Sterilization and reprocessing of FFP3 face masks through supercritical CO_2 technology

V. Santos-Rosales[a], C. López-Iglesias[a,b], Samaneh Ghazanfari[c,d], B. Magariños[e], C. Alvarez-Lorenzo[a] and C.A. García-González[a,*]

[a]*Departamento de Farmacología, Farmacia y Tecnología Farmacéutica, I+D Farma (GI-1645), Faculty of Pharmacy, iMATUS and Health Research Institute of Santiago de Compostela (IDIS), Universidade de Santiago de Compostela, 15782 Santiago de Compostela, Spain.*

[b]*Institute of Pharmacy (Pharmaceutical Chemistry), Freie Universität Berlin, Berlin, Germany.*

[c]*Aachen-Maastricht Institute for Biobased Materials (AMIBM), Faculty of Science and Engineering, Maastricht University, 6167 RD Geleen, The Netherlands.*

[d]*Department of Biohybrid and Medical Textiles (BioTex), AME-Helmholtz Institute for Biomedical Engineering, RWTH Aachen University, 52074 Aachen, Germany.*

[e]*Departamento de Microbiología y Parasitología, Facultad de Biología, CIBUS, Universidade de Santiago de Compostela, 15782 Santiago de Compostela, Spain.*

carlos.garcia@usc.es

1. Introduction

The outbreak of COVID-19 pandemic unveiled an unprecedented scarcity of personal protective equipment (PPE), particularly face masks, available for the population worldwide and particularly in hospital settings. This situation prompted the evaluation of face mask reuse using traditional sterilization techniques (steam/dry heat, ethylene oxide sterilization and gamma irradiation). However, these methodologies may alter the functional properties of the face masks and leave toxic residues in the materials. The development of novel sterilization technologies is of utmost relevance to extend the life cycle of face masks, whose disposal has emerged as a global environmental hazard.

Sterilization with supercritical CO_2 ($scCO_2$) has emerged as a green alternative to conventional sterilization processes, being particularly effective for the processing of sensitive materials, such as novel polymeric scaffolds or synthetic tissues [1,2]. Supercritical CO_2-based sterilization can achieve high sterilization levels (6-logarithmic reductions) of a wide range of microorganisms, including the resistance forms (bacterial endospores).

In this work, $scCO_2$ sterilization is proposed as a safe, sustainable, and rapid sterilization method for contaminated FFP3 face masks whilst preserving their functional performance. First, a sterilization protocol was developed achieving log-6 sterilization (logR-6) against *Bacillus pumilus* endospores, the proposed biological indicator to control $scCO_2$-based sterilization methods [1]. The sterilization method was further applied to FFP3 masks. The functional (bacterial filtration efficiency; BFE, splash resistance and straps elasticity) properties of the sterilized FFP3 face masks were evaluated after 1 and 10 cycle of sterilization.

2. Materials and Methods

Sterilization tests of bacterial endospores were performed in a 600-mL NovaGenesis equipment provided with agitation (NovaSterilis Inc., Ithaca, NY, USA). For a 1-sterilization cycle, the system was heated to 39 ºC and pressurized to 100 bar in presence of low contents of H_2O_2. After 30 min in the batch mode, the system was depressurized to atmospheric pressure.

The sterilized masks were observed under scanning electron microscopy (SEM) and compared to untreated masks (control). In addition, the physicochemical properties of the FFP3 face masks after multiple sterilizations (1 and 10 sterilization cycles) were tested with filtration tests following UNE-EN 14683.

3. Results and discussion

The main component of FFP3 masks is polypropylene (PP), and it may experiment swelling under a $scCO_2$ atmosphere. Preliminary tests were performed to define the feasible operating window and a range of temperatures (35 to 45 ºC) and exposure to $scCO_2$ times (15 to 120 min) were screened. No relevant changes

were observed in FFP3 masks subjected to those processing conditions, and the sterilization method was developed considering those thresholds of temperature, pressure, and contact time.

An optimized sterilization procedure achieving 6-logarithmic reductions of *B. pumilus* spores was developed requiring only 30 min of exposure to $scCO_2$ (39 ºC, 100 bar) environment and using 150 ppm of H_2O_2. Compared to previously reported $scCO_2$ sterilization methods, a remarkable reduction of the processing conditions (pressure, exposure time, temperature, and additive content) was achieved [1, 3].

The porosity, surface, and filter dimensions of the sterilized FFP3 masks were not compromised even after 10 sterilization cycles, as observed by SEM imaging (Figure 1). On the other hand, sterilized FFP3 masks presented a significant (1-way ANOVA, $p<0.05$) reduction of 1.5 % on the BFE values, although the overall value was in the range for type II masks, according to ISO standards (≥ 98%).

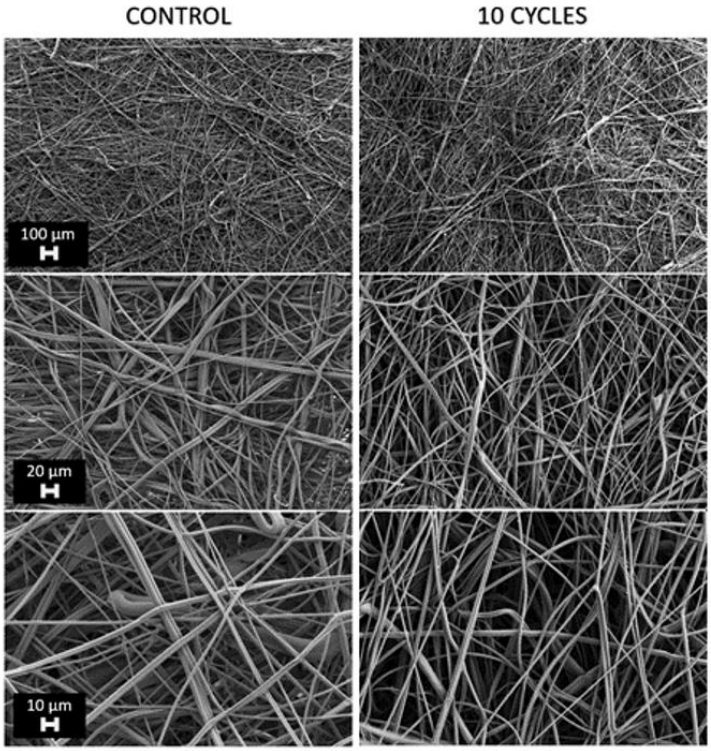

Figure 1. SEM images of melt-blown PP filter (25g/m2), the tested FFP3 masks. Morphological differences were not observed between control and sterilized filters even after 10 cycles

Sterilized FFP3 masks successfully passed the splash resistance tests according to ISO 22609:2004. The $scCO_2$ sterilization also preserved intact the mechanical integrity of the elastic straps when subjected to cyclic loads and following ASTM standards for textile fabrics.

4. Conclusions

The use of $scCO_2$ technology resulted in a successful method for sterilizing FFP3 masks while preserving their filtration and functional properties. High sterilization levels (logR-6) were achieved for spores of *B. pumilus*, a microorganism particularly resistant towards $scCO_2$ sterilization. This sterilization procedure represents an efficient, fast, safe, and sustainable method for the multiple reprocessing (at least for 10 cycles) of face masks in the absence of an alternative procedure. Although $scCO_2$ sterilization had an impact on the filtering properties of the FFP3 masks, the general performance of the PPEs was not remarkably compromised and could be used in hospital settings.

References

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