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Comparing mask fit and usability of traditional and nanofibre N95 filtering facepiece respirators before and after nursing procedures

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SUMMARY

Background: The reliability of N95 filtering facepiece respirators (FFRs) depends on correct fitting. The perceived usability of FFRs is equally important because discomfort during usage may affect compliance. Body movements during nursing procedures may also increase the risk of face seal leakage.

Aim: To evaluate the mask fit and usability of the best-fitting 3M N95 FFR and the nanofibre N95 FFR before and after nursing procedures. The physical properties of these FFRs were also examined.

Methods: This experimental study had a one-group multiple comparison design. In total, 104 nursing students participated, and performed nursing procedures for 10 min when wearing the best-fitting 3M FFR and the nanofibre FFR. Mask fit and perceived usability of the FFRs were evaluated.

Findings: More participants failed to obtain a fit factor $\geq$100 when using the best-fitting 3M FFR than when wearing the nanofibre FFR (33.7% vs 21.2%) after the procedures (P=0.417). The nanofibre FFR also demonstrated higher usability than the 3M FFRs in terms of facial heat, breathability, facial pressure, speech intelligibility, itchiness, difficulty of maintaining the mask in place, and comfort level (P<0.001). The nanofibre FFR was also lighter, thinner and had slightly higher bacterial filtration efficiency than the 3M FFRs.

Conclusion: The nanofibre FFR demonstrated significantly better usability than the 3M FFRs. None of the respirators were able to provide consistent protection for the wearer, as detected by face seal leakage after performing nursing procedures. Further improvement in the prototype design is needed to increase compliance and ensure the respiratory protection of users.

Introduction

The N95 particulate filtering facepiece respirator (FFR) has been recommended by public health organizations as a tool to reduce the transmission of airborne infectious diseases (e.g. tuberculosis, measles and chickenpox) and to provide protection from other aerosol-generating procedures with

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infectious patients [1]. The numerical designation '95' indicates the ability to filter at least 95% of particles with the most penetrating particle size range of 0.3 μm under test conditions [2]. Reliability of N95 FFRs depends on correct fitting [2,3]. Healthcare workers (HCWs) who use a respirator in their workplace must undergo training on proper usage and pass a fit test [4]. HCWs may be infected in clinical settings via exposure to a minimal amount of micro-organisms. Thus, the leakage of protective respirators must be prevented to ensure adequate protection for users [5,6].

To fulfil the stringent requirements, manufacturers should ensure that the thickness of a respirator must be increased and fibre diameter must be decreased [7]. Hence, the traditional N95 FFRs are thicker than surgical masks, thereby compromising breathability [8–10]. Although surgical masks have been recommended as part of universal precautions in the clinical setting, they cannot provide adequate protection for users under specific contagious conditions [11]. Discomfort experienced by HCWs who wear N95 respirators is often associated with the tight-fit models [12]. A variety of sensations and experiences, such as facial pressure, facial heat, facial movement or skin itchiness, may lead to discomfort, thereby affecting compliance during usage [1,8]. Perceived exertion, perceived shortness of air, complaints of headache or lightheadedness, difficulty in communication and respirator adjustments by users may increase over time [13]. Discomfort associated with the device may also interfere with the occupational duties of workers [14]. Therefore, the perceived usability of FFRs is as important as mask fit. Evidently, the improvement and modification of FFRs warrants further investigation to increase the acceptance of this tool and improve the compliance rates of users.

Electrospinning technology has enabled the Nano and Advanced Materials Research Institute of Hong Kong (NAMI), a research and development centre designated by the Innovation and Technology Commission of the Government of Hong Kong Special Administrative Region, to successfully combine melt-blown and spunbond fibres with nanofibres with diameters ranging from a few nanometres to a few hundred nanometres, which cannot be obtained via traditional fabrication techniques. However, an experimental study illustrated that body movements during nursing procedures may increase the risk of face seal leakage [15]. Thus, the purpose of the current study was to evaluate the mask fit and usability of traditional N95 and nanofibre N95 FFRs before and after nursing procedures. In addition, the physical properties of FFRs under testing were examined.

Methods

This experimental study had a one-group multiple comparison design.

Respirators

The three 3M models tested were 1860, 1860S and 1870+ (3M, St Paul, MN, USA); these are the most commonly used FFR models in hospitals under the Hospital Authority of Hong Kong. For the N95 nanofibre FFR, the prototype was composed of an ultrafine fibrous coating on a microfibrous substrate. This ultrafine fibrous coating comprised partially gelled submicron fibres interweaved with nanofibres. The material and structural details of the nanofibre FFR can be found in US10201198B2 (filed on 10th December 2015, granted on 12th February 2019).

Study participants

The participants were a group of students from a university baccalaureate nursing programme. They had no prior experience in using an N95 FFR in the clinical setting, but had received formal training in performing the nursing procedures tested [15]. This inclusion criterion ensured that prior experience in using an N95 FFR would not be a confounder of the outcome [16]. Subjects who were smokers or drinkers (apart from being social drinkers) were excluded because alcohol and smoking may have negative effects on exercise performance and breathing capacity. Subjects who were pregnant, had a beard or were diagnosed as having respiratory problems were also excluded.

Procedures for mask fitness and usability evaluation

The experiments were conducted at the 'Mask Fitting and Personal Protective Equipment Skill Station' of the university. To minimize variation in concentration of the suspended particles and dust in the environment, all procedures were performed in a standardized setting at a mean temperature of 23.05 °C and humidity of 57.08% [17]. Ethical approval was obtained from the Human Research Ethics Review Committee of The Hong Kong Polytechnic University (Reference No. HSEARS20150717001), which approved all experimental protocols adopted in this study. All methods used were implemented in accordance with the relevant guidelines and regulations. Participation in this study was voluntary. Written informed consent was obtained from each subject following explanation of the risks and benefits of their participation.

Prior to the trial, sociodemographic data of the participants, including sex, age, body mass index (kg/m^2), years of study and clinical experience (in weeks), were collected. After briefing the participants on the protocol for the proper donning of the N95 FFRs, every participant underwent a quantitative fit test (QNFT) using Portacount Plus (TSI Inc., Shoreview, MN, USA) [18]. Thereafter, the best-fitting 3M FFR was identified from the three commonly used FFR models in hospitals under the Hospital Authority of Hong Kong, namely, 1860, 1860S and 1870+ (3M). The best-fitting 3M FFR model for each participant was confirmed based on the fit factor readings. All participants were required to perform the user seal check to ensure that no leakage would occur before the procedure [3].

The trial for comparing the two respirators (i.e. best-fitting 3M FFR and nanofibre FFR) commenced after identifying the best-fitting 3M FFR model for the individual participants. The sequence of wearing FFRs was determined using a computer-generated randomized table to ensure that user performance was unaffected by the experience of receiving either the 3M N95 FFR or nanofibre N95 FFR during the experiment. The baseline QNFT measurements of face seal leakage were taken after each subject wearing the first FFR had remained seated for 10 min. Thereafter, the participants performed two nursing procedures for 10 min. Suctioning and Ryle's tube insertion procedures may induce aerosol generation in clinical settings. In addition, these procedures might involve patient positioning and procedures that might increase the level of physical

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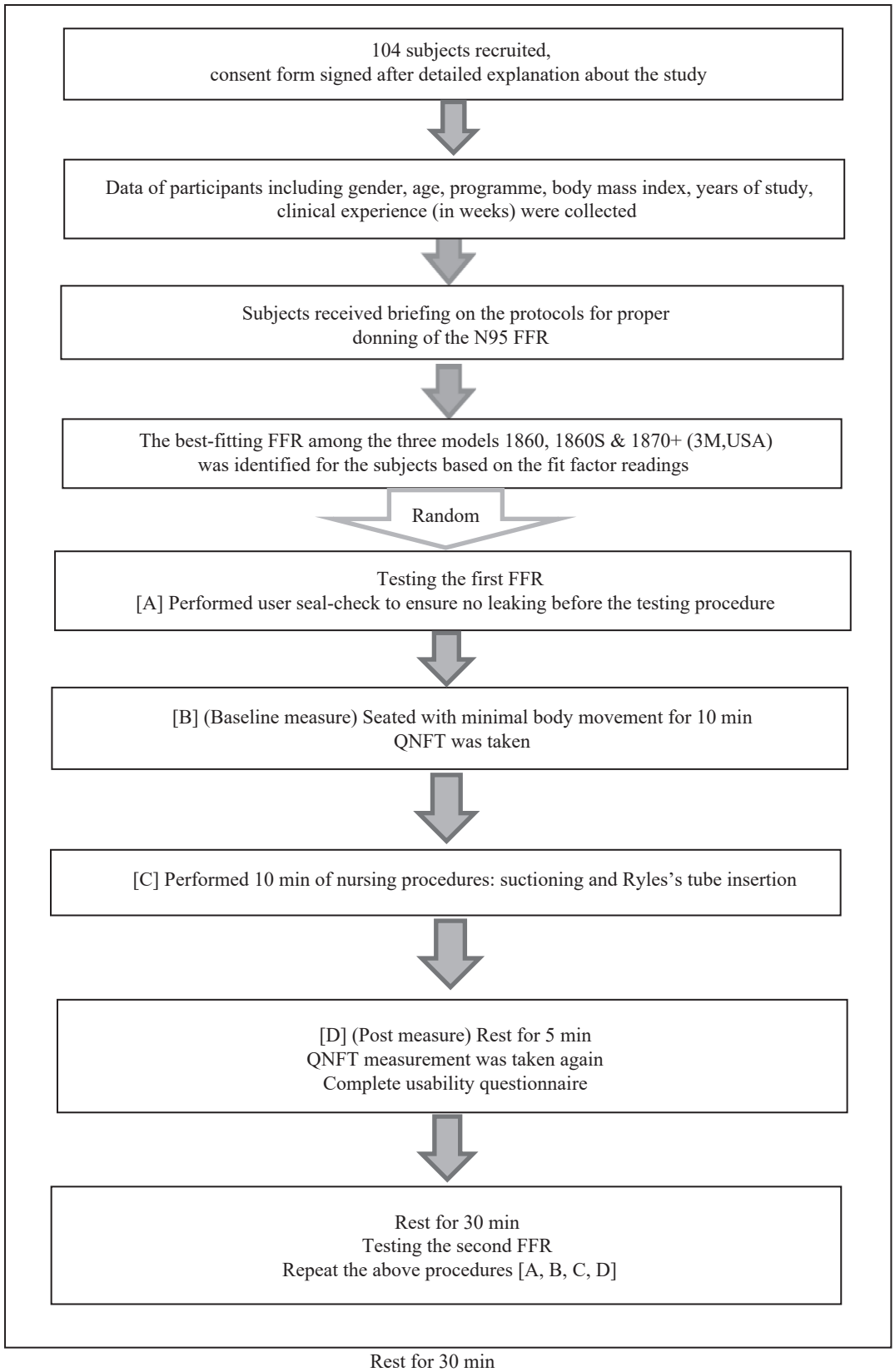

Figure 1. Data collection procedures. FFR, filtering facepiece respirator; QNFT, quantitative fit testing.

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exertion, thus challenging the wearability, comfort level and filtration capacity of the FFRs under testing. The performance of all participants should be consistent, given that everyone had received prior training in performing these procedures. After the procedures were completed, the participants were asked to rest for 5 min before QNFT readings were collected again.

A 30-min rest was provided before testing the second FFR in order to avoid fatigue that may affect performance. The participants were blinded to the type of FFR being used to prevent bias in evaluating the usability level of the respirators. They were likewise instructed that regardless of the test outcome, no re-adjustment or re-donning of FFRs should be performed during and after the nursing procedures. Figure 1 shows the details of the data collection procedures.

When evaluating usability, the subjects were asked to evaluate eight perceptions, including facial heat, breathability, facial pressure, speech intelligibility (ease in talking), itchiness, difficulty of maintaining the mask in place, comfort on ear lobe and overall comfort level after wearing each FFR. Each parameter was rated using a five-point scale from 1 (very unsatisfactory) to 5 (very satisfactory). This scale was modified from the usability scale of Meyer *et al.* (1997) [19]. Upon completion of the experiment, a shopping coupon of HK$100 (approximately £10) was provided to the participants as a token of appreciation for their participation.

Examination of physical properties of the respirators

The following physical properties of the tested FFRs were examined: weight (g/m^2), thickness (mm), air permeability [ventilation resistance R (kPa s/m)], cumulative one-way transport capacity (OWTC), overall moisture management capacity (OMMC) and bacterial filtration efficiency (BFE).

Fabric weight was defined as the mass per unit area of the fabric and was measured in g/m^2 in accordance with the ASTM D3776 Standard Method (2017) [20]. Fabric thickness was defined as the distance between two fabric surfaces under a specified applied pressure [21], and was measured on the basis of ASTM D1777 [22]. Air permeability was measured using KES-F8 API (Kato Tech Co., Ltd, Kyoto, Japan), which enables the measurement of ventilation resistance, in which values can be obtained with minute amounts of ventilation. Measurement conditions were similar to the ventilation of the clothing worn, in which lower values indicate higher breathability and permeability [23].

OWTC was defined as the difference in the cumulative moisture content between the two surfaces of a fabric in the unit testing time period, and was tested using the moisture management tester (MMT) to evaluate the textile moisture management properties [24]. The values were graded as follows: Grade 1: $<$ 50, poor; Grade 2: 50–100, fair; Grade 3: 101–200, good; Grade 4: 201–400, very good; and Grade 5: $>$ 400, excellent [25].

OMMC shows the overall ability of a fabric to manage the transport of liquid moisture, and involves the moisture absorption rate of the bottom side, one-way liquid transport ability and moisture drying speed of the bottom side (represented by the maximum spreading speed). OMMC was also tested using MMT [24]. High values indicate high overall moisture management ability of a fabric. The value grading system was adapted from Yao [25]: Grade 1: 0–0.2, poor; Grade 2: $>$0.2–0.4, fair; Grade 3: $>$0.4–0.6, good; Grade 4: $>$0.6–0.8, very good; and Grade 5: $>$0.8, excellent [25]. BFE was defined as the percentage of particles filtered by the respiratory protection material. High numbers in this test indicate superior barrier efficiency [26].

Statistical analyses

Descriptive statistics were used to compute the socio-demographic characteristics of the participants and the physical properties of the 3M and nanofibre FFRs. Fit factors of $\geq$100 and $<$100 indicate pass and fail results, respectively, in the PortaCount Plus Fit test. Chi-squared analysis was conducted to identify the association between demographic characteristics and fit factor (99, fail; $\geq$100, pass) after the procedures. Paired *t*-test was used to compare the fit factor of the best-fitting 3M FFR and nanofibre FFR before and after the nursing procedures. Wilcoxon signed ranks test was conducted to compare the usability of FFRs tested.

Results

In total, 104 undergraduate nursing students (21 males and 83 females) participated in this study. The best-fitting 3M FFRs (in sequence) were 1870+ (*N*=60), 1860S (*N*=40) and 1860 (*N*=4) (Table I). The average fit factor of both types of FFR (i.e. 3M model vs nanofibre) decreased significantly after completion of the nursing procedures (3M model: 185.08 vs 135.52; nanofibre mask: 188.44 vs 149.13). That is, the 3M model resulted in a consistent lower fit factor during the different body movements than the nanofibre model. When the cut-off fit factor was used as an indicator (i.e. 0–99, fail; $\geq$100, pass), approximately one-third of the participants (*N*=35, 33.7%) failed to obtain an overall fit factor $\geq$100 when using the best-fitting 3M FFR. In contrast, only 21.2% (*N*=21) of the

Table I
Baseline background and demographic characteristics of the study sample (*N*=104)

Variables	Values
Sex	
Male	21 (20.2%)
Female	83 (79.8%)
Year of study	
1	16 (15.4%)
2	37 (35.6%)
3	27 (26.0%)
4	22 (21.2%)
5	2 (1.9%)
Best-fitting N95 3M FFR	
1860S	40 (38.5%)
1860	4 (3.8%)
1870+	60 (57.7%)
Age, years	22.08±2.56
Clinical experiences, weeks	11.65±15.48
Body mass index (kg/m^2)	21.05±2.74
Room temperature, °C	22.91±1.40
Room relative humidity,%	57.63±10.18

FFR, filtering facepiece respirator.
Values are *N*, *N* (%) or mean±standard deviation.

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Table II
Fit factors determined by the quantitative fit test between the best-fitting 3M filtering facepiece respirator (FFR) and nanofibre FFR before and after nursing procedures

Body movements	Fit factor before procedures			Fit factor after procedures		
	Best-fitting 3M FFR	Nanofibre FFR	*P*-value	Best-fitting 3M FFR	Nanofibre FFR	*P*-value
Normal breathing	198.09±7.62	199.48±2.97	>0.05	151.27±69.56	169.64±59.84	>0.05
Deep breathing	197.27±11.95	198.53±10.58	>0.05	152.07±68.20	169.34±57.84	<0.05[a]
Head side to side	192.06±25.07	198.31±8.17	<0.05[a]	149.80±70.62	161.97±63.84	>0.05
Head up and down	186.98±30.89	194.56±20.84	<0.05[a]	143.48±70.24	165.06±60.67	<0.05[a]
Talking	191.08±23.46	195.33 (19.30)	>0.05	150.94±61.32	164.39 (54.28)	>0.05
Bending over	174.86±42.63	179.16±47.46	>0.05	129.27±72.63	144.78±67.78	>0.05
Normal breathing	184.68±33.95	191.12±30.29	>0.05	143.26±70.13	159.73±66.48	>0.05
Overall fit factor	185.08±24.52	188.44±25.28	>0.05	135.52±68.33	149.13±59.95	>0.05
				N (%)	*N* (%)	
Fit factor (1–99)	–	–	–	35 (33.7%)	21 (21.2%)	$\chi^2 = 0.66$,
Fit factor (≥100)				69 (66.3%)	82 (78.8%)	*P*=0.417

Values are mean±standard deviation unless otherwise indicated.
[a] Statistically significant at $P<0.05$, computed by paired Student's *t*-test.

participants failed after the procedures when wearing the nanofibre FFR (χ^2=0.66, *P*=0.417) (Table II). No association was found between the specific variables (sex, year of study, age, clinical experience and body mass index) and fit factor (pass/fail) following the procedures (Table SI, see online supplementary material). The nanofibre FFR had consistent and significant higher usability than the 3M FFRs for all eight parameters (i.e. facial heat, breathability, facial pressure, speech intelligibility, itchiness, difficulty of maintaining the mask in place, comfort on ear lobe and overall comfort level) (*t*=5.28, *P*<0.001) (Table III). For physical properties, 10 FFRs of each model were tested, and the average of the values were taken. The nanofibre FFR was lighter and thinner than the three 3M FFRs (i.e. 1860, 1860S, 1870 Plus). Air permeability of the nanofibre FFR was lower than that of the N95 flat-fold model (1.050 kPa·s/m vs.1.2716 kPa·s/m) but slightly higher than the cup-shaped model. The OWTC and OMMC values of all FFRs were <50 and 0–0.2, respectively, indicating Grade 1 (poor). The bacterial filtration efficiency of the nanofibre FFR was slightly higher than that of the 3M models (99.9% vs 99.0%). Table IV shows the details of the physical properties of FFRs.

Discussion

This study showed that the nanofibre FFR has a better facial seal and higher usability than the 3M FFRs. Although the fit factors of the nanofibre FFR were higher than the best-fitting 3M FFR before and after the nursing procedures, the average fit factor of both FFRs decreased significantly after completion of the nursing procedures, as measured using QNFT at different body postures. This result is consistent with those from a previous study, which found that adequately sealed N95 FFRs may not provide consistent protection for the wearer whilst performing nursing procedures and that body movements may increase the risk of face seal leakage [15]. Accordingly, the prototype should be further enhanced for an improved respirator fit to guarantee the respiratory protection of users. In particular, the development of a superior fit FFR should be prioritized to eliminate or at least minimize face seal leakage during usage for procedures requiring body movements.

Meanwhile, discomfort was the most common reason given by HCWs for improper use of respirators [27]. Perceptions of increased body heat when wearing the N95 FFR are likely not

Table III
Comparison of usability between the best-fitting 3M filtering facepiece respirator (FFR) and nanofibre FFR after nursing procedures (*N*=104)

	Best-fitting 3M FFR	Nanofibre FFR	*P*-values[a]
Facial heat	3.76±0.87	4.12±0.73	<0.001[c]
Breathability	3.63±0.99	4.32±0.61	<0.001[c]
Facial pressure	3.54±1.10	4.08±0.82	<0.001[c]
Speech intelligibility	3.81±0.92	4.20±0.78	<0.01[b]
Itchiness	3.82±0.92	4.23±0.85	<0.001[c]
Difficulty of maintaining the mask in place	3.74±0.94	4.05±0.70	<0.01[b]
Comfort on ear lobe	3.85±1.02	4.23±0.71	<0.01[b]
Overall comfort	3.71±0.89	4.21±0.53	<0.001[c]

Values are mean±standard deviation unless otherwise indicated.
1, very unsatisfactory; 5, very satisfactory.
[a] Comparison of means using Wilcoxon signed ranks test.
[b] Statistically significant at $P<0.01$.
[c] Statistically significant at $P<0.001$.

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Table IV
Physical properties of N95 3M and nanofibre filtering facepiece respirators (FFRs)[a]

	3M 1860/1860S	3M 1870 Plus	Nanofibre
			
NIOSH approved	N95	N95	N95
Shape	Cup	Flat-fold	Flat-fold
Size	Regular or small	Standard (one size only)	Standard (one size only)
Weight (g/m^2) Mean (SD)	9.04356 ± 0.00017	10.14386 ± 0.00029	4.8795±0.442
Thickness (mm) Mean (SD)	2.506±0.063	1.846±0.038	0.5184±0.025
Air permeability [ventilation resistance R (kPa·s/m)]	0.9280±0.0024	1.2716±0.0611	1.050±0.065
Cumulative one-way transport capacity	-195.085±53.250	-309.692±97.127	-696.261±19.759
Overall moisture management capacity	0.000±0.000	0.044±0.066	0.000±0.000
Bacterial filtration efficiency	99.0%	>99.0%	>99.9% (Nelson lab tested)
Exhalation valve	No	No	No
Tethering devices	Braided headbands, cushioning nose foam	Soft inner materials and soft nose foam; sculpted top panel helps improve field of vision, and reduce eyewear fogging; chin tab for ease of positioning, donning and adjustment	Soft inner materials and soft nose foam
Other features	–	Three-panel flat-fold design for convenient storage prior to use	Flat-fold design for convenient storage prior to use
FDA cleared	Yes	Yes	No

NIOSH, National Institute for Occupational Safety and Health; FDA, Food and Drug Administration; SD, standard deviation.
[a] Ten specimens were tested for each FFR.

caused by effects on core temperature but may be associated with warming of facial skin covered by the respirator and warming of inspired air [28,29]. Poor communication and speech intelligibility have been shown to be concerns when wearing a respirator, given the potential for miscommunication that leads to critical treatment mistakes [12]. The nanofibre FFR tested in this study had consistent and significantly higher usability than the 3M FFRs for all eight parameters, thereby providing an alternate option for HCWs.

Electrospinning technology has enabled NAMI to successfully combine meltblown and spunbond fibres with nanofibres with diameters ranging from a few nanometres to a few hundred nanometres. This result cannot be obtained using traditional fabrication techniques. The nanofibre FFR can trap small particles effectively using various mechanisms, such as Brownian diffusion, because these masks are characterized by a small fibre diameter and high specific surface area [30]. Therefore, the nanofibre FFR was thinner and more breathable than traditional N95 FFRs (as indicated in the usability results), thereby enhancing general comfort for users. This feature encourages users to keep nanofibre FFRs on their faces, thereby possibly leading to improved user compliance.

In this study, the best-fitting 3M FFRs for the participants (in sequence) were 1870+, 1860S and 1860. Model 1870+ and the nanofibre FFR are flat-fold in shape, whereas the 1860 series are cup-shaped. An experimental study using stereophotogrammetry technology on 20 subjects found that more individuals passed fit testing when wearing flat-fold respirators than when wearing cup-shaped respirators. It was demonstrated that flat-fold N95 respirators offer the possibility of enhanced facial comfort without compromising protection [31].

Studies have shown that FFRs with additional weight could impose an ergonomic burden that translates into cardiac stress [32] and reduce work performance time [33]. The nanofibre FFR tested in this study was lighter than the 3M models, thereby possibly contributing to minimal cardiac stress burden and longer work performance time for the nanofibre mask. A study on the in-vivo protective performance of surgical marks and N95 respirators demonstrated that nano-masks have stronger water repellency and antibacterial activities than normal N95 and surgical masks. The coating of nano-functional particles for enhancement of water repellency could account for a slightly higher bacterial filtration efficiency in the nanofibre FFR than in 3M models (99.9% vs 99.0%).

The nanofibre FFR has significantly higher air permeability (lower air resistance) than the N95 flat-fold model, indicating that the nanofibre FFR is more breathable. The three FFR models are made of non-woven fabrics, which provide specific functions such as filtration and can be used as a bacterial barrier. However, these fabrics are also liquid repellent. Thus, the three FFR models have poor cumulative one-way transport capacity and overall moisture management capacity.

The Project Better Respiratory Equipment using Advanced Technologies for Healthcare Employees (BREATHE) Working Group, which comprises numerous federal stakeholders, was formed in the USA in 2008 to discuss strategies for improving respirator compliance, including the need for comfortable respirators. The Working Group developed 28 desirable performance characteristics for a new class of respirators (B95) which would substantially address the unique needs of HCWs [12]. Although the nanofibre FFR tested in this study could not fulfil all the B95 recommendations, this project attempted to address those wearer-subjective factors on respirator usability that may enhance compliance, including improvement of breathability, causing minimal discomfort from pressure on the face, inducing minimal facial heat and causing minimal facial irritation and allergenicity. Considerable effort should be exerted to improve the prototype design to attain the other B95 recommendations in the near future.

Limitations and recommendations

Given the limited scope of this study, the prolonged tolerability, cost-effectiveness and shelf-life durability of FFRs were not examined. Moreover, the thermophysiologic impact (e.g. cardio-respiratory parameters and thermal stress) of N95 FFRs on HCWs under prolonged use of respirators should be determined in future studies to simulate clinical situations.

In conclusion, the findings of this study demonstrated that the nanofibre FFR had a higher pass rate on fit testing and significantly better usability than the 3M FFRs. The nanofibre FFR was also lighter, thinner and had slightly higher bacterial filtration efficiency than the 3M FFRs. However, none of the FFRs could provide consistent protection for the wearer, as detected by face seal leakage after performing nursing procedures. Consequently, further effort should be exerted to improve the prototype design with superior fitness and high usability, thereby increasing compliance and ensuring the respiratory protection of users.

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Conflict of interest statement

None declared. To prevent any potential conflict of interest, the Profit Royal Pharmaceutical Limited, which supplied the nanofibre masks tested in this study, did not participate in the data analyses.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jhin.2019.09.014.

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