Original papers

Additive manufacturing technologies enabling rapid and interventional production of protective face shields and masks during the COVID-19 pandemic

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Abstract

Background. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is transmitted through respiratory droplets and contact routes, hence the demand for personal protective equipment (PPE) has increased during the outbreak of coronavirus disease 2019 (COVID-19). Among the most noticeable shortages was the lack of face shields. The urgent demand for PPE induced interdisciplinary cooperation to overcome the shortages, and additive manufacturing proved to be ideal for the crisis situation.

Objectives. To investigate the possibilities of implementing additive manufacturing technologies in the interventional fabrication of protective face shields for medical staff.

Material and methods. An Ender 3 Pro 3D printer was used to print headbands and Cura 4.4 was chosen as the slicing software. Open source face shield designs were downloaded as standard tessellation language (STL) files and compared. Only models with scientific support were taken under consideration.

Results. The mean time for producing the headbands tested ranged from 59 min to almost 3 h, depending on the design. After setting up our low budget printer and choosing the Prusa RC 3 protective face shield as the main product, we were able to fabricate about 30 face shields per week at a cost of about €1 each. During 4 weeks, 126 face shields were produced and delivered to various hospital wards, which substantially eased the shortages.

Conclusions. Additive manufacturing enables immediate responses to needs in emergency situations, and allows for mass production of personal protective equipment in a short time due the rapid exchange of data among printer users. Despite the unregulated legal situation and insufficient scientific evidence, such protective equipment has been approved by clinicians and is currently used by medical personnel around the world.

Key words: personal protective equipment, additive manufacturing, 3-dimensional printing, COVID-19, face shield

Historically, each pandemic has provoked many unexpected changes in both national and international health systems.[1,2] This is due to the fact that the course of a pandemic is always unexpected, often characterized by a turbulent course and social panic.[3] From the first well-documented pandemics like the plague or Spanish influenza to recent well-known and widely studied epidemics like Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS), it is clear that international efforts to contain a given pathogen should always be multidisciplinary and multistage.[4–6] The first medical doctors, researchers and people combating with a new and unknown disease have very quickly noticed that apart from the search for the biological causes of a pandemic or the search for a remedy in the form of an active drug or vaccine, another important aspect is to quickly introduce preventive methods and tools that minimize the number of infected persons.[7,8] The current coronavirus disease 2019 (COVID-19) outbreak, which was initially a regional problem, is now an emerging global challenge involving health care, governments and international institutions.

Classification of the novel coronavirus

The virus causing COVID-19 was tentatively named by the World Health Organization (WHO) as "2019 novel coronavirus" (2019-nCov). However, the Coronaviridae Study Group of the International Committee on Taxonomy of Viruses classified 2019-nCoV and renamed it "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) on the basis of scientific evidence.[9]

SARS-CoV-2, like MERS-CoV and SARS-Cov, belongs to the Coronaviridae family[9], and causes similar symptoms in humans, including fever, dyspnea, cough or gastrointestinal manifestations, often leading to pneumonia or severe acute respiratory illness.[10–12] The original place from which COVID-19 derived is the city of Wuhan in Hubei Province, China, from where it spread worldwide.[13] The origin of the virus is still unknown and controversial. Most papers suggest that the probable explanation is that SARS-CoV-2 is a β-coronavirus with a genome very similar to bat coronavirus, which progressed into human-to-human transmission through a seafood market zoonotic infection.[14,15]

Infectivity and uniqueness of SARS-CoV-2

The first clinical reports raised concerns due to the high mortality and transmissibility of SARS-CoV-2.[16,17] Subsequent reviews showed that the infection demonstrates an exponential model of growth, doubling in just over 6 days.[13] Moreover, information about the virus being spread by people with no signs of the disease appeared which indicated that preventing SARS-CoV-2 transmission could be very challenging.[18,19] Other factors involved in the exceptional virulence of the virus are its viability in aerosols and durability on various surfaces, like SARS-CoV-1. Studies have shown that SARS-CoV-2 remains stable for up to 72 h on plastic and stainless steel, whereas in aerosols it remains viable for 3 h.[20] Further research found that the virus may be transferred through airflows and settle on protective personal equipment (PPE) as well as on objects in the closest environment of infected people.[21] Therefore, global prevalence of the pathogen has become inevitable.

All of the above has made the virus an unusual opponent. As a result of insufficient effectiveness of the fight to contain it, on March 11, 2020, the WHO announced that we are currently dealing with a pandemic.

Additive manufacturing versus the pandemic

The international struggle against COVID-19 requires the use of similar resources, which rapidly leads to their depletion. Shortages of PPE on the front lines raised deep concerns due to the effects on pandemic development and patient care.[22]

In response to the growing demand for PPE for healthcare workers, there have been grassroots initiatives, industrial efforts and scientists using different approaches to produce medical equipment. Especially during the first phase of the pandemic, additive manufacturing (AM) was perfectly suited to the mass production of PPE.[23] Additive manufacturing techniques, commonly known as 3-dimensional printing, have made appreciable progress since their implementation in the 1980s. Their complementary advantages, such as the ease of use, low costs and a wide range of materials allow for rapid adaptation to immediate needs.[24,25] Moreover, their flexibility means they can be used in many different branches of science and industry.[26,27] The most common 3D printers use fused deposition modeling (FDM) technology, where the nozzle releases a heated filament onto a moving platform and, layer by layer, recreates a previously designed shape.[28]

During the COVID-19 pandemic, the adaptability of AM has become particularly apparent. The online community was able to share ideas for 3D-printed devices (Fig. 1) from the very first days of the pandemic.[24,29] Open-source websites made it possible for hobbyists and specialists to meet, and peer-to-peer comments allowed for quick data exchange.[30] The aim of this paper was to review and analyze the current additive manufacturing technologies enabling rapid interventional production of protective face shields for medical staff during the SARS-CoV-2 pandemic.

Material and methods

In order to choose the most optimal solutions, it was necessary to establish an action plan. The following steps were defined by our team: identification of possible problems;

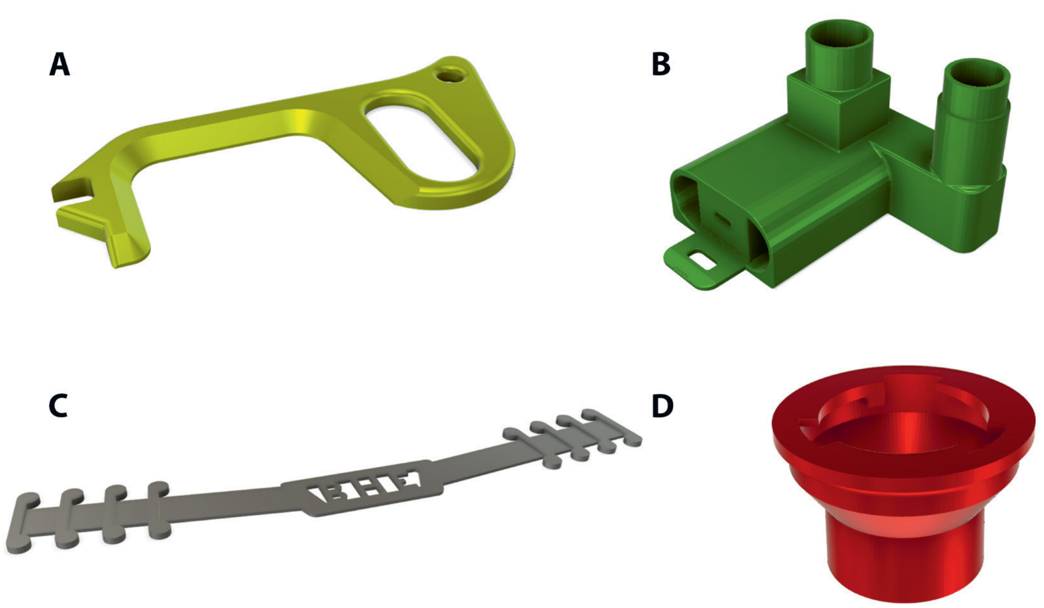


Fig. 1. Available designs for COVID-19-related devices

A – contactless door opener; B – adapter valve for converting a snorkeling mask into an oxygen mask; C – mask extender to reduce pain from wearing a mask; D – Secura mask connector to a DAR filter.

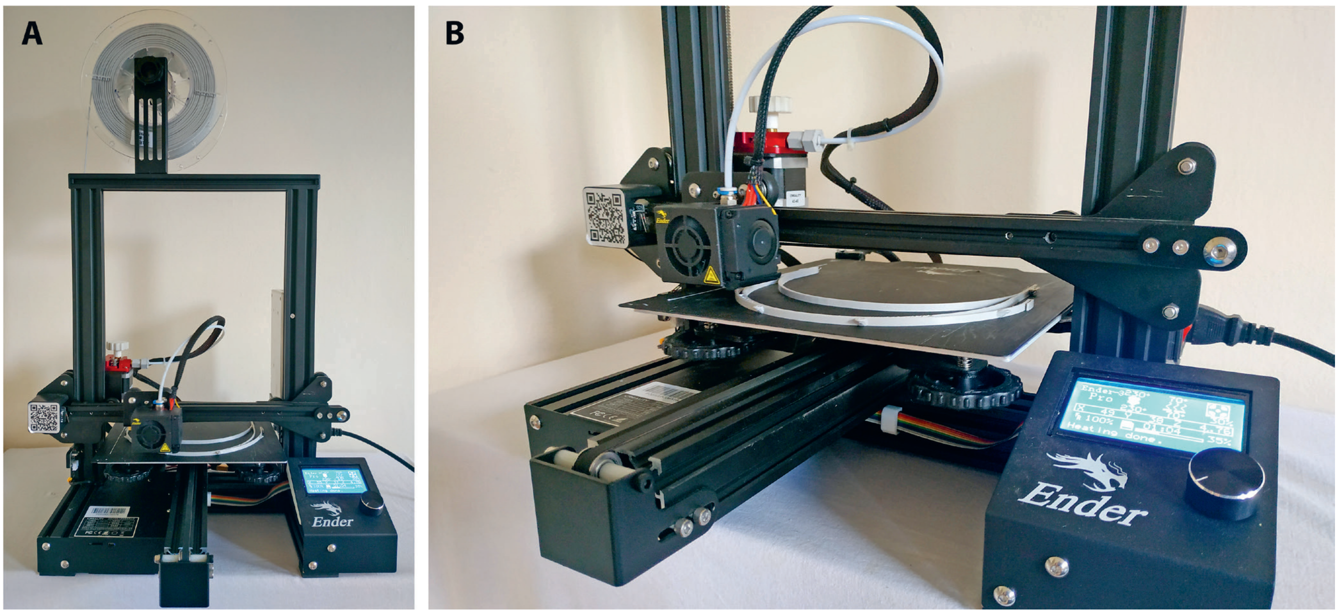


Fig. 2. Ender 3 Pro Creality

A – overall view of the printer; B – layer-by-layer process of face shield production.

test of available face shield designs; fabrication of a prototype series; assessment of usage in clinical conditions; "mass" production and extensive evaluation under real conditions. In the last days of March we intensively tested different designs of visors and assessed our capacity.

Face shields as standard tessellation language (STL) files were downloaded from the official web pages of the inventors. A low-budget 3D printer capable of producing accurate models[31], a stock version of Ender 3 Pro (Creality 3D Technology Co. Ltd, Shenzhen, China) (Fig. 2) was used for production, and Cura 4.4 freeware (Ultimaker, Utrecht, the Netherlands) was chosen for the slicing process. For prototyping, testing various available models and ultimately printing the first series, polylactic acid (PLA) was used due to availability and ease of use. After the test series we changed the filament to glycol-modified polyethylene terephthalate (PETG) due to its higher temperature resistance, durability and proven safety.[32]

We have decided to describe only our experience using PETG. Despite the fact that PETG is a recommended material for face shield manufacturing, its use is controversial. To the best of our knowledge, there have been no comparative studies about PETG sterilization methods and usage protocols in this kind of situation.

We had to adjust some of our printing settings in Cura. As a result of durability tests, the height of a layer was set to 0.28 mm with 20% infill. A 0.4 mm nozzle was used and the temperature was maintained at 230°C, with a bed temperature of 70°C. After the test series and having established a satisfactory ratio of quality to speed, the printing speed was set at 60 mm/s. The most problematic issues were the retraction distance and retraction speed; in the end these were set to 4 mm and 25 mm/s, respectively. Incorrect retraction would cause so-called oozing, affecting the surface smoothness and the overall appearance.[33] All of the face shields delivered to the medical departments were printed at the given settings.

Results

A multitude of face shield designs

We followed the developments and experiences of other groups and finally decided to implement AM techniques for the production of face shields, a shortage of which had been officially reported in our region. In our review during the tests, we took into consideration available designs of visors with scientific support. All of the designs presented in Table 1, apart from the so-called peaked headband, which is popular in Poland, have undergone review in a clinical setting by the National Institutes of Health (NIH; Bethesda, USA). The general assumption of all the designs is the same: A 3D-printed framework is combined with elastic rubber and a transparent visor.[34] It is worth pointing out that all of the resources necessary to produce a face shield can be obtained online without leaving home.

Simplicity of production and significant support from many institutions, laboratories and clinicians in our region were our main reasons for choosing the Prusa RC 3 protective face shield (Prusa Research, Prague, Czech Republic; https://www.prusaprinters.org/prints/25857-protective-face-shield-rc1) (Fig. 3). Moreover, the design was developed and analyzed in accordance with the Czech Ministry of Health guidelines. It is noteworthy that the assembly time for this design is about 30 s.

The use of buttonhole rubber (0.6–1.2 mm wide, polyester, purchased by the meter), commonly available in sewing goods stores, means that it is possible to adjust the face shields regardless of head circumference.

For the face covering, different materials may be used depending on accessibility. It is possible to use 0.2–0.7 mm PET foil formed in sheets or available in A4 format. The stiffness of this material increases with thickness; however, the thicker it is, the more difficult it is to process, especially without a laser plotter. We mainly used document-binding covers (A4, 0.2 mm). Thicker foils were harder to obtain and significantly more expensive, due to mass production of face shields in our region. The foil sheets were perforated with a standard office hole puncher and clamped into designated pins.

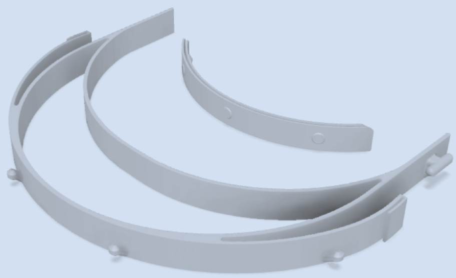
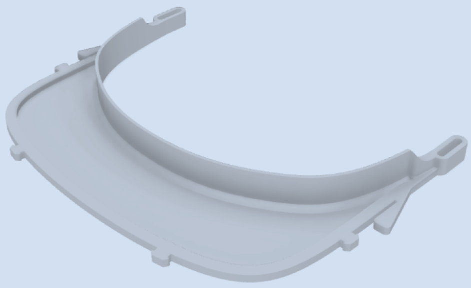
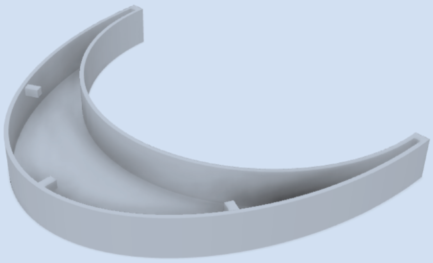
Fig. 3. Prusa RC 3 protective face shield

Due to the urgent demand for PPE, the US Food and Drug Administration allows production of 3D-printed visors outside of the normal mode if they are printed in accordance with instructions.[35] There are various regulations in different regions of the world and it is essential to follow the appropriate authority guidelines. Despite controversies, these visors are accepted and used by medical staff all over the world and are constantly tested by specialists and clinicians. There is a lack of robust evidence in this area, but it is encouraging that the first scientific reports on the use of 3D-printed face shields have appeared.[36]

Financial aspects

Printers that allow continuous operation and provide relatively high quality are available in the €200–300 price range. The approximate price of 1 kg of average quality PETG filament is about €18, but the cost of each face shield depends on the printing quality and reliability.[37] In our case it was possible to fabricate an average of 28 face shields from 1 kg of PETG, resulting in a cost of €0.62 per item. It is difficult to assess the cost of electricity needed to print a mask, but in our experience it is approx. €0.05 for 2 h of printing. The estimated prices of a single foil and 20 cm of elastic rubber is €0.07 and €0.30, respectively. Summarizing, in our case the cost of producing 1 reusable face shield was €1.04, which was significantly lower than in other groups.[38] This calculation takes into account the price increases that followed the increased demand for the materials.

Table 1. Comparison of available face shields produced using Fused Deposition Modeling (FDM)

Project name	Scheme	Printing time (at our settings)	Filament usage [g]	Estimated cost [€]
Prusa RC 3 protective face shield (A)		2 h 12 min	34	0.61
3D Verkstan face shield [B]		59 min	13	0.23
IC3D Budmen face shield [C]		2 h	28	0.50
DTM v3.1 face shield [D]		2 h 52 min	54	0.97
Peaked headband DDS2 [E]		2 h 49 min	47	0.85

Details were estimated based on our settings of the Cura 4.4 slicer; A – Prusa Research, Prague, Czech Republic; https://www.prusaprinters.org/prints/25857-protective-face-shield-rc1. Accessed April 26, 2020; B – 3DVerkstan, Stockholm, Sweden; https://3dverkstan.se/protective-visor/. Accessed April 26, 2020; C – IC3D Industries, Columbus, USA; https://3dprint.nih.gov/discover/3dpx-013309/Accessed April 26, 2020; D – Prusa Research; https://3dprint.nih.gov/discover/3dpx-013359. Accessed April 26, 2020; E – #Drukarzedlaszpitali (grassroot initiative), Poland; https://www.drukarzedlaszpitali.pl/Pliki/. Accessed April 26, 2020.

Current knowledge and controversy

Due to the mode of transmission of SARS-CoV-2[14] the 3D printing community is focused on the fabrication of devices to protect the respiratory tract. An unprecedented need for PPE elicited a major cooperative initiative at an international level.[39] However, mass production of protective gear outside of the standard certification system raises controversy, and minimum requirements for self-produced PPE should be developed to ensure the safety of medical personnel.[40]

The use of face shields is not standardized; it depends on different departments' specific protocols and on the availability of PPE. According to Prusa Research recommendations, currently the only safe way to use the face shield is single-use. To our knowledge, paramedics who received our shields have used them that way. Nevertheless, they were well equipped with protective gear due to the fact that they were on the front line. The situation was entirely different in the case of departments potentially less exposed to the novel coronavirus, where multiple uses of equipment, disinfection and replacement of foils and rubber were taken into consideration.[34] Therefore, it was necessary to develop methods for cleaning the face shields so that they could be reused without the risk of infection.

There is a wide range of possible sterilization methods, which are mainly based on 3 factors: gases, temperature and chemical reagents.[41] However, certain characteristics of AM-produced items have implications for disinfection. The primary limitations of sterilizing 3D-printed medical devices are their porous structure and microscopic crevices created during the layer-by-layer process, where pathogens may theoretically withstand disinfection conditions.[42] Another obstacle is the high temperature used in sterilization processes. In the case of synthetic polymers, high temperatures may damage various widely used filaments and cause losses of structural integrity.[43] This partially explains why PETG is the most widely recommended material despite insufficient evidence. In cooperation with leading Czech laboratories and hospitals, Prusa Research performed a series of tests, and as a result they selected recommended methods of sterilization, which are presented in Table 2. These sanitizing practices are in line with the guidelines available on the GetUsPPE web platform for physicians and medical researchers in the USA.[44] Further studies are necessary to determine if these procedures are effective enough to prevent infection.

Table 2. Verified methods of sterilizing the Prusa RC 3 protective face shield

Method	Conditions
Hot air dryer	65°C (149°F), 60 min
WHO handrub disinfection	75% IPA, 5 min
Isopropanol (IPA)	96%, 5 min
Isopropanol (IPA)	75%, 5 min
Sodium hypochlorite (household bleach)	min. 0.01% of hypochlorite (e.g., SAVO 1:10), 2 min+
UV-C	radiation, 30 W, wavelength below 280 nm, 15 min
Ethanol	70–80% max, 5 min
Hydrogen peroxide	25%, 5 min

Subsequent reports and our experience confirm that PPE produced quickly and at low cost should be used by medical staff even if they are not as effective as certified equipment.[36,38] Apart from psychological comfort, simple face shields work as a physical barrier against airborne droplets. The indisputable advantage of face shields is that they protect not only the nose and mouth (surgical masks), or the eyes (protective goggles), but the whole face.[39] Furthermore, 3D-printed visors are lightweight and have sufficient space for goggles, a mask or a N95 respirator.[36]

Discussion

A pandemic is a difficult period for all the governments of the world. It is necessary not only to introduce optimal restrictions and appropriate financial management, but also to properly distribute protective gear for all services, especially for healthcare workers most exposed to infection.[36] However, it is hard to provide PPE to medical services when its worldwide production cannot keep up with its utilization, which raises various issues.

In the United Kingdom, members of the British Medical Association (BMA) reported that PPE was distributed in small quantities, did not protect medical personnel well enough or in some cases did not reach National Health Service (NHS) staff at all.[45] Reports received from nurses also confirmed a total lack of protection against the coronavirus.[46] A survey carried out by the BMA revealed that more than 40% of the general practitioners (GPs) asked were affected by a lack of fluid-repellent facemasks. Moreover, more than 55% of surveyed hospital doctors reported that they felt only slightly secured against SARS-CoV-2, and 1/3 of them felt unprotected. Among GPs these values were almost 50–50.[47]

Information related to concerns about the lack of protective equipment has also emerged from all around the world. In Australia, recently devastated by the massive bushfires, GPs reported a shortage of face masks as people wore them to protect from harmful smoke.[48] In the USA, the shortage of protective measures included not only PPE for medical personnel, such as masks, gloves, gowns and face shields, but also ventilators for patients.[49] The rapid mobilization of AM printers enabled the production of face shields as well as other protective items on a mass scale. Furthermore, more efficient and personalized N95 masks, ventilator valves and even medications have been designed.[23,36] Concerns about ventilator shortages have been partially alleviated thanks to a variety of free projects.[49]

Rapid implementation of AM techniques was important for another reason. As a result of deficiencies in PPE and increased contact with infected people, the problem of COVID-19 infection strongly limited medical personnel's ability to work. In the Netherlands, a quick two-day study on health-care workers at 9 hospitals revealed that 4.1% of the staff that presenting slight signs of respiratory infection tested positive for SARS-CoV-2.[50] In China, in turn, on February 24th, 2020, the National Health Commission of the People's Republic of China stated that among medical staff, 2055 persons were infected with COVID-19, of whom 22 died.[51] For those who are in the front lines of the fight against the pandemic, PPE is an essential element of everyday life. NHS doctors stated that "health-care workers on the front line without PPE is the equivalent of going to war without armor and protection".[46] Protective gear not only plays a role in building mental comfort and a sense of safety, but also protects wearers from infection and limits transmission.[52] Additive manufacturing is particularly promising in the production of PPE due to a fact that the barrier against transmission of the virus can be not only physical, but also biological, through the use of antimicrobial polymers.[29]

When a pandemic breaks out, medical personnel struggle with rapidly growing numbers of patients, time pressure and information chaos. Consequently, they have to deal with a greater workload, longer working hours and an increased mental burden.[52] In these conditions, medical staff has to cope with variety of sensations from fear and anger, through stress, anxiety and a sense of isolation, to depressive symptoms and/or insomnia.[53] Mental health among medical workers is quite a serious issue, because it results in overall well-being, which leads to grounded self-confidence. In turn, self-efficacy increases their work performance thus their effectiveness in treating patients.[54] Among the most important factors that relate to mental health is a sense of safety, and PPE is a relevant medium to support feeling secure during a pandemic.

Conclusions

The special role of PPE cannot be overlooked. Apart from preventing the spread of the novel coronavirus, PPE enables medical personnel to treat dramatically ill patients. Furthermore, COVID-19-related shortages of protective gear significantly affect the mental health of medical workers. In accordance with the antique maxim "prevention is better than a cure", emphasis should be placed on ensuring safety and appropriate working conditions for those who are directly exposed to the novel coronavirus and who can limit the ongoing pandemic.

During the COVID-19 pandemic it has been encouraging to see novel approaches to solving problems through global cooperation using open sources and free sharing. A 3D printer alone is definitely not the most efficient tool for mass production; however, the large number of users means that currently there are thousands of 3D-printed face shields in use in many sectors of public health and there is still a great demand for them. Face shields produced by specialists, companies, hospitals and hobbyists may to some measure reduce the disruptions in supply chains observed around the world. We hope that the data we have presented may reduce the deficit of PPE for medical staff and save valuable time for those who implement these techniques.

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