95 FFR, 25% of participants indicated they  
40 would prefer to wear our mask and 60% indicated no preference between our mask and a N95 FFR,  
41 with only 15% indicating they would prefer to wear a standard issue N95 FFR (**figure 3D**).  
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### 49 **Discussion**

50 During times of pandemics, it is essential to protect healthcare workers from infection and  
51 transmission of disease with adequate PPE.<sup>4,9</sup> As stocks of N95 FFRs have reduced, healthcare  
52 workers are forced to find alternative strategies of protection, including re-sterilizing masks and  
53 using alternative mask materials that may result in less protection.<sup>9-10</sup> Our approach here was to  
54 develop a scalable, reusable face mask that can extend the amount of N95 material. The iMASC  
55 system withstood decontamination using three methods and was shown to successfully fit multiple  
56 different face sizes and shapes using an OSHA approved testing method. The iMASC system could  
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1 be scaled up for use across many locations once additional certification testing, including the  
2 sodium chloride aerosol challenge test, dioctyl phthalate aerosol test, and inhalation and exhalation  
3 tests, has been completed. By selecting injection molding as the fabrication technique for the  
4 iMASC system, we believe we possess a fundamental advantage to other initiatives using three-  
5 dimensional (3D) printing techniques because injection molding is highly scalable and has  
6 decreased production time when compared to 3D printing.  
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8  
9 These are initial proof-of-concept studies and have some limitations. First, the small sample  
10 size and single institutional nature of this prospective study limit generalizability and warrants  
11 evaluation in a larger cohort involving multiple institutions. As a result of the lack of availability  
12 of standard N95 FFRs, the iMASC system was not compared to standard of care N95 FFRs.  
13 Previous studies have demonstrated that a respirator user gains experience with subsequent  
14 donnings and may result in improved fit-test pass rate biasing our results<sup>11-13</sup>; thus, it will important  
15 to assess fit testing in inexperienced subjects. While Bitrex is the preferred choice for fit test  
16 solution as a leak detection<sup>14</sup>, saccharin was chosen due to availability and use in OSHA approved  
17 qualitative fit tests. Additional development for smaller face sizes and shapes are warranted since  
18 the iMASC system was modeled from the 3M 1860 model. Furthermore, all testing was performed  
19 in North America, and it is possible face shapes and sizes may differ for workers outside of this  
20 region. Modifications to the filter system and elastic straps would likely improve the fit and  
21 robustness of the mask. All post injection-molding manufacturing steps were completed in-house  
22 and in large scale production would be outsourced to contracted manufacturers with greater quality  
23 control of filter components. Further, the testing of mechanical properties after combinations of  
24 different sterilization techniques could provide a better representation of what would be used in the  
25 hospital. Additional quantitative fit testing, extended wearer testing, and certification testing,  
26 including NIOSH 42 CFR part 84 (or equivalent), will be needed to validate the iMASC system for  
27 use in the healthcare setting as qualitative fit testing is unable to verify the protection factor of the  
28 respirator. To source additional filter materials in the future, we will plan to perform filter efficiency  
29 testing on these materials, such as the NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059.  
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31  
32 Newer face masks, such as our iMASC system, have potential to resupply and sustain  
33 hospitals with effective N95-comparable masks. Furthermore, a 2018 consensus report from the  
34 National Academies of Engineering, Science, and Medicine recommended that the durability and  
35 reusability of elastomeric respirators made them desirable for stockpiling for emergencies.<sup>5</sup> This  
36 approach could be applicable to users outside of the healthcare setting, including people in the  
37 research, home improvement, and manufacturing settings.  
38

#### 39 **Author Statement**

40 **Acknowledgments:** We thank Ania Hupalowska for her illustrations of the clinical workflow. We  
41 thank Prof. R. Langer for helpful discussions around mask development.  
42

43  
44 **Contributors:** J.D.B. and A.J.W. designed and fabricated the iMASC system, assisted with the  
45 clinical trial, analyzed and interpreted data, and wrote the manuscript. P.R.C. performed the clinical  
46 trial, analyzed and interpreted data, and wrote the manuscript. H.W.H. and S.B. designed the face  
47 scanning and performed FEA modeling, analyzed data, and wrote the manuscript. S.B., C.T., and  
48 S.M. analyzed data and designed prototypes. G.T. supervised, reviewed the data and edited the  
49 manuscript.  
50

**Funding:** This work was supported in part by the Prostate Cancer Foundation. J.D.B. was supported by the Prostate Cancer Foundation Young Investigator Award. G.T. was supported in part by the Department of Mechanical Engineering, MIT and Brigham and Women's Hospital. P.R.C was supported by NIHK23DA044874, and investigator-initiated research grants from e-ink corporation, Gilead Sciences, Philips Biosensing and the Hans and Mavis Lopater Psychosocial Foundation. Support for the materials and supplies was from discretionary funds to G.T. from Brigham and Women's Hospital and the Department of Mechanical Engineer, MIT.

**Competing Interests:** There are no competing interests related to the work described in the manuscript. Complete details of all other relationships for profit and not for profit for G.T. can be found at the following link: <https://www.dropbox.com/sh/szi7vnr4a2ajb56/AABs5N5i0q9Aft1IqJAE-T5a?dl=0>

**Patient and public involvement:** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Data Availability Statement:** The authors declare that the data supporting the findings of this study are available within the paper and its supplementary information files.

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## Figures

**Figure 1. iMASC system for aerosol-based protection.** (A) Front and (B) side images of the iMASC system. (C) Workflow for sterilization and reuse of iMASC system.

**Figure 2. Finite Element modeling of flexible masks.** (A) Representative numerical images showing the deformation of the elastomeric mask at different levels of reaction forces,  $F = 0, 4.5,$  and  $10\text{ N}$  in two different views (top and bottom rows). The colors represent the magnitude of displacement field,  $U$ . (B) The corresponding distribution of the normal contact forces,  $F^N$ , between the mask and face. (C) Reaction forces for the subject numbers  $n=1,2,3,\dots, 20$  computed from simulations.

**Figure 3. Fit testing of iMASC system in healthcare workers and their user experience.** (A) Demographics of participants ( $N = 24$ ) enrolled in fit testing clinical trial. (B) User experience ( $N = 20$ ) with the mask based upon a Likert scale. User preferences ( $N = 20$ ) comparing the iMASC system to the (C) standard surgical mask and (D) N95 respirators.

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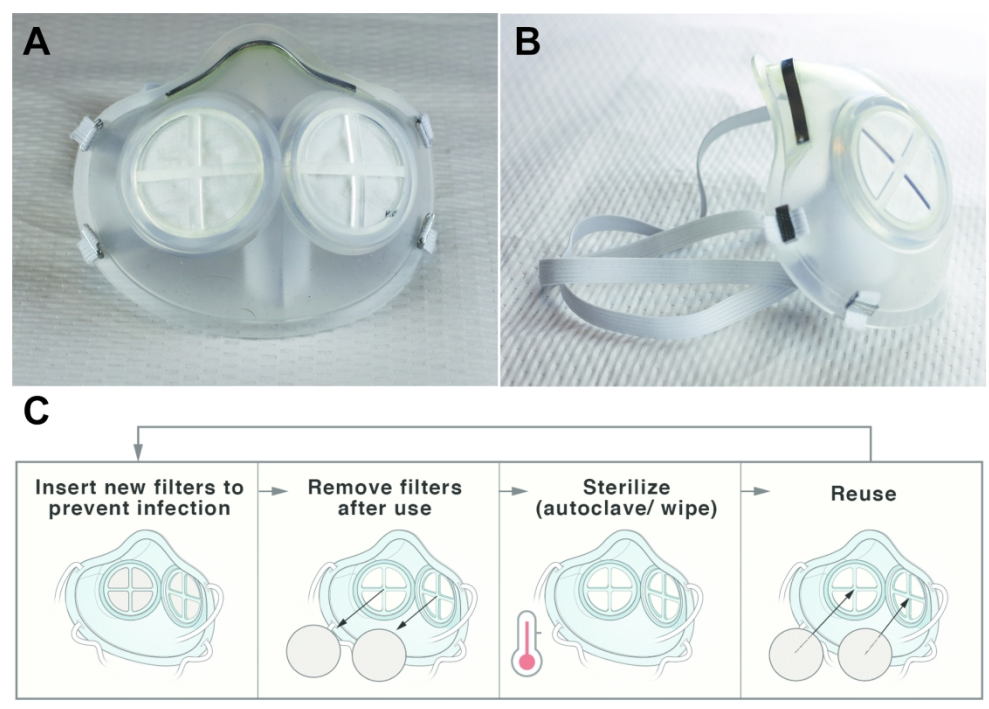


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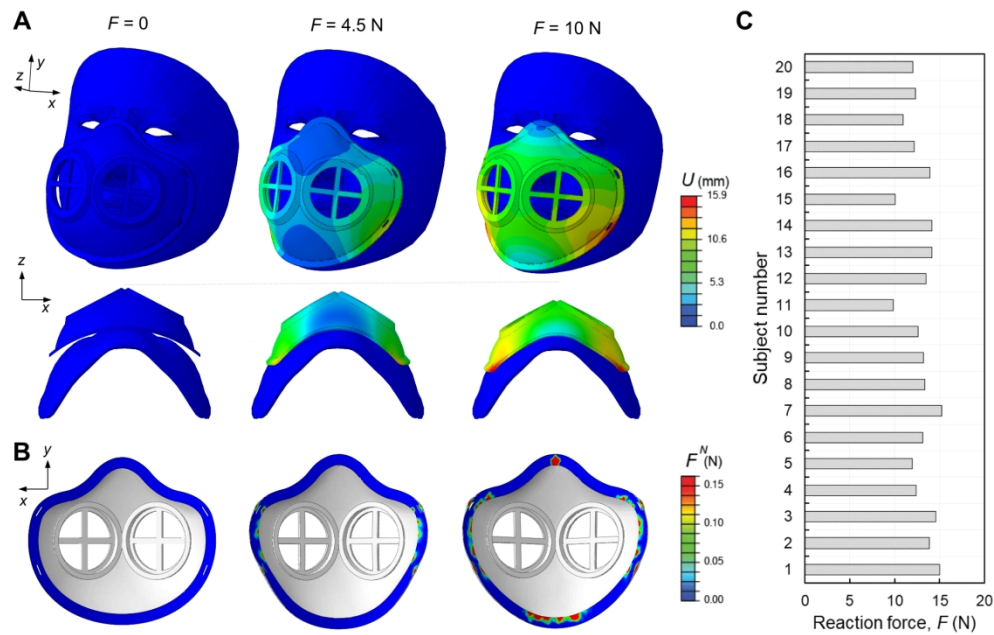


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259x165mm (220 x 220 DPI)

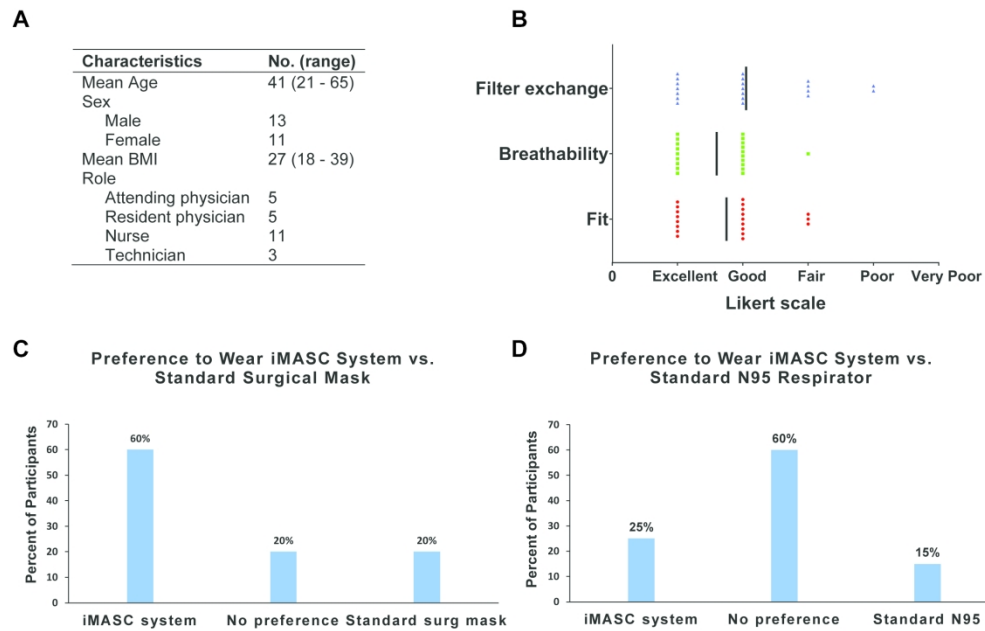


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## Supplementary Information

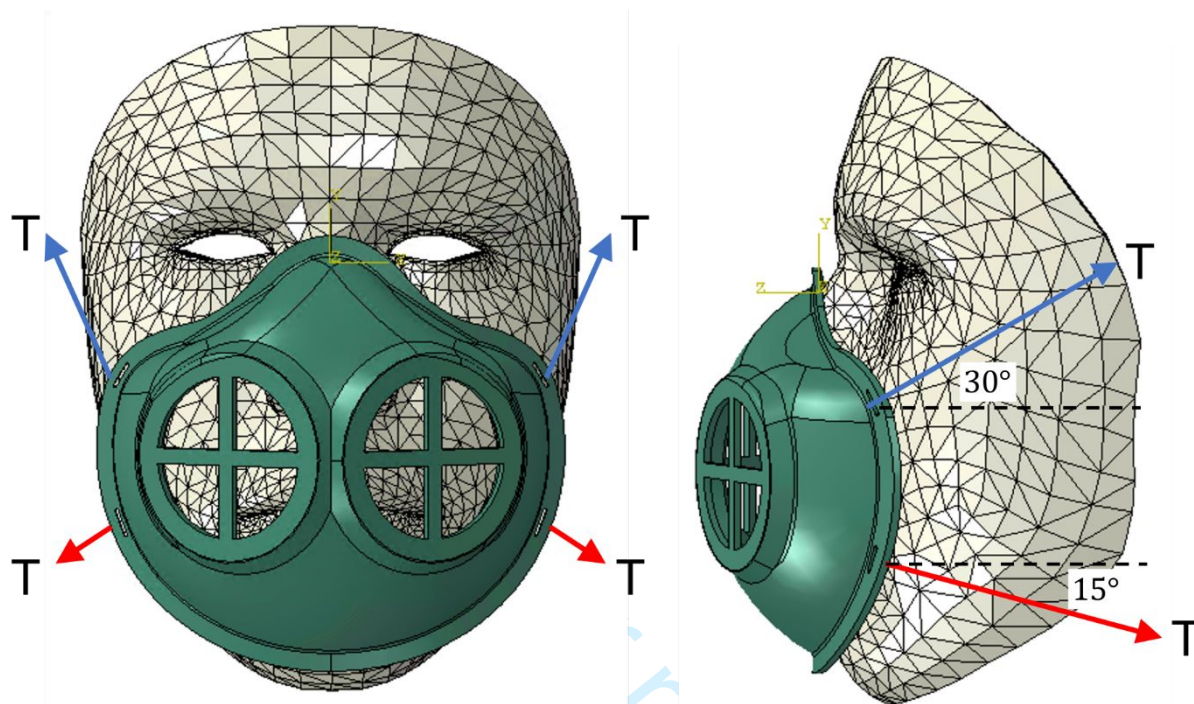
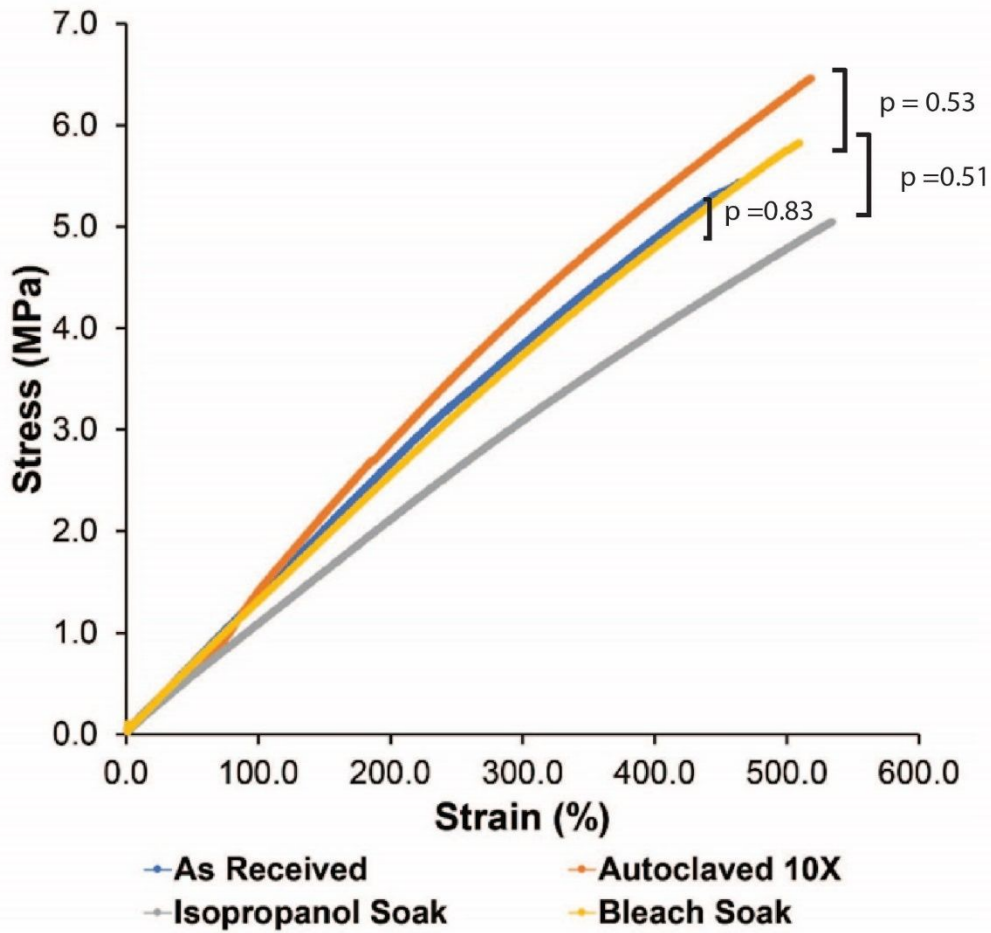
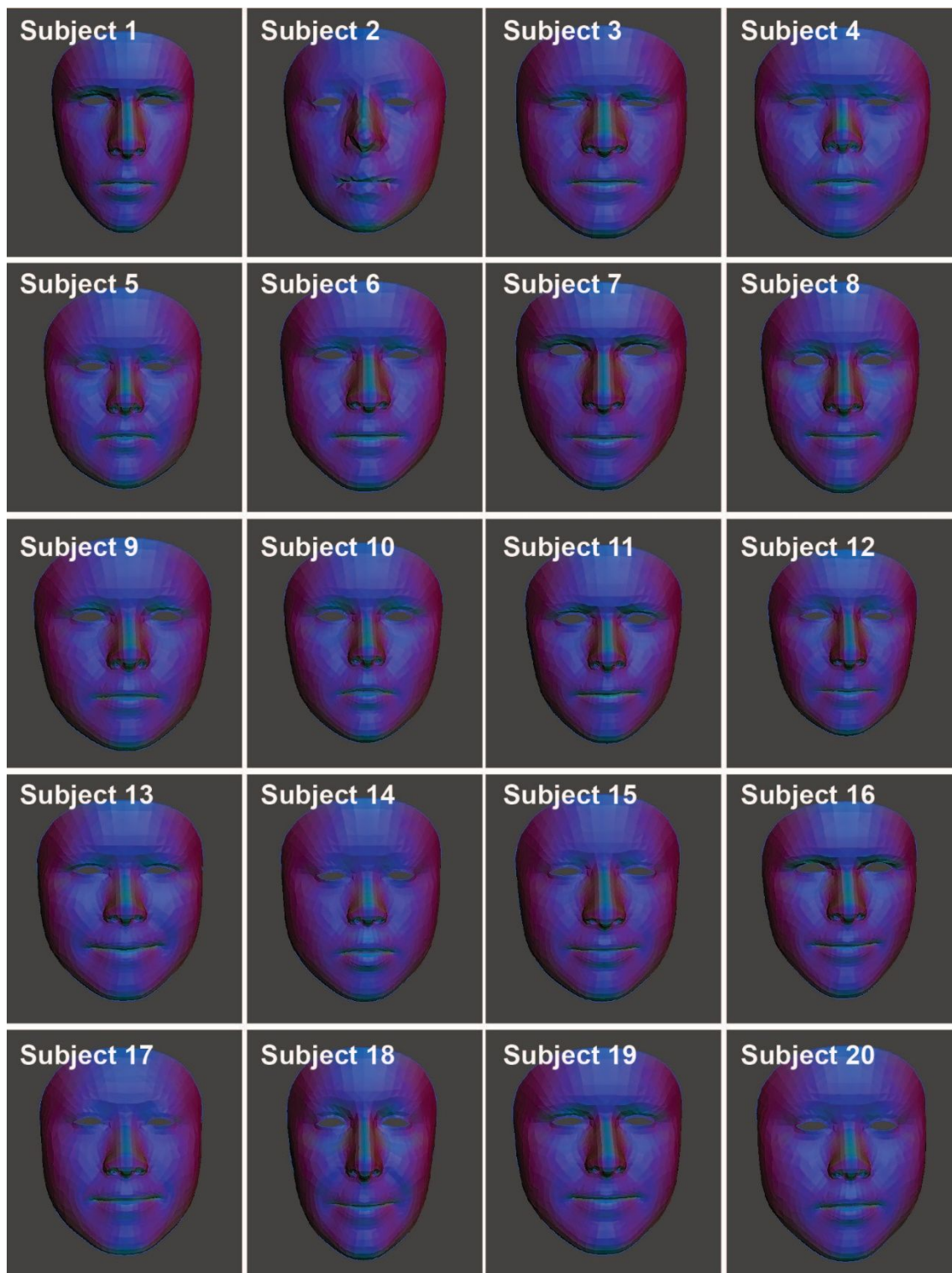


Figure S1. Illustration of the applied loads via mask straps.



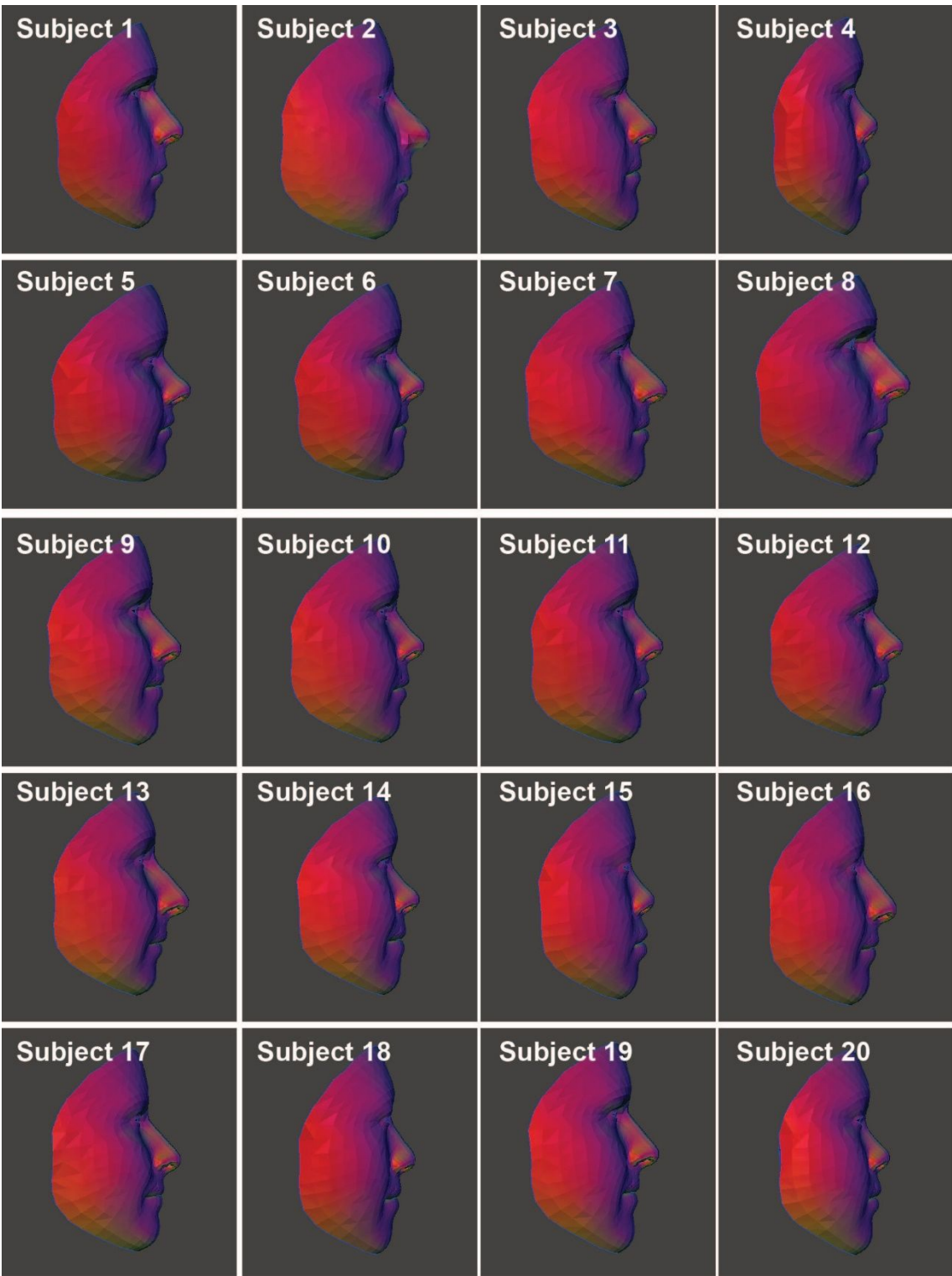
**Figure S2.** Mechanical testing on samples cut directly from masks exposed to a variety of sterilization methods including 10 cycles of autoclaving, 10-minute soak in 10% bleach solution, and 10-minute soak in isopropanol.









**Figure S3.** Front view of 3D facial reconstruction of participants faces in fit trial of the iMASC system.

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**Figure S4.** Side view of 3D facial reconstruction of participants faces in fit trial of the iMASC system.

**Table S1.** Array of N95 and N95-comparable technologies.

Type	Ex \$US Dollars (USD)/Unit	Pros	Cons	Recommended Sterilization Method
Disposable FFR 	3M 8210Plus \$1.02 USD <a href="http://mcmaster.com/5450T42">mcmaster.com/5450T42</a>	<ul style="list-style-type: none"> <li>Ease of fit/use</li> <li>Low cost per use compared to HFRR and FFRR</li> <li>Some models come with exhaust valve</li> </ul>	<ul style="list-style-type: none"> <li>Not reusable</li> <li>If exhaust valve is available, it's not filtered</li> <li>No eye protection</li> </ul>	N/A
iMASC system 	Mask: < \$7.00 USD  Filter: \$0.50 USD	<ul style="list-style-type: none"> <li>Low cost</li> <li>Ease/accessibility of manufacturing</li> <li>Potentially autoclavable</li> </ul>	<ul style="list-style-type: none"> <li>No exhaust valve for humidity/ease of use relief</li> <li>No eye protection</li> </ul>	Autoclave, Clorox wipe, IPA wipe, detergent and sterilization agent wash
Half-Face Reusable (HFRR) 	Mask: \$58.98 USD <a href="http://mcmaster.com/5541T16-5541T162">mcmaster.com/5541T16-5541T162</a>  Replacement Cartridge: \$14.32/pair USD <a href="http://mcmaster.com/54445T229">mcmaster.com/54445T229</a>  Replacement Filter: \$2.65/pair USD <a href="http://mcmaster.com/54445T189">mcmaster.com/54445T189</a>	<ul style="list-style-type: none"> <li>Powered air compatible with select models</li> <li>Exhaust valve reduces humidity and breathing resistance</li> <li>Flange/gusset provides comfortable seal skin</li> </ul>	<ul style="list-style-type: none"> <li>Expensive</li> <li>Exhaust valve not filtered</li> <li>No eye protection</li> </ul>	Detergent and sterilization agent wash
Full-Face Reusable (FFRR) 	Mask: \$168.47 USD <a href="http://mcmaster.com/5541T28">mcmaster.com/5541T28</a>  Replacement Filter: \$2.65/pair USD <a href="http://mcmaster.com/54445T189">mcmaster.com/54445T189</a>	<ul style="list-style-type: none"> <li>Best coverage</li> <li>Powered air compatible with select models</li> <li>Exhaust valve reduces humidity and breathing resistance</li> <li>Comfortable seal to skin</li> </ul>	<ul style="list-style-type: none"> <li>Expensive</li> <li>Exhaust valve not filtered</li> <li>Potential visual obstruction due to fogging</li> </ul>	Detergent and sterilization agent wash

# BMJ Open

## Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection: a prospective single arm feasibility study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-039120.R3
Article Type:	Original research
Date Submitted by the Author:	12-Jun-2020
Complete List of Authors:	Byrne, James; Brigham and Women's Hospital, Radiation Oncology; Massachusetts Institute of Technology, Koch Institute Wentworth, Adam; Brigham and Women's Hospital, Medicine / Division of Gastroenterology; Massachusetts Institute of Technology, Koch Institute Chai, Peter; Brigham and Women's Hospital, Emergency Medicine Huang, Hen-Wei; Massachusetts Institute of Technology, Koch Institute; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Babae, Sahab; Massachusetts Institute of Technology, Mechanical Engineering; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Li, Canchen; Massachusetts Institute of Technology, Koch Institute Becker, Sarah; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Tov, Caitlynn; Brigham and Women's Hospital, Medicine / Division of Gastroenterology Min, Seokkee; Massachusetts Institute of Technology, Koch Institute Traverso, Giovanni; Massachusetts Institute of Technology, Mechanical Engineering; Brigham and Women's Hospital, Medicine / Division of Gastroenterology
<b>Primary Subject Heading</b>:	Global health
Secondary Subject Heading:	Public health, Global health
Keywords:	PUBLIC HEALTH, RESPIRATORY MEDICINE (see Thoracic Medicine), Respiratory infections < THORACIC MEDICINE

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6 **Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for**  
7 **aerosol-based protection: a prospective single arm feasibility study**  
8

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43  
44

45 **Word count:** 3298  
46

47 **Abstract**

48 **Objective** To develop and test a new reusable, sterilizable N95 filtering facepiece respirator (FFR)-  
49 comparable face mask, known as the iMASC system, given the dire need for personal protective  
50 equipment (PPE) within healthcare settings during the COVID-19 pandemic  
51

52 **Design** Single arm feasibility study  
53

54 **Setting** Emergency department and outpatient oncology clinic

55 **Participants** Healthcare workers that have previously undergone N95 fit testing

56 **Interventions** Fit testing of new iMASC system  
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**Primary and secondary outcome measures** Primary outcome is success of fit testing using an Occupational Safety and Health Administration (OSHA)-approved testing method, and secondary outcomes are user experience with fit, breathability, and filter replacement.

**Results** Twenty-four subjects were recruited to undergo fit testing, and the average age of subjects was 41 years (range of 21-65 years) with an average BMI of 26.5. The breakdown of participants by profession was 46% nurses (n=11), 21% attending physicians (n=5), 21% resident physicians (n=5), and 12% technicians (n=3). Of these participants, 4 did not perform the fit testing due to the inability to detect saccharin solution on pre-mask placement sensitivity test, lack of time, and inability to place mask over hair. All participants (n=20) that performed the fit test were successfully fitted for the iMASC system using an OSHA-approved testing method. User experience with the iMASC system, as evaluated using a Likert scale with a score of 1 indicating excellent and a score of 5 indicating very poor, demonstrated an average fit score was 1.75, breathability was 1.6, and ease of replacing the filter on the mask was scored on average as a 2.05.

**Conclusions** The iMASC system was shown to successfully fit multiple different face sizes and shapes using an OSHA-approved testing method. These data support further certification testing needed for use in the healthcare setting.

## Article summary

### Strengths and limitations of this study

- Development of a new N95-comparable mask that can be sterilized and reused
- Mechanical testing of iMASC system determining stability under sterilization conditions
- Finite elemental analysis showcasing mask deformation and reaction forces from facial scans of twenty different wearers
- Testing of iMASC system among physicians, nurses, and technicians with faces that were different sizes and shapes
- The iMASC system as a promising alternative sustainable solution to the dwindling supply of disposable N95 FFRs

## Introduction

Dwindling supplies of personal protective equipment (PPE) in hospitals is forcing healthcare workers to reuse and clean PPE using anecdotal strategies, which may weaken the effectiveness of PPE in protecting workers from acquisition of COVID-19 disease. In some places, the complete lack of PPE has resulted in healthcare workers using PPE that may have variable droplet protection.<sup>1</sup> Shortages of PPE have significant impact among healthcare workers who evaluate individuals with suspected and confirmed COVID-19 disease.<sup>1-2</sup> First, individuals using PPE acquired outside of the hospital may inadvertently be using PPE without droplet protection resulting in inadequate protection. Second, workers without PPE will acquire infections, including COVID-19, at greater rates than those with adequate PPE.<sup>3</sup> Infected healthcare workers may transmit disease to family members, worsening the pandemic.<sup>4</sup> Third, with increased COVID-19 infection among healthcare workers, the available workforce to address sick patients decreases, resulting in increasing morbidity and mortality.<sup>4</sup> There is therefore a critical need to develop innovative measures to generate safe, reusable PPE.<sup>5</sup>

Thus, we have designed and fabricated an Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection with N95 material filters that can be inserted and replaced as needed. To understand the ability of our mask to conform to multiple face

1 sizes and shapes, we have undertaken finite element analysis evaluating the deformability of the  
2 iMASC system. Lastly, we performed a prospective clinical trial for fit testing of our mask as well  
3 as qualitative assessment of the mask compared to the current N95 FFRs. Our goal is to address the  
4 critical shortage of N95 FFRs to maximally protect healthcare workers and provide an enduring  
5 supply chain of N95 FFRs to reduce and prevent COVID-19 transmission among healthcare  
6 workers and patients.  
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9

## 10 **Methods**

### 11 *Materials*

12  
13 The mask material was DOW Corning QP1-250 liquid silicone rubber (LSR) sourced to  
14 Protolabs (Maple Plain, Minnesota, USA). The nasal bridge and elastic holders were 5mm wide by  
15 1 mm thick aluminum strips obtained from Amazon, and nylon elastic bands were obtained from a  
16 local fabric store. Adhesive for the nasal bridge was 3M Scotch-Weld (PR40). Filters were laser  
17 cut from 3M 1860 N95 FFRs. The filters were adhered to laser cut acrylic sheeting (3.2 mm thick,  
18 46 mm diameter) (McMaster Carr, Product 8560K257) using fabric adhesive obtained from a local  
19 fabric store.  
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### 24 *iMASC fabrication*

25  
26 Masks were designed in the three-dimensional (3D) computer aided design (CAD) software  
27 SolidWorks (Dassault Systems) based upon current 3M 1860 N95 FFRs that were in use at the  
28 hospitals in the Partners Healthcare network. Reusable face masks were then generated by Protolabs  
29 through injection molding out of liquid silicone rubber. Elastic straps were used to secure the mask  
30 to the wearer's face. The mask utilized dual, replaceable filters. A 7.6 cm long aluminum strip was  
31 bonded across the bridge of the nose section of the mask similar to traditional N95 FFRs.  
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### 35 *Material testing*

36  
37 To evaluate sterilization of the iMASC system, the masks (n = 4 per group) were exposed  
38 to a variety of sterilization methods, including 10 cycles of autoclaving (dry cycle - 121 Celsius for  
39 15 minutes), 10-minute soak in 1:10 bleach solution, and 10-minute soak in 100% isopropanol.  
40 These sterilization methods were performed mutually exclusively. These solutions were selected to  
41 simulate on shift sterilization by healthcare workers using standard hospital cleaning solutions.  
42 Mechanical testing according to ASTM D412 (Standard Test Methods for Vulcanized Rubber and  
43 Thermoplastic Elastomers) was performed on samples cut directly from the sterilized masks.  
44 Unpaired t-test was performed on tensile stress at maximum force between groups to evaluate for  
45 statistical differences.  
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### 50 *Face scans*

51  
52 To obtain the 3D face geometry of the participants, we developed an IOS application (app)  
53 using the TrueDepth camera from an iPhone 11 to capture the face image of the participants. The  
54 app employs the ARKit developed by Apple for the use of face tracking in augmented reality to  
55 transform a 2D image with depth information into a 3D mesh. The output 3D mesh would then be  
56 converted into a solid model for finite element (FE) analysis.  
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### *Deformation studies*

The commercial FE package ABAQUS/standard 2017 was used for simulating the deformation of the iMASC system. The 3D FE models were constructed by importing the CAD model of the mask from SolidWorks and scanned images of the participant faces. In all the analyses, we discretized the mask using four-node 3D linear tetrahedron elements with hybrid formulation (C3D4H Abaqus element type). The material behavior of the elastomeric mask was captured using an almost incompressible Neo-Hookean hyperelastic model with Poisson's ratio of  $\nu_0 = 0.499$  and density of  $1.12E3 \text{ kg/m}^3$  with directly imported stress-strain curves from mechanical testing. A simplified contact law ("surface to surface" type interaction) was assigned to the model with a penalty friction coefficient 0.2 for tangential behavior and a "hard" contact for normal behavior. The top-middle edge of the mask was positioned to the node at the center of the line connecting the eyes. The "Quasi-static" dynamic implicit solver (\*DYNAMIC module in Abaqus) was used. The mask was deformed by applying tensile forces along bands, shown in **figure S1** using SMOOTH step amplitude curve, while completely constraining the motion of the face. The reaction force of the mask against the face as well as contact pressures were recorded as a function of applied load. Multiple levels of the reaction forces were exerted from the mask to the face, including  $F = 0$  (undeformed), 4.5 (initial contact), and 10 (full contact) N.

### *Clinical studies*

Partners Healthcare Institutional Review Board (IRB) approval was obtained prior to any human testing of the iMASC system (Partners IRB 2020P000852). Subjects were comprised of adult Partners Healthcare staff including physicians, residents, nurses, and technicians who were recruited on a voluntary basis and had undergone OSHA-approved fit testing over the past year. Healthcare workers with facial hair were excluded from enrollment. Subjects were enrolled by study staff and gave informed verbal consent to participate in the study. Verbal informed consent was obtained due to non-invasive nature and short duration of the study. Following enrollment and consent, all subjects were briefed on the study procedure by the same member of the research team and then completed a baseline assessment to obtain general demographic information and ensure they had previously been fit tested successfully.

Subjects underwent fit testing in accordance to the Saccharin Solution Aerosol Protocol per OSHA §1910.134 using the Gerson Respirator Fit Test kit (Gerson part # 065000, Middleboro, Massachusetts.) with the saccharin solution. The fit testing was performed by a member of the study staff. This fit test system was the same system used for fit testing healthcare workers at the hospitals in the Partners Healthcare system. After successful completion of the threshold screening test, subjects donned the iMASC system and a hood with a fitted collar. They were instructed to report if they could taste the test solution. A nebulizer of the saccharin solution was inserted into the hole in the front of the hood and sprayed at the same concentration (10, 20, or 30 squeezes) as the subject was able to taste in their initial threshold test. The subject was instructed to perform the following exercises while the aerosolized solution was replenished every 30 seconds: normal breathing, deep breathing, turning the head side to side, moving the head up and down, counting backwards from 100, grimacing, bending over, and finally normal breathing for a second time. If the subject at any time during the fit test was able to taste the solution, they indicated to the study staff and the test was considered failed. If the subject did not report tasting the solution the test was considered passed. Subjects who passed the fit test were introduced to how to properly replace the filter with a

demonstration by study staff. Subjects were then asked to replace the filter and perform a user seal check to ensure an adequate fit. This procedure allowed us to simulate the replacement of filters by healthcare workers prior to the start of a workday. Finally, subjects completed an exit assessment where they ranked fit, breathability, and difficulty of replacing the filter according to a Likert scale. Subjects were also asked about their willingness to wear the mask compared to either a surgical mask or an N95 mask. All testing was performed at Brigham and Women's Hospital.

## Results

### *Design and generation of injection molded liquid silicone rubber mask*

The iMASC system was designed to function as an N95 FFR-comparable face mask (**figure 1**). The shape of the iMASC system was modeled from disposable regular N95 FFRs used in the hospital. Medical grade liquid silicone rubber (LSR) was identified as an optimal material for mask fabrication due to its conformable capacity, sterilizability through multiple methods and compatibility with injection molding for fabrication scalability. The weight of the iMASC system was  $44.84 \pm 0.05$  grams ( $n = 3$ ) compared to  $10.41 \pm 0.13$  grams ( $n = 3$ ) of current N95 FFRs. We employed a dual filter approach similar to half-mask elastomeric respirators to increase breathability and filtration area.<sup>5</sup> A single regular N95 FFR generated up to 5 filters for the iMASC system, thus extending the N95 material use.

### *Characterization of mask material after sterilization*

An advantage of the iMASC system over the half-mask respirators is the methods of sterilization (see **table S1**). We have performed tensile tests of the mask material after 10 autoclave cycles and 5 minutes in a 1:10 bleach solution and 70% isopropyl alcohol. We found that 10 autoclave cycles make the mask slightly stiffer, while the bleach soak resulted in no change and the isopropanol alcohol soak makes the material less stiff (**figure S2**). Evaluation of the tensile stress at maximum forces between groups were found to not be significantly different ( $p > 0.05$ ). Despite these small changes in tensile strength, there were no gross differences in the mask compared to the non-sterilized mask.

### *Finite element analysis for mask deformation upon different face shapes and sizes*

We used non-linear finite element (FE) analyses (see "Deformation studies" in Methods) to evaluate the deformation of the flexible mask frames while wearing and determine the forces required to keep the mask in place across a range of subject faces. In **figure 2A**, we reported the numerical snapshots of the face mask when subjected to the strap's tensile loads, denoted by  $T$  shown in **figure S1**, and monitored the deformation of the mask at different levels of the reaction force exerted from the mask to the face. The color maps represent the distribution of displacement's magnitude,  $U$ , showing relatively large deformation of the mask required to fit in to the subject face. We also calculated the normal contact forces,  $F^N$ , and contact pressures,  $P$ , as a function of  $F$  to evaluate the interaction between the mask and face. In **figure 2B**, the distribution of the  $F^N$  are shown at the different  $F$ . As expected, no  $F^N$  was recorded at  $F = 0$ . By pulling the straps, the mask starts to be engaged with the face, and at  $F = 4.5$  N the maximum  $F^N$  occurs around the cheek. Further pulling the straps ( $F = 10$  N) induces a relatively higher  $F^N$  along the edge of the mask in the cheek and chin (lower lips) rather than the nose and cheekbones. This is a signature of the need to the Aluminum strip to bond across the bridge of the nose to enhance the contact pressure.

1 Next, we estimated the reaction force required to achieve an average contact pressure of  $P$   
2 = 10 KPa (relatively uniformly distributed along the edge of the mask) as a higher limit of the  
3 contact pressure that results in a suitable fit between the mask and skin faces.<sup>6</sup> This reaction force  
4 is equivalent to the force applied through the straps. In **figure 2C**, we reported the reaction forces  
5 for twenty different subjects, ranging from 9.5 to 15 N. These variations are due to the difference  
6 in shape and size of the subject's faces especially in the jaw and cheekbone parts. Through  
7 application of these forces via the straps combined with the aluminum strip across the nose bridge,  
8 the mask should remain in place.  
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### 12 *Clinical trial evaluating mask fitting*

13 In a prospective trial, we enrolled 24 healthcare workers at a large, urban, academic medical  
14 center who had been previously certified to wear a N95 respirator into our IRB-approved study. We  
15 excluded individuals with facial hair or those that had failed an N95 fit test. Consenting individuals  
16 were subject to a fit test as defined by OSHA.<sup>7-8</sup> **Figure 3A** shows the demographics of the  
17 participants, and **figures S3** and **S4** showcase the 3D facial reconstructions demonstrating  
18 variability of facial sizes and shapes among the participants. The average age of participants was  
19 41 years with a range of 21-65 years with an average BMI of 26.5. The breakdown of participants  
20 by profession was 46% nurses (n=11), 21% attending physicians (n=5), 21% resident physicians  
21 (n=5), and 12% technicians (n=3). Of these participants, 4 did not perform the fit testing (1 due to  
22 inability to detect saccharin solution on pre-mask placement sensitivity test, 2 due to time, and 1  
23 due to the inability to get the elastic straps over her hair and face).  
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29 All participants (n=20) that performed the fit test successfully completed the fit test as part  
30 of the hospital annual policy. All participants passed their fit test and were also able to successfully  
31 replace the filter into the mask, resulting in a 100% success rate for both fit testing and filter  
32 exchange. User experience with the iMASC system was evaluated using a Likert scale with a score  
33 of 1 indicating excellent and a score of 5 indicating very poor. Participants scored the fit of the  
34 iMASC system as excellent (8 participants), good (9 participants), or fair (3 participants) (**figure**  
35 **3B**). Participants scored the breathability of the iMASC system as excellent (9 participants), good  
36 (10 participants), or fair (1 participants). Finally, participants scored the filter replacement of the  
37 iMASC system as excellent (7 participants), good (7 participants), fair (4 participants), or poor (2  
38 participants). Participants' preference to wear the iMASC over a surgical mask or an N95 respirator  
39 was also assessed. Sixty percent of participants indicated they would be willing to wear our mask  
40 instead of a surgical mask, with 20% indicating no preference between our mask and a standard  
41 surgical mask and 20% indicating they would prefer to wear a surgical mask (**figure 3C**). When  
42 asked about preference to wear our mask instead of an N95 FFR, 25% of participants indicated they  
43 would prefer to wear our mask and 60% indicated no preference between our mask and a N95 FFR,  
44 with only 15% indicating they would prefer to wear a standard issue N95 FFR (**figure 3D**).  
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### 51 **Discussion**

52 During times of pandemics, it is essential to protect healthcare workers from infection and  
53 transmission of disease with adequate PPE.<sup>4,9</sup> As stocks of N95 FFRs have reduced, healthcare  
54 workers are forced to find alternative strategies of protection, including re-sterilizing masks and  
55 using alternative mask materials that may result in less protection.<sup>9-10</sup> Our approach here was to  
56 develop a scalable, reusable face mask that can extend the amount of N95 material. The iMASC  
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1 system withstood decontamination using three methods and was shown to successfully fit multiple  
2 different face sizes and shapes using an OSHA approved testing method. The iMASC system could  
3 be scaled up for use across many locations once additional certification testing, including the  
4 sodium chloride aerosol challenge test, dioctyl phthalate aerosol test, and inhalation and exhalation  
5 tests, has been completed. By selecting injection molding as the fabrication technique for the  
6 iMASC system, we believe we possess a fundamental advantage to other initiatives using three-  
7 dimensional (3D) printing techniques because injection molding is highly scalable and has  
8 decreased production time when compared to 3D printing.

9 These are initial proof-of-concept studies and have some limitations. First, the small sample  
10 size and single institutional nature of this prospective study limit generalizability and warrants  
11 evaluation in a larger cohort involving multiple institutions. As a result of the lack of availability  
12 of standard N95 FFRs, the iMASC system was not compared to standard of care N95 FFRs.  
13 Previous studies have demonstrated that a respirator user gains experience with subsequent  
14 donnings and may result in improved fit-test pass rate biasing our results<sup>11-13</sup>; thus, it will important  
15 to assess fit testing in inexperienced subjects. While Bitrex is the preferred choice for fit test  
16 solution as a leak detection<sup>14</sup>, saccharin was chosen due to availability and use in OSHA approved  
17 qualitative fit tests. Additional development for smaller face sizes and shapes are warranted since  
18 the iMASC system was modeled from the 3M 1860 model. Furthermore, all testing was performed  
19 in North America, and it is possible face shapes and sizes may differ for workers outside of this  
20 region. Modifications to the filter system and elastic straps would likely improve the fit and  
21 robustness of the mask. All post injection-molding manufacturing steps were completed in-house  
22 and in large scale production would be outsourced to contracted manufacturers with greater quality  
23 control of filter components. Further, the testing of mechanical properties after combinations of  
24 different sterilization techniques could provide a better representation of what would be used in the  
25 hospital. Additional quantitative fit testing, extended wearer testing, and certification testing,  
26 including NIOSH 42 CFR part 84 (or equivalent), will be needed to validate the iMASC system for  
27 use in the healthcare setting as qualitative fit testing is unable to verify the protection factor of the  
28 respirator. To source additional filter materials in the future, we will plan to perform filter efficiency  
29 testing on these materials, such as the NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059.

30 Newer face masks, such as our iMASC system, have potential to resupply and sustain  
31 hospitals with effective N95-comparable masks. Furthermore, a 2018 consensus report from the  
32 National Academies of Engineering, Science, and Medicine recommended that the durability and  
33 reusability of elastomeric respirators made them desirable for stockpiling for emergencies.<sup>5</sup> This  
34 approach could be applicable to users outside of the healthcare setting, including people in the  
35 research, home improvement, and manufacturing settings.

### 48 **Author Statement**

49 **Acknowledgments:** We thank Ania Hupalowska for her illustrations of the clinical workflow. We  
50 thank Prof. R. Langer for helpful discussions around mask development.

51 **Contributors:** J.D.B. and A.J.W. designed and fabricated the iMASC system, assisted with the  
52 clinical trial, analyzed and interpreted data, and wrote the manuscript. P.R.C. performed the clinical  
53 trial, analyzed and interpreted data, and wrote the manuscript. H.W.H., S.B., and C.L. designed the  
54 face scanning and performed FEA modeling, analyzed data, and wrote the manuscript. S.L.B., C.T.,  
55  
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1 and S.M. analyzed data and designed prototypes. G.T. supervised, reviewed the data and edited the  
2 manuscript.  
3

4  
5 **Funding:** This work was supported in part by the Prostate Cancer Foundation. J.D.B. was supported  
6 by the Prostate Cancer Foundation Young Investigator Award. G.T. was supported in part by the  
7 Department of Mechanical Engineering, MIT and Brigham and Women's Hospital. P.R.C was  
8 supported by NIHK23DA044874, and investigator-initiated research grants from e-ink corporation,  
9 Gilead Sciences, Philips Biosensing and the Hans and Mavis Lopater Psychosocial Foundation.  
10 Support for the materials and supplies was from discretionary funds to G.T. from Brigham and  
11 Women's Hospital and the Department of Mechanical Engineer, MIT.  
12  
13  
14  
15

16 **Competing Interests:** There are no competing interests related to the work described in the  
17 manuscript. Complete details of all other relationships for profit and not for profit for G.T. can be  
18 found at the following link: [https://www.dropbox.com/sh/szi7vnr4a2ajb56/AABs5N5i0q9Aft1IqIJAE-  
19 T5a?dl=0](https://www.dropbox.com/sh/szi7vnr4a2ajb56/AABs5N5i0q9Aft1IqIJAE-T5a?dl=0)  
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22 **Patient and public involvement:** Patients and/or the public were not involved in the design, or  
23 conduct, or reporting, or dissemination plans of this research.  
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26 **Data Availability Statement:** The authors declare that the data supporting the findings of this  
27 study are available within the paper and its supplementary information files.  
28  
29  
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### 31 **References and Notes**

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## Figures

**Figure 1. iMASC system for aerosol-based protection.** (A) Front and (B) side images of the iMASC system. (C) Workflow for sterilization and reuse of iMASC system.

**Figure 2. Finite Element modeling of flexible masks.** (A) Representative numerical images showing the deformation of the elastomeric mask at different levels of reaction forces,  $F=0, 4.5,$  and  $10\text{ N}$  in two different views (top and bottom rows). The colors represent the magnitude of displacement field,  $U$ . (B) The corresponding distribution of the normal contact forces,  $F^N$ , between the mask and face. (C) Reaction forces for the subject numbers  $n=1,2,3,\dots, 20$  computed from simulations.

**Figure 3. Fit testing of iMASC system in healthcare workers and their user experience.** (A) Demographics of participants ( $N = 24$ ) enrolled in fit testing clinical trial. (B) User experience ( $N = 20$ ) with the mask based upon a Likert scale. User preferences ( $N = 20$ ) comparing the iMASC system to the (C) standard surgical mask and (D) N95 respirators.

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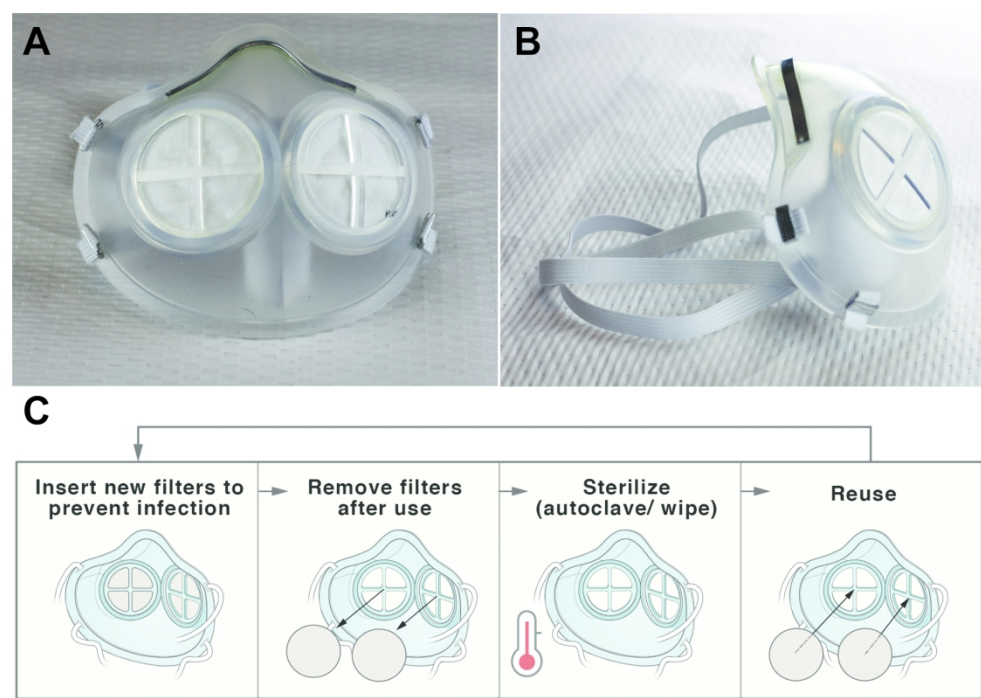


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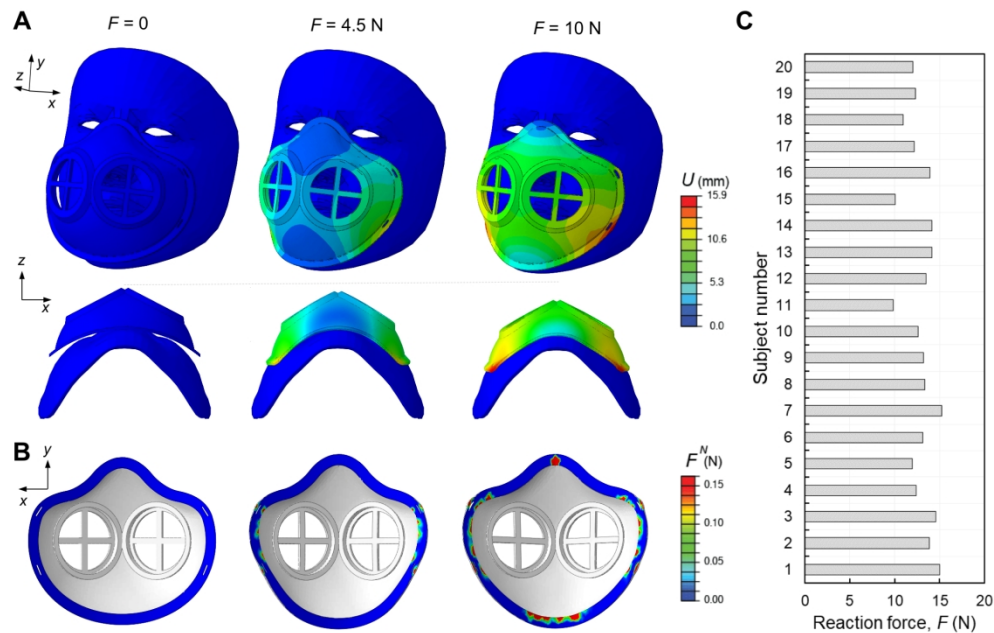


Figure 2. Finite Element modeling of flexible masks. (A) Numerical images showing the deformation of the elastomeric mask at different levels of reaction forces,  $F = 0, 4.5,$  and  $10$  N in two different views (top and bottom rows). The colors represent the magnitude of displacement field,  $U$ . (B) The corresponding distribution of the normal contact forces,  $F^N$ , between the mask and face. (C) Reaction forces for the subject numbers  $n=1,2,3,\dots, 20$  computed from simulations.

259x165mm (220 x 220 DPI)



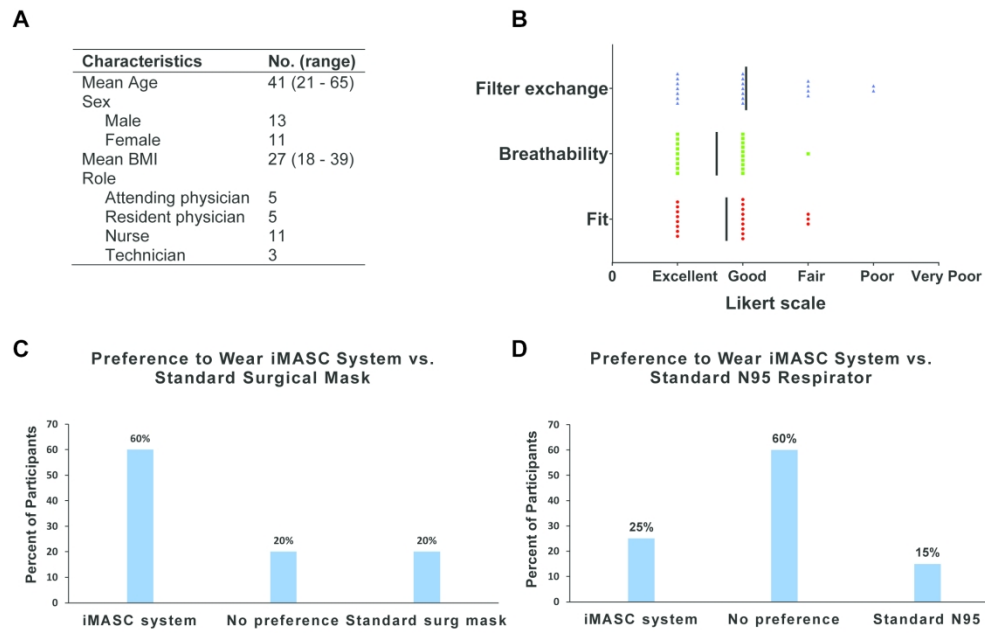


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## Supplementary Information

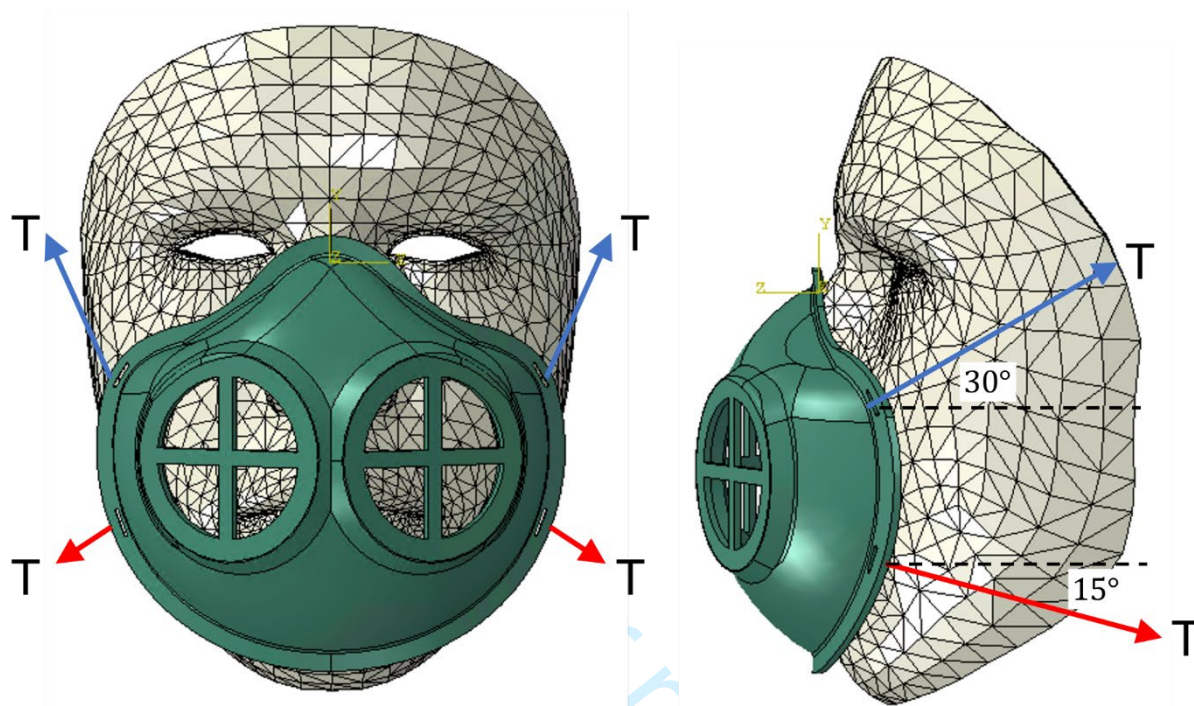
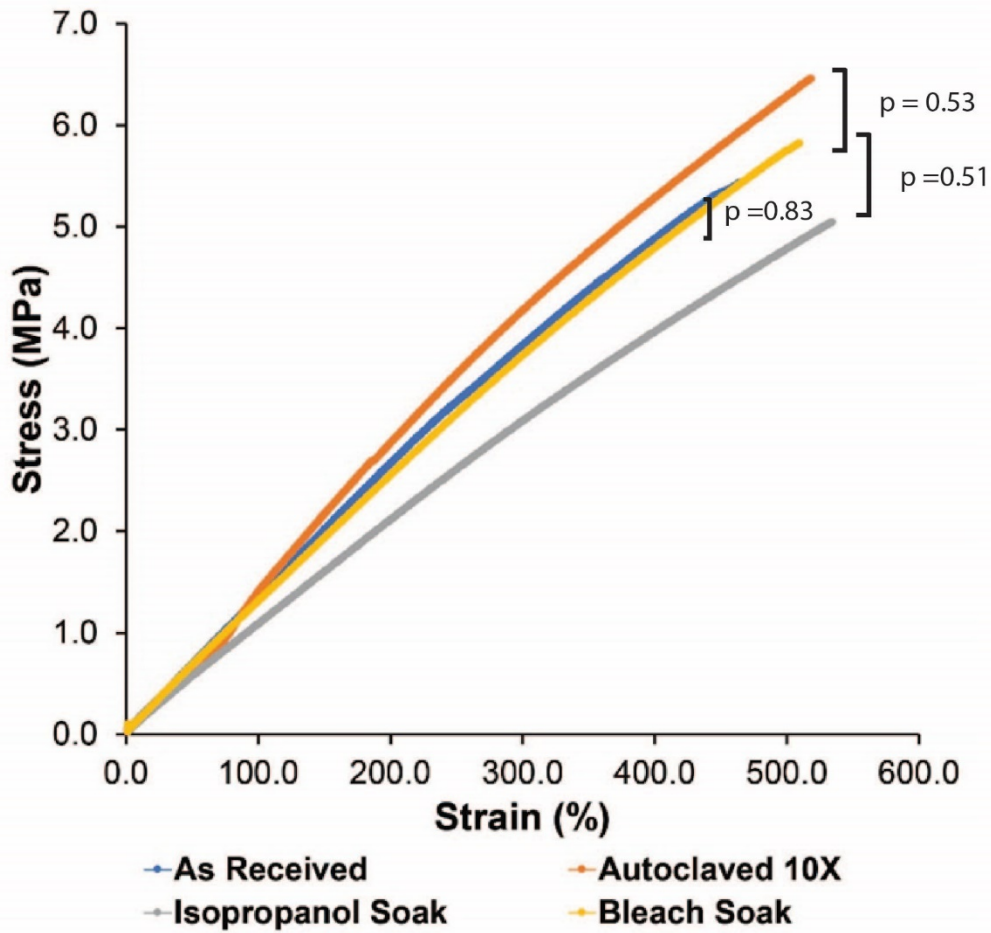
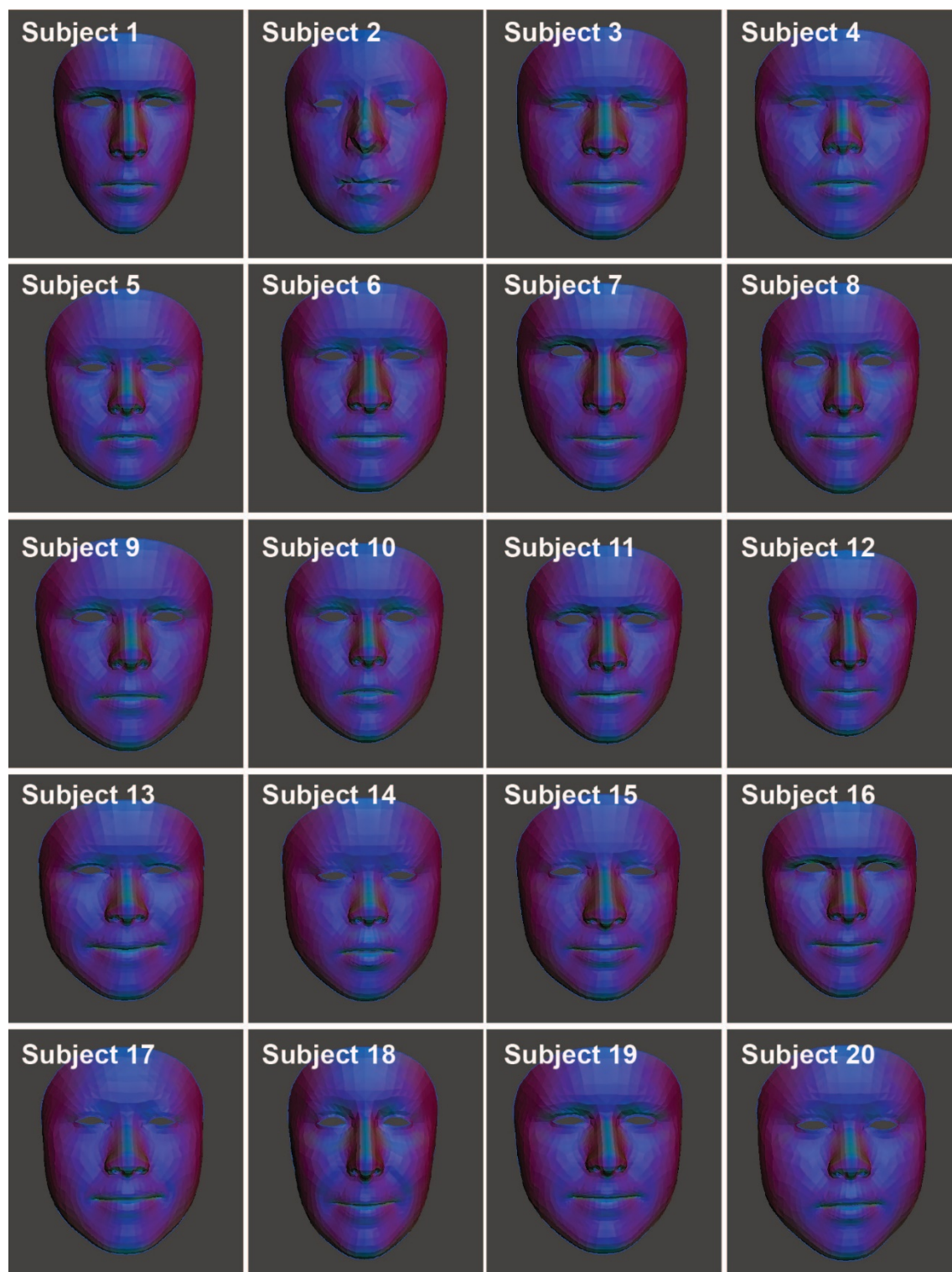


Figure S1. Illustration of the applied loads via mask straps.

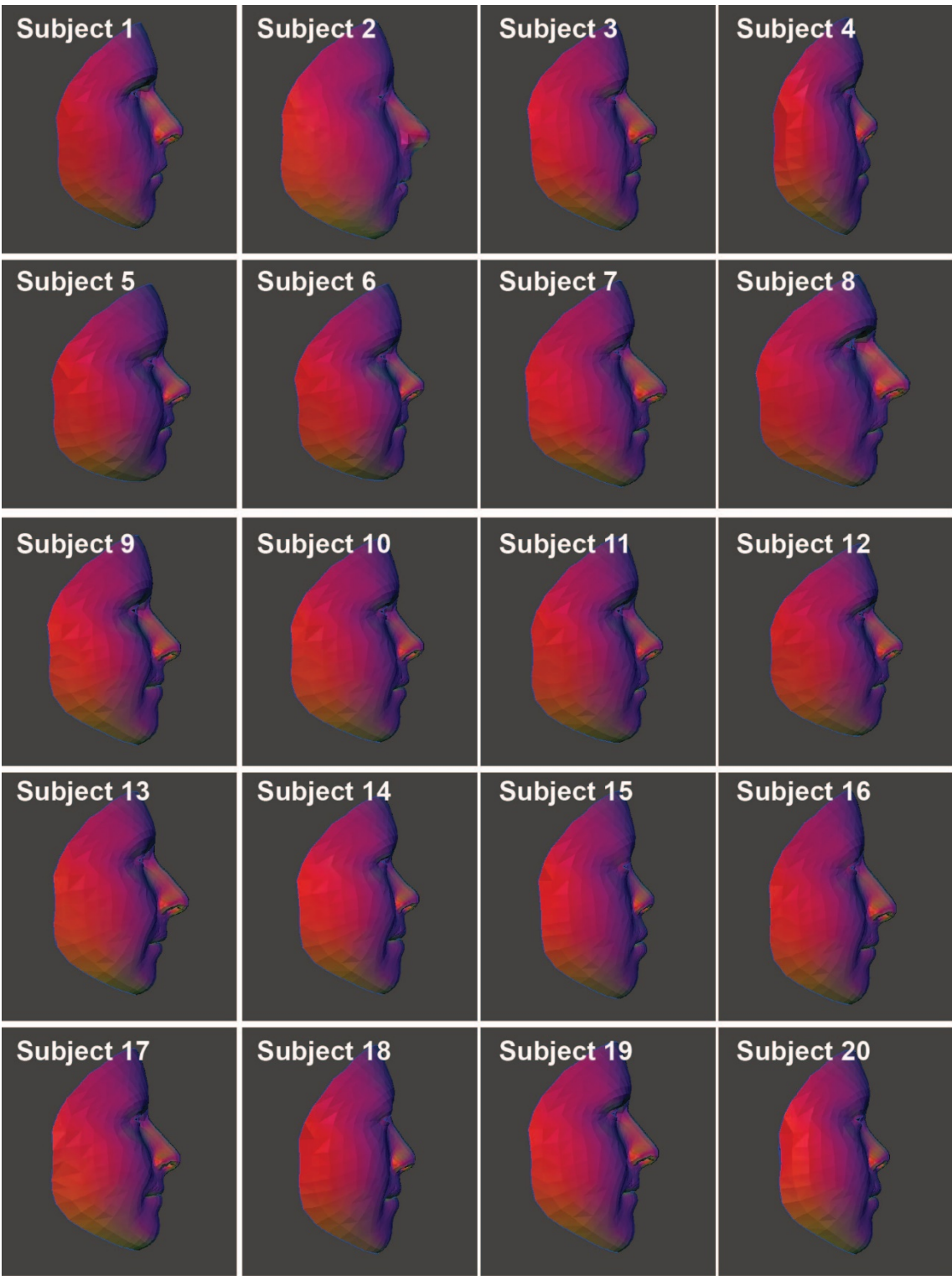


**Figure S2.** Mechanical testing on samples cut directly from masks exposed to a variety of sterilization methods including 10 cycles of autoclaving, 10-minute soak in 10% bleach solution, and 10-minute soak in isopropanol.




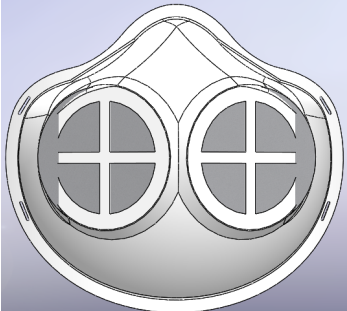


**Figure S3.** Front view of 3D facial reconstruction of participants faces in fit trial of the iMASC system.

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**Figure S4.** Side view of 3D facial reconstruction of participants faces in fit trial of the iMASC system.

**Table S1.** Array of N95 and N95-comparable technologies.

Type	Ex \$US Dollars (USD)/Unit	Pros	Cons	Recommended Sterilization Method
Disposable FFR 	3M 8210Plus \$1.02 USD <a href="http://mcmaster.com/5450T42">mcmaster.com/5450T42</a>	<ul style="list-style-type: none"> <li>Ease of fit/use</li> <li>Low cost per use compared to HFRR and FFRR</li> <li>Some models come with exhaust valve</li> </ul>	<ul style="list-style-type: none"> <li>Not reusable</li> <li>If exhaust valve is available, it's not filtered</li> <li>No eye protection</li> </ul>	N/A
iMASC system 	Mask: < \$7.00 USD  Filter: \$0.50 USD	<ul style="list-style-type: none"> <li>Low cost</li> <li>Ease/accessibility of manufacturing</li> <li>Potentially autoclavable</li> </ul>	<ul style="list-style-type: none"> <li>No exhaust valve for humidity/ease of use relief</li> <li>No eye protection</li> </ul>	Autoclave, Clorox wipe, IPA wipe, detergent and sterilization agent wash
Half-Face Reusable (HFRR) 	Mask: \$58.98 USD <a href="http://mcmaster.com/5541T16-5541T162">mcmaster.com/5541T16-5541T162</a>  Replacement Cartridge: \$14.32/pair USD <a href="http://mcmaster.com/54445T229">mcmaster.com/54445T229</a>  Replacement Filter: \$2.65/pair USD <a href="http://mcmaster.com/54445T189">mcmaster.com/54445T189</a>	<ul style="list-style-type: none"> <li>Powered air compatible with select models</li> <li>Exhaust valve reduces humidity and breathing resistance</li> <li>Flange/gusset provides comfortable seal skin</li> </ul>	<ul style="list-style-type: none"> <li>Expensive</li> <li>Exhaust valve not filtered</li> <li>No eye protection</li> </ul>	Detergent and sterilization agent wash
Full-Face Reusable (FFRR) 	Mask: \$168.47 USD <a href="http://mcmaster.com/5541T28">mcmaster.com/5541T28</a>  Replacement Filter: \$2.65/pair USD <a href="http://mcmaster.com/54445T189">mcmaster.com/54445T189</a>	<ul style="list-style-type: none"> <li>Best coverage</li> <li>Powered air compatible with select models</li> <li>Exhaust valve reduces humidity and breathing resistance</li> <li>Comfortable seal to skin</li> </ul>	<ul style="list-style-type: none"> <li>Expensive</li> <li>Exhaust valve not filtered</li> <li>Potential visual obstruction due to fogging</li> </ul>	Detergent and sterilization agent wash