Letter

Prospective Evaluation of the Transparent, Elastomeric, Adaptable, Long-Lasting (TEAL) Respirator

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ABSTRACT: N95 filtering facepiece respirators (FFR) and surgical masks are essential in reducing airborne disease transmission, particularly during the COVID-19 pandemic. However, currently available FFR's and masks have major limitations, including masking facial features, waste, and integrity after decontamination. In a multi-institutional trial, we evaluated a transparent, elastomeric, adaptable, long-lasting (TEAL) respirator to evaluate success of qualitative fit test with user experience and biometric evaluation of temperature, respiratory rate, and fit of respirator using a novel sensor. There was a 100% successful fit test among participants, with feedback demonstrating excellent or good fit (90% of participants), breathability (77.5%), and filter exchange (95%). Biometric testing demonstrated significant differences between exhalation and inhalation pressures among a poorly fitting respirator, well-fitting respirator, and the occlusion of one filter of the respirator. We have designed and evaluated a transparent elastomeric respirator and a novel biometric feedback system that could be implemented in the hospital setting.

KEYWORDS: FFR, respirator, COVID-19, biometric, facial recognition

The use of personal protective equipment (PPE), including N95 filtering facepiece respirators (FFRs) and surgical masks, has become essential in the management of COVID-19 patients to prevent transmission of disease and protect healthcare workers.[1,2] Universal masking in the healthcare setting has demonstrated a reduced transmission rate among healthcare workers.[3] Unfortunately, PPE shortages remain in the United States and across the world.[4,5]

The introduction of decontamination strategies for disposable N95 FFRs, including hydrogen peroxide vapor sterilization, has greatly enhanced the supply chain of respirators. The Food and Drug Administration (FDA) has authorized Emergency Use Authorization for the decontamination of FFRs. Despite numbers of cycles allowed by the FDA, hospitals have been limiting the numbers of cycles.[6] Thus, there are potential shortcomings with reuse after decontamination, including reduced integrity of the respirators, elastic straps, and inadequacy of fit.[7−9] Elastomeric half-mask respirators have been found to be an appropriate alternative to disposable N95 FFRs.[10] A 2018 consensus report from the National Academies of Engineering, Science, and Medicine recommended the use of elastomeric respirators during national and international medical emergencies due to fit and reusability.[11] Disadvantages to current elastomeric respirators are cost, exhalation valve, and suitability to decontamination strategies in the hospital.[12]

Further, there are key needs in the hospital and community involving communication with the hearing-impaired and wearer feedback on respirator fit and physiology.[13−16] Healthcare workers that have previously positively fit tested FFRs have been shown to have high rates of fit test failure at 3 months after their most recent fit test.[17] Addressing these limitations would improve healthcare worker−patient interaction and may reduce infection rates among healthcare workers through proper fit. We have developed the transparent, elastomeric, adaptable, long-lasting (TEAL) respirator platform capable of providing visualization of the lips and wearer feedback regarding fit quality. Here, we describe proof-of-concept studies focused on the generation of a new respirator platform, fit test of the respirator in multiple institutions, and fabrication and testing of a sensor
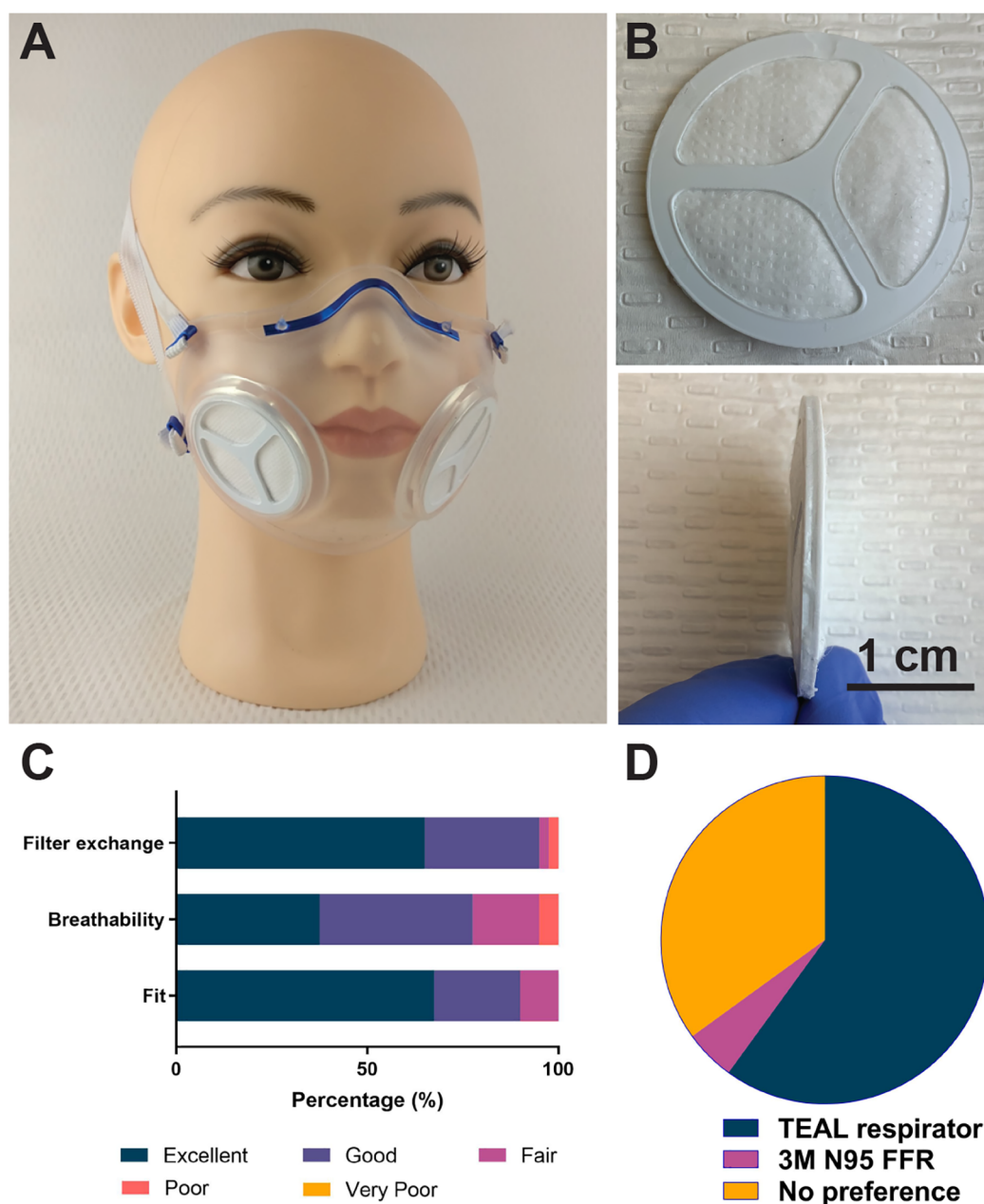
Figure 1. TEAL respirator fit tested in multi-institutional setting. (A) TEAL system on a mannequin and (B) front and side image of N95 filter cartridges. (C) User experience among 40 participants on a Likert scale including evaluation of fit, breathability, and filter exchange and (D) preference between the TEAL respirator and a standard hospital FFR.

incorporated in the respirator to provide the user real-time biometric feedback.

RESULTS AND DISCUSSION

The respirators were fabricated using a clear liquid silicone rubber (LSR) as established in our previous work.[18] Lateralization of the filter reservoirs enabled visualization of the lips (Figures 1A,B and S1). Various decontamination methods were evaluated individually, including 100 cycles of autoclaving and 100 cycles of microwaving, as well as prolonged exposure to UV treatment (405 nm), high heat (200 °C), 100% isopropyl alcohol, and 8.25% bleach. There were minimal differences between the elasticity of the respirators after undergoing decontamination (Figure S2 and Table S1). Thermochromic coatings (1 wt %) were evaluated

on the TEAL respirator to provide feedback to the user. After 2 min of donning the respirator, the color of the coating changes from black to pink in the areas that had direct contact with the skin (Figure S3). Lastly, finite element analyses (FEA) of the subjects participating in the multi-institutional trial demonstrated the reaction force range of 10 to 17.2 N to maintain a contact pressure of 10 kPa (Figure S4). The reaction forces were within a range that would feel comfortable to the users while maintaining appropriate fit.[18] The methods for characterization of the TEAL respirator, including decontamination methods, thermochromic coatings, and FEA, can be found in the Supporting Information.

Next, we proceeded to evaluate the mask's performance in a clinical setting. A total of 47 subjects were enrolled in a multi-institutional trial. All subjects had completed a fit test for an

Figure 2. Clinical evaluation of customized respirator sensor for biometrics. (A) Active sensors on printed circuit board within the respirator. (B) Respiratory rate and exhalation breath temperature ($n = 7$) and (C) pressure differences in respirator between exhalation and inhalation in setting of leaky respirator, well-fitting respirator, and covering one filter with hand ($n = 7$).

N95 FFR within 1 year of the study. Table S2 shows the demographics of the study population. Participants underwent a facial scan, found in Figures S5−S9 and Tables S3 and S4, showcasing the variability of face sizes and shapes. The mean bizygomatic diameter of subjects was 14.3 cm (range 13.2− 15.6 cm), top of nose to chin was 10.9 cm (range 10.1−11.9 cm), and nose protrusion was 2.2 cm (range 1.8−2.5 cm). Seven of the subjects were excluded from the study due to lack of ability to taste the nebulized saccharin.

Of the participants that underwent fit testing ($n = 40$), all successfully completed the fit test with the TEAL respirator platform. Furthermore, all participants successfully replaced the filters within the filter reservoir after initial instruction. Participants scored the fit of the TEAL respirator as excellent ($n = 27$ (67.5%)), good ($n = 9$ (22.5%)), and fair ($n = 4$ (10%)) (Figure 1C). Participants scored the breathability of the TEAL respirator as excellent ($n = 15$ (37.5%)), good ($n = 16$ (40%)), fair ($n = 7$ (17.5%)), and poor ($n = 4$ (10%)). Participants scored the ease of filter exchange of the TEAL respirator as excellent ($n = 26$ (65%)), good ($n = 12$ (30%)), fair ($n = 1$ (2.5%)), and poor ($n = 1$ (2.5%)). In addition, participants were asked for their preference to wear the TEAL respirator compared to the standard hospital supplied FFR, and 24 participants (60%) preferred the TEAL respirator, two participants (5%) preferred the standard hospital supplied FFR, and 14 participants (35%) had no preference (Figure 1D).

Sensors integrated into the TEAL system (Figures 2A and S9) were evaluated in an additional seven subjects. The sensors were able to simultaneously detect the respiratory rate,

exhalation temperature, and exhalation and inhalation pressures, as shown in Figures 2B and S10. The magnitude of difference in pressure between exhalation and inhalation was found to be significant for a leaky TEAL system compared to a well-fitting system (Figure 2C). In addition, a significantly large pressure difference was found between a respirator with one blocked filter compared to a well-fitting functional respirator. These pressure differences are at the upper limits of National Institute for Occupational Safety and Health (NIOSH) standards for N95 FFR certification and are slightly above pressures determined for early model FFRs.[19]

This investigation demonstrates an alternative method to fabricate sustainable respirators which also provide biofeedback to wearers, allowing them to detect poor fit and adjust the fit. During the COVID-19 pandemic, there has been a substantial need for FFRs and surgical masks to provide droplet and aerosol protection to healthcare workers.[3] Decontamination strategies have extended the use of the current supply of respirators; however, there remains a shortage in the U.S. and worldwide.[4,5] Additionally, current FFRs do not provide users with feedback regarding adequacy of fit, leading to potential mask failures. Our novel transparent respirator has been successfully fit tested among healthcare workers at two large hospitals. In addition, we further evaluated a biometric system that can be incorporated into this respirator to provide the wearer feedback on their physiology, respirator fit, and filter functionality. The respirator uses less filter media, reducing overall waste, and these filter cartridges have the additional advantage of the ability to be decontaminated using established methods of hydrogen

peroxide vaporization. The transparent, elastomeric shell of the respirator can be decontaminated through a variety of simple methodologies that are widely available in hospitals, none of which damage the mechanical properties of the system. Lastly, additives in coatings may be applied to the respirator to increase feedback of respirator fit using thermochromism. Standard opaque respirators and masks have been shown to limit interaction between healthcare workers and patients, especially with the hearing-impaired population.[13−16] Due to the TEAL respirator's transparency, it will allow individuals who are dependent on lip reading to better communicate with providers. Additionally, the emotive aspect of medicine that is limited due to the nature of obstructive PPE required to protect healthcare workers may be improved using transparent materials for respirators.

Despite successful clinical evaluation of the respirator, there are limitations to the study. The sample size of the study was small and warrants additional evaluation in a large cohort of individuals. Evaluation of the respirator over a longer time frame would provide additional information on the functionality of the respirator. In addition, fit testing of the respirator after numerous decontamination cycles would inform functionality. The preferred testing solution for the OSHA-approved fit test is Bitrex; saccharin was used due to availability.[20] Quantitative fit testing of the respirator will be important to determine the protection factor of the system. To use the respirator in the healthcare setting, additional testing according to NIOSH criteria will be needed (42 CFR 84). The filters within the respirators provide adequate filter characteristics for qualitative fit testing (Table S5), but increasing the surface area of the filter may result in preservation of the functionality of the filter media for a longer duration as well as improve breathability.[21] Furthermore, increasing surface area to meet face velocity and pressure drop requirements per NIOSH standards (42 CFR 84) will be important. Moisture buildup within the respirator may limit visualization of the lips, and thus, antifog coatings are being investigated. Although we incorporated biometric feedback into the TEAL respirator, we did not specifically assess whether this feedback may help guide individuals to an adequate fit or detect a poor fit of the respirator. Future studies of the respirator include evaluation of novel filter materials and additional ways to incorporate the sensors that can be easily sterilized. The TEAL respirator with novel biometric systems may enhance the functionality of the respirator by providing healthcare workers with additional confirmation of respirator fit and the wearer's physiologic state while improving communication with other providers and patients.

■ MATERIALS AND METHODS

TEAL Respirator Fabrication. The respirator was designed using the computer-aided design (CAD) software, SolidWorks (Waltham, MA), based upon the iMASC system.[18] Using this design, Protolabs (Maple Plain, Minnesota, USA) manufactured the respirator using the CAD design by injection molding of a liquid silicone rubber, Elastosil 3003 50A/B. A 7.6 cm long and 0.5 cm wide aluminum strip was shaped to form the nasal bridge and connected to the respirator using snap fittings. A silicone adhesive (Smooth-On, Silpoxy) fastened the aluminum strip onto the respirator at the snap fittings. Elastic straps were used to secure the respirator to the wearer's face. The elastic straps were purchased from a local craft supply store. The dimensions of the straps were 0.1 × 0.9

× 38.1 cm (top strap) and 0.1 × 0.9 × 34.3 cm (bottom strap), which was comparable to standard N95 FFRs (0.1 × 0.7 × 38.1 cm (top strap) and 0.1 × 0.7 × 34.3 cm (bottom strap)). Furthermore, the elasticity of the TEAL respirator elastic strap was similar to the standard N95 FFR (Figure S11). Straps were threaded through a slit in the side of the respirator and fastened using crimped aluminum strips. Two circular filters measuring 4.7 cm in diameter were laser cut directly from 3 M 8210Plus N95 FFRs; all layers were included in the circular filters. Laser cut polystyrene support structures were adhered to either side of the filter media with fabric adhesive and compressed, creating a filter cartridge. The filter cartridges were then inserted into the filter reservoirs of the respirator.

Biometric Sensor Development. A printed circuit board (PCB) was designed using the software, Eagle (Figure S9). The PCB was devised to provide exhalation breath temperature, humidity, and pressure using a Bosch Sensortec BME280 sensor that collected data at a 10 Hz sampling rate. The BME280 sensor has the following sensing parameters: for humidity, the resolution is 0.008% relative humidity and accuracy of ±3% relative humidity; for temperature, the resolution is 0.01 °C and accuracy is ±1.0 °C in conditions between 0 and 65 °C, and for pressure, the resolution is 0.12 hPa and accuracy of ±1.0 hPa in conditions between 0 and 65 °C.[22] The PCB was fabricated using Pcbway (Hangzhou, China) and powered by a 3 V lithium coin cell battery (Duracell 2032). The low-power microcontroller wirelessly transmitted the sampled data to an encrypted computer using Bluetooth Low Energy. The PCB was mounted on a filter cartridge that could be inserted and removed from the filter reservoir of the respirator.

Respirator Fit Testing. Mass General Brigham Institutional Review Board (IRB) approval was granted prior to all human testing of the TEAL respirator (Partners IRB 2020P000852 and clinicaltrials.gov identifier NCT04511390). All participants were Massachusetts General Hospital or Brigham and Women's Hospital staff including physicians, residents, nurses, and technicians who were voluntarily recruited and had undergone Occupational Safety and Health Administration (OSHA)-approved fit testing within the past year. Healthcare workers with facial hair were excluded from the study. Subjects were recruited by study staff from surgical intensive care units and outpatient clinics for gastroenterology, interventional radiology, and radiation oncology and gave informed verbal consent to participate in the study. Following enrollment and consent, the same research team member informed each participant of the study procedure, and a baseline assessment was conducted to generate basic demographic information.

Subjects performed fit testing in accordance with the Saccharin Solution Aerosol Protocol per OSHA §1910.134 using the Gerson Respirator Fit Test kit (Gerson part #065000, Middleboro, Massachusetts). Threshold screening tests were performed by having the participants don a hood with a fitted collar. Saccharin solution was nebulized through a hole in the front of the hood. The solution was sprayed for 10, 20, or 30 squeezes until the participants reported tasting the test solution. After successful completion of the threshold screening test, subjects donned the TEAL respirator and hood and were instructed to report if they could taste the solution at any time during the fit testing with the respirator. The same process as the threshold test was performed with the same number of nebulized sprays (10, 20, or 30 squeezes)

administered as the threshold test for each subject. The aerosolized solution was replenished every 30 s while the subject performed the following exercises in order: normal breathing, deep breathing, turning the head side to side, moving the head up and down, counting backward from 100, grimacing, bending over, and finally normal breathing for a second time. If the subject reported tasting the solution at any time during the fit test, they informed the study staff and the test was deemed failed. If the subject did not report tasting the solution, the test was considered passed. Subjects who passed the fit test received a demonstration on the proper procedure for replacing the filter and were then asked to replace the filter and perform a user seal check for proper fit. Finally, subjects were given a quantitative assessment to evaluate the fit and breathability of the respirator and difficulty of replacing the filter according to a Likert scale. Additionally, subjects were asked if they preferred to wear the TEAL respirator compared to an N95 FFR.

To assess the functionality of the sensors integrated into the respirator, subjects were instructed to don the respirator without adjusting the nasal bridge and straps. Next, they were asked to adjust the nasal bridge and straps to create a tight fit that conformed to their face. Finally, subjects were asked to cover the filter that did not contain the sensor with their hand. During each of these maneuvers, the sensor continuously recorded pressure, temperature, and humidity in 30 s increments. Pressure differences between exhalation and inhalation were compared between all three groups using a paired t test.

Statistical Analyses. Statistical analysis was performed using SAS v9.3 software. Copyright 2019 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA. All values of n can be found in the Results and Discussion section and refer to number of human subjects, in total $n = 47$ human subjects. Comparison of pressure differences between exhalation and inhalation were performed using paired t test. A p value of <0.05 was considered significant.

ASSOCIATED CONTENT

Supporting Information

The Supporting Information is available free of charge at https://pubs.acs.org/doi/10.1021/acsptsci.0c00157.

Description of the thermochromic coatings used to obtain biometric feedback, testing of the sterilization methods to ensure respirator integrity, development of the facial scan technology employed, a characterization of the deformation studies conducted, and accompanying figures: an assembly drawing of the respirator to demonstrate filter cartridge insertion, the PCB design of the biometric sensor, mechanical testing of the respirator postdecontamination for each method tested, a demonstration of the thermochromic coating, finite element analysis of the respirator for subjects participating in the trial, facial profiles of subjects participating in the trial, and representative waveforms from the biometric sensor testing; several tables are included, detailing the mechanical properties for each sterilization method, the demographics of the study population, facial measurements for all subjects participating in the trial, facial measurements of the United States' general

population, and the filtration characteristics for our respirator system (PDF)

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Author Contributions

A.J.W. and J.D.B. contributed equally to this work. A.J.W. and J.D.B. designed and fabricated the TEAL respirator, assisted with the clinical trial, analyzed and interpreted data, and wrote the manuscript. S.O., J.S., and S.M. designed and fabricated the PCB, assisted with clinical testing, analyzed and interpreted data, and wrote the manuscript. C.T. fabricated the TEAL respirator, assisted with the clinical trial, and analyzed and interpreted data. S.B. and H.W.H. designed the face scanning and performed FEA modeling, analyzed data, and wrote the manuscript. H.B. assisted with the decontamination testing of the respirators, analyzed and interpreted data, and wrote the manuscript. S.M. designed and fabricated the TEAL respirator. C.L. designed the face scanning. P.R.C., J.N.C., A.S., and S.L.B. performed the clinical trial, analyzed and interpreted data, and wrote the manuscript. M.G., A.C., and G.T. supervised, reviewed the data, and edited the manuscript.

Notes

The authors declare the following competing financial interest(s): A.J.W., J.D.B., S.O. J.S., C.T., S.M., A.C., and G.T. have filed multiple patents surrounding the respirator and sensors. In addition, A.J.W., J.D.B. and G.T. have a financial interest in TEAL Bio, a biotechnology company focused on developing the next generation of personal protective equipment. A.C. is on the board of directors for Analog Devices.

■ ABBREVIATIONS

FFR: filtering facepiece respirators
TEAL: transparent, elastomeric, adaptable, long-lasting
PPE: personal protective equipment
COVID-19: coronavirus disease 2019

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