JIDC | THE JOURNAL OF INFECTION IN DEVELOPING COUNTRIES

Coronavirus Pandemic

Facing COVID-19 pandemic: development of custom-made face mask with rapid prototyping system

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Abstract

Background: COVID-19 is a global pandemic. The virus spreads through respiratory droplets and close contact. Therefore, the availability of personal protective equipment (PPE) for healthcare professionals is essential. 3D printing technology could represent a valid option to ameliorate PPE shortages.

Methodology: Custom-made face mask were designed on the basis of facial scan and then 3D-printed. The whole protocol is executed with freeware software and only required a 3D printer. Six healthcare workers wore the device weekly thus expressing a judgment regarding quality of work, respiratory and skin comfort.

Results: The estimated total cost of a single mask is approximately 5 USD. The virtual design of a complete mask lasted 68 minutes on average. Most healthcare workers rated comfort as very good.

Conclusions: Based on the encouraging results obtained, we can confidently confirm that custom-made masks are novel and useful devices that may be used in the fight against COVID-19.

Key words: COVID-19; face mask; personal protective equipment; PPE; 3D-printed.

J Infect Dev Ctries 2021; 15(1):51-57. doi:10.3855/jidc.13384

(Received 01 July 2020 – Accepted 08 October 2020)

Introduction

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) epidemic originated in Wuhan in December 2019 [1]. As at 10 September 2020, the global spread of the pandemic accounted for 27,981,242 confirmed infections and 905,851 deaths worldwide [2]. The rapid spread of SARS-CoV-2 was promoted by its easy interpersonal transmission through respiratory droplets [3]. Upon infection, the virus causes coronavirus disease 2019 (COVID-19), a flu-like syndrome mainly characterized by fever, chemosensitive dysfunctions and respiratory symptoms [4,5]. In about 20% of cases, COVID-19 evolves into more severe forms with respiratory distress that requires intensive care hospitalization and assisted ventilation [6-8].

To prevent interpersonal diffusion of the virus, different measures such as social distancing and hand washing have become crucial. The global contamination rate is particularly high among healthcare workers engaged in the treatment of infected patients [9]. Therefore, the use of personal protective equipment (PPE), such as face masks, face shields, and coveralls is essential. However, in the critical phase of lockdown for COVID-19, a greater request takes precedence over PPE availability. It is mandatory, especially for doctors, nurses, dentists and all healthcare workers to obtain adequate PPE, at least the FFP2 (N95) protective face masks, ensuring sufficient self-protection and limiting the spread of the virus.

3D printing technology could represent a valid alternative to the lack of PPE. Nowadays, this technology is widely diffused in cranio-maxillo-facial surgery practice, particularly in reconstructive and traumatology surgery [10].

The aim of our study was to investigate the reliability and efficiency of a protocol (Project Mask3d) established to obtain a custom-made facial mask manufactured in-house. Using the CAD/CAM system and a low-cost self-made prototyping technique, we could improve the need for personal protective equipment for healthcare workers of our Department. Our goal is to offer a practical solution to deal with the COVID-19 emergency.

Methodology

Our study included 6 healthcare workers who were subjected to a 3D-facial scan in order to produce a custom-made FFP2 facial mask. The entire procedure, from design (Computer Aided Design, CAD) to manufacturing (Computer Aided Manufacturing, CAM) of the 3D masks (Project Mask3d) was performed at the Department of Oral and Maxillofacial Surgery of the "Federico II" University Hospital (Naples, Italy). Our protocol was involved during the lockdown phase from 9th March to 4th May 2020.

The mask consisted of two main parts: the face cover section and the filter slot, with an additional, printable face-shield accessory. Other non-3D-printed items that were needed included elastic cords, FFP2 filter and plastic sheeting for shield. Obviously, in the same way the mask can be equipped with an FFP3 filter. For each case, the same workflow was applied as defined below.

CAD phase

Facial scan

In the design phase of our study, an established facial scan acquisition system, 3dMD face scanner (3dMD Inc., Atlanta, GA, USA) [11] was adopted. This scanner, commonly used in our department for orthognathic surgery planning, is based on three modular units of nine cameras synchronized in a single acquisition. At the end of the scan, the system produces an object (OBJ) file, a 3D geometrical graphic element

Figure 2. Phases of the Meshmixer system: A orientation, B surface selection, C setting thickness, D4 Boolean Difference, E surface smoothening, F elements union, G loops insertion, H refinements, I saving mask as STL-file.

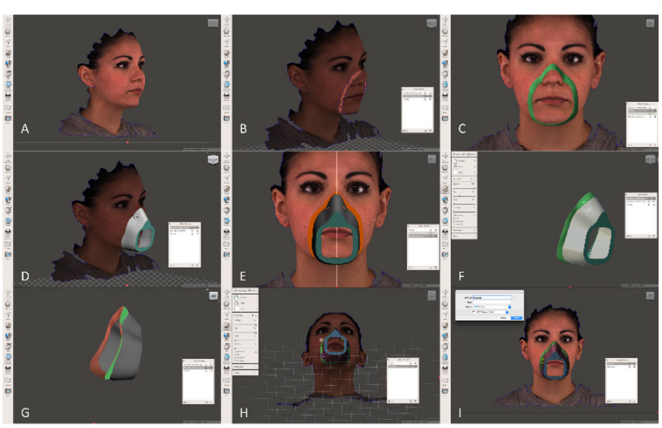
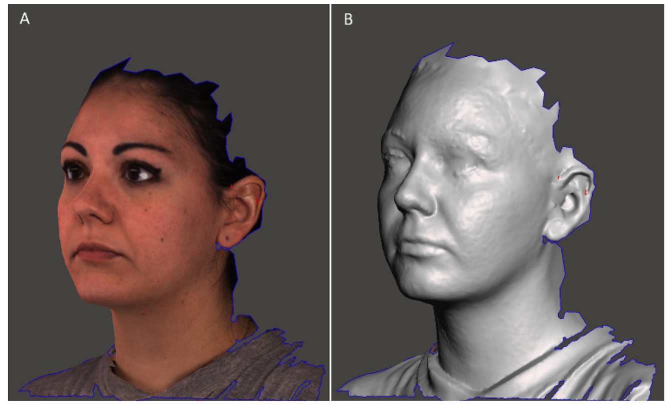


Figure 1. Facial scan using the 3dMd software (A) and Bellus3D application (B).



that is compatible with any 3D design and slicing software (Figure 1). Upon gaining experience with the protocol, we rejected the 3dMD face scanner and acquired the 3D facial image with a smartphone free application (Bellus 3D, Campbell, CA, USA) instead. Consequently, the costs related to the facial scanner were completely cut down without significantly reducing the accuracy of the procedure, thereby making the protocol applicable to any hospital setting.

Editing

The 3D OBJ file thus produced was then easily modified with the freeware Meshmixer Software (Autodesk Inc, San Rafael, CA, USA, version 3.5) [12] (Figure 2). Using an "Orientation" tool the image was positioned on the orthogonal plane, and through "Selection", the area of maximal adhesion for our device was defined. Generally, this area was identified among the peri-oral district, the naso-jugal groove, and the sub-mental area. To set the thickness of the mask (1.6 mm) the "Extrusion" tool was used. Outline mask boarders were defined with "Sculpting" and functions like "Move" and "Brushes". All holes and failures to join were corrected through the "Erase and Fill" function. Once the definitive shape of the device was obtained, the "Boolean Subtraction" function was used to clean incorrect interactions in order to develop maximal adherence between the mask and skin surface. Through the "Merge" function the filter slot on the mask surface was positioned. To wear our device, a loop system was projected to insert elastic cords. The best option was a 4-loop system with the attachment oriented in such a way as to support the ear anatomy, reducing the stress in this area while wearing the mask. Finally, this project was exported as a standard tessellation language (STL) file.

Slicing

The STL file was then imported into Ultimaker Cura (Ultimaker, version 4.6.1, USA), an open source software that generated a code file in order to make the 3D object readable by the 3D printer (Figure 3). This software included all settings for 3D printer slicing application. It allows to set the type of printing filament, design any supports and everything related to the print of the model in the best possible way and in the shortest time.

CAM phase

The three parts (mask, filter slot and face-shield) of the Mask3d were 3D-printed using the Ultimaker 2 Extended+ (Ultimaker, Geldermalsen, Netherlands) 3D printer incorporating fused filament fabrication (FFF) technology. Two types of filaments were used: thermoplastic polyurethane (Rubber TPU D27, Bioflex, Bioalfa, Soria Vecchia, Milan, Italy) and polylactic acid (Eco PLA, 3DJake Italia, Niceshops GmbH, Paldau, Austria).

A 2.85 mm thermoplastic polyurethane (TPU) filament was used for the realization of the mask. The print resolution was set to 0.1 mm (fine) and a nuzzle of 0.4 mm was used. For the filter slot and the shield, a 2.85 mm polylactic acid (PLA) filament was used, with a resolution set to 0.15 mm and using a 0.6 mm nuzzle.

The total amount of material necessary for the Mask3d was 32 g (4.21 m of filament), 8 g (1.06 m) for the filter slot and the shield, and 24 g (3.15 m of filament) for the mask.

Mask assembly

All components of the mask can be rapidly assembled owing to a system based on joints slots, grooves and pins. The project thought to facilitate the easy replacement of each component in case of damage. The filter unit comprised of two fitted shells containing the actual filter inside. The pin system allowed the filter unit to be joined to the face mask. The mask can be equipped with FFP2, FFP3 or N95 filters obtained from a FFP2, FFP3 or N95 face mask. Six filters can be obtained from a single mask (Figure 4). Finally, the elastic cords were inserted in their loops.

The face-shield can be mounted when necessary. In our project, the frame of the shield had been shaped to the healthcare worker's head. The assembly of the shield involved fixing a glossy sheet with double-sided

Figure 3. The Ultimaker Cura software used for 3D slicing application.

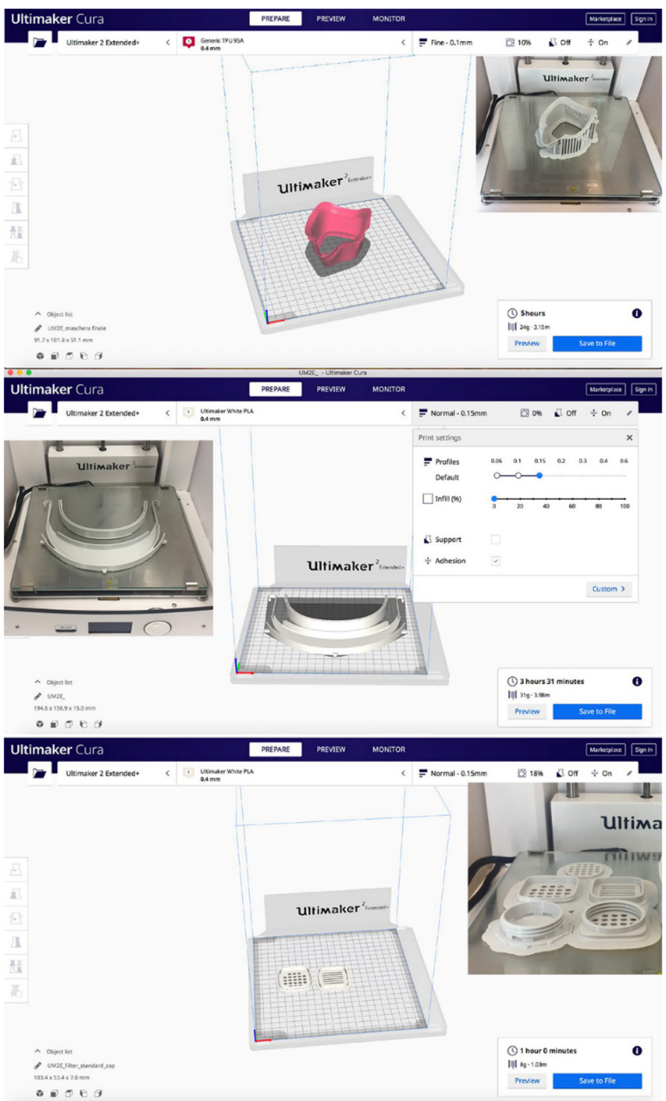
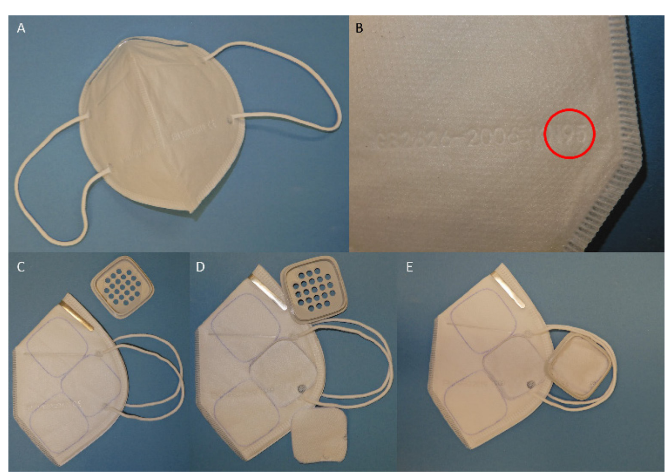


Figure 4. Obtaining filters for mask3d. A typical example of a N95 face mask for COVID-19 (A) with the code to identify the mask type (B). Three copies of the filter disk are made on either side of the N95 mask (C), which is then cut (D) and inserted into the shell of the filter slot (E).



tape to the frame itself. An office elastic band was then sufficient to maintain the frame at the head (Figure 5).

Quality evaluation

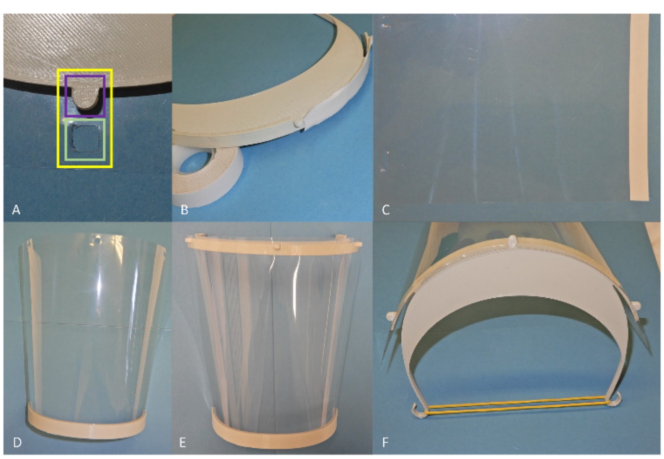
The masks were then tested by surgeons of the Department of Maxillofacial Surgery at the "Federico II" University Hospital in Naples for 7 days. During this period, each doctor underwent rotation in the following units: maxillofacial surgery ward, medical clinic and surgery room.

At the end of each shift, the subjects filled out a questionnaire assessing the degree of comfort of the mask. The questionnaire consisted of three items and was built and evaluated according to a 5-point Likert scale. The three questions investigated three aspects of the mask comfort including: skin comfort, respiratory comfort, quality of work shift whilst wearing the mask.

For each question, the subject could give a score from 1 (intolerable) to 5 (very comfortable) corresponding to the degree of tolerability of the mask. An overall score ranging between 12 and 15 was considered as very good, between 8 and 11 as good, from 4 to 7 as acceptable and less than 4 as poor.

The reliability of the questionnaire was evaluated by calculating the Cronbach's alpha using MedCalc 19.1 statistical software for biomedical research (MedCalc Software Ltd, Ostend, Belgium). Cronbach's alpha [13] is defined as a statistical indicator used to measure the reliability of the questionnaire or to verify reproducibility over time under the same conditions. Highly reliable values were those with a score ≥ 0.70.

Figure 5. Face shield assembly. Holes are made in the glossy sheet (A). Double-sided tape is placed on the periphery of the upper frame (B) and on the longest side of the glossy sheet (C). The lower frame is inserted onto the glossy sheet using double-sided tape (D), while the upper frame is fixed using pins and holes (E). Finally, the rubber band is inserted behind the upper frame (F).



Results

Six masks were produced and supplied to six surgeons who used them for seven days (Figure 6).

Time and cost

The average time needed to design the mask was 33 minutes (range: 24 – 51 minutes), from facial scan to the beginning of printing of the STL file containing the mask. The average duration of the filter slot design (both the one compatible with the FFP2 mask and the one compatible with a N95 mask) was 14 minutes (range: 10 – 21 minutes). The duration of the face shield design was 21 minutes on average (range: 14 to 30 minutes).

The 3D printer took about 6 hours (range: 5,5 to 6.5 hours) to print the mask body, 1 hour (range: 46 - 73 minutes) for the filter slot and 3 hours (range: 2.5 – 3.5 hours) for the face shield.

The cost of the used filament is estimated at $1 for the mask body, $0.30 for the filter slot and $1.50 for the face shield. The estimated cost for the prototyping process was around $1.90 per case. Considering that an FFP2 mask in Italy now costs around $5, and six filters could be obtained from a single mask ($0.83 each), adding the price of the elastics ($0.25), it was possible to manufacture the final device for less than $5.

Multiple choice questionnaire results

The multiple-choice questionnaire was provided to 6 health workers at the end of their shift. In the medical clinic scenario, 33.33% (2 workers) classified the device as very good, scoring between 13 and 15 and 66.67% (4 workers) reported a good outcome, giving a

Figure 6. Our devices: 3 face masks for male surgeons, 3 face masks for female surgeons.

score between 8 and 11. The Cronbach's alpha was 0.9970. Post standardization, the Cronbach's alpha was 0.9992. In the surgery room, 50% (3 workers) classified the device as very good, giving a score between 13 and 15 and 50% (3 workers) reported a good outcome, scoring between 8 and 11. The Cronbach's alpha was 0.9975 while the Cronbach's alpha score after standardization was 0.9992. In the maxillofacial surgery ward, 33.33% (2 workers) reported a very good outcome, giving a score between 13 and 15, whilst 66.67% (4 workers) classified the device as good, giving a score between 8 and 11. The Cronbach alpha was 0.9975. After the standardization, the Cronbach's alpha was 0.9992.

For each item, the Cronbach's alpha coefficient was > 0,70 indicating a highly reliable value.

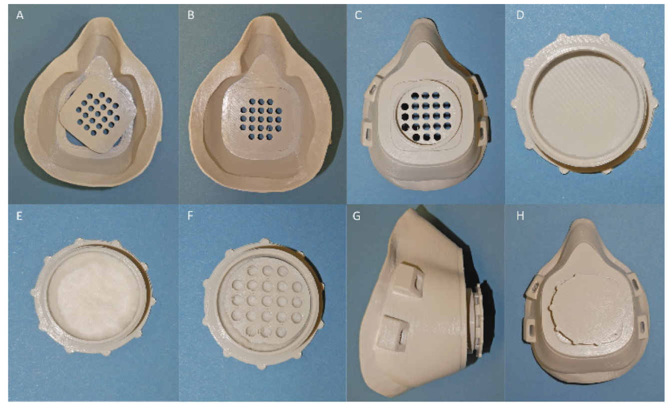
Discussion

During the health crisis related to the COVID-19 pandemic, it is essential to protect healthcare workers by providing them with adequate personal protective equipment. Considering the main transmission pathways of SARS-CoV-2, face masks are a fundamental tool to prevent contamination [14,15].

Nowadays, there is clear evidence in the literature of the high accuracy of 3D facial scanning and it is accepted that facial digitizing procedures produce clinically acceptable outcomes for virtual treatment planning [16-18]. As represented by reconstructive and trauma surgery, the CAD/CAM technology maximizes aesthetic and functional outcomes [19]. The reliability and effectiveness of an ''in-house'' rapid prototyping (RP) protocol for medical manufacture is already highlighted in literature [12,20].

In Naples, the COVID-19 emergency started on 9th March 2020. From the 16th of March, we began to design and print the Mask3d. Upon completion, the six surgeons included in this study used the masks whilst continuing their normal activities. To date (May 2020), all six healthcare workers continue to use the customized masks and remain uninfected.

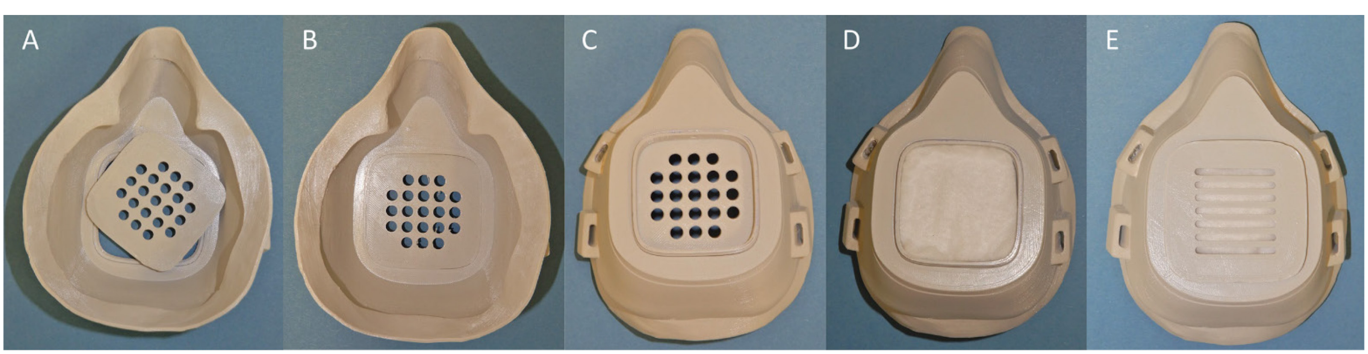
Figure 8. Assembly of the N95-like mask kit. The shell containing holes is inserted at back end of the N95-like face mask and clicked into place (B). The face mask is turned over (C). The upper shell of the filter slot (D) contains the filter (E) and the buttress (F). Finally, the upper shell is placed and fastened onto the lower slot (G) yielding a completely assembled N95-like mask (H).



The perfect adherence of the mask to the skin surface allows for breathing function exclusively through the filter unit, providing good personal protection to the worker. In addition, the presence of a FFP2 bi-directional filter reduces the risk of viral transmission, helping to limit the spread of the pandemic. The mask avoids the phenomenon of fogging for workers who wear glasses. In the operating room, it allows for good respiratory function and skin comfort (Figure 7 and Figure 8).

Using Bellus 3D, a free mobile application, the present workflow protocol could be accessible to anyone. This open-source application is capable of creating a good facial scan within a few seconds and saving it in an OBJ format. As reported by Swennen *et al.* [21], the introduction of new generation

Figure 7. Assembling FFP2/FFP3-like mask kit. The shell containing holes is inserted facing the back end of the face mask (A) and clicked into place (B). The face mask is turned over (C) and the filter is inserted into the filter slot (D). The cover shell with multiple slits is used to close the filter unit (E).



smartphones with two cameras and dedicated applications, like Bellus3D allows this system to be practical and available worldwide [22]. Therefore, our project is simple, low cost and globally accessible, requiring only a smartphone and a 3D printer.

In order to guarantee comfort and functionally, we used thermoplastic polyurethane. Its main features are represented by softness and flexibility. The high performance, suitability and the medical certification (USP XXXII:2009 Class VI e ISO 10993-4/5/10) of this material influenced our choice. Moreover, it is resistant to high temperatures and can therefore be sterilized (15 minutes at 135 °C).

Polylactic acid was chosen for the filter slot and the shield. This is a biodegradable and non-toxic material suitable for 3D printing. While the filter for the filter slot is easily purchased, in the event of a shortage it is possible to cut a FFP2 or FFP3 mask to obtain 6 fitted filters. Generally, in our custom-made mask we used a FFP2 filter validated in the EU, but we decided to also project a N95 filter slot useful for US healthcare workers, thereby ensuring worldwide availability of these mask components. The main advantage of a replaceable, quick-maintenance filter unit is to be able to replace this unit more frequently, further reducing operating costs. Therefore, another advantage of having a removable filter unit is to facilitate its reuse and its disinfection.

Our protocol is based on a low-cost, "home-made" rapid prototyping facial mask. The estimated cost of the prototyping process is less the $5 per case. Currently, due to the COVID-19 emergency there are no certifications available, however the use of homemade masks has been approved by the Italian government (Figure 9). The masks were produced according to medical conscience after discussion with a team of infectious disease specialists and anesthesiologists involved in the COVID-19 emergency [23]. The procedures followed were in accordance with the Helsinki Declaration of 1975, as revised in 1983.

In conclusion COVID-19 is a condition with a high infectious risk, therefore it has quickly been established as a pandemic. In order to guarantee safety to health workers and to prevent the diffusion of the virus, it is essential to have personal protective equipment. Our proposal is an effective, low-cost and rapid prototyping device which can be available worldwide while still reducing manufacturing effort and cost. Based on the encouraging results obtained, we can confidently confirm that custom-made masks are novel and useful devices that may be used in the fight against COVID-19.

Figure 9. Male and female surgeon wearing Mask3d device and face shield.

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Conflict of interests: No conflict of interests is declared.