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Evaluation of the Bitrex™ Qualitative Fit Test Method Using N95 Filtering-Facepiece Respirators

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Abstract

Aerosolized Bitrex™ is a qualitative fit-testing agent used to screen out respirators having poor facepiece fits and thereby aids the selection of respirators with adequate facepiece fits. In this study, a total penetration test was used as an indicator of whether a respirator provided an adequate facepiece fit to its wearer using the PortaCount™. Total penetration is face seal leakage and filter penetration. Adequate protection was defined as a total penetration ≤ 10 percent (a fit factor ≤ 10). This is the level of protection expected for a half-mask respirator. A panel of 25 subjects with varying facial sizes wore five different models of N95 filtering-facepiece respirators; this resulted in 125 tests. The results of the Bitrex™ fit tests were compared to total penetration values. The order in which testing was performed was randomized. The subject redonned the respirator between the Bitrex™ fit test and the total penetration test. In 59% of the tests, passing a Bitrex™ test correctly identified respirators having an adequate fit. In 9% of the cases, wearers passed the Bitrex™ test but received inadequate protection. In 41% of the tests, Bitrex™ results caused respirators providing adequate protection to be rejected. In 91% of the tests, failing a Bitrex™ test correctly identified respirators which did not provide adequate protection. These results suggest passing a Bitrex™ may not ensure an adequately fitting respirator.

Introduction

The only qualitative facepiece fit-testing agents available before 1981 were iso-amyl acetate (banana oil) and irritant smoke (ANSI, 1980). The iso-amyl acetate test requires the use of organic vapor cartridges and the irritant smoke test requires the use of high-efficiency filters. Consequently, neither test was suitable for fit testing low-efficiency, filtering-facepiece respirators for particulates certified under Title 30, Code of Federal Regulations, Part 11 (CFR, 1981; NIOSH, 1976). In 1981, the Minnesota Mining and Manufacturing Company (3M) developed a protocol for a saccharin qualitative fit test (Federal Register, 1981). However, due to a report

that stated saccharin was found to cause cancer in laboratory animals, the National Institute for Occupational Safety and Health (NIOSH) recommended that saccharin should not be used for facepiece fit testing and also developed a list of possible replacement agents (NIOSH, 1991). One of the replacements suggested was denatonium benzoate which is commonly referred to by its trade name Bitrex™ (Macfarland Smith Ltd., Montvale, N.J.). Bitrex™ has a bitter, unpleasant taste and is used as a taste-aversion agent in toxic household liquids to help prevent children from drinking them.

In response to NIOSH's concern regarding the carcinogenicity of saccharin, 3M developed a facepiece fit-testing protocol using Bitrex™ based on the saccharin protocol (NIOSH, 1991; Mullins, 1995). This test consists of aerosolizing Bitrex™ and 5% sodium chloride aerosol in deionized water using a nebulizer. The resulting aerosol has a geometric mean of 2.38 μm and a geometric standard deviation of 1.45 (Mullins, 1995). This aerosol can be removed by even low-efficiency filter material (i.e., having a filter efficiency less than 99.97% against a most penetrating size aerosol) but is still small enough to penetrate small imperfections in a face seal (Schwabe,

1980). In evaluating the Bitrex™ fit test, 3M found 96 percent of the subjects having a quantitative fit factor less than 100 also failed the Bitrex™ fit test while wearing a negative pressure half-mask respirators equipped with high-efficiency filters (Mullins, 1995). No research has been done using the Bitrex™ method to test the facepiece fits of N95 **filtering-facepiece** respirators. The purpose of this study was to determine if the Bitrex™ method adequately screened out poorly fitting N95 **filtering-facepiece** respirators. A comparison was made of the Bitrex™ pass/fail results to the total penetration values of five N95, half-mask, **filtering-facepiece** respirators.

Materials and Methods

Subjects

Thirty-one subjects (17 females and 14 males) participated in this study. For each respirator model tested, a panel of 25 subjects was used to measure its performance. Panel members had facial sizes in accordance with the Los Alamos National Laboratory **25-member** Respirator Panel for testing half-masks (see Fig. 1; Los Alamos, 1974). All test subjects

previously performed both qualitative and quantitative fit tests.

Respirators

Five models of NIOSH-certified, N95 **valveless**, cup-shaped, **filtering-facepiece** respirators (see Table 1) were used in this study. The **filtering-facepiece** models were selected at random from those

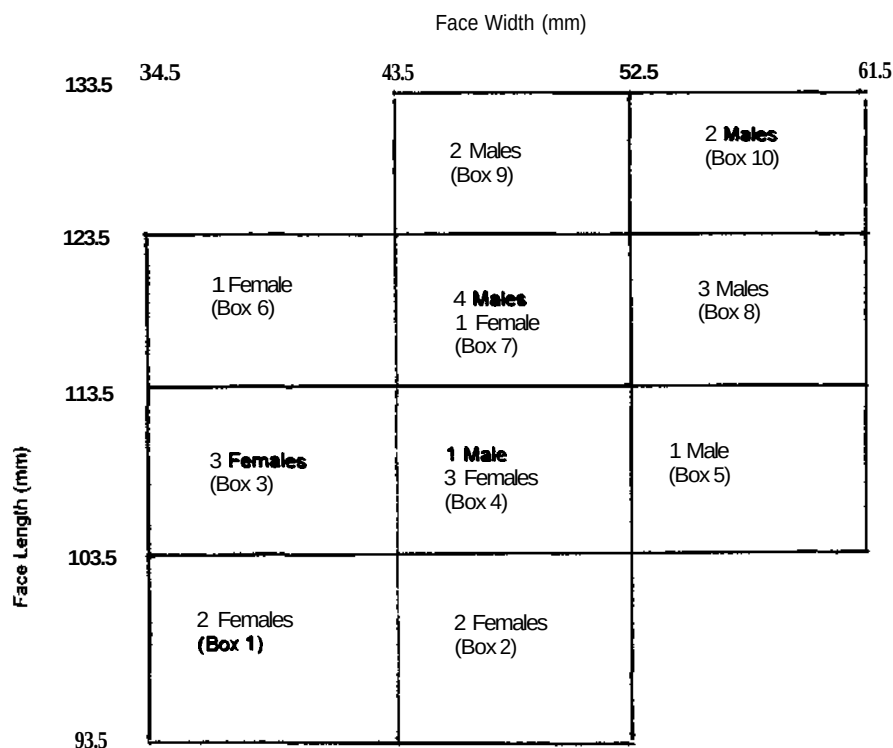


Figure 1. Facial sizes, gender, and number of subjects comprising the **25-member** Los Alamos National Laboratory panel for testing half-mask respirators (Los Alamos, 1974).

Table 1. N95 filtering-facepiece respirators tested.

Company	Model	Approval number	Nose clip	Adjustable straps
3M Company, St. Paul, MN	8210	TC-84A-0007	Yes	No
Better Breathing, Lawrence, MA	RX-2	TC-84A-0329	Yes	No
MSA Company, Pittsburgh, PA	Affinity Pro	TC-84A-0981	No	No
Uvex Safety, Inc., Smithfield, RI	Pro-Tech-N95	TC-84A-0016	No	Yes
Willson Safety Inc., Reading, PA	N9501	TC-84A-1164	Yes	No

models manufactured at the time the study began. For total penetration testing, all respirators were probed approximately half way between the nose and mouth using the TSI Fit Test Probe Kit (P/N 8025-N95, TSI Inc., St. Paul, MN). Respirators available in multiple sizes did not have instructions describing how to choose the appropriate size. Therefore, test subjects were given a respirator based on their face size. For example, subjects having face sizes in boxes 1 through 3 were given small size respirators when the respirator had three sizes.

Bitrex™ Fit Test

Although generally found to be safe, it has been reported that at least one person experienced an asthmatic reaction to the Bitrex™ (Bjorkner, 1980). The Bitrex™ test was performed in accordance with the protocol contained in the Occupational Safety and Health Administration's (OSHA) respiratory protection standard (Federal Register, 1998). Since a person's ability to taste the bitter solution is used to determine whether the respirator fits, subjects did not eat any food or drink anything other than plain water for 15 minutes before a fit test. Also, each subject was given a taste-threshold screening test to ensure that he or she could detect the taste of Bitrex™. An Allegro Industries Qualitative Respirator Fit Test Kit (Bitrex™), part number 2041 (Allegro Industries, Paramount, CA), was used for both Bitrex™ screening and fit tests. A screening test involved placing a hood approximately 12 inches in diameter by 14 inches tall over a subject's head. A taste-screening aerosol (13.5 g Bitrex™ in 100 ml of a 5% salt solution in water) was generated in the hood using a nebulizer. All thirty-one subjects reported tasting the Bitrex™ during each screening test.

After the screening test, a subject left the laboratory, got a drink of water, and rinsed his or her lips. Immediately afterward, the subject returned to the laboratory and the Bitrex™ fit test was conducted. The test subject donned the respirator per the respirator manufacturer's instructions. The hood was then placed over the subject's head. The subject was instructed to breathe through the mouth only and to report immediately if the bitter taste of Bitrex™ was detected. A fit test aerosol (338.2 g Bitrex™ in 200 ml of water) was sprayed into the hood with a second nebulizer bulb. This concentration produces a taste response 100 times greater than the concentration used during the screening test. Therefore, if the person does not taste the Bitrex™ during the fit test, it is assumed a fit factor of at least 100 was achieved. The Bitrex™ concentration in the hood was replenished every 30 seconds. If the subject reported the taste of Bitrex™ at any time, the test was considered a failure and stopped. After every Bitrex™ test, the test respirator was removed and returned to the test operator.

Total Penetration Test

A TSI PortaCount Plus™ Model 8020 was used to measure the performance of the test respirators. The PortaCount Plus™ is a quantitative fit-testing instrument using ambient particles as the challenge agent and counts the number of particles inside and outside the facepiece. The number of particles inside is divided into the number outside to obtain a fit factor (TSI, Inc., 1994). The PortaCount Plus™ was chosen because it has been demonstrated that the fit factors obtained using this instrument and this procedure during simulated workplace testing had a high correlation with actual exposures (Coffey *et al.*, 1998). However, the fit factors reported by the

PortaCount Plus™ could not be used as a direct measure of respirator performance because it has been shown that the leakage of ambient particles through N95 filter media is significant (Zhuang *et al.*, in review). Therefore, total penetration was used as the indicator of performance. Total penetration was calculated using equation (1).

$$TP(\%) = \frac{100}{FF} \quad (1)$$

where TP = total penetration in percent and FF = PortaCount Fit Factor. Since the PortaCount Plus™ uses a condensation nuclei counter to count particles, test subjects who smoked refrained from smoking for at least one hour before the tests.

Before starting a total penetration test, a subject donned the respirator per the respirator manufacturer's instructions. After a subject was satisfied the respirator was donned properly, total penetration testing began. An overall total penetration value was obtained. Total penetration is a measure of the protection received from a respirator and includes both filter penetration and face seal leakage. After completing each test, the subject removed the respirator and returned it to the test operator. The order of performing the Bitrex™ and total penetration tests was randomized and no re-donning of the respirator occurred between the Bitrex™ and total penetration tests.

Exercises

For both Bitrex™ and total penetration testing, test subjects performed the following six exercises: (1) normal breathing, (2) deep breathing, (3) moving their head side to side, (4) moving their head up and down, (5) reading the rainbow passage out loud, and (6) normal breathing. During a Bitrex™ test, each exercise was performed for 60 seconds. During a total penetration test, each exercise was performed for approximately 80 seconds.

Statistical Analysis

A respirator providing adequate protection was defined as one having an overall total penetration less than or equal to 10 percent (equivalent to a

protection factor of 10). This is the level of protection expected for any half-mask respirator (ANSI, 1992; NIOSH, 1987). To determine if the Bitrex™ qualitative fit test adequately screened out poorly fitting N95 filtering-facepiece respirators, a statistical approach similar to that used in biomedical applications was used in this study (Brown and Hollander, 1977; Vecchio, 1966). Five statistics were calculated from a two-by-two contingency table. These statistics were test sensitivity, predictive value of a pass, test specificity, predictive value of a fail, and the kappa statistic (Fleiss, 1981). Test sensitivity is defined as the fraction of subjects having a total penetration greater than 10 percent and failing the Bitrex™ test. For most statistical analysis, a test sensitivity of at least 0.95 is required. The predictive value of a pass is the fraction of test subjects passing the Bitrex™ test having a total penetration less than or equal to 10 percent. It is desirable to have a predictive value of a pass of at least 0.95. The test specificity is the fraction of those subjects achieving a total penetration less than or equal to 10 percent which passed the Bitrex™ test. A test specificity >0.5 is usually considered as acceptable. The predictive value of a failure is the fraction of test subjects failing the Bitrex™ test having a total penetration greater than 10 percent. A predictive value of a failure of 0.5 or greater is considered to be acceptable.

The kappa statistic is used to calculate some degree of agreement between the total penetration values and the Bitrex™ test results. It compares the observed proportion of the values that are in agreement, and the proportion that would be expected if the two types of values were statistically independent. Generally, a kappa statistic of 0.7 or greater is considered to be acceptable. In addition to these statistics, alpha (a) and beta (b) errors were calculated. An error is commonly called a false **positive**, which would occur if a respirator providing adequate protection failed the Bitrex™ test. A p error is called a false **negative**, which would occur if a respirator providing inadequate protection passed the Bitrex™ test. A p error is more important than the error from a respiratory protection perspective because it can lead to overexposure of a respirator wearer. Calculations for these statistics are summarized in Table 2.

Results and Discussion

Table 3 is the two-by-two contingency table of the Bitrex™ and total penetration tests. Of the total of 125 Bitrex™ qualitative fit tests, 62 were passes (the taste of Bitrex™ was not detected) and 63 were

failures. Of the 62 passes, 60 had total penetration values less than or equal to 10 percent. The remaining two had total penetrations of 11 and 25 percent. Of the 63 failures, 23 had total penetration values

Table 2. Definition of the five study statistics and two errors.

Test statistic	Definition ¹
Sensitivity	$C/(A+C)$
Predictive value of a pass	$B/(A+B)$
Specificity	$B/(B+D)$
Predictive value of a failure	$C/(C+D)$
Kappa	$(P_o - P_e)/(1 - P_e)$
α Error	$D/(B+D)$
β Error	$A/(A+C)$

¹ A = Number of subjects passing the Bitrex™ test and having a total penetration value >10%.

B = Number of subjects passing the Bitrex™ test and having a total penetration value ≤10%.

C = Number of subjects having a total penetration value >10% and failing the Bitrex™ test.

D = Number of subjects having a total penetration value ≤10% and failing the Bitrex™ test.

$P_o = (B+C)/(A+B+C+D)$

$P_e = [(A+B)(B+D) + (C+D)(A+C)] / (A+B+C+D)^2$

Table 3. Completed two-by-two contingency table summarizing test conclusions reached.

Bitrex™ results	Total penetration results	
	Fail (>10%)	Pass (≤10%)
Pass	False adequate protection conclusion 9% [2 of 23 tests (A)]	True adequate protection conclusion 59% [60 of 102 tests (B)]
Fail	True inadequate protection conclusion 91% [21 of 23 tests (C)]	False inadequate protection conclusion 41% [42 of 102 tests (D)]
Total	23	102

greater than 10 percent. The remaining 40 subjects had total penetration values ranging from 0.47 to 10 percent. Table 4 is a summary of the five statistics and their confidence limits. The Bitrex™ failed three out of the five statistics with the most important being test sensitivity since it is the one that indicates whether a person passing a Bitrex™ fit test would receive adequate protection from the respirator. When considering the 95% confidence limits, it is possible that none of the statistical tests would have met the requirement. In addition, the 95% confidence limit for the test sensitivity statistic suggests that it is possible for it to be greater than 0.95. Table 5 is a summary of the adequate protection conclusions reached by using the Bitrex™ test. Forty-one percent of the time, the Bitrex™ test rejected a respirator that provided adequate protection after redonning. Even more important, the false adequate rate or "false pass rate" for the Bitrex™ test in this study was 9%. This means that one of 10 wearers of N95 filtering-facepiece respirators may

receive inadequate protection after passing a Bitrex™ qualitative fit test. The data of this study suggest that only in 65% of the tests (81 of 125), a correct conclusion was reached regarding the adequacy of protection with the Bitrex™ test. A false adequate protection and a false inadequate protection conclusion happened 35% of the time. It has been shown that user seal checks are good discriminators between good and poor donnings (Myers *et al.*, 1995). In this study, eighteen percent of the wearers performing a satisfactory user seal check had respirators with total penetrations exceeding 10 percent. This could be due to the differences between the study methodologies. The Myers' study measured only face seal leakage while this study measured total penetration. Myers used 30 CFR 11 respirators which may have had different designs (e.g., nose clips, face seals, exhalation valves, etc.) than the respirators used in this study which could affect the efficacy of the user seal check.

Table 4. Summary of the seven study statistics.

Test statistic	Requirement	Result	95% confidence limit ^A
Sensitivity	>0.95	0.91	0.79-1.00
Predictive value of a Pass	≥0.95	0.97	0.93-1.00
Specificity	>0.50	0.59	0.49-0.69
Predictive value of a Failure	>0.50	0.33	0.21-0.45
Kappa	>0.70	0.30	0.22- 0.38
a Error	≤0.50	0.41	0.31- 0.51
P Error	≤0.05	0.09	0.00- 0.21

^A95% Confidence Limits = $P \pm 1.96[P(1.00-P)/n]^{1/2}$; where P = study result.

Table 5. Summary of test conclusions made with the N95 filtering-facepiece respirators using the total penetration (TP) and Bitrex^T methods.

Frequency of correct protection conclusions made with the Bitrex TM method			
True adequate (Bitrex TM - pass; TP≤10%)	True inadequate (Bitrex TM - fail; TP>10%)	False adequate (Bitrex TM - pass; TP>10%)	False inadequate (Bitrex TM - fail; TP≤10%)
59%	91%	9%	41%

Conclusions

The results of this study suggest that a fit test operator may not reach a correct decision about whether an N95 filtering-facepiece respirator will be sufficiently protective upon **redonning**. Study data also suggest that an operator may frequently accept an inadequately protecting respirator and reject almost half of those respirators providing adequate protection. One possible explanation for the high error (false negatives and false positives) seen in this

study could be an inherent variation in **facepiece** fit between different **donnings**. Another possible explanation is that the total penetrations measured by the **PortaCount PlusTM** varied significantly between models and individual respirators. Additional research involving repeated donnings of N95 filtering-facepiece respirators may be needed to evaluate this effect.

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