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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) $\geq$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 $\geq$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.

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 ($21 \pm 2^{\circ}C$; relative humidity of $50\% \pm 10\%$).

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 $\geq$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.