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Opinion

Applications of Additive Manufacturing Technologies in Healthcare Sectors During Covid-19 Pandemic

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Abstract

COVID-19 is a highly infectious respiratory illness caused by the SARS-CoV-2 virus, primarily spread through respiratory droplets when an infected person talks, coughs, or sneezes. To control the spread of this pandemic, various measures have been implemented worldwide, including social distancing, wearing masks, and frequent hand washing. At the same time, healthcare system has been overwhelmed with increase demand for healthcare services, shortages of medical resources, including hospital beds, and medical equipment, and healthcare workers burnout. Additionally, the pandemic has also caused disruptions to global supply chains, due to changes in transportation, demand/supply, inventory management challenges, and logistic difficulties. All these factors have resulted in shortages of essential goods and services, including medical supplies, Protective Equipment (PPE), and medical equipment. To overcome this, clinical sectors have adapted and implemented new strategies to continue to provide effective healthcare services despite these challenges. Additive manufacturing or 3D printing has facilitated production of these scarce resources, quicker and cheaper, filling the supply chain gap. This article reviews the major efforts of healthcare sectors that have utilized rapid prototyping technologies to address some of the medical supply's shortage issues. Efforts made in production of numerous medical devices, including nasal swabs, face masks and shields, respiratory valves and other related jigs and fixtures are discussed.

Keywords: COVID-19, Additive manufacturing, 3D Printing, Rapid prototyping, Supply chain, Medical supplies, PPE

Introduction

COVID-19 is an infectious disease caused by a newly discovered coronavirus, SARS-CoV-2, in December 2019. This virus quickly spread across the globe to start worldwide outbreak of a pandemic. COVID-19 is primarily transmitted through respiratory droplets when an infected person coughs, sneezes, or talks [1]. In addition to being transferred via droplets and aerosols, this virus also has the capability of transferring via direct or indirect physical contact with contaminated surfaces and objects [2]. Due to the severity of the contamination and to control the spread of this pandemic, various measures have been implemented worldwide, including social distancing, wearing masks, and frequent hand washing [3]. Point-of-care systems have been overwhelmed with increase demand for healthcare services, shortages of medical resources, including hospital beds, and medical equipment, and healthcare workers burnout. Additionally, the pandemic has also caused disruptions to global supply chains, due to changes in transportation, demand/supply, inventory management challenges, and logistic difficulties. All these factors have resulted in shortages of essential goods and services, including medical supplies, Personal Protective Equipment (PPE), and medical equipment [4].

To overcome this medical equipment scarcity, numerous institutions, multiple corporations and many individuals stepped up and started working together to provide necessary support. Institutions, including universities and research centers, redirected their resources and facilities towards developing new designs

and manufacturing critical medical equipment such as PPE and ventilators. Multiple corporations shifted their production lines to produce medical supplies. Automobile manufacturing corporations, such as ford and General Motors retooled their factories to produce ventilators. Numerous volunteer organizations were formed, and crowdfunding campaigns were raised to support the production and distribution of critical medical supplies. Additive manufacturing has played a critical role in addressing this shortage by enabling the rapid production of essential medical equipment and supplies. Due to its versatile nature and quick turnaround times, 3D printing techniques enabled generation of new designs and easy sharing of the CAD files among peers [5].

List of Medical Supplies Produced Using 3D Printing

PPE, including face shields, face masks with filter inserts and ear protectors, are some of the most common medical equipment that has been widely produced using various 3D printing technologies by individuals, institutes, and organizations during the pandemic. Simple design requirements, easy shareability of CAD files, access to inexpensive 3D printers and low risk categorization are some of the factors that have driven production of PPE using additive manufacturing technologies during the shortage. Additionally, 3D printers can be operated by individuals or small businesses, allowing for decentralized production and distribution. This allowed for the rapid production of PPE in areas where traditional manufacturing was not available or was disrupted due to pandemic. Moreover, 3D printing allowed for customization and adaption of PPE to meet the specific needs of healthcare workers [6].

In a proof-of-concept study, *Swennen, et al.* [7]. designed reusable, custom made face masks with filtrate membrane support [7]. They have also provided their CAD files to the open public to use. *Cortes, et al.* [8]. Utilized 3D scanning techniques to perform face scans, which were in turn used to customize the face masks according to the face contours. Fused deposition modeling type of 3D printing technique was used to make these custom designed face masks. Their evaluation showed that these customized face masks showed greater adaptation when compared with conventional masks [8]. In another pilot study conducted by *Makowski, et al*. [9] similar 3D scanning and 3D printing techniques were used to make personalized face masks, except for they used Selective Laser Sintering (SLS) type of 3D printing technology to produce the face masks [9]. As a response to PPE shortage, *Ballard, et al.* [10]. Developed alternative N95 3D printed masks using CT imaging and 3D printing technology. Their evaluations showed the 3D printed alternative N95 masks have contours matching topographical features of the face, as shown in computed tomography images, and have also passed Occupational Safety and Health Administration (OSHA)-certified quantitative respiratory testing [10].

CDC has recommended nasopharyngeal swabs, FDA class I devices, as the gold standard for collecting samples to test the individuals for COVID-19 infection [11]. As a result of this, the demand for nasal swabs increased drastically and disrupted supply chain globally. Engineers and researchers from companies including, Formlabs [12], EnvisionTEC [13], Carbon [14], and Origin [15] were able to develop numerous nasal swab designs that could be 3D printed to help address this shortage of nasal swab supplies. Although numerous companies have jumped in to aid with the designing and production of nasal swabs, it is crucial for these products to be thoroughly tested and evaluated before being used in clinical settings. *Tooker, et al*. [16]. Evaluated the performance of various designs and swabs 3D printed using different additive manufacturing technologies to emulate the clinical use as well as identify potential failure modes. Their research has shown that majority of the 3D printed swabs showed comparable, if not outperformed, in mechanical properties when compared with conventional swabs. Additionally, this study results also showed that conventional swabs showed greater uptake and retention of sample compared to few of the designs [16].

Connectors, Splitters and Valves

Severe acute respiratory syndrome (SARS) is the most common symptom shown by patients affected by coronavirus. This symptom can be devastating and life threatening. Corona patients exhibiting SARS are treated with some of the procedures including, Invasive Mechanical Ventilation procedures (IMV), Non-invasive Ventilation procedure (NIV) [17], and/or Continuous Positive Airways Pressure Procedure (CPAP) [18]. In any of these procedures, ventilators are essential to help patients breathe. Rapid spread of the virus, high hospitalization rates and increased demand for these ventilators has created a shortage of critical components, including connectors and valves, needed to operate these ventilators.

To address this shortage, engineers and researchers around the world began developing designs for 3D printed connectors, splitters and valves that could be rapidly produced using 3D printed technology. These designs were based on existing parts and were tested and validated to ensure that they were safe and effective. During this time of shortage, single ventilator was used for multiple patients in need using splitters. In a research study conducted by *Neyman, et al*. [19]. Single ventilator was used to four different simulated patients using ventilator splitters to evaluate the efficacy. Results have shown that ventilator splitters can be used to provide ventilation for four adults simultaneously to meet disaster surge [19]. Additive manufacturing companies including Formlabs, in conjugation with 3D Design and Northwell Health innovation labs, have developed novel ventilator splitter designs and made CAD models available for public for 3D printing [20]. Another notable example of 3D printed ventilator splitter was the ventilator circuit splitter team from San Antonio, Texas, USA, that has designed, developed and vetted novel splitters that can

be 3D printed and made the CAD files available for public with all the necessary printing parameters listed [21]. *Longhitano, et al*. [22]. Provided novel ways to convert full-face snorkeling masks in conjugation with 3D printed valves to be used for NIV procedures. The authors have redesigned popular charlotte valves and 3D printed them using SLS type of additive manufacturing technique. Evaluation studies on these prototypes have shown that the masks were airtight, and the valves successfully served the purpose of NIV procedures [22].

Regulatory Compliance

The 3D printing was used to produce a wide range of medical devices and equipment during the pandemic, it was important to ensure that these devices were safe and effective for use in a clinical setting. Regulatory agency, the US Food and Drug Administration (FDA), in conjugation with NIH, VA and America Makes, provided guidance on the use of 3D printing technology for medical devices during the pandemic [23]. The FDA also issued an Emergency Use Authorization (EUA) that allowed for the use of certain 3D-printed medical devices to address the shortage of critical medical supplies during the pandemic [24]. Guidance on the use of 3D printing technology for medical devices, emphasizing the importance of validating designs and ensuring that devices meet regulatory requirements were laid.

In addition to these FDA's efforts, organizations such as ASTM International, and the International Organization for Standardization (ISO) developed standards for 3D printing in the medical device industry [25,26]. These standards help ensure that devices produced using 3D printing technology are safe, effective, and meet regulatory requirements. These organizations provide guidance on the use of 3D printing technology for medical devices and equipment, including best practices for design, testing, and validation.

Conclusions

Additive manufacturing has been a valuable tool in addressing the shortage of medical supplies during the COVID-19 pandemic. Its speed, flexibility, and ability to produce medical equipment locally have been critical in responding to the urgent needs of healthcare workers and patients during the challenging time. This technology has shown tremendous success in producing PPE's, nasal swabs and ventilator components including connectors, splitters and valves, and other similar equipment and supplies. Since this is a new technology redirected for emergency purposes, standards and regulatory compliances were challenging. Numerous regulatory agencies and standards organizations including, FDA, ISO, and ASTM, provided guidance and regulations to ensure the safe and effective use of 3D printing technology for medical devices and equipment during the COVID-19 pandemic. By following these regulations and standards, healthcare facilities were able to use 3D printing technology to address the shortage of critical medical supplies while maintaining patient safety and quality of care. This case study highlights the robustness of 3D printed devices and underlines their potential to be used more broadly in the medical field.

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None.

Conflict of Interest

The authors declare no conflict of interest.

References

1. (2021) Coronavirus disease (COVID-19): How is it transmitted? WHO.
2. (2021) Scientific Brief: SARS-CoV-2 Transmission. CDC.
3. Rahmet Güner, Imran Hasanoğlu, Firdevs Aktaş (2020) Covid-19: Prevention and control measures in community. Turk J Med Sci 50(SI-1): 571-577.
4. (2023) Medical Device Shortages During the COVID-19 Public Health Emergency. FDA.
5. J Rupesh Kumar, K Mayandi, S Joe Patrick Gnanaraj, K Chandrasekar, P Sethu Ramalingam (2022) A critical review of an additive manufacturing role in Covid-19 epidemic. Mater Today Proc 68: 1521-1527.
6. Y C Niranjan, S G Channabasavanna, Shankar Krishnapillai, R Velmurugan, A Rajesh Kannan, et al. (2022) The Unprecedented Role of 3D Printing Technology in Fighting the COVID-19 Pandemic: A Comprehensive Review. Materials 15(19): 6827.
7. G R J Swennen, L Pottel,P E Haers (2020) Custom-made 3D-printed face masks in case of pandemic crisis situations with a lack of commercially available FFP2/3 masks. Int J Oral Maxillofac Surg 49(5): 673-677.
8. A R G Cortes, K Galea, J No Cortes, E J Sammut, E E Alzoubi, et al. (2020) Use of free CAD design software for 3D printing individualized face masks based on face scans. Int J Comput Dent 23(2).
9. K Makowski, M Okrasa (2019) Application of 3D scanning and 3D printing for designing and fabricating customized half-mask facepieces: A pilot study. Work 63(1): 125-135.
10. DH Ballard, Udayabhanu Jammalamadaka, Kathleen W Meacham, Mark J Hoegger, Broc A Burke, et al. (2021) Quantitative Fit Tested N95 Respirator-Alternatives Generated With CT Imaging and 3D Printing: A Response to Potential Shortages During the COVID-19 Pandemic. Acad Radiol 28(2): 158-165.
11. Centers for Disease Control and Prevention (2020) Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons under Investigation (PUIs) for Coronavirus Disease 2019 COVID-19. Cdc 2019.
12. Formlabs (2021) 3D Printed Nasopharyngeal Test Swabs Honored as a World Changing Idea by Fast Company | Formlabs.
13. Envision TEC to 3D Print Mass Quantities of Nasopharyngeal Swabs. Digital Engineering 24/7.
14. Carbon s Response to the COVID-19 Pandemic-Carbon.
15. Origin-Manufacture the impossible.
16. A Tooker, Monica L Moya, Daniel N Wang, Dennis Freeman, Monica Borucki, et al. (2021) Performance of three-dimensional printed nasopharyngeal swabs for COVID-19 testing. MRS Bull 46(9): 813-821.

17. S Tabashi, Alireza Mirkheshti, Mastaneh Dahi, Dariush Abtahi, Maryam Vosoughian, et al. (2020) Supplemental oxygen therapy and non-invasive ventilation in Corona Virus disease 2019 (COVID-19). JCMA 5(1): 27-31.

18. L Cavallo, A Marcianò, M Cicciù, and G Oteri (2020) 3D Printing beyond Dentistry during COVID 19 Epidemic: A Technical Note for Producing Connectors to Breathing Devices. Prosthesis 2(2): 46-52.

19. G Neyman, C B Irvin, (2006) A Single Ventilator for Multiple Simulated Patients to Meet Disaster Surge. Academic Emergency Medicine, 13(11):1246-1249.

20. Ventilator Splitter | Formlabs.

21. ventsplitter.org – Free 3D Printable Ventilator Circuit Splitter.

22. G A Longhitano, Geovany Candido, Leonardo Mendes Ribeiro Machado, Paulo Inforçatti Neto, Marcelo Fernandes de Oliveira, et al. (2020) 3D-printed valves to assist noninvasive ventilation procedures during the COVID-19 pandemic: a case study. J 3D Print Med 4: 4.

23. 3D Printing in FDA's Rapid Response to COVID-19 | FDA.

24. Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices | FDA.

25. ASTM Level 3 Face Mask Requirements - Dental and Surgical Masks.

26. COVID 19 - Standards & Publications - Products & Services.