Novel design and development process for 3D printed personal protective equipment against COVID-19

M. Schmidt[1*], M. Schmidt[1], J. Roitenberg[2], R. Sims[3], J. Inziello[3], F. Lobo Fenoglietto[3], and J. Stubbs[3]

[1] Strategic Innovations, Orlando Health, Orlando, USA
[2] Education, Stratasys Ltd., Minneapolis, USA
[3] Institute for Simulation and Training, University of Central Florida, Orlando, USA
[*] Corresponding author, email: jstubbs@ist.ucf.edu

Abstract: In response to the personal protective equipment shortages caused by the COVID-19 pandemic, our team established a collaboration with Orlando Health and Stratasys for the development, validation and mass production of 3D-printed, custom-fit N95 respirators and face shields. The partnership has delivered more than 5000 face shields to local Central Florida hospitals, including Orlando Health and Lakeland Regional.

I. Introduction

On March 11, 2020, The World Health Organization declared COVID-19 a pandemic. [1, 2] In response to the COVID-19 pandemic, Orlando Health, Stratasys Ltd. and University of Central Florida established a collaboration to design and validate PPE alternatives that could be mass produced using an autonomous, additive manufacturing platform. Due to the potential shortage of available PPE, regulatory requirements were reduced for Emergency Use Authorization [3].

The combined effort produced a 3D-printed face shield design optimized for Stratasys' Continuous Build 3D Printer (CB3D) and a N95 respirator ergonomically designed to the facial features of each healthcare worker.

II. Materials and methods

II.I. N95 Respirator Design

Multiple face scans were obtained using the Artec EVA optical scanner and an iPhone 11 with the iOS app Bellus3D. Both scanning methods produced .OBJ surface mesh models of the users' face.

Scans were imported into Z-Brush to generate form-fitting contours representing the outermost edge of each respirator. Three size contours resulted from this process: small (S), medium (M), and large (L). Contours consisted of quadrilateral-based surface meshes exported as .OBJ files.

A procedural network was created in Houdini to: (1) generate a respirator inlet, (2) bridge facial contours to inlets, and (3) ensure the design can be printed in the Stratasys Continuous Build 3D(CB3D) print system.

The distal end of the mask containing the filter material attachment was designed using a custom procedure built in Houdini that allows rapid redesign based on user specified parameters, i.e. diameter and grate spacing. Maximum air flow was achieved by allowing the distal end to be a 100mm annular opening wrapped completely with the filter material. This allows fast and easy filter material change. The fitting edge and the filter attachment were combined by using a bridge to interpolate the shape of the fitted edge to the shape of the filter. The bridged surface was then able to be created at any thickness allowing automated procedural customization of the mask designs.

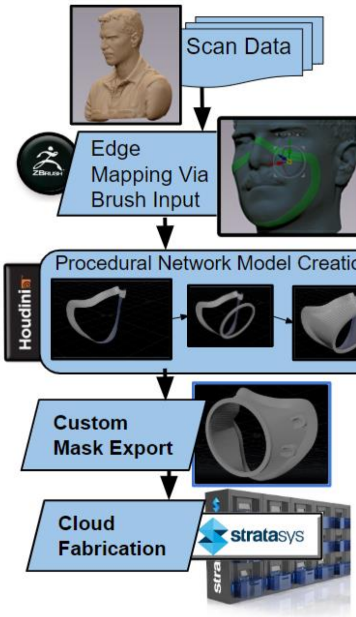


Figure 1: Procedural approach to design and 3D-print PPE

DOI: 10.18416/AMMM.2020.2009002

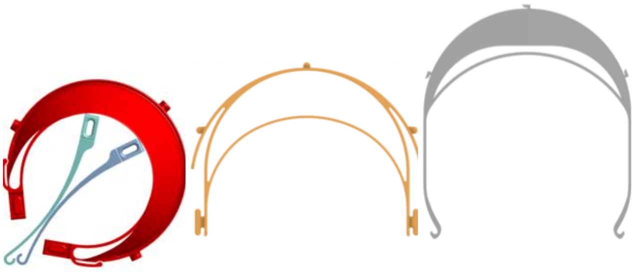
Filter modules consist of multiple layers of Halyard H600 surgical wrap and 3M Filtrete MPR 2800 laser cut to specific dimensions. Filters were secured onto the 3D printed mask's inlet using two zip 300mm ties. Elastic bands anchored to the top and bottom provide strap loops.

II.II. Face Shield

Most open-source face shield designs require printers with build volumes >150mm3. Designs that did not feature a visor originally now offer add-ons that print separately.

To optimize build size, provide for more printer varieties and decrease build time, our team created a face shield design that fits printers with a build volume < 150mm3. The model can be described as a curled version of a regular face shield, headband, or visor. The design also features bows and a support clip, all of which fit in the same build. The design provides a prestressed configuration with spring tension to help with fitting to multiple sizes.

Table 1. 3D-printed face shield designs



PD3D	*Prusa Research*	*Stratasys*
127 x 127 x 38 mm	*203 x 152 x 19 mm*	*178 x 203 x 25 mm*

II.III. Fabrication

N95 respirator replacements and face shields were fabricated in ABS using Stratasys' Continuous Build 3D Printer (CB3D). The CB3D system is a cloud-enabled, fully autonomous system capable of queueing, calibrating, printing and clearing the build plate. This autonomy eliminates the need for an operator and, therefore, the associated labor cost.

3D-printed respirators and face shields were printed in ABS material at 0.2mm layer resolution and sparse infill. Both were designed requiring no support material to reduce time and cost.

III. Results and discussion

In response to the COVID-19 pandemic, our team successfully developed a 3D-printed respirator and a 3D-printed mask that: (1) can be 3D printed quickly and efficiently on continuous build, automated 3D printers at a competitive cost, (2) will custom fit to the end user for fit, function and comfort, and (3) provides required PPE protection.

Proper fit-testing was performed to validate the effectiveness of the N95 mask alternative as per Orlando Health procedures. 3D-printed respirators met the requirements for Level 3 Surgical masks, protecting the user from droplet, splashes, and airborne particles. The face shield met fluid resistance requirements based on reviews from Orlando Health's Infection Prevention and Corporate Safety teams.

In a matter of two and a half weeks, there were 16 iterations of the headband with the efforts of PD3D, Orlando Health and Stratasys to ensure that the headband was comfortable, protective and printable. In a three-week span, Stratasys produced 18,500 headbands and distributed them to nine states and four different countries. These efforts showcased the power of communication via email and cloud and the importance of rapid manufacturing, while the traditional manufacturing methods caught up to the demand of PPE in healthcare facilities.

Additional information about our 3D-printed PPE designs, including 3D files (.STL), post-processing, filter fabrication and assembly instructions can be found on the NIH 3D Print Exchange website [4], under Model ID: 3DPX-013948. And Model ID: 3DPX-014257.

IV. Conclusions

Using 3D scans of Users faces, and parameterized automated meshing procedures, PD3D, Orlando Health and Stratasys, were able to create multiple iterations of custom respirator mask designs in a two-week period and were able to adapt to new specifications determined by front line users. This approach will be used in the future to develop custom fit personal protection devices.

Modifying the Face shield design with pre-stressed curvature allowed printing on the CB3D system to provide efficiency in time and cost of manufacturing

ACKNOWLEDGMENTS

The authors would like to acknowledge the entire healthcare community and healthcare workers in the front lines of the COVID-19 pandemic.

AUTHOR'S STATEMENT

Authors state no conflict of interest.

REFERENCES

[1] Tino, R., Moore, R., Antoline, S. et al. *COVID-19 and the role of 3D printing in medicine*. 3D Print Med 6, 11 (2020). https://doi.org/10.1186/s41205-020-00064-7
[2] Ranney ML, Griffeth V, Jha AK. *Critical Supply Shortages - The Need for Ventilators and Personal Protective Equipment during the Covid-19 Pandemic*. N Engl J Med 2020. March 25. https://doi.org/10.1056/NEJMp2006141
[3] U.S. Food & Drug Administration. Emergency Use Authorization. COVID-19: Personal Protective Equipment https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe
[4] National Institutes of Health (NIH). NIH 3D Print Exchange - COVID-19 Supply Chain Response. https://3dprint.nih.gov/collections/covid-19-response