Comparison of N95 Disposable Filtering Facepiece Fits Using Bitrex Qualitative and TSI Portacount® Quantitative Fit Testing

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As a means of evaluating the use of denatonium benzoate (bitrex) as a qualitative fit test agent with filtering facepiece respirators, the bitrex qualitative and TSI Protacount® quantitative fit-test methods were compared using N95 filtering facepieces. Seventy-nine paired tests (trial) were performed. Detection of bitrex during a qualitative fit test or measurement of a fit factor of <100 during a quantitative fit test constituted a failure. Qualitative and quantitative methods were performed using identical test protocols. Data were analyzed using pass/fail criteria, and matched-pair analysis methods were applied. The results of this study indicate that the use of bitrex during qualitative fit testing of N95 disposable filtering facepieces results in an increase in failure and/or rejection in cases where a TSI Portacount (plus N95 companion accessory) quantitatively establishes an acceptable fit. *Key words:* respirator fit test; bitrex; disposable filtering facepiece.

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It is not uncommon for workers in the industrial environment to be exposed to airborne hazardous substances through the course of performing their everyday duties. Where possible, such exposure hazards are minimized through engineering and workforce-management techniques. Where avoidance is physically or economically infeasible, workers often rely on air-purifying respiratory protective equipment. In order to ensure that an appropriate level of protection is afforded by a respirator to wearers in the United States, the Occupational Safety and Health Administration (OSHA) has mandated testing the acceptability of the fit of a respirator on the worker, or fit testing. Fit testing is performed using a specific protocol identified in OSHA regulations.[1] There are two types of tests that satisfy the regulations, qualitative and quantitative. The qualitative test is a subjective pass/fail test, based on the ability of the respirator wearer to sense an airborne chemical fit-test agent. The quantitative test determines the degree of fit by measuring atmospheric concentrations outside the respirator versus atmospheric concentrations inside. During both tests the wearer performs a series of breathing exercises that are designed to place stress on the seal of the respirator.

A new qualitative method using denatonium benzoate (bitrex) was recently approved by OSHA.[2] Bitrex is a bitter-tasting substance that is commonly used as an additive to household products to discourage ingestion by young children.[3] The use of bitrex as a qualitative fit-test agent was evaluated by Mullins et al.[4] The Mullins group demonstrated that the use of bitrex could effectively determine an acceptable fit factor for half-face respirators, showing a sensitivity (the ability of a test to identify an acceptable fit factor) of 0.96 and a specificity (the ability of a test to identify an unacceptable fit factor) of 0.88 for tight-fitting, rubber-seal half-face respirators with high-efficiency particulate air (HEPA) cartridges. To date, the study by Mullins et al. is the only apparent published literature evaluating the use of bitrex during qualitative fit testing.

Disposable filtering facepiece respirators are often used in place of rubber-seal half-face air-purifying respirators. Filtering facepiece performances regarding fit, leak effects, workplace performance, and fit-testing methods under various conditions have been documented.[5–7] The OSHA Respiratory Standard (29 CFR 1910.134) permits use of the bitrex test with filtering facepieces, presumably under the assumption that performance will be similar to that of rubber-seal half-face respirators tested by Mullins et al.[4] Because there are fundamental differences in construction and materials between these two respirator types, this study evaluated the use of bitrex as a qualitative fit-testing agent using disposable N95 filtering facepiece respirators.

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MATERIALS AND METHODS

Seventy-nine paired fit tests (trials) were performed matching the bitrex and TSI Portacount® fit-test methods using N95 disposable respirators. A trial was composed of four basic parts: threshold sensitivity testing, fitting, quantitative testing, and qualitative testing. The study design controlled for test order and respirator brand through randomization. Fit-test subjects were drawn from the general population, with 40 test subjects being male and 39 female, ranging in age from 18 to 42 years. Test subjects were required to meet criteria set forth in a respiratory-fitness questionnaire based on requirements located in the OSHA Respiratory Protection Standard.[1] Approval by the University of Utah's Institutional Review Board for the participation of human subjects in research was given prior to the fit-testing component of this project. Test subjects were assigned trial slots consecutively as they became available.

Four brands of filtering facepiece respirators were selected to control for any potential design bias. The 3M 8210, Gerson 2737, MSA Ultrafit Affinity, and Wilson N9510 models were chosen. The presence of a NIOSH approval label and local market availability were factors in the facepiece type selection. Quantitative fit testing was accomplished using a Portacount particle-counting device with an N95 companion attachment, and was performed according to OSHA protocol.[1] In order to determine atmospheric concentration inside the respirator, each facepiece was fitted with predesigned rivets (provided with the N95 companion attachment) to allow for insertion of a sampling probe. Probes were inserted in the lower central region of the mask. Placement of the rivet and probe was performed according to the manufacturer's instructions.

The model of respirator and test order for each trial was determined randomly from a prepared table of random digits.[8] Each model was assigned a two-digit designation (odd/even, odd/odd, even/odd, even/even). The first two digits of each line on the table were used to determine the model. The third digit determined test order in a similar manner (odd or even). Twenty trial slots were assigned to each model (fit-test data for one trial using the Gerson 2737 were thrown out due to Portacount error). In order to ensure that similar fits were being tested in all trials, the same respirator remained in place for the duration of both the qualitative and the quantitative portions of a given trial.

As the ability to sense bitrex was an integral part of the study, a taste-threshold screening test was performed at the beginning of each trial (prior to the donning of a respirator by the test subject). This threshold screening test was performed according to the standard saccharin test protocol cited in the OSHA respiratory standard[1] and was used to determine the bitrex concentration to be administered during the qualitative fit test. If a test subject was not able to taste bitrex, he or she was excluded from the study.

A fit-test operator having a graduate degree in industrial hygiene performed all respirator fittings in order to control for fitting technique and competency. The fit-test operator determined respirator size, based on the facial features of the wearer. Three of the models had a malleable component on the seam of the respirator, which covers the bridge of the nose. For these models, the fit-test operator shaped the respirator to fit the subject. When the operator and subject found the fit to be acceptable, the decision to begin a trial with a qualitative or quantitative fit test was determined at random. During a quantitative fit test, the respirator was attached to the TSI Portacount Companion Sampling Pendant via a detachable tygon interconnect tube. During a qualitative fit test, the tube was removed from the sampling pendant and the opening sealed. This mode of attachment permitted the operator to alternate between tests without disturbing the fit of the respirator.

During a qualitative fit test, test subjects were exposed to bitrex mist at a concentration predetermined by the taste-threshold screening test. Each test subject was asked to perform the following exercises in succession for one minute each: 1) normal breathing, 2) deep breathing, 3) normal breathing while rotating the head from side to side, pausing at each side long enough to inhale, 4) normal breathing while nodding the head up and down, inhaling while at the extreme positions, 5) reading a short narrative (Rainbow Passage), 6) bending down to touch one's toes, or as close as was possible without unreasonable discomfort, and 7) normal breathing. The test subjects were asked to hold the sampling pendant against their chests during the bending exercise to minimize artificial disturbance of the seal of the respirator. The test ended upon completion of the exercises or when the taste of bitrex was reported. Performance of the exercises without sensing the flavor of bitrex signified a pass. If the test subject reported tasting bitrex at any time during the fit test, a failure was recorded.

The quantitative fit test was carried out using a Portacount with a TSI N95 companion accessory in combination with a laptop computer and the appropriate accompanying software in accordance with the manufacturer's instructions. A TSI Model 8026 Particle Generator placed on the floor 2 to 3 feet from the test subject was used during all trials to augment the ambient particle concentration by emitting a polydispersed saline aerosol in the size range (0.02 μm to more than 1 μm) required for detection by the Portacount and accessory component. A particle concentration registering a minimum of 70 counts per second was required by the Portacount for testing. If the count fell below this level at any time during the test, the Portacount automatically aborted the test. If the particle count requirements could not be met in a normal room environment,

TABLE 1 Pass/Fail Results for Respirator Fit-test Trials

	Portacount Quantitative Fit-test Method		
	Pass	Fail	Total
Bitrex qualitative fit-test method			
Pass	6	5	11 (14%)
Fail	38	30	68 (86%)
TOTAL	44 (56%)	35 (44%)	79 (100%)

quantitative fit tests were performed in a portable testing booth (30" × 30" × 84"). Quantitative fit testing was conducted according to the prescribed OSHA method for Portacount respiratory fit testing using half-face respirators.[1] Subjects repeated the series of seven breathing exercises performed in the qualitative fit test. Each exercise was 80 seconds in length. The additional 20 seconds per exercise is a design feature of the Portacount and is necessary to purge the instrument between fit-test exercises. A fit-factor score for each exercise was recorded in a database. A fit-factor score of ≥100 for each exercise was required for the test to be considered a pass. The quantitative test was considered a failure if the fit-factor score during any individual exercise was < 100. This requirement exceeds the OSHA respiratory-protection standard, which requires that the average fit factor for all of exercises be ≥ 100. The change to require a fit factor of 100 during every exercise was made to better match the qualitative test, where taste detection during any individual exercise constituted a failure.

RESULTS AND DISCUSSION

Seventy-nine fit-test trials (79 qualitative, 79 quantitative) were performed and the results prepared for matched-pair analysis. Due to the acute sensitivity of the human palate to bitrex, no test subject was excluded from respiratory fit testing on the basis of not being able to taste this chemical agent. Pass/fail results were tabulated using the 2 × 2 table of matched pairs and are shown in Table 1. Differences in the paired data were analyzed for significance using a McNemar two-sided test for correlated proportions. The significance level was set at $\alpha = 0.05$ (critical value = 3.841). The calculated test statistic was 23.8. Comparing the critical value against the test statistic, the null hypothesis (H_0 = any difference between the qualitative bitrex fit-test method and the quantitative Portacount fit-test method is a product of chance) was rejected. Thus, using the data obtained in this study, the findings with the fit-test methods are assumed to be different.

As a means of evaluating specific differences between the qualitative and quantitative methods, histograms depicting points of initial failures during the fit-test exercise series are shown in Figures 1 and 2. The bars on each histogram represent the frequencies of initial failure points during the performance of the seven fit-test exercises. A cumulative frequency curve for the initial failure points is also shown.

Figure 1 demonstrates that of all quantitative fit-test failures ($n = 35$), approximately 54% had occurred by the end of the first two exercises, and approximately 88% had occurred by the end of the fourth exercise. Thus, a majority of the filtering facepiece respirators not meeting this study's criteria for an acceptable fit were identified within the first four exercises by the Portacount fit-test method. Figure 2 demonstrates that of all qualitative fit-test failures ($n = 68$), approximately 88% occurred during the first exercise. This result shows that for the majority of the failure cases, bitrex was sensed shortly after the test subject was exposed to the bitrex test agent, prior to the performance of the more rigorous breathing exercises.

To further evaluate the performance of the bitrex as a test agent, the validity of the fit test was analyzed using the quantitative Portacount fit-test method as the indicator of a true pass or true fail. The 2 × 2 data table shown in Table 1 is also used for this analysis. The sensitivity of the bitrex fit test was found to be 0.14. This means that of the 44 fit-test passes identified by the Portacount method, 6 (14%) were also identified by the bitrex method. The specificity of the bitrex method was found to be 0.86. This means that of the 35 fit-test failures identified by the Portacount method, 30 (86%) were also identified by the bitrex method. The predictive value of a positive test (PV_{pos}) was found to be 0.55. This means that of the 11 fit-test passes identified by the bitrex method, six (55%) were true passes (identified by the Portacount method as passes). The predictive value of a negative test (PV_{neg}) was found to be 0.45. This means that the 68 fit-test failures identified by the bitrex method, 30 (45%) were true failures (identified by the Portacount method as failures).

In order to evaluate potential bias introduced by the use of the portable testing booth, fit-test trials were placed in two pools, those performed in a booth ($n = 36$) and those performed without a booth ($n = 43$). A standard normal deviate test was used to examine the pools for individual significance. Both in-booth and without-a-booth fit tests were significant, having Z values of 7.3 and 8.3, respectively ($Z_{null} = 1.96$). Based on these results, the introduction of the fit-testing booth did not affect the overall outcome of the study.

CONCLUSION

The results of McNemar's two-sided test for correlated proportions suggest that the difference between the performances of the qualitative and quantitative fit-test methods evaluated in this study was real and not a product of chance.

Comparative results of the two fit-test methods re-

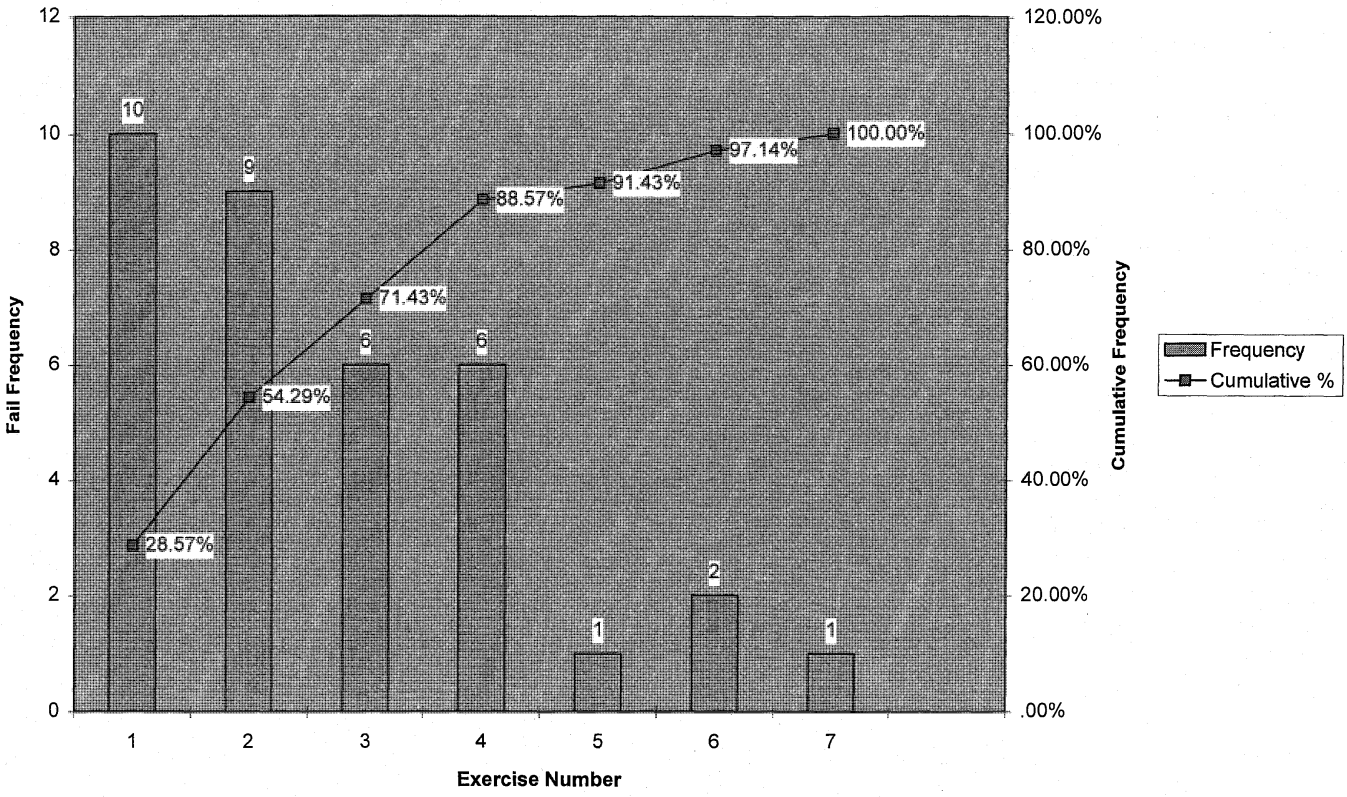

Figure 1—Quantitative (Portacount) fit-test failure distribution.

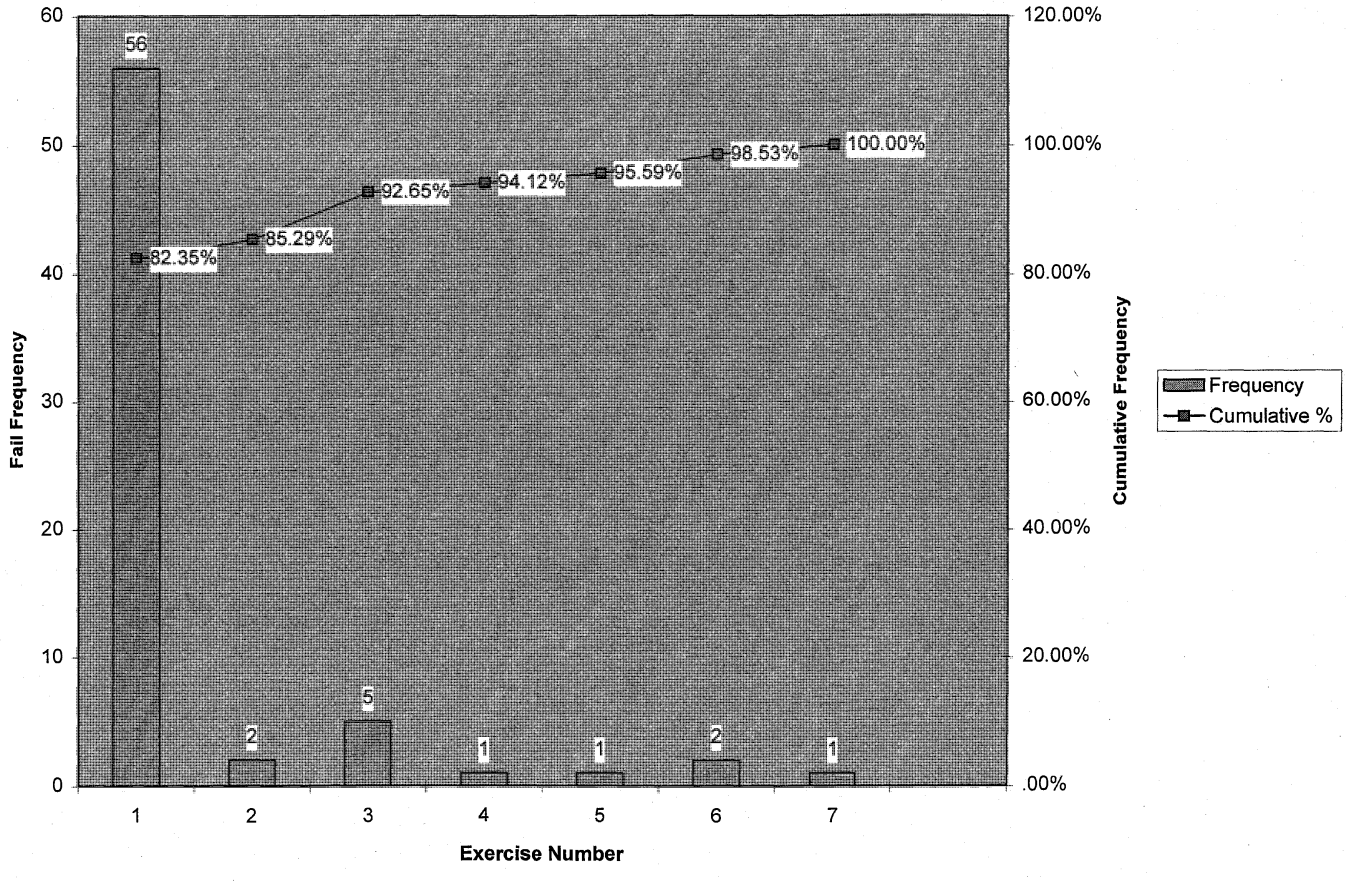

Figure 2—Qualitative (Bitrex) fit-test failure distribution.

vealed that the bitrex qualitative method yielded a low sensitivity to identify a pass when a pass had been identified by the Portacount quantitative method. This result may be explained by an acute susceptibility to bitrex by the respirator wearer, causing the qualitative test to record a failure at a concentration that is deemed acceptable by the quantitative test. Thus, it appears that this laboratory application of a bitrex qualitative fit-test method to evaluate the fit of filtering facepiece respirators will cause a high number of failure outcomes where acceptable fits exist as measured by quantitative means.

In contrast to this finding, the bitrex qualitative method showed a high specificity to identify a failure when a failure had been identified by the Portacount quantitative method. This finding suggests that the bitrex of qualitative fit-test method may be useful in identifying a poorly-fitting filtering facepiece respirator.

The numbers of total failures identified with both fit-test methods are probably a product of the high variability of obtaining a good fit with filtering facepiece respirators. These failure results emphasize the importance of fit testing prior to the use of filtering facepiece respirators.

Based upon the results of this study, it is recommended that further study evaluating bitrex as a qualitative fit-testing agent be performed. In addition, as little research about qualitative fit-testing methods using disposable filtering facepiece respirators is available, it is recommended that studies be performed to further examine this issue.

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