Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Brief Report

Safety code blue! Assessing the use of blue surgical sterilization wrap for homemade respirator masks during the COVID-19 crisis

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The use of surgical sterilization wrap for respirator masks during the COVID-19 crisis has become a popularized personal protective equipment alternative option due to claims supporting its ability to meet N95 standards. This study sought to assess these claims using standardized filter testing. The tested material failed to meet N95 standards and suggests its use may place medical personnel at increased risk of harm when managing COVID-19 patients.

INTRODUCTION

Critical shortages of medical-grade personal protective equipment (PPE) during the ongoing COVID-19 crisis have left the health care system in a vulnerable state. In response, numerous innovative, self-made PPE practices have surfaced. While many well-intentioned individuals, organizations, and health care systems are turning to these approaches, objective safety data to support their use is lacking. Surgical sterilization wrap has become an increasingly popular material for respirator mask use based on claims that these masks pass N95 fit testing, a qualitative test to detect leakage of irritants around the mask-skin interface, and are easily made from readily available materials (Fig 1).[1] While appealing, quantitative data regarding the sterilization wrap's ability to filter viral particulate matter is not present within the current literature. Although N95 fit testing is a required step for the safe and effective use of respirator masks, it is not sufficient and each mask must pass a set of strict guidelines implemented by the National Institute for Occupational Safety and Health (NIOSH) in order to receive the N95 rating. We sought to subject the popularly used surgical sterilization wrap material used for respirator mask creation to these strict quantitative NIOSH N95 standards via standardized industrial testing.

METHODS

O&M Halyard H600 surgical sterilization wrap was utilized for this study. The sterilization wrap was subjected to TSI 8130 automated filter testing in accordance with NIOSH standards for the N95 respirator mask. Standardized testing to include penetrance assessment with a sodium chloride aerosol comprised of a 0.075 μm count median diameter and a 0.3 μm aerodynamic mass median diameter at flow rates of 85 L/min was performed. The sterilization wrap was tested in single and double layers and compared to N95 standard. Primary outcomes included aerosol penetrance as well as the pressure drop across the filter material.

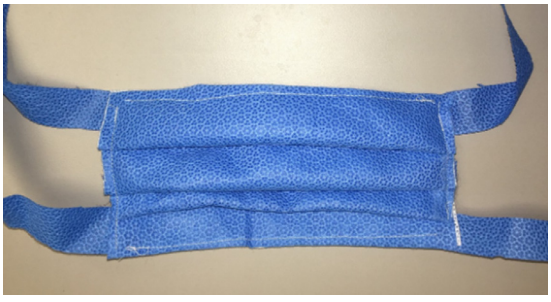

Fig 1. Example of respirator mask devised from surgical sterilization wrap.

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NIOSH Certification Test Standards (42 CFR Part 84)
• A sodium chloride (for N-series filters) or a dioctyl phthalate oil (for R- and P-series filters) test aerosol with a mass median aerodynamic diameter particle of about 0.3 μm, which is in the MPPS-range for most filters • Airflow rate of 85 L/min, which represents a moderately-high work rate • Conditioning at 85% relative humidity and 38°C for 24 hours prior to testing • An initial breathing resistance (resistance to airflow) not exceeding 35 mm water column* height pressure and initial exhalation resistance not exceeding 25 mm water column height pressure • A charge-neutralized aerosol • Aerosol loading conducted to a minimum of 200 mg, which represents a very high workplace exposure • The filter efficiency cannot fall below the certification class level at any time during the NIOSH certification tests

Fig 2. Current NIOSH certification standards.[2]

RESULTS

Halyard H600 failed to meet NIOSH N95 standards. The Halyard H600 demonstrated pressure differences of 37.4 and 67.8 mm H2O across single and double layered material, respectively, representing values higher than the NIOSH maximal resistance criteria of 35 mm H2O (Fig 2).[2] NIOSH mandates a 95% filtration efficacy (Efficacy = 1 − penetrance) of a 0.3 μm aerodynamic mass median diameter particle for N95 certification. The Halyard H600 demonstrated high penetrance at both single and double layered testing resulting in efficacy rates of 64.5% and 78.3%, respectively.

DISCUSSION

Objective data on Halyard H600's ability to safely filter viral particulate is lacking, as is data regarding the breathing resistance of the material. Numerous claims report the Halyard H600 has a 99% filtration rate suggesting it is more effective than the standard N95 mask.[3,4] This statement, however, remains misleading with the potential for unsafe interpretation as this filtration rating stems from the material's bacterial filtration efficacy (BFE). The BFE test utilizes aerosolized *Staphylococcus aureus*, which has a documented mean particulate size of 3 ± 0.3 μm, in order to assess a material's resistance to bacterial penetration.[5] Current N95 standards require that respirators prohibit at least 95% of very small (0.3 μm via aerodynamic mass median diameter) particulate through their barrier for which the Halyard H600 did not achieve.[2] As such, these findings suggest that BFE data cannot be extrapolated to N95 standards, nor should it be applied to viral particulate. Equally as important, the Halyard H600 did not meet current standards for resistance across the filtration membranes suggesting decreased breathability and the potential for unsafe levels of exhaled carbon dioxide retention. This increased resistance may further cause over pressurization at the mask-skin interface resulting in air leaks at the seal posing potential health risks due to an improper fit. Finally, it is important to note that O&M Halyard, the wrap's manufacturer, does not endorse the off-label use of its instrument wrap for homemade respirator masks.[6]

To our knowledge these results are the first to assess the safety and efficacy of the Halyard H600 instrument wrap as a respiratory mask alternative for the COVID-19 pandemic. In doing so, we demonstrated that the current claims suggesting superior filtration results when compared to medical-grade N95 masks were derived from an incorrect interpretation of industry-grade testing. Although these novel alternatives may demonstrate some potential as a last hope option in scenarios lacking medical-grade respirators, this data suggests they should be utilized during times of complete necessity and with an abundance of caution. As such, novel alternatives should continue to be sought; however, it remains critically important they are subjected to objective industry standards in order to provide the most accurate safety data available.

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References

1. Mask Alternative. *University of Florida Department of Anesthesia*. 2020. Available at: https://anest.ufl.edu/clinical-divisions/mask-alternative/. Accessed May 4, 2020.
2. *N-95 respirators and surgical masks: NIOSH and CDC recommendation. Industrial Safety & Hygiene News*. 2009. Available at: https://www.ishn.com/articles/88631-n95-respirators-and-surgical-masks-niosh-and-cdc-recommendations-. Accessed May 4, 2020.
3. Sookne K. Second life: sterile wrap fashioned into masks. *Healthc Packag*. 2020. Available at: https://www.healthcarepackaging.com/home/article/21124863/second-life-sterile-wrap-fashioned-into-masks. Accessed May 5, 2020.
4. McReynolds T. N95 mask production ramping up, but you have options if you're crafty and in a hurry. *Am Anim Hosp Assoc*. 2020. Available at: https://www.aaha.org/publications/newstat/articles/2020-03/n95-mask-production-ramping-up-but-you-have-options-if-youre-crafty-and-in-a-hurry/. Accessed May 4, 2020.
5. ASTM. F2101-01: standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of Staphylococcus aereus. *Ann ASTM Stand*. 2001;F2101-01:1553–1557.
6. Covid 19 PPE Frequently Asked Questions. Halyard: part of the owens & minor family. Available at: https://www.halyardhealth.com/solutions/infection-prevention/covid-19-ppe-frequently-asked-questions.aspx. Accessed May 4, 2020.