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Fit factor compliance of masks and FFP3 respirators in nurses: A case–control gender study

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Abstract

Aims: To determine the fit factor and compliance with American Industrial Hygiene Association (AIHA) and Occupational Safety and Health Administration (OSHA) requirements of surgical masks and filtering respirators in male versus female nurses.

Design: A case–control gender study performed from 2016 to 2019.

Methods: A gender and age matched-paired sample of 74 nurses was recruited and divided into men (n = 37) and women (n = 37). FFP3 filtering respirators and surgical masks fit factors were compared between male and female nurses by Mann–Whitney U tests. These measurements were tested to pass or fail according to the OSHA (≥100) and AIHA (≥50) criteria by Fisher exact tests for a 95% confidence interval.

Results: Global fit factor mean (standard deviation) was 2.86 (2.73) and 3.55 (6.34) for male and female nurses wearing surgical masks (p = .180), respectively, and nobody passed neither OSHA nor AIHA criteria (p = 1.00). Nevertheless, global fit factor were 30.82 (28.42) and 49.65 (43.04) for male and female nurses wearing FFP3 respirators, respectively, being significantly lower and worse in male nurses (p = .037). According to OSHA criteria, only 2.70% and 13.51% of male and females nurses, respectively, passed with non-significant difference (p = .199), meanwhile 21.62% and 48.64% of male and female nurses, respectively, passed AIHA criteria showing significant differences (p = .027) wearing FFP3 respirators.

Conclusions: All male and female nurses wearing surgical masks failed to pass OSHA and AIHA criteria. Global fit factor of the proposed FFP3 filtering respirators was decreased and worse in male than female nurses.

Impact: Our recommendation is to avoid surgical masks use for protective purposes and use the proposed FFP3 filtering respirators among nurses. Each nurse should be fit tested for its own respirator with special caution in male nurses due to their lower fit factor achieved and most of them failed to pass OSHA and AIHA criteria, especially during COVID-19 pandemic.

KEYWORDS
evidence-based practice, gender, health services research, infection control, nursing assessment, respiratory nursing

1 | INTRODUCTION

Currently, the use of masks and filtering respirators as part of the independent protective equipment has been increasing in the COVID-19 pandemic (Yu et al., 2020). Nurses are at the forefront during COVID-19 pandemic presenting great probabilities for infection. According to the most frequent transmission routes which seem to be via aerosols or droplets inhalation, filtering respirators and masks are considered as first-line prevention interventions for nurses (Umer et al., 2020).

In addition, surgical masks did not show enough effectiveness to avoid virus dissemination leading to the entry of contaminated aerosols into nurses' respiratory system (Teleman et al., 2004). Nevertheless, filtering respirators get a better protection avoiding the entry of droplets and aerosols by forming a seal on nurses' nose and mouth (Umer et al., 2020). Indeed, N95 filtering face piece (FFP) respirators are considered as the most frequently used respirators, getting a tight fit with a particles filtering effectiveness of up to 95% considering a particles size median of 0.3 μm (Bergman et al., 2015; Umer et al., 2020).

The Center for Disease Control and Prevention (CDCP) recommended nurses to wear filtering respirators, especially under organic aerosols dissemination which currently occurs during COVID-19 pandemic. Therefore, facial fitting of filtering respirators and surgical masks should be rigorously checked during their use by nurses. Furthermore, surgical masks filtering capacity seemed to be poor (Frieden, 2017; MacIntyre & Chughtai, 2015; Offeddu et al., 2017; Radonovich et al., 2019). Worldwide, the CDCP have detailed unsafe nursing practices, which could put nurses at risk to be infected, concluding that infection prevention strategies should be paid as a priority in nursing settings (Wise et al., 2015).

Indeed, fit factor could be defined as a quantitative measurement to determine the individual filtration rate considering a specific respiration device. This factor estimates the concentration ratio regarding particles number at ambient air with respect to particles concentration number inside this respirator device. Filtering capacity was mainly associated with the ability of surgical masks or filtering respirators to form a tight seal with nurses' face, removing air leakage between both respirator device's contour and nurse's face (Spies et al., 2011). In addition, several fit tests have been described to determine the mask or respirator capacity to produce a facial seal, concluding that fit factor may be considered as the most used numerical value to detail the facial fit-ability of surgical masks and filtering respirators (Au et al., 2010; Derrick & Gomersall, 2005a; Derrick et al., 2006; Spies et al., 2011).

The American Industrial Hygiene Association (AIHA) proposed the reduction of the fit factor to ≥50, due to a fit factor of 100 to pass this test is not well-documented nor achieved and a fit factor of 50 may be enough to protect even 100% nurses reducing the spent time and burden during respiratory tests (Coffey et al., 1998). Nevertheless, the Occupational Safety and Health Administration (OSHA) required a more exigent fit factor ≥100 to pass this test with a N95 technology device (McKay, 2018).

1.1 | Background

Despite the common use of masks or filtering respirators, up to 71% of COVID-19 fatalities corresponded to men according to an epidemiological analysis in China (Chen et al., 2020). Among other intensive care measures, the increase of the ratio of nurses per patient has shown to reduce the ratio of intensive care unit transfer up to 12% in Italy (Lagi et al., 2020). In addition to this, nursing homes presented the highest morbidity and mortality rates in North America (Stall et al., 2020). Thus, nurses are exposed to a high infection risk of COVID-19 disease and up to 3.2% of nursing staff has suffered from this infection (Roxby et al., 2020). Among relevant recommendations to avoid COVID-19 infection and mortality in nurses, the correct use of surgical masks and filtering respirators as a main part of the individual protective equipment devices plays a key role among nursing staff (Xiang et al., 2020).

Worldwide, Spain has reached one of the highest burdens of COVID-19 disease showing a growing percentage of nurses who are exposed to infected patients and developed this disease (Legido-Quigley et al., 2020). Indeed, Spanish male nurses seemed to show a greater fatality ratio of 9.86% male with respect to 5.62% female nurses (8.41%) with positive COVID-19 tests and an Odds Ratio for fatality of 2.12 more probabilities to die for male versus female nurses (Davis et al., 2020). Among other COVID-19 infection and mortality risk factors in nurses (Legido-Quigley et al., 2020; Xiang et al., 2020), a possible decreased fit factor of masks and filtering respirators could be shown in male versus female nurses due to prior studies have reported that different facial features such as facial size, form or hair presence may influence fit factor (Floyd et al., 2018; Parry et al., 2016; Sandaradura et al., 2020; Loschoavo, 1984; Umer et al., 2020), although previous studies have not specifically addressed their fit factor compliance according to AIHA (Coffey et al., 1998) and OSHA (McKay, 2018) by nurse gender. According to these antecedents, we hypothesize that this individual quantitative filtration rate could be reduced for a particular mask or filtering respirator device in men versus women, passing more particles into the respiratory system of female nurses and increasing the infection risk.

2 | THE STUDY

2.1 | Aim

The main purpose of this study was to determine the fit factor as well as compliance with AIHA and OSHA requirements of surgical masks and filtering respirators in male versus female nurses.

2.2 | Design

A case–control gender study was carried out among nurses from the Asturias Principality, Spain, from June 2016 to June 2019, according to the Strengthening the Reporting of Observational

Studies in Epidemiology (STROBE) recommendations (White et al., 2015). Partial data from some already published results have been studied in deeper details of a larger sample from healthcare providers (De-Yñigo-Mojado et al., 2020). For this study, a gender and age matched-paired sample of 74 nurses was recruited and divided into men (n = 37) and women (n = 37). Fit factor was assessed during a protocol composed by eight exercises to detail the ratio of particles count into FFP3 filtering respirators and surgical masks with respect to particles count outside of both filtering respirators and surgical masks compared between male and female nurses (Spies et al., 2011). In addition, fit factor measurements were tested to pass or fail according to the OSHA (≥100) and AIHA (≥50) criteria and were compared by gender distribution (Coffey et al., 1998; McKay, 2018).

2.3 | Participants

A sample of 74 nurses was recruited by a consecutive sampling method in primary care centres, matched-paired by age and gender as well as divided into males (n = 37) and females (n = 37). Inclusion criteria were nurses older than 18 years old from both genders. Exclusion criteria were nurses previously diagnosed of lung conditions, pregnancy, refuse to sign the informed consent form, and nurses who did not perform primary healthcare following the OSHA recommendations (McKay, 2018).

The version 19.2 of MedCalc© statistical software (www.medcal.org) was applied to calculate the sample size through the Fisher´s exact test for two proportions according to categorical variables. To achieve an improvement of 50% between-two independent groups difference to pass the fit factor criteria proposed by the AIHA (Coffey et al., 1998), an error probability for α of 0.05, a confidence interval (CI) of 95%, a β error of 20% with a power analysis of 80% and an allocation ratio for N2/N1 of 1 was applied for the Fisher´s exact test. Therefore, a total sample size for both groups together was 30 nurses, with 15 males and 15 females in each group. According to a possible 15% loss to follow-up, a total sample size of 38 nurses was required. Controls were matched to cases according to gender and age.

2.4 | Data collection

2.4.1 | Descriptive data

Gender (male or female), height (cm) assessed by measuring tape (M807-20 model, Brueder Mannesmann Werkzeuge; Remscheid, Germany), weight (kg) evaluated by a digital tool (Bosch; AxxenceSlim Line model; Gerlingen, Germany), body mass index (BMI =kg/m^2), face length (mm), depth (mm) and width (mm) as well as mouth width (mm) evaluated by a compass tool (Staedtler; Mars basic 554 model; Nüremberg, Germany) (McKay, 2018; Spies et al., 2011).

2.4.2 | Surgical masks and FFP3 filtering respirators

First, surgical masks commonly used by nurses were analysed to determine their fit factors. Second, FFP3 filtering respirators were also analysed to detail their fit factor due to this filtering respirator type may be considered as the most efficacious FFP filtering respirator to avoid virus and bacteria dissemination. The proposed sub-types of FFP3 filtering respirators were the Aura 9332+ device (3 M St Paul; MN, USA) including duck beak shape, a nasal adjustment clip and an inferior side valve, the Moldex 2505 device (Culver City; CA, USA) comprised by a preformed mask without nasal adjustment clip and with a front valve, and the K 113 (3 M St Paul; MN, USA) device comprised by a folded mask with a nasal adjustment clip and a front valve. All these devices presented universal size and exhalation valve. Each participant chose the most comfortable proposed FFP3 filtering respirator for himself or herself. These devices were used and grouped into a single group according to a prior similar methodology research carried out by our research group in physicians to describe the most common used masks and FFP3 filtering respirators and their fit factors in clinical settings (De-Yñigo-Mojado et al., 2020). Surgical masks commonly used by nurses (Moulded Shell-Type Mouth Nose Cover) were applied (Parry et al., 2016).

2.4.3 | Fit factor estimation

Fit factors for FFP3 filtering respirators and surgical masks were compared between male and female nurses (Parry et al., 2016; Sandaradura et al., 2020; Loschoavo, 1984). According to the recommendations provided by the AIHA (Coffey et al., 1998) and OSHA (McKay, 2018), fit factors were detailed as the gold standard procedure to quantify the filtration capacity of both surgical masks and filtering respirators. Fit factor may be considered as an individual quantitative rate which shows the capacity of particles filtration for a specific surgical mask or filtering respirator. This fit factor details the particles count at ambient air compared with particles count inside the respirator device during worn, showing the ability of masks and respirators to provide a tight seal with the nurses´ face, avoiding air leakage between contour of these devices and their faces (Clayton & Vaughan, 2005; Spies et al., 2011).

According to the described protocol of prior studies (Au et al., 2010; Derrick & Gomersall, 2005b; Han, 2000; Myong et al., 2016; Sreenath et al., 2001), AIHA (Coffey et al., 1998) and OSHA recommendations (McKay, 2018), fit factors estimation was used as a quantitative procedure to determine particles count into filtering respirators and surgical masks compared with particles count outside of these respiratory tools while nurses carried out a protocol of eight exercises (Table 1). First, fit factor measurements were performed in nurses who wore the surgical masks. Second, fit factor measurements were detailed in nurses who wore the proposed FFP3 filtering respirators.

Regarding fit factor analyses, adjusted quantitative analyses were performed by a reliable device (PortaCount ® Pro +Model

TABLE 1 Exercise protocol to determine fit factor

Number	Name	Description (Duration of 1 minute for each exercise, except for the exercise number 6 which lasted 15 seconds)
Exercise 1	Usual breathing	Nurses were at rest performing usual breathing
Exercise 2	Deep breathing	Nurses carried out deep breathing
Exercise 3	Neck side bending	Nurses performed side bending of their necks and stretched their neck muscles during usual breathing
Exercise 4	Speak out loud	Nurses spoke out loud counting numbers from 0
Exercise 5	Neck flexion and extension	Nursed performed flexion and extension movements of their neck during usual breathing
Exercise 6	Grimaces	Nurses frowned or smiled during 15 seconds
Exercise 7	Trunk flexion	Nurses carried out trunk flexion in order to touch their toes
Exercise 8	Usual breathing	Similar to exercise 1, nurses were at rest performing usual breathing

8038) (Coffey et al., 2006), which was calibrated before all measurements. This device counted particles a size ranged from 0.02 μm to 1 μm. From this tool, two catheters were provided to connect the longest catheter with the FFP3 filtering respirators or surgical masks by a leak-proof kit which provided catheters and adapters (TSI; Tsi Inc; St Paul; MN, USA). This transducer was applied between the nose and mouth located at 5 mm with respect to the interior of the mask surface and 10–15 mm from the nurses' mouth, containing an air sample inside of the filtering respirator or surgical mask. In addition, these measurements were carried out in a normal room cleaned with antiseptic with an approximately area of 15 m^2 according to our prior described protocol (De-Yñigo-Mojado et al., 2020).

Considering prior studies (Au et al., 2010; Derrick & Gomersall, 2005b; Han, 2000; Myong et al., 2016; Sreenath et al., 2001) as well as the AIHA (Coffey et al., 1998) and OSHA (McKay, 2018) recommendations, the global fit factor (GFF) was calculated by a "global" fit factor adjusted used a pondered mean of eight proposed exercises measuring the particles rate which may be inhaled by a nurse by the following formula that included "N" as the number of performed exercises and "FFn" as the fit factor determined for a specific number of exercise:

$$\mathrm{GFF} = N / \left[(1/FF1) + (1/FF2) + (1/FF3) + \ldots + (1/FFn-1) + (1/FFn) \right]$$

2.4.4 | AIHA and OSHA protocols compliance

Two categorical dichotomous variables were tested according to pass or fail the AIHA and OSHA requirements (Coffey et al., 1998; McKay, 2018). First, the AIHA test passed if the fit factor was ≥50 and failed if this fit factor was <50, since a fit factor of 100 was not well-documented and difficult to achieve while a fit factor of 50 was enough to protection purposes in 100% of nurses spending less time and burden during these tests (Coffey et al., 1998). Second, the OSHA test passed if the fit factor was ≥100 and failed if this fit factor was <100 using a N95 Companion^{TM} technology device like the PortaCount ® and providing a more rigorous test (McKay, 2018).

2.5 | Ethicaln considerations

This case–control study was carried out according to the Helsinki Declaration ("World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects," 2013). The Ethics Committee of the University of Rey Juan Carlos (Spain) informed positively with approval code of 09/2015. Before beginning this study, all nurses were accurately informed about procedures and signed the informed consent form.

2.6 | Data analysis

For quantitative data, normality analysis was performed by the Shapiro–Wilk test. All quantitative data were detailed as mean, standard deviation (SD) and lower and upper limits of the 95% confidence interval (CI), as well as median and interquartile range (IR). For categorical data, frequencies (n) and percentages (%) were used to describe these data.

Comparisons between male and female nurses were performed using U Mann–Whitney test for non-parametric data and independent t Student test for parametric data. In addition, the Fisher Exact Test was used for categorical variables. Statistical analyses were carried out using the 23.0 version for SPSS software (IBM-SPSS Statistics; Windows; IBM-Corp; Armonk, NY, USA). For these analyses, *p*-value <.05 considering a 95% CI was considered for statistically significant differences.

2.7 | Validity, reliability and rigour

Considering internal validity, adjusted quantitative analyses were carried out by a reliable and calibrated device (Coffey et al., 2006), according to the previous used protocol (Au et al., 2010; Derrick & Gomersall, 2005b; Han, 2000; Myong et al., 2016; Sreenath et al., 2001), as well as AIHA (Coffey et al., 1998) and OSHA recommendations (McKay, 2018), using fit factor as a quantitative estimations procedure to determine particles count into filtering respirators and surgical masks.

Regarding external validity, the sample size calculation was accurately detailed as previously described using the Fisher´s exact test to achieve a 50% improvement between two independent groups according to pass the AIHA's fit factor criteria (Coffey et al., 1998). In addition, a possible 15% loss to follow-up was considered to fulfil the required sample size. Finally, male nurses were age and gender matched to female nurses to balance the study sample.

3 | RESULTS

3.1 | Descriptive data

There were no statistically significant differences ($p > .05$) for age, BMI and mouth width by gender distribution. Nevertheless, there were statistically significant differences ($p < .05$) showing greater height, weight and face length, depth and width for male nurses compared with female nurses. Table 2 showed descriptive data of the nursing sample. In addition, all data showed normal distribution ($p < .05$), except for age ($p < .05$).

3.2 | Surgical masks fit factor comparison by gender distribution

Considering Table 3, fit factor comparison of nurses wearing surgical masks did not show any statistically significant differences ($p > .05$) between male and female nurses for global scores and scores for each exercise of the protocol.

3.3 | FFP3 filtering respirators fit factor comparison by gender distribution

Regarding Table 4, fit factor comparison of nurses wearing FFP3 filtering respirators showed statistically significant differences ($p < .05$) for global fit factor scores and scores of most exercises from number 1 to 5 between both male and female nurses showing lower and worse fit factor scores for male nurses compared with female nurses, except for exercises from number 6 to 8 about grimace, trunk flexion and final usual breathing.

3.4 | AIHA and OSHA protocols compliance comparison by gender distribution

Table 5 showed the percentage of nurses who passed or failed the fit factor compliance according to OSHA and AIHA protocols. Nobody passed neither OSHA nor AIHA criteria ($P = 1.00$) wearing surgical masks. According to OSHA criteria, only 2.70% and 13.51% of male and females nurses, respectively, passed with no significant difference ($p = .199$), meanwhile 21.62% and 48.64% of male and female nurses, respectively, passed AIHA criteria showing significant differences ($p = .027$) wearing FFP3 filtering respirators.

4 | DISCUSSION

Worldwide, filtering respirators and surgical masks are considered a main individual protective equipment tool for nurses to remove virus dissemination via aerosols or droplets inhalation

TABLE 2 Descriptive data of the nursing sample by gender distribution

Variables	Total (N = 74)		Male (n = 37)		Female (n = 37)		
Descriptive data	Mean (SD) [95% CI]	Median (IR)	Mean (SD) [95% CI]	Median (IR)	Mean (SD) [95% CI]	Median (IR)	*p* value
Age (years)	34.31 (7.13) [32.70–35.92]	34.00 (7.00)	34.78 (8.17) [32.05–37.50]	34.00 (7.00)	33.87 (6.12) [31.94–335.81]	32.00 (7.50)	.579**
Weight (kg)	69.58 (12.49) [66.75–72.38]	68.50 (17.00)	76.83 (9.71) [73.59–80.07]	77.00 (9.50)	63.00 (11.07) [59.50–66.49]	62.00 (9.00)	<.001*
Height (cm)	169 (8.90) [167.32–171.34]	170.00 (12.50)	175 (8.09) [173–178]	175 (6.50)	163 (6.44) [161–165]	164 (6.50)	<.001*
BMI	24.14 (3.29) [23.40–24.88]	10.87 (3.82)	24.78 (2.79) [23.85–25.71]	24.51 (2.94)	23.57 (3.63) [22.42–24.71]	23.38 (4.23)	.101*
Face length (mm)	112.47 (8.95) [110.45–114.49]	112.00 (11.25)	117.02 (7.73) [114.44–119.50]	117.00 (11.00)	108.36 (8.00) [105.83–110.89]	108.00 (12.00)	<.001*
Face depth (mm)	122.82 (8.19) [121.07–124.77]	123.00 (11.25)	127.18 (6.67) [124.96–129.41]	126.00 (9.00)	119.07 (7.55) [116.68–121.45]	120.00 (11.00)	<.001*
Face width (mm)	134.05 (8.15) [132.21–135.89]	134.50 (12.25)	139.02 (7.17) [136.63–141.42]	140.00 (7.50)	129.56 (6.17) [127.61–131.51]	129.00 (8.00)	<.001*
Mouth width (mm)	48.39 (4.21) [47.44–49.34]	48.00 (7.00)	49.02 (4.31) [47.58–50.46]	48.00 (6.00)	47.82 (4.10) [46.53–49.12]	48.00 (6.00)	.214*

Abbreviations: * *p* value from Independent t test.
***p* value from U Mann–Whitney testBMI, body mass index; CI, confidence interval; IR, Interquartile range; SD, standard deviation.

TABLE 3 Fit factor comparison for exercises and global scores by gender distribution wearing surgical masks

Exercise	Male (n = 37) Mean (SD) [95% CI]	Male (n = 37) Median (IR)	Female (n = 37) Mean (SD) [95% CI]	Female (n = 37) Median (IR)	*p* value*
Exercise 1	3.24 (4.33) [1.79–4.68]	2.20 (1.05)	7.13 (23.82) [−0.38–14.65]	2.00 (0.65)	.226
Exercise 2	3.18 (3.51) [2.00–4.35]	2.30 (1.20)	6.08 (15.72) [1.12–11.04]	2.20 (0.80)	.223
Exercise 3	3.15 (4.62) [1.61–4.69]	2.20 (0.85)	5.57 (15.41) [0.70–10.43]	2.00 (0.60)	.174
Exercise 4	2.87 (2.53) [2.03–3.72]	2.20 (0.80)	4.82 (12.32) [0.93–8.71]	2.00 (0.70)	.155
Exercise 5	4.67 (8.52) [1.83–7.51]	2.90 (1.40)	7.07 (22.25) [0.85–14.10]	2.50 (1.00)	.178
Exercise 6	2.41 (1.18) [2.02–2.81]	1.90 (1.30)	2.68 (2.94) [1.75–3.60]	2.00 (0.80)	.802
Exercise 7	2.65 (3.06) [1.62–3.67]	2.00 (0.75)	2.98 (5.18) [1.34–4.61]	1.80 (0.35)	.191
Exercise 8	2.91 (3.69) [1.68–4.14]	2.005 (0.80)	4.01 (10.13) [0.82–7.21]	2.00 (0.80)	.581
Global score	2.86 (2.73) [1.95–3.77]	2.20 (1.00)	3.55 (6.34) [1.55–5.56]	2.00 (0.55)	.180

Abbreviations: CI, confidence interval; SD, standard deviation. *U Mann–Whitney for independent groups. $p < 0.05$ was considered as statistically significant for a 95% CI.

TABLE 4 Fit factor comparison for exercises and global scores by gender distribution wearing FFP3 filtering respirators

Exercise	Male with FFP3 respirator (n = 37) Mean (SD) [95% CI]	Male with FFP3 respirator (n = 37) Median (IR)	Female with FFP3 respirator (n = 37) Mean (SD) [95% CI]	Female with FFP3 respirator (n = 37) Median (IR)	*p** value
Exercise 1	48.19 (54.24) [30.10–66.27]	23.00 (72.50)	150.02 (199.37) [87.09–212.95]	63.00 (211.50)	.007
Exercise 2	45.83 (42.99) [31.49–60.16]	31.00 (75.25)	114.82 (123.74) [75.76–153.88]	73.00 (160.00)	.010
Exercise 3	56.22 (60.97) [35.89–76.55]	22.00 (83.75)	98.34 (99.35) [66.98–129.70]	56.00 (139.00)	.035
Exercise 4	49.52 (50.45) [32.70–66.34]	24.00 (74.20)	89.26 (93.75) [59.67–118.85]	47.00 (122.00)	.049
Exercise 5	39.13 (27.71) [29.892–48.37]	35.00 (24.00)	67.44 (53.84) [50.44–84.44]	46.00 (76.50)	.037
Exercise 6	20.51 (20.49) [13.68–27.35]	11.00 (28.55)	36.83 (40.81) [23.95–49.71]	20.00 (49.00)	.117
Exercise 7	36.04 (40.41) [22.56–49.51]	24.00 (55.15)	41.19 (39.53) [28.71–53.66]	25.00 (53.30)	.310
Exercise 8	50.85 (55.69) [32.28–69.42]	24.00 (80.65)	85.46 (104.77) [53.39–119.54]	59.00 (120.50)	.055
Global score	30.82 (28.42) [21.34–40.30]	19.00 (40.05)	49.65 (43.04) [36.06–63.24]	40.00 (70.00)	.037

Abbreviations: CI, confidence interval; SD, standard deviation.
*U Mann–Whitney for independent groups. $p < .05$ was considered as statistically significant for a 95% CI.

during COVID-19 pandemic (Umer et al., 2020; Yu et al., 2020). The World Health Organization (WHO) recommended the use of FFP3 filtering respirators as first-line personal protective equipment to avoid the exposure to respiratory aerosols during COVID-19 disease (Hirschmann et al., 2020). The present findings highlight that fit tests should be carried out especially

TABLE 5 Fit factor comparisons according to OSHA and AIHA fit factor compliance between male and female nurses wearing surgical mask and FFP3 filtering respirators

		OSHA Criteria[b]			AIHA Criteria[c]		
Group	Intervention	Pass Frequency (%)	Fail Frequency (%)	*p*-value[a]	Pass Frequency (%)	Fail Frequency (%)	*p*-value[a]
Male (*n* = 37)	Surgical Mask	0 of 37 (0.00%)	37 of 37 (100%)	1.000	0 of 37 (0.00%)	37 of 37 (100%)	1.000
Female (*n* = 37)	Surgical Mask	0 of 37 (0.00%)	37 of 37 (100%)		0 of 37 (0.00%)	37 of 37 (100%)	
Male (n = 37)	FFP3	1 of 37 (2.70%)	36 of 37 (97.29%)	.199	8 of 37 (21.62%)	29 of 37 (78.37%)	.027
Female (*n* = 37)	FFP3	5 of 37 (13.51%)	32 of 37 (86.48%)		18 of 37 (48.64%)	19 of 37 (51.35%)	

[a]Fisher Exact Test. $p < .05$ was considered as statistically significant for a 95% confidence interval.
[b]OSHA, Occupational Safety and Health Administration Fit Factor ≥100 to pass (McKay, 2018).
[c]AIHA, American Industrial Hygiene Association Fit Factor ≥50 to pass (C C Coffey et al., 1998).

in male nurses according to a worst global fit factor and failed AIHA protocol compliance wearing the proposed FFP3 respirators compared with female nurses. For our best knowledge, this novel study may be considered as the first research that carried out a comparison of the compliance to achieve an adequate fit factor according to OSHA (McKay, 2018) and AIHA (Coffey et al., 1998) recommendations between male and female nurses wearing masks and respirators.

To the light of our results, FFP3 respirators seemed to show a better fit factor in female than male nurses and this difference could be partially associated to women's face dimensions were statistically significantly smaller compared with men`s face dimensions, except for the mouth width. These greater face length, depth and width for male nurses in addition to the facial hair commonly presented in men could be responsible for this worse fit factor and AIHA protocol compliance in accordance with prior studies (Floyd et al., 2018; Parry et al., 2016; Sandaradura et al., 2020; Loschoavo, 1984; Umer et al., 2020). Facial hair presence showed a worse fit factor using negative pressure respirators (Sandaradura et al., 2020; Loschoavo, 1984). Concretely, fit factor of filtering respirators was especially reduced under a beard length longer than 0.125 inches, prediction a worse fit factor under greater beard areal density and length (Floyd et al., 2018). Despite the standard DIN EN 149 clearly stated that fit test should be performed by a panel of clean-shaven persons, the authors include male nurses with or without facial hair to reflect the fit factor compliance of nurses wearing masks and FFP3 respirators in similar conditions with respect to their daily clinical practice following the protocol of a prior study of our research group in clinical settings (De-Yñigo-Mojado et al., 2020). Nevertheless, prior publications highlighted the problem of gender and size of personal protective equipment claiming that respirators fit generally better in males than females (Regli et al., 2020; TUC, 2017). These controversial findings may be due to our investigations reflected the respirators and masks fit factor conditions of healthcare providers in daily clinical practice, avoiding prior instructions for clean-shaving (De-Yñigo-Mojado et al., 2020).

4.1 | Implications for nursing and global practice

Authors encourage male nurses to test the fit factor before wearing FFP3 filtering respirators according to AIHA criteria (Coffey et al., 1998). In addition, the use of full-mask FFP respirators could be another suitable option. These recommendations are not applicable to surgical masks as fit factor did not achieve neither OSHA (McKay, 2018) nor AIHA (Coffey et al., 1998) compliance to achieve an adequate fit factor. Finally, FFP filtering respirators get a better fit factor and should be especially used by nurses during the COVID-19 pandemic (Umer et al., 2020).

Linking evidence to action, masks and filtering respirators are commonly used by nurses, especially during the current COVID-19 pandemic. Fit factor may be considered as a quantitative filtration rate of particles into a specific device with respect to outside of these masks and filtering respirators. Different facial features between male and female nurses, such as facial size, form or hair presence, could decrease surgical masks and filtering respirators fit factor, leading to a high risk of infection in male nurses. Filtering respirators fit factor of male nurses was decreased and failed to pass the AIHA tests and all nurses did not pass using surgical masks. To our knowledge, this is the first study addressing a worse fit factor score and failed AIHA tests of filtering respirators in male versus female nurse. Authors strongly encourage male nurses to use fitting tests before wearing filtering respirators, especially during the COVID-19 pandemic. In addition, it should be noted that the recommendation for proper use of respirators should be strictly followed, such as those given in the National Institute for Occupational Safety and Health's Chemical, Biological, Radiological, and Nuclear respiratory protection handbook in 2018 (CDC, NIOSH, & NPPTL, 2018) which stated that "Employees who are required to be qualified to wear a tight fitting respirator must be clean-shaven where the respirator seal touches the face when the respirator is used" and “if an employee cannot shave for personal or ethical reasons, another type of respirators (such as a positive pressure hoods) should be used".

4.2 | Limitations

Some limitations may be recognized in the present study. Firstly, the design of this study was a case–control research paired-matched by gender and age. Future randomized sampling methods and controlled clinical trials should be carried out in male nurses to determine the best strategies like using fitting tests or full-piece respirators to achieve an adequate fit factor according to AIHA compliance (Coffey et al., 1998). Second, a larger sample size could improve the study strength and provide prediction models to determine a better fit factor. Third, our results showed that FFP3 respirators provided a better fit factor in women than men associated to women face dimensions were smaller, except for the mouth width. Although face length, depth and width as well as mouth width were collected in the present study, facial hair presence was not registered and this issue could influence the difference in fit factors between male and female. According to Table 4, while the five first exercises showed a significant difference between male and female nurses, the three last exercises did not show this difference possibly as sweat is known to have a "sealing effect" between the skin and the respirators. Future studies should compare masks and respirators fit factor compliance with and without facial hair and detail the possibility to develop personalized filtering respirators to get a better fit between the face of male nurses and the respirator contour. In spite of the type and model of FFP3, respirators have been tested depending on the most comfortable device selected for each nurse according to a prior research methodology of our research group in healthcare providers (De-Yñigo-Mojado et al., 2020), different style and size of respirators may have different fitting on different people with different face anthropomorphic dimensions. Thus, our findings may not be generalized to all type and models of FFP3 filtering respirators. Finally, one limitation of the study was that the three subtypes of FFP3 respirators were grouped into a single group and the fit factor was not analyzed according to each FFP3 subtype. Therefore, future studies should be carried out to assess the fit factor in nurses depending on the type of mask, either FFP2 or FFP3.

5 | CONCLUSIONS

All male and female nurses wearing surgical masks failed to pass OSHA and AIHA criteria. Global fit factor of the proposed FFP3 filtering respirators was decreased and worse in male than female nurses. Our recommendation during COVID-19 pandemic is to avoid the surgical masks use for protective purposes and use the proposed FFP3 filtering respirators among nurses. Each nurse should be fit tested for its own respirator with special caution in male nurses due to their lower fit factor achieved and most of them failed to pass OSHA and AIHA criteria.

CONFLICT OF INTEREST

The authors report no conflicts of interest in this work.

AUTHOR CONTRIBUTIONS

All authors contributed to concept, design, analyses, interpretation of data, drafting of manuscript or revising it critically for important intellectual content.

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