Received: 15 October 2020 | Revised: 18 November 2020 | Accepted: 1 December 2020

DOI: 10.1002/emp2.12335

JACEP OPEN
JOURNAL OF THE AMERICAN COLLEGE OF EMERGENCY PHYSICIANS OPEN
A GLOBAL JOURNAL OF EMERGENCY MEDICINE
Open Access
WILEY

BRIEF RESEARCH REPORT

Infectious Disease

The "double eights mask brace" improves the fit and protection of a basic surgical mask amidst COVID-19 pandemic

Daniel P. Runde MD, MME[1] | **Karisa K. Harland PhD, MPH**[1,2] | **Paul Van Heukelom MD**[1] | **Brett Faine PharmD, MS**[5] | **Patrick O'Shaughnessy PhD**[4] | **Nicholas M. Mohr MD, MS**[1,2,3]

[1] Department of Emergency Medicine, University of Iowa College of Medicine, Iowa City, Iowa, USA

[2] Department of Epidemiology, University of Iowa College of Public Health, Iowa City, Iowa, USA

[3] Division of Critical Care, Department of Anesthesia, University of Iowa Carver College of Medicine, Iowa City, Iowa, USA

[4] Department of Occupational and Environmental Health, University of Iowa College of Public Health, Iowa City, Iowa, USA

[5] Department of Pharmacy Practice and Science, College of Pharmacy, Iowa City, Iowa, USA

Correspondence
Daniel P. Runde, University of Iowa Carver College of Medicine; 200 Hawkins Dr., 1008 RCP; Iowa City, IA 52242, USA.
Email: daniel-runde@uiowa.edu

Funding and support: By *JACEP Open* policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article as per ICMJE conflict of interest guidelines (see www.icmje.org). The authors have stated that no such relationships exist.

Abstract

Study objective: The COVID-19 pandemic has resulted in widespread shortages of personal protective equipment, including N95 respirators. Although basic surgical facemasks are more commonly available, their efficacy is limited due primarily to their poor face seal. This pilot study examined the impact of a rubber band mask brace on a basic surgical mask, as determined by quantitative fit testing.

Methods: Subjects wearing a basic surgical facemask and the rubber band mask brace underwent quantitative fit testing using machinery designed to certify N95 mask fit. Subjects were tested with the brace anchored behind their ears, with a paperclip behind the head, and on the side knobs of their face shields. The primary outcome measure was whether the subject passed the quantitative fit test at or above the Occupational Safety and Health Administration (OSHA)-verified standard for N95 masks.

Results: Subjects (n = 11) were 54.5% female, with a median height of 70 inches (interquartile range [IQR] = 68–74), weight of 170 pounds (IQR = 145–215), and body mass index (BMI) of 24.6 (IQR = 22.2–27.2), and encompassing 5 distinct N95 mask fit types. We found that 45%, 100%, and 100% of subjects passed the quantitative fit test when the brace was anchored behind the ears, with a paperclip and on a face shield, respectively.

Conclusion: Of the 11 subjects included in the analysis, across a range of body habitus and N95 mask fit types, all passed the quantitative fit test when the mask brace was anchored on either face shield or with a paperclip. This data suggests that although the brace does not create an N95 equivalent in terms of filtration, it would offer improved protection from airborne viruses when worn with a basic surgical mask.

KEYWORDS
COVID-19, infectious disease transmission, masks, patient-to-professional, SARS-CoV-2

1 | INTRODUCTION

The COVID-19 pandemic has resulted in widespread shortages in personal protective equipment (PPE), including N95 respirators used by frontline health care workers.[1–3] Although basic surgical facemasks are more commonly available, they are not designed to filter all airborne or droplet particles, with their efficacy then limited due primarily to their poor seal. The lack of seal increases exposure to aerosolized droplets,

Supervising Editor: Michael Blaivas, MD, MBA.

as these droplets will follow the path of least resistance, which is, by definition, anywhere the mask does not have a good seal with the face, negating the filtering capabilities of the mask itself. We present an improvement that can be worn with a basic surgical mask, comprised of 3 interlocking rubber bands, that substantially improves the facial seal of the mask and may allow it to serve as a substitute for the N95 respirator in times of shortage. We refer to this improvement as the "double eights mask brace."

The Bottom Line

The COVID-19 pandemic has repeatedly revealed PPE shortages and reminded us of the fit challenges of face masks. This study evaluated a simple method using a rubber band brace to improve surgical mask fit and tested the seal obtained using quantitative fit testing using machinery designed to certify N95 mask fit to meet OSHA guidelines. All 11 subjects passed the fit test. This study highlights that simple design modifications may improve surgical mask seal and fit.

2 | METHODS

This study was an unblinded, open-label, convenience sample of subjects recruited via a department-wide email requesting volunteers and individuals were scheduled for testing on a first-come, first-served basis. No compensation was offered. No subjects declined to participate after volunteering or during testing. Subjects wore an ASTM Level 1 mask (ASTM International F2100-11 Standard Level 1, Halyard 47567) accompanied by the double eights mask brace. The brace consists of a central size #64 (3.5 × 0.25 inch) rubber band, which is fitted over the bridge of the nose and under the chin, and 2 size #33 (3.5 × 0.125 inch) rubber bands knotted together with the central band, which serve as anchors for the brace. Appropriate application of the double eights mask brace involves placing the central rubber band under the chin inferiorly and directly beneath the metal band inside the mask superiorly, where it crosses the nasal bridge (Figure 1). The masks were fitted with a grommet and then subjected to Occupational Safety and Health Administration (OSHA) standard quantitative fit testing (29 CFR 1910.134). Using the TSI PortaCount Pro Model 8038 and Model 8026 Particle Generator (Shoreview, MN), ambient saline particles were generated within the testing area and the concentration of these particles was sampled both inside and outside the mask (Figure 2). DPR performed all fit tests after being trained on the procedure by nurse RL (see Acknowledgements), who performs quantitative fit testing daily and who trains other employees on the procedure. The external and internal measurements were continuously compared while the subject underwent the OSHA-specified testing components: normal breathing, deep breathing, rotating the head side to side, flexing and extending the neck, talking while reading a pre-specified script, standing and bending continuously from the waist, and finally normal breathing again. The degree of mask seal present during each testing component was recorded, as was the overall fit factor of the mask. All evaluations were performed at the level of N95 respirator fit test standards, which requires an overall fit factor ≥100 on a 0–200 scale. For reference, the fit factor is expressed as the challenge aerosol concentration outside the respirator divided by the challenge aerosol concentration that leaks inside the respirator during the fit test. Subjects were tested in 3 scenarios, all in the following order: with the fit aid anchored behind the ears, behind the head with a paperclip, and on the side knobs of their face shields. In addition to whether the subject passed the quantitative fit test in each scenario, data on overall fit factor and the fit factor for the 7 individual components of the test were recorded. Baseline characteristics were analyzed with summary statistics, and fit testing was compared between the 3 securement locations. There was no sample size calculation for this exploratory study.

3 | FILTER PRESSURE DROP TESTING

Filter pressure drop, or "breathing resistance," measurements were conducted using a pass-through cylinder with an inner diameter of 2.7 cm. A portion of the surgical mask was tightly clamped between the upper and lower portions of the cylinder. The air flow rate through the cylinder was induced with a vacuum pump such that the velocity of air going through the mask portion of 1.4 and 8.1 cm/s was the same as if testing the entire mask at inflow rates of 15 and 85 LPM. These inflow rates represent the range of minute volumes experienced by a sedentary to a highly active person.[4] Furthermore, 85 LPM is equivalent to the testing flow rate when performing the National Institute for Occupational Safety and Health (NIOSH) certification test for N95s. The velocity calculation was conducted by comparing the area of the inner hole of the testing column with the measured area between the rubber bands encircling the nose and mouth of 154 cm^2. Flexible tubing was used to connect a calibrated pressure transmitter (Series 646, Dwyer Instruments, Michigan City, MI) that measures in the range of 0–65 mm H_2O air pressure to pressure taps installed above and below the mask media. NIOSH stipulates that an N95 should not exceed 35 mm H_2O when tested at 85 L/min, and this pressure level was used as the standard for the Halyard 47567 mask used in this study. The voltage output signal of the transmitter was received by an analog-to-digital converter and read using the Labview software system (National Instruments, Austin, TX) every 0.25 s. The average of 100 such measurements established the pressure drop across the mask section.

4 | RESULTS

Subjects (n = 11) were 54.5% female, with a median height of 70 inches (interquartile range [IQR] = 68–74), weight of 170 pounds (IQR = 145–215), and body mass index (BMI) of 24.6 (IQR = 22.2–27.2), and

FIGURE 1 (A–C) Demonstration of the way the 3 rubber bands are knotted together. (D–G) How to anchor and fit over a mask using a paper clip. (H and I) How to fit and anchor the rubber bands using a face shield with side knobs. The red arrows in image (G) demonstrate proper positioning on the bridge of the nose and below the chin. The red circles in image (H) indicate proper position of the brace knots inside the edges of the mask

encompassing 5 distinct N95 mask fit types (1804S, 1860 Regular, 1870, 1870+ and Vflex 1805). Results demonstrated that 45%, 100%, and 100% of subjects passed the quantitative fit test when the brace was anchored behind the ears, with a paperclip and on a face shield, respectively, with mean/median overall fit factors of 114/108.5, 167.9/176, and 167.8/176 (Figure 3).

Pressure drop ranged between 1.3–7.7 mm H_20 across the range of tested flow rates. These values demonstrate that breathing through the average 154 cm^2 area circumscribed by the double eights mask brace produces very reasonable breathing resistance even at high exertion breathing (85 LPM minute volume).

5 | LIMITATIONS

There are several limitations of this study. First, it is an exploratory study of a small number of subjects in a convenience sample and was performed in an unblinded and open-label fashion. As an exploratory

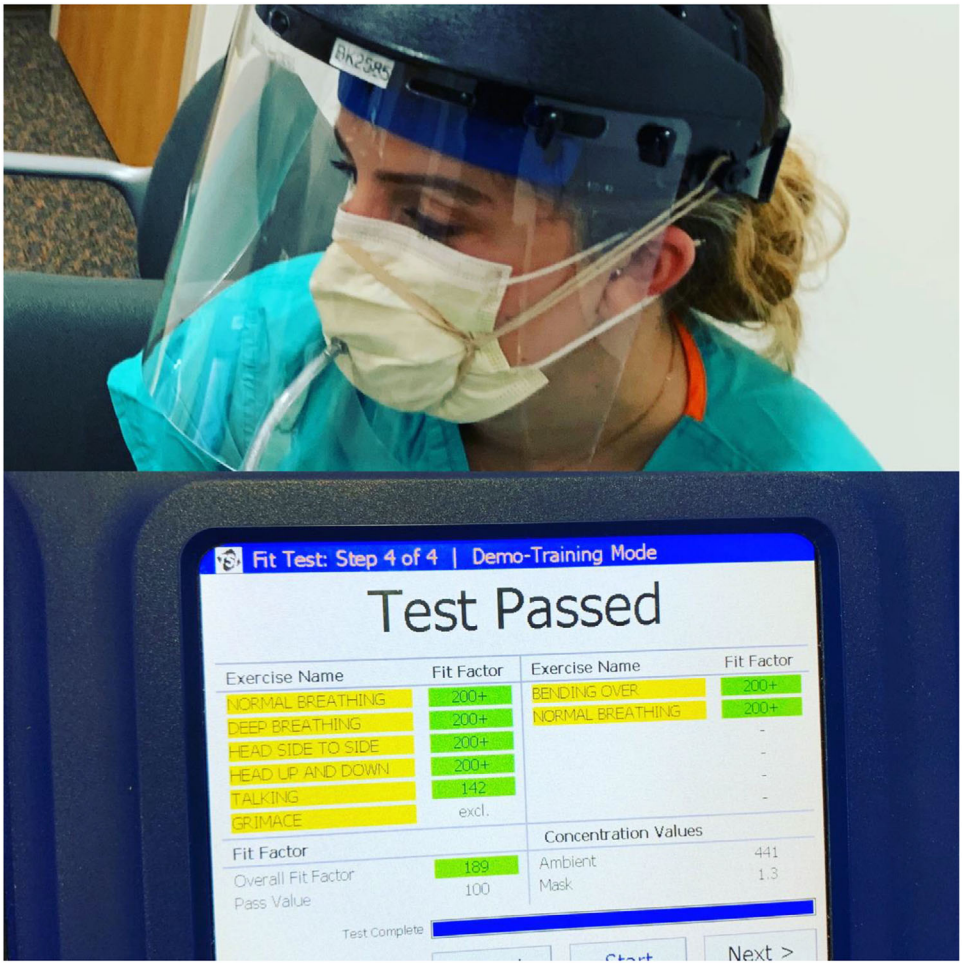

FIGURE 2 Halyard 47567 yellow mask fitted with a grommet and connect to the TSI PortaCount Pro along with final results of quantitative fit testing

study, no sample size calculation was performed and we chose not to conduct hypothesis testing with our convenience sample, so our conclusions are based on summary statistics alone. Findings of this single-site study may not be applicable to all types of basic surgical masks or to every type of facial morphology, which could conceivably prevent adequate mask seal in particular individuals. It is also possible that heterogeneity in the specific available rubber bands or in the configuration of a particular face shield could lead to variable brace performance. Importantly, the comfort and wearability of the double eights mask brace were not formally assessed in this study and warrant further investigation, because this could impact its use during clinical care. However, the results of the pressure drop testing do indicate that the mask remains quite breathable when the brace is applied. It is also essential to note that filtration performance of ASTM Level 1 mask material is not equivalent to that of an N95 mask, which maintains a >95% particle capture efficiency across a wide spectrum of particle size (0.01–10 μm), a standard that a basic surgical facemask does not meet. Finally, only one surgical mask type was tested quantitatively, and the performance of the double eights mask brace in a clinical setting was not evaluated, which precludes drawing any definitive conclusions about its ability to prevent viral transmission.

6 | DISCUSSION

Of the 11 subjects included in the analysis, across a range of body habitus and N95 mask fit types, all passed the quantitative fit test when the double eights mask brace was anchored on the face shield or behind the head with a paperclip, suggesting that the implement offers a substantially augmented degree of facial seal, to the point that it was able to meet the rigorous standards applied to fit tested N95 masks. Even the less robust performance of the mask brace when anchored behind the ears offered an improved seal compared to wearing the mask alone, though it appears that in this configuration, the double eights mask brace does not always apply adequate pressure around the mask to create an effective seal.

ASTM Level 1 masks (standard surgical masks) are certified to have a minimum bacterial filtration and sub-micron particulate filtration

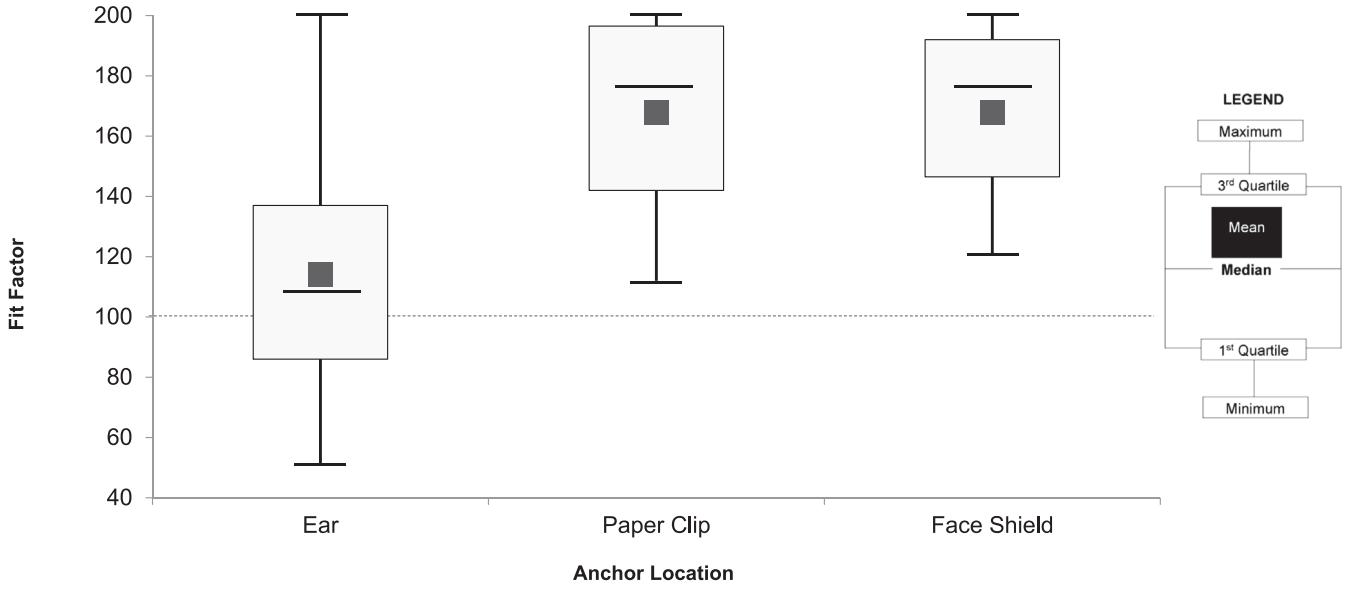

FIGURE 3 Distribution of fit factor by mask fit anchor type among healthcare providers fit. *Dashed line represents the N95 Fit Score requirement for passing as a protective fit

efficiency at 0.1 μm of ≥95%[5] Importantly, even poorly performing filters have been shown to have near 100% efficiency for particles approaching 5 μm in diameter[6], which covers the range of 5–10 μm respiratory droplets widely considered to be the primary route of SARS-CoV-2 transmission.[7,8]

Although this mask brace does appear to offer an increased margin of protection over a standard surgical mask, we do not intend it to be viewed as a true substitute for an approved filtering facepiece respirator like the N95 (or a powered air purifying respirator/controlled air-purifying respirator for individuals who cannot be fitted for an N95 respirator). Although the double eights mask brace allowed a standard surgical mask to pass an N95 fit test, which is largely a function of the mask face seal, we did not formally evaluate the filtering efficiency of the mask material compared to an N95 and do not claim that it meets the same efficiency standard. With that in mind, we do not want to suggest that a modified standard mask is equivalent to a fitted respirator and would not recommend use of the double eights mask brace during aerosolizing procedures, like intubation, which pose a high risk for viral transmission, unless respirator masks were completely unavailable. Rather, we believe it has use when used during encounters with known or suspected Covid-19 positive patients, where the use of standard surgical masks and face shields/eye protection are currently recommended. Given that CDC guidance deems standard surgical masks as "an acceptable alternative" while still noting that "N95 or higher respirators are preferred" and the remaining clinical equipoise as to whether N95s are superior to standard face masks when providing care during the SARS-CoV-2 pandemic, adopting the double eights mask brace has the potential to decrease N95 use during routine patient encounters.[9,10]

Future study of the double eights mask brace will need to include analysis of brace comfort and wearability, in addition to testing on a larger cohort of individuals with a more formal assessment of facial morphology.

Given the high burden of health care worker infection and the critical shortage in PPE, the dramatic improvement in mask face seal created by this affordable and practical mask brace offers an additional margin of protection that has the potential to prevent transmission and save lives.

AUTHOR CONTRIBUTIONS

DPR and PVH designed the study. KKH, NMM, BF, and PO provided expertise in the interpretation of the data. DPR, NMM, and KKH were responsible for managing the data and provided oversight of statistical analyses. DPR and KKH had full access to the data set and analyzed the data. DPR and KKH drafted the article, and all authors contributed substantially to its revision. DPR takes responsibility for the paper as a whole.

ACKNOWLEDGMENTS

Sabrina Paseman, Megan Duong, Michelle Duong Davenport, and their collaborators at FixTheMask.com for creating the original concept for this mask brace. Barb Schuessler and Rachel Lewis of the University of Iowa Hospitals and Clinics for providing access to and training on the quantitative fit testing equipment used in this study.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to disclose.

REFERENCES

1. https://www.who.int/news-room/detail/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workersworldwide
2. https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letterhealthcare-providers
3. https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html
4. Janssen LL, Anderson NJ, Cassidy PE, Weber RA, Nelson TJ. Interpretation of inhalation airflow measurements for respirator design and testing. *J Int Soc Respir Prot*. 2005;22(3/4):122.
5. https://www.astm.org/READINGLIBRARY/VIEW/F2100.html
6. Chen CC, Lehtimäki M, Willeke K. Loading and filtration characteristics of filtering facepieces. *Am Ind Hyg Assoc J*. 1993;54(2):51-60.
7. https://www.who.int/publications-detail/modes-of-transmission-of-virus-causing-covid-19-implications-for-ipc-precaution-recommendations
8. Konda A, Prakash A, Moss G, Schmoldt M, Grant G, Guha S. Aerosol filtration efficiency of common fabrics used in respiratory cloth masks. *ACS Nano*. 2020. https://doi.org/10.1021/acsnano.0c03252
9. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
10. Chu D, Duda S, Solo K, Yaacoub S, Schünemann H. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. Published Online June 1, 2020. https://doi.org/10.1016/S0140-6736(20)31142-9

AUTHOR BIOGRAPHY

Daniel P. Runde, MD, MME, is Clinical Associate Professor of Emergency Medicine in the Carver College of Medicine, University of Iowa.

How to cite this article: Runde DP, Harland KK, Van Heukelom P, Faine B, O'Shaughnessy P, Mohr NM. The "double eights mask brace" improves the fit and protection of a basic surgical mask amidst COVID-19 pandemic. *JACEP Open*. 2021;2:e12335. https://doi.org/10.1002/emp2.12335