Is additive manufacturing a magic bullet to resupply lacking PPE? Producing respirators and face shields during COVID-19 pandemic: A systematic review

Czy druk 3D to skuteczny sposób na dostarczenie brakujących środków ochrony osobistej? Produkcja maseczek ochronnych i przyłbic podczas pandemii COVID-19 – przegląd systematyczny

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Abstract

Coronavirus Disease 2019 (COVID-19) pandemic caused an increase in the demand for personal protective equipment (PPE) and disruptions in production chains, resulting in an acute shortage of PPE. A possible solution to this problem was additive manufacturing (AM) technology – allowing for a quick start of the production of PPE and potentially able to meet the demand until the production is restored. In addition, AM allows for the production of PPE prototypes with potentially greater comfort of use or degree of protection. In order to assess the production of PPE in AM during the COVID-19 pandemic, previously published articles in this field were analyzed. After analyzing abstracts and full texts, 30 original works were selected from the initially collected 487 articles.

Based on the analyzed literature, it was found that there are not enough studies comparing traditional and AM PPE as well as not enough comparisons of the different types of AM PPE with each other. In many cases, researchers focused only on the subjective assessment of the comfort of using PPE, without assessing their effectiveness in preventing infections. Despite that, AM has a great potential to quickly produce lacking PPE. Respirators and shields made by AM were rated by the vast majority of users as comfortable to wear. Some of the respirators could be adapted to a specific user, by designing on the basis of a face scan or after warming up the finished print and modeling the shape.

Key words: COVID-19, personal protective equipment, three-dimensional printing

Streszczenie

Pandemia COVID-19 doprowadziła do jednoczesnego wzrostu zapotrzebowania na środki ochrony indywidualnej (ŚOI) oraz przerwania łańcuchów produkcji, co poskutkowało dotkliwym niedoborem ŚOI. Możliwym rozwiązaniem tego problemu okazała się technologia druku 3D, pozwalająca na szybkie rozpoczęcie wytwarzania ŚOI i potencjalnie mogąca zaspokoić popyt do czasu przywrócenia produkcji dotychczasowymi metodami. Ponadto technologia druku 3D pozwala na wykonanie prototypów ŚOI o potencjalnie większym komforcie użytkowania lub stopniu ochrony.

W celu oceny produkcji ŚOI w technologii druku 3D w trakcie pandemii COVID-19, przeanalizowano dotychczas opublikowane artykuły w tej dziedzinie. Po analizie abstraktów oraz pełnych tekstów, z początkowo zebranych 487 artykułów wyłoniono 30 oryginalnych prac.

Na podstawie przeanalizowanego piśmiennictwa stwierdzono, że brakuje badań porównujących tradycyjne oraz wydrukowane ŚOI oraz porównań wykonanych już ŚOI między sobą. Ponadto w wielu przypadkach badacze skupili się jedynie na subiektywnej ocenie komfortu użytkowania ŚOI, bez oceny ich skuteczności w ochronie przed zakażeniem. Pomimo tych zastrzeżeń druk 3D ma duży potencjał szybkiego wyprodukowania brakujących ŚOI. Wykonane w tej technologii maseczki oraz przyłbice ochronne były oceniane przez zdecydowaną większość użytkowników jako komfortowe w noszeniu. Część maseczek ochronnych dawała możliwość dostosowania do konkretnego użytkownika poprzez zaprojektowanie na podstawie skanu twarzy lub po rozgrzaniu gotowego wydruku i wymodelowaniu kształtu.

Słowa kluczowe: COVID-19, środki ochrony osobistej, druk trójwymiarowy

Introduction

In December 2019, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first isolated in Wuhan, China. Since then, the virus has spread all over the world causing a global outbreak. In March 2020, the World Health Organization (WHO) announced the current situation as pandemic with overall 118,000 cases worldwide.[1] The increasingly high numbers of Coronavirus Disease 2019 (COVID-19) cases made it difficult to ensure protection not only for patients but also for healthcare workers. Wang et al. proved that 29% of in-hospital infections had health professionals involved.[2]

The virus spreads by respiratory droplets, e.g., coughing and sneezing, and is present in the upper respiratory tract for approx. 2–10 days before any symptoms appear.[3] Face shields combined with additional mouth and nose masks have been recommended to reduce the risks of inhalational exposure, specifically when performing activities with aerosol formations. Considering that no causative treatment is available, prevention has become the main objective. These aspects made it a necessity to cover the face and disinfect all used surfaces.[4,5] The global situation made it necessary for everyone to gain access to personal protective equipment (PPE). The pandemic created a great shortage in PPE and additive manufacturing (AM) was an alternative solution to this problem. Face shields are PPE devices used in many professions for protection of the face area from splashes and sprays of body fluids. Nonetheless, to be effective during the COVID-19 pandemic, they should be used with other protective equipment.[6,7]

The traditional manufacturing industries almost shut down because of lockdown measures, so AM stepped in to supply medical professionals. The steps for AM production of the PPE consist of creating or obtaining the project for the parts, and producing and assembling them with the additional required supplies. Additive manufacturing is a process which involves adding the material layer by layer in line with a computer-aided design model.[8] Models can be created using numerous 3D design software. Eventually, the designed model is conveyed to a slicer software to set production parameters, such as the height of the layers and the thickness of the shell of the models. Finally, the AM machine uses the resulting file to manufacture the model. The last step is post-processing: for example, removal of supports and sanding.[9] There are many methods of AM such as fused deposition modeling (FDM), stereolithography (SLA) and digital light processing. However, most of the analyzed papers described the use of FDM technology.

Materials and methods

A systematic literature review was done using the PubMed and Scopus databases. The search strategy was extensive to ensure that no significant articles were missed. The search algorithm consisted of 3 conditions, all of which had to be met: 1) connected with AM ("additive manufacturing", "3D printing" and names of individual AM techniques); 2) connected with COVID-19 pandemic ("covid 19", "sars cov 2", "pandemic", "coronavirus", "severe acute respiratory syndrome coronavirus 2"); 3) date of publication between November 1, 2019 and July 31, 2021, to exclude publications from before the outbreak of the COVID-19 pandemic. Also, in the case of the Scopus database, due to its multidisciplinary characteristics, the search criteria have been narrowed down to the Medicine category.

Only original papers were selected. Publications written in languages other than English or without a full article available were excluded from the analysis. Papers about virtual 3D rendering or modeling without manufactured AM parts were not included. Only articles where AM technology was used to produce or assist with testing and designing face respirators or face shields during the COVID-19 pandemic were selected.

The research team was divided into 2 workgroups. At each step, where biased selection had to be taken into consideration (2 stages: abstract screening and full-text screening), each group separately performed a manual selection. After that, the differences in the assessment were summarized and a discussion was held between both groups to establish a consensus. If no consensus was possible to achieve at the abstract screening step, the final decision was postponed until the full text was analyzed.

The articles that passed the full-text review were analyzed in detail using the table of evidence to present the relevant features and results of the study. Based on the results commonly reported in literature, the following variables were included: AM-made PPE types, analyzed PPE parameters, number of participants, test duration, test results, AM technology, and machinery and materials used. Detailed procedure of the article screening is presented in Fig. 1.

Face mask design

Many mask designs have come to light during the pandemic. Most of them consist of 3 reusable parts: the mask base, the filter grill and the filter insert (Fig. 2A). The mask straps are assembled using phlebotomy straps, Velcro/elastic bands or simple strings.[10–13] The disposable filter is placed between the filter insert and the filter grill. The filters inserted were: nano-sized Cumminis, IsoGuard filters, FFP2/FFP3 and HEPA. The FDM mask offered the possibility of reshaping, using both microwave and hot water since it is thermoplastic – this ensures a better fit on a user's face.[14] Face masks can be also custom-made by using face scanning programs. The obtained data are then used to design a 3D model.[11]

The limitation of available commercial standard masks is the poor variety of face shape. To ensure better protection, the design can be personalized. Fit testing of respirators is mandatory in some workplaces.[15] In particular, it is essential while performing procedures posing high risk of virus exposition, such as nasolaryngoscopy.[16]

Many researchers took advantage of computer-aided design software to implement some improvements in their projects. Helman et al. used the open-source design and modified it, enclosing more of the midface and adding 2 ports (they used software such as Blender (www.blender.org) and Fusion 360 (https://www.autodesk.com/products/fusion-360/overview)).[17] Piombino et al. used Meshmixer (www.meshmixer.com), which is available for free – that was important during the episodes of lack of PPE during the COVID-19 pandemic.[18] Shaheen et al. and Swennen
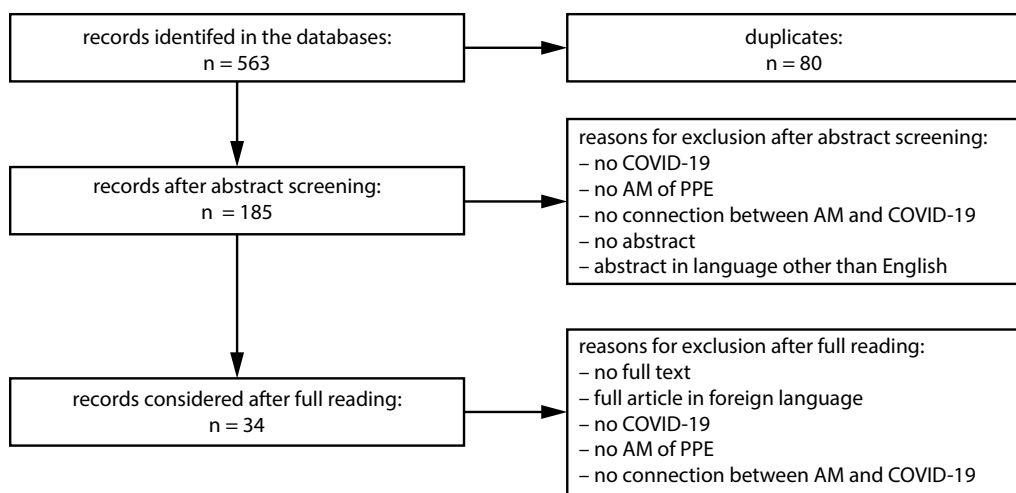
Fig. 1. Algorithm of articles selection

COVID-19 – Coronavirus Disease 2019; AM – additive manufacturing; PPE – personal protective equipment.
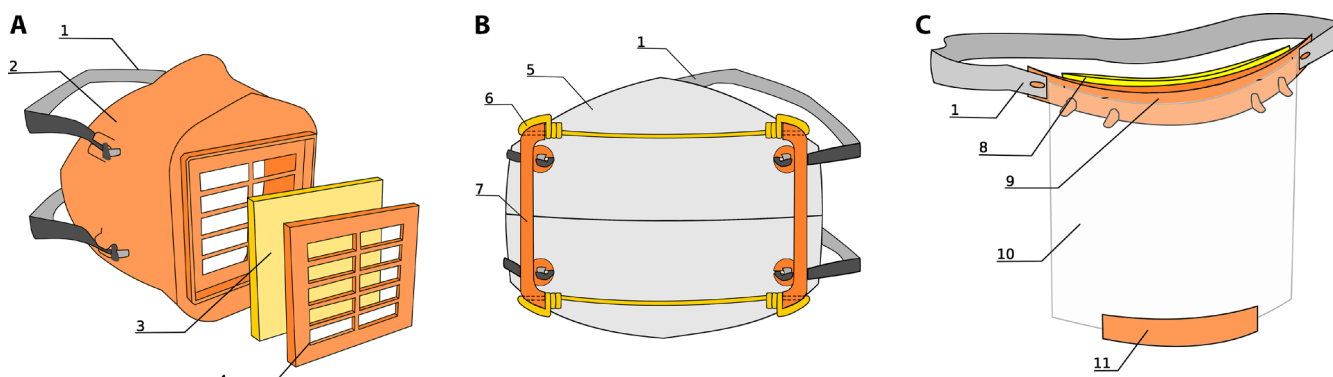
Fig. 2. A. An example of additive manufacturing (AM)-made face mask: 1 – straps, 2 – mask base, 3 – filter insert, 4 – filter grill; B. An example of AM-made face frame: 1 – straps, 5 – commercially available respirator, 6 – wire, 7 – frame; C. An example of AM-made face shield: 1 – straps, 8 – adhesive foam, 9 – headband, 10 – transparent layer, 11 – chin support

et al. used VECTRA Face Sculptor® to automatically put key landmarks on soft tissues on the face.[5,11] Davies et al. added port to existing face mask model (Copper 3D Nanohack; Copper 3D, Santiago, Chile) with Materialise Mimics software (www.materialise.com).[16]

There are various methods of minimizing the risk of virus transmission. Some designs (e.g., Helman et al.) were filled with vacuum seal between the face and the mask.[17] As tightness of the face mask increases, the protection becomes more effective. Another way to optimize the fitting of PPE is 3D face scanning. Swennen et al. used new generation smartphone with 2 cameras supported with Bellus3D app to generate individual 3D face scans.[11] Shaheen et al. used 3D camera VECTRA® H1 (Canfield Scientific Inc., Parsippany, USA),[5] while Piombino et al. used smartphone and Bellus3D application (Bellus3D, Campbell, USA).[18] These customized face masks can be complemented with a disposable filter membrane support, also designed using computer-aided design – those masks become consistent PPE after quick assembly. Both elements are connected with each other using screw fixation, which also improves tightness.[11]

Another interesting design concept is a project whose originators are Ng et al. Their design was adopted from a simple silicon respirator and was modified and produced with silicone injection molding. This one provides tightness and good filtration; it is also equipped with a port for a pleated-membrane respiratory filter.[19]

Anwari et al. designed a reusable mask, called a "simple silicone mask" (SSM). The SSM was invented for the appropriate fitting to a user's face shape. This was achieved by designing a special harness added to the basic mask construction and using silicone that provided air-tight seal. The design was supplied with a heat-moisture exchange filter. The mask was cast using original FDM molds.[20]

Bezek et al. found that the application of an epoxy sealant to the Stopgap respirator (made of polylactic acid (PLA)) increased the filtration efficiency from ~55% to a peak of ~75%.[21]

Face mask accessories

Not only masks but also accessories improving their quality and effectiveness, such as mask adapters, can be produced using AM technology. The design created by Imbrie-Moore et al. consisted of 3M N95 face mask (3M, Saint Paul, Minnesota) and SLA rigid cartridge with sealing flange.[22] Another PPE which was complemented with AM-made accessory, the adapter, was a full-face diving mask.[23]

Davies et al. designed face masks and adapters that may be used by patients undergoing medical procedures, such as nasal endoscopy. When examining a patient equipped with AM-made PPE, healthcare workers are less exposed to viruses.[16]

McAvoy et al. described the development of the design of the FDM face frames (Fig. 2B) that prolongs the lifespan of masks and allows them to be reused. The simple design enables it to be easily molded for customization.[24]

Face shield design

Most of the face shields consist of 3 main parts: the head band, the transparent layer attached to the band, and string/straps and additional parts that include optional chin support and adhesive foam (Fig. 2C). In addition to the manufactured parts, straps and transparent film are needed to assemble the shield. During the usage of face shields one should have in mind that they are inadequate as an individual protection, and will not be sufficient without a face mask.[10,25]

In the designing process, it is crucial to adjust further properties of the face shields to special medical allocation of this PPE. Hence, the design must be adapted to the needs of medical staff during the COVID-19 pandemic, the shortage of materials and lack of time for PPE preparation. Moreover, AM can make PPE more customized. Thanks to individual design modifications, AM-made face shields have features not present in commercially available ones.[26,27] For example, Critical Cover Coverall Face Shield by AlphaProTech (Markham, Canada) does not provide adequate liquid protection at the top and on the sides of the visor.[26]

Most of the studies focus on such parts of the design as: efficient protection (e.g., from aerosols and liquids), comfort of wearing (especially when worn for a long time), the possibility of fast assemblage of a PPE, and making it easy to manufacture. There are different methods that help to achieve these goals, for example, adjusting the length of the face shield to clinicians' needs, easy attachment, limitation of holes in the PPE, and adding the lip above the visor.[26,27] The most popular face shield design in analyzed studies was PRUSA RC2.[6,26,28]

A much more complicated design was presented in the study conducted by Huang et al. – a design consisting of 4 elements: goggles, lenses, exact face shield, and elastic bands. The goggles are the most comprehensive part of this design, because, as any other part of the shield they must fit the user properly. They were designed in 3 sizes (large, medium and small).[27]

Lemarteleur et al. designed a face shield that required 3 h to manufacture. The project was inspired by the open-source PRUSA RC2 and PRUSA RC3 models (Prusa, Prague, Czech Republic). The headband consisted of 2 arches: one to support the forehead, the other one to deflect the shield from the face. This construction prevented from fogging and was obtained with FDM using polylactic acid (PLA).[29]

It is crucial to mention that not only the significant features of face shields, but also the method and efficiency of production and a potential for large-scale manufacturing are the key elements in evaluation of a particular project.[6,25,26] Stacking – producing multiple parts on top of each other (they require post-processing for separation) – may be a factor providing effectiveness and reducing the costs of production.[25,26] The lack of this feature may be an exclusion criterion for the design due to its impracticability. A detailed comparison of face shield designs is presented in Table 1.

Table 1. Different face shields design comparison[6,26,30–32]

Parameters	Prusa RC1	Prusa RC2	3D Face Shield V3 (Budmen)	Easy 3D Face Shield	Modified Prusa (PanFab)
Tools for assembling	DIN A4 perforator	DIN A4 perforator	DIN A4 perforator	none	additional laser cutting or rotary die cutting of the transparent shield
Weight [g]*	39	51	42	30	no exact data, but it was mentioned that the design was based on RC2
Wearing comfort according to analyzed articles	worse because of a clamp for head frame (might be too tight)	increased (when compared to RC1) due to no clamp for head frame	less comfortable for medical staff than RC2 (e.g., due to rigidity)	similarly comfortable to RC2 (e.g., due to lower weight)	perceived as more comfortable for medical staff (e.g., due to reduction of tightness) than RC2
Anchor point	placed lateral to the headband	similar to RC1	similar to RC1	visor is put into a small continuous slot with clamping retention	placed in line with headbands – reduction of tightness
Dimensions and print volume requirements [mm²]	240 × 240	144 × 191	requirements as in RC2	requirements as in RC2	240 × 305
Attachment (shield to strap)	four-point attachment; necessity of perforation	similar to RC1	similar to RC1	visor is put into a small continuous slot with clamping retention	six-point attachment; necessity of perforation
Protection from liquids (during special medical procedures) on the top and sides of visor	restricted in the area on the top of the visor	similar to RC1	no data	no data	fin on the top of headband and additional plastic lip
Additional equipment	lower space between face and visors (when compared to RC2)	increased space between face and visors (when compared to RC1) – easier to put eye or mouth-nose personal protective equipment (PPE) (goggles, masks)	space between face and visors comparable to RC2	space between face and visors comparable to RC2	no direct data, but space between face and visors regarded as comparable to RC2
Possibility of stack printing	no	yes	no	no	no exact data

* fused deposition modeling (FDM) technology was used; the weight can differ depending on the type of used materials or print parameters (e.g., the number of walls, infill density).

Face masks – materials

The transmission of SARS-CoV-2 occurs primarily by droplets. Most of the studies for testing filtration efficiency use particles with the size of 300 nm, whereas viruses are slightly smaller.[33]

Swennen et al. designed a reusable face mask design, which consisted of 4 elements, 2 of which were produced using selective laser sintering (SLS) and were reusable. The most important component was the mask itself, which was made of polyamide composite (PA11-SX 1450). This material has ISO/USP Class VI medical certification, which proves that there are no negative, long-term effects on the organism resulting from its use. The replaceable elements were the head fixation band and the polypropylene particle filter membrane (Moldex 8080).[11]

A filter project published by He et al. assumed the use of nanofiber mat made of 10% PLA (polylactic acid) solution dissolved in chloroform and n,n-dimethylformamide. The main body of the filter, on which the nanofiber mat was embedded in order to strengthen and avoid damage to its fibers, was made of the same solution, previously dried for 12 h at 80°C. The optimal printing temperature was 210°C. Higher temperatures led to a loss of transparency and filtration efficiency. The effectiveness of the surgical mask (filtration efficiency at least 55% for 700 nm mass median aerodynamic diameter) was exceeded with the use of 1 layer. The use of 2 layers allowed to achieve over 80% (FFP1 criteria), and the use of 4 layers – over 94% (FFP2), in some cases even above 95% of filtration efficiency (KN95/N95).[33]

In case of face masks, in order to prevent the virus from getting into the respiratory tract, a suitable, close fit to the face is necessary. Rendeki et al. describe the Face Mask v. 2.0 model, in which a layer of silicone has been added to reduce air leakage at the point of contact between the mask and the face. Disinfection does not adversely affect the mechanical properties of this material, and moreover, it is long-lasting and durable.[34]

The design of individual face masks on the basis of a 3D face scan was proposed by Shaheen et al. VeroClear

photopolymer, which is characterized by hardness and transparency, was used to print 6 components. The last element, a soft rim, was made of TangoPlus photopolymer, a soft transparent rubber-like material.[5]

Imbrie-Moore et al. shared an idea to transform one N95 face mask into 4 new masks with the same properties. They used SLA technology. The main materials of the mask adapter were multi-purpose polyurethane and biocompatible silicone. The filter was made of an N95 mask and it was attached using a nontoxic thermoplastic adhesive.[22]

Proper disinfection is a challenge that must be faced when using PPE made with AM technology. Vaňková et al. published an article comparing the disinfection efficiency of PLA using 96% ethanol, 70% isopropanol or 0.85% sodium hypochlorite. A suspension of bacteria and viruses (SARS-CoV-2) was applied to the reference object made of PLA. All 3 agents were effective in terms of complete decontamination against SARS-CoV-2. It is worth noting that in the case of ethanol, there was also a slight melting of filaments made of PLA. It led to a decrease in the distance between individual filaments, an increase in density and, presumably, the improvement of the filtration properties.[35] Welch et al. tested several materials, including PA12, acrylonitrile butadiene styrene (ABS) and PLA. A single application by wipe of quaternary ammonium (Sani-Cloth germicidal disposable wipe), 3% H_2O_2 and 10% bleach resulted in a complete inactivation of tested viruses, including SARS-CoV-2. However, a single wipe of 70% isopropyl alcohol led only to >95% inactivation, as compared to >99% effectivity of other compounds. For complete virus inactivation, stronger application might be required.[36]

Table 2 provides a summary of the properties, advantages and disadvantages of the filaments used in the production of face shields and masks using FDM technique.

Face shields – materials

Several tools and components are required to make the face shield. In most cases, only the main body of the face shield is made using AM techniques, to which the remaining accessories are then attached.[25]

The face shield project designed and published by Amin et al. contained a main body made of PLA filament. The protective barrier was a transparency film made of plastic. The face shield was attached to the head with 2 Velcro strips. In order to increase the comfort of use, a sponge was glued to the contact point of the AM-made headband with the forehead. The authors allow the use of Super Sani-Cloth® Germicidal Disposable Wipes (PDI, Woodcliff Lake, USA) for disinfecting and cleaning the face shields.[25]

A model designed by Armijo et al. consisted of 2 elements produced with FDM technology: a headband and a chin piece, which were manufactured using PLA. A transparent polyvinyl chloride (PVC) sheet and a head strap were installed to the headband. It is also possible to use plexiglass or laminating foil as a protective layer. The biggest disadvantage of PVC was the gradual loss of transparency due to the used cleaning solution. Optionally, in order to increase the comfort of use, the authors recommend gluing the foam to the inside of the headband. However, this will make it impossible to reuse the face shield after sterilization, which is done by disassembling the model and then dipping individual elements into the dilute bleach solution, followed by drying.[10]

Wesemann et al. published an article comparing 4 face shield designs. The main body of each of them was made of the biodegradable material Extrudr Green-TEC PRO (Extrudr GmbH, Lauterbach, Germany; carbon filament based on lignin). The protective layer was a transparent foil made of polyethylene terephthalate. In order to keep the face shield on the head, an elastic polyester strap was used.[6]

In the article published by Rendeki et al., scientists tested the disinfection of face shields manufactured with PLA, and the transparent protective layer made of poly(methyl methacrylate) (PMMA). As a disinfectant, they used a solution consisting of sodium perborate and tetraacetylethylenediamine. One disinfection cycle was run at 24°C and

Table 2. Properties, advantages and disadvantages of various filaments used for the production of face shields and masks using fused deposition modeling (FDM) technique[6,10,33,37,38]

Material property	PLA polylactic acid	ABS acrylonitrile butadiene styrene	PET polyethylene terephthalate	Green-TEC PRO based on lignin
Printing temperature	180–220°C	230–255°C	220–235°C	160–190°C
Durability	brittle	durable	durable	stable
Warp deformation*	little	prone	moderate	little
Autoclave sterilization – temperature stability	volume change	not recommended – low heat resistance	volume change	dimensionally stable
Other	high-speed low-cost material; ease of use; completely biodegradable	possibility of generating toxic gas fumes during printing; higher risk of shrinkage during cooling; not biodegradable	absorbs water – needs to be stored in specific conditions; not biodegradable	biodegradable

*warp deformation – bending towards the energy source caused by inner stresses resulting from the contraction of layer, lack of pre-heating the base plate, non-uniform distribution of temperature inside the build chamber, or improper control of process parameters.[39]

lasted for 1 h. Scientists compared the face shields after 0, 5 and 10 cycles, in terms of light transmission (using spectrophotometry – measurability of light transmission) and mechanical parameters: flexibility (tensile strength) and brittleness (three-point bending test). In terms of mechanical parameters and visibility, no significant changes were observed after 5 and 10 disinfection cycles.[34]

Perez et al. in their review article brought up the topic of sterilization of items made using AM technology. There are 4 main sterilization techniques commonly used in medicine: autoclave, gamma radiation, hydrogen peroxide gas plasma, and ethylene oxide gas. The following different materials were used for the tests: PC-ABS, ABS-ESD7, ABS-M30i, ABS-M30, and ABSi. From each of them, 30 specimens of the ASTM D638 Type I design were made and sterilized using the above methods. Then, each of the samples (including test samples, not sterilized) was placed in an airtight glass container in 60 mL of tryptic soy broth and incubated for 14 days. Efficacy evaluation was performed through the observation of tryptic soy broth, which became cloudy after the contamination with fungal or microbial agent. The authors report that individual samples gave a positive test result, but note that the contamination could have occurred after sterilization, during the transfer of the material to the incubation site. Of all the methods, it is worth noting the disadvantages of the autoclave as a method of sterilization of samples made of acrylonitrile butadiene styrene (ABS) derivatives. Humidity and high temperature had a negative effect on this material, leading to indentations, bending and color change.[37]

Sterilization of products made with the FDM technique using ultraviolet light is ineffective because these objects are not watertight or airtight.[10]

Noguera et al. tested possible damage of PPE due to 0.1% sodium hypochlorite, 70% ethanol and H_2O_2-quaternary ammonium salt mixture. The FDM face shields headbands were made using different materials (including PLA, ABS and polyethylene terephthalate glycol (PETG)) and layer thickness. Visors were made of 0.5 mm PETG, 0.5 mm poly(ethylene terephthalate) (PET), 0.75 mm polycarbonate, or 0.5 mm/0.75 mm polyethylene glycol (PEG). Disinfection was done using gas soaked in chemical solution, 30 times to headbands and 40 times to visors, followed by spontaneous drying. Researchers observed no physical changes in visual integrity to tested models.[40]

A comparison of commonly used materials for AM is presented in the previous chapter (Table 2).

Discussion

Most of the analyzed articles were peer-reviewed (excluding the article by McAvoy et al.[24]). There are concerns about the technical aspects of AM in this field, in particular FDM, as it was the dominant technology in the analyzed articles. For example, Gomes et al. defines the process

speed as 100%,[28] which is a relative parameter, and therefore it is difficult to estimate the absolute value of the speed. It should be reported in millimeters per second with acceleration and jerk values. Moreover, it should be taken under consideration that any comparison of production times is also relative as there are many parameters that can be modified to accelerate production, often with (acceptable) decrease of quality.

Neijhoft et al. assessed the quality of the manufactured parts by assigning each FDM machine a different filament color.[41] Unfortunately, there is no information about the selected production temperatures, but it should be noted that the correct production temperature of PLA varies depending on the color of the filament.[42] It adds additional complication to the production – instead of quality assurance, each machine should be using individually modified file, for example with a simple marking (number of the machine) on the surface of the model.

Bezek et al.[21] describe a lot of flaws in their AM-made mask respirators, without any concern about possible errors during the manufacture process. Afinia H800 3D printer (Afinia, Chanhassen, USA) was used in their research. It is a fully enclosed FDM machine and as the picture of their product made of PLA suggest, a problem with the part cooling had occurred. The air cooling the model (during the printing) is warmer due to enclosure (air is taken from the inside); enclosure is used to provide slower cooling of the model (and usually is used without active cooling). There is a possibility that this problem affected PLA mask respirators manufactured by this team.

Parameters that were taken into account during face mask analyses included qualitative fit testing,[24] quantitative fit testing,[19,22,43] filtration efficiency,[13,21] and overall comfort or discomfort (Table 3).[18,19,43]

It is worth emphasizing that the use of 3D face scanning techniques allows for producing a mask with the highest degree of adhesion, and thus, tightness.[5,11,18] In order to increase the comfort wearing of a face mask obtained using AM techniques, the use of soft rim, most often made of silicone, has become common.[5,22,34] Designs of a modified full-face diving mask with AM-made additives and an additional filter were also described.[13,23] To increase the fit, microwave and hot water can be used, which allows for reshaping of an FDM face mask made of PLA.[14]

The methodology of the papers analyzing face shields varied (Table 4). Only 2 of them compared different types of AM-made face shields,[6,44] other assessed only 1 type,[26,27,45–47] and 1 compared N95 mask, goggles and face shield to modified full-face snorkel mask (with AM-made elements).[48] Number of participants (face shields testers) was between 9 and 300. The observation time was from 30 to 60 min in most cases, but multiple articles lack this information. The parameters included in the analyzes were COVID-19 infection,[27] participants' physiological parameters such as blood pressure,[48] fogging and splash protection,[26] but most of all, the individual evaluation

Table 3. Review of validations of additive manufacturing (AM)-made face respirators studies (including AM-made respirators accessories). Analyzed parameters included: qualitative fit testing (QLFT), quantitative fit testing (QNFT), filtration efficiency, and subjective users' opinion on the respirator

Study	Compared face respirators types	Parameters	Number of participants	Duration of test	Results	AM technology, machine, material	Comments
McAvoy et al.[24]	AM-made mask frames combined with masks: – 1860 N95 – 8210 N95 – KN95 – Kimberly-Clark duckbill	– QLFT – QNFT	45	unknown	passing rates with the frame in the absence of the original straps (in case of proper fit with original straps) were: – 1860 N95: 24/30 – KN95: 11/12 – Kimberly-Clark duckbill 12/15 – 8210: N95 9/9	FDM, no data, PLA	not every mask type was tested on each participant
Liu et al.[49]	AM-made adapter for the 3M 7501 and 3M 6200 elastomeric respirators to interface with anesthesia circuit filters	– end-tidal carbon dioxide – respiratory rate – self-reported of discomfort	8	60 min	mean end-tidal carbon dioxide and mean respiratory rate were not statistically different ($p > 0.05$); 4/8 (50.0%) subjects self-reported discomfort	FDM, Ultimaker S5, PLA (Premium PLA, Formfutura BV)	all participants passed qualitative positive and negative pressure leak testing, quantitative and qualitative fit testing
Bezek et al.[21]	AM-made masks: – Montana – Factoria – Stopgap; masks were manufactured once with each method	– filtration efficiency – masks were compared before and after post-processing	not applicable	not applicable	Factoria respirator provided the highest observed performance, with a filtration efficiency 90–95%; post-processing modifications to the produced respirators generally improved performance	FDM, Afinia H800, ABS and PLA; SLS; DTM Sinterstation 2500 Plus, nylon-12; FDM, Fortus 400 mc, ULTEM 9085	–
Gierthmuehlen et al.[13]	– AM-made COVID-19 MASK v. 2.0 – modified scuba-diving mask (Easybreath®) – mask sewn from a vacuum cleaner bag	– filtration efficiency	not applicable	not applicable	filter efficacy: – sewn mask: 69.76% – AM-made COVID-19 MASK v. 2.0: 39.27% – scuba-diving mask: 85.07%	FDM, Ender 3 pro Printer, PLA (Primacreator Primavalue); FDM, custom core XY machine, Tefabloc TPE (Verbatim), PLA (Verbatim) and PLA (Filamentworld)	–
Piombino et al.[18]	AM-made person-tailored Mask 3D	– skin comfort – respiratory comfort – quality of work shift whilst wearing the mask (five-point Likert scale) in 3 localizations: surgery room, medical clinic and maxillofacial surgery ward	6	7 days	overall rating: – in the surgery room: 3/6 very good, 3/6 good; – in the medical clinic: 2/6 very good, 4/6 good; – in the maxillofacial surgery ward: 2/6 very good, 4/6 good	FDM, Ultimaker 2 Extended+, TPU (Rubber TPU D27 (Bioflex, Bioalfa, Soria Vecchia) and PLA (Eco PLA, 3DJake Italia, Niceshops GmbH)	for such small test group results should be presented individually for each test subject
Davies et al.[16]	AM-made modified Copper 3D Nanohack (added a central port to permit attachment of bronchoscope adapter)	– spread of phosphor fluorescent dye during simulated bronchoscopy	1	not applicable	AM-made mask reduced to zero spread of phosphor fluorescent dye	SLA, Form 2, biocompatible photopolymer resin (Dental SG, Formlabs Inc.)	–

Table 3. Review of validations of additive manufacturing (AM)-made face respirators studies (including AM-made respirators accessories). Analyzed parameters included: qualitative fit testing (QLFT), quantitative fit testing (QNFT), filtration efficiency, subjective users' opinion on the respirator – cont

Study	Compared face respirators types	Parameters	Number of participants	Duration of test	Results	AM technology, machine, material	Comments
Imbrie-Moore et al.[22]	AM-made cartridge with an inner ridge and soft silicone base used to seal 1/4 of a 3M 1860 N95 mask	– QNFT	6	not applicable/no data	overall fit factor was 148 ±29	SLA, Carbon M2, biocompatible Silicone (SIL 30, Carbon) and Multipurpose Polyurethane (MPU 100, Carbon)	–
Ballard et al.[43]	AM-made 5 rigid and 5 flexible mask prototypes of own design	– QNFT – comfort level	4	7 min	2 designs produced with flexible polymers passed QNFT with a mean fit factor of 138; comfort level was similar to N95 respirators	SLA, Form 2; elastic and flexible (V2) resins (FormLabs); PolyJet; Stratasys J750; Agilus30, Biocompatible Clear MED610, Tango and Vero; FDM Makerbot 5th Gen; PLA	–
George et al.[50]	SNAP – AM-made, single-use, valved endoscopic port, retrofitted to any surgical mask	– spread of fluorescein – adverse effects	9	no data	no spread of fluorescein; no adverse effects	FDM, Flashforge Creator Pro 3D, no data	–
Ng et al.[19]	AM-made reusable silicone-molded face mask (SSM), N95 3M face mask	– QNFT – comfort – breathability	40	not applicable/no data	SSM scored 3.5/5 and 4/5 for comfort and breathability; overall passing rates in disposable and SSM respirators on QNFT were 65% and 100%	Mold: FDM; PRUSA I3 MK3S, no data; Harness FDM, PRUSA I3 MK3S, PLA and PETG	–
Felinska et al.[23]	modified Easybreath full-face diving mask (addition of filter), standard surgical mask	– time until proficiency – number of attempts until proficiency (laparoscopic suturing) – Objective Structured Assessment of Technical Skills scores (laparoscopic cholecystectomy) – comfort	40	not applicable	no statistically significant difference	FDM, no data, PLA	participants were laparoscopically naive medical students
Helman et al.[17]	AM-made endoscopic mask	– surgical freedom – test of aerosolization	not applicable	not applicable/no data	mask reduced particle spillage: – by 86% for anteriol surgery – by 71% for posterior surgery – the trocar system reduced spillage by 97%; mask allowed for an appropriate surgical range of motion	FDM, Ultimaker 2 and Pulse XE, TPU and Polyamide 12 (NylonX, MatterHackers)	tested on 2 cadavers

FDM – fused deposition modeling; PLA – polylactic acid; SSM – simple silicone mask; TPU – thermoplastic polyurethane.

Table 4. Review of validations of additive manufacturing (AM)-made face shields studies. Analyzed parameters included: fogging testing, splash protection, users' body parameters like respiratory rate, and subjective users' opinion on the respirator

Study	Compared AM-made face shields types	Parameters	Number of participants	Duration of test	Results	AM technology, machine, materials
Wesemann et al.[6]	RC1, RC2, Budmen V3, Easy 3D	– fit – comfort – wearing – protection – overall evaluation (Visual Analogue Scale (VAS))	10	60 min	overall Easy 3D (87 ±4) and RC2 (81 ±5) received the highest scores, which differed significantly from those for RC1 (63 ±6) and Budmen V3 (56 ±4) (p = 0.001)	FDM, Prusa I3 MK3S, PLA (GreenTEC PRO, Extrudr)
Sapoval et al.[45]	3D4Care face shield (modified RC2)	– ability to perform the assigned intervention as usual – quality of visual comfort – musculo-skeletal tolerance (1–5 Likert scale)	38	mean time 59 min	ability to perform the assigned intervention as usual was 1.7 ±0.8 (SD); mean visual tolerance rating was 1.6 ±0.7 (SD); the mean tolerability rating was 1.4 ±0.7 (SD)	FDM, no data, PLA and ABS
Celik et al.[46]	own unnamed design	– functionality – design – quality – satisfaction of use – first impression – ergonomics – originality of design – material quality (insufficient/poor/average/good/excellent)	15	no data	in most questions about 80% good or excellent answers	FDM, no data, PLA
Chaturvedi et al.[47]	own unnamed design	i.a.: – ease of use – visibility during the procedures – comfort during the procedures – ease of assembly – ease of disassembly – ease of cleaning – confidence to reuse (0–10 scale)	37	no data	overall mean score was 7.92 ±2.13 (SD)	FDM, no data, PLA
Kusano et al.[48]	set (N95 mask, goggle and face shield), modified full-face snorkel mask (with AM-made elements)	– blood pressure – pulse – oxygen saturation – respiratory rate (assessed twice: before and after the procedure of endoscopy)	9	30 min	statistically significant: set decreased oxygen saturation by 0.9 percent point; modified snorkel mask increased respiratory rate by 1.5 breaths/min	no data
Mostaghimi et al.[26]	PanFab face shield (modified RC2)	– fogging testing (min. 30 min) – testing splash protection (subjective) – durability – ease of use – comfort (five-point Likert scale)	92	30–60 min	average scores were: – splash protection – 4.7 – durability – 4.6 – ease of use – 4.3 – comfort – 4.4	FDM, Ender 3 Pro, PLA (Hatchbox)
Huang et al.[27]	own unnamed design	COVID-19 infection	over 300	no data	none of participants were reported to be infected with COVID-19	SLA, no data
Desselle et al.[44]	Prusa RC3, MSD headband	– presence of visible contamination on the face and forehead	5 participants, 10 reviewers	no data	overall pass rates: MSD headband 75%, Prusa RC3 100%	no data

SD – standard deviation; FDM – fused deposition modeling; PLA – polylactic acid; ABS – acrylonitrile butadiene styrene.

of the face shield model by participants.[6,26,45–47] Most of the researches tested only if AM-made face shields are comfortable to wear, not if they protect against infection (especially COVID-19). Huang et al. mentioned that none

of the users of their face shield were reported to be infected with COVID-19, but they did not report the methodology for this finding. There is no information if the participants of that study were tested for SARS-CoV-2 on a regular

basis. There is lack of control group of non-AM-made shields users to determine the true usefulness of this PPE.[27]

Wesemann et al. found out that Easy 3D (https://www.thingiverse.com/thing:4233193) and Prusa RC2 achieved better overall score than Prusa RC1 and Budmen V3 (IC3D Printers, Columbus, USA).[6] Desselle et al. proved that the Prusa RC3 is better than the MSD headband (University of Melbourne, Australia).[44] In the remaining papers, researchers tested 3D4Care face shield (modified RC2; 3D4Care, Paris, France), PanFab face shield (also modified RC2; Greater Boston Pandemic Fabrication Team, USA) and other, unnamed designs. All of them received a subjective positive rating.

Proper disinfection, which allows AM-made PPE to be reused, is a major challenge. The polymers used for FDM production are prone to high temperature and humidity (autoclave). Therefore, the most common decontamination method, especially against SARS-CoV-2, was the use of 96% ethanol, 70% ethanol, 70% isopropanol, 0.85% or 0.1% sodium hypochlorite, 3% H_2O_2, 10% bleach and quaternary ammonium, or H_2O_2-quaternary ammonium salt mixture.[36,40]

The quality control of the finished part should be considered. It is difficult to compare between the analyzed papers regarding which models are the fastest and cheapest to produce, due to the differences between used machines, materials, process parameters and models included in the comparison, and is beyond the scope of this article.

The authors of the analyzed articles did not provide any information whether the used materials and processes are certified (or verified) for skin contact, apart from Swennen et al. (PA11-SX 1450 which meets USP Class VI requirements).[11] The additional research of materials used in the reviewed articles did not reveal any other skin-safe materials.

Conclusions

In the design phase, it is crucial to focus on effective protection, comfortable wearing and the possibility of easy production of the PPE. It is also commendable to make the project publicly available for free, with open source data. In addition to helping to produce PPE, it encourages global collaboration to improve the design. The current situation requires efficient cooperation of the scientific community to overcome the challenges posed by the COVID-19 pandemic.

The face masks are the most important element of PPE, as the transmission of SARS-CoV-2 occurs primarily by droplets. They can be produced with AM to replace shortages, but also can be personalized for potential better comfort or protection and a better fit than commercially available ones (e.g., SSM respirator). Presumably, personalized masks would be more expensive, and in a crisis such like the COVID-19 pandemic, there would be no time or resources for it.

Unfortunately, most researchers have only tested 1 type of AM-made respirators and did not compare them with other respirators (AM-made or commercially available). In comparison, the Factoria respirator provided the highest performance observed, with a filtration efficiency of 90–95%.

Furthermore, the face shield is an important part of the PPE utilized during the COVID-19 pandemic. It can be concluded that, with certain limitations, AM-made face shields can be designed and manufactured. There is no research comparing commercially available face shields and AM-made ones. Basing on insufficient data (mainly questionnaires), RC2 (and its newer version – RC3 or their modifications) is the best choice for the FDM face shield model. It has good fitting and wearing comfort, and offers space for additional PPE and stacking possibility.

Additive manufacturing is not adequate for high-volume production of PPE, but it is still useful. It has the potential to temporarily fix the broken supply chains and it is useful in designing new PPE products. It allows for the production of personalized PPE or accessories to improve existing PPE (e.g., frames for better fit of face masks). A significant limitation of AM-made PPE in the analyzed papers is the lack of data on the safety of skin contact of the produced PPE.

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