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Lessons learned from COVID-19 and 3D printing

The use of 3D printing in medicine is not new, with consolidated and growing applications in surgical procedure planning, the creation of both personalized implants or prostheses, developing of medical devices or improvement and personalization of existing ones and anatomical models for improving medical training and education [1]. Moreover, nowadays is not uncommon to find 3D printing units or labs at radiology departments and hospitals approaching medical imaging to personalized medicine. The new COVID-19 pandemic has pushed healthcare resources to the limit. The frontline workforce, such as healthcare workers, armed forces, police and security bodies as well as the rest of service sector has suffered the lack of enough personal protective equipment (PPE), which includes facemasks or face shields, eye protection and gloves [1]. These physical barriers, together with maintaining social distance and cleaning hands, are essential to minimize the spread of COVID-19, not only among healthcare professionals but also at general population [2]. Furthermore, in a considerable number of hospitals, PPEs have been re-used, looking for certain grade of protection. In spite of all these efforts, hospitals and medical centers have become one of the most important points of viral dissemination during the outbreak, with an increased in the risk of infection by COVID-19 of patients admitted at hospital for other reasons, such as emergent or oncological surgical procedures. Unfortunately, this shortage of supply has also involved other critical medical material such as artificial respirators or ventilators, supposing a major drawback to manage the huge number of patients that require advanced medical support due to lung involvement by COVID-19. Finally, limitations in the access to COVID-19 testing swabs and kits have supposed a clear limitation to know the real proportion of infected population.

At this devastating scenario, the 3D printing community has raised several spontaneous or coordinated initiatives in an intend to mitigate the global deficit of basic devices for minimizing the COVID-19 spread. In this manner, in the aim of increase the production of physical barriers and specific medical materials for healthcare professionals and general population, multiple proposals have aroused from governments, non-governmental public and private organizations, or even private persons (Table 1). In this setting, news on innovative applications of 3D printed material has flourished on the media during the pandemic. However, beyond the shown solidarity, additive manufacturing has also exemplified how technology can change traditional models, demonstrating a real capacity to implement on-demand manufacturing of specific medical material. Definitively, 3D printing has demonstrated to be able to adapt to COVID-19 crisis requirements [3]. Several open-source and private files of different types of physical barrier material have been launched, sharing free 3D-models in compatible formats ready for being sent to 3D printers. These models include mainly masks and facial protective screens with different designs and properties, but also limitations, mostly regarding the incorporation of homologated air filters. Nevertheless, other smart devices for facilitating common activities such as open or close doors, or even pushing buttons have been developed to reduce the expand of infection [4] [5]. The design of these devices usually carries short impression times which allows to produce a considerable number of units per day. The most extended 3D printing technologies to print these devices have been stereolithography (SLA) and, above all, Fused Deposition Modelling (FDM) [6]. The main reason of using these technologies is because the popularity of this type of 3D printers and the low cost of printing. For the same reasons, Polylactic Acid (PLA) is being widely used for printing face shields or smart devices, and, due to the possibility of disinfecting it with bleach, which allows to reuse them. More complex products are commonly printed using Polyethylene Terephthalate Glycol-modified (PETG) filament and resins. For example, these materials are being used for printing valves and connection tubes or adapters that are intended to be in contact with the patient, or to form part of breathing devices, since they are biocompatible materials USP class VI or ISO 10993-1. In the same direction, prototypes of nasal swabs, an essential part of COVID-19 test kits, have been developed using biocompatible and autoclavable resins.

However, all these 3D-printed materials have faced to the reality of regulations of medical devices regarding safety and quality guarantee. Most of the official regulatory bodies are slow for the urgency of the COVID-19 crisis and have put bureaucratic hurdles for the approvement of 3D-printed prototypes, which has limited its real use to very specific scenarios. Depending on governments and own institution's quality criteria, most of these initiatives and 3D printed models have been relegated to the second tier due to non-compliance of basic safety requirements, particularly those related to healthcare preservations. However, in several countries and healthcare institutions, the emergent needs for protection have pushed to use these kind of un-approved protective printed materials, following the basic principle that some protection is better than no protection at all.

Higher restrictions have been applied to the development of artificial ventilators. Multiple initiatives have explored the possibility of creating ventilators of hybrid models using software solutions and 3D printing for creating some specific parts. Other groups have printed divers' components for invasive and non-invasive ventilation, such as reusable 3D valves or connection tubes for ventilators. However, all these initiatives have dealt not only with the official regulatory bodies' rules, if not with the uncertainty and concern on whom is placed the liability of using unregulated materials in the real clinical world. Intellectual property and owners' copyright legal issues have also been areas of growing concern for the medical 3D printing community. It is urgent and mandatory to clarify all these conflictive areas and rapidly adapt regulations to emergent scenarios as the one lived during this pandemic.

Nevertheless, the positive impact of using of 3D printing solutions during COVID-19 outbreak may goes beyond the creation of devices related to direct fight against the virus, being an opportunity to reinforce the use of 3D-printing in some of their common clinical applications. During the steepest curve of viral dissemination, hospitals have reduced

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Table 1
Summary of 3D printed models for patients support, healthcare professionals and general population protection in the era of COVID-19

Personal protective equipment	Face masks
	Face shields
	Mask ear savers/mask straps
Patient's support	Respirators
	Venturi valves
	Ventilation Adaptors
Other devices	Door handles and hooks
	Button switches

surgical procedures to almost only non-delayable oncological and emergent procedures to minimize both the level of bed occupancy and the risk of intrahospitalary SARS-COV-2 infection. In this setting, the use of 3D printed models for planning surgical procedures may have several advantages. It has been largely demonstrated that complicated surgeries may benefit from the use of 3D printed models [7] [8]. This approach is useful for planning complex orthopedic surgeries, particularly comminute bone fractures involving soft tissues. The value of this approach has specifically shown in trauma surgery of pelvic ring fractures with involvement of neurovascular bundles [9]. In the same line, some authors reported the benefits of using 3D printed models in the planning of surgical procedures of brain and abdominal tumors that encase vital structures [10] [11]. Derived benefits of this approach are a better selection of the type of surgery (open vs laparoscopy), including the route of entry, reduction of intraoperative surgery times and minimizing immediate and late surgical complications [12]. Finally, the use of 3D printed models in this scenario has demonstrated to reduce the admission time at the hospital after surgery being an indirect manner to protect people at risk from SARS-COV-2.

In our opinion, it is necessary to explore and exploit the alternative of incorporating 3D printing technology for helping in the fight against COVID-19 due to the actual needs of basic resources. However, clearly is mandatory the establishment of regulatory policies that allows to rejoint all the public and private initiatives for the development and mass production of 3D printed medical devices. These regulatory policies are needed to ensure healthcare and public services professionals' safety as well as the security of the rest of the population. In an indirect manner, the use of 3D printed models for surgical planning may help to minimize the risk of nosocomial COVID-19 infection through reducing the patient's admission times at hospitals.

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