How to Produce Cheap and Easy Custom-Made Sterilizable Filtering Facepiece 2/3 Masks for Healthcare Providers During Pandemic COVID-19 Emergency

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Abstract: On January 8, 2020, a novel coronavirus was officially announced as the causative pathogen of coronavirus disease (COVID-19) by the Chinese Center for Disease Control and Prevention.

On February 26, COVID-19 has been recognized in 34 countries, with a total of 80,239 laboratory-confirmed patients and 2700 deaths.

Protecting healthcare workers from infectious hazards is paramount to ensuring their safety in delivering health care.

In addition, being able to protect healthcare workers, constituting the front-line response against high-threat respiratory pathogens, such as severe acute respiratory syndrome coronavirus 2, is important for reducing secondary transmission in healthcare-associated outbreaks.

Authors present a simple, reliable, and cheap protocol to produce a custom-made sterilizable filtering facepiece 2/3 masks for healthcare providers during pandemic COVID-19 emergency.

Key Words: COVID, facial mask, filtering facepiece 2, filtering facepiece 3, pandemia

On January 8, 2020, a novel coronavirus was officially announced as the causative pathogen of coronavirus disease (COVID-19) by the Chinese Center for Disease Control and Prevention.[1]

The epidemics of COVID-19 started from Wuhan, China, last December and have become a major challenging public health problem for not only China but also countries around the world.[2] On January 30, 2020, the World Health Organization (WHO) announced that this outbreak had constituted a public health emergency of international concern.[3] The novel coronavirus was initially named 2019-nCoV and officially as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On February 26, COVID-19 has been recognized in 34 countries, with a total of 80,239 laboratory-confirmed patients and 2700 deaths.[4]

The COVID-19, up to now, has become a constant challenge to healthcare resources worldwide. Basic measures such as personal hand cleaning and social distancing are crucial.

However, according to WHO guidelines,[5] protective material is essential for all healthcare providers. The shortage of filtering facepiece 2 (FFP2)/FFP3 protective face masks for healthcare professionals such as doctors, nurses, dentists, carers, and paramedics in hospitals and other healthcare settings is the main problem in this situation.

European Standard (EN 149:2001) classifies FFP respirators (FFR) into 3 classes: FFP1, FFP2, and FFP3 with filtration efficiencies of 80%, 94%, and 99%, respectively.

Being able to protect healthcare workers from high threat respiratory pathogens, such as SARS-CoV-2 is important for being able to reduce secondary transmission of SARS-CoV-2 in healthcare-associated outbreaks. By extension, reducing infection in healthcare workers improves continuity of care for all patients within healthcare facilities.

In 2008, the authors presented their Security Hi-tech Individual Extra-Light Device Mask (SHIELD), a customizable protective shield based on the soccer player's face cast.[6]

In 2017 and 2019, the authors presented an update in the realization process, based on computer-aided design (CAD)/computer-aided manufacturing technology (SHIELD 2.0)[7] and volumetric 3-dimensional (3D) model of the patient's face through 3D stereophotogrammetry (SHIELD 3.0).[8]

Authors present a simple, reliable and cheap protocol to produce a custom-made sterilizable filtering facepiece 2/3 masks for healthcare providers during pandemic COVID-19 emergency.

METHODS

A custom-made 3D protective face mask was developed, consisting of a reusable 3D-printed component facepiece with integrated bayonet mount to stock filter.

The first step consists in 3D facial image acquisition.

The 3D facial scanning was performed using a smartphone (iPhone X; Apple Inc, Cupertino, CA) and the Bellus3D FaceApp (Bellus3D, Campbell, CA), which was downloaded from the App Store.

The individual face scan was then exported in high-definition geometry definition file format (OBJ) and forwarded by secured e-mail to any 3D laboratory.

The 3D laboratory then provides to fit the FFP2/3 masks prototypes on the 3D facial scanning using a 3D modeling process with CAD freeware Meshmixer (Autodesk , San Rafael, CA). FFP2/3 masks prototypes can include the choice of possible support for the eye visor.

Through an appropriate arrangement, it was possible to choose the depth at which the respirator should suitably fit the patient's profile, then carry out a Boolean subtraction that allowed to "dig" the patient's surface from the inside of the respirator. In this way, the ergonomic respirator portion that comes into contact with the face was obtained (Fig. 1).

Starting from the facial scan stereo lithography interface format (STL) file an individualized facial mask is designed and melt with the STL file of the bayonet mount for the most common available filters on the market (Fig. 2).

Custom-made FFP2/3 masks are then printed using a commercially available resin-based stereolithography apparatus desktop 3D printer (Form 2, Dental SG Resin; Formlabs, Somerville, MA) to allow for sterilization of the mask.

Dental SG is a class I biocompatible photopolymer resin made of a mixture of methacrylic esters and photoinitiators, it can only be

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Received April 10, 2020.
Accepted for publication April 26, 2020.

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The authors report no conflicts of interest.

ISSN: 1049-2275
DOI: 10.1097/SCS.0000000000006696

FIGURE 1. Mask fitted on the patient's facial scanning.

used exclusively with Formlabs stereolithographic 3D printers. It is designed primarily for the manufacture of 3D printed parts for use as dental surgical guides or similar applications.

The whole process from design to final production took 1 week; production time slightly varies basing on the specific shape of the mask and on the type of filter used.

Production time required 5 hours. Required postprocessing took an additional 2 hours (solvent bath to remove excess resin, remove the printing supports, and finalize the photopolymerization in a ultraviolet oven, polishing the piece to give a correct functional and aesthetic result).

FIGURE 2. Starting from the facial scan stereo lithography interface format (STL) file an individualized facial mask is designed and melt with the STL file of the bayonet mount for the most common available filters on the market.

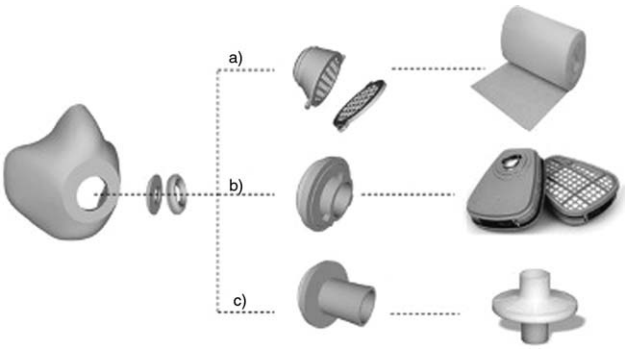

FIGURE 3. The figure shows how different filters can be adapted to the mask. This example shows how it is possible to use filtering fabric (A), a commercial filtering cartridge (B), or a medical antiviral filter (C).

The custom-made 3D-printed face mask requires two disposable components: a head fixation band and a filter membrane.

For the purpose of head fixation, a worldwide commercially available elastic band can be used.

Filtering systems available on the market have different shapes; any of them can be used because the designer can adapt the shape of the connection to the specific shape of the filter (Fig. 3).

Sterilization can be performed with autoclave or gamma-ray. Standardized steam sterilization procedures required 15 minutes at 121°C or 3 minutes at 138°C. Disinfecting also can be performed, but it is recommended to clean with nonchemical products. If chemical disinfection methods are necessary, ethanol solution is recommended. Authors suggest to apply disinfection protocol described by Swennen et al.[9]

DISCUSSION

Italy has had 124.527 confirmed patients (12.681 of which are healthcare provider) according to the Istituto Superiore di Sanità as of April 6, and 14,860 deaths.[10]

To date, 88 medical doctors are dead during this pandemia.[11]

In the case of life-threatening pandemic situations with a lack of professional FFP2/3 face masks for healthcare workers inside and outside hospitals, a potential alternative solution should be easily accessible, at low cost, and with global availability.[9]

The WHO recommends for healthcare workers using at least the FFP2 mask.[12]

Protecting healthcare workers from infectious hazards is paramount to ensuring their safety in delivering health care. In addition, being able to protect healthcare workers, constituting the front-line response against high-threat respiratory pathogens, such as SARS-CoV-2, is important for reducing secondary transmission in healthcare-associated outbreaks. Reducing infection in healthcare workers, even if their infection does not cause morbidity or mortality, will improve the continuity of care for all patients in the same healthcare facility.

More powerful commercially available 3D printers could increase the volume up to 60 individual 3D-printed face masks per 3D printer within 24 hours, including postprocessing.

Dental SG resin has been engineered to comply with the industry standards specifically identified in the safety data sheet and have been tested according to relevant testing protocols for those standards.

Dental SG resin is a specialty product, developed for use by medical professionals, and should be used in accordance with the instructions for use. Users should independently verify the suitability of the material for their particular application and intended purpose.

Dental SG resin is tested at NAMSA (Chasse sur Rhône in France) and is certified biocompatible per EN-ISO 10993-1:2009/AC:2010: this product is nonmutagenic, noncytotoxic, does not

induce any erythema or edema reactions, it is not a sensitizer and does not cause systemic toxicity.

The head fixation bands (Velcro or elastic bands) are believed to be easily available worldwide.

The disposable filter membrane can be acquired globally from nonmedical vendors selling nonwoven melt blown FFP2/3 industrial fabrics.

In addition, the CAD design of the 3D face mask can be adjusted to the specific disposable filter membrane and head fixation components available in different regional parts of the pandemic.

Standardized steam sterilization procedures required 15 minutes at 121°C or 3 minutes at 138°C while the disinfection protocol described by Swennen et al[9] required 15 minutes.

Moreover, the perfect custom-made mask fitting may decrease discomfort and decubitus lesions, especially at the nasal bridge, after prolonged application of the individual 3D face mask in humid and warm infected virologic units.

The main problem to solve to make possible a general use of each kind of protective mask is testing performances' certification. For this reason, the research group of Mechanical and Thermal Measurement of the Engineering Department of University of Perugia, with a long-time experience of testing for certification of mechanical and medical devices is actually working to support the production of new devices for reduce coronavirus diffusion.

Until now, in Italy, there is a dramatic lack of knowledge, resources, and laboratories to support industrial production of protective mask.

Only a few laboratories, the main in Bologna and Modena are active for certification of mainly chirurgical mask. This kind of mask needs certification of tissue sample accordingly to the UNI EN 14683 standard that needs requirements mainly in terms of bacterial filtration efficiency more than 95% or 98% for the different kind, differential pressure (respirability) <40 or 60 Pa/cm^2, splash resistance pressure not required or higher than 16.0 kPa for the best kind, microbical cleanliness better than 30 CFU/g.

It is authors' thinking that the presented cheap and easy custom-made sterilizable mask is a simple, reliable, and cheap protocol to produce a custom-made sterilizable masks in combination with FFP2/3 filter membranes for healthcare providers during pandemic COVID-19 emergency and may prove a valid alternative resource.

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Craniofacial Surgeons in Different Settings Facing the COVID-19 Pandemic

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As the COVID-19 pandemic continues to spread and impact life globally, with a profound impact on healthcare system at all levels including surgical practices with suspension of nonemergent consultations and procedures and a potential high risk of infection during manipulation of oral and nasal mucosal surfaces. Critical recommendations could assist craniofacial surgeons in decision making during this ongoing COVID-19 outbreak.[1,2] However, the overall impact on government, healthcare system, workforce, and citizens vary among countries.[3,4] The authors explore their recent interaction as craniofacial surgery fellow and supervisor in Taiwan to illustrate how this unprecedented global health crisis can drive future change.

The first author finished a long-term international craniofacial surgery fellowship in Taiwan (Chang Gung Craniofacial Center) under the supervision of the 2nd author and returned to Brazil just a few weeks before the beginning of the COVID-19 outbreak in China. Curiously, the fellow's reflection on this pandemic era revealed that the fellowship period was not only a scientifically productive year[5,6] but was also marked by sociocultural differences. The regular wearing of masks in public places (a practice that the fellow had previously

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Received April 27, 2020.
Accepted for publication April 30, 2020.

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The authors report no conflicts of interest.

ISSN: 1049-2275
DOI: 10.1097/SCS.0000000000006722