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Major article

Impact of multiple consecutive donnings on filtering facepiece respirator fit

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Background: A concern with reuse of National Institute for Occupational Safety and Health—certified N95 filtering facepiece respirators (FFRs) is that multiple donnings could stress FFR components, impairing fit. This study investigated the impact of multiple donnings on the facepiece fit of 6 N95 FFR models using a group of 10 experienced test subjects per model.

Methods: The TSI PORTACOUNT Plus and N95 Companion accessory were used for all tests. After qualifying by passing a standard Occupational Safety and Health Administration fit test, subjects performed up to 20 consecutive tests on an individual FFR sample using a modified protocol. Regression analyses were performed for the percentage of donnings resulting in fit factors (FFs) ≥100 for all 6 FFR models combined.

Results: Regression analyses showed statistical significance for donning groups 1-10, 1-15, and 1-20. The mean percentage of donnings with an FF ≥100 was 81%-93% for donning group 1-5, but dropped to 53%-75% for donning group 16-20.

Conclusions: Our results show that multiple donnings had a model-dependent impact on fit for the 6 N95 models evaluated. The data suggest that 5 consecutive donnings can be performed before FFs consistently drop below 100.

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The National Institute for Occupational Safety and Health (NIOSH) certifies respirators under federal regulation 42 CFR 84.[1] The N95 class of filtering facepiece respirators (FFRs) is commonly used to reduce exposure to airborne particulates, including solid and nonoil liquid aerosols in industrial settings and influenza and *Mycobacterium tuberculosis* in health care settings.[2-6] Components of a respiratory protection program are described in the Occupational Safety and Health Administration's (OSHA) Respiratory Protection Standard 29 CFR 1910.134.[7] N95 FFRs and N95 disposable filter elements for elastomeric respirators can be used and reused in accordance with current NIOSH recommendations, which limit the service time based on considerations of hygiene, damage, increased breathing resistance, and total mass filter loading of <200 mg.[8] The facepiece is reusable in elastomeric respirators, and these service time recommendations apply only to their disposable filter elements. FFR reuse also may be appropriate in a respiratory protection program designed to reduce exposure to *M tuberculosis*.[3,4] In the context of reuse, it is important to understand that *M tuberculosis* is usually transmitted only through air, not by surface contact.[3] One study determined that FFRs can be reused for protection against *M tuberculosis* with little risk of internal contamination if handled and stored properly.[9] FFR reuse in the context of other organisms, such as influenza, may be more complicated due to the risk of contact transmission from touching a contaminated FFR surface and subsequently touching facial mucous membranes.[10] However, given the potential for an N95 FFR supply shortage during an influenza pandemic,[11] the Centers for Disease Control and Prevention suggests that health care facilities can conserve supplies of N95 FFRs by considering a multilayered approach to infection control that includes extended use (ie, wearing an FFR for serial patient encounters without removing or redonning) and reuse (ie, removing and redonning an FFR between patient encounters).[10]

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A concern with FFR reuse is that multiple donnings could stress components (ie, head straps, strap attachments, adjustable nosepieces, etc), which over time could impair the fit. A poorly fitting FFR facepiece allows leakage of contaminants into the breathing zone by introducing gaps in the interface region between the face and the respirator seal. Only a few previous studies have studied FFR facepiece fit over multiple donnings. Campbell et al[12] described a quantitative analysis of fit test errors that suggested that improved consistency and accuracy of fit tests can be achieved by developing a 5-donning fit test. Coffey and coworkers[13-15] incorporated multiple-donning methods into their fit test studies of N95 respirators; however, their studies did not assess the trend in fit factor (FF) changes, but rather calculated means and standard deviations. Viscusi et al[16] found that the facepiece fit of N95 FFRs that had been through a cycle of various decontamination processes retained good fit characteristics over 5 consecutive donnings. Because the effects of multiple donnings on facepiece fit have not been well studied, NIOSH is continuing its research efforts in this area.

Given the possibility of a future need to reuse FFRs multiple times in the event of supply shortages caused by an influenza pandemic or another type of large-scale infectious disease event, the present study was undertaken to assess the impact of multiple serial donnings on FFR facepiece fit. A sequence of 10 consecutive donnings was determined to be a reasonable testing scenario, assuming a hypothetical (maximum) 10-hour work shift during which an FFR would be donned once per hour; however, we chose to double the number of donnings to 20 to provide a rigorous worst-case testing scenario. This study tested the experimental hypothesis that FFR fit is expected to decrease (ie, become worse) over multiple consecutive donnings.

MATERIALS AND METHODS

Respirator selection

Six different NIOSH-certified N95 FFR models were evaluated, including 3 N95 respirators (Moldex 2200 [Moldex, Culver City, CA], 3M 8000 [3M, St. Paul, MN], and 3M 8210 [3M]) and 3 surgical N95 respirators (Kimberly Clark PFR95-270 [46767] [Kimberly Clark, Neenah, WI], 3M 1860 [3M], and 3M 1870 [3M]). Surgical N95 respirators are NIOSH-certified N95 respirators that also have been approved by the US Food and Drug Administration for use in health care settings.[17] The models used in the present study are among those purchased for the US Strategic National Stockpile (SNS), and their facepiece fit was previously evaluated by our research group.[16] The 3 N95 respirators were randomly coded as N95-A, N95-B, and N95-C; the 3 surgical N95 respirators, as SN95-D, SN95-E, and SN95-F. The 6 models chosen varied in terms of head strap materials and method of attachment to the FFR body (ie, stapled or welded).[16] To simplify the study, only the regular or universal size of these models was included; no other FFR sizes (eg, small, large) were tested. Five models had a formable metallic nosepiece, and 1 model had an inner nonadjustable nose cushion.

Fit testing

Fit tests were conducted using the model 8020A PORTACOUNT Plus Fit Tester with a model 8095 N95 Companion accessory (TSI, Shoreview, MN).[18] FitPlus for Windows software (TSI) installed on a laptop computer automated the fit test data collection and was used for data recording purposes. The PORTACOUNT tester uses condensation nuclei counting technology to count individual particles to determine a quantitative estimate of respirator fit. Fit testing was carried out in a controlled laboratory environment (21 ± 2°C; relative humidity of 50% ± 10%).

Study qualification

This study was approved by the NIOSH Human Subject Review Board, and all subjects provided written consent to participate. Study participants were experienced respirator test subjects who had participated in previous fit test studies at our laboratory. Each subject was first required to pass a standard OSHA-accepted 8-exercise fit test[7] to establish that he or she could achieve an FF ≥100 (passing) with each N95 FFR model. Subjects were allowed 2 trials to achieve a passing result. If a passing result was not achieved on the first trial, the same FFR sample was redonned for a second attempt. Only subjects who could achieve a passing result for each particular FFR model were qualified to test that model in the multiple-donning evaluation. This qualification fit testing resulted in a total of 17 subjects (10 men and 7 women) participating in the study to achieve a group of 10 qualifying subjects for each of the 6 different FFR models. Thus, each FFR model had a slightly different cohort of 10 subjects depending on which subjects were qualified for each model. Of the 17 subjects, only 3 subjects were qualified for all 6 models; the other 14 subjects were qualified for varying numbers of models.

Experimental phase

A shortened 121-second PORTACOUNT protocol was used for the multiple-donning fit testing (Fig 1). This protocol was developed and used by Viscusi et al[16] to minimize subject test time when performing multiple-donning fit tests. The protocol has the subject perform only 6 test exercises, compared with 8 exercises for the standard OSHA-accepted test. The first normal breathing exercise is longer (70 seconds) because of the additional time required to clear internal pathways of particles and measure the ambient particle concentration. The typical grimacing and bending exercises are not included in this protocol, in an effort to shorten the test. The modified protocol calculates an integrated FF for the 6 test exercises. This calculation method differs from the standard OSHA-accepted 8-exercise fit test method in which the overall FF is calculated as the harmonic mean of FFs obtained from 7 of the fit test exercises; an FF for the grimacing exercise is not included in the calculation. The FF for the modified protocol was calculated as the ratio of the ambient particle concentration divided by the mask concentration.

Two replicate FFR samples were tested by each subject in the multiple-donning fit test portion of the study. All subjects were trained on the proper donning and user seal check procedures for each model following the manufacturer's user instructions. To begin, the subject donned the FFR, performed the user seal check, and made any necessary adjustments to the FFR until they felt they had achieved a good fit. Next, the subject wore the FFR for a 3-minute acclimatization period. After acclimatization, the FFR was then consecutively fit tested up to 20 times, with the user seal check procedure and acclimatization period applied for each test. In the FFRs with a metallic nosepiece, the nosepiece was straightened to its original position by the test technician after each fit test. Although this straightening step might not be representative of actual workplace use, it was felt that performing this procedure would encourage the subject to correctly perform all of the necessary adjustments to the FFR before each fit test. The procedure also provided a rigorous test of the integrity of the nosepiece as it was adjusted for each donning.

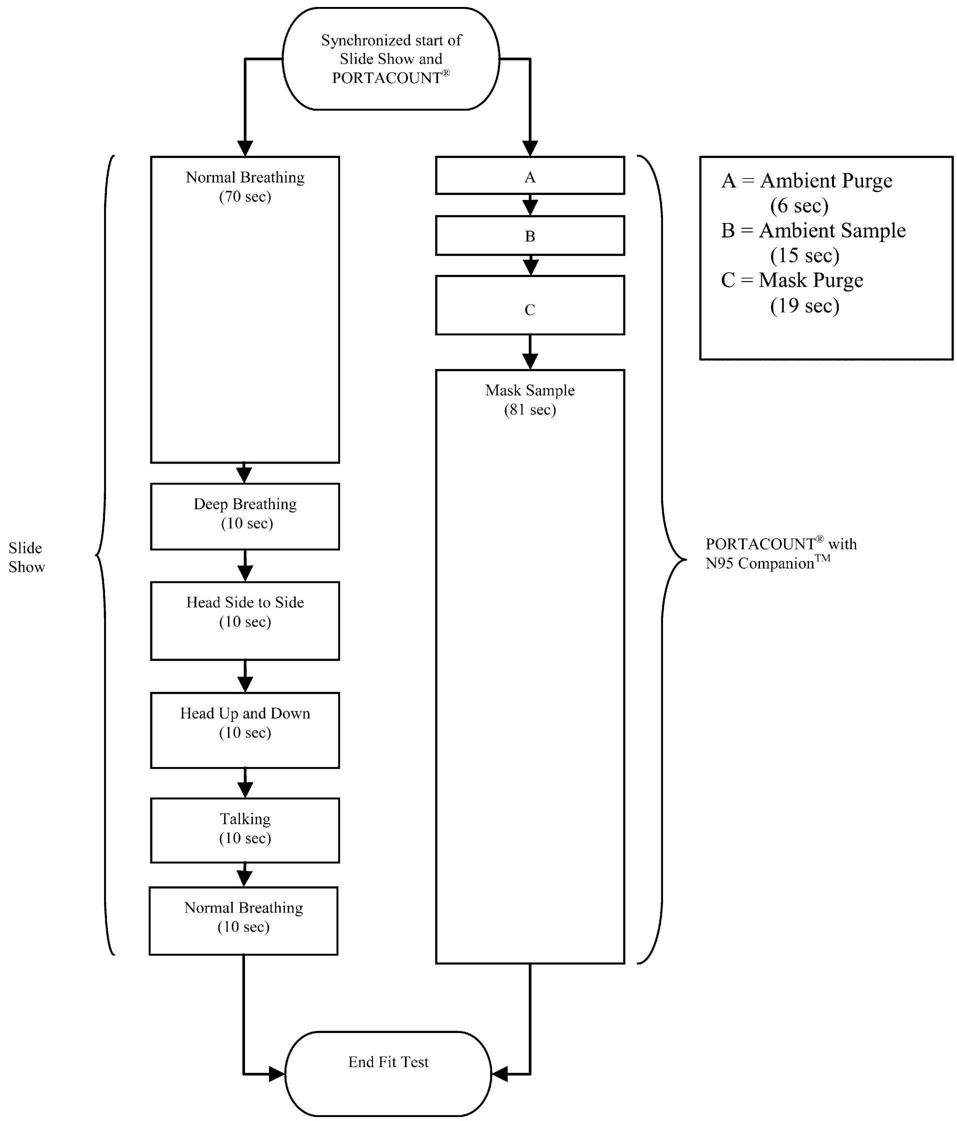

Fig 1. Fit test protocol flow chart.

For these experiments, an FF ≥100 was considered "passing," and an FF <100 was considered "failing." Even though the multiple-donning fit test protocol was not designed to be equivalent to the standard OSHA-accepted PORTACOUNT test, similar pass/fail criteria were used. Consecutive fit testing was terminated after the recording of 3 consecutive fit tests with an FF <100. This decision was based on the expectation that the test performance of an FFR with 3 consecutive FFs <100 would be unlikely to improve, and thus continuing testing would be of little value. This expectation was based on data trends observed in a previous multiple-donning fit test study in which FFs for 5 sequential donnings were generally observed to follow a trend of either >100 or <100 over 5 donnings.[16] Testing also was terminated if a head strap break occurred, which precluded proper donning of the FFR. During testing, 5 instances of unanticipated nosepiece breakage occurred for the SN95-D; the nosepieces broke in the center, but did not become detached from the FFR body. In an actual workplace setting, an FFR with a broken nosepiece would immediately be discarded and replaced with a new one in accordance with NIOSH service time recommendations;[8] however, we chose to continue testing to determine the negative consequences of continuing to use a broken device.

Data analysis and statistics

Two replicate samples were tested for each of the 10 qualifying test subjects, resulting in 20 samples for each FFR model. For each model, the donnings with an FF ≥100 at each donning interval were counted for each of the 20 donning sets. If testing had been terminated due to the occurrence of 3 consecutive fit tests with an FF <100 or a strap break, then the later remaining "nontests" for that sample were counted as failures; for example, if testing was stopped at donning 12, then donnings 13-20 were all counted as failures. Next, the percentage of fit tests with an FF ≥100 was calculated for each of the 20 donning sets.

For each FFR model, the arithmetic mean and standard deviation percentage of fit tests with an FF ≥100 were calculated for donnings 1-5, 6-10, 11-15, and 16-20. Finally, paired 1-tailed *t* tests were used to compare the mean values from the first set of 5 donnings (1-5) with those of the second set (6-10), the third set (11-15), and the fourth set (16-20).

Regression analyses were performed to evaluate the relationship between donning interval and the percentage of fit tests with an FF ≥100 for all FFR models combined as well as for each FFR model individually. In addition, the frequency of terminal failures—3 consecutive FFs <100, head strap breaks, and nosepiece breaks—were tabulated. All statistical analyses were performed using Microsoft Office Excel 2007 (Microsoft, Redmond, WA).

RESULTS

Table 1 summarizes the occurrences of 3 consecutive fit tests with FFs <100 and 2 types of damage that occurred during testing: head strap breaks and nosepiece breaks. For the purpose of discussion, we term these occurrences "terminal failures" because testing was discontinued after 3 consecutive fit tests with an FF <100 and a head strap break; although we continued testing FFRs with broken nosepieces to determine the effects on fit, broken nosepieces are counted as terminal failures in Table 1. This is because in an actual workplace, an FFR damaged in this way would be immediately discarded and replaced with a new one. Head strap breaks occurred in only 2 FFR models (N95-C and SN95-E), each of which had 4 breaks. The last completed fit test donnings before the breaks occurred were donnings 3, 4, 5, and 8 for 4 different N95-C samples and donnings 5, 17, 17, and 18 for 4 different SN95-E samples.

The SN95-D was the only model to experience nosepiece breaks (5 total), and all of the nosepiece breaks were associated with 3 consecutive fit test failures (FF <100), demonstrating that a broken nosepiece does not allow a good fit. All of the broken nosepieces were noticed by the test subjects on either the first or second consecutive fit test. Interestingly, 1 subject experienced a broken nosepiece on both test samples, and the 3 consecutive FFs <100 for both samples occurred on donnings 8-10. The other 3 incidents of 3 consecutive fit tests resulting in an FF <100 associated with a broken nosepiece occurred during donnings 16-18, 17-19, and 18-20 in 3 different test subjects.

Figure 2 plots the percentage of fit tests with an FF ≥100 for each model for all 20 donnings. An overall reduction for all models is shown; however, it is notable that for donning 20, values range from 55% (for N95-A, N95-B, and SN95-D) to 65% (for SN95-E and SN95-F). The trend line shown with $R^2 = 0.48$ was computed from a regression analysis of all data for all 6 FFR models.

Regression analysis of percentage of fit tests with an FF ≥100 for all 6 FFR models combined for donnings 1-5, 1-10, 1-15, and 1-20 resulted in R^2 values of 0.04, 0.23, 0.30, and 0.48, respectively, indicating that more variation in the regression line is accounted for when more donnings are added to the regression. Significant *P* values (<.05) were obtained for the regression models of donnings 1-10, 1-15, and 1-20. In addition, when the regression analyses were performed separately for each model for all 20 donnings, the regression models for all 6 FFR models demonstrated statistical significance ($P < .05$) and R^2 values ranging from 0.40 (for SN95-D) to 0.78 (for N95-B).

Table 2 summarizes the mean percentage of fit tests with FFs ≥100 for the groups of 5 donnings for each model, showing an overall reduction in mean values for the later donning groups. Nonetheless, the values were >50% for donning group 16-20, with a range of 53% ± 4% (N95-B) to 75% ± 9% (SN95-E). *t* tests for each FFR model comparing means for donnings 1-5 with those for the later donning groups found statistically significant reductions for donnings 11-15 for N95-A, N95-B, and N95-C. For all 6 models, the means for donnings 16-20 were statistically reduced compared with those for donnings 1-5.

The frequency of terminal failures by donning number for all 6 FFR models combined are presented in Table 3. For the purpose of this analysis, failures are classified as type 1 or type 2. Type 1 failures include all 3 types of terminal failures (ie, 3 consecutive FFs <100, head strap breaks, and nosepiece breaks). Type 2 failures include only 3 consecutive FFs <100. The importance of the type 2 classification is that this is the only type of terminal failure that cannot be detected by a user in the workplace setting. Because all occurrences of nosepiece breaks were also associated with 3 consecutive FFs <100, their type 1 frequency was counted only once for the donning number of the first fit test with an FF <100. For head strap breaks, the type 1 frequency was counted at the donning at which data could no longer be collected. For example, if the last successful fit test occurred on donning 3, then the failure was counted for donning 4. For both type 1 and type 2 classifications, the frequency for a set of 3 consecutive FFs <100 was counted once for the donning of the first failure.

Table 1
Frequency of terminal failures by the FFR model

FFR model	3 consecutive FFs <100	Head strap break	Nosepiece break
N95-A	6	0	0
N95-B	7	0	0
N95-C	4	4	0
SN95-D	1	0	5*
SN95-E	2	4	0
SN95-F	4	0	0
Total	24	8	5

*The 5 nosepiece breaks also experienced 3 consecutive FFs <100.

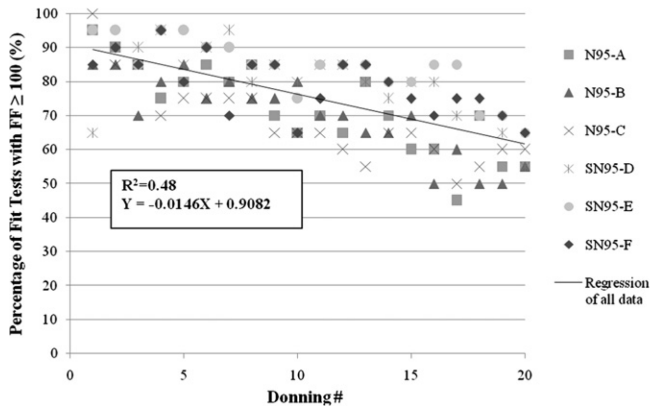

Fig 2. Percentage of fit tests with an FF ≥100 for each FFR model.

Table 3 shows a cumulative failure rate of 3.3% for donning 1 for both type 1 and type 2 failures. This cumulative failure rate for donning 1 comprises only fit tests beginning on the first donning that resulted in 3 consecutive FFs <100 for each of donnings 1, 2, and 3; no test subjects experienced a head strap or nosepiece break on their first donning. We refer to this cumulative failure rate for donning 1 as the fit test error rate. It is likely caused by some combination of fit test beta (β) error, respirator sample-to-sample variability, and the inherent variable nature of respirator fit testing. Coffey et al[15] described the fit test β error as the fraction of test subjects who passed a fit test in error. Their study found a 6% β error for 33 different FFR models tested using the PORTACOUNT with N95 Companion. The β error in the present study can be attributed to any test subjects who passed the standard OSHA-accepted qualifying fit test in error (ie, should not have qualified for that particular model). Sample-to-sample variability of individual FFR models and variable respirator fit test results (as observed in other studies) are other likely contributors to this fit test error rate.[19-22]

The raw fit test data with anonymously coded manufacturer/model identifiers will be made available to the public at the NIOSH/National Personal Protective Technology Laboratory Web site (http://www.cdc.gov/niosh/npptl/). These raw data may be of

Table 2
Mean percentage of fit tests with an FF ≥100 by the FFR model

Donning	N95-A, %	N95-B, %	N95-C, %	SN95-D, %	SN95-E, %	SN95-F, %
1-5	85 ± 8	81 ± 7	83 ± 12	85 ± 12	93 ± 4	87 ± 6
6-10	77 ± 9	77 ± 3	71 ± 5	86 ± 7	85 ± 6	79 ± 11
11-15	69 ± 7	68 ± 3	62 ± 4	81 ± 4	83 ± 3	80 ± 5
16-20	57 ± 9	53 ± 4	57 ± 4	68 ± 9	75 ± 9	71 ± 4

interest to researchers, respirator program administrators, and respirator use policy developers.

DISCUSSION

Changes in facepiece fit over multiple donnings is an issue requiring evaluation for effective FFR reuse. A respirator cannot provide optimal protection unless it fits properly, with a good seal around the face. A recent study found that most of the aerosol contaminants that enter an N95 FFR worn by human test subjects are the result of face seal leakage, not filtration performance.[23] Human subject studies also have demonstrated the importance of fit testing for achieving high levels of simulated workplace protection factors.[13,24]

The statistical analyses of percentage of fit tests with an FF ≥100 in this study support the experimental hypothesis that FFR fit gradually decreases after multiple consecutive donnings; however, good fit was observed for some subjects even after 20 donnings. The best levels of fit were observed for donnings 1-5 (Table 2), likely because of the relatively little wear on FFR components (eg, head straps and nosepieces) compared with later donnings, although the role of the criteria used for determining terminal failures cannot be discounted. Interestingly, FFs ≥100 were achieved in 55%-65% of the tests on the 20th donning (Fig 2). This result was unexpected, given that the FFR models tested were not necessarily designed for multiple reuse. In addition, for donning 20, the percentage of fit tests with an FF of 200 (the highest achievable FF) ranged from 30% (for SN95-D) to 65% (for SN95-E). Another interesting observation was the number of tests (out of a possible 20) for each model that achieved an FF of 200 for all 20 donnings: 3/20 tests for N95-A, 3/20 tests for N95-B, 5/20 tests for N95-C, 1/20 tests for SN95-D, 7/20 tests for SN95-E, and 6/20 tests for SN95-F. Overall, the good levels of fit achieved for some test subjects after 20 donnings are notable, because N95 FFRs are generally considered to be limited-use devices.

For type 1 failures, which comprise all 3 types of terminal failures, a cumulative failure rate of 8.3% was seen at donning 3 (Table 3). When the fit test error rate of 3.3% is subtracted, the resulting rate is 5.0%. If we arbitrarily consider that a 5.0% failure rate should not be exceeded in the workplace, then we can argue that only 2 donnings should be performed before the FFR is discarded. It might be better to consider this type of analysis for type 2 failures, where the failure rate is tabulated only on the basis of 3 consecutive FFs <100, because users in the workplace have no way of knowing the numerical FF achieved on each donning; this analysis excludes head strap and nosepiece breaks, which would readily be noticed by users. Here donning 6 becomes important, because when the fit test error of 3.3% is subtracted from its failure rate of 9.2%, the resulting rate is 5.9%. Again if we deem that an arbitrary 5.0% failure rate should not be exceeded in the workplace, then we can recommend that only 5 donnings be performed before the FFR is discarded, although the surprising number of donnings with an FF >100 measured at donning 20 suggests that further studies are needed before any specific recommendations can be made.

Table 3
Frequency of terminal failures by donning for all 6 FFR models combined

Donning	Frequency type 1*,§	Cumulative type 1 failure rate, %†	Frequency type 2‡	Cumulative type 2 failure rate, %†
1	4	3.3	4	3.3
2	2	5.0	2	5.0
3	4	8.3	2	6.7
4	1	9.2	0	6.7
5	1	10.0	0	6.7
6	4	13.3	3	9.2
7	0	13.3	0	9.2
8	2	15.0	0	9.2
9	2	16.7	1	10.0
10	2	18.3	2	11.7
11	0	18.3	0	11.7
12	0	18.3	0	11.7
13	3	20.8	3	14.2
14	1	21.7	2	15.8
15	1	22.5	1	16.7
16	4	25.8	3	19.2
17	2	27.5	1	20.0
18	3	30.0	0	20.0
19	1	30.8	0	20.0
20	0	30.8	0	20.0

*Type 1 terminal failures include 3 consecutive FFs <100, head strap breaks, and nosepiece breaks.
†The denominator is 120 fit tests for all rows. 120 fit tests = 6 FFR models × 10 test subjects × 2 FFR samples.
‡Type 2 terminal failures are 3 consecutive FFs <100 only.
§Because all occurrences of nosepiece breaks were also associated with 3 consecutive FF failures (FF <100), their frequency is counted only once.

The results of this study should be viewed within the context of a laboratory study that used an abbreviated fit test protocol and a small group of test subjects. Moreover, test subjects wore the FFRs for a shorter total test time of ~5 minutes (which includes the 3-minute acclimatization period) using our modified protocol compared with the ~12 minutes in the standard OSHA-accepted protocol. Had the OSHA-accepted protocol been used instead for the multiple-donning tests, lower FFs might have resulted from the greater stress imparted on head straps and other FFR components. The continuous duration of FFR use in health care settings is likely to vary under different circumstances (eg, type of procedure being performed), and thus our results might not directly correlate with FFR use in the workplace under some circumstances. Our protocol incorporated straightening of the nosepiece before each fit test, which also may not represent actual workplace practice. In addition, different criteria for terminating testing (eg, changing from 3 to 5 consecutive FFs <100) would have resulted in slightly different results. Because of the limitations and context of this study, our findings do not directly translate to FFR reuse under actual workplace conditions or correlate with clinical protection against airborne disease. Given that both NIOSH and Centers for Disease Control and Prevention guidelines permit multiple reuse of FFRs under certain conditions, more research is needed to assess how FFR reuse affects fit under actual workplace conditions. Workplace protection factor studies could be designed for this purpose. Building a larger body of research in this area will provide data for regulatory agencies and public health organizations to use in developing new or revised guidelines for multiple reuse of FFRs.

CONCLUSION

Using our criteria for terminating testing, our results indicate that multiple donnings have an impact on the fit of all 6 N95 FFR models evaluated, and that this impact is model- dependent. Although statistical decreases in fit were observed, FFs ≥100 were achieved for 55%-65% of tests on the 20th donning. By calculating terminal failure rates resulting from 3 consecutive fit tests achieving FFs <100 and subtracting the fit test error of 3.3%, the data suggest that 5 consecutive donnings can be performed before FFs consistently drop below 100. However, this conclusion does not constitute a recommendation to limit the number of consecutive donnings to 5 for the FFR models studied or any other models outside of this study. The data presented here combine the terminal failure rates of the 6 FFR models evaluated, and, as shown in Table 1, the occurrences and types of terminal failures varied by model. Our results can be used as a starting point for further research on the effects of multiple donnings and by respirator manufacturers in efforts to improve product design or revise service life recommendations. Further research is needed to better understand the limitations of FFR reuse, especially in actual workplace settings.

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