

Kaizen Inspired 3D Printed Novel PPE Production During COVID-19 Pandemic Shortages Led by Radiology

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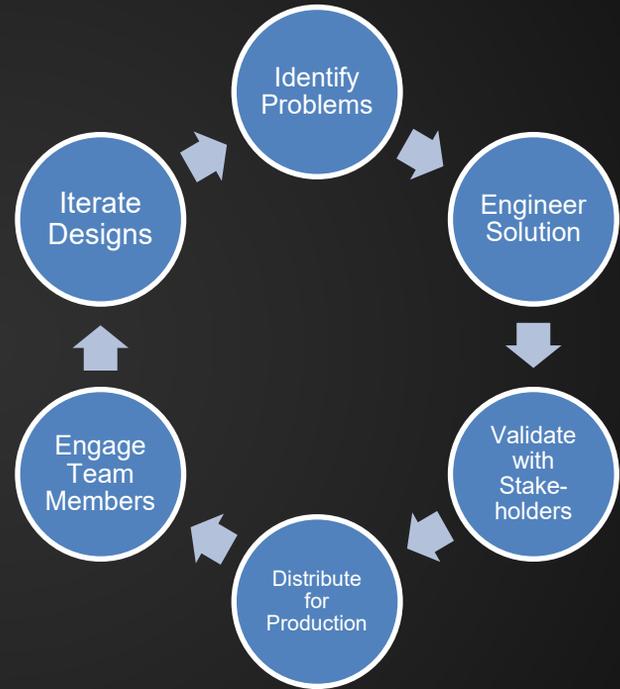
COVID-19 Global Impact & PPE Shortages

- By mid-April, SARS-CoV-2 had spread to 206 countries, with close to 2,000,000 reported cases worldwide^[1].
- Personal Protective Equipment (PPE) shortages were brought about by an unexpected demand and the disruption of global supply chains
 - China, which previously exported 50% of the world's face masks, focused instead on domestic distribution^[2].
 - Increased utilization and “panic buying” led many hospitals to ask employees to ration and reuse PPE^[3,4].
- The shortage forced healthcare systems to establish alternative means to ensure the safety of frontline workers and patients.
- Many in the 3D printing community began printing PPE designs with good intentions but resulted in making PPE which was suboptimal for frontline healthcare workers.
- To prepare for potential surge, we initiated a kaizen process to create novel PPE using 3D printing technology.



Kaizen Workflow

- Kaizen is a Japanese business philosophy of continuous improvement of working practices, personal efficiency, etc.^[5]
- The COVID-19 pandemic required a new workflow due to the novel conditions created by the virus and the disruption of the global supply chain.
- Kaizen workflow was deployed by Keck Medical Center of USC to rapidly address the lack of PPE.
- The workflow allowed the creation, evaluation, and iteration of items to address the emergency.
- The COVID-19 pandemic and shortages of PPE are an on-going issue in our region.



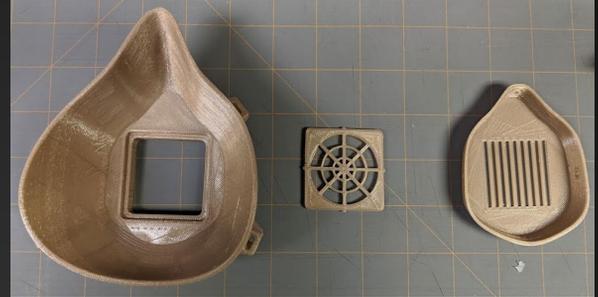
Addressing the Mask Shortage

- Staffed by faculty in both the Schools of Medicine and Engineering, the 4D Quantitative Imaging Lab was uniquely positioned to coordinate design, validation, and production of the 3D printed novel PPEs.
- In collaboration with Infection Prevention and Respiratory Services personnel, rapid idea generation and vetting allowed for a design which suited deployment in a clinical environment.
- Social media and personal connections were used to identify and form a network of makers, makerspaces, and artists. Our collaborators had access to 3D printers and the expertise to not only fabricate the models, but also evolve the designs.
 - Notable community partners included:
 - *Makerspace*: CRASH Space
 - *Entertainment Industry*: Sunweaver Creative
 - *Academia*: USC Viterbi School of Engineering, USC School of Architecture, and USC Iovine and Young Academy
- In the span of a week, the first version of the Reusable Filtered Mask (RFM) went from found 3D model to a provisionally approved design distributed for community printing.



Reusable Filtered Masks (RFM)

- We began by manufacturing 3D printed RFMs using an open-source design by La Factoria 3D.
- Prototype masks were printed in 3 parts using a Lulzbot TAZ5 fused filament fabrication printer for evaluation.
- Masks were assembled and fitted with air filtration materials purchased from local hardware stores.
- As many of these filtration systems meet N95 performance specifications, we hypothesized that a similar airtight seal could be achieved for clinical utility.



Initial prototype design of the 3-part Reusable Filtered Mask (RFM)



D-profile weather stripping was adhered to the mask lip using a hot glue gun. This prototype technique was further adapted in later iterations to allow for altered fits for different face shapes.



Reusable Filtered Masks (RFM)

- Professionals and hobbyists teamed together to evolve designs for standardization of components, generation of multiple sizes, evolution of seals, and optimization for printing with the 4D Lab monitoring quality control and clinical needs.
- Infection prevention experts approved the design changes to ensure adequate protection for healthcare workers.
- RFMs are currently being used as substitutes for isolation masks.
- RFM are being held as backups for N95 disposable masks and being adapted as fitment aids for ill-fitting N95 masks.



Masks underwent CAD design modifications to produce small, medium, and large versions. Different sizes maintained the same nose cap and hatch pieces, thus allowing for interchangeability of parts



Masks were fitted with a platinum silicone gasket, which rests directly against the face, adhered with silicon adhesives. The gasket design both improves comfort for the mask wearer and allows for an airtight seal.

The mask and gasket system can also be used as a fit-assist device to be worn on top of N95 and KN95 masks to provide improved seal.



Production & Expansion

- Local production of PPE expanded with coordinated daily drop-offs of donated printed materials.
- Parallel efforts from the Schools of Architecture and Engineering allowed for streamlined focus to bolster increased production capacities and knowledge sharing.
- Our diverse team helped to expand production into traditional industrial manufacturing, such as die cutting and injection molding.
- The freedom from department silos led to subsequent PPE projects including face shields, mask strain relievers, mask frames, and PAPR augmentations.
- Projects are classified in two categories: immediate deployment and emergency deployment.
 - Face shields and mask strain relievers have been distributed directly to workers and are reusable.
 - Filtered masks and PAPRs have been developed for non-hospital and are reserved for emergency hospital use as defined by CDC guidelines.



Results

- The unique position of the 4D Lab as an intersection between the hospital, academia, and industry allowed for the creation and curation of models which fulfilled the requirements of clinical use.
- The ability to quickly prototype designs for testing and validation combined with direct access for collaboration with hospital-based stakeholders yielded guidance for the production community.
- Currently, over 4000+ reusable face shields are being deployed in the clinical setting to protect both healthcare workers and patients. 9000+ reusable filtered masks have been received with 3200 completed with facial gaskets.



RFM assembly team



Two of the authors shortly following the first qualitative fit testing of the prototype reusable filtered mask



Conclusion

- When standard PPE resupply was unpredictable due to the COVID-19 pandemic, the 4D Lab implemented a kaizen approach to PPE to exceed standards and to scale and adapt accordingly to demand.
- Solutions at the time of crisis focused on safety, availability, and ease of use.
- The 4D Lab provides a direct link between the technological developments in community driven PPE production and the design requirements, consulting, and validation of the hospital.
- 3D printing is an application which is a natural extension of 3D imaging and is uniquely suited for rapid development and prototyping.
- We are continuing to evolve ideas in novel PPE to solve problems and shortages.



PAPR prototypes



3D printed face shield for Keeler Indirect Ophthalmoscope



Selected References

1. Roser M, Neva MH, El-Sharkawi M, Valacco M, Sciubba DM, Chutkan NB, ARitchie H, Ortiz-Ospina E. Coronavirus Disease (COVID-19) – Statistics and Research. OurWorldInData.org. <https://ourworldindata.org/coronavirus>. Updated April 15, 2020. Accessed April 15, 2020.
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;382(18):e41. doi: 10.1056/NEJMp2006141
3. Amid coronavirus, will hospitals run out of face masks? (Or ventilators? Or beds?). Advisory Board website. <https://www.advisory.com/daily-briefing/2020/03/12/facemasks>. Published March 12, 2020. Accessed July 23, 2020.
4. Jacobs A, Richtel M, Baker M. ‘At War With No Ammo’: Doctors Say Shortage of Protective Gear Is Dire. *New York Times* website. <https://www.nytimes.com/2020/03/19/health/coronavirus-masks-shortage.html>. Published March 19, 2020. Accessed July 23, 2020.
5. Kaizen. Oxford Reference. <https://www.oxfordreference.com/view/10.1093/oi/authority.20110803100028627>. Accessed October 20, 2020.

