Lecture Notes in Bioengineering

Kamalpreet Sandhu · Sunpreet Singh · Chander Prakash · Neeta Raj Sharma · Karupppasamy Subburaj *Editors*

Emerging Applications of 3D Printing During CoVID 19 Pandemic



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Emerging Applications of 3D Printing During CoVID 19 Pandemic



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 ISSN 2195-271X
 ISSN 2195-2728
 (electronic)

 Lecture Notes in Bioengineering
 ISBN 978-981-33-6702-9
 ISBN 978-981-33-6703-6
 (eBook)

 https://doi.org/10.1007/978-981-33-6703-6
 ISBN 978-981-33-6703-6
 (eBook)

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Preface

The book entitled *Emerging Application of 3D printing during COVID-19 Pandemic* presents various practical outbreaks of 3D printing technologies on developing different types of tools and gadgets to get prepared for fighting COVID-19. This book presents multidisciplinary aspects of the evolutionary growth of this exceptional technology, including social, medical, administration, and scientific. This book presents state-of-the-art applications of 3D printing technology including the development of PPE, ventilators, respiratory, and customized drugs. Moreover, a variety of research activities, at R&D centers, academic institutions, and commercial enterprises, are covered via incorporating research, review, technical notes, and short communications. Overall, it is believed that the combined efforts of the editorial team members and contributing authors will provide this book a huge attention across R&D, manufacturing, medical, and academic platforms.

Phagwara, India Singapore, Singapore Phagwara, India Phagwara, India Singapore, Singapore Kamalpreet Sandhu Sunpreet Singh Chander Prakash Neeta Raj Sharma Karupppasamy Subburaj

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Kamalpreet Sandhu is an Assistant Professor in the Product and Industrial Design department at Lovely Professional University, Phagwara, Punjab, INDIA. His primary focus is on the design and development of footwear products and injuries prevention. He was done different projects in Podiatric Medicine at the Defence Institute of Physiology and Allied Sciences, DRDO, Delhi, i.e., Design and developed a new kind of orthosis for social needs and work resulted in a publication "Effect of Shod Walking on Plantar Pressure with Varying Insole". His area of research is Design Thinking, 3D printing and Ergonomics for Podiatric Medicine. He is also the editor of various books: Sustainability for 3D Printing, Revolutions in Product Design for Healthcare, Food Printing: 3D printing in Food Sector and 3D printing in Podiatric Medicine. He is also acting as an Editorial Review board member for the International Journal of Technology and Human Interaction (IJTHI), Advances in Science, Technology and Engineering Systems Journal (ASTESJ) and also a review editor for Frontiers in Manufacturing Technology section "Additive Processes". He has established a research collaboration with Prof. Karupppasamy Subburaj at Singapore University of Technology and Design (SUTD), SINGAPORE on Medical Device Design and Biomechanics.

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Karupppasamy Subburaj is an Assistant Professor in the Pillar of Engineering Product Development (EPD) at Singapore University of Technology and Design (SUTD). He leads an interdisciplinary research team to design and develop medical devices, assistive technologies, image-based quantitative biomarkers, and computing tools (machine learning, artificial intelligence) for diagnosing, monitoring, treating, and potentially preventing musculoskeletal disorders (osteoarthritis/ osteoporosis) and disabilities by understanding bio-mechanical implications of those diseases and disabilities. He collaborates with physicians and clinical researchers from Tan Tock Seng Hospital (TTSH), Technical University of Munich (TUM), Singapore General Hospital (SGH), and Changi General Hospital (CGH) to combine research and technical expertise to address real-life clinical problems affecting Asia-Pacific and the World. Before joining SUTD, he did his postdoctoral work in the Musculoskeletal Quantitative Imaging Research (MQIR) laboratory at the University of California San Francisco (UCSF). At UCSF, he worked with a spectrum of clinicians (from radiology, orthopaedic surgeons, sports medicine, and physiotherapy/rehabilitation science) on characterizing magnetic resonance image (MRI) based bio-markers to understand the physiological and biochemical response of knee joint cartilage to physical exercise and acute loading. He has also developed and validated 3D modelling and quantification methods to study joint (hip/knee) loading patterns and contact kinematics in young healthy adults and patients with osteoarthritis. He received his PhD from the Indian Institute of Technology Bombay (IIT Bombay), India, in 2009. During his PhD, he collaborated with Tata Memorial Hospital (TMH), Mumbai, on developing a Surgery Planning System for Tumour Knee Reconstruction. He also worked with orthodontists from local hospitals in on designing and developing prostheses and Mumbai, India, surgical instruments/guides for reconstructing maxillofacial defects. After his PhD, he worked as a research specialist (surgery planning) in the Biomedical Engineering Technology incubation Centre (BETiC) at IIT Bombay, before moving to UCSF for his postdoctoral studies.

Practical Frontline 3D Printing of Biomedical Equipment: From Design to Distribution—A North American Experience



Leonid Chepelev, Prashanth Ravi, and Frank J. Rybicki

Abstract With its versatility, wide availability, and a worldwide active community of enthusiasts, scientists, engineers, and physicians, 3D printing has demonstrated practical value and potential in providing stopgap solutions to shortages of key equipment. Despite enthusiastic support for 3D printing to meet some equipment shortages, the effectiveness of practical implementation of such prototypes has been variable. In this work, we draw on the practical experiences of our groups in Canada and in the United States that used 3D printing for pandemic-related equipment shortages. We describe challenges and solutions for implementing and coordinating programs for 3D printing response in addressing shortages of personal protective equipment (PPE), specialized equipment for intubation and respiratory support, and development of simpler hardware to extend the lifecycle and applications of existing equipment.

Keywords COVID-19 · 3D printing · Personal protective equipment

1 Introduction

The sudden explosive growth in COVID-19 cases and the ensuing shutdown or slowdown in manufacturing and logistics operations worldwide, coupled with limited stockpiles of key medical equipment locally have created a perfect storm of supply shortages. The severity of equipment shortages was not homogeneous across North America and was driven by a combination of local case volumes, testing availability, local healthcare system capacity, and the uncertainty related to projected evolution of case volumes, among other factors. Both, the shortages of vital equipment and the potential for stopgap manufacturing using 3D printing were recognized by the United States Food and Drug Administration (FDA) and Health Canada, resulting

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[©] The Author(s), under exclusive license to Springer Nature Singapore Pte Ltd. 2022 K. Sandhu et al. (eds.), *Emerging Applications of 3D Printing During CoVID 19 Pandemic*, Lecture Notes in Bioengineering, https://doi.org/10.1007/978-981-33-6703-6_1

in early directives on 3D printable medical equipment FDA emergency use authorization for key equipment and designs. After an initial period of organization and process review, the US FDA has arrived at an integrated workflow for 3D printable medical equipment design review and validation. In this workflow, nonprofit organization America Makes, at the National Additive Manufacturing Innovation Institute, driven by the National Center for Defense Manufacturing and Machining, integrated the needs of the healthcare community, considered available designs from a range of sources, and matched these to the available 3D printing resources to coordinate stopgap solution response. A key part of this strategy is the development of key equipment designs by community designers, storage of these designs at the National Institutes of Health 3D Print Exchange, and review of these designs by dedicated Veterans Affairs (VA) engineers. The VA review of models for appropriateness of use in a clinical setting would result in a clinical use designation at the NIH 3D Print Exchange for the models passing VA testing. Additionally, in consultation with VA engineers, FDA would mark selected models for emergency use authorization at the NIH 3D Print Exchange. The review of designs and associated designations by VA and FDA does not guarantee that the final manufactured product would be of clinically acceptable quality, but rather makes statements on the designs and processes themselves. Of note, certain types of medical equipment, like nasopharyngeal swabs (Ford et al. 2020; Decker et al. 2020; Rybicki 2020) and surgical masks, are Class I exempt medical devices, and thus will never be formally "cleared" by the FDA. While this additional vetting is in theory an improvement over local efforts without the infrastructure, the overall efforts have varied according to expertise, experience, and comfort levels of local 3D printing community members. 3D Printing has buttressed the supply chain (Tino et al. 2020; Coté et al. 2020). This chapter reviews these experiences, with specific attention on the time period between March and May 2020 at the University of Cincinnati with team members including physicians, healthcare providers, industry, and university-based engineers working together to best deploy the available 3D printing resources in Cincinnati, Ohio, USA.

While 3D printing efforts have attempted to integrate the collective technologies in mainstream health care in North America (Rybicki 2015, 2018; Mitsouras et al. 2015, 2020; George et al. 2016, 2017; Christensen and Rybicki 2017; Giannopoulos et al. 2015; Chepelev et al. 2018; Di Prima et al. 2015), in many ways the integration is less mature than in Asia where there are longstanding relationships and trust among 3D printing groups and hospitals. Pulling groups of diverse professionals together to build devices and relationships had many success stories and challenges. In Cincinnati, the team of makers had a strong engineering representation in nearly daily meetings progressing over four months. We first detail the basic principles and general practical experiences and then focus on specific projects addressing the shortages.

2 Practical Financial Considerations

Despite the relatively high per-capita expense for healthcare in the United States (Peter 2020), dedicated resources were not available for 3D-printing-based stopgap solutions. The main consideration has been the reluctance of hospitals and local governments in paying for 3D printed medical supplies that were not regulated by the FDA. This has been a significant contributor to uncertainty around the implementation of unorthodox yet effective solutions, such as procurement of the well-publicized 3D printed conversion kits to turn snorkeling masks into N95-grade respirators. From a practical perspective, what this meant is that while there was some emergency funding to carry out engineering research, including locally in Cincinnati, there was often a disconnect between specific requests for 3D printed parts and the price per unit the requesting parties were able to reimburse. Determination of the price points itself was in question, as there were great disparities in cost among materials and the operational costs between hardware platforms, which built unreasonable expectations at times. In some cases, the design of a part required specifications that could only be achieved with certain hardware and material combinations, which translated into combinations of cost and maximal throughput that were not favorable for widespread adoption of 3D printed solutions as the mainstay of stopgap measures. For example, while the community efforts could be coordinated to create virtual 3D print farms to build face shield holders for minimal cost and at nearly sufficient throughputs, the construction of parts such as laryngoscope blades and ventilator parts required the use of limited printers capable of creating airtight or watertight models using medically compatible materials. In the end, most 3D printed stopgap solutions were financed using a combination of existing operational funds and institutional emergency procurement funds. Ultimately, the decision to proceed with the manufacturing of a specific device was thus determined on the basis of the acuity of need, the financial considerations, the limitations on technology used (e.g., biocompatible materials, specific sterilization needs), and the expected throughput accessible in the context of 3D printing.

3 Industrial Resources and Partnerships

The gestures of goodwill from the community and industrial partners played a key role in several efforts. For example, the consumer goods corporation Procter and Gamble, which has its global headquarters in Cincinnati, provided tremendous volunteerism and goodwill to our medical center during the COVID-19 pandemic. Their simple designs for personal protective equipment proved reliable and reproducible—albeit it is important to note that the tens of thousands of PPE parts donated throughout Cincinnati and beyond were ultimately not 3D printed. For larger scale manufacturing, 3D printing is not efficient for companies capable of deploying alternative established manufacturing technologies such as injection molding and other scalable

technologies. The 3D printable designs could, however, provide an intermediate step in design development and testing before partners with plastic manufacturing capabilities could step in with alternative scalable manufacturing solutions. For an example of 3D printed contributions, the University of Cincinnati benefited from the local company AtriCure, which designed and 3D printed thousands of face shields that were used at the main adult teaching hospital Intensive Care Units. Other companies contributed to local efforts to fight COVID-19 by applying their engineering efforts to design simple 3D printable parts. For example, the simple 3D printable mask designed by Mark Fuller was widely considered and adopted by several enthusiasts. Consisting of a simple 3D printed frame, this mask was touted as a Do-It-Yourself project accessible to the general public—so long as the general public had access to a 3D printer. The 3D printing company Materialise developed a series of solutions, from face masks and respirators to hands-free door handles designed to minimize fomite-based transmission of COVID.

4 Community Contributions

Volunteers organized and have been tremendously helpful. For example, the community efforts in Ottawa, Canada, in conjunction with local university-based 3D printing resources produced thousands of simple face shield designs which were donated to The Ottawa Hospital and Children's Hospital of Eastern Ontario. In Cincinnati, the community volunteers countless hours for the production of essential personal protective equipment, most notably reusable masks for the patients and ear tension relief devices (O'Connor et al. in press).

Where the community-based 3D printed equipment was donated to the hospital, the local community efforts were generally organized by a small group of community coordinators, with a set hospital liaison. The hospital liaison was typically tasked with further processing of the community contributions, which typically comprised of ensuring either the final minimal stages of end-product assembly or setting up resources for material disinfection. In our experience, such disinfection typically comprised of high-level chemical disinfection guided by the chemical compatibility profiles of the materials in question.

5 Device Sterilization and Reuse

The practical aspects of device sterilization must be addressed at the initial stages of device design considerations, as the required level of disinfection or sterilization will guide material selection and factor into throughput and costs. Briefly, there are three general levels of removal of unwanted bacterial and chemical contamination: cleaning, disinfection, and sterilization. Cleaning is typically the first step; it refers to the removal of macroscopic foreign material from the sterilized part, typically using enzymatic agents, solvents, or detergents. Cleaning is typically followed either by disinfection or sterilization. In disinfection, either most or all living pathogens are removed from the surface of the disinfected material, depending on whether disinfection is low-level or high-level, respectively. In chemical disinfection, the degree of disinfection is controlled by the concentration of the disinfectant and the exposure time. Ultimately, some forms of chemical disinfection, after sufficient exposure and at sufficiently high concentrations of the agent used, can be termed 'chemical sterilization'. In most applications with skin and mucosal surface contact, high-level disinfection is sufficient. Where contact with sterile tissues is anticipated, sterilization of the involved device is indicated. Chemical sterilization uses agents such as concentrated hydrogen peroxide for a specific amount of time to destroy all surface pathogens. More commonly used forms of sterilization are based on physical techniques-specifically, the exposure of sterilized parts to steam at up to 132 °C for 40 min is typically sufficient to achieve sterilization of most items. In the context of some printing materials, such as thermoplastic polyurethane (TPU), exposure to such high temperatures is undesirable as it may result in dramatic changes in the properties and the configuration of the 3D printed parts. For this reason, chemical sterilization or chemical high-level disinfection may be preferred, using guidance derived from a combination of manufacturer-supplied chemical compatibility charts for key components of the stopgap 3D-printed part and the chemical agent-specific instructions for achieving the desired degree of disinfection or sterilization.

6 Specific Implementation Examples

6.1 Personal Protective Equipment: Face Masks

Early 3D printing during the pandemic focused on face masks and filter carriers. Community designs based on the properties of thermoplastic polyurethane (TPU) were among the earliest designs identified, modified, and tested. The attractive features included the putative ability to conform the masks to the wearer's face in order to ensure the best fit, and the ability to print these masks without significant expenditure of support material since the ability to bend these masks after printing meant that the printed flat mask could be folded after heating into its final configuration. Finally, these masks could be created using desktop printer farms or outsourced to community volunteers. We experienced several practical challenges with TPUbased masks. Most importantly, the prints available to us were not reliable, in that following assembly, the masks were not airtight; this limited utility significantly. The flexibility of the material, especially following heat exposure, limited its utility in practical scenarios. Limited material procurement was also a barrier, and ultimately no TPU-based foldable designs were delivered to our front-line healthcare workers. We considered the manufacture and adaptation of full-face snorkeling mask conversion kits. While technically promising and eventually passing N95 testing, such

solutions were complicated by the limited availability of the funds allocated to the purchase of snorkeling masks and the limited availability of stock of such masks at the scales necessary to fill the medical demand. We also have problems obtaining adaptable filter and filter material. We, therefore, considered the application of a wide range of designs. For instance, we prototyped individualized designs based on face scanning with conformal dome-shaped masks with replaceable filter carriers at the anterior aspect of the mask. These designs had significant associated material and printing time costs. We considered hybrid masks with minimal 3D printed frames where the seal was formed by crafting rubber tubing or door/window seal material around the expected location of the facial seal to ensure an airtight fit. The greatest challenge with manufacturing these masks at sufficiently large scales has been the selection of a filtration material capable of providing sufficient protection while ensuring the comfort of the wearer. For these purposes, materials ranging from combinations of fabrics, paper towels, surgical cover materials that are typically discarded, and even vacuum cleaner bags were investigated for use in viral filtration. We applied local expertise at the University of Cincinnati to quantitatively examine the filtration potential of such materials and were able to objectively identify the optimal combinations of materials for our mask designs from the standpoint of availability and comfort. Ultimately, several hundred masks of different types were produced as manufacturing by the industry ramped up (Fig. 1).

Of note, parallel community efforts in Cincinnati involved the development and production of masks for the wider general population, by various community groups organizing for a response. These groups benefitted from 3D printable tools to facilitate mask production, but generally functioned autonomously and were ultimately capable of distributing thousands of simple cloth masks to the general population.



Fig. 1 Various mask designs evaluated or refined at our laboratories, ranging from minimal 3D printed frame-based ones to fully 3D printed filter carriers

6.2 Personal Protective Equipment: Face Shields

Various 3D printing designs were evaluated in the context of a rapid 3D printing response. However, given the tremendous numbers of face shields required, the requirement for reusability, and the limited throughput potential given the existing resources, injection molding-based manufacturing was preferred. While community efforts did significantly contribute to providing face shields through coordination by community organizers, creating a virtual desktop printer farm, such efforts often required separate procurement of pre-cut transparent polycarbonate shields to couple with the 3D printed holder. Given a significant and unexpected surge in demand, the strain placed on commercial entities capable of providing such materials often resulted in delays for Canadians, and to a certain extent in the United States as well.

The state of Ohio has arranged to acquire and distribute at least one million reusable face shields in the early stages of the pandemic. These shields were developed in collaboration with several Ohio organizations. The State of Ohio committed to maintaining this stockpile and to coordinating its distribution through the MAGNET Ohio Manufacturing Alliance and the Ohio Hospital Association. The design ultimately supported was identical to that being produced by Proctor & Gamble and consisted of three parts, two of which were injection molded. The parts underwent engineering evaluation with extensive testing, and it was confirmed that these could stand many use cycles. The contribution of commercial partners has been indispensable in reaching this goal.

6.3 Nasopharyngeal Swabs

While limited throughput capabilities for 3D printing of nasopharyngeal swabs were available at the University of Cincinnati, it was clear that broader commercial partnerships were necessary to ensure sufficient supplies for the wider needs of the city. There are many swab designs with a focus on the design initiated at the University of South Florida; some of the controversies surrounding swab printing have been discussed (Rybicki 2020). The 3D printed swabs have been demonstrated to be either equal to, or to outperform existing commercially available swabs and were capable of obtaining enough viral particles to ensure a confident diagnosis of COVID-19 infection.

6.4 Environmental Modifiers

Simple modifiers in behavior or equipment can often yield surprisingly positive results. A shining example of this principle has been the institution of handwashing, proposed in modern medicine initially by Semmelweis, and likely responsible for millions of lives saved since widespread adoption. Simple 3D printed devices have emerged to capitalize on this principle. Our groups have been involved in the manufacturing and distribution of several such devices, and we will use door handle openers and ear savers as examples of these efforts.

Inanimate objects capable of transmitting pathogens are referred to as fomites. In hospital environments, there are dozens of door handles that patients and clinicians touch on the way to their appointments and duties. While at destination, hand washing is tremendously helpful in reducing fomite transmission. Unfortunately, unconscious reflexes may result in hand–face contact and possible pathogen transmission on the road to the destination. To help address this, multiple groups, most notably engineers at Materialise (Leuven, Belgium), have proposed 3D printable door openers. At the University of Cincinnati, we were able to rapidly capitalize on such designs to manufacture hundreds of door openers and distribute these two key areas within the hospital (Fig. 2).

Similarly, wearing a masks is very strongly recommended to limit the spread of COVID-19. In our experience, the incessant wearing of a mask can be a tremendous source of discomfort, focused on posterior ears, and resulting in some personnel removing the mask for extended periods of time. Simple designs of the so-called "ear-savers" are easy and cheap to manufacture in bulk and often provide significant relief to posterior ear pain. We have distributed thousands of such devices broadly, with only minimal time and capital investment for production.



Fig. 2 Examples of a door handle opener (left) and ear saver (right)

6.5 Specialized Equipment: Laryngoscope Blades

A surprisingly unforeseen shortage was encountered when reports of limited stocks of video-assisted laryngoscopy equipment emerged. Laryngoscopes are devices used for the intubation of patients. Specifically, laryngoscopes help clear the pathway for the placement of a tube used to deliver oxygen to the lungs (via an endotracheal tube). If endotracheal tube placement is conducted blindly, the risks include damage of the laryngeal structures and intubation of the stomach with the resultant aspiration of gastric contents by the patient, partial airway compromise, and transport of gastric configuration of the mouth and neck can be intubated using direct visualization with a reusable metallic laryngoscope, some patients have neck anatomy that precludes direct visualization. For these cases, video laryngoscopy has been devised. In video laryngoscopy, a curved reusable blade contains a hollow cavity where a reusable camera is fixed in place (Figs. 3 and 4). Laryngoscopy blades typically cannot be reused.

The design of these blades is subject to significant constraints. First, the material should be biocompatible. Second, the part must be watertight. Third, there must be a completely transparent window that protects the sensitive camera from vapors and secretions to ensure optimal visualization and prolong the camera lifecycle. Fourth, during the limited supply chain during the pandemic, the blade would ideally be reusable. At our laboratories, we developed stopgap blades by using PolyJet printing with medically compatible materials. Adapting the initial overall design from segmentation of a CT scan of the existing laryngoscope blade, we carried out numerous design and testing iterations on placing a window at the end of the laryngoscope, in a 6×6 mm footprint, with the inability to polish or buff the surface to ensure transparency. Our final design included the placement of a polycarbonate sheet into the window, held in place by traps within a specially designed canal.

Fig. 3 The tip of a 3D printed laryngoscope blade with the expected location of the camera window. Note the lack of window transparency





Fig. 4 The fitting of video laryngoscopy camera within the 3D printed laryngoscope prototype. A notch on the camera (left) closely fits into a groove on the blade (right), ensuring an adequate tight fit of the camera within the blade (center)

Extensive testing confirmed reusability under chemical disinfection conditions and the complete absence of mechanical motion of the entrapped polycarbonate window. Operating with batches of 12 laryngoscope blades, we were able to deliver up to 40 blades per week. Fortunately, last-minute procurement deals staved off the need for 3D printed blades in favor of a complete replacement of the video laryngoscopy platform at the hospital level.

6.6 Specialized Equipment: Ventilators and Ventilator Parts

Our teams prototyped several ventilator designs. The designs evaluated were based initially on replicating the general principles employed by established commercial ventilators such as Go2Vent (Vortran, Sacramento, USA) and later by employing publicly available designs distributed by the Illinois Rapid Vent (University of Illinois Urbana-Champaign 2020). While the development and 3D printing of simpler parts such as tubing and various connectors for the use of existing equipment with a wider range of options of adapters, filters, and suction devices have significantly contributed to the care of the patients in the Intensive Care Units, a fully functional 3D printable ventilator likely represents the apex of the medical equipment design space in the context of COVID. Not only are there requirements for the material to be airtight, but the allowable manufacturing tolerances are quite small, with the potential for injury or loss of life being quite high in either the inappropriate manufacturing or deployment of experimental designs. To provide an illustrative example, one of the challenges addressed by our team during the design refinement phase has been to ensure that a high-pressure pop-off valve functions appropriately. This pop-off valve is designed for cases where pressure within the ventilator exceeds 60 mm Hg, which