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Use of AM technologies to face the Covid-19 emergency: workflow and practical examples

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Abstract: The present work aims at describing the workflow applied for the use of AM technologies during the worst phase of Covid-19 emergency. AM technologies have proved to be effective for the production in short time of many components to be used within ventilation systems, and which rapidly run out of stock due to unprecedent high demand. Moreover, many systems required modifications to prevent personnel's infection. We report the workflow applied to face production needs, in terms of materials and technologies selection according to the specific requirements (disinfection, device criticality) and some practical examples.

I. Introduction

3D printing or Additive Manufacturing (AM) can play a fundamental role in the context of Covid-19 emergency. Due to the unprecedent request of ventilation systems and related components, hospitals rapidly run out of many of them and are struggling to supply. Furthermore, the pandemic has posed many new challenges which require a rapid response.

Shortening the time from design to production, AM can provide a prompt production of the required devices and components, as it happens in many industrial fields. In the pandemic framework, such production involves medical devices, which are subjected to strict certification processes before coming to the market (CE Marking).

An emergency or a critical situation allows exceptions to the use of not certified medical devices, if it is proved that no certified choices are available or suitable for the specific purpose and in accordance with the local ethical committee. Permission modalities are subjected to differences from country to country, according to local regulation. Furthermore, the current pandemic imposes a short time for the production, making impossible to run extensive testing campaigns on the components. This must not prevent any AM operator from paying close attention to the selection of materials and technologies suitable for the specific application, considering the risk classification of the components to be produced and their operational environment.

To this aim, we report our experience, summarizing the workflow applied for the production of the requested components by means of AM technologies at 3D4Med (http://www.3d4med.eu) – the Clinical 3D Printing Laboratory of Fondazione IRCCS Policlinico San Matteo of Pavia – and Protolab (http://www.unipv.it/compmech/proto-lab.html) – its engineering counterpart at the University of Pavia.

II. Material and methods

Each production request has been processed according to the following workflow:

(I) Definition of the required cleaning, disinfection, or sterilization procedures [1-2]: equipment used for respiratory therapy (e.g. items that come into contact with mucous membranes) is considered semicritical according to Spaulding's classification [3]. Such items should be cleaned and then receive at least high-level disinfection between patients [4]. High-level disinfection of respiratory equipment is accomplished by chemical germicides or physical methods [5-6].

(II) Evaluation of available commercial disinfectants against viruses, tested on previous Coronaviruses (SARS-CoV, HCoV-229E, MHV-2, MHV-N, CCV, TGEV) [7]:

- 0.1% sodium hypochlorite (dilution 1:50 if household bleach at an initial concentration of 5% is used) after cleaning with a neutral detergent;
- 70% concentration of ethanol after cleaning with a neutral detergent, for surfaces that may become damaged by sodium hypochlorite;
- Sodium dichloroisocyanurate dihydrate (NaDCC), avoiding contact with easily oxidizable organic materials [8].

(III) Evaluation of the compatibility of available commercial disinfectants with 3D printed materials, in terms of absence of degradation issues or release of toxic substances. Since there is no perfect correspondence between commercially available disinfectants, which have been proven effective in eliminating coronaviruses, and the ones recommended by manufacturers of 3D printing

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materials, we suggest to test the resistance to disinfection at least qualitatively, assessing that no alterations are visible after the disinfection for the prescribed time. We had experience with:

- NaDCC: Acrylonitrile Butadiene Styrene (ABS) and Acrylonitrile Styrene Acrylate (ASA) thermoplastic polymers are proved to be chemical resistant.
- IsoPropyl Alcohol (IPA): IPA is chemically close to ethanol - one of the recommended disinfectants - and most photopolymer resins are proved to be chemical resistant to it. We commonly use pure IPA for the cleaning of Stratasys PolyJet materials and Formlabs resins.

Attention must be payed to the time required for disinfection. For example, photopolymer resins have limited resistance in IPA.

(IV) Mechanical resistance of 3D printed materials to disinfection: even though a material is tested against a chemical agent, a reduction in static strength can still be present. For example, ABS and ASA (see for example https://3ntr.net/materials/) can show a slight mechanical impairment after NaDCC disinfection. We have successfully tested ABS components in low pressure devices without any mechanical issue. We suggest testing the component at least from a qualitative point of view after disinfection, to assess its performance, for example checking possible gas leakages (refer to the following point).

(V) Gas permeability tests of 3D printed components: considering the specific application, gas permeability should be avoided to not interfere with the therapy. Photopolymer based technologies (Material Jetting/Vat photopolymerization) and powder-based technologies (Binder Jetting and Powder Bed Fusion) can provide a good impermeabilization of the component, thanks to the curing strategy, while Material Extrusion technologies, as Fused Filament Fabrication (FFF), suffer more this issue. As for FFF printers, we successfully tested 3D printed ABS components at low pressure without any gas leakage. Further investigations may be necessary for fluids' applications. A heated building chamber, high infill percentage and at least two perimeters are recommended.

III. Results and discussion

We have successfully applied the proposed workflow to the production of several components, briefly presented in the following, along with major constraints and manufacturing strategies (Fig. 1). Details on the products design and manufacturing are available at [9]: (I) scavenging system for continuous positive airway pressure (CPAP) outflow; (II) adapters to connect ventilation systems outflow to the anesthetic gas scavenging system; (III) tubing connector for CPAP systems; (IV) venturi system suction unit; (V) adapter for snorkeling masks to be used as substitutes for CPAP helmets.

Components feature different critical levels. For (I-II) no sterilization/disinfection constraints are required, since the device is placed in a ventilation circuit that has no return to the patient, while for (III-V) disinfection is mandatory since they are placed in the patient inflow circuit. According to the possible disinfection strategies and operational requirements, (I, III, V) are produced with a 3NTR A4v3 FFF printer with 3NTR black ABS and High Impact PolyStyrene for the support structure, (II) is produced with a Stratasys Objet 260 Connex 3 with FLX-MT-S40-DM, a compliant material, and (IV) is produced with a Stratasys Objet 260 Connex 3 with VeroMagenta, a rigid material.

IV. Conclusions

The proposed workflow can aid AM production of medical devices and components in emergency situations as Covid-19 pandemic, in which limited time is given for products testing. The time shortage must not prevent from a thorough assessment of production options, for which a defined workflow can help. Production must be always carried out by trained AM operators able to properly evaluate and select materials and technologies.

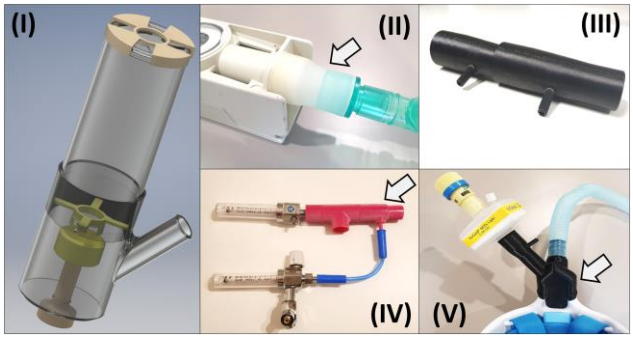

Figure 1: Examples of 3D printed components produced by means of AM technologies for the COVID-19 pandemic. See [9] for further details on design and manufacturing.

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AUTHOR'S STATEMENT

Authors state no conflict of interest.

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