



Validation of 3D Printed Laboratory Safety Product in Pathology from Online COVID-19 Related 3D Print Resource

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Abstract

COVID19 pandemic introduced several challenges in all aspect of life and bring new normal. The health sector was most affected area worldwide and task forces handle the several aspects of it in the patient management. One such area is medical 3D printing and several COVID19 related products were designed and tried at local level for patient care. Across the world the laboratory safety products were well planned such as visor for face shield, goggles, heavy duty respirators, and door handle. These products are useful in diagnostic laboratories such as cytology. Author attempted 3D printed visor for face shield having potential for its use in diagnostic laboratory.

Keywords: 3D printed; COVID-19; Safety Product in Pathology

Abbreviations: PPE: Personal Protection Equipment; Stl: Stereolithography Files.

Introduction

The World Health Organization declared March 12, 2020 coronavirus disease 2019 (COVID-19) as a pandemic affecting nearly all countries across the globe [1]. This strain the global health care system with limited availability of desired product to combat COVID-19 pandemic. At this point of time India was not manufacturing PPE and limited N95 masks produce. This was the story in many countries irrespective of under developed, developing or developed nations. Although almost all countries across world made task force and preparedness committee to combat COVID-19 pandemic, but 3D medical printing was not much included in India at that point of time [2]. Several pathology laboratory preparedness guidelines are prevailing both by the contributions of international and national experts. The area for frozen section and cytology fine needle aspiration are among such high-risk laboratory areas [3]. All health care staffs involved in patient management are at risk. Medical Institutes were gearing up

to support and prioritising the delivery of limited PPE supply in COVID-19 wards. Government and health care agencies especially ICMR covered multiple dimensions and issued guidelines time to time. Research Agencies also facilitated funds for diagnostic kit development, pharma Industry and vaccine preparation [2]. The COVID-19 pandemic initiated significant number of product development on site in view of worldwide lock down practice to maintain the social distancing in the society, hospital services and the diagnostic pathology laboratories In India. Products related to personal protection equipment (PPE) such as masks (cotton, three layer surgical masks and N95 respirators), face shields, visors, non-touch door handles are important gadgets required for routine laboratory functioning to minimise contamination and biohazards [4-6]. In view of lock down these equipment's are not readily available even at higher price due to interruption in supply chain. In India trains and flights for travel purpose stopped in late march 2020. Only good trains and cargo flights are maintaining restricted supply chain of essential goods, medicines. There is promotion from government to large scale production of masks, PPE etc for patient care. Worldwide at several advance medical centre's

the biomedical divisions and bio-engineers are attempting to produce biosafety products with the help of 3D printers available in-house and are showcasing that this alternate mechanism is equally effective till supply chain normalise for these products. These centres are also developing printable files and allowing usage of it free of cost as online resource material under Covid19 support in form of 3D printable .stl files. To meet the requirement of hospital supply for patient care and the keeping laboratory functional, the services provided by these .stl files can be readily printed for generating the some of the above laboratory safety products by 3D printers [4-6]. Authors are herewith approaching to develop the prototype of these resource material at AIIMS Bhopal and understanding its usage and limitation(s) for diagnostic laboratory preparedness during COVID-19 pandemic.

Materials and Methods

The 3D printer of Flash forge inventor series with double extruder was used to prototype the laboratory safety products. Author reviewed the literature to develop prototype products such as visor for face shield, PPE mask, non-touch door opening handles and N95 mask sterilisation stands by printable .stl files readily available from various online resources were attempted to prototype. Several designs were attempted through FDA, NIH3D Print Exchange and United states Veterans Association and were tested. Among them author aimed to print visor for face shield as it is most commonly used product generated by 3D printing as face shields were readily used in cytology laboratory specially at aerosol generating areas such as in procedure room for fine needle aspiration, area of slide preparation, near biosafety cabinets etc. The investigator has institute permission to scan, print and develop prototype products of medical educations wide letter no. IHEC-LOP/2019/IM0227.

Initial Description, Design and Stacking

The stereolithography files (.stl) were used to print above mentioned objects. The author expertise of hobbyist owner to academic. The designs were selected carefully fulfilling the objectives. The main objectives were easy to print with limited consumption of PLA material, durability and user friendly acceptable product and prototype were generated Each prototype took variable hours for printing. The design selection was based on discussion with medical professionals and end users. The transparent plastic sheets were arranged from market. The product was checked and compared with readily available face shields and masks. PLA was used as biomaterial compatible with 3D printer available in house. In shield design hooks are available on either side where stretchable threads were tied to check feasibility. It is feasible to print multiple shield frames and parts of mask

and mask stand in one go. The minor change in program is doable to initiate this activity. It is helpful to save time.

Filament and Plastic Sheets and Stretchable Treads

PLA and PETG are suitable due to cost-effective option and due to availability, we used PLA in variable colours red, brown, white etc. As we know PETG is durable and have better tensile strength.

Disinfection: In view of high temperature required to perform 3D printing. The process is itself sterile. However, once the printed product is exposed to environment and its use in medical practice, The use of 70% alcohol is helpful and effective against COVID-19 after removing the visible dust/ debris. Alcohol based antiseptics are readily available in health care laboratory settings. In India protocols from environmental control agencies are yet to come and not readily available in authors knowledge. However, all laboratories are equipped with alcohol based disinfectant. Few labs in setup have hot oven, Ultraviolet hoods. All these systems are working to inactivate virus [7,8].

Results

Visor for face shield is most commonly used product generated by 3D printing and presently observed at various sites but due to lockdown and cost, these durable 3D products are less in use. This product is easy to print singly with minimal modification to print easily (Figure 1). Author attempted successfully and can print it in bulk of 2 or 4 simultaneously to save the time. The product was compared and found suitable for routine day to day activity, fieldwork (Figure 1D) and while working in the laboratory.



Figure 1: 3D printed visor for face shield. The 3D printed product (A); Partly cleaned product (B); The clean product ready for use; Its use in field (D).

Discussion

It is important in country like India that 3D printing experts appraise the hospital supply chain and national policy makers. A centralized approach to handle COVID-19 pandemic crisis requires organized communication and may lead by MOH&FW and National Disaster management system [2]. In the western countries and United states of America, the medical devices are highly regulated for safety. Therefore, we choose to 3D print such products from renowned universities websites. The experts worldwide are responding in unprecedented manner, the 3D printing in India must work simultaneously and ensure that the product must prepare in time and emergency parts will be safe during a pandemic. Even during this pandemic standard safety and quality measures of 3D printing labs are very important and they should work with larger academic medical Institutes such as All India Institute of Medical Sciences or other Institute of National Importance. That develop partnerships between university-based 3D printing resources and hospitals, this is often already in place; however, appropriate safety protocols should always be reviewed. Like in our centre we reviewed 3D printed face shield is better than the locally available shield as is reusable and user can replace transparencies multiple time. Therefore, it is cost effective with same protection. Another important point is safe implementation of unregulated product or risk/ benefit ratio is essential. Intellectual property is a concern as reverse-engineering medical parts or standard print materials/ filaments that cannot be purchased in COVID-19 19 pandemic.

This further generate scope for Indian regulators, legal experts and academic Industry partnership both at national level and support from International academic community. In view of above author used this product himself and only physically compared with other face shield of supply chain commercially available. Author found that 3D printed visor for face shield in present study qualify to be used in cytology laboratory as trained pathologist. This product was not used in view of paucity of guidelines on 3D printed lab safety issue during pandemic. Overall 3D printing in medicine is coming close to its goal of education, diagnosis, and treatment during this pandemic and undoubtedly it bridges the gap between health professionals and engineers. These products potentially fulfil laboratory safety as various such product

supply used on daily basis and maintained by simple alcohol clean.

Recommendation and Conclusions

Author felt that there is paucity of awareness about medical 3D printing in India. Therefore, 3D printing experts and vendors must communicate and understand local demand and supply potential in this area presented through this article. The state government and premier medical Institute may take a lead in this area. As we know that the medical devices are highly regulated for safety. In the pandemic dedicated experts' response was unprecedented. The need of appropriate safety protocol is always be reviewed. The most essential part is safe implementation of unregulated parts. The 3D printing companies must work readily and efficiently with bio-medical counter parts. The intellectual property remains a concern. Across the world we are able to perform 3D printing of such designs as designers, institutes and academia is making it freely available. Therefore, academic-Industry partnership must be visible for medical 3D printing similar to cheap diagnostic kits and vaccine development across India and globally.

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