



Reuse of FFP2 masks

Amendment after discussion in OMT on March 18, 2020: The point regarding surgical masks and protection against corona virus was removed.

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Summary

The Dutch National Institute for Public Health and the Environment (RIVM) has conducted a pilot study and found a reprocessing method that leads to an acceptable quality of reprocessed face masks. The caveat is that only limited research has been done on the retention of particles by reprocessed face masks.

This study shows that FFP2 face masks retained their shape and were able to retain particles in a 'quick' test after sterilizing once and twice with a short hydrogen peroxide process. In times of scarcity, FFP2 masks can be used three times when sterilized twice with hydrogen peroxide in between use.

This note was discussed in the outbreak management team (OMT). The OMT endorses the usefulness of this application if urgent shortages arise.

Introduction

The outbreak of SARS-CoV-2, a new corona virus, end 2019/early 2020, has led to a shortage of face masks. This shortage is caused by the decreased manufacturing capacity in China, the higher demand by healthcare workers and the high demand from civilians. The Dutch Ministry of Health, Welfare and Sport has requested the Dutch National Institute for Public Health and the Environment (RIVM) to perform a study into the possibilities of reprocessing so-called FFP2 face masks.

This type of mask is intended for single use and reprocessing is usually not desirable. Manufacturers of face masks share this opinion. However, when a method for reprocessing, which could still lead to an adequate protection, would be available, this method of reprocessing can be used in case of emergency.

FFP2 face masks versus surgical masks

Type FFP2 face masks have a close fit to the face and are available with and without valve. These masks are designed to protect caregivers against the coronavirus and other pathogens that are transmitted through aerosols.

The so-called surgical face masks were not included in this investigation. These face masks are worn by caregivers during procedures, such as surgery, in order to protect the patient against micro-organisms. In addition, these masks protect the caregiver against blood splashes and other fluids.

There are indications that the field is experiencing a shortage in surgical masks, however this lies outside the scope of this document.

Considerations

The research into the reuse of these disposable FFP2 face masks has focused on methods that could be applied in practice using already available equipment. A processing method that is available in as many healthcare institutions as possible is therefore preferred.

Details of the face masks

The study was conducted on unused 3M FFP2 NR D face masks (type 8822). These masks consist mainly of polypropylene and do not contain cellulose.

Testing face masks

The so-called fit test has been used to get an impression of the effect of the reprocessing on the effectiveness of the face masks. The fit test is a method of examining whether a mask fits the user's face properly without air leakage, and whether the filter material is a good barrier against particles. This test is used to determine whether a mask provides sufficient protection for a user to work in the high-containment laboratory of the RIVM. The test was performed with a TSI PortaCount Pro + 8038. The amount of particles outside and inside the mask was measured and compared. All testing was performed on the same test subject. An average test value of more than 100 (= ratio between number of particles outside and inside the mask) indicates that the mask retains a sufficient amount of particles.

A fit test has been performed using an untreated face mask first, resulting in an average value of 162. After reprocessing, a face mask must have a minimum average value of 100 in the fit test.

Applied processes for reprocessing

Unused FFP2 masks were reprocessed in the Central Sterilization Department of the University Medical Center Utrecht using the following processes (two masks per condition):

1. 60 °Celsius cleaning process (12 minutes) with drying step, without detergent, without chemical disinfection
2. cleaning process with drying step, without detergent, thermal disinfection at 90 °C (5 minutes)
3. cleaning process with drying step, with cleaning agent (MediClean forte), thermal disinfection at 90 °C (5 minutes)
4. vaporized hydrogen peroxide low pressure gas sterilization (Sterrad NX 100 Express cycle with allclear technology (drying phase)); applied once, twice, three times and four times
5. steam sterilization at 134 °C

The effectiveness of the above processes is sufficient to inactivate the coronavirus based on knowledge of inactivation of such viruses. Sterilization processes have been developed to inactivate all microorganisms. Exploratory research at the University Medical Center in Maastricht has shown that microorganisms could no longer be cultured from used oral masks after sterilization with hydrogen peroxide (Sterrad 100NX standard program) after pieces of the oral masks were placed in a growth medium for 72 hours.

The masks that were not visually deformed were subsequently subjected to a fit test at the RIVM, as described in the section on testing face masks.

First results

The first results are depicted in the table below.

Process	Face mask deformation yes/no	Fit test outcome +/-
Control	N/A	+ (162)
1. 60 °Celsius cleaning without detergent and disinfectants	No	- (60)
2. 90 °C cleaning without detergent	Yes	N/A
3. 90 °C cleaning with detergent	Yes	N/A
4. Hydrogen peroxide sterilisation 1x	No	+ (151)
Hydrogen peroxide sterilisation 2x	No	+ (103)
Hydrogen peroxide sterilisation 3x	No	- (28)
Hydrogen peroxide sterilisation 4x	Yes	N/A
5. Steam sterilization 134 °C	Yes	N/A

The cleaning processes with a disinfection step at 90 °Celsius deformed the masks to such an extent that they were no longer usable. This also applied to the steam sterilization process. The face masks sterilized four times with hydrogen peroxide were also deformed, which could compromise usability.

The fit test was performed on the face masks sterilized once, twice and three times with hydrogen peroxide and on a face mask that had been cleaned without detergent at 60 °C, because these masks had not been deformed and the elastic bands were intact. Face masks sterilized once, twice and three times with hydrogen peroxide gave an average fit test value of 151, 103 and 28, respectively, indicating that masks can be sterilized twice with hydrogen peroxide and still be usable.

The mask that had been cleaned at 60 °C did not give a satisfactory result in the fit test. This was the case for both the moist mask and the thoroughly air dried mask.

On the basis of these preliminary exploratory tests and results, the preliminary conclusion can be drawn that once and twice sterilization using a short process with hydrogen peroxide gives an acceptable result, both after visual inspection and based on the results of the fit test.

Limitations

- For each condition, only one fit test was performed
- Only one type of FFP2 face mask has been tested. Other available masks could for instance contain cellulose. The presence of cellulose can be a limitation when using hydrogen peroxide. However, an initial exploratory study (without fit test) at the Martini hospital in Groningen indicated no problems with

sterilization of cellulose-containing face masks using hydrogen peroxide.

- The treated masks were not worn or soiled. Soiling can negatively affect the effectiveness of the sterilization process. It has not been investigated to what extent the processes used can reduce soiling.
- The face masks were individually packaged in a laminate bag before sterilization.
- The applied processes have not been validated for the treatment of face masks.
- Until now, a limited number of masks have been sterilized per cycle (usually two, maximum four).

The effectiveness of treated masks has only been investigated with a fit test, no further studies have been carried out with regard to residues, material properties or biological safety. No studies have been conducted to determine whether masks still meet the requirements for FFP2.

Application in institutions

Based on the results of the above exploratory research, it appears that reprocessing disposable FFP2 face masks is possible. The following points should be taken into consideration:

- Reprocessing potentially contaminated masks should not affect the normal processes in the Central Sterilization Department in such a way that could compromise the quality of other items that need to be sterilized. Aspects that should be considered are e.g.:
 - Whether or not the masks should be packaged before sterilization
 - The location where the face masks will be packaged (if applicable)
 - Protective measures necessary for the personnel handling the masks
- A process must be set up in the institutions to collect worn masks in a safe manner. The institution must pay attention to the duration that face masks can be stored without this negatively affecting the quality of the masks or the reprocessing process.
- The institution must at least visually and physically inspect that the face masks are not affected by the process after reprocessing (shape and properties of the material).
- Since the masks were individually packaged during this study, no statements can be made about the effects of sterilizing multiple face masks in one package.
- Since moisture will enter the mask during normal use, a drying phase in the hydrogen peroxide sterilization process is likely to be necessary to prevent premature termination of the sterilization process due to the presence of moisture.
- A system should be set up that indicates a mask has been reprocessed and, if possible, keeps track of the number of reprocessing steps per mask

- Hydrogen peroxide sterilizers are not available in all Dutch institutions. Therefore, regional agreements should be made on the use of this equipment.
- The shelf life of reprocessed face masks should be determined.