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Review on 3D printing: Fight against COVID-19

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HIGHLIGHTS

- 3D printer and software fight against COVID-19,due to the PPE shortage during the pandemic.
- Presents the detailed procedure for printing 3D face shields and ventilator promptly and effectively.
- Evaluates the potential of 3D printing for the flow of medical devices for fighting COVID-19.
- Reviews innovative breakthroughs in major 3D printing in various institutions.
- Proposes a futuristic pathway of a medical device for preventing and treating COVID-19.

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ABSTRACT

The outbreak of coronavirus disease in 2019 (COVID-19) caused by the SARS-CoV-2 virus and its pandemic effects have created a demand for essential medical equipment. To date, there are no specific, clinically significant licensed drugs and vaccines available for COVID-19. Hence, mapping out COVID-19 problems and preventing the spread with relevant technology are very urgent. This study is a review of the work done till October, 2020 on solving COVID-19 with 3D printing. Many patients who need to be hospitalized because of COVID-19 can only survive on bio-macromolecules antiviral respiratory assistance and other medical devices. A bio-cellular face shield with relative comfortability made of bio-macromolecules polymerized polyvinyl chloride (BPVC) and other biomaterials are produced with 3D printers. Summarily, it was evident from this review study that additive manufacturing (AM) is a proffered technology for efficient production of an improved bio-macromolecules capable of significant COVID-19 test and personal protective equipment (PPE) to reduce the effect of COVID-19 on the world economy. Innovative AM applications can play an essential role to combat invisible killers (COVID-19) and its hydra-headed pandemic effects on humans, economics and society.

1. Introduction

In recent months, severe acute respiratory syndrome coronavirus disease in 2019 (COVID-19) has continued to spread worldwide at an alarming rate, regardless of pre-existing medical conditions, age or other patient demographics [1–3]. The death rate is significantly higher than that of the flu, and the death rate in the United States gives the impression to be higher than in China and Europe. Every morning and afternoon, their degree of illness, their health and safety are threatened [4–6]. The medical community has experienced a worrying reality: there is a complete lack of resources for patients and caregivers. In particular, personal protective equipment (PPE) has a critically low supply power. Consequently, it puts both patients and care-givers at unacceptable risk.

During a severe outbreak of fatal acute respiratory syndrome of the coronavirus in the following year 2020, healthcare professionals blamed 21% of cases for an alarming situation, a trend that should be avoided. Many people and companies have implemented different strategies to meet or respond to these needs [7–9]. Improvisation without the necessary equipment to protect healthcare professionals will lead to a significant deterioration in hospital affairs and inaccessible pressures in the supply chain, and a severe risk to the lives of those who seek

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Abbreviations

3D	Three-dimensional
ACL	Anterior cruciate ligament
AM	Additive manufacturing
AP-HP	Paris public hospital assistance
CAD	Computer-aided design
CDCP	Centre for disease control and prevention
CHU	Centre hospitalize universities
COVID-19	Corona virus disease in 2019
DLP	Digital light processing
ECG	Electrocardiogram
EPP	Erythropoietin protoporphyria
VR	Virtual reality
FDA	Food and drug administration
FDM	Fusion deposition modelling
HP	Hewlett-Packard
NHS	National health service
NP	Nasopharyngeal
PETG	Polyethylene terephthalate glycol
PPE	Personal protective equipment
PVC	Poly vinyl chloride
SLA	Stereolithography
TI	Texas instruments
USF	University of South Florida
ETH	Eidgenössische technische hochschule

healthcare rest of society. The spread of COVID-19 is mediated by different droplet contacts and direct exposure to air. Different levels of protection are necessary for various procedures and interactions between patients [10,11]. For any healthcare professional, there is always at least one suspected patient or proven infection. Therefore, wearing PPE, such as overall clothing, gloves, some antibacterial bio-cellulose masks and eye/face protection mask, is an unavoidable practice [12–14] (Fig. 1). The universal ideologies governing the biological evaluation of medical devices within a risk management process are recognition of extra data sets essential to analyze the medical device's physical protection of the valuation of the biological safety of the medical device. This research applies to the biological evaluation of all types of medical devices, including active and non-active. In this research, the assessment of biological hazards arising from risks, such as variations to the medical device over time, is essential and described explicitly as part of the overall biological safety assessment. To comprehend how this transpires, it is vital to distinguish the unique structure of different masks and PPE and understand their biomolecules that could cause their designs modified due to the action of a given chemical agent and thus, lose their biological action capacity.

Furthermore, to perform the COVID-19 tests, healthcare workers need nasopharyngeal (NP) antibacterial bio-cellulose swabs, small flexible rods to insert into a patient's nose to take samples made of biomaterials. Once the model has been taken, it is stored in a bottle containing a culture medium. These antibacterial bio-cellulose swabs are necessary for today's medical sector, which faces a severe shortage of equipment to fight the virus [15–17]. It has been demonstrated in many ways, such as using a three-dimensional (3D) printing initiative, to avoid the shortage of resources. To offer solutions to this situation, there are Carbon, Formlabs and two resin 3D printer manufacturers, who produce thousands of antibacterial bio-cellulose swabs every day [18–20]. Some researchers [20–22] had effectively manipulated 3D printing technology to help health care workers on the front line of the COVID-19 anti-epidemic and make antibacterial bio-cellulose masks from biocomposite materials. The extraordinary period requires extraordinary measures, as stated by a packaging engineering manager in Malaysia [21–23]. Initial programming with a 3D-printed antiviral bio-cellulose masks design online was started and proposed using Texas instruments' (TI) production site in Kuala Lumpur. A faster, easier-to-assemble scheme that cuts print time to half was developed.

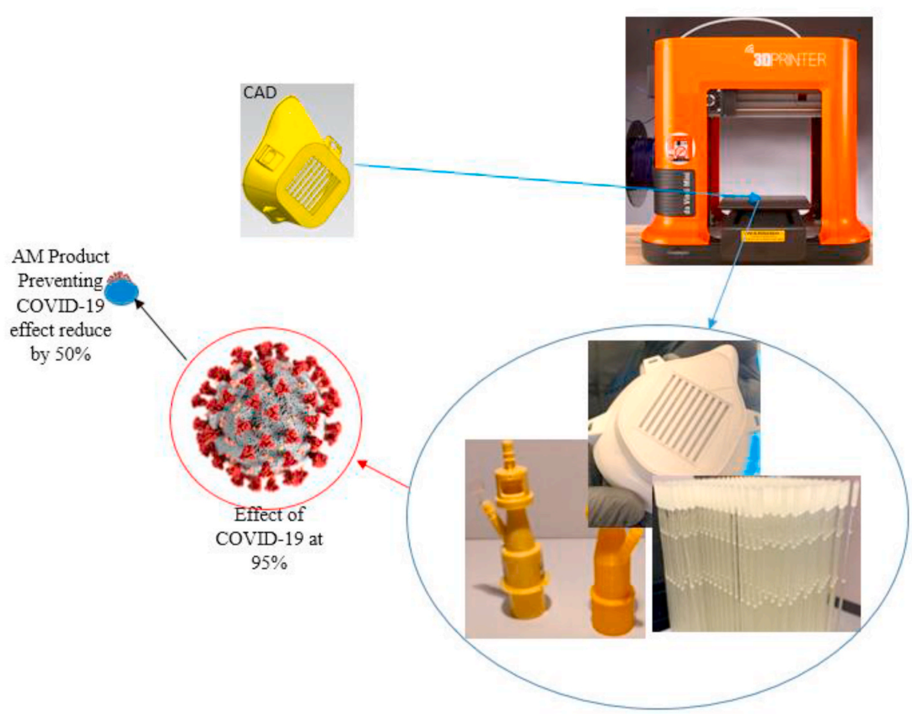

Fig. 1. Step description of the effect of additive manufacturing (AM) on COVID-19.

Three days later, the prototype was made. It is essential to provide a more efficient product design. It was followed by printing about 20 masks made of antibacterial bio-cellulose masks in a day and delivered them to public health care providers every week.

The shortage of medical supplies is increasing as the COVID-19 pandemic strains global supply chains. Malaysia team uses 3D printing technology to manufacture medical devices and supplies worldwide, including medical devices such as bio-cellulose swabs, antibacterial bio-cellulose masks and test boxes [24–26]. According to Fig. 2, the highest number of cases from the World Health Organization as of September 14, 2020 is from the American continent. The lowest occurs in Africa and some other Asian countries. There are countries without any reported new case, according to the figure. This is a 14-day COVID-19 case notification rate per 100,000. American continent recorded above 120, 000 out of the total confirmed number of COVID-19 cases and how rapidly they increase in the American continent?. The number of confirmed COVID-19 instances is lower than the number of total points. This is due to limited testing materials, such as PPE, to protect the sample collector/health workers and sweb for testing.

After connecting to compressed air or oxygen at a rate of 15 L/min, air flows through the hood and prevents the supplier from inhaling the patient's aerosol kit. It is essential to emphasize it. One of the additional gas flow is not used with the face protection configuration, a venturi effect can be created, and the atomized particles can be transported to the supplier's face. This PPE is not designed to be used in Place of robust air purification systems capable of producing more than 100 L per min. To avoid hypercapnia, it should be used for a short period with a different mask of bio-cellulose materials on the hood [27–29]. Fig. 3 represents the schematic process of the need for design and 3D printing of PPE to tackles the shortage of medical devices during the COVID-19 pandemic. This process is taken seriously, because of the increasing number of the confirmed death of COVID-19 patients per day data, especially in the highest affected country from the first day with over 100 cumulative death from world meters of National Health Agency.

1.1. Brief evolution of 3D printing

The evolution of medical 3D printing over the past decade has followed imagination and problem-solving ways. Starting as a novelty with limited practical value, 3D printing has grown to find primary uses and acceptances in various industries, including engineering, car manufacturing, military manufacturing and healthcare. Although, the variety of these paths is impressive, it requires to combine efforts to satisfy a collective need. The concentrated efforts of 3D printing enthusiasts and 3D printing laboratories can address the critical deficiency of PPE during the global COVID-19 outbreak. This research aims at reviewing the role of 3D printing, especially in the production of face shields, to examine feasibility and engagement under the new Centre for Disease Control and Prevention (CDCP) and Food and Drug Administration (FDA) pandemic guidelines, and to propose a concentrated effort towards improvement of the 3D printing industries [30–32], as depicted in Fig. 4.

1.2. Relevance of 3D printing to the medical profession

Therefore, with these aforementioned new and comfortable guidelines, 3D-printed face shields have an exact role to play. Support and encouragement must be continued efforts across the country. Professional companies, such as Prusa Research, based in the Czech Republic, began sharing open-source mask designs and allowed anyone with a 3D printer to download and use the free plan. The family that buys 3D home printers can now print several hundred face shields in a week. On a larger scale, 3D printing manufacturers are also transforming their efforts to produce face shields and other PPE. In particular, the military and automotive industries include news organizations reporting joint efforts to work together in the military, consolidate resources, and determine the scope and volume of 3D printing resources [33–35]. Ford Motor Company has facilities that operate on 3D-printed PPE, including a facility that produces approximately 1,000,000 face shields per week in Plymouth, United Kingdom [36–38]. 3D printing factories have machines that support wireless connectivity and sensors. These sensors are connected to a system that can view and monitor the entire production line and make its own decisions. 3D printing uses smart manufacturing processes to manufacture primary disposable products to solve the COVID-19 outbreak deficiency [39–41]. This crisis provides a supply chain and intelligent disposable medical supplies of equipment, where patients can obtain essential medical supplies on time. In this comprehensive review, the applications and benefits of 3D printing technologies to manage the COVID-19 outbreak have been subsequently considered.

2. Outstanding benefits of 3D printing for COVID-19

Additive manufacturing technology has the capability of providing

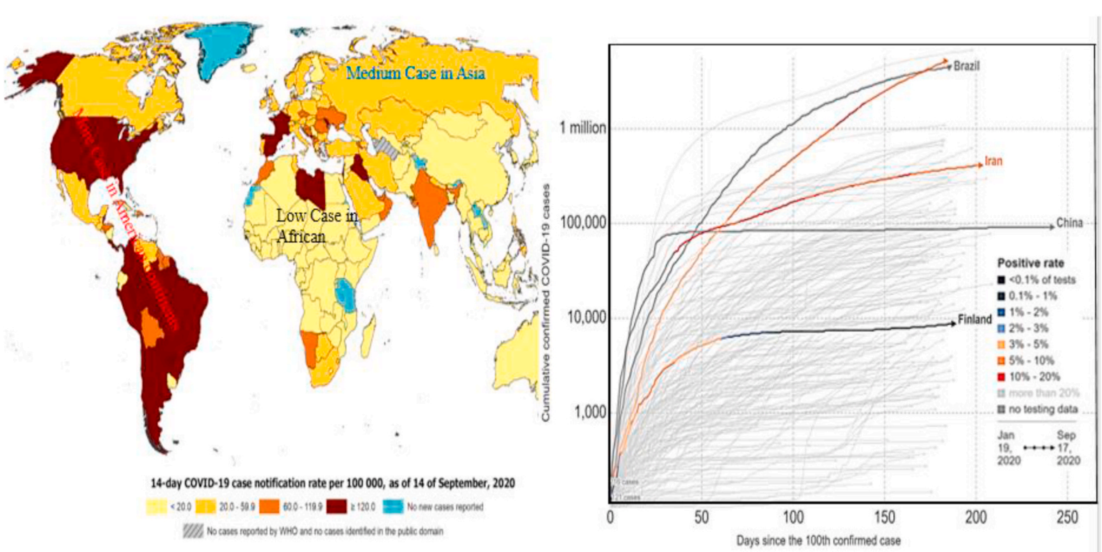

Fig. 2. Geographic distribution of a cumulative number of confirmed COVID-19 cases per one hundred population, worldwide, as of September 14, 2020 for the 14-day interval [24,25].

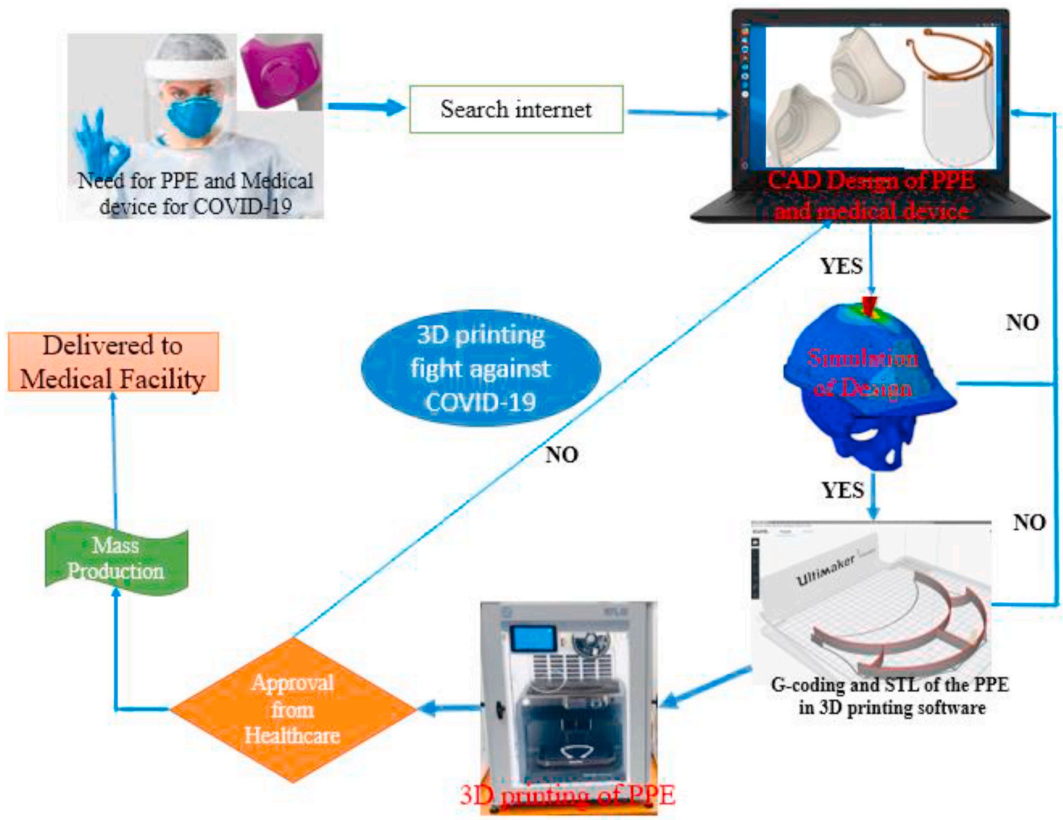

Fig. 3. Schematic process of the need, design and 3D printing of PPE to tackle the shortage of medical device during COVID-19 pandemic.

Fig. 4. The different 3D-printed respiratory antibacterial bio-cellulose masks that allow inflow and out of oxygen during COVID-19: (a) oxygen inflow for respiration, (b) nose and eyes biomaterial mask, (c,d) respiratory mask with an eye, (e) micropore nose antibacterial bio-cellulose mask and (f) lateral nose mask [17–23].

better digital solutions for daily lives during this crisis. More also, digital technologies include, but are not limited to, virtual reality, holography, 3D scanning, 3D printing and biosensing. These modern technologies support the effective printing of several and specially designed PPE relevant to combat the COVID-19 pandemic, with less stress, time, and material usage. The effects of limited testing and challenges in the attribution of death mean before the use of masks and lockdown and after the introduction of mask are represented in Fig. 5. Some highly affected countries controlled the death rate: China, UK and Iran, because of the quick intervention of lockdown and face mask to prevent the spread of the invisible killer. The 3D printing of different PPE helped to meet the demand. While some affected countries still experienced some

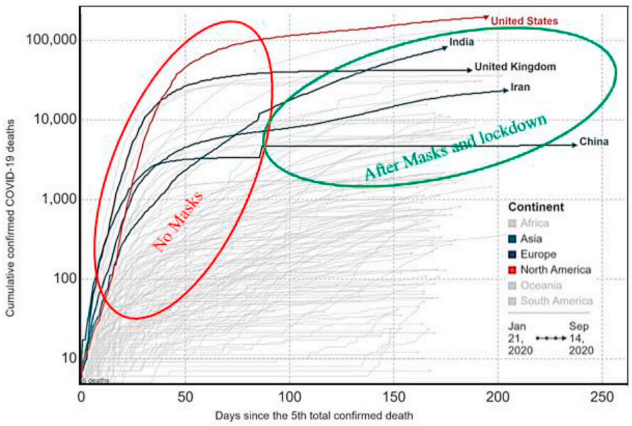

Fig. 5. a Cumulative number of confirmed deaths *versus* the number of days in continents, modified from Our World in Data chart points to establish the importance of face masks and lockdown mechanisms [66,67].

loss, due to their slow intervention. But for many countries, the spread was minima due to the introduction of use of PPE, which can be majorly attributed to 3D printing materials. The information presented in Fig. 5 is the latest data from the Our World in Data as of September 14, 2020, from the European update worldwide from January 21 to September 14, 2020.

2.1. 3D antibacterial bio-cellulose swabs lattice structure for COVID-19 test

As earlier mentioned, the Manufacturer Volumic has 3D-printed thousands of test tubes validated by the competent laboratories to detect the virus. This is good news for the health sector, which can rely on this type of solution and technology in emergencies. Volumic 3D prints the test tubes needed to screen for COVID-19. Further south, on the Nice side, Cerballiance, Volumic and LaFerme3D Laboratories have joined forces to produce COVID-19 testing tools, using 3D printing. In 3 days, a solution to the Cerballiance laboratory problem was provided, as explained by Stéphane Malaussena, co-founder of Volumic 3D. As of today, there are thousands of test tubes printed in France daily in an attempt to expedite COVID-19 screenings. Cerballiance, an initiator of the project, shipped the test tubes produced in Nice to its various laboratories on the territory (600 in France) and its conferees who need the equipment [42–45]. Volumic's boss stated that they continue to produce up to date since there is no instruction to stop production (Fig. 6).

Furthermore, printing glass objects is now possible, and the most common method involves either extruding melted glass or selective sintering laser heating ceramic powder, which is converted into glass. The former requires high temperatures and therefore requires heat-resistant equipment, while the latter cannot produce incredibly complex objects. Eidgenössische Technische Hochschule's (ETH) new technology aims to improve these two disadvantages. It contains a photosensitive resin consisting of liquid plastics and organic macromolecules that bond with silicon-containing macromolecules, in other words, ceramic macromolecules. Using an existing process called digital light treatment, the resin is exposed to the pattern of ultra-violet (UV) light. Plastic monomers are cross-linked to form solid polymers wherever the light hits the wax. The polymer has a maze-like internal structure, and the space inside the maze is filled with ceramic macromolecules [46–48]. The resulting 3D object is then burned at a temperature of 600 °C, burning the polymer, leaving only the ceramic. In the second roasting, the roasting weather is about 1000 °C, and the ceramic is compacted into the transparent porous glass. The object does shrink significantly when converted to glass, which is a factor that must be taken into account in the design process. Although, the objects created so far are small, the shapes are somewhat complicated, as reported. Also, the aperture can be adjusted by changing the UV intensity, or other properties of the glass can be altered by mixing borate or phosphate into the resin. A major Swiss glassware distributor has expressed interest in using the technology, which is similar to the equipment developed by the Karlsruhe Institute of Technology in Germany [49–51], as shown in Fig. 7.

2.2. 3D-printed antibacterial bio-cellulose masks and respirator valves

COVID-19 ravaged Italy. Despite the medical system in the country, Italy was overwhelmed. According to the latest statistics on March 19, 2020, Italy recorded 3405 deaths from the outbreak. The data for the first time was more than the total death outbreaks recorded in China. To save Italy, the European 3D printing industry moved to solve the urgent problem through open masks but of antibacterial bio-cellulose materials, small door-to-door objects of 3D printing design files, and helped in a rush to print respirator valves [52–54]. The outbreak of pneumonia in Wuhan, Italy was out of control; the number of confirmed explosion struck and collapsed the medical system. To help the first line of medical care share the pressure, the European technology industry has to assist them. The first is in the mask section, although the antibacterial bio-cellulose mask is essential for the public to fight the virus. Still, because the outbreak was snapped up, Italy's 3D printing industry brain-headed, launched a *Pugliese-Sicilian* open original code [55–57].

The team behind the programme, which builds a web platform that allows users to freely download mask design files to print antibacterial bio-cellulose masks at home with 3D printing devices, as reported by their program's leaders. They built a platform that everyone can adapt, improve and spread, and hope to find other applications in the future, in addition to fighting viruses. Also, 250 patients with coronavirus were in intensive care at a hospital in Brescia, Italy. Still, they all needed respirators, which were in short supply and must be replaced for up to 8 h each, but suppliers have suddenly burst into collection, because of market demand [58–60]. At this point, Cristian Fracassi, chief executive of Isinnova, an Italian 3D printing manufacturer, decided to come forward and, within 3 h of studying the valve, returned to the hospital with a 3D-printed respirator valve prototype (Fig. 8a and b) to test the

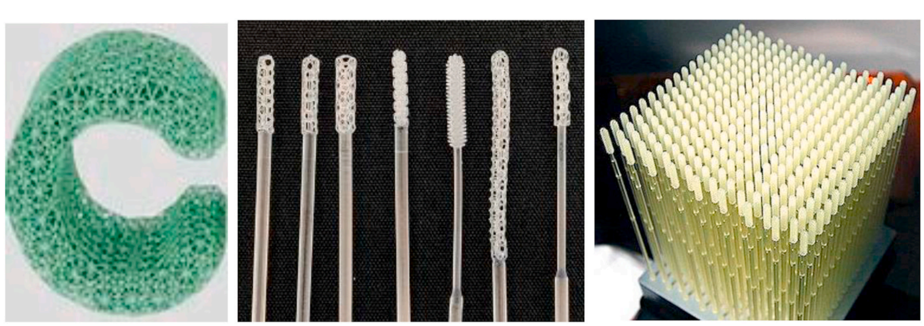

Fig. 6. Lattice structures of the 3D-printed antibacterial bio-cellulose swabs were produced for the COVID-19 test [34–38].

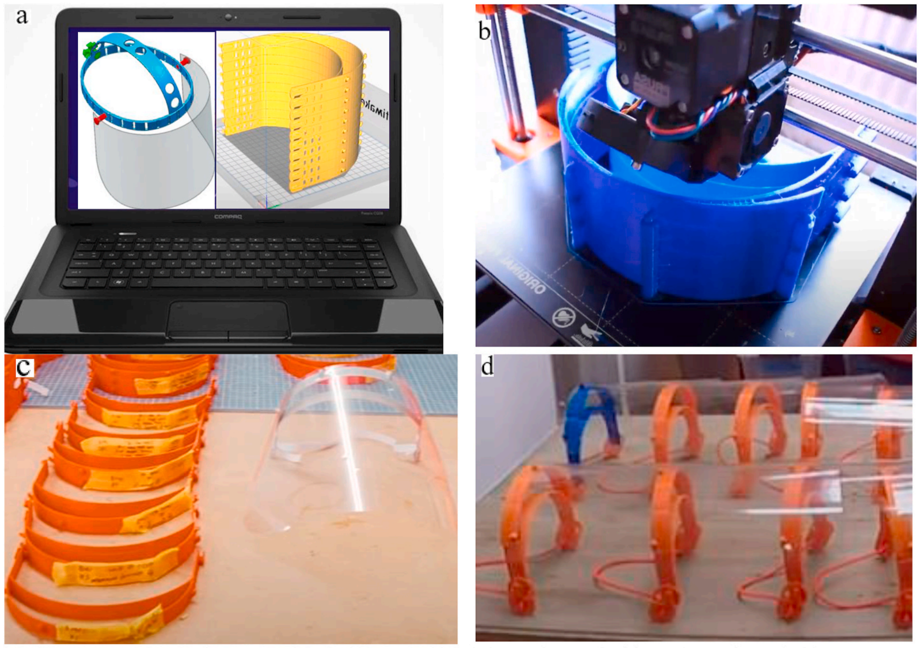

Fig. 7. 3D printing of respiratory face shield using double-sided tape, showing the (a) computer-aided design (CAD) of Face shield holder and shield, (b) 3D printing process, (c) finished product of the shield holder and (d) complete face shield holder with films.

patient. When they found out that the valves made out of 3D printing could work, they immediately returned to the Company to start a large number of printing, quickly put into production. It took a day to design and print 100 respirator valves for a hospital, successfully solving the shortage of hospital medical equipment [61–64]. Fig. 8c represents different designed, coding and 3D-printeddoor opener.

3. The development of respirators through 3D printing

Central News Agency reporter Dai Yazhen London 24 thumped by Wuhan pneumonia, the demand for respirators increased, cross-cutting team to develop rapid deployment, and production of respirators is now entering the clinical testing stage. The cross-disciplinary team, led by engineers, anesthesiologists, and surgeons, aims to develop a production model for breathing equipment that meets safety and stability needs and uses off-the-shelf components to increase the capacity of respirators in the UK [65–67]. Research of Oxford University, School of Engineering says the time of crisis or pandemic requires extraordinary responses. They assembled an excellent team with endless creativity and outstanding skill levels, using their experience to transform existing research results into devices used in medicine. The team is building and testing a new respirator prototype that can be produced by universities with equipment, as well as small and medium-sized businesses, to address the massive demand for respirators in the UK in the face of the invisible killer (COVID-19) outbreak (Fig. 8). The team said that by developing an open-source design that meets security and stability needs and complies with local laws and regulations, it would achieve significant capacity potential through decentralized production. Under government regulation and market competition, better models will be developed, universities, small and medium-sized enterprises, and factories will be able to produce from existing equipment, assemble local medical facilities, and adjust capacity to local needs, thereby reducing the pressure on the National Health Service (NHS) to allocate medical resources [68–71]. Farmery, a professor at the School of Clinical Neurosciences at The University of Oxford's Nuffield and Wadham states that medical equipment development usually takes several years and is an extensive project. They designed a reliable and straightforward breathing device to meet the needs of critically endangered patients during an outbreak with the collaboration of experts, the open-source design, and the fast approval process. They are pleased to be able to take such a rapid step into this outbreak. Not only do, but they also have to share their experiences with countries that don't yet have the resources to have a ready-made respirator, and they are continually improving this relatively low-cost technology. A researcher from the Oxford University, School of Medical Engineering in Taiwan assisted in mechanical design, 3D modeling, and printing in this project (OxVent). He studied biomechanics, bone dynamics, gait analysis, 3D printing, and modeling, and has served as President of the Robotics and 3D Printing Society at Oxford University [30,31,72–75], as depicted in Fig. 9, Also designate from Oregon designed and fabricate ventilator prototype in March 2020 with a 3D-printed prototype with bearings and wheels.

Mr. Zhan appreciated the 3D printing technology for reducing the time it takes to manufacture and test prototypes. And, 3D-printed components can be distributed and produced rapidly around the world, helping countries with scarce medical resources. They are developing day and night in the hope of contributing to the outbreak of pneumonia. The UK is hit by new coronary pneumonia, and demand for respirators has increased, with Oxford University and a cross-cutting team at King's College London developing rapidly deployable and produced respirators that are now in clinical testing.

4. Shortage of medical supplies: Rescue through 3D printing

Under the outbreak of new COVID-19 pneumonia, some local medical supplies are in short supply, 3D printing technology is widely available, print protective antibacterial bio-cellulose masks, among others. It helps to ease the tension of materials. There are also some 3D printing epidemic prevention supplies. The UK has set up its online platform, 3D Crowd UK to recruit volunteers to work on 3D-printed antibacterial bio-cellulose masks. As of Friday, April 10, 2020, the website received requests from local health care for 500,000 3D-printed antibacterial bio-cellulose masks, bringing together more than 6000 volunteers as of preceding Monday. In Hertfordshire, England, a software engineer responded to the call by using two 3D-printed macromolecular mechanisms to remove 150 masks from his home and gave 39 of them to local nurses and midwives. Maker Nexus, a California-based

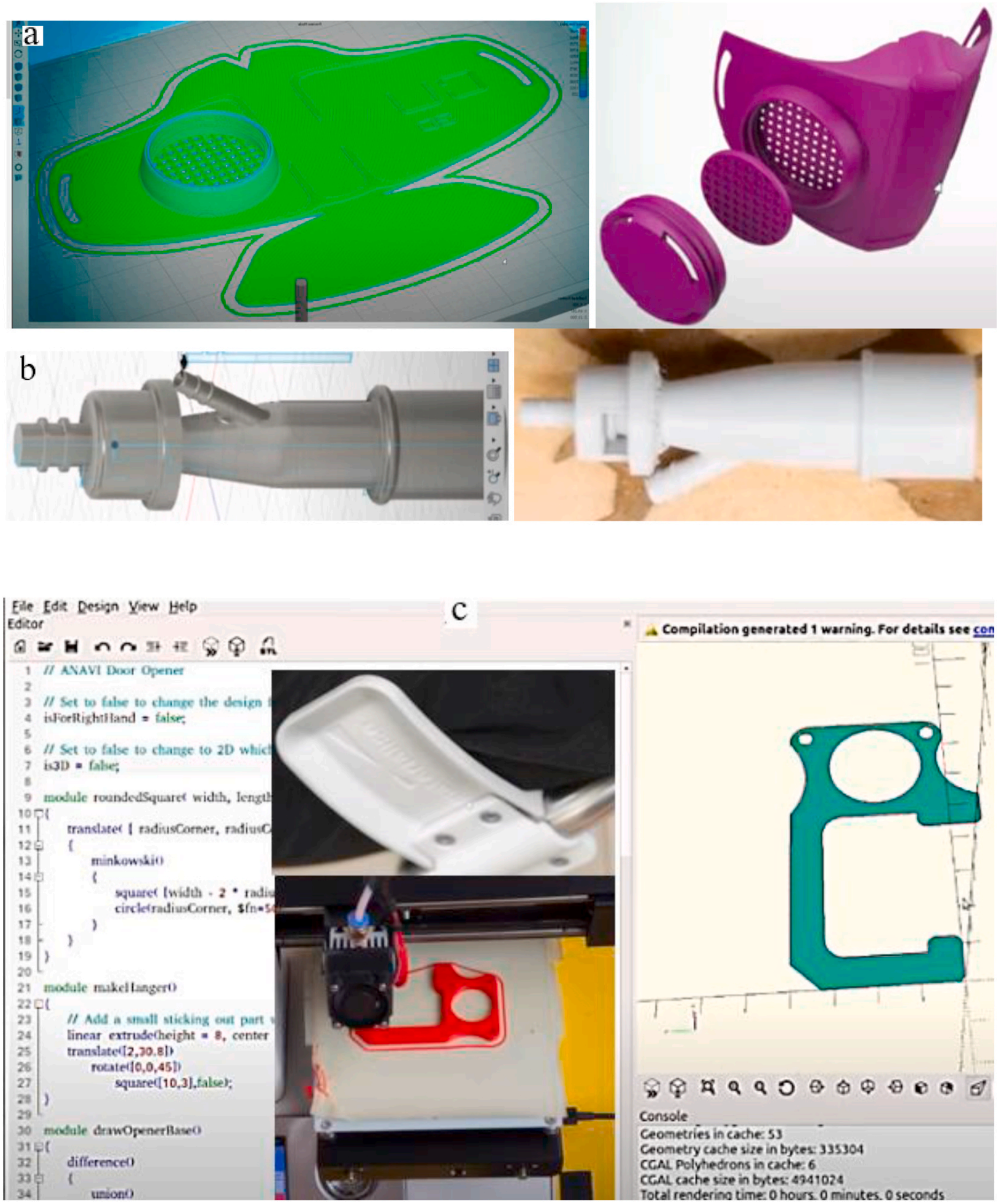

Fig. 8. A respirator valve made of 3D printing, showing (a) 3D printing of a respiratory face mask, (b) CAD model and 3D-printed respirator valve and (c) different designed, coding and 3D-printed door opener.

non-profit organization, uses 13 3D printers and three laser cutters to make 1800 protective antibacterial bio-cellulose masks for local hospitals, and General Manager Eric Hess says 300 volunteers help search the web for raw materials for making. In daily life, the door attendant is less necessary to touch the door handle. Still, the door handle is easy to become a virus temperature, Belgian Company materializes a screw-free hand door opener, as previously shown in Fig. 8b, made with 3D printer within 4 h, only three ropes can be fixed in the door handle, with arm down to open the door, without touching the door handle. Hence, it reduces the risk of infection [76–79]. It was initiated by 3D natives and mobilized industrialists, such as L'Oréal, Schneider Electric, Renault, and Faurecia, to mass-produce hospital staff visors.

Also, 3D-printed circuit splitter and flow restriction devices for multiple patient lung ventilation and Prusa protective face shield - RC2 have been invented. The makers are involved in the fight against the pandemic, such as the collective La Fabrik-Ephémer, where some forty passionate handymen make up to 600 visors a day in a space made available municipality. Initiatives of this kind are multiplying [80–82]. The University of Nantes (Loire-Atlantique) has teamed up with the *Centre Hospitalier Universitaire* (CHU) and the industrial Armor to design protective visors. At least 800 were delivered to the hospital. Each is designed with polyethylene terephthalate glycol (PETG), or glycolysis polyester, which adds a supporting elastic and a headband produced by Armor. The whole device is assembled in The West Hall 6 on the island of Nantes. In the Yvelines, the Renault group has mobilized its Flins site and the Technocentre in Guyancourt to print 2000 visors for the André Mignot hospital in Chesnay-Rocquencourt [83–85].

4.1. Involvement of other non-medical manufacturing companies

In this race against time to equip caregivers, machine manufacturers have made all their capabilities available. The American Hewlett-

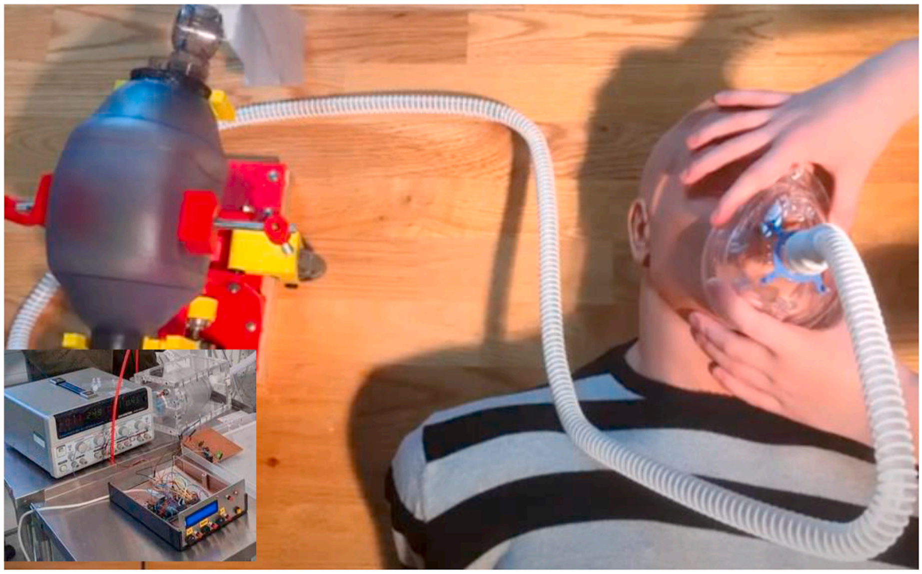

Fig. 9. 3D-printed ventilator and respiratory system in Oxford University [30–33].

Packard (HP) Company has published in open source five digital plans validated and adapted to its machines. Its emergency catalog ranges from the *elbow handle* for doors to protective visors. Nicolas Aubert, director of 3D printing at HP France, argues that they are reaching relatively large production volumes. This is the advantage of an industrial system. HP's machines, such as fellow Stratasys, use powder bed fusion technology rather than wire-depositing technology from desktop printers [86–88]. They can produce several parts at the same time: in a single print, an HP machine has 70 visors simultaneously, in 24 h. And the details are more vital, resistant in particular to high-temperature sterilization in an autoclave, making them reusable. Another advantage is that production is relocated to customers. Jos Burger, chief executive officer (CEO) of desktop printer brand Ultimaker reported that they connected more than 4000 printers worldwide in less than a week to Universities, designers, makers, engineers, among others. It has a whole network coming together [89–91]. HP mobilized its L'Oréal and Decathlon customers, and Stratasys formed a coalition of more than 150 companies, including Boeing, Toyota and Medtronic. They are brands that link the requests of the hospitals to different points of production. They also connect with design experts, biocompatibility, and designers. This is enough to create an entire ecosystem of open innovation, involved in an unprecedented mobilization [92–94].

5. Progress of 3D printing in medical

5.1. 3D-printed medicals

A year ago, some medical practitioners were worried that advances in 3D printing would put them out of work. Medicine is one of the fields that will have a revolutionary impact on 3D printing. In contrast, repair doctors and other medical practitioners are worried that traditional industries that were otherwise "calm" have been invaded by the new 3D printing technology [94–96]. According to the research firm Industry Arc, the global 3D printing market will reach $1.2 billion by 2020 [96–98]. It is a technology that uses a digital object created in the software, with melted plastic or metal powder, superimposed on layers on a 3D scale. 3D printing technology existed as early as the 1980s. However, 3D printers, priced between $2000 and $8000 and small enough to be on a table, have only begun to appear in the last decade. The latest medical applications of 3D printing started a few decades ago. In 2016, 3D printing continued to thrive in the healthcare industry. The world's first 3D-printed prescription drug, Spritam, was approved by the US FDA in March 2020, it has gone on sale. 3D-printed medical devices now cover surgical instruments and human implants, such as certified Medical Shape titanium bone connecting plates [98–100].

Institutions, such as Boston Children's Hospital, are also increasingly using 3D-printed organ and bone models to plan and practice complex surgeries. Earlier this year, the Department of Neurosurgery at the University of St. Louis and the St. Louis School of Engineering jointly designed a highly simulated, 3D-printed brain aneurysm [99–101]. Stratasys, one of the world's largest manufacturers of desktop and industrial 3D printers, produced the final model. All aneurysms are different in size, contour, and position, as reported by Saleem Abdulrauf, director of neurosurgery at St. Louis University Hospital. There are hundreds of different sizes and types of surgical clips. The decisions on which one to choose are made during surgery. He said that practice on the model in advance and select an excellent surgical clip model can improve the procedure after simulating surgery on a 3D-printed aneurysm model [100–102].

5.2. Prosthetics, 3D-printed trachea splints and stratasys brain model for surgical simulation

Analysts have predicted that 3D printing will be a disruptive force in the healthcare industry by 2020. According to research by Gartner Study, one in ten people in developed countries will have 3D printing devices physically or in the body by 2019. Also, about one-third of remediation and implant surgery will use 3D printing as a core tool [101–103]. Prosthetics are a good example. It shows how 3D printing can improve people's lives. Typically, making a prosthesis involves measuring the rest of the limb's size, creating a plastic replica, and then hand-out the specification improvement score. Standard Cyborg, a San Francisco-based start-up, sells 3D scanners and software that allow customers to make prosthetics, modify shapes and print them out. The result is a fully functional prosthesis that is made available in a short time. In contrast, traditional methods of making prosthetics take 4 h [66–69].

Lei Feng stated that, at first, practitioners considered 3D printing as a threat. Now, Jeff Huber, co-founder of Standard Cyborg, said that his clients and the repair doctors are more likely to introduce 3D printing and design into clinical applications [68–70]. The main reason for the shift is that 3D printing allows experts to create complex geometric shapes to ensure a precise fit. Machines are not intimidated by complexity, and for patients, a more refined design delivers superior comfort. 3D printing also allows surgeons to treat patients with the help of a copy of the human anatomy. Researchers at the University of Michigan, for example, worked with surgeons at C.S. Mott Children's Hospital to develop 3D-printed trachea splints that were implanted into five children with congenital bronchitis. Developers are applying for special FDA permission to treat more patients [68–71], as the quest to improve health care continues.

5.3. Ethical considerations for 3D-printed PPE for COVID-19 and other related medical applications

It is evidence that Additive manufacturing has complete applications in biomedical engineering. It has been well integrated into the medicine and pharmaceuticals for organ/tissue bio-printing and drug delivery, respectively [104,105]. This is attributed to its capability to provide patient-specific design, on-demand, cost-effective printing, high productivity, and complexity, to mention but a few [106]. Presently, AM/3D printing technology has been effectively used to print various PPE to combat the invisible killer (COVID-19). The conceptual design stage of PPE, creation of low-price and customized precise anatomic prostheses (such as lower limbs, hands and arms) and orthoses (foot, ankle-foot and wrist splints) [106], among other artificial body parts utilized in various medical applications. The use of those above 3D-printed medical safety devices/PPE, patient-specific prostheses, and orthoses required careful ethical considerations and approval by the authorized medical/health organizations.

The ethical issue includes whether AM products meet the stringent medical requirements, especially given AM's potential to be employed for long-term COVID-19 and other related medical applications. For example, there is an ethical concern (challenge) with the 3D printing of PPE against COVID-19. This includes PPE material reaction with other substances: water, sweat, chemicals, such as different types of sanitizers, among other medical sterilization materials, with human body parts (especially face/head and hand). Care must be taken to ensure that none of these materials has health risks or hazardous effects on the users. Also, PPE's cost should be affordable to avoid widening the gap between the rich and poor. Both the 3D printing process and product tests are very pertinent for human safety. Importantly, the government has started regulating the workflow associated with 3D printing in medicine by weighing the benefits and disadvantages of this innovative and revolutionary technology. This involves preventing the possibility of making unprofessional and destructive changes to the digital file when creating an organ after hacking into the 3D printers. The concern is that how will this injurious act be known earlier than the time that the 3D-printed organ started displaying trouble, shortly after transplant and when it is in full use [107]. The principal ethical consideration in device regulation is to avoid acceptance of a high level of risk during the market approval stage. Hence, both pre-market and post-market studies, investigation or compliance must be enforced [108] to protect health care providers and patients.

Furthermore, the cost of 3D printing-assisted treatment offer to the patient is a serious ethical issue. This may not be affordable or inexpensive if the medical application of 3D printing is left in the hand of the private health care sector. It is worth remembering that one of the main goals of a private company is to maximize profits. Also, there is an anticipated lengthy procedure and time before the patient can benefit. Therefore, patients may decide to pay more to get the service. This may lead to the crime through organ smuggling. It is an ethical measure for the government to regulate the cost of 3D printing-assisted treatment. Also, it may end up becoming a technology for wealthy people only. What will be the hope of the poor? If measures are not properly taken, there may be a repetition of the past with 3D printing technology. There was a wide discrepancy between the poor and rich in terms of medical treatments. Though 3D printing is already in the customer-use domain, 3D printers designed for medical applications are insufficient [107].

Close to the aforementioned points is to know the efficient method to test the 3D printing-assisted treatment. Foremost, the treatment's safety must be guaranteed before the treatment is made available for the patients. It is expected and mandatory that all the human or *in-vivo* tests must be accurately conducted, and the results obtained must be 100% satisfactory. Moving forward, the usage of the 3D printing-assisted medical treatment must be stringently regulated. This should involve numerous 3D printing applications in the medical sector, including essential and personal enhancements, such as cosmetic surgeries. The essential medical treatment should be regulated, while the non-crucial counterparts are ignored. To identify the differences between the two may be a challenge because it depends on individual interest. The government can help to find the difference and make decisive regulations [107]. These regulations include design control (21CFR820.30), purchasing controls (21CFR820.50), traceability (21CFR820.65), production and process control (21CFR820.70), process validation (21CFR820.75) as well as acceptance activities (21CFR820.80), among others [108]. The introduction of new and manageable regulatory considerations are expected from new processes, materials, and value chains of 3D printing technology [108].

Moreover, present ethical challenges of using 3D printing technology for medical purposes include, but are not limited to, availability, acceptance, and approval of some AM processes and volunteers for *in-vivo* tests. Also, the absence of recent international regulatory directives to guide these tests is a part of the limitations [110]. For instance, there is no developed 3D bio-printing strategy by the European Union, despite the commercialization of numerous 3D bioprinting applications. However, these drawbacks are not insurmountable, as there is an increase in the number of people who are making themselves available voluntarily for COVID-19 drug trial tests recently. Also, support and ethical approval from medical organizations are increasing. However, some American companies hesitate to adopt 3D printing technology because of US FDA regulations' complexity and the requirement of long days for approval [108,109]. Also, xenotransplantation has some ethical dilemmas (cross-species transplantation, especially from animal/human to human). When it is between humans, it is unethical if the donor is not well informed of either current or future use (or both) of his/her cells and tissues. Therefore, a consent form is needed to contain full details of the bio-printed part composition, implantation procedure, all possible results, all conflicts of interest as well as prospective adverse effects [111].

Summarily, in a bid to maximize the potentials of 3D printing to fight COVID-19 in addition to other related medical applications, it must be well regulated by carefully bearing in mind all the possible related ethical issues. Now, can mutated organs be 3D-printed for a healthier lifestyle and, consequently, a longer life span, probably to live for 15 decades on earth? [107]. The bright and promising future of 3D printing-assisted medical treatment has the answer to give.

6. Concluding remarks

A comprehensive evaluation of relevant biological safety endpoints in compliance with relevant ethical regulatory directives and applicable safety standards, such as the biological safety standards series ISO 10993 for antibacterial bio-cellulose masks and Ventilator, is essential. Any vapors, wear debris, degradation products and processing residues that may be released from the 3D- printed part must be demonstrated to be non-toxic to a high level of assurance. The respiratory illness due to the COVID-19 pandemic can be reduced and may be stopped eventually, using AM technology. The steps involved in the supply chain management of ventilators must be increased with AM to produce more PPE to prevent the spread of COVID-19. The 3D-printed face shield is well accepted in several interventions. 3D printing provides an automated solution for various manufacturing industries and other related fields to produce medical equipment during the COVID-19 crisis. AM technologies provide an innovative method to adequately isolate the infected patient to reduce high mortality risk . With the application of 3D printing technologies, efficient production of PPE and other medical equipment is possible. 3D printing can work remotely with smart technologies that are useful for monitoring and prevention of COVID-19 spread. In any environment with a high oxygen atmosphere, fire risk is certainly a concern and should be discussed and mitigated. In the authors' opinion, during the COVID-19 pandemic, all of the above risks are outweighed by the benefits of protecting healthcare professionals and enhancing patient safety during this global crisis, using innovative and revolutionary 3D printing technology. As a respiratory disease, due to the COVID-19 pandemic spreads across the world, healthcare systems and national governments face the difficult challenges of getting ventilators to help several patients. AM/3D printing technology can ensure that antibacterial bio-cellulose masks and ventilators, among other equipment, get to patients and prepare us better for such viral outbreaks in the future, probably and undesirably in the next ten decades.

Ethical statement

The authors declare no ethical issue; the study was conducted in full agreement with ethical standards.

CRediT authorship contribution statement

Bankole I. Oladapo: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing - original draft, Visualization. **Sikiru O. Ismail:** Supervision, Writing - review & editing, Resources, Validation, Project administration. **Temitope D. Afolalu:** Writing - review & editing, Methodology, Conceptualization, Resources, Data curation, Validation. **David B. Olawade:** Investigation, Data curation, Conceptualization, Methodology, Validation, Project administration. **Mohsen Zahedi:** Resources, Writing - review & editing, Visualization, Validation.

Declaration of competing interest

The authors declare that they have no known competing for conflict of interest, financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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