Research Article

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Potential risks of a widespread use of 3D printing for the manufacturing of face masks during the severe acute respiratory syndrome coronavirus 2 pandemic

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Background: In 2020, the severe acute respiratory syndrome coronavirus 2 pandemic caused serious concerns about the availability of face masks. This paper studies the technical feasibility of user-specific face mask production by 3D printing and the effectiveness of these masks. **Material & methods:** Six different face mask designs were produced by 3D printing and tested by subjective experimenter evaluation and using a respirator fit testing kit. Results were compared with the requirements as given for standard protective face masks. **Results:** None of the printed masks came anywhere near the required standards for personal protective gear. **Conclusion:** In spite of their euphoric presentation in the press, none of the currently advertised 3D printed mask designs are suitable as reliable personal protective equipment.

Lay abstract: The 3D printing community contributed to overcome potential supply bottlenecks for personal protective gear during the worldwide spread of the corona virus disease by providing open-source data for 3D printing of personal protective equipment. In this study, different mask designs were produced by 3D printing and subjected to a technical examination to evaluate the protective properties of these masks. In spite of their euphoric presentation in the press, none of the tested masks are suitable as reliable personal protective equipment.

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Keywords: 3D printing • additive manufacturing • COVID-19 • face masks • SARS-CoV-2

In 2020, as the severe acute respiratory syndrome coronavirus 2 pandemic spread, serious concerns about the availability of suitable face masks arose even in advanced countries with highly specialized healthcare systems [1]. Due to a lack of availability of protective face masks, improvised masks were considered even in the healthcare sector [2]. The demand for protective face masks increased even further when the call for a widespread use of face masks among the public grew louder [3]. As opposed to this, the WHO did not recommend the public use of face masks due to a lack of evidence [4]. However, the strict adherence to evidence-based medicine in cases of pandemics of previously not known and potentially lethal agents has been a subject of scientific dispute, given that measures of containment have to be applied rapidly, while the completion of valid randomized controlled studies is usually very time consuming [5]. Earlier studies showed evidence that homemade face masks can aid to reduce particle inhalation and expectoration but their protective capability remains questionable [6,7]. Next to freely available sewing instructions for face masks from fabric, the widespread use of 3D printing led to a large number of different open-source, non-certified face masks available for download and 3D printing on a desktop 3D printer. The impact of 3D printing on the management of potential supply bottlenecks and the concept of hybrid production within

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a network of engineers and a team of physicians at the point-of-care was recently published from our research group [8]. Swennen *et al.* already published a proof of concept for the production of 3D printed face masks [9]. Cortes *et al.* improved the aptness of 3D printed face masks by aligning the mask design to the face of the test subject using CAD software [10]. Thomas *et al.* impressively showed how to implement in-house 3D printing of face masks within a hospital within 10 days [11]. However, serious concerns regarding the protective capacity of the 3D printed masks have risen and there is a need of in-depth testing prior to promoting them as the solution for supply shortages [12]. In a first comparative analysis of a single 3D printed mask design, to other improvised face masks using a filter efficiency testing, the 3D printed face masks showed poor performance [13].

In this study, we investigated the safety and effectiveness of a number of foldable and rigid 3D printed face masks. To our knowledge, this is the first study to present the evaluation of different mask designs with respect to production within a hybrid-network and testing using a respirator fit test. Included in the study, were first, mask designs, which were based on freely available designs downloaded from highly advertised sites in the worldwide web, but were modified and further developed by the Working Group for 3D Printing in Neurosurgery of the Armed Forces Hospital in Westerstede (BwKWST) in cooperation with the Laboratory for Manufacturing Technology of the University of the German Armed Forces in Hamburg (HSU). Given their high level of publicity in the online press as well as in social media, we additionally included mask designs without modification by this cooperation. After, thus producing a number of protective mask prototypes, an independent evaluation of these prototypes regarding their efficiency and safety was warranted.

The Bundeswehr Research Institute for Protection Technologies and NBC (nuclear, biological and chemical) Protection (WIS) in Munster was contacted for the purpose of performing independent testing of the mask prototypes. They agreed to test six different prototypes of masks, of which two had been developed and/or been modified by our working group and four were directly downloaded from websites advertising the use of specific designs. As a means of reference, two masks known to correspond two different levels of requirements for protective efficiency defined by German normative authorities (DIN EN 149, German Institute for Standardization, European Norm 149) as well as a mask sewn from fabric according to a design freely published on the internet were also subject to an identical array of tests.

Material & methods

Design process HSU/BwKWST face masks

In order to simulate a typical chain of development, production and supply, the medical members of the research group, in other words, the working group '3D Printing in Neurosurgery' were assigned the role of 'users'. Since it is an adaptive design, product development according to VDI 2221 (Association of German Engineers) begins as early as the design phase. To ensure that this phase can be completed as effectively and quickly as possible, the evaluation of the designs is carried out directly at the user's premises by the user. The direct user feedback enables a target-oriented development according to the needs of the user. For this purpose, desktop 3D printers, such as Ultimaker 3 (Ultimaker, Geldermalsen, The Netherlands), were installed at the user's premises at the Neurosurgical Department of the German Armed Forces Hospital in Westerstede. Mask designs were developed and constructed at the Laboratory for Manufacturing Technologies of the University of the German Armed Forces in Hamburg by using the design software Fusion 360 (Autodesk, WA DC, USA). The designs were then digitally transferred to the user environment for prototype production and evaluation (Figure 1). By directly involving the user in the product development process, the time to the finished product can be minimized. Even if designer, constructor and user are not at the same place, a fast iteration to the final product can be carried out by the digital transmission of the model data and the production at the users site. The feedback about possible design changes is then again carried out via a digital medium and can be immediately implemented in a new version/draft. This process enables the development department to respond directly to new user requirements and test them. Product errors can be detected and corrected at an early stage through the extensive use of prototypes in final product quality.

3D printing & assembly of open-source face masks

The open-source Standard Triangulation Language (STL-data) of four different face masks (Copper 3D NanoHack, www.copper3d.com; Lafactoria3D corona virus disease (COVID-19) Mask V2, www.lafactoria3d.es; Maker Mask Respirator, www.makermask.com; Montana Mask, www.longliveyoursmile.com) were downloaded from the internet. The foldable Copper 3D NanoHack mask was further developed and adapted to the requirements of the physicians represented in the working group using the previously described design process. This led to the produc-

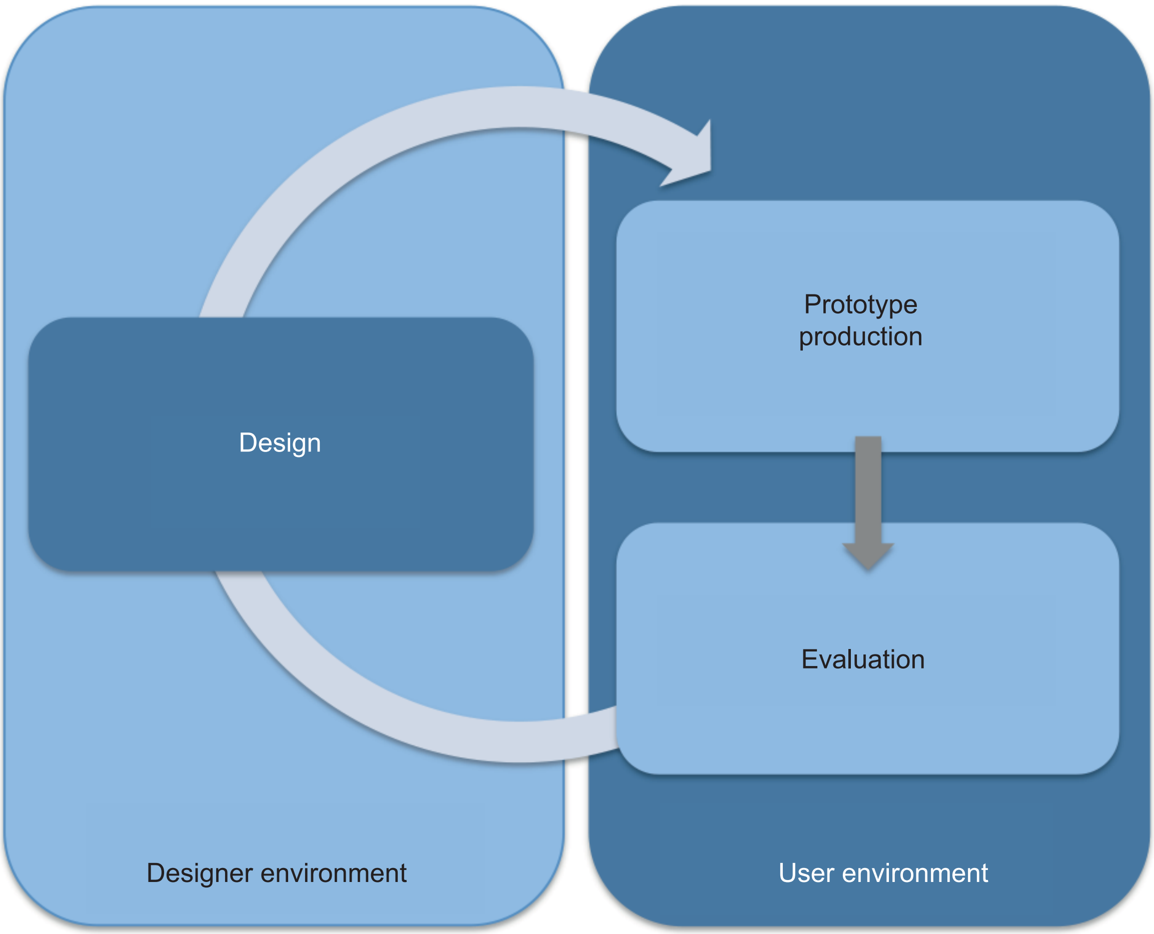

Figure 1. Design process. Mask design development was performed at the designer environment at the Laboratory for Manufacturing Technology at the University of the German Armed Forces in Hamburg. The design variants were then digitally transferred to the user environment at the Department of Neurosurgery at the Hospital of the German Armed Forces in Westerstede. After prototype production, the mask designs were evaluated. The requirements for the next design variant were then sent to the designer for further modification and development.

tion of two modified face mask (FM) versions, the HSU/BwKWST FM V3 (V3) and HSU/BwKWST FM V4 (V4). The COVID-19 Mask V2 was available in different sizes. For comparison, printing of the large mask with thick wall diameter, which was provided in the downloadable file, was chosen.

3D printing of all masks was prepared using the software Cura (Ultimaker) and performed using Ultimaker 3 printers (Ultimaker) and white polylactic acid (PLA, Ultimaker) or black thermoplastic polyurethane (TPU95A, Ultimaker) filament. Printjob parameters, like printing temperature (200°C), layer thickness (0.2 mm), infill (10%) and printing speeds (45–70 mm/s) were set. Afterward, a machine code (G Code) was generated. Small parts (i.e., filters, fastening clips and caps) were printed using the 0.4 mm nozzle at a printing speed of 70 mm/s and additional build plate adhesion was applied. Masks were printed using the 0.8 mm nozzle at a printing speed of 45 mm/s. Afterward, the masks were assembled according to the provider's instructions. Combined filtering face piece 3 (FFP3) fleece (Freudenberg SE, Weinheim, Germany) was trimmed to fit the filters and used as filter material.

Mask design evaluation & respirator fit testing

The simplified testing array consisted first in a thorough descriptive evaluation of application and wearing comfort as well as subjective estimation of permeability by between two and four participants for each mask and second in a determination of the protective factor (PF) of each mask for each participant in three different measurements. The participants wore the different mask designs for a period of 30 min for subjective evaluation. These PF measurements were put into practice using the respirator leakage tester PortaCount® 8020M (TSI Inc., MN, USA), which is the standard equipment of the German Armed Forces for the testing of chemical, biological, radiological and nuclear protective gear. The PortaCount device is a condensation nucleus counter, that counts particles between 0.02 and 1 μm in the ambient air and within the mask by means of alcohol condensation and a light impulse. A user seal check was regularly performed prior to each investigation. Each measurement took 40 s and was performed three times. Then a mean value was calculated.

Using the measured PF, the total inward leakage (TIL) was calculated and compared with the requirements as given in the DIN EN149 regulation.

The PF is defined as the quotient between particle concentration outside the mask (pco) and particle concentration inside the mask (pci):

$$\mathrm{PF} = \mathrm{pco}/\mathrm{pci}$$

The TIL is a percentage, which can be calculated as the quotient between 100 and the PF (mean) of each mask type:

$$\mathrm{TIL}\ \ (\%) = 100/\mathrm{PF}$$

Statistical analysis

Data is presented as mean ± standard deviation of the mean. Microsoft Excel (Microsoft Corporation, WA, USA) was used for data analysis and graphical illustration. Results were analyzed for significant differences using the Welch-Test for normally distributed and Mann–Whitney-U-Test for not normally distributed data. A p-value of <0.05 was considered to indicate statistically significant differences between groups.

Results

Design process HSU/BwKWST masks

By outsourcing prototype production to the user, a significant increase in iteration speed was achieved in the design process for the face mask. At the beginning of the design phase, there was no 3D printer available on the user side, so additive manufacturing capabilities were used in the designer's environment to produce the first prototypes. These were then sent to the user by mail to get direct feedback. Due to the postal dispatch, there was a delay of 2–3 days. With the use of 3D printers at the users environment and on site prototype production, the postal dispatch could be eliminated. The time between the completion of the design process of a new iteration and the direct user feedback took only 3–4 h (manufacturing time). Using this process, three iteration loops could be drawn within one working day. This represents a time saving of 9 days compared with the previous procedure.

The basic design of the mask from www.copper3d.com has been adapted for HSU/BwKWST FM V1 (V1) shown in Figure 2A. Due to the symmetrical design, the filter area has been doubled. Furthermore, a thread has been added, so that a freely available FFP3 filter could be used. However, the use of commercially available filter inserts was not considered further in the following versions due to their potentially limited availability. For this reason, an integrated replaceable filter material was added to the HSU/BwKWST FM V2 (V2) (Figure 2B). Moreover, the slotted holes for the rubber bands have been divided to increase the wearing comfort. In order to protect the wearer's eye area, pins, which act as holding points for a face shield, were integrated. The material surfaces at the lower mask margin were expanded to provide a better sealing at the chin area. During thermoforming, a fold is created here instead of a slit, which had to be sealed afterward. This feature was retained for all subsequent versions, as it is more suitable for sealing the mask to the face. The HSU/BwKWST FM V3 (V3) uses a sealing lip made of thermoplastic polyurethane (TPU), which is placed around the outer contour due to the sealing problems in the edge area (Figure 2C). By using the flexible material, an attempt was made to seal the mask tightly to the face. As there is a strong curvature in the area of the nose and the nostrils during the thermal adaptation of the mask to the face, the possibility of leakage is very high here. Several design approaches have been followed, as shown in HSU/BwKWST FM V1, V2 and V3 with different cutouts, with V3 providing the best seal. Four strap fastening clips, which allow an adjustment of the rubber band, were added to the openings for the rubber bands to improve the mask fitment and wearing comfort in the HSU/BwKWST FM V4 (V4) (Figure 2D). The rubber bands were fixed with knots to the previous masks. A later adjustment of the rubber bands was therefore only possible by removing the mask or by a second person. Two different versions of the removable filter inserts were

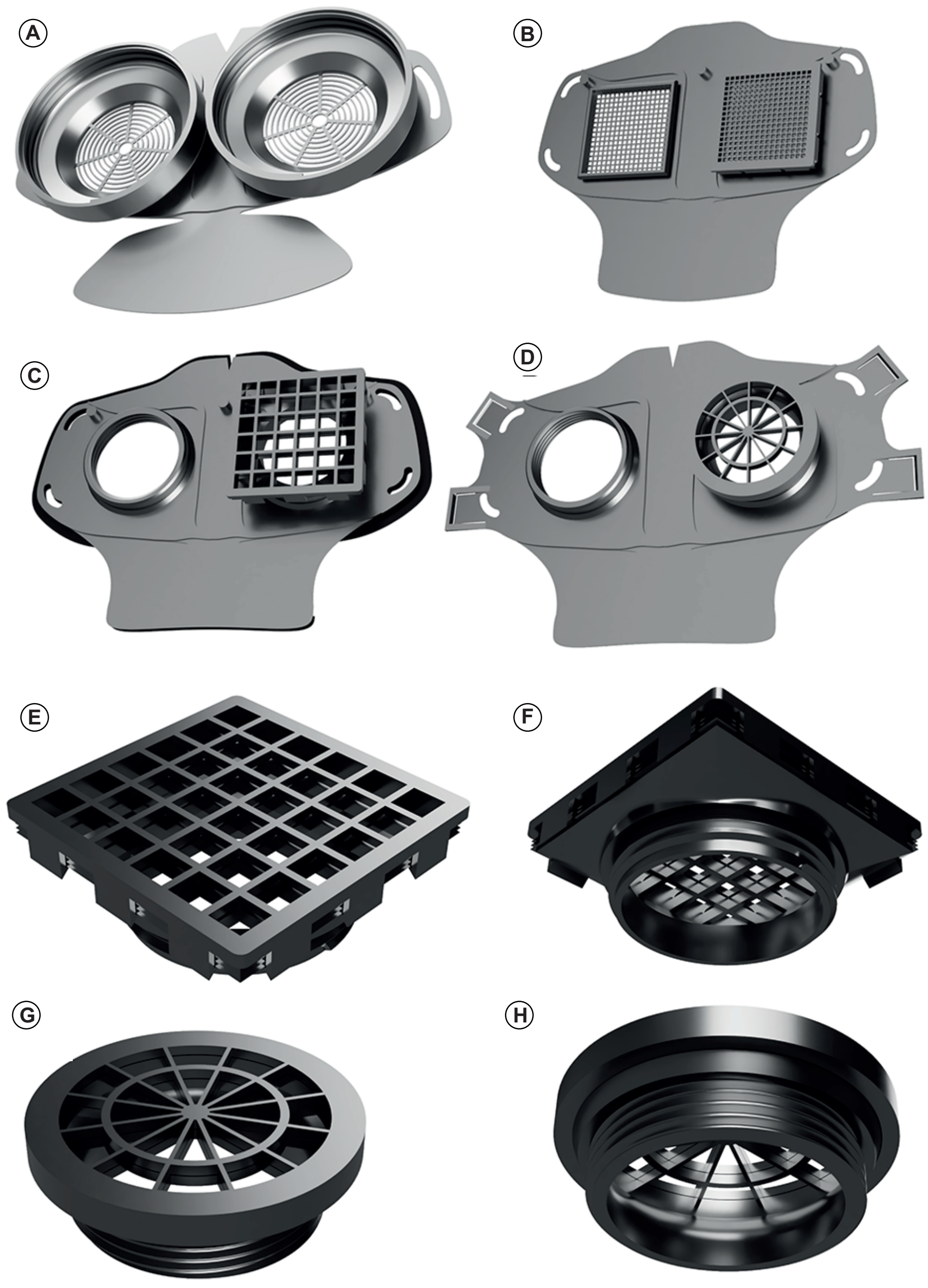

Figure 2. Mask design variants of the HSU/BwKWST face masks. Four different variants of the HSU/BwKWST face masks were produced. The HSU/BwKWST FM V1 is shown in **(A)**. **(B)** depicts the HSU/BwKWST FM V2 with a new mask design at the chin area, fixation pins for an additional face shield and altered fixation holes for elastic bands. **(C)** HSU/BwKWST FM V3 with an additional inlay made from black TPU95A (black rim) and a novel design of the nasal cut. **(D)** shows the further developed HSU/BwKWST FM V4 with four fastening strips and without the TPU inlay that was previously incorporated to V3. **(E)** and **(F)** show the square filter design with a clip fastening mechanism and **(G)** and **(H)** the round filter design with a fastening thread.
BwKWST: Armed Forces Hospital in Westerstede; HSU: University of the German Armed Forces in Hamburg; TPU: Thermoplastic polyurethane.

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developed for V3 and V4. The main objective was a simple change of the filters instead of changing the filter material within the mask. When changing the filter material, a significant additional effort is required due to the possible contamination. When changing the filter insert, the risk of contamination is lower, because the test person does not come into contact with the contaminated filter material. The variants differ with respect to the shape of the filter surface (Figure 2E & F, square filter design; Figure 2G & H, round filter design). The advantage of the square variant is that the shape of the filter material makes it easier to cut to size. On the other hand, the installation of the round insert is advantageous. With both filter inserts, the filter material is inserted between the lower part and the cover. The HSU/BwKWST FM V1 and V2 were designed, shipped, printed and evaluated according to the described design process between the Laboratory for Manufacturing Technologies at the University of the German Armed Forces and the Department of Neurosurgery at the German Armed Forces Hospital in Westerstede. Only the HSU/BwKWST FM V3 and V4 were released for further tests.

3D printing & assembly of open-source face masks

3D printing of open-source face masks

3D printing of the different open-source face masks was successfully carried out using Ultimaker 3 printers (Ultimaker). The HSU/BwKWST FM V3 was printed in 5 h 10 min, the HSU/BwKWST FM V4 in 3 h 8 min, the COVID-19 Mask V2 (PLA and TPU95A, respectively) in 2 h 24 min, the Montana Mask in 4 h 38 min and the Maker Mask in 10 h 54 min. Material requirements were 6 g TPU and 72 g PLA for the HSUBwKWST FM V3, 97 g PLA for the HSU/BwKWST FM V4, 37.3 g PLA or TPU95A for the COVID-19 Mask V2, 45 g PLA for the Montana Mask and 126 g PLA for production of the Maker Mask, respectively.

Assembly of 3D printed face masks

The foldable HSU/BwKWST FM V3 and V4 were fitted to the face by heating of the thermoplastic material with a hair dryer and adapting the form to the experimenter's face. The filter boxes were screwed to the masks after the filter material was trimmed and elastic bands were attached. The HSU/BwKWST FM V3 had an additional TPU95A inlay to seal the mask / face junction (Figure 3A & B). A further assembly was not necessary. Filter sizes were 5000 mm^2 for the HSU/BwKWST FM V3 and 4000 mm^2 for the HSU/BwKWST FM V4, respectively. The HSU/BwKWST FM V4 is presented in Figure 3C & D. Assembling the COVID-19 Mask V2 (PLA and TPU95A versions) as well as the very similar Montana Mask was easier. For the Covid 19 Mask V2, the filter material was loosely laid into a 1600 mm^2 filterbox, which then had to be clipped to the mask, giving rise to leakage concerns (Figure 3E & F). The filter material was directly clipped to the frame of the Montana Mask resulting in a filter area of 4225 mm^2 (Figure 3G & H). Additionally, the mask had a sealing line around the mask body. Due to the rather small filter area, both types of filter connections caused subjective difficulties with respect to the respiratory resistance. However, due to the even smaller filter area, this problem appeared to be more important in the case of the Covid 19 Mask V2 than in the case of the Montana Mask.

Building the Maker Mask was a much more complicated procedure, given that it consists of 24 different parts, which have to be assembled by the user (Figure 3I & J). First, the in- and outlet valves were assembled using super glue. Hot-melt adhesive was used to mount the filter boxes. Afterward, an elastic band was fixed to the printed straps and was attached to the mask with hooks. Following the recommendation of the designers, an effort was made to seal the rim with a standard window sealing (P-profile, tesamoll, tesa SE, Norderstedt, Germany). The filter size of the Maker Mask was calculated to be 7670 mm^2. For an overview printing parameters and mask specifications are presented in Table 1.

Mask design evaluation & respirator fit testing

Mask design evaluation

Both the HSU/BwKWST FM V3 and HSU/BwKWST FM V4 were based on the principle of thermoplastic fitting by heating up the printed items. Even though this method leads to individually tailored masks, with a subjectively almost perfect fit, the procedure is not without difficulty and requires skill, patience and experience. For both types, a second weakness was identified in relation with the screw mechanism to connect filters to the mask. This is another probable major source of leakages, given that the mechanism may be subject to alterations by the process of thermoplastic fitting.

The subjective impression regarding the fitting of the masks to the experimenter's faces was rather disappointing in the case of the PLA Version of the Covid-19 Mask V2 as well as of the Montana mask, which was also printed

Figure 3. Mask overview. (A) Depiction of the individual parts of the foldable HSU/BwKWST FM V3 made from thermoplastic PLA and the TPU95A inlay. **(B)** HSU/BwKWST FM V3 test fitted to the experimenters face. **(C)** Depiction of the individual parts of the foldable HSU/BwKWST FM V4 made from thermoplastic PLA. **(D)** HSU/BwKWST FM V4 test fitted to the experimenters face. **(E)** The individual parts of the COVID-19 Mask V2 made from PLA are shown. **(F)** The COVID-19 Mask V2 test fitted to the experimenters face. A picture of the COVID-19 Mask V2 made from TPU95A is not provided, as it would not provide additional information. **(G)** Image of the parts of the Montana Mask. **(H)** The Montana Mask fitted to the researchers face. **(I)** The individual parts of the Maker Mask are presented with the mask being test fitted in **(J)**.
BwKWST: Armed Forces Hospital in Westerstede; COVID-19: Corona virus disease; HSU: University of the German Armed Forces in Hamburg; TPU: Thermoplastic polyurethane.

Table 1. Mask printing and assembly parameters.

Mask design	Material	Weight (g)	Printing time (h)	Costs (€)	Filter area (mm^2)
Lafactoria3D COVID-19 mask V2	TPU PLA	38.13 33.70	6 h 8 m 4 h 7 m	6.45 4.03	1600
Maker mask respirator	PLA	110.7	12 h 4 m	9.10	7670
Montana mask	PLA	45.03	4 h 45 m	2.01	4225
HSU/BwKWST FM V3	TPU/PLA	10/70.75	1 h 30 m/7 h 46 m	7.64	5000
HSU/BwKWST FM V4	PLA	54.33	5 h 40 m	5.16	4000

The material, weight, printing time, costs and filter area of the different 3D printed mask designs are presented. For the COVID-19 Mask V2 parameters are summarized in a row. The results presented are derived from a theoretical approach with the printing parameters (layer height 0.2 mm, 15 % infill, 0.4 mm nozzle) being the same for all masks and individual parts, whereas the printing parameters were optimized within the actual study to improve the mask performance during the testing.
BwKWST: Armed Forces Hospital in Westerstede; COVID-19: Corona virus disease; HSU: University of the German Armed Forces in Hamburg; TPU: Thermoplastic polyurethane.

using PLA. The basic form of the mask is taken from a respirator, and thus, fits well to the standard contour of a human face. However, due to the rigidity of this material, there are necessarily leakages whenever the experimenter is talking or performing any other face movements. In this regard, the much more flexible TPU95A COVID-19 Mask V2 was estimated by the experimenters as being clearly superior, given that its flexibility allowed all facial movements without producing the same kind of obvious leakages.

Inspection of the Maker Mask identified the junction between the outlet valve and the mask itself as a problematic weakness, given that it can easily be inadvertently loosened, and thus, produce a major leakage. It turned out to be almost impossible to produce a complete sealing, given that the groove for the placement of the p-profile was too small and led to displacements. Also the fact that the sealing material was not a closed ring produced necessarily a *locus minoris resistentiae* at the point where both ends had to be connected. All participants found the mask to be extremely uncomfortable during the testing. Inbreathing was difficult and expiration revealed that the outlet valve is of limited benefit, given the leakages. The mask left a deep and rather painful pressure mark in the facial skin even after only a short test period of only a few minutes.

Respirator fit testing

Mean values and standard deviations of the PF for all tested masks as determined by our examination by the respirator fit testing are represented in Figure 4. The PF of the HSU/BwKWST FM V3 and V4 were 2.19 ± 0.45 (n = 9, best single result 2.5) and 2.43 ± 0.35 (n = 12, best single result 3.0), respectively. The Montana Mask had a PF of 1.72 ± 0.13 (n = 6, best single result 1.8) and the Maker Mask of 1.88 ± 0.37 (n = 9, best single result 2.7). Made from TPU95A the PF of the COVID-19 Mask V2 was 2.33 ± 0.75 (n = 12, best single result 3.6). When printed from PLA the PF of the COVID-19 Mask V2 was 2.80 ± 1.33 (n = 6, best single result 4.8). For the masks made from fabric a PF of 2.23 ± 0.18 (n = 6, best single result 2.5) was measured. For each mask, the single best result of all the tests has been identified and marked with an x. The overall best single result was present in the COVID-19 V2 Mask PLA group with a PF of 4.80. With a PF of 1.80 the best single result of the Montana Mask was the worst in our analysis. The PF of the FFP2 mask (n = 3, 8825+, 3M Deutschland GmbH, Neuss, Germany) was 43.67 ± 6.03 and the PF of the FFP3 mask (n = 3, 8835+, 3M Deutschland GmbH) was 231.33 ± 32.13 (data not shown). The PF of HSU/BwKWST FM V4 ($p < 0.01$) and fabric mask ($p < 0.05$) was significantly greater than the PF of the maker mask. Other significant inter-group differences were not found as the FFP2 and FFP3 masks were not part of the statistical analysis due to obvious differences and a small sample size.

The values for the TIL as calculated based on the respirator fit testing findings are represented in Figure 4. Additionally the reference values of FFP2 (red, TIL 8%) and FFP3 (black, TIL 2%) masks according to DIN EN 149 have been printed as target levels for high-quality masks. The TIL of the HSU/BwKWST FM V3 (n = 9) and V4 (n = 12) were 45.69 and 41.24%, respectively. The Montana Mask had a TIL of 58.25% (n = 6) and the TIL of the Maker Mask was 53.35% (n = 9). Made from TPU95A the COVID-19 Mask V2 had a TIL of 43.01% (n = 12) and the COVID-19 Mask V2 made from PLA had a TIL of 35.71% (n = 6). The TIL of the masks made from fabric was 44.78% (Figure 5).

Discussion

In this study, different open-source masks available for 3D printing on desktop 3D printers were manufactured and analyzed using a descriptive evaluation and a respirator fit testing kit.

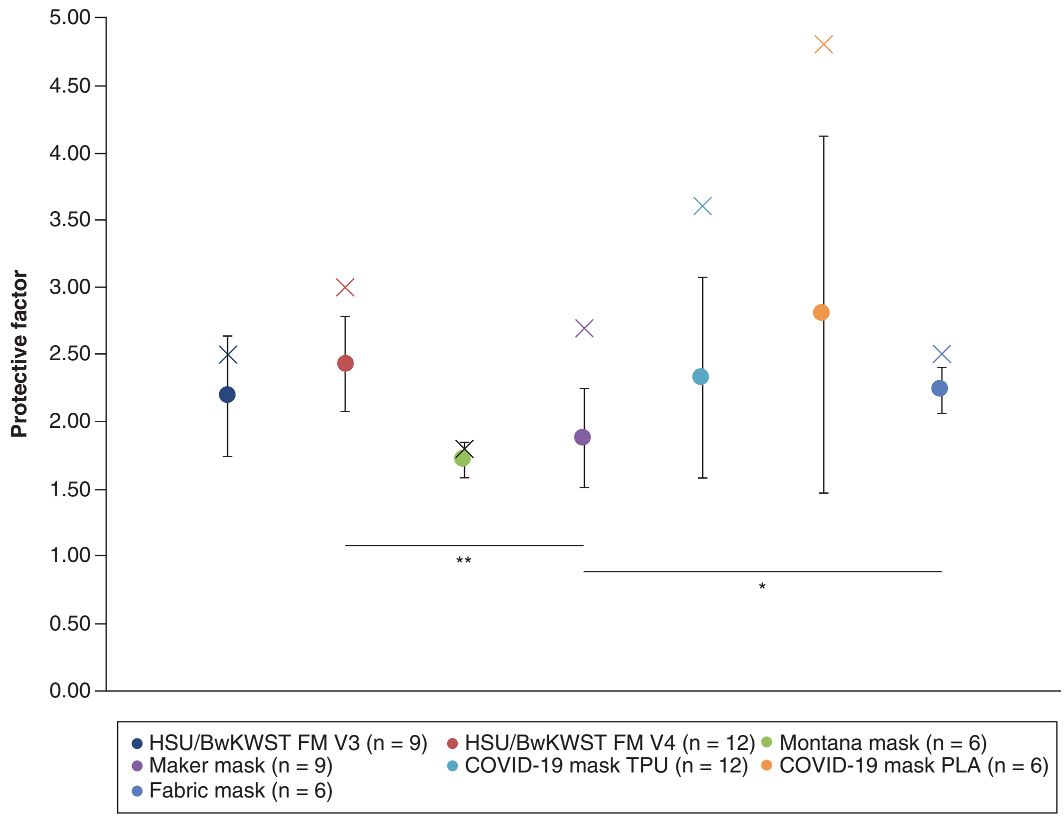

Figure 4. Protective factor of 3D printed face masks. The protective factor was calculated from the particle concentration outside the mask divided by the particle concentration inside the mask. Data are presented as mean ± standard deviation of the mean. The best single value calculated for each mask is represented as **x** in the corresponding, group specific, color.

The different mask types were successfully printed using widely available desktop 3D printers. The material requirements and printing time of the HSU/BwKWST FM V3 and V4 masks were in the same range as the Montana Mask and two-times as high as for the COVID-19 Mask V2 with the set printing parameters. Printing of the Maker Mask needed the most material and time. Additionally the assembly of the Maker Mask was complex and included permanent hot-melt and super glue fixation of the filter boxes and valves, respectively. The absence of the possibility to fully disassemble the Maker Mask disqualifies this mask for chemical disinfection, which we considered to be one of the major benefits of reusable 3D printed face masks. Similar concerns had risen with respect to disinfection of the foldable HSU/BwKWST FM V3 and V4 where small folds, that could impair the disinfection process, resulted from the thermoforming of the masks. The forming of the foldable masks proved to be unsuitable, as the folding principle cannot lead to a leakage free facial sealing line. Next to that an investigation of whether the folding of the previously flat masks affects the filament and fiber structure of the PLA within the HSU/BwKWST FM V3 and V4 is necessary, as it could have led to micro leakages.

Additionally, the folding is a possible source of danger, since even minor imperfections lead to leakages at the mask body itself or at the filter threads, in other words, due to the individualized handling, there can be no guarantee for stable safety levels in the use of this type of mask. Moreover, the subjective impression of a 'perfect fit' can lead to a false sense of safety.

The filter areas of the tested masks vary between 1600 mm^2 (COVID-19 Mask V2) 4225 mm^2 (Montana Mask), 4000/5000 mm^2 (round/square HSU/BwKWST FM V3 and V4, respectively), which is significantly smaller than the filter area of medical N95 masks (~15000 mm^2). Except for the filters of the Maker Mask (7670 mm^2), the filter areas of the 3D printed masks were considered to be too small by the experts of the *WIS*. With respect to the effective filter area, it has to be taken into account, that the filter caps cover at least part of the given filter sizes resulting in an even smaller effective filter area. Small filter areas lead to a high breathing resistance and due to the high flow through the material, the filter load is significantly higher than for certified FFP masks. Thus,

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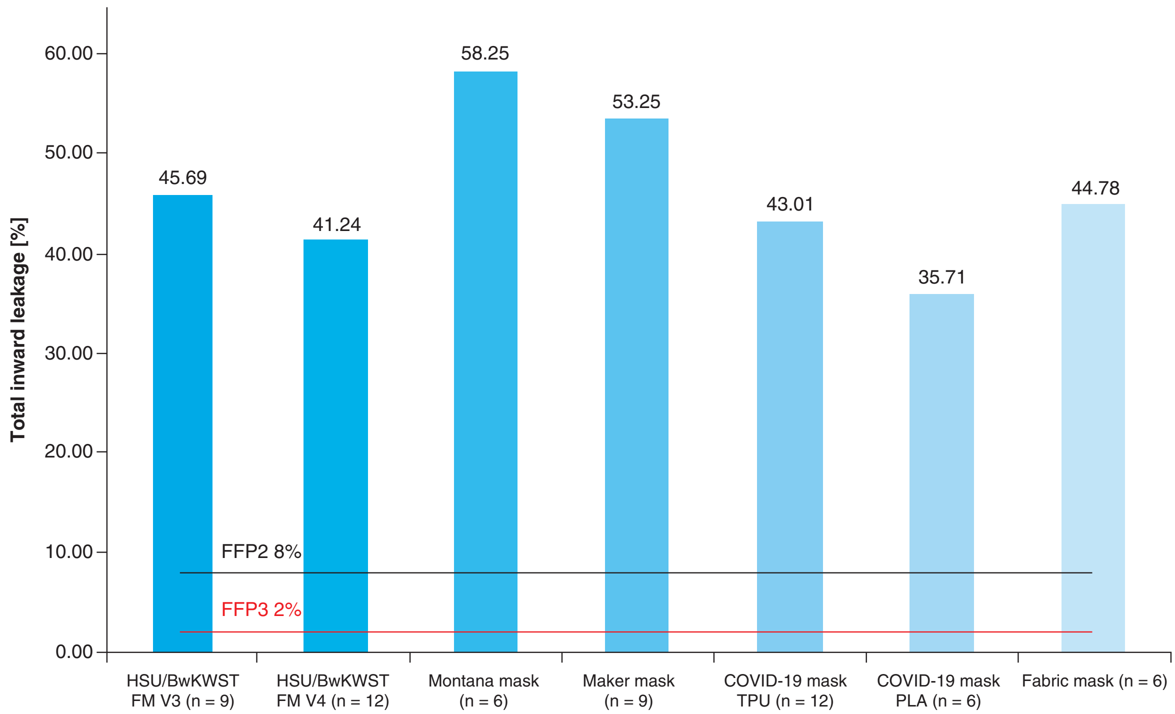

Figure 5. Total inward leakage of the tested mask designs. The total inward leakage, % was calculated from 100 divided by the protective factor and is presented in %. Reference parameters are FFP2 (red line, 8%) and FFP3 standards (black line, 2%) according to the DIN EN 149 regulation.
FFP2: Filtering face piece 2; FFP3: Filtering face piece 3.

the exhalation resistance is higher than in the HSU/BwKWST FM V3 and V4 and Maker Mask resulting in a potentially higher leakage [14]. Filter fixation was rated to be best in Montana and Maker Masks, whereas the filter boxes of the other masks were found to be associated with air leakage. Due to the fused filament fabrication (FFF) process, the threads of the filter inserts cannot be manufactured with the needed tolerances for remaining airtight. They, thus, cause the user to breathe unfiltered air alongside the filter. With respect to comfort and utility in the medical sector, the COVID-19 Mask V2 made from TPU95A and HSU/BwKWST FM V3 and V4 were rated best by the participants' subjective impressions, as these masks facilitated a good fit and did not lead to obvious leakages while talking.

Given the fact that the *WIS* has faced an unusual number of requests for testing of protective equipment due to the pandemic, a simplified test array has been developed, in order to reach preliminary conclusions for the conceptual aptness of 3D printing in the production of reliable protective masks in medical environments. Strictly speaking, the experimental setup is not suitable to measure the TIL as a particle counter was used instead of measuring a sodium chloride (NaCl) aerosol with a flame photometer. Sun *et al.* recently published that the PortaCount examination is applicable for these measurements, as it showed comparable results with the flame photometer [15]. Due to local availability, the TIL was in our case calculated from the PF, which is a limitation of our experimental setup. In case of the identification of prototypes, which qualify in principle, further more detailed testing arrays would have been warranted. Due to the PF of the masks being not satisfactory, a filter efficiency testing, which was initially planned, was not performed for all masks (data not shown).

The mean PF values ranged from 1.72 ± 0.13 (Montana Mask) to 2.80 ± 1.33 (COVID-19 Mask V2 PLA), the latter representing the best single result (PF 4.8). Remarkably, the COVID-19 Mask V2 TPU95A group had a best single result of 3.6 corresponding to the good subjective fitment to the face. The use of flexible thermoplastics such as TPU can lead to a higher seal, but skin compatibility is questionable because TPU contains plasticizers. Significant inter-group differences were only found for the HSU/BwKWST FM V4 (2.43 ± 0.35) and Fabric Mask (2.23 ± 0.18) showing a significantly higher PF for the V4 ($p < 0.01$) and Fabric Mask ($p < 0.05$), when compared with the Maker Mask (1.88 ± 0.37). The statistical analysis is limited in general, as the data of the Montana Mask and COVID-19 Mask V2 TPU95A were not normally distributed. Thus, the tests involving these groups were nonparametric tests despite the data of the reference groups being sometimes normally distributed. This could have led to false nonsignificant test results for inter-group comparisons. Additionally, sample sizes were generally small and not equal in the different groups.

In accordance with recent concerns and findings, none of the tested 3D printed masks came anywhere near the FFP2 (8%) and FFP3 (2%) reference levels for TIL [12,13]. The Maker Mask (53.25%) and the Montana Mask (58.25%) had markedly worse results than the masks made from fabric (44.78%). The HSU/BwKWST FM V3 had a slightly worse result (45.69%). The HSU/BwKWST FM V4 (41.24%) and the two versions of COVID-19 Mask V2 (TPU95A, 43.01%; PLA 35.71%) had better results. The PLA version of the COVID-19 Mask V2 reached the best result overall, markedly better than all competitors, but still by far missing the standard required by the DIN EN 149 regulation. The previous and rather euphoric presentation of 3D printing of face masks within several proof-of-principle articles, as being the solution to supply bottlenecks for personal protective equipment in the medical sector, is therefore no longer justified without further material and design development and in-depth testing [9,11,16,17].

Conclusion

Regarding the question of technical feasibility, our study has shown that the widespread availability of relatively low-cost 3D printing technology allows to quickly develop user-specific design solutions and improvements. The key to a more efficient and less time consuming design process was the transfer of printing infrastructure to the user environment and the permanent online exchange of information between the user and the designer environment.

Regarding the problem of safety of a widespread use of 3D printed face masks in a pandemic, we conclude that in spite of their sometimes overly euphoric presentation in the press and the online media, none of the currently advertised 3D printed face mask designs looked at in our study are suitable as a reliable personal protective equipment. Main reasons for this are the low flexibility of the material and the thin sealing line preventing the necessary sealing performance on the face and leakages related to the connection of the masks with the filter material, especially unwanted leakages caused by the simplified filter box construction.

Thus, in summary we cannot recommend the use of a face mask produced in the FFF process as a protective gear in medical environments. The risk resulting from usage may be significant as the protective effect of the mask designs we have looked at is poor. We also strongly recommend to desist from advertising 3D printed solutions for face mask production in cases of supply shortages, especially on websites related to well reputed medical or scientific institutions to avoid a false sense of security in users of possibly defective products unless the designs have been fully qualified to a regulation such as DIN EN 149. Changes of certified designs would require a new qualification process. Subjective impressions might suggest a protective effect that does not exist.

Further investigations may be beneficial; one possible field would be to investigate the feasibility and safety of the production of molds using FFF to produce masks from silicone.

Future perspective

In the future, 3D printing will play a main role within the hybrid network of engineers and physicians to achieve fast point-of-care prototype production and evaluation. Due to the medical product and product liability laws the contribution of 3D printing to overcome supply bottlenecks of personal protective gear is currently limited.

With further development of process technology, materials, printing techniques and the handling of these, the production of medical products within the clinical environment may be possible in the future. Further mask design changes will be able to overcome the presented limitations of current designs. However, an in-depth testing of the products according to medical product regulation is inevitable.

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Ethical conduct of research

Informed consent was obtained from the research associates of the Institute for Protection Technologies, who functioned as test persons.

Summary points

- A 3D printing facilitates production of different rigid and foldable face masks.
- Point-of-care 3D printing accelerates product development and prototype evaluation.
- The 3D printed masks tested in this study do not qualify as personal protective gear with FFP2/FFP3 standard and do not qualify for use during the treatment of corona virus disease patients.
- Further design changes and selection of the appropriate material are necessary to further develop 3D printed personal protective gear.
- Medical product and product liability laws rule out a widespread use of 3D printed masks in Germany without further development of in-depth testing.
- Point-of-care 3D printing will remain a vital element of fast, user-oriented prototype development but due to high material and production costs, other manufacturing techniques will be used for mass production of these prototypes.

References

1. Wang M-W, Zhou M-Y, Ji G-H *et al.* Mask crisis during the COVID-19 outbreak. *Eur. Rev. Med. Pharmacol. Sci.* 24(6), 3397–3399 (2020).
2. Abd-Elsayed A, Karri J. Utility of substandard face mask options for health care workers during the COVID-19 pandemic. *Anesth. Analg.* 131(1), 4–6 (2020).
3. Javid B, Weekes MP, Matheson NJ. Covid-19: should the public wear face masks? *BMJ* 369, m1442 (2020).
4. World Health Organization. Advice on the use of masks in the context of COVID-19: interim guidance. (2020). www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak
5. Greenhalgh T, Schmid MB, Czypionka T, Bassler D, Gruer L. Face masks for the public during the covid-19 crisis. *BMJ* 369, m1435 (2020).
6. Davies A, Thompson K-A, Giri K, Kafatos G, Walker J, Bennett A. Testing the efficacy of homemade masks: would they protect in an influenza pandemic? *Disaster Med. Public Health Prep.* 7(4), 413–418 (2013).
7. Bowen LE. Does that face mask really protect you? *Appl. Biosaf.* 15(2), 67–71 (2010).
8. Hartig S, Duda S, Hildebrandt L. Urgent need hybridproduction – what sars-cov-2 can teach us about dislocated production and the maker scene. *3D Print. Med.* (In Press).
9. Swennen GRJ, Pottel L, Haers PE. Custom-made 3D-printed face masks in case of pandemic crisis situations with a lack of commercially available FFP2/3 masks. *Int. J. Oral Maxillofac. Surg.* 49(5), 673–677 (2020).
10. Cortes ARG, Galea K, No-Cortes J, Sammut EJ, Alzoubi EE, Attard NJ. Use of free CAD software for 3D printing individualized face masks based on face scans. *Int. J. Comput. Dent.* 23(2), 183–189 (2020).
11. Thomas CN, Schroder LK, Cole PA. Ten days to implementation of 3D-printed masks for a level-i orthopaedic trauma practice during the COVID-19 pandemic. *J. Bone Joint Surg.* 102(16), e95 (2020).
12. Scott AR, Hu J, Gan C, Morris JA, Meacham KW, Ballard DH. Safety concerns for facial topography customized 3D-printed N95 filtering face-piece respirator produced for the COVID-19 pandemic: initial step is respiratory fit testing. *Int. J. Oral Maxillofac. Surg.* 49(12), 1660–1661 (2020). S0901502720303337

13. Gierthmuehlen M, Kuhlenkoetter B, Parpaley Y, Gierthmuehlen S, Köhler D, Dellweg D. Evaluation and discussion of handmade face-masks and commercial diving-equipment as personal protection in pandemic scenarios. *PLoS ONE* 15(8), e0237899 (2020).

14. Nelson TJ, Colton CE. The effect of inhalation resistance on facepiece leakage. *AIHAJ* 61(1), 102–105 (2000).

15. Sun C, Thelen C, Sancho Sanz I, Wittmann A. Evaluation of a new workplace protection factor – measuring method for filtering facepiece respirator. *Saf. Health Work* 11(1), 61–70 (2020).

16. Wierzbicki J, Nowacki M, Chrzanowska M *et al.* Additive manufacturing technologies enabling rapid and interventional production of protective face shields and masks during the COVID-19 pandemic. *Adv. Clin. Exp. Med.* 29(9), 1021–1028 (2020).

17. Belhouideg S. Impact of 3D printed medical equipment on the management of the Covid19 pandemic. *Int. J. Health Plann. Manage.* 35(5), 1014–1022 (2020).