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Quantitative Fit Testing on Filtering Facepiece Respirators in Use by Peruvian Healthcare Workers Caring for Tuberculosis Patients during the COVID-19 Pandemic: PROFIT Study 2020

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Background: The COVID-19 pandemic has promoted a shortage of filtering facepiece respirators (FFRs) and the emergence of new FFRs brands. We aimed to determine the fit provided by in-use FFRs in Peruvian healthcare workers (HCWs) during the COVID-19 pandemic. **Methods:** We enrolled 279 HCWs from 37 primary healthcare centers with highest burden of care for TB in Peru, of which 263 were assessed using quantitative fit tests (QNFT). Results were expressed as real-time fit factor (rt-FF) and overall fit factor (overall-FF), which was categorized as ≥100 (optimal result), 50-99, and <50. **Results:** We identified 3M 1860 FFRs (33.1%), Xiantao Zhong Yi ZYB-11 FFRs (24.7%) and Makrite 9500 FFRs (20.5%), mainly. Eighty-seven HCWs (33.1%) had an optimal overall-FF, 27 (10.3%) between 50-99, and 149 (56.7%) less than 50. Of the 87 HCWs with optimal overall-FF, 73 (83.9%) were 3M 1860 FFR. Of the 27 participants with overall-FF between 50-99, 7 (25.9%) were Makrite 9500, while of the 149 with overall-FF less than 50, 58 (38.9%), and 47 (31.5%) were Xiantao Zhong Yi ZYB-11 and Makrite 9500, respectively. **Conclusion:** The Xiantao Zhong Yi and Makrite FFRs do not adapt adequately to the face of Peruvian HCWs, most having fit factors less than 50.

Keywords: respirator; fit testing; tuberculosis; respiratory protection

1. Introduction

Traditionally, tuberculosis (TB) has been the leading occupational health problem in healthcare workers (HCW) who provide medical care under poor infection control conditions [1]. However, during 2020 and 2021, the disease caused by SARS-CoV-2 (COVID-19) has become the primary occupational respiratory infection in unvaccinated HCWs [2]. The World Health Organization (WHO) recommends the use of filtering-facepiece respirators (FFR) type N95 (NIOSH 42 CFR84 standard) or FFP2 (EN149:2001 standard) for the care of patients with TB and COVID-19, especially when they involve aerosol-generating procedures [3-5]. Type N95 and FFP2 FFRs provide 94-95% filtration efficiency of aerosol particles with a mean diameter of 0.3 µm [6]. However, the protective capacity of FFRs is not only based on filtration efficiency but also the quality of the facial fit [7]. A non-optimal facial fit can account for one-sixth of the airflow entering the FFRs [8], one of the main routes of contamination [9].

The evaluation of facial fit is named the fit test. It is the main parameter of the Respiratory Protection Program proposed by the National Institute for Occupational Safety and Health (NIOSH) [10]. According to the US Occupational Safety and Health Administration (OSHA), the fit test must be applied to each worker to select the design and size of FFR that provides an appropriate and acceptable fit and protection when appropriately [11]. This activity will allow the worker to know which FFR fits his/her face and look for large stocks of FFR for its permanent replacement. The

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quantitative fit test (QNFT) is considered the gold standard and is based on the count of environmental particles outside and inside the FFR through air sampling lines, from which a ratio, called the fit factor, is calculated [12, 13]. This value measures the degree of particles entering through the edges of the FFR and the face due to a poor seal. A fit factor equal to or greater than 100 (pass level) for type N95 and FFP2 FFRs is necessary to ensures optimal tightness of the design and size of the FFR evaluated whenever it is used in the same way [14].

The fit test is an essential procedure in the field of occupational health, specifically aimed at workers exposed to biological risks such as tuberculosis in endemic countries[15]. In this regard, Peru is the country with the second highest burden of TB in Latin America and the Caribbean, [16] and one of the 30 countries with the highest burden of Multidrug-Resistant TB (MDR-TB) in the world [17]. Peruvian legislation regulates the application of administrative, environmental, and respiratory protection control measures for the prevention and control of TB [18]. However, fit testing in Peruvian HCWs of primary healthcare centers is almost nonexistent due to the absence of a respiratory protection program [19]. Additionally, due to the global shortage of FFRs generated by the COVID-19 pandemic, new FFRs with poorly technical specifications or suspected of being counterfeit were provided to HCWs [20]. In this sense, we evaluated the respiratory protection measures focused on applying QNFT in FFR by HCWs who care for TB patients under our PROFIT (PROmoting the FIT) study 2020.

2. Materials and Methods

2.1. Study design

The PROFIT study 2020 represents an initiative of the National Center for Occupational Health and Environmental Health (CENSOPAS in Spanish) of the Peruvian National Institute of Health to evaluate respiratory protection measures focused on FFR facial fit in Peruvian HCW developed within the framework of Institutional Operational Plan. During November and December 2020, we visited 37 primary healthcare centers (PHC) to enroll HCWs in work conditions to apply QNFT in FFRs worn by them. The PHC were selected based on the highest burden of care for TB cases in the metropolitan area of Lima and Callao in Peru through data from the SIGTB platform (tuberculosis management information system) of the Tuberculosis Prevention and Control Directorate of the Ministry of Health of Peru [21]. The selection of the participants was for convenience according to the time availability of the HCWs, prioritizing those who work in the TB Control Program, the unit responsible for detecting, diagnosing, and treating TB cases in PHC [22]. We asked enrolled participants about their sex, occupation, age, work area, and the number of hours of FFR use through a questionnaire. The FFRs evaluated by QNFT were N95, FFP2, KN95, and other equivalent types. They were characterized according to their brand, model, type, size, design, presence of batch number on their surface, and country of origin of the manufacturer. We excluded from the analysis workers with facial hair [23], workers with 3M 1860 FFRs suspected of counterfeiting [24], or workers with expired FFRs as long as we had access to the boxes where the expiration date is indicated.

2.2. Quantitative fit testing

We used the PortaCount® model 8048 equipment (TSI Inc., St. Paul, MN, USA) with which we determined two fit factors: real-time fit factor (rt-FF) and overall fit factor (overall-FF) [25, 26]. Initially, we determine the rt-FF to train on properly donning the FFR and making adjustments in real-time [25]. The rt-FF is updated with intervals per second on the PortaCount® screen when using FitCheck® mode and allows us to identify non-tight adjustment areas to adapt the FFR to face manually. Subsequently, we determine the overall-FF by applying the OSHA 29 CFR 1910.134 Appendix A standard, which consists of 08 movements that simulate work conditions: normal breathing, deep breathing, left-right head turns, up-down head turns, speaking loudly, gestures and grimaces, leaning forward and normal breathing [14]. Each movement lasted 60 seconds except for gestures and faces, which lasted 15 seconds. A fit factor (rt-FF or overall-FF) equal to or greater than

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100 was optimal (passing result), while a fit factor (rt-FF or overall-FF) less than 100 was non-optimal (failed result).

2.3. Procedures

We ask the participant to give us their FFR to connect it to the PortaCount® through an air sampling line, and then ask them to put on the FFR as they usually do at work without our support. Subsequently, we recorded the pre-instruction rt-FF 10 seconds after the participant was put on the FFR. The post-instruction rt-FF was recorded 10 seconds after providing instruction focused on improving the position of the elastic band, adjusting the nose clip, and fit check based on the recommendations of the Centers for Disease Control and Prevention [27]. The results of rt-FF pre- and post-instruction were determined only for the last 184 participants because this process was incorporated during the study. Regardless of the result of the rt-FF, we perform a first QNFT to determine the overall-FF. We gave the participant the option of requesting from the employer a new FFR of any brand or model to carry out a second QNFT in case they obtained a non-optimal overall-FF in the first QNFT. Each PortaCount® sample line was cleaned with isopropyl alcohol at the end of each QNFT, according to the manufacturer's recommendations in the context of the COVID-19 pandemic [28].

2.4. Data analysis

The rt-FF and overall-FF were expressed as geometric means and were also categorized into ≥100 and <100, which were arbitrarily subcategorized into 50 -99 and <50 for a better understanding of the level of fit. We compared the pre- and post-instruction geometric means of rt-FF categories using a paired T-test comparing two population proportions with a significance of 95%. We performed the analyzes using Stata version 16 software (Stata Corporation, College Station, TX, USA) and the graphs using Graph Pad Prism software v5.

3. Results

3.1. Description

We interviewed 279 participants, of whom 263 (94.6%) were enrolled according to inclusion criteria. Of the 263 participants enrolled **(Table S1)**, we obtained rt-FF pre- and post-instruction results in 184 (70.3%) participants and overall-FF results participants in all the 263 participants (first QNFT) **(Table S2).** Furthermore, only 10 participants who previously had a non-optimal overall-FF with the FFR in use had another QNFT with a new FFR (second QNFT). The excluded sixteen participants from the analysis were due the following reasons: 11 with facial hair, 3 with counterfeit FFR, and 2 with timeout FFR. However, due to the characteristics of the PROFIT study 2020, the excluded participants were also evaluated by QNFT to provide evidence to health authorities **(Table 3).**

We identified 12 types of FFR models, all one size fits all (standard, regular, or adult) and predominantly of Asian origin: Chinese (91/263) and Taiwanese (55/263) **(Table 1 and Figure 1).** All the FFRs were provided by the PHC except 03 FFR, which the workers acquired on their account: 02 3M 1860 FFR and 01 Lucca Light FFR. The main FFRs identified were 3M model 1860 (33.1%), Xiantao Zhong Yi model ZYB-11 (24.7%), and Makrite model 9500 (20.5%), mainly. All the Xiantao Zhong Yi FFRs identified in the 37 PHCs belonged to only 3 batch numbers (200701, 200601, and 200901), while the 3M 1860 FFR had 18 different lot numbers. The Makrite, Grande, Y&Z, PGT Care, Lucca Light, and GIKO FFRs evaluated in our study do not display their batch numbers on their surface.

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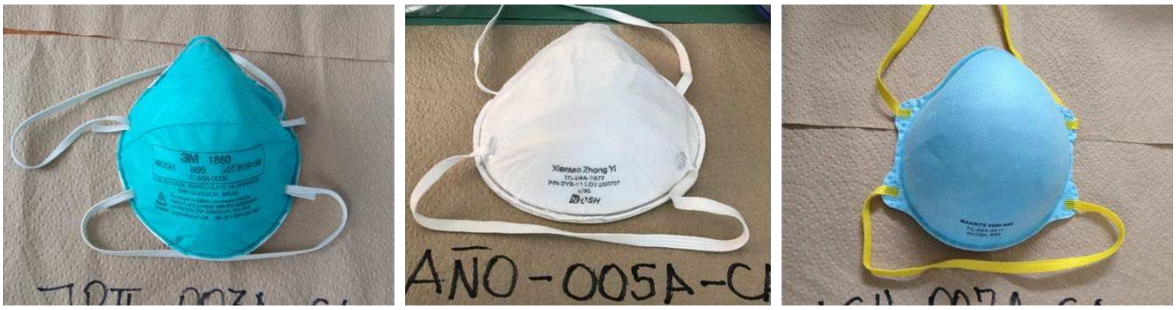
Table 1. Characteristics of the FFR in use by HCWs in the PROFIT study 2020 (N = 263).

Brand, model, and type of FFR	NIOSH number approval	Design of FFR	Batch number on FFR	Manufacturer	n (%)
3M, 1860, N95	TC-84A-0006	Cup / headloop	Yes	3M, USA	87 (33.1)
Xiantao Zhong Yi, ZYB-11, N95	TC-84A-7877	Cup/head loop	Yes	Xiantao Zhongyi Safety Protecting Products Co. Ltd., China	65 (24.7)
Makrite, 9500, N95	TC-84A-5411	Cup / headloop	Not	Makrite Industries Inc., Taiwan	54 (20.5)
3M, 9010, N95	TC-84A-4243	Folding/ headloop	Yes	3M, USA	19 (7.2)
3M, 9920H, PFF [c]	-	Folding/ head loop	Yes	3M, Brasil	11 (4.2)
Grande, CDN3S-P2, FFP2	-	Cup/head loop	Not	Jiangyin Chang-hung Industrial, China	11 (4.2)
PGT Care, PGT-0095, FFP2	-	Folding/ earloop	Not	Fujian Dahong Industry & Development Co. Ltd., China	6 (2.3)
Brand and model unknown, KN95 [a]	-	Folding/ earloop	Not	Unknown, China	6 (2.3)
GIKO, 1200H, N95	TC-84A-4006	Cup/head loop	Not	Shanghai Gangkai Purifying Products Co. Ltd., China	1 (0.4)
Benehal, MS6115L, N95	TC-84A-8474	Cup/head loop	Yes	Suzhou Sanical Protective Product Manufacturing Co. Ltd., China	1 (0.4)
Y&Z, Safety Work F720, N95	TC-84A-4227	Cup/head loop	Not	Fido Mask Co. Ltd., Taiwan	1 (0.4)
Lucca Light, Lucca Care, KN95 / FFP2	-	Folding/ earloop	Not	Unknown, China	1 (0.4)
		Total			263

[a] FFR with no brand or model present on its surface.



(a) (b) (c)

Figure 1. Three of the top FFR identified in the PROFIT study 2020: (a) 3M 1860; (b) Makrite 9500; (c) Xiantao Zhong Yi ZYB-11.

3.2. Instruction and real-time fit factor assessment

The proportion of optimal rt-FF increased significantly from 21 (11.4%) to 72 (39.1%) ($p<0.01$) because of instruction, while the frequency of non-optimal fit factor less than 50 decreased significantly from 146 (79.4%) to 83 (45.1%) ($p<0.01$) **(Table 2).** 3M 1860 FFRs had an optimal pre-instructional rt-FF of 38.3% (18/47) and a significantly higher optimal post-instructional rt-FF of 93.6% (44/47) ($p<0.01$). 3M 9010 FFRs had an optimal pre-instruction rt-FF of 5.6% (1/18) that increased significantly post-instruction to 61.1% (11/18) ($p<0.01$). Similarly, 3M 9920H FFRs had an optimal pre-instruction rt-FF of 9.1% (1/11), increasing to 54.5% (6/11) ($p=0.01$). Neither Xiantao Zhong Yi ZYB-11

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nor Makrite 9500 FFRs achieved optimal pre-instruction rt-FF, but after instruction, five of them achieved an optimal rt-FF. Grande and PGT FFRs showed minimal increase in optimal rt-FF ratio, while KN95, Y&Z, Lucca Light, and Giko FFRs did not show optimal post-instruction rt-FF **(Figure 2).**

Table 2. Real-time fit factors in evaluated FFR in use by HCWs in the PROFIT study 2020 (N = 184).

Brand, model, and type of FFR	rt-FF pre-instruction, n = 184				rt-FF post-instruction, n = 184			
	< 50	50 - 99	≥ 100	Geometric	< 50	50 - 99	≥ 100	Geometric
	n (%)	n (%)	n (%)	mean (IC 95%)	n (%)	n (%)	n (%)	mean (IC 95%)
3M, 1860, N95	19 (13.0)	10 (58.8)	18 (85.7)	42.2 (27.5-64.5)	1 (1.2)	2 (6.9)	44 (61.1)	168.7 (141.4-201-5)
Xiantao Zhong Yi, ZYB-11, N95	34 (23.3)	2 (11.8)	-	8.0 (5.6-11.3)	25 (30.1)	10 (34.5)	1 (1.4)	29.0 (21.0-40.0)
Makrite, 9500, N95	46 (31.5)	1 (5.9)	-	4.0 (2.9-5.6)	33 (39.8)	10 (34.5)	4 (5.6)	24.6 (18.1-33.4)
3M, 9010, N95	14 (9.6)	3 (17.6)	1 (4.8)	7.22 (3.1-16.9)	3 (3.6)	4 (13.8)	11 (15.3)	98.0 (61.1-157.2)
3M, 9920H, PFF	9 (6.2)	1 (5.9)	1 (4.8)	12.7 (6.2-26.1)	4 (4.8)	1 (3.4)	6 (8.4)	62.3 (27.3-142.2)
Grande, CDN3S-P2, FFP2	10 (6.8)	-	1 (4.8)	6.5 (2.5-16.8)	6 (7.2)	2 (6.9)	3 (4.2)	22.8 (6.8-76.5)
Brand and model unknown, KN95 [a]	5 (3.4)	-	-	2.6 (0.7-9.3)	5 (6.0)	-	-	13.7 (4.4-42.2)
PGT Care, PGT-0095, FFP2	6 (4.1)	-	-	7.6 (2.2-25.7)	3 (3.6)	-	3 (4.2)	53.5 (13.0-220.8)
GIKO, 1200H, N95	1 (0.7)	-	-	-	1 (1.2)	-	-	-
Y&Z, Safety Work F720, N95	1 (0.7)	-	-	-	1 (1.2)	-	-	-
Lucca Light, Lucca Care, KN95 / FFP2	1 (0.7)	-	-	-	1 (1.2)	-	-	-
Total	146 (79.4)	17 (9.2)	21 (11.4)	9.7 (7.8-12.2)	83 (45.1)	29 (15.8)	72 (39.1)	49.1 (40.5-59.6)

[a] FFR with no brand or model present on its surface.

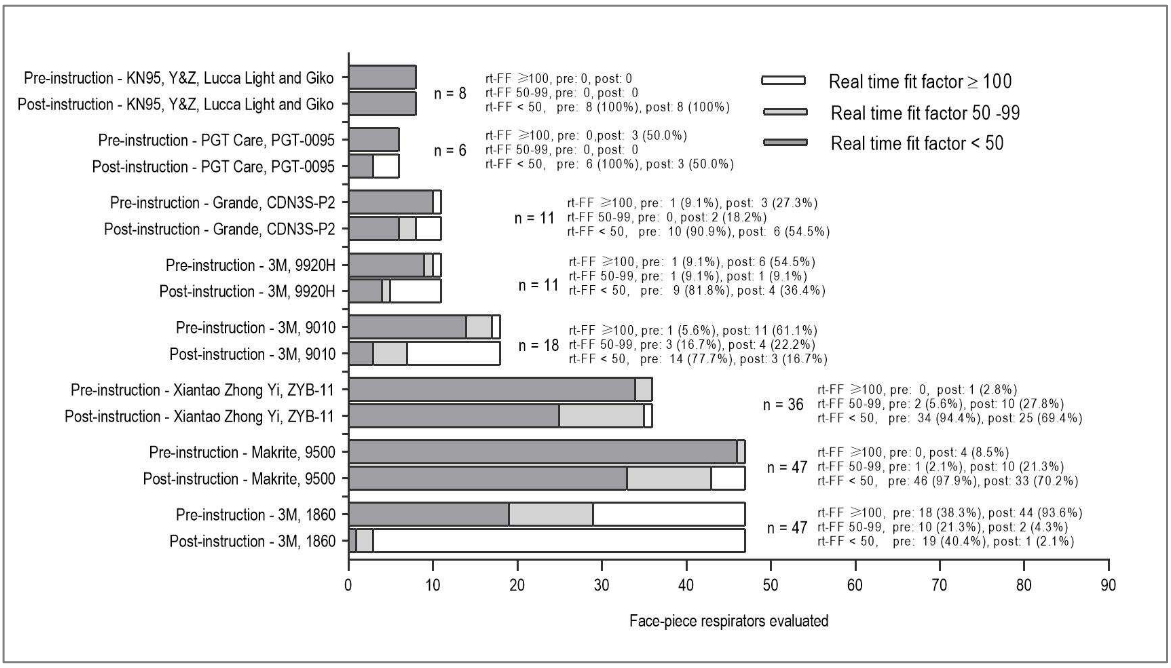

Figure 2. Frequencies and percentages of real time fit factor pre- and post-instruction of 184 FFR in the PROFIT study 2020.

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3.3. Overall fit factor assessment

The 3M 1860 showed an optimal overall-FF at 73 (83.9%) FFR. The 3M 9010 and 3M 9920H FFRs had an optimal overall-FF of 33.4% (10/30). The Xiantao Zhong Yi ZYB-11 has a single FFR with optimal overall-FF (1.5%), while the Makrite 9500 had a non-optimal result, as well as the FFRs of the brands Lucca Light, Giko, and Benehal. The percentage of HCWs using FFRs with an overall-FF of less than 50 were high (56.7%) were represented mainly by two of the most widely used FFRs: Xiantao Zhong Yi ZYB-11 and Makrite 9500 **(Figure 3).** The overall-FF did not show a statistical association with age, sex, FFR design (conical or foldable), or elastic band arrangement (earloop or head loop) of the FFR.

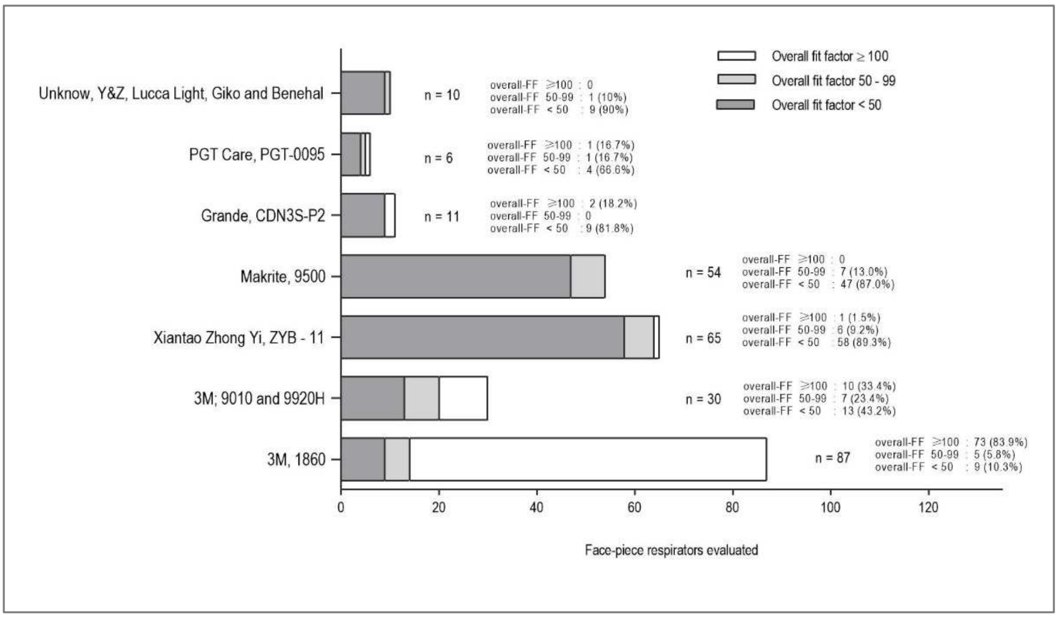

Figure 3. Frequencies and percentages of overall-FF in the first QNFT in 263 participants included in the analysis of the PROFIT study 2020.

Of the 263 evaluations carried out, 87 (33.1%) participants had an optimal overall-FF, 27 (10.3%) had an overall-FF between 50-99, and 149 (56.7%) had an overall-FF less than 50 **(Table 3).** Of the 87 participants with optimal overall-FF, 73 (83.9%) were 3M model 1860 FFR. The 3M model 1860 FFR had a geometric mean of 126.3 (95% CI: 109.4–146.6), the only one that exceeds the threshold of 100. Likewise, of the 27 participants with overall-FF between 50-99, 7 (25.9%) were FFR Makrite model 9500, while of the 149 with overall-FF less than 50, 58 (38.9%) and 47 (31.5%) were Xiantao Zhong Yi model ZYB-11 and Makrite model 9500, respectively. The FFRs evaluated in the first QNFT had a median time of use of 12 hours (interquartile range: 18.0), which were also not associated with the overall-FF (p>0.05).

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Table 3. Overall fit factors in evaluated FFR in use by HCWs in the PROFIT study 2020 (N = 263).

Brand, model, and type of FFR	Hours of FFR use [a]	overall-FF, n = 263			
		< 50 n (%)	50 - 99 n (%)	≥ 100 n (%)	Geometric mean (IC 95%)
3M, 1860, N95	12 (19)	9 (6.0)	5 (18.5)	73 (83.9)	126.0 (109.4-146.6)
Xiantao Zhong Yi, ZYB-11, N95	12 (26)	58 (38.9)	6 (22.2)	1 (1.2)	15.1 (11.7-19.4)
Makrite, 9500, N95	6 (14)	47 (31.5)	7 (25.9)	-	12.4 (9.1-17.0)
3M, 9010, N95	5.5 (16)	7 (4.7)	5 (18.5)	7 (8.0)	44.9 (22.7-88.9)
3M, 9920H, PFF	18 (20)	6 (4.0)	2 (7.4)	3 (3.4)	34.1 (11.2-103.5)
Grande, CDN3S-P2, FFP2	12 (20)	9 (6.0)	-	2 (2.3)	13.8 (5.0-37.7)
Brand and model unknown, KN95 [b]	6 (9)	6 (4.0)	-	-	2.8 (1.1-7.4)
PGT Care, PGT-0095, FFP2	3 (15)	4 (2.7)	1 (3.7)	1 (1.2)	21.0 (4.6-96.0)
GIKO, 1200H, N95	6	1 (0.7)	-	-	-
Benehal, MS6115L, N95	3	-	1 (3.7)	-	-
Y&Z, Safety Work F720, N95	3	1 (0.7)	-	-	-
Lucca Light, Lucca Care, KN95 / FFP2	-	1 (0.7)	-	-	-
Total	12 (18)	149 (56.7)	27 (10.3)	87 (33.0)	31.5 (26.3-37.8)

[a] Median (interquartile range); [b] FFR with no brand or model present on its surface.

3.4. Second QNFT

Finally, we evaluated the results of the second QNFT in FFR of 10 participants expressed in overall-FF and its comparation with the results of the first QNFT **(Figure 4).** Of them, 7 opted for a different brand FFR, and 3 opted for a new FFR of the same brand and model (3M 1860). Of the ten new evaluations, all had optimal results, except for 3 participants with 3M 9920H (ID. 2236), Makrite 9500 (ID 7209), and 3M 1860 FFR (ID 9205). Three participants used 3M 1860 FFR in the first and second QNFTs (ID 3226, ID 7233, ID 9205), of which 02 had optimal overall-FF in the second QNFT. Of the total participants evaluated in the second QNFT, 07 had an optimal overall-FF: 06 were 3M FFR (1860, 9010, and 8210 models), and 1 was Grande FFR.

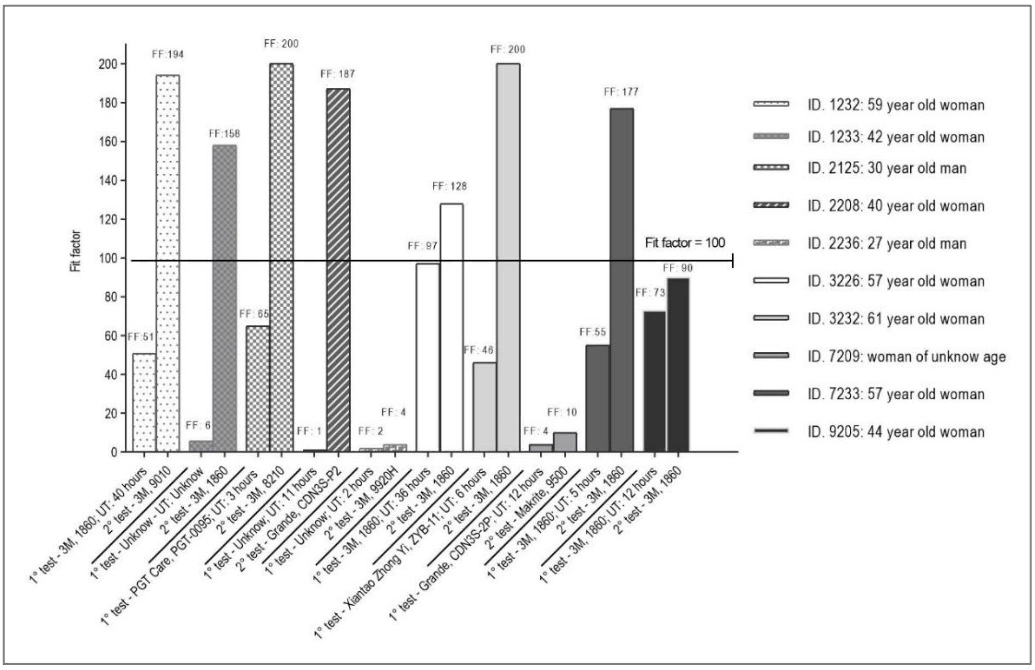

Figure 4. Frequencies and percentages of overall fit factor in the first and second QNFT in 10 participants included in the analysis of the PROFIT study 2020.

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4. Discussion

We found a non-optimal overall-FF in the first QNFT of 67.0% (176/263) of the evaluated participants, of which 84.6% (149/176) present an overall-FF of less than 50. The 3M FFRs had a significantly higher adaptability capacity for facial adjustment than the Xiantao Zhong Yi and Makrite FFRs. The non-optimal overall-FF in the first QNFT was not related to the gender, age, design of the FFR (foldable or conical) or time of use. Indeed, the Xiantao Zhong Yi and Makrite FFRs showed poor adaptability to the facial dimensions, mainly in the nasal and chin areas.

The nose clip of most of the Makrite and Xiantao Zhong Yi FFR did not adapt correctly to the shape of the nose of the participants, despite the attempts. This limitation generated noticeable openings in the nasal area that would explain the lower overall-FF. Some participants reported that the nose clip of Makrite FFR, initially in the form of an arch, has limited malleability and yields to its original shape after adjustment. We also observed a loss of fit in the chin region, partly evidenced by the excess length of the elastic bands. Given this, some participants reported that the elastic bands tend to remain stretched due to the loss of their elasticity, and therefore, they must tie them to increase the fit. The nose clip and the elastic bands of the FFR can show serious flaws and affect the facial fit, being necessary to be evaluated more precisely with appropriate instruments [29] **(Figure S1).**

On the other hand, we identified some FFRs that show insufficient technical characteristics. Six FFRs only display the KN95 GB2626-2006 inscription on their surface, with no known brand, model, or manufacturer. The Y&Z FFR identified in our study was produced by the Fido Mask Company and had a NIOSH TC-841-4227 voluntary certification revocation since August 2014 [30]. It cannot be manufactured, assembled, sold, or distributed as a NIOSH-approved product, so it is probably a timeout. We also identified a Lucca Light FFR of Chinese origin and an unknown manufacturer that was banned in the European Union for having a filtration efficiency of less than 57.2% [31]. The Y&Z FFR was worn by a nursing staff and provided by the PHC, while the Lucca Light FFR was worn by a security staff and purchased at their own expense.

The lack of adaptability of the FFR in our study may be mainly due to 03 factors: (i) incorrect size, (ii) damage to its support structure (elastic bands, nose clip) due to excessive reuse, and/or (iii) deficiencies in its filtration efficiency. Regarding the first factor, the overall-FF of 10 achieved by a new Makrite FFR in the second QNFT in ID 7209 would demonstrate its limited adaptability to the participant's facial dimensions. The second factor would support those two participants (ID 3226 and ID 7233) with 3M 1860 FFR and usage time of 36 hours, had a non-optimal result in the first QNFT changing to optimal in the second QNFT using the same FFR model (figure 3). Likewise, we must consider that all the FFRs evaluated in the analysis were standard sizes. Regarding the third factor, it is crucial to indicate that the overall-FF does not discriminate between particles that have entered through the edges of the FFR or the filter [7]. This situation leads us to consider if the high proportion of non-optimal overall-FF of less than 50 would involve filter penetration.

Except for 3M FFRs, there is no information in the literature on most of the FFRs evaluated in our study. A recent study evaluated the overall-FF of 03 FFRs: Xiantao Zhong Yi ZYB-11, Makrite 9500, and KN95 (manufactured by Zhong Jian Le of Chengde Technology Co. Ltd.) in 07 participants [32]. Of the 07 participants with the Xiantao Zhong Yi FFR, none had an optimal overall-FF; however, all had values less than 60. On the other hand, of the 07 participants with the Makrite FFR, one had an optimal overall-FF; however, the rest had an overall-FF lower than 20. Regarding the KN95 FFRs, the overall-FF results were all lower than 3, having the same performance as a cloth mask. The study suggests that the fit loss was due to the inadequate sealing of the FFR in the chin area.

One publication evaluating the tightness of FFRs available at a PHC in the United States found KN95 FFRs that did not display brand, model, or lot number data; and had non-optimal overall-FF results [33]. These FFRs did not show elastic band support on the head and had perforations on their surface with the text "KN95" and "GB2626-2006" in low-relief that gave rise to a thin non-protective layer of the filter. Likewise, a study applied a qualitative fit test to a panel of 7 individuals using 12 types of FFR between KN95 and N95 FFR (3M 1860) and their results showed an optimal fit percentage of 3% (1/36) for KN95 FFR, while the 3M 1860 FFR had a 100% (12/12) best fit [34].

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Regarding limitations, our study was making a single measurement of QNFT per FFR in use, unlike other studies that perform up to three measurements, considering that the overall-FF presents a level of error [37, 38]. Also, we did not check the expiration date of all the FFRs because that depended on access to the boxes. On the other hand, we identified 3M 1860 counterfeit FFRs as we are familiar with them since their use was predominant before the pandemic. However, we could not identify counterfeit FFRs from other brands, such as the Makrite 9500. This point is essential given the continual reporting of fake alerts by Makrite displayed on their website [39]. Therefore, our results should be taken with caution.

The PROFIT study allowed us to evaluate respiratory protection measures focused on FFR facial fit in Peruvian HCW in the context of the COVID-19 pandemic. The main strength of the study was the application of QNFT, which does not depend on the sensitivity or attitude of the person, unlike qualitative fit tests [40]. We believe that our findings are important to consider for tuberculosis-endemic countries that have not yet implemented respiratory protection measures. Finally, it is essential that the PHC, through the Occupational Health and Safety services, comply with the programs for the prevention and control of occupational risks and diseases, including those transmitted by air, to strengthen the primary prevention activities in workplaces.

5. Conclusions

We found a non-optimal fit provided by in-use FFRs in Peruvian healthcare workers (HCWs) during the COVID-19 pandemic. Most of these FFRs were new brands not previously used by HCWs, which appeared due to shortages of FFRs. This finding helps us to understand the exposure to TB transmission during a pandemic scenario where there was a limited access to diagnosis, follow-up and treatment that could increase the TB cases in settings with precarious health system.

We recommend implementing measures that prioritize educational interventions with a practical approach to recognizing the FFR, correct handling, fit check, and good storage practices. Compliance with these activities must be monitored, supervised, and evaluated by the Respiratory Infection Control Plan established in the Technical Health Standard for TB Care in Peru.

Supplementary Materials: Table S1. Characteristics of 263 workers enrolled in the PROFIT study 2020. Table S2. Real-time and overall fit factor obtained in FFR included of analysis (N = 263)； Table S3. Real-time and overall fit factor obtained in FFR excluded of analysis (N = 16). Figure S1. Visible openings in the nasal area in participants using the Makrite 9500 FFR (top photographs) and loss of FFR adjustment mainly in users with elastic bands that are too extended and therefore must be tied to increase the FFR adjustment (lower photographs).

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Institutional Review Board Statement: This study was approved by the Institutional Ethics Committee of the Universidad Privada San Juan Bautista with code number 445-2023-CIEI-UPSJB.

Informed Consent Statement: We apply an informed consent to all subjects involved in the study which describes the purpose of the study, the procedures, benefits, and rights of the participants. The participation of the HCWs was voluntary, and the management of the participant's data was encrypted to guarantee their anonymity.

Data Availability Statement: No new data were created or analyzed in this study. Data sharing is not applicable to this article.

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