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Major article

Safety and structural integrity of N95/PFF2 respirators decontamination

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Key Words:

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Background: COVID-19 is caused by the SARS-CoV-2 virus, an emerging respiratory pathogen. The work environment represents a high-risk factor for health professionals. Given the scarcity of protective personal equipment due to global demand, decontamination and reuse studies should be carried out. Thus, the aim of this study was to evaluate the safety of a method of decontamination of N95/PFF2 respirators, especially regarding structural integrity.

Methods: N95/PFF2 respirators were subjected to hydrogen peroxide decontamination and analyzed using scanning electron microscopy and thermogravimetric analysis. Seven respirators of the same brand and lot were used, one being a control and the other six subjected to decontamination process. As for the sealing, a qualitative test was applied, in order to identify the changes in the structure that could damage the sealing of respirators.

Results: Indicated that the fiber morphology in all layers was not affected by the six decontamination cycles. Also, the thermal stability in the different layers was very similar. Fit testing showed that the respirators submitted to all cycles of decontamination were approved.

Conclusions: Thus, it is possible to conclude that the hydrogen peroxide decontamination method is effective, since it does not alter the physical properties of the respirators.

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The novel coronavirus disease-2019 (COVID-19) with development of severe acute respiratory syndrome due to SARS-CoV-2/2019-nCoV, an emerging respiratory pathogen, has caused severe public health and economic problems.¹

The World Health Organization (WHO) is constantly updating the number of COVID-19 cases around the world. The number of deaths and the overall data are alarming. WHO informs that research and development efforts are advancing quickly around the world.² The Head of WHO reiterates the need of seeking possibly alternative actions and strategies to reduce the impacts of the pandemic, mainly among underserved populations and the general community.^{3,4}

COVID-19 pandemic has put healthcare workers (HCW) under pressure with highly potential to affect their physical and mental health.⁵ HCW are constantly exposed to infected environment,

physical and mental exhaustion related to scarcity of protective personal equipment (PPE) and loss of a patient.^{6,7} The working environment is placing HCWs at highly risky, given the impressive number of both symptomatic and asymptomatic patients infected by SARS-CoV-2.^{8,9}

Moreover, there is evidence that when the PPE are used correctly during assistance to patients infected by SARS-CoV-2 the infection risks are lower than when the HCWs are exposed to non-occupational environment¹⁰. To reduce these risks and infections there are instructions to promote the use of PPEs, practice of hand hygiene, support for psychological needs, improve of logistics of medical supplies¹¹, care of communities and population vaccination.¹⁰

In the face of the pandemic, there is a relentless search for strategies that may guide and minimize dissemination levels within the population and allow the rational use of personal protective equipment by frontline providers. Thus, minimizing the spread of the pandemic within the community is paramount.⁴

The current COVID-19 pandemic has considerably disrupted the global supply chain of personal protective equipment (PPE), thus straining the capability of healthcare systems around the world.³

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The National Institute for Occupational Safety and Health and Centers for Disease Control and Prevention have recommended extended use and reuse of respirators and recommended multiple decontamination methodologies for reuse when healthcare systems are faced with supply shortages. In case of local scarcity that forces the choice between decontamination and reuse of respirators, there are some decontamination methods that can be used, such as heat and humidity, UV irradiation, ozone and hydrogen peroxide vapor.¹²

In situations of shortages of N95/PFF2, decontamination of respirators before reuse is important as it increases the safety of users given the high rate of contamination by the new coronavirus. The Food and Drug Administration had authorized the emergency use of decontamination at low temperature by Advanced Sterilization Products for decontamination of N95 disposable respirators.¹³ In April 2021, Food and Drug Administration recommended the use of decontamination of respirators only in cases of scarcity or when new respirators are not available, recommending acquisition of new respirators whenever possible.¹⁴

The Hydrogen Peroxide decontamination process is already approved and certified as sterilizing equipment widely used in material sterilization units. Decontamination with vaporized hydrogen peroxide (VHP) is the most promising for N95 respirators, as it combines the reliable inactivation of respiratory viruses and can maintain the structural integrity of the treated respirators after multiple decontamination cycles.^{15,16} VHP technique demonstrated to be viable for many cycles (around 50) and maintaining the safety properties of the respirators, based on the performance of the elastic fiber and degradation.^{17,18} Moreover, the inactivation of SARS-CoV-2 with the use of VHP has been demonstrated in previous studies with cut-outs of disposable respirators.^{19,20}

In this context, studies that evaluate methods of decontamination of N95 / PFF2 respirators are important and will contribute to the rational use of personal protective equipment and guarantee environmentally sustainable alternatives.

In this study, we evaluated the possibility to reuse of respirators of type N95 / PFF2, analyzing their structural integrity and sealing after undergoing decontamination by vaporized hydrogen peroxide.

MATERIAL AND METHODS

The study was conducted at the Validation Center in patnership with LEENF, ICAQF and Hospital São Paulo of Universidade Federal de São Paulo, Brazil. It is an analytical, experimental and quantitative study in which N95/PFF2 respirators were subjected to hydrogen peroxide decontamination processes and analyzed for fit and structural properties using scanning electron microscopy (SEM) and Thermogravimetric analyses (TGA).

For this study, seven new N95/PFF2 respirators of Delta Plus brand, model PFF2, without exhalation valve, unique size and from the same lot were analyzed. One of these respirators, chosen randomly, was not submitted to the decontamination process, this being considered as control. The other six respirators were subjected to Hydrogen Peroxide decontamination processes and, in each reprocessing cycle, a respirato was removed and identified with the submitted cycle number until the last respirator that was subjected to six cycles.

Hydrogen peroxide decontamination process

For the decontamination process, the respirators were placed inside packages appropriate to this type of processing (Tyvek), heat sealed and placed in the hydrogen peroxide gas plasma sterilizer device STERRAD 100S. Sterrad is a chamber that injects 59% H₂O₂, in a time of 55 minute at 45°C-50°C. The hydrogen peroxide is

transformed into plasma and chemically recombined, leaving oxygen gas and water, without toxic components. After the decontamination process, the respirators were analyzed regarding the fit testing, according to the OSHA Standards recommendation (standard number 1910.134).²¹

Fit testing

The adequacy of the fit of the N95/PFF2 respirator to the professional's face was measured through the sealing and qualitative fit test. The qualitative fit test is a pass/fail method that uses the sense of taste or smell or the reaction to an irritant to detect leaks in the respirator's face piece. The qualitative fit test does not measure the actual amount of leakage. The respirator can be approved or disapproved based on detecting leaks of the substance on your face piece by detecting or not the bitter taste.

For the fit testing, the control and the six respirators submitted to the decontamination processes were evaluated using the 3M qualitative fit test kit FT10 (3M, USA). The experiment was carried out for each of seven respirators while the test person was performing seven different exercises.

Scanning electron microscopy (SEM)

The morphology of the four polymeric layers, on both sides (internal and external faces) (Fig 1) of N95/PFF2 respirators were analyzed by scanning electron microscopy (SEM) in order to verify structural changes due to the sterilization process. The images were acquired with a microscope model Quanta FEG 650 (FEI Company, USA), using backscattered electron detector. For this, the samples were fixed in stubs and coated with a thin layer of platinum.

Thermogravimetric analysis (TGA)

Thermogravimetric analyses (TGA) of each layer of the N95/PFF2 respirators were also carried out in order to verify possible thermal degradation on the material during the sterilization process. Measurements were performed using a thermogravimetric analyzer (model TGA/DSC1, Mettler Toledo, USA) in an inert atmosphere of N₂, with flow rate of 50 mL/min. Samples were heated from room temperature to 600°C at a heating rate of 10°C/min.

Statistical analysis

Statistical analyses were performed using Microsoft Excel software. Significant differences were determined by the Tukey test and the level of confidence was set at 95%.

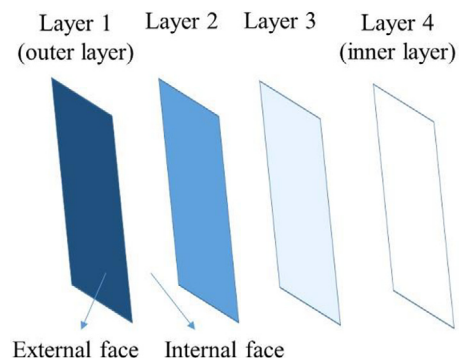


Fig 1. Schematic representation of N95/PFF2 respirator layers.

Table 1
Number and percentage of approval of the exercises performed during the qualitative fit testing

Evaluated exercise	Approved	
	N°	%
A. Breathing normally	7	100
B. Breathing deeply	7	100
C. Moving the head from side to side	7	100
D. Moving the head up and down	7	100
E. Speak or read	7	100
F. Simulate slow running (without moving)	7	100
G. Breathing normally	7	100
Final result:	49	100

RESULTS

Fit testing

Table 1 shows the result of fit testing applied for the respirators submitted to different cycles of decontamination with seven different exercises. Fit testing was also applied to the control respirator, which was not submitted to any decontamination process, and a result we

observed 100% of approval. It means that the test person did not feel the taste of the substance injected inside the helmet while the seven proposed exercises were performed.

For all respirators that were submitted to the decontamination process, from the first to the sixth cycles, the user did not report the taste of the substance injected into the helmet, being 100% approved.

Scanning electron microscopy (SEM)

Figure 2 shows the SEM images of the internal and external faces of four layers of untreated respirator (control) and the respirator treated by 6 cycles with H₂O₂ plasma. The N95/PFF2 respirators are composed by 4 polymeric layers, as represented at Figure 1. The first and outer layer is composed of spunbonded polypropylene (layer 1), the second layer is composed by a mixture between cellulose and polyester (layer 2), the third one is formed by melt blown polypropylene (layer 3) and the fourth layer is also made by spunbonded polypropylene (layer 4). These differences in the layer composition could be observed by the SEM images. Respirator layers composed by spunbonded polypropylene (layers 1 and 4) showed relatively uniform fibers with diameter around 20 μm forming a random fiber network. Layer composed by the mixture between cellulose and polyester (layer 2) was very similar, but showed larger fibers, with diameter around 25 μm. The most different structure was verified for the layer

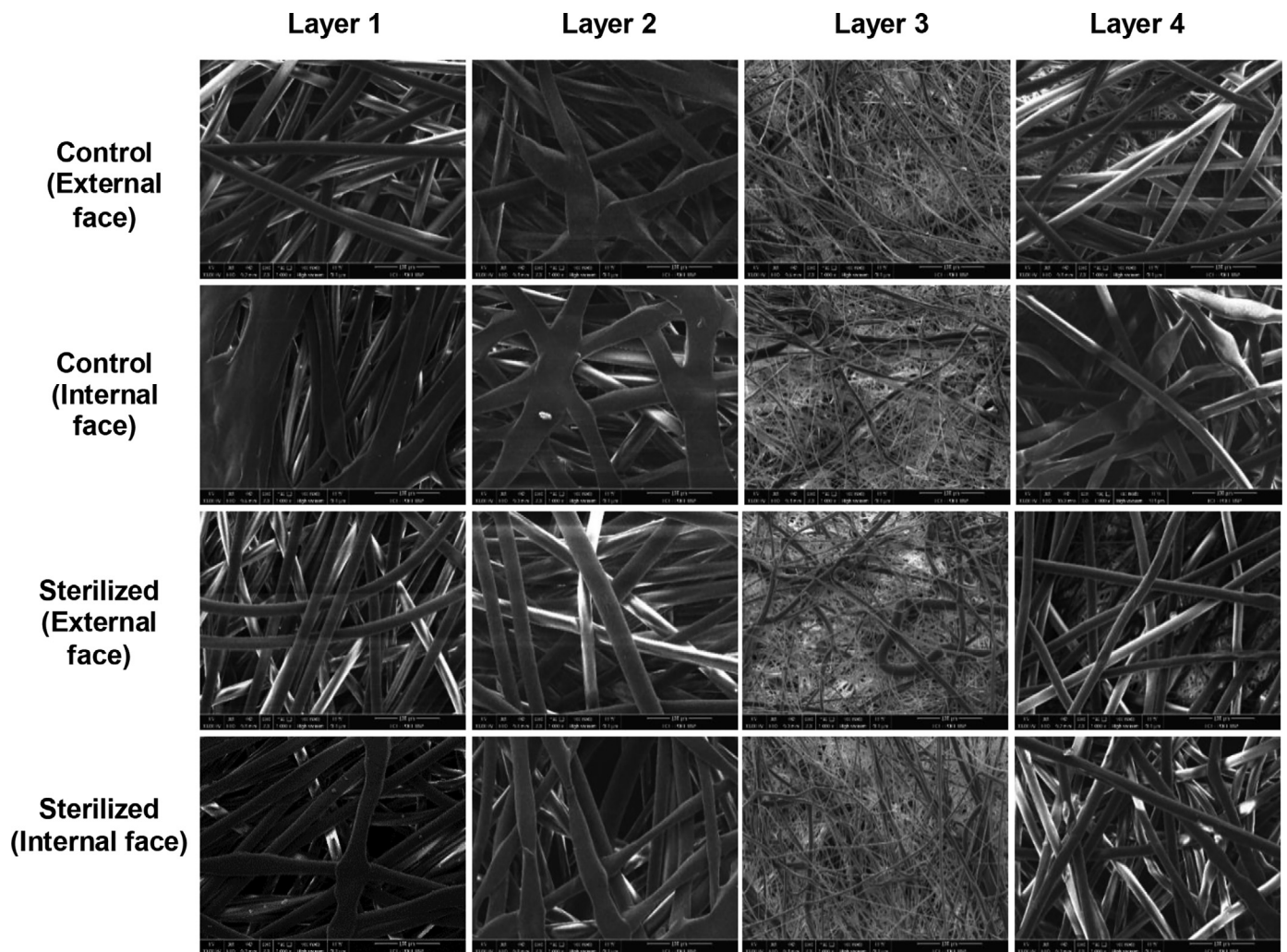


Fig 2. SEM images of the external and internal faces of the four layers of untreated respirators and respirators treated by six cycles of H₂O₂ plasma.

Table 2
Comparison of fiber diameters of the different layers of N95/PFF2 respirators without treatment and after 6 cycles of treatment with H₂O₂ plasma (sterilized)

		Fiber diameter (μm)			
		Layer 1 (outer layer)	Layer 2	Layer 3	Layer 4 (inner layer)
Control	External face	17.80 \pm 1.24*	23.07 \pm 2.63*	4.06 \pm 2.92*	15.19 \pm 0.95*
	Internal face	20.07 \pm 3.94*	25.54 \pm 4.65*	5.98 \pm 3.79*	16.74 \pm 1.75*
Sterilized	External face	17.66 \pm 1.12*	25.21 \pm 5.98*	6.40 \pm 5.97*	15.25 \pm 0.77*
	Internal face	20.04 \pm 2.89*	23.78 \pm 11.20*	3.97 \pm 2.42*	16.39 \pm 2.21*

Layer 1: spunbonded polypropylene (outer layer); layer 2: mixture between cellulose and polyester; layer 3: melt blown polypropylene; layer 4: spunbonded polypropylene (inner layer).

*Different letters indicate significant differences at $P < .05$.

made by melt blown polypropylene (layer 3), which showed a heterogeneous network formed by two types of fibers with diameters around 8 μm and 2 μm and smaller porous in the fibrous network. Similar microstructures of spunbonded polypropylene and melt blown polypropylene were verified by Zhao et al.²² and Yesil and Bhat²³, respectively. According to Saini et al.²⁴, the melt blown layer is essential for proper filtration of N95/PFF2 respirators. The evaluation of external and internal faces of each layer did not show significant difference (Fig 2).

The evaluation of the effect of decontamination process indicated that the morphology of fibers in all the respirator layers was not affected by the six cycles of sterilization. This result was confirmed by the measurement of fiber diameter, which did not show statistical differences between untreated and sterilized respirators (Table 2). Saini et al.²⁴ also evaluated the disinfection of N95/PFF2 respirators by VHP and did not observe any significant change in the microscopic structure of outer layer and melt blown layer (layer 3) even after 15 repeated cycles.

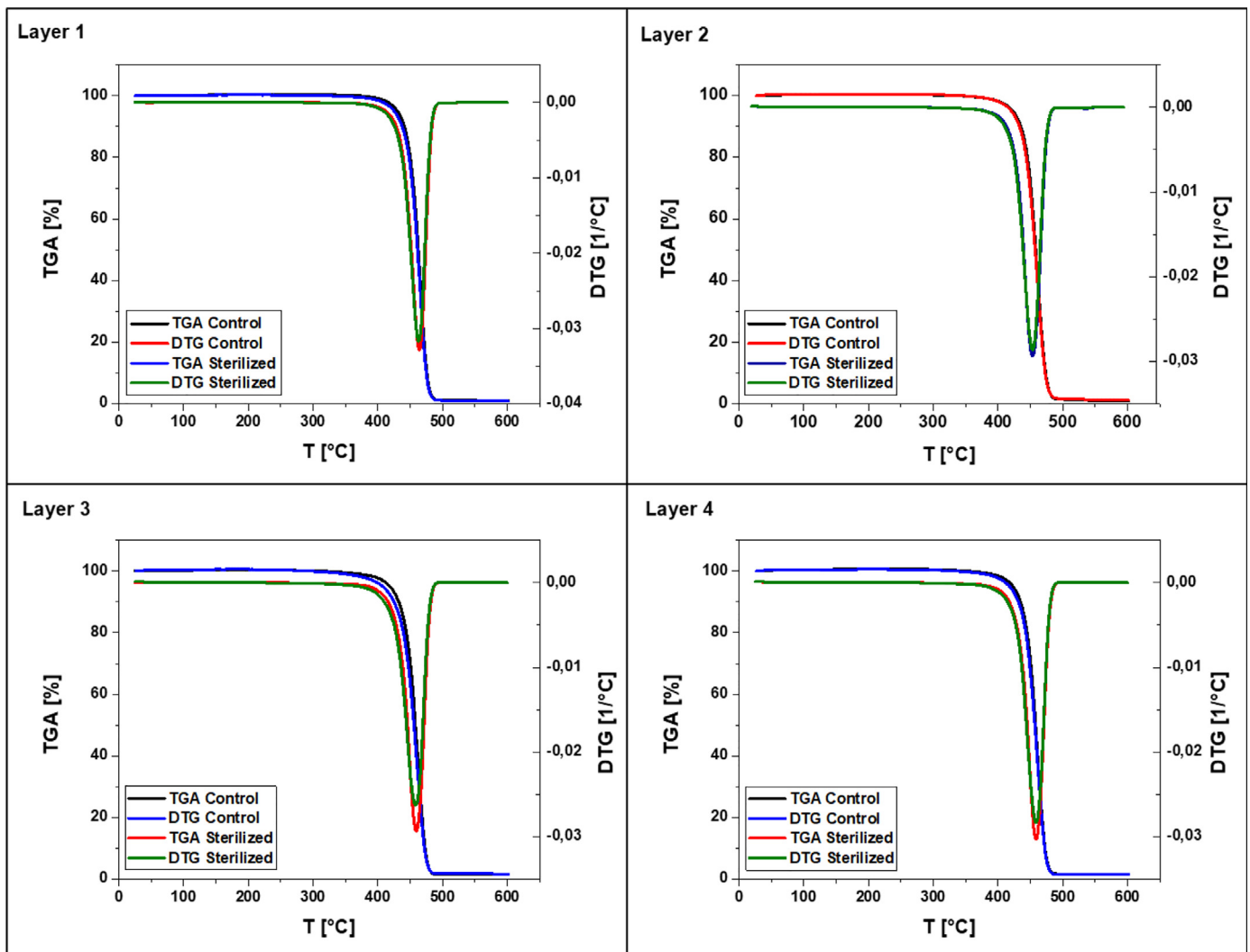


Fig 3. Thermogravimetric analysis (TGA and DTG) of the four layers of untreated respirators and respirators treated by 6 cycles of H₂O₂ plasma.

Thermogravimetric analysis (TGA)

Thermal stability of the different respirator layers before and after sterilization process was assessed by thermogravimetric analysis (TGA), and the results are presented in Figure 3. The results obtained for the different layers were very similar, with no thermal event between room temperature up to 400°C and a thermal event peak around 450°C. This peak is related to the thermal degradation of polymers, since thermal degradation peak of polypropylene is 480°C²⁵, of cellulose is around 370°C²⁶ and of polyester is around 430°C²⁷.

High degradation temperatures suggested that these respirator layers are resistant to several sterilization processes, including those that apply high temperatures. Nevertheless, the sterilization process applied in the present work uses low temperatures (<35°C)²⁸, indicating that these materials will not be degraded after H₂O₂ plasma treatment. This fact can be confirmed by the TGA analysis of sterilized samples, which showed the same behavior than control samples for all the respirator layers.

DISCUSSION

Our study demonstrated that after six cycles of decontamination with hydrogen peroxide, N95/PFF2 respirators kept their integrity and sealing capacity.

The present study is necessary for the scenario of crisis and risk of shortages, in addition to the need to use respirators with high filtration capacity for the safety of health professionals, these results are extremely important when faced with the need for reuse during a period of global scarcity and as a biosafety strategy for health professionals.

We emphasize that our study was based on previous studies that demonstrate the effectiveness of virus elimination of the hydrogen peroxide technique^{15–19,29–31} and our focus was to analyze the integrity of the material and the sealing capacity for use in health emergency situations.³

No country has been prepared for this COVID-19 pandemic, and this fact has important negative effects on the economy and health care for the whole of society. The main challenges for health services are to reorganize the care provided, to increase the number of beds in intensive care units, to ensure the provision of personnel protective equipment, and to have an adequate number of trained professionals available (3). An important fact that has been already noted is that care with biosafety will be doubled and the use of personal protective equipment by health professionals will be constant and more rigorous even with the advent of vaccines.

Therefore, the consumption of respirators will be higher as well as the need to reuse these devices safely, with safe decontamination protocols after each use.¹⁷ The procedures developed must be applicable in hospital environments and in challenging conditions such as those observed at this time, in which a respiratory disease pandemic occurs.

Decontamination of respirators before reuse is important, as it increases user safety given the high rate of contamination by the new coronavirus or microorganisms. Although the manufacturers do not provide instructions for cleaning and decontamination of the respirators, the application of these methodologies against infection by the new coronavirus must be evaluated, since the response of this new microorganism to the various chemical and physical agents is not yet established.

Among some gaps in knowledge about the effectiveness of this decontamination technique was the ability to maintain the integrity of the materials and the sealing capacity, guaranteeing the necessary safety for health professionals and for these criteria the SEM, TGA and fit testing were used. From results of fit testing, we could observe that the reprocessing method employed in the present work did not

change the respirator seal in all the cycles performed, indicating that the respirators can be used safely after decontamination process. The morphology of fibers and their diameters were also not affected by the decontamination process (Fig 2 and Table 2). The results of TGA (Fig 3) showed the same behavior for the control and decontaminated respirators, which confirmed that the respirators were not degraded after sterilization process.

As limitations of this study, we highlight that we developed a pilot study with analysis of respirators without previous use and of only one brand and lot. With the findings, our goal is to expand the routine to increase health safety into practical application.

CONCLUSION

This study shows that the use of up to six cycles of hydrogen peroxide decontamination method does not alter the physical properties of the respirators, such as morphology and thermal behavior, which can indicate that the filtration and sealing are maintained. However, further studies are needed to verify if the same occurs with N95/PFF2 respirators or equivalents from other brands, as well as with respirators that were used by professionals.

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