

Proposal for a EN 149 Acceptable Reprocessing Method for FFP2 Respirators in Times of Severe Shortage

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Conclusion: In severe shortages, FFP2 respirator can be safely reprocessed one time

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Abstract

Introduction:

Transmission to health care workers (HCW) poses a major burden in the current Covid-19 pandemic. Unprotected exposure to a SARS-CoV-2 patient is a key risk factor for HCWs. Droplet transmission, and high transmission during aerosol-generating procedures are modes of transmission, requiring a respirator such as N95 or FFP2 respirator to protect the HCWs, likely the most important part of personal protection equipment (PPE). However, many HCW were infected due to lack of PPE, or failure to use them. The worldwide shortage of respirators triggered the development of reprocessing used N95 or FFP2 respirator. Our proposal with H₂O₂ plasma sterilization for decontamination allows to reprocess a type of FFP2 still meeting filtration effectiveness of EN 149, the European standard for new respirators. The protocol is simple, uses available resources in hospitals and can be rapidly implemented to decrease the shortage of respirators during this crisis. The goal of the study was to evaluate if respirators can be reprocessed without hampering filtration capacity outlined by EN 149

Methods

Used FFP2 respirators – Model 3M Aura™ 1862+ - were sterilized using a low temperature process Hydrogen peroxide (H₂O₂) V-PRO® maX Low Temperature, a FDA approved method to decontaminate FFP2 respirator. Decontaminated respirators were further checked for residual peroxide by a single-gas detector for H₂O₂. The Total Inward Leakage of the protective respirators was quantitatively tested with 10 test persons in an atmosphere charged with Paraffin aerosol according to EN 149. The fit factor was calculated as the inverse of the Total Inward Leakage.

Results

Ten new and ten decontaminated FFP2 respirators were simultaneously tested for filtration effectiveness. None of the respirators exceeded peroxide maximum acceptable concentration of peroxide before use. More than 4000 respirators have been reprocessed so far, at cost of approximately 0.3 Euro/piece.

Conclusions

FFP 2 respirators can be safely reprocessed once after decontamination with plasma peroxid sterilization still meeting EN 149 requirements as new respirators. This allows to almost double the current number of FFP2 respirators that are in serious shortage.

Introduction

March 11, 2020, the World Health Organization (WHO) declared coronavirus disease (COVID-19) a pandemic (1, 2). More than two million individuals have been infected from all continents. At least a part of COVID-19 patients appear to be infectious 2–3 days prior to present symptoms (3). Current infection

control practices for PPE includes gloves, gowns and surgical respirator as minimum standard of care for treating COVID19 patients in hospitals. During aerosol generating procedures, a FFP2 respirator is recommended by WHO, and many national authorities. However, the demand on respirators largely exceeds available resources. Lacking PPE, many HCWs were exposed to COVID19 patients without appropriate PPW, and contracted the disease (4, 5).

As PPEs getting more and more of limited supply, strategies to extend the use of such respirator have proposed. In the US, Emergency Use Authorization allows today even expired NIOSH-approved filtering facepiece respirators, and recipes to create your own respirator have been published by CDC. However, filtration capacity is much lower with cloth respirators than with commercially available respirators(6),(7). One study claimed for influenza, that respirators “can effectively serve as personal bioaerosol samplers.”(8)

Dry heat, UV light and ethylene oxide has been used to decontaminate respirators, but did not ensure effectiveness of filtering after decontamination (9). The protocol of Nebraska (<https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf>) also provides an option for reprocessing. In the US, the FDA finally approved march 30,2020, the “Battelle respirator-sterilizing technology” for multiple N95 reprocessing using hydrogen peroxide vapour (Clarus C system, Bioquell, Horsham, PA). The system allows safe reprocessing without losing filtration effectiveness (<https://www.battelle.org/newsroom/news-details/coronavirus-fda-provides-full-ok-for-battelle-respirator-sterilizing-technology>).

However, all protocols have some deficiencies, require a UVc device, or are dependent on a commercially available reprocessing company, or are not ready for hospitals within days or weeks.

.We therefore looked for a rapid, inexpensive decontamination process commonly available to hospitals on-site, rely on available human resources and are safe after reprocessing with EN 149 as requirement.

Methods

Decontamination

Used FFP2 respirators – Model Aura™ 1862+, - were collected in designated containers, and full containers sent to Central Sterilization. After a 24 h storage, staff of CS checked under the magnifying glass each FFP2 respirator for intact surfaces, residual debris and visual changes on the respirator, such as residual lipstick, make- up and other residuals from humans. Respirators that passed this test were individually packed in bags as recommended by the manufacturer. The respirators were sterilized using a Low temperature process Hydrogen peroxide (H₂O₂) V-PRO® maX Low Temperature Sterilization (STERIS 5960 Heisley Road Mentor, OH 44060, USA) with short program (<https://www.steris.com/healthcare/products/v-pro-sterilizers/v-pro-max-low-temperature-sterilization-system>)

Individually packed respirators were further checked for residual H_2O_2 before shipping to central storage. They got an individual purchasing number to ensure that reprocessed respirators can be shipped to defined wards only. Residual H_2O_2 was detected after the process with single-gas detector for H_2O_2 Dräger X-am® 5100 (Drägerwerk AG & Co.Lübeck, Germany)

Testing For En 149 After Reprocessing

New and reprocessed respirators (each $n = 10$) have been tested at Spiez Laboratory, Federal Office for Civil Protection FOCP, Switzerland. The Total Inward Leakage of the protective respirators was quantitatively tested with 10 test persons in an atmosphere charged with Paraffin aerosol. The aerosol concentration was measured with the Portacount® PRO + 8038 outside and inside the respirator while the test persons were performing a series of tasks (movement) according to EN 149. The Total Inward Leakage is the ratio of both concentrations. The fit factor (FF) is the inverse of the Total Inward Leakage (Table).

The cost was estimated by applying time for decontamination, but not included time for collecting and distributing respirators

Results

Around 10% of the more than 5000 respirators were discarded prior sterilization since residual debris (lipstick, make-up, visible dirt) was detected. Decontamination using the more than 4500 FFP2 respirators have been reprocessed by Low temperature process Hydrogen peroxide H_2O_2 V-PRO® maX Low Temperature Sterilization.. The process is routinely validated by the device itself: the device automatically interrupts the sterilization process if the defined parameters are not fulfilled (10). None of the cycles did interrupt. The sterility assurance level requires for sterilization a 6 log reduction of the spores most resistant to the sterilization technique (11). SARS-CoV-2 belongs to the enveloped viruses that are highly susceptible to this sterilization technique (11) and are killed by this process. Individually packed FFP2 respirators demonstrated 1.5 ± 0.1 mg/m³ immediately after sterilization. Those respirators without packing had relatively high concentration of H_2O_2 immediately after sterilization 3.62 ± 1.5 mg/ m³, but aeration for 24 h lead to very low values of 0.24 ± 0.1 mg/m³, much below maximum allowed concentration of 0.7 mg/.

The filtration capacity of reprocessed FFP2 respirators was reduced on average of 30% (Table). However, all the processed FFP2 respirators still fulfilled the EN 149, after one single reprocessing cycle. We calculated 0.3 Euro/reprocessed respirator for human resources not taking into account cost for the sterilization. However, we assume cost for bags for sterilization, handling and transporting respirators a maximum of 0.2 Euro /respirator, summing up to 0.5 Euro/piece of reprocessed respirators, below the cost of a new one.

Discussion

Respirators have been designed as single-use device, generally including multiple steps such as disassembling, cleaning, and if necessary, refurbishing after they have been used. Therefore, reprocessing must ensure that the product still meets all requirements as the new product.. April 9, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the STERIS V-PRO 1 Plus, maX, and maX2 Low Temperature Sterilization System to decontaminate N95 respirators to a maximum of 10 times <https://www.fda.gov/media/136843/download>. Aerating bags before use, or even storage of bags in non-air-tight containers will eliminate this even very low risk for exposure of HCWs. The current situation of severe shortages of respirators require the next best solution to ensure adequate supply of respirators and other parts of PPE.

Several other methods are available to safely decontaminate used FFP2 or equivalent respirators (12, 13): The Robert-Koch-Institute – the German health institute – recommends dry heat at 65 °C-70 °C for 30 Minutes (https://www.bmas.de/SharedDocs/Downloads/DE/Thema-Arbeitsschutz/einsatz-schutzrespiratoren-einrichtungen-gesundheitswesen.pdf?__blob=publicationFile, accessed April 8, 2020), but do not prove equivalent filtration capacity

Our proposal has several advantages: decontamination is safe by using a sterilization technique, approved by FDA, that uses low temperature. The temperatures are below 70 °C, a temperature that must be tolerated by a FFP2 respirator passing the EN 149 test requirements. The technique is widely available, and requires less human resources than decontamination with UVc. In addition, EN 149 test have been performed with individuals, not in the laboratory only. Decontamination with steam partly destroys the respirators, decreases at least for surgical respirator filtration capacity by more than 30%, and has not been followed (data not shown).

Some limitations must be mentioned: we only reprocessed the respirators once. Multiple cycles of reprocessing may impede filtration effectiveness, but appear to be feasible up to 10 times based on FDA. In addition, the number of reprocessings must be securely written on the device without altering the effectiveness of the respirators to keep track on the number of reprocessing. Design of other types of respirator may limit extrapolation of this technique to other types of respirators such as N95.

In conclusion, the proposed method for reprocessing FFP2 respirator may allow to decrease the shortage of FFP2 respirators with technologies that are widely available in hospitals and can rapidly introduced during this crisis at low cost. Most importantly, the filtration capacity after reprocessing still pass the filtration and leakage test by EN 149 for FFP2 respirators.

Table 1

Fit factors of masks tested with the test persons, new and reprocessed masks. 200 is the upper detection limit of Portacount®

Test Person	Fit Factor	
	new	reprocessed
1	170	> 200
2	> 200	85
3	> 200	> 200
4	189	108
5	> 200	> 200
6	143	127
7	> 200	> 200
8	> 200	152
9	28	23
10	178	130

The requirements according to standard EN 149:2001 + A1:2009 are met for all the 10 test persons, both with new and reprocessed masks.

Declaration

Ethics approval and consent to participate:

in-vitro study, not applicable

Consent for publication

Not applicable

Availability of data and material

Data sharing not applicable to this article as no datasets were generated or analysed during the current study

Competing interests

None

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Authors' contributions

A.widmer designed the study, had the idea, and wrote the manuscript G.-Richner conducted the EN 149 tests and wrote the interpretation

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