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ORIGINAL ARTICLE

FEASIBILITY OF REUSING PFF2 RESPIRATORS DURING THE COVID-19 PANDEMIC IN BRAZIL: QUASI-EXPERIMENTAL STUDY*

HIGHLIGHTS

1. Decontamination of PFF2 can mitigate its shortage during pandemics.
2. Sweat/makeup are not factors that prevent maintenance of filtration.
3. No variation between usage time and type of treatment.

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ABSTRACT

Objective: Evaluate the feasibility of decontaminating PFF2 respirators in pandemic situations. **Method:** Quasi-experiment in a public hospital in South Brazil between April and June 2021. The sample consisted of PFF2 respirators used for six and 42 hours in the intensive care unit, divided into groups (usage time and types of intervention) and a control group. They were evaluated for resistance, integrity, and flammability. Descriptive and inferential statistics were used to compare multiple groups to verify whether the respirator remained safe after decontamination, among the different treatments and the mask usage time. **Results:** There was a significant difference in filter efficiency (p=0.002) and resistance (p<=0.001) between PFF2. Decontaminations did not influence integrity when their interaction with usage time was evaluated. **Conclusion:** Decontamination, separately or together, was a viable alternative.

KEYWORDS: Coronavirus infections; Nursing; Evidence-Based Nursing; Sterilization; Health Services Administration.

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INTRODUCTION

The disease caused by the new coronavirus (COVID-19) was reported for the first time on December 30, 2019, in Wuhan, China, with transmissibility and lethality still unknown at that time[1-2]. From the first quarter of 2020, all continents experienced a growing and accelerated increase in the number of cases of this pathology, elevated in March 2020, to the status of pandemic by the World Health Organization[3].

Based on the initial knowledge of the disease transmission form, it was identified that the procedures involving the highest risk of contagion by droplets and aerosols with the SARS-CoV2 virus within health services were those related to aspiration, intubation, bronchoscopy, and surgical procedures such as tracheostomy[4-6]. In this way, implementing barrier systems that would allow the interruption or non-contamination of professionals, preventing the spread of the COVID-19 virus in the environment, was necessary, with the standardization of personal protective equipment (PPE) being among the first actions [7].

Among the set of PPEs indicated for carrying out services during the pandemic were goggles, face shields, surgical and cleaning gloves, waterproof gowns, and N95/PFF2 respirators. These last ones quickly entered into situations of scarcity[7].

PFF masks are considered respiratory protection equipment (PPE). They are classified according to their level of penetration, breathing resistance, and ability to retain solid and liquid particles[8]. The masks indicated as PPE for use during COVID-19 were the PFF2 or N95, as both have a filtering piece that blocks at least 95% of particles of size 0.3μ (zero point three microns)[7].

According to the U.S. Food and Drug Administration (FDA), such respirators, properly fitted to the professional's face, although not completely and definitively eliminating, reduce the risk of contamination[9]. Given the difficulties in supplying this disposable PPE, which is not approved for routine decontamination, alternatives must be evaluated[10-11].

Considering that the safety of the professional is related to the capacity of the assistance provided by the team and that there was a shortage of N95/PFF2 masks in different countries, the question was raised: in pandemic situations, does the practice of decontaminating PFF2-type respirators allow for the maintenance of filtration capacity? What factors can influence the performance of this type of PPE after decontamination?

The objective of this study was to evaluate the feasibility of decontaminating PFF2 respirators in pandemic situations and, as a secondary objective, to assess whether sweat and makeup residues are impediments to maintaining the filtration of decontaminated PFF2 respirators.

METHOD

This was a quantitative approach study with a quasi-experimental design[12-13]. The study's conception was based on the IOWA model of evidence-based practice in nursing[14].

The research was conducted at the Center for Materials and Sterilization (CME) of a public university and federal hospital in the southern region of Brazil. The CME processes an average of 250,000 pieces/month to serve approximately 880 beds and research centers linked to the institution. The hospital was a reference in high-complexity care during the

COVID-19 pandemic, reaching 105 intensive care beds dedicated exclusively to treating patients with the disease.

The study samples were sent and analyzed in a technological laboratory of materials and products for quality control in the city of São Paulo, certified by the Brazilian Network of Testing Laboratories (RBLE), by the precepts of ABNT NBR ISSO/IEC 17025[15].

The study population consisted of PFF2 respirators used by healthcare professionals who provided care in two intensive care units (ICU) of the institution: the one that attended to patients during the COVID-19 pandemic (COVID-ICU) and the one that attended to patients without the diagnosis (non-COVID ICU). The sample was non-probabilistic with sequential recruitment in the Intensive Care Unit (ICU).

Samples of PFF2 masks used for 42 hours and discarded by professionals were collected in the non-COVID ICU. At the time of collection, it was confirmed how long the respirator had been used. Samples used by non-COVID ICU professionals for less than 42 hours were discarded. Samples were also collected from masks of ICU-COVID professionals, which were used and discarded after six hours of use.

Data collection was carried out between April and June 2021. On the occasion, the institutional protocol was to use the same respirator for a six-hour shift for the COVID-ICU and seven days in six-hour shifts for the non-COVID ICU. The instituted protocol met the requirements of the technical note of exceptionality issued by the National Health Surveillance Agency (ANVISA)[16].

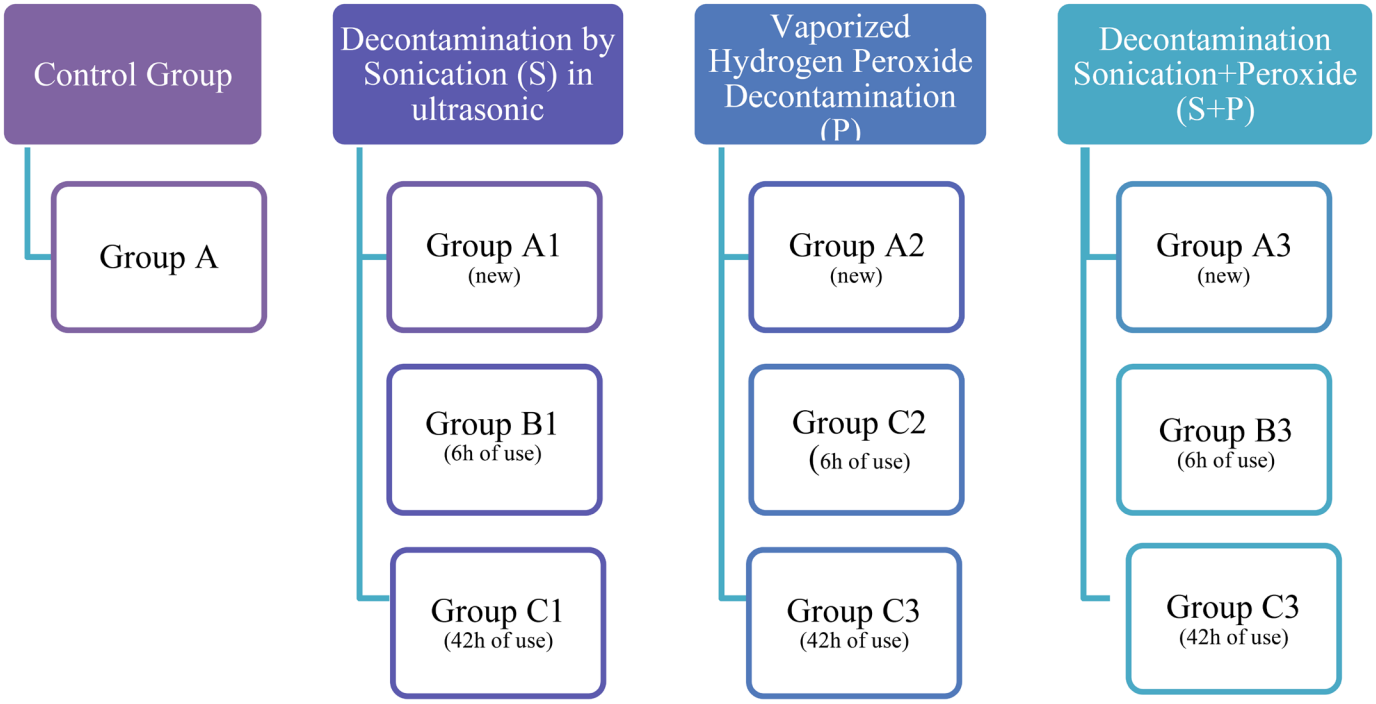
According to protocol, the inclusion criteria were as follows: PFF2 type respirators provided by the institution for professional use by professionals in COVID and non-COVID ICUs. The following exclusion criteria were considered: damaged respirators, with apparent loss of integrity, with markings not resulting from use, valved respirators, as well as those respirators from the non-COVID ICU that were discarded with usage time less than or greater than the recommended 42 hours (seven shifts, each of six hours). Due to the difference in design and construction between different brands and models, it was defined that the study would evaluate the 9920H model from the 3M® brand of national manufacture.

Based on a study that calculated the minimum sample size, a power analysis of 90% was used, with two standard deviations. From the 95% confidence level, a sample of six PFF2 respirators was calculated for each type of intervention and usage time. The final sample (N=84) consisted of three major groups regarding usage time: a group of new respirators (A); a group with respirators discarded in the COVID-ICU after six hours of use (B); and, the third group with respirators discarded in the non-COVID ICU after 42 hours of use (C). Each group was subdivided into three types of intervention (Figure 1).

The PFF2 masks were subjected to three types of decontamination treatments: ultrasonic sonication (S), Hydrogen Peroxide (P), and a combination of S+P. For each respirator, by group (ICU-COVID, non-COVID ICU), the type of decontamination was randomly selected, the mask was labeled with the numerical identification (Id), and subsequently, the preparation for each type of decontamination was performed.

To characterize the randomness of the sample selection for the treatment groups, an assistant who was not the researcher carried out the distribution of respirators used by professionals among the intervention groups.

Figure 1 - Division of the Control and Intervention groups for assessing feasibility and safety in reusing PFF2 respirators during the COVID-19 pandemic. Porto Alegre, RS, Brazil, 2022.



Source: The authors (2022).

The following were considered quantitative dependent numerical variables: the results of the breathing resistance tests, filter penetration, and flammability related to user safety after the decontamination process of PFF2 respirators. The following were considered qualitative independent variables: the types of decontamination processes (sonication, hydrogen peroxide vapor, and combined decontamination of sonication + peroxide).

In the sonication treatment, an ultrasonic cleaning equipment, model Caviwave-Pro®, from the brand Steris® SN 0219ST0130089 was used. This microprocessed ultrasonic-type cleaning equipment has sonic generators with a frequency of 132 kHz. According to the ANVISA Resolution 17 recommendations, the equipment was previously qualified. No agents or chemical solutions were used. Only temperature and sonication activity were used. The respirators from groups A1, B1, and C1 were subjected to immersion in filtered water at a temperature of 40°C for 10 minutes of sonication. The records issued by the equipment were used to monitor mechanical parameters. To monitor ultrasonic activity, a qualitative test of sonocheck type (AMCOR®, batch 402176) was used. The respirators were subjected to drying in the equipment itself for 30 minutes.

For decontamination with hydrogen peroxide, a low-temperature sterilizer with hydrogen peroxide vapor (V-Pro max®, Steris® SN 032451910) was used in a specific cycle for non-lumens. The non-lumen cycle consists of three distinct phases: conditioning, sterilization, and aeration[18], with a total cycle time of 40 minutes.

The masks of groups A2, B2, and C2 were packaged in Tyvek® The packaging was pre-cut to an approximate size of 200 mm in length and 150 mm in width, with a type I chemical test for hydrogen peroxide on the inner and central part of the filtering piece of each PFF2. The packages were sealed by heat sealing in calibrated equipment[17].

The load assembly with samples was placed on the two shelves of the sterilizer. On each shelf, 12 packages were placed, positioned vertically, with the Tyvek®-Tyvek®, plastic-plastic[18] positioning. Together with the load, to evaluate the biological parameter and the effectiveness of the decontamination process, a biological indicator (BI) with a 6-log population of *Geobacillus stearothermophilus* (brand Steris®, batch 20210821), and an extra chemical indicator in the load were used.

For groups A3, B3, and C3, referring to sonication + hydrogen peroxide decontamination, the samples were subjected to combined interventions sequentially in isolation under the same parameters previously described.

After the cycles, the equipment's mechanical parameters were evaluated, and the chemical and biological indicators of the treatments that used hydrogen peroxide were read.

The samples were analyzed in the laboratory and tested according to the ABNT NBR 13698:2022[8] standard, which specifies the requirements for semi-facial filtering pieces of non-motorized air-purifying respiratory protection equipment. As for the usage time, the control group (A) was used as a baseline for analysis and comparison with the new PFF2 mask samples, subjected to the same treatments as the groups of units used by professionals.

To evaluate breathing resistance, equipment certified by Inmetro and with international proficiency in breathing resistance evaluation was used. This equipment generates continuous airflow at room temperature, with flow rates of 30 l/min and 95 l/min for inhalation and 160 l/min for exhalation. The result is satisfactory if the maximum resistance during inhalation is up to 70 pascals (Pa), 240 Pa, and 300 Pa of pressure for flow rates of 30 l/min, 95 l/min, and 160 l/min, respectively[8].

For the filter's integrity assessment, the test was performed on Automated Filter Tester equipment, Model 8130A, using 150 mg of sodium chloride (NaCl) aerosolized for five minutes, with the penetration result read by light scattering photometry. For approval, the maximum penetration of the aerosol with sodium chloride in a continuous air flow at 95 l/min could not exceed 6%[8].

A flammability test was conducted to verify whether the material used in the PFF2 after decontamination could pose a risk to the user. As an approval criterion, the PFF2 could not burn or remain on fire for more than 5 seconds after removal from fire exposure[8].

The test results were typed and tabulated using Microsoft Windows Excel® software. The data were analyzed using descriptive statistics, with mean and standard deviation; in addition to inferential for comparison of multiple groups, with the help of the statistical software SPSS - Statistical Package for the Social Sciences® (SPSS), version 18. Given the symmetric distribution of the data, the Student's t-test was employed to verify if the respirator remained safe for use after decontamination compared to the control group. The Anova Test was used to compare the groups to verify the difference in breathing resistance (inhalation and exhalation) and filter penetration of the PFF2 between different treatments and mask usage times of six or 42 hours. Values of $p < 0.05$ were considered significant.

This research is part of a project approved by the institution's ethics committee with opinion number 2.183.123 regarding ethical principles.

RESULTS

Table 1 summarizes the findings, with values for resistance to breathing, filter penetration, and flammability of PFF2 masks by type of use (new or used) and time (zero, six, and 42 hours).

In the breathing resistance tests during inhalation, using a flow rate of 30 l/min, it is verified that the used masks, regardless of the usage time and type of treatment, showed an average resistance of 38.89 Pa and that the new masks demonstrated an average resistance of 41.06 Pa. When subjected to a flow rate of 95 l/min, the used masks showed an average resistance of 99.96 Pa, and the new ones maintained an average resistance of 107.33 Pa.

In the test with a flow rate of 95 l/min, however, in the comparison between the masks used for six hours and those used for 42 hours, it was identified that the former (100.67 Pa) showed a significant difference ($p<0.05$) by Bonferroni's multiple comparisons test when compared to the latter (99.26 Pa). Similar evidence is verified when performing the exhalation resistance test; the 6-hour ones had an average resistance of 117.44 Pa, and those used for 42 hours had an average resistance of 115.37 Pa.

As for the integrity assessment of the filter, new masks had lower penetration {2.38%} when compared to used masks {3.36%}, with those used for {42 hours} {3.67%} showing higher penetration of sodium chloride aerosol, in the continuous air flow at {95 l/min}.

Table 1 - Respiratory resistance, filter penetration, and flammability of decontaminated, new, and used masks by type and usage time. Porto Alegre, RS, Brazil, 2022.

Groups		Inhalation resistance - Pa				Exhalation resistance - Pa		Average penetration %		Flammability (seconds)
		30 l/min		95 l/min		160 l/min				
Type of Use	Usage Time	Average (SD)	value p*	Média (DP)	value p*	Average (SD)	value p*	Average (SD)	valor p*	
Total	sin tratamiento y con tratamiento	41,06 ± (2,18)		107,33 ± (6,30)		130,64 ± (5,27)		2,38 ± (0,25)		<5
	(6h, 42h)	38,89 ± (3,93)	0,001*	99,96 ± (8,29)	<0,001*	116,41 ± (11,95)	<0,001*	3,36 ± (2,2)	0,002*	<5
New	0h (A)	41,06 ± (2,18)	a	107,33 ± (6,30)		130,64 ± (5,27)		2,38 ± (0,25)		<5
	6h (B)	39,19 ± (3,77)	ab	100,67 ± (7,76)	0,004*	117,44 ± (10,79)	<0,001*	3,04 ± (1,81)		<5
Used	42h (C)	38,59 ± (4,14)	b	99,26 ± (8,88)	<0,001*	115,37 ± (13,13)	<0,001*	3,67 ± (2,54)	0,012*	<5

SD=standard deviation; *Student's t-test; means followed by the same letter do not present a significant difference of $p<0.05$ by Bonferroni's multiple comparison test

Source: The authors (2022).

The results (Table 1) show that the PFF2's resistance to breathing remained within the limits recommended by the standard at different pressure flows. There are significant differences (p = 0.001) in the comparison between new and used masks, regardless of usage time.

When analyzing the masks used at different usage times, the resistance shows a significant difference from the flow of 95 l/min in inhalation (p=0.004) and exhalation (p<0.001) for six hours. Similarly, both flows have a significant difference (p< 0.001) for 42 hours.

Regarding the maintenance of PFF2 filtration, it was found that all groups remained within the recommended penetration limit (<6%), using sodium chloride in a continuous flow of 95 l/min. However, there is a significant difference (p=0.002) between the decontaminated masks and the new ones, regardless of the type of treatment, in the penetration requirement. When evaluating the usage time, the masks used for 42 hours and decontaminated showed, when compared to new masks, a significant difference in penetration (p=0.012).

As for flammability, 100% of the masks did not burn for more than 5 seconds after removing the flame.

Table 2 presents the values related to breathing resistance and filter penetration of new and used decontaminated PFF2 masks by time and type of treatment, as well as the comparison if there was an interaction between usage time (zero, six, and 42 hours) and type of treatment (S, P, S+P).

Table 2 - Breathing resistance, filter penetration, and flammability for new and used decontaminated PFF2 masks by time, type of treatment, and interaction between usage time and type of treatment. Porto Alegre, RS, Brazil, 2022.

Usage time (ut)	Tests	Treatments (ttm)				ANOVA results (p-value)		
		S	P	S+P	Total	ut	ttm	Interaction ut x ttm
	Inhalation resistance - Pa							
	30 l/min					0,014*	0,529	0,482
0h (A)		41,44 ±1,81	40,89 ±2,09	41,33 ±2,35	41,06 ±2,18[a]			
6h (B)		37,89 ±4,46	41,22 ±3,53	38,44 ±2,60	39,19 ±3,77[ab]			
42h (C)		38,33 ±3,24	39,11 ±5,28	38,33 ±4,09	38,59 ±4,14[b]			
Total		38,11 ±3,79	40,17 ±4,49	38,39 ±3,33	38,89 ±3,93			
	95l /min					0,001*	0,946	0,899
0h (A)		107,56 ±7,16	107,78 ±5,95	106,89 ±5,88	107,33 ±6,30			
6h (B)		98,67 ±10,72	101,78 ±5,04	101,56 ±6,95	100,67 ±7,76[c]			
42h (C)		100,00 ±7,81	100,00 ±11,98	97,78 ±6,92	99,26 ±8,88[c]			
Total		102,07 ±9,27	103,19 ±8,63	102,07 ±7,40	102,91 ±8,35			
	Exhalation resistance - Pa							
	160 l/min					<0,001*	0,280	0,715
0h (A)		130,44 ±5,18	131,78 ±6,57	129,89 ±4,20	130,64 ±5,27			
6h (B)		114,00 ±11,64	122,89 ±8,15	115,44 ±11,18	117,44 ±10,79			
42h (C)		116,22 ±14,86	117,89 ±15,03	112,00 ±9,62	115,37 ±13,12			
Total		120,22 ±13,15	124,19 ±11,72	119,11 ±11,61	122,10 ±12,04			
	Average penetration %					0,025*	1,000	0,163
0h (A)		2,47 ±0,22	2,33 ±0,24	2,30 ±0,25	2,38 ±0,25[d]			
6h (B)		2,46 ±0,88	3,86 ±2,43	2,80 ±1,67	3,04 ±1,81[de]			
42h (C)		4,23 ±3,62	2,82 ±1,10	3,96 ±1,32	3,67 ±2,54[e]			
Total		3,05 ±2,24	3,00 ±1,62	3,02 ±1,74	2,96 ±1,78			

*p significant; means followed by the same letter do not show a significant difference of p<0.05 by Bonferroni's multiple comparisons test.

Source: The authors (2022).

No significant difference was identified between the different treatments in inhalation at 30 and 95 l/min (p= 0.529 and p= 0.946, respectively) and exhalation at 160 l/min (p= 0.280). The same can be said for the penetration of the filter (p= 1,000) (Table 2).

When analyzing the interaction between usage times and treatments, the results show no significant variation in the averages between usage time and treatment type that could influence changes in resistance and penetration.

The data shows that the usage time is the factor that can interfere with the performance (resistance) of the PFF2 9920H mask. In all resistance tests, the difference was significant (p=0.014 for 30 l/min, p=0.001 for 95 l/min, p<0.001 for 160 l/min).

DISCUSSION

Based on the results, it can be stated that, when comparing new masks to used ones, there were significant differences in resistance without compromising the requirements and limits recommended in the standard. On the other hand, the lowest average inhalation and exhalation resistance may represent greater comfort for professionals during breathing when compared to a new PFF2 of the 9920H model.

The findings of this study converge with other evidence using thermal disinfection at 70°C for 60 minutes, with 58 N95 respirators subjected to five or ten decontamination cycles, in which an airflow of 85 ± 2 l/min was tested, which identified that there was a significant reduction in respiratory resistance (p<0.001) for all groups[19]. On the other hand, such findings diverge from a study that tested six respirators, limited to three uses, with different amounts of U-VC decontamination, in which it was identified that the average pressure of breathing resistance did not show significant alteration with the number of reuses and decontaminations[20].

In the different treatments proposed in this study, it is noticed that the decontamination of used masks decreased the filtration efficiency when compared to new units. It is noted that, even with the difference in filtration of the used decontaminated mask compared to a new one, the former still keeps the professional safe[8]. Regardless of usage and decontamination time, all decontaminated masks maintained an average filtration above 95%. However, it is noticed that the treatments were not factors that could have influenced such a finding regarding filtration, but rather the usage time.

Based on the present study's findings, it is assumed that there is a significant difference related to filtration between new and decontaminated PFF2 respirators of the 9920H model from the 3M brand of national manufacture.

The findings of this research differ from other studies that have shown that the reduction in filtration efficiency was influenced by the types of decontamination, even though filtration was maintained above 95%[21-22]. Another piece of evidence, which evaluated the decontamination with hydrogen peroxide vapor after five cycles, highlights that there may be a difference in the functional integrity of the filter in different brands and models23, which was not tested in this study as only one brand and model were used.

A study that subjected PFF2 masks of different brands and models to 10 decontamination cycles identified that, in some cases, the filter penetration capacity was lower. According to the study's authors, it was not possible to state whether the particles used in the test form a kind of barrier between the layers of the filter as the masks are subjected to repeated decontaminations, which, according to the PPF2 model, results in an increase in filtration capacity[24].

Another study, which subjected the masks to vaporized hydrogen peroxide (VHP) decontamination, found that using VHP is not detrimental to filtration efficiency. However, he emphasized that masks past the manufacturer's expiration date (expired) do not maintain equivalent protection after decontamination[25].

When evaluating sweat and/or makeup residues, it is stated that these are not factors that prevent the maintenance of filtration of used decontaminated respirators compared to new ones. Even with the variability of filtration between the two groups, both maintained average filtration within normative prerequisites, with six and 42 hours of use. No literature was identified that evaluated respirators with makeup and/or sweat residues to compare this finding.

A study that tested 13,049 respirators used by healthcare professionals had as a discard criterion masks that showed visible blood residue or secretions/fluids, as well as those that were damaged/deformed. However, it was not explicit whether masks with internal residues, such as sweat or makeup, were also discarded[26].

No studies that attempted to clean the masks using an ultrasonic washer were identified, which is considered this research's differential and innovative factor. As with other research, it is recognized that the reuse and decontamination of PFF2 respirators are not ideal.

The limitations of this study are the use of masks from a single manufacturer and the exclusive use of three decontamination techniques. Furthermore, this study compared the filter's efficiency, resistance to breathing, and flammability after a single decontamination cycle, which prevents findings regarding the durability of the positive results found. It is noteworthy, however, that the filter material may degrade after several cycles or, furthermore, when exposed to factors related to use, such as secretions, sweat, or makeup, which suggests that a decontamination cycle is an alternative that adds feasibility and safety in sanitary crises.

Although there is previous evidence in the literature about the effectiveness of different types of decontamination on SARS-CoV2, it was not tested in this study's interventions, which is also understood as a limitation. It is recommended that studies be conducted, adding the evaluation of efficacy against the virus and the electronic analysis of the fibers of the filters to identify the microscopic structure of the filtering piece, using decontaminated masks with internal residues from use.

CONCLUSION

It is concluded that the use of ultrasonic cleaning equipment or hydrogen peroxide vapor, used together or separately in a sequential manner for the decontamination of PFF2 masks, was a viable and safe alternative in facing the COVID-19 pandemic when evaluating the requirements of resistance and maintenance of filtration. Sweat and/or makeup residues did not hinder maintaining the filtration of PFF2 respirators.

As advances in the health field, it is recommended that the practice of reusing PFF2 masks be restricted to situations of pandemic and resource scarcity by exception. Furthermore, it is recommended that protocols be developed and validated by brand and type, as well as labeling the respirators to allow control of the number of reuses and performing regular fit tests. Furthermore, decontamination requires resource management planning, both structural and logistical, as well as human resources, and it is not recommended that this practice be used routinely.

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