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PERSPECTIVE

Considerations and Cautions for Three-Dimensional-Printed Personal Protective Equipment in the COVID-19 Crisis

William Clifton,[1,2] Aaron Damon,[1,2] and Archer K. Martin[3]

Abstract

The recent decline in available personal protective equipment (PPE) due to the novel coronavirus (COVID-19) pandemic has given rise to a host of three-dimensional (3D) printed prototypes for facemask and respirator units. Many of these models have been made open access and publicly available for printing and use, and have been promoted by various media outlets. Although these desktop 3D printing measures have provided a possible venue for success in providing homemade and cost-effective PPE to health care workers, the rapid dissemination of these prototypes has been performed without reproducible methods of standardization and vetted safety in use. Although these methods have not been sanctioned by authoritative organizations as viable production approaches to address the PPE shortage, a concerted effort within the 3D printing community to adhere to scientific methodology and organized research efforts has the potential to provide a solution to this critical issue.

Keywords: COVID-19, additive manufacturing, personal protective equipment, pandemic, 3D printing

Introduction

The COVID-19 pandemic has caused an enormous demand for personal protective equipment (PPE) both in the United States and abroad.[1] Owing to an increased requirement from standard suppliers and the limited ability to produce PPE through organized means, there has been a recent increase in dissemination of three-dimensional (3D) printing methods for PPE models including face masks, shields, and respirators. The majority of investigators using 3D printing to create face-wear prototypes are public members who employ desktop fused deposition modeling (FDM) and stereolithography techniques. The rapid availability and production of these prototypes have created opportunities to fill a large need in areas with limited PPE. As such, these investigations have been increasingly promoted within various media outlets, and have generated a growing cultural movement within the 3D printing community to experiment with new PPE designs and to openly distribute them through electronic public forums. Many of these designs appear similar to standard N95 and N99 masks in shape, form, and use in apparel. However, the current validation methods employed to ensure safe use of these prototypes in place of National Institute for Occupational Safety and Health (NIOSH)-approved PPE are heterogeneous, unregulated, and generally undisclosed. A common disclaimer by media propagators to this lack of objective data for proposed 3D printed prototypes is *better than nothing*. But is it? Although resembling commercially available vetted masks and respirators in design, these prototypes do not appear to have undergone standardized and reproducible methods of testing and approval.

Federal Statements on Rapid Prototyping of PPE

The Food and Drug Administration (FDA) recently released official statements on the use of 3D-printed PPE with

[1]Department of Neurologic Surgery, Mayo Clinic, Jacksonville, Florida, USA.
[2]Department of Neurologic Surgery, Biotechnology Research and Innovation Neuroscience (B.R.A.I.N.) Additive Manufacturing Laboratory, Jacksonville, Florida, USA.
[3]Division of Cardiovascular and Thoracic Anesthesiology, Mayo Clinic Florida, Jacksonville, Florida, USA.

respect to COVID-19 transmission prevention, especially with respect to face masks and respirator prototypes: ''3D-printed PPE are unlikely to provide the same fluid barrier and air filtration protection as FDA-cleared surgical masks and N95 respirators.'' The statement also disclosed emergency use authorization guidelines for the use of 3D-printed connectors and accessory equipment for ventilators, but did not provide detailed guidelines on the role of 3D-printed PPE for protection of virus transmission.[2] The Centers for Disease Control and Prevention (CDC) released a statement categorizing the use of home-made face wear as non-PPE, and recommended exercising caution when using these methods even as a last resort.[3] The National Institutes of Health (NIH) in combination with the FDA has created an online repository for publicly created 3D-printed PPE prototypes for expedited investigation; however, it acknowledged the limitations of safety claims due to the heterogeneity of rapid prototyping methods across different printer types and users, even with standard testing.[4]

Reproducibility and Considerations in 3D Printing PPE Prototypes

Leaders at MIT recently discussed the limitations and dangers of using 3D printing for PPE fabrication.[5] Although mechanical blockade of particles can be replicated to a degree, the reproduction of electrostatic properties of approved filter media using 3D-printed materials presents a considerable challenge. Print specifications for prototype development are vitally important to ensure reproducibility across multiple printer types. The standard tessellation (STL) files that are available for download only provide the virtual shape of the model, but functional prototypes may differ between production methods. With respect to additive manufacturing, small differences in g-code variables between two printers producing the same STL file will produce two similar appearing, but functionally different models.[6] Thermoplastic filaments used for FDM printing also vary tremendously in material composition, porosity, and environmental stability.[7] Many FDM filaments retain ambient moisture, which could pose a paradoxically increased risk for virus transmission during use or reuse.[8] In addition, the combination with filter media such as high efficiency particulate air (HEPA) filtration systems has not currently been endorsed as a means of increasing the safety profile of 3D-printed PPE prototypes.

Desktop to Distribution

There has been a recent surge of media spotlights denoting the benefits of 3D-printed PPE prototypes, both from commercial organizations and unaffiliated individuals. A physician group in Billings, Montana, released a series of STL files comprising a 3D-printed mask prototype for public dissemination, and in similar turn a 3D printing organization released a video describing and promoting the design of a 3D-printed face mask to potentially serve as an alternative to approved PPE for prevention of COVID-19 transmission. The STL files were made available for download to the public; however, substantiation of standard conformity claims to infectious preventions was not outlined. Additional reports include engineers, students, and other civilians who are creating and distributing 3D-printed masks for public use with claims of equivalency to approved PPE. Although these efforts are of noble intention and deserve recognition, various 3D-printed PPE prototypes are reported to be currently and actively used by health care workers, even though quantifiable validation in methods or production of these devices is currently lacking. These are but several examples of innumerable open-access STL files of mask prototypes that have precipitously surfaced online and are available for download.

Solidarity in Scientific Validation

The principles of modern medicine are built upon rigorous validation of hypothesis-driven research. The current approach for investigation within the scope of 3D-printed PPE appears to be reversed, as the open distribution and propagation of PPE prototypes are occurring *before* validation and hypothesis formulation. Fundamentally important factors of prototype testing such as number needed to treat and harm for patients and providers have been left out of the equation thus far. The greatest danger with continuing to broadcast unvetted PPE production mechanisms is the possibility of hindering transmission curve flattening. There is no doubt that a prompt solution must be implemented and the prevalent usage of 3D printing has the potential to help solve the PPE crisis across the globe using robust methodology and concentrated vetting. It is reasonable to propose that this can be accomplished by a concerted effort between 3D printing innovators and regulative authorities. Together, thorough investigation of proposed models can be achieved in a standardized manner before dissemination and claims of benefit. In this way, true innovation can prevail over brief notoriety and avoid unintentional harm from good intentions led by poor science.

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Address correspondence to:
William Clifton
Department of Neurosurgery
Mayo Clinic
4500 San Pablo Road
Jacksonville, FL 32224
USA

E-mail: clifton.william@mayo.edu