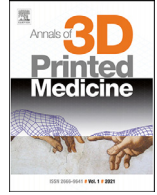




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# Use of 3D printed connectors to redesign full face snorkeling masks in the COVID-19 era: A preliminary technical case-study

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## ABSTRACT

The COVID-19 pandemic resulted in severe shortages of personal protection equipment and non-invasive ventilation devices. As traditional supply chains could not meet up with the demand, makeshift solutions were developed and locally manufactured by rapid prototyping networks. Among the different global initiatives, retrofitting of full-face snorkeling masks for Non-Invasive-Ventilation (NIV) applications seems the most challenging. This article provides a systematic overview of rapid prototyped - 3D printed - designs that enable attachment of medical equipment to snorkeling masks, highlighting potential and challenges in additive manufacturing. The different NIV connector designs are compared on low-cost 3D fabrication time and costs, which allows a rapid assessment of developed connectors for health care workers in urgent need of retrofitting snorkeling masks for NIV purposes. Challenges and safety issues of the rapid prototyping approach for healthcare applications during the pandemic are discussed as well. When critical parameters such as the final product cost, geographical availability of the feedstock and the 3D printers and the medical efficiency of the rapid prototyped products are well considered before deploying decentralized 3D printing as manufacturing method, this rapid prototyping strategy contributed to reduce personal protective equipment and NIV shortages during the first wave of the COVID-19 pandemic. It is also concluded that it is crucial to carefully optimize material and printer parameter settings to realize best fitting and airtight connector-mask connections, which is heavily depending on the chosen feedstock and type of printer.

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## 1. Introduction

The outbreak of the pandemic coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2), has caused over 55.6 million infections and 1.34 million deaths worldwide during the first pandemic wave (reported cases as of November 22, 2020) [1,2]. The potential of the additive manufacturing (AM) community has been highlighted during this life-threatening pandemic [3–8]. By using a versatile, local, and rapid prototyping approach it has been possible to contribute in resolving the temporary shortage of different medical items such as protective face masks and respirator masks during the global pandemic peak

from April to June 2020 [3,8–12]. Unlike traditional production methods, AM can provide different products (layer by layer) within one production batch using digital three-dimensional (3D) models as input. This enables fast prototyping and running of multiple tests in a relatively short period of time using the same machine. Notably, due to the popularity of this technology in recent years, independent and local production systems have been rapidly launched. Although the overall production capacity of AM technologies remains low and its costs are relatively high (depending on machine type), the creation of local networks provided a strong manufacturing flexibility, mitigating supply chain disruptions, which proved to be essential during this pandemic [13–16]. Accessible open-source software for computer-aided design (CAD) was used to tailor the medical products in demand. Most of the developed ideas and designs were shared on different 3D printing online repositories (e.g. Covid3D [17], Thingiverse [18], 3dprint.nih [19], Prusaprinters [20], Grabcad [21], etc.). These

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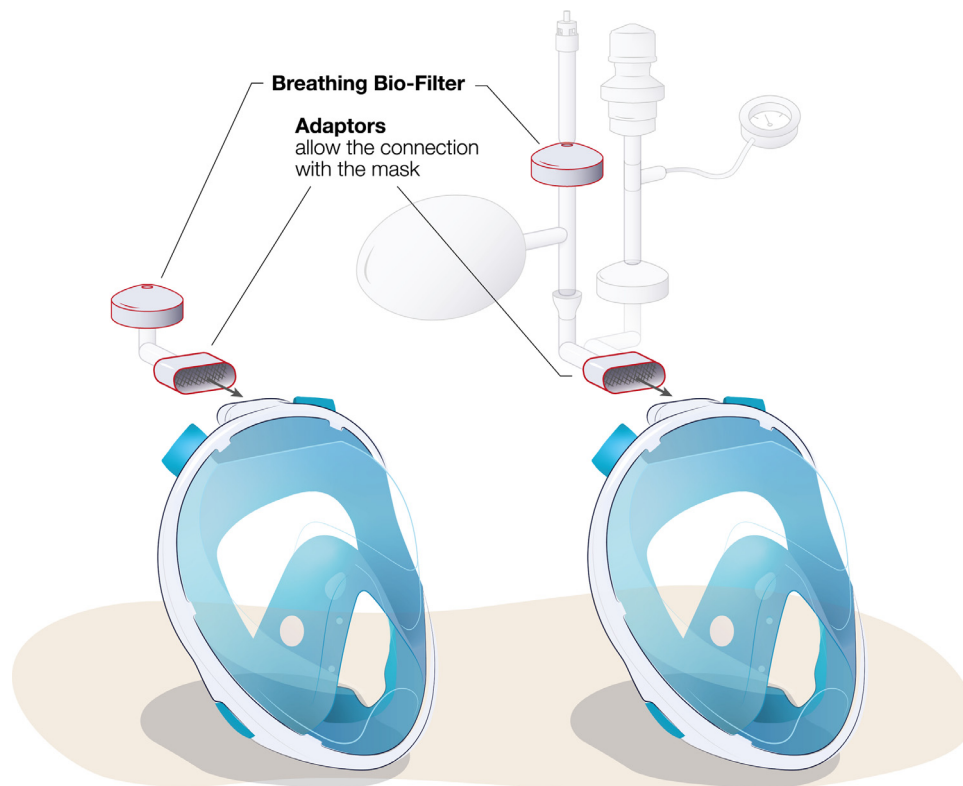
designs have contributed to reducing the risk of in-hospital cross-infections and viral shedding. The main explored design concepts, during the pandemic, were focused on:

- Personal protective equipment (PPE) [22–24]:
  - Face masks [25,26],
  - Splash-proof face shields [27],
  - Air-purifying respirator (PAPR) hoods.
- Hospital respiratory support equipment:
  - Venturi valves [28],
  - Ventilator splitters [29],
  - Adjustable flow control valves,
  - Non-invasive respiratory (NIV) systems.

Both maker- and academic communities have remarkably contributed by providing different models and knowledge of PPE and respiratory support equipment rapid prototyping. For example, a proof of concept of a reusable custom-made 3D printed face mask, based on individual facial scanning, was reported by Swennen et al. [30]. Other key applications using 3D printing technology during the pandemic were also reported [31]. Remarkable pioneering work on retrofitting commercial snorkeling masks with 3D printed adapters for the development of new PPE products is among these key applications. As an example, we mention here the work done by the Prakash lab which resulted in the foundation of an international industrial-academic network [32]. This consortium has led to the creation of a community in France [33]. The current pandemic situation revealed the need to build solid networks between “makers” (academic laboratories, industry, individuals, maker communities) and “users”

(hospitals, healthcare workers, individuals)[6], often referred to as “living lab” approaches [34]. Among the different new proofs-of-concept explored during the pandemic significant efforts have been put towards the fabrication of connectors allowing the use of snorkeling masks for healthcare applications. These modified masks have been mostly used as PPE, such as splash-proof face shields or respiratory facemasks (replacing standard N-95 masks) to support health-care workers (HCW) [16]. Some authors also evaluated the potential of these modified snorkeling masks as a new Non-Invasive-Ventilation (NIV) device adapted to the care of COVID-19 patients suffering from acute respiratory failure as highlighted in Fig. 1.

In this case, the mask’s function was redesigned to assist the breathing of non-intubated patients. Because of the growing number of patients to be treated during the first pandemic wave, the masks along with the connectors have been used complementary to existing medical protocols. The use of such modified mask system aims to mitigate the shortage of standard oxygenation mask and flowmeter devices (e.g. continuous positive airway pressure (CPAP) devices or Bilevel Positive Airway Pressure (B(i)PAP) devices), which could traditionally be deployed to treat patients with Acute Respiratory Failure (ARF). In this sense, the retrofitted masks have been described as a new system having operational functionality between oxygenation and CPAP devices. These modified devices aims to work similarly to classical “helmet system”, which demonstrated reduction of intubation rates compared to classical commercial face masks [35]. In comparison to the helmet, the snorkeling mask has the potential to provide a better comfort for the patient (*i.e.* reduced noises from the gaseous flow and increase of the freedom of movement for the patient). It is important to notice that different medical protocols and devices have been used during the pandemic depending on the health care systems and cultural habits. Therefore, the modified snorkeling masks have been developed to be adaptable to different medical configurations. The maker community focused mostly on the



**Fig. 1.** Different deployed strategies to redesign snorkeling masks for medical use during the COVID-19 pandemic: (a) connector and filter for use of the mask as personal protective equipment (PPE); (b) connectors, filter and tubing system for use of the mask as Non Invasive ventilation (NIV) system.

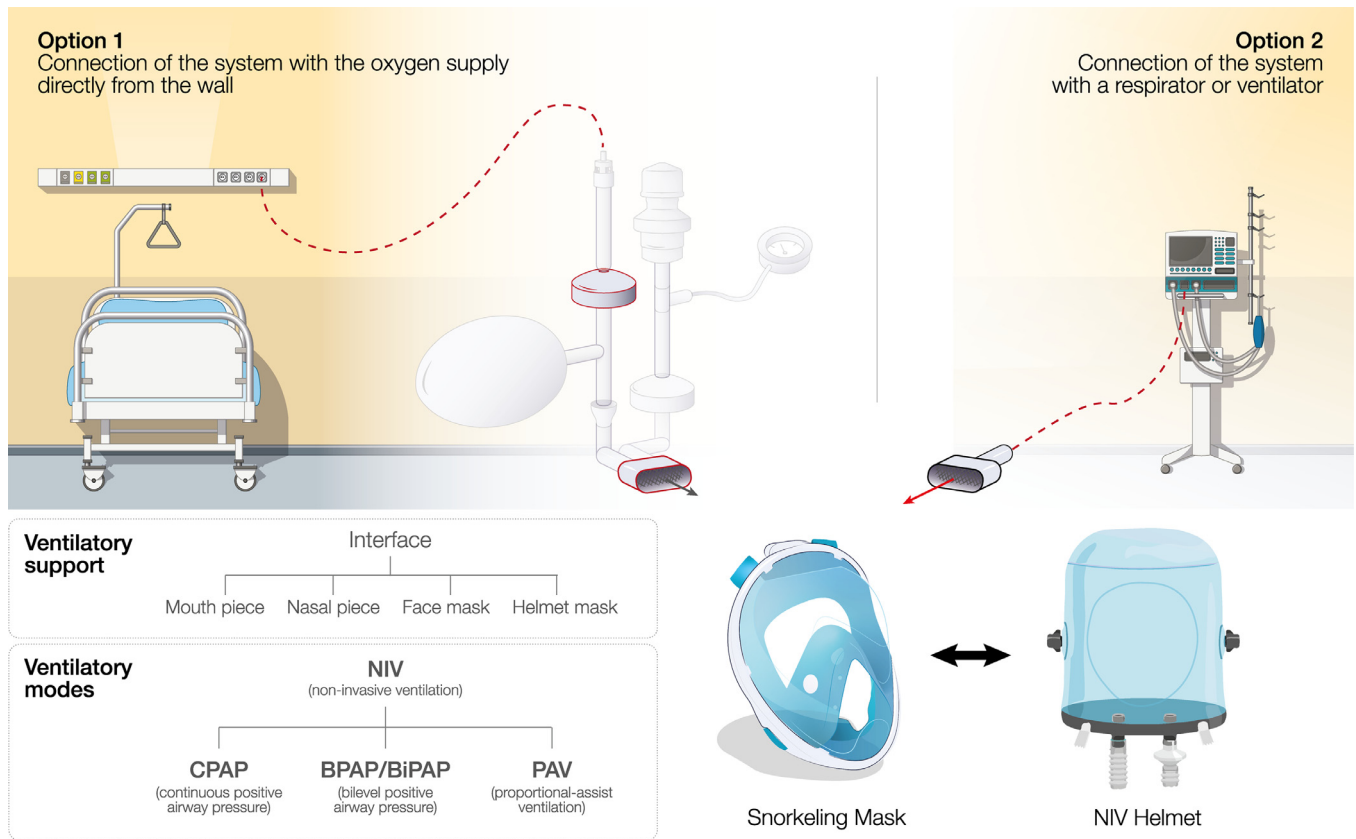


Fig. 2. Different configurations of snorkeling mask usage and connections as Non-Invasive-Ventilation device.

development of new connectors allowing snorkeling masks to be linked either with a CPAP device and other standard ventilation systems or directly with oxygen supply from the wall (standard hospital infrastructure). These different ventilation connection options are highlighted in Fig. 2 (option 1 vs. option 2) together with the developed connectors (or valves) for a snorkeling mask versus a classical NIV helmet. In addition, Fig. 2 presents a brief overview on standard ventilatory support interfaces (mouth and nasal pieces, face masks and helmet masks) and on different commonly used ventilatory modes (CPAP, B(i)PAP, proportional-assist ventilation (PAV)).

Extensive recent literature is widely available on rapid prototyping developments of PPE. However, literature on rapid prototyping developments of connectors for the NIV systems as breathing support delivering air for patients suffering from ARF are scarce and it is lacking a comprehensive overview of these developments during the actual pandemic.

In this review paper, we report a systematic overview describing the use of 3D printed connectors to retrofit full face snorkeling masks for the fabrication of NIV devices. This case study aims to (1) structure recent developments in 3D printed snorkeling mask connectors and their designs to facilitate their use, and (2) to highlight the potential and the challenges of deploying AM in the COVID-19 pandemic.

## 2. Three-dimensional connectors for non-invasive-ventilation (NIV) devices

### 2.1. Introduction

The first use of snorkeling masks for NIV therapy was reported in Italy by Isinnova [36], an engineering firm based in Brescia. Engineers were initially contacted by Dr. Renato Favero, former head physician at Gardone Valtrompia Hospital (IT) to find a solution to the shortage of masks in local hospitals [36], which could be used for NIV to supply

oxygen for patients suffering from respiratory failures. In a few days, engineers have been able to redesign the connectors of full-face snorkeling masks, enabling the oxygenation of patients in sub-intensive care. The 3D object was initially designed to fit on the Easybreath model from Decathlon [37]. The prototype has been tested on non-COVID patients in Chiari Hospital, and it received the approval from local doctors a few days later (March 25th, 2020) [38]. In this context, Isinnova decided to remove the original breathing tube from the snorkeling masks and to replace it with a new 3D printed connectors (called “Charlotte valve” by manufacturers [36]) fabricated by fused deposition modeling (FDM). This “valve” has been used to connect the ventilation ports located on the masks with standard oxygen tubing in the hospital. Fig. 3 depicts the original CAD of the connector. One can note that the initial shape of the connector remains close to the original breathing tube system designed by Decathlon. For fabrication (i.e. 3D printing), the authors suggest the use of polylactic acid (PLA) filament to reduce possible issues related to biocompatibility and/or the release of toxic gasses and detrimental aerosol emission usually observed with other materials, such as the thermoplastic polymer acrylonitrile butadiene styrene (ABS) [39,40]. Following this first design, the model has been improved to mechanically strengthen the connector’s attachment to the snorkeling mask with an additionally developed (3D printable) reinforcement part [41].

Two separated tube connectors are identified, which are used respectively as “inlet” (inhaling) and “outlet” (exhaling) of the breathing support when the NIV modified mask system is connected to a standard hospital oxygen source (Fig. 2 – option 1). Both plugs have 90-degree elbows which makes the design simpler but can increase the pressure drop of the inhaled and exhaled medium (e.g. air/oxygen) during respiration [42]. Both tube connectors are separated by 45 mm, which allows the use of filters with a maximum diameter of 45 mm each or any other value respecting:  $diameter_{filter1} + diameter_{filter2} \leq 90$  mm. The dimensions are kept

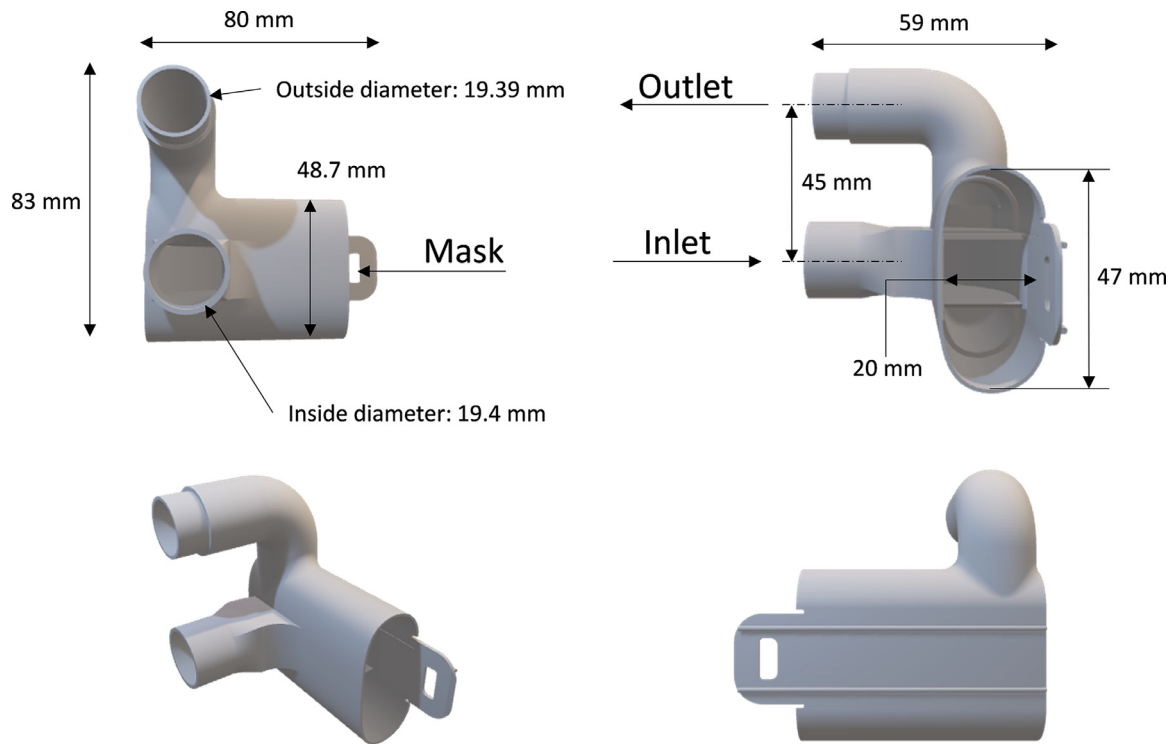


Fig. 3. Original CAD design of the “Charlotte” valve – 3D printed connectors for retrofitting snorkeling masks as positive airway pressure masks for NIV.

minimal ( $83 \times 80 \times 59$  mm) to reduce its weight (32.4 g – PLA) and the quantity of material used during the printing.

From the initial work proposed by Isinnova, a variety of initiatives have been created by other companies, researchers, and makers across the globe to improve and/or adapt the original “Charlotte” valve design.

## 2.2. Detailed overview of developed connectors for snorkeling mask retrofitting for NIV

Table 1 reports a brief overview of the most deployed connectors derived from the original “Charlotte valve” developed to adapt Easy-breath snorkeling mask models for use as NIV systems (note: design No. 6 is developed for the Ocean Reef Group snorkeling mask models). Appendix I (Table A1.) presents a more complete and more detailed list of connectors to attach snorkeling masks to medical ventilation equipment as supplementary information. Considering the different designs, one should note that modifications have been made mainly to improve the printability and/or the mechanical resistance of the connectors. Design No. 4 and No. 7 are specifically designed for fabrication by injection molding enabling mass-production.








Design No. 1 (called “Emily” by the manufacturers) has been developed to increase mechanical strength and to be better adapted to Stratasys 3D printers. The authors also report that this design minimized post-process modifications thanks to the modified 3D printing support structure and the more uniform printing results. It is optimized for ABS material printed at 100% fill density. According to the engineers, some improvements may be needed depending on the type of filament used. The plastic shrinkage must also be considered if polyetherimide (PEI)-like materials (e.g. ULTEM™) are used. Such PEI based materials are interesting to use because of their high tensile strength, high-thermal stability (e.g. sterilizable by autoclave), food-contact certification and biocompatibility [49,50]. Nevertheless, because of their very high glass transition temperature ( $T_{glass-}$

$ULTEM = 217$  °C, compared to  $T_{glass-PLA} = 60$  °C), a specialized 3D printer hardware is needed to work with these materials.

Design No. 2 (called “Silvana” by the manufacturers) has been designed by postdoc Vincent Groenhuis from UT (University of Twente, The Netherlands) [51] to supply French hospitals (i.e. IHU Strasbourg), with connectors used for CPAP purposes. For this project, a large collection of adapters is provided (more information here [44]) including models having two or three separate inlets/outlets and slightly different fits. These modifications allowed to (1) improve the fit with medical equipment (i.e. different male/female conversions and proper fit dimensions), (2) to increase the sealing (airtight) between the connector and the mask, as well as (3) to enhance the printability of the model. Thus, the entrance has been carefully designed to limit overhangs to  $45^\circ$  and to minimize difficult bridging features in the intake pathway. Also, the design does not require support structure which makes the object printable with simpler, therefore less expensive, 3D-printers. The authors recommend (1) printing with 100% fill density to avoid creation of internal cavities, which may trap liquids, (2) the use of a heat gun for a short time (2 s) to melt the very thin hairs of filaments present after printing, and (3) cleaning printed pieces to prevent dangerous inhalation of plastic residues. Although these models can be printed with different materials, it is advised to use polyethylene terephthalate glycol (PET-G) or Co-Polyester (CPE) filaments because they withstand treatments at high temperature (15 min at 80 °C), leading to inactivation of most viruses [52].

Design No. 3, created by a team associated with the Covid3D initiative in France [17], has been adapted to work only with a CPAP device. This model has only a one-way channel for both inlet and outlet, which is specifically developed for use in conjunction with CPAP devices having single-port connection. This connector has been tested and validated by medical staff at the Henri Mondor hospital but never used in a NIV configuration for COVID-19 patients. According to the team, printing can be carried out by FDM using standard 3D printing materials such as ABS and PLA, depending on local provisions. Note that the original design was optimized for ABS and needs

**Table 1**  
Connectors to convert full face snorkeling masks to positive airway pressure masks for NIV.

Name	3D model	Organization (developed by...)	Fabrication
Design 1		From Solid Energy (IT) [43] Tested in Sassuolo hospital (IT)	3D printing (FDM)
Design 2		From University of Twente (NL) [44] Tested at IHU Strasbourg (FR) with patients	3D printing (FDM)
Design 3		From Covid3D (FR) [45] Tested in CHU Henri Mondor (FR)	3D printing (FDM)
Design 4		From ULB (BE) [46] No available information for the test	Injection molding
Design 5		From Safran (FR) [47] No available information for the test	3D printing (FDM)
Design 6		From 3dprint NIH [48] (USA) Tested in Dep. Veteran Affairs (USA)	3D printing (FDM)
Design 7		From University of Twente (NL) No available information for the test	Injection moulding

a structural support increasing the printing time. It should be noted that careful evaluation should be carried out on this design to validate if the volume within a Decathlon snorkeling mask is not too large (too much dead volume) to be effective in single-port CPAP.

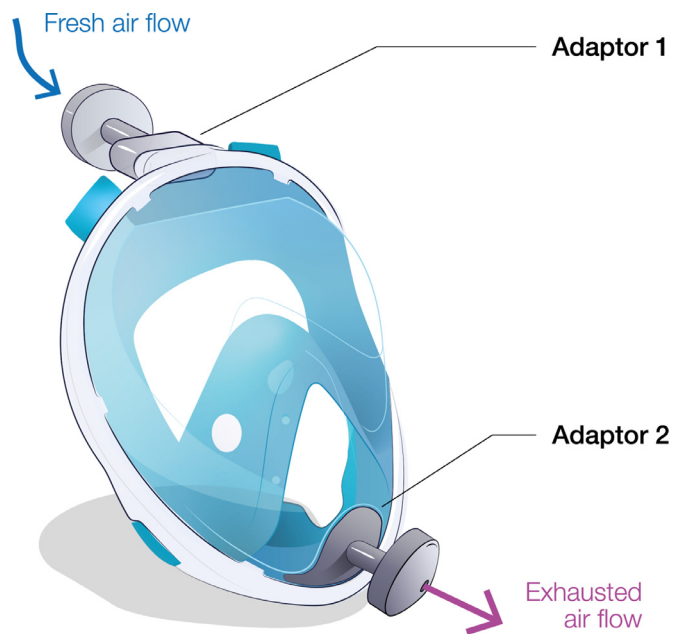
*Design No. 4* (called AIRasme by the manufacturers) has been developed by a team at the Erasme hospital at ULB (Université Libre de Bruxelles, Belgium). The device has been created to work with a CPAP system. In contrast to most of the models described in the literature, this connector is divided into two parts that must be connected by using glue. It is designed to be produced by injection molding, as fabrication of this connector by 3D printing is not recommended. Although no compliance tests have been performed for connecting sections, this model has been designed according to the EN ISO 5356 –1: 2015 standard [53].

*Design No. 5* is the result of a collaboration between two private companies, Safran [54] and Segula Technologies [55]. It can be considered as an example of private companies that decided to volunteer to support the alternative use of snorkeling masks during the COVID-19 pandemic. The developed product is made of two separated parts, which are connected to the snorkeling mask by using the standard port at the top (inlet), as well as the opening near the mouth/chin area (outlet). Fig. 4 shows a schematic of this prototype inspired by the developer's schematics [47].

To the best of our knowledge, Design n°5 is one of the few designs that uses two ports placed at different places on the mask. One can easily note that the modified system will strongly affect the fluid mechanisms inside the mask. As the expiratory system is placed in the front, healthcare workers have a higher probability of being exposed to viral airborne particles if the sealing is not perfect. In addition, the tubing system in the frontal region can induce claustrophobic phenomena and reduce visibility of the patient's face. In the

absence of further scientific data, it remains difficult to compare the efficiency of this configuration with previous ones.

*Design No. 6* (called BrooklynST by the manufacturers) is an example of an adaptor developed for a different mask model than the



**Fig. 4.** Developed snorkeling mask connector design, by Safran and Sugala Technologies, consisting of two separate components for air inlet and outlet (adaptor 1 and adaptor 2).

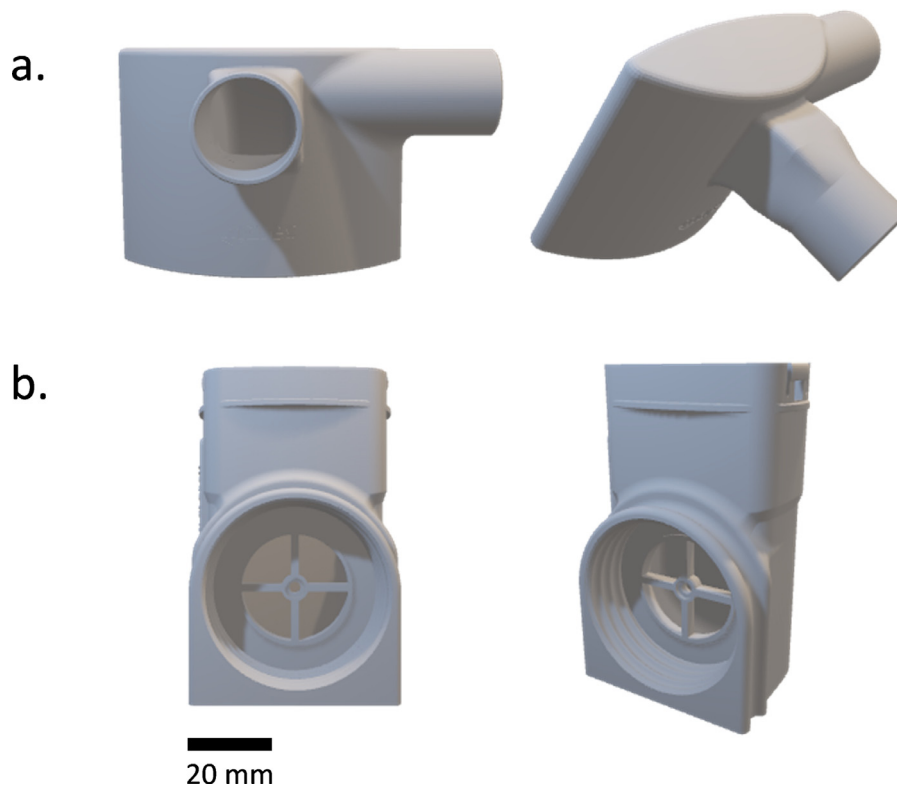


Fig. 5. (a.) Connector developed by Mares (b.) Connector developed by Ocean Reef Group.

Decathlon one. In this specific case, Salvatore Tatta (James J. Peters, Department of Veterans Affairs Medical Center [56]), and Will Haude (3D Brooklyn [57]) have used a snorkeling mask from Ocean Reef because Decathlon scuba masks weren't available online during the pandemic in the United States. This modified NIV system is designed to be used in a closed BiPAP (Bilevel Positive Airway Pressure) or CPAP loop circuit. The adaptor is composed of three parts: a central body on which two gas connectors are attached. The main part is made of PLA, while the separated inlet and outlet are fabricated in PETG to compensate the brittle aspects of the main structure. The designers clearly labelled input and output areas to avoid any possible connection mistake by the medical staff. Compared to the model produced by Isinnova, the length of the output arm was extended to enable the integration of two 20 mm bio-filters side by side on the gas ports. To increase the mechanical strength, the base of the model has been reinforced. The authors recommend sterilizing the printed parts by using Ethylene Oxide (EtO -  $C_2H_4O$ ), highlighting that hydrogen peroxide vapours were too toxic for this system and that steam would damage other components.

*Design No. 7* (called "Silvana IM" by the manufacturers) was developed at UT and is an injection-moulded adapter with its three ports directly connected to the three channels of the Decathlon mask. The central port is the intake while the two outermost ports serve as exhausts. Due to limitations in the injection-moulding process (it must be releasable from the mold plates without additional complexities) the two exhaust ports are not internally connected. In a CPAP application, it therefore requires an additional exhaust filter and PEEP valve, or the two exhaust ports must be joined externally. The injection-moulded adapter offers superior airtightness and sterilizability over 3D printed adapters. The relatively long development time (especially mold design and production) limited effective use of the injection-moulded adapters during the first phase of the COVID-19 pandemic.

Similar prototypes have been also reported by manufacturers of snorkeling mask/scuba equipment, like the Mares company [58]

(Fig. 5a.) and the Ocean Reef Group [59] (Fig. 5b). It is interesting to note that both manufacturers have a very strong commercial activity in Italy, which was among the most affected countries at the beginning of the COVID-19 pandemic in Europe. Both companies offer the possibility to send the produced connectors by using their industrial network, or to use their CAD designs to reproduce the connectors in other parts of the world. Both designs are depicted on Fig. 5. For the Ocean Reef Group design (Fig. 5b.), the inlet consists of three different components with a non-return valve integrated into the inlet/outlet channel, decreasing "dead air" space of the modified device, and avoiding re-breathing exhaust air through the filter. One of the main advantages of this design is the use of a silicone seal that helps reducing possible leakages (a similar idea has also been suggested by Groenhuis et al. [44]). Airflow and the  $CO_2$  levels have been tested for this design with its modification.

The model from Mares (Fig. 5a) is simpler, with two inlets and the possibility to be printed in one piece [60]. In contrast, the Ocean Reef design (Fig. 5b), initially developed as a device for personal protection, can be used as NIV device when coupled with the connector near the mouth/chin area (like design n°5) [61]. Interestingly, other industries have also contributed with similar designs. In April 2020 Ferrari (Italy) [62] has launched the fabrication of modified connectors by using an injection molding process [63]. Similarly, Custom Surgical [64], a German company producing and selling medical devices, proposed different connectors online. Finally, Materialise [65] (Belgium), an industry specialized in 3D printing for medical devices, has developed an original 3D Printed Oxygen PEEP that does not need a snorkeling mask [66]. Although these works have provided a non-negligible help for the health-care community, some limitations related to the use of these modified NIV devices deserve to be highlighted. Preliminary discussions (phone calls, virtual meetings) with persons from different medical institutes across the world (Linköping University Hospital in Sweden, Brescia Civil Hospital Brescia in Italy, Azienda Ospedaliera Papa Giovanni XXIII in Italy, San Giovanni Bosco University Hospital in Italy, St.Bartholomew's hospital in

London, Hôpital Henri Mondor in France, Minneapolis VA Hospital in the USA, Center hospitalier de l'Université de Montréal (CHUM) in Canada) shed the light on the remaining *complexity* of these systems, compared to commercial solutions (*i.e.* non-invasive ventilation systems delivered by helmets [67]). Also, the *not optimized sealing* from the facial mask remains a limitation because it can inadvertently increase the spread of infections in the hospital [68]. Indeed, commercial snorkeling masks have been designed to work with an external positive pressure when immersed in water and have a reduced performance with an internal positive pressure. In this context, Greig et al. discussed the results obtained from a sealing test by using protective equipment based on a modified full-face snorkeling mask. In their study, their design failed the quantitative fit-testing process despite the apparently successful fit-check [69]. Thus, users should pay attention to the different factors affecting the contact between the mask and the skin (*i.e.* presence of facial hair, size of the mask vs shape of the face, eyeglasses) [68]. HCWs can adjust head straps to hold the modified NIV device securely. Additionally, one must consider the *imperfect fit between the 3D printed objects*. In this case, the configuration can be temporarily sealed with nontoxic duct tape or glue. Another limitation is related to the *type and number of modifications* made to the original commercial mask designs. For example, by modifying the position of the original mushroom valves and/or by adding new one-way valves, the gas exchange performance and the CO<sub>2</sub> rebreathing rate can be affected [68]. It is strongly advised to test the modified NIV models before using them inside hospital environments. *Minor discomforts* have also been reported when the device was worn for extended periods mainly due to the strong tightening of the elastics to reduce leaks. Nicholson et al. reported the experience of a radiation therapist wearing the snorkel mask during a work activity [68]. They noted some breathing discomforts and described communication difficulties during the interaction with medical staff as well as patients. Finally, from a commercial point of view, it is important to consider the *cost* behind the use of these systems. For example, all snorkel masks possessing basic functionalities comparable to standard NIV medical masks cost between USD 30 and USD 90. For this reason, economically viable use of modified NIV systems (using retrofitted snorkeling masks) can be justified only if the masks are repeatedly reused. Initiatives to study *reusability* of the described systems (masks + connectors/valves) are ongoing and are beyond the scope of this review. A final point of attention is the *handling* of a mask with its straps while respecting cleaning and disinfection protocols [70,71], which might hamper the ease of its use by HCWs.

### 3. Technical discussion on the use of 3D printed connectors for medical devices

Considering many scientific communications and the outcomes of discussions with different actors involved in the development of 3D objects during the pandemic, we summarize some main technical points that should be considered for the development of printed objects during similar times. Fused Deposition Modeling (FDM) [72,73] is the most common 3D printing technology among the global maker community and researchers, due to its printing speed, its relative low-cost of use and its low investment costs, and its ease of use compared to other polymer printing technologies (*e.g.* resin-based) such as SLA (selective layer adhesion), DLP (digital light processing), SLS (selective layer adhesion), Polyjet and binder jetting [74]. Therefore, we primarily focus this technical discussion on FDM technology.

#### 3.1. Technical challenges for the fabrication of medical devices by using 3D printing technology

It is well known that the quality of 3D printed parts depends on different parameters during the fabrication process [75]. Here, by “quality” we consider the efficiency of printed items for a specific

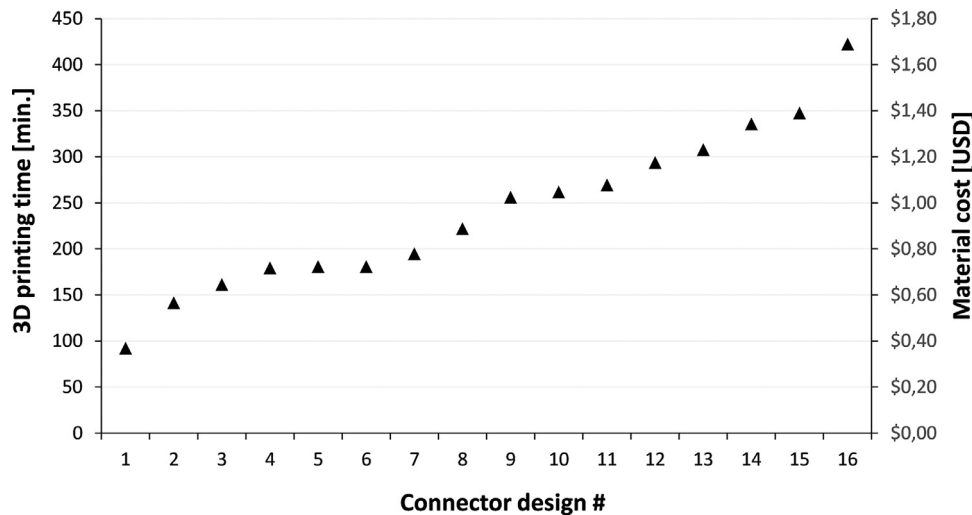
application. As a result, the efficiency of printed connectors is linked to the optimal functioning of the assembly used as a non-invasive ventilator (NIV). This can be affected by the presence of leaks, the mechanical durability of the mounted object, the chemical compatibility of the product in the medical field, as well as the use of simple configurations suitable for non-technical HCWs. In the following paragraphs, we will briefly discuss the main parameters to consider during additive manufacturing of efficient connectors for snorkeling masks.

#### 3.2. Materials used for connectors

The materials used for the filament (or the resin/powder) strongly affect the proprieties of the printed items [72,75]. For example, connectors must be airtight in order not to alter intended FiO<sub>2</sub> levels (*i.e.* the fraction of inspired oxygen) during respiration, or exhaust virus-transmitting aerosols. Nicholson et al. highlighted that the weakest link of the device remains the connection between the adapter and the mask [68]. In their work, the authors use a small amount of putty and a tie wrap to seal the connection. They also suggest using high-resolution printers, such as the white Somos GP resin (DSM), to allow a better fit. As gaseous species inside the connectors remain in intimate contact with the respiratory apparatus, only materials that do not exhibit degassing are recommended for use by HCW. The same authors report the use of XTC-3D (Smooth-On, Inc., Pennsylvania, United States) to coat the connectors and improve their airtightness [68]. Although the authors consider the polymeric resin does not have any vapor pressure, no information on the aspiration hazard can be found on the chemical datasheet [76]. Other studies report the use of manually glued connectors, using adhesive chemicals (*i.e.* Loctite 4601 glue or acetone CAS 67–64–1) [77]. It is recommended to use as much as possible materials already approved for medical use. More information is provided from different governmental agencies promoting public health around the world (*e.g.* the FDA website [78]). It is also necessary to distinguish between materials for the prototyping step, and materials that will be used to manufacture medical devices.

#### 3.3. The lifetime of manufactured products

Other important factors to consider are the chemical and mechanical durability of connectors. For instance, all connectors must be cleaned and sterilized before their use to compensate uncontrolled manipulations during printing and assembling. The Erasme team (Belgium) soaked printed items in a 70% IPA/water mixture before packaging [77]. Similarly, the medical staff at Center hospitalier de université (CHU) Henri-Mondor developed a cold sterilization method using a combined H<sub>2</sub>O<sub>2</sub> plasma process with UV treatment (Sterrad, more information here [79]) on ABS connectors. Other authors suggest the use of dry sterilization (*i.e.* heating) to eliminate the accumulation of liquids in remaining pores of 3D printed parts after their fabrication [44]. On this basis, it is often recommended to use PETG/CPE for the fabrication of connectors because this material can resist higher temperatures (80°) than PLA-objects (65°). On the other hand, PLA is easier to print and has less stringing resulting in a cleaner appearance of the printed product. UV sterilization is not recommended because of the low penetration in the rough surface and the opacity of some printed objects. However, to our knowledge, there are no scientific data describing the physical and chemical effects on printed connectors subject to different cleaning processes. Accordingly, although some suggest the reuse of modified NIV devices to decrease their cost (Ocean Reef highlights the possibility to reuse their mask by easily sanitizing the latter in boiling water), one can conclude that these systems were not intended to be reusable and further studies are required to provide more clear information.



**Fig. 6.** Graph overviewing estimated FDM printing time (minutes) and average material cost (US dollar) when using PLA feedstock for the discussed snorkeling mask designs tabulated in Table A1 (Appendix I).

### 3.4. 3D fabrication process modes

During the pandemic, the fabrication of 3D printed objects has partially compensated for the shortage of healthcare devices, and a local manufacturing approach has been privileged. It is important to notice that most of the 3D printed prototypes were developed using FDM technology. FDM has the advantage to be easily accessible by the maker community and it provides a low-cost product rapidly. However, one must consider that FDM 3D printing processes are in most cases (1) not adapted for mass production of objects, and (2) used for rapid prototyping. Therefore, a multi-part printing approach has been used for printing connectors. Depending on the printing mode selected, such approaches can increase the production rate of objects while reducing associated costs. It is important to mention that key FDM printing parameters such as building orientation, nozzle (size, geometry, material) and printing bed temperature [80–82], infill patterns [83], and porosity [84,85] control the mechanical properties (e.g. strength, stiffness, toughness) of the printed parts [86]. To ensure best performances of these parts, it is essential to optimize the parameter settings [87] and to design the model respecting basic 3D printing guidelines [88]. More specifically, adhering to technical considerations for printed medical devices established by the FDA [89] is crucial. The airtight sealing of printed connectors appear crucial for its use in the COVID-19 pandemic context. Printing with sufficient wall thickness infill and material extrusion rate is proven to significantly reduce the permeability of FDM printed parts. We refer to literature for a study outlining details on quality improvement by elimination of microscopic structural defects [90]. One adapter typically weights around 25 g depending on the model. A typical FDM printer with 0.4 mm nozzle printing 0.2 mm thick layers at an average printing speed of 30 mm/s has an extrusion rate of  $(0.4 \cdot 0.2 \cdot 30) \text{ mm}^3/\text{s} = 2.4 \text{ mm}^3/\text{s}$  which prints a 25,000 mm<sup>3</sup> model in just under three hours. Fig. 6 presents an overview of the estimated FDM printing time (min.), based on the average 2.4 mm<sup>3</sup>/s printing speed, and average material cost (in US dollars (USD), averaging five global feedstock suppliers) when using PLA feedstock for the discussed snorkeling mask designs tabulated in Table A1 (Appendix I).

To optimize printing efficiency a set of connectors is usually printed in a single batch, e.g. on average eight connectors which can then be printed in 24 h. Printing one batch usually follows the “Multiple Process, Continuous Printing Mode” in which all connectors are printed layer by layer at the same time. If space allows then “Single Process Printing Mode” may also be possible in which the connectors are printed one by one, which has the advantages that travel

movements between objects are minimized, reducing oozing. If the printer configuration allows, special slicing settings allow to automatically “pop” connectors off the printing bed (by the printer head) to enable uninterrupted sequential printing of the same object at the same location.

Besides FDM there are also 3D printing technologies that work using fine materials (e.g. powders) which are first deposited layer by layer and then locally joined by lithography (SLA), laser sintering (SLS) or binder jetting. These techniques are much more expensive than FDM and therefore less cost-effective when mass-producing adapters. The printing arrangement and support structures also follow different guidelines than in FDM. Fig. 7 is depicting the final assembly of the 3D designs before printing considering two different technologies. Fig. 7a. shows the arrangement of multiple “Silvana” adapters for printing in PLA material on an FDM printer (Prusa i3 MK3). Fig. 7b. presents a configuration for printing adapters in PA12 material on a binder jetting printer (HP Multi Jet Fusion 580) as described by Castegnaro [91]. One can note the optimized arrangement of the different components to maximize the number of adapters printed in one batch.

## 4. Conclusion

This paper reports a systematic overview describing the use of 3D printed connectors to retrofit full face snorkeling masks for the fabrication of NIV devices. This contribution aims to 1) structure recent developments in 3D printed snorkeling mask connectors and their designs to facilitate their use, and 2) to highlight the potential and the challenges of deploying AM/3D printing for producing parts in the COVID-19 pandemic. A detailed overview of the most significant contributions on snorkeling mask connectors is presented providing its 3D models, printing volumes and estimated fabrication times and printing costs when using PLA feedstock. This study allows a rapid assessment of developed connectors for HCW in urgent need of retrofitting snorkeling masks for NIV purposes (e.g. CPAP mode).

From a technical point of view, several parameters should be considered to ensure the benefit of employing innovative 3D printed products to optimize the manufacturing process: (1) The *final cost* should be reasonable for consumable products to guarantee the fabrication at large scale. (2) *Geographical availability* of the *feedstock* (polymers, ceramics, resins) and *printers* should be optimized as healthcare institutes have often centralized supply demand, and (3) The final printed product must demonstrate a *medical efficiency* comparable to commercial items sharing similar features. However,



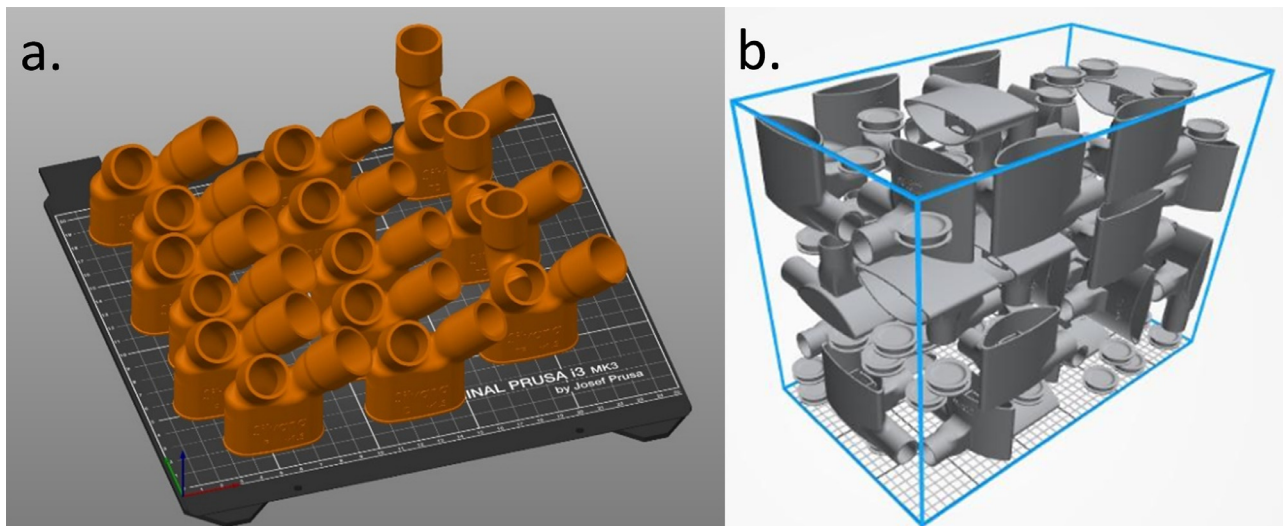


Fig. 7. (a.) Object arrangement in a typical FDM printer. (b.) Arrangement of the 3D design established by Nuovamacut in a binder jetting printer.

several concerns were raised when using the AM method and care should be taken in using the best printer parameter settings to realize best fitting and airtight connector-mask connections.

In overall, the possibility to decentralize rapid manufacturing by deploying 3D printing and to create “citizen maker supply chains” resulted in a reduction of PPE and NIV equipment shortages, leading to improved healthcare and personnel safety in the midst of the pandemic.

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#### Conflict of interest

The authors declare that they have not known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. The authors declare no conflict of interest.

#### CRedit authorship contribution statement

**Jacopo Profili:** Conceptualization, Methodology, Investigation, Validation, Writing – original draft, Writing – review & editing, Visualization, Project administration. **Rafael Brunet:** Investigation, Writing – review & editing. **Émilie L Dubois:** Validation, Writing – review & editing, Visualization. **Vincent Groenhuis:** Investigation, Validation, Writing – original draft, Writing – review & editing. **Lucas A Hof:** Conceptualization, Methodology, Investigation, Validation, Writing – original draft, Writing – review & editing, Supervision, Project administration.

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#### Supplementary materials

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