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Major Article

Surgical helmets can be converted into efficient disinfectable powered air-purifying respirators

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A B S T R A C T

Background: Filtering facepiece respirators often fail to provide sufficient protection due to a poor fit. Powered air-purifying respirators (PAPRs) are not designed for healthcare personnel, and are challenging to disinfect. Surgical helmets (SH) are available in many United States hospitals but do not provide respiratory protection. Several modifications to SH have been suggested, but none are sufficiently compliant with safety and efficiency standards. The purpose of this investigation was the development of a filter adaptor, which converts SHs into efficient, safe, and disinfectable PAPRs.

Methods: Four critical features were investigated close to regulatory requirements: total inward leakage of particles, CO_2 concentrations, intra-helmet differential pressure, and automated disinfection.

Results: The average total inward leakage in the 2 independent tests were 0.005% and 0.01%. CO_2 concentrations were lower than in the original SH. The modification generates a positive differential pressure. The filter's performance was not compromised after 50 cycles in a sterilization machine.

Discussion: The modified SH provides several hundred times better protection than FFP-3 masks.

Conclusions: Surgical helmets can be modified into safe, efficient, and disinfectable PAPRs, suitable for HCP and the operating room in particular. They can play a role in the preparedness for upcoming events requiring efficient respiratory protection.

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Conflicts of interest: The first author owns the intellectual property (IP) rights of the device described in this paper with a patent-pending.

Ethics approval and consent to participate: This investigation has been approved by the research board of the department of orthopedics at our institution [02.04.2020]. This investigation does not fall under the Norwegian law of "medical and health-related research" ("Lov om medisinsk og helsefaglig Forskning"). Therefore, ethical committee approval does not apply in the Norwegian jurisdiction.

† Max Joachim Temmesfeld owns the intellectual property (IP) rights of the device described in this paper with a patent-pending.

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INTRODUCTION

The risk of transmission of droplet- and/or airborne pathogens, such as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), while treating patients has been proven with numerous reports of healthcare personnel (HCP) around the globe falling ill and, not infrequently, also dying.[1] Therefore, the adequate respiratory protection of healthcare personnel (HCP) during the care of infectious patients, including in the operating room (OR) is mandatory.[2, 3] At the same time, the pandemic led to increased worldwide demand and a substantial shortage of respiratory protective devices (RPD) in different areas.[4, 5]

Filtering facepieces

Filtering facepiece respirators (FFR), such as filtering facepieces (FFP) according to the European standard,[6] are perhaps the most often used RPDs in hospital settings. Performance requirements for crucial parameters, such as the filtering efficiency (FE) and the total inward leakage (TIL), are summarized in Table B.1. FFRs usually feature a very high FE; however, their performance strongly depends on the fit to the user's face to establish a leak-free face seal. In this respect, TIL is a valuable indicator of the FFR's performance since it reflects the concentration of contaminants entering the mask via the filter and via potential leaks in the face seal due to a poor fit. TIL can be calculated according to the following formula:

$$TIL = \frac{contaminant\ concentration\ inside\ RPD}{contaminant\ concentration\ outside\ RPD}$$

Achieving and maintaining an FFR's proper fit is challenging, as several factors such as facial hair and anthropomorphic features affect the fit quality.[7-10] Foereland et al. performed 701 quantitative respirator fitting tests on 127 industrial workers with 14 respirator models. The pass rate for all fit tests was only 62%.[10] In addition, HCP reported ulcers and pressure sores after the long-term use of FFR. [11] Finally, HCP will have to wear additional eye protection to minimize transocular transmission.[12, 13]

Powered air-purifying respirators

In commercially available powered air-purifying respirators (PAPRs), a waist-worn battery-driven fan draws air through a filter into a corrugated breathing hose, which leads the airstream upwards into a hood to generate a positive differential pressure. While PAPRs offer superior protection than FFP by avoiding an improper fit, their use in the OR remains a challenge: the waist-worn fan unit can suck itself to surgical drapes and other objects. Some industrial PAPRs also feature an anterior exhalation valve, which directly blows the surgeon's unfiltered exhaled air into the surgical wound. A recent experimental study indicated a 100% reduction of surgical field contamination by a standard industrial PAPR. However, the exhalation valves of the 2 PAPR models used in this investigation were equipped with a filter. It remains unclear, whether PAPR models without filtered exhalation valve will perform similarity. Finally, the corrugated breathing hose, the hood's textile, belt, and the fan unit are not designed for sterile use in the OR and are challenging to disinfect with manual routines.[14] Consequently, PAPRs will often have to be off-label disinfected in sterilization machines. This process takes significant time, during which the PAPR is not available for the following user. To ensure continuous operation, hospitals will have to invest substantially into the acquisition of enough PAPR units.

Surgical helmets

Surgical helmets (SH) with an internal fan and a sterile single-use hood are routinely used in orthopedic arthroplasty surgery. They are designed to prevent the surgical team from contaminating the surgical field and to protect the surgical team from fluid splashes. SHs do share many features with PAPRs, but the air is not drawn through a certified filter medium, and the SH does not generate a positive differential pressure. We investigated the inherent filtration capacity of the original Stryker Flyte SH and found that the average TIL was 81% - unacceptably high for an RPD. Additionally, we recorded an accumulation of 0.3 μm particles inside the helmet.[15] Our findings support the finding in previous investigations during the SARS-CoV-1 outbreak in Hong Kong.[16]

Still, surgical helmets are available at many hospitals worldwide. They could serve as an RPD if modified to fulfill the following requirements:

1) be fitted with an efficient particulate filter medium
2) supply a sufficient airflow through the filter medium to vent out the user's carbon dioxide (CO_2) and bring in oxygen
3) produce a constant positive differential pressure inside the helmet.

The primary objective of this study was the rapid intrahospital development and small-series production of a filter adaptor, which reversibly renders surgical helmets into disinfectable, safe, and efficient PAPR units for use in the OR. The secondary objective was an upscalable design, which yields reproducible test results.

METHODS

Design concept

The PAPR filter adaptor ended up consisting of 2 parts: (1) the helmet adaptor and (2) the filter adaptor, see Figure 1 and Figure A.1.

A bayoneted snap-lock combined with an FDA-approved O-ring (Otto Olsen AS, Skedsmokorset, Norway) establishes an air-tight mechanical coupling between the helmet- and the filter adaptor. The helmet adaptor's conduit passes through a circular hole, cut into the air-permeable top portion of the hood. The hole's edges are sandwiched between the filter and helmet adaptor's external flanges, which hold the hood sturdy in place, see Figure 1. This principle is widely applied in ventilated suit applications.

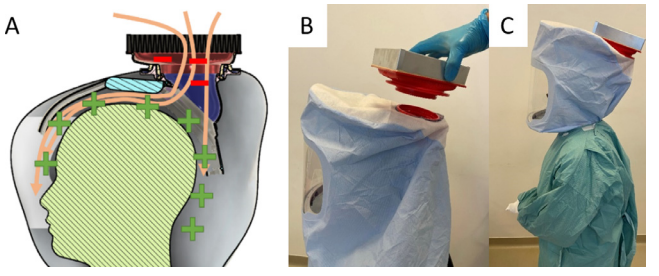

Fig 1. (A) Illustration of the PAPR filter adaptor, which comprises the helmet adaptor (blue) and the filter adaptor with filter medium (red and grey). The fan generates a local vacuum under the filter medium (red minus) and draws filtered air inside the helmet (orange arrows). The system will generate a positive differential pressure (green plus). (B) A bayoneted snap-lock will compress the edges of the hole between the external flanges of the helmet- and filter adaptor and thus hold the hood's fabric sturdy in place (C) Healthcare personnel with the fully donned PAPR filter adaptor for a surgical helmet

The fan draws filtered air in, generating a positive pressure at the fan's output side, that is, inside the helmet, see Figure 1. We calculated filter medium, size, and filtration area based on experimentally determined fan and filter charts. A customized HEPA filter medium was glued into an aluminum frame, and the frame was glued onto the filter adaptor. The top grid over the fan intake was removed, and the helmet adaptor was finally glued onto the fan intake of the SH. This conversion is reversible. The design is adaptable for future injection molding for mass production.

Prototyping and manufacturing

We utilized computer-aided design (CAD) and computational fluid dynamics (CFD) for the design process. CFD simulations enabled a weight reduction and improved the center of gravity without reducing airflow. In an iterative development process, physical copies were prototyped by fused filament fabrication (FFF) at the hospital's 3-dimensional (3D) printer lab (S5, Ultimaker, Utrecht, The Netherlands) and selective laser sintering (SLS) (P-series, EOS, Munich, Germany). The advantages of SLS include fewer manufacturing limitations, weight reduction, and a lower risk of permeability.

CO_2 concentrations

CO_2 concentrations were recorded using a wireless CO_2 probe with a detection limit of 12 000 parts per million (PPM) (Testo 440, Testo SE, Titisee-Neustadt, Germany) mounted close to the user's nasal orifice inside the helmet with the help of a 3D printed jig. After one minute, CO_2 levels reached a steady-state, and 3 test persons performed a customized 8-minute exercise protocol on a treadmill, which was designed to provoke a CO_2 accumulation. Each test person reported respiratory comfort on a Likert scale every minute. The ambient CO_2 levels were also recorded to quantify potential CO_2 accumulation at the test site. Finally, the same 3 test persons performed the identical test protocol using the unmodified SH.

Disinfection

Manual surface disinfection comprised thoroughly wiping all available surfaces with 2,5% hydrogen peroxide-containing wipes (OxyWipes, Ecolab, Saint Paul, MN) over 2 minutes**.** The internal surfaces of the SH's air conduits are not physically reachable with a wipe. However, only filtrated air passes along these surfaces; hence these surfaces will not be contaminated, even if the user is infected. For automated disinfection, the filter adapter was sterilized 50 times with the "Express" and the "Standard" cycle of the hospital's low-temperature hydrogen peroxide plasma sterilization machine (STERAD 100NX, Advanced Sterilization Products, Irvine, CA).

Particle loading tests

HEPA test rig

The PAPR filter adaptor's filtration efficiency was examined in a high-efficiency particulate air (HEPA) test rig, compliant with the European HEPA standard, see Figure A.2.[17]

Total Inward Leakage test in an aerosol chamber

The TIL of the whole modified helmet was measured under conditions analogical to the European PAPR standard.[18] A treadmill was placed in a closed chamber (290 × 110 × 250 cm). Two particle generators (TSI 8026, TSI Inc., Shoreview, MN, USA) generated a steady-state sodium chloride (NaCl) aerosol. A particle detector (PortaCount 8038, TSI Inc., Shoreview, MN, USA) tube was attached to a 3D-printed perforated ball probe, placed adjacent to the lips of the test person see Figure A.3. The particle concentration was continuously recorded and analyzed (CPG Protect Software, Royal Military College of Canada, Canada). TIL was measured for 6 test persons (5 females and 1 male) who performed standardized exercises, including head, torso, and facial muscle movements while walking on a treadmill, see Figure A.3. The last 100 seconds of each exercise were included in TIL calculations.[18] TIL was multiplied with a correction factor of 1.25 to compensate for pulmonary absorption of NaCl droplets.[18]

Total inward leakage test in an operation theatre

TIL was tested on a mannequin with the same method as previously described.[15] In brief, a particle generator (Air Techniques International, Owings Mills, MD, USA) generated an FDA-approved test aerosol in a certified operation theatre with a mixed ventilation.[19] One particle counter (Solair 3100, Lighthouse, Fremont, CA, USA) was placed inside the helmet, while another identical particle counter detected particles approximately 20 cm from the filter outside the helmet. TIL was calculated over a cycle of 23 minutes.

Differential pressure measurements

The differential pressure inside the modified SH was recorded with a differential pressure probe (MP50, Kimo, Lerwick, UK) for different body positions of the test person.

All data were analyzed in Prism (Graphpad, San Diego, CA) and Origin (Origin Lab Corporation, Northhampton, MA).

RESULTS

Prototyping and manufacturing

A timeline of the prototyping milestones is presented in Table B.2. After 7 weeks of prototyping, we were able to take 2 functional FFF prototypes to the operation theatre for clinical testing. Each copy was individually tested in the HEPA test rig prior to the release for clinical use. Then, the design was adopted to SLS, and eight copies were manufactured for this investigation.

CO_2 concentrations

Results are summarized in Figure 2.

The inward airflow was experimentally measured and ranges from 15.2m^3/h to 29.2m^3/h.Test persons one and 2 were females (62 and 66 kg), while test person 3 was male (92 kg). With test person 3, at minimum fan speed, CO_2 levels exceeded the detection limit after 05:40 minutes on the treadmill, that is, after 01:40 minutes at 9 km/h but declined under 10,000 PPM after 07:10 minutes. With the fan at maximum speed, the maximum CO_2 concentration among all test users peaked at 7333 PPM.

While test person 3 control-tested the unmodified SH at minimum fan speed, CO_2 levels increased over the detection limit after one minute. Concentrations did not decline for the rest of the experiment. During the heaviest exercise with 9km/h on the treadmill, respiratory comfort was rated 2/5, and the test person reported dizziness. For this reason, the control experiment with the unmodified SH was aborted.

Disinfection

Filtration efficiency and resistance to airflow (pressure drop) were recorded before and after sterilization. No significant difference was found, and the filter still passed the HEPA H13 standard.

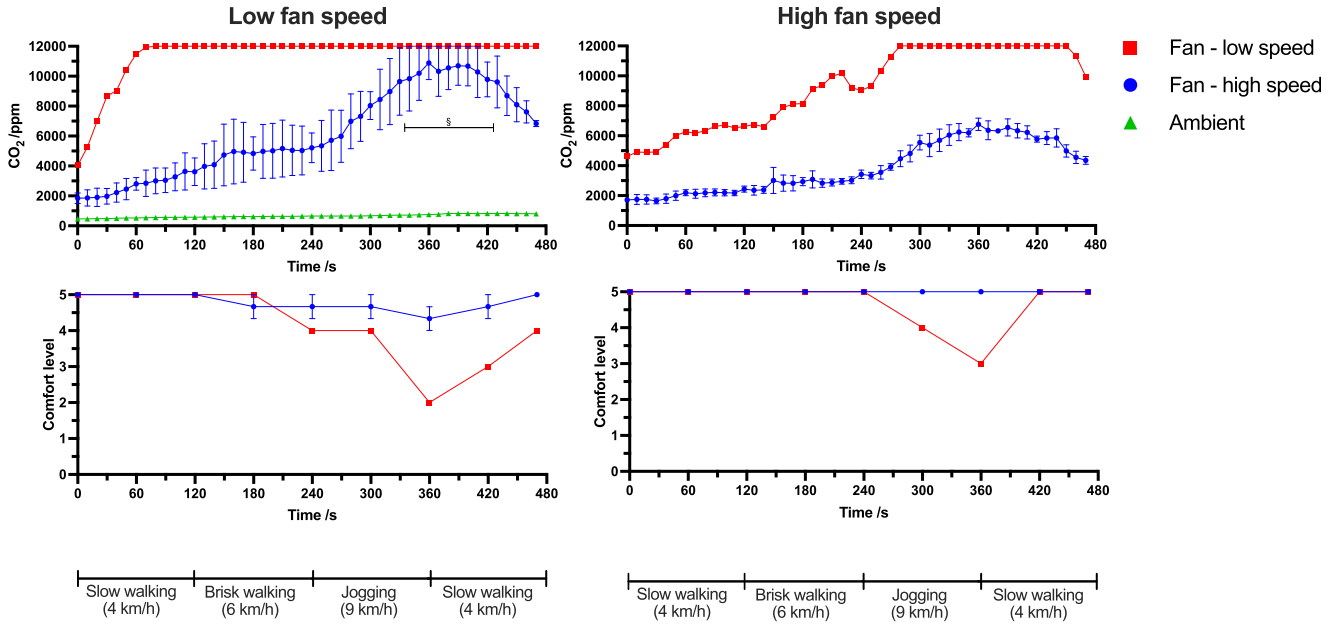

Fig 2. Upper graphs: CO_2 levels inside the surgical helmet with PAPR filter adaptor (blue) and without modification (red). The blue curve depicts the means of 3 test persons for the helmet with filter adaptor, errorbars are SEM. The test with the unmodified helmet was aborted after the first run due to respiratory discomfort. § marks the time period where CO_2-levels exceeded the sensor limit of 12,000 ppm for one testuser at minimum fan speed. Lower graphs: corresponding user-reported respiratory comfort level on a scale from 1 (very uncomfortable) to 5 (comfortable).

Particle loading test

HEPA test rig

Seven units were tested. The minimum filtration efficiency at the most penetrating particle size (MPPS) ranged from 99.96% to 99.997%, while MPPS was 0.074 μm. The filtration efficiency of all tested units meets the HEPA H13 standard.[17]

Total Inward Leakage test in an aerosol chamber

Results are summarized in Table 1 and Figure 3. The average TIL was under 0.05%.

Total inward leakage test in an operation theatre

Results are summarized in Figure 4 and Table B.3.

TIL did not exceed 0.07% for any particle size at any time of the 23-minute-lasting loading cycle. The TIL for the smallest particles (0.3 μm) was slightly higher than for 0.5 μm, and 5 μm sized particles. A TIL spike of 0.07% was detected at about 16 minutes in the cycle. Since absolute particle counts inside the SH were very low, ranging from 5 particles/ft^3/minute to 345 particles/ft^3/minute (minute 19 and minute 1; both 0.3 μm) we regard the 16-minute spike to be within the random statistical variations of the sampling method.

Differential pressure measurements

A positive differential pressure inside the helmet was recorded at all times, ranging from 4 – 10 Pa, depending on the fan speed. The positive differential pressure resulted in the hood appearing slightly "blown-up."

DISCUSSION

This paper presents a 3D printed filter adaptor, which renders readily available surgical helmets into disinfectable PAPRs suitable for the use in the OR, providing better protection and comfort than face filtering respirators. Challenges of commercially available PAPRs and problems with the fitting of FFR can be avoided. The filtration capacity of the modified helmet is about 430 times better compared to FFP-3. Three independent particle loading tests and a CO_2 accumulation test demonstrate the overall safety and efficiency of the device.

We attempted to meet as many European PAPR standard[18] requirements as possible, focusing on TIL, CO_2 levels, and a recordable positive intra-helmet differential pressure. The adaptor was deliberately designed for additive manufacturing (AM) on commercially available 3-dimensional (3D)-printers. The in-house availability of this technology enabled our institution to swiftly react to the emergent need for efficient RPD for the OR. The Flyte SH (Stryker Instruments, Kalamazoo, MI) was chosen for the retrofit since our hospital routinely utilizes these helmets for arthroplasty surgery. Nevertheless, the design can be easily modified to fit SHs from other manufacturers.

Disinfection

The filter adaptor with the filter medium is the only part of the assembly exposed to infectious particles from the surroundings, see Figure 8. The rest of the assembly is protected under the single-use hood. While the hood is thrown away after use, the filter adaptor can be disinfected manually or by low-temperature hydrogen peroxide plasma disinfection machines. The rest of the helmet is be disinfected with manual surface disinfection to avoid cross-contamination between users. After a few minutes, the device is again ready for use.

Table 1
Total Inward Leakage (TIL) of the surgical helmet with PAPR filter adaptor in analogy to the European PAPR standard EN12941

Exercise	TIL* average	TIL* max	TIL* min
Head side to side (2 min)	0.00641 %	0.01183 %	0.00331 %
Head up and down (2 min)	0.00480 %	0.00685 %	0.00284 %
Speech (2 min)	0.00383 %	0.00611 %	0.00253 %
Walking (2 min)	0.00356 %	0.00556 %	0.00267 %
Average	0.00465 %	0.00759 %	0.00284 %

*TIL; total inward leakage.The last 100 seconds of each exercise are included in the TIL calculation.

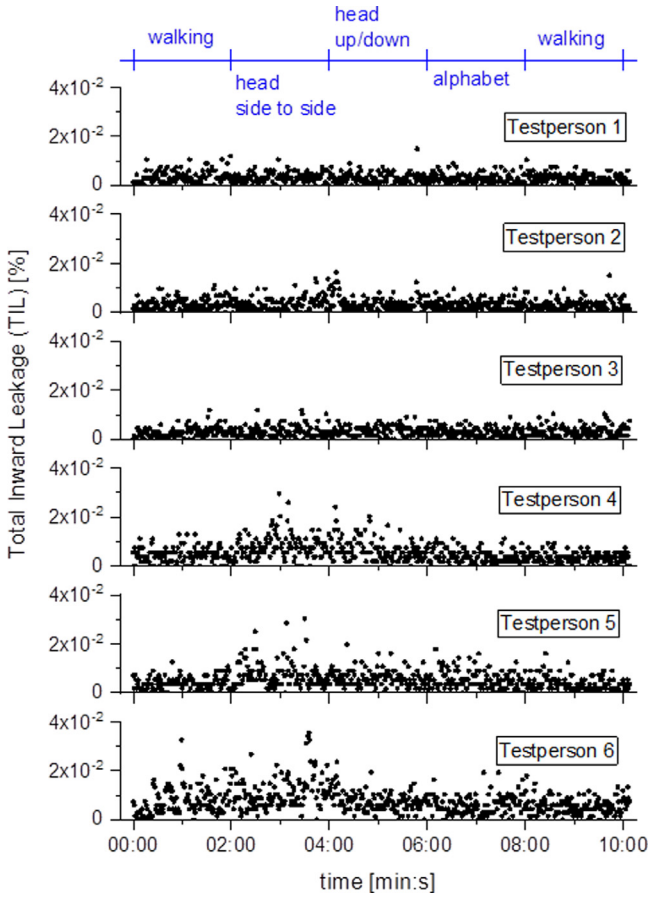

Fig 3. Total Inward Leakage (TIL) was measured on 6 test persons (1 male and 5 females) wearing a surgical helmet with 3D printed PAPR filter adaptor according to the European PAPR standard EN12941.

Carbon dioxide

Carbon dioxide accumulation inside the helmet is a potential hazard for the user. With the fan at maximum speed, CO_2 levels never exceeded the requirements of the European PAPR standard, which defines 10,000 ppm as the maximum allowed CO_2 concentration.[18] The standard requires recordings on a Sheffield dummy attached to a breathing machine, with a CO_2 production of 2,5 L/min CO_2. The purpose is to mimic an average adult in light activity. We did not follow this standard's test procedure. Human CO_2 production varies enormously depending on age, sex, weight, basal metabolic rate, among other individual factors. Nevertheless, all test persons likely produced significantly more CO_2 during our test protocol than specified in the standard since our protocol included relatively challenging exercises on the treadmill at 9 km/h. Even at minimum fan speed, only the heaviest test person exceeded 10,000 pm. The maximum CO_2 level at full fan speed was 7,333 ppm, well below the maximally allowed 10000 ppm. CO_2 levels inside the modified helmet were markedly lower compared to the original Flyte SH, which the surgical team usually wears for many hours during arthroplasty surgery. The reason for this finding might be the substantially different airflow pattern of the unmodified SH compared to the modified SH with filter adaptor. In the original SH, all gas exchange takes place within the same physical compartment, that is, under the hood. Some CO_2-enriched exhaled air from the user will be recirculated and drawn back into the fan again, rather than diffusing out of the helmet. The filter adaptor modification presented here, physically separates the inward- and the outward airflow, and thus prevents CO_2 recirculation. In this respect, the airflow pattern in the modified SH with filter adaptor resembles a commercial PAPR and likely explains the lower CO_2 levels. Additionally, the HEPA filter's resistance to airflow (pressure drop) is could be lower compared to the original hood's fabric.

We recorded an airflow of 15.2m^3/h to 29.2m^3/h, which is substantially higher compared to most commercial PAPRs. We assume that the relatively high airflow is necessary for the unmodified original helmet to vent-out CO_2, since some of the CO_2 enriched air is recirculated. In the modified helmet with filter adaptor, where CO_2 recirculation is not an issue, such a high airflow is probably not necessary.

Previous literature

During the pandemic, several modifications of surgical helmets have been suggested in the literature.[20-23] Nevertheless, many of these investigations utilize non-standardized testing procedures, making a direct comparison with the benchmark equipment difficult, if not impossible. Furthermore, most papers lack a complete characterization of the equipment considering the safety issues and the specific threats from bio-aerosols such as the SARS-CoV-19 virus. For example, Gibbons et al. reported an attempt to filtrate the inflowing air with a particulate filter medium mounted over the fan-intake with duct tape. However, according to the referenced datasheet, the filter medium was a general ventilation filter[24] and not a HEPA grade medium as stated. The minimum allowed initial efficiency at 0.4 μm particle size for the highest classification F9 is 70% according to the respective standard.[24] There is no evidence of the minimum filtration capacity and/or MPPS for this filter medium. The customized particle detection test was not performed according to any standard for RPD,[6] for example TIL testing during physical exercises in a controlled atmosphere. Instead, testing was performed in ambient atmosphere without generating a challenge aerosol and the non-simultaneous detection of particles inside and outside the modified helmet. In our investigation, filtration efficiency with a realistic particle load and standardized test procedure was over 99,95%. CO_2 concentrations in Gibbons et al. paper ranged from 11,000 PPM to 16,000 PPM, measured at rest, significantly over the European standard's allowed limit of 10,000 PPM.[18] CO_2 levels during any activity will likely increase 5 to 10-fold with the risk for pulmonary CO_2 retention, dizziness, or even syncope. CO_2 levels in our investigations peaked at 7,333 PPM during a 9 km/h exercise on a treadmill.

Erickson et al. 3D-printed a manifold for the fan intake of the Stryker Flyte surgical helmet.[20] Two ventilator hoses attached to the manifold and were equipped with one in-line ventilator filter each (eg, BB50T, Pall International, Fribourg, Switzerland). While in-line ventilator filters provide an excellent filtration capacity, the inherent pressure drop of 2 parallel in-line filter units is approximately 680 Pa at 25m^3/h airflow, according to the manufacturer.[25] The pressure drop of the HEPA filter used in the PAPR filter adaptor described here is about 7 times lower. The high pressure drop in Erickson et al. device will likely choke the airflow and thus raises the concern of CO_2 accumulation. Unfortunately, the authors did not present any quantifiable CO_2 and / or airflow data.

Shah et al. 3D-printed a mold over the fan-grid of the Stryker Flyte helmet, which holds an N95 filter medium in place over the fan.[21] In theory, the fan will draw filtered air into the helmet. While Shah et al. concept excels in its simplicity, it is unclear whether the fan might draw particles inside the hood, bypassing the filter, for

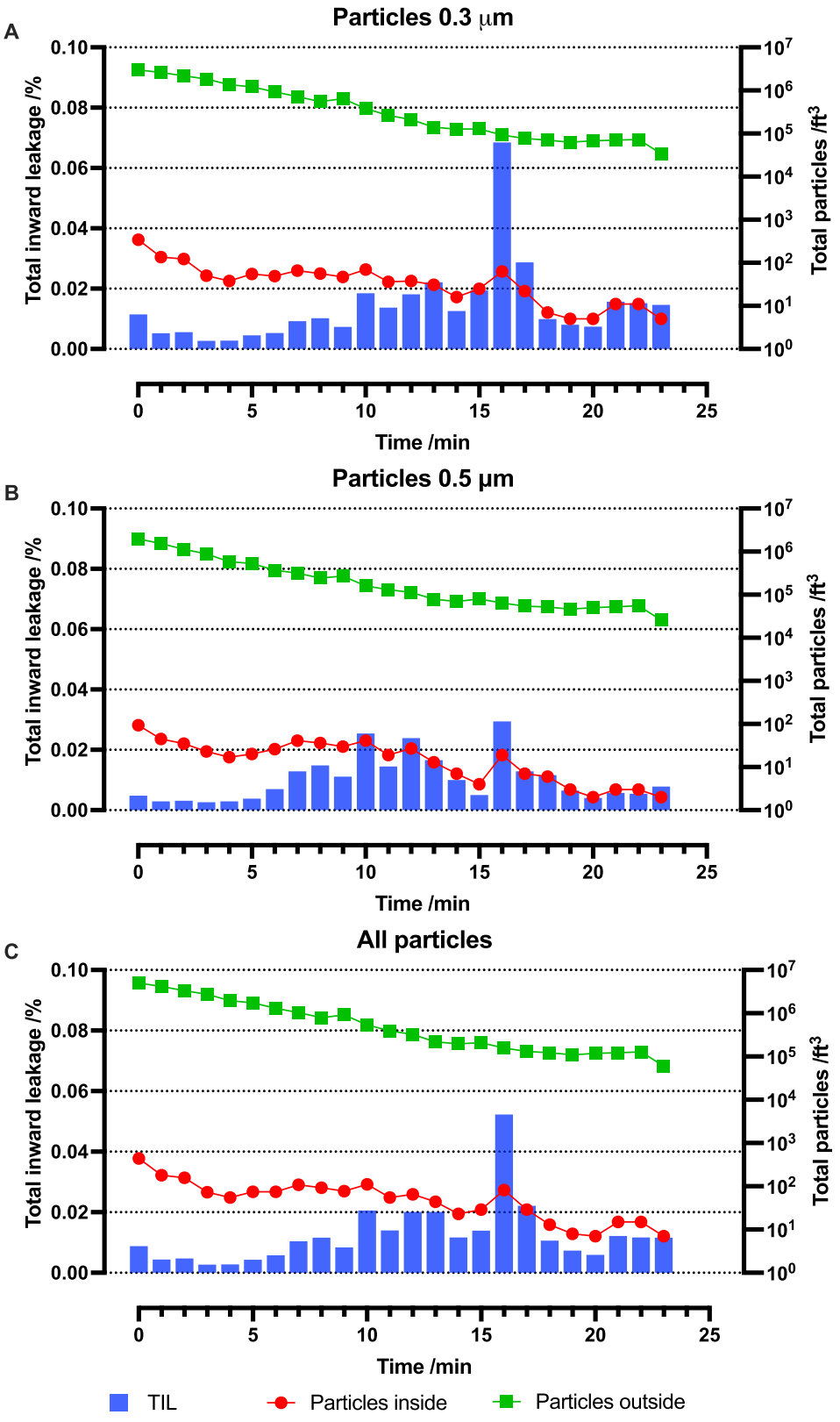

Fig 4. Total Inward Leakage (TIL) of the surgical helmet with PAPR filter adaptor at maximum fan speed in an operation theatre over 23 minutes, after an experimental setup according to Jakobsen et Temmesfeld et al., 2020. TIL (blue bars), the ambient particle count (green) and the particle count inside the helmet (red) are depicted for 0.3μm (A), 0.5μm (B) large particles of an FDA-approved test aerosol. The graph for 5μm large particles is not shown, because TIL was 0. Panel (C) depicts all particle sizes.

example, during head movements. The authors report a filtration efficiency of over 95% for 0.3 μm NaCl particles. Unfortunately, the paper does not explain the essential details of these tests nor refers to any standard. Furthermore, Shah did not report recordable and objective CO_2 concentrations.

Limitations

Even though one of the 3-particle loading tests essentially follows the respective European PAPR standard,[18] our device is not yet formally certified and not fully compliant with the required standard. A modified SH, in line with commercially available PAPRs, does not protect against the aerosols generated by possibly infected users. Infected HCP can transmit particulate contaminants, such as the SARS-CoV-2 virus to patients, even if they wear the device described here – or any other PAPR. Daily testing, the use of additional surgical masks below the SH, or a filtrating exhaust valve are possible means to minimize this risk. At our institution, as in most Western ORs, HEPA filters constantly filter the circulating air.

An SH with a mounted filter adaptor increases the total weight of the helmet to approximately 800g, which is heavier than some commercial PAPRs. Finally, staff will have to remove the glue to remove the helmet's modifications when PAPR graded protection is no longer needed. Further design iterations will be necessary to establish a more effortless switch between surgical helmets and PAPR function.

CONCLUSION

Surgical helmets can be modified into safe, efficient, and disinfectable PAPRs, which are suitable for the use in the OR. The modified SH serves as a standard surgical helmet for arthroplasty surgery in routine operation and as a PAPR in high-risk situations for droplet- and/or airborne infection. This “walking storage” of emergency preparedness equipment can save costs for storage facilities and the introduction of multiple rather complicated personal protective equipment. Surgical helmets are readily available and can be a valuable RPD resource in times of crisis and as a preparedness measure for upcoming epi- and pandemics.

DISCLAIMER

The device described in this paper is a modification of the Stryker Flyte helmet, produced by Stryker Instruments (Kalamazoo, MI), and is a non-certified medical device. Stryker Instruments has not authorized any of the modifications described here. Appendix B

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.ajic.2021.12.002.

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