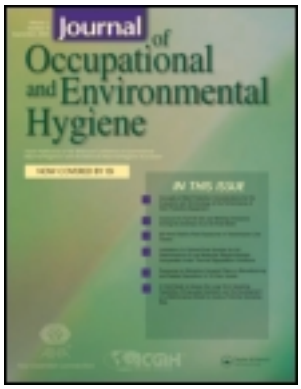

Journal of Occupational and Environmental Hygiene
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/uoeh20

Evaluation of the Benefit of the User Seal Check on N95 Filtering Facepiece Respirator Fit

Dennis J. Viscusi [a], Michael S. Bergman [a], Ziqing Zhuang [a] & Ronald E. Shaffer [a]
[a] National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, Pennsylvania

Available online: 13 Apr 2012

To cite this article: Dennis J. Viscusi, Michael S. Bergman, Ziqing Zhuang & Ronald E. Shaffer (2012): Evaluation of the Benefit of the User Seal Check on N95 Filtering Facepiece Respirator Fit, Journal of Occupational and Environmental Hygiene, 9:6, 408-416

To link to this article: http://dx.doi.org/10.1080/15459624.2012.683757

Journal of Occupational and Environmental Hygiene, 9: 408–416
ISSN: 1545-9624 print / 1545-9632 online
DOI: 10.1080/15459624.2012.683757

Evaluation of the Benefit of the User Seal Check on N95 Filtering Facepiece Respirator Fit

Dennis J. Viscusi, Michael S. Bergman, Ziqing Zhuang, and Ronald E. Shaffer

National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, Pennsylvania

The objective of this study was to better understand the benefit of the user seal check step for respirator test subjects in the N95 filtering facepiece respirator donning process. To qualify for the study, subjects were required to pass a standard quantitative fit test on at least one of the three N95 filtering facepiece respirator models: 3M 1860 (cup), 3M 1870 (flat-fold), and Kimberly Clark PFR95-270 (duckbill). Eleven subjects were enrolled and performed a series of abbreviated, quantitative fit tests where they were randomly asked either to perform or not perform a user seal check with 20 different respirator samples of each model. The experimental design included 3 respirator models × 10 subjects × 2 treatment levels with 10 replications. Geometric mean (GM) fit factors and percentages of times a fit factor ≥ 100 was achieved for a donning were compared for each subject with and without the user seal check across all models and for each model. Higher GM fit factors and smaller geometric standard deviations across all models were achieved for 10 of the 11 subjects when performing a user seal check compared with not performing a user seal check. Geometric mean fit factors of 148, 184, and 156, compared with 126, 187, and 115, respectively, were obtained for the 3M 1860, 3M 1870, and Kimberly Clark PFR95-270 models when the user seal check was performed vs. not performed. Differences in the GM fit factors for the 3M 1860 and Kimberly Clark PFR95-270 models were statistically significant ($p < 0.05$) when performing a user seal check vs. not performing a user seal check. These data suggest that there may be some benefit to performing the user seal check for at least some models during the filtering facepiece respirator donning process for workers who have previously passed a fit test for those respirator models. Additional research is needed with larger groups of subjects and respirator models/types.

Keywords filtering facepiece respirator, fit check, fit test, health care workers, respiratory protection, user seal check

Correspondence to: Ronald E. Shaffer, Technology Research Branch, National Personal Protective Technology Lab (NPPTL), National Institute for Occupational Safety and Health (NIOSH), 626 Cochrans Mill Road, Building 29, P.O. Box 18070, Pittsburgh, PA 15236; e-mail: RShaffer@cdc.gov.

The findings and conclusions in this manuscript are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health (NIOSH). Mention of company names or products does not constitute endorsement by NIOSH.

INTRODUCTION

Both industry and health care commonly use National Institute for Occupational Safety and Health (NIOSH)-certified N95 filtering facepiece respirators (FFRs) to reduce their exposure to particulate hazards, including infectious aerosols. Research has shown that fit testing is necessary to ensure that tight-fitting respirators are properly worn and provide an expected level of protection.[1–3] Fit is the most important aspect of respiratory protection, as poorly fitting respirators allow contaminants to pass into the breathing zone by entering through leak sites around the periphery of the face-to-facepiece seal. Many studies have investigated the sizes and shapes and locations of leaks associated with the fit of elastomeric half-mask respirators, but less work has been with N95 FFRs.[4–9]

One important component of an Occupational Safety and Health Administration (OSHA) respiratory protection program is the user seal check (USC), which is a mandatory procedure performed while donning (putting on) an FFR during the initial and annual fit test, as well as part of the donning process during use.[10] A USC is performed to verify that an adequate face seal has been achieved. During the revision of ANSI Z88.2-1992 Standard for Respiratory Protection, the term "fit check" was changed to "user seal check" to avoid confusion between a fit check and a fit test.[11] This suggested change was subsequently incorporated into 29 CFR Part 1910.134 in 1998.[10] Brosseau[12] recently summarized the history of the USC, also citing the confusion in terminology surrounding "USC," "fit check," and "fit test." The term "respirators" may refer to both tight-fitting and loose-fitting facepieces, but as USCs are not performed on loose-fitting facepieces, only tight-fitting facepieces will be discussed in this article.

The effectiveness of the USC to detect poorly fitting N95 FFRs has been addressed in only a few studies.[13–16] Prior to 1998 (when positive and negative pressure USCs were still called +/− fit checks), Myers et al.[14] compared the number of successful donnings in two groups of 32 each inexperienced respirators users (one group was trained to perform a +/− fit

check and the second was not) for three models of FFRs and one model of elastomeric dual-cartridge half mask respirator. In general, the group that performed the +/− fit check on the FFRs achieved fewer unsuccessful donnings and more consistent donnings; however, the +/− fit check was shown to be less useful when there was already a good initial fit of the FFR.

In a second set of experiments in the same study, another population of 64 inexperienced subjects donned FFRs with pre-adjusted nosepieces and the elastomeric model with pre-adjusted straps, then performed the USC but were not permitted to readjust the respirators before the fit test. A measure of sensitivity was then calculated by dividing the number of failed fit tests where the user indicated a failed user seal check by the total number of failed fit tests. The sensitivity of fit checks ranged from 80–100% for FFRs and was 100% for the elastomeric half-mask respirator model indicating the user seal check provided a good indication of poor fit to the user.

Derrick et al.[14] conducted a retrospective review of nurses working in an intensive care unit in China. Study results indicated that the USC performed by subjects wearing N95 and N99 FFR wrongly indicated a good fit on 18–31% of occasions and wrongly indicated a bad fit on 21–40% of occasions. The USC was correct on 71–75% of occasions.

Lam et al.[15] did a prospective and cross-sectional research design involving 204 Chinese undergraduate nursing students and found that the USC step offers good specificity (89–90%), but low sensitivity (15–23%).

In the Danyluk et al.[16] study, 784 health care workers (containing both naïve and experienced users) were asked to perform a USC prior to both a qualitative and quantitative fit test. Of the 643 naïve users who "passed" the USC, 25% and 14% subsequently failed the quantitative and qualitative fit tests, respectively. Overall, these last three studies concluded that the USC was incapable of functioning as an alternative fit test, as it has unacceptably high incorrect passing and failure rates.

However, due to the limited number of studies, gross generalizations about USCs are difficult to make. For example, none of the previous studies focused on whether the USC benefits users operating within the context of an OSHA respiratory protection program (i.e., received training and passed an OSHA-accepted qualitative or quantitative fit test prior to use).

The objective of this study was to better understand the benefit of the USC step in the N95 FFR donning process for respirator users operating within the context of an OSHA-compliant respiratory protection program. To meet this objective, test subjects were first recruited, trained, and demonstrated proficiency by passing a standard OSHA quantitative fit test similar to a worker in an OSHA-compliant respiratory protection program. On a subsequent visit, they were asked to don the FFR multiple times (sometimes performing the USC during the donning process and sometimes not) and wear the device for several minutes prior to assessing whether the fit was acceptable or not.

METHODS AND MATERIALS

Respirators

Three commercially available, negative pressure, half-facepiece N95 FFR models (3M 1860, 3M 1870, and Kimberly Clark PFR95-270) were randomly selected from those surgical N95 FFR models present in the U.S. Strategic National Stockpile (SNS) at the time this research began. The FFR models chosen were also models widely used in U.S. hospitals and the health care community at the time of this writing. Surgical N95 respirators are NIOSH-certified N95 FFRs that are additionally cleared as medical devices by the U.S. Food and Drug Administration (FDA) for use in a health care setting.[17] Only the regular or universal size of these models was included in this study; no other FFR size such as small or large was included for the sake of simplicity. All FFRs were purchased and verified to be from the same respective manufacturing lot at the beginning of the study to minimize any lot-to-lot variation. The three models chosen each had a malleable metallic nosepiece for forming to the bridge of the nose and were diverse in their overall shape [3M 1860 (cup), 3M 1870 (flat-fold), and Kimberly Clark PFR95-270 (duckbill)].

Subjects

Eleven healthy, medically cleared test subjects (six men and five women) qualified for the study by passing a standard, eight-exercise OSHA quantitative fit test to establish that each subject could achieve an acceptable fit with each candidate N95 FFR model. This same qualifying methodology was used previously.[18–21] Only subjects that could achieve a passing fit factor (FF $\geq$ 100) for the standard OSHA quantitative fit test qualified to enroll in the follow-up USC evaluation with that particular FFR model. Only the first 10 subjects to qualify while wearing each model tested in the USC evaluation. This resulted in a slightly different cohort of 10 test subjects for each model, since 8 subjects qualified with all three models while the other 3 subjects qualified with only two FFR models each. The study was approved by the NIOSH Human Subjects Review Board. Subjects provided written consent to participate.

Although it was not the goal of this study to meet any particular distribution of facial sizes, all subjects had their face length (menton-sellion) and face width (bizygomatic breadth) measured using traditional measuring instruments (i.e., sliding and spreading calipers).

Experimental Design and Procedures

The experimental design used in this study involved 3 respirator models $\times$ 10 subjects $\times$ 2 treatment levels with 10 replications. The treatment levels are "performing USC" and "not performing USC." This design was needed because fit factors have large variability among respirator models and test subjects.[22] Donning to donning variability is also large.[23,24]

All fit testing was conducted using the Model 8020A PORTACOUNT Fit Tester with a model 8095 N95-Companion

(TSI, Inc., Shoreview, Minn.) accessory.[25] FitPlus for Windows (software developed by TSI, Inc.) installed on a laptop computer automated the fit test data collection. The maximum fit test value that can be obtained with this equipment in this configuration is >200. TSI Model 8026 particle generators were employed to supplement the room air with sodium chloride aerosol, as needed. The N95-Companion requires a minimum of 70 particles/cm^3 to operate within an optimal concentration range of 100–300 particles/cm^3.[25] Fit testing occurred under typical laboratory conditions (23 ± 2°C and relative humidity of 50 ± 10%) in a controlled laboratory environment. Technicians measured the ambient concentration of particles at least twice daily, typically at the beginning and end of a testing day.

In this experimental design, the USC step is a brief "self-test" occurring prior to an actual fit test to determine that a given FFR develops an acceptable "leak-free" seal with a subject's face. A successful USC determines whether or not the wearer feels that the respirator seals well enough with his or her face to proceed forward with the actual fit test.

In this study, a shortened 2-min fit test protocol was used.[18,19] A detailed explanation can be found elsewhere but will be described here briefly.[22] This protocol was chosen in an attempt to maximize the number of fit tests that could be accomplished in two hours, but still allow sufficient time between fit tests for the subject's face to acclimatize to the fit of the next FFR.

The test technician began each fit test by simultaneously starting the PORTACOUNT and a timed PowerPoint (Microsoft Corp., Redmond, Wash.) slide show used to cue the test subject of which exercise to perform and when to perform it. The six-exercise sequence in the abbreviated protocol included, in order: (1) normal breathing, (2) deep breathing, (3) turning head side to side, (4) moving head up and down, (5) talking (recitation of the "Rainbow Passage"), and (6) normal breathing. The first normal breathing exercise was longer (70 sec) due to an additional amount of time required by the system to clear internal pathways of particles and measure the ambient particle concentration; the subsequent five exercises were performed for 10 sec each. The normally included grimace and bending at the waist exercises were not included in this protocol to conserve test time.

The modified protocol calculates an integrated fit factor for the six test exercises. This calculation method differs from the standard OSHA-accepted eight-exercise quantitative fit test method where the PORTACOUNT calculates the overall fit factor as the harmonic mean of fit factors obtained from seven of the eight individual fit test exercises (a fit factor for the "grimace" exercise is not included in the calculation). The fit factor for this protocol was calculated as the ratio of the ambient particle concentration (sampled for 15 sec during the first normal breathing exercise) divided by the mask concentration (sampled for 81 sec during the six exercises).

Ten subjects per FFR model were selected a priori based on a power analysis that suggested that 10 subjects provided enough power to detect expected differences in fit between the two study conditions.[26] Test subjects were tested with 20 samples of each FFR model for which they qualified (10 samples tested with the USC step and 10 samples tested without the USC step). The samples were tested in two groups of 10 samples each; each group of 10 samples was randomized so that 5 samples were specified to be tested with the USC step and 5 samples were to be tested without the USC step. The time to test one group of 10 samples was approximately 1 hr. Depending on the length of time the subject was able to stay for each visit, some subjects tested both groups of 10 samples of an individual FFR model in the same visit, while some subjects tested each group of 10 samples on two separate visits.

For each donning, as instructed and observed by the test operator, the participant donned the FFR in accordance with manufacturer's user instructions. Based on the predetermined random sequence, the test operator told the subject to either perform or not perform a USC prior to donning the FFR. For those donnings where the subject performed a USC, he or she followed the manufacturer's USC instructions and was then asked to assess whether the FFR seal to his or her face was adequate or inadequate. If the subject judged the seal as inadequate, he or she doffed (removed) the FFR, gave it back to the technician who readjusted it as though it were new, and the subject redonned that FFR sample for up to two more times in an attempt to get an adequate seal. All subjects felt that they obtained a satisfactory seal within three trials.

Next, the FFR was worn for at least 3 min to acclimatize the user to wearing the respirator and to allow the FFR and the user's face time to equilibrate (warm and mold) and develop a seal with the subject's facial skin. This step also serves to simulate use of the FFR by a worker. The quantitative fit test began after the 3-min acclimation period. Once the fit test was completed, the subject doffed that FFR and was given another new FFR for the next trial or was finished testing for that day.

To decrease any possible unintentional learning effects from performing multiple donnings within a given test session, subjects were not informed of the results of the fit test (i.e., "blinded"). Although the computer that displayed the raw fit test data was not hidden from the subject's field of view, the test technicians did not verbalize the fit test outcome as "pass" or "fail," nor were subjects instructed to perform the next donning any differently based on the fit test outcome.

Statistical Analysis

To visualize differences in the individual fit factors (FF) obtained (by model) when performing the USC versus when not performing the USC, cumulative frequency distributions were created using Microsoft Excel (Microsoft). These distributions were created by graphing the number of FFs less than or equal to a specified FF (e.g., 10, 20, . . ., 200). Next, geometric mean (GM) and geometric standard deviation (GSD) fit factors were calculated and compared for each subject with and without the USC step across all models and for each model. Since FFs are

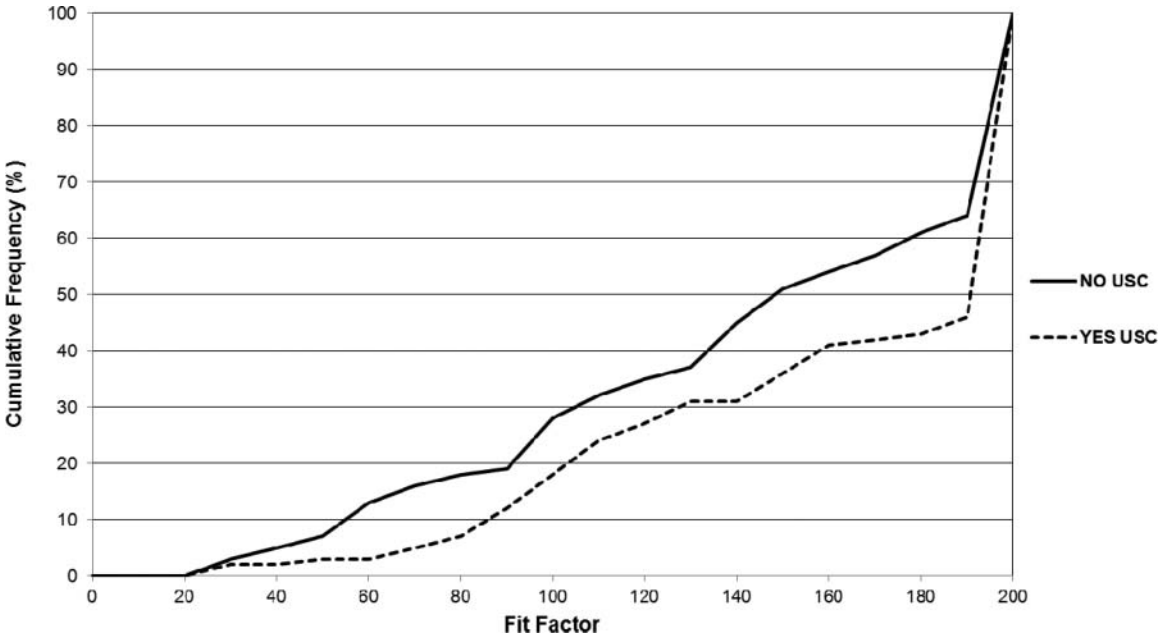

FIGURE 1. 3M 1860 FFs with and without USC

usually lognormally distributed, all FFs were analyzed after log-transformation.

A two-way analysis of variance (ANOVA) was conducted for each respirator model to determine if a USC affected the FF values by using PROC GLM in SAS for Windows version 9.2 (SAS Institute Inc., Cary, N.C.). The dependent variable was "log-transformed fit factors." The independent variables were "subject" and "treatment level" with two-factor interaction. For each respirator model and each subject, a one-way ANOVA was also conducted. Treatment level was the only independent variable.

A one-way ANOVA was conducted for each respirator model to determine if gender affected FF values for test conditions with and without USC. This analysis was performed to investigate the possibility that females may have a decreased ability to successfully perform a USC, given that females may have smaller hands than males. The dependent variable was "log-transformed fit factors" and the independent variable "treatment level." All ANOVA tests in this study were considered statistically significant for p-values < 0.05.

For each respirator model/subject combination, FFs for each donning were compared with a pass/fail criterion of 100 to determine if the subject wearing a particular model on that donning was deemed to have "passed" the fit test. The percentage of donnings with FFs exceeding or equaling this criterion was then calculated for each respirator model/subject combination when conducting a USC and for the same subject when not conducting a USC. For each respirator model, a two-way ANOVA was also conducted to determine if USC affected the passing rate. The dependent variable was "% of FFs ≥ 100," and the independent variables were "subject" and "treatment level" with two-factor interaction.

RESULTS

The cumulative frequency distributions of individual FFs ($n = 100$) obtained with and without a USC for each FFR model are illustrated in Figures 1–3. The cumulative frequency distribution curves for performing a USC for the 3M 1860 and KC PFR95-270 appear to the right of those for not performing the USC. This indicates that percentage of donnings associated with performing a USC for the same level of fit factor was less than that for not performing a USC, i.e., there was some benefit in performing a USC.

Ten of the 11 subjects achieved higher GM FFs and had smaller GSDs across all models tested when performing a USC compared with not performing a USC (Table I). GM, GSD, and fifth percentile FFs from the three FFR models with and without USCs are summarized in Table II. GM FFs when performing a USC are statistically higher than the GM FFs when not performing a USC for the 3M 1860 and the KCPFR95-270 (Table II). There is no statistical difference in GM FFs between performing a USC and not performing a USC for the 3M 1870.

Table I summarizes face length, face width, and the corresponding updated NIOSH bivariate panel cell number for each subject.[27] Two of the 11 subjects fell outside the NIOSH panel. The remaining nine subjects fell into six of the 10 cells (Cells 1, 3, 4, 5, 6, and 7); Cell 3 contained three subjects and Cell 6 contained two subjects. The remaining four cells (2, 8, 9, and 10) contained no subjects.

For gender comparisons by FFR model, GM fit factor was higher for performing the USC in five of the six comparisons (Table III). Only the 3M 1870 comparison for males showed a lower GM fit factor for performing the USC, although the

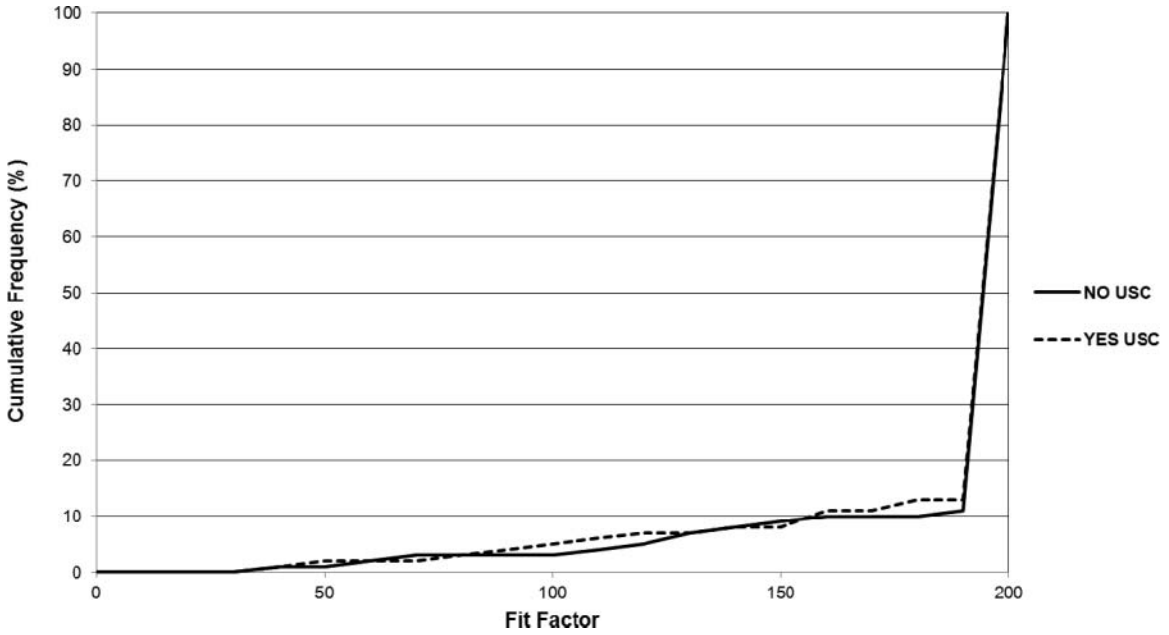

FIGURE 2. 3M 1870 FFs with and without USC

results for the two test conditions were not significantly different (GM FF with USC was 181, GM FF without USC was 190). Overall, these results indicate that, for both genders, there was some benefit for performing the USC.

The percentage of donnings with FFs $\geq$ 100 for the three FFR models (n = 20) with and without a USC for each subject are also summarized in Table IV. For the 3M 1860, the percentage of donnings with FFs $\geq$ 100 ranged from 40% to 90% (avg. = 72%) when not performing a USC, and 60% to 100% (avg. = 82%) when performing a USC. For this model, 6 of the 10 subjects exhibited increases in the percentage of donnings with FFs $\geq$ 100 when performing a USC. For the 3M 1870, the percentage of donnings with FFs $\geq$ 100 ranged from 80% to 100% (avg. = 97%) when not performing a USC, and 70% to 100% (avg. = 95%) when performing a USC. For the KC PFR95-270, the rate ranged from 10% to 100%

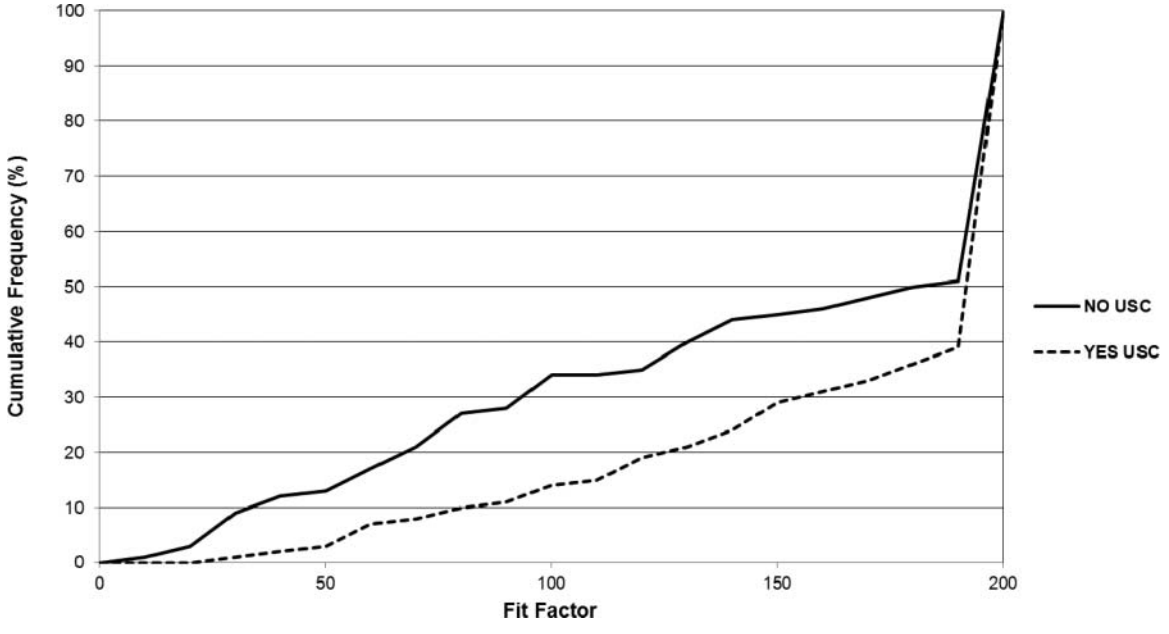

FIGURE 3. Kimberly Clark PFR95-270 FFs with and without USC

TABLE I. Test Subject Facial Dimensions and GM FFs and SDs Across All Models

ID	Face Length (mm)	Face Width (mm)	NIOSH Bivariate Panel Cell	No. Models Tested	n	USC Performed	USC not Performed
0335	116	146	5	2	20	186 ± 1.2	148 ± 2.0
1649	113	140	4	2	20	148 ± 1.5	143 ± 1.6
2767	125	112	Outside panel	3	30	159 ± 1.6	127 ± 2.0
3108	122	116	Outside panel	3	30	189 ± 1.2	183 ± 1.2
3771	121	133	6	2	20	162 ± 1.5	123 ± 2.2
3828	129	123	6	3	30	200 ± 1.0	181 ± 1.4
4322	113	126	3	3	30	169 ± 1.3	152 ± 1.6
4615	117	124	3	3	30	150 ± 1.7	162 ± 1.4
7705	120	138	7	3	30	138 ± 1.5	85 ± 2.2
8302	114	129	3	3	30	132 ± 1.8	115 ± 1.9
9867	106	128	1	3	30	166 ± 1.6	146 ± 1.7

(avg. = 66%) when not performing a USC, and 70% to 100% (avg. = 86%) when performing a USC. The two-way ANOVA showed that 66% and 86% are also statistically significantly different. For this model, most subjects (8 out of 10) exhibited increases in the percentage of donnings with FFs $\geq$ 100 when performing a USC.

When GM FFs for individual subjects were compared, there was no statistical difference between performing a USC and not performing a USC for all subjects and FFR models, with the exception of one subject (ID = 7705) wearing a KC PFR95-270. This also is the case with the percentages of donnings with FFs $\geq$ 100 for the individual subjects (Table IV). For example, in the case of subject ID = 7705 and KC PFR95-270, the percentage of donnings achieving a fit factor $\geq$ 100 without the USC step was 10% compared with 70% with the USC step.

DISCUSSION

A respirator cannot provide optimal respiratory protection unless it fits the wearer properly (i.e., has a good seal to the wearer's face). A recent study has shown that most of the aerosol contaminants that enter an N95 FFR worn by a human test subject are the result of face-seal leakage and not filtration performance.[28] Human subject studies have also demonstrated the importance of fit testing for achieving high levels of simulated workplace protection factors.[3,29–32]

NIOSH certifies respirators; however, current certification tests do not evaluate FFR fit or the effectiveness of the USC. The OSHA Respiratory Protection standard specifies that for all tight-fitting respirators, the employer is required to ensure that employees perform a USC each time the respirator is donned for use in the workplace.[10] Further, the wearer must use the procedures specified in Appendix B-1 of the standard or equally effective procedures recommended by the respirator manufacturer.[10] For a standard OSHA fit test, if a "leak free" seal cannot be achieved during the USC step, the wearer is given a different size or model to try until success is achieved.

Although respirator manufacturers' instructions for performing USCs vary slightly among respirator models, for most FFRs without an exhalation valve, a wearer performs a USC by inhaling and/or exhaling sharply while he or she cups both hands over the entire filtering facepiece. The FFR should collapse slightly and draw toward one's face on inhaling or seem to expand slightly and lift away from one's face upon exhaling. If the wearer does not detect air escaping along the face-to-facepiece seal perimeter, it is assumed that the wearer has achieved an adequate (non-leaking) seal of the FFR to the face. If air is felt escaping between the FFR and face of the wearer, then the procedure is repeated until no escaping air is felt. This perception is subjective, hence, easily apt to be missed by wearer.

Myers et al.[13] observed some differences in USC effectiveness between elastomeric half mask respirators and FFRs. Furthermore, some experts have expressed concerns about the effectiveness of a USC with FFRs because FFRs differ from their elastomeric counterparts in that the entire body of the FFR is composed of porous (air permeable) filtration media.[12,33,34]

TABLE II. Geometric Mean, Geometric Standard Deviation, and Fifth Percentile FFs Across All Subjects for three FFR Models With and Without USC

Model	USC	GM	GSD	5th Percentile
3M1860	No	126 [A]	1.7	51
	Yes	148 [A]	1.5	73
3M1870	No	187	1.3	127
	Yes	184	1.3	115
KCPFR95-270	No	115 [A]	2.2	33
	Yes	156 [A]	1.6	75

[A]Within each respirator model, GM values with asterisks are significantly different.

TABLE III. Gender Comparisons for Three FFR Models With and Without USC

Model	Gender	USC	GM	GSD	5th Percentile
3M 1860	Female	No	119	1.7	51
		Yes	131	1.6	58
	Male	No	134[A]	1.8	52
		Yes	169[A]	1.4	100
3M 1870	Female	No	183	1.3	112
		Yes	187	1.3	119
	Male	No	190	1.2	140
		Yes	181	1.3	113
KC PFR95-270	Female	No	122[A]	2.0	38
		Yes	157[A]	1.6	75
	Male	No	109[A]	2.3	28
		Yes	154[A]	1.6	75

[A] Within each gender for each respirator model, GM values with asterisks are significantly different.

This fact isolates one key issue when considering the success and feasibility of an FFR USC. That is, it is difficult to equate cupping one's hands over the porous media of an FFR while inhaling and/or exhaling to the suggested USC procedures for elastomeric respirators described in Appendix B-1 of the OSHA Respiratory Protection Standard; these elastomeric USC procedures are described as having the wearer perform a subjective assessment of faceseal leakage when holding either

TABLE IV. Differences in Percentages of Donnings with FFs ≥ 100 for Three FFR Models (n = 20) With and Without USC

3M 1860			3M 1870			KC PFR95-270		
ID	USC	%	ID	USC	%	ID	USC	%
1649	No	70	0335	No	100	0335	No	60
2767	No	70	2767	No	100	1649	No	90
3108	No	100	3108	No	100	2767	No	60
3771	No	40	3771	No	100	3108	No	90
3828	No	90	3828	No	100	3828	No	100
4322	No	50	4322	No	100	4322	No	90
4615	No	100	4615	No	100	4615	No	50
7705	No	60	7705	No	80	7705	No	10
8302	No	50	8302	No	100	8302	No	40
9867	No	90	9867	No	90	9867	No	70
		72			**97**			**66**
1649	Yes	60	0335	Yes	100	0335	Yes	90
2767	Yes	90	2767	Yes	100	1649	Yes	100
3108	Yes	100	3108	Yes	100	2767	Yes	90
3771	Yes	60	3771	Yes	100	3108	Yes	90
3828	Yes	100	3828	Yes	100	3828	Yes	100
4322	Yes	80	4322	Yes	100	4322	Yes	100
4615	Yes	90	4615	Yes	90	4615	Yes	70
7705	Yes	90	7705	Yes	70	7705	Yes	70
8302	Yes	70	8302	Yes	90	8302	Yes	70
9867	Yes	80	9867	Yes	100	9867	Yes	80
		82			**95**			**86**

Bolded numbers are arithmetic means.

Notes: For model KC PFR95-270, the mean percentage of donnings with fit factors ≥ 100 of 86% for performing USC was significantly different from the mean of 66% for not performing USC.

a low positive pressure when blocking off airflow through an exhalation valve (a positive USC) or by holding a slight vacuum for 10 sec by blocking airflow through cartridges (a negative USC).[10]

Another key criterion for a proper USC is that one must not perceive leakage at the seal of the respirator to the wearer's face while performing the USC. A portion of the ambiguity attributed to USCs for FFRs may also be rooted in one's ability or inability to "feel" or "sense" air escaping between the FFR and the face, which also may vary across users.

If the USC step were demonstrated to be able to accurately screen for poorly fitting respirators during annual or initial fit testing, it would be cost-effective for employers because the USC can be done quickly by the user without the need for expensive fit test equipment. However, the research done to date does not support that option. Recent findings from Lam et al.,[15] Danyluk et al.,[16] and Derrick et al.[14] suggest that a USC is of limited value in detecting FFR leakage. A similar observation was made by Delaney et al.[35] in a study to determine whether the USC could identify damaged exhalation valves in full-facepiece elastomeric respirators. These studies conclude that the USC is not reliable enough to serve as a fit test. Data currently do not support replacing initial or periodic fit testing with a USC.

However, the data shown in the current study suggest that there may be some benefit to performing a USC for at least some models (e.g., fewer poorer donnings for users who had previously passed a fit test on that model). For two of the three models studied, the USC step during the donning process led to more reproducible FFs, resulting in higher GM FFs, lower GSD FFs, as well as higher percentages of donnings with FFs $\geq$ 100. As seen in Figure 2, there is very little separation between the "with" and "without USCs" for the 3M 1870, which indicates little to no improvement in quality of fit achieved by doing USCs for this model.

The 3M 1870 did not allow much opportunity to reach statistical significance (given a sample size of 10 subjects) since 8 of 10 (80%) of the subject/respirator combinations already achieved an FF $\geq$ 100 (already fit well without the USC). This also supports Myers'[13] finding that USCs were less useful when the initial fit was already good.[13] It is likely that the other two models show improvement because the USC caused subjects to take added care while donning (as suggested by Myers), and this led to better donnings (i.e., the added care from performing a USC led to donnings of higher quality).

Better donnings resulted in improved FFs demonstrated by the asterisks in Table II for the 3M 1860 and the KCPFR95-270. Also, the 20% difference (86% vs. 66%) in arithmetic mean passing rates between performing a USC and not performing a USC for the KCPFR95-270 shown in Table IV supports donning improvement by showing a statistically significant difference in the direction of improvement. Overall, these data support the USC step as providing some value to the user during routine use within an OSHA-compliant respiratory protection program.

LIMITATIONS

There are some limitations to this study that must be acknowledged. The study was underpowered to detect small differences in fit from performing the USC vs. not performing the USC and employed only a few FFR models (n = 3). Although possibly underpowered for some of the possible outcomes, there were enough subjects to find statistically significant differences in FFs for two of the models. To detect smaller differences in fit a larger sample size would have been needed. This study used an abbreviated fit test protocol, rather than the standard OSHA-accepted quantitative fit test. Longer sampling times associated with the standard quantitative fit test might have allowed smaller differences in fit to be detected. Additional work is needed to discern differences in fit factors measured by the abbreviated and standard quantitative fit test protocols. The FFRs used in this study were all classified by FDA as surgical N95 respirators. The exterior surface of the FFR was hydrophobic (resistant to liquid), which may cause these FFRs to respond differently when a USC is performed compared with other types of FFRs. Only one model of each FFR style (cup, flat-fold, or duckbill) was studied, making it difficult to generalize study findings to other models of that style.

The test subjects in this study had considerable experience with the three respirator models evaluated in this study from other research studies at NPPTL, and all passed a standard OSHA quantitative fit test to be enrolled in the study. Inexperienced or less experienced subjects may have performed differently and as a result may have produced different outcomes. Perhaps testing a wider range of sizes or varied facial anthropometries would have yielded different results.

Future studies are needed to evaluate the possibility of better methods for conducting a USC or perhaps an alternative USC for FFRs. For example, health care workers often wear gloves for infection control, and some have suggested that the use of gloves might improve the user's ability to hold a slight vacuum better during the USC step, resulting in a more accurate USC, although this requires experimental validation. Additional research is needed with more respirator models performing different experiments specifically designed to assess the sensitivity and specificity of the USC with FFRs. Future data collection should focus on investigating the predictive abilities of the current USC step as part of a larger study including both experienced and less experienced FFR test subjects.

CONCLUSION

Qualified test subjects performing a USC achieved higher fit factors and a higher rate of obtaining a fit factor greater than or equal to 100 compared with not performing the USC step for two of the three N95 FFR models studied. These data suggest there may be some benefit to performing the USC step for at least some models during the FFR donning process for workers who have previously passed a fit test for those

respirator models. Results from this study suggest that studies using subjects having more diverse facial anthropometrics and additional models of varying sizes and types are warranted to better understand the benefits of the USC in the donning process.

ACKNOWLEDGMENTS

The authors would like to express their sincere gratitude to Andrew Palmiero and Jeffrey Powell for their attention to detail while collecting data and their contributions throughout the project. The authors would also like to offer sincere thanks to William Newcomb, William King, and Kimberly Faulkner for their constructive review, criticism, and expertise.

REFERENCES

1. **Campbell, D.L., C.C. Coffey, and S.W. Lenhart:** Respiratory protection as a function of respirator fitting characteristics and fit test accuracy. *Am. Ind. Hyg. Assoc. J. 62*:36–44 (2001).
2. **Coffey, C.C., R.B. Lawrence, Z. Zhuang, D.L. Campbell, P.A. Jensen, and W.R. Myers:** Comparison of five methods for fit-testing N95 filtering-facepiece respirators. *Appl. Occup. Environ. Hyg. 17*:723–730 (2002).
3. **Coffey, C.C., R.B. Lawrence, D.L. Campbell, Z.Q. Zhuang, C.A. Calvert, and P.A. Jensen:** Fitting characteristics of eighteen N95 filtering-facepiece respirators. *J. Occup. Environ. Hyg. 1*:262–271 (2004).
4. **Oestenstad, R.K., and A.A. Bartolucci:** Factors affecting the location and shape of face seal leak sites on half-mask respirators. *J. Occup. Environ. Hyg. 7*:332–341 (2010).
5. **Oestenstad, R.K., H.K. Dillon, and L.L. Perkins:** Distribution of faceseal leak sites on a half-mask respirator and their association with facial dimensions. *Am. Ind. Hyg. Assoc. J. 51*:285–290 (1990).
6. **Oestenstad, R.K., J.L. Perkins, and V.E. Rose:** Identification of faceseal leak sites on a half-mask respirator. *Am. Ind. Hyg. Assoc. J. 51*:280–284 (1990).
7. **Krishnan, U., K. Willeke, A. Juozaitis, T. Myojo, G. Talaska, and R. Shukla:** Variation in quantitative respirator fit factors due to fluctuations in leak size during fit testing. *Am. Ind. Hyg. Assoc. J. 55*:309–314 (1994).
8. **Weber, A., K. Willeke, R. Marchioni, et al.:** Aerosol penetration and leakage characteristics of masks used in the health-care industry. *Am. J. Infect. Control 21(4)*:167–173 (1993).
9. **Chen, C.C., and K. Willeke:** Characteristics of face seal leakage in filtering facepieces. *Am. Ind. Hyg. Assoc. J. 53*:533–539 (1992).
10. "Respiratory Protection: Final Rule," *Federal Register 63:5* (8 January 1998). pp. 1152–1300.
11. **American National Standards Institute (ANSI):** American National Standard for Respiratory Protection (ANSI Z88.2). New York: ANSI, 1992.
12. **Brosseau, L.M.:** "Toward Better Fitting Respirators. No Fit Test Respirator Workshop and Research Roadmap. Final Report. RFQ 2008-Q-10205."
13. **Myers, W.R., M. Jaraiedi, and L. Hendricks:** Effectiveness of fit check methods on half mask respirators. *Ann. Occup. Environ Hyg. 10(11)*:934–942 (1995).
14. **Derrick, J.L., Y.F. Chan, C.D. Gomersall, and S.F. Lui:** Predictive value of the user seat check in determining half-face respirator fit. *J. Hosp. Infect. 59(2)*:152–155 (2005).
15. **Lam, S.C., J.K. Lee, S.Y. Yau, and C.Y. Charm:** Sensitivity and specificity of the user-seal-check in determining the fit of N95 respirators. *J. Hosp. Infect. 77(3)*:252–256 (2011).
16. **Danyluk, Q., C.Y. Hon, M. Neudorf, et al.:** Health care workers and respiratory protection: Is the user seal check a surrogate for respirator fit-testing? *J. Occup. Environ. Hyg. 8*:267–270 (2011).
17. "Masks and N95 Respirators." [Online] Available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/PersonalProtectiveEquipment/ucm055977.htm (accessed March 30, 2012).
18. **Viscusi, D.J., M.S. Bergman, D.A. Novak, et al.:** Impact of three biological decontamination methods on filtering facepiece respirator fit, odor, comfort, and donning ease. *J. Occup. Environ. Hyg. 8*:426–436 (2011).
19. **Roberge, R.J., W.D. Monaghan, A.J. Palmiero, R. Shaffer, and M.S. Bergman:** Infrared imaging for leak detection of N95 filtering facepiece respirators: A pilot study. *Am. J. Ind. Med. 54(8)*:628–636 (2011).
20. **Bergman, M.S., D.J. Viscusi, Z. Zhuang, A.J. Palmiero, J.B. Powell, and R.E. Shaffer:** Impact of multiple consecutive donnings on filtering facepiece respirator fit. *Am. J. Infect. Control*. Aug. 22, 2011 [Epub ahead of print].
21. **Bergman, M.S., D.J. Viscusi, A.J. Palmiero, J.B. Powell, and R.E. Shaffer:** Impact of three cycles of decontamination treatments on filtering facepiece respirator fit. *J. Int. Soc. Resp. Protect. 28(1)*:48–59 (2011).
22. **Campbell, D.L., C.C. Coffey, P.A. Jensen, and Z. Zhuang:** Reducing respirator fit test errors: A multi-donning approach. *J. Occup. Environ. Hyg. 2*:391–399 (2005).
23. **Nicas, M., and J. Neuhaus:** Variability in respiratory protection and the assigned protection factor. *J. Occup. Environ. Hyg. 1*:99–109 (2004).
24. **Da Roza, R.A., C.A. Cadena-Fix, G.J. Carlson, K.E. Hardis, and B.J. Held:** Reproducibilty of respirator fit as measured by quantitative fitting tests. *Am. Ind. Hyg. Assoc. J. 44*:788–794 (1983).
25. **TSI Inc.:** *Model 8095 N-95-Companion to the PORTACOUNT Plus, Operation and Service Manual* (P/N 1980308, Revision H). Shoreview, Minn.: TSI Inc., 2005.
26. "Statistical considerations for a cross-over study where the outcome is a measurement." [Online] Available at http://hedwig.mgh.harvard.edu/sample_size/js/js_crossover_quant.html (accessed March 30, 2012).
27. **Zhuang, Z., B. Bradtmiller, and R.E. Shaffer:** New respirator fit test panels representing the current U.S. civilian workforce. *J. Occup. Environ. Hyg. 4*:647–659 (2007).
28. **Grinshpun, S.A., H. Haruta, R.M. Eninger, T. Reponen, R.T. McKay, and S.A. Lee:** Performance of an N95 filtering facepiece particulate respirator and a surgical mask during human breathing: Two pathways for particle penetration. *J. Occup. Environ. Hyg. 6*:593–603 (2009).
29. **Coffey, C.C., D.L. Campbell, and Z. Zhuang:** Simulated workplace performance of N95 respirators. *Am. Ind. Hyg. Assoc. J. 60*:618–624 (1999).
30. **Coffey, C.C., R.B. Lawrence, Z.Q. Zhuang, M.G. Duling, and D.L. Campbell:** Errors associated with three methods of assessing respirator fit. *J. Occup. Environ. Hyg. 3*:44–52 (2006).
31. **Duling, M.G., R.B. Lawrence, J.E. Slaven, and C.C. Coffey:** Simulated workplace protection factors for half-facepiece respiratory protective devices. *J. Occup Environ. Hyg. 4(6)*: 420–431 (2007).
32. **Zhuang, Z., C.C. Coffey, P.A. Jensen, D.L. Campbell, R.B. Lawrence, and W.R. Myers:** Correlation between quantitative fit factors and workplace protection factors measured in actual workplace environments at a steel foundry. *Am. Ind. Hyg. Assoc. J. 64*:730–738 (2003).
33. **Centers for Disease Control and Prevention (CDC):** "Workshop on Respiratory Protection for Airborne Infectious Agents, November 30–December 1, 2004 " [Online] Available at http://www.cdc.gov/niosh/npptl/resources/pressrel/announcements/113004wkshp/questions.html (accessed April 2, 2012).
34. **American Industrial Hygiene Association (AIHA) Respiratory Protection Committee:** "Research Needs in Respiratory Protection. White Paper." [Online] Available at http://www.aiha.org/news-pubs/govtaffairs/Documents/Research-Resp%20Protection-11-09-09.pdf (accessed April 2, 2012).
35. **Delaney, L.J., R.T. McKay, and A. Freeman:** Determination of known exhalation valve damage using a negative pressure user seal check method on full facepiece respirators. *Appl. Occup. Environ. Hyg. 18*:237–243 (2003).