ORIGINAL ARTICLE

METHODOLOGY FOR EVALUATING THE LEVEL OF RESPIRATORY PROTECTION OF MASKS AND RESPIRATORS AGAINST PARTICLES SIMILAR TO THOSE THAT TRANSMIT SARS-CoV-2

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ABSTRACT

Objective: To develop a methodology for evaluating the level of respiratory protection provided by respirators, surgical masks and community face masks used by the Peruvian population; protection was evaluated against particles of a size similar to those containing active SARS-CoV-2 virus. **Materials and methods**: A direct linear relationship has been determined between the logarithm of the concentration of airborne particles and the elapsed time; thus, it is possible to compare the quantity of particles inside and outside of the mask or respirator in the same time period, as well as to obtain the percentage of respiratory protection for each evaluated sample. **Results**: A methodology was established to evaluate the level of respiratory protection against aerosols smaller than 5.0 µm. Also, the use of accessories such as rubber bands or adjusters behind the head and neck, and the use of robust nasal clips, significantly increased the level of respiratory protection against particles with a high probability of containing SARS-CoV-2. **Conclusions**: We found concordance between the obtained respiratory protection values and those expected, considering the filtration level of the material used for each surgical mask or respirator, as well as the tightness. A significant increase in the levels of respiratory protection was observed.

Keywords: Respirator; Mask; Aerosols; SARS-CoV-2; Transmition; COVID-19; Pandemic; Respiratory Protection Devices; Filtration, Exposure Time (source: MeSH NLM).

INTRODUCTION

The current pandemic of the new SARS-CoV-2 coronavirus, which causes acute respiratory distress syndrome [1], continues to decimate entire communities worldwide, challenging the capacity of health systems and threatening economic stability [2].

The main transmission route of SARS-CoV-2 are respiratory aerosols or droplets [3]. Simulation and modeling studies of the microdroplets that are expelled when talking, coughing or sneezing show a wide variety of sizes [4]; however, it is estimated that more than 90% are found in the form of aerosols, smaller than 5 µm in diameter [5,6]. These particles can remain suspended in the air of unventilated environments for three hours [7]. Another study reports a suspension time of up to 16 hours [8,9], which favors the probability of contact with circulating people.

The mandatory use of respiratory protective equipment (RPE) is a primary prevention measure aimed at limiting the chain of viral transmission. Certified respirators and facemasks limit the passage of particles of a wide range of sizes and composition. N95 respirators support a particle filtration efficiency (PFE) of at least 95% of non-oily particles of 0.3 µm in diameter, which is why

Cite as: Chavez-Ruiz M, Rueda-Torres L, Ruffner-Camargo B, Bellido-Achahui C. [Methodology for evaluating the level of respiratory protection of masks and respirators against particles similar to those that transmit SARS-CoV-2]. Rev Peru Med Exp Salud Publica. 2021;38(3):391-8. doi: https://doi.org/10.17843/rpmesp.2021.383.8036.

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Received: 06/05/2021
Approved: 08/09/2021
Online: 31/09/2021

they are mainly used in high biohazard environments, such as hospital areas [10]. However, a high PFE index is not necessarily linked to a good respiratory protection level (RPL) against microparticles, especially due to the lack of fit, which generates air leakage through which particles escape and enter.

Non-medical masks are widely available at the community level, in various materials, combinations and designs, according to the guidelines of each country. Despite showing considerably lower filtration efficiency than N95 respirators [11,12], the effectiveness of this intervention in certain populations seems to contribute positively to the mitigation of viral transmissibility [13,14]. In the context of the new variants of SARS-CoV-2 that show greater transmissibility and lethality, it is urgent to pay attention to simple and feasible measures that support a greater degree of protection in the community environment.

Affordable and proven measures are important anti-pandemic strategies as long as the vaccination process is extended to the largest possible population. This study proposes a methodology for assessing the respiratory protection level (RPL) of surgical masks, KN95 respirators, and other community-use respirators, as well as evaluating the addition of accessories and various types of uses to improve mask fit and thus the RPL.

KEY MESSAGES

Motivation for the study: The lack of available methodologies to assess the level of respiratory protection against particles with probable SARS-CoV-2 burden.

Main findings: We found that improving the fit of respirators, as well as the use of accessories such as behind-the-head adjusters and robust nose clips, can significantly increase the level of respiratory protection.

Implications: Decision makers could apply these findings to improve the effectiveness of respiratory protective equipment against SARS-CoV-2.

MATERIALS AND METHODS

Design

This experimental study was carried out at the Laboratory of Occupational Risk Assessment of the Instituto Nacional de Salud del Perú.

Variables

The RPL is defined as the amount of microparticles that manage to penetrate the RPE with the external particles; this is determined for surgical masks, KN95 respirators and some modifications that seek to improve the RPL by increasing the tightness. The PFE is defined as a parameter that seeks to determine the contribution to the RPL of the filtration capacity of the material used during the manufacturing of the RPE.

Procedure

The methodology proposed in this study to determine the RPL is based on the measurement of particle concentration, defined as the number of particles per liter of air, from the external environment ($\#P_{ext}$) and those that managed to penetrate the RPE ($\#P_{int}$). For this measurement, a mannequin was used, to which a silicone sheet was added to improve the adherence of the RPE to the surface. Two probes were used, placed on the back, one for sampling the particles that penetrated the RPE and the other to simulate human respiration (Figure 1), which was adapted to six liters per minute (volume of respiration per minute).

To ensure the presence, quantity and size of aerosols, particles were released into the environment where the test was carried out; for this purpose, a pneumatic particle generator developed at the Chemistry Laboratory of the Instituto Nacional de Salud was used, which generates polydisperse particles from a 2% sodium chloride solution; the generated particles were 2.5 μm in diameter. The measurement was performed when the quantity of particles in the environment was significantly higher than the quantity of particles when equilibrium was achieved. For this purpose, a PCE model 01L particle counter was used, which was previously calibrated. The tests took place in a site that had an area of 1.5 × 2.5 m, with a relative humidity and ambient temperature between 50-60% and 20-25 °C, respectively. The RPL was obtained by relating $\#P_{ext}$ to $\#P_{int}$ in the same period and was expressed as a percentage.

$$RPL = (1 - \#P_{int}/\#P_{ext}) \times 100$$

RPL: respiratory protection level; #Pint: number of particles per liter of air internal to the RPE; #Pext: number of particles per liter of air from the external environment.

To determine the $\#P_{ext}$, readings were taken from the environment every 15 seconds; a graph of $\#P_{ext}$ versus elapsed time was constructed (Figure 2A) where a logarithmic relationship between the two can be seen. The graph in Figure 2A was linearized with the logarithm of $\#P_{ext}$ versus elapsed time (Figure 2B). Finally, the equation of this new linear relationship

https://doi.org/10.17843/rpmesp.383.8036

was obtained, with which the $\#P_{ext}$ could be obtained in the same period where the probe of the particle counter equipment was taking readings inside the RPE, to obtain the $\#P_{int}$ data.

$$\log(\#P_{ext}) = b \times t + a$$

b: slope of the equation; t: time elapsed in seconds from the beginning of the test; a: constant derived from the linear relationship.

Additionally, we determined the PFE in order to evaluate the filtration capacity of the material with which the RPEs are manufactured. For this test, we followed the procedure of the National Institute for Occupational and Safety and Health (NIOSH), TEB-APR-STP-0059 [15]. It should be noted that this methodology analyzes the RPE placed in a sample holder and hermetically sealed by the contour, which eliminates air leaking, but does not consider the RPE tightness, unlike the method proposed by this study.

Surgical masks and KN95 respirators were evaluated, as well as the increase in RPL by making modifications in the way to use them and the addition of accessories that improve the fit of the RPEs (Table 1).

Statistical analysis

The tests were conducted three times to determine the RPL and six times to determine the PFE. The results of both tests were expressed as mean and standard deviation.

RESULTS

The PFE and RPL for the surgical mask were 97% and 32%, respectively; RPL values were measured for the modifications described in Table 1, which resulted in increases of the RPL according to the following order: SM-SM (41%), SM-CM (74%), SM-RB (66%), SM-RB-CL (91%). The PFE and RPL of the KN95 ventilator were 99% and 75%, respectively. Likewise, the RPLs of the modifications proposed in Table 1 resulted in increased RPL in the following order: SM- KN95 (89%) and KN95-RB (97%) (Table 2, Figure 3).

DISCUSSION

High PFE was observed for both devices evaluated, 99% for the KN95 ventilator and 97% for the surgical mask. However, the RPL for both devices (75% and 32%, respectively) showed

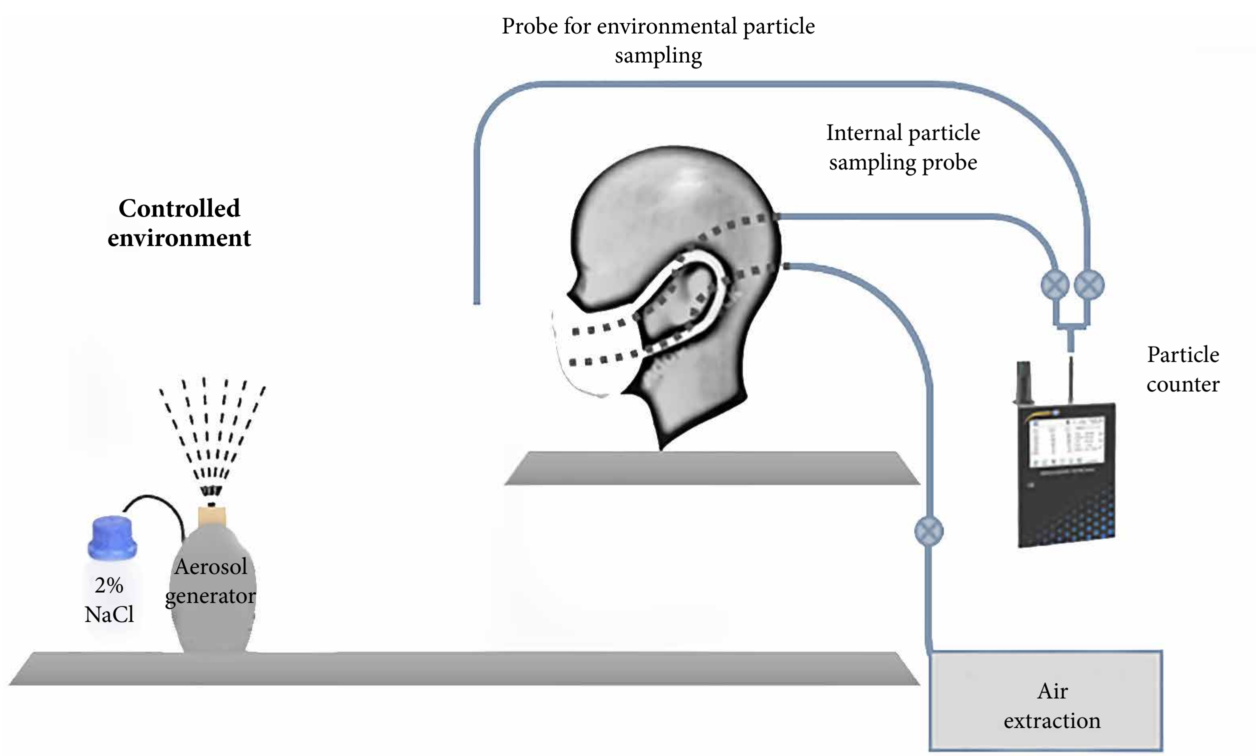

Figure 1. System for measuring particles external and internal to the respiratory protection equipment to determine the level of respiratory protection.

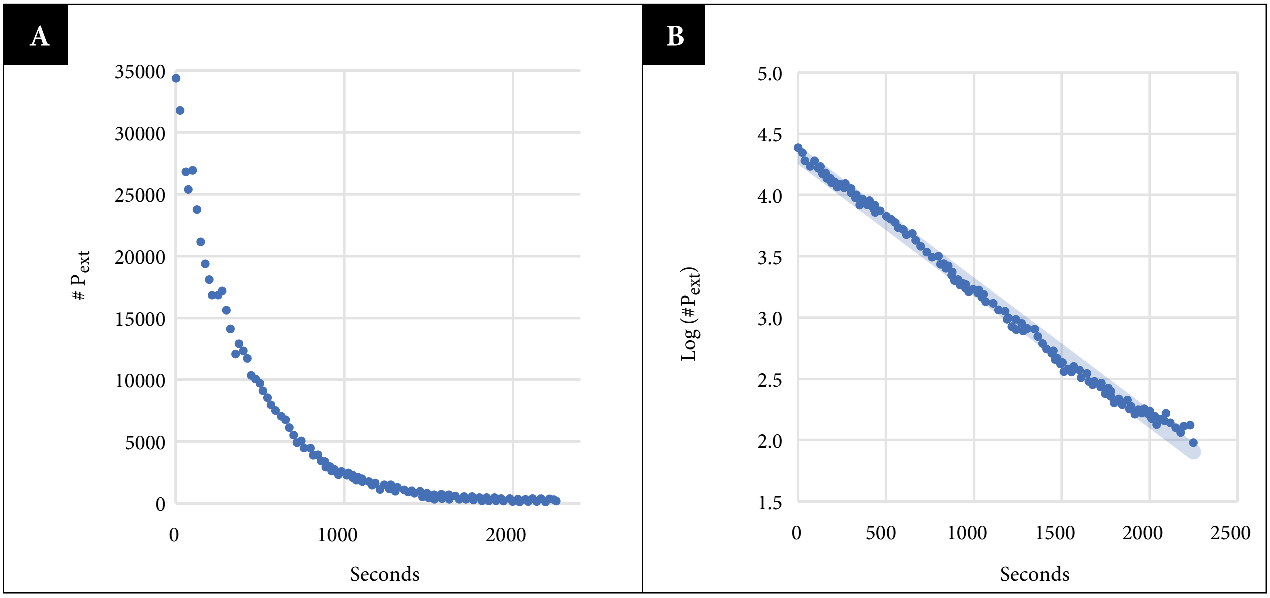

Figura 2. Aerosol behavior over time. A) Ratio of the number of external ambient particles per liter of air versus elapsed time in seconds. B) Ratio of the logarithm of the number of external ambient particles per liter of air versus elapsed time in seconds.

tightness problems, which shows that the RPL does not depend only on the PFE of the RPE material. On the other hand, there are some alternatives that significantly improve the tightness and thus the RPL.

The methodology proposed in our study is based on the measurement of the particles that managed to pass through the RPE, unlike the Fit Testing Procedure method, indicated by the Occupational Safety & Health Administration (OSHA) [16], where a detector is used, based on the condensation principle, which includes the measurement of particles of 0.02 to 0.08 µm, which are unlikely to contain at least one unit of active SARS-CoV-2 virus, whose size has been estimated at 0.08 +/- 0.01 µm [17,18].

Table 1. Description of modifications and tested combinations for determining respiratory protection levels of protective equipment commonly used by the population.

Type of protection	Modification	Code	Commentary
Surgical Mask	No modification	SM	R&G brand surgical mask, lot 2732220301, three-layer, with weak nose clip and ear straps
	Addition of a second surgical mask	SM-SM	Two surgical masks placed one on top of the other with ear straps
	Addition of elastomeric rubber band for head adjustment	SM-RB	Insertion of elastomeric rubber band for head adjustment.
	Additional second cloth mask on top of the other mask	SM-CM	Addition of head-fitting cloth face mask and robust aluminum nose clip
	Addition of elastomeric rubber band for head fit and sturdy nose clip	SM-RB-CL	Insertion of elastomeric rubber band for head adjustment and robust aluminum nose clip
KN95 respirator	No modification	KN95	Wenzhou Kanghong brand KN95 respirator, lot Hy20200501, with ear clip and medium-strength metal nose clip.
	Fitting a surgical mask under the KN95 respirator	SM-KN95	Surgical mask strapped to the ears and over respirator KN95
	Addition of elastomeric rubber band for head adjustment	KN95-RB	KN95 respirator to which an elastomeric rubber band has been added for head adjustment.
Certified N95 respirator	No modification	N95	3M brand N95 respirator, lot 8060, NIOSH certified, head straps, robust aluminum nose clip.

https://doi.org/10.17843/rpmesp.383.8036

Table 2. Results of particle filtration efficiency and respiratory protection level of protective equipment and its modifications.

Code	PFE (%) Mean (SD)	RPL (%) Mean (SD)
SM	97 (0.8)	32 (10)
SM-SM	-	41 (0.5)
SM-RB	-	66 (3.9)
SM-CM	-	74 (4.6)
KN95	99 (0.1)	75 (4.7)
SM-KN95	-	89 (2.2)
SM-RB-CL	-	91 (1.7)
KN95-RB	-	97 (1.2)
N95	99 (0.2)	99.6 (0.1)

PFE: particulate filtration efficiency; RPL: respiratory protection level; SD: standard deviation; SM: surgical mask; SM-SM: two surgical masks; SM-RB: surgical mask with elastomeric rubber band; SM-CM: surgical mask with the addition of a head-fitting cloth mask and robust aluminum nose clip; KN95: KN95 respirator; SM-KN95: surgical mask and KN95 respirator; SM-RB-CL: surgical mask with elastomeric rubber band and robust aluminum nose clip; KN95-RB: KN95 respirator with the addition of an elastomeric rubber band; N95: N95 respirator.

Despite the limited evidence on the presence of active SARS-CoV-2 and its distribution in particles smaller than 10 μm, the capacity of particles to transport active viruses has been determined to increase with their size, which could be explained by a greater shielding effect of the virus as the size of the droplets increases [(19)]. The presence of influenza A virus (IAV) and porcine reproductive and respiratory syndrome (PRRS) has been described in particles equal to and larger than 2.1 μm [(20)]; while other studies [(21)] have demonstrated the presence of SARS-CoV-2 in particles smaller than 10 μm.

In an exposure study using the murine model, influenza virus aerosolized in 2 μm particles produced less infection when compared to larger particles (10 μm) [(22)]. On the other hand, fine particles of 2.5 μm aerodynamic diameter represent a health concern because they are small enough to penetrate into the lungs and damage the alveolar wall [(23)]. Due to the above facts, it was convenient to work with particles of 2.5 μm in our study, because of the high probability of containing viruses and in order to measure the concentration of environmental and internal particles in the respiratory protection device.

The Centers for Disease Control and Prevention (CDC) reports that placing a cloth mask over a surgical mask significantly improves filtration efficiency [(24)]. Some options to improve the RPL, such as knotting the mask straps, use of gauze to seal visible openings, among others, have shown better results in respiratory protection in relation to the traditional way [(24,25)].

The RPL result for the KN95 respirator of 75%, related to the 99% obtained for its PFE, indicates that the fit with ear support is not optimal, so this would improve with a surgical mask underneath it (89%). Another aspect to take into account is that these RPEs come in one size, so these results could vary according to the anatomical characteristics of each person. The maximum RPL for this device is obtained by adding an elastomeric rubber band with head adjustment (RPL = 97%).

Regarding the measurement of RPL of surgical masks (as they are sold), we found that, despite their high PFE (97%), they have a poor RPL (32%), this is due to the poor fit of these devices, which have been developed to prevent the emission of particles by the user to the outside and not as a respiratory protection device.

Within the evaluated modifications, the best results were obtained by adding an elastomeric rubber band and nose clip (91%), which improved the fit and sealing of air leaks at the top of the nose. This was verified when measuring the modification that included the use of the head strap (RPL = 66%), which highlights the importance of leaks on the sides of the nose for respiratory protection. The cloth mask on top increased the RPL (74%); however, it should be mentioned that the cloth mask used had head and neck straps and a nasal clip, so the use of poorly fitting cloth masks could yield much lower values than those found in this study. The use of two surgical masks with ear-fitting had an RPL of 41% and showed only a slight increase; this modification maintains the basic configuration with obvious side openings, so the CDC does not recommend its use [(26)].

The RPL value of 99.6% found for the 3M model 1860 N95 respirator is in agreement with the PFE value and the fit shown by the RPE, which serves as a validation test of the proposed methodology.

Our findings highlight that the tightness of the respirator is as important as the material it's made of. Simple attachments such as elastic bands behind the head and neck greatly increase protection levels, and nose clips can significantly increase the level of respiratory protection of RPEs.

One limitation of our study is the lack of scientific evidence on the range of particle sizes that can be considered as the minimum size required to carry SARS-CoV-2. Also, the variety and origin of surgical masks and KN95 respirators is very wide, so the sample used in this study would not be representative of the universe of these devices.

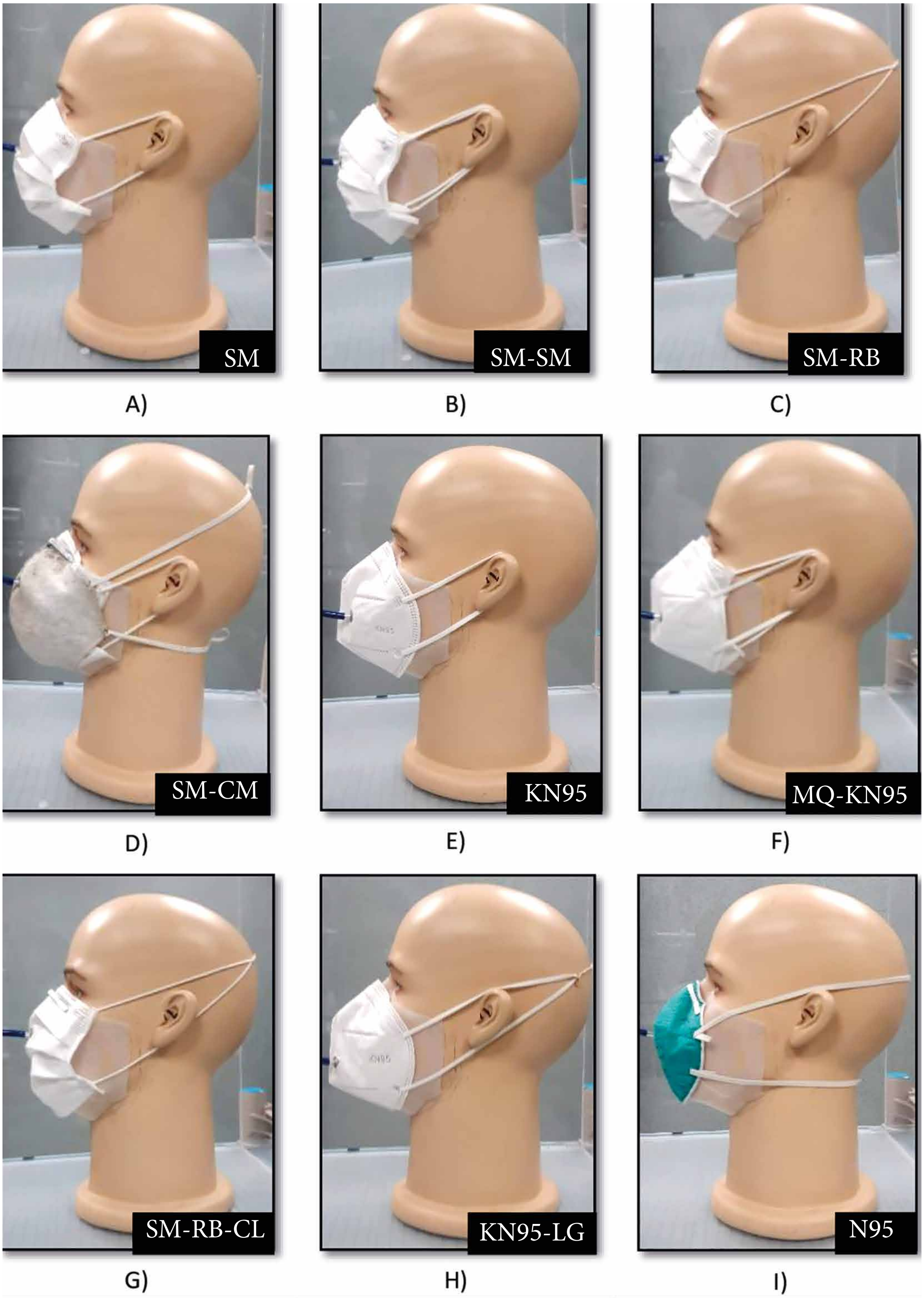

Figure 3. A) SM: three-layer surgical mask with weak nasal clip strapped to the ears. B) SM-SM: two surgical masks placed one on top of the other strapped to the ears. C) SM-RB: surgical mask with elastomeric rubber band for head adjustment. D) SM-CM: surgical mask with the addition of a head-fitting cloth mask and robust aluminum nose clip. E) KN95: KN95 respirator with ear clip and medium-strength metal nose clip. F) SM-KN95: surgical mask strapped to the ears and KN95 respirator on top. G) SM-RB- CL: surgical mask with elastomeric rubber band for head adjustment and robust aluminum nose clip. H) KN95-RB: KN95 respirator with the addition of an elastomeric rubber band. I) N95: NIOSH certified N95 respirator with head strap and robust aluminum nose clip.

https://doi.org/10.17843/rpmesp.383.8036

In conclusion, the proposed methodology to evaluate the RPL against aerosols represented by fine particles of 2.5 μm has results consistent with the PFE values of the evaluated samples, and the observed tightness level. In the case of surgical masks, we found a poor RPL due to poor fit, and for KN95 respirators we obtained a higher RPL; however, it has been shown that modifications that use nasal rubber bands and clips can considerably improve the fit of both RPEs. These findings can be considered for implementing public health regulations to improve prevention policies regarding exposure to aerosols with a high probability of containing SARS-CoV-2.

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